Letters

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Article makes simple errors and could cause unnecessary deaths

Editor—The worldwide meta-analysis of antiplatelet trials shows that low dose aspirin (or some other effective antiplatelet regimen) reduces non-fatal myocardial infarction, non-fatal stroke, and vascular death in a wide range of patients who are at high risk of occlusive vascular disease.[1] A paper disputing this was published concurrently in the For Debate section of the journal,[2] but the arguments in it (some of which the author also published on the same date in an editorial in the *Lancet*)[3] depend strongly on quite simple mistakes about the randomised evidence and could cause unnecessary deaths.

Consider, for example, the ISIS-2 trial of short term antiplatelet therapy, in which 17 187 patients with suspected acute myocardial infarction were randomised, half to active aspirin and half to placebo.[4] This trial showed a clear reduction in five week all cause mortality (811/8587 (9.4%) aspirin *v* 1030/8600 (12.0%) placebo deaths, $2P < 0.00001$).[5] Bizarrely, in a section entitled "Trials do not show that aspirin saves lives," the For Debate paper attempts to dismiss the ISIS-2 findings by suggesting that "all patients lost to follow up in the active group should be considered to have died and none of those in the control arm. Such an analysis would neutralise the benefit observed in one of the few seemingly convincingly positive studies of aspirin, the ISIS-2 trial."[2]

This is not even arithmetically correct, and such a statement should not be part of any serious debate in the *BMJ*. The five week follow up was 97% complete when this trial was first reported,[4] and 99% complete when further follow up was reported in the *BMJ*.[5] This slightly greater completeness yielded, in fact, only 13 extra deaths (6 in the aspirin group, 7 in the placebo), and the even slighter incompleteness that remains cannot, of course, be of any material relevance (especially since most of the few still untraced at five weeks are known to have been discharged alive from hospital: for only 0.2% of the patients given aspirin and 0.2% of those given placebo is there no follow up at all).

Likewise, among about 20 000 patients in the 12 trials of long term (mean two years) antiplatelet therapy among patients with a history of previous myocardial infarction, the odds of having a non-fatal reinfarction were reduced by 30% (SE 6; $2P < 0.00001$), with no significant heterogeneity between the results in different studies.[1] The For Debate paper purports to account for this 30% reduction by suggesting (without good evidence of any such effect) that the proportion of non-fatal infarctions that would be reported might be 70% with aspirin and 75% without. Again, however, this argument is arithmetically wrong, for 70 *v* 75 would represent a reduction of only 7%, not 30%.

Furthermore, having suggested earlier that it is only analyses of all cause mortality that can be trusted, the paper then goes on to elaborate a curious theory that involves trusting the somewhat arbitrary distinction between mortality attributed to sudden death and to other cardiac causes. From this it eventually concludes that aspirin could be producing "an increased risk of sudden death among concealed, and therefore untreated, events."[2] But, there is no good evidence that this is true.

More importantly, in the worldwide meta-analysis, vascular mortality—which is highly significantly reduced—already included both sudden death and death from unknown causes (as well as death from any type of stroke).[1] In the 12 trials of long term antiplatelet therapy during the years after myocardial infarction the reduction in vascular mortality was 15% (SE 5; $2P = 0.002$) again with no significant heterogeneity between the effects in different antiplatelet trials (or 17%; $2P < 0.0010$), with even less heterogeneity, if the imbalance in prognostic features in the AMIS trial is appropriately allowed for).[6] Moreover, all cause mortality was also reduced, as there was no significant excess of non-vascular deaths in this category of patient, or in any of the other four main categories of patients at high risk. Indeed, taking the 135 000 patients in all five categories together, non-vascular mortality was 1.1% with antiplatelet therapy and 1.2% without, which looks pretty safe. Thus, there is no good evidence from these trials that non-vascular mortality offsets the highly significant reduction in vascular death or in non-fatal myocardial infarction or stroke among high risk patients.

A recent study of the costs of the secondary prevention of such vascular events by aspirin is cited in the For Debate paper as concluding that the cost per event prevented would be over £3000. If true, this could be money well spent, but it is included in a section misleadingly entitled "Neither safe nor cheap."[2] (No other cost estimates in that section are relevant to secondary prevention.) The author also suggests that "the greatest potential detriment of aspirin on health care, however, is that it diverts attention away from treatments that are of unequivocal benefit." No good evidence for this assertion is provided and, moreover, there is no good reason why other effective treatments (such as angiotensin converting enzyme inhibitors, β blockers, and statins) should not be used in addition to aspirin, conferring additional benefit.[7]

There are several other errors of judgment, partly from failure to understand the proper role of meta-analysis in the interpretation of randomised evidence. Given this, none of the substantive points in the For Debate article is of material relevance (except, perhaps, as a warning about the power of prejudice), and the chief ones have been dealt with adequately in the current or previous antiplatelet reports. In retrospect, it would perhaps have been better for the *BMJ* to have sought review of the paper from, among others, those whose work it criticises. This would have given the journal the opportunity to avoid publication of arguments and conclusions that are wrong for trivial reasons and potentially damaging to patients.

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1 Antithrombotic Trialists' Collaboration. Collaborative meta-analysis of randomised trials of antiplatelet therapy for prevention of death, myocardial infarction and stroke in high risk patients. *BMJ* 2002; 324:71-86. (12 January.)
2 Cleland JGF. For debate: Preventing atherosclerotic events with aspirin. *BMJ* 2002;324:103-5. (12 January.)
3 Cleland JGF. No reduction in cardiovascular risk with NSAIDS—including aspirin? *Lancet* 2002; 359: 92-3.
4 ISIS-2 Collaborative Group. Randomised trial of intravenous streptokinase, oral aspirin, both, or neither among 17,187 cases of suspected acute myocardial infarction. *Lancet* 1988;ii:349-60.
5 Baigent C, Collins R, Appleby P, Parish S, Sleight P, Peto R on behalf of the ISIS-2 Collaborative Group. ISIS-2: 10-year survival among patients with suspected acute myocardial infarction in randomised comparison of intravenous streptokinase, oral aspirin, both, or neither. *BMJ* 1998;316:1337-43.
6 Antiplatelet Trialists' Collaboration. Secondary prevention of vascular disease by prolonged antiplatelet treatment. *BMJ* 1988;296:320-31.
7 Flather MD, Yusuf S, Køber L, Pfeffer M, Hall A, Murray G, et al. Long-term ACE-inhibitor therapy in patients with heart failure or left ventricular dysfunction: a systematic overview of data from individual patients. *Lancet* 2000;355:1575-81.

GMC must recognise and deal with vexatious complaints fast

Editor—A letter in *GMC News* asked what the General Medical Council's strategy was for dealing with frivolous complaints.[1] It generated a far from reassuring reply[2] that is

at odds with what the NHS ombudsman believes is needed.[3] The time taken for most complaints to be dealt with is already a matter for concern, and doctors increasingly face suspension by their employer when under investigation.[4]

A recent ruling by the Privy Council[5] is likely to exacerbate these delays further despite the best efforts of the GMC to recruit more panellists to its professional conduct committee by reducing the role of the preliminary screeners.[1] In addition, since the media can make known the names of those under investigation, even a simple factual statement saying that someone is under investigation can be enough to damage a doctor's reputation.

We accept that a complaint can often be classified as frivolous only after careful scrutiny. However, multiple complaints by a small vocal pressure group are vexatious rather than frivolous, so more easily recognised; the law has long known how to deal with vexatious litigants, but, unfortunately, the GMC seems to lack any such mechanism.

According to a widely accessed website (MAMA (Mothers against Munchausen syndrome by proxy allegations) www.msbp.com), the 18 authors of this letter have all been reported by the same small group of people, although attempts to clarify the situation with the GMC have been unsuccessful. One formal letter from a defence society merely generated (after five months' delay) a reply that the person in question was not "currently" under investigation. One of us used the Data Protection Act to obtain material held on file about him by the council and was disturbed to find that members of the council's staff and a regular complainant were on first name terms.

Were we the only people so targeted we might have accepted this as the price for our involvement in child protection work or our support for those who are. However, we know nurses who have been reported to the United Kingdom Central Council for Nursing, Midwifery and Health Visiting by the same small group. We invited them to sign this letter, but they declined on the advice of their college, fearing that this would provoke further adverse publicity, with the media judging them guilty until proved innocent. Such pressure makes it all the more important for the GMC and UK Central Council for Nursing, Midwifery and Health Visiting to develop a joint strategy for recognising frivolous and vexatious complaints, identifying them publicly and rejecting them promptly.

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The following 17 people are cosignatories of this letter: Frank Bamford, retired consultant paediatrician, University of Manchester; Arnon Bentovim, honorary consultant child psychiatrist, Child and Family Consultation Service, London; Elaine Carter, consultant paediatrician, Leicester Royal Infirmary; Iain Chalmers, director, UK Cochrane Centre, NHS R&D programme, Oxford; Paul Davis, consultant paediatrician, Cardiff and Vale NHS Trust; Dewi R Evans, consultant paediatrician, Singleton Hospital, Swansea; David Foreman, consultant child and adolescent psychiatrist, South Derbyshire Health Authority; Danya Glaser, consultant child psychiatrist, Great Ormond Street Hospital, London; Edmund Hey, retired consultant paediatrician, Newcastle upon Tyne; Michael Lowry, consultant paediatrician, Sunderland Royal Hospital; Roy Meadow, emeritus professor of paediatrics and child health, University of Leeds; Peter Milla, professor of paediatric gastroenterology and nutrition, Institute of Child Health, London; James Paton, senior lecturer in paediatric respiratory disease, Royal Hospital for Sick Children, Glasgow; Martin Samuels, consultant paediatrician, North Staffordshire Hospital; Jo Sibert, professor of community child health, University of Wales, Cardiff; David Southall, consultant paediatrician, North Staffordshire Hospital; John Stephenson, retired consultant in paediatric neurology, University of Glasgow.

1 Campbell DA. Unfair and one-sided. *GMC News* 2001;issue 4 (Feb):6.
2 How doctors can handle frivolous complaints. *GMC News* 2001;issue 5 (Apr):1, 7.
3 Words to the wise. *BMA News* 2001;23 June:7-8.
4 Weaver J. Accused doctors falling victim to suspension fad. *BMA News* 2001;22 September:1.
5 R *v* General Medical Council ex parte Toth (2000) 1 WLR 2209. (www.lawreports.co.uk/qbjun8.htm; accessed 13 Jan 2002.)

GMC member forced to stand down from disciplinary panel

See news item by Dyer

GMC member responds

Editor—There are two sides to every story. You have only heard one in the news report by Dyer.[1]

When I was elected to the General Medical Council one of my nominators, himself a council member, wrote to colleagues: "The fundamental injustice which those of us who know Dr Colman feel she has suffered is admirably summed up at page 58 of the transcript of her restoration hearing in 1989 where Mr David Bolt, Chairman of the PCC [professional conduct committee] said, 'If the circumstances surrounding this case had been fully known at the time of the original hearing there is no doubt in my mind that the matter would be in the hands of the Health Committee, where it ought to have been.'" This was an open hearing to which the public and press had access and is a matter of public record.

Many doctors voted for me because they knew my story. Others did not. I reminded the GMC and asked for its advice before I sent in my nomination papers. Doctors should reflect on a system of false transparency selectively spinning itself into the abyss.

I like my browbeaten colleagues at the GMC and my unfortunate story could have been yours. As you reflect ask yourselves whether the latest episode you have read about me is also one sided and ask yourselves why. Now more than ever the profession needs strong inspired leadership to rescue it from the shadowlands.

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1 Dyer C. GMC member forced to stand down from disciplinary panel. *BMJ* 2001;322:1565. (30 June.)

Colman's withdrawal from committee is issue of organisational governance

Editor—There are two sides to every story. That a member of the professional conduct committee should have to stand down in the circumstances that forced Colman's withdrawal is a matter of grave concern.[1] It should prompt an investigation and public report by the General Medical Council.

When we elected Colman to serve on the GMC we chose a woman who had a number of convictions for alcohol related driving offences, court appearances for assault, and an involvement in a fatal car accident in which the car she was driving struck two children on a bicycle.

Colman-Archer failed her degree course and obtained her primary qualifications through the apothecaries some years after finishing medical school. Her medical career was brief. During her pre-registration year her name was removed from the register for very serious neglect of patient care and for homophobic and racial abuse. She was restored to the register in 1989. She changed her name to Colman but does not work as a doctor.

In her election statement for the GMC she made no mention of her previous problems or change in name but did say that she was a medically qualified barrister. Of the approximately 30 000 doctors who voted, 5717 cast their vote for her. She was subsequently co-opted to the professional conduct committee.

The rules of standing for election to the GMC require that a candidate be on the register and supported by six registered doctors. The election statement is not checked for accuracy or content or edited, except for the number of words it contains. There is no obligation to disclose any criminal record or disciplinary problems. The GMC has not changed these rules.

Colman's election was arguably unavoidable; the failure to change the rules that allowed it is not. That the GMC should then choose to place Colman on a committee that judges the conduct of doctors does not give confidence in the organisation's probity. It was bound to attract adverse publicity and bring the profession into disrepute. Apart from the issue of her previous record, Colman has almost no experience of practising as a doctor or of the stresses and problems they face.

The GMC has remained silent on the issue. Perhaps those, such as Sir Donald Irvine, who supported Colman's role on the professional conduct committee would like to explain their reasoning? The members of the committee who voted to co-opt Colman on to the committee owe the profession an explanation and an apology and should consider their position.

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1 Dyer C. GMC member forced to stand down from disciplinary panel. *BMJ* 2001;322:1565. (30 June.)

GMC should have protected Colman

Editor—I knew Jennie Colman when we were both medical students at Cambridge. There it was my belief that she was unsuited to practise medicine, and she was, in fact,

never awarded a degree. She qualified from the Society of Apothecaries after having left medical school, and I read in the national press later that her name had been removed from the medical register after only a brief career as a doctor.

At her subsequent reinstatement in 1989 it was revealed that Colman suffered from a neurological condition accounting for her behaviour. This diagnosis had not been reached until after the events that led to her suspension. Specialists advised the General Medical Committee that, with appropriate drug treatment, control of symptoms should permit her reinstatement to the register. She did not, however, continue her medical career.

I was surprised to see her name on the list of candidates for election to the General Medical Council in 2000. I was concerned that a doctor who had enjoyed such a short and controversial career some 10 years before should consider herself suitable to stand for election. It may have been another manifestation of the lack of insight that had characterised her behaviour and was caused by the episodic neurological illness diagnosed after her suspension. In my view it should have prompted medical review by the GMC. Instead she was appointed to a sensitive post on the conduct commitee.

Now once again this unfortunate person finds her name emblazoned across the national press for inappropriate behaviour.[1] Knowing her medical history, could the GMC not have protected her?

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1 Dyer C. GMC member forced to stand down from disciplinary panel. *BMJ* 2001;322:1565. (30 June.)

Maintaining the integrity of the scientific record

Scientific standards observed by medical journals can still be improved

Editor—The average scientific standard of what pharmaceutical sponsors present to regulators is far superior to that observed by medical journals.[1] Despite laudable efforts recently by various editors in employing statistical reviewers, much still finds its way into print that is, essentially, nonsense. If the Medicines Control Agency did its gate keeping job as badly I would be alarmed.

Despite Smith's comments, ethical standards are often not superior outside the pharmaceutical industry. During my work for the industry I came across the following behaviour from the sort of external investigator that Smith would like the industry to use: the faking of data; the changing of procedures in the interests of personal research without approval being sought from either the company or the ethics committee; and refusal to agree to abide by the prespecified (and mutually agreed) analysis because this would jeopardise the possibility of publication.

One example of refusal to abide by the prespecified analysis was particularly illustrative of the arrogance towards the industry that may be encountered if one works in it. I was informed that my source of employment meant that my opinion regarding statistical analysis carried no weight. (This was a crossover trial, a topic on which I had written a monograph.)[2] A third and academic opinion was insisted on, and when this person, although chosen by the investigator, agreed with me the investigator then disagreed with us both. To my then employer's credit, it refused to be party to the publication that resulted, even though the results would have been more positive to it than the prespecified analysis was.

I believe that a much greater improvement in our evidence base would be obtained if the Medicines Control Agency influenced the standards observed by medical journals than if the editors of these journals influenced the regulatory process. My hope for the future is that sponsors and regulators will move towards publication of regulatory dossiers on the web. This development should not, of course, be seen as an attack on journal editors.

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Professor Senn is a consultant to the pharmaceutical industry. This letter represents his personal opinion.

1 Smith R. Maintaining the integrity of the scientific record. *BMJ* 2001;323:588. (15 September.)
2 Senn S. *Cross-over trials in clinical research.* Chichester: Wiley, 1993.

New policy is unlikely to give investigators more control over studies

Editor—I have worked in contract research organisations for the past 20 years. During this time I have worked on many trials designed by these organisations or by pharmaceutical companies. I have also worked on some trials in which the investigator was given full control over the study and its analysis, interpretation, and reporting; the sponsoring company simply provided funding and technical help. I have no hesitation in saying that the trials controlled by the companies are conducted to a far higher scientific standard than those left in the control of the investigators.[1]

It would be astonishing if it were otherwise. Most investigators who take part in these trials are not professional researchers, they are primarily clinicians. Their training is aimed at treating patients; if they had any training in research methods it was usually a single course in statistics in the first or second year of their degree, before they really appreciated how important rigorous research methods are in order to do good science.

Pharmaceutical companies and contract research organisations, on the other hand, have staff whose primary professional skill lies in knowing how to run a clinical trial efficiently and in such a way that it gives meaningful and unbiased results. The analysis and interpretation of data from a major clinical trial take a team of people many weeks to achieve. It would be impossible for individual investigators to do this to a satisfactory standard, even given the appropriate skills, while at the same time juggling with their primary duties as doctors.

Currently, when the industry publishes its trials it usually does so under the name of the principal investigator in the belief that this will help influence medical opinion. Instead of giving investigators greater control over design, interpretation, and publication, the effect of the new policy outlined by Smith may well be that more trials will now be published under the names of the professional trialists who actually designed and analysed them. This is perhaps a better way of addressing the criticism that editors and readers are being deceived.

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The views expressed in this letter are the author's personal views.

1 Smith R. Maintaining the integrity of the scientific record. *BMJ* 2001;323:588. (15 September.)

Anaesthetic machines and anti-hypoxia devices

Interim solution is to remove nitrous oxide cylinders and pipelines and cap their connections

Editor—Saunders and Meek point out that anaesthetic machines without hypoxic guards confer an appreciable risk.[1] Many latent errors in the health system are solved only after tragedies. As the authors say, in an underfunded system the replacement of such machines, at considerable cost (£8000-£40 000 depending on the type of machine), has to compete with many other high priorities for small capital funds. Awaiting replacement leaves patients at risk and is thus unacceptable.

An interim solution could be used in most situations. It is perfectly possible to deliver an anaesthetic without giving nitrous oxide at all; indeed, there are several benefits from avoiding the use of nitrous oxide. Furthermore, the use of nitrous oxide outside operating theatres is of dubious benefit (other than when Entonox is given; this comes premixed with 50% oxygen, thus removing the risk of hypoxia in normal conditions).

In the short term it is thus perfectly possible to prevent this latent risk outside theatre by removing all nitrous oxide cylinders and pipeline supplies and capping their connections. This is a quick and cost effective safety measure that can be instituted within days in most hospitals. In operating theatres most anaesthetic monitoring is of high enough standard to detect a hypoxic mix before it becomes a problem. When monitoring is inadequate these

machines should be withdrawn, thus enforcing change and removing a latent error.

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1 Saunders DI, Meek T. Almost 30% of anaesthetic machines in UK do not have anti-hypoxia device. *BMJ* 2001;323:629. (15 September.)

When is an anti-hypoxia device not an anti-hypoxia device?

EDITOR—The European Standard for anaesthetic machines (EN740) requires them to have means to prevent the delivery of a gas mixture with an oxygen concentration below 20%. Some of the respondents to Saunders and Meek's survey probably regarded compliance with this standard as synonymous with the presence of an anti-hypoxia device on their anaesthetic machine.[1]

The European Standard refers to machines in the workshop. I have to attach these machines to patients via a patient circuit, and thus my interest is whether the machine in this configuration will prevent the inadvertent delivery of a hypoxic inspired gas mixture. In machines with a simple (ratio) oxygen/nitrous oxide linkage, a combination of 300 ml oxygen/min and 900 ml nitrous oxide/min into a circle absorber circuit is permissible and the machine will conform to EN740 but a hypoxic inspiratory mix will develop in adults and in children as young as 8. This machine will prevent the administration of an anoxic mix, and probably of a severely hypoxic mix, but not the administration of a hypoxic mix. Does it therefore qualify as having an anti-hypoxia device? I suggest not.

I believe that in the United Kingdom many anaesthetic machines—if not the vast majority—are fitted with an anti-hypoxia device of this ratio linkage type. Some machines on the market, however, do have a true anti-hypoxia capability at all flow rates. The Royal College of Anaesthetists has instructed that after 31 December 2002 trainees will not be allowed to give nitrous oxide from machines that are not fitted with an anti-hypoxia device.[2] Will we see the replacement of almost all the anaesthetic machines in the United Kingdom or witness large queues of trainees behind the few that comply with the standards, or might "fuzzy" anti-hypoxia devices be allowable?

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1 Saunders DI, Meek T. Almost 30% of anaesthetic machines in UK do not have anti-hypoxia device. *BMJ* 2001;323:629. (15 September.)
2 Safety notice on prevention of hypoxic gas mixtures. *Royal College of Anaesthetists Bulletin* 2001 July (No 8):354.

Doctors must read drug labels, not whinge about them

EDITOR—Twice last year the *BMJ* gave column space to doctors reporting confusion between ampoules of water, saline, and lignocaine (also called lidocaine) for injection.[1,2] These doctors blame the similarity in ampoule shape and colour rather than admitting to the fundamental problem of having simply failed to read the label.

In my view, the differences between the labels in both the illustrations used are readily apparent.[1,2] To blame that labelling is a diversion of personal responsibility that I find unacceptable; even for doctors "in a busy plastic surgery unit"[2] the check takes only a second. The journal is right to draw attention to the issue, but the arguments against change need to be presented as well.

Those who clamour for change must recognise that there are only a few shapes (round, square, and triangular in cross section) that might be used to hold fluids, and only a few colours (black, white, violet, indigo, blue, green, yellow, orange, and red) that might be used for labels (many combinations are ineligible if the lettering is to be legible). The range of injectable drug preparations (remember that variations in volume and drug concentration must be dealt with too) far outnumbers the possible combinations of usable colours and shapes. Thus responsibility will always lie with the user to read the label before use.

Introducing shape and colour differences will undoubtedly increase manufacturing costs but do nothing to reduce the need for this fundamental check or reduce the number of errors. It might even increase the errors if clinicians thought that they were absolved from the responsibility of reading carefully what is on the label.

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1 Correspondence. Not gain! *BMJ* 2001;322:548-9. (3 March.)
2 Nduka C, Leff D. Medical mishaps: mistaken identity. *BMJ* 2001;323:615. (15 September.)

Safety of acupuncture

Studies of safety must look at communication and organisational issues

EDITOR—In his editorial Vincent pointed out that the two studies on the safety of acupuncture are reassuring.[1-3] He also pointed out that considering safety alone is unhelpful and a risk : benefit ratio should be derived. However, harm does not come only from adverse events. Another area of concern with complementary practitioners is the lack of communication with conventional carers, and in particular primary care.

If one core element of primary care is coordination of care then poor communication between complementary practitioners and primary care can only serve the patient poorly. Indeed, harm may occur.[4] Without full knowledge of the patient, his or her condition, and drugs taken, inadvisable treatments might be advocated. There therefore needs to be a clear link between complementary practitioners and the patient's primary care provider.

To create a linkage between primary care provider and complementary therapist requires a different approach. In the practice where I work we have forged strong links with a chiropractic doctor (in the past, placing a fundholding contract with one), offered accommodation to an acupuncturist, and held evening meetings with complementary therapists to discuss the merits of their treatments. Two partners in the practice are trained in the basics of complementary therapies (acupuncture and homoeopathy). All this adds up to an open relationship between patient, his or her general practitioner, and his or her complementary therapist.

We have not succeeded in linking with herbalists. This is of some concern, given the possible interactions between herbal remedies and allopathic treatment and the potential problem of herbal toxicity, which may not be recognised for what it is.[5]

Safety studies of complementary therapy need to look at broader aspects of care and, in particular, communication and organisational problems that might arise.

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1 Vincent C. The safety of acupuncture. *BMJ* 2001;323:467-8. (1 September.)
2 White A, Hayhoe S, Hart A, Ernst E. Adverse events following acupuncture: prospective survey of 32 000 consultations with doctors and physiotherapists. *BMJ* 2001;323:485-6. (1 September.)
3 MacPherson H, Thomas K, Walters S, Fitter M. The York acupuncture safety study: prospective survey of 34 000 treatments by traditional acupuncturists. *BMJ* 2001;323:486-7. (1 September.)
4 Starfield B. *Primary care: balancing health needs, services and technology*. Oxford: Oxford University Press, 1998.
5 Borins M. The dangers of using herbs. What your patients need to know. *Postgrad Med* 1998;104:91-5.

Incident reporting and feedback may reduce risks

EDITOR—White et al and MacPherson et al reported prospective surveys of adverse events after acupuncture.[1,2] We conducted the same kind of survey at a Japanese national college clinic.[3] Interestingly, the incidences of significant (but actually minor) adverse events were similar: 14 per 10 000 treatment sessions in medical acupuncture,[1] 13 per 10 000 in traditional acupuncture,[2] and 14 per 10 000 in Japanese acupuncture.[3] Although some cases may have gone unreported, these studies show that acupuncture is relatively safe in standard practice, regardless of schools or modes of practice.

In non-standard practice, on the other hand, many serious adverse events have been reported.[4] Thus education and rigorous qualification of acupuncture practitioners are important. We have proposed that therapists' negligence and patients' reactions should be discussed separately.[3] After conducting a prospective survey of the incidence of adverse reactions after acupuncture that seem essentially unavoidable in standard practice[5] we

Incidence of cases involving forgotten needles during or after acupuncture at Tsukuba College of Technology Clinic, Japan

Month	No of incidents	Total No of treatment sessions	Incidence (%)
2000			
April	3	857	0.35
May	5	871	0.57
June	6	921	0.65
July	1	934	0.11
August	2	926	0.22
September	10	903	1.11
October	3	952	0.32
November	3	880	0.34
December	1	899	0.11
2001			
January	1	766	0.13
February	3	784	0.38
March	0	744	0
April	1	704	0.14
May	1	786	0.13
June	4	788	0.51
July	3	786	0.38
August	2	789	0.25

have been tackling the problem of how to reduce cases of negligence.

At our clinic, where roughly 30 acupuncturists practise, all incidents during and after acupuncture must be reported to the acupuncture office. We define an incident as being not only an adverse event that actually occurred but also one that nearly occurred. Twenty seven incidents involving forgotten needles were reported from April to September 2000 (table).

In monthly meetings since April 2000, using analyses of incident reports, we have informed all the acupuncturists of how the incidents occurred. We have discussed the following factors: needles tend to be forgotten mainly in the lower extremities or the head, where they are hidden by a towel or the hair; many of the acupuncturists who forgot needles were acting on behalf of the acupuncturist who had inserted them; and the incidence was substantially higher during treatments when the acupuncturists were conducting clinical instruction for their students. The occurrence of incidents involving forgotten needles has decreased since we started the feedback system, although we realise that the total number of treatment sessions each month has decreased as well (table).

After showing that acupuncture is inherently safe, we should focus on how to reduce the risk of negligence acupuncture. Even a simple system of incident reporting and constant feedback in a group setting might be used to achieve this aim.

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1 White A, Hayhoe S, Hart A, Ernst E. Adverse events following acupuncture: prospective survey of 32 000 consultations with doctors and physiotherapists. *BMJ* 2001;323:485-6. (1 September.)
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Complexity science

Let them eat complexity: the emperor's new toolkit

Editor—Plsek and Greenhalgh's example of complexity in health care is absurd.[1] Do they really encourage us to believe that, if only Dr Simon had some grounding in complexity theory, she would have been able to understand why getting rid of lunch time upsets her colleagues? We do not have to appeal to the science of complex adaptive systems, chaos theory, catastrophe theory, Einstein's general theory of relativity, quantum mechanics, or even Freudian psychoanalysis to appreciate the distress of Dr Simon's hungry staff.

Although Plsek and Greenhalgh's aim may have been to make some fairly abstract science more accessible, the result is misleading and potentially harmful. The series does not articulate honestly the background to the emerging study of complex adaptive systems by switching repeatedly between misapplied metaphor and empirically grounded science. I suppose contemporary NHS managerialism has to have its own body of knowledge and set of techniques to bolster a sense of expertise, but it could do better than borrow from the wilder shores of the popular business section of the airport bookstore.

Greenhalgh's series continues the tradition of misusing scientific concepts by confusing technical terms (for example, non-linear, attractor pattern) with "homey" everyday ideas (for example, hidden needs and motivations), in the manner described by Sokal and Bricmont.[2] This misuse of mathematical metaphor is hardly an original treatment and was regularly promulgated among business management organisations in the United States for at least a decade. Late and a bit stale, it is beginning to appear regularly in the *BMJ*.[3] The antirationalist outcome has more in common with 19th century romanticism than the sophisticated, postmodern thinking that proponents imagine they practise—serving political and careerist, rather than scientific, ends. There are useful applications of chaos theory (an established subset of the more speculative complexity theory) in the clinical sciences: the analysis of cardiac electrical rhythms; electroencephalography in epilepsy; sugar concentrations in diabetes patients; the behaviour of waiting lists; and so on. Unfortunately these ideas may be swamped by the intellectual snake oil of "complexity theory as metaphor," easily identified by the absence of mathematical modelling, which I fear we can expect to see spattered, expensively, across massed ranks of flip charts by healthcare administration faddists in the United Kingdom.

Plsek and Greenhalgh seem to authorise a means by which uncomfortable situations (for example, tension caused by poorly managed services) may be dismissed as spooky natural phenomena over which to stroke one's chin—a handy conceptual toolkit for the credulous healthcare manager on an inadequate budget.

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New approaches to evaluation of treatments are needed

Editor—I enjoyed the fresh look at the world of medicine provided by the four articles on complexity science,[1] but I am not sure that swapping the old rules for the mathematics of complexity theory are right. Maybe the rules of complex systems are simpler and more fundamental than we think. In his seminal work *The Tao of Physics* Capra identifies six things that should govern scientific thinking[2]:

- Knowledge of the structure does not predict function
- Process is primary and determines structure
- The observer is part of the whole system
- There are no fundamental equations
- All descriptions are approximations
- Cooperation not dominance should prevail.

These paradigms can be applied to the world of medicine[2] and have provided me with a different perspective in my clinical practice. I suspect that they are applicable to all other specialties; if they are not then Capra's paradigms are flawed.

I was sorry that the articles in the series did not address the issue of research. When I applied Capra's paradigms to research into chronic pain[3] I was able to understand why it is so difficult to undertake. Classical approaches to clinical trials (randomised controlled trials, for example) fail when one is trying to assess the effects of drugs with complex neurochemical effects in patients whose pains are a complex of biological, psychological, social, and spiritual elements. A look through the leading pain journals shows the rarity of classical clinical trials. Yet chronic pain afflicts about 1 person in 12.

In complexity lies the reason why it is so difficult to evaluate the effects of interferon beta or cannabinoids in multiple sclerosis. Clinical trial methodology does not overcome the problem of complexity in patients. We need new approaches to the evaluation of treatments that not only move away from the analytical reductionist approach but also remain rigorous and acceptable.

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Prevalence of permanent childhood hearing impairment

Family friendly hearing seervices are needed in the United Kingdom

Editor—We are the parents of a baby with profound sensorineural deafness, and the article by Fortnum et al rang many bells.[1] The absence of universal screening of newborn infants seems a national scandal to us. If it had been in place we would not have waited nearly a year to discover that our baby has profound deafness. A year is a long time to lose when the early years are critical to the development of language and speech. The family friendly culture and seamless collaboration aspired to in the pilot protocols for universal screening seem a long way off. Lack of urgency from health professionals, a system that designs delay into it rather than managing delay out, and no real focus on customers or families are the dominant characteristics of the health service we have encountered.

Simple changes could make all the difference. Medical professionals are still dictating letters to secretaries and using the postal system to take a week or more to refer cases onwards when email could do it in minutes. A leading London hospital relied on a retired professional who comes in once a month to interpret computed tomography scans, automatically building in a six week delay. When we tried to track him down we discovered that he had been off sick for four weeks, yet this was not known to the departments that relied on him for results, and no alternative arrangements had been put in place.

When our daughter received her hearing aids, it would have been helpful to know that we could have battery covers that guard against the tiny batteries falling out and being accidentally swallowed. It would have been useful to be given a simple tubing tool and shown how to fit new tubing, vital after a baby has pulled the tubing out countless times. It should be obvious for the hospital to demand improvements from its earmould supplier when faced with turnaround times of two weeks that do not keep up with fast growing babies' ears.

These are just a few of the problems we have encountered. None of them is difficult to solve. The fact that they exist suggests that the family friendly hearing services, with a culture of service evaluation and feedback from parents that Fortnum et al hope for, cannot arrive a moment too soon.

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Pilot programme in Australia shows promising results

Editor—We read the paper by Fortnum et al on the prevalence of permanent childhood hearing impairment and the accompanying editorial by Russ.[1 2] Russ stressed the need for adequate evaluation of new universal programmes screening the hearing of newborn babies and the need for population based prevalence data.

Since February 2000 such a programme has been piloted in Western Australia. All babies born in the five largest hospitals in Perth or admitted to the neonatal unit at the major children's hospital are offered screening. These babies account for about 45% of the 25 000 babies born in Western Australia each year. Western Australia is a very large state geographically, but many services are centralised. For example, all the state's neonatal nurseries at levels two and three are in hospitals in the Perth metropolitan area and are included in the pilot programme.

But there are many rural and remote centres where 20-500 births a year take place. Because of this, careful evaluation of the screening programme is needed before it is expanded. Over the first 17 months of the programme we have detected a prevalence of congenital bilateral permanent hearing loss of less than one per 1000. This prevalence is in the low range of rates reported elsewhere.[3 4] Thus we have recognised the possibility that either the prevalence of permanent childhood hearing loss in Western Australia is truly low or that babies with hearing loss are passing the hearing screen (false negatives). Given that hearing loss in babies who pass the screen is likely not to be diagnosed for several years there is a need for continuing surveillance of the whole cohort.

We are currently setting up a population based database to obtain prevalence data and ensure ongoing monitoring. This database will contain details of all children born in Western Australia in 1999 and later who have received a diagnosis of permanent hearing loss by the age of 5 years. Given the results reported by Fortnum et al, we may now need to consider extending the database to children whose diagnosis is made beyond the age of 5 years. We support the need for databases that can ensure continuing monitoring of screening programmes for newborns and providing population based prevalence of permanent childhood hearing impairment.

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Doctors' management should not make things worse for patients

Editor—Much has been written about the need for "do not resuscitate" orders to be explicitly determined by discussion with patients or their relatives, or both. This has mostly been driven by fear—of litigation (by hospitals), of relatives (that not enough was done), and by patient groups (that some effective treatment was denied). Consequently, trusts have declared that policies based on a controversial document by the BMA, Resuscitation Council, and Royal College of Nursing should be in place.[1] As Fallowfield says, who in their right mind would discuss a treatment that is futile with a patient with widespread metastatic malignant disease nearing the end of his or her life?[2] Well, sadly, increasing numbers do.

Recently we were involved in the care of a 44 year old woman with metastatic carcinoma. The disease progressed relentlessly despite radiotherapy and chemotherapy, and much support was needed for her and her family. Recognising that time was short, she decided to have a holiday with her children. Not unexpectedly, but sooner than she had hoped, her condition deteriorated and on her admission to hospital it was found that she had developed lymphangitis

carcinomatosa. She was breathless and anxious to return home, so arrangements were made for her to be taken by ambulance back to her oncology centre in Scotland. Physically and emotionally she was distraught.

Just before she was taken to the ambulance, a doctor whom she had met once before came to tell her that it was policy for patients in her situation not to be resuscitated should their heart stop in the ambulance. She was asked to sign a form confirming her agreement. She knew she was dying, her mother knew she was dying, and one presumes the doctor also knew this. Nevertheless, a signature was required. She spent seven hours in the ambulance terrified that her heart was going to stop. The paramedics were sympathetic, but she could not forget this conversation and was inconsolable; it haunted her until she died one week later.

There is something deeply disturbing about our response to impending death as a result of advanced incurable illness. Death due to cancer is cruel enough; our management should not make it worse.

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Medical students are demoralised by some teachers

Editor—I wish to draw attention to what I think is a serious problem in medical education. Since I became a consultant in 1985, some senior staff have been complaining that medical students nowadays do not know as much as they used to. This complaint has been given greater impetus by the invention of "new" medical curricula, which means that teachers now believe that they have an identifiable reason why today's medical students are not as good as they used to be. My impression is that these complaints long predate any new curricula. It is demoralising for new students to be given the impression that they are not as knowledgeable as they should be or as others were at an equivalent stage.

Most teachers cannot possibly remember what they did and did not know at any particular point in time, especially when there is a 20 year gap between the two. It is common to imagine that one's knowledge and skills were similar in the past to what they currently are. The burden of medical knowledge is much greater than it was 20 years ago. When I was a student, patients with uncomplicated acute myocardial infarction used to receive virtually only oxygen and pain relief, but now the key required knowledge base for this common disease has to include thrombolytic treatment, aspirin, β-blockers, angiotensin converting enzyme inhibitors, statins, risk stratification, etc. The length of the medical course is still five years. Yet if students should now know all their teachers used to know, plus all the new key knowledge, it needs to be expanded to much longer than that.

Medical teachers who complain about students' lack of knowledge should wake up to several facts.

Firstly, they probably overestimate what they knew when they were students.

Secondly, the knowledge base has expanded so dramatically since they qualified that students could not possibly know all they used to, plus all the new facts.

Thirdly, it is probably not the new curricula that have caused this, but they may be a convenient scapegoat.

Fourthly, complaining to the students not only demoralises them but also decreases any esteem that they may then feel towards that teacher. It could even explain why medical graduates are increasingly turning towards non-medical careers. If there is a genuine problem, then we need to address it, but it is counterproductive to make the students feel substandard or infer to them that their medical course is substandard.

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Tired surgical trainees: unfit to drive but fit to operate?

Editor—Last week Mr Gary Hart was sentenced to five years' imprisonment for causing the Selby rail crash and the deaths of 10 people by dangerous driving after falling asleep at the wheel. A tragic chain of events led to the deaths of 10 people and injury of more than 70 people when Mr Hart fell asleep while driving his Land Rover, causing it to veer off the M62 and on to a railway. The prosecution provided evidence that Mr Hart had had no sleep the previous night, which had led to impairment in his ability to drive. At the trial the judge, Mr Justice Mackay, warned: "The sentence of the court will be a sentence of immediate imprisonment of a substantial term and disqualification of a longer term." Indeed, people have been campaigning to make driving while tired as socially unacceptable as drink-driving.

We have great sympathy for those who died in this tragic crash and for their relatives, but we would like to highlight the problems of sleep deprivation facing many doctors. For example, we as trainee orthopaedic surgeons still work band 3 on-call contracts and frequently work more than 72 hours a week, often with little or no sleep during a 32 or 56 hour shift. After such shifts we both have to drive home by motorway, often falling asleep quickly once home.

We do not want to enter the political debate about working hours and practice, but we suspect that many doctors are uneasy about driving after a busy on-call shift. Strict guidelines about rest periods for driving or flying are enforced for haulage drivers and pilots, and concerns have been raised about the legal considerations of sleep deprivation in doctors.[1] Sleep deprivation is known to have a detrimental effect on cognition, decision making, and driving ability.[2–4]

We are told by sources within the BMA that around 3500 junior surgical trainees in England and Wales are still working band 3 contracts (J Cross, Junior Doctors Committee, personal communication). We are particularly concerned about the legal implications of surgical trainees driving home after a busy on-call shift. If the law judges us unfit to drive in this state, what are the implications for operating?

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