Letters

Informed consent in medical research

Doctors are arrogant to think they need to debate issue of patient consent

EDITOR—The editorial by Richard Smith raised the issue of publishing studies in which the researchers did not seek patients' consent.[1] Firstly, I would think that of all the professions, only in medicine would there be any sort of debate about whether people need to be told that they, their bodies, their body fluids, their emotions, or whatever were to be subjects of research. This is arrogance on the part of doctors. Has anyone thought of asking these "patients" what their opinions are?

Secondly, I also think that doctors in developing countries need to be especially careful about obtaining consent from patients for anything, not only research. I would like to know that when I read a paper from a developing country in the *BMJ*, I can be sure that the individuals on whom the research was done had given informed consent.

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1 Smith R. Informed consent: the intricacies. *BMJ* 1997;314:1059-60. (12 April.)

No one has a monopoly on deciding what is ethical

EDITOR—Having just come to the end of my term as chairman of our local research ethics committee, I would like to contribute to the debate on informed consent.

I have no doubt that informed consent should be obtained in virtually all research studies. The difficulty comes in those rare instances when the need to obtain informed consent may be waived. Len Doyal has made a thoughtful and useful contribution to the debate,[1] but it is interesting that, whereas I would have said that the study by Satish Bhagwanjee and colleagues qualified under his suggestions,[2] he seems to imply that it would not.

The commentaries of Rajendra Kale and Sheila McLean were critical of the two studies published in the *BMJ*, [2 3] but they failed to address the specific issues raised by the trials and resorted instead to vague generalisations. Neither was prepared to consider seriously the harm that can be done by not performing trials from which bias has been excluded as far as possible.[4] In contrast, Martin Dennis and Bhagwanjee and colleagues, who defended their decision not to obtain informed consent, wrote clearly about the different issues entailed and had obviously agonised about the problem.[2 3] I believe that it was perfectly reasonable in both studies not to obtain informed consent. In neither case was there any possibility of harming the participants and important information for the care of future patients was obtained. I do not subscribe to the view that not seeking informed consent indicates a failure to respect the subjects in these studies. Indeed, the care with which the issues were considered before starting the studies and the safeguards that were put in place indicate that the reverse was true.

Richard Smith asked whether the *BMJ* should publish papers describing studies in which informed consent was not obtained.[4] There is clearly so much disagreement about the situations in which such trials might be conducted that it would be wrong for the *BMJ* to decline to publish the results of these studies if they have been given the approval of properly constituted research ethics committees. No one can claim to have a monopoly on deciding what is ethical. By publishing such trials the *BMJ* will provide important material showing what different research ethics committees think. These data may then inform the continuing debate with the decisions taken by a wide range of concerned individuals, dealing with real life issues.

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1 Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ* 1997;314:1107-11. (12 April.)
2 Bhagwanjee S, Muckart DJJ, Jeena PM, Moodley P. Does HIV status influence the outcome of patients admitted to a surgical intensive care unit? A prospective double blind study (with commentaries by R Kale, S Bhagwanjee *et al*, and YK Seedat). *BMJ* 1997;314:1077-84. (12 April.)
3 Dennis M, O'Rourke S, Slattery J, Staniforth T, Warlow C. Evaluation of a stroke family care worker: results of a randomised controlled trial. *BMJ* 1997;314:1071-7. (12 April.)
4 Tobias JS. *BMJ*'s present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct. *BMJ* 1997;314:1111-4. (12 April.)
5 Smith R. Informed consent: the intricacies. *BMJ* 1997;314:1059-60. (12 April.)

Let readers judge for themselves

EDITOR—I am a medical statistician, not a doctor, so my experience is rather remote from the patient. I think there are two issues here: Is it ever right to randomise people without their consent? Is it ever right to treat or measure people without their consent? I think it can be right to randomise people without their consent when randomisation is to what the person would have received in the absence of the trial. Thus the stroke worker study seems defensible.[1] I did such a study—the "Know your midwife" study—in which the lead researcher, very committed to the scheme, thought that no woman who knew of the scheme would accept anything else.[2] Women were randomised to be offered the continuity of a midwifery care regimen and then offered a choice of that regimen or standard care. Others were offered standard care only. All were asked to consent to a study of events around birth and interviewed. I thought this was all right and still do. Sometimes we randomise people by general practice. I don't think we could get consent to randomisation. However, we can still obtain consent to treatment.

I think it is rarely acceptable to treat a person without consent. But consider a patient who is unconscious after an overdose. Should we revive the patient? The patient's action suggests that consent is not given, but I think we might do it anyway. I have recently discussed a trial of different methods of treatment for these cases. I think my conclusion would have to be that if it is ethical outside a trial it would be ethical inside a trial, too. However, the Durban

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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.

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Letters will be edited and may be shortened.

patients were mostly able to consent, as the HIV test could presumably have been done afterwards with stored blood.[3] I think that study was unethical.

I think it is dangerous to let one moral principle—informed consent—become absolute. Hence I would not banish all such research from the *BMJ* and only if the editor thought the work indefensible would I keep it out. If the issue was debatable I think I would publish the paper, though I would expect authors to justify their actions. Readers could then judge for themselves.

Thanks for a stimulating issue.

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1 Dennis M, O'Rourke S, Slattery J, Staniforth T, Warlow C. Evaluation of a stroke family care worker: results of a randomised controlled trial (with commentaries by S McLean, M Dennis). *BMJ* 1997;314:1071-6. (12 April.)
2 Flint C, Poulengeris P, Grant A. The "Know your midwife" scheme—a randomised trial of continuity of care by a team of midwives. *Midwifery* 1989;5:11-6.
3 Bhagwanjee S, Muckart DJJ, Jeena PM, Moodley P. Does HIV status influence the outcome of patients admitted to a surgical intensive care unit? A prospective double blind study (with commentaries by R Kale, S Bhagwanjee *et al*, and Y K Seedat). *BMJ* 1997;314:1077-81. (12 April.)

Ethics committees and the *BMJ* should continue to consider the overall benefit to patients

EDITOR—We support Martin Dennis in his commentary to his and his colleagues' paper that the decision to fully or partially inform consent should take into account the likely effect on important outcome measures, as well as the benefit of good research for all patients.[1]

We made the difficult decision—in consultation with local ethics committees—that patients attending their general practitioner with sore throat should be asked to consent to the procedures and to the aim of assessing the natural history, but in trying to "mimic" normal practice, doctors were encouraged not to discuss the randomisation to one of three approaches in common clinical use: antibiotics, no antibiotics, or the offer of delayed antibiotics.[2] Randomisation to the three approaches replaced the normal bias or preference of the general practitioner, which the patient is also uninformed about.

We showed that prescribing antibiotics medicalises sore throat and increases intention to consult. We believe that a full discussion of the educational purpose of the research, and of the different management groups—which must be rare in normal practice—would have significantly biased the results so that groups would have been much more similar. High prescribers would then see no benefit from changing their prescribing, with encouragement to waste the £60m-120m of NHS money spent annually on sore throat, with disbenefit to all future patients. Similar arguments apply to fully informing the control group of many other important open studies—for example, effect of leaflets on stopping smoking and the Oxcheck study. The technical breach of autonomy—to give complete information for some patients on one occasion—has to be seen in the context of deviancy from routine practice and judged against breaching the same principle the next time the same patient sees their doctor—that is, not being able to inform the patient fully of correct management, as well as the beneficence to many more patients. This utilitarian argument was made by Len Doyal in condoning the use of medical records,[3] and there is no clear justification of why the ethical issues for randomised trials should be different.

Adopting an absolute ethical view in open trials ignores the realities of—and would undermine the ability of research to inform—normal practice and thus could ultimately harm patients, including those who agree to take part in trials. The *BMJ* and ethics committees should continue to judge the overall benefit for patients.

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1 Dennis M, O'Rourke S, Slattery J, Staniford T, Warlow C. Evaluation of a stroke family care worker: results of a randomised controlled trial (with commentaries by S McLean, M Dennis). *BMJ* 1997;314:1071-7. (12 April.)
2 Little P, Williamson I, Warner G, Gould C, Gantley M, Kinmonth AL. Open randomised trial of prescribing strategies for sore throat. *BMJ* 1997;314:722-27. (8 March.)
3 Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ* 1997;314:1107-11. (12 April.)

Risk of bias may be another reason not to seek consent

EDITOR—Reading through the various articles in the 12 April issue has confirmed the view I already held that there are situations in which informed consent is more trouble than it is worth. Consequently, I am of the view that the *BMJ* was right to publish the papers in question and would be wrong to impose a ban on publishing such papers in future.

The rights of individual patients must, of course, be protected, but not to the exclusion of all other considerations; people have obligations as well as rights. I consider it sufficient that a study is approved by an ethics committee. If the members can be convinced that the study remains ethical without informed consent, then the paper should be considered for publication. It would be unethical not to publish a sound and valuable piece of work, thus denying useful knowledge to the medical community simply because informed consent was not sought. Presumably the lobby in favour of the ban hopes that such studies would not then be done. This I doubt.

I think any policy adopted by the *BMJ* on this issue should be framed in terms of ethics committee approval. If the *BMJ* decides to follow a policy along the lines proposed by Doyal[1] I would like to see at least one other category of exception—that is, where there is a perceived risk that seeking informed consent might bias the conclusions of the study (as in the stroke family care worker study[2] and the breast cancer study of McArdle *et al*[3]).

As another example, suppose one wished to set up a study comparing methods of persuading pregnant women to stop smoking during pregnancy. If you tell the patient that you are going to try to stop her from smoking either by not haranguing her or by haranguing her frequently her ultimate behaviour might be influenced by this knowledge. This is a testable hypothesis. It would be possible to set up such a study as a two by two factorial in which one of the treatment factors was informed consent and the other was whatever intervention treatment was of interest. The presence of an interaction between the two factors would support the hypothesis. I am not aware that such a study has ever been done, but it would help to settle the question of whether seeking informed consent can bias the results of a study. If the *BMJ* had already implemented a ban on publishing papers without informed consent how would the results of such a study see the light of day?

Finally, I applaud the *BMJ*'s decision to open this issue to wider debate and seek the readership's views. I hope it generates a lively response.

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1 Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ* 1997:314:1107-11. (12 April.)
2 Dennis M, O'Rourke S, Slattery J, Staniforth T, Warlow C. Evaluation of a stroke family care worker: results of a randomised controlled trial (with commentaries by S McLean, M Dennis). *BMJ* 1997;314:1071-6. (12 April.)
3 McArdle JMC, George WD, McArdle CS, Smith DC, Moodie AR, Mark AV, *et al.* Psychological support for patients undergoing breast cancer surgery: a randomised study. *BMJ* 1996;312:813-7.

Clinicians are being disingenuous with themselves

EDITOR—I would like to raise a concern about the relation between the ethics of medical research and the ethics of clinical medicine. Clinicians play a lead role in the great majority of medical research projects and the framework within which they practice medicine plays a part in their judgment of the ethics of their research. Although the principle of informed consent is widely accepted, the actuality may be different, as illustrated by Ganapati Mudur's report of the condemnation by ethicists of a study in India of the clinical course of cervical dysplasia.[1] The study is necessary because the available evidence is insufficient to quantify the risks of dysplasia, and shows that cervical dysplasia normally resolves spontaneously rather than progressing to cancer. A gynaecologist objecting to the study argued that it was unethical because "the investigators had not informed the study participants that their lesions were known to progress to cancer."[1] While clinicians are being disingenuous with themselves it is hard to see how they can be truly honest with their patients.

In Britain, thousands of women receive treatment for cervical dysplasia each year, believing that it is saving them from cancer, when the chances are that they have been subjected to an unnecessary intervention. This suggests that they are being treated on false pretenses rather than on the basis of informed consent.

If, as proposed, the *BMJ* and other journals refused to publish the results of studies in which informed consent had been obtained,[2] the problem of not obtaining informed consent in research would eventually be solved—but though researchers would be learning the lesson the hard way, this would abuse the time, energy, and goodwill of patients who had volunteered to participate in studies without informed consent, on the grounds that their participation would benefit humankind. If the real problem is informed consent in clinical practice, making researchers do things the right way won't solve it.

It is excellent that the editorial board of the *BMJ* is concerned to tackle this problem and is opening the debate on the way to proceed. Ensuring that those who have been abused by the present system are given a public voice, as in the anonymous personal view,[3] might be a more ethical way to proceed than a blanket ban on publication of the results of some studies.

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1 Mudur G. Indian study of women with cervical lesions called unethical. *BMJ* 1997;314:1065. (12 April.)
2 Smith R. Informed consent: the intricacies. *BMJ* 1997; 314:1059. (12 April.)
3 Anonymous. All treatment and trials must have informed consent. *BMJ* 1997;314:1134-5. (12 April.)

We all have a responsibility to contribute to research

EDITOR—Jeffrey S Tobias identified an atmosphere of mistrust by patients towards clinical trials.[1] Perhaps we can begin to reverse this atmosphere by involving those groups of thoughtful bystanders who were round the outside of the arena[2] but have now been encouraged to clamber in to join the combat.[3] Collaboration is the name of the game. Research is for the benefit of us all: all should be involved in debates about its improvement and promotion.

The Consumers' Advisory Group for Clinical Trials, a distinctive working group of professionals and patients, sees the need to promote a new image of research as an ongoing process of extreme importance. It works directly with the professions, helping to develop their protocols and to prepare their information leaflets for patients. The group identifies an urgent need to advance public education about clinical trials. Concepts such as randomisation, risk perception, and probability are poorly understood. Educating members of the public when they are well,[4] identifying the importance of language, and educating children and medical students about research concepts are all strategies that would widen appreciation of the need for research while balancing these responsibilities with the right to informed consent, as and when it is appropriate to the particular study.[5]

Such cooperation, shared responsibility, and greater understanding of research concepts will create a different attitude to research, which will be seen not as an imposition but as an activity to which we all have a responsibility to contribute.

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1 Tobias JS. *BMJ*'s present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct. *BMJ* 1997;314:1111-4. (12 April.)
2 Thornton HM. Breast cancer trials: a patient's viewpoint. *Lancet.* 1992;339;44-5.
3 Baum M. The ethics of randomised controlled trials. *Eur J Surg Oncol* 1995;21:136-9.
4 Thornton H. A "ladyplan" for trial recruitment? Everyone's business! *Lancet* 1993;341:796.
5 Thornton H. What can patients contribute to the design of clinical trials? In: Tobias J, Houghton J, eds. *New horizons in breast cancer: current controversies, future directions.* London: Chapman and Hall (in press).

Minimum ethical standards should not vary among countries

EDITOR—I am glad that you have opened discussion on the important issue of informed consent in medical research, and in such a comprehensive way.[1] I have recently been teaching research methods in different countries. The courses always include a session on ethics in research (including qualitative research—sometimes thought not to need informed consent). Many developing countries, including some Asian countries, have not yet established research ethics committees, although there are individuals keen for this to happen. However, in one country, where members of the medical profession tend to be part of a small elite, some course participants said in a discussion on informed consent: "But if we ask the subjects they might say no."

I agree that there is a danger that researchers from developed countries may undertake certain studies in developing countries where they may believe, or argue, that ethical issues are different. I have heard the argument that informed consent by individuals is not required or appropriate where people tend to have a "group" rather than an "individual" identity, that it is sufficient to obtain consent from, for example, a village chief. I am wary of such arguments. By all means get consent from the chief, but also from every individual concerned. Although cultural differences need to be taken into account in ensuring that a study is carried out in a sensitive and ethical way, minimum ethical standards should not vary among countries.

Although Satish Bhagwanjee and colleagues clearly considered the ethical issues with great care in their study on HIV status,[2] I think that you should not publish such studies. But editorials that remind readers of this policy from time to time, and the reason for it, would be very helpful. A series of articles in simple language on different ethical issues, such as informed consent, privacy, ownership of data, community involvement, dissemination of data, responsibility for publicity, etc (including how to establish an institutional ethics committee) would be interesting and valuable.

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1 Informed consent: the intricacies. *BMJ* 1997;314:1059-60. (12 April.)
2 Bhagwanjee S, Muckart DJJ, Jeena PM, Moodley P. Does HIV status influence the outcome of patients admitted to a surgical intensive care unit? A prospective double blind study (with commentaries by R Kale, S Bhagwanjee *et al*, and Y K Seedat). *BMJ* 1997;314:1077-84. (12 April.)

South African study raises the ghosts of Nuremberg and apartheid

EDITOR—I am astonished that the *BMJ* should publish the findings of a research study that failed to seek the consent of the patients.[1] In particular by tacitly condoning this most unethical practice from a group of researchers from South Africa, the *BMJ* has missed an opportunity to teach them how the civilised world outside the confines of apartheid treats its patients. The *BMJ* also lost the opportunity to show its local edition partners all over the democratic and emerging democratic world how to stand up for ethics and human rights even in the face of extreme pressure from prospective authors (big and influential) who fail to observe accepted ethical practice.

Even before the Nuremberg code was designed in 1947[2] and then reasserted by the Helsinki declaration of 1964[3], the inviolability of the right of patients to an unambiguous and informed consent in all forms of experimentation was already standard practice. In 1898 Albert Neisser, the discoverer of the gonococcus and a pre-eminent professor of his generation, was prosecuted and fined for conducting experiments with prostitutes without their consent. The disciplinary court based its judgment not on questionable science but on the lack of patients' consent. It also concluded that intervention without consent fulfilled the criteria for causing physical injury in criminal law.[4]

Bhagwanjee and colleagues state that their study was deemed to be of sufficient importance to waive patients' right to informed consent. The Helsinki declaration prohibits absolutely any human experimentation in dying patients because it recognises that respect for the rights of patients has the same importance for the good of mankind as medical and scientific progress. Would any ethics committee in the United Kingdom, the home of the *BMJ,* approve a study without patients' consent? How many of the South African study victims were black men and women? And considering the recent experience of that country during the apartheid years, how many of such unethical practices were condoned? Who compensates for the injury that these human guinea pigs suffer? This study raises the ghosts of Nuremberg and apartheid, and it is a big shame that the *BMJ* should indirectly encourage it. There is no point in closing the stable door after the horse has escaped.[5] In this case why publish the paper before asking readers for their views on the issue of informed consent in research? I fail to see what new ground this study was going to break for mankind and even then the patient's right to give or withhold consent must not be violated.

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1 Bhagwanjee S, Muckart DJJ, Jeena PM, Moodley P. Does HIV status influence the outcome of patients admitted to a surgical intensive care unit? A prospective double blind study (with commentaries by R Kale, S Bhagwanjee *et al*, and Y K Seedat). *BMJ* 1997;314:1077-81. (12 April.)
2 The Nuremberg code (1947). *BMJ* 1996;313:1448. (7 December.)
3 Declaration of Helsinki. *BMJ* 1996;313:1448. (7 December.)
4 Vollmann J, Winau R. Informed consent in human experimentation before the Nuremberg code. *BMJ* 1996;313: 1445-7. (7 December.)
5 Smith R. Informed consent: the intricacies. *BMJ* 1997; 314:1059-60. (12 April.)

Consent is not always practical in emergency treatments

EDITOR—Richard Smith asks for readers' views on whether papers should be published only if there has been informed consent for the study.[1]

I agree completely that for the vast majority of clinical research the patient should be fully informed about all aspects of the trial or study and their consent freely and willingly obtained. However, there are occasions when this is not practical. In the main, these are clinical trials related to emergency treatment. Some aspects of care of newborn infants at birth have not been properly investigated and badly need data from good randomised trials—for example, the treatment of meconium aspiration. When meconium aspiration has occurred there is no time to ask for consent to a trial and it is rarely possible to predict the problem and ask for consent beforehand. Even with warning signs the mother is not in a position to give fully informed consent; the father may not be present, and even if he is he will be worried by what is happening to his wife and child so that it is inappropriate to try to inform him about a randomised trial and ask for his consent. There are several possible solutions to this problem, although none are ideal.

(1) Inform every woman entering the maternity hospital about the trial and ask for consent if her baby has meconium aspiration. However, to obtain such blanket consent in a busy delivery unit would be difficult and probably inappropriate as meconium aspiration occurs in a small proportion of babies. Consent would not be obtained from a woman with an acute problem on admission and the baby would not be enrolled. This will bias the trial because such babies would be likely subjects for the trial.

(2) Enrol only babies for whom consent could be obtained from the parents. This is possible, but it is likely to result in a biased trial because the most difficult acute cases will not be enrolled and therefore the babies will not represent the full clinical spectrum.

(3) Conduct a trial with the approval of a professional peer group and the hospital ethics committee that asks for consent when possible, but if this is not possible because of the nature of the emergency the patient is allowed to be enrolled in the trial. The parents would be informed and asked for their consent as soon as possible, allowing them to withdraw from the trial if they wish.

(4) Not do a randomised trial and continue to use the unproved treatment.

None of these solutions is ideal and all have ethical problems. The question is which technique is the most ethical? I suggest that the least unethical solution is to conduct a good, well planned, vetted, and approved trial even if previous consent cannot be obtained in all cases and then inform the patients, or in this case parents, afterwards. If such trials are refused publication it will impede research in emergency procedures and those that are published will be unsatisfactory because they will not represent the full range of patients.

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1 Smith R. Informed consent: the intricacies. *BMJ* 1997; 314:1059-60. (12 April.)

Children from the age of 5 should be presumed competent

EDITOR—When considering informed consent in medical research Len Doyal states that one of the three circumstances in which research should be allowed to proceed in the absence of informed consent is when subjects are not competent to give consent.[1] One group given as an example was that of young and immature children. Before this statement is accepted the terms young and immature have to be defined.

Alderson and Montgomery argue that children can and should play a greater part in decisions about their own health care.[2] They recommend that any child who can express a view should be given information, listened to, and have his or her views taken into account when decisions about treatment are being considered. Their suggestions for a statutory description of capacity would be present when a child understands the type and purpose of the proposed treatment, the nature and effects of the treatment in broad terms, the principal benefits and risks, and the consequences of not receiving treatment and when he or she has the capacity to choose whether to accept the treatment. When children are competent to take responsibility for a decision the responsibility for that decision would become theirs.

They argue that young people from the age of 5—that is, of compulsory school age—should be presumed competent. The young age was chosen as the presumption does not exclude parents from discussion. It also encourages recognition that young children may be competent to make certain decisions—for example, whether to take more analgesics, if not more complex ones—and allows for the children to be deemed not competent and for their decisions to be overruled, especially if their decision would result in serious irreparable harm to their health. Perhaps these criteria could be used as a basis for discussion when considering how to assess children and young people's competence to consent to participation in research. This would be in line with Doyal's additional statement that "the levels of autonomy that patients who are thus incompetent do possess should still be respected (for example, if they resist participation then it should not be forced)." [1]

A third point is that, just as in adults, competence in children is not something which is merely present or absent. Its presence may vary in children of the same age, depending on when, where, and how the question is asked, the cognitive capacities of the child at that time, and the level of competence[3] required—for example, the mere ability to assent or a full understanding of the decision and the possible consequences for the individual.

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1 Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ* 1997;314:1109-11. (12 April.)
2 Alderson P, Montgomery J. *Health care choices: making decisions with children.* London: Institute for Public Policy Research, 1996.
3 Appelbaum PS, Grisso T. Assessing patients' capacities to consent to treatment. *N Engl J Med* 1988;319:1635.

Research in patients with mental retardation poses special problems

EDITOR—In response to the editorial by Richard Smith and the articles on informed consent in biomedical research by Len Doyal and Jeffrey S Tobias,[1-3] I suggest that the issues surrounding incompetent patients as in cases of mental illness or mental retardation are particularly important. People with mental retardation warrant specific mention, especially because those with severe degrees of disability will never be able to exercise their right to autonomous decision making. Yet, they as patients have the most intensive needs and have increased rates of challenging behaviour or mental illness, or both, and the treatments for these conditions remain symptomatic and have probably been investigated (originally) only in normal subjects.

The advent of community care for this population and the emphasis on social care[4] has created a resistance to research carried out in children and adults with learning disabilities, further aided by the ever present and gruesome memories of the eugenics movement in the early 20th century and the Nazi experiments. However, time and again, clinicians are faced with intractable disorders in their patients with learning disabilities which compromise the patient's quality of life, may be extremely stressful to manage and cope with, and may put other residents and staff at risk. In addition, self injurious behaviour may be extremely severe, thus compounding the effects of the disability. Research on the pharmacological treatment of developmental disorders has been mainly based on small scale studies with inadequate methodology—that is, the use of antipsychotics/antidepressants and opioid antagonists in severe and unremitting aggression and self injurious behaviour. Evidence is still scant on the advantages and disadvantages of the different types of drugs for controlling challenging behaviour, with serious financial and clinical practice implications. It is a pity that the recent advances in medical technology and non-invasive procedures and improved understanding of the interaction between brain function and

environment, which could yield important results for patients with learning disabilities, are not used to their full potential. Doyal's guidelines[2] certainly go some way towards addressing the issue of consent with incompetent patients, although more work, such as canvassing views of service users and carers and promoting advocacy for this client group, will be necessary before the stigma of unethical research stops beneficial treatments from being used.

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1 Smith R. Informed consent: the intricacies. *BMJ* 1997; 314:1059-60. (12 April.)
2 Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ* 1997;314:1107-11. (12 April.)
3 Tobias JS. *BMJ*'s present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct. *BMJ* 1997;314:1111-4. (12 April.)
4 Neuroscience Approach to Human Health Initiative Steering Committee. *Mental handicap research: new technologies and approaches. Report of the workshop organised under the initiative of the Neuroscience Approach to Human Health Initiative Steering Committee.* Warwick: University of Warwick, 1993.

Studies with important conclusions but without patient consent should be published

EDITOR—Your debate on informed patient consent for medical research this week made fascinating reading, and the situations where informed consent is, and is not, appropriate were comprehensively discussed by Len Doyal and Jeffrey S Tobias. [1 2]

That a study is methodologically sound so that meaningful conclusions can be drawn is of paramount importance and is the greatest problem we face in medical research. While those authors who have spent time and effort in designing a study adequate to produce a sound paper will probably also have obtained informed consent in appropriate cases, this will not be a perfect correlation, partly because of varying interpretations of what constitutes an appropriate case. An occasional paper will therefore emerge with valid and important conclusions, but no patient consent. A prohibition on publication of papers without patient consent would cause valuable information to be absent from the literature, a scientifically and morally unacceptable situation. Each paper should be judged on its merits, with the appropriate presence of informed consent representing an important, but not paramount, consideration.

The *BMJ*'s present policy of sometimes publishing research in which patients have not given fully informed consent is indeed wholly correct.

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1 Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ* 1997;314:1107-11. (12 April.)
2 Tobias J. *BMJ*'s present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct. *BMJ* 1997;314:1111-4. (12 April.)

Failure to publish completed randomised controlled trials is unethical in itself

EDITOR—In response to Richard Smith's request for help in deciding the *BMJ*'s policy on informed consent,[1] we would argue strongly in favour of maintaining the journal's present position. Nobody wishes to promote unethical research, but failure to publish completed randomised controlled trials is unethical in its own right: the efforts of all those who participated in the trial are wasted, and both health professionals and patients are deprived of information that they may need to make informed decisions.[2]

There is a good deal of hypocrisy in clinical medicine about informed consent. Many so called established treatments have been poorly evaluated so that their true benefits and risks remain unclear. These treatments should still be regarded as experimental and yet, because they are accepted, they are widely given without any form of consent being required. For example, many treatments are widely used in different countries to treat patients with acute stroke—for example, aspirin, heparin, glycerol, haemodilution, corticosteroids, ancrod[3 4]—but none of these have definitely been shown to reduce the risk of death or disability and many could be harming patients—for example, antithrombotic agents could increase the risk of intracranial haemorrhage.[5] Many more patients are exposed to this abuse of consent than in randomised controlled trials but this is rarely questioned. Hardening of the already stringent requirements for informed consent in randomised controlled trials will lead to fewer and smaller randomised trials and continued uncertainty over the risks and benefits of many treatments and hence to continued widescale abuse of patients' consent in clinical practice.

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Subjects may be coerced into participating in studies

EDITOR—Whether prospective research with no explicit statement about informed consent should be published is an issue avoided by journals for too long.[1] Subjects in some experiments believe that they are receiving standard treatment when there is no evidence of utility.[2-4] Recently I reviewed a prospective multicentre study of myocardial infarction in which the end points included death. There was no statement about ethics approval or informed consent. I suggested that if this was not an oversight the journal "would have to decide whether it wants to publish an unethical trial."

When subjects give informed consent the experiments may still be unethical if consent is not given freely. Subjects may be coerced by poverty into participation or find it difficult to refuse a request from an employer, colleague, or teacher. I am aware of recent research involving military staff who were ordered to volunteer.

I have particular concerns about research in diving medicine. Most is performed outside hospitals and without the safeguard of hospital ethics committees. In *Diver* magazine I reported that volume 9 of *Undersea and Hyperbaric Physiology* contained 111 scientific papers, of which 47 described human research.[5] Twelve studies were on patients and 35 on so called volunteers, who were often military staff or employees of the commercial diving organisations that conducted the research. Only seven papers mentioned that ethics approval was granted and only 12 mentioned informed consent. Some experiments were highly hazardous and might be best described as adventures in survival for the participants. Many studies failed to mention adverse effects. When they did, it was evident that at least 38 of the so called volunteers had decompression illness in studies which were often too small or incorrectly designed to give a statistically valid result.

Senior institutions are not above reproach. Eight years ago the Medical Research Council Decompression Sickness Panel proposed introducing "professional diver super medicals." Like the current medical assessments, the super medicals would be performed at intervals during a diver's career but would include additional expensive investigations such as radionuclide scanning. The results were to be used in a prospective survey of long term health hazards of diving, but the divers were to be told that it was for individual screening and that they would be asked to pay for the investigations. Those who refused would lose their licence and livelihood. The plan was abandoned only recently, though I and others expressed concerns about the ethics when it was first proposed.

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The whole population must be mobilised in the war against cancer

EDITOR—Ethicists should carefully avoid absolutism lest they become hostages to fortune. Len Doyal, an ethicist whom I much admire, has fallen into this trap.[1] For example, he states and restates his belief that it is unacceptable to compromise individual rights, even if the public interest demands it. I presume therefore that he is too young to remember the conscription that was necessary to fight a just war against the Nazi powers: the very ones guilty of the worst atrocities committed in the name of medical science.

Cancer commits atrocities on the human body, and the fight against cancer has often been likened to a war: "The war against disease and for health cannot be fought by physicians alone it is a people's war in which the entire population must be moblised permanently."[2] If there is to be a war against cancer and if it is considered unethical to conscript patients as the foot soldiers in this war, then it is up to the lay public to recognise their responsibilities to society on a voluntary basis, in addition to demanding their rights of autonomy and progress for the treatment of malignant disease. It was precisely that argument that I described in my paper in the *Lancet* in 1993,[3] which was inappropriately cited by Doyal to support his argument about access to medical records.

I am glad to report that many women with breast cancer have risen to this challenge,[3 4] and we now have a consumer's advisory group of committed lay women chaired by Hazel Thornton who see themselves as equal stakeholders in the fight against cancer. Until we have permanently mobilised the whole population in this war the agonising debate about the process and ethics of informed consent will continue to thunder on and on. In the meantime, in a less than perfect world I have to side with Jeffrey S Tobias, who like me, every day of his working life, has to make these tough decisions.[5] It would help the debate if the armchair ethicists got down from their verandas and mixed with the natives—perhaps first hand experience would dilute their uncompromising zeal.

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Patients may not understand enough to give their informed consent

EDITOR—Much debate has focused on the need for informed consent and the ethical difficulties that arise when this is not obtained.[1] Little attention has been paid to what patients understand that they have consented to.

We report preliminary data from a study of 102 patients receiving radiotherapy for cancer. Twenty two per cent (22/99) had no recollection of consenting to the procedure (all had consented). Thirty six per cent (29/80) of those who did recall consenting thought that they had consented to "any procedure that the doctor thinks is necessary including chemotherapy, radiotherapy, or surgery." Moreover, 60% (48/80) thought that by consenting they had undertaken to accept "any side effects caused by the treatment," and 44% (42/95) believed that by consenting they would be unable subsequently to complain about side effects.

Clearly, the issue of informed consent implies a sharing of information, yet 24% (24/99) of our sample could not recall being told about any side effects from radiotherapy, not even common effects such as burning skin or tiredness, of which they were informed. These were all patients who had had an appointment with their consultant when treatment options and side effects were discussed followed by a pretreatment meeting with a radiographer. In addition, 60% (54/90) of patients received information leaflets and 47 out of 100 saw a specialist cancer counsellor on at least one occasion. If patients are not retaining the information that they have been provided with or if they are misunderstanding precisely what they are consenting to they are being ill equipped to make the psychological adjustment that will be necessary throughout their treatment.

Our findings highlight the need for more research to be conducted into the process for obtaining informed consent and whether patients take in and understand information given to them. If the subject has not taken in the information then their consent is hardly informed. It may be that the timing of information sharing is crucial as to whether it is retained and that this should be viewed as more of a process than a one off event.

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1 Smith R. Informed consent: the intricacies. *BMJ* 1977; 314:1059-60. (12 April.)

Communication with potential subjects needs to be effective

EDITOR—As a past chairman of a local research ethics committee and a recently practising clinical oncologist and clinical researcher, I endorse the views of Len Doyal.[1] I would argue that Jeffrey S Tobias's highly reasonable anxieties for the wellbeing of individual research volunteers[2] would be better served by much greater attention being paid to the comparatively neglected area of clinical interpersonal communication. Nowhere in either article is this fundamental issue clearly addressed.

My experience of dealing with research protocols from a wide range of sources, some of them extremely august, leads me to the reluctant conclusion that the last feature to be tackled by a researcher is the means by which the nature of the research will be made comprehensible to potential subjects. It is not uncommon for the local research ethics committee to have to rewrite the patient information and consent literature for the applicant, and this is a common source of delay in obtaining approval.

Even when the written material is deemed acceptable the diverse nature of the circumstances and abilities of research subjects demands a personal presentation of the information by a senior member of the research team. This is, I suspect, the most vulnerable point in the process, dependent as it is on the range of communication skills available to the informer. The profession places a lower value on having effective abilities in interpersonal communication than it does on having more obviously acceptable concrete medical and scientific skills.

I have seen in my own practice that with the use of effective communication skills most patients can be given an individualised, accurate, and comprehensible paraphrase of the protocol information leaflet, within an acceptable time frame. It is, however, essential to have formally learnt the necessary skills to do so. Is this so different from having had to master any other useful clinical skill?

Those who aspire to undertake clinical research should place as much emphasis on their ability to communicate effectively as on the methodology and statistics considered to be essential to the conduct of a trial. Surely this is a more acceptable means of extending the range of trial opportunities than being forced into the ethical dilemma resulting from denying the fundamental rights of individuals?

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1 Doyal L. Journals should not publish research to which patients have not given fully informed consent—with three exceptions. *BMJ* 1997;314:1107-11. (12 April.)
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In routine practice the consent form is a request form and informed consent is informed choice

EDITOR—We read with interest Richard Smith's editorial on the ethical problems of informed consent in research.[1] However, for the most part, doctors face the issues of informed consent in their daily routine practice of patient care. It is in daily practice that many doctors feel uncertain of their role and may fear litigation, despite the publication of general guidelines. We think that the principle of informed consent implies that it is for the benefit of the doctor

and not the patient to provide medical care, and this is especially reflected in the written operative consent form. It is ultimately the patients' decision to opt or not to opt for care and the doctor's duty to provide relevant information. Therefore, we recommend informed consent for routine, non-research care should be renamed informed choice. We also suggest that the consent form be renamed a request form. We believe that this terminology would be more informative to both doctors and patients.

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❄At the time of going to press we had received 18 other letters on informed consent. We could not publish all of these because of lack of space, but we do plan to publish another round of letters on this subject. The 18 letters were equally divided between those which thought that we should never publish trials that do not include consent and those that thought we should.

Reintroduction of medical officers of health would solve many problems

EDITOR—As the son of the secretary of the Society of Medical Officers of Health who successfully defended that splendid Victorian Liberal office against the Baldwin government (Dr V F Soothill), I write to express enthusiasm for Dr Lewis Moonie and Mr Sam Galbraith's proposal that medical officers of health should be reintroduced.[1] It is strange that Dr Moonie and Mr Galbraith are Labour MPs, since the deterioration in the attention paid to hygiene resulted from the introduction of the National "Illth" Service (ignorant Beveridge wrote that improved therapeutic services would improve health and so reduce costs); the elimination of medical officers of health by the Heath government was just the last step in a trend.

The attention of consultants in public health medicine to hygiene was lost to long term care and disability. The recent outbreak of food poisoning due to *Escherichia coli* in Scotland is a good example of the need for medical officers of health; such outbreaks would surely be eliminated if raw meat was sold only in shops that sold nothing else and if meat based cooked products were produced in production lines in which different equipment and staff were used before and after cooking. That is the sort of sensible independent suggestion that medical officers of health would make.

Medicine's greatest achievements are in prevention (hygiene, immunisation, nutrition, and birth control); if a patient sees a doctor then medicine has failed. Let us restore the medical officer of health but with the independence and protection that resulted from the recognition in the wiser 19th century that this is something too important for politicians. Medical officers of health should not be appointed by the secretary of state, as these MPs suggested, but, as of old, should be hired and fired only at the instruction of a committee of their peers, and their reports should be published unaltered. A dirty butcher may have a cousin who is a councillor.

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Many children remain unrestrained in cars

EDITOR—While we agree with the points that Ian Roberts and Carolyn DiGuiseppi make in their editorial on children in cars,[1] we wish to draw attention to other important aspects of children's safety in cars. Over the past few years three surveys have been carried out on the use of restraints by car occupants in Fife, Scotland. In total, 13 933 car occupants in 7793 vehicles have been surveyed at several survey points throughout the county.[2 3] In addition we have carried out detailed examinations of the use of restraints by 596 car occupants.[4]

The use of restraints by drivers and front seat passengers was high, at 94% and 93% respectively. The use of restraints by children in the rear seats, however, was considerably lower and fell with increasing age of the child; thus 70% of 0-1 year olds, 79% of 1-4 year olds, 59% of 5-9 year olds, and 54% of 10-14 year olds were restrained. The use of restraints was much lower in rear middle seats than rear side seats (40% *v* 61%). These data relate to the use of restraints after the introduction of the legislation in July 1991 that required adult rear seat passengers to wear a seat belt; we observed that the legislation was associated with a 77% increase in the use of rear seat belts by both adults and children.[3]

Three issues should be highlighted. Firstly, a substantial proportion of children remain unrestrained in cars, although the use of seat belts by drivers and front seat passengers is almost universal. The use of restraints was about 15% higher in vehicles that had rear seat belts fitted, as would be expected, but this still means that a substantial proportion of children in rear seats travel unrestrained in these cars. Secondly, we have consistently found that the use of restraints in taxis is low, with only 67% of front seat passengers and 21% of rear seat passengers being restrained. Lastly, passengers were using restraint devices incorrectly in 52% of vehicles surveyed. Rates of incorrect use were highest with child seat restraints, reaching 60% for two way seats and 44% for rear facing seats. Thus 28% of children were secured incorrectly.[4] As incorrect use reduces the effectiveness of restraints and can itself result in injury[5] we believe that this is an important and under-recognised factor in injuries to child passengers in Britain.

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Solar ultraviolet radiation is not a major cause of primary cutaneous non-Hodgkin's lymphoma

See p 1451

EDITOR—Ultraviolet radiation is known to cause cutaneous malignancies such as squamous and basal cell carcinoma and melanoma. It has been hypothesised that ultraviolet radiation may also increase the risk of non-Hodgkin's lymphoma.[1] As evidence exists that specific local factors are important in the aetiology of non-Hodgkin's lymphomas at certain extranodal sites—for example, *Helicobacter pylori* infection is associated with primary gastric lymphoma but not with lymphomas at other sites[2]—I investigated the relation between the incidence of primary cutaneous non-Hodgkin's lymphoma and ambient levels of solar ultraviolet radiation using routinely collected, population based data on cancer incidence and published measures of ambient solar ultraviolet radiation.[3 4]

Age adjusted and sex adjusted incidence rates of cutaneous non-Hodgkin's lymphoma in white people were derived (with 95% confidence intervals) for 10 areas in the United States (fig 1). Few countries have such information available, and the

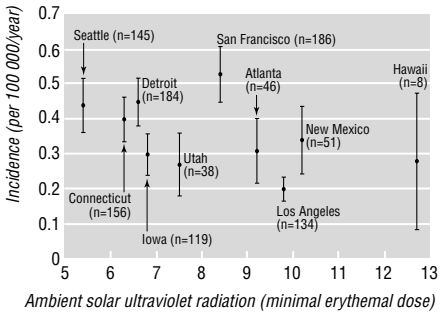

Fig 1 Incidence (adjusted for age and sex) of primary cutaneous non-Hodgkin's lymphoma in white people in 10 areas of the United States, in relation to ambient solar ultraviolet radiation

analyses were restricted to the United States because of the scale, consistency, and quality of data collection; the broad range of ultraviolet exposure between locations; and the need to avoid inclusion of diverse racial groups. At each location, the average daily dose of ultraviolet radiation (UVB) was calculated from annual measurements of ambient ultraviolet light between the hours of 0830 and 1830 for each 10° of latitude, after adjustment for seasonal cloud cover.[4]

Overall, the incidence of primary cutaneous non-Hodgkin's lymphoma does not increase with increasing levels of ambient solar ultraviolet radiation (fig 1; regression coefficient −0.02, P=0.16), nor is there a positive association for all non-Hodgkin's lymphomas in relation to solar ultraviolet exposure in the United States.[5] Similarly, the proportion of all non-Hodgkin's lymphomas manifest as primary cutaneous tumours does not increase with increasing levels of ultraviolet radiation (−0.97, P=0.39). For all areas combined there is no clear excess in white people (incidence 0.35 per 100 000 (95% confidence interval 0.33 to 0.37) a year, based on 1067 cases) compared with black people (0.41 per 100 000 (0.34 to 0.48) a year, based on 147 cases), which might be expected if ultraviolet radiation increased the risk of cutaneous non-Hodgkin's lymphoma. Hence, these results suggest that exposure to ultraviolet radiation is not—as it is with melanocytic and other non-melanocytic skin cancers—a major risk factor for primary non-Hodgkin's lymphoma of the skin.

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I thank Jacques Ferlay for his help.

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What is it acceptable to die of?

EDITOR—The issue of 15 February was indeed thought provoking. Having had a recent series of four articles in the journal, the Rationing Agenda Group aired yet more of its ideas,[1 2] while authors of letters showed just how impossible it will be to reach any consensus. In one of these letters J Dunstan asked that a minimum requirement for a civilised health system should be that people should not have to die in avoidable distress.[3] Do we, on that single criterion, fail the civilisation test?

David P Taggart and Stephen Westaby reviewed the surgical management of heart failure,[4] telling us that the annual mortality is 25-50% and describing this as "dismal." Leaving aside those patients with truly remediable causes of heart disease, such as unsuspected valve disease, surely a good proportion of these patients are dying, as we all must, and our duty is that they do not die in distress. People with terminal cancer can be accepted as dying (although paradoxically many people with incurable cancer are not so obviously ill as those with incurable heart disease); it seems that people with terminal heart disease cannot.

Minerva, in the same issue, pointed out that declining mortality from coronary heart disease is a factor in the increasing number of hospital admissions for heart failure. So we rescue people from a relatively sudden death from myocardial infarction only to inflict on them a more prolonged death from progressive heart failure. Taggart and Westaby describe heart failure as a major health problem, but surely it will always be so. Surgery, even if successful, will only postpone the inevitable; and heart failure is likely to be a major cause of death when these patients eventually die—which they will.

With a request that they do not deflect the argument or risk accusations of ageism by concentrating on younger patients with heart failure, I should like to ask Taggart and Westaby the question that J P Richards posed in a personal view[5]: what do you consider it is acceptable to die of?

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Redback spider is now established in Japan: bites can be recognised by a unique sign

EDITOR—The infamous Australian redback spider (*Latrodectus mactans hasselti*; fig 1), known for inhabiting the underside of toilet seats and biting bottoms, is now in Japan. More alarming to the Japanese is that these spiders—relations of the black widow—are continuing to breed and spread in the Japanese winter, surviving temperatures as low as 4°C by living near heating systems. The spiders often live near or beneath houses and females will bite defending their nests, which can contain 300 eggs. Japan, like England, does not have poisonous spiders and public panic is escalating. Despite prompt action by the authorities, fumigation programmes have not eradicated the pest.


A.N.T./NHPA

Fig 1 Australian redback spider

These Japanese redbacks could conceivably survive in Britain and therefore constitute a real threat if accidentally imported.

The spider is ubiquitous in Australia[1] and may have been introduced in the 1870s. Bites have caused death[1 2] in children. Anaphylaxis and death in adults have occasionally been reported. The venom is a neurotoxin called latrotoxin, which depletes acetylcholine from nerve terminal vesicles and causes presynaptic blockade. A safe antivenom[3] has been available since 1956[1] but delay in giving it may occur[2] if the spider is squashed beyond recognition. Around 78% of bites are on hands, feet, and the extremities[3] and initially the bite causes little discomfort. Later intense pain begins and uniquely the bitten area sweats profusely. Only 2.3% of bites are now on the bottom and genitalia[3] compared with 9.7% in 1978.[4] The shortest time recorded between the bite and death is 54 hours. Deaths from bites of *Latrodectus* species have been recorded in Italy and Yugoslavia.[5]

The larger and more dangerous female spiders (males are smaller and have fangs which cannot penetrate human skin) are black and have an abdomen the size of a pea with an orange-red, pink, or grey stripe.[1] Australians have learnt to ignore the company of the redback but it is a pest that Japan and the rest of the world can do without. Having found a large female redback and eggs under my patio table this weekend in Sydney, the reaction provoked is like discovering that the property has lice. I have identified only one pleasure associated with possession of the redback spider. Friends tell me that as children they would disturb a nest and drop bricks on the insects; apparently the abdomen makes a loud pop when squashed.

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Segregated health statistics perpetuate racial stereotypes

EDITOR—Unlike Alexander R P Walker, we welcome the desegregation of health statistics in South Africa[1] and believe that the routine use of ethnic or racial categories in health research is often ill conceived, misleading, and divisive.[2] It is ill conceived because using nationality and physical characteristics (such as African, European, black, and white) to differentiate between various groups tends to reinforce the discredited view that geographically isolated and genetically distinct human races exist. It is misleading because using these categories to assess disparities in health focuses attention on inherent biological and behavioural causes and ignores the impact of social forces that determine access to health and health care. It is divisive because using these categories legitimises the process of discrimination and reinforces a racially structured view of society.

Nowhere are these issues more relevant than in post-apartheid South Africa, where the "population group" categories created and enforced by the 1950 Population Registration Act have been used to document patterns of disease. Indeed, Walker *et al*'s interethnic comparison of temporal changes in mortality from ischaemic heart disease used population group categories to identify those groups most at risk.[3] Although the authors acknowledged that ischaemic heart disease is linked to a variety of behavioural and socioeconomic factors, the absence of these variables in the South African database distorted their interpretation of differences in disease between different groups. By comparing the incidence of ischaemic heart disease among black, Asian, and white South Africans with that found in studies of African, Indian, and British subjects they reinforced the view that heritable characteristics were somehow responsible for the interethnic differences they observed. They also stigmatised the least healthy groups by suggesting that the relative decline in mortality from ischaemic heart disease among white South Africans indicated that "whites have...taken some preventive action, although Asians and coloureds apparently little." Nowhere did they acknowledge the impact of discrimination on the socioeconomic and health status of different "population groups."

Using ethnic and racial categories to rectify inequalities in health is perhaps the most justifiable use of these categories in health research.[4] But using these categories to "identify and quantify the target populations who are most in need of help," as Walker suggests, raises two fundamental problems: firstly, it would necessitate the continued use of the externally imposed categories traditionally used to enforce disadvantage, and, secondly, it would perpetuate inequality by ignoring disadvantaged subjects from other groups. Targeting all socioeconomically disadvantaged subjects would help rectify the impact of past and current social injustice, including ethnic discrimination and racism, without relying on ethnic or racial categories to identify disadvantage.[5]

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Incidence of myocardial infarction is affected by deprivation in Buckinghamshire too

EDITOR—Caroline Morrison and colleagues report that within a relatively deprived part of north Glasgow the incidence of myocardial infarction in the poorest areas was roughly double that in the more affluent neighbourhoods.[1] It may be a surprise that similar results have been obtained in a more prosperous part of Britain (table 1).

The numerator data in table 1 were taken from Buckinghamshire Health Authority's contract monitoring database for 1994-5. The denominator data were taken from the census, updated with data from a postal survey conducted by Buckinghamshire County Council in 1994. All electoral wards in the county were grouped into fifths of roughly equal population according to the ward Townsend score (a census based deprivation score[2]). Hospital admission rates standardised for age and sex were calculated for acute myocardial infarction and various other categories of admission for these aggregated populations.

The incidence figures for the two studies are not directly comparable—for example, those for Glasgow include deaths occurring outside hospital. Despite these differences, the two datasets show a strikingly similar twofold variation in incidence according to deprivation. Inequalities by social class are clearly not restricted to inner city communities.[3] It is also encouraging that routine NHS data seem to be sufficiently robust to document local inequalities.

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Project will assess effects of patients writing about their terminal illness on self perceived quality of life

EDITOR—Naomi Craft writes of autobiographies about dying.[1-3] She reasons that these accounts can help readers feel better about their own deaths and satisfy some fearful curiosity about dying; publishing such accounts can fulfil a need of the writers to create a powerful memorial.

The process of writing expressively and exploratively about dying can also have intensely therapeutic benefits, we believe. "Writing therapy in palliative care" is a pilot project started by the palliative medicine section of Sheffield University last September. Writing therapy is being offered to inpatients and day patients at Ashgate Hospice, Chesterfield, with effects on the control of symptoms and on spiritual distress being reported by medical and nursing staff. It builds on the experience of the "writing therapy in primary care" project at the department of general practice, Sheffield University (unpublished findings).

One inpatient arrived at the hospice very distressed, expressing herself as unable to come to terms with having cancer and requesting psychological help. Her monologue, which was taken down verbatim, was interrupted only by thoughtful silence; she reread and checked the writing. Here are two extracts: "You wake up in the morning and, no, the cancer's not gone, I know it's not.... It [the writing] must be coming from the inside, the tears are rolling down." Later, she emotionally dictated about wishing to

Table 1 Relative risk of admission for acute myocardial infarction in population of Buckinghamshire

Fifth of population by deprivation score	Total population	Admissions for acute myocardial infarction*	Relative risk adjusted for age and sex†
1 (least deprived)	120 540	35	1
2	121 450	53	1.63
3	118 818	45	1.47
4	118 887	62	2.07
5 (most deprived)	120 636	69	2.54

*Aged 35-64 only. †χ^2 for trend=22.5, P<0.0001.

commit suicide: "I never thought I'd tell anyone that, no I didn't. And cried again. Three times I've seen you and always cried. Never with anyone else. My son wanted to know what we did and I said, 'How can I tell you? I don't know! But this lady, she seems to get right inside you. Right into the centre of your being.'"

Although there have been many writing residencies in hospices,[4 5] the approach has not yet been researched. Our pilot study is beginning to define measurable outcomes. In a proposed full scale project we intend to test the effect of the process of writing on self perceived quality of life, linking it to the level of cognitive functioning (and drug related impairment by, for example, opioids) and opioid dose. Finished writings can offer insight to nursing and medical staff and support to other sufferers, as well as therapeutic benefit to the writer and the help to readers, as Craft suggests.

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South Asian diabetic patients need more education about their illness

EDITOR—I hope that Veena Soni Raleigh's article on the necessity to plan now for the future health needs of Britain's South Asians is read and understood by the people who matter (Britain's health planners and the holders of the health budgets).[1] We are certainly facing a serious problem for the South Asian community in the next few decades. The article quotes a study from Nottingham in 1990 on the knowledge of diabetes and its complications among South Asians attending a hospital diabetic clinic, which compared them with matched white diabetic patients.[2] A more recent study, of 200 randomly selected South Asian patients attending Manchester Diabetes Centre in 1993-4, found similar results: 168 patients could not name any diabetic complications, 99 were unsure of the reasons for monitoring and controlling glucose concentrations, 175 did not know the purpose of attendances at the clinic to screen for early complications, and 183 did not know what a chiropodist did or how to see one. In addition, a hard core, consisting of older women with no experience of formal education, was found to have poorer diabetic control than the rest as well as less knowledge of diabetes (the average glycated haemoglobin concentration for the 107 women in the study was 8.79%, compared with 8.14% for the 94 men ($P = 0.04$)). These patients' educational requirements need to be urgently addressed if we are to prevent further morbidity, improve quality of life, and use resources effectively.

The patients reported on in the Nottingham and Manchester studies were largely Pakistani Moslems. British South Asian communities vary enormously in terms of language, culture, religion, diet, and degree of Westernisation. In addition, this variation is dynamic: it changes from year to year as the younger generations grow up in a British environment. Any educational interventions or health service programmes for South Asians need cultural assessment in the environment of the target community and also careful audit by the community itself to avoid irrelevance and to promote optimal uptake.

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Shorter preoperative fluid fasts reduce postoperative emesis

EDITOR—We support the recommendations on preoperative fasting offered by S M Greenfield and colleagues.[1] Not only are fasting times far longer even than is traditionally thought necessary but reducing the fluid fast, as they advocate, seems to benefit patients after anaesthesia too.

We audited fasting times and postoperative emesis in inpatients having elective gynaecological surgery after some members of our department became concerned that shortening the preoperative fluid fast would make postoperative emesis more likely. Data were collected on 93 patients fasted conventionally; 89 more were allowed to drink water until two hours before the induction of anaesthesia. The two groups were comparable with respect to risk factors for postoperative emesis.

We had three main findings.

(1) The mean duration of fasting was 10.0 hours in the patients fasted conventionally (range 5.5-18); this was reduced to 3.4 hours (1.7-6.0) in our second group.

(2) No adverse effects were seen in the patients given water to drink.

(3) Nausea and vomiting were common, as might be expected in gynaecological patients; 24 (26%) of the patients fasted conventionally had postoperative nausea and 33 (35%) vomited. However, drinking water up to two hours before surgery seemed to make postoperative emesis less likely: only 19 (21%) in the second group experienced nausea and 16 (18%) vomited.

One reason why patients may have nausea postoperatively was alluded to by Palazzo and Strunin, who observed that a substantial number of patients felt sick after fasting for up to 8.5 hours[2]; if patients go to sleep nauseated the nausea is likely to persist into the postoperative period. Alternatively, vomiting after surgery is often caused by drinking too soon during recovery; patients who have drunk water within a few hours of induction of anaesthesia should be less thirsty postoperatively and not try to drink so soon.

We urge colleagues to ensure that patients are not deprived of fluid for longer than six hours even when a minimum six hour fast is imposed. As a result of our audit we have changed our departmental guidelines to allow most patients to drink water until two hours before sedation or anaesthesia.

Our study was sequential and the anaesthetic techniques, though well matched, were not standardised; we would be interested to see whether the results of a randomised trial confirm our suspicions that a shortened fluid fast not only makes patients more comfortable but also reduces postoperative emesis.

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Pharmacists are key members of primary health care teams

EDITOR—I was disappointed by the article by Colin P Bradley and colleagues.[1] In their summary the authors suggest that the initiatives that may have the biggest impact are those encouraging closer collaboration between general practitioners and community pharmacists. Unfortunately, the article concentrates almost exclusively on the way in which this collaboration controls the cost of prescribing. The much greater benefits that could arise for the two professions are dismissed in a few words.[2 3]

My practice has had a full time non-dispensing pharmacist for nearly three years. Formulary and prescribing policies now form little of her work; we have moved beyond mere cost control to tackle the real issues of rational prescribing—safe, effective, available, and acceptable to the patient. All of us in the team, including patients, find her role invaluable. To dismiss this model as being "unlikely to be acceptable to the pharmacy profession as a whole" grossly underestimates the full potential of this partnership. The authors seemingly wish to keep the pharmacist at arm's length, not as a key member of the primary health care team, notwithstanding staffing problems. The authors mention that this model already exists in secondary care; it is now logical to extend it into primary care.

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