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.

Counselling in primary care

Sir,

We wish to raise a number of problems in Harvey *et al*'s paper, 'A randomized controlled trial and economic evaluation of counselling in primary care' (March *Journal*),[1] which we believe make the conclusions untenable. Our main concerns are as follows.

The Cardiff arm of the research was originally written up as a Final Evaluation Report to the South Glamorgan Family Health Services Authority (FHSA) (dated 27 February 1995), and it appears that the Swansea arm was a separate evaluation undertaken at a later time.

In the Final Evaluation Report to the FHSA, 74% of the sample (the 'Cardiff arm' of Harvey *et al*'s paper) received psychotropic medication. Assuming data was available on 90% of the patients, this would suggest that 63 patients were on medication, which exceeds the total number of the two-centre trial of 49 by a substantial margin. Which is the correct figure?

If the figure for the February 1995 Cardiff Final Evaluation Report is correct, this would go some way to explaining the differing characteristics of the Swansea sample compared with the Cardiff sample. This is statistically significant for both social class ($\chi^2 = 18.79$; df = 2; $P \leqslant 0.005$) and the presenting problems reported ($\chi^2 = 12.5$; df = 4; $P = 0.014$). With such obvious differences, it would be preferable if the authors had provided a stratified analysis. Although this appears to have been carried out, the details of the difference between treatments is not given, apart from a comment in the text (p.1046). In addition, in the original Cardiff report, 40% of all the patients seen by counsellors in the study period were reportedly randomized.

As presented, the study has many flaws in the methodology. It is not clear what the primary outcome measure is. In our opinion, the use of COOP and SF36 instruments is not relevant to the study hypothesis because a relative effect size of 0.6 was used to calculate sample size rather than being based on the variance of the primary outcome measure. We suspect that a sample size chosen to detect a minimum clinically important effect on a primary outcome measure would be much larger. As it stands, the study is underpowered.

Although described as a two-centre study with similar GP practices and counsellors of similar skills and experience, it was reported in the original FHSA report (1995) that the Cardiff arm GP practices were, in fact, specially selected as having a special interest in mental health. One of the authors of this letter (GHCJ) also assisted in the selection of the counsellors. They were specially selected because they possessed a wide range of clinical skills, experience in many settings including health settings, and professional experience. Was this the case in the Swansea arm? If not, these might have shown a significant difference between the two centres that would have been concealed by aggregation of the data.

We believe that the methodological flaws in this paper demonstrate the need for the *Journal* to adopt the consort guideline for reporting trials that have been adopted by many other journals.

We are also concerned that, although the authors criticize a number of other RCTs and other research studies of counselling in general practice, they seem unwilling to discuss the limitation of their own study.

We believe that, given the number of flaws we have identified and, above all, the failure of the authors to state that the Cardiff report of 1995 reported that a large number of eligible patients were not randomized by the GPs, it would be unwise to act on the conclusions of the study. In particular, potential purchasers should on no account take into consideration these findings when allocating resources.

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1. Harvey I, Nelson SJ, Lyons RA, *et al.* A randomized controlled trial and economic evaluation of counselling in primary care. *Br J Gen Pract* 1998; **48:** 1043-1048.

Authors' response

Sir,

Drs Jenkins and Tylee raise a number of interesting points. Dr Jenkins — in view of the fact that the Counselling in Primary Care Trust contributed to part of the Cardiff costs — has had access to the project report that was produced for the commissioning FHSA on the Cardiff element of the study.

The Swansea element of the study was not a separate evaluation but was developed when the, then, West Glamorgan Health Authority embarked on a similar pilot project and became aware of events in Cardiff. The same research design and methods (with the addition of the SF36) were adopted, merely adding more concurrent practices to what was already a miltipractice study.

We reject the suggestion that the study is worryingly underpowered, quite simply on the grounds that the confidence limits around the differences between the trial arms (in Table 3)[1] are, we believe, sufficiently narrow to exclude differences of clinical interest. Others, of course, may disagree.

The difference between Cardiff and

Swansea recruits are, in fact, smaller than Jenkins and Tylee outline. In part, this is because of an error in the project report to the South Glamorgan FHSA in which it should have been stated that 24% of subjects were on psychotropic medication (compared with 40% among Swansea subjects). There were, as identified, significant social class differences (mainly owing to the high proportion of economically inactive subjects in Swansea), but we are unable to replicate the significant difference in the pattern of presenting problems that Jenkins and Tylee describe. They propose that a stratified analysis separating the Cardiff and Swansea elements of the study might have revealed differences that have been masked by aggregation. The grounds for this include the fact that the mode of selection of counsellors and practices in the two cities may have differed. Having read the report to the South Glamorgan FHSA, however, these correspondents will be aware that the contrast between the study arms in Cardiff was essentially similar to that for the two cities combined. We do not believe, therefore, that a 'city' difference has been missed.

We would strongly agree that the Consort statement on reporting of clinical trials is an admirable gold standard. We aimed at the outset to present data on the proportion of *eligible* subjects randomized. Despite designing our data forms to identify this, poor completion of forms for all eligible subjects (as opposed to those recruited and randomized) meant that we do not know this proportion. In the report to the FHSA, we did comment on the low proportion (16%) of all *new* patients referred to the Cardiff counsellors that had been recruited to the study, but only *some* of these new patients would have met the eligibility criteria. We most emphatically did *not*, in the FHSA report, describe the proportion of eligibles randomized and then omit this information from the published paper. We were, of course, aware of the issue of external validity and drew attention to this in our discussion. We readily accept that, had we obtained these data, the quality of the study would have been enhanced.

Clearly, no study in the real world can be perfect, and our experiences illuminate some of the problems of undertaking randomized trials in primary care. We are reassured by the fact, however, that our findings are similar to those of another recently published study.[2] It may also interest those who are strong advocates of counselling that our findings have been interpreted by many as strengthening the case for counselling. This has been on the grounds of its similar cost and effectiveness to GP care, but with the added potential benefit — which we did not seek to measure — of reducing GP stress.

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Sickness certification

Sir,

In the Viewpoint in the 'Back Pages' of the June *Journal*,[1] Fiona Ford comments on the giving of 'permission to adopt the sick role' notes, known as Med3s, by GPs. The viewpoint refers to the rather polarized division between the well, who can do any work, and the sick, who cannot do any work, with nothing in between.

The equivalent certificate in New Zealand would be the ARC 18 form. This form is A4 in size and requires the doctor to fill in, not just the diagnosis, but also brief details of treatment so that there is some communication to the employer about the need to attend clinics and follow-up appointments, and any dressings that may be in place.

In the 'capacity for work' section, the doctor is not asked to say just yes or no to the question asking whether or not a patient is able to carry out 'all normal work', but is actually given boxes to tick off for a number of common work restrictions and asked to say, if they think the patient can do some work, specifically what work restrictions should be imposed in terms of time, breaks, strenuous activity, type of work, etc. This information is used by the employer to, if necessary, arrange alternative work, aids at work, or to plan shifts. Employers are given the choice whether to keep people with restrictions off work, but are encouraged (by the sick pay arrangements) to keep them at work by providing them with tasks they can do.

Obviously, not all employers can offer suitable alternatives, and some patients can be signed off work completely by the doctor, but a number of employers I had contact with were able to cooperate with us to provide a stage of 'convalescent ability' somewhere between 'normal' and the 'sick role' in order to maintain the patient's self-perception. Except in very small workplaces, and particularly on farms, this part of the system seemed to work very well.

Decisions on the longer-term incapacity of patients are made by the Accident Compensation Corporation, not by the patient's GP, except where an obvious disability, such as fracture, is certified by the doctor.

It might be worthwhile considering a similar system in Britain, but, until then, perhaps we could encourage doctors to use the 'doctor's comments' space on the Med3 form to convey information that may be useful to the employer in a similar way?

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1. Ford F. Sickness certification: time to scrap the Med3? *Br J Gen Pract* 1998; **48:** 1353.

Author's response

Sir,

Dr Church raises a number of interesting points relating to sickness certification in New Zealand, and in particular the incentive for active rehabilitation of patients, mediated by the GP's certification of the need for treatment, restrictions on working ability, etc.

While doctors can, theoretically, write comments on the Med3 certificate, to suggest that a patient is, for example, 'fit for therapeutic work' (i.e. less than 16 hours per week), the small size and layout of the certificate does not encourage this.

To extend the certification process to include work limitations and treatment could be a very positive development, especially if GPs were given the cooperation of employers and access to adequate resources, including rehabilitation programmes, such as the psychoeducational group therapy we are researching in Liverpool for patients with anxiety/depression. (ODIN project: Outcomes of Depression in Europe).

The ideal situation might be one in which the initial decision regarding fitness for work was taken by the patient, policed long term by independent medical advisers (e.g. Benefits Agency Medical Service), and the GP acted as gatekeeper

to the rehabilitation process, rather than signatory to the sick role.

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Simulated surgery

Sir

The letter by Professor Murray (July *Journal*)[1] concerning the two articles we published,[2,3] raises a number of issues that require answering, particularly as some are covered in the papers.

First, it is not true to say that we do not describe situations that cannot be simulated — this is quite specifically referred to in the paper on validity.[2] Elderly patients are included, as are many continuing problems — despite them being new to the candidate doctors. The whole construct of our method is based around a holistic view of the synthesis of skills required to consult competently. Physical examination can be tested by simulated patients, and is used for this purpose by others. This is not the purpose of this assessment method, and physical examination skills are in fact not systematically assessed in the current video method: the trainer's report is the element of summative assessment that covers physical examination.

It is also a total misinterpretation of the papers to suggest that the decision regarding pass or fail is taken by the simulators. This is equivalent to saying that, in a multiple choice questionnaire paper, the decision is taken by the computer scanner! The pass/fail standards are set by the expert group of doctors; the simulators act as trained recorders of the events they experience. It is also a specious suggestion that the experience of satisfaction must be simulated. The patient-rating scale is very much based in the type of work referred to by Professor Murray. A fail decision will only be reached after consultation with 16 patients, not eight patients as suggested, and this decision will be taken by a panel of doctors.

Direct comparison with the video method developed by Professor Murray and colleagues is difficult, as the constructs of the two methods are very different. In the current 'over assessment' climate, it has not been possible to compare final outcomes concurrently, which is the only comparison of the whole processes.

The issues of numbers of consultations to be passed in the clinical list is addressed in the paper on validity. Competence is not a single entity. We are looking for capability of the registrar to consult in an acceptable manner. Case specificity may lead to poor performance in some situations, therefore, the decision was taken that registrars only need to demonstrate that they are capable on six consultations. Interestingly, this is the average number of consultations viewed by the video assessors in order to decide on competence.

Sensitivity and specificity figures are not quoted as there is no absolute 'gold standard' of competence against which to compare. The initial work on the current video method[4] relied on raters picking one bad video out of 10. In this preliminary research, we tested several candidates who were felt by their teachers to have major problems and the surgeries have identified them as such.

Finally, any assessment method provides evidence on which examiners make judgements: this is the referral process described by Professor Murray. In the application of our method, the evidence on failing candidates, including all marking sheets and information on the content of the consultations undertaken, would be given to a referral panel of doctors who would make the final judgement.

We therefore feel justified in repeating our claim that the simulated surgery is a fair, valid, and reliable method of assessing consulting skills, and that it has several advantages over the present system of video-recording.

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Deprivation payments and workload

Sir,

The editorial on 'Matching policy and incentives in deprived areas' (July *Journal*)[1] appears to assume that general practitioners practising in deprived areas work harder than those who do not.

Deprivation payments are based on the Jarman index for underprivileged areas originally derived from eight census factors subjectively perceived by GPs as most affecting their workload.[2] However, there is little objective evidence for such assumptions. One study showed that wards with high deprivation scores also had higher doctor–patient ratios, and that GPs with surgeries in the worst wards spent less time on average with their patients than those in the best wards.[3]

More recently, the workload of 100 full-time GPs in Sheffield in 1991 was compared with the proportion of patients on their lists who lived in wards qualifying for deprivation payments as derived from the 1991 consensus. There was a consistent negative correlation between the proportion of patients attracting deprivation payments, and measures of workload in terms of numbers of patients seen per week and hours spent providing general medical services per week.[4]

Deprivation payments were introduced in the 1990 Contract, at least partly to counterbalance the difficulty for inner-city practices of achieving targets for immunization and cervical cytology payments. Dr Hodgkin is right to question the appropriateness of deprivation payments to GPs as an incentive to recruiting doctors to inner-city areas, or as a means of targeting resources into inner-city primary care. But more fundamentally, there is no consistent evidence to support the underlying assumption that GPs work harder in deprived areas.

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A comparison of three methods of setting prescribing budgets

Sir,

Maxwell *et al* (August *Journal*)[1] allude to the different methods of calculating deprivation, and, certainly, the plethora of papers[2,3,4] describing alternatives seem to testify to how unsatisfactory the existing measures are. The data they describe give the impression that, excluding the growing and highly expansive area of central nervous system drugs, deprivation has little effect on prescribing volume.

The measure of deprivation used in Scotland (and in this study) takes into account neither unemployment nor low income. My own practice in West Lothian has been recognized by Lothian Health Authority as a 'priority area of deprivation', with high chronic illness rates, and yet none of my patients qualify for deprivation allowance. In this study, my practice would be one of those described as 'low deprivation'.

Care must therefore be taken in drawing wider conclusions concerning the relationship between deprivation and prescribing when a flawed method of determining deprivation is used.

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GP out-of-hours service

Sir,

The GP out-of-hours service changes reported by Hansen and Munck (August *Journal*)[1] bear a striking resemblance to those in Britian, with the comforting exception that, in areas covered by cooperatives, the patient satisfaction rate remains high. The Danish and British reforms originated for the same principle reason; i.e. GP dissatisfaction with working conditions produced mainly from escalating patient demand, and there is evidence that the changes in both countries have reduced face-to-face consultations at the expense of a greatly increased telephone consultation rate.[2]

The Danish regions cover a similar population (50 000–600 000) to most of the 250+ UK cooperatives. MAIDDOC began operation in 1990 as one of the pioneer services. It now covers 140 000 patients and 78 GP lists, making it an 'average' service.[3]

In Denmark, Christensen and Olesen have reported a doubling of telephone consultations to 48%. Hansen and Munck also demonstrate more than twice as many telephone consultations as before the changes (22% to 54% of total consultations). We have noticed a similarly striking increase from 37% in 1990 to 59% in 1997. The actual numbers of telephone consultations increased by 333%, whereas membership, and therefore patients covered, only increased 50% over the seven years. The same authors also report a much reduced home visiting rate to 18%[2] and 19%[1] respectively. MAIDDOC's visiting rate has decreased from 63% to 23% between 1990 and 1997. The actual number of home visits has decreased by 23% despite covering for 50% more patients. Face-to-face consultations have only increased by 35% over the same period: also reflecting the reduction in patient contacts shown by Hansen and Munck.[1] This goes some way to argue against the initial criticism of cooperatives: that it would lead to escalating and uncontrollable demand.

The problem for the future is the soaring telephone consultation rate, which is in danger of keeping doctors from more worthy cases and has distinct implications for the NHS Direct scheme currently being piloted.

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Private health screening

Sir,

Some aspects of private screening, particularly through anecdotal comments, were significantly misrepresented in the paper 'General practitioners' perceptions of private health screening' (June *Journal*).[1] I would like to put the record straight.

Most of the tests we offer in our health screens show evidence of benefit. These include cervical cytology, breast mammography, blood pressure monitoring, and blood lipid measurement. A 45-minute consultation with a doctor is also highly rated by our customers, who value time with a doctor to undergo a thorough examination and discuss any concerns; this individual service is not easily accessible in other settings.

In all cases where there are concerns, we write a short summary letter clearly outlining the abnormalities. We ask GPs if they are happy to continue any further investigation or treatment and, if they are not, we ask them to contact us; there would, quite rightly, be a furore if we were to take on the treatment of another doctor's patient. A copy of the investigation results is sent to GPs as a matter of courtesy, but there are good arguments for limiting this paperwork and we are currently reviewing our approach to this.

Finally, in addition to providing health screening services to many thousands of people every year, BUPA has, for some considerable time, participated in clinical research with leading institutions, and our large database is drawn on by researchers from all over the world. There is, for instance, a cohort of over 20 000 men who are being prospectively followed-up from the 1970s by epidemiologists, and recent papers include a prospective study on the effects on mortality of switching from cigarettes to pipes or cigars from three smoking-related diseases. We are also collaborating on research on *Helicobacter pylori* infection and mortality from ischaemic heart disease.

Therefore, despite the cynicism shown by some of the responders in the published survey, we are not only providing a useful service that is difficult to find elsewhere, but we are also playing our part in contributing to some important research, and, of course, providing sessional employment for a significant number of general practitioners around the country.

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Screening for cervical cancer

Sir,

Dr Fylan is to be congratulated on her review article on screening for cervical cancer and on her extensive literature search (August *Journal*).[1] However, I have to admit to being disappointed that she did not mention some of the very important reasons why women do not have smears, which I have previously tried to highlight.[2] The areas she covered are valid, or have been in the past, though some, such as administrative problems and screening organization, have largely been overcome with increasing computerization within primary care. Leaflets and information available to women having cervical smears and colposcopy have also improved, and most practices can provide a trained female health professional to take smears.

There are, however, some very important reasons why women do not have smears that were not mentioned. I became interested in this in our group practice. We regularly achieve over 90% uptake of cervical smears, and so many of the problems outlined in the paper no longer exist. I became aware of a small number of women who persistently declined cervical smears and I decided to look for explanations. It is essential to remember as well that women have the right to refuse a smear although we have a duty to make sure that this is an informed decision.

It is widely accepted that women who have never had sexual intercourse are at little risk of getting cervical cancer and that, in this instance, they should be allowed to make an informed decision not to have a smear taken. Young women should be kept on recall should their circumstances change. It should also be recognized that, though rare, non-consumation of marriage does occur. If a married woman has no children and has never had a smear, this should be considered. Previous sexual abuse is also a reason why women may refuse a cervical smear. This may seem obvious, but it is rarely mentioned in articles on the subject, and all health professionals should be aware of this as it may sometimes be revealed for the first time in a cervical screening consultation.

There will also be women with serious physical and mental illnesses who do not feel able to have a smear. In our practice, we have also found that, although women with learning disabilities are offered cervical smears, some have found it too distressing and it has had to be abandoned.

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Recruitment of general practitioners to a randomized trial

Sir,

The success of a primary care led NHS depends on the development and evaluation of cost-effective approaches to health care. The recruitment of GPs to randomized controlled trials (RCTs) is, therefore, a prerequisite. As part of an RCT to evaluate the cost effectiveness of training GPs in brief cognitive behaviour therapy (CBT) for patients with depression and anxiety, we report on our efforts in recruiting 115 GPs.

GPs in five London health authorities were sent a personal letter inviting them to participate in the RCT. An information flyer was distributed to GPs by two health authorities and, in one, the RCT was advertized in a GP news letter. Brief details of the pilot and progress of the RCT were also published in this *Journal*.[1] The training course was PGEA approved, free of charge, and practice staff were offered payment for administering part of the RCT. All GPs who expressed an interest were sent a registration form and GPs were followed-up personally by telephone if the registration form was not returned.

Of 1121 GPs contacted, 210 (18%) expressed an interest in the RCT and, of these, 115/1121 (10%) were recruited. Expression of interest was not increased in those who received an additional flyer, those whose health authority advertized the study, or by the publication of the pilot. Only 43/210 (20%) GPs returned the registration form and 144/210 (68%) required at least three personal telephone calls to establish whether or not to undertake training and participate in the study. There were no significant differences in the number of personal telephone follow-up calls required for GPs recruited to the study compared with GPs not recruited. The most commonly stated reasons for GPs not wanting to enrol were constraints on time (52%) and not wanting to take part in the evaluation (21%).

Despite our efforts, a personal letter and at least three personal follow-up telephone calls to interested GPs were necessary for recruitment. The level of recruitment was similar to that of previously published studies.[2,3] We recommend that even greater incentives are needed to promote participation in research within general practice; e.g. resources for locum cover, extra financial incentives, changes in contractual agreements to support research and development. The success of the primary care led NHS maybe limited if such measures to increase primary care-based research are not considered.

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