Letters

CONSORT statement on the reporting standards of clinical trials

Recommendations are inappropriate for trial reports

EDITOR—In his editorial on the CONSORT statement Douglas G Altman states that since "only randomised trials have the potential directly to affect patient care ... it is ... reasonable to require higher standards for papers reporting randomised trials than those describing other types of study."[1] But although randomised trials are usually the preferred approach for the unbiased evaluation of treatments, non-randomised observational studies also influence treatment. Because the correct interpretation of observational studies is much more difficult, largely due to uncontrollable biases, their description and analysis call for at least as much care as do randomised trials. Sometimes, of course, randomised comparisons are unnecessary—for example, to determine the value of α fetoprotein screening for neural tube defects.

CONSORT is the product of deliberations conducted almost entirely through North American journals.[2] Journal editors and statisticians are well represented among those involved, but clinicians and others with experience in actually conducting trials less so. Experience of the procedures recommended seems to be limited and not wholly positive. The authors of one trial report who had been persuaded to rewrite it[3] in the structured format expressed mixed feelings: the paper was rendered less readable with "ideas that are logically linked together (such as point estimates with 95% confidence intervals) torn asunder."[4] Inflexibility and a lengthier manuscript were other reported disadvantages. The editor stated that a journal "should change the way it structures articles only when there is good agreement on the new format in the communities we serve"[4]; this includes writers and readers of trial reports as well as editors. Feedback from the test case[3] or from other commentators does not seem to have materially altered the final version of CONSORT. By announcing its decision, less than a fortnight after publication of CONSORT, the *BMJ* pre-empted input from many with experience of planning, conducting, and reporting trials.

Few will dispute the need for improvements in the reporting of all studies with implications for patient care, whatever their design. But without appropriate consultation, the *BMJ* seems to have made its decision on CONSORT prematurely. The requirement that randomised trials report the numbers of patients excluded is generally pointless,[5] and making authors indicate where a large number of checklist items are dealt with would be unduly prescriptive. The CONSORT recommendations should not be imposed unilaterally. Others with experience of trial conduct should be consulted on the nature of any guidelines for the reporting of randomised trials and, more importantly, of observational studies of treatments.

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1 Altman DG. Better reporting of randomised controlled trials: the CONSORT statement. *BMJ* 1996;313:570-1. (7 September.)
2 Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, *et al.* Improving the quality of reporting of randomized controlled trials: the CONSORT statement. *JAMA* 1996;276:637-9.
3 Williams JW, Holleman DR, Samsa GP, Simel DL. Randomized controlled trial of 3 *vs* 10 days of trimethoprim/sulfamethoxazole for acute maxillary sinusitis. *JAMA* 1995;273:1015-21.
4 Rennie D. Reporting randomized controlled trials: an experiment and a call for responses from readers. *JAMA* 1995;273:1054-5.
5 Peto R. Clinical trial reporting. *Lancet* 1996;348:894-5.

Reporting of refusal of consent to take part in clinical trials is still poor

EDITOR—The CONSORT statement, summarised by Douglas G Altman,[1] requires investigators to give details of eligible patients not recruited to a clinical trial, which means stating explicitly how many patients refused to give their informed consent.

We surveyed 11 specialist clinical journals from 1995 published or distributed by BMJ Publishing available in our local medical library; seven were British and four North American. We looked at all full reports of randomised clinical trials for explicit statements or implicit suggestions (such as "all consecutive patients were studied") about refusal of consent. We sent questionnaires to all first authors of reports containing implicit suggestions and to a random sample of first authors of reports that gave no mention of refusals.

There were 195 suitable reports. Consent rate was given in nine reports, with rates of refusal between 0% and 84% (median 7%; mean 25%). A further nine reports contained implicit suggestions of no refusals; all the first authors of these reports returned their questionnaires, and in two of the studies there had been refusals (10% and 8%).

Eighteen first authors replied from our random sample of 20 taken from the remaining 177 reports that gave no information on refusal of consent. Four authors had kept records of refusals, one did not know, and the rest estimated or stated from memory the rates of refusal, which were up to 20%. One respondent, commenting on the low refusal rate, added that "the doctor personally following them helped patients to agree to anything—rightly or wrongly." Wager *et al* commented that refusal "may indicate that you are conscientious enough to ensure that [subjects] are properly informed and make a free decision."[2]

There have been earlier surveys about consent bias—for example, one in which refusal rate was stated in about 40% of reports[3] —and comments (for example, by Charlson and Horwitz[4]), but reporting of consent rates in our surveyed journals was unusual, and the information was often not available. Even when an implicit statement is given, readers cannot assume that all

Advice to authors

We receive more letters than we can publish: we can currently accept only about one third. We prefer short letters that relate to articles published within the past four weeks. We also publish some "out of the blue" letters, which usually relate to matters of public policy.

When deciding which letters to publish we favour originality, assertions supported by data or by citation, and a clear prose style. Letters should have fewer than 400 words (please give a word count) and no more than five references (including one to the BMJ article to which they relate); references should be in the Vancouver style. We welcome pictures.

Letters should be typed and signed by each author, and each author's current appointment and address should be stated. We encourage you to declare any conflict of interest. Please enclose a stamped addressed envelope if you would like to know whether your letter has been accepted or rejected.

We may post some letters submitted to us on the world wide web before we decide on publication in the paper version. We will assume that correspondents consent to this unless they specifically say no.

Letters will be edited and may be shortened.

subjects have given consent. A large improvement is needed to conform to CONSORT.

A different worry concerned the two first authors who did not reply to a repeated request for information, despite being offered the chance simply to put the unanswered questionnaire back in the prepaid return envelope. The authors may have moved on, but for papers published in 1995 this is unsatisfactory, especially if data are supposed to be more freely available.[5] We hope that their silence does not indicate some abuse of consent.

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1 Altman DG. Better reporting of randomised controlled trials: the CONSORT statement. *BMJ* 1996;313:570-1.
2 Wager E, Tooley PJH, Emanuel MB, Wood SF. How to get patients' consent to enter clinical trials. *BMJ* 1995;311:734-7.
3 Douglas S, Briones J, Chronister C. The incidence of reporting consent rates in nursing research articles. *Image J Nurs Sch* 1994;26:35-40.
4 Charlson ME, Horwitz RI. Applying results of randomised trials to clinical practice: impact of losses before randomisation. *BMJ* 1984;289:1281-4.
5 Delamothe T. Whose data are they anyway? *BMJ* 1996;312:1241-2.

MRC uses checklist similar to CONSORT's

EDITOR—Douglas G Altman's editorial highlights the educational potential of the CONSORT checklist in increasing awareness of what constitutes a good trial.[1] As of this year the Medical Research Council requires all investigators who seek funds for clinical trials to present their applications in a structured format. Potential applicants are sent a list of headings similar to the CONSORT checklist and asked to make an entry under each heading. The reasons the council has adopted this approach are twofold—firstly, to make the peer review process more cost effective both for applicants and reviewers, and, secondly, to introduce an increased awareness of the requirements of a good trial at an early stage of trial development. The drafting of this checklist was informed by two 1994 publications on the reporting of clinical trials,[2 3] and after a pilot period we shall review its structure. At this stage we will take into account the details of the CONSORT statement with a view to encouraging a continuity from trial inception to publication.

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1 Altman, DG. Better reporting, of randomised controlled trials: the CONSORT statement. *BMJ* 1996;313:570-1.
2 Standards of Reporting Trials Group. A proposal for structured reporting of randomised controlled trials. *JAMA* 1994;272:1926-31.
3 Working Group on Recommendations for Reporting of Clinical Trials in the Biomedical Literature. Call for comments on a proposal to improve reporting of clinical trials in the biomedical literature; a position paper. *Ann Intern Med* 1994;121:894-5.

Authors' reply

EDITOR—We agree with T W Meade and colleagues that important information may be gained from observational studies. It is because the interpretation of such studies is harder and because less evidence was available in this area of reporting that we decided to see how the statement on reporting of randomised trials fared. Now that CONSORT has been published and is being evaluated, our attention has moved to the reporting of systematic reviews and observational studies.

Meade and colleagues are confused about the various initiatives. As they may see from the editorial by one of us which they cite,[1] two independent groups—the SORT and the Asilomar group—met almost simultaneously to set up standards for the reporting of randomised trials. SORT in particular involved several active clinical trialists who have randomised many tens of thousands of patients between them. Both groups published their statements.[2 3] As an experiment, one clinical trial was rewritten in the SORT format; as was noted in the editorial,[1] the authors found this tedious. So did readers. After receiving numerous comments, representatives of both groups got together and worked out a simpler solution, more friendly to researchers, reviewers, and readers. This was published as the CONSORT statement,[4] accompanied by an explanatory editorial.[5] In contrast, therefore, to what Meade and colleagues write, feedback has strongly influenced the final statement.

The *BMJ* is by no means alone or precipitate in adopting CONSORT. About 80 journals from around the world have adopted CONSORT or are seriously thinking of doing so. The vast majority of letters that we have received have been positive. Though we do not understand why good scientific standards should not be universal, we are happy to note that Freemantle and his colleagues in England liked the initiative.[6] We are not suggesting to people how they should conduct clinical trials, merely how to improve the quality of the reporting. We are delighted that Meade and colleagues have not raised a single substantive scientific criticism, which suggests that the journals adopting the CONSORT statement have made a wise choice. Still, CONSORT is not set in concrete and is likely to change in the light of experience.

We believe that CONSORT represents a reasonable request from editors, reviewers, and readers that authors should include the various bits of information without which the report would be meaningless. Given that the information is provided, we think it is reasonable that they are asked to say where it can be found.

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1 Rennie D. Reporting randomized controlled trials. An experiment and a call for responses from readers. *JAMA* 1995;273:1054-5.
2 Standards of Reporting Trials Group. A proposal for structured reporting of randomized controlled trials. *JAMA* 1994;272:1926-31.
3 The Asilomar Working Group on Recommendations for Reporting Clinical Trials in the Biomedical Literature. Checklist for inclusion in reports of clinical trials. *Ann Intern Med* 1996;124:741-3.
4 Begg C, Cho M, Eastwood S, Horton R, Moher D, Olkin I, *et al.* Improving the quality of reporting of randomized controlled trials. The CONSORT statement. *JAMA* 1996;276:637-9.
5 Rennie D. How to report randomized controlled trials. *JAMA* 1996;276:649.
6 Freemantle N, Mason JM, Haynes A, Eccles MP. CONSORT: an important step towards evidence-based health care. *Ann Intern Med* 1997;1226:81-2.

Details of patients' consent in studies should be reported

EDITOR—Marcel G M Olde Rikkert and colleagues found that the frequency with which information on informed consent and approval by an ethics committee was given in reports of trials was low.[1] Browsing through various medical journals shows that this phenomenon is not limited to geriatrics. Olde Rikkert and colleagues are therefore right to request more open declarations on when and how informed consent was given or, in special circumstances, why consent was not obtained.

Protection of patients' rights is increasingly important at all stages of medical research.[2] "Patients have rights to privacy that should not be infringed without informed consent," states the International Committee of Medical Journal Editors (the Vancouver Group).[3] In the recruitment of patients to medical research, informed consent has long been both a legal requirement and an ethical imperative. This is based on the principle that competent individuals should choose freely whether to participate in research. "For all biomedical research involving human subjects, the investigator must obtain the informed consent of the prospective subject or, in the case of an individual who is not capable of giving informed consent, the proxy consent of a properly authorised representative," state international ethical guidelines based on the Declaration of Helsinki.[4]

Though consent is normally seen as an absolute requirement, occasional exceptions exist in some forms of epidemiological research—for example, that based solely on medical records. In some studies full disclosure of aims and methods might even jeopardise the outcome. Responsible ethics committees will consider the different aspects of patients' consent when a study is approved.[4]

Securing and declaring consent and approval of ethics committees are primarily the responsibility of authors, but editors should ensure that details are included in articles. Editors cannot hide behind their referees—as seems to have been the misunderstanding by the editors questioned by Olde Rikkert and colleagues. Referees are advisers to the editor, not decision makers. The final decision whether, and what, to publish is made by the editor. The editor can turn down a paper on ethical grounds even

though the study has been approved by an ethics committee. The editor may even decide to waive the requirement for such approval if he or she considers it warranted. This gives editors a power that must be executed carefully. Open declarations—for example, on informed consent—give readers an opportunity to see how the ethics of medical publishing is handled. "When informed consent has been obtained it should be indicated in the published article," ends the Vancouver Group's statement on patients' rights to privacy.[3]

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1 Olde Rikkert MGM, ten Have HAMJ, Hoefnagels WHL. Informed consent in biomedical studies on aging: survey of four journals. *BMJ* 1996;313:1117. (2 November.)
2 Goodare H, Smith R. The rights of patients in research. *BMJ* 1995;310:1277-8.
3 International Committee of Medical Journal Editors. Protection of patients' right to privacy. *BMJ* 1995;311:1272.
4 Council for International Organisations of Medical Sciences. *International ethical guidelines for biomedical research involving human subjects.* Geneva: CIOMS, 1993.

The *BMJ*'s Nuremberg issue

Force of moral duty was greater for conscientious objectors

EDITOR—John Pemberton's letter giving the details of the experiments in Sheffield on conscientious objectors during the second world war has the subtitle "Nobody died during experiments on vitamin C and vitamin A intakes in Sheffield."[1] This implies that the risks were less and that in that way the courage of the subjects was diminished. The letter is factual and cannot deal with the ideas of those concerned.

I was brought up in the Plymouth Brethren and agonised with my friends and contemporaries over the morality of killing for the sake of our country and to resist evil—though we did not know then just how evil that evil was. Our discussion went on continuously, at length, in depth, and without mercy, in the way that young men discuss personal matters. Several of these young men stood out for the truth that they believed in and refused to have anything to do with fighting or to support it directly. I am certain that none of them were otherwise less willing to do their perceived duty than the rest of us and to accept the risks involved.

Thus I am sure that these Sheffield subjects would have signed informed consent forms as we know them today, and would have accepted any risk then. The fact that nobody died does not alter the risk. That the researchers did not do any direct harm or push the experiment to the point of death is, somehow, the real difference between them and their Nazi contemporaries.

It is hard for people today to understand how we thought then, and I hope this view helps to explain us. The idea that we might die a violent and early death because of the war was common to us all. For those who might now be called slaves of conscience the force of our moral duty to accept related risks was not less: it was perhaps even greater.

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1 Pemberton J. The BMJ's Nuremberg issue. *BMJ* 1997;314:540. (8 February.)

Physicians' "form of faith" is being reviewed

EDITOR—The Royal College of Physicians is grateful to Geoffrey Nicholson for drawing its attention to the "form of faith" signed by fellows.[1] The college has recently adopted a "statement of purpose," which reads: "The purpose of the Royal College of Physicians of London is to promote health and counter disease by providing education and support for physicians to practise at the highest standard and through advice to government, governmental bodies and the public." Thus its position, both in public and in private, is that it stands for the welfare of the public it serves, ill or not. Stimulated by Nicholson, we are reviewing our forms of faith to make sure that they reflect this.

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1 Nicholson G. The BMJ's Nuremberg issue. *BMJ* 1997;314:439. (8 February.)

Arabs were skilled in anaesthesia

EDITOR—Anthony John Carter's review of sedative plants skipped several centuries and did not mention the "Arabic anaesthetic sponge."[1] Opium infusion was known to Arab clinicians throughout the middle ages and was used commonly to relieve pain associated with inflammation or procedures such as tooth extraction and reduction of fractures. Poppy seeds were used in oral perioperative analgesic syrups or paste; their boiled solution was often used for inhalation.

Anaesthesia by inhalation was mentioned in R Burton's *Arabian Nights*, and Theodoric of Bologna (1206-98), whose name is associated with the soporific sponge, got his information from Arabic sources.[2] The sponge was steeped in aromatics and soporifics and dried; when required it was moistened and applied to lips and nostrils. The Arabic innovation was to immerse the "anaesthetic sponge" in a boiled solution made of water with hashish (from Arabic hasheesh), opium (from Arabic afiun), c-hyoscine (from Arabic cit al huscin), and zo'an (Arabic for wheat infusion) acting as a carrier for active ingredients after water evaporation.

Arabs in Andalusia were the pioneers of artificial ice making. Freezing or rubbing with ice was used for local anaesthesia in minor external operations. Abdominal surgery (laparotomy and caesarean section) was practised around 900-1000 AD and was dependent on detailed knowledge of anatomy, anaesthesia, antisepsis, and proper instruments.[3]

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1 Carter AJ. Narcosis and night shade. *BMJ* 1996;313:1630-2. (21-28 December.)
2 Al-Fallouji M. History of surgery of the abdominal cavity: Arabic contributions. *Int Surg* 1993;78:236-8.
3 Al-Fallouji M. Arabic caesarean section. *Scott Med J* 1993;38:3-4.

Promoting health in prisons

Discussion is needed between prison health service and NHS

EDITOR—The chief inspector of prisons recently proposed that the NHS should assume responsibility for the delivery of all health care, including that required in prisons.[1 2] The prison health service under-

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Arab clinicians used opium infusions throughout the middle ages

standably believes that this implies criticism of its previous performance and threatens its future. For example, J M Hall claims that in many ways the prison healthcare service provides a better service for its patients than does the NHS and that the NHS would provide an inferior service for prisons.[3] Perhaps this view rests on the assumption that the existing staff would be replaced and the existing service revamped by people with no experience of the special problems encountered in prisons.

Prison health care requires special skill and needs to build on the existing base of caring staff to provide support and rehabilitation for inmates. The service's problems, however, include isolation and the low pay and status of healthcare staff. Prisoners are part of the general population, who will shortly re-enter society—hopefully, better able to contribute to it. The provision of rehabilitation for drug misuse, care and support for those with learning disability or psychiatric illness, immunisation against hepatitis B, and health education about bloodborne viruses are an essential part of the care required in prison and are already being supplied by the service. Acute psychiatric care is often, however, lacking, because NHS psychiatrists may not regard inmates as their responsibility. Better support from the NHS would greatly enhance the effectiveness of these interventions and provide seamless care for prisoners moving back into the community.

The chief inspector of prisons advises discussion about urgent, genuine, and lasting improvements, and the prison health service should welcome this proposal.

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1 Inspectorate of Prisons for England and Wales. *Patient or prisoner? A new strategy for health care in prisons.* London: Home Office, 1996.
2 Squires N. Promoting health in prisons. *BMJ* 1996;313:1161. (9 November.)
3 Hall JM. Promoting health in prisons. *BMJ* 1997;314:302. (25 January.)

More resources are needed

EDITOR—I fear that, since the somewhat vacuous statements from the Inspectorate of Prisons suggesting that the NHS should take over prison care, a predictable argument is developing over whether the healthcare service for prisoners or the NHS would provide a better service to patients who are prisoners.[1 2] This is a meaningless debate. Having worked in the NHS for 10 years and now moved into the healthcare service for prisoners, I see a great deal of talent and enthusiasm among medical and non-medical healthcare staff. What is lacking is resources. When this subject is raised there is a great temptation among those who pass their time by shifting paper in Whitehall to determine that resources do not count and that the only question is which logo should adorn the front door of the healthcare centre in prisons, or whether yet another costly change in management structure would improve the likelihood of patients receiving adequate care. The result is that few people in prisons now have the slightest idea of who is responsible for providing each service.

Currently the main lack in the provision of medical care in my prison is the absence of any strategy for helping mentally disordered offenders. A costed bid to provide this service, which had the backing of all the healthcare workers in this establishment plus the governor, has received no backing at all. Apparently the answer to my problems is to come from another reorganisation, in which another tier of management is to be placed above me and a senior medical officer will be added to the healthcare adviser to advise me on how to handle the psychiatric morbidity at my prison. Needless to say, my hopes that the senior medical officer appointed might work in the same county as my patients at the prison have proved vain. The solution is obvious: provide the doctors and other healthcare staff who are actually working with patients with the resources necessary to fulfil their roles.

I fear that the problem will continue; while the great and the good spend their time arguing over which particular bureaucrat should be managing this structure they fail to divert their attention and resources to the people who are the most important parts of this organisation.

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1 Squires N. Promoting health in prisons. *BMJ* 1996;313:1161. (9 November.)
2 Hall JM. Promoting health in prisons. *BMJ* 1997;314:302. (25 January.)

Medicosocial aspects of depopulation in Belarus

EDITOR—In 1994 the population of Belarus began to decline progressively: during 1994 the population fall was 22 200 (0.2% of inhabitants), in 1995 it was 32 800 (0.35%), and in the first half of 1996 it was 17 300. Such depopulation predominately shows the demographic consequences of social policy in the former Soviet Union. Currently, during a time of dramatic disturbances, a truly vicious circle is operating in the sick social organism. On the one hand, the social malfunctioning harms the physical and mental health of the nation. On the other hand, national revival requires a healthy workforce, but the proportion of able bodied people in the population has steadily decreased. Furthermore, people living in a sick social environment often develop stable, psychologically deviant behaviour, which is usually followed by the development of pseudosocial norms of behaviour, thus confirming the existing social reality.

Depopulation is an integral process that reflects the functional exhaustion of the whole social system, but certain medicosocial problems are crucially important.

Firstly, there is the problem of alcohol misuse. Belarus has the highest indices for the consumption of alcohol per head of population among the countries of the Commonwealth of Independent States.[1] The increase in mortality, both from natural causes—for example, cardiovascular diseases—and from violence, is mainly caused by heavy drinking. Lethal alcohol intoxication has become one of the leading causes of unnatural death in middle aged men. In general, parental misuse of alcohol has more consequences for children's healthy development than has the Chernobyl nuclear disaster. Hard drinking leads to moral and social degradation of the person, which adds to the vicious circle mentioned above.

Secondly, the lack of measures of social and medical prevention is extremely pernicious for young people, who now find themselves in a social and moral vacuum. Most of them cannot find any internal, nationally related links with society. As a result, all social weakness manifests more sharply in young people. Thus, from 1990 to 1992 the suicide rate among men under 20 doubled. The spread of antisocial and unhealthy behaviour among young people will considerably worsen the demographic situation in the near future.

Finally, the healthcare system is disastrous. The weak national health service is incapable of dealing with the increasing burden of social and ecological problems. Radical changes in health care are necessary, but they cannot precede political and economic reform.

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1 Gosudarstvenniy doclad o soctoyanii zdorov'ya naseleniya Rossiiskoi Federatsii v 1992 g. *Zdravookhranenie Rossiiskoi Federatsii* 1994;3:3-8.

Routine follow up of breast cancer in primary care

EDITOR—The question of whether and then how to follow up patients after the diagnosis of breast cancer and who should do it remains vexingly unanswered by the inadequacies of retrospective reviews and short term small prospective studies. Most studies concentrate on the efficiency or otherwise of various forms of routine follow up to detect local or distant recurrence. Occasionally the views of patients are surveyed. No studies seem to address what for me is an equally crucial issue—the need for clinicians to learn about the behaviour of this disease and to measure, investigate, and understand the physical and psychological morbidity associated with what doctors and the disease do to these patients.

Specialists are not created. They do not mysteriously acquire acumen, expertise, and understanding overnight when they become fellows of a royal college. They learn much as registrars, and that learning does not stop at elevation to consultant.

When asked by patients why I need to continue to see them I gladly inform them that they do more for me and my juniors and, hopefully, for other subsequent patients than I do for them—and I am grateful.

As a result of seeing patients treated over many years in routine follow up, my colleagues and I in Edinburgh recognised morbidity problems that are associated with postmastectomy radiotherapy, discussed and then altered the technique and fractionation, and over the subsequent 11 years assessed the outcome in terms of local recurrence, survival, and morbidity.[1] A policy to devolve follow up to general practitioners, who see relatively few breast cancer patients,[2] or to specialist nurses,[3] who may have a relatively short career in an institution, or to patients' inclination[4] may not be useful in educating future oncologists or re-educating established ones.

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1 Rodger A, Jack WJL, Kerr G. A change in postmastectomy radiotherapy fractionation: an audit of tumour control, acute and late morbidity. *Breast* 1996;5:244-9.
2 Rainsbury D. Routine follow up of breast cancer in primary care: follow up by non-specialists should not be encouraged. *BMJ* 1996;313:1547. (14 December.)
3 Kunkler I, Tienney A, Jodrell N, Forbes J. Routine follow up of breast cancer in primary care: more use should be made of specialist nurses *BMJ* 1996;313:1547-8. (14 December.)
4 Kirkbridge P, Vallis K. Routine follow up of breast cancer in primary care: study of open access centre for patients with breast cancer is planned. *BMJ* 1996;313:1547. (14 December.)

Second study supports results of Whitehall study after retirement

EDITOR—M G Marmot and Martin J Shipley's finding of persistent socioeconomic differences in mortality among male civil servants beyond retirement ages has evident implications for social policy issues.[1] We present corroborative evidence from the longitudinal study of the Office for National Statistics. Whereas the Whitehall study is based on a sample of civil servants, the longitudinal study is a study of a representative 1% sample of the total population of England and Wales (about 650 000 people). Details of the study can be found elsewhere.[2]

Current analyses use deaths between 1971 and 1992 to compare groups classified by occupation based social class, housing tenure, and access to a car. Using person years at risk, we derived standardised mortality ratios for all causes adjusted for age and calendar period.[3] Women are classified by their partner's social class, or otherwise by their own. Table 1 shows the effects of occupation, housing tenure, and access to a car after retirement age. Mortality is uniformly higher among both men and women without access to a car than among those with access to a car, except among women aged 75 and over who live in local authority housing and are in a non-manual social class. There is also systematic variation by housing tenure and social class. Marmot and Shipley show that the predictive power of occupational status fell with age, more than did that of car ownership. Our analyses suggest that housing tenure may also be an important indicator of variation in mortality among elderly people.

In summary, our work supports Marmot and Shipley's general assertion that household based measures continue to predict relative differences in mortality after retirement.

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1 Marmot MG, Shipley MJ. Do socioeconomic differences in mortality persist after retirement? 25 Year follow up of civil servants from the first Whitehall study. *BMJ* 1996;313:1177-80. (9 November.)
2 Hattereley L, Creeser R. *Longitudinal study 1971-1991. History, organisation and quality of data.* London: HMSO, 1995. (Series LS, No 7.)
3 Goldblatt P, Jones D. Methods. In: Goldblatt P, ed. *Longitudinal study. Mortality and social organisation.* London: HMSO, 1990:51-66.

Table 1 Standardised mortality ratio (SMR)* for men and women by access to a car, housing tenure, and social class, according to Office for National Statistics' longitudinal study 1971-92. Figures in parentheses are 95% confidence intervals

	Age at death (years)			
	65-74 (men) or 60-74 (women)		≥75	
Socioeconomic status	Men	Women	Men	Women
Access to a car				
Owner occupied housing:				
Non-manual	75 (73 to 78)†	71 (68 to 74)†	82 (79 to 84)†	81 (78 to 85)†
Manual	83 (80 to 87)†	86 (82 to 90)†	93 (90 to 97)†	88 (84 to 92)†
Local authority housing:				
Non-manual	90 (81 to 99)†	86 (77 to 97)†	95 (84 to 107)	97 (83 to 112)
Manual	104 (99 to 109)	101 (96 to 107)	105 (99 to 111)	97 (90 to 105)
Privately rented housing:				
Non-manual	89 (82 to 96)†	84 (77 to 93)†	82 (75 to 89)†	90 (81 to 99)†
Manual	100 (94 to 107)	91 (83 to 99)†	104 (97 to 112)	100 (91 to 109)
No access to car				
Owner occupied housing:				
Non-manual	95 (89 to 102)	84 (78 to 90)†	98 (94 to 102)	90 (86 to 93)†
Manual	103 (99 to 107)	101 (96 to 106)	102 (99 to 105)	96 (92 to 99)†
Local authority housing:				
Non-manual	118 (106 to 130)†	100 (98 to 117)	100 (90 to 111)	92 (85 to 100)
Manual	122 (118 to 126)†	122 (118 to 127)†	116 (113 to 120)†	107 (103 to 111)†
Privately rented housing:				
Non-manual	111 (100 to 123)	108 (98 to 118)	102 (94 to 109)	95 (89 to 101)
Manual	114 (109 to 120)†	110 (104 to 117)†	102 (105 to 113)†	104 (100 to 108)

*Relative to all men (SMR=100) and all women.
†SMR significantly different from 100.

New Zealand priority criteria project

More use should be made of patient oriented quality of life measures

EDITOR—The New Zealand priority criteria project is worthy of wide debate, and Britain has much to learn from it.[1 2] Unlike the approach taken in Oregon, the project recognises that benefits from treatment depend on the selection of patients and the threshold for intervention, which is important in maximising the health gain from healthcare resources. The New Zealand approach also provides a mechanism for addressing equity based on need rather than on service measures such as waiting times and levels of activity.

The criteria used in the project are a mix of symptoms, clinical signs, impairments, and disabilities. However, the symptoms and clinical signs (which are impairments themselves) account for most of the available 100 points, while disability as represented by the criterion "ability to work, care for dependants, or live independently" can score only 10-16 points maximum. This is explained by the fact that "a certain degree of misgiving was usually noted about incorporating these social factors" during the professional advisory groups' discussions.

This weighting can be criticised because the most important criterion for treatment is surely the impact of a condition on a person's lifestyle rather than the simple presence of a symptom, clinical sign, impairment, or disability. A recent survey of ophthalmologists found that most regarded disability as being more important than visual acuity when considering whether to offer cataract extractions[3]—for example, a visual acuity that would prevent driving has a much greater impact on someone whose work entails driving than on non-drivers. The imbalance in the New Zealand weight-

ings might be explained by the fact that there are already well known assessment procedures with severity gradings for symptoms and signs. This adds additional weight to the argument that further development and greater use of disability or patient oriented quality of life measures are urgently needed in effectiveness and cost effectiveness studies.

Finally, we wish to make a more specific point. Ocular comorbidity, for which treatment is less successful, is usually regarded as a relative contraindication to cataract surgery and should not therefore contribute positively to the overall score.

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1 Hadorn DC, Holmes AC. The New Zealand priority criteria project. Part 1. Overview. *BMJ* 1997;314:131-4. (11 January.)
2 Hadorn DC, Holmes AC. The New Zealand priority criteria project. Part 2. Coronary artery bypass graft surgery. *BMJ* 1997;314:135-8. (11 January.)
3 Mordue A, Parkin DW, Baxter C, Fawcett G, Stewart M. Thresholds for treatment in cataract surgery. *J Public Health Med* 1994;16:393-8.

Project has potential to improve patient care, but only with injection of funds

Editor—The report by David C Hadorn and Andrew C Holmes about the New Zealand priority criteria project implies a consensus among cardiologists and cardiac surgeons in New Zealand.[1] Alas, it is not so.

Between 1990 and 1994 the rate of publicly funded coronary bypass surgery in New Zealand fell by 9% to 33/100 000, while discharges from hospital of patients with angina or infarction rose by 19%. There are no plans for any long term increase in rates of coronary surgery, and patients requiring surgery are waiting longer.

We have compared a consecutive case series of patients referred for isolated coronary bypass surgery from Christchurch Hospital (referral base for 500 000 people) between 1 July and 31 December 1993[2] with two Canadian case series.[3 4] Of the 88 patients accepted for surgery over this period, a quarter had stenoses of ⩾50% diameter in the left main coronary artery and another three fifths had multivessel disease that included the proximal left anterior descending coronary artery.[2] Just over three fifths had angina at rest or on minimal exertion. Priority scores used in Ontario[5] and New Zealand[1] were applied retrospectively. The clinical characteristics of the Christchurch and Canadian patients were similar, as were median Ontario priority scores, but New Zealanders waited a median of 92 days compared with 17 days in the larger Canadian series.[3] Of the Christchurch patients waiting at home for surgery, a quarter were readmitted with unstable syndromes or myocardial infarction before their surgery. One patient died. Patients with left main coronary disease waited a median of 41 days, versus 7 days in Ontario.[3]

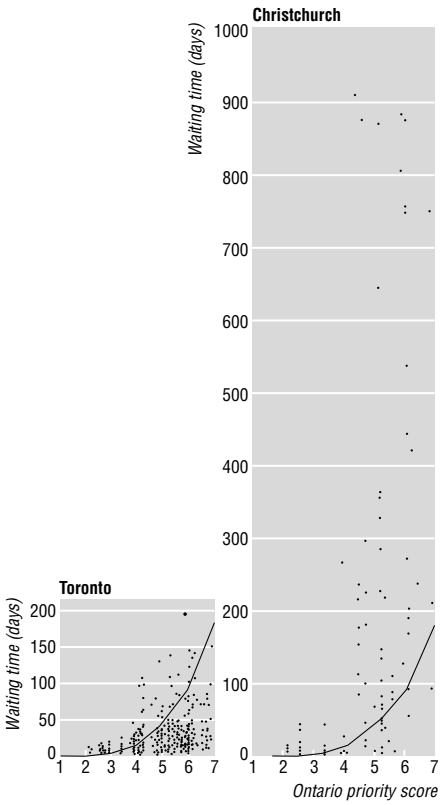

Fig 1 Waiting times for coronary bypass surgery

Figure 1 shows the difference in waiting times between our 1993 case series and the Toronto series reported in 1993,[4] with patients classified according to the Ontario priority score. The problem is getting worse in New Zealand: of 415 patients referred from Christchurch between 1 January 1994 and 31 December 1995, 13 died while on the waiting list. Patients with left main coronary disease now wait a median of 73 days.

The priority criteria project has the potential to improve patient care, but only with the injection of sufficient funds to ensure that people who need surgery get it. Our rate of coronary surgery is two thirds that in Canada and half that in Australia. Use of the previously validated urgency score[5] makes it obvious that New Zealanders wait far too long for bypass surgery. We do not need a system that solves the problem of waiting lists by taking half of the deserving patients off such lists. There will be more deaths, more readmissions, and more health dollars wasted.

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In Scotland, Mental Welfare Commission inquires into homicides by psychiatric patients

Editor—Elaine Murphy and Louis Appleby and colleagues write about inquiries into homicides by psychiatric patients.[1 2] I thought it relevant to give some information about the situation in Scotland, which combines some of the advantages of the proposals in the two letters.

In Scotland the Mental Welfare Commission has a duty under the Mental Health (Scotland) Act 1984 to inquire into any case in which it seems that there may be a deficiency in care or treatment. This permits the commission to make inquiries into homicides by psychiatric patients as well as into other potential deficiencies in care. This inquiry is normally carried out by commissioners and officers of the commission on an informal and confidential basis, with reporting to the relevant authorities, although an inquiry into a homicide carried out in 1995 at the request of the secretary of state was made public by him.[3] The commission also has a power under the act to carry out a formal inquiry with the power of a court of law, but it has not used this yet, regarding it as a valuable reserve power to use if necessary.

I believe that the commission's approach offers an appropriate and cost effective solution to the need for independent inquiry into homicide and other situations. (It should be remembered that an act in which the intention might have been to kill may prove non-fatal through chance factors. Inquiry into such events is also important.)

There is an advantage in having a single body conducting such external inquiries in terms of the accumulation of experience and consistency of approach. The commission sees its role as complementary to the national confidential inquiry into suicide and homicide by people with mental illness, since it is able to take up issues arising from the inquiry with organisations and individuals involved in the previous care of the patient. A range of professional skill is available within the commission, but the commission can also call on external expert evidence if required.

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1 Murphy E. Inquiry into homicides by psychiatric patients. *BMJ* 1997;314:375. (1 February.)
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Which doctors die first?

Lower mean age at death in doctors of Indian origin may reflect different age structures

EDITOR—In their analysis of the age at death of doctors in the *BMJ*'s obituary columns D J M Wright and A P Roberts make the classic and fundamental error of inferring risk based solely on cases without denominators.[1] They confuse lower mean age of death with earlier mortality; different mean age at death in doctors of Indian origin compared with doctors of United Kingdom origin may, however, simply reflect differing age structures of the two groups. In Great Britain the percentages of the population aged 60-74 years and over 74 years are higher among white people (14% and 7% respectively) than among some other ethnic groups (Indian 6%, 1%; Black African 2%, 1%; Black Caribbean 11%, 1%).[2] The corresponding estimated median ages are 37, 29, 27, and 31.[2]

The differing age structures may be due to differing birth and mortality rates and, more probably, immigration and migration cohort patterns. The lower proportion of people aged 60 years and over in the Indian and black groups results in lower median or mean age than in white people. Similarly, the lower mean age of death of anaesthetists is difficult to interpret without knowledge of the age distributions of the various specialties in medicine.

There are undoubtedly ethnic variations in health.[3] However, analyses without denominators are unlikely to provide convincing evidence and may lead to erroneous conclusions.

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1 Wright DJM, Roberts AP. Which doctors die first? Analysis of *BMJ* obituary columns. *BMJ* 1996;313:1581-2. (21-28 December.)
2 Haskey J. The ethnic minority populations of Great Britain: their estimated sizes and age profiles. *Population Trends* 1996;84:33-9.
3 Balajaran R. Ethnicity and variations in the nation's health. *Health Trends* 1995/6;27:114-9.

Recording the doctors' sex might have led authors to suspect their conclusions

EDITOR—D J M Wright and A P Roberts conclude that "anaesthetists died younger than those in primary care" and that "doctors from the Indian subcontinent died before those from the rest of the English speaking world."[1] Although I realise that the Christmas issue of the *BMJ* is no place for serious science, I would be surprised if in the future I did not see citations of these cavalier and erroneous claims. They suffer from a classic error of interpretation,[2] one from which two years ago the *Lancet* also suffered indirectly in a lead editorial[3] citing a claim, also based on obituary data,[4] that women doctors died earlier, which was attributed to greater stress. If Wright and Roberts had recorded the sex of the doctors, as they should have done, then their error might have become more apparent and made them suspect the rest of their conclusions.

There seems little doubt from the data that anaesthetists, Indian doctors, and women doctors have an earlier age of death reported in their obituaries. That is not in dispute. But, seemingly paradoxically, that finding does not mean that these doctors die relatively earlier. To show that a group of individuals dies earlier one must know the ages not only of those who are dead but also of those who are alive. Any study carried out now would find that anaesthetists, Indian doctors, and women doctors are also younger than other doctors. That is because anaesthetics is a relatively young specialty, because the influx of Indian doctors into Britain occurred only since the second world war, and because medical schools have only recently admitted many women medical students. Increased mortality can therefore be shown only when average age at death is disproportionately lower than the average age of those living.

The fallacy would be readily seen if one knew whether the doctors whose obituaries were published owned an Oasis CD, were called Tracy or Kevin, had recently become members of the Royal College of Physicians, had done molecular biology research, or even, dare I suggest it, had published a paper in the *BMJ*. Each of these subgroups would also have died at an earlier age—not, however, because of those characteristics but because, as a result of secular changes, they are markers of coming from a younger cohort and therefore of having a lower average age, either in life or at death.

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1 Wright DJM, Roberts AP. Which doctors die first? Analysis of *BMJ* obituary columns. *BMJ* 1996;313:1581-2. (21-28 December.)
2 McManus IC. Increased mortality in women doctors [letter]. *Lancet* 1995;345:796-7.
3 Burnished or burnt out: the delights and dangers of working in health [editorial]. *Lancet* 1994;344:1583-4.
4 Falck J, Thiels C. Das Sterbealter der Ärzte in Berlin-West und Hessen von 1964 bis 1976. *Med Klin* 1979;74:1140-3.

Authors' reply

EDITOR—We were aware of the absence of denominators of the age of deaths in the article. This caveat had been included in a preliminary draft, but we felt that our admission that the dataset was incomplete for a number of reasons covered the point. It might be argued that when the numerator is death, especially if the population is substantial, then it will affect subsequent age groups, which would partially compromise the denominator.

We suggest that a valid denominator, for which we know no source, would be the number of doctors born in each area and still living in Britain. The data referred to by Professor Khaw are not apposite, since theyrelate to the group that the respondents considered they belonged to rather than to where they were born. The data were also based on percentage populations including age groups for 0-24 years, which were disproportionately high in the ethnic populations, and "white" cannot be related to "United Kingdom" as country of origin.

We are also not sure why Professor McManus regards anaesthetics as a young specialty as two of the 26 anaesthetists died at age 92 years and a further three at 88 years. The lower mean age was largely a result of seven dying under the age of 50, of whom four were aged under 40. The earlier death of anaesthetists was first foreshadowed in a Russian study, when inhalation of noxious gases was incriminated.[1] If this was so, why should other theatre staff—such as surgeons—not be similarly affected? However, suicide as an alternative explanation was presented,[2 3] a suggestion perhaps reinforced by a stereotype of anaesthetists as tense and introverted, happier with more solitary rather than social pursuits.[4] More recent studies imply that although doctors have twice the rate of suicide of a comparable social group, anaesthetists are no more prone to it than any other members of the medical profession.[5] What may be significant is the increased number of early retirements of anaesthetists because of ill health and the greater number of deaths.[5] The reason for this remains uncertain.

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1 Vaisman AI. Work in operating theatres and its effect on health of anaesthiologists. *Eksperimenta'naia Khirurgiia Anesteziologiia* 1967;12:44-9.
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5 McNamee R, Keen RI, Corkhill CM. Morbidity and early retirement among anaesthetists and other specialists. *Anaesthesia* 1987;42:133-40.

Correction

Prescribing antidepressants in general practice

An editorial error occurred in the fifth letter of this cluster, by Imad M Ali (15 March, p 827). In the last sentence the words "studies based on" were omitted before "patients." The sentence should have read: "The important thing is that studies based on patients with a diagnosis of depression from a general practitioner (without a concurrent standardised psychiatric assessment) may be flawed because the concept of depression in primary care is broad and the use of antidepressants in itself does not mean that major depression is being treated."