

patient. Surely this is an argument not for compliance but for concordance.

Thirdly, they remind us that threats to the public health (posed, in their example, by non-compliant patients with open pulmonary tuberculosis) demand nothing less than strict compliance with drug treatment, in the public interest. There are similar examples from forensic mental health. Nothing in the concept of concordance asserts the necessary primacy of individual autonomy over the needs of society.

In setting out our agenda of research, training, and public awareness, our working party was only too aware that we were not providing definitive answers to the problems caused by non-compliance in medicine taking. Rather, we wished to suggest a more productive way of asking the questions

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- 1 Bamforth I. Compliance and concordance with treatment. *BMJ* 1997;314:1905-6. (28 June.)
- 2 Marinker M. Writing prescriptions is easy. *BMJ* 1997;314:747-8.
- 3 Royal Pharmaceutical Society of Great Britain. *From compliance to concordance: towards shared goals in medicine taking* London: RPSGB, 1997.
- 4 Milburn HJ, Cochrane GM. Compliance and concordance with treatment. *BMJ* 1997;314:1906. (28 June.)

## Assessing methodological quality of published papers

### Pre-allocation bias in randomised controlled trials must be taken into account

EDITOR—In her article on assessing the methodological quality of published papers, Greenhalgh does not draw sufficient attention to one of the main sources of bias found in randomised controlled trials.<sup>1</sup> This can occur before the allocation procedure itself and is, therefore, easy to miss.

Recruitment to the trial usually requires that subjects accept the offer of either of two forms of treatment. In many cases, one of the treatments may be so strongly preferred to the other on a priori grounds that the offer is rejected at this stage. Since the patients' attitudes, beliefs, and expectations may affect their response to and compliance with treatment procedures, this issue has considerable importance for research into the effectiveness of treatment.

Providing full data on how many people were initially approached to generate the trial sample is a necessary requirement for any research trial, but these data are often not given. Where refusal rates are relatively high it becomes imperative to re-examine the characteristics of subjects entering the trial to ensure that these are comparable with those of the intended target group. For some of the more overt characteristics (such as age, sex, and severity of symptoms) this may be relatively straightforward. Where the factors influencing entry to the trial are covert (such as expectations about treatment) or unknown (which is often the case) the detection of this sort of pre-selection bias and the

assessment of representativeness is often complex and extremely problematic.

Randomised controlled trials are correctly seen as potentially one of the most powerful tools in research into treatment, and results from trials claiming to be randomised controlled trials are often given greater weight than those from other research designs. It is doubly important, therefore, that researchers and readers of published papers be alert to the pitfalls that may compromise the validity of results from such research trials. It is always worth asking who is being randomised as well as what is being controlled for.

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- 1 Greenhalgh T. Assessing the methodological quality of published papers. *BMJ* 1997;315:305-8. (2 August.)

### Did study require subjects to change sex?

EDITOR—In one of her articles on how to read a paper Greenhalgh quotes as an example of problematic description: "We approached 147 white American teenagers aged 12-18 (85 males) at a summer camp; 100 of them (31 males) agreed to participate."<sup>1</sup> She notes a recruitment bias towards females. This is an understatement: her figures indicate that the researchers were so biased towards females that seven unfortunate males were forced to change sex.

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- 1 Greenhalgh T. Assessing the methodological quality of published papers. *BMJ* 1997;315:305-8. (2 August.)

## Home Office addicts index no longer exists

EDITOR—In their article on use of illicit drugs Gerada and Ashworth state that the chief medical officer maintains, at the Home Office, an index of addicts to help doctors in the clinical management of drug misusers and to provide epidemiological information on trends in drug misuse.<sup>1</sup> This index was closed on 1 May 1997. All doctors in England are now expected to continue to report treatment demands of drug misusers by returning reporting forms to their local drug misuse database, which provide anonymised data to the appropriate regional database. Information is not limited to opiate and cocaine misuse but includes any misused drug that generates demand for treatment.

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- 1 Gerada C, Ashworth M. ABC of mental health: addiction and dependence—I: illicit drugs. *BMJ* 1997;315:297-300. (2 August.)

## *Clostridium botulinum* was named because of association with "sausage poisoning"

EDITOR—I wish to add some mustard to Aronson's recent diet of sausages<sup>1</sup> by suggesting that the bacterium *Clostridium botulinum* is indeed so called because of its pathological association with the delicatessen in question and not (as Aronson says) because of its shape. In 1793, 13 people in Wildbad, Germany, became ill after sharing a large sausage; six of them died.<sup>2</sup> Not long after this, Justinus Kerner, a district health officer in southern Germany, recognised the connection between sausage and a paralytic illness affecting 230 patients. He made "sausage poisoning," or botulism as it came to be known, a notifiable disease.<sup>3</sup> It wasn't until 1897 that van Ermengen published the first description of the causative organism and showed the production of a toxin (later identified as type B) that induced weakness in animals.<sup>4</sup> As far as I know, this account is accurate and free of boloney.

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- 1 Aronson J. When I use a word ... sausages. *BMJ* 1997; 315:599. (6 September.)
- 2 Mims CA. *The pathogenesis of infectious disease*. London: Academic Press, 1987.
- 3 Mandell GL, Bennett JE, Dolin R, eds. *Principles and practice of infectious diseases*. New York: Churchill Livingstone, 1995.
- 4 Van Ermengen E. Ueber einen neuen anaeroben Bacillus und seine Beziehungen zum Botulismus. *Z Hyg Infekt* 1897;26:1-56.

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