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."¹ 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^2) > 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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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.¹ 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_m values (modifiability) and P_a 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.¹ 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."¹ 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.² 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.)

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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,¹ and the response elicited from the Department of Health's mental health policy unit provides welcome clarification.² 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."² 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.¹

The practical implications of attempting to fulfil these expectations are immense.³ 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

liberties are being infringed, both by their being placed on a register and by their being subjected to the close surveillance that this entails. Costly judicial review will follow,¹ the beneficial outcome of which may be that a legal framework for supervision is derived ultimately from case law. In the meantime, others who seek the aid of mental health services may find themselves disadvantaged by the shift of resources necessary to service the registers.

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Most patients in Bow and Poplar would be on the register

EDITOR,—Robert Pugh and colleagues report a census of psychiatric inpatients to calculate the possible impact of supervision registers on psychiatric services.¹ Using operational criteria, they found that a high number (179 of 234 inpatients) fulfilled the Department of Health's criteria for inclusion on the register, and they conclude that the register would have considerable resource implications for community teams. The register is "intended first and foremost for patients being cared for outside hospital."²

The Bow and Poplar locality mental health team provides a multidisciplinary service to an inner city population of 60 000 in a socially deprived area of London. On 23 June we had a caseload of 229 patients. Keyworkers were asked to answer a questionnaire on each patient, covering six criteria for inclusion on the supervision register as specified by the Department of Health (table). The questionnaire was completed for 209 (91.3%)

Number of patients fulfilling each criterion for inclusion on supervision register (n=229)*

Criterion	No
Current risk of suicide or serious self harm	15
Current risk of serious self neglect	9
Current risk of serious harm to others	10
If untreated, risk of serious self harm	59
If untreated, risk of serious self neglect	69
If untreated, risk of serious harm to others	38

*Data available for only 209 patients.

patients; data were missing on the other patients because certain keyworkers left at this time. Ninety eight patients fulfilled at least one of the six criteria; 24 fulfilled one or more of the first three criteria, representing current risk.

These data are based on the subjective opinion of the keyworker (a community psychiatric nurse, nurse behavioural therapist, or team psychiatrist). The decision to place a patient on the register would be made by the consultant psychiatrist. The keyworker, however, is often the professional with most knowledge of the patient and, having responsibility for his or her aftercare, would be "under the spotlight with the consultant psychiatrist."³ The high number of patients fulfilling the criteria for inclusion on the register in this community sample is consistent with Pugh and colleagues' findings for inpatients. The main reason for the potentially high numbers of supervision registers would be the potential risk resulting from failure to comply with drug treatment.

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Medical ethics

Justice has a wider scope

EDITOR,—I am concerned that Raanan Gillon's article on the four principles of medical ethics may be in danger of oversimplifying a complex subject beyond reason—in particular in respect of the idea of justice.¹ Whereas the first three principles may be thought of as relatively straightforward concepts affecting a clinician's personal moral behaviour in relation to the care of individual patients, justice is of much wider scope: it is capable of interpretation in formal, ethicopolitical, individual, and sociopolitical terms, each of which has its own range and scope of application and finds a specific role in relation to health care ethics.

The question of the social and political definitions is particularly fraught in these times of the ready identification of justice with economic values, and it is in this area that people look for a more sophisticated analysis of how they may approach allocative questions. In answering their questions I am concerned that we do not start by saying that justice was defined by Aristotle as the equal treatment of equals and the unequal treatment of unequals; in fact, in Heller's view he was saying, in criticising *The Republic*, just the opposite.² He did not believe that people could be equal in any way, and his idea of distributive justice was that it should follow the existing political and economic structure of society. Unfortunately, many people take Gillon's view, and in most cases they have already decided to treat people in accordance with their own definition of whether they are already equal or unequal. This runs counter to Gillon's point that we should not seek to impose our views on others.

Thus, though I agree that the principles of autonomy, beneficence, and non-maleficence can and should be usefully discussed together as guides in medical practice, I believe firmly that justice is a concept of an entirely different order and should be treated separately. Perhaps what is really needed is a deeper exploration of each of these important concepts, when ethical questions are exercising the minds of us all.

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- Gillon R. Medical ethics: four principles plus attention to scope. *BMJ* 1994;309:184-8. (16 July.)
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The four principles may clash

EDITOR,—Raanan Gillon describes the four principles of medical ethics and gives a commentary on their scope for health care workers.¹ In several places he hints at the likelihood of a clash in the application of these principles, and it might have been helpful if he had worked through an example.

For instance, I agree that to practise beneficence and non-maleficence we need empirical information about the probabilities of the various harms and benefits that may result from proposed health care interventions. The gold standard for accurately estimating the cost versus benefits of any new intervention is the randomised controlled trial, yet patients participating in randomised controlled trials are to some extent objects rather than subjects and therefore, according to Kant's

definition, have lost their right to self determination. Here we observe a classic clash of categorical imperatives.

The conventional argument in dealing with this paradox is that patients can retain their autonomy by volunteering for these trials and giving full informed consent. Yet how often is this consent fully informed, and what about the danger, when consent is being sought, of alarming patients by giving them unsolicited and frightening information, which in itself is a breach of the moral principles of beneficence and non-maleficence? (M Baum, Francis Fraser lecture, British Postgraduate Medical Federation academic assembly, 1986.)²

Another problem arises when increasing numbers of patients exercise their right to self determination by refusing to participate in the randomised controlled trial while at the same time demanding the best treatments based on the outcomes in volunteers in previous generations of trials. Do such patients have the right to autonomy while denying their responsibility to the very society that presumably confers these rights?^{3,4}

For too long people such as myself at the cutting edge of research on cancer have been subjected to the ill informed attacks of self appointed ethicists and "consumers' advocates." Gillon puts it eloquently when he states, "such disagreement about scope does not justify accusing those who disagree with us of bad faith or incompatible moral standards. In principle it is open to resolution within our shared moral commitment." Please help me to resolve this ethical dilemma.

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Author's reply

EDITOR,—Does Paul J Heath's moral stance really allow him to believe that doctors do not need to concern themselves with being just or fair in their medical practice? If not, as I assume, then he agrees that justice is a relevant part of medical ethics. Of course justice is a complex and vigorously debated moral issue, as I tried to indicate—but there is no getting away from the need for it. As for Aristotle, I think that I gave a reasonable and fairly standard interpretation, but exegesis too is inherently contestable.

In response to M Baum, I do not have a general answer to how to resolve conflicts between the principles, though I believe that as a profession we should do so collectively and within the norms of our society provided that it too is committed to these fundamental moral principles. With regard to clinical research and Kant's categorical imperative, however, no such conflict need arise. It is morally acceptable to treat people as means to an end provided that they understand and agree—that is, provided that they are also respected as ends in themselves. Such respect does not require full information in relation to consent, which is just as well since full information is unattainable. What is required is adequate information, and adequacy varies with people and circumstances.

Yes, it is undoubtedly true that sometimes people, having been given adequate information, do refuse to participate in clinical trials even though they themselves may have benefited from clinical trials on previous patients. Nonetheless, for my own part I would reject any attempt to coerce them into such participation. The participation of patients in clinical trials is admirable but