| Research and clinical practice  |      | Pauline Bryant   | 1614    |
|---|------|--|---------|
| Martin Marshall, Manjo Luthra,<br>Liz Plastow, David Russell                                | 1612 | The applicability of randomized trials to it ual patients            | ndivid- |
| Applying the results of clinical trials to patients   |      | Tom Fahey  | 1614    |
| Kieran Sweeney, Philip Evans,<br>Denis Pereira Gray, Russell Steele,<br>Helen Keenan        | 1612 | Primary care education centres  Malcolm J Valentine,  Fiona H French | 1614    |
| Improving GP records Steve Price 1613   |      | Expanding the medical undergraduate curriculum                       |         |
| Triage of house call requests   |      | Mekala Mahalingam  | 1615    |
| Morris Gallagher, Carol Johnson,<br>Valerie Elsy  | 1613 | Recruitment methods for drug trials<br>Elizabeth Armstrong           | 1615    |
| The more you look the more you find: problems of biases inherent in non-randomized studies. |      | Near patient testing for anticoagulation                             | 1615    |

Practice nurses roles in caring for people with mental health problems

Graham Curtis Jenkins 1616

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.

#### Research and clinical practice

Sir,

We are reassured rather than concerned by the results of the paper by Thomas *et al* reviewing the content and methodology of research papers in UK primary care journals (May *Journal*). The paper raises important issues that are fundamental to the future of research general practice. The most important of these are the relationship between research and clinical practice and the epistemological debate concerning the most appropriate research paradigms of our discipline.

Good research should reflect and develop good practice. General practice is characterized by the emphasis on personal and longitudinal care, the undifferentiated nature of presenting problems, and the integration of social, psychological, spiritual, and traditional biomedical dimensions. It is therefore not surprising that nearly half the published studies were concerned with organizational or social problems, nor that the most common research designs were non-experimental. The chosen methodology should be determined by the question, rather than a desire to ape other academic disciplines. In turn, the question should be determined by what is useful and important to clinicians, managers, and policy makers.

There is undoubtedly a need for more randomized controlled trials, conducted on relevant community populations, to address clinical effectiveness issues. However, this should not be at the expense of other important primary care research areas.

The paper touches upon an important and unresolved issue for primary care researchers. The University Research Assessment Exercise has made it increasingly difficult for committed academics to practice 'real' general practice. A potential gulf is emerging between high quality methodologists working in academic units on one hand, and practising clinicians working in service practices on the other.

The former are increasingly answering research questions irrelevant to the latter. who have neither time nor expertise to address problems related to clinical practice. The research general practice initiative, launched by the College and now adopted by many regional research and development directorates, helps to address this issue. Our experience as one such practice has demonstrated how a serviceoriented practice can, with adequate resources, build an effective multi-professional research team, create a research culture within the primary health care team, and use clinical practice as a catalyst to ask relevant research questions.

MARTIN MARSHALL
MANJO LUTHRA
LIZ PLASTOW
DAVID RUSSELL

Mount Pleasant Research and Development General Practice Mount Pleasant Road Exeter EX4 7BW

#### Reference

Thomas T, Fahey T, Somerset M. The content and methodology of research papers published in three United Kingdom primary care journals. Br J Gen Pract 1998; 48: 1229-1232.

# Applying the results of clinical trials to patients

Sir

Tom Fahey presents a clear and robust defence of the randomized controlled trial (RCT) and has usefully described innovative ways of considering how the average statistic from such experiments can be applied to individuals in general practice consultations (April *Journal*). We have three reservations about his article.

The first concern is the diagnostic process. In both of Fahey's examples, the

presenting complaint is described as a discrete and well-developed entity. We know that the diagnostic process in general practice is much more fluid and imprecise.<sup>2</sup> Such difficulties have led Howie to describe the diagnostic process as an Achilles' heel, where decision making is often based more on symptoms than physical signs.3 Crucially, Fahey's thinking in framing his diagnostic question is the result of inductive course thinking. Marinker, many years ago, pointed out that this kind of thinking is often inappropriate in general practice where hypothetico-deductive (or simply guessing and testing) are more often the decision strategies involved.4

Secondly, Fahey does not consider the issue of auxometry in the progression of an RCT. This has long been our concern, repeatedly described by Feinstein. <sup>5</sup> Auxometry refers to the rate of progression in a particular illness, and crucially the often inexplicable ways in which an illness will progress in one individual in a particular way but not in another individual. The evolutionary nature of an illness is something that is not captured within the setting of an RCT.

Fahey is able to frame his diagnostic question that leads his evidence-based medicine strategy down a clear productive path. In our experience, patients with 'sinusitis' in general practice will not present in the clear and precise way described by Fahey. Often they will come with a clear expectation of antibiotics: 'It's my sinuses doctor, I always get antibiotics for them.' The issue facing the doctor is not simply the biomedical decision about the correct diagnosis and the appropriate treatment.

The doctor may be faced with someone whose imprecise symptoms do suggest sinusitis and who feels that there is at least a possibility that the discomfort of the condition may be resolved by antibiotics. The patient may be under considerable pressure not to lose time off work because of the presenting infection, and these

influences will be brought to bear crucially on the final decision to proceed with the treatment or not.

Thirdly, and most importantly, the flaw in Fahey's essay is to restrict the decisionmaking strategy in the consultation to material based on the biomedical paradigm. We have argued elsewhere that doctors in general practice have to use paradigms that include the biomedical but go beyond that to embrace sociological and cultural paradigms too.6 As presented by Fahey, the diagnostic and therapeutic decisions are ultimately cognitive. We argue that these processes are not simply cognitive but are a combination of cognitive and intuitive processes that are crucially shared by both doctor and patient with a reciprocal influence of each other. The final decision is based upon a synthesis of the statistical and clinical significance derived from RCTs and what we have described as the personal significance derived ultimately from the therapeutic relationship with the patient.

We commend Fahey for clear and articulate defence of the RCT and for introducing the new components for applying the results to individuals. However, in doing this he has revealed the weakness of evidence that is based on the RCT by demonstrating that it is predicated exclusively on the biomedical paradigm and is a function of exclusively cognitive processes. There is certainly an appeal in the clarity that Fahey brings to his argument, but we are very concerned that his presentation is deceptively simple. Decision making in general practice involves much more than simply applying the evidence from RCTs.

KIERAN SWEENEY
PHILIP EVANS
DENIS PEREIRA GRAY
RUSSELL STEELE
HELEN KEENAN

St Leonard's Medical Practice 34 Denmark Road Exeter EX1 1SF

#### References

- Fahey T. Applying the results of clinical trials to patients in general practice: perceived problems, strengths, assumptions, and challenges for the future. Br J Gen Pract 1998; 48: 1173-1178.
- Sweeney KG. Evidence and uncertainty. In: Marinker M (ed.). Sense and sensibility in healthcare. London: BMJ Publishing Group, 1996.
- 3. Howie JGR. Diagnosis: the Achilles' heel? *J R Coll Gen Pract* 1972; **22:** 310-315.
- Marinker M. Clinical method. In: Cormack J, Marinker M, Morrell D (eds). *Teaching* clinical method. London: Kluwer Medical, 1981.

- Feinstein AR, Horwitz RI. Problems in the 'evidence' of 'evidence based medicine'. *JAMA* 1997; 103: 529-535.
- Sweeney KG, Mac Auley D, Pereira Gray DJ. Personal significance: the third dimension. *Lancet* 1998; 351: 134-136.

#### **Improving GP records**

Sir

I was intrigued to read the Australian paper on clinical records (June *Journal*).<sup>1</sup> I have recently spent a year working in general practice in Brisbane and was surprised to find that there is no standardized clinical record keeping. The Royal Australian College of General Practitioners does have its 'college record' system, which is used by some of the better practices, but in my experience these were few and far between.

The 'Medicare' system of health care is, in theory, means tested, and doctors get paid per consultation. This means that the more customers that are seen, the greater is the remuneration. If the patient is not entitled to pay with their medicare card, then they have to pay out of their pockets (not on Social Security). In fact, a lot of surgeries advertize that they will accept medicare cards regardless, which seems to encourage more customers. Because the system seems to be consumer based, patients are free to see whichever GP they choose; in fact, a lot of people have several GPs that they see (especially drug addicts). This means that notes are invariably incomplete, which is of relevance to the study design. Interestingly, the 'intervention and assessment instrument for record quality' that was used did not have a drug history section but did record aller-

Computer use is very limited, so data collection is poor. Accounting systems abound, but I didn't work at any surgeries that used computers in the consultation, except perhaps for prescriptions.

I applaud the authors of the article for their aims, and feel that there needs to be a major restructuring of certain elements of general practice in Queensland, if not nationally. I did meet a lot of excellent clinicians there, as well as some very sensible patients who appreciated the need to keep with one doctor, so hopefully something will be done in the near future.

STEVE PRICE

West Street Surgery 89 West Street Dunstable Beds LU6 1SF

#### Reference

 Del Mar CB, Lowe JB, Adkins P, et al. Improving general practitioner clinical records with a quality assurance minimal intervention. Br J Gen Pract 1998; 48: 1307-1306.

#### Triage of house call requests

Sir.

Jones *et al* (June *Journal*)<sup>1</sup> conclude that the majority of their patients were 'completely satisfied in every way' with their nurses triaging house call requests. Our experience, in a neighbouring health authority, with a similar sized practice and with four experienced triage nurses,<sup>2</sup> is that house call triage is not popular with a substantial minority of patients, and is more difficult than triaging requests for same-day surgery consultations.

Between January and May 1997, our practice nurses recorded 1145 requests for house calls between 8.30 am and 10.30 am (same times as Jones *et al*), of which 980 (86%) callers were visited, 40 (3%) had a surgery consultation, and 107 (9%) had telephone advice form the nurse. This contrasts with Jones's study where only 41% received a domicillary visit, 18% had a surgery consultation, and 24% had telephone advice from the nurse. How can we explain this startling difference between two apparently similar practices?

The answer may lie in three factors: natural variations in home visiting rates, the experience and attitudes of triage nurses, and the practice patient culture about home visiting.

Using data from 60 practices, Aylin showed an eight-fold variation in home visiting in England and Wales.<sup>3</sup> Rates were highest in patients aged over 85, those with respiratory problems, and in people of low social class. There may be less scope for reducing home visits in a practice with an elderly population, where there are more patients with respiratory problems, and where there is greater social deprivation. That assumes, of course, that these variables are less responsive to the triage process than others.

Like Jones *et al*, we find that patients have positive views about the communications process with the practice nurse. Patients also prefer talking to a nurse rather than a receptionist. However, we note that 41% of responders from their second postal survey indicated negative views or did not respond to a question on future telephone communications with the nurse. This reflects our experience that a

significant minority of patients are not enthusiastic about home visit triage. We believe that this is because home visit triage challenges deeply-rooted societal belief in the sanctity of, and right to have, a home visit. This has been recognized by other such as Ann Cartwright's. <sup>4</sup> It is, therefore, not surprising that any home visit triage, particularly if the nurses are highly directive, has the potential to produce patient discontent.

MORRIS GALLAGHER CAROL JOHNSON VALERIE ELSY

Central Surgery Gordon Street South Shields Tyne and Wear NE33 4HX

#### References

- Jones K, Gilbert M, Little JKW. Nurse triage for house call requests in a Tyneside general practice: patients' views and effect on doctor workload. Br J Gen Pract 1998; 48: 1303-1306.
- Gallagher M, Huddart T, Henderson B. Telephone triage of acute illness by a practice nurse in general practice: outcomes of care. *Br J Gen Pract* 1998; 48: 1141-1145.
- Aylin P, Majeed F, Cook D. Home visiting by general practitioners in England and Wales. *BMJ* 1996; 313: 207-210.
- Cartwright A, Anderson R. General practice revisited: a second study of patients and their doctors. London: Tavistock Publications, 1981.

# The more you look the more you find: problems of biases inherent in non-randomized studies.

Sir,

I read with interest the paper by Dunn and Pickering (May *Journal*), 'Does good practice organization improve the outcome of care for diabetic patients?' The authors have produced a large amount of valuable data on this under-researched subject. They suggest that the results of their survey may be of interest to health authorities and health commissions, who may use process or structure data to assess the performance of practices. I would like to highlight why this should be done with extreme caution.

In analysing percentage HbA1c tests carried out versus average HbA1c, the authors found that, on average, it was not improved among patients in the more highly organized practices. They concluded that a high proportion of process measurements does not correlate with an improved outcome.

In analysis of these results, however,

consideration must be taken of selection bias. The population of diabetics attending for blood tests in practices that organize a recall system will differ from diabetics attending practices that do not. It is of interest that, although it is not statistically significant, the average HbA1c in those practices that organize a recall system is actually higher than in those practices that do not (7.87 versus 7.58; P = 0.439). It is possible that, as practices become more 'efficient' and measure a greater percentage of their diabetics' HbA1cs, the average HbA1c may increase due to the inclusion of less well-controlled diabetics. The graph of percentage HbA1c measured versus mean HbA1c (Figure 1)1 may show a positive correlation (r = 0.2088; P =0.215).

It is of great importance that before any interpretation is made regarding the performance of practices, data should be carefully analysed. Finally, there is some evidence that good organization does improve outcome for diabetic patients. Farmer and Coulter found that admission rates were lower in practices that had an average amount, or many, facilities compared with those who only had a few.<sup>2</sup> There remains, however, an urgent need for further evaluation of the value of organized care for diabetics in general practice.

PAULINE BRYANT

Department of Primary Care
UCLMS
Royal Free Hospital School of Medicine
Rowland Hill Street
London NW3 2PF

#### References

- Dunn N, Pickering R. Does good practice organization improve the outcome of care for diabetic patients? Br J Gen Pract 1998; 48: 1237-1240.
- Farmer A, Coulter A. Organization of care for diabetic patients in general practice: influence on hospital admissions. Br J Gen Pract 1990; 40: 56-58.

## The applicability of randomized trials to individual patients

Sir.

In my discussion paper outlining the applicability of randomized trials to individual patients (April *Journal*), the original sources concerning the *s* and *f* values and the likelihood of being helped or harmed given as an example in Table 3 were derived from a published abstract, not simply from the Evidence-Based

Medicine discussion group as stated in the acknowledgements. My apologies to the authors for not making this clearer in my paper.

TOM FAHEY

Division of Primary Care Department of Social Medicine University of Bristol Canynge Hall Whiteladies Road Bristol BS8 2PR

#### References

- Fahey T. Applying the results of clinical trials to patients in general practice: perceived problems, strengths, assumptions, and challenges for the future. Br J Gen Pract 1998; 48: 1173-1178.
- Straus SE, Sackett DL. The likelihood of being helped versus harmed - a new method of presenting information to patients about the risks and benefits of therapy. Amsterdam: Cochrane Colloquium, 1997.

#### **Primary care education centres**

Sir,

A recent editorial (May *Journal*) proposed the development of primary care education centres (PCECs) to enhance the education of all members of the primary health care team (PHCT). The authors agree that this is essential for the reasons cited by LFP Smith: the fact that most NHS consultations occur in the primary care setting, the increasing transfer of care from secondary to primary care, and the increasing need for service flexibility and experimentation.

However, it is important that the following points are noted. The likely advent of recertification may now be less likely owing to changes in policy by the Royal College of General Practitioners (personal communication: Dr JA Repper, recertification fellow). While it is agreed that education should be needs led, the debate continues regarding whether or not GPs are able to accurately identify their own learning needs.<sup>2-6</sup> During the recent introduction of Personal Learning Plans (PLPs) in north-east Scotland,7 it was concluded that there is indeed a need for the preliminary step of enhancing learning needs assessment by individual practitioners, while the number of practices reporting a desire to move towards PLPs was small.

Consequently, it is suggested that a step-by-step process is required commencing with the individuals in the PHCT, followed by a move towards professional groups and finally multiprofessional groups, if learners remain motivated. Topdown pressure should be resisted in education as this is in direct opposition to the principles of adult learning.<sup>8</sup>

In conclusion, PCECs are indeed an exciting possibility for continuing professional development in primary care. However, any move towards their development must be handled sensitively and with respect for the learners.

#### MALCOLM J VALENTINE FIONA H FRENCH

Aberdeen Postgraduate Centre Medical School University of Aberdeen Foresterhill Aberdeen AB25 2ZD

#### References

- Smith LFP. Primary care education centres: educational innovation for all of the primary health care team is needed. Br J Gen Pract 1998; 48: 1215-1216.
- Tracey JM, Arroll B, Richmond DE, Barham PM. The validity of general practitioners' self assessment of knowledge: cross-sectional study. *BMJ* 1997; 315: 1426-1428.
- Edwards A, Matthews MR, Matthews S, et al. General practitioners' self assessment of knowledge: the vast range of clinical conditions means that doctors cannot know everything. [Letter.] BMJ 1998; 316: 1609.
- Crilly M. Knowledge gaps were identified by general practitioners. [Letter.] *BMJ* 1998; 316: 1610.
- Taylor P. Testing can be valid only if questions are relevant to those tested. [Letter.] BMJ 1998; 316: 1610.
- 6. Tracey J. Author's reply. [Letter.] *BMJ* 1998; **316**: 1610.
- Valentine MJ, French FH. The introduction of Personal Learning Plans for GP principals in Grampian, Orkney and Shetland (1995-1998). Final report to Scottish Council for Postgraduate Medical and Dental Education, 1998.
- Brookfield SD. *Understanding and facilitating adult learning*. Milton Keynes: Open University Press, 1986.

### Expanding the medical undergraduate curriculum

Sir,

In Blair Smith's discussion paper (June *Journal*)<sup>1</sup> he has suggested that introducing the study of English literature to the medical undergraduate curriculum would 'enrich the profession and individuals therein', and that its role in medical education is 'crucial'. Although I would agree with this in principle, I feel it would be difficult and completely impracticable to implement.

The medical undergraduate curriculum is already overloaded with information. One way in which to deal with this would

be to have a core curriculum with options for study of other subjects such as literature. However, in a manner analogous to the 'inverse care law', this would encourage students who already have an interest in art and literature to pursue this option, whereas the students who might benefit from studying literature would perhaps choose the scientific options.

Besides which, who is to say which literature would be beneficial to students? One could argue that reading *Brave New World* by Aldous Huxley would be ideal for further discussion on medical genetics and ethics in our fast developing world. It would be difficult to justify how a 19th century novel, for example, would have similar relevance to the present society in which we live.

Yet surely the aims of enriching our lives through literature would have been achieved in secondary school? Most medical schools require an 'A' level in Higher English, or the equivalent GCSE, before considering a candidate for the study of medicine, and medical students invariably are a self-selected group of well-read, well-educated individuals who have chosen to study medicine and not English literature. To suggest that these students need to be taught English literature in order for them to become better doctors is frankly patronizing.

If anything should be added to the undergraduate curriculum, then it should be verbal communication skills. Good communication skills are essential for every doctor, no matter what branch of medicine they decide to specialize in. It would have been far more helpful to have been taught how to break bad news in medical school, rather than being confronted with speaking to relatives about a seriously ill patient on one's first day on the hospital ward.

I would argue that rather than adding the study of literature to an already overloaded curriculum, medical students should be taught verbal communication skills and medical ethics, which will have far-reaching benefits to their future medical careers. Communication skills, and not literature, should play a 'crucial' role in medical education.

MEKALA MAHALINGAM

The Minster Practice Cabourne Court Cabourne Avenue Lincoln LN2 2JP

#### Reference

 Smith BH. Literature in our medical schools. Br J Gen Pract 1998; 48: 1337-1339.

### Recruitment methods for drug trials

Sir,

There have recently been several advertisements in the local and national papers asking for people with manic depression to volunteer to participate in a drug trial. The trial involves putting the patient on lamatrogine, then stopping their ordinary medication and randomizing them to receive either lamotrigine, lithium, or a placebo.

I am unhappy that major drug companies see fit to recruit patients in this manner, rather than through more orthodox channels. I am concerned that patients should be encouraged to discontinue their medication for such a serious condition by gambling on the chance of a placebo. Moreover, I am by no means convinced that where there is a standard and well-proven treatment, such as lithium, that it is acceptable or necessary to use placebos.

I work as a medical adviser to the Manic Depression Fellowship and am unable to continue to recommend that members take part in this trial. I hope that fellow general practitioners will also feel this way.

**ELIZABETH ARMSTRONG** 

17 Broadwalk House Hyde Park Gate London SW7 5DZ

## Near patient testing for anticoagulation

Sir,

General practitioners are increasingly asked to undertake anticoagulation within primary care. However, little work has been done on the costs of providing such a service in this setting. We looked at the cost implication for a local fundholding practice, which changed from using a local haematology department to using a Thrombolytic Assessment System (TAS) to measure the INR. Under both systems, a nurse would decide the warfarin dose from the INR measurement according to a warfarin nomogram. The nurses use the TAS analyser allowing a one-stop service to be set up with both measuring and dosing in one visit. The nursing time under both systems was the same and so nursing costs are not shown in the cost analysis (Table 1).

There was no change in the level of anticoagulant control between the two five-month periods studied, before and

lems. Br J Gen Pract 1998; 48: 1383-1386.

**Table 1.** Costs of a nurse-led clinic with and without a coagulometer.

| Nurse clinic without TAS analyser Hospital charge for INR Transport of specimen to hospital to the practice | £5.25 per test<br>Provided by hospital courier at no charge |
|---|---|
| Overall cost per test   | £5.25   |
| Nurse clinic with TAS analyser<br>Set-up costs  |   |
| Machine   | £2937.00  |
| Sundries  | £80.00  |
| Training staff  | £270.00   |
| Total   | (Assuming 3 hours x 3 G grade nurses)<br>£3287.00           |
| Per year over 5 years   | £657.40   |
| Yearly costs  |   |
| NEQAS <sup>a</sup>  | £130.00   |
| Controls (52@£4.83)   | £251.16   |
| Annual lab charges  | £210.00   |
| Extended warranty   | £352.50   |
| Cost of test (312 per year)   | £916.50   |
| Total   | £1860.16  |
| Overall cost per test   | £5.96 (£2.11 per test additionally if include set-up costs) |

<sup>&</sup>lt;sup>a</sup>This is the quality assurance scheme operated nationally.

after the introduction of the TAS analyser, as measured by the number of INRs within the appropriate range and the period of time spent in range.

The cost of the TAS-led service was 71 pence more expensive per visit with no change in the control achieved. This excludes the set-up costs, which would add an additional £2.11 per test; however, this would be reduced if more tests were performed. Transport costs for the hospital-based service were also excluded.

In a study by Fitzmaurice, a near patient device led to cost savings by a fundholding practice. A figure of £5 per visit was used in that study to allow for transport costs. If this was applied to our figures, the new model would be £4.29 cheaper than the old one.

No allowance was made for GP time in support of the clinic, receptionist costs, and premises costs; these were constant between the two study periods and should not affect the cost difference.

This uncontrolled study suggests that the simple addition of a near patient testing device was more expensive at the practice level. However, if we take a wider view and include all costs incurred, irrespective of who incurs them, the costs of both services become much cheaper.

#### Reference

 Fitzmaurice DA, Hobbs FDR, Murray ET, et al. Evaluation of a comuterized decision support for oral anticoagulation management based in primary care. Br J Gen Pract 1996; 46: 533-535.

### Practice nurses roles in caring for people with mental health problems

Sir

Some of Crosland and Kai's conclusions (July *Journal*) are at odds with their own findings. They report that 89% of the nurses felt there was no time available to them for the work and that 80% were concerned that their current workloads were too heavy. Even more worrying are their findings that most practice nurses were giving psychotropic depot medication and taking part in monitoring serum lithium levels despite the fact that 52% had never received any form of training about mental health problems, and a further 30% had only received training as a component of their pre-registration education.

I do not believe that, given the current position regarding workload and training, practice nurses 'may ideally be placed to identify mental health problems'. Placed they may be, but in a potentially dangerous and unstable environment which is far from ideal.

#### GRAHAM CURTIS JENKINS

Counselling in Primary care Trust First Floor, Majestic House High Street Staines TW18 4DG

#### Reference

1. Crosland A, Kai J. 'They think they can talk to nurses': practice nurses views of their roles in caring for mental health prob-

#### Correction

We would like to apologize for the typing errors in Tim Alexanders's letter, 'Urine Sample collection', which appeared in the August issue of the *Journal*. The figures appeared as £30.53 and £350 respectively; however, the sentence should have read as follows: NHS supplies replied that this order would cost £0.53, but were unwilling to accept any order for a cost less than £50.