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From the Editor's desk

By Peter Tyrer

Deconstructing bias in clinical trials

'The way medical journals publish the results of clinical trials has become a serious threat to public health'.[1] With this arresting sentence Richard Smith, former editor of the *BMJ*, began an article published 4 years ago. Why did Richard get so aerated? Well, let him explain. 'Although most editors would like to meet expectant researchers shortly after a clinical trial's conception (or even before), to find out who the parents are and to ensure that the trial receives high-quality antenatal care, more often than not labouring researchers arrive at their offices heavily pregnant with results that require immediate, fast-track delivery. Some trials are deposited on the editor's doorstep, so that it is hard to tell who the parents are'.[1] So Richard is asking the awkward question: 'do authors manipulate editors in order to get trials published in journals?' Unfortunately I think he is right. Medical editors are certainly midwives in this conspiracy, for we all reject papers that do not follow the rules for publication of trials, so isn't it to be expected that authors will fillet, finesse and finagle their papers to fit a journal's requirements and preferably produce positive results? Like most editors I like to feel I am publishing giant strides in science rather than shuffling backwards and forwards in centimetres, so I connive quietly in this deception. We publish two randomised trials (Kellner *et al*, pp. 226–234; Yip *et al*, pp. 241–242) and one systematic review in this issue and another paper that shows the importance of attention to methodology in clinical trials (Bethell *et al*, pp. 243–244). Cuijpers *et al* (pp. 173–178) do a valuable service in pointing out that publication bias is not restricted to drug trials supported by the pharmaceutical industry; psychological treatments suffer in the same way and, if their findings with cognitive–behavioural therapy in depression were replicated with other disorders, the effect size of this treatment would be reduced by 30% compared with equivalent controls. The defence that failure to find benefit may be a consequence of poor therapeutic competence[2] may be valid but such trials still need to be published. Seeing the review by Cuijpers *et al* had me rushing back to recent issues to see to what extent we could be castigated for publication bias. I was convinced our high-standing journal must have learnt something from Richard Smith's admonishments – sadly I was wrong. In 2009 we published five randomised controlled trials of psychological treatments; four reported clearly positive results[3–6] with only one being unequivocally negative.[7] The valuable editorial by Scott (pp. 171–172) shows that much can still be learnt from trials with equivocal results and I hope that solid honest studies illustrated by the careful diligence of Kellner *et al* will still find a place between these covers.

We also must not feel that randomised trials should be automatically at the top of our publishing agenda. We still need reminding of this[8] and Rawlins has recently reinforced it in a magisterial account of different forms of scientific evidence.[9] The notion of randomised controlled trials as the gold standard of evidence of efficacy should be revised. The standard is only silver or bronze; in the High School of Evidence the randomised controlled trial is at the top of class B but no one has yet passed the examination allowing access to class A. So when you read the results of randomised trials in the *British Journal of Psychiatry* look at them carefully and be prepared to cavil as much as to marvel, to read reviews and commentaries[10] that put them into perspective, and spare a tear for the many manuscripts that gather dust on shelves forlornly waiting for a call to see their negative findings.

A global tribute

Mental health initiatives rarely get the same accolades as those in other parts of medicine, so they are worth celebrating when they arrive, especially when they concern the plight of the forgotten needy in so many countries of the world. The Health Service and Population Research Group, led by Professor Graham Thornicroft at King's College London, has been recognised with a Queen's Anniversary Award, the first to be given in mental health, for 'its commitment to enabling the recovery and improving the quality of life of people with mental health problems throughout the world'. We report often on the mental ill-effects of neglect, abuse and deprivation; indeed we do so in this issue (Oladeji *et al*, pp. 186–191; Nayak *et al*, pp. 192–199), and collectively this evidence is a call for action to correct preventable disease. Thornicroft has identified one of the main reasons for inaction in one word, 'shunned',[11] and his group are being rightly acknowledged for their courage in taking this task on. It may even call for a small piece of doggerel:

Most fights for global mental health come face to face with stigma
Mincing in the shadowlands with its friend discrimination
How to defeat this enemy is proving an enigma
It needs research commitment with a steer from education
A doughty warrior leads the way whose hand I hold aloft
As we celebrate the force led by Graham Thornicroft.

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7 de Graaf LE, Gerhards SAH, Arntz A, Riper H, Metsemakers JFM, Evers SMAA, et al. Clinical effectiveness of online computerised cognitive–behavioural therapy without support for depression in primary care: randomised trial. *Br J Psychiatry* 2009; **195**: 73–80.

8 Slade M, Priebe S. Are randomised controlled trials the only gold that glitters? *Br J Psychiatry* 2001; **179**: 286–7.

9 Rawlins M. De Testimonio: on the evidence for decisions about the use of therapeutic interventions. *Clin Med* 2008; **8**: 579–88.

10 Parker G. Antidepressants on trial: how valid is the evidence? *Br J Psychiatry* 2009; **194**: 1–3.

11 Thornicroft G. *Shunned: Discrimination against People with Mental Illness.* Oxford University Press, 2006.