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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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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1 Cairns J. Measuring health outcomes. *BMJ* 1996;313:6. (6 July.)

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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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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- 1 Sochart DH, Long AJ, Porter ML. Joint responsibility: the need for a national arthroplasty register. *BMJ* 1996;313:66-7. (13 July.)
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- 4 Faro LMC, Huiskes R. Quality assurance in joint replacement. *Acta Orth Scand* 1992;63(suppl 250):1-33.
- 5 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 centre⁴); the recruitment of, and visits to, units; liaison with, and support of, software developers incorporat-

ing the dataset specification; training and continuing support of those who collect data; and the development and testing of in house database and reporting systems.

To date, 108 units have been recruited—that is, 46% of the units in England and Wales.⁵ With a remit to be self financing within two years, the audit is run on a cost recovery basis and makes a small annual charge to each participating unit. It should be noted that the extraction, collection, and entry of accurate data require resources for staff, software, and hardware. The total cost, however, is barely 1% of the annual budget for an average intensive care unit.

The centre was established as a charitable company separate from the society so that it could provide independent and objective audit and research into intensive care. As well as providing feedback to units for audit purposes, the resultant database will be a valuable resource for research. Through the centre's work with the Cochrane Collaboration, identifying and systematically reviewing trials relevant to intensive care, we hope to contribute to the scientific evidence on which future practice in intensive care should be based.

Without a role model to follow, we have learnt several lessons along the way—for example, how to deal with confidentiality and the ownership of data. If the orthopaedic surgeons take up Sochart and colleagues' call we would be happy to share our experiences.

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Current evaluations of information technology in health care are often inadequate

EDITOR,—Two recent articles debated the value of information technology to the NHS and called for further evidence from evaluation studies to inform future investment in information technology.^{1,2} These articles draw attention to both the scarcity of evaluation studies of information technology in health care and the lack of scientific rigour of such studies. They reflect current opinion, which strongly advocates the use of economic analyses and randomised controlled trials.

While we agree with the need to provide evidence of the benefits of information technology in health care, we believe that current thinking and practice concerning evaluation are short sighted and detrimental to long term progress. By concentrating on economic analyses of information technology (the results of which have not been encouraging), current evaluation methods overlook potential benefits, such as improved quality of care through better access to more reliable information. By insisting on evidence from randomised controlled trials we waste precious resources on evaluation work that is methodologically flawed and impractical and at best provides results that are difficult or impossible to generalise. An additional problem is that of timing. Many of the benefits of information technol-

ogy cannot be expected to become evident until several years or more after its introduction, yet we call for evidence of immediate benefits.

In the current climate, in which information technology is viewed suspiciously by many people, it may be argued that evaluation is implicitly used as a barrier to progress. We have inadvertently created a catch 22 situation whereby we cannot move forward with information technology in health care because of the lack of evaluation, yet our failure to deploy systems in routine clinical practice and allow them to mature means that we have nothing of any substance to evaluate.

Information technology is an abstract phenomenon that can be moulded into many forms, often rapidly. It does not operate in a vacuum but is embedded within a complex social and organisational context. The priorities, therefore, should be to develop richer understanding of the effects of its benefits in health care and to develop new evaluation methods that help us to understand the process of implementing it.

Negative results from current inadequate evaluations should not be used to impede general research and development. There is a pressing need to build foundations of fundamental research and development in information technology in health care.

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1 Lock C. What value do computers provide to NHS hospitals? *BMJ* 1996;312:1407-10. (1 June.)

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Placebo mania

Placebos are essential when extent and variability of placebo response are unknown

EDITOR,—We need placebo controlled trials¹ because responses to placebo are remarkably variable. Figure 1 shows the results of randomised double blind trials of anticonvulsants,² antidepressants,³ and topical capsaicin⁴ in painful diabetic neuropathy. The proportion of patients in whom the active drug relieved at least 50% of the pain is plotted against the proportion in whom placebo relieved at least 50% of the pain. The active treatments achieved this degree of pain relief in 50-90% of the patients, while placebo did so in 0-80%.

This variation has no simple cause related to the design of the study or to measurement, nor is such variation rare. Trials in other chronic pain conditions showed a placebo response varying from 7% to 86%² and from 4% to 47%.³ In trials of antiemetics 0-50% of patients given a placebo vomited soon after general surgery,⁵ and after correction of squint the range of the placebo response was 18% to 88%.⁶ In trials of surfactant in the respiratory distress syndrome the range of the placebo response was 24% to 69%.⁷

B Jones and colleagues emphasise the need to know that "both treatments were indeed effective" in a trial of two active drugs.⁸ Only if we know the extent of the placebo response and that it does not vary can this criterion be fulfilled. Performing studies of drug A versus drug B when the extent and variability of the placebo response are unknown can be misleading. As Jones and colleagues point out, the results could mean that both A and B were effective or that neither A nor B was effective. The only current defence is to have a

Fig 1—L'Abbé plot of proportion of patients in whom active drug relieved at least 50% of pain against proportion in whom placebo relieved at least 50% of pain in randomised controlled trials of various drugs in diabetic neuropathy

placebo group. Designs of trials of analgesics 30 years ago understood this and included both standard active and placebo groups.⁹ Only in trials in which sensitivity is proved (that is, standard treatment beats placebo) can correct conclusions of equivalence be made.

If we already know the answer then it is unethical to include a placebo group: the condition of equipoise is not met. If we do not know the answer, and in particular if we do not know the extent and variability of the placebo response, then it is unethical to enrol patients into trials whose design precludes a sensible answer. In these circumstances a placebo group is essential and ethically acceptable.

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Placebo controlled trials are needed to provide data on effectiveness of active treatment

EDITOR,—Kenneth J Rothman questions whether there is any point in using a placebo group if blind assessment can be achieved in a comparative trial of two active treatments.¹ He minimises both the practical advantages of placebo controlled trials and their advantages for hypothesis testing. The limitations of statistical