Letters

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We may be in danger of bribing volunteers

EDITOR—Christie's news article has highlighted an important inconsistency in the World Medical Association's fifth revision of the Declaration of Helsinki.[1] This fundamental document, first adopted by the association in 1964, defines the ethical and moral responsibilities of physicians and others participating in research on human subjects.

The document insists that all subjects should be volunteers, having freely given informed consent to the research proposed. The latest revision is also particularly concerned with protecting the rights of economically or medically disadvantaged populations, typified by those in developing countries. Paragraph 29 identifies the concept of testing new treatments against the best existing treatment, where such exists, rather than against placebo. Paragraph 30 takes this theme further by saying that, at the conclusion of the study, every patient entered into the study should be assured of access to the best proved prophylactic, diagnostic, or therapeutic method identified by the study. Christie interprets these statements to mean that people in developing countries would at least get access to the best current treatment if they agreed to take part in research into new treatments.[2]

Economically or medically disadvantaged populations are those in whom the best or most up to date medical services may not be available. If the principles in the revised declaration are put into practice, then those participating will clearly not have freely consented and will not be volunteers (according to *Collins Dictionary of the English Language*, a volunteer is a person who does some act without being promised any remuneration[3]). By promising treatments either during or at the conclusion of a research study that would otherwise be inaccessible to the local population, those organising the study would be tempting or coercing subjects into participation. This is precisely what the Declaration of Helsinki is designed to prevent. Although revision and updating of the declaration is important to ensure that it remains up to date, we must be careful not to stray too far from its original goals.

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More on BMA's approval of acupuncture

BMA replies to correspondence

EDITOR—Moore et al and Kovacs and Gil del Real criticise the BMA's report on acupuncture.[1 2] Our review of the evidence base of acupuncture rested heavily on the comprehensive work of Ernst and White, which summarised the clinical evidence for and against the effectiveness of acupuncture.[3]

The conclusion of this work is that acupuncture seems to be more effective than sham acupuncture or other control interventions for some conditions, including nausea and vomiting, back pain, dental pain, and migraine. However, for smoking cessation, weight loss, and a range of other conditions the present evidence is unclear. We discussed the problems introduced in basing conclusions on poor quality studies or reports.

Our survey of general practice throughout the United Kingdom showed that acupuncture is the complementary therapy most used by general practitioners, with most patients being referred for pain relief and musculoskeletal disorders. Acupuncture is now reported to be used routinely ahead of physiotherapy and drug delivery systems in 86% of chronic pain services.[4]

The thrust of our recommendations seems to have been missed. The BMA calls for substantial research funding, the production of guidelines, and a formal appraisal of acupuncture. Kovacs and Gil del Real should note that our recommendation about availability of acupuncture in the NHS was subject firstly to having policies, guidelines, and mechanisms for making this treatment generally available—hence the need for appraisal by the National Institute for Clinical Excellence (NICE). Improvements in training and regulation of non-medical practitioners are required, and doctors need to know the basics of complementary and alternative medicine so that they are better able to advise patients. Our detailed review of safety and adverse reactions to acupuncture should reassure Moore et al that the treatment is comparatively safe—the more important risk is likely to arise through misdiagnosis and the withholding of orthodox treatment.

There are more than 5500 acupuncturists in the United Kingdom, of whom over 3500 are statutory health professionals, an increase of 51% in two years.[5] Acupuncture treatment has flourished despite a lack of widespread knowledge of its efficacy, and without comprehensive guidelines for either general practitioners or patients. Recommendations clarifying whether acupuncture should be used in the NHS are urgently needed.

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1 Correspondence. BMA approves acupuncture. *BMJ* 2000; 321:1220. (11 November.)
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BMA report is not wrong

EDITOR—The letter by Moore et al denouncing the BMA report on acupuncture is couched in strong language, but their account of the report is selective and misleading.[1] They ignores its recommen-

dation that acupuncture is effective for nausea and vomiting (particularly postoperative symptoms in adults), for which there is a sound body of evidence.[2]

Moore et al misrepresent the BMA's position on smoking cessation; in fact, the report states clearly that "at present there is no evidence to support any role for acupuncture in the management of smoking cessation."

Moore et al state: "There is evidence that it [acupuncture] harms" without reference; in fact, current evidence shows that the incidence of adverse reactions to acupuncture is low.[3]

The evidence remains equivocal on the use of acupuncture for chronic pain. The most recent systematic review found that acupuncture is better than no treatment (waiting list controls) but that it is premature to draw conclusions about the effectiveness of acupuncture compared with placebo or standard care.[4]

Performing double blind placebo controlled trials of acupuncture is exceptionally difficult. Pending such gold standard evidence, the BMA accepted the task of dispassionately evaluating the available literature to define an appropriate role for acupuncture in the NHS. Its report is not "quite simply wrong," and such dogmatism does not serve our patients or enhance the quality of debate on this important subject.

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Acupuncture techniques should be tested logically and methodically

EDITOR—Neither the BMA in its report on acupuncture nor the comments of Moore et al are entirely right or wrong.[1] Lack of evidence for efficacy does not equal evidence for lack of efficacy. Obtaining evidence of efficacy for acupuncture has been hampered by methodological problems unique to this kind of manual therapy, particularly that of finding a credible, truly inactive, control procedure. There are now credible sham acupuncture procedures in which skin penetration in the control group is avoided, and the first trial to use such a procedure indicates a specific effect for acupuncture.[2]

Systematic reviews of acupuncture for back pain include trials that use different techniques and control procedures. These would usually be considered far too heterogeneous to be included in a review. The highest quality trials compare needling of classic acupuncture points with control procedures that entail exactly the same type of needling at other points. The intragroup effects in these trials nearly always indicate a noticeable improvement after needling, but, inevitably, the difference between what is described as real acupuncture and what is described as placebo is rarely significant. As discussed by Moore and McQuay, the controls used in blinded studies of acupuncture for chronic back pain were 50% effective.[3] These controls entailed skin penetration, so one form of acupuncture was compared with another. A 50% response rate is typical of effective treatments for acute and chronic pain.[4]

In their drive for academic rigour, reviewers are distracted from taking a logical overview of the subject. There is no evidence that acupuncture points exist, so subjecting acupuncture points to rigorous testing is unlikely to be rewarding. There is a wealth of evidence, however, that somatic sensory stimulation can modulate pain.[5] Needle penetration of tissues is a potent form of sensory stimulation. It is on this basis that the British Medical Acupuncture Society trains doctors in an evidence based approach to dry needling therapy. Safety issues are important, but for general practitioners or pain specialists acupuncture is still probably one of the safest of the physical or pharmacological interventions they use.

There is a dearth of randomised control trials with positive results, but this may be due more to methodological difficulties than a lack of efficacy. The positive results in lower quality trials may not be attributable solely to bias. The pain community would be done a disservice if acupuncture techniques were not tested in both a logical and methodologically sound manner.

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Avoidance of ingestion of anti-inflammatory drugs in dyspepsia is confounding variable

EDITOR—Langman et al in their paper on the effect of anti-inflammatory drugs on overall risk of common cancer describe a method using coded data from the general practice research database to support their hypothesis that anti-inflammatory drugs may protect against oesophageal and gastric cancer.[1] The study reported the association between a reduction of coded cases of cancer of the oesophagus, stomach, colon, and rectum in a subpopulation who had received at least seven prescriptions in the 13-36 months before diagnosis.

This conclusion seems to be ambitious as aetiologically it seems unreasonable to anticipate that the use of a drug in the 36 months before diagnosis will halt a neoplastic process that may have began many months or years before. Gastrointestinal cancer (particularly of the oesophagus and stomach) is often associated with abdominal pain and dyspepsia. Patients and their attending clinicians will avoid the use of anti-inflammatory drugs in the presence of such dyspepsia. Thus the reported association between the use of anti-inflammatory drugs near the time of diagnosis is more elegantly explained by the confounding avoidance of these drugs in dyspepsia associated with malignancy.

Langman et al also describe a possible dose effect, and once again this is equally well explained by the greater avoidance of these drugs in patients with increased dyspepsia rather than by invoking a hypothetical mechanism of gut epithelial protection. One of the great advantages of collecting clinical information in a coded format is that new associations may be discovered by using a variety of techniques including knowledge discovery in databases (P J B Brown and V Raymond-Smith, unpublished data).[2] If such exploitation of repositories of data is to gain recognition and acceptance in medicine vigilance is needed in interpreting these associations and a full consideration of possible confounding factors is essential before proposing new theories.

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Risk of torsades de pointes with non-cardiac drugs

Prolongation of QT interval is probably a class effect of fluoroquinolones

EDITOR—Yap and Camm emphasise the risk of torsades de pointes associated with non-cardiac drugs that prolong the QT interval.[1] They comment on the fluoroquinolone antimicrobial agents grepafloxacin and sparfloxacin causing QT prolongation but also the apparent lack of this effect with levofloxacin. We recently cared for a patient who developed torsades de pointes while taking levofloxacin, which prompted us to examine retrospectively paired electrocardiograms in other patients to compare QTc intervals before and after they started treatment with this drug.

Twenty three patients who received a standard dose of 500 mg levofloxacin daily had cardiograms that could be compared for QTc prolongation. Prolongation of >30 ms was found in four patients and of >60 ms in

two patients. Absolute QT interval prolongation of >500 ms was present in four, one of whom developed torsades de pointes. This patient was also receiving amiodarone, which is known to prolong the QTc interval but not commonly associated with pro-arrhythmia when used alone.

The United States Food and Drug Administration's spontaneous reporting system documents 11 other cases of torsades de pointes in patients receiving levofloxacin, and Samaha reported on an additional patient who also was receiving amiodarone.[2] Studies in rabbit Purkinje fibres have shown a concentration-dependent prolongation of the maximal rate of depolarisation at concentrations of ofloxacin up to 100 µmol/l, but the trend did not achieve significance.[3] Serum concentrations of 8 µmol/l are achieved by levofloxacin, but the affinity for cardiac tissues is unknown. The Food and Drug Administration has recently requested studies of levofloxacin on cardiac electrophysiology.

Our data indicate that prolongation of the QT interval is probably a class effect of the fluoroquinolones including levofloxacin. Care should be taken when this agent is used with type IA and type III antiarrhythmic agents and in situations such as hypokalaemia and hypomagnesaemia that increase the risk of pro-arrhythmic events.

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Competing interests: PBI is a consultant for Bristol-Myers Squibb, Aventis, SmithKline Beecham, Bayer, Roche, Glaxo, TAP, and Abbott pharmaceutical companies. None declared for SD, EB, IC, and HK.

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Grapefruit juice is source of potentially life threatening adverse drug reactions

Editor—Yap and Camm state that "In clinical practice, adverse effects of QT prolonging drugs can be prevented by not exceeding the recommended dose; by restricting the dose in patients with pre-existing heart disease or other risk factors; and by avoiding concomitant administration of drugs that inhibit drug metabolism or excretion, prolong the QT interval, or produce hypokalaemia."[1] This leaves out one important point.

Grapefruit juice inhibits the same cytochrome P450 as the imidazoles and macrolides.[2] As a result, QT prolongation from interactions between these drugs and cisapride or terfenadine (among others) is just as likely as QT prolongation from interactions between grapefruit juice and cisapride or terfenadine. It was my understanding that the regulatory changes that led to terfenadine being removed from the shelves and made a prescription only drug were partly a result of this effect.[3]

The effect was first noted in 1989 when grapefruit juice was used as a masking agent for the taste of felodipine in a small study on the interaction between alcohol and felodipine.[4] The effect has been widely studied and involves not only cisapride and felodipine (but not non-dihydropyridine calcium channel blockers) but also carbamazepine, caffeine (but not theophylline), ethinyloestradiol, cyclosporin, coumarin, some of the statins, saquinavir, and some benzodiazepines.[1 5]

The effect of grapefruit juice is perhaps not as well known or appreciated as it should be and is a source of potentially life threatening adverse drug reactions that are easily avoidable. Doctors and the general public need to be aware of this effect as even seemingly harmless drugs may lead to serious effects.

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1 Yap YG, Camm J. Risk of torsades de pointes with non-cardiac drugs. *BMJ* 2000;320:1158-9. (29 April.)
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Outpatient hysteroscopy versus day case hysteroscopy

Larger and more robust studies are needed

Editor—Studies that may reduce the number of unnecessary investigations or treatments are always welcomed by clinicians. Kremer et al perceive a reluctance to abandon general anaesthetic procedures for the investigation of menstrual problems,[1] and this has also been reported by Penney et al.[2]

Kremer et al compared a group given outpatient hysteroscopy with one given day case hysteroscopy. They found no significant difference between the two groups with respect to postoperative pain, but it is difficult to compare these groups accurately for several reasons. Outpatient hysteroscopy was performed without analgesia, but general anaesthetic procedures presumably included a short acting opiate with the anaesthetic. The analgesics used for general anaesthesia are unfortunately not described. Was the method of anaesthesia standardised?

Only 62% of the patients who had outpatient hysteroscopy underwent endometrial sampling, whereas all of the women who had hysteroscopy under general anaesthesia had curettage. This makes comparison of the groups difficult as curettage may be a painful procedure in itself.

It may be possible to reduce the pain associated with outpatient hysteroscopy further by using mefenamic acid before the procedure[3] or using smaller diameter scopes than the 3.6 mm hysteroscope used in this study. There is no evidence that smaller hysteroscopes are less sensitive for endometrial disease.

Postmenopausal women were less satisfied with outpatient hysteroscopy; the question here is whether these women needed hysteroscopy as a primary investigation. Transvaginal ultrasonography combined with endometrial sampling is as sensitive as hysteroscopy for the detection of endometrial adenocarcinoma and is more sensitive than vaginal examination for the detection of ovarian disease.[4] It must be accepted that a considerable number of these women will eventually need hysteroscopy because of common benign abnormalities causing false positive results on ultrasonography.[5]

If reluctance to initiate services for the outpatient investigation of menstrual symptoms is to be overcome it must be backed by larger and more robust studies.

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Author's reply

Editor—The purpose of this study was to compare a relatively new method of investigation such as outpatient hysteroscopy with a standard and well established form of investigation such as day case hysteroscopy. Consequently one would logically insist on the standard investigation to be performed in the usual manner—that is, with a short acting opiate and curettage.

We are aware that curettage is associated with postoperative cramping. What Hardwick must also recognise is that endometrial sampling with a Pipelle device is far from being painless; in practice it is often more painful than the hysteroscopy itself.[1]

We did not standardise the method of anaesthesia, partly because this was a pragmatic trial and several different anaesthetists were involved. We do know that mefenamic acid before the procedure reduces postoperative cramps,[2] but this evidence was not available for us to use at the start of our trial.

Transvaginal ultrasonography combined with endometrial sampling may well have a place in the management of patients with postmenopausal bleeding. This role, however, needs to be assessed in randomised trials

similar to that of Tahir et al.[3] As Hardwick mentions, a considerable number of postmenopausal patients will eventually need hysteroscopy, not only because of false positive findings on ultrasonography but also because of true positive findings (43%[4]). These findings could have been evaluated if the patients had had a hysteroscopy in the first place.

Theoretically it is often preferable to do a larger study, but one should question the clinical relevance of the eventual findings. For example, if we had chosen a difference of interest of 10% (instead of 25%) we would have required over 600 patients to keep a study power of 85%.[5] But is a difference in satisfaction rates of 10% clinically useful?

Overall we think that too much emphasis is put on the issue of pain surrounding outpatient hysteroscopy. A small proportion of patients do, undeniably, experience considerable pain, but most patients do not, and they trade off the minimal discomfort they experience with the convenience and interaction of outpatient hysteroscopy.

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What exactly is patient satisfaction?

Editor—Increasingly, trials of new interventions include patient satisfaction as an outcome measure. As the editorial by Naftalin and Habiba points out, this is to be welcomed.[1] Yet the methods used to measure satisfaction are often questionable. The problem is illustrated by the study of patient satisfaction with outpatient hysteroscopy versus day case hysteroscopy.[2]

Firstly, what is meant by satisfaction?[3] In this study, it is defined as the respondent choosing to have the procedure in the same way if it should be required again. Is there justification for assuming that this indicates satisfaction? In other words, is this a valid measure?

It is conceivable that a patient may be dissatisfied with aspects of her experience yet still choose the same procedure, perhaps because of convenience or other factors. Also, those who have not experienced the alternative cannot make a fully informed choice. In such studies, it is common to find that patients express preferences for what they have experienced. Preliminary investigation of the factors determining satisfaction might have overcome these problems. In a qualitative study the issues of importance to patients could have been identified, the findings being used to guide the selection of appropriate questions to ask.[4]

Secondly, is asking a single question the best measurement method? Single questions tend to have lower reliability than groups of questions. Does a yes/no response adequately account for the range of patients' views? Can a single question adequately account for the various factors that constitute satisfaction?

Kremer et al should be applauded for measuring patient satisfaction. It would be unreasonable to single them out for criticism since their methods are typical of those usually used in trials. Researchers planning to measure satisfaction in future trials, however, should give careful thought to what they mean by patient satisfaction and how it should be measured.

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Pharmacological prevention of acute mountain sickness

Many climbers and trekkers find acetazolamide 500 mg/day to be useful

Editor—Dumont et al reach a false, potentially harmful conclusion in their paper on the efficacy and harm of pharmacological prevention of acute mountain sickness.[1] Their claim that acetazolamide 500 mg/day does not work in preventing acute mountain sickness must be challenged. Their analysis is flawed for three reasons.

Firstly, they used only nine of 25 available controlled studies, and analysed only four of 10 trials with acetazolamide 500 mg/day. Consequently, only 143 individuals taking acetazolamide 500 mg/day were included, 120 from one study.[2] In that investigation the rate of ascent in one of the two trials was so slow that acetazolamide made no difference in acute mountain sickness scores. The other trial, with faster rate of ascent, showed acetazolamide to be very effective. Another meta-analysis, of 10 trials of acetazolamide 500 mg/day (306 participants), concluded that it was effective.[3] If Dumont et al included more trials they would find that acetazolamide 500 mg/day is indeed effective.

Secondly, rate of ascent was not adequately controlled. The authors compared acetazolamide 750 mg/day (250 mg three times a day) during particularly rapid ascent with 500 mg/day with much slower ascent. If the 500 mg dose is not tested during an abrupt ascent similar to that by the group taking the 750 mg dose the comparison is not valid.

Thirdly, Dumont et al chose an unnecessarily strict end point for their analysis: the dichotomous presence or absence of acute mountain sickness. Many people with symptoms of acute mountain sickness, while not meeting criteria for acute mountain sickness, do indeed find acetazolamide helpful. In fact, Dumont et al did note that the drug was found to be effective prevention for headache, insomnia, nausea, and dizziness in various studies not included in their analysis.

Rigorous trials comparing dosages of acetazolamide are lacking, but a huge clinical experience cannot be ignored: climbers, trekkers, and tourists find lower doses of acetazolamide very useful, with fewer side effects. Moreover, the clinical impression that acetazolamide works at 250 mg twice daily has been so strong that many clinicians (myself included) have lowered the dose further, to 125 mg twice daily, with no apparent decrease in effectiveness.

Pending further research, I urge doctors to recommend acetazolamide 125-250 mg twice a day (depending on body size) for the prevention of acute mountain sickness. Since renal carbonic anhydrase inhibition is complete with acetazolamide 5 mg/kg/day, even 500 mg/day is more than most people need. Trials directly comparing effectiveness of varied dosages are essential; this meta-analysis is flawed.

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1 Dumont L, Mardirosoff C, Tramèr M. Efficacy and harm of pharmacological prevention of acute mountain sickness: quantitative systematic review. *BMJ* 2000;321:267-72. (29 July.)
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Same ascent rates must be used to assess effectiveness of different doses of acetazolamide

Editor—Dumont et al's meta-analysis included only controlled studies reporting dichotomous data on acetazolamide for the prevention of acute mountain sickness.[1] Their conclusion that "contrary to widespread belief, 500 mg of acetazolamide does not work" is not supported by the data presented or by many papers excluded from the analysis.

Figure 3 of the paper shows that the relative risk depends on the rate of ascent. The effects of different doses of acetazolamide should therefore be compared at the same ascent rate. The ascent rates of four of the five field studies in which 750 mg acetazolamide was used were above 2400 m/day (100 m/h). In contrast, the three studies in which 500 mg acetazolamide was used had

ascent rates of ≤500 m/day (20 m/h). Two datapoints referring to these studies (fig 3) have a high number needed to treat (≥20). One of these can most probably be attributed to a slow ascent rate with a low relative risk and insufficient statistical power. Thus there remains one study that seems to support the main message of the meta-analysis.[2]

A careful look at this paper shows, however, that this is not the case. Cerebral symptoms (AMS-C (acute mountain sickness-C) score) and respiratory symptoms (AMS-R score) were assessed by the environmental symptom questionnaire[3] for several days at 3650-4050 m. During the first three days the number needed to treat was always below 4.7 for assessments with both scores (except for AMS-R on day 1, when it was 27.8). Interestingly, Dumont et al consider only this single value for classifying the study. The investigators of the study, however, report an overall incidence of acute mountain sickness assessed by the AMS-C score of 38% for placebo and 16% for acetazolamide, which gives a number needed to treat of 4.5. The corresponding values when the AMS-R score is used are 63% *v* 31% and 3.0. Thus the paper is falsely classified by Dumont et al.

Studies reporting symptom scores rather than presence or absence of acute mountain sickness show that 500 mg acetazolamide daily significantly reduces symptoms. A meta-analysis of all controlled trials until 1993 lists five studies (122 subjects altogether) that found a significant decrease in symptom scores with 500 mg acetazolamide daily, while in two studies (32 subjects) the decrease was not significant.[4]

We conclude that the recommendation of 500 mg acetazolamide daily for the prevention of acute mountain sickness during rapid ascent is supported by scientific evidence. The question whether 500 mg or 750 mg or another daily dose is more effective should be investigated under equal ascent rates.

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Authors' reply

Editor—Some of these comments on our systematic review (and others sent as rapid responses to bmj.com[1]) are based more on assumptions than on evidence. Statements that acetazolamide 250 mg is often sufficient to prevent acute mountain sickness are not helpful. Maté de Coca has been recommended for centuries by the Incas, and even magnesium,[2] pervincamine,[3] and methylene blue[4] may be beneficial. In the absence of valid randomised controlled trials, however, an observation stays an observation.

We would like to clarify some of the issues raised.

Firstly, it seems odd to us that some people make a fuss about acetazolamide**.** Acetazolamide is an old and cheap drug with a low adverse effect profile. There was evidence that 750 mg was effective in the prevention of acute mountain sickness, and there was a lack of evidence for 500 mg with the same end point.

Secondly, the increased efficacy of acetazolamide 750 mg is plausible. Only a few people would argue that a 50% increase in the dose of a drug may not lead to increased efficacy.

Thirdly, our main efficacy end point was complete prevention of acute mountain sickness. This is different from improving symptoms. We concentrated on this high hurdle of efficacy to avoid both observational bias and unnecessary heterogeneity of the data. As with all systematic reviews, the advantage of such rigorous analyses is that readers may get the papers and redo the analysis using their own end points. To reanalyse the 500 mg data using a different end point as suggested would change the pooled number needed to treat for prevention of acute mountain sickness from 7.1 to 6.6. This difference is unlikely to be of clinical relevance.

Finally, the suspicion has been raised that our analysis was based on a biased selection of studies and that we did not include all 10 trials of acetazolamide 500 mg, as in a previously published meta-analysis.[5] We did not include 10 trials for three reasons. Firstly, there are only nine; secondly, four were not randomised; and, thirdly, one did not report any dichotomous data on efficacy or harm. We could have analysed continuous data. The clinical relevance of weighted mean differences and P values, however, is not obvious. What, for instance, does an effect size of −0.61 (95% confidence interval −0.29 to −0.93) indicate?[5] For rational decision making we need to know how well something works, and not only that it works.

We agree that the pivotal trial should randomise subjects at similar rates of ascent to different doses of acetazolamide.

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Trial experience and problems of parental recollection of consent

Editor—The Griffiths report refers to papers providing qualitative research evidence about informed consent in the neonatal extracorporeal membrane oxygenation trial.[1–5] As authors (CS, DE, JG) and principal investigator (DF) of this trial, we focus on one aspect of the report.

The report states that several parents in North Staffordshire had a clear recollection of being asked to allow their children to have continuous negative extrathoracic pressure but no recollection of giving consent to randomisation in a research project (9.3.2). Our research with parents of surviving babies from trials of extracorporeal membrane oxygenation suggests that, in this trial at least, many complicated factors affected the consent process and subsequent recall and reactions.

We interviewed parents some time after their baby had been discharged. A small number had no recollection of randomisation. Others gave varied details about the trial and treatment allocation. The consent process could be difficult, and transmission and reception of important information could be blocked or distorted by several factors. Views and recall could, for instance, relate to treatment allocation. All parents described consenting to extracorporeal membrane oxygenation, but the trial's comparative nature was clear for more of the parents of babies allocated to conventional ventilation. If the comparison was unclear at consent, there was not necessarily a subsequent clarification if allocated to extracorporeal membrane oxygenation; some believed that they simply consented to and used a new treatment. When probed, however, these parents remembered the words randomisation and trial (with various understandings of the terms).

Later views of the trial could be similarly shaped by allocation and perceptions of its consequences. Extracorporeal membrane oxygenation was shown to be more effective than conventional ventilation, and it was viewed as a desirable treatment (new and life saving) that parents had wished to access. Continuous negative extrathoracic pressure is not viewed positively now, but as experimental and risky, and this may also have shaped reactions and later recall of traumatic events for parents in Staffordshire.

The research community is obliged to ensure trials are conducted in the best possible way. To guide practice, scientifically, ethically, and humanely, we need to know how they affect all involved. The research into

extracorporeal membrane oxygenation has effected practical changes (including all treatments in trial titles to highlight comparisons), but more research is needed.

The Nuffield Foundation has funded research to examine views in several perinatal trials. It involves interviewing parents (including bereaved parents) and medical and nursing staff, and occasionally tape recording the consent process. Such research should lead to better informed practice, and address some of the uncertainties remaining following the Griffiths report.

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Birth events and cerebral palsy: facts were not presented clearly

EDITOR—It is regrettable that a report of a conference in a scientific journal should have a headline such as the article by Silvert.[1] Its tone belongs to the counterproductive adversarial approach of lawyers concerned with litigation. It is common ground that causes of the heterogeneous group that comprises the cerebral palsies include antenatal, intrapartum, and postnatal events. The precise proportions contributed by each remain uncertain.

The consensus statement reportedly attacked at the conference, far from denying the importance of intrapartum causes, was entitled: A template for defining a causal relation between acute intrapartum events and cerebral palsy.[2] This well describes its aims, which were to recognise those cases in whom acute intrapartum hypoxia was most likely to have caused cerebral palsy and consider their preventability. There was wide consultation before this consensus was agreed and published.

Certain facts are largely consistent and undisputed. In developed countries the prevalence quoted in the report of 2-2.5 per1000 births includes about 10% cases with a postneonatal cause. About 25% are very preterm births, in which there is often a causal chain spanning both the antenatal and the postnatal period, and they include a proportion of those in whom infective and genetic causes can be firmly established. The identification of these is constantly increasing with developments in medical technology.

A history of the cluster of characteristics suggesting that adverse intrapartum events have contributed to the causal pathway has been reported in about 16%, but in only 10% is there no additional evidence of antenatal damage.[3] Not all cases in these 10% are necessarily the result of medical accidents. Some might not have been preventable even with the best obstetric care, both because there may have been unrecognised antenatal damage and because the professionals in charge are neither omniscient nor omnipotent, and there are often problems in the systems under which they work. Among these 10%, however, are the cases the most likely to have been preventable by better intrapartum medical care, and it is important that they be recognised, not simply for the purposes of litigation, but to prevent recurrence. In an issue as sensitive as this it is a disservice to both parents and the health professions not to present the facts clearly, or to reiterate views for which there is no substantive evidence.

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Reducing speed limit to 20 mph in urban areas

Evidence based principles should be applied to non-health sector interventions

EDITOR—Pilkington supports a reduction in traffic speeds to 20 mph (32 kph) on the basis of research that would be methodologically unacceptable in clinical practice.[1] He implies that absolute reductions in accidents can be interpreted in terms of reductions in risk to individuals.

One hypothesis is that traffic calming schemes simply redirect traffic and accidents to other roads, with no overall reduction in risk. The Transport Research Laboratory described the findings of 72 schemes to reduce traffic speeds to ⩽20 mph.[2] Information on accidents on surrounding roads was available from only 40 sites, and overall no significant change occurred.

Pilkington accepts the laboratory's conclusion that there was no apparent accident migration on to surrounding roads. But this is absence of evidence that accidents migrate and not evidence of absence. The overall summary statistic masks increases in accidents on surrounding roads of up to 50% in 17 of the 40 sites. Consider basing a clinical decision on these criteria: the harm to benefit odds are only 1:1.4, and the magnitudes of harmful and beneficial effects are similar (21% (range 2-50%) *v* 24% (3-54%) respectively).

Pilkington drew extensively from a newspaper article that got facts wrong.[3] The 30 kph (19 mph) traffic calming measures in Graz, Austria, did not reduce air pollution, and local approval rose to 68% (G Sammer, 76th annual meeting of Transportation Research Board, Washington, DC, January 1997), not "8 out of 10."[1]

There is an important distinction between reductions in accidents and reductions in risk, illustrated by the effects of the introduction of laws concerning compulsory use of bicycle safety helmets in Victoria, Australia, in 1990. Deaths and serious injuries in cyclists fell by around a quarter,[4] but there was a concomitant reduction of 36% in bicycle use by children. It was not clear whether risk had been reduced or laws had discouraged a healthy activity that should be promoted. Consequently the BMA's board of education and science advised that cycle helmets should not be compulsory in the United Kingdom. Until reductions in accidents after the introduction of traffic calming measures are expressed in terms of risks to pedestrians, cyclists, and motorists we cannot separate numerator and denominator effects.

Evidence for health effects of non-health sector interventions ought to be of the same standard as we require in health services; the potential for health effects is much greater. Would we argue to use a new treatment on the basis of evidence that its potential effects were negligible and its potential side effects included serious injury or death?

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Long term sequelae of road traffic accidents must not be underestimated

EDITOR—Pilkington highlights the major threat to the lives of children in the United Kingdom that is posed by road traffic accidents.[1] The devastating consequences for the survivors of these accidents and their families need further elaboration. The chronic sequelae that create difficulties in

interpersonal, educational, and social functioning are the behavioural and cognitive problems.[2] A large proportion of children who sustain a traumatic brain injury after the age of 3 present with emotional problems.[3] The implications for further education and eventual employment opportunities are obvious.

The acute medical care of individuals with a traumatic brain injury has made considerable advances over the past three decades, resulting in an increased number of survivors. Limited rehabilitation programmes have been developed for these patients in the United Kingdom.[4] The impact on the individual, the family, and society (including the NHS) is enormous and should not be underestimated. The economic cost (both direct and indirect) of traumatic brain injury is immense.[5] This takes on added weight when one considers that most people who survive a traumatic brain injury have a normal life expectancy.

Any measure to reduce the incidence of traumatic brain injuries resulting from road traffic accidents should be supported. This includes a reduction in the speed limit to 20 mph (32 kph) in urban areas. As Pilkington points out, other issues such as driver education and enforcement also need to be addressed. The potential for reducing deaths and injuries as well as costs to the NHS may be considerable.

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Health professionals should ensure that local authorities reduce speed limits

Editor—The positive effect on child health of reducing speed limits in urban areas[1] should not be underestimated. Road traffic accidents are a major cause of death in children. The silence of organisations such as the Royal College of Paediatrics and Child Health is a great disappointment. If a new drug or vaccine could prevent the deaths of 70 children each year there would be a demand to make it readily available to all communities.

The simple measure of reducing the speed limit in residential areas, near schools and play areas, would not only save lives but also improve the quality of life for residents, especially young and elderly people. Health professionals have a responsibility to ensure that local authorities reduce speed limits, explain why they are doing so, and enforce the new speed limits. If we do not do so then we will continue to kill more children than our European neighbours do.

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Both advisory and mandatory speed limits are being introduced in Edinburgh

Editor—Pilkington writes about the benefits of 20 mph (32 kph) speed limits.[1] Councils throughout Scotland are conducting trials of advisory 20 mph limits as part of a Scottish Executive initiative. In Lothian these are generally in residential areas and often linked with "safe routes to schools" projects. A small number of mandatory 20 mph zones exist, with proposals in Edinburgh for a city-wide 20 mph limit in residential areas and on shopping streets.

Road traffic accidents are not spread evenly across communities; disadvantaged children are much more likely to be involved in them.[2 3] In Edinburgh the city council has made traffic calming measures in areas with high accident rates a feature of its road safety strategy since the early 1990s. These measures have been mainly engineering measures to calm traffic in more disadvantaged parts of the city.

These measures have resulted in lower speeds and a 39% reduction in reported accidents in areas calmed under the casualty reduction programme (versus 29% reduction where environmental traffic management was the aim and 4% reduction where measures were in connection with bus priority routes). This is against a picture of relatively stable accident levels in the council area during the 1990s and suggests that targeting areas with high accident levels can produce good results; it ties in with other Scotland-wide data.[4]

Engineering measures are costly, with the city council spending some £1.2m for the casualty reduction programme. Whether the much less expensive advisory 20 mph schemes will be of similar benefit remains to be seen, but some lessons about implementing and enforcing them have emerged. As the schemes are merely advisory, they can be enforced only if motorists are driving dangerously.

Anecdotal evidence from early schemes suggests that, while speeds are generally falling, many motorists have not moderated their speed. These motorists are often local residents who believe that they know the road (Lothian and Borders Police, personal communication). This emphasises the importance of community consultation before schemes are introduced and regular feedback to the community after they are in place—in Scotland only around a third of residents have rated the consultation as sufficient. Where consultation is good, satisfaction with the scheme put in place is high.

The Scottish needs assessment programme recently conducted a health impact assessment of Edinburgh's transport policy, which endorses the city council's transport policy as a means to promote social inclusion and reduce inequalities.[5] The policy supports less reliance on cars and promotes walking and cycling, development of public transport, and integrated land use policies.

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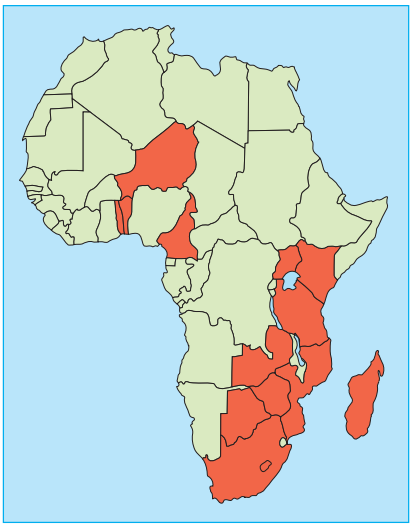
Email health support service is already operating in Africa

Editor—We agree with Fraser and McGrath that email is an effective and practical medium for healthcare support in remote regions[1] and that many patients in rural areas may soon benefit from telemedicine projects.[2] In Britain we have been providing an international email health support service since April 1998,[3] which has been accessed frequently in sub-Saharan Africa. Our service is successful and highly valued,[4] and it is constantly being improved and expanded. It was initially developed for the overseas training programme of Voluntary Service Overseas, which is the largest independent agency in the world to send volunteers. Trainees in this programme (age 18-25) are placed in community based projects overseas for up to 12 months. Many placements are in extremely remote areas, but in spite of this, email is a medium that can be readily used. In many cases it is easier to email the overseas training programme doctor in the United Kingdom than contact the local doctor. A large proportion of trainees are in sub-Saharan Africa, and so far the email service has been accessed in Cameroon, Benin, Zimbabwe, Botswana, Tanzania, Kenya, Mozambique, Togo, Lesotho, Niger, Uganda, Zambia, South Africa, and Madagascar (figure).

We have developed a health support service that incorporates the use of email. Our service includes advice before departure, medical support while in the field, and follow up on return to the United Kingdom. The success of our email consultation service hinges on personal knowledge of the individual, their medical history, their placement, and their local doctor and healthcare facilities, which may be some distance away



Countries in Africa where overseas training programme email service has been successfully used

and not easily contacted by email or telephone. Our email response is within 24 hours, and we can communicate with doctors in the country when required. Various medical and psychological conditions have been successfully identified and managed, aided by appropriate background knowledge and liaison with local services. In addition to expanding the current service we intend to develop it further to support also local doctors participating in these development projects.

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Doesn't everyone know that purpose of advertising is to promote products?

EDITOR—Hastings and MacFadyen's paper about tobacco advertising tried to establish that the tobacco industry targeted those below the legal age for smoking, but the conclusion seems uncertain.[1] They wrote: "The precise definition of 'young' remains contentious." Later they said "Whether the industry is deliberately targeting under 16 years olds remains a matter for dispute." Words like "contentious" and "dispute" imply uncertainty. The industry insisted that it only targeted young adults—young but adults nevertheless—and there is no concrete evidence from industry documents to disprove this. Documents from Synergy Consulting that are quoted (box 4) are not tobacco companies' documents.

The authors pointed out that voluntary agreements with the industry prohibit "any attempts to play on the susceptibilities of those who are emotionally or physically vulnerable, especially young people," and suggested that the industry had done exactly that. But the paper does not have any definition of the age of "young people."

When the voluntary agreements with the industry refer to young people the industry means children and teenagers under the legal age for smoking, to whom the sale of cigarettes is illegal. If that's what the law says, one could not blame the industry for marketing to 17 year olds.

But when health communities discuss youth smoking their definition of young tends to be vague: anyone up to 25 or even older is considered young. If that is the case the health community should advocate raising the legal age.

The authors said industry "is doing everything it can to encourage smoking." This is not surprising: every manufacturer of a legal product will do everything within the law to encourage use. As for the industry not acknowledging health consequences of smoking, is this necessary? Is there any teenager (the most vulnerable age for taking up smoking) in the United Kingdom who genuinely believes that smoking is good for health? Of course not.

What about mobile phones and health hazards? The public (mature adults, not teenagers this time) is puzzled about this issue, but would mobile phone companies advertise the health consequences of their product? No, of course not. Will mobile phone companies do everything to encourage use? Yes, of course.

There is probably no need to do research on the subject. Everyone knows that the purpose of advertising and marketing (regardless of the product) is to promote and sell a product. Is there any manufacturer in the world who spends money on advertising to encourage consumers to stop using its product? None, of course. So what is the point of any research? Simply ban advertising of any product that is detrimental to health.

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Support from pharmacies can help people stop smoking

EDITOR—Lancaster et al reported that advice from general practitioners and structured interventions from nurses are effective in helping people stop smoking.[1] They did not mention the potential contribution of other members of the primary healthcare team.

Pharmacists and their staff are well placed to support people wanting to stop smoking. They can provide advice over the counter or, for those pharmacies with consultation facilities, in a more formal clinic setting. Many people entering a pharmacy for help with stopping smoking will be considering purchasing nicotine replacement therapy as part of a serious attempt to stop. Suitably trained pharmacy staff can increase the effectiveness of nicotine replacement therapy by offering brief counselling at the point of sale.

We have shown the efficacy[2] and cost effectiveness[3] of such an approach. We commissioned a two hour smoking cessation training package, based on the stage of change model, for community pharmacists and their staff and evaluated its effect in a randomised controlled trial.

Pharmacy customers who were starting a new attempt to stop smoking were recruited, and were followed up after one, four, and nine months. We assumed that non-respondents were continuing smokers. One month point prevalence of abstinence was claimed by 30% of intervention customers and 24% of controls ($P=0.12$); four months' continuous abstinence was claimed by 16% of intervention customers and 11% of controls ($P=0.094$); and nine months' continuous abstinence was claimed by 12% of intervention customers and 7% of controls ($P=0.089$). These trends in outcome were not affected by potential confounders or by clustering at the pharmacy level. The intervention was also associated with increased and more highly rated counselling.

Pharmacy staff working on their own can make a large contribution to smoking cessation. Much more could be achieved through a coordinated approach to intervention that uses all members of the primary care team.[4]

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