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These rules are not ready yet

Two papers in January's *BJGP* illustrated the contrast between the cut and thrust of clinical practice and the tentative way in which scientific evidence is expressed.[1,2]

A paper by Alastair Hay and colleagues reports a cohort study of acute cough in pre-school children, which combined data from GPs and parents in an attempt to identify features that predict complications.[1] GPs are said to be busy, and this one began reading at the Conclusion line of the Summary. Wonderful, there's a rule! Wonderful, if you can find it. You have to look quite carefully — there's no fanfare, or indeed specific heading for it — but it's worth the effort. In essence, you are on safe ground reassuring parents whose children have no fever and whose chests are clear. But are you? The authors say that the rule is 'not ready for application in clinical practice without validation'. Oh dear, better stop then. What will I do until someone publishes another study?

The other paper aims to provide a rule for distinguishing viral from bacterial lower respiratory tract infection (LRTI) in adults.[2] Again, finding 'the rule' is not for the faint hearted — there's no box or heading entitled 'The Rule: this is what you're looking for' — but, as with the other paper, the first section of the Discussion is where to look (for at least part of the rule). Bacterial LRTIs are associated with headache, fever, and painful cervical lymph nodes, whereas viral LRTIs are more likely to be associated with diarrhoea and rhinitis. As before, the rule is not recommended for practice without further validation.

I am not alone in being disheartened; the authors of an accompanying editorial conclude that 'there are still too many questions with too few answers'.[3] Well, despite the paucity of evidence for conditions that take up, perhaps, 20% of our time, we have to give and do give answers. The scientific basis may be shaky, but the patient will not go away until some pronouncement has been made and a management plan agreed. The rules suggested[1,2] seemed reasonable intuitively, and may affect my practice, even if their proponents believe this to be unduly daring.

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Complications defining 'complications'

I read Hay *et al*'s study on the prediction of complications in children with cough[1] with great interest, hoping for some useful advice on this common problem. Unfortunately, it proved a complete disappointment, owing to two major faults in the study.

The first was the hopelessly vague definition of what counts as a 'complication'. Since any change in the diagnostic label applied by GPs during the course of the illness was classified as a complication, many of the supposed complications were, in fact, not the kind of thing that would ever be considered a complication in practice. (It's hardly surprising that a child with a cough might receive a diagnosis of 'viral illness' at some point in the course of the illness, and it's absurdly tautological to find that children with a cough and chest signs have an increased chance of being diagnosed with 'cough and wheeze'.)

However, an even greater flaw was that the decision of what counted as a complication was based totally on the diagnosis of the GP. What this means is that the study tells us nothing about appropriate diagnosis or management of complications of cough — it only tells us what leads GPs to apply particular diagnostic labels. It's hardly a surprising or helpful finding to discover that children with fever and chest signs are more likely to receive a diagnosis of bronchiolitis, pneumonia, or chest infection from their GPs — these are precisely the signs that doctors are traditionally trained to take into account when making these diagnoses. However, this totally fails to tell us whether these diagnoses are appropriate or — even more to the point — whether they should lead on to any changes in management.

Thanks to these two faults, I found the study to be of no practical use whatsoever. It may be of some academic interest in that it tells us what we are doing, but it certainly isn't of any help in telling us what we should be doing.

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Authors' response

We thank Stuart Handysides and Sarah Vaughan for their responses to our paper.[1] There are three steps in the development of a clinical prediction rule: derivation (which is what our paper describes), validation of the rule in a different population, and assessment of impact on clinical practice.[2] The reason why we are cautious in recommending the application of our rule in clinical practice, is that it has not been validated, and this is necessary for two reasons. First, owing to the paucity of data, there is rarely any reason to pre-suppose associations between clinical predictors and outcomes. To ensure that the clinical predictors in our study were not owing to chance effects or biased sampling, validation is necessary in a different population. Secondly, the strength of association between clinical predictors (in this case fever and chest signs) and outcome (complications that warrant reconsultation) can be overestimated in derivation studies.[2] Although our clinical predictors appear to have construct validity (they appear consistent with clinical practice), and the low *P*-values (fever $P = 0.005$ and chest signs $P = 0.05$) suggest that fever is unlikely to be a chance finding, they could be idiosyncratic to our study patients, clinicians, or setting. If this were the case, a different set of clinical predictors would emerge from another group of patients or setting, and the rule would fail.

Dr Vaughan's response regarding the definition of complications in our study stems from a misunderstanding concerning the purpose of our definition and objectives of our study. Regarding the first, we used a similar definition of complications to that used in previous studies,[3] namely the presence of new symptoms, signs or diagnoses suggesting deterioration in the child's condition compared with the recruitment consultation. Compared with previous studies, however, we believe ours was an improvement as the child's parent also had to be sufficiently concerned to initiate a reconsultation. We eliminated reconsultations related to other problems by including only those that took place prior to resolution of the child's cough. Thus, we feel justified in using the term complication to describe children with bronchiolitis or vomiting, when these were not present initially and parents were sufficiently concerned to seek further medical attention.

Second, we think that Dr Vaughan, and possibly other readers, may have missed an important objective of our study; namely that fever and chest signs were associated with complications as a future; that is prognostic, event as opposed to a current (diagnostic) label, which we agree would be absurdly tautological. We chose a prognostic outcome, because we believe that clinicians are more interested in knowing which patients will improve and which will deteriorate than distinguishing, for example, viral from bacterial respiratory tract aetiology.

So should clinicians use the rule in the meantime? In our practice, we generally take a 'watchful waiting' approach to children with acute cough associated with respiratory tract infection, but feel more confident in those without fever or chest signs.

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Influence of NICE guidelines

On reading the study by Wathen and Dean,[1] it was somewhat reassuring to learn that GPs appear not to be unduly influenced by the guidelines issued by the National Institute of Clinical Excellence (NICE).

Interestingly, from the results of the questionnaire surveys and interviews, it seems that many GPs rejected the conclusions of NICE guidelines, certainly with respect to rosiglitazone, zanamivir, orlistat and Cox II inhibitors. What is not clear, however, is whether they question the validity of the studies on which the guidelines are based or, instead, disagree with the interpretation of these data by NICE. On the one hand, it would not be surprising if GPs were unimpressed by the currently fashionable large-scale randomised trials which promise so much yet deliver so very little.[2,3] On the other hand, they would be entirely justified in being suspicious of the motives of the contributors, especially when studies have shown that those involved in drawing up guidelines frequently have a vested interest in the final product.[3,4] In this context, it is worth remembering that, by their very nature, large-scale randomised trials yield data that are readily open to manipulation.[3]

Unfortunately, the determination of central authorities to dictate the medical management of patients and erode clinical freedom shows little sign of abating. On the contrary, the momentum increases inexorably. And so, when NICE fails, there is always the new GP contract to cajole and coerce formerly independent-thinking practitioners into the era of mindless, guideline-driven medicine. Perhaps Wathen and Dean might consider

repeating their study, this time measuring prescribing practices before and after the introduction of the new contract — then again, perhaps it would be better if we never had to endure the bad news in black and white!

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Author's response

During this study the GPs did not question the research studied by NICE. On the whole I would not say that the GPs rejected the conclusions of the NICE guidelines. With rosiglitazone, orlistat and Cox II inhibitors there was evidence that the NICE guideline accelerated prescribing. However, it was the doctors' own experiences with the drugs that subsequently affected prescribing rates. With rosiglitazone (insufficient effect) and orlistat (adverse effects) the initial acceleration in prescribing was not maintained. With the Cox II inhibitors (safer drugs) the rate continued to increase.

The one exception was with zanamivir. Doctors did question the evidence that led NICE to its conclusions. Why did the advice from NICE differ from that of other publications? Were they pressurised by the drug company? Was there political interference?

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Impact of the women's health initiative study

In 1968, gynaecologist Robert Wilson claimed that by taking oestrogen during menopause, 'Women will be much more pleasant to live with and will not become dull and unattractive'.[1] The women's health initiative (WHI) and subsequently the million women study have led us to re-examine the indications for prescribing hormone replacement therapy (HRT).[2,3]

HRT is prescribed predominately in the primary care setting and we wished to investigate how comfortable GPs in the Lothian area of Scotland were with the new WHI data and with HRT in general. A questionnaire (anonymous return) was sent to 588 GP principals from Lothian and West Lothian, 9 months following the WHI. Case vignettes, multiple-choice questions, and visual analogue scores were used.

The response rate was 56%. Only 47% of the responders felt fully versed with the new data from WHI. However, 64% had changed their prescribing pattern. An estimated extra 824 women in Lothian had been advised to stop HRT following the WHI. This represents approximately 2.45% of current users of HRT.[4]

Male GPs tended towards earlier cessation and this occurred over a shorter time interval. Fewer male (44%) than female GPs (59%) felt well versed with the WHI data. Sixty-three per cent of male GPs, compared with 77% of female GPs, stated that the WHI had changed their prescribing pattern ($P<0.01$). Among GPs in middle class areas (as defined by GPs themselves), 72% would continue HRT for vasomotor symptom control, whereas only 58% and 56% of GPs from deprived and mixed areas, respectively, would do the same. GPs from middle class practices were more inclined to consider taking HRT themselves at some time (81%), compared with 57% of GPs from deprived areas.

As a direct consequence of the WHI data, most GPs had advised some women to stop taking HRT. The study identified two areas of confusion, namely the use of HRT in the prevention of osteoporosis in women and management of premature menopause. GPs felt less confident advising women how to stop rather than initiating HRT (Figure 1). Little has been published on the optimum regime for cessation of HRT, and many women need support in coping with the return of unpleasant menopausal symptoms. Lagro-Janssen *et al*, in their *Lancet* editorial accompanying the million women study, stated: 'It is now up to general practice to pick up the pieces'.[5]

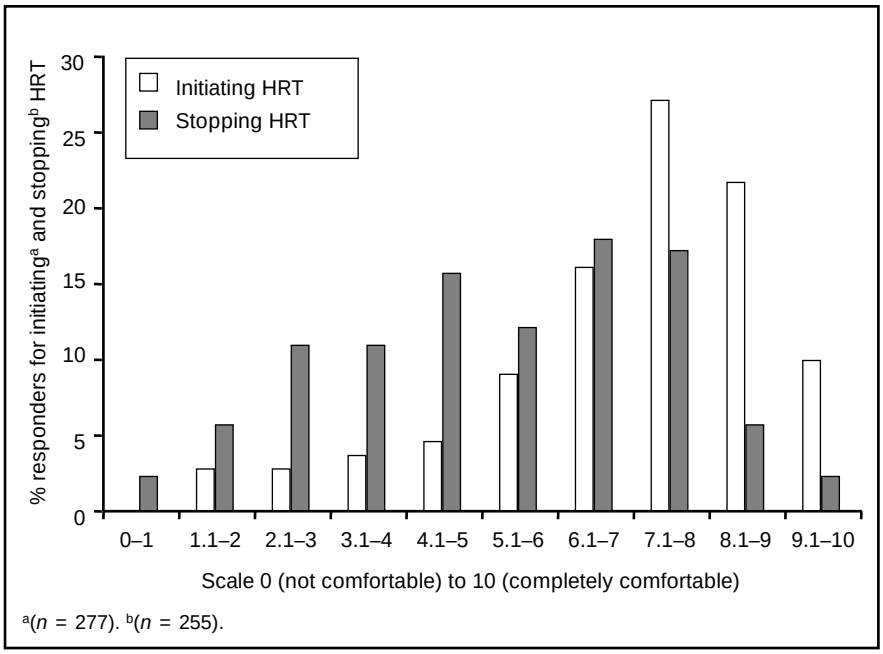

Figure 1. How comfortable are GPs at initiating and stopping HRT (visual analogue scale).

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Supplementary list inaccuracy

Non-principals have long been the members of the UK medical profession most difficult to track, thus missing out on educational and governance opportunities. Following recommendations from bodies such as the Standing Committee of Postgraduate Medical Education, the Department of Health instigated primary care trust-(PCT-) held supplementary lists of non-principals to facilitate their continuing professional development, governance, and appraisal.[1] Registration became compulsory from June 2002.

Setting up a research study looking at non-principal education and retention, we attempted to locate every non-principal in two urban PCTs.

The supplementary list was cross-referenced with deanery lists, personal medical services (PMS) practitioner lists, and any other local data available. A 'master list' was created by telephoning every practice to gather the names of non-principals who had worked there in the previous 3 months. The accuracy of the supplementary list was then assessed. PMS non-principals were disregarded in assessing sensitivity (that is, proportion of master list doctors appearing on supplementary list), since they were not obliged to appear on the supplementary list at that time (November 2003). Registrars were also excluded.

In one PCT with a master list of 29 'GMS' non-principals, 69% were listed on the local supplementary list (sensitivity) whereas only 55% of those listed were identified on the master list (specificity).

In the second PCT, 94% of practices were PMS, so there was no requirement for supplementary list registration for the vast majority of non-principals in this PCT. Nevertheless, 37% of non-principals were registered on the supplementary list.

These results only apply to two PCTs so cannot be generalised, however, we feel that it is likely that these results could well be found elsewhere in the country. The results suggest that non-principals are still an 'invisible' group, with great inaccuracies and inconsistencies in the lists. This has important implications. Overseeing continuing professional development and appraisal for some doctors may be impossible — the PCTs do not know of their existence. The concern is that it may be precisely those doctors most in need of support that are most likely to be working without the knowledge of the PCTs.

Provisional Department of Health guidance on the new contract promises that a new system of 'practitioner lists' will be introduced later this year.[2] Our findings show that careful thought must be given to ensuring that the lists should be accurate and contemporaneous to ensure that doctors are given the support they need and patients' interests are fully protected.

This research is supported by the BMA Sir Charles Hastings and Charles Oliver Hawthorne award but this report does not necessarily reflect the views of the British Medical Association.

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Post-traumatic stress disorder and primary care

Diagnosing post-traumatic stress disorder (PTSD) is indeed not easy, as your leader writer concludes.[1] Its very definition has become a minor industry for mental health specialists. The primary literature is dominated by laboratory studies on behavioural, biochemical, and electro-physiological markers in highly selected subjects. Rarefied academic debate has, paradoxically, been accompanied by the 'dumbing down' of the diagnostic criteria, to the point where every bereavement reaction might qualify as PTSD.

Bringing this into the realm of primary care discourse is long overdue. The impact of traumatic experience on mental and physical health is a matter of daily practice for GPs. We ought to have much to contribute to the literature and understanding of this area.

My professional life began amid the turmoil that marked the beginning of the recent Northern Ireland 'troubles', which have formed the background of the working lives of most GPs in Northern Ireland ever since. Along with GPs everywhere, I have had patients who have killed themselves, killed others, been in prison, been mugged, been raped, suffered transport accidents, died falling downstairs; others have died peacefully in bed but have left a spouse traumatised by deep

grief. Trauma is not confined to war in far-off places.

Few of the survivors or relatives have been diagnosed with PTSD, but very many have required intensive intervention and prolonged support at the level of general practice. Most have achieved functional recovery with the help of relatively naïf therapy — listening, interpreting, supporting, and symptomatic treatment. As with grief therapy, re-traumatisation is a common feature. Those whose reactions are unusually prolonged or intense are referred for specialist care, where a minority are diagnosed and treated for PTSD.

This provides a functional classification: those who need referral and those who don't. The latter could be described as suffering from a reactive neurosis. The term I use is 'stress following trauma'.

Reliance on the US classification (DSM-IV) is unhelpful. It creates a disease without a readily available remedy. If PTSD is a common diagnosis that demands specialist referral and the deployment of relatively rare resources (cognitive behavioural therapy or eye movement desensitisation) we could flood the community mental health teams tomorrow. Long delays in accessing services following trauma greatly reduce the effectiveness of intervention.

Two reports from Northern Ireland, Bloomfield[2] and the Social Services Inspectorate[3] on the consequences of the Northern Ireland troubles, have made useful contributions to the literature. According to these reports:

- Traumatic experience gives rise to a spectrum of clinical response which encompasses the pre-trauma state of the victim, features of the traumatic event[s] and the course of post-traumatic recovery. In this model, PTSD lies at the extreme of the spectrum and is a matter for specialist services, perhaps trauma centres.
- Most victims of the troubles got by with the support of their families, community, clergy and general practitioners, with no specialised back up.

It is not surprising that general practice, even in Northern Ireland, has made little contribution to the literature of PTSD, as Rosenbaum observes. Practitioners in traumatised communities have more to be thinking about, like coping with the days' work. What is surprising is the poverty of relevant literature and lack of guidance to empower them to manage with confidence the aftermath of every day traumatic events.

There is much that can usefully be done within primary care. The experience of GPs needs to be collated to produce guidelines for what works.

The contribution of the RCGP Northern Ireland to GP Awareness Week 2003 (celebrating the 50th year of the College) was a seminar held in Londonderry on this theme. This was conceived as an opportunity to acknowledge the distinctive achievement of GPs in Northern Ireland; that of supporting a deeply traumatised and divided community through the last 35 challenging years.

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More information on complementary medicine

As a busy GP, I am a little concerned by Edzard Ernst's article,[1] but would like to suggest some positive ways forward.

I was unaware, for example, of the actions and interactions of gingko biloba, despite regularly reading the *BMJ* and GP magazines such as *PULSE*. I feel it is unreasonable to expect people to have an encyclopaedic knowledge, and for this reason I have an up-to-date *British National Formulary* (*BNF*) on my desk, and my computer prescribing system also alerts me to any interactions I may have overlooked. If I am now expected to be aware of all complementary medications and their interactions then I am sure I speak for many GPs in suggesting that those who are well informed in these matters, such as Professor Ernst, discuss this with the authors of the *BNF* and the various medical software companies to add such information to their databases.

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Value in venlafaxine study

The letter from Dr Hopayian and others seems to suggest that we are damned if we publish and damned if we don't.[1] One of the ways that knowledge in medicine is advanced is by performing randomised controlled trials, which are then published in peer-reviewed journals. I wonder if Dr Hopayian would prefer it if we did not publish our studies and only presented the key data; somehow I think we would be criticised even more.

As to what our study adds to what is known, the review by Casacalenda,[2] cited by Dr Hopayian only looks at short-term data in general anxiety disorder (GAD), and there is no mention of venlafaxine. If we were to rely on short-term data then there would be no necessity to move on from the benzodiazepines. In reality, however, as it is now known that benzodiazepines can have issues such as tolerance in the longer term, then alternatives must be sought. Our study demonstrated that venlafaxine could be used for up to 6 months without problems of tolerance, and thus could be a useful option in the longer-term treatment of GAD. Furthermore, as our study was performed in the UK in primary care, this gives added reassurance to a prescribing physician who will be prescribing to just such a population.

It would seem preferable and more transparent to publish new trial data in a peer-reviewed journal such as the *BJGP* (especially if the patient population is taken from general practice in the UK), than to keep data in-house where it cannot undergo scrutiny and debate, such as has taken place here.

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Council tax banding and missed appointments

The paper by Hussain-Gambles *et al,* on missed appointments in primary care,[1] is of great interest to our research group. We are investigating the power and validity of the council tax valuation band (CTVB) for patients' home addresses as a socioeconomic and clinical marker (latterly supported by a grant from the British Medical Association). We have already reported that CTVB is a significant predictor of social indicators,[2] of general practice workload,[2] and of mortality.[3]

We have recently examined whether missing appointed consultations is also associated with CTVB. In our study year, there were 1098 occasions when a patient defaulted without cancelling (4% of all possible Northlands Surgery doctor appointments). This antisocial behaviour is usually linked to the patient's age (peaking between 20 and 40 years) and to lower social class (less consistently defined). Our own findings further corroborate this spectrum. There was no significant difference in the sex of our defaulters, but the median age was 31 years (50% were 20–39 years), whereas the median age for our practice list is 38 years, with only 27% aged 20–39 years. Our further, unique, findings arise from the fact that it is now possible to determine the CTVB of any address in the UK (with the exception of Scotland) from a government website[4] and therefore infer the socioeconomic status of the household. Eighty-nine point four per cent of defaulters aged 20–39 years lived in CTVB homes A–C (our practice list statistic for this subgroup was 74%).

Of the patients who failed to attend, many had defaulted before. In fact, 295 patients 'wasted' 790 appointments. But which patients make up this 'hard core'? There was again little difference between sexes, defaulters were still aged 20–39 years in 50% (*n* = 147) of occasions and, of these, 91% (*n* = 134) lived in CTVBs A, B or C.

So, what can be done? The authors are seeking evidence-based interventions. Clearly it is futile to think of contacting all patients every time they default, but it strikes us that we now have two additive and easily retrievable markers for those patients who are most prone to repeat defaulting. These can therefore be confronted before this negative behaviour is established. Practices might consider sending a letter (the content of which is best determined locally) to defaulting patients who are both aged between 20 and 40 years and living in CTVB homes A–C. If we extrapolate from our own data, this strategy would appear to be cost- and time-efficient. One hundred and thirty-four letters in a year would have the potential to save 360 otherwise wasted appointments. In other words, in every working week, three letters could 'rescue' up to seven appointments. With the format of the letters predetermined and the protocol established (incidence of both age and CTVB), this preventive process could then be delegated to reception staff. After all, it is their morale and motivation that is worst affected by this problem, as the Hussain-Gambles team rightly concluded.

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The GP contract: reasons to be cheerful?

Dr Jeffries asks why he is wrong in his belief that the new GP contract will harm the profession of general practice,[1] but subsequent letters have largely supported Dr Jeffries' fears.[2-5] Although we do not claim that these fears are unfounded, we believe that there are reasons for optimism, and would like to suggest some practical ways in which GPs can lessen any adverse impact.

We conducted some interviews with a sample of primary care trust (PCT) prescribing leads (all practising GPs) to find out their views about the new contract.[6] Responses were mixed; whereas there were concerns that resonated with those of your previous letter writers, positive aspects of the contract were also welcomed. For example, some of our interviewees thought that the contract could encourage care to be more patient centred and that it offered the opportunity for PCTs, through enhanced services, to improve care for the disadvantaged:

'It is the intention of the contract and most PCTs that services should be redeveloped on a more patient-focused basis.'

'It would be great if a few practices could specialise and employ good translators to help with care for asylum seekers. We could really improve

access for the underprivileged in society.'

Most GPs expected an increase in the use of technologies targeted by the quality framework. Some interviewees felt this was a good thing, improving care in targeted areas and encouraging GPs to reappraise care more generally. However, others thought that the framework might jeopardise the quality of care:

'People will prioritise the areas where they get the money. Areas such as heart disease and diabetes are important but others ... where there is no quality framework in place might get left behind.'

'People will look at the hoops that have been set up and make every effort to jump through. The thyroid target requires annual checking but the BMJ *says this is a waste of time, it should be 3 years. GPs might not be happy about it but most will bow to the financial incentive rather than what's clinically sound.'*

One GP felt strongly that the use of targets was the wrong approach for general practice, and that the move to specialisation, embodied in the enhanced services part of the contract, could exacerbate this effect:

'The drawback of targets in general is that they discourage a holistic view and mean that people forget about everything else ... [the contract] *will be detrimental to the holistic nature of general practice.'*

Echoing Dr Berry's concern that the contract heralds 'the demise of professional doctoring',[2] some of our interviewees feared a fundamental change to the character of general practice:

'Opting out of out-of-hours will change the way people work ...'

'Even with a quality focus, GPs will only be able to get to where they are now. They might say, "I can't get where I'm supposed to be by working hard, so I won't bother"'.

'Under the new contract, there will be more people coming into a practice for a short period of time with less commitment to change things. There will be more 9-to-5 doctors and some of the drive and commitment will be lost.'

Nobody knows what the impact of the contract will be, but we suggest that things may not be as black as they seem. Firstly, the contract's intention is clearly to uphold, not to undermine, the holistic nature of general practice; for example, the holistic care payments exist 'to support the intrinsic nature of general practice'.[7] This is good news because if the contract has unintended (that is, dysfunctional) consequences, then GPs will be in a strong position to argue for its revision. Secondly, the NHS Confederation has explicitly stated that the quality framework part of the contract is not set in stone:

'*Given the pioneering nature of the quality framework and its pricing, the scorecard arrangements will be kept under review. Beyond 2005/2006 it may be adjusted in the light of lessons arising from its practical application in consultation and negotiation with the GPC* [General Practitioners Committee].'[7]

We do not yet know the details of this review process, but it should offer GPs the opportunity to record their experience of the quality framework and its impact on patient care. Practices can also encourage patients to record their views in the 'patient experience questionnaires' that are part of the quality framework. Thirdly, GPs could make appropriate use of the 'informed dissent' clause, which is an option for almost all targets.[7] This may be particularly important if the proposed publication of GP performance data goes ahead,[8] since it is well-known that this approach can distort clinical priorities.[9] Patients that formally register their dissent will be removed from the denominator of the target equation, taking the pressure off GPs to pursue them and preserving trust and respect in the doctor–patient relationship.

If the contract is to improve the working lives of GPs and the quality of care for patients, GPs need to rise above the plethora of directives and guidance and make their voices heard loud and clear. They owe this to themselves, to their patients, and to future generations in order to safeguard the jewel in the crown of the NHS: general practice.

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Correction

In the February 2004 issue, in Oakeshott P, Kerry S, Hay S and Hay P. Bacterial vaginosis and preterm birth: a prospective community-based cohort study. (*Br J Gen Pract* 2004; **54:** 119–122), there is a correction to the 'Comparision with other studies' section of the Discussion on page 122. The second sentence of the second paragraph should have been:

'It found that women with asymptomatic bacterial vaginosis, who were treated with oral clindamycin before 22 weeks gestation, had fewer second trimester miscarriages and preterm births, with a number needed to treat of 10.[8]'

In the printed version the number needed to treat was given in error as 108. The eight should refer to reference eight.

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