

often offered to patients as an alternative to drug therapies, and the absence of risk related to adverse drug effects can offset the potential for lesser efficacy. In our trial, both treatment groups had marked improvement from baseline. In this regard, placebo is not 'no treatment'.

Drs Campbell and Jainer suggest drawing conclusions about drug efficacy based solely on comparisons of active agents. Unfortunately, in many trials a drug previously shown to be active is not superior to placebo despite adequate powering and the use of standard trial designs. Such trials are often referred to as 'failed' and in anxiety and depression are extremely common. A comparison of a new agent against a drug previously shown to be active without a placebo comparator is uninterpretable unless one agent is superior to the other. Concluding that a drug is efficacious without a placebo comparison can lead to an incorrect assumption of drug-specific effects if neither the investigational drug nor the active drug was, in that trial, any better than placebo would have been if included. Introducing a drug into therapeutic use on the basis of such a trial would expose patients to a compound with no greater benefit than placebo but all the risks of a pharmacological intervention (Temple & Ellenberg, 2000). Placebo is also critical in the assessment of safety, as it provides a base rate for determining which adverse events are truly related to the investigational drug. For these reasons, placebo-controlled trials are almost universally demanded by regulatory bodies to demonstrate efficacy for new pharmacological interventions.

Drs Campbell and Jainer also assert 'no new treatments should be introduced into medicine unless they have been shown . . . to be superior to existing treatments . . . [or] cheaper and safer'. This absolute statement reflects several misconceptions and confounds the investigation of a drug with its introduction into general use. There is no general agreement about how to define or demonstrate equivalent or relative efficacy – precisely the reasons why most regulatory bodies will not consider relative efficacy claims in labelling. Furthermore, clinical trials provide information about group responses. Individual patients may not respond to or tolerate a particular drug, yet benefit from a different drug that is not, on average, more efficacious or safer than the first agent – it is in patients' interest to have several choices. For example, using Campbell and Jainer's procedure,

the selective serotonin reuptake inhibitors, now proven to be safer and better tolerated than tricyclic antidepressants, might well not have been introduced into practice.

Finally, price is not an issue of trial design or science, but determined by the value that patients and purchasers put on a drug, based on evidence about the drug and experience with it (effectiveness as well as efficacy). Whether new drugs for panic or other psychiatric disorders should be 'introduced into medicine' and how they should be priced are decisions made on the basis of assessments of data about safety, efficacy and potential place in the therapeutic armamentarium – decisions that cannot be made before the data are collected. Campbell and Jainer may feel that the results of this trial do not warrant further investigation of the use of fluoxetine for panic disorder, although we would disagree. It is, however, wrong to suggest that the trial as designed should not have been performed or published.

Declaration of interest

D.M. is an employee of Eli Lilly and Co.

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D. Michelson Lilly Research Laboratories, Indianapolis, IN 46285, USA

User-led research and evidence in psychiatry

The editorial by Faulkner & Thomas (2002) raises serious issues, as did another recent paper (Bracken & Thomas, 2001; see van Beinum, 2001). They present a false dichotomy between (morally good) 'users' and (morally irresponsible) researchers, from which flows an unwarranted assumption that somehow psychiatric research rarely has the interests of patients at heart. Their editorial, with its unsubstantiated statements, poor definitions, political banner-waving and lack of understanding of both science and the research process, is the antithesis of considered and evidence-based argument.

There is, however, no doubt that patients and their families should have a substantial voice in helping to set the questions that research attempts to answer, and in

establishing mechanisms for ensuring the importance of this process. This does not mean, however, that being a 'user' somehow qualifies a person as a top-notch research scientist. Thus, for example, the user-led research quoted by the authors (Faulkner, 2000) was deeply flawed, in that it did not address the issue of researcher bias and some of the conclusions bore no relation to the evidence presented. User groups have their own political agendas and are not representative of the body of patients as a whole.

There is a difference between asking socially relevant questions and conducting sound research. Good research is difficult to do and is best done by teams of well-trained research scientists. Arguing, as Faulkner and Thomas do, that psychiatrists and funding bodies should give equal weight to research conducted by groups of users and by professional researchers is a travesty. We do patients (and ourselves, for many of us have been, or will become, users) no favours by confounding good research with political correctness, for there is nothing more unethical or wasteful than poor research on vulnerable patients.

van Beinum, M. (2001) Psychiatrists need different training for 21st century (letter). *BMJ*, **323**, 452.

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Faulkner, A. (2000) *Strategies for Living: A Report of User-Led Research into People's Strategies for Living with Mental Distress*. London: Mental Health Foundation.

___ & Thomas, P. (2002) User-led research and evidence-based medicine. *British Journal of Psychiatry*, **180**, 1–3.

M. van Beinum MRC Social and Public Health Sciences Unit, University of Glasgow, 4 Lilybank Gardens, Glasgow G12 8RZ, UK

Authors' reply: We are grateful to Dr van Beinum for drawing our attention to the weaknesses of our editorial. In particular, it is good that he has highlighted the issues of researcher bias and the reprehensible wastefulness of 'poor research on vulnerable patients'. Presumably, he assumes that professional research, undertaken by 'teams of well-trained research scientists', is of high quality and free of bias. Is this so? Let us consider by way of example the drug treatment of schizophrenia. Thornley & Adams (1998) examined the quality of 2000 controlled trials for treatment for schizophrenia from the Cochrane Schizophrenia Group's register. They concluded