therefore the use of the term emergency contraception for early abortion is erroneous. According to the datasheet, "Schering PC4 is primarily aimed to prevent implantation of the fertilised ovum in the endometrium." Insertion of a foreign body such as an intrauterine contraceptive device achieves the same effect.

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Contract minimum dataset includes confidential data

EDITOR,—R Basu Roy and P Sriskandabalan are right to be concerned about the threat to the privacy of data related to AIDS,¹ but for inpatients it is already too late. Data on HIV status are included in the clinical coding that forms part of the contract minimum dataset,² together with the patient's name, address, postcode, date of birth, sex, and other information. Until April 1995 HIV positive status was coded according to the *International Classification of Diseases* (ICD), ninth revision, which specified a subsidiary code of 079.4. Since then the ICD-10 codes have been used, which expand illness related to HIV into main codes B20 through to B24. Similar levels of detail for other sexually transmissible diseases, abortions, and fertility treatment are also included in the contract minimum dataset. Even when, as is often the case, patients' names and addresses are removed from contract minimum dataset databases, intelligent querying strategies can be used to establish individuals' identities.³ It is well established that the combination of date of birth, sex, and postcode is sufficient to identify almost everyone except monozygotic twin children.

The contract minimum dataset forms the basis of trading in the reformed NHS: it is routinely passed between administrative and clerical staff as part of the contracting process. Without its exchange the internal market would probably not be able to operate, at least in its present form, but it may not be possible to reconcile this exchange with existing legislation on confidentiality of personal clinical data and therefore with the requirements of the Data Protection Act.

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Assessing the quality of care

Measuring the process of care is not always straightforward

EDITOR,—Huw T O Davies and Iain K Crombie identify the problems of monitoring outcomes to assess quality of care and suggest that the process of care may be easier to measure and interpret.¹ This idea seems attractive, but Davies and Crombie sensibly add two caveats. We wish to discuss these further, illustrating some of the problems with an example from stroke medicine.

Firstly, the authors state that measuring process as an indicator of quality is appropriate only for

interventions that have been shown to be effective, either in large randomised controlled trials or in meta-analyses. In their example (thrombolysis for myocardial infarction) the process is well defined and performance (that is, the proportion of patients receiving treatment and the speed with which this is given) is easily measured. But if we consider another well proved yet less well defined and generalisable intervention (stroke units^{2,3}) the measurement of process is less straightforward. Why stroke units work remains unclear (although several features, such as regular multidisciplinary team meetings, may be important⁴), and therefore it is not obvious which processes should be measured. Perhaps we could simply measure the proportion of patients managed in stroke units, but this assumes, unrealistically, that all units are uniformly effective.

The second point concerns the difficulty of defining appropriate processes for specific groups of patients and the influence of case mix on process. In myocardial infarction, thrombolysis is probably effective for most groups of patients (young and old patients, those with anterior and those with inferior infarcts, etc), provided there are no contraindications. But in other diseases patients may be considerably more heterogeneous, and thus interpretation of process becomes difficult. For example, use of antithrombotic drugs as prophylaxis is an appropriate process after an acute ischaemic stroke but not after a haemorrhagic stroke; if we measured the use of such drugs as an indicator of quality between units then interpretation would depend on case mix (that is, the ratio of ischaemic to haemorrhagic strokes), which may vary considerably (for example, in a neuroscience unit compared with a geriatric unit).

We agree that measurement of the process of care has much to commend it, and it avoids the huge problems of measuring and interpreting outcome data; but it may raise other problems of its own, particularly in diseases such as stroke.

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Systematic methods must be used to develop review criteria

EDITOR,—We agree with Huw T O Davies and Iain K Crombie's comments about the difficulties sometimes encountered in identifying and using outcome measures for assessing the quality of care, and we too advocate the selective use of process measures.¹ This, however, begs the question of how high quality process measures should be developed.

Review criteria (audit criteria) are "systematically developed statements that can be used to assess the appropriateness of specific health care decisions, services and outcome."² They are therefore measures of aspects of care, including process. We have described a framework for the development of evidence based audit criteria,³ and we suggest that process measures should not only be based on research evidence but also have a strong influence on outcome. For example, many audits of asthma in primary care include criteria for the

routine measurement of peak flow rate or the routine use of self management plans. Unfortunately, as a measure of the quality of care neither of these is supported by strong research evidence, and their influence on outcome is not clearly established.⁴ Since priority must be given to processes that are genuinely important—for example, checking inhaler technique in asthma—Lilly Centre protocols categorise criteria as "must do" or "should do." Furthermore, audit criteria must be clear and precise and appropriate to the clinical setting.

A more general question concerns how evidence based audit criteria are developed and disseminated. This requires extensive resources. The development of valid process measures is analogous to the development of clinical guidelines, on which an extensive literature now exists. To ensure that improvements in care take place, however, it is not sufficient only to provide statements about appropriate care. The appropriateness of care must also be measured and modified when indicated. Thus attention is now beginning to be focused on review criteria.⁵

If recommendations for changes in performance are to be based on research evidence it is essential that systematic methods are used to develop review criteria.

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How to get patients' consent to enter clinical trials

Reports of trials should state proportion of people who refuse to participate

EDITOR,—We agree with Elizabeth Wager and colleagues that "large proportions of patients refusing to enter studies may signal a problem with study design."¹ The proportion of refusals, however, may vary with the nature of the trial, the disease studied, and the type of treatment investigated.

We have recently been involved in a trial of anti-endotoxin treatment in meningococcal septic shock in children. Most parents who were approached about taking part wanted the possible benefit of the treatment being studied and consented. Four out of 28 parents refused, all for different reasons. One was unwilling to risk any adverse events, one could not accept the uncertainty of the trial, one was unable to make a decision while her child was critically ill, and one did not want her child "used as a guinea pig." In contrast, no parents refused to take part in observational studies of children with meningococcal disease that was not life threatening.

Investigators obtaining consent for trials of