Note to authors of letters: Letters submitted for publication should not exceed 400 words. All letters are subject to editing and may be shortened. Letters may be sent either by post (please use *double spacing* and, if possible, include a Word for Windows or plain text version on an IBM PC-formatted disk), or by e-mail (addressed to journal@rcgp.org.uk; please include your postal address). All letters are acknowledged on receipt, but we regret that we cannot notify authors regarding publication.

QT lengthening and life-threatening arrhythmias associated with fexofenadine

Sir,

Fexofenadine is the active metabolite of the non-sedating antihistamine, terfenadine. Accumulation of terfenadine can cause prolongation of the QT interval and significant cardiac arrhythmias.[1] Fexofenadine is reported to have no potential for QT interval disturbance.[2] Phase II and III clinical trials in over 6000 patients showed no mean increases in mean QTc or serious cardiac arrhythmias when comparing fexofenadine with placebo groups.[3] There has been one case report of ventricular tachycardia causally associated with exposure to fexofenadine in a patient prone to a long QTc interval.[4] A recent search of AdisBase and MEDLINE did not reveal any other case reports of ventricular tachycardia associated with exposure to fexofenadine.[5]

The Drug Safety Research Unit used the technique of Prescription Event Monitoring to study events in patients prescribed fexofenadine following its launch in England in March 1997.[6] A total of 35 817 green forms were posted to 8057 GPs who had written prescriptions for fexofenadine between March and August 1997. In all, 18 238 were returned, giving a response rate of 50.9%. The final cohort totalled 16 638 patients. Less than 1% of patients discontinued the drug because of intolerance, and there were no specific reports of drug interactions involving fexofenadine. All cardiac events were examined in detail, and eight that resolved on stopping fexofenadine were possible side-effects: palpitations (three), chest pain (three), arrhythmia (one), and chest tightness (one). There were no reports of ventricular tachycardia, prolonged QT interval, or serious cardiac events.

Our study of patients taking fexofenadine in routine clinical practice failed to show any serious adverse cardiac events that could have been a result of drug exposure. The characteristics of our cohort (age, concomitant medication, and indication for use of fexofenadine) suggest that, for this drug, the clinical trial population and the community patients are comparable except for the delivery of care. Although the study was on a large cohort, the response rate was only 51%, and this could introduce an under-reporting bias. With a very rare event, a few cases could make a big difference to the generation of a safety signal.

Our results, the results from clinical trials, and a single case report from a drug now in widespread use suggest that, even if serious cardiac arrhythmias are associated with exposure to fexofenadine, they are very rare. In the absence of dedicated case registries, the only practicable way to detect such very rare events is the spontaneous reporting made by vigilant practitioners.

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Sex differences in incidence rates and referral ratios for first attack angina pectoris

Sir,

Three issues must be considered in the study by Vogels *et al* (December *Journal*)[1] on sex differences in cardiovascular diseases.

First, they found that the sex differences in morbidity from first attack angina pectoris decreased with increasing age and became insignificant above 65 years of age. Given that they also explored the sex differences in referral ratios later on, it was reasonable to study only those with first attack angina pectoris, as the criteria for referral for first and subsequent attacks are different. However, in calculating the incidences of first attack angina pectoris, they should have excluded from the denominators those with a previous history of angina pectoris. As more men than women had previous histories of angina in the older age group, the failure to make this adjustment would underestimate the incidence in men relative to women, and hence the sex differences in morbidity. This may explain the apparent disappearance in sex differences above 65 years of age.

Secondly, the authors found that women were less likely to be referred to the cardiologist than men. They properly acknowledged the limitations that the morbidity consisted of health problems presented to the physicians only, and no data were available on the severity of angina pectoris. Women's rates of use of almost all health care services have consistently been found to be higher than men's in primary care studies, and one would expect the severity of symptoms were less severe in women than men among those presented to the general practitioners. This prediction is supported by our own studies[2] on the severity of coronary heart diseases among those referred to the cardiologists in Sunderland in 1995/96 using the New Zealand priority scores.[3] Although the number of men (133) referred to the cardiologists were more than twice that for women (60), the severity of the coronary artery disease for the men referred (mean priority score = 38.7) were significantly higher than for the women (mean priority score = 32.4).

Thirdly, the authors concluded that women with low socioeconomic status were referred significantly less than men ($P = 0.03$). However, we must be cautious

of the danger of multiple testing, particularly as the authors had no reasons to expect this finding. The results should have been adjusted for multiple testing, as statistical tests were applied to three socioeconomic groups.

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Patient-centredness and outcomes in primary care

Sir,

Kinnersley *et al* (September *Journal*),[1] in their paper on patient-centredness and outcomes in primary care, have rather underplayed the difficulties in measuring patient-centredness. The standardised method they used has not, to our knowledge, been widely used by researchers other than the Canadian group who devised the method.[2] We have been attempting to apply this methodology in two studies of doctor–patient communication (one in the UK and one in Ireland), using transcripts of consultations and by listening to audio-recordings of consultations. We have been using the detailed manual prepared by Brown *et al*, although we have not had specialised training.[2]

We have found the method rather difficult to apply. It necessitates making a lot of judgements, some of which can be surprisingly difficult. Such judgement is required to allocate units of speech to components of the consultation, as per Brown *et al*'s definitions.[2] For instance, it can be difficult to decide if a unit of speech relates to symptoms only or has moved into the realm of problem definition. The method also requires qualitative judgements regarding the quality of such interaction; e.g. whether they obtain reliability between raters. We note that Kinnersley *et al* had the assistance of Tessier, one of the original collaborators of the Canadian group, which may have helped them achieve higher inter-rater reliability.

There are also conceptual difficulties about the notion of patient-centredness. Patient-centredness may be viewed as a philosophical disposition in order to attach more significance to the patient's social context and perspective on their problem than has, perhaps, been traditional in the practice of medicine. It is judged in relation to the behaviour of doctors in consultations with patients. However, it is possible for a doctor to purport to be patient-centred, in the sense of attributing importance to the patient's perspective, and yet fail to manifest this behaviourally in any given consultation. There are consultations where either the behaviour of the patient or the minimal and straight-forward content of the consultation may make it less necessary for the doctor to display any behaviour indicative of his or her disposition. Thus, while the display of certain consultation behaviours by the doctor can be said to be indicative of a patient-centred disposition, their absence cannot necessarily be taken to indicate the opposite. However, it may also be the case that a doctor who purports to be patient-centred may never demonstrate this behaviourally because of the well-recognised phenomenon that states that attitudes are not invariably reflected in behaviour. A doctor may also, from a patient's perspective, be quite patient-centred because of behaviours adopted over a series of consultations, even though this patient-centredness is not apparent in any single consultation. There is a hint in some of the later work by the Canadian group that this may be so.[3] In a study of audio-recordings and transcripts of all the visits of seven patients to their three family doctors over a one-year period, it was noted that patient-centredness' scores fluctuated from visit to visit. A method has yet to be devised that measures net patient-centredness over several doctor–patient encounters.

Finally, while it us argued that patient-centredness on the part of doctors is good and is associated with desirable outcomes such as improved adherence to therapy, there are also indications that what might be construed as patient-centred behaviour is not always preferred by patients.[4] This may be because certain patients are not comfortable with their doctor behaving in such a way, especially if such behaviour is uncharacteristic and unfamiliar. It may also be that what is said to be a patient-centred consulting style is not appropriate to all conditions or circumstances. Indeed, given the great variety of problems and patients that present to general practitioners, it may be that there are no simple global behavioural markers of patient-centredness that can be applied to all types of patient and all types of consultation. In this regard, Kinnersley *et al* confined their analysis to patients with new problems, which may have helped them achieve their apparently clear conclusion. That said, the one outcome that did correlate with the measure of patient-centredness was patient satisfaction, which, when one examines the detail of the satisfaction measure used, might be argued to be measuring the extent to which the patient notices those self-same behaviours being measured in the patient-centredness measure; i.e. there is an element of circularity in their argument.

The whole concept of patient-centredness and how it might be measured requires much greater intellectual and methodological development. However, we welcome Kinnersley *et al*'s paper, as we hope this will encourage debate on these issues on this side of the Atlantic.

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Randomised controlled trials in general practice

Sir,

Although some authors[1,2] have questioned whether randomised controlled trials (RCTs) provide an appropriate framework for primary care research, they clearly contribute to questions of efficacy and effectiveness. However, recruiting patients into trials or prospective studies often seems to raise major difficulties in primary care.

We have recently completed a RCT of treatment for tennis elbow in primary care.[3] Our trial recruited and followed up 164 patients for a 12-month period, and the following account reviews why the employment of a research nurse might have ensured the success of this trial. The nurse performed all the patient assessments, coordinated the trial, and gained informed consent to the trial.

The reluctance of GPs to enter into RCTs may stem from a number of sources. Lack of time within a routine consultation is a major barrier, especially for a detailed explanation of the trial before consent can be gained.[4] GPs may have difficulty in shifting from 'confident practitioner' to 'doubting researcher',[5] and explaining that current practice is not evidence based can also be a barrier. Avazini[6] concluded that the *idea* of research may be more inviting than the practicalities, but, if a research protocol reflected a real need and did not introduce artificial changes in to daily practice, an appreciable number of GPs would be sufficiently motivated to enter a study. Finally, feeling distanced from the academic centre may be a barrier; Jonker's[7] group, for example, increased recruitment after they sent out personal letters and subsequently visited each practitioner.

The employment of the nurse in our trial addressed a number of these problems. First, it provided time for patients to assimilate the information and for explaining that present treatments were not scientifically proven. As the nurse was employed specifically to work on the trial, she had the time outside the context of a clinical consultation to fully explain what was involved and to allow questions and discussion. This process was carried out in the patients' own homes where the assessments were also carried out at their convenience. This maintained goodwill and relieved the practice of the use of space and time. The nurse was also able to carry out the detailed review of inclusion and exclusion criteria that might be difficult or impossible in the course of a GP's routine surgery.

After the initial consultation and subsequent visits to receive treatment, there was no need within the protocol for the patient to visit the GP again. The nurse maintained contact with patients, arranging and performing follow-up assessments. Thus the workload for the GPs and practice staff was kept to a minimum. This resulted in an exceptionally good follow-up rate (only one patient lost at the 12-month stage), which probably reflects the dedicated time and personal contact that a research nurse could bring to the project.

One of the key approaches in the trial was to involve the participating practices in the early stages of protocol development. The nurse was then able to ensure continued active involvement of the practices by maintaining regular contact with all the GPs involved, including newsletters and up-dating them on recruitment. Other authors[7] have found this approach beneficial.

The main problems of the trial were the variable rates of recruitment and the inevitable difficulties of combining research and routine clinical practice. A nurse researcher dedicated to the project brought reduced workload plus feedback and encouragement for the practices, and the time and opportunity to ensure fully-informed consent.

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Colorectal cancer

Sir,

Your timely editorial concerning the early detection of colorectal cancer (December *Journal*)[1] ignores a significant role for primary care: that of improving public education about the disease. Delays in presentation are as significant as delays in diagnosis, and will only be reduced by a concerted public information campaign to accompany other improvements in service provision. In particular, we need to make patients appreciate the significance of rectal bleeding as a reason for consulting their GP.

In conjunction with the local trust, I have been involved in the creation of a local charity (Craven CLEAR — CoLoRectal Education and Research), which is running a public information campaign as well as educating members of local PHCTs and pharmacists. It is also running evening 'one-stop' clinics for patients with rectal bleeding. These are direct access; patients may refer themselves or be sent to the clinic by any health care professional.

In advance of our launch we distributed a questionnaire to 150 local adults (aged 35 to 55 years). Over 50% of responders failed to identify rectal bleeding as a possible sign of bowel cancer, and 25% of those who developed this symptom would not have consulted their GP about it. This is consistent with previous findings[2] where 41% of patients who developed rectal bleeding were found never to have consulted their GP. Only a minority (15%) of our responders was put off consulting by embarrassment, which leads to the conclusion that patients do not appreciate the potential significance of rectal bleeding.

The success of any future screening programme will depend, in part, on raising the profile of colorectal cancer as an important disease that can be cured if detected early. Informing patients about the early signs of disease takes time but can be achieved with persistence (as has been the case with meningitis and skin cancer, for example). It is time to begin that process for colorectal cancer.

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Prescribing and French trainees

Sir,

I read Ian Bamforth's recent essay with interest (November *Journal*: Back Pages).[1] As a Scottish doctor who worked for a year (1995 to 1996) in SHO-equivalent posts in university teaching hospitals in the South of France, I have had the opportunity to work closely alongside French specialists and generalists in training.

Among the many disorientating features of moving into the French medical world, the very different approach to prescribing, as described by Dr Bamforth, ranked highly. This led to some interesting discussions with my French colleagues during training in an attempt to understand our differences.

'Drug companies' were generally referred to as 'Laboratoires' — a nuance that summarises a profoundly different relationship between the pharmaceutical industry and trainees, whose positive appreciation of the research and economic role of the industry contrasted with my own more sceptical attitude. Consequently, generic prescribing was perceived as both giving medication of dubious quality to the patient and undermining the research process by depriving the prime (French) innovators of the due return on their investment.

As a result, laboratory representatives played an important role in teaching and were seen as key resources for accessing up-to-date information. The information that trainees sought related largely to the theoretical mode of action and pharmacology of drugs, and I was frequently embarrassed by my own ignorance in these areas. Randomised controlled trials were mentioned only in passing; I never heard economic appraisal or comparative trials being discussed. The emphasis in training was on the differences between drugs within a given class, with prescribing from a wide range of choices, and doctors were appalled at the notion of a formulary that they could only view as a cost-cutting exercise rather than an attempt to apply evidence-based medicine.

This was more than clever marketing and, in the best French manner, my colleagues were quick to place it in a philosophical context, contrasting their rational 'Cartesian' approach to knowledge with my merely 'pragmatic' British attitude. Their prime concern was the freedom of the individual practician to tailor the application of scientific knowledge to the individual unique case. This robust defence of professional freedom has been central to the character of French medicine.

Both the British and French health care systems obviously have significant strengths and weaknesses. What is clear is that a mutual understanding can give important insights into our own values and priorities. It is important that we create opportunities to look beyond our own backyard — even if it is only to our next-door neighbours.

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Non-attendance at psychiatric outpatient clinics

Sir,

Killaspy *et al* (November Journal)[1] address the question of what action should be taken after a patient fails to attend a psychiatric clinic. They interviewed the referring GP, with 44% suggesting that the most appropriate action is to send another appointment. Only 7% considered that they should contact the patient themselves. The authors reasonably concluded that GPs see no role for themselves in addressing the issue of outpatient non-attendance. However, we should examine the problem from another perspective.

We measured the non-attendance rate (22%) in patients sent a second appointment after missing the first in a cohort study.[2] Taking all new referrals, 11% nationally[3] will not attend. If all these are sent another appointment and 22% again default, the end result is that about 2% of all new appointments are wasted as second time non-attendances. In short, a policy of routinely sending a second appointment is very inefficient.

What alternatives are there? One possibility is to take no action. While this may be the correct course for those whose condition has improved and who no longer need an appointment,[4] it is not so for those whose condition is unchanged and whose non-attendance was outside their control.

The middle course, of routinely writing to the GP after a new patient non-attendance, requesting re-referral if necessary, has several advantages. First, the communication to the GP may uncover an administrative error, such as a wrong address. One survey[4] found that 20% of outpatient non-attendance is because the patient did not receive the appointment. Some of these will be address errors. Secondly, the GP may know of a change in the patient's condition, or of other reasons preventing attendance, such as family illness. Finally, the GP may be able to emphasise the importance of attendance to a re-referred patient.

It is possible that GPs were cautious about taking on this role because of additional work it may create. However, the current haphazard system is of some departments handling second appointments, while others do not, with others not even notifying the GP. This also generates work in handling queries from patients who await an appointment. Patients who miss follow-up appointments are different; the specialist team should know them and be able to judge for themselves the importance of offering another appointment.

Reducing non-attendance benefits everyone, particularly our patients. They should see a fall in waiting times and less reliance on the unpopular policy of overbooking clinics.

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