

obesity represents one of the worst risks for an anaesthetist and also complicates the whole obstetric episode. Its incidence is rising for various reasons, and the problem is not being addressed. Anaesthetists can improve their practice, as recommended in the report, but cannot alone counter the consequences of patients' self abuse.

The health education message should not be blurred and needs to be directed in particular at younger patients, such as those in the obstetric population. The findings of the report represent an opportunity to promote the present benefits of weight reduction that should not be missed.

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- 1 Garrow JS, Wooley SC, Garner DM. Should obesity be treated? [With commentary by P C Rubin.] *BMJ* 1994;309:654-6. (10 September.)
- 2 Department of Health. *Report of confidential enquiries into maternal deaths in the United Kingdom 1988-1990*. London: HMSO, 1994.

### Those who consult should be treated

EDITOR,—It is not helpful for Peter C Rubin to tell us that when a doctor is confronted with an obese patient who is happy with his or her obesity and has no cardiovascular risk factors "it is probably best to leave well alone."<sup>1</sup> Such a situation occurs rarely, since such people have no incentive to seek medical advice. The real issue, which affects more than a million people in Britain, is how to deal with a young adult who is obese (body mass index (kg/m<sup>2</sup>) > 30); is not happy about it; and has (or will shortly develop) shortness of breath, raised blood pressure, impaired glucose tolerance, or osteoarthritis in weightbearing joints. If Rubin offers no help the patient will go elsewhere and be lost to follow up, so Rubin will have no reason to doubt that it is probably best to leave well alone.

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- 1 Garrow JS, Wooley SC, Garner DM. Should obesity be treated? [With commentary by P C Rubin.] *BMJ* 1994;309:654-6. (10 September.)

### Interpreting results of observational research

#### Tools may be blamed for shortcomings of workers

EDITOR,—Most statisticians will understand Paul Brennan and Peter Croft's concern over the use of P values and confidence intervals in observational studies.<sup>1</sup> The authors' remarks are aimed, however, specifically at studies in which researchers are interested in "a presumed cause or treatment." This is by no means all studies. Many case-control and cohort studies include variables likely to be associated with several potential causes not explicitly stated, the intention being to exploit confounding to narrow down the range of factors that must be examined. A significant P value or range of odds ratios not including unity is then a useful indication that factors associated with the variable are worth investigating. Common examples of such variables are place of residence, social class, and age.

Even in clinical trials we are often not interested in causality in quite the sense that the authors seem to be using it. For instance, to modify one of their examples, a clinical trial in which the treatment consisted of limiting access to oral contraceptives

might find a reduction in cervical cancer purely due to increased use of condoms protecting the treatment group from sexually transmitted diseases. This is undoubtedly bias due to lack of blinding. The effect measured, however, is real and potentially clinically applicable, and hence knowledge of the confidence interval is useful.

In damning P values and confidence intervals the authors may to some extent be blaming the tools for the shortcomings of the workers. The way in which these concepts are used in randomised trials is quite different from that in observational studies, and we should make this clear; perhaps we should even use different notation in the two cases. A clinical trial attempts to assess the potential for modification of an outcome through modification of a risk factor (treatment) while an observational study is an attempt to measure an association (whether or not it is confounded). Perhaps we should replace P values with P<sub>m</sub> values (modifiability) and P<sub>a</sub> values (indicating association alone).

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- 1 Brennan P, Croft P. Interpreting the results of observational research: chance is not such a fine thing. *BMJ* 1994;309:727-30. (17 September.)

#### Requires more, not less, statistical analysis

EDITOR,—In their paper on the validity of observational studies Paul Brennan and Peter Croft highlight the fact that confounding may give rise to misleading conclusions.<sup>1</sup> The conclusion from their analysis, however, is surely that more, not less, statistical analysis is required and that it should be more explicit.

Firstly, it is worth clarifying what a randomised controlled trial does and does not do. In particular, it does not "ensure that the allocation of treatment is independent of other exposures which may affect outcome."<sup>1</sup> Matching can ensure this with certain selected variables, but in general randomisation alone cannot. It may be that a drug works only in those wearing blue socks and that by chance alone more of those taking the drug than taking the placebo wore blue socks. As Fisher pointed out, the important thing is that such allocation is as likely by chance to be one way round as another and that, given a large number of small such effects, they will tend to cancel one another.<sup>2</sup> Nevertheless such potential confounders, of which there is an infinite number, will still be present, and this probably results in the variability found in all trials. If, say, only people of genotype X respond to a drug then without genotyping it is impossible to ensure precise matching; any genetic locus might act in this way. All one can say is that on average it is unlikely.

Observational studies have these problems plus the additional one that natural variation in a measure such as smoking, in contrast to variation controlled by the experiments, may be confounded by a host of other unmeasured measures, any of which may explain the difference found. The problem of using significance tests is that they are shorthand for a more complex turn of phrase. Significance ultimately means something to the effect of, "having fitted a particular model, which includes several explicit variables that I have estimated from the data, and taking into account the inherent variability within and between subjects and the association between variables, I believe that the non-zero estimate of this particular variable which differs between groups is unlikely to result from chance allocation alone." In a more complex model—and there must be an infinite number of more complex models—the estimate of the variable may become compatible with chance

allocation (that is, non-significant). But in that case another variable, the confounder, will have entered the model. If the confounder makes biological sense (for example, genotype and not sock colour) we will prefer to treat it as a prior cause and to use it instead as an explanation for the effects found.

The solution to the problem of observational studies is to be more explicit in our statement of the implicit models we are using so that the assumptions become apparent. That also has the advantage that the onus is placed on critics to propose effective confounders rather than merely to roll their eyes and complain about the infinite possibilities and say that nothing can ever be proved. That is not a scientific position, unlike explicitly stating one's model and its assumptions, which allows testable, and hence falsifiable, hypotheses.

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- 1 Brennan P, Croft P. Interpreting the results of observational research: chance is not such a fine thing. *BMJ* 1994;309:727-30. (17 September.)
- 2 Fisher RA. *The design of experiments*. 8th ed. New York: Hafner, 1971:41-4.

### Implications of supervision registers in psychiatry

#### Being on the register will not remove the risk

EDITOR,—Glynn Harrison and Peter Bartlett's editorial draws attention to several ambiguities surrounding the introduction of supervision registers,<sup>1</sup> and the response elicited from the Department of Health's mental health policy unit provides welcome clarification.<sup>2</sup> Neither of these, however, helps us to gain an understanding of the practical importance of supervision. Clearly, this understanding will differ in important respects among clinicians, patients and their advocates, and the general public.

Clinicians may find reassurance in the statement that "the decision on whether a patient should be placed on or taken off the register must always be a clinical one."<sup>2</sup> This is because clinical decisions are based on available evidence evaluated in the light of experience and current clinical opinion: they acknowledge the possibility of error in each.

The public perception is likely to be different. As with registers of children at risk of non-accidental injury, members of the public will assume that placing mentally ill people on a supervision register removes the risk that they pose to themselves or others. This perception does not admit the possibility of either clinical or statistical error. It is hard to escape the conclusion that this is also the expectation of the Department of Health, and anxiety persists that the courts will take a similar view.<sup>1</sup>

The practical implications of attempting to fulfil these expectations are immense.<sup>3</sup> Supervision registers will include many patients who are reluctant to receive any input from mental health services or to comply with drug treatment. Some, indeed, will make every effort to evade supervision. To have any chance of success mental health services will need to operate a supervision system rivalling or exceeding any powers that the police may use to monitor persistent offenders.

If such a course is embarked on without the prior authority of the courts some predictable effects will result. For instance, while the public good may be served by the diminution in risk resulting from supervision, individual patients and their legal advisers will argue that the patients' civil