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Children and clinical trials

The representativeness of children entered into clinical trials is indeed an important issue, as raised by Bain.¹ Recruitment of all children seen by the participating doctors will always remain utopian. However, this does not imply that results cannot be extrapolated to the population from which the participants of the trial were taken. Bain mentioned that our trial² did not report on how representative the children entered into the trial were. This is simply not true. Baseline characteristics of the included children were presented and compared with the characteristics of children with acute otitis media from a large and well conceived registration study conducted in a general practice setting in the Netherlands.³ It was also recorded that 27 children of the 425 registered were not entered into the trial since the GP had the opinion that these children were too sick to be treated without antibiotics. Therefore I can agree with Bain's conclusion that it is still justified to treat children presenting with severe disease with antibiotics. This conclusion can be drawn by just reading the trial report — there is no lack of information as is suggested by Bain. By raising the question of whether children entered into clinical trials on acute otitis media are representative Bain tackled an important issue. However, his answer is disappointing and suggests that well executed trials are not fit for day-to-day practice. Our conclusion that watchful waiting is justified for the majority of these children is still important for daily practice and has been recently reconfirmed.⁴ The decision on whether or not to prescribe an antibiotic should be guided by good clinical reasoning, not by fear. By ignoring the minimal effect of antibiotics for acute otitis media, Bain seems willing to

go back to the antibiotics era with the consequence of increasing resistance of microbes.

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Health centres and GP surgeries should provide bicycle parking

Recently I went by bicycle to visit a practice attached to an academic department of general practice, all in a nice spacious modern building. There was no parking for bikes. Primary Care Groups, Health Authorities, the RCGP, and the BMA should officially encourage the provision of such parking space for patients and staff. Do your readers know of any that have done so? It would be a cheap, visible, and useful cross-sectoral health improvement project, easy to pilot and evaluate.

The costs of providing Sheffield ('inverted U') rails are modest, and could be shared by the NHS, the practice, and the local authority; they would also

share the credit.

I hope that readers who agree will consider this for their own practice and also put it to the Chair of their local PCG/PCT, their local Director of Public Health, and the Chair of the Local Authority's Transport and Environment Committee.

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Identifying alcohol dependency

It was encouraging to read the editorial by Paul Wallace¹ in the March edition of the *BJGP* for two reasons. First, his highlighting of the work by Aertgeerts,² which confirms that the CAGE questionnaire is neither sensitive nor specific enough for use in reliably identifying alcohol dependency. Secondly, for highlighting the appropriateness of general practitioners being involved with the management of this client group. However I was disappointed that the editorial made no mention of the therapeutic agents of disulfiram and acamprosate. There is clear evidence to show that disulfiram reduces the number of drinking days.³

Recent evidence also shows that efficiency is improved further when its administration is directly observed by a third party.⁴ There is emerging evidence that acamprosate is more effective than naltrexone in preventing relapse into alcohol dependency.⁵

In keeping with many chronic conditions, health gain is greatest when pharmacological medications are used alongside counselling or behavioural

treatment interventions.⁶ I would encourage GPs to adopt this approach and for the academic general practice community to rigorously evaluate their benefits at primary care level.

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Cognitive behaviour therapy and chronic fatigue syndrome

Ridsdale and colleagues¹ state that there is evidence that cognitive behaviour therapy (CBT) is effective for patients with chronic fatigue syndrome (CFS), but fail to point out that such evidence derives only from studies performed in the United Kingdom, where CFS is diagnosed on the basis of the Oxford criteria.² There is no evidence that CBT is beneficial to patients fulfilling the Australian criteria for CFS³ or the American ones, namely, the original criteria of the Centers for Disease Control.²

Patients meeting the original criteria for CFS could hardly find CBT useful because their illness, which shares 40 features with Addison's disease,^{4,5} may simply be a form of adrenal deficiency,⁴ a purely physical condition that nobody would treat with CBT. In fact, the adrenal abnormalities (hypocortisolism, impaired adrenal cortical function, reduced adrenal gland size, and antibodies against the adrenal gland)⁴ that underlie both CFS and Addison's dis-

ease⁴ cannot be corrected by psychological therapies.

Chronic fatigue and all the physical and neuropsychological symptoms listed in the original criteria for CFS are also present in Addison's disease.⁴ Considering that fatigue and those neuropsychological symptoms, but not the physical ones, are found in depression too, it is clear that the physical symptoms of CFS (enlarged lymph nodes, fever, and sore throat)^{2,4} represent essential diagnostic tools for distinguishing CFS from depression.²

Unfortunately, the Oxford criteria for CFS ignore those physical symptoms,² thereby rendering it difficult to reliably determine whether a patient's fatigue and neuropsychological complaints are due to CFS or to depression. This diagnostic difficulty has probably misled researchers to include inadvertently several depressed subjects in the groups of CFS patients who were treated with CBT in the studies performed in the United Kingdom. Given that depressed subjects are far more likely than patients with adrenal deficiency to respond to psychological treatments, it is arguable that CBT, in actuality, may have benefited depressed subjects, not patients with CFS.

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Author's response

Dr Baschetti points out that there are several different case definitions for

chronic fatigue syndrome, which make it difficult to compare the results of studies undertaken in specialist centres. In presenting our results we found that many general practitioners are unaware that specialists differentiate patients with chronic fatigue from those with chronic fatigue syndrome. From the point of view of management in primary care, GPs will need evidence before we can decide whether this is an important distinction to make. It is important to emphasise that 82% of the patients with fatigue in our general practice trial did not conform to consensus criteria for chronic fatigue syndrome.¹

Dr Baschetti seems to be concerned that GPs are failing to make physical diagnoses. In a previous cohort study,² we found that when patients presented with fatigue, GPs did diagnose the main problem as physical in 20% of cases. Common causes they attributed were anaemia, hypothyroidism, and infection.³ Fatigue may occasionally be the sole presenting symptom of other disorders, such as cancer and diabetes.³ We found that 69% of patients who presented with fatigue in general practice believe their symptoms had a physical cause² and 75% had concurrent symptoms of psychological distress.³ In this context, GPs need to take a balanced view; searching for common and uncommon conditions, exploring patient's ideas and concerns, and helping to alleviate avoidable suffering, be it physical or psychological.

To reiterate, in our previous cohort study, we found that GPs diagnosed a mainly physical cause for fatigue in 20% of patients.² We excluded patients who had a physical cause for fatigue from entry to the current trial.¹ There is evidence that fatigue may be the sole initial presenting symptom of depression, cancer, and diabetes.³ We do not know of evidence to support a hypothesis that Addison's disease is common in general practice, nor that it is commonly missed. However, there is evidence that cortisol levels do not correlate with complaints of fatigue in population-based samples.⁴

Fatigue is a symptom of depression and Tylee *et al* have shown this presentation of symptoms, together with patients' physical attributions, may be associated with GPs not recognising depression⁵ and therefore not treating it.

There is evidence from general practice that antidepressants,⁶ cognitive behavioural therapy (CBT), and counselling do help depression.⁷

We believe it is important to identify and describe the characteristics of patients which predict better response to therapy with CBT and counseling and to identify what factors in the process of therapy are associated with a better outcome. We will be reporting on this.

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Chronic fatigue in general practice

Ridsdale and colleagues¹ are to be congratulated on performing a randomised controlled trial of different treatments for chronic fatigue. However, their data do not substantiate their conclusions.

The trial was set up to demonstrate that cognitive behavioural therapy was

better than counselling for patients seen in general practice with fatigue symptoms. No difference in the main outcome measures was found between the intervention and control groups. This has been interpreted as showing that the two treatments are equivalent. The sample size required for, and analysis of, equivalence studies are different than those required for trials designed to show differences,² not least the requirement that equivalence be defined before the trial starts. This trial was not designed to show equivalence. Thus, although the results for the main outcome measures are similar they should not be reported as being equivalent. Without a definition of equivalence, calculating the study's power to show equivalence is not possible. Also, part of the conclusions depend on a sub-group analysis which, while acknowledged as being underpowered, is given more weight than is justified. If equivalence is defined as six points on the fatigue score then, in this subgroup, the trial only has a power of 36% to show equivalence based on a 95% confidence interval. With a more conservative definition of equivalence even the main study lacks power.

The evidence presented in the discussion for the effectiveness of the treatments (counselling or cognitive behavioural therapy) offered in this trial is based partially on combining data from other studies. These studies had the same entry criteria, follow-up, and outcome. As the paper points out, however, used in this context they provide historical controls and no information is given in the paper about baseline values to enable readers to evaluate this pooling. Other evidence from secondary care may not be directly relevant because of the setting and patient selection.

Thus, the evidence for effectiveness of these treatments appears suggestive rather than confirmatory and the evidence for equivalence of the treatments is even less secure.

We acknowledge the useful contribution that this study has made to the debate surrounding issues of treatment for chronic fatigue. However, we believe that a trial is still needed to show if either cognitive behavioural therapy or counselling is better than usual care for patients seen with chronic fatigue in pri-

mary care.

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Authors' response

We agree with Underwood and Eldridge that a 'no treatment' aim would have been helpful. Our original proposal was to compare cognitive behavioural therapy (CBT) with usual care. However, one of the funder's referees opposed this. They reasoned that the interventions should be comparable in terms of the extra time and attention a therapist provides. One option we considered was to ask the CBT therapists to provide some different intervention to that which they usually provide, such as relaxation. However, we reasoned that if CBT therapists do not usually practice relaxation therapy, and do not necessarily believe that relaxation is likely to be beneficial, this might have a negative effect. On these methodological grounds, we decided to find, as a comparator, an intervention which the therapist 'believed in' and which they usually provided. At the time the study started, counselling was widely practised by counsellors in primary care, but there was little evidence that it had a beneficial effect.¹

Specialists have demonstrated beneficial effects when CBT has been compared with usual care or relaxation in hospital clinics for patients who had been referred for chronic fatigue syndrome.^{2,3} We agree that evidence from secondary care may not be directly relevant for many reasons and we also agree that a larger group would be necessary to replicate these findings in patients with chronic fatigue syndrome in general practice. In this context we

believe that our findings will be helpful to investigators planning such studies.

Underwood and Eldridge are right also to say that the trial was originally planned and power calculation carried out with a view to finding a difference between the two treatments, rather than demonstrating equivalence. However, we do not accept that our conclusions should be limited to accepting or rejecting the original null hypothesis. The power calculation serves mainly to ensure that the study is large enough to provide accurate estimates of treatment effect with tight confidence intervals. It also draws attention to the primary endpoint to be used in the analysis.

Post hoc power calculations, such as Underwood and Eldridge give, are not particularly useful in interpreting results. The use of power calculations based on P-values in the planning and of confidence intervals in the analysis and reporting is recommended by the ICH 4 and by the CONSORT statement.⁵ It is scientifically correct to draw conclusions that arise naturally and unambiguously from the results, whether or not they contradict prior beliefs. It would be poor science to maintain a belief in non-equivalence that is contradicted by the main finding.

Because the Chalder fatigue scale⁶ is relatively new, there is no published definition of equivalence. The researchers in this trial include several of those involved in developing and testing the instrument. Our consensus view was that a difference of less than four, using a Likert scale, is not important. We found that the apparent advantage six months after therapy of CBT over counselling was only 1.04 points with a 95% confidence interval from -1.7 to 3.7. Arriving at this estimate was always the main aim of the trial. Jones et al⁷ (on whom Underwood and Eldridge rely) state 'If every point within this range (i.e. the confidence interval) corresponds to a difference of no clinical importance then the treatments may be considered to be equivalent.' We conclude that the treatments are clinically equivalent.

A clinician that was concerned about differences of two or three points could legitimately claim that the question is still open.

We thank them for their interest in the study and for the valid points they have made about the care that is needed

before a declaration of equivalence can be made. We agree that a trial is needed to show if either CBT or counselling is better than usual care for patients with chronic fatigue in general practice.

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Rapid referral in the electrical cardioversion of atrial fibrillation

Houghton and colleagues (September Journal)¹ examined retrospectively their hospital database of patients submitted to electrical cardioversion for atrial fibrillation and flutter. The authors identified the duration of the arrhythmia as the unique predictor of efficacy in the electrical cardioversion and in the subsequent maintenance of sinus rhythm, emphasising the importance of a rapid referral of these patients. However, in this interesting article, I felt the lack of information regarding the energy delivered in the direct current shock was regrettable.

At least two studies reported that the energy necessary to restore sinus rhythm depends on the duration of atrial

fibrillation, demonstrating that patients with arrhythmia of shorter onset seem to have lower defibrillation threshold. Initially, Dalzell and colleagues² observed that all patients with atrial fibrillation of less than 24 hours were successfully cardioverted with less than or equal to 100 J, while the success rate for shocks with less than or equal to 200 J was only 21% in the remaining cases. In a prospective study, Ricard and colleagues³ demonstrated that lower energy shocks are more likely to be effective when atrial fibrillation lasted less than 24 hours. In this trial, the overall cardioversion rate was 75% with energies less than or equal to 200 J, however, in their patients with atrial fibrillation of more than 24 hours, the overall success rate for shocks less than or equal to 200 J was only 62%.

The investigation of Houghton and colleagues¹ demonstrated the importance of a rapid referral of patients with atrial fibrillation or flutter. In my opinion, this finding should be strengthened by the probable reduction of the energy necessary to convert atrial arrhythmias.

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School students and the clinical arena

Drs Stuart and Vautrey are right to point out the potential dangers and possible inequities when school students are permitted to participate in doctor-patient contacts.^{1,2} However there are other considerations which possibly favour such arrangements. First, A-level results alone are a relatively crude indicator of potential doctoring skills and, where an interview takes place as well, the validity

and bias between medical schools is unquantified and seemingly quite variable.

Secondly, the children of medically qualified parents have considerably more first-hand experience of what it means in personal terms to be a doctor; they also have daily access to terminology, current thinking, and important trends. It seems only fair that children from non-medical families are offered similar exposure.

This would not be considered unusual in other professions or industry and, arguably, allows for a better informed and more realistic career choice. Of course stringent guidelines and genuinely informed consent must be paramount; but, given this proviso, there is perhaps a good case for offering valuable real-life experience to potential students, to their benefit and ultimately the profession.

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The general practitioner's expectations of a general physician/rheumatologist

There is an undiscussed matter that may put patients, general practitioners, and consultants at risk, namely that general physicians with a specialist interest carry different models and standards of examination to different clinics. General training emphasises complete examination of all patients. Physicians use professional judgement and may limit examinations in high volume specialist clinics — in my case rheumatology.

The patient who brought this hazard to my attention was a 13-year-old boy with minor musculoskeletal pain. I saw him and recommended appropriate treatment — it later transpired that he was hypertensive and had coarctation of the aorta. I (a general physician) had seen him and not taken his blood pressure — an omission unlikely to be regarded sympathetically by my col-

leagues — but I suspect not uncommon in high volume clinics that deal with minor musculoskeletal problems in otherwise healthy young people.

On reflection I felt that referring GPs needed to know which elements of the full examination had been omitted before counselling or reassuring patients. Nineteen GPs and I attempted to clarify local understanding by sharing histories of patients with the following typical diagnoses:

1. tenosynovitis; 2. adhesive capsulitis; 3. back pain; 4. seropositive rheumatoid arthritis; and 5. fibromyalgia. The GPs indicated which examinations they believed essential in the clinic.

In case 1, 16 out of 19 GPs did not expect a general examination in a patient with tenosynovitis, for case 2, eight out of 19 expected chest auscultation. In case 3, 13 out of 19 expected abdominal examination. In cases 4 and 5 there was a majority expectation of abdominal and chest examination. General practitioners expected routine urine tests (16 out of 19), blood pressure (13 out of 19), and weight measurement (17 out of 19) for all patients.

I agreed with the majority opinions. A consensus may still be incorrect, but this understanding simplified subsequent clinic management and all patients thereafter had routine blood pressure, urine, and weight examinations.

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Acknowledgement

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What can general practice learn from complementary medicine?

Dr Philip White pointed out why patients choose complementary therapies in his paper.¹ We wholly agree that it is important for general practitioners to communicate with users of complementary medicine. In Japan, complementary medicine is also popular, and recently it has become an important issue for GPs. We especially agree with him that users of complementary medicine have a greater

sense of self-control. On the other hand, it is important to note that the use of complementary medicine is not always because of dissatisfaction with conventional medicine.²

We performed qualitative research on the reasons for the use of complementary medicine in Japan by interviewing 26 patients with common diseases in a primary care setting in February 2000 using a semi-structured one-to-one interview. We asked about the experience of use, types, and reason for use of complementary medicine and used a grounded theory approach. Some patients mentioned that 'self-control is an important reason for use', similar to the opinion stated by Dr. White.¹ However, it is also of interest that patients emphasised that they had chosen to use complementary medicine, because of 'deficiencies' but also because of the 'different' approach to the care provided by their GPs. Thus, we consider that such patients use complementary medicine in different ways depending on their own purpose. They distinguish between conventional medicine and complementary medicine according to their own purpose, health condition, and circumstances. We feel that this is a consideration for GPs and that further study is needed.

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1. White P. What can general practice learn from complementary medicine. *Br J Gen Pract* 2000; **50**: 821-823.
2. Astin JA. Why patients use alternative medicine. *JAMA* 1998; **280**: 1548-1553.

Correction

In the paper entitled 'General practitioners' and practice nurses' knowledge of how much patients should and do drink' by Philip Webster-Harrison, Andrew Barton, Sheila Barton, and Susan Anderson (*March Journal*, page 218), the figure given for the volume of a bottle of wine in Table 1 is incorrect. The correct volume of a bottle of wine is 75 cl, not 70 cl. We apologise for any confusion this may have caused.