to establish the relation between the structure or process of care and the outcome, and thereafter it is structure and process rather than outcomes that should be audited.⁵

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- 1 Davenport RJ, Dennis MS, Warlow CP. Effect of correcting outcome data for case mix: an example from stroke medicine. *BMJ* 1996;312:1503-5. (15 June.)
- 2 Benbow SJ, Watkins C, Sangster G, Ellul J, Barer D. The availability and reliability of information on the premorbid functional status of stroke patients in hospital. *Clin Rehabil* 1994;8:281-5.
- 3 Shinar D, Gross CR, Mohr JP, Caplan LR, Price TR, Wolf PA, et al. Inter-observer variability in the assessment of neurologic history and examination in the stroke data bank. *Arch Neurol* 1985;42:557-65.
- 4 Barer D, Ellul J, and ESDB Collaborators. The European stroke database project: developing a common clinical language for stroke. *Eur J Neurol* 1995;2(suppl 2):11-2.
- 5 Mant J, Hicks N. Detecting differences in quality of care: the sensitivity of measures of process and outcome in treating acute myocardial infarction. *BMJ* 1995;311:793-6.

Further studies are needed to assess current outcome indicators

EDITOR,—Richard J Davenport and colleagues question the validity of the clinical outcome indicators published by the Scottish Office.¹ In fact, the results that they present suggest that the outcome indicators published in Scotland do their intended job—raising meaningful questions, nothing more—reasonably well.

The indicators in the authors' study—that is, the study data standardised for age and sex—suggest that mortality associated with standard care is higher than that associated with the care provided in a stroke unit. In a real context, such a result might well lead to a call for further analysis or audit to establish whether this difference remains after adjustment for case mix. The authors follow this logic and conclude that, "because of the imprecision of the corrected data, the results are still consistent with a moderate but non-significant beneficial effect." Thus the indicator is shown to raise a valid issue even in artificial circumstances far removed from those for which the indicators were designed, involving a comparison over time (with an associated major shift in case mix) rather than between hospitals at one point in time, and also involving a number of cases well below the threshold for publication.

The authors' study is not an appropriate way to test the validity of the Scottish outcome indicators. Even according to the rule of thumb that the authors use to justify their statistical procedure, the analysis may well have "overcorrected" by forcing the inclusion of 19 explanatory variables. Eighty nine deaths within 30 days does not represent five outcome events for each explanatory variable.

Davenport and colleagues, in collaboration with the producers of the Scottish outcome indicators, are engaged in a major study to assess the feasibility of routinely monitoring outcomes of stroke by looking at enhanced administrative data. This study will soon make possible a linked comparison, on a case by case basis, between outcomes derived from Scottish hospital discharge data as they currently stand and outcomes derived from data enhanced to enable adjustment for case mix. Such a comparison, based on adequate numbers and across five hospitals, will help us to come to a much more precise and balanced understanding of the strengths and limitations of the current outcome indica-

tors and how to improve them. We look forward to collaborating in this analysis.

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Study should have had more patients or longer time scale

EDITOR,—We welcome Richard J Davenport and colleagues' reminder of the importance of correcting outcome data for case mix.¹ Given the size of their study, however, they should not be surprised or disappointed that they were unable to show a beneficial impact of their stroke unit on mortality.

The 12 month mortality before the introduction of their stroke unit in Edinburgh was 39%.¹ A meta-analysis of the effect of stroke units reports a 23% (95% confidence interval 4% to 37%) reduction in the odds of death at final review (median follow up one year) in the intervention group.² Such an effect would lead to a lowering of the death rate in Edinburgh to 33%. To be able to detect this change with 80% power and at a (two sided) significance level of 5% would require a study of 2066 patients (1033 before the introduction of the stroke unit and 1033 after its introduction). Davenport and colleagues' study was of 468 patients identified over 27 months. To be confident that the introduction of their stroke unit had a smaller impact on mortality than that predicted by the meta-analysis, Davenport and colleagues' study would have needed to be much longer (119 months as opposed to 27).

The study is a clear illustration of why it can be impractical to try to compare performance among or within providers by monitoring outcomes, even when they are adequately adjusted for case mix: large numbers of patients or long time scales may be necessary to overcome the play of chance.³ In areas of health care in which the results of randomised controlled trials are available it is possible to ensure that clinical practice reflects this evidence by the use of appropriate measures of the process of care. In this case, there is good evidence that introducing a stroke unit saves lives. Purchasers would thus do better to ensure that their providers offer "well organised services for acute stroke patients which provide comprehensive care centred on an integrated multi-disciplinary team who have a specialist interest in stroke rehabilitation"² rather than seek to interpret their case fatality rates.

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- 1 Davenport RJ, Dennis MS, Warlow CP. Effect of correcting outcome data for case mix: an example from stroke medicine. *BMJ* 1996;312:1503-5. (15 June.)
- 2 Stroke Unit Trialists' Collaboration. A systematic review of specialist multidisciplinary team (stroke unit) care for stroke inpatients. In: Warlow C, Van Gijn J, Sandercock P, eds. *Stroke module of the Cochrane database of systematic reviews*. Oxford: Cochrane Centre, 1996 [updated 23 February 1996].
- 3 Mant J, Hicks N. Detecting differences in quality of care: the sensitivity of measures of process and outcome in treating acute myocardial infarction. *BMJ* 1995;311:793-6.

Authors' reply

EDITOR,—All of the authors of the letters about our paper seem to agree with its central tenet. David Barer and colleagues and Steve Kendrick and Marion Bain suggest that our regression models may have overcorrected the data, and we discussed this possibility in our paper. While multiple logistic regression modelling is far from perfect, we thought that attempting to correct for case mix in this way was a more sensible approach than simply ignoring the problem. As discussed, we were reassured that we obtained almost identical results when we applied other prognostic models, which had been derived from and validated on different stroke datasets.¹ We had developed these considerably simpler models (which rely on five or six variables, such as age and systolic blood pressure on admission) because we realised that collecting the amount of data included in our study is beyond the resources of most hospitals, at least in routine clinical practice. We are currently testing the applicability of these models in several hospitals (as referred to by Kendrick and Bain). We agree with the suggestion that the structure and process of care may be more appropriate measures of quality of care, although there are still considerable problems associated with this approach.^{2,3}

We have conducted a similar study to that of Barer and colleagues, comparing the accuracy of routine hospital coding statistics with our stroke register.⁴ Of 566 patients registered as having a stroke, 84 (15%) were not given a code (*International Classification of Diseases*, ninth revision) for stroke; although better than Barer and colleagues' experience, this is far from perfect.

Finally, while we agree with Kendrick and Bain that the purpose of the Scottish outcome indicators is to raise meaningful questions, we are aware that they have been interpreted by many people as comparative league tables of hospitals' performance, and the purpose of our paper was to show the dangers of using the data as a direct measure of quality of care. As an example of this problem, the *BMJ* recently published a news item which suggested that the clinical outcomes initiative could identify hospitals which "seemed to perform badly."⁵ We were interested to note that this report also raised doubts about whether the outcomes initiative would continue.

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- 1 Counsell C, McDowall M, Slattery J, Dennis M. Prediction of functional outcome following stroke using a validated model [abstract]. *Cerebrovasc Dis* 1996;6(suppl 2):50.
- 2 Davenport RJ, Dennis MS, Warlow CP. Can non-randomised studies reliably measure the quality of care provided for stroke patients? [Abstract.] *Cerebrovasc Dis* 1996;6(suppl 2):50.
- 3 Davenport RJ, Dennis MS. Assessing the quality of care. *BMJ* 1996;312:185. (20 January.)
- 4 Davenport RJ, Dennis MS, Warlow CP. The accuracy of Scottish morbidity record (SMR1) data for identifying hospitalised stroke patients. *Health Bull* 1996;54:402-5.
- 5 Christie B. Scotland has wide health care variations. *BMJ* 1996;313:578. (7 September.)

Measuring health outcomes

Negative values should be allowed in ratings of quality of life

EDITOR,—Ability to assess treatment and the outcomes of diseases continues to improve, and the schedule for evaluating individual quality of

life developed by Anne M Hickey and colleagues clearly represents another advance.¹ Accepted methodology now seems to be, however, that instruments that measure quality of life set the floor at zero (equivalent to being dead) and do not permit negative scores. This new instrument is no exception. As a result, these scales do not allow a situation in which death may be preferable to the current state, and they assume that life should be prolonged at all cost because any life must have a positive, if potentially low, score. This position is hard to reconcile with the commonly quoted statement that one "need not strive officiously to keep alive."

The problems of not permitting a negative score can be seen in Hickey and colleagues' paper. In their figure 4 the terminally ill patient scored four areas as reasonably good to very good yet gave them zero weight. The reason for this was that his health was awful but he was unable to give it a negative score, so he chose to emphasise its poor quality by inappropriately exaggerating its weight at the expense of other areas that were important to him. Allowing a negative score for quality of life seems to equate better to the clinical situation. Some treatments, such as cardiopulmonary resuscitation and chemotherapy for advanced malignant disease, might carry a negative score for quality of life. We justify the use of these treatments if we expect that, after their completion, the rating of the patient's quality of life will return to a positive value. Equally, we could not justify such treatments if no such return to a positive value could reasonably be expected.

The assumption that quality of life cannot have a negative rating is clearly questioned by the general public; this is highlighted by the debate over euthanasia. But the issue seems to have been prejudged by the current quality of life instruments, which do not allow such a possibility to exist.

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1 Hickey AM, Bury G, O'Boyle CA, Bradley F, O'Kelly FD, Shannon W. A new short form individual quality of life measure (SEIQoL-DW): application in a cohort of individuals with HIV/AIDS. *BMJ* 1996;313:29-33. (6 July.)

Measuring quality of life is important

EDITOR,—John Cairns raises important issues relating to the use of quality of life measures in decision making in health care.¹ He seems to imply that allocation of resources is the principal purpose for developing such measures and that they should therefore be designed with this as their main function.

The primary concern of clinicians, however, is not, or should not be, the allocation of resources but the care of patients, whose responses to disease and its treatment are essentially personal and individual. While it is necessary to find measures that try to quantify these responses so that information can be disseminated, it is a mistake to suppose that any one type of measure is likely to reflect accurately the complexity of patients' experience of illness. Both disease specific and patient specific measures of quality of life are therefore valuable in this context.

Conversely, the quality adjusted life year seems to be of limited use in clinical decision making. The idea that the personal element can be removed entirely from the experience of illness and that that experience can be reduced to a single numerical value is, at best, suspect.

As the widely held assumption that the NHS has been and will continue to be underresourced becomes confirmed by evidence it could be argued that those who initiate treatment have a

duty not to squander any resource that might be used for the benefit of future patients. Nevertheless, clinicians should continue to assert that their main concern is the treatment and wellbeing of patients known to them. Assessing patients' quality of life is part of this concern. The use of measures designed to provide information relevant to the clinical, as opposed to the economic, context is therefore neither a secondary consideration nor a trivial pursuit.

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Journal is right to require patients' consent to publication

EDITOR,—In his commentary on Keith Andrews and colleagues' paper on misdiagnosis of the vegetative state Richard Smith discusses the *BMJ's* decision to obtain consent from all patients described in case reports.¹ I endorse this decision. In 1972 the *Lancet* published details of two patients with the rare condition myositis ossificans progressiva.² One of the patients happened to be a family friend, and I could easily identify her in the article, thereby obtaining personal information of which I was previously unaware.

I am sure that there was nothing in this case that my friend would not have wished me to know. Nevertheless, there is clearly a risk of a serious breach of confidentiality if consent is not obtained, even when obvious identifying information has been removed.

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- Andrews K, Murphy L, Munday R, Littlewood C. Misdiagnosis of the vegetative state: retrospective study in a rehabilitation unit. *BMJ* 1996;313:13-6. (6 July.) [With commentary by R Smith.]
- Russell RGG, Smith R, Bishop MC, Price DA, Squire CM. Treatment of myositis ossificans progressiva with a diphosphonate. *Lancet* 1972;ii:10-2.

Need for a national arthroplasty register

Funding is important

EDITOR,—Several points arise from David H Sochart and colleagues' editorial outlining the need for a national arthroplasty register.¹ The authors are correct in stating that there is a regional register of hip and knee arthroplasties in Trent, funded by the region; as this has been functioning since 1990 and has funding from the Department of Health to assess the five year outcome of the 1990 cohort of primary total hip replacements, however, we would not term it a pilot study. Also, we were surprised that the authors do not mention the current national audit of primary total hip replacements by the Royal College of Surgeons, which could indeed act as a pilot for a national register.²

The need for a national hip register has been highlighted previously.³ In Trent all the surgeons have cooperated and the feedback has been positive. To set up a register on a national level in England would, however, be a huge undertaking with many difficulties, as the editorial states. The

Norwegian and Swedish registers are cited as examples, but it must be appreciated that the population of these countries is only 4.7 million and 8.7 million, respectively (the population of Trent is 4.7 million). There also seems to be greater agreement about prostheses and techniques used among the surgeons in Norway and Sweden, with few of the operations being performed in the private sector; and, crucially, every person in these countries has a unique national identity number, which is universally used. These factors, along with experience of several other national registers in each country, contribute to the success of the Scandinavian registers.

We agree that this kind of prospective observational study is of great value. It should be emphasised, however, that techniques such as stereo radiogrammetry and digitised image analysis are not alternatives to a register but should be used in conjunction with it, for the evaluation and introduction of new hip implant technology.^{4 5}

Finally, if the consensus is that a national register is imperative, who should take charge: the royal colleges, the orthopaedic community (perhaps through the British Orthopaedic Association), or the manufacturers of implants? The other vital aspect is funding: from Trent's experience we estimate that it costs roughly £50 per total hip replacement for registration and to provide a one year questionnaire assessment and a five year clinical and radiological review. We think that this is a drop in the ocean compared with the overall cost of about £4000 per primary total hip replacement in the NHS.

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- Sochart DH, Long AJ, Porter ML. Joint responsibility: the need for a national arthroplasty register. *BMJ* 1996;313:66-7. (13 July.)
- Gregg PJ. National total hip replacement audit project. *British Orthopaedic News* 1996;13:1.
- Murray DW, Carr AJ, Bulstrode CJ. Which primary hip replacement? *J Bone Joint Surg [Br]* 1995;77:520-7.
- Faro LMC, Huiskes R. Quality assurance in joint replacement. *Acta Orth Scand* 1992;63(suppl 250):1-33.
- Malchau H. On the importance of stepwise introduction of new hip implant technology. Gothenburg: University of Gothenburg, 1995. (MD thesis.)

Intensive Care Society has set up a centre for national audit

EDITOR,—The issues raised by David H Sochart and colleagues in their editorial on the need for a national arthroplasty register are similar to those that the Intensive Care Society faced in 1990.¹ Although many intensive care units were collecting data on their patients, the way in which the data were collected was not standardised, which made valid aggregation of data impossible.

The society, building on its study of outcomes at 26 units,² sought funds to establish a national, comparative audit of outcome. In 1994 the Department of Health and the Welsh Health Common Services Authority provided two years' funding to establish a centre (the Intensive Care National Audit and Research Centre) and a national audit (the case mix programme). Development has progressed through the dissemination of documents outlining our objectives³; the development and production of a specification for the dataset (incorporating a specific method to code clinical conditions in intensive care developed and validated by the centre)⁴; the recruitment of, and visits to, units; liaison with, and support of, software developers incorporat-