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.

JOHN SCOTSON
General practitioner

5 Woodville Road,
Altrincham,
Cheshire WA14 2AN

1 Cayley J. Emergency contraception. *BMJ* 1995;311:762-3. (23 September.)

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.

O M GOODYEAR
Information manager

Southlands Hospital,
Shoreham by Sea,
West Sussex BN43 6TQ

1 Basu Roy R, Sriskandabalan P. NHS computer network will breach venereal disease regulations. *BMJ* 1995;311:754. (16 September.)

2 Department of Health. *Framework for information systems: the next steps*. London: HMSO, 1990:117-20.

3 Kay S, Goble CA. Protection and control of information in medical databases. *Current perspectives in health care computing* 1988. Weybridge: British Journal of Healthcare Computing, 1988:103-12.

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.

RICHARD J DAVENPORT
Clinical research fellow
MARTIN S DENNIS
Senior lecturer in stroke medicine

Neurosciences Trials Unit,
University of Edinburgh,
Western General Hospitals NHS Trust,
Edinburgh EH4 2XU

1 Davies HTO, Crombie IK. Assessing the quality of care. *BMJ* 1995;311:766. (23 September.)

2 Langhorne P, Williams BO, Gilchrist W, Howie K. Do stroke units save lives? *Lancet* 1993;342:395-8.

3 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*. London: BMJ Publishing Group, 1995.

4 Langhorne P on behalf of Stroke Unit Trialists' Collaboration. What is a stroke unit? A survey of randomised trials [abstract]. *Cerebrovascular Diseases* 1995;5:228.

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.

MAYUR LAKHANI
Clinical lecturer

RICHARD BAKER
Director

ROBIN FRASER
Professor of general practice

Eli Lilly National Clinical Audit Centre,
Department of General Practice and
Primary Health Care,
University of Leicester,
Leicester General Hospital,
Leicester LE5 4PW

1 Davies HTO, Crombie IK. Assessing the quality of care. *BMJ* 1995;311:766. (23 September.)

2 Lohr M, Lohr KN, eds. *Institute of Medicine guidelines for clinical practice. From development to practice*. Washington, DC: National Academy Press, 1992.

3 Baker R, Fraser RC. Development of review criteria: linking guidelines and assessment of quality. *BMJ* 1995;311:370-3. (5 August.)

4 Grampian Asthma Study of Integrated Care (GRASSIC). Effectiveness of routine self monitoring of peak flow in patients with asthma. *BMJ* 1994;308:564-7.

5 Agency for Health Care Policy and Research. *Using clinical guidelines to evaluate quality of care*. Vol 1. Rockville: US Department of Health and Human Services, 1995. (AHCPR publication No 95-0045.)

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

novel treatments in children with acute life threatening disease might expect parents to agree to anything that might increase their child's chance of survival. Our experience shows that this is not true in all cases. Most local research ethics committees are now moving towards asking for reports of trials they have approved. It is rare, however, for them to ask about refusals to participate. Reports of trials to the committees and for publication should routinely state the proportion of people who refuse to participate and the reasons for this. This information may suggest whether patients are being properly informed, may help with study design, and might also be a means of detecting scientific fraud.

F ANDREW I RIORIAN
Lecturer in paediatrics and child health

Undergraduate Teaching Centre,
Birmingham Heartlands Hospital,
Birmingham B9 5SS

ALISTAIR P J THOMSON
Consultant paediatrician

Leighton Hospital,
Crewe,
Cheshire CW1 4QJ

1 Wager E, Tooley PJH, Emanuel MB, Wood SF. How to get patients' consent to enter clinical trials. *BMJ* 1995;311:734-7. (16 September.)

Information and consent forms should use short words and sentences

EDITOR,—In their article on how to get patients' consent to enter clinical trials Elizabeth Wager and colleagues mention the need for short sentences in forms that give information about consent.¹ They do not discuss the merits of using short words. The model consent form that they reproduce uses long words and phrases when short ones would easily do. It also begins by assuming literacy ("Have you read the information provided?") although many people cannot read English or speak little English and may not have been given a translated form. Forms with short words can aid oral explanations that make sense to people from a wide range of ages and abilities. Informed consent can depend as much on professionals' clear explanations as on patients' understanding.

The national forum Consumers for Ethics in Research publishes a booklet on preparing information for people who are asked to help with medical research; it suggests clear phrases to explain research concepts and techniques.²

NAOMI PFEFFER
Member

Consumers for Ethics in Research,
PO Box 1365,
London N16 0BW

1 Wager E, Tooley PJH, Emanuel MB, Wood SJ. How to get patients' consent to enter trials. *BMJ* 1995;311:734-7. (16 September.)

2 Alderson P. *Spreading the word on research or patient information: how can we get it better?* London: Consumers for Ethics in Research (CERES), 1995.

Participants should be given feedback about the trial

EDITOR,—Elizabeth Wager and colleagues have set out extremely useful guidelines for gaining patients' consent to enter clinical trials.¹ I have undertaken an anonymous, retrospective postal survey of 90 patients who participated in five trials of treatment for rheumatoid arthritis and one for ankylosing spondylitis. Seventy patients returned questionnaires (78% response rate). Most (69) thought that they had received a full explanation of the study and (67) that they had not been put under any pressure to take part, and all thought that they had been given enough time to consider taking part. Nevertheless, a considerable number (11) said that at some time during the study they wished that they had decided not to take part.

Twenty one patients could not identify the particular drug trial in which they had taken part when they looked at the names of the six drugs that were investigated (one patient ticked three of the names). Two questions concerned only those patients who had withdrawn from the study because of side effects or lack of efficacy of the study drug. Of the 24 patients who answered these questions, 19 expressed satisfaction with the resolution of their problems and subsequent treatment.

Gaining informed consent is the start of participation in a clinical trial. Results of this survey show that those who obtain consent should audit patients' assimilation of the information given them at this time. It is also important to ensure that patients are satisfied with their treatment during the study. Of the 11 patients who said that at some point they wished that they had decided not to participate, six said that this was because of side effects but five gave no reason. This suggests that researchers should be diligent in recognising uncertainties and anxieties experienced by patients and a wish to withdraw from a clinical study during its progress. The concerns of patients are not always the same as those of researchers.

Patients also reported a strong desire to have feedback about the results of the study in which they were participating. It has been recommended that patients should receive written thanks for cooperating in a study.² A plea has also been made for patients to be the first people to hear the results of a study.³ Not everyone would agree with this, but it is surely right that patients are informed of the results by the investigator, preferably at the time of publication.

SALLY MARSHALL
Clinical metrologist

Rheumatology Department,
Mount Gould Hospital,
Plymouth PL4 7QD

1 Wager E, Tooley PJH, Emanuel MB, Wood SF. How to get patients' consent to enter clinical trials. *BMJ* 1995;311:734-7. (16 September.)

2 Royal College of Physicians. *Research involving patients*. London: RCP, 1990.

3 Goodacre H, Smith R. The rights of patients in research. *BMJ* 1995;310:1277-8.

Nurses could halve GP workload

EDITOR,—Keith Thompson complains that most of a general practitioner's workload consists of dealing with trivia and routine tasks (for example, cervical cytology and measurement of blood pressure).¹ I accept that general practitioners, as the public's first port of call, are likely to see many patients with minor and self limiting conditions. Patients attend the surgery because they are concerned or need advice about a problem, not to waste their general practitioner's time. What may seem to be minor or routine to the general practitioner may be of great importance to the patient. It is only general practitioners' training that enables them to recognise these minor or self limiting conditions and to reassure their patients. Furthermore, the importance of interpretation and counselling for even the most routine of procedures should not be minimised: they should be seen as a vital part of the general practitioner's workload.

The second issue arising from Thompson's letter concerns the use of nurses in general practice. The nursing profession has spent years trying to move away from performing single tasks on many patients to being involved in all the aspects of each patient's care. Nursing is a profession complementary to but separate from medicine. Nurses have different skills and should not be seen as underqualified doctors to be trained to do the tasks that general practitioners find too trivial and

menial to complete themselves. I fully support the concept of nurse practitioners, but they should be seen as professionals with their own specialised role, not as cheap medical labour.

General practitioners should not underestimate their importance in dealing with minor complaints and undertaking routine procedures. They should pass on the responsibility for these matters to nurse practitioners only when to do so will improve patients' care, and having regard to the nurses' professionalism. Nurse practitioners should be allowed to apply all their skills and not be used purely as technical assistants.

RUTH HUDDART
Nurse adviser

Access 24,
Reigate,
Surrey

1 Thompson K. Nurses could halve GP workload. *BMJ* 1995;311: 808. (23 September.)

Training in substance abuse is lacking for GPs

EDITOR,—My practice looks after 45 patients who misuse opiates and amphetamines, for whom it has a prescribing programme.¹⁻³ The local police drug squad has commented that the care given to these patients has decreased the availability of heroin on the streets of north Bedfordshire. Six months ago the practice looked after more than 60 patients, and the strain of this led to the breakdown of the health of one of the partners. None of us has any training in this aspect of medicine.

After a visit by the NHS Drug Advisory Service, Bedfordshire Health has made money available for training in counselling and for support services for this work. As the leading partner in this work, I contacted the regional adviser in general practice, several treatment programmes for drug misuse, and the Institute for the Study of Drug Dependence to ask about training courses for general practitioners. I was told that no intensive short courses existed. Records showed that only two one-hour sessions were available—one of them run by me. All that was available was a part time diploma course, requiring attendance in London half a day a week for a year. As I do not wish to become a specialist in treating drug misusers, however, I cannot justify spending a whole year studying this subject intensively. The practice has as many patients with epilepsy as with drug problems, and many more with diabetes and hypertension. I do not have diplomas in any of these aspects of medicine, but I do attend courses in them. Our local drug treatment centre provides a good standard of care for the patients registered with it, but it cares for fewer patients than our practice, there is little consultant input, and it does not provide training for general practitioners.

My partners and I wish to look after our patients who misuse drugs in the same way that we look after patients with other chronic problems. The government has specifically encouraged this course of action. At the moment, however, general practitioners who treat drug misusers are flying by the seat of their pants with little support. If any problems arise the media are very ready to criticise. It seems wrong that general practitioners are encouraged to get involved in a problematic aspect of medicine when no relevant training courses are available. The only thing that keeps us going is that, as well as having 45 current drug misusers on our list, we have 28 former drug misusers. These people can be helped.

EDWIN MARTIN
General practitioner

2 Goldington Road,
Bedford MK40 3NG

1 Martin E. Drug addiction in general practice. The reality behind the guidelines. A discussion paper. *J R Soc Med* 1987;80: 305-7.