Ethical debate

Informed consent in medical research

In the issue of 12 April 1997 the *BMJ* invited comment on the acceptable limits of informed consent in medical studies. In view of the large correspondence this generated, we invited the two original commentators, Len Doyal and Jeffrey Tobias, to revisit the subject. We also invited comments from three people who are not doctors, researchers, or medical ethicists: two of them represent the views of patients and potential patients

Informed consent—a response to recent correspondence

Len Doyal

Editorial by Smith and *Personal views* pp 1026-7

St Bartholomew's and The Royal London Hospital School of Medicine and Dentistry, London E1 2AD

Len Doyal, *professor of medical ethics*

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The publication of the debate between myself and Jeffrey Tobias about the acceptable limits of informed consent in medical research has generated an immense and varied number of letters to the *BMJ*.[1–4] This in itself is gratifying, whether or not correspondents agree with my arguments. It provides ample evidence of widespread and serious deliberation about the moral boundaries of the rights of participants in research.

Many correspondents either explicitly or implicitly endorse the hard line that I take in my paper on the right of competent people to an acceptable level of information before agreeing to participate in medical research. Other contributions confirm my emphasis on the moral importance of the principle of informed consent but, in light of the highly specific circumstances where I argue that the principle must be qualified, question the degree or clarity of my own commitment to it. What is important here is our shared belief in the moral imperative of respecting human autonomy in almost all circumstances.

I still disagree with those authors who argue that it is not necessary to obtain informed consent if this will lead to the methodological compromise, or possible cancellation, of potentially beneficial studies involving clinical interventions that carry minimal risks. What these correspondents either fail to recognise or to take seriously is that to fail to respect the autonomy of competent people is to inflict harm on them that is just as morally unacceptable as direct physical or mental harm. To do so rejects the letter and spirit of the Helsinki Declaration—the "interests of the subject must always prevail over the interest of science or society." Simply to assert that the declaration is wrong in this regard—without even attempting to rebut counterarguments, which, for example, I outline in my paper—is to embrace the dogma of scientific progress at any price. When human autonomy and dignity are at stake the cost of such progress is too high.

Previous articles and comment on informed consent are available on our website (see Collections)

The *BMJ* and the Committee on Publication Ethics are hosting a conference on Friday, May 15, on informed consent in research, teaching, and clinical practice. The conference will be at Regent's College Conference Centre in London's Regent's Park. Contact the BMA's conference unit. Tel 0171 383 6605. Fax 0171 383 6663. Email eoliver@bma.org.uk

Some correspondents simply misunderstood or misread my paper. For example, Naomi Pfeffer and Priscilla Alderson maintain that I somehow claim that research may be done on children without parental consent.[5] In the relevant section I specifically state, "Informed consent should always be obtained from someone with parental authority."[1] Similarly, Pat Souter suggests that the HIV study of Satish Bhagwanjee and colleagues, which did not obtain informed consent from patients for seropositive testing, conforms to qualifications of the principle of informed consent that I outlined in my paper.[6 7] It does not. I specifically exclude all studies in which there is an intent to contact subjects in the future, an inevitable consequence of the HIV study in question since it was designed to inform patients later that they had been tested.

This same mistake is made by Paul Little and Ian Williamson, who suggest that arguments in my paper are consistent with randomised trials without consent.[8] It is true that I do morally defend some epidemiological research that is based not on direct patient involvement but on medical records—provided, among a long list of other things, that, again, there is no anticipation of further contact with the patients concerned.[1] Yet Little and Williamson try to defend their position with reference to the merits of an antibiotic study in which patients were directly involved without obtaining their informed consent. Then, through making this fact clear in their letter, they go on precisely to initiate further

potential contact with these patients. We can only speculate about the patients' potential distress and anger when they read or hear about this self confessed violation of their autonomy. This is the danger: patients may well (and do) find out about such abuse through, among other things, talking to other patients. Then utilitarian justifications can blow up in the face of those who use them to justify disrespect for human rights.

The most puzzling response of all to my paper was that of Michael Baum, a surgeon for whom I have great respect.[9] Professor Baum seems to want it both ways. On the one hand, he draws an analogy between the moral appropriateness of conscription in warfare and the "responsibilities" of the lay public to participate as subjects in medical research in the "war against cancer" (and presumably other disease). On the other hand, he never really comes clean about what he proposes to do if members of the public do not live up to his perception of their responsibilities. If, ultimately, he accepts their right to refuse to participate then he agrees with me that they should be given enough information to do so on an informed basis—and does so despite my "absolutism," "uncompromising zeal," and professional life in an "armchair" on a "veranda." If he rejects this right—as some of his comments and his agreement with Jeffrey Tobias's paper suggest—and really does support the quite extraordinary idea of conscription then let him say so and try morally to defend himself. It will take more than ad hominem arguments to do so successfully.

Failure to respect the autonomy of competent people is to inflict harm on them

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.
2 Tobias J. BMJ's present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct. *BMJ* 1997;314:1111-3.
3 Informed consent in medical research [letters]. *BMJ* 1997;314:1477-83.
4 Informed consent [letters]. *BMJ* 1997;315:247-54.
5 Pfeffer N, Alderson P. The central problem is often poor design and conduct of trials. *BMJ* 1997;315:247.
6 Soutter P. No one has a monopoly on deciding what is ethical. *BMJ* 1997;314:1477.
7 Bhagwanjee S, Muckart DJJ, Jenna PM, Moodley P. Does HIV status influence the outcome of patients admitted to a surgical intensive care unit? A prospective double blind study. *BMJ* 1997;314:1077-81.
8 Little P, Williamson I. Ethics committees and the BMJ should continue to consider the overall benefit to patients. *BMJ* 1997;314:1478.
9 Baum M. The whole population must be mobilised in the war against cancer. *BMJ* 1997;314:1482.

Changing the *BMJ*'s position on informed consent would be counterproductive

J S Tobias

Meyerstein Institute of Oncology, Middlesex Hospital, London W1N 8AA

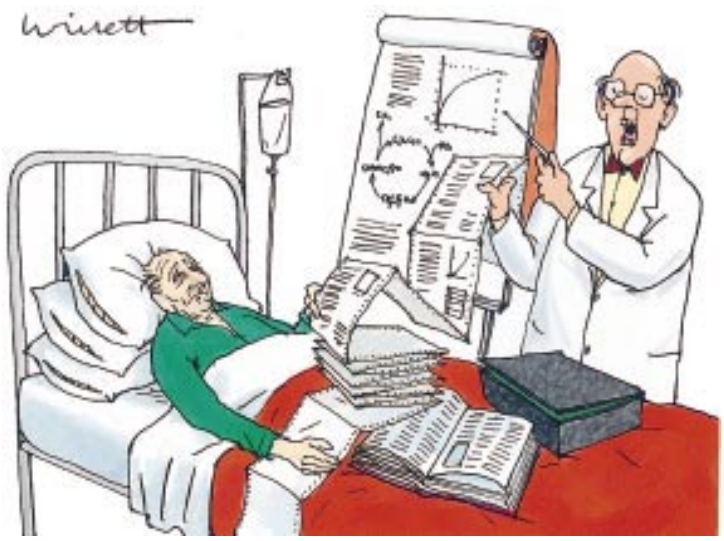
J S Tobias, *consultant in radiotherapy and oncology*

Any author would be gratified by an overwhelming postbag in response to a provocative article—provided, of course, that not all the voices are raised in condemnation. Fortunately, however, it is clear even from the titles of the letters published by the *BMJ* 17 May and 26 July 1997 that a wide variety of views persists. On the one hand, titles such as "Doctors are arrogant to think they need to debate issue of patient consent"[1] and "Lack of respect for patients in medical research may reflect wider disrespect in clinical practice"[2] provide a clear and unambiguous view. But on the other, "Ethics committees and the *BMJ* should continue to consider the overall benefit to patients,"[3] "Consent is not always practical in emergency treatments,"[4] and "Let readers judge for themselves"[5] offer a more relaxed view. As Little and Williamson point out,[3] writing from a department of primary medical care, "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."

As one of the protagonists of the debate, I am greatly concerned by many of the specific issues raised by correspondents. As well as the problem of, for example, emergency medical situations, the issue of risk of bias raised by a senior statistician[6] is of particular importance since well conducted randomised trials tend to form the most influential basis of today's evidence based medical practice. Added to this, we have a past chairman of a research ethics committee at one of London's most prestigious research hospitals pointing to the wide disagreement as to which clinical situations require trial without fully informed consent—reminding us that "no one can claim to have a monopoly on deciding what is ethical."[7]

Equally difficult is the argument—supported by preliminary data—that many patients may not digest information sufficiently well to permit a genuinely informed level of consent[8]; at the very least, it is clear that many patients in this study by Montgomery et al had no recollection whatever of consenting even to a course of radiotherapy—a consent which, we are assured from the article, had most certainly been given. If, as I believe, fully informed consent can sometimes be needlessly cruel,[9] what is the point of insisting on it in all cases when about a quarter of patients (judging by Montgomery et al's study) cannot even recall being told about common side effects of treatment when all had been provided with this information?

As I pointed out when first setting out my stall, one of my chief anxieties concerns the somewhat old fashioned concept of doctoring in its traditional pastoral sense. While applauding the use of evidence based approaches and recognising the need for powerful



Obtaining fully informed consent can be needlessly cruel

trials to generate essential information, I do, nevertheless, feel a responsibility of equal importance—to act as patients' adviser, counsellor, advocate, and support. With many sophisticated patients, well informed and willing to enter into a robust two way dialogue, the medical scientist occupying a fair portion (I hope) of my brain can take the lead. For the majority, however—less educated, less well informed, and less able to marshal their arguments—a somewhat more directive or (without being pejorative) "paternalistic" approach will often be far more appropriate, and gratefully received. As Dr Thurstan Brewin, past chairman of Health Watch points out, "Those who want the *BMJ* to take a rigid view should spend a day in a ward full of elderly people. They would probably find many who, though far from being mentally incompetent, are at times confused and forgetful. What could be more unrealistic than to refuse to recognise this for fear of being called patronising? … Some people underestimate the harm that can be done to many sick patients when fully informed consent for every trial is sought, no matter how tense or difficult the situation."[10]

I willingly give Ms Hazel Thornton, chairwoman of the Consumers' Advisory Group for Clinical Trials, the final word.[11] As she clearly explains, her group "works directly with the professions … [and] identifies an urgent need to advance public education about clinical trials. Concepts such as randomisation, risk perception, and probability are poorly understood …. Such co-operation … 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." Her letter, entitled "We all have a responsibility to contribute to research," echoes my own view that both doctors and patients have much to gain from this type of partnership and that overzealous directives attempting to monopolise the moral high ground will surely prove counterproductive. The *BMJ* would be unwise to stifle important research by confining too closely the outline, structure, and phraseology of trial consent—details that are far better left to the originators of the studies and their local ethics committees.

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3 Little P, Williamson I. Ethics committees and the BMJ should continue to consider the overall benefit to patients. *BMJ* 1997;314:1478.
4 Morley C. Consent is not always practical in emergency treatments. *BMJ* 1997;314:1480.
5 Bland M. Let readers judge for themselves. *BMJ* 1997;314:1477.
6 Chanter DO. Risk of bias may be another reason not to seek consent. *BMJ* 1997;314:1478.
7 Soutter P. No one has a monopoly on deciding what is ethical. *BMJ* 1997;314:1477.
8 Montgomery C, Lydon A, Lloyd K. Patients may not understand enough to give their informed consent. *BMJ* 1997;314:1482.
9 Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:1199-201.
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11 Thornton H. We all have a responsibility to contribute to research. *BMJ* 1997;314:1479.

Informed consent—a publisher's duty

Mary Warnock

Great Bedwyn, Marlborough SN8 3PE

Mary Warnock, *former chair of the Committee of Inquiry into Human Fertilisation*

Informed consent has become a shibboleth: you cannot be a respectable member of the medical research world unless you invoke the concept and accede to its demands, nor can you be a respectable publisher of research papers unless you ensure that your authors have clean hands in this regard. Informed consent is also, and perhaps more urgently, required in the case of medical and surgical procedures; but it is in the context of research requirements that the following remarks are offered.

The concept itself is not wholly simple. Questions may be raised about what counts as full consent or sufficiently informed consent, especially in the case of subjects who may find the idea of randomisation difficult to grasp or who may have problems, as we all do, with the calculation of risk. I believe, however, that we should not make too much of these difficulties, which are inherent in the nature of medical research and which can be minimised by tactful and sympathetic dialogue with potential subjects. The central moral problem, however, is concerned with the possible exploitation of the subjects of research. For research, including clinical research, is aimed, not at the good of the individual patient, but at the production of medical knowledge, which is for the good of society at large (although the individual patient may benefit from it by chance). This is the difference between research and the use even of innovative treatment for an individual patient.

In a research programme the subjects are being used as a means, not as an end in themselves. To treat someone merely as a means is widely agreed to be a moral evil, a breach of the "categorical imperative," on which the very possibility of morality was held by Kant to depend. Philosophy apart, to make use of people, especially when they are not aware of what is going on, is generally agreed to be wrong. This evil is removed if

people offer their services voluntarily. They then become willing partners in a joint enterprise rather than mere tools in it. Since they are free to decline to take part, their power of choice has not been overridden. They are being treated as befits a human as opposed to any other animal. The moral principle involved here is often referred to as the principle of autonomy. I prefer the more precise title of the principle of non-exploitation. Since it is especially easy to exploit the helpless and incompetent—those who, though human, seem to have little power of understanding or making a serious choice—the principle ought to be considered scrupulously in the case of such people. However, if research into the very conditions that produce such incompetence, such as Alzheimer's disease, is to continue it may be necessary to resort to consent by proxy. It seems morally important that such consent should be sought.

The principle of non-exploitation has come to seem to many to be by far the most important moral principle that should govern research using human subjects. This is understandable on historical grounds: there are far too many cases, in the second world war and, sadly, more recently, of whole populations of people being damaged or destroyed as victims of research programmes about which they were ignorant or had no choice. The relevance of history is that it causes people to deploy the "slippery slope" argument—if once the principle of non-exploitation is allowed to be breached where will it end? To which the answer implied is that it will end in horrors such as were revealed at Nuremberg.

However, the slippery slope is a weak argument (though it exercises an enormous power over the imagination) in that there is no logical connection between allowing the principle to be breached in some cases and allowing it to be totally forgotten. The argument relies on a poor view of human nature: "Give them an inch and they'll take an ell." Biological and medical scientists are especially suspect these days, and this arises from the power of the slippery slope. It is crucial, therefore, that in this context editors should keep their heads and differentiate between different cases in which the principle has been breached.

There is all the difference in the world between, on the one hand, extending the use of anonymous data, collected for a particular study, to a further, previously unthought of, study and, on the other hand, the randomised testing of drugs in the treatment of a specific disease. In the first case there is no question of harm accruing to the subjects, and thus the use of the word "exploitation" is an exaggeration. It seems to me a misuse of words to suggest that not obtaining informed consent in itself constitutes a harm; sometimes it amounts to exploitation, sometimes it does not. Nor does it seem that the use for research purposes of discarded or unwanted tissue is exploitation—though there exists a lack of clarity about the relation between an individual and his or her body parts, which ought to be remedied. The matter becomes critical when a pharmaceutical company may make vast profits from the use of, say, a spleen that has been removed from the body of an individual. Does the person have property rights over something that was once, in some sense, his or her property but is so no longer?

The conclusion is that editors must try, in the words of a prayer much used in Hertford College Chapel, "to distinguish things that differ." This makes the editorial function hazardous, with editors potentially subject to accusations of failing in their duty to ensure the moral respectability of research. But any other policy seems to me to rely on a dogma—that there are no other principles worth considering in the ethics of research except the principle of non-exploitation—and to rely also on an exceptionally wide and unrealistic view of what counts as exploitation.

Trial subjects must be fully involved in design and approval of trials

Lisa Power

Terrence Higgins Trust, London WC1X 8JU
Lisa Power, *health advocacy manager*

Reading the *BMJ* debate about informed consent and publication recently, it seemed to me that there was a basic flaw in the premise. Instead of "Why?" I wanted "How?" If informed consent is about the dignity and empowerment of trial subjects and the genuine participation of patients in our health research, then how can this be maximised throughout the trial process? If we look at the overall issue—the involvement of patients or potential patients—rather than the single aspect of informed consent we can begin to treat the disease rather than arguing over the symptoms.

I do not believe that you can obtain better practice about informed consent merely by making a rule about publication. There will always be some people prepared to obtain such consent technically without any real commitment to its spirit, because all they see it as is a signature at the bottom of a form and not a partnership. This is not to impugn the motives with which they entered research, but lack of time and money and urgency of need can put pressure upon the best of intentions. Of course, there are trials in which informed consent cannot be obtained, as Len Doyal outlined, and any hard and fast rule that the *BMJ* made about publication would probably have to be broken at some point. But the onus of justifying failure to obtain consent should not arise at publication stage for the first time; questions should be being asked far earlier in the process.

To improve the practice of obtaining informed consent wherever possible there must be a number of changes in attitudes. There needs to be a greater emphasis in doctors' education on interpersonal and communication skills, and a greater willingness on the part of some trial investigators to involve nursing staff in communicating with trial volunteers; doctors are not the only people with a voice and a brain. Secondly, there needs to be an understanding that giving patients or potential patients some say in the design and approval of trials is a positive process and not just a hoop to jump

through. This involvement can stretch from trial design to writing information sheets and sitting on ethics committees. Thirdly, the onus should be clearly on those designing trials to show, as part of their basic data, their process for subject consent and uptake, rather than on others to challenge them in retrospect.

Placing the subjects of a trial at the centre of the process is not an easy matter. It may need extra finance or education, or other forms of support, and it may take time. Sometimes, I agree, it is not possible because of the nature of the trial, but this should be the exception—the question about informed consent should always be "Why not?" rather than "Why?" In my experience, as a participant in a vaccine trial and as an activist pressing drug companies to talk with us about their trial designs, such involvement is always to the good. I can appreciate that it feels like a nuisance to people who have not had to consider us before, but it leads to better trials with better uptake and, of equal importance, to greater involvement of individuals in their own health.

By fostering debate about informed consent, the *BMJ* has already added more to this process than any simple rule would do. I hope that it continues to do so.

Studies that do not have informed consent from participants should not be published

Heather Goodare

Horsham, West Sussex RH13 6DF
Heather Goodare, *personal counsellor*

In his editorial of 12 April 1997 the editor asks, "Should the *BMJ* reject all studies that do not include informed consent?"[1] The simple answer is "Yes." This is the stated policy of others that observe the "uniform requirements for manuscripts submitted to biomedical journals."[2] There is no good reason why the *BMJ* should not follow suit.

It is clear that the Declaration of Helsinki is no longer entirely satisfactory as a standard to which medical journals should adhere. The declaration is a watered down version of the Nuremberg Code, formulated after the trials of Nazi doctors who had experimented on concentration camp inmates during the second world war.[3] The code states unequivocally: "The voluntary consent of the human subject is absolutely essential." But the Helsinki Declaration introduced a section on clinical research which says: "If the doctor considers it essential not to obtain informed consent, the specific reasons for this proposal should be stated in the experimental protocol for transmission to the independent committee" (Clause II.5).

Lack of consent in cancer trials has long been a matter of concern,[4 5] and this clause could have been used as an excuse for not seeking consent from competent patients in recent examples of clinical research.[6–10] There is some evidence that not seeking consent, far from eliminating bias (which is usually the reason given), actually adds to it. Patients who find that others in the same category are receiving different treatment will want to know why.[11] It is best to come clean at the outset: patients who discover they have been deceived lose trust in their doctors.

If the present debate leads to a radical rethink of the way clinical research is conducted, matters may improve. Researchers are ignoring a valuable resource if they do not consult patients in designing their trials in the first place. This can save time and money and lead to better outcomes.[12] Also, "joint ownership of the work being done keeps patients involved, instead of isolating them."[9] There should be no more debate about the need to seek consent from competent patients. There are, however, some grey areas that need further consideration.

The Helsinki Declaration makes provision for cases of legal incompetence, or physical or mental incapacity, though national legislation varies, and there is a case for amending legislation when it is deficient, to make proper provision for proxy responsibility where appropriate. We cannot take it for granted that an unconscious person would have consented to a trial had he or she been conscious: indeed, we have a special duty to respect the rights of those who cannot speak for themselves. If a proxy for the patient cannot be found the research should not proceed. In an emergency the doctor's duty is to do his or her best for the patient in the light of current knowledge. The rights of children, too, need to be respected: in the words of Lisa Hammond, aged 15, "Society should accept people of all types, and respect everyone's right to make their own decisions once they have all the facts, be they adults or children."[13]

There remains the matter of clinical audit and epidemiological research. We cannot assume that patients will not mind their data being used for such purposes. As Doyal observes, "Normally patients should give their explicit consent for their records to be accessed."[14] Moreover, these data must be anonymised: we cannot be sure that patients will not mind if researchers and civil servants (who could well be colleagues in the same office) see their clinical details. Researchers may have overstepped the mark in a recent breast cancer audit,[15] by requiring personal data—including names, dates of birth, and postcodes—not from the patients themselves but from doctors and administrators. This sheds light on the uses to which cancer registries could be put and raises awkward questions.[16] It seems that careful thought needs to be given to this matter, including the possibility of a standard question to patients at the time of treatment asking permission to review their records for research purposes. Some clinicians already follow this procedure.[17] Patients are well aware of the importance of such research, and if it is conducted appropriately they could be enthusiastic participants. But their consent must not be taken for granted.

A further problem occurs with the use of stored human tissue. Donors of blood, organs, or cadavers usually give explicit consent to the use of their bodies for therapeutic purposes, medical education, or

research, but patients who provide tissue specimens during the course of their own treatment normally do not. If any use of this material for other purposes is proposed, patients' permission (or that of a responsible relative) should be sought. There have already been examples of commercial exploitation and even attempts to patent such material: any possible profit should be used in accordance with patients' wishes. A moving story is told by Steingraber of the cell line MCF-7, widely used in medical research. The initials stand for Michigan Cancer Foundation, and the 7 for the seventh attempt to establish a self perpetuating stock of cells from the body of the patient. The woman was a nun, Sister Catherine Frances, who died in 1970.[18] Would she have wished a donation by way of royalty to be made to her convent every time her cells were used? Was she asked?

A breast cancer patient expressed the dilemma to me as: "In Victorian times they got upset about body snatching. Now they steal bits of your body when you're still alive." These issues need further debate, with members of the public and patients themselves taking a full part in the discussion.

HG experienced breast cancer in 1986 and now works as a counsellor. She chairs the research committee of the UK Breast Cancer Coalition.

I thank Clare Dimmer, Carolyn Faulder, Andrew Herxheimer, Pamela Goldberg, Ann Johnson, Margaret King, and Charlotte Williamson for helpful comments on an earlier draft. Responsibility for the final version is, however, mine alone.

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Thrombolytic treatment for acute ischaemic stroke: consent can be ethical

Richard I Lindley

According to proposed guidelines by Len Doyal it is unethical to randomise patients who are not competent to give informed consent in a randomised controlled trial when the treatment risks are not "minimal in relation to the standard available treatment."[1] This would rule out trials of many forms of medical and surgical treatment for a wide range of disabling and life threatening conditions. Is it ethical to condemn millions of "mentally incompetent" patients to no prospect of improving outcome? I believe a better guideline would be that such a trial is ethical if the treatment is promising but unproved provided that the potential risks are considered acceptable by the public. I illustrate my argument by discussing the role of thrombolytic treatment for acute ischaemic stroke.

Summary points

Recently suggested ethical guidelines would limit inclusion of mentally incompetent patients to trials of treatment that had only "minimal risk"

Some new treatments may have a substantial risk, but their potential for substantial benefit means that we should not exclude them from further evaluation

The criterion of "minimal risk" should be changed to "promising but unproved," provided that the public agrees that the risk is worth taking

A new type of card, the randomised controlled trial card, may help educate the public about trials

With proper safeguards, it is ethical to randomise mentally incompetent patients into further trials of thrombolytic treatment for acute ischaemic stroke

Department of Clinical Neurosciences, Edinburgh University, Western General Hospital, Edinburgh EH4 2XU
Richard I Lindley, *part time senior lecturer*

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Ethical requirements for trials of thrombolytic treatment

The box shows the major requirements that I consider necessary for further randomised controlled trials of early thrombolytic treatment for acute ischaemic stroke.

Criteria needed to justify trials of thrombolytic treatment for acute stroke

- Treatment promising but unproved
- Patients would be prepared to risk early death in order to avoid the severe consequences of a stroke
- Information overload at randomisation is reduced by local education programmes for those at risk of stroke
- Lay people agree to and contribute to the trial design
- Local ethics committee agrees to the trial design

Thrombolytic treatment promising but unproved

This is an absolute ethical requirement for a trial—we must not test unpromising treatments, and we should not withhold proved treatments. Why is thrombolytic treatment for acute ischaemic stroke promising but unproved?

Several small trials have been published, and in a recent overview a consistent picture emerged.[2] There is a definite early risk of death (chiefly due to cerebral haemorrhage), yet those who survive seem to be less disabled. Despite only one of the five trials of recombinant tissue plasminogen activator showing benefits,[3] this has been licensed for use in the United States. In this study of 624 patients, recombinant tissue plasminogen activator was given within 3 hours of onset stroke, and the benefits seemed substantial. For the equivalent of about every 1000 patients treated, about 80-100 avoided a poor outcome (death or dependency) but the net effect of the treatment on mortality was unclear.

Should we base treatment decisions for the next few million people who have strokes in the world on only one positive trial?[4,5] I suggest not. Indeed, the data from the recent overview suggested that other thrombolytic agents may also be effective if given early.[2] Overall, those randomised to treatment within 3 hours of onset of stroke had a non-significant excess risk of early death of about 9/1000 but a significant increase in long term independent survival (about 141/1000). So uncertainties remain. Is recombinant tissue plasminogen activator the best drug? What is the optimal dose? What is the effect of treatment in different patient subgroups? What is the time window of efficacy? Is it safe to use aspirin or heparin after thrombolysis? Is treatment safe when early infarction is visible on a computed tomographic brain scan? Are the impressive results from a few specialist stroke units in the United States generalisable? In view of the uncertainties, thrombolytic treatment seems promising but unproved.

LARRY MULVEHILL/SPL

In emergency situations it may be inappropriate to try to obtain informed consent

The main problem with further trials is the difficulty of getting consent. Many patients are dysphasic, drowsy, or have anosognosia (no recognition of their stroke deficit) and are therefore mentally incompetent or physically unable to give consent. Doyal has stated that the trial risks must be "minimal" if such patients are to be included into a randomised controlled trial. Some may not consider the risks of early thrombolytic treatment minimal, with an estimated excess of nine deaths for every 1000 patients treated, but may view the potential benefits (more than 100 extra independent survivors per 1000) worth the risk. I would prefer an ethical guideline to be based on the clinicians' uncertainty (that is, the treatment is promising but unproved).

Patients would consider risky treatments to avoid severe consequences of stroke

Would patients with acute stroke accept the risk of thrombolytic treatment? Unfortunately, the same problems of obtaining consent apply to any efforts to obtain patients' opinions on this matter. However, some recent studies can help to inform this discussion. Solomon et al asked elderly people for their views on stroke disability, and most respondents rated severe stroke deficits (in language, cognition, and motor weakness) as bad as, if not worse than, death.[6] However, there was no consensus about the impact of minor and moderate deficits. In a similar study Gage et al calculated quality of life for three different stroke scenarios representing mild, moderate, or severe stroke deficit.[7] While most subjects rated the description of a severe disabling stroke as worse than or equal to death, some scored it similar to their current health status. Conversely, some people scored mildly disabling stroke as equally bad as death; the scores for moderate stroke were bimodally distributed.

These studies confirm a widely held belief that many, but not all, people consider severe disabling stroke to be a fate worse than death. Presumably, these people would be prepared to accept a risky treatment. But what about those who do not want to be exposed to such risks? How can we give patients a choice in a thrombolytic trial? One potential solution is to get some of this information across by public education before the patients have a stroke.

Information needed for consent to a trial of potentially risky treatments

The box shows the sort of information required for consent. This is given in language that has good readability (easy to check with standard computer word processors), but it still represents a substantial amount of information—perhaps too much. Would a public education campaign (based on the box) help? This strategy has been suggested for women with breast cancer,[8,9] and a similar approach for stroke medicine is worth a try. In these days of evidence based medicine, surely the purchasers and providers of

Information needed for informed consent for a thrombolytic trial

- "You have had a stroke"
- After appropriate brain imaging: "Your stroke has been due to a blood clot blocking the blood supply to the brain"
- "Immediate treatment with aspirin may help but it is not a powerful treatment"
- "Clot busting drugs (thrombolytic therapy) can sometimes reverse the stroke and speed recovery"
- "However, these clot busting drugs can sometimes cause massive bleeding in the brain which can make the stroke worse or even kill you"
- "If you are happy to consider the trial, your treatment may, or may not, include the new clot busting drug. This is decided by the study design, a random allocation, a bit like tossing a coin to decide which treatment to use."

(Readability: Flesch Reading Ease 70; Flesch-Kincaid Grade 7; Coleman-Liau 10; Bormuth 9.5 (Microsoft Word 6 Grammar check))

health care (and politicians) have a duty to inform the population on the means to obtain the best evidence? Stroke researchers should "sell" their trial to their "at risk" population. The risk for middle aged people having a stroke if they live to the age of 85 years is about 20-25%, and about 16% of all women and 8% of all men die of stroke.[10] It therefore seems reasonable to educate the public about stroke—perhaps adding a bit of preventive medicine along the way (such as stopping smoking, reducing dietary salt, improving diet, etc).

Encouraging participation in randomised controlled trials

Everyone is a potential subject for a randomised controlled trial. Consent is often considered difficult by doctors and patients,[11] and I suspect this is a reflection of poor understanding. Patients demand the best treatment, and a randomised controlled trial should be evaluating the current "gold standard" with one considered, by all available evidence, to be a more promising treatment. This may or may not prove to be the case, but routine data monitoring of trials in progress will limit any hazard to a minimum. This sort of reassuring information may encourage people to participate.

As a method of educating the public, I suggest we introduce a new type of card—the randomised controlled trial card—to be carried by people who understand randomised controlled trials and wish to be considered for future appropriate trials. The card could be issued to all those who have been randomised into such a trial, and its use could be extended if successful. For example, patients who have just had a transient ischaemic attack could be issued with a randomised controlled trial card if they were happy to carry it. If such a high risk patient subsequently had a dysphasic stroke their relatives would be more informed about prior wishes, which should help them give or refuse assent for an appropriate randomised controlled trial. The main drawback to such a scheme would be if some unscrupulous researchers used the card to bypass all consent procedures.

The legal situation in the United Kingdom is also unclear. Doctors can proceed with medical treatments without consent (for example, in cases of coma or severe injury) provided that they act in the patient's best interests and the treatment is reasonable as judged by usual medical practice.[12 13] I consider that randomisation into a well conducted, randomised controlled trial "best practice" for many clinical situations, but this particular situation has never been challenged in court. While many ethics committees have allowed (and continue to allow) relatives to assent to randomisation for those who are mentally incompetent, this grey area of the law may need to be clarified for the future protection of patients and to facilitate research.

As I am not sure whether a randomised controlled trial card would work, evaluation would be needed to check that the benefits (more people recruited in trials) outweigh the potential risks (a worried population).

Conclusions

If we adopt Professor Doyal's ethical guidelines we will not be able to improve the care for many patients with stroke (or other mentally disabling conditions). I suspect the public would disapprove of such a move, and I believe that medical researchers have a duty to inform the public of ethical dilemmas and propose potential solutions.

In the case of a new trial of thrombolytic treatment for acute ischaemic stroke I believe we need to inform our local, at risk population about stroke, thrombolytic treatment, and the concept of randomised controlled trials and get a general agreement from our local public that the study is reasonable. The introduction of a randomised controlled trial card may benefit the population by improving participation into clinical trials.

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Informed consent and research

David Benatar, Solomon R Benatar

Department of Philosophy and Bioethics Centre, University of Cape Town, Private Bag, Rondebosch 7700, South Africa
David Benatar, *lecturer*

Department of Medicine and Bioethics Centre, University of Cape Town, Observatory 7925, Western Cape, South Africa
Solomon R Benatar, *professor of medicine*

Correspondence to: Dr D Benatar dbenatar@socsci.uct.ac.za

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In the debate opened by the *BMJ* on whether research is ethical if it meets the standards of the Declaration of Helsinki but is conducted without informed consent, Len Doyal provides some powerful arguments for why the request for informed consent should be inviolable.[1]

While vigorously defending the inviolability of informed consent, he concedes that it is not necessary in certain circumstances. An uncontroversial case is that of incompetent patients (although even here other rigorous requirements must be met). However, the other exceptional cases he mentions seem to have some unfortunate implications for his defence of informed consent. He thinks that for epidemiological research on patient records the informed consent requirement may be waived if certain conditions are met: (*a*) that access to the clinical record is essential to the research; (*b*) that consent is not practicable; (*c*) that the research is of sufficient merit; (*d*) that it may benefit the patient whose records are studied; (*e*) that, when possible, the researchers are unable to connect the records with the patient's identity, but that where this is not possible, patients will not be identifiable when the results are made public; (*f*) that it is not anticipated that contact will be made with the patients as a result of research findings; and (*g*) that access is restricted to specific categories of information that have been approved by the local ethics committee. Professor Doyal thinks that similar conditions should apply to research on stored tissue from unconsenting anonymous donors.

The South African HIV study, which Professor Doyal criticised for not obtaining patients' informed consent for HIV tests, involved performing a blood test and not simply viewing records,[2] and thus does not precisely slot into one of his three exceptional categories. However, this point does not seem to be a pivotal issue: one can, after all, have consent to draw blood without having consent to test it for HIV seropositivity. Drawing blood without consent would introduce a problem not permitted by the list of conditions Professor Doyal stipulates, but, assuming that there was consent to draw blood, the anonymous testing of that blood for HIV in the Natal study meets all the conditions enumerated above. Condition (*f*) lends itself to variable interpretations, but it seems to us that merely informing patients that they had been subject to an HIV test as part of a study does not constitute contact with patients as a result of research findings. Telling them the result of the test, and counselling for HIV positive status, would constitute such contact, but it would be with the consent of the patients.

It seems then that Professor Doyal gives with one hand what he takes with another. He criticises the South African study for failing to obtain informed consent, yet this study meets the very conditions that he thinks he must obtain in those exceptional cases in which informed consent is not necessary.

The crucial condition is whether the researcher can link the medical record to the identity of the patient. We agree that informed consent is unnecessary in research that involves no withholding or providing of an intervention and which meets the other conditions but where the identity of the patient cannot be linked, even by the researcher, to the medical record. Knowing that there is an unidentified person who has HIV does not inhibit that person's autonomy or violate his or her privacy. By contrast, obtaining the knowledge that an identifiable person has HIV is an invasion of the person's privacy if he or she has not consented to this information being obtained. Thus, the difficult case is when the researcher gains sensitive information about a research subject without consent. In such a case informed consent is important, and if it is to be overridden a strong argument will have to be made. Professor Doyal's conditions suggest that he may have sympathy for the view that the requirement for informed consent may be overridden in this case, but his arguments suggest that no such exception should be made. We can think of no compelling argument for why an exception should be made in this case.

What are the implications of this for the Natal study? The ethics committee and researchers went to great lengths to ensure that all but one of the researchers were prevented from connecting HIV status with the identity of patients. Moreover, all means of linking the HIV tests with the identity of patients were destroyed at the end of the study. If we are correct that there are no compelling arguments to justify such unauthorised violations of privacy, then the Natal study is ethically defective, even though to only a limited degree. This shortcoming is especially regrettable given that even the limited invasion of privacy could have been avoided by encoding patient identity and thereby ensuring that none of the researchers could have been able to establish a link between a patient's identity and HIV status. Even if one thinks that minor invasions of privacy or other limitations on autonomy are justified if they can bring great benefits, one must agree that it is better if these minor intrusions can be avoided.

A longer version of this article is available on our website

GISELE WULFSOHN/PANOS PICTURES

Are the criteria for informed consent the same in Third World situations as in Western countries?

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Videos, photographs, and patient consent

Catherine A Hood, Tony Hope, Phillip Dove

A video showing real surgical operations was about to be sold through high street shops during the closing months of 1996. The BMA, GMC (General Medical Council), and the Institute of Medical Illustrators were quick to condemn this commercial exploitation of sensitive and confidential material. Media coverage was generally critical.[1] A temporary injunction stopped any sales of the video, and a subsequent court order permanently prevented its distribution. Although the film's producer claimed that the surgeons concerned had given their permission for the video footage to be used, it emerged that many of the patients had not.

It is common practice to illustrate medical books with photographs of patients. In how many such cases have the patients given valid consent for publication? The advent of digital imaging has allowed photographs and video recordings to be stored, accessed, and distributed around the world with ease. Consequently, there is an increasing demand for medical images. Does valid consent for the use of a photograph in book publication cover the use of the same picture in electronic publishing? In most cases we doubt whether there is sufficient documentation to find out for what uses the patients originally gave consent.

Summary points

- The internet and electronic publishing are powerful tools for the dissemination of medical information and have created a demand for medical images
- Consent should be requested from patients for all medical photography and for the subsequent use of their images whether or not they can be identified by the picture
- Specific consent should be obtained if an image will be used in electronic publishing and we describe a new consent procedure that covers such use of pictures
- Review of this procedure after 4 months shows that 85% of patients continue to give consent for publication of their image despite explicit discussion of the possibility of the image becoming available on the internet

Ethox, Division of Public Health and Primary Care, Institute of Health Care Sciences, Headington, Oxford OX3 7LF
Catherine Hood, *OMIR project director*
Tony Hope, *reader in medicine*
Oxford Medical Illustration, John Radcliffe Hospital, Oxford
Phillip Dove, *director*
Correspondence to: Dr Hood

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Ethical principles

Respect for patient autonomy is generally regarded as one of the central ethical principles in medical practice.[2–4] Such respect has two related implications for the use of medical images: the first is to do with consent, the second with confidentiality. In general, information about patients that doctors obtain in the course of their clinical work is confidential.[5] A doctor should normally have the patient's consent before sharing that information with others beyond the healthcare team, particularly if the individual might be identifiable from that information.

This issue has been discussed with regard to published case histories in the *BMJ*.[6 7] The editor wrote: "Authors and editors must thus ensure that patients have given their consent to publication whenever there is a possibility that the patient may be identified." Although some exceptions to this position have been suggested, such as when interests of public health outweigh the importance of confidentiality,[8–10] it is broadly the position agreed by the International Committee of Medical Journal editors.[11] Images taken in the medical context, just like the information that a patient gives a doctor, form part of a patient's confidential records and should therefore be treated in exactly the same way.

Fully informed consent

Existing BMA and GMC guidelines state that patients have the right to be given as much information as possible on where an image might be used.[12 13] It seems clear that, if a patient has given permission for a picture to be shown only to appropriate professional staff, such an image should not be used in publication. However, does explicit consent for publication of a photograph in a medical textbook cover its use in electronic publishing?

It has always been possible for members of the general public to have access to medical images by browsing through textbooks, although we imagine this rarely happens in practice. The situation with electronically published images could be very different. Even if these are published in CD ROM "textbooks" it is easy for them to be copied and, for example, put on to the internet, where they would become readily available to a large number of people. Indeed, for educational purposes, it may well be desirable to put such images directly on to the internet. With current levels of security on the internet, there is little to ensure that such images are not widely seen, distributed, or misused.

It is therefore important that when an image is taken for medical publication the patient is made aware of the possible forms of publication now in existence and of the lack of control that it is possible to exercise over who will see the images. If patients have given consent for book publication only, it is doubtful whether such consent validly covers publication in electronic formats and on the internet.

Patients' rights—to ownership or just to confidentiality?

Medical images can be categorised into those from which the patient can be identified and those from which identification is unlikely. Just as much care needs to be taken in using this categorisation with images as with case descriptions.[6] A traditional way of preserving anonymity when a photograph includes a patient's face is by blacking out the eyes. It is questionable whether

Patient consent form is available on our website

this successfully disguises identity.[11] Digital imaging can distort features a little more effectively (see figure), but what seems unidentifiable to a doctor may not be so to patients and their family or friends. Distinguishing marks, tattoos, posture, and gait may all reveal identity.

In many cases identification is most unlikely, such as from a photograph of a small area of skin or from a chest radiograph. In such cases is consent required? It could be argued that if patients cannot possibly be recognised from a picture they have no right to restrict its use. This has been the position taken in a number of discussions about written information[6 11] and is presumably the principle behind Smith's conclusion: "If we have an epidemiological paper with data on 5000 individuals will we require consent from all of these people? The answer will always be no when, as is usual, the data are presented in a combined form: no individual is identifiable."[7]

However, patients may have rights akin to ownership, rather than confidentiality, over an image of themselves. For example, it would certainly seem wrong for a doctor to take a photograph of a skin lesion without the patient's consent, and, if it is wrong to take the photograph without consent in the first place, should the patient not be able to restrict the use of the photograph? Patients do have the right, we believe, to give consent for photographs to be filed in their notes but refuse permission for them to be placed in the public domain. If this is correct then it would seem that, even when an image does not identify the patient, the patient's consent would be needed for publication. This is the position now taken by this journal, and by the GMC in its recent guidelines on visual and audio recordings of patients.[13] According to these guidelines, even when a patient could not possibly be identified, a recording cannot be used beyond the medical setting without specific consent. Continuing this line of reasoning, even when a patient has given consent for book publication it is not sufficient to assume that this allows electronic publication.

Revised consent form

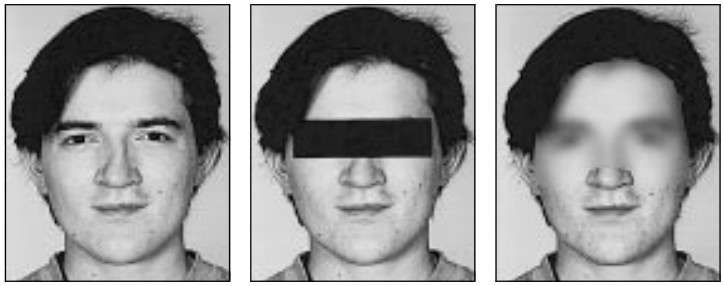
Oxford Medical Illustration are currently involved in collecting an electronic database of photographs and video recordings for teaching and publication, including electronic publication. The controversy prompted by the surgical video led us to carefully consider the issue of patient consent. Review of consent forms used by several medical illustration departments showed them to vary greatly in design and in the degree of information presented to patients. None of these forms mentioned the possibility of electronic publication or of distribution through the internet. To address this, we constructed a new consent procedure and consent form (see box). In developing this procedure, we rejected the possibility of relying on "implied consent," which is raised in the GMC guidelines.[13] While such consent may sometimes be valid with regard to recording the image, it cannot provide valid consent for the image's publication.

Particular care needs to be taken with regard to minors. The guidelines of the International Committee of Medical Journal Editors allow parents or guardians to give consent for the publication of written information.[11] In our procedure the photographer requires consent from both parent (or guardian) and a competent minor (even if below 16 years old). The fact that the image cannot be removed once it is in the public domain is emphasised.

This procedure and consent form have been in use for several months. Some patients have expressed concern over the potential use of their images on the internet, and for this reason have refused to give consent for publication. Others have not wanted their image to be used for commercial gain, in which case the image is not entered onto the main database. An audit of the first four months of using the new procedure showed that only 15% of the 518 patients

New procedure for obtaining patients' consent for publication of medical images

1 The clinical photographers have been trained in asking consent from patients. A new consent form has been produced for this purpose
2 The patient is asked to read through the consent form (available on our website www.bmj.com)
3 The photographer explicitly discusses each of the sections of the consent form with the patient and invites questions
4 The patient is informed precisely about the nature of the images to be taken and whether the patient is likely to be recognisable
5 Patients who give consent and who may be identified from the images are given two weeks from the date of photography, during which they can withdraw consent, before the pictures are available for publication
6 Three categories of consent are presented to patients: (*a*) use of the images in their confidential notes, for medical teaching, and for publication; (*b*) use restricted to patient notes and medical teaching; (*c*) use limited to confidential notes alone
7 In discussion with the patient attention is drawn to the possibility that the image will be used in electronic publication
8 The patient may view the images at any time and can withdraw consent, in which case the image is deleted permanently from the database. However, it is emphasised at the time of consent that full recovery of the image may not be possible once it has been made available for publication
9 It is made clear that refusal to give consent for the image to be made, or to be used in any specific way, does not affect the patient's medical care
10 If the patient is aged under 16 then consent is requested from a parent or guardian. However, the views of competent minors are taken into account, and if they refuse to give consent no images are taken
11 After a video image has been taken the patient is asked to confirm the initial consent



Facial view (left), with traditional masking (centre), and with digital disguise (right). Picture reproduced with subject's permission

referred for clinical photography refused to give consent.

As consent procedures in medicine, medical research, and medical reporting continue to develop, the procedure for the publication of medical images needs to be scrutinised. This issue is relevant not only to departments of medical illustration but also to individual physicians who wish to continue using personal slide collections for lectures and publication.

Contributors: CAH and PD developed the new consent procedure. CAH, PD, and TH jointly developed the wording of the consent form. TH and CAH explored the ethical issues associated with medical photography. The paper was written jointly by CAH and TH and edited by PD. Revisions were by TH and CAH.

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Coping with loss

Separation and other problems that threaten relationships

Robert S Weiss

This is the third in a series of 10 articles dealing with the different types of loss that doctors will meet in their practice

Gerontology Institute, University of Massachusetts, Boston, Boston, MA 02125, USA

Robert S Weiss, *emeritus professor of sociology*

Series editors: Colin Murray Parkes and Andrew Markus

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Summary points

- Relationships are an important source of security and are influenced, for good or ill, by the expectations arising out of secure or insecure attachments earlier in life
- Distrust undermines security and causes grief and anger which may further undermine trust
- Children are often at risk when parental relationships break down
- Relationships that are ending are a cause of grief in both parents and their children and may cause symptoms and requests for help
- Doctors can reassure people of the normality of their grief, provide a safe place for its expression, and assess the need for specialist help

The secure or insecure attachments made to parents in childhood often prefigure the attachments which we make in adult life and predict the pattern of grief to which they give rise after the death of a partner.[1] This article examines the problems of change and loss that can arise within an established "pair bond" relationship and cause it to go wrong and, sometimes, to end. It focuses on the particular problems that may bring people into medical care.

Although people rarely come to their doctors complaining of problems in living, many psychosomatic and psychiatric disorders are caused by marital stress, and doctors often become aware that a patient is struggling with an unhappy relationship, or dealing with its loss, in the course of a diagnostic inquiry or a discussion of treatment procedures. In such cases an understanding of the emotional causes and consequences of relational problems, and how they might best be responded to, will be useful to the practitioner. I have covered these issues in more detail elsewhere.[2–4]

Relationships in adult life

Marriages and similar relationships—all the strong pair bonds between adults, regardless of marital status—are not only partnerships in the management of personal and familial life but also adult attachments. They provide each of the partners with an emotional base with which is associated a sense of security.

Relationships arise out of complex associations between the mutual perceptions of the two people and their earlier experiences of attachments, particularly those to parents. These complex associations are further modified, for good or ill, by events within the relationship.

In the early days of the relationship, when the partners are together, each is likely to feel a sense of comfort or completion. They will be raptly attentive to the other. Each will have learned to associate the other's image and voice with feelings of security and wellbeing. If a marriage is reasonably happy, simply hearing the other's voice in a telephone call, or seeing the other's image in a photograph, can foster feelings of wellbeing.

Problems in relationships

Problems can arise for various reasons. Sometimes the attachment of one or both partners is a reflection of an earlier attachment that was insecure and gave rise to distrust. When problems arise, as they will in all our lives, the partners may make negative assumptions about each other that belong to these earlier relationships rather than to the present situation. Alternatively, a new partner may fail to live up to ideal-

ised expectations arising from an earlier relationship. Whatever the cause, marital problems are devastating in their effects because the relationship that should foster security becomes a source of threat instead. Conversation is defensive, each partner protecting himself or herself against an expected assault by the other. Even when anger explodes into blind rage, other elements are being expressed by words and actions; these include despair, fear, and a misguided belief that the other can be intimidated into becoming once again a loving figure.

In many unhappy relationships, conflict is limited, and instead one or both partners withhold their love. At home, partners avoid each other. Each then feels utterly alone in the world: isolated within the relationship but unwilling to invite friends into an emotionally chilly household.

A truly unhappy couple may not divulge just how bad things are without sensitive, sympathetic interviewing; each partner feels there is too much chance of being misunderstood. Yet it will be found that the couple no longer kiss, perhaps no longer eat together, and the spirit of cooperation necessary for working together is absent.

Children and marital conflict

Some unhappily married parents are able, at least to an extent, to conceal from the child their feelings about each other and to show interest in and affection for the child. However, the child of such a marriage is likely to be aware of the parents' distance from each other, and underlying anger.

In general, children do not do well when their parents are unhappy with each other. Sometimes one of the parents establishes an alliance with the child from which the other parent is excluded. This imposes on the child impossible dilemmas of maintaining incompatible loyalties and unrealisable commitments.

Children whose parents are preoccupied by their unhappy marriage are likely to feel isolated and alone. They may seek support from outside the family, from teachers or friends, or they may turn in on themselves or show other aberrant behaviour. Most children in unhappy homes make do, as best they can, with too little emotional and moral sustenance.

Helping troubled marriages

Couples whose relationship is troubled can seldom be helped in a single session in their doctor's office; they are likely to need marital counselling. The doctor may have to strongly support this in order to overcome the couple's fear that counselling will make things worse. At the same time the doctor must be careful not to push the idea too strongly, in case one of the partners feels further alienated and further mutual disappointment ensues.

Separation

Should the couple separate, both partners are likely to be distressed. Unlike the grief which follows a loss by death, the grief of marital breakup is likely to be confused and mixed with intense anger, and to give rise to uncertainties about personal acceptability and worth.

ADRIANA DORSETT

The ending of relationships gives rise to mixed urges to re-establish the relationship coexisting with distrust of the relationship. Persisting tension is likely to express itself in preoccupations and in sleep difficulties. For a time each partner may experience an anxious, driving preoccupation with regaining the other, a preoccupation that can coexist with intense anger and determination to be rid of the other. Friends may take sides or may back off, leaving one or both partners socially adrift.

Children and separation

Parents experiencing the separation distress that accompanies the end of the relationship are likely to have little energy for attending to the needs of their children. However, the children of a couple who are breaking up will inescapably be distressed and in need of parental attention. They are likely to grieve over one of their parents departing from the home, to worry about the wellbeing of both parents, and to worry about their own wellbeing. If they are 9 or 10 or older they may express anger with one or both of their parents, despite their continued need for both parents' caring support. Their schoolwork is likely to suffer as they become preoccupied with their familial situation. Most at risk of negative consequences are those children who are recruited as allies by one or both parents or used by one or both parents as messengers to the other parent. Children do badly when put in the middle.

Custody of the children

The parent who does not have custody of the children will have to deal with feelings of loss. Grief may be so intense and painful that it causes the parent to make unreasonable attempts to regain custody or to demand unreasonable access. Here the doctor can help by providing parents without custody an opportunity to express and work through their grief and by assuring them that their devotion to the children, despite its difficulties, will be recognised and appreciated by the children.

Helping at times of breakup

People going through separation, particularly those with children, have many important decisions to make.

At the same time, the parents are apt to be confused and unsure of themselves. Hence the parents are, at this time, likely to be unusually amenable to advice.

The doctor who becomes aware that a patient is going through separation from a partner can explore with the patient the extent to which help is needed. It may be enough to reassure a distressed patient that intermittent feelings of desolation are normal accompaniments of separation, and that such feelings will subside with time. The patient might also be cautioned that, although anger is natural in separations, it sometimes causes people to say and do things that they later regret.

It may be useful for the doctor to schedule a further appointment with the patient for one or two months later, to be cancelled by the patient if things are going well. This demonstration of the doctor's continued concern and availability can in itself be helpful to the patient. If, in a second appointment, emotional problems seem to be becoming chronic, referral to a mental health professional may be justified.

The single parent household

Single parents are likely to find themselves close to overload. If this occurs they may give up and become depressed, or they may turn to their children for help, no matter how old the children are. They often become easily irritated with their children. Feelings of being overwhelmed may make them tearful and overly anxious.

The doctor can help by giving reassurance, sympathetic understanding, and an appointment for a talk. There is, however, a limit to the degree of involvement that is appropriate, and the doctor should be prepared to refer patients needing more than occasional support to a mental health professional, social worker, or Relate counsellor.

New relationships

Children may be apprehensive of a parent's new relationships; they may resent the new figure's entrance into their family. They are also likely to worry about how they can reconcile their continued loyalty toward their biological parent with acceptance of the new figure.

The parent's marriage to the new figure can make things worse, although it can also provide the parent with needed help and companionship. If the step-parent has children from a former marriage, the children may worry that they will have to compete with their step-siblings for their parent's attention. They will also feel themselves required to adapt to a strange and often unappealing new family organisation.

The doctor can be helpful to the children—and to the parent—by encouraging the parent to listen sympathetically to the children's concerns. This will reassure the children that they have not been deserted by the parent.

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Economics notes

Economic evaluation: an introduction

James Raftery

Economic evaluation has increasingly become part of modern health care. Rising costs, often associated with new technologies, and spending limits have prompted a search for greater efficiency. This need to demonstrate the relative cost effectiveness of new health technologies has led some countries, specifically Australia,[1] to make economic evaluation a requirement for public sector funding of new drugs. Furthermore, the American state of Oregon used economic evaluation in defining what services should be included in Medicare (although the rationing eventually implemented relied mainly on effectiveness rather than cost effectiveness[2]). This growing requirement to demonstrate the efficiency of new technologies means that economic evaluation is increasingly specified in research grants from both the NHS[3] and pharmaceutical companies.

Economic theory, which takes private markets and rational individual decision making as the norm, has developed techniques—primarily cost benefit analysis—to evaluate programmes funded by the public sector. As the earliest forms of cost benefit analysis measured both costs and benefits in monetary terms, the term cost benefit analysis has come to mean those analyses which measure outcomes in monetary terms. Other forms, specifically cost effectiveness and cost utility analysis, have been developed to cover analyses in which outcomes are measured in health related terms. The results of such studies are usually ratios of costs to outcome. The most generalisable, cost per quality adjusted life year (QALY) gained, has provoked controversy and, despite its apparent simplicity, raises many technical complexities.[4]

Economic theory favours measuring costs and benefits in monetary terms because it avoids the problems of measuring and valuing non-monetary benefits, such as health gain or patient satisfaction. The branch of economics that deals with individuals—welfare economics—uses great ingenuity to avoid measuring the "utility" or satisfaction of different individuals. According to welfare economics, rational individuals will maximise their utilities and that of society in perfectly competitive markets. However, as discussed in

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Health Economics Facility, Health Services Management Centre, University of Birmingham, Birmingham B15 2RT
James Raftery, *director*

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Terminology

Welfare economics is a branch of economics concerned with maximising social welfare. It assumes rational individuals who maximise their utilities, and that the overall welfare of society is a function of individual utilities.

Health economics as welfare economics applies welfare economics to health care.

Health economics as extra-welfarist is concerned with maximising health which may include both individual and social preferences. It builds on but goes beyond the individualist focus in welfare economics.

this series, most healthcare evaluations have to grapple with benefits that are specific to health care, and about which consumers often have limited information. This pushes conventional economics thinking to its limits, raising difficult welfare comparisons between individuals and over time, leading some health economists to propose an "extra welfarist economics."[5]

Although many problems of economic evaluation relate to measuring and valuing benefits, some also relate to costs. Economics defines costs much more broadly than accountancy. The concept of "opportunity cost" defines the cost in terms of the next best opportunity foregone. As welfare economics takes a societal perspective, the relevant opportunity cost is that to society rather than to an individual or an organisation. Opportunity cost includes not only the direct costs of treatments, but also the knock on costs of treatments averted or postponed and the costs to patients such as time spent waiting or off work or due to being cared for. Such definitions of costs, while comprehensive, are rarely available from routine sources.

As the popularity of economic evaluation of health care has increased, so too has the demand for rigour in its methods. While some have argued long and persuasively for measures such as cost per QALY, others have pointed to the limited range of interventions that have been evaluated and to the lack of standard methods in deriving such estimates as are available. In response, standardised methods for economic evaluation have been suggested.[6]

The problems of combining costs and benefits in evaluating health care have led some to caution against doing economic evaluation as part of clinical trials.[3] The argument relates partly to the difficulty of capturing the full extent of costs in trials, the fact that the power of trials is usually set in terms of benefits not costs, and the fact that trials may be atypical. Modelling and simulations, which have been proposed as alternatives to economic evaluations alongside clinical trials, have, however, also been criticised for being open to bias.[7] Economic evaluation has been dubbed a "half way technology"[8] because of the lack of standardised approaches which requires each study to start anew rather than build on previous work. Others have doubted the benefits of standardisation, favouring instead research on unresolved topics such as outcome measurement, discounting, and the uses to which economic evaluations have been put.

Owing to the increasing importance of using economics in healthcare decision making the *BMJ* will publish a series of economics notes. These do not attempt a comprehensive review of economic evaluation[4]: rather they aim to discuss issues which have arisen in the course of designing and carrying out evaluations. Furthermore, the series will try to clarify economic terminologies.

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Good engineering is not good medicine

"What are you doing with the rest of your life?" I was 18 and didn't quite know. My Dad wanted me to be an engineer. I thought I wanted to be a doctor.

On Tuesday mornings I would stare out the classroom window. Our physics teacher tried in vain to convey to us the incomprehensible. He told us about quantum mechanics, fission, and the theory of relativity. One day, he told us about bimetallic plates.

On Saturday mornings I would stare out of the window of a bright green 48A bus. This was our parole from prison—that is, boarding school in Dublin. Every Saturday morning we would pass by an elderly man. He struggled along, bent double. He had ankylosing spondylitis.

One fine morning I stood up and opened a window. I had decided. I would become a doctor. I would cure the old man and others like him. I would place a bimetallic plate into his vertebral column. Around this plate would be wound an electrical coil. The coil would be insulated. A current would be passed through the coil and the plate would hence be heated. Because of the difference in expansivity of aluminium and brass, the bimetallic plate would straighten slowly and gently together with the old man's spine. I would help him walk down Grafton Street upright and proud—or so I thought.

I became a doctor and, thankfully for all concerned, I stayed away from orthopaedics.

Stephen Ong, *specialist registrar in obstetrics and gynaecology, Aberdeen*

We welcome articles up to 600 words on topics such as *A memorable patient, A paper that changed my practice, My most unfortunate mistake,* or any other piece conveying instruction, pathos, or humour. If possible the article should be supplied on a disk. Permission is needed from the patient or a relative if an identifiable patient is referred to. We also welcome contributions for "Endpieces," consisting of quotations of up to 80 words (but most are considerably shorter), from any source, ancient or modern, which have appealed to the reader.