

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.

Temple, R. & Ellenberg, S. (2000) Placebo-controlled trials and active control trials in the evaluation of new treatments: part I: ethical and scientific issues. *Annals of Internal Medicine*, **133**, 455–463.

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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.

Bracken, P. & Thomas, P. (2001) Postpsychiatry; a new direction for mental health. *BMJ*, **322**, 724–727.

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.

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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

that half a century of studies of limited quality, duration and clinical utility left much scope for well-planned, conducted and reported trials. The consistently poor quality of reporting is likely to have resulted in an overoptimistic estimation of the effects of drug treatments for the condition. So much for good-quality research in the professional evidence base. What about bias?

The editors of our leading medical journals are clearly concerned about bias in research, particularly that which originates in conflicts of financial interest. Stelfox *et al* (1998) studied papers published in the *New England Journal of Medicine* on the use of calcium-channel antagonists in the treatment of cardiovascular disorders. They found that 96% of the authors of positive studies have received financial support from drug companies, compared with 37% of authors of negative studies. In a recent editorial in the *New England Journal of Medicine*, Marcia Angell (2000: p. 1516) has described the intertwining of academic medicine and the pharmaceutical industry in America, which extends far beyond grant support for research to include:

... a host of other financial arrangements. Researchers serve as consultants to companies whose products they are studying, join advisory boards and speakers' bureaus, enter into patent and royalty arrangements, agree to be the listed authors of articles ghostwritten by interested companies, promote drugs and devices at company-sponsored symposiums, and allow themselves to be plied with expensive gifts and trips to luxurious settings. Many also have equity interest in the companies.'

She argues that these links are less to do with the transfer of technology across from academia to industry, than they are to do with marketing and profit. This influence also extends to guidelines on clinical practice. In a recent survey (Choudhry *et al*, 2002), 87% of 200 authors of clinical guidelines had financial links with at least one drug company, including companies whose products they endorsed. Over half of the authors had been paid to conduct research.

Of course user-led research is biased, but so is most research. Some psychiatric research is of high quality and undertaken out of the highest ideals. Equally, much of it has a murky, less idealistic pedigree, driven by commercial interest. User groups certainly have their own 'political agendas', but to pretend that psychiatry does not is either extremely naïve or dishonest. It is

time for us to reflect on the need for a little honesty and humility, and for us to acknowledge that there are serious doubts about the independence and integrity of much of what we, as psychiatrists, consider to be 'evidence'. To begin with, we need a debate about the influence that the drug companies have on our academic institutions, at our conferences, in our journals and in our consulting rooms.

Angell, M. (2000) Is academic medicine for sale? *New England Journal of Medicine*, **342**, 1516–1518.

Choudhry, N., Stelfox, H. & Detsky, A. (2002) Relationships between authors of clinical practice guidelines and the pharmaceutical industry. *JAMA*, **287**, 612–617.

Stelfox, H., Chua, G., O'Rourke, K., et al (1998) Conflict of interest in the debate over calcium channel antagonists. *New England Journal of Medicine*, **338**, 101–105.

Thornley, B. & Adams, C. (1998) Content and quality of 2000 controlled trials in schizophrenia over 50 years. *BMJ*, **317**, 1181–1184.

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Perceived failure of community care

In his editorial on care in the community, Julian Leff (2001) describes processes comparable with those in The Netherlands, resulting in a call for 'increasing restrictive mental health legislation enacted by governments pandering to public misperceptions'. This may be an indication that this process is more universal and not restricted to the situation in the UK. A few points may lead to more 'perceived failure' if not addressed.

Dr Leff states that 'there is substantial evidence of considerable success ... of the 130 psychiatric hospitals ... in 1975, only 14 remain open, with fewer than 200 patients in each'. Does this imply that it would have been a failure if it were 25 hospitals with 300 patients each? Closing hospitals should not be a goal as such, but a means to provide better services to patients. That a new generation of psychiatrists 'not only have never worked in a psychiatric hospital but have never seen one!' may not be such a desired development. In the coming decades in-patient facilities will still be needed and the number of them

may fluctuate because of new treatment modalities and the capacity of society to harbour patients. An increase or decrease should not be an indicator of success or failure at all.

The 'invisibility of a community service' as grounds for 'perceived failure' is interesting in relation to the statement that 'the architectural presence of the asylums has been replaced by an apparent absence'. Were many asylums not tucked away at the outskirts of the city, if not further away? Mental health care should make itself, and its diversity of services, more visible. Could it be that professionals, patients and relatives have a somewhat defensive stance regarding the public and the media? In The Hague after the merger in 1999 of all psychiatric hospitals, community mental health organisations and addiction organisations, posters were put on trams and bus stops leading to a high visibility, which was well perceived.

Would 'a comprehensive community psychiatric service catering to all the needs of the catchment area population' enhance the perception of success? In The Netherlands in recent years this development has started in some areas owing to large-scale mergers of mental health organisations. This has led to a disappearance of administrative and financial boundaries between in-, out- and day-care patient services. In The Hague there are indications that the needs of patients, family, general practitioners and police are better identified and addressed, leading to a visible profile and higher perceived success.

If we want to know what our targets are in 'a public relations job of this kind', we are at the brink of a more fundamental shift of defining and positioning the concept of (community) mental health. Who can identify him or herself with a psychiatric patient? Are there not fundamental differences between a patient with schizophrenia, agoraphobia or bipolar disorder? In The Netherlands generalisation and stereotyping lead to the situation that the acts of one person with an addiction and personality disorder may damage the positive image of mental health in general for a certain period.

Community-oriented care is a success for a subgroup of patients with psychiatric disorders. Perceived failure in one area should not lead to a situation that the whole of mental health services, including care in the community, is perceived as a failure.