the relative risks. Mitchell may have misunderstood one aspect of our model by suggesting it estimates the excess of non-fatal suicidal acts. We derived our estimates from prescribing data, the suicide rate among patients receiving antidepressants in primary care,[1] and we assumed (see above) that the relative risk of non-fatal suicidal behaviour in paediatric trials of selective serotonin reuptake inhibitors (SSRIs) is similar for suicide and all ages. If we had wished to estimate effects on non-fatal self-harm we would have used the rate among people receiving antidepressants rather than the suicide rate; as rates of non-fatal self harm are over 20 times higher than those for suicide this would result in a higher estimate.

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Competing interests: DG and DA are members of the Medical and Healthcare Products Regulatory Agency's expert working group on the safety of SSRIs, and DA is a member of the Committee on Safety of Medicines. Both act as independent advisers, receiving travel expenses and a small fee for attending meetings and reading materials in preparation for the meeting. DA has spoken on the methods of adverse drugs reactions in HIV at a scientific meeting attended by several pharmaceutical companies, and sponsored by GlaxoSmithKline. An honorarium was paid to her department.

1 Jick HSS, Dean AD, Jick H. Antidepressants and suicide. *BMJ* 1995;310:215-8.

BMJ statistical errors

Editor—Abbasi in his Editor's choice discusses a study that found statistical errors in 25% of papers published by the *BMJ* in 2001.[1] As statistical advisers to the *BMJ* we aim to improve the quality of published papers by ensuring that their conclusions are consistent with the data. To this end we hope to identify important errors that affect the interpretation of the findings, but care less about more minor errors. Any stricter policy would be impossibly time consuming. That said, we recognise that important errors do slip through from time to time, and are always keen to improve our performance.

The particular errors flagged in the paper[2] were inconsistencies between test statistics and P values. Out of 63 tests seven (11%) were wrong (for example χ^2 on 1 df = 4.2, P reported = 0.024, P actual = 0.0404). Yet in no case did the error affect the test's interpretation as to whether or not the results could have arisen by chance. This supports our belief that more extreme errors are likely to be weeded out at the review stage. The paper is disappointing in focusing on P values and by implication hypothesis testing. By contrast the *BMJ*'s policy is to present the main findings as confidence intervals where the emphasis is on estimation.[3]

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Competing interests: All authors take responsibility for the statistical quality of papers published in the *BMJ* to the extent that the study design, data, and analysis appear appropriate and internally consistent, and that they support the conclusions drawn.

1 Editor's Choice. Do mistakes matter? *BMJ* 2004;328:0. (12 June.)
2 Garcia-Berthou E, Alcaraz C. Incongruence between test statistics and P values in medical papers. *BMC Med Res Methodol* 2004;4:13.
3 Gardner MJ, Altman DG. Confidence intervals rather than P values—estimation rather than hypothesis testing. *BMJ* 1986;292:746-50.

Government regulation is needed to prevent biased under-reporting of clinical trials

Editor—In 1996, Schering Healthcare published details of its ongoing randomised clinical trials in the *Cochrane Library*. The chief executive told me that he was doing this because industry's failure to disclose the results of its phase 3 trials could not be defended ethically or scientifically. Two years later, the chief executive of GlaxoWellcome announced his company's decision to register and seek to report all its randomised clinical trials.[1] A few years after that, the Association of the British Pharmaceutical Industry commended GlaxoWellcome's policies to its other member companies.

After GlaxoWellcome had become part of GlaxoSmithKline (GSK), I wrote to the chief executive of the new company, urging him to support the efforts of those within industry who were attempting to promulgate guidelines for good publication practice (www.gpp-guidelines.org). I received no acknowledgement, and, soon after, his company sacked one of the leaders of the initiative and closed the department she headed.

In response to accusations of biased under-reporting of research, GSK has now announced that it intends to institute policies announced seven years ago by GlaxoWellcome.[2] It would be churlish not to welcome this. But the past record of the pharmaceutical industry, and the reactions of some other companies to GSK's announcement, prompt deep scepticism that the industry will ever voluntarily implement ethical trial registration and publication policies.

Biased under-reporting of clinical trials kills patients and wastes money, and government regulation is needed to put a stop to it.[3]

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Competing interests: None declared.

1 Sykes R. Being a modern pharmaceutical company. *BMJ* 1998;317:1172-80.
2 Gibson L. GlaxoSmithKline to publish clinical trials after US lawsuit. *BMJ* 2004;328:1513.
3 Chalmers I. In the dark. *New Scientist* 2004 March 6:9.

Access to every trial dataset is crucial

Editor—Herxheimer's pleas for access to industry's trial data[1] reminded me that I wrote to the Department of Health two or three years ago, "demanding" that all clinical trials be published either in a journal or on a company website within two years of completion. I had a less than satisfactory response which boiled down to "we can't do anything about it."

As a urologist interested in functional lower urinary tract problems (overactive bladder and possible prostatic obstruction) I have worked with many companies' "competing interests declared." In the light of this experience I approached the argument from a different perspective, that of the patients' altruism in taking part in any trial. English patients are often very committed to helping the advancement of knowledge by taking part in clinical trials and will often say "Yes, if it will help others I would like to take part." I made additional efforts to involve the Patients Association, a journal of medical ethics, and a body overseeing ethics committees in the United Kingdom, but didn't make progress.

I believe the way forward is for ethics committees to stipulate that companies must agree to publish results of any trial for which ethical approval is given. Further, ethics committees could register all trials in a single register administered by a government body, perhaps the National Institute for Clinical Excellence (NICE).

Research is important and, as Herxheimer says, it is crucial that we all have access to every trial dataset in a form that is useful, such as advised by CONSORT.

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Competing interests: None declared.

1 Herxheimer A. Open access to industry's clinically relevant data. *BMJ* 2004;329:64-5. (10 July.)