Letters

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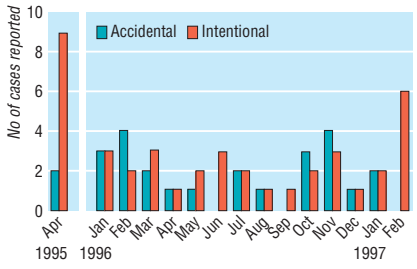
Effects of drug overdose in television drama on presentations for self poisoning

Antifreeze poisonings give more insight into copycat behaviour

EDITOR—Hawton et al highlight the effect of the media on influencing the incidence of deliberate self poisoning.[1] However, they and other authors suggest that the changes noted are the result of spontaneous variation in the patterns of particular overdoses rather than a direct effect of the specific televised incident.[2 3] One of the limitations of previous studies has been that the investigators have monitored the total numbers of deliberate self poisoning and, specifically, paracetamol overdoses, which are comparatively common. A clearer picture emerges for agents used less commonly for deliberate self harm, such as antifreeze, which commonly contains ethylene glycol or methanol.

The figure shows the numbers of intentional and accidental cases of poisoning by ethylene glycol reported to the National Poisons Information Service (London) during two specific months and, for comparison, from January 1996 to January 1997. In April 1995 the *Independent* reported an inquest into an antifreeze poisoning,[4] which subsequently received further media coverage. On 15 February 1997 an episode of the BBC television drama *Casualty* depicted an incident of self harm with ingestion of antifreeze.

The mean number of intentional antifreeze poisonings for 1996 was 2.0 per month (range 1-3 per month). Moreover, the mean number of cases reported during 1995 and 1997, excluding the incident months, was 1.9 and 1.8 respectively. For April 1995 and February 1997 the number of reported cases was 9 and 6—a significant increase ($P = 0.016$). Interestingly, all the cases of intentional ingestion of antifreeze during April 1995 and February 1997 occurred after the announcements in the media. Furthermore, in one specific case not only the agent but also the manner in which the antifreeze was taken (mixed with lemonade and drunk in a field) was identical with that reported.



Numbers of intentional and accidental cases of ethylene glycol posoning reported to the National Poisons Information Service (London)

These data further support the concept that media portrayal of self poisoning influences subsequent self harm behaviour.

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1 Hawton K, Simkin S, Deeks JJ, O'Connor S, Keen A, Altman DG, et al. Effects of a drug overdose in a television drama on presentations to hospital for self poisoning: time series and questionnaire study. *BMJ* 1999;318:972-7. (10 April.)
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A causal association cannot yet be inferred

EDITOR—Hawton et al compared hospital presentations for self poisoning during the three week periods before and after the screening of a medical television drama.[1] Their aim was to ascertain whether the programme altered the incidence of self poisoning. They attributed the increased frequency during the second period to a possible short term influence.

The Scottish morbidity record system collects information on all admissions to Scottish NHS hospitals. These data are collated by the Information and Statistics Division of the Common Services Agency and linked to the general registrar for Scotland's database, which provides supplementary information on deaths outside hospital. Data were obtained on admissions and deaths attributed to all self poisoning and paracetamol overdoses between January 1995 and December 1997 inclusive.

During this time the number of admissions attributed to deliberate poisoning rose steadily and showed substantial monthly variation. The number attributed to accidental poisoning remained comparatively constant, implying that the trend in deliberate poisoning was unlikely to be an artefact due to changes in coding practice. Deaths attributed to all self poisoning and paracetamol poisoning varied widely by month.

If the conclusions of Hawton et al were correct, a significant increase would be expected in the numbers of admissions to hospital and deaths in November 1996. In fact, the number of admissions for all self poisonings fell in November 1996 and continued to fall until March 1997. Admissions for paracetamol poisoning rose in November 1996, but the rate of increase was lower than that for the rise from September 1996 to October 1996 and was well within the parameters of chance variation. The number of deaths from all poisonings rose slightly but was also within the range of chance variation.

Although the episode of *Casualty* may have had an impact on hospital presentations, a causal association cannot be inferred without showing among other things that the increase shown by Hawton et al could not be explained simply by an existing upwards trend or normal chance variation.

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We thank Scott Reald and Jennifer Riddell at the Information and Statistics Division for providing the data on which the analyses were based.

1 Hawton K, Simkin S, Deeks JJ, O'Connor S, Keen A, Altman DG, et al. Effects of a drug overdose in a television drama on presentations to hospital for self poisoning: time series and questionnaire study. *BMJ* 1999;318:972-7. (10 April.)

Study is impressive but raises methodological concerns

EDITOR—The study by Hawton et al examining the effects of a medical television drama on the incidence and nature of general hospital presentations for deliberate self poisoning[1] has provoked considerable interest in medical and popular media. The role of imitation in suicide attempts is not a new phenomenon. It was named the Werther effect after an epidemic of copycat suicides in young men who read Goethe's *Die Leiden des Jungen Werthers*. The effect has been described after television films depicting fictional suicide.[2] Television is certainly a powerful medium in contemporary society.

We have a methodological concern about the study of Hawton et al which was not addressed in the discussion: the study was not well controlled. They compared overdose rates between a baseline period before the drama was broadcast and each of the three weeks after the index episode.

The authors acknowledge the possibility that an overdose depicted in a second soap opera six days after the index episode may have had a minor influence on results. We note that the end of British summer time also coincided with the observed trend of increasing rates of overdoses that began in the week before the drama was broadcast. The consequent reduction in evening daylight represents an external stressor that could be associated with parasuicide. Although Shapiro et al could not confirm such an association,[3] the temporal relation of the return to winter time with the rise in overdose rates raises the possibility of this being a confounding factor that cannot be excluded given the methods of the study. Other potential confounding factors include seasonal changes in weather and temperature and the impact of unrelated items in national and international news.

A more robust study design would entail a comparison of the change in overdose rates before and after the November 1996 screening to the change over a similar period one year earlier or later. An alternative would be an investigation of any change in overdose rates in a region or state where the index episode was broadcast compared with an area where it was not shown.

The study of Hawton et al was certainly impressive in its coordination of data from many sources. It will continue to stimulate valuable debate on the responsibilities of media producers in portraying self harming behaviour. We believe that the results must be interpreted with caution. The limitations of the study design should be recognised.

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Authors' reply

Editor—These correspondents express concerns about the design and conclusions of our study of presentations for self poisoning after the broadcast of an episode of *Casualty*. They contest the robustness of our comparison and suggest that seasonal trends, random variability, or other confounding factors could explain our findings.

Pell and Murdoch also report that there was no increase in monthly admission rates for self poisoning in Scotland after the broadcast, but we are concerned that aggregation at a monthly level may obscure an increase that at most lasted two weeks.

To estimate random variability in weekly self poisoning rates we recorded presentations in 49 centres for three weeks immediately before the broadcast. Our statistical analysis showed the observed 17% increase in presentation rates after the broadcast to be substantially larger than could reasonably be explained by natural variation. Random variability is not a tenable explanation.

Interrupted time series studies cannot provide totally convincing evidence of effect as it is impossible to exclude the possibility that other unknown factors and trends may confound the comparison. However, we do not think that the suggested mechanisms are of concern. Studies of seasonal effects on suicide attempts across Europe consistently show peaks in the spring and nadirs in December, with a maximum variation of 26% between the two, the variation being stronger in women than men.[1] This pattern is contrary to the suggestion of Davies et al but in line with the observations of Pell and Murdoch. Changes in suicide rates with weather do exist but are small,[2] as is the ongoing upward trend in admissions for self harm. These factors are unlikely to have caused the increase in self poisoning presentations of 17% in one week across 49 centres.

Although alternative comparison groups may seem preferable, the practicalities of undertaking this project make many suggestions impossible, and others are not as reliable as one might first think. Studies based on comparisons between places or between disjoint time periods may be seriously biased, not only because of confounding but also because of the difficulties in ensuring consistent data collection. We aimed at minimising these problems by collecting data from adjacent time periods and making comparisons within centres.

We anticipated the weaknesses of a time series design and additionally surveyed a sample of patients admitted with self poisoning throughout the study, asking about their motivations and television viewing. We found that those among them who watched *Casualty* changed their choice of substance after the broadcast, the proportion using paracetamol increasing by 106% (95% confidence interval 28% to 232%). This is the crucial supporting evidence on which judgments of causality should be made.

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1 Jessen G, Andersen K, Arensman E, Bille-Brahe U, Crepet P, de Leo D, et al. Temporal fluctuations and seasonality in attempted suicide in Europe: findings from the WHO/EURO multicentre study on parasuicide. *Archives of Suicide Research* 1999;5:57-69.
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Medical fiction could be misleading

Editor—Medical fiction series undoubtedly have a deep impact on people. As mentioned by Collee, millions of viewers are so dependent on television that it has become their main source of information.[1] Though some concern may result from the possibility of encouraging harmful behaviour, as discussed by Hawton et al,[2] there are other medical issues.

As a professor of emergency medicine, I know very well the everyday reality of emergency physicians. I agree with Collee: "If things are too obvious, there is no drama in them. If there is no drama, the story doesn't engage us emotionally." Series such as *ER* are tailored to reality in the United States—patients being admitted with harmful severe arrhythmias who are rescued by defibrillation and discharged only a few hours later, patients undergoing sophisticated diagnostic examinations within a few minutes of having been admitted, and so on. Though I accept that this is fiction, I believe that such presentations of reality are non-educational. My students, full of enthusiasm and convinced of the almost mythical status of staff and patients,[3] are suddenly faced with a quite different everyday reality: hundreds of visits, much monotonous medical activity which, for the most part could be dealt with by general practitioners, and less than 10% of cases being urgent.

Moreover, lay people often do not understand the differences between healthcare systems and expect to receive free, immediate, and sophisticated treatment to resolve their health problems: "I suffer from headache, and I am here to have my brain scan." Unfortunately, they are not received by the staff of *ER*. Instead, they find overcrowded spaces, long waiting lines for visits or examinations, and a long term lack of hospital beds for elderly people with more than one disease. Severe pressure on services is well known in Italy (where until a few years ago all medical care was free of charge) but is now also present in North America.[4] In these times of economic restrictions emergency departments are the last haven of free assistance.

The subtitle to Collee's editorial says that medical fiction should be accurate, but need not be didactic. Medical fiction viewed in the confines of a lecture hall with students could be didactic, but to lay Italians such didacticism could be a source of misleading expectations and delusions when seeking a doctor's help.

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1 Collee J. Medical fiction. *BMJ* 1999;318:955-6. (10 April.)
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Association between type 1 diabetes and Hib vaccine

Causal relation is likely

EDITOR—We initiated and funded a collaborative study with Tuomilehto on the effect of the *Haemophilus influenzae* type b vaccine on type 1 diabetes and found that the data support a causal relation (paper submitted for publication). Furthermore, the potential risk of the vaccine exceeds the potential benefit. We compared a group that received four doses of the vaccine, a group that received one dose, and a group that was not vaccinated. The cumulative incidence of diabetes per 100 000 in the three groups receiving four, one, and no doses of the vaccine was 261, 237, and 207 at age 7 and 398, 376, and 340 at age 10 respectively.

Karvonen et al's analysis is not rational, and their conclusion is not supported by our data.[1] Their calculations of relative risk are also misleadingly low, and we urge readers to check them. Most researchers would compare the group who received four doses with the group that was not vaccinated or the two vaccinated groups with the group that was not vaccinated. The results of both comparisons reach significance. The cumulative difference in cases of type 1 diabetes per100 000 between those receiving four doses and those who were not vaccinated is 54 cases (P = 0.013) at 7 years and 58 cases at 10 years (P = 0.029; single tail Fisher test). The relative risk is 1.26 at 7 years. The cumulative difference between those receiving four doses or one dose of the vaccine and those who were not vaccinated is 42 cases (P = 0.016) at 7 years and 47 cases at 10 years (P = 0.028).

The rise in diabetes, just one potential adverse effect, exceeds the benefit of the vaccine, which has been estimated to prevent seven deaths and 7-26 cases of severe disability per 100 000 children immunised.[2] Even the difference in cases of diabetes between the groups receiving four doses and one dose exceeds the mean expected benefit. Temporal changes in the incidence of diabetes do not explain the differences since there were an extra 31 cases of type 1 diabetes per 100 000 children aged 5-10, and the incidence of diabetes in this group had been stable for about 10 years before this.[3] Furthermore, sharp rises in diabetes have been recorded in the United States[4] and the United Kingdom[5] after the introduction of the haemophilus vaccine.

Public health officials want to avoid scaring the public, but they risk depriving damaged children of compensation. Denials of safety issues may erode public confidence, especially since diabetes induced by the vaccine may be avoided by starting vaccination a few weeks earlier.

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Competing interests: Methods used in the authors' research (including methods of testing vaccines for the induction of diabetes and methods of giving vaccines without inducing diabetes) are covered by patents owned by Classen Immunotherapies. Dr John Classen holds shares in Classen Immunotherapies; Dr David Classen owns no shares in the company, receives no funding from it, and has no financial ties to it or this research.

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More research is still needed

EDITOR—I read Classen and Classen's comments in the *eBMJ*[1] [edited letter printed here, above] on the paper by Karvonen et al.[2] Classen and Classen question the way that the data in the paper were analysed and presented. They highlight the fact that in table 2 the relative risk of type 1 diabetes was only compared between cohorts 1 and 3 (those who did not receive any *Haemophilus influenzae* type b vaccine and those who received the vaccine at 24 months only) and cohorts 2 and 3 (those who received four doses of the vaccine from 3 months and those who received the vaccine at 24 months only). Why did Karvonen et al not give a comparison between cohorts 1 and 2 (those who did not receive any vaccine and those who received four doses from 3 months)?

Furthermore, in figure 1 of this paper (cumulative incidence of type 1 diabetes per 100 000 person years in Finnish children aged 10 or under) only the data for cohorts 2 and 3 were plotted. Why were the data for cohort 1 excluded? Could it be that including the data for cohort 1 on the graph would have allowed a more direct visual comparison between cohorts 1 and 2 to be made? And would this have then made it more difficult for Karvonen et al to convince casual observers that there is no link between the introduction of *H influenzae* type b vaccine and an increase in the incidence of type 1 diabetes?

The greatest increase in type 1 diabetes has occurred in children aged under 4 (fig 2),[2] which coincides with the period when *H influenzae* type b vaccine was introduced in the mid-1980s. This should raise our suspicions as to whether the vaccine could be responsible for this increase. Karvonen et al have dismissed the data as not being significant; however, the impact on the lives of a further 58 cases per 100 000 children at the age of 10 who will have to learn how to deal with a lifelong chronic disease such as type 1 diabetes should not be trivialised.

Further research would do well to focus on the incidence of type 1 diabetes before and after the introduction of *H influenzae* type b vaccination programmes in other countries, such as Australia, the United States, and the United Kingdom.

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Competing interests: None declared.

1 Electronic responses. Association between type 1 diabetes and Haemophilus influenzae type b vaccination: birth cohort study. *eBMJ* 1999;318 www.bmj.com/cgi/content/full/318/7192/1169#responses (accessed 7 May 1999).
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Radioiodine and thyroid eye disease

Routine steroid prophylaxis is not yet justified

EDITOR—The relation between treatment with radioiodine and thyroid eye disease, discussed in Walsh et al's editorial, troubles many endocrinologists and patients.[1] There have been concerns that the use of radioiodine for thyrotoxicosis due to Graves' disease may be associated with a deterioration in ophthalmopathy, raising the question of whether radioiodine is safe for patients with mild ophthalmic Graves' disease. This question has been addressed recently by Bartalena et al, who showed that there is a small but significant risk of deterioration in mild ophthalmopathy after the use of radioiodine and that this risk may be reduced by simultaneous administration of systemic glucocorticoids.[2]

Walsh et al go further and advocate that high dose prednisone, as used in Bartalena et al's trial, should be used routinely in all patients with mild ophthalmopathy who are to receive radioiodine, to reduce the risk of deterioration in eye disease. Surely this is not yet justified. No account has been taken of the appreciable adverse effects of giving prednisone for three months (typically 30-40 mg/day for the first month and then reducing over the next two months). In Bartalena et al's study under a tenth of patients (7/72) with mild pre-existing ophthalmopathy who received radioiodine had a deterioration that was more than transient and required treatment.

Routine use of glucocorticoids exposes all patients who receive them to important adverse effects, while the benefit is limited to a few. Certain clinical features (for example, mild but active or progressive ophthalmopathy) are likely to mark out those who are at risk. Further studies are needed to examine this and to determine the minimum dose and duration of glucocorticoid treatment that protects against deterioration of eye disease.

At present there is a case for limiting treatment with glucocorticoids to those who have an appreciable symptomatic worsening of ophthalmopathy rather than treating all

routinely. Bartalena et al did not go so far as to advocate routine glucocorticoid treatment for all patients with mild ophthalmopathy who receive radioiodine, and with good reason. Clinical trials showing that a treatment is effective are immensely useful but need to be supported by further, balanced evaluation of the risks and benefits of treatment before the original demonstration of efficacy is translated directly into routine clinical practice—a message for all clinicians, not just endocrinologists. First do no harm.

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Authors' reply

EDITOR—Ahlquist suggests that the adverse effects of corticosteroid treatment outweigh the beneficial effect on the course of thyroid eye disease after radioiodine treatment. With regard to patients without pre-existing ophthalmopathy we agree, as the study of Bartalena et al showed a low risk (1%) of severe eye disease developing de novo.[1]

Of 72 patients with mild ophthalmopathy at baseline (defined as mild conjunctival oedema and periorbital inflammation) who were not treated with steroids, however, 17 (24%) showed a deterioration in their eye disease after radioiodine treatment. Although in many cases this was transient (lasting two to three months), it is nevertheless likely to have caused distress to those who were affected. Even more importantly, seven (10%) patients had an exacerbation requiring orbital radiotherapy and high dose steroid treatment. Adjuvant steroid treatment at a substantially lower dose reduced the risk of exacerbation of thyroid eye disease to $<1\%$.

We believe that a 24% risk of a short term deterioration in thyroid eye disease and a 10% risk of a more prolonged and severe exacerbation justify the risks of adjuvant, moderated dose corticosteroid treatment. We do not underestimate the problems that some patients experience from prednisolone treatment at a mean dose of 20 mg daily for three months, but similar doses are widely used to treat conditions such as polymyalgia rheumatica and asthma, with few long term adverse effects over this period.

Limiting treatment to patients with mild eye disease (and avoiding radioiodine treatment in patients with moderate, severe, or active eye disease) means that only one patient with Graves' disease in five who are referred for radioiodine will require corticosteroid treatment. At the very least, the 24% risk of exacerbation of thyroid eye disease needs to be fully discussed with the patient. Trials to see if lower steroid doses are effective would be desirable but, in view of the number of patients required, would prove a major undertaking.

We suggest that using appropriate treatment to prevent iatrogenic exacerbation of a disease that is distressing, disfiguring, and difficult to treat is entirely consistent with Ahlquist's philosophy of first do no harm.

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Non-attendance at outpatients departments

More information was needed for non-UK readers

EDITOR—The trial by Hamilton et al[1] examining the effect of giving patients a copy of their referral letter on non-attendance at outpatient departments raises several interesting and controversial issues, but it is difficult to assess for an international audience who may not be familiar with the British healthcare system. This issue of being international has been raised by others,[2] and surely if the *BMJ* aspires to be an international journal, the research setting needs to be clarified for international readers.

For example, what is the usual referral procedure in the United Kingdom? In Hong Kong a referral letter is always given to the patient and is required for access to secondary care. Patients make their own appointments. Hamilton et al also fail to establish the justification for the research under discussion.

What was the rationale for this randomised controlled trial? They hypothesise that a lack of communication between the patient and the referring doctor is the cause of non-attendance. If so, how will a copy of the referral letter be expected to improve this communication or guarantee attendance? An explanation of the topic antecedents and justification of the research question are required together with a discussion of the cost implications of this intervention.

Although Hamilton et al quote a national (England or United Kingdom) non-attendance rate of 12%, their own study had a much lower non-attendance rate. The situation in Hong Kong is very different, despite patients receiving a referral letter, and such low rates would be welcomed in Hong Kong. The authors offer no explanation to account for the difference between the study and the national non-attendance rates. This may be due to the study selection criteria. Excluding patients because of severity of disease, previous suboptimal care, or patients' attitude or lifestyle may have biased the sample and led to an incorrect estimate of the non-attendance rates. The intervention was intended to reduce non-attendance and it did not target the appropriate population, the non-attenders. As the authors have not specified the reasons for patients' non-attendance, the reader does not know whether the intervention is appropriate.

The *BMJ* is a widely read journal, and to reach an international audience enough information should be provided to facilitate the assessment of the research and its potential for application elsewhere.

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1 Hamilton W, Round A, Sharp D. Effect on hospital attendance rate of giving patients a copy of their referral letter: randomised controlled trial. *BMJ* 1999;318:1392-5. (22 May.)
2 Smith R. Avoiding becoming the English Medical Journal. *BMJ* 1999;318:1158-59. (1 May.)

Key messages did not accurately summarise the study

EDITOR—We should like to suggest two additional "key points" for the paper by Hamilton et al concerning hospital attendance rates.[1] Firstly, the setting may affect the ability of a randomised controlled trial to produce valid results, and, secondly, the *BMJ* key messages boxes may not provide a reliable summary of the data contained in the paper.

Non-attendance at hospital outpatient departments wastes resources, frustrates staff, and may result in unmet health needs. However, chance, human nature, and the complexities of modern life make it unlikely that 100% attendance will ever be achieved, whatever measures are used. The authors quote a national non-attendance rate of 12% and studies showing a range from 9.9 to 29%.[2 3] Yet only 6% of the patients in their pilot study did not keep their hospital appointments; this level is so low that we wonder whether it is possible to reduce it further.

The first key point in the box asserts that copy letters do not reduce non-attendance at hospital outpatient departments. This has been demonstrated in an area where non-attendance was already half the national average, but we know nothing about the effectiveness of the intervention elsewhere. If the underlying hypothesis about the relation between information sharing and non-attendance is true, the low rate in their area may reflect doctor-patient communication that is already optimal. Influences on attendance may also vary as the rates change, and qualitative research to generate further hypotheses is probably needed.

The second key point states that the concept of copying letters to patients is acceptable to doctors and patients. The perceived acceptability of the copy letter was investigated in a questionnaire sent to participating practices, and all were prepared to send copy letters if they were shown to be beneficial and the cost could be offset. Ten of the 13 practices received positive comments from patients. However, we do not know how many patients

commented, and as the patients were not approached directly these views may not be representative. The third key point, that it may be possible to apply interventions from primary care to reduce non-attendance, is intuitive but cannot be deduced from any of the data presented.

This study used a practical intervention to address an important problem, but we would like to see it repeated in a different setting before the copy letter is dismissed as ineffective.

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Authors' reply

EDITOR—Castan-Cameo et al comment that international readers may be unused to the United Kingdom's system of referral. In brief, a referral decision is made between patient and general practitioner; the general practitioner writes to the hospital consultant, and an appointment is sent to the patient by post from the hospital. Our hypothesis was that offering information to patients would perhaps allow them to make a more informed decision on the value of attending. The written summary that the copy letter provided should have allowed patients to reflect on their condition, perhaps increased their understanding, and given an opportunity for further discussion with their general practitioner or family and friends. We expected increased attendances, increased cancellations, and reduced non-attendances.

Both Castan-Cameo et al and Lawlor and Hanratty must have missed our first sentence, which stated that the 12% figure included new and follow up appointments; follow up appointments have a higher non-attendance rate,[1–3] but our study only targeted new appointments. They are the appointments most influenced by the general practitioner. It may prove impossible to reduce new patient non-attendance from 6%, but at £65 per appointment[2] even small reductions are worth while. Castan-Cameo et al wonder if the low non-attendance rate was due to exclusions; not so, only 117/2078 (5.6%) were excluded from the randomisation and only four (3.6%) of these failed to attend. Reasons for non-attendance are well researched,[4] such as forgetting or not receiving the appointment or getting better.

Lawlor and Hanratty consider our key points unrepresentative of the paper. However, it is incorrect to say that the setting affects the ability of a randomised controlled trial to produce valid results. Validity depends on the design and conduct of a trial. Perhaps what they intended to say was that the results of a trial in one setting may not be applicable in another—we agree with this. Our study was representative of patient behaviour in one geographical area. Although the trial was not primarily designed to establish acceptability, this having been tested in the pilot study (when patients were directly approached),[5] our study confirmed that patients and doctors seemed satisfied with the process. Finally, we consider that the trial did establish the feasibility of applying interventions from primary care to reduce non-attendance because this is what we actually did. It is a pity that it did not work.

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Anaesthetists need consent, but not written consent

EDITOR—Dobson's article concerning information and consent for anaesthesia appeared under the headline "Anaesthetists do not need separate consent before surgery," and stated that "New guidelines on obtaining consent for anaesthesia recommend that consent from patients specifically for a general anaesthetic is not needed."[1] These statements are incorrect, and I believe that they may mislead readers.

The guidelines issued by the Association of Anaesthetists of Great Britain and Ireland state that express consent should be obtained for any procedure which carries a material risk. The working party noted that express consent may be obtained orally or in writing. As Dobson indicated correctly, the working party saw no virtue in getting the patient to sign a separate consent form for general anaesthesia. However, we indicated explicitly that, if oral consent is obtained, then an entry should be made in the clinical records indicating the advice which was given and that consent was provided. In the final section of the recommendations, we made the following statement: "The anaesthetist should make a record of the anaesthetic techniques (e.g. general anaesthesia, regional anaesthesia, local anaesthesia, or a combination) which have been discussed with and agreed by the patient, and should list the material risks which have been explained."

The working party believed that discussion with and provision of information to patients about anaesthesia are vitally important. We wished to emphasise that two way communication is more important than merely obtaining a signature on a consent form and were keen that anaesthetists should not be misled into believing that a signature on a consent form is evidence that valid consent has been obtained. It is regrettable that Dobson's article equated consent with written consent and failed to acknowledge the clear signal in the document that competent patients must be given appropriate information, and must give consent, before any anaesthetic procedure.

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1 Dobson R. Anaesthetists do not need separate consent before surgery. *BMJ* 1999;319:142. (17 July.)

Risks of medicine and air travel

EDITOR—Berwick and Leape draw comparisons between the risks of delivering health care to patients and the safety statistics of airline travel,[1] with air travel being over 10 000 times safer for the passenger than medicine for the patient. Although nobody doubts the importance of designing safer healthcare systems that reduce adverse effects, serious drug errors, etc, this comparison is fundamentally flawed. It is not simply because old aeroplanes are grounded before they fall out of the sky.

More importantly, if you want to compare health care with aviation then like should be compared with like—that is, care of the patient with the aeroplane itself and not with the individual passenger. If a separate team looked after each patient or, conversely, if the team flying the aeroplane flew twenty or more planes simultaneously, as is the case with patient care in hospitals, safety indicators of these two different fields would be closer. Problems with air controllers over London, a recent hot topic in the media, also illustrate this. On the other hand, in surgery the presence of a well staffed high dependency unit reduces complication rates: where funds are available for an increased number of trained staff to look after patients then complications and presumably the rate of adverse effects are reduced.[2]

Further research is necessary. In the meantime superficial comparisons worthy more of a tabloid newspaper than the *BMJ* are best avoided; they may harm patient care by obscuring important contributing factors to current difficulties in delivering health care.

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Immunosuppression in renal transplantation

Meta-analysis should not have included one of the studies

EDITOR—Several points relating to Knoll and Bell's meta-analysis of randomised trials comparing cyclosporin (Sandimmun) and tacrolimus may have a bearing on its conclusions.[1] Unfortunately, the first study cited—that by Shapiro et al—does not have a minimum of one year's follow up; the "median follow-up is 1.12 years, with a range of 0.17 to 2.25 years."[2] This trial by Shapiro et al should also be excluded on the grounds that it is not a randomised trial but compares a group of patients treated with tacrolimus with "a nearly concurrent group of patients treated with cyclosporine."

Drawing conclusions is also difficult because two of the studies routinely used antibody induction therapy and a third study did not detail whether it did or not. This is a practice not commonly adopted in the United Kingdom. Furthermore, the drug doses, routes of administration, drug monitoring, and treatment of rejection episodes differed considerably between studies. The fact that three of the studies were multicentre trials with allowances for local protocols leads to further potential variation.

All four studies evaluated the old cyclosporin preparation Sandimmun, which is no longer available in the United Kingdom. Its successor, Neoral, has improved absorption and a lower acute rejection rate than Sandimmun, so that any direct comparisons between the formulations are impossible.

In an attempt to compare cyclosporin (Neoral) and tacrolimus (Prograf) we are conducting a single centre randomised controlled trial for patients undergoing cadaveric renal transplantation. We have so far recruited 200 patients, 179 of whom (90 treated with tacrolimus and 89 treated with cyclosporin) have been followed up for a minimum of six months (median follow up 25 months). The acute rejection rate was 32% for patients treated with tacrolimus and 39% for patients treated with cyclosporin (NS).

Serum creatinine concentrations were better in the tacrolimus group at both one year (129 μmol/l *v* 153 μmol/l; $P < 0.05$) and two years (129 μmol/l *v* 157 μmol/l; $P < 0.05$). The use of muromonab-CD3 or antilymphocyte globulin was lower in the tacrolimus group, as was the need for conversion to mycophenolate mofetil. The incidence of glucose intolerance after transplantation was greater in the tacrolimus group (0% *v* 20%; $P < 0.05$), while hypercholesterolaemia was more common in the cyclosporin group (5.8% *v* 5.0%; $P < 0.05$).

Tacrolimus is more expensive than cyclosporin, but the additional costs of treatment with muromonab-CD3 and mycophenolate mofetil mean that in the short term the overall packages of care closely balance.[3] Our study is continuing so as to evaluate the long term effects of these two calcineurin inhibitors.

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Competing interests: The authors' study is funded in part by a research grant from Fujisawa, which manufactures tacrolimus; by Novartis, which manufactures cyclosporin; and by Roche, which manufactures mycophenolate mofetil.

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This meta-analysis has little relevance to current practice

EDITOR—If nothing else, the meta-analysis by Knoll and Bell on immunosuppression in renal transplantation shows the paucity of high quality comparative research in this field.[1] It is, however, of little relevance to current practice.

Since the early 1990s the introduction of a microemulsion version of cyclosporin (Neoral) has substantially improved the results of transplantation using cyclosporin as induction and maintenance treatment. Although first shown in liver transplantation,[2 3] the effect of Neoral is increasingly clear in renal transplantation. For example, a recent study in which the two versions of cyclosporin were directly compared showed a 13% reduction in the incidence of acute rejection in the group taking Neoral compared with the group taking the original preparation (Sandimmun).[4] This compares with reductions of 1%, 15.7%, and 19.8% in the three trials in the meta-analysis for which data are available. Clearly, correction for this would substantially alter the interpretation when extrapolation is made from this meta-analysis to current clinical practice.

Interpretation of the data is not helped by the increasing view that the relation between early acute rejection and graft survival is not straightforward. Indeed, the absolute number of rejection episodes, particularly those that resolve completely after steroid treatment, may not be a good surrogate for long term outcome.[4 5] In contrast, most doctors would accept that the severity of rejection is strongly correlated with outcome. The authors note an increased use of rescue treatment in the cyclosporin group, consistent with a higher incidence of severe rejection, but interpretation is subject to the same criticism when extrapolation is made to the microemulsion formulation of cyclosporin.

These indices are, in fact, of little true relevance. The critical information required by both the transplant community and patients relates to graft survival and patient survival. Only long term follow up of the large cohorts who receive tacrolimus and microemulsion versions of cyclosporin will resolve the issue of where the advantage, if any, lies. Other, new immunosuppressive drugs will also have an impact on this equation. In the meantime, clinicians have a delicate task in balancing the higher incidence of diabetes and glucose intolerance with tacrolimus against the worse lipid profile and the cosmetic side effects of cyclosporin.

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Competing interest: Dr Andrews has received expenses and travel costs for attending conferences from both Novartis and Fujisawa, manufacturers of cyclosporin and tacrolimus respectively. He has used both drugs as part of immunosuppressive protocols in several transplant units.

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Postoperative glucose intolerance was almost certainly underestimated

EDITOR—The development of de novo postoperative diabetes is a well recognised complication of organ transplantation, for which the calcineurin inhibitor immunosuppressant drugs cyclosporin and tacrolimus are used.[1 2] In their meta-analysis of four randomised trials in which these agents were compared, Knoll and Bell report an odds ratio of 5.0 (95% confidence interval 2.04 to 12.36) for diabetes mellitus after renal transplantation with tacrolimus relative to cyclosporin.[3] They base this analysis on the prevalence of diabetes one year after transplantation. There are several inherent limitations in this analysis.

Criteria for the diagnosis of diabetes differed between the studies. For each trial diabetes was arbitrarily defined, only diabetes requiring insulin treatment being included in three. Strict World Health Organisation diagnostic criteria have rarely been applied in such studies.[1 4] Thus the incidence and prevalence of the lesser category of impaired glucose tolerance (which requires a 75 g oral glucose tolerance

test for diagnosis) was not determined in any of these trials. This may be of clinical importance; in non-transplant populations impaired glucose tolerance (a component of the insulin resistance syndrome) is a risk factor for both the subsequent development of diabetes and coronary heart disease.[5]

Finally, there seems to have been scope for unintentional investigator bias since the criteria determining treatment of post-operative diabetes were not specified in advance. Is it feasible that more patients treated with tacrolimus received insulin as part of a more cautious response to an adverse effect occurring with an unfamiliar agent?

Thus postoperative glucose intolerance has almost certainly been underestimated in these studies, the odds ratio derived by Knoll and Bell reflecting rates of only more pronounced degrees of hyperglycaemia. A reappraisal of post-transplant diabetes using the recently revised diagnostic criteria is required.[5] Not only would this provide a more accurate picture of the scale of the problem but it would also facilitate comparisons between drug regimens and between centres.

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Competing interests: None declared.

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Authors' reply

EDITOR—We disagree with all these comments about our meta-analysis. Morris-Stiff et al state, firstly, that in Shapiro et al's study, which we included in our meta-analysis, the median follow up was 1.12 years; secondly, they say that we should have excluded the study because it was not a randomised trial.[1] These statements pertain only to Shapiro et al's combined analysis of 425 patients. Within that group of patients the authors report on 57 who were enrolled in a randomised trial comparing cyclosporin and tacrolimus. From table 1 of our paper it is clear that we included only these 57 patients in our meta-analysis. The randomised patients in Shapiro et al's study fulfilled all of our selection criteria, which is why we included them.

Both Morris-Stiff et al and Andrews comment that the studies in our meta-analysis used the old formulation of cyclosporin (Sandimmune). There were no studies comparing tacrolimus with the new formulation (Neoral) at the time of our meta-analysis. Immunosuppressive protocols are constantly evolving. As we mentioned in our paper, further well designed studies are needed comparing tacrolimus with newer immunosuppressants (such as Neoral) to determine the most effective combination of drugs. Until that evidence is available our analysis provides useful information about the risks and benefits of cyclosporin based immunosuppression versus tacrolimus based immunosuppression in renal transplantation.

We agree with Krentz that diabetes mellitus that develops after transplantation is an important complication of calcineurin inhibitor treatment that requires further study.

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Competing interests: Dr Knoll has been reimbursed by Sangstat to attend a meeting on induction therapy in transplantation. Dr Bell has spoken at a meeting sponsored by Fujisawa (manufacturers of Prograf (tacrolimus)) but did not receive any financial support or honorarium.

1 Shapiro R, Jordan M, Scantlebury V, Fung J, Jensen C, Tzakis A, et al. FK506 in clinical kidney transplantation. *Transplant Proc* 1991;23:3065-7.

Australia has considerable experience of transporting critically ill patients

EDITOR—Having just returned from a medical retrieval post in New South Wales, Australia, I was interested in Wallace and Ridley's article on the transport of critically ill patients.[1] New South Wales is roughly 3.5 times as large as the United Kingdom, and patients are transported between intensive care units by land ambulance in the metropolitan areas, by helicopter for journeys of < 400 km, and by fixed wing aircraft for journeys of ≥400 km. I have experienced the transfer system in the United Kingdom as well and have three points to make.

Firstly, staff safety is emphasised continuously in the New South Wales system; a prerequisite for helicopter operations there is that all crew (including the doctor) undertake helicopter underwater escape training and pass a proficiency test in safety procedures. This is laid down in civil aviation law in Australia (civil aviation order 20.11). It is obviously impractical to train all staff of hospital intensive care units in such procedures as they may only occasionally be involved in such transfers, but having a core number who were always up to date in aspects of flight safety would not be unreasonable. Working parties in the United Kingdom suggested several years ago that safety training of staff should be a part of running services that provide transfers by helicopter or fixed wing aircraft.[2 3] This might also result in lower insurance costs.

Secondly, lightweight transfer equipment and in particular self contained stretcher bridges have been developed in Australia over the past 15 years, and there is a programme of continuous upgrading.[4 5] Sydney Aeromedical Retrieval Service has recently switched to using carbon fibre stretchers for its road ambulances and aluminium frames for its equipment bridges. All this is workshop tested and crash rated before use.

Thirdly, in July this year the Australian incident monitoring study for retrieval medicine was launched. This is a centrally funded and anonymous voluntary reporting system for everyone involved in medical retrieval (clinicians, flight nurses, paramedics, pilots, and aircrew). Any incident in which a patient, member of staff, or aircraft is perceived to have been at risk can be reported; this risk may be clinical, technical, or organisational.

The transport of patients is still developing in the United Kingdom; we should draw on experiences everywhere to improve it still further.

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