Authors' reply

EDITOR,—Tom O'Connell reiterates our point that the differences in psychosocial outcomes in our study, although significant, were small. Consequently their importance is uncertain. We will soon begin a two year follow up of women in the antenatal care project to evaluate possible long term effects of reduced schedules of visits on maternal psychological health, the relationship between mother and child, and use of the health service postnatally. We hope that this study will help to clarify the clinical importance of the differences in psychosocial outcome that we found.

O'Connell also questions the generalisability of our findings, given our non-participation rate of 26%. Similar trials have reported non-participation rates of 33%¹ and 52%.² Non-participation may indicate women's dissatisfaction with reduced schedules; indeed, this is what we found from our questionnaire for non-participants. We advocate that the views of non-participants are sought in all trials in which there is considerable non-participation.

Sarah Vause and colleagues state that we failed to address the influence of parity on psychosocial outcomes and maternal satisfaction. While we were aware of the potential influence of parity, we would have required a much larger sample for subgroup analysis to study this. Unplanned post hoc comparison of subgroups is, of course, inappropriate. We have, however, investigated the influence of parity (using logistic regression); we found that it did not predict satisfaction.³ The fact that appreciably fewer nulliparous women took part in the trial suggests, however, that reduced schedules may be less appropriate for first time mothers.

We disagree with Vause and colleagues' view on measures of continuity. The absolute number of times that a woman sees her main carer is arguably a more appropriate index of whether she will have an opportunity to develop a relationship with that carer than is the proportion of visits in which she sees her main carer.

Like Douglas Tincello, we appreciate the importance of postnatal depression as a key psychosocial outcome of pregnancy. We reported data from the Edinburgh postnatal depression scale as means and SD because of the basic principle that statistical power is lost by dichotomising continuous variables. When we compared the proportions of women scoring above the threshold score of 12 we found no significant difference between the two groups, with 112 (13%) of 842 women in the intervention group scoring above 12 compared with 114 (14%) of 829 women in the control group ($\chi^2 = 0.039$, $df = 1$, $P = 0.844$).

We agree with Ruth Bell that further evaluation is needed of changes in the pattern of postnatal care that have the potential to affect psychosocial outcomes.

Kim Hinshaw and colleagues highlight a possible discrepancy between the indicators of success in *Changing Childbirth* and results of research on women's preferences. Their caveats about familiarity with a style of care are important. Nevertheless, we agree with them that the concept of woman centred care should be based on research evidence about women's preferences as well as their psychosocial and clinical needs.

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Recent advances in ophthalmology are not solely technological

EDITOR,—Because they concentrate on technological advances in ophthalmology Hamish M A Towler and Susan Lightman fail to mention a recent advance in knowledge that could prevent or reduce blindness and that has been subjected to a rigorous randomised controlled clinical trial.¹ We refer to the results of the diabetes control and complications trial.² In this trial of intensive treatment for patients with insulin dependent diabetes tight glycaemic control reduced the risk of retinopathy developing by 76% in patients with no baseline retinopathy and slowed the progression of retinopathy by 54% in patients with mild baseline retinopathy. Results from a longitudinal observational study,³ a randomised controlled clinical trial,⁴ and expert consensus⁵ also suggest that improved glycaemic control will reduce microvascular complications (such as retinopathy) in people with non-insulin dependent diabetes.

Translating these results into daily medical practice poses several challenges, and many primary care practitioners do not yet understand the need to improve glycaemic control to a level that would achieve reductions in microvascular disease.⁶ Including these results as a recent advance in ophthalmology would be helpful.

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Evidence based medicine

Rich sources of evidence are ignored

EDITOR,—It is reassuring that David L Sackett and colleagues have made two important concessions from their previous extreme position relating to evidence based medicine^{1,2}: firstly,

they have recognised the importance of clinical skill, as distinct from the consideration of scientific evidence; and, secondly, they have allowed other forms of evidence to take a step towards the hallowed position held by the randomised controlled trial.

A contradiction then ensues. Clinical skill is essentially derived from experience and is expressed as judgment in decision making.² But the variation in the ways in which different individuals interpret experience and formulate judgments renders this aspect difficult to expose to "big statistical ways of thinking."¹ It is therefore difficult to apportion scientifically the appropriate use of "best available clinical evidence"² in any particular decision process. We are thus led back or on to a wider view of medicine as a humane art that is supported by science.³ In this view the discipline of evidence based medicine is important for certain aspects of clinical decision making but is a relatively small part of the practice of medicine.

Forms of evidence allowable in evidence based medicine, while now extending beyond the randomised controlled trial, remain heavily numerate. This encourages emphasis on the quantifiable and physical aspects of any clinical dilemma, which may be inappropriate. Denial of social and psychological aspects may be detrimental, and ignoring the less readily measured dimensions may be dangerous. Rich sources of evidence also include the anecdotal, which are so often slated,⁴ and the qualitative, which is not mentioned by this lobby yet has developed considerably and provides illuminative results.⁵ The search for justification continues.

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Scientific method and raw data should be considered

EDITOR,—Proponents of evidence based medicine claim that it is the conscientious, explicit, and judicious use of current best available external evidence about medical care.¹ What about scientific method and raw data? Scientific method—the fundamental intellectual activity of obtaining data, assessing them by a series of valid arguments, and obtaining a series of conclusions in descending order of likelihood in all subjects—does not seem to merit consideration.

Paradoxically, evidence based medicine seems to avoid all contact with the first hand evidence by replacing original findings with subjectively selected, arbitrarily summarised, laundered, and biased conclusions of indeterminate validity or completeness. It has been carried out by people of unknown ability, experience, and skills using methods whose opacity prevents assessment of the original data.

The new journal *Evidence-based Medicine* makes no reference in its first issue to methodology, experimental design, or statistics. No reason is given for the selection of the 24 papers that are published. No explanation of the sources and techniques of the added manipulations is included. No evidence of authorship

within the new journal can be divined. There is no reference to the second hand methodology, just the quoting of subjectively attractive and unqualified conclusions, fourth hand.

Those who are concerned with validity will examine raw data and access much more extensive databases by standard methods on the Internet on a more comprehensive scale at only second hand level. Those who are not concerned with validity will find a ready substitute for thought and effort. At best, evidence based medicine is a heuristic method for a lower level partial abstracting service. There is little new or of merit in this allegedly new discipline. Assessing the raw data and understanding their validity and the means of their creation make up the true evidence based foundation of scientific and academic inquiry.

Evidence based medicine in its present form is inconsistent and incompatible with science, and its lack of soundness is sufficient for us to consider whether it is even ethical. Neither the Renaissance nor the Reformation, during which the direct examination of the human body by Vesalius and Leonardo da Vinci replaced the evidence based teachings of Galen, would have been possible without the abandonment of contemporary evidence based systems. To a scientist, the advent of evidence based medicine creates an unassailable gulf and denies the fundamental tenets of millenniums of thought and philosophy of inquiry. To a university teacher devoted to honest original inquiry, it is a falsehood. And we are going to teach it, as an allegedly new specialty, in the new medical school curriculum recommended by the General Medical Council's medical education subcommittee.

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Authors' redefinition is better but not perfect

EDITOR,—Although David L Sackett and colleagues have attempted to redefine evidence based medicine, they still argue that not everyone can be using it as striking variations in the uptake of treatments remain.¹ This look at outcome data raises a further question about outcomes: are cohort mortalities strikingly different in the various regions where uptake is different? We are given data to say whether people are using evidence based medicine but not whether treatment, according to the new principles, is working. Is the best evidence to be found in an evidence based database, or for certain questions can we be sure that such databases will be useless and we should look elsewhere?

We think it unlikely that papers that report harm will get into evidence based databases. In the same issue of the *BMJ* as Sackett and colleagues' editorial, Teifion Davies, in a commentary on a paper, states that "the clearest evidence of a causal relation [between antipsychotic drugs and sudden death] comes from a series of case reports."² As that evidence is a series of case reports³ one will look for it in an evidence based database in vain. It will have been excluded because one of the prime criteria for inclusion, a control group for comparison, is lacking.

Sackett and colleagues say that criticism of evidence based medicine ranges from it "being old hat to it being a dangerous innovation," but they do not say that a criticism is also that the databases may not contain the information we want, or perhaps need, to avoid litigation. For

example, if anaesthetists wish to have information on side effects of new drugs they may, if they access a database, be misled into thinking that no evidence exists when it does exist but has been excluded. Even old evidence on old drugs may not be there: McBride's original observations on thalidomide did not have a control group.⁴ Case series of side effects of suxamethonium⁵ or propofol would, because of a lack of controls, not feature in databases of best practice; nevertheless, it would be difficult to say that anaesthetists' practice is better because they do not know of them.

Sackett and colleagues' efforts to redefine evidence based medicine can be summed up as "better but not perfect."

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Needs to be within framework of decision making based on decision analysis

EDITOR,—What evidence is there that clinicians' skill includes knowledge of how, explicitly, to integrate the best external evidence into an optimal decision for the patient in front of them?¹ A reasonable answer would be "none." Is the process involved in evidence based medicine, as reported, capable of ensuring that decision owners (patients) know how, explicitly, their preferences are to be integrated into decisions affecting them? A reasonable answer would be "no."

These two answers lead to the conclusion that the many undoubted virtues of evidence based medicine will bear fruit for most patients only when they occur within the overarching framework provided by medical decision making based on decision analysis.² Unless this happens, evidence based medicine is likely to prove an expensive way of changing the process and appearance of medical practice without improving the quality of outcomes for patients, properly evaluated.

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Cost effectiveness and equity are ignored

EDITOR,—David L Sackett and colleagues' editorial on evidence based medicine is confused and inadequate.¹ The authors argue, among other things, that "doctors practising evidence based medicine will identify and apply the most

efficacious interventions to maximise the quality and quantity of life for individual patients." (Note the use of "apply" (does the patient have no choice?) and "efficacious" rather than effective.)

This individual medical ethic has to be traded off against the social ethic of the efficient use of scarce resources. While the individual patient might welcome treatment regardless of cost, any health care system is unlikely to be able to afford or condone such behaviour. Society requires doctors to allocate resources on the basis of knowledge of cost effectiveness. This obliges doctors to deny patients access to efficacious treatments if such interventions are not cost effective. Failure to do this without reasonable cause means that scarce resources are wasted and patients who could benefit from care are left untreated. Such inefficient treatment is unethical and should be construed by employers as *prima facie* evidence for dismissal in an NHS striving to maximise health benefits from its £40 bn budget.

The necessity to ration or allocate care on the basis of cost effectiveness was recognised by Archie Cochrane nearly 25 years ago: "Allocations of funds and facilities are nearly always based on the opinions of senior consultants, but, more and more, requests for additional facilities will have to be based on detailed arguments with 'hard evidence' as to the gain to be expected from the patient's angle and the cost. Few can possibly object to this."²

Nowadays we would complement Cochrane's position by noting that the goal of efficiency might be mediated by considerations of equity—that is, society might deliberately decide to forgo efficiency (health gains) to discriminate in favour of poor people. It is remarkable that the approach of evidence based medicine ignores such considerations and, in so doing, favours the middle class, which has a greater capacity to benefit from care, rather than poor people, who, if treated, will yield fewer health gains because of their "mean" condition.

It is a pity that the so called apostles of Cochrane have yet to understand his gospel of cost effectiveness and be concerned by considerations of equity, which would have been close to his heart.

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Authors' reply

EDITOR,—Blair H Smith and Nigel T James have not done their homework. The crucial importance of clinical skill and the roles of both patients' needs and non-randomised evidence were emphasised four years ago in our initial paper on evidence based medicine.¹ Methodological and clinical criteria for articles in *Evidence-Based Medicine* are published in every issue, as is a glossary explaining methods and terms. Commentaries are signed, and both the commentators and authors of the original articles collaborate in writing the abstracts.

We agree with Oliver R Dearlove and colleagues about the challenges that clinicians face in searching for the best external evidence. When secondary sources of best evidence are silent we must extend our search into the primary literature.

Jack Dowie maintains that only decision analysis can provide the framework necessary for making evidence based medicine (and economic analysis) work. As we have described in texts²