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Response to 'Wishful pharmaceutical thinking'

Dr Hartman raises an important issue in the November issue of the *BJGP*, namely the clinical interpretation of studies in mental health based on rating scales.¹

A consensus meeting on how to investigate generalised anxiety disorder (GAD) was published last year that raised the same question — 'A significant difference registered on a pivotal scale between a treatment and placebo may not necessarily be clinically relevant'.² It goes on to state that clinical relevance should be determined by other outcome measures identified as clinically relevant, such as response rates (using Hamilton anxiety (HAM-A) or clinical global impression (CGI) scores). In our study we looked at response and remission rates using both scales.³ We believe that remission rates are the most clinically relevant endpoint, and these showed a 50% increase on venlafaxine compared to placebo, and although not statistically significant, we believe that this is due to the low number of patients, and had the trial contained more patients then this would have been statistically significant. Quality of life scales are generally insensitive to change. Thus, there is good evidence that the results are clinically relevant.

With hindsight, 4 points was not an appropriate figure for the power calculation for several reasons as outlined below:

- The definition of GAD in the 3rd edition of *Diagnostic and statistical manual of mental disorders* (DSM-III) used in most older studies only requires anxiety to have been present for a month

making it more akin to acute anxiety. The definition of DSM-IV requires symptoms for at least 6 months, which makes it a chronic condition. Thus, it may not be appropriate to compare results from older trials to the newer ones.

- Older studies were not analysed with the same 'vigour' as current studies and often used 'protocol analyses' without carrying forward data in the normal way these days. Thus, larger differences would be seen in older studies.
- The criteria of GAD has changed in other ways, with the psychic symptoms given more prominence in DSM-IV, making the HAM-A (which gives equal prominence to both psychic and somatic symptoms) rather insensitive to change, and thus differences between placebo and active treatments are likely to be small.

The 2.1 difference seen with venlafaxine is in line with the 2.8 difference seen overall in our five pivotal studies submitted to the regulatory authorities (who granted a licence for GAD), and also with a recent study of paroxetine.

In summary, we believe that the study performed in the UK supports the use of venlafaxine in patients with GAD in primary care as demonstrated by the statistical significance seen in the primary endpoint and the clinical relevance demonstrated by the 50% reduction in remission rates and supported by the quality of life scales.

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'Just a GP'

As a GP registrar with a rather enthusiastic trainer, I often find myself subjected to various 'learning experiences'. Perhaps the most enlightening of them is when the result is unexpected.

My latest venture was a case study of three patients with a chronic illness, in this case multiple sclerosis. The task was to find out what expectations and requirements these patients had of their GP. So, hidden among others was the question 'Which doctor has been a good doctor to you?'. Expected answers might have included the GP, who was all-knowing, all-caring, available day or night with a listening ear, and the GP who was coordinator of the many NHS departments involved in such an illness, i.e. a really good GP. However, my three patients uniformly and separately stated that it was their hospital consultant who was the best doctor. How annoying. But why? 'He made the diagnosis and sorts out my treatment'. Not to be outdone on this venture, I then asked 'But what about your own GP?' to which I received fairly positive replies of 'Oh

well he's lovely, always ready to visit, a good listener' etc.

My trainer and I pondered these findings and came up with a few speculative conclusions. As GPs we are obviously not as important as we might think we are. A trip to see the hospital consultant involves a long and much hyped wait, with an often difficult journey to get there, a very big and imposing hospital, and a doctor wearing a white coat with lots of attendants speaking in very impressive jargon and giving a life-changing diagnosis. Vastly different to the GP who's just around the corner, available within 48 hours at the most, and talks in very basic language that anyone can understand. Not so surprising then that little importance is attached to us.

How nice to be 'just a GP'. The pressure is off — no need to make clever diagnoses or treatment plans, we can forget national service frameworks, targets, and guidelines. It seems that the most a patient expects of us is to be available, be a good listener, and to visit when called upon.

So it's all really quite easy then, being a GP?

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Delayed prescriptions — not a good option for infants

Infants with a respiratory tract infection should not be sent home with a prescription to be cashed later. In the November issue of the *BJGP*, three papers dealt with the advantages of delayed prescriptions for reducing the consumption of antibiotics. For the older children and adults, it was shown that the amount of antibiotics for respiratory tract infections could be safely reduced by at least 50%. Arrol *et al* mentioned that caution should be displayed with infants, remembering the child in our trial that developed meningitis in the placebo group.^{1,2} I

feel that there is no problem in withholding antibiotics for infants with acute otitis media, since it has been shown that the effect of antibiotics is poor. But if you give the parents a prescription to be cashed when symptoms persist, you place an unfair responsibility on the parents. First of all, it has been shown that in these younger children symptoms last longer, whether they receive antibiotics or not; half of the children in our study had symptoms lasting more than 8 days.³ Second, we cannot expect parents to be able to judge whether the child becomes toxic. Cates mentioned in his editorial that when a child is toxic, antibiotics are indicated.⁴ Most doctors know what is meant by toxic due to their clinical experience over many years. How can we expect to teach this clinical entity to the parents in 10 minutes? The child with meningitis mentioned in our trial was already on antibiotics on the second day because his symptoms became worse. On the third day, the signs pointed to meningitis and the child was admitted to hospital. This boy turned toxic, and in this situation a doctor should decide whether antibiotics are indicated or if the child should be admitted to hospital. Parents should not be given this responsibility. If they have a prescription they could decide to start oral antibiotics when the child should already be receiving further treatment.

Doctors should be aware that they cannot buy safety with an antibiotic prescription nor with a delayed prescription. Oral antibiotics do not prevent all cases of meningitis.⁵ Doctors should monitor signs and symptoms and then judge on their clinical experience.

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A clinical indication on every repeat prescription

Over the last 6 months I have been putting a clinical indication on every repeat prescription, and so I was interested to read about the paper on automatic quality checks on repeat prescribing.¹ The article in the *BJGP* was driven by quality prescribing, whereas my aim was patient understanding and education. Certainly, my patients now assume that it is quite normal to have a clinical indication on their repeat prescriptions and they find it extremely useful. In this post-millennium era of general practice, where poly-pharmacy is normal practice, it is becoming increasingly essential for patients to be able to identify the main use of each drug. To illustrate, some examples:

- Take one simvastatin tablet at night to reduce heart attacks and strokes.
- Take alendronic acid once weekly to strengthen bones.
- Take fluoxetine, one daily to prevent recurrence of depressive episodes.

This is printed out both on the white and green parts of the repeat prescription.

The local pharmacist, district nurses, carers, and reception staff have found it increasingly helpful, and I am sure I now have fewer interruptions for queries over repeat medication.

It seems such a powerful and simple way forward that I have been evaluating it further and there are additional spin-offs that I can see ahead. Firstly, it is very useful in the validation of medical summaries, as one can check that the clinical indication correlates with an appropriate medical item on the summary of the patient. Secondly, it is extremely useful in providing education

to patients and all members of staff. As we are a training practice, my new registrars find it very useful, when signing bunches of repeat prescriptions, to see the clear clinical indication. I am sure that it must enhance prescription safety. Further phrases that I use which may help this are:

- as directed by anticoagulation clinic;
- regular blood checks required;
- under hospital supervision;
- and contact doctor if sore throat or illness.

I am also planning to start to trial a prescription-history feature; for example, a start date could be added to HRT repeat prescriptions and also, in a similar way, to tamoxifen prescriptions.

In conclusion, I suspect that clinical indications on every repeat prescription will become a valuable, essential part of modern general practice in the future.

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Accuracy of electronic sphygmomanometers

The Pendleside Medical Practice, in line with national directions arising from the need for disposal of mercury, changed to electronic sphygmomanometers in 2002.

Several doctors have been concerned about apparent higher readings with electronic sphygmomanometers, in spite of the brand used (Omron M5-I) having been validated by the British Hypertension Society.¹⁻³ A snapshot of a mean of 10 patients for each of the authors produced a mean difference between electronic and mercury sphygmomanometers of 11.8/8.7. On the basis of concern around these findings, we asked all members our primary healthcare team to record blood pressures using both electronic and mercury sphygmomanometers for 5 days in November 2003, and the

results for the whole practice were 10.5/7.8 ($n = 52$ patients).

This practice currently has 981 patients registered as hypertensive, from a total list of 8650. Clearly there is need for more research into this area, as electronic sphygmomanometers are becoming universally adopted. If our suspicions are correct it could mean very substantial resources being directed towards treatment of incorrectly diagnosed hypertension, particularly in the light of the new GMS contract.

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A very different life?

Being retired from general practice for 11 years, I watch with astonishment the transformation that has been visited on the job that I enjoyed for 33 years. My generation were not all paragons of virtue, but we sought to deliver a caring, personal service 24 hours a day, 7 days a week. I know that many factors have made this ideal no longer sustainable, but we were still a profession deciding ourselves how best to do the job and monitoring our own standards.

The two bastions of our freedom from excessive outside interference were the 24-hour commitment and our independent contractor status. We had political power, and governments

had to negotiate on an equal basis. Now it seems to me that you have lost most of the initiative and in the not too distant future, I suspect, our political masters will seek to replace you with the cheaper option of nurse practitioners. This is already happening in some areas, and the personal service is already discouraged by this government.

With minimal visiting and no out-of-hours work, it must be a very different life and, I suspect, less interesting, more confrontational, but still well paid ... but for how long?

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Changing roles

Douglas Jeffries raises an important issue about whether the new contract, with its focus on quality indicators — a population issue — will detract from the personal issues that GPs have traditionally focussed on.¹ What is particularly difficult for many GPs is that the doctor-patient relationship, which derives from dealing with these personal issues, is not only central to a GP's effectiveness but is also, for many GPs, the most rewarding part of the job. Consequently, there is a personal reluctance to take on this new task, especially if it is at the expense of the traditional role. However, it is possible that by switching the focus from the GP to the practice and using the resources of its practice team (such as by expanding the role of nurses and receptionists) to develop a system that both delivers the targets and protects those GPs who wish to continue to focus on the more traditional roles.

What is, in my mind, a much more worrying development is the increasing access that patients are being given to services without going through their practice. This is being done in the name of patient empowerment and will result in an expensive free-for-all supermarket approach to health care. This trend erodes not just the traditional role of the GP, but even that of the practice itself — a role that contains distress, provides continuity of care, makes sense for patients of symptoms

within the wider context of their lives (and thereby makes appropriate referrals) — in essence provides at best a well resourced and skilled team who can care for patients facing complex medical and social issues.

International comparisons show that robust, well-developed primary care is cost-effective. It is also central to any system that purports to provide 'health' rather than just disease management.

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Condemned to education by telemedicine

I see from The Back Pages that doctors who work in towns are again telling those of us who work in the sticks how we should organise our education by telemedicine.¹ (And I know the objection will be that they've 'been there', but for how long?) Anything is better than nothing, but the same sort of strictures apply to learning as to providing care. Just because cover is 'difficult to find' doesn't mean we should abandon the attempt. I'm afraid that the prospect of sitting in front of a monitor in our own practice, which is what we increasingly do anyway, doesn't compare favourably with spending a few days away from the telephone, having discussions with colleagues, and maybe even going to the theatre or a movie! It's a truism that a lot of the learning that occurs at courses takes place outside the formal sessions. We have enough isolation in our lives, don't condemn us to it in our educational activity as well!

So, an angry letter for you?

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Dream or nightmare — vocational training

As a group of experienced 'grass-roots' trainers, we have read and discussed the editorial from Patrick McEvoy.¹ We identify with and recognise all of the issues that the article raises and we have attempted to identify some possible solutions.

Firstly, we recommend the application of stern realism to the issues of training and teaching capacity, both human and physical. Most of the 'lean and competent training practices' so aptly described are at physical capacity, and yet there is no secure and recurring identified funding stream for the building of teaching facilities within or around GP surgeries in our locality. Investment now in teaching facilities within surgeries will at least give us the space to meet future demand.

We are aware that becoming a training practice can be perceived by non-trainers as an arduous process, not attractive in the current climate of organisational change. Until current recruitment problems are overcome there are only two ways of increasing teaching capacity: either more group and less individual teaching, or the recruitment of more non-teaching practices into the fold. To achieve the latter will require realism in the funding of start-up costs, and the provision of funded sessions to provide teaching without compromising service delivery. Enhanced service payments for teaching may be the way forward; funding will certainly need to be non-discretionary and recurring. This will have the advantage of 'delivering resources to the coal-face'.

The piecemeal development of GP training activity has led to complexity, fragmentation, and bureaucracy in our organisational and assessment structures. Positive strategies must be created and implemented with the specific aim of tackling these issues. Our current competence assessment processes should be simplified to the minimum necessary to achieve their purpose. Kramer *et al* have demonstrated that training schemes can work,² and duly accredited schemes should be left with minimum interference to do their work. Just as new building developments face a planning inspection, so

any proposals for new educational work or process should have to pass a scrutiny to ensure that bureaucracy and duplication are minimised.

Our final proposal echoes that of Howe *et al* and calls for a career structure for GP educationalists.³ This is an essential ingredient to ensure that a flow of suitably qualified and motivated GPs continue to provide a professional teaching and training service. Their proposal was for this role to be consolidated into the General Practitioners with a Special Interest policy, and to do this would ensure that future educators would not suffer financial penalty for their interests.

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The recent editorial by McEvoy on general practice vocational training¹ was thought provoking but perhaps bewildering.

His editorial starts by highlighting the lack of published evidence of the effects of a training programme, and then paints a nightmarish scenario in which increasing and complex demands are made upon the traditional educational training structure. We think it was useful to outline the challenges and possible pitfalls ahead, but believe the message is unduly pessimistic.

The challenges to be met in offering a general practice component to foundation programmes are huge but we

should not shirk from the opportunity and responsibility for providing it. A recent editorial in another journal has outlined the opportunities and skills that general practice can offer, reviewing the evidence from GP pre-registration house officer (PRHO) posts.² These studies have shown that a general practice attachment offers a unique environment to gain skills and understanding that are useful both immediately on the PRHO rotation, but later in a hospital career. These advantages were seen by both the doctors themselves and their consultant education supervisors.³

Advances in innovative GP registrar posts combined with hospital trust attachments⁴ and improved management of GP senior house officer posts have been published.⁵ Undoubtedly there are implementation obstacles to overcome, and it may be the model for foundation programme teaching is closer to that seen in undergraduate students than GP registrars. In the former, placements often take place in pairs, with a larger group forming to meet for joint learning and case discussions. Problem-based learning approaches could encourage more self-direction, and developments in computer and web-based sources would reduce the need for face-to-face teaching. Some investment in rooms and equipment will be necessary, but may not be needed in every training practice.

The Department of Health and the General Practitioners Committee have recognised that a single basic training grant does not reflect the panoply of tasks and sophistication expected from GP trainers. A new system of providing a 'training payment' has been proposed by the Committee of GP Education Directors, which should provide a postgraduate GP teacher adequate reward and support to develop and expand his or her skills appropriately.

We do not claim the Nobel prize offered by McEvoy for this work so far, or even a gold star, but are excited by the opportunity to work with innovative primary care educators to meet these challenges.

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Author's response

It is indeed an exciting and challenging time to be involved in general practice education and these contributions from trainers and directors, respectively, ably illustrate complementary perspectives.

Blythe *et al* make three points that I wish to applaud:

- the need to deliver resources to the coal-face;
- to streamline the appointment of trainers and the expectations of them;
- and to enhance recruitment and retention through a proper career structure.

There is some good news, as outlined by Smith and Lane. The latter is negotiating a constructive career/pay ladder with the Department of Health. The process is well advanced but, curiously, does not include trainers. They continue to be treated as if they were 'outside the loop'.

Our system of training has long depended on the idealism of GP teachers and their partners who have had to redirect a significant proportion of practice resources to support the training commitment. The more entrepreneurial our professional ethos becomes the more strain this places on practice partnerships. Many GP

teachers at all levels know this to their personal cost, a matter deserving of research.

Trainers know the realities of trying to balance service delivery and training, but feel excluded from the lofty circles that debate and formulate policy. They have yet to find an effective voice at national level. They have a great deal to contribute. Groups of trainers, such as Blythe *et al*, meet regularly in trainers' workshops throughout the length and breadth of the UK. Indeed, they are probably the most comprehensive and representative network of activity that this, or any profession, can claim. It should not be difficult for this network to organise itself into an intelligent and forceful entity. Is anyone 'up there' tapping into the wealth of experience they collectively represent?

Does anyone else 'out there' want to join the conversation represented by these two constructive responses to my editorial and contribute towards shaping the future of education in, and for, general practice?

If so, I am sure the Editor would be happy to hear from you.

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Correction

In the November 2003 issue, in Coid J, Petrukevitch A, Chung WS, *et al*. Sexual violence against adult women primary care attenders in east London (*Br J Gen Pract* 2003; **53**: 858-862), there is a correction to Table 2 on page 860. The bottom three rows of odds ratios have 'Yes' and 'No' in the incorrect order. The left-hand column labels should read as follows:

Forced sex	No
	Yes
Rape	No
	Yes
Sexual assault	No
	Yes

An amended version of this paper is available on the journal website:
<http://www.rcgp.org.uk/rcgpjournal/index.asp>