Informed consent in medical research

Is the demand for informed consent absolute? In the first of this pair of articles a professor of medical ethics argues that the principle of informed consent to participate in medical research is fundamental if patients are competent volunteers. Consent is not needed when patients are incompetent to give it (young children, unconscious patients, etc); when research uses only medical records; and when stored human tissue is used. Before publishing the results of such research, however, journals must ensure that certain minimal conditions are complied with. In the second article an oncologist argues that journals should be free sometimes to publish research in which patients have not given fully informed consent. He points to the practical difficulties of obtaining fully informed consent from all patients and, because of this, poor recruitment into trials. He suggests that a helpful approach would be to obtain "blanket" approval at the outset of treatment for inclusion in studies that might be in progress during the patient's illness—accepting that the doctor would always act in good faith and be prepared to explain treatments at any time.

Journals should not publish research to which patients have not given fully informed consent—with three exceptions

Len Doyal

Fifty years ago, the immorality of which clinicians are capable in the name of medical research was made clear at Nuremberg.[1] The code of research ethics which was articulated to judge them was uncompromising about the importance of informed consent in preventing such outrages against humanity from occurring again.[2] Volunteers competent to do so should choose whether or not to participate in medical research after being given correct information about the "nature, purpose, and duration of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment." Participants should not be subject to "force, fraud, deceit, duress ... or coercion." [3]

It took almost 30 years for many medical researchers to accept the full implications of this doctrine of informed consent. The prevailing attitude during this period was that the Nuremberg code primarily applied to Nazis and similar fanatics.[4] Such optimism became quickly tarnished in the late 1960s and '70s with the recognition that in the United States and the United Kingdom, for example, horrors continued to be inflicted on vulnerable groups in the name of medical progress. By the late '80s it was obvious that this problem knew no national boundaries.[5]

As a result, the professional and legal regulation of medical research has been made more rigorous, with the right of volunteers to informed consent remaining at its heart.[5] Yet some now argue that things have gone too far and that full disclosure of information to research subjects who are competent may not always be warranted.[6] Local research ethics committees have allowed research to proceed with variable standards of informed consent, and journals have published the results of studies where no consent was obtained.[7-10]

In this paper I oppose such moves through arguing that, with three exceptions, the principle of informed consent to participate in medical research should remain inviolate. The focus of discussion will be on

AWARENESS OF RANDOMISATION CAN CONFOUND RESULTS

See editorial by Smith and pp 1071, 1077, 1111, 1134

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competent patients who volunteer for either therapeutic or non-therapeutic research. No one questions the strict right of healthy volunteers to informed consent. I will outline a draft editorial policy for medical journals for the rejection of research where informed consent has not been appropriately obtained. Interestingly, had it been adopted at least three papers would not have appeared or be appearing in the *BMJ*.[8-10]

The moral and legal importance of informed consent

Patients who volunteer for medical research can face risks over and above those normally encountered in their everyday lives. The degree of such risks can often be known only after the research has been completed. Professional pressure can lead researchers to underestimate inconvenience and hazard, misleading volunteers in the process.[11] Volunteers must have accurate and detailed information about potential risks in order to protect themselves. Equally, for them to weigh up their personal willingness to face such hazards against whatever motivations they might have for participation, volunteers must also have adequate information about goals, methods, and possible benefits of the research.

To deny volunteers such information is a clear breach of their moral rights. Our abilities to deliberate, to choose, and to plan for the future are the focus of the dignity and respect which we associate with being an autonomous person capable of participation in civic life. Such respect is now widely regarded as essential for good medical care and should dominate the practice of medical research.[12] This is especially important in the case of volunteers who are patients and who, despite their vulnerability, often accept extra inconvenience and risk in the public interest, sometimes with no potential benefit to themselves.

This moral emphasis on informed consent is reflected by the law.[13] Legally, a battery is committed if volunteers who participate in medical research are touched without being provided with adequate information about what the researchers propose to do and why. The specific circumstances under which different interventions under investigation will be offered should also be communicated (for example, whether the participants will be randomised). Researchers will be negligent if they do not adhere to their professional duty to communicate adequate information about risks. Here the standard of disclosure is stronger than for ordinary treatment. Prudent researchers should warn volunteers of risks in the detail that any "reasonable person" would want, and researchers should recognise and attempt to satisfy specific informational needs of individual volunteers (such as those relating to language or employment).

In short, unless they respect the right of volunteers to informed consent, researchers should be morally and, where possible, legally censured.

Arguments against informed consent

Despite the preceding arguments, some researchers maintain that there is now too much emphasis on informed consent for patient volunteers for medical research. Three reasons are usually given, although in practice they are often combined.

Firstly, patient volunteers might be distressed by detailed information about aims, methods, and risks.[14] To weigh up the balance of potential benefits over risks will entail a good understanding of both, and patients may discover for the first time how poor their prognosis really is. Further, patients may realise the full implications of randomisation—that neither they nor their doctor will know which intervention they will receive and that their doctor does not know what the best treatment is. Such patients may not want full disclosure of information but still wish to be included in trials thought by their clinicians to be in their best interests. To force unwanted information on them is needlessly cruel, may compromise recovery, and may keep patients from entering trials in sufficient numbers to make such trials possible.[15] Clinical researchers, therefore, should have more discretion about how much detail to communicate.

Secondly, while informed consent may be necessary for studies where there are considerable risks, it does not follow that it should be obtained for research where invasiveness and risks are negligible. This is especially so if the requirement for informed consent might jeopardise methodological rigour.[16] For example, knowledge of the aims of some research might bias responses to related therapies or questionnaires. Awareness of randomisation—including the possibility of inclusion in the placebo arm of an investigation—can equally confound results through biasing the attitudes and behaviour of volunteers.[17] If the research is worth doing and the risks are minimal then it is surely being obsessive to continue to insist on full disclosure of information.

And thirdly, the interests of the public in medical progress will be undermined by too much emphasis on the rights of individuals. Existing effective clinical interventions are based on the willingness of previous patient volunteers to participate in medical research. Thus it can be argued that patients receiving such care have a duty to promote further research for future generations. Yet we know that in the face of full disclosure of aims, methods, and risks of research, patients might not do their duty to serve the public interest—sometimes making the research impossible.[18] A more limited disclosure of information about the research might encourage more patients to volunteer.

It follows from these reasons that local research ethics committees should implement the clause in the Helsinki Declaration which states that there may be circumstances in which informed consent is not required.[19] Similarly, journals should publish the results of medical research approved by committees adopting this lower standard of disclosure.

Why these arguments should be rejected

Each of these arguments is flawed. Potential for distress is not a sufficient reason to deny patient volunteers full disclosure of information. Such arguments are extensions of a tired and discredited paternalism. If volunteers discover that information has been withheld, their distress and sense of betrayal may be far greater than that engendered by learning the truth.[20] This will particularly be so if participation has

interfered with the achievement of other personal goals about which the researchers knew nothing. In any case, surveys have indicated that in ordinary therapeutic situations patients—even those who are terminally ill—want accurate information and are not necessarily upset by it. There is no reason to believe that this same desire does not apply all the more so to participants in medical research.[21-23]

Anticipated negligibility of risks does nothing to abate the right of patient volunteers to information about them. An acceptable hazard for one may be rejected by another.[24] Even minimally risky interventions (venepuncture and questionnaires, for example) can have unwanted side effects (bruising and depression). Equally, it is sometimes argued that minimal risks might justify the randomisation of patient volunteers without their consent (for example, in studies where one group is unknowingly used as a control). Yet some patients have been outraged to discover that they were used in a trial without their knowledge.[25] The fact that they faced small risks in the process was not the point. Aside from the potential distress to volunteers who discover that they were denied informed consent, such denial also jeopardises the reputation of the researcher, along with the enterprise of medical research. If patients feel that they might be inadequately informed, this fact in itself may dissuade them from participating in research.[26] The moral price of keeping volunteers in ignorance is too high and against the public interest.

It is unlikely that any of these arguments against informed consent would be taken seriously unless they were linked to the further belief that it is acceptable to compromise individual rights if the public interest demands it. Such arguments amount to justifying exploitation of individuals and ignore the objective harm which is inflicted upon them by disrespect for their autonomy. Harm of this kind should not be equated with physical damage or emotional distress and is therefore not affected by the level of risk of either. Rather it is an attack on human dignity: the harm is to the moral integrity of the uninformed volunteer.[27] Accepting the unconscionability of inflicting such harm in the public interest may well mean that some potentially fruitful medical research cannot be done because of the problem of under-recruitment. So be it; this is the price we pay for living in a society which is morally worth preserving, one where we treat each other with respect and where we take human rights seriously.

Despite the discretion offered by the Helsinki Declaration to do otherwise, research ethics committees should be rigid in their application of the principle of informed consent to competent patients asked to participate actively in research.[19] They should not approve research proposals which breach it, and journals should not publish the results of such research, even if it has been so approved.

When informed consent is not necessary

The demand thus far has been that competent patients should be protected from exploitation by being allowed to evaluate for themselves whether or not participation is consistent with their best interests. Sometimes, however, research that is of potential importance should be permitted without the requirement of informed consent. Generally speaking, this will either be when patients are unable to provide consent because of their incompetence or when, for practical reasons, consent is difficult or impossible to obtain. Research without informed consent should be allowed to proceed and be published only in three circumstances.

Incompetence to give informed consent

Firstly, some categories of patient volunteers will be incompetent to give informed consent—for example, young and immature children, patients with learning disabilities, and unconscious or semiconscious patients in intensive care or accident and emergency.[28-31] To exclude them from participation in research specific to their conditions and treatments might deprive both them and others of potential benefit. To allow such research is not an affront to their human dignity if they really are incompetent to provide informed consent. We have no moral obligation to respect others in ways that are practically impossible. However, 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), and their vulnerability demands that they should be protected from harm (for example, if the research can be done on a less vulnerable group then it should be). Local research ethics committees should have the discretion to approve both therapeutic and non-therapeutic research involving incompetent patients, and journals should have the discretion to publish the results under certain conditions.[32] Minimally, it should be clear that:

- There are important potential benefits from the research;
- The research cannot be completed with patients or healthy volunteers who are able to provide informed consent;
- Participation in therapeutic research will entail risks which are minimal in relation to the standard available treatment. For non-therapeutic research, this level should not exceed that associated with everyday life or minimally invasive therapeutic interventions;
- Informed consent in research with incompetent children will always be obtained from someone with parental authority;
- Informed "assent" for incompetent adults will ordinarily be sought from appropriate advocates (such as relatives) provided with the same information which would have been given to the patient if competent;
- Such "assent" may not be required for therapeutic research with adults when it is impossible to obtain and when there is minimal risk, again, by comparison with standard available treatment (for example, research in intensive care and in accident and emergency medicine);
- The purpose and methods of the research are explained after its completion to participants who were unable to consent to it but then regained their competence to do so. This does not amount to retrospective consent.

Conditions on use of medical records

Secondly, we have seen that informed consent should always be obtained from competent patients who are

actively involved in medical research—where they either receive or are denied some form of intervention under investigation. However, some research occurs without such involvement and entails only the use of medical records. Normally, patients should give their explicit consent for their records to be accessed for this purpose; they should have received appropriate information about who will use them and why and about how confidentiality will be maintained. Yet suppose that the research is epidemiological, that patients might benefit from it in the long term but that for practical reasons informed consent cannot be obtained. Also assume that no further consequences should follow for such patients—for example, that there is no intent to ask the patient to receive or be denied any intervention as a result of the research. In spite of the arguments already outlined in favour of informed consent, should we allow this kind of research to proceed without it?[33]

The moral balance here is a fine one. If such research proceeds, there is little doubt that through not obtaining consent a moral wrong is being done. The issue is the degree of this wrong in light of the potential benefit which can follow for the patient—provided that confidentiality is maintained and no further active involvement is expected. Clearly, the public interest will also be served. This moral tension will be minimised through better informing patients about the importance of medical research and the desirability at times for their records to be accessed by researchers.[34] They should also be reassured about confidentiality and given the opportunity to decline. Yet these steps have not widely been taken. The most that can be said for now is that the moral balance favours local research ethics committees having the discretion to approve such research and journals to publish the findings. Minimal conditions are:[35 36]

- Access to the clinical record is essential for the completion of the research and consent is not practicable;
- The research is of sufficient merit;
- The research pertains to some future planning, preventive, or therapeutic initiative which may benefit the patients whose records are studied;
- Where possible, identifiers have been removed from the parts of the record to which researchers have access; where not, patients will not be identifiable when the results are made public;
- It is not anticipated that contact will be made with the patients as a result of research findings;
- Access is restricted to specific categories of information which have been approved by the local research ethics committee;
- Permission is obtained from the clinician responsible for the patient's care and, depending on the type of record and access concerned, the person responsible for its administration;
- Researchers who are non-clinicians are formally instructed about their duty of confidentiality. They must also have a clinical supervisor who formally accepts professional responsibility for any breach of confidentiality that may occur.

Stored tissue from anonymous donors

The third exception where research is permissible without informed consent concerns the use of human tissue which is the byproduct of surgical intervention or other stored clinical material (for example, frozen serum). Such tissue or materials may have been recently removed and stored, or archived for considerable time. Where the link between the identity of patients and their stored material is broken, research may be conducted without further explicit consent, always assuming that it conforms to other moral principles governing good research.[37] Where the identity of the patient might become known to the researcher, the local research ethics committee must review and agree the research. Here again, the moral balance is a delicate one.[38] Consent need not necessarily be obtained, provided that the committee is satisfied that patients (if alive) might at some time derive benefit from the research under consideration, that there is no intent to further involve them in the research, and that adequate standards of confidentiality will be maintained. In general, similar rules apply as have been outlined above on the use of clinical records without consent, and journals should only publish accordingly.

This third exception does not apply to research into the genetic causes of or predispositions to disease where research materials have not been strictly anonymised and where there is any possibility of further patient contact. Here informed consent should always be obtained and counselling offered to people who are potential sources of such materials. If not, the results of such studies should not be published.[39]

Conclusion

The suffering and indignity which some medical research has visited upon unsuspecting and vulnerable patients must never be allowed to happen again. To ignore the lessons of the past through not taking the right of informed consent seriously is to insult the memory of those who paid such an unacceptably high price in the name of medical progress. This paper has argued that local research ethics committees and professional and academic journals like the *BMJ* should not approve or publish research which violates this right. Three exceptions have been outlined. Further work is required, however, to clarify the moral foundations of these exceptions, including the nature and scope of the duty of individuals to act in the public interest. For now, the reasonably strict interpretation of the principle of informed consent developed here should be seen to be consistent with such interest even if this means that some potentially worthwhile research is not allowed to proceed or be published. In the words of Hans Jonas: "Society would indeed be threatened by the erosion of those moral values whose loss, possibly caused by too ruthless a pursuit of scientific progress, would make its most dazzling triumphs not worth having."[30 40]

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1 Leaning J. War crimes and medical science. *BMJ* 1996;313:1413-5.
2 Appelbaum PS, Lidz CW, Meisel A. *Informed consent: legal theory and clinical practice.* New York: Oxford University Press, 1987:212.
3 Nuremberg Code. *BMJ* 1996;313:1448.
4 Rothman DJ. Ethics and human experimentation: Henry Beecher revisited. *N Engl J Med* 1987;317:1195-9.
5 McNeill PM. *The ethics and politics of human experimentation.* Cambridge: Cambridge University Press, 1993:17-36, 53-115.
6 Tobias JS, Houghton J. Is informed consent essential for all chemotherapy studies? *Eur J Cancer* 1994;30A:907-10.

7 Harries, HJ, Fentem PGH, Tuxworth W, Hoinville GW. Local research ethics committees. *J R Coll Physicians* 1994;28:150-4.
8 McArdle JMC, George WD, McArdle CS, Smith DC, Moodie AR, Hughson AVM, *et al.* Psychological support for patients undergoing breast cancer surgery: a randomised study. *BMJ* 1996;312:813-7.
9 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;314:1071-6.
10 Bhagwanjee S, Muckart D, Jenna PM, Moodley P. Does HIV status influence the outcome of patients admitted to a surgical intensive care unit? *BMJ* 1997;314:1077-81.
11 Evans D, Evans M. *A decent proposal—ethical review of clincial research.* Chichester: Wiley, 1996:62-7.
12 Doyal L. Needs, rights and the moral duties of clinicians. In: Gillon R, ed. *Principles of health care ethics.* Chichester: Wiley, 1994:217-30.
13 Kennedy I, Grubb A. *Medical law - texts and materials.* London: Butterworths, 1994: 1042-67.
14 Tobias J, Souhami R. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:1199-201.
15 Collins R, Doll R, Peto R. Ethics of clinical trials. In: Williams CJ, ed. *Introducing new treatments for cancer: practical, ethical and legal problems.* New York: Wiley, 1992:49-65.
16 Kanis J, Bergmann J. Full consent may bias outcome of trials. *BMJ* 1993;307:1497.
17 Barer D. Patients' preferences and randomised trials. *Lancet* 1994;344:688.
18 Baum M. The ethics of randomised controlled trials. *Eur J Surg Oncol* 1995;21:136-7.
19 Helsinki Declaration. *BMJ* 1996;313:1448.
20 Bok S. *Lying.* Brighton, Sussex: Harvester, 1978.
21 Fallowfield L, Ford S. Lewis S. Information preferences of patients with cancer. *Lancet* 1994;344:1576.
22 Kerrigan DD, Thevasagayam RS, Woods TO, McWelch I, *et al.* Who's afraid of informed consent. *BMJ* 1993;306:298-300.
23 Deber R. Physicians in health care management. 7. The patient-physician partnership: changing roles and the desire for information. *Can Med Assoc J* 1994;151:171-6.
24 Martin D, Meslin E, Kohut N, Singer P. The incommensurability of research risks and benefits: practical help for research ethics committees. *IRB* 1995 March-April:8-10.
25 Research without consent continue in the UK. *Bull Inst Med Ethics* 1988; 40:1315.
26 Thornton HM. Breast cancer trials: a patient's viewpoint. *Lancet* 1992;339:44-5.
27 Crisp R. Medical negligence, assault, informed consent and autonomy. *Journal of Law and Society* 1990;17:77-89.
28 Mason JK, McCall Smith RA. *Law and medical ethics.* London: Butterworths, 1994:369-74.
29 Fulford K, Howse K. Ethics of research with psychiatric patients: principles, problems and the primary responsibilities of researchers. *J Med Ethics* 1993;19:85-91.
30 Dresser R. Mentally disabled research subjects: the enduring policy issues. *JAMA* 1996;276:67-72.
31 Biros M, Lewis R, Olson CM, Runge JW, Cummins RO, Fost N. Informed consent in emergency research: consensus statement from the coalition conference of acute resuscitation and critical care researchers. *JAMA* 1995;273:1283-7.
32 Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research involving ethics committees.* London: RCP, 1996.
33 Wald N, Law M, Meade T, Miller G, Alberman E, Dickenson J. Use of personal medical records for research purposes. *BMJ* 1994;309: 1422-4.
34 Baum M. New approach for recruitment into randomised controlled trials. *Lancet* 1993;341:812-4.
35 East London and City Health Authority. *Guidelines for the completion of application forms—research ethics committee.* London: ELCHA, 1996.
36 Working Group to the Royal College of Physicians Committee on Ethical Issues in Medicine. Independent ethical review of studies involving medical records. *J R Coll Physicians* 1994;28:439-43.
37 Nuffield Council on Bioethics. *Human tissue—ethical and legal issues.* London: Nuffield Foundation, 1995:23-9, 39-54.
38 Clayton EW, Steinberg KW, Khoury MJ, Thomson E, Andrews L, Ellis Khan MJ, *et al.* Informed consent for genetic research on stored tissue sample. *JAMA* 1995;242:1786-92.
39 Nuffield Council on Bioethics. *Genetic screening—ethical issues.* London: Nuffield Foundation, 1993:29-40.
40 Jonas H. Philosophical reflections on experimenting with human subjects. In: Freund PA, ed. *Experimentation with human subjects.* New York: George Braziller, 1970:1-31.

BMJ's present policy (sometimes approving research in which patients have not given fully informed consent) is wholly correct

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See editorial by Smith and pp 1071, 1077, 1107, 1134

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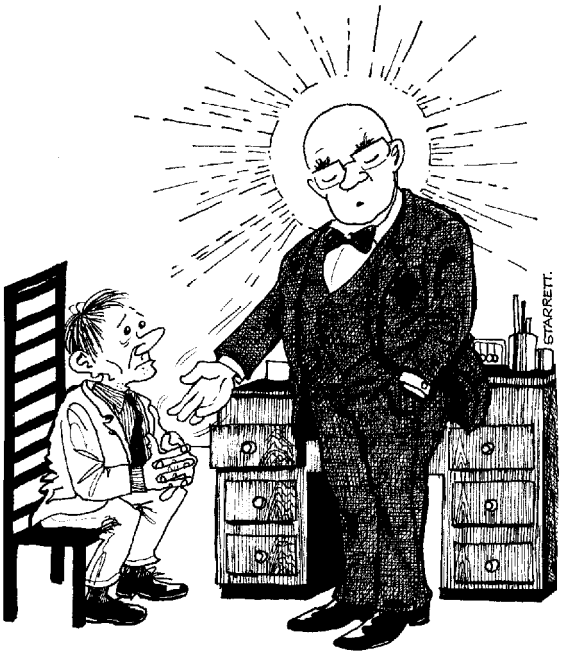
Few if any issues engender such passionate—often acrimonious—disagreement among clinicians, ethicists, statisticians, and representatives of patient groups as does the continuing debate about informed consent and clinical research trials. In the blue corner: clinicians and biostatisticians keen to "move the field forward," so to speak, and answer as quickly as possible the research question currently under investigation. In the red corner ... just about everyone else. Anyone left in the centre? Only the hapless referee, in this case the somewhat perplexed journal, whose editorial board—constantly hectored from both sides—somehow has to give all parties a decent airing and ensure fair play.

Those arguing in favour of fully informed consent as an inviolable rule (except, perhaps, in very special circumstances) often point out the essential, non-negotiable nature of a patient's right to autonomy and self determination. Quite rightly they remind clinicians that patients now wish to participate in decisions concerning their own management, to a far greater degree than ever before. Indeed, over the past decade, the move towards fully informed consent for all participants in clinical trials has become increasingly difficult to resist and is now formalised in various guidelines.[1] However, neither lawyers, ethicists, nor medical scientists have so far agreed precisely what this term actually means—though it is generally held to imply a full declaration of the competing treatment options for any patient participating in a clinical research study, particularly one which involves randomisation between two or more treatment options. Together with the full description of treatments, there should be an explanation of the possible side effects of both new and standard therapies and a clear explanation that the "choice" of treatment is no choice at all—in the conventional sense—but is no more than a computerised flip of the coin.

Most clinicians recognise that the anxious patient sitting opposite them in the consulting room requires both reassurance and a clear exposition of what needs to be done to provide a cure.[2] However, an increasing degree of frankness on the part of the doctor, for the most part laudable and constructive, may also cause considerable distress to patients who would prefer to be directed rather than participate as equal partner. For clinicians who genuinely believe in evidence based medicine and recognise the central role of randomised trials, it is the need for explaining the randomisation concept, coupled with a detailed account of the shortcomings of standard treatment, which jointly symbolise the difficulty of the task: how to put these points across to a frightened patient in a highly charged atmosphere, with limited time available yet so much ground to cover and so many questions to answer. As Souhami and I



....THE NEED TO FEEL FULL CONFIDENCE BOTH IN THE JUDGMENT AND TECHNICAL COMPETENCE OF THOSE LOOKING AFTER YOU

have previously pointed out, many doctors repeatedly faced with this difficult task will not surprisingly decide that for them the game is simply not worth the candle.[2] Hence the lamentable record in Britain of poor patient recruitment even where excellent clinical trials are on offer. British clinicians certainly don't seem to be signed up to the proud Harvard Medical School slogan, "Clinical research is an obligation not an option."

Doctors' concerns about their patients' anxieties in these circumstances were supported by the findings of an Australian study which compared two methods of seeking consent for clinical trials of different standard treatments for cancer: an individual approach at the discretion of each doctor, or a policy of total disclosure of relevant information given both verbally and in writing.[3] This study found that although patients having total disclosure became more knowledgeable about their illness and treatment, and about the research aspects of what was proposed, these same participants were less willing to enter as subjects for the trial and had a significantly higher anxiety score. As many clinicians had expected, there are clearly trade offs to be made in the amount of information patients are given before consenting to studies, at least in the field of cancer. Detailed information, given indiscriminately, resulted in a more knowledgeable yet more reluctant and anxious patient. What is more, the ethical position of clinicians who decide, for whatever reason, not to inform patients about appropriate clinical trials for their particular condition has increasingly—and rightly—been questioned.[4]

Concerns for patients' rights

Although ethicists, counsellors, and other commentators argue their case—as research clinicians do—with the best possible intentions and concerns for patients' rights to information (and retention of as much control as possible in the face of serious illness), an atmosphere of mistrust has clearly developed. For example, last year the *BMJ* published a randomised study of psychological support for patients undergoing breast cancer, in which they were randomised (without informed consent) to receive routine care from ward staff, or with interventional support from a breast care nurse, a voluntary organisation, or both.[5] Yet after publication of the paper, one distinguished member of the journal's editorial board felt moved to write that "the hospital ethics committee was surely at fault in allowing the research to proceed in contravention of the Nuremberg code" and even complained at the fact that two of the authors of the study were related.[6] The authors of the study were clearly concerned to assess the potential benefits of an expensive and labour intensive form of intervention, and the journal felt the paper important enough to publish with a commentary regarding the ethics of clinical research without patient consent.[7] But the letters to the editor were heated and even produced friction among the trialists, with a published reply from one of them as dissenting author.[8]

In my view, the origins of this mistrust stem largely from a single source of disagreement: the passionate belief of those who insist that the individual patient in the consulting room should be the sole focus of concern for the doctor, and those who feel—and are prepared to say publicly—that they owe a duty not only to the patient sitting opposite but also to society at large which, with an equally urgent passion, has charged us to get on in all haste and find that cure. No point in pinning one's colour firmly to the fence: I'm for the latter group. This does not in any sense mean that the clinical trial is more important than the patient sitting so anxiously in the waiting room. A kind and caring approach to patients should always be the sine qua non of the doctor-patient relationship, as Sally Magnusson reminded us in the Christmas issue of this journal, even when (especially when) there is little that can be done.[9]

But a proper respect for the patient's individual circumstances inevitably leads the research clinician to a varied set of approaches. The highly informed, articulate 39 year old journalist with a small but operable node positive breast cancer may be a candidate for several randomised trials and is likely to need a full, frank discussion with total disclosure of not only all the available treatment choices, but also the limitations of current treatment. In the enthusiasm to engage this intelligent and questioning patient in a proper dialogue, the chief danger generally lies in forgetting that above all she's a patient and, instead, falling into the trap of conducting a two way research seminar rather than a kindly and courteous consultation. On the other hand, and often at the other extreme of the social spectrum, the patient so characteristic of the clientele in a head and neck cancer clinic is much more likely to be male, older, far less educated, an enthusiastic consumer of cigarettes and alcohol: in short, someone quite unused to being "in control" of his own circumstances. Such patients are often homeless or struggling in an inner city hostel to retain what they can of their dignity and self respect. A cool and dispassionate discussion about the current research study (at present a trial essentially addressing the question of

whether or not to offer chemotherapy in addition to radical surgery or radiotherapy) may be highly inappropriate since it pays no attention to the circumstances and culture—and, dare I say it, the need—of this particular patient. Indeed, as Brewin has pointed out, it may be better to consider that doctors participating in randomised treatment trials should not be thought of as research workers at all (in the normal sense of the word "research") but simply as clinicians with an ethical duty to their patients "not to go on giving them treatments without doing everything possible to assess their true worth." [10]

Practical difficulties with informed consent

Quite apart from the difficulty with randomisation—such an elegant, reliable, sophisticated concept to the research clinician, but so brutal and harsh from the patient's viewpoint—it is the nearness of the consent discussion to the diagnosis which causes greatest concern, together with the patient's perception of the intensity of the threat. Imagine yourself (this is often worth doing: after all, we're all of us either patients or potential patients) in the shoes of the thousands of patients taken each year to hospital with severe chest pain and acutely aware that this could be a fatal heart attack. We now know (through well conducted randomised clinical controlled trials, of course) that clotbusting drugs such as streptokinase play a valuable part in recovery; but would you really wish at this moment of crisis to be faced with a medical registrar keen to treat you properly but equally aware of the need to gain your informed consent before randomising you to one or other of the appropriate treatments? It's not that you're no longer competent to take it all in, but simply that there are likely to be other concerns on your mind—to say nothing of the need to feel full confidence both in the judgment and technical competence of those looking after you.

As Collins and others have pointed out, at the time when the key studies addressing this issue were taking place, the differing ethical requirements (relatively low key in the United Kingdom but far tougher and with more constraint in the United States) led to a greatly differing recruitment rate (6000 patients from Britain compared with 400 from the United States despite an approximately equivalent degree of apparent interest by cardiologists in the two countries).[11] In turn this led to a compelling statistic: if the United States had recruited as fast as Britain then the trial would have ended six months earlier, and since the eventual results transformed medical practice (improving the treatment of several hundred thousands of patients a year worldwide), that six month delay meant about 10 000 unnecessary deaths "directly due to whatever it was that slowed recruitment" in the United States. It should at least be a matter of some concern when what is judged ethical in one civilised society is dealt with so differently in another.

Ah yes, the proponents of universal informed consent might reply, this is just one of those "special circumstances" which we all agree should be exempt from the usual rules. But how then might we go on to define these circumstances further? I have previously tried to divide or classify studies in oncological practice (at least those involving studies of new types of chemotherapy) into those which might or might not require fully informed consent.[12] As others in similar or analogous situations have discovered, it is not always easy to recognise the differing circumstances which might demand full, partial, or non-disclosure when the study in question is randomised.[13]

In the case of cancer trials, highly refined studies investigating technical differences between the two arms of treatment may be reasonably straightforward, in the sense that the patient will realise that the difference between the treatments represents only a relatively minor point of detail—not too alarming. On the other hand, where the treatment options are startlingly different the situation is altogether more charged. It can be extremely unnerving to discuss, for example, the possible use of chemotherapy in cancers such as those of the cervix or head and neck, in which we don't yet know for sure whether such treatment is genuinely valuable or simply meddlesome; with full disclosure of options, one finds oneself explaining carefully the pros and cons of the new treatment, then randomising half the patients to the control (the current "best buy") treatment, to be met later with a disappointed patient who often feels "let down" by the loss of perceived benefit from the newer treatment (chemotherapy) which, naturally enough, in previous discussion had been described as "promising." This often leads the doctor towards a rather shabby display of back pedalling in which the possible advantages of the chemotherapy are "talked down" and perhaps the side effects "talked up." [14]

Still more difficult were the studies undertaken a few years ago to try to establish whether or not mastectomy for breast cancer—the traditional treatment during the first half of this century, hallowed by tradition but never validated by science—was tested for the first time against less mutilating surgical alternatives. The outcome of these studies, showing no clear superiority for the traditional approach,[15] has proved hugely influential; yet it is hard to envisage how a strict and honest adherence to principles of fully informed consent could have been possible. I don't know about the American studies, but it certainly proved impossible in Britain. Although it was described as "the breast cancer trial that everybody needs but nobody wants," [16] the Cancer Research Campaign, which supported and paid for the study, had to accept that recruitment was impossibly slow as a result of the disinclination of even the most committed trialists to put their patients through the rigours of informed consent.

Yet partial disclosure[17] or disclosure of the facts of the randomised study only to some (usually half: those in the "new treatment" arm) of the participants, is clearly regarded as an ethical minefield, making it unattractive to many clinical researchers and almost all health ethicists. Although it protects the right of patients not to be allocated novel treatments which are not yet fully established (and might never be) and ensures reasonable recruitment for clinical studies, it is generally rejected by hardliners as unethical since it denies the right to autonomy and self determination to each and every patient in the study—even though carrying the obvious and humane advantage of sparing all the patients treated to the best of current standards (the control arm) the anxiety of knowing that

further improvements or refinements in their treatment are still urgently required. In my view, these benefits represent substantial gains for the individuals concerned and for any group of patients with the same illness, since valuable academic information might well flow from the study.

Perhaps a still more helpful approach would be for patients to be informed at the outset of their treatment that several clinical and laboratory studies (some randomised, some not) might be in progress during their illness; might they be prepared to offer "blanket" approval here and now, accepting that the doctor would always act in good faith and be prepared to explain further any unconventional or novel treatment, if required, at any future point? In childhood leukaemia, for example, it is already commonplace for pretreatment blood samples to be stored and used later for laboratory tests not available when the sample was obtained. I greatly dislike the current trend towards ownership and commercial exploitation of medical samples—blood, tissues, cell lines—and admire the altruism behind this type of donorship. Shouldn't medical material be treated just as a personal letter might be after it has been posted through the letterbox slot—no longer strictly yours, even though you created its content in the first place. The posting is a consignment to a higher authority. Once again, Brewin has provided an elegant and clear headed argument designed to protect patients and at the same time allow sensible research studies to be conducted without unnecessary constraint: "The idea that the mere fact of randomisation always requires special informed consent—with all its disadvantages and potential for causing misconception and anxiety—is surely illogical. A doctor in his normal practice, giving treatment without randomisation, is trusted to choose from several options, even though there may be no way that he can be sure which is best. Why should we not also trust a doctor who submits such options to randomisation, while taking full responsibility for the suitability of each? Are the two situations really so different?" [18]

Buried in the quotation is that small but compelling word "trust." Not really a word at all: a concept, a philosophy. Somewhat outmoded, certainly unfashionable. Yet most patients, it seems, still trust their doctors; and for their part, most doctors are well aware of the responsibilities that the trusting patient-as-supplicant brings to them. The correspondence pages of this journal are fine and lofty places to discuss these issues in a detached and intellectual manner—but do they approximate closely enough to the demands of the real world, in which the doctor must somehow juggle the multiple responsibilities of expert, humane, and above all respectful support for the patient in his consulting room with the wider healthcare concerns and requirements of society as a whole?

1 Royal College of Physicians. *Guidelines on the practice of ethics committees in medical research involving human subjects.* 2nd ed. London: RCP, 1990.
2 Tobias JS, Souhami RL. Fully informed consent can be needlessly cruel. *BMJ* 1993;307:119-20.
3 Simes RJ, Tattersall MHN, Coates AS, Raghavan D, Solomon HJ, Smartt H. Randomised comparison of procedures for obtaining informed consent in clinical trial of treatment for cancer. *BMJ* 1986;293:1065-8.
4 Segelov E, Tattersall MHN, Coates AS. Redressing the balance—the ethics of not entering an eligible patient on a randomised clinical trial. *Ann Oncol* 1992;3:103-5.
5 McArdle MC, George WD, McArdle CS, Smith DC, Moodie R, Hughson, AVM, *et al.* Psychological support for patients undergoing breast cancer surgery: a randomised study. *BMJ* 1996;312:813-7.
6 Goodare H. Patients' consent should have been sought. *BMJ* 1996;313:361.
7 Foster C. Commentary: ethics of clinical research without patients' consent. *BMJ* 1996;312:817.
8 Moodie AR. Reply from dissenting author. *BMJ* 1996;313:362.
9 Magnusson S. Oh, for a little humanity. *BMJ* 1996;313:1601-3.
10 Brewin TB. Truth, trust, paternalism. *Lancet* 1985;ii:490-2.
11 Collins R, Doll R, Peto R. Ethics of clinical trials. In: Williams CJ, ed. *Introducing new treatments of cancer: practical ethical and legal problems.* Chichester: Wiley, 1992:49-65.
12 Tobias JS, Houghton J. Is informed consent essential for all chemotherapy studies? *Eur J Cancer* 1994;30A:897-9.
13 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. *BMJ* 1997;314:1077-81.
14 Tobias JS. Informed consent and controlled trials. *Lancet* 1988;ii:1194.
15 Fisher B, Bauer M, Margolese R, Poisson R, Pilch Y, Redmond C, *et al.* Five year results of a randomised clinical trial comparing total mastectomy and segmental mastectomy with or without radiation in the treatment of breast cancer. *N Engl J Med* 1985;312:665-71.
16 Le Fanu J. The breast cancer trial that nobody wants but everybody needs. *Med News* 1983;12:30-1.
17 Zelen M. A new design for randomised clinical trials. *N Engl J Med* 1979;300:1242-5.
18 Brewin TB. Consent to randomised treatment. *Lancet* 1982;ii:919-22.

The rationing debate

Rationing within the NHS should be explicit

The case for

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Rationing should be made explicit at all levels of NHS decision making

BMJ 1997;314:1114–8

continued over

Much recent discussion has revolved around whether the rationing of health care that is occurring within the NHS should be explicit or implicit.[1] Many commentators argue in favour of implicit rationing, for a range of reasons. Opinion appears to be divided between those who claim that implicit rationing will (*a*) be inevitable since there are no clear criteria on which to base explicit rationing, (*b*) make patients and providers happier, (*c*) make the administrative and political processes of healthcare provision run more smoothly. I provide reasons for rejecting each of these contentions, arguing instead that explicit rationing is vital for the moral management of health care.

The argument from confused criteria

The creation of an internal market in the NHS appeared to place explicit rationing on the agenda of

healthcare providers. Rationing had always occurred within the service but previously it had been camouflaged under clinical judgment. Now purchasers were to draw up plans showing how much was to be allocated to what type of care and why. Providers were to audit clinical staff to ensure that their work conformed to agreed criteria of effectiveness and all was to be open to public scrutiny.

The expected transparency has not occurred. Health authorities have generally not come clean about their inability to meet demand and have awarded block contracts primarily on the basis of past expenditure, with shortfalls shared between existing clinical services. As a result, the realities of rationing within the NHS have remained where they always were—with clinicians making decisions on the basis of varied and conflicting criteria, often dressed in the guise of clinical necessity.[2]

These developments have led to a weary resignation that any ambition to make rationing explicit within the NHS is hopelessly optimistic. It is argued that there are no clear rules according to which rationing should occur and a lack of political will to implement what criteria there are. For example, the health committee of the House of Commons proclaims: "There is no such thing as a correct set of priorities, or even a correct way of setting priorities."[3] Klein concurs: "Given the plurality of often conflicting values that can be brought to any discussion of priorities in health care, it is positively undesirable (as well as foolish) to search for some set of principles that will make our decisions for us."[4] So does David Hunter: "Rationing will always be a messy affair. We should not seek to deny the mess but accept it."[5]

Thus, since "ought implies can" and since explicit rationing seems practically impossible, we are said to be stuck with implicit rationing.

The argument from the utility of ignorance

The second argument against explicit healthcare rationing derives from health economics[6] and emphasises the emotional consequences of explicit rationing. Explicitly to confront individuals with the fact that because of scarce resources they will not receive health care which they need will make them more unhappy than believing that there is no clinical option but to take what is offered. This distress will be compounded if they discover that other patients deemed more worthy of resources will receive treatments denied them.[7] Two noted health economists have described the "deprivation utility" of being kept in ignorance in such circumstances.[8]

This idea can be extended to healthcare rationers themselves. Telling patients they will not receive appropriate clinical care for economic reasons is stressful, more so than pretending that the treatment will be futile or just not mentioning it at all.[9] As a result, it is again argued, on utilitarian grounds, that implicit rationing makes more sense than that which is explicit.

The argument from bureaucratic and political effectiveness

A third defence focuses on the bureaucratic and political difficulties that are said to accompany explicit rationing. Attempting to strike the right balance between competing claims for funding within health authorities is not easy, and the same argument holds for central government attempting to weigh up conflicting demands on the public purse. In such circumstances complaints by the public about the management of explicit rationing will certainly make life more difficult for those responsible for organising health care. Much better then to continue the myth that decisions about the allocation of such care are based on clinical criteria alone.

> *"Nothing could be clearer than the ethical principles at the heart of the health service"*

Hunter, for example, has supported such mythology: "The public is more likely to accept rationing decisions made by doctors rather than managers and politicians."[5] Clinical discretion in rationing is essential given the diversity of individual cases. If the public becomes aware that more general value judgments—say about cost effectiveness, moral desert, and quality of life—are behind rationing decisions then such discretion may be undermined. Letting the cat out of the bag would then advantage articulate patients who will know how to play the now transparent system. "Lack of visibility," Klein argues on the same note, "may be a necessary condition for the political paternalism required to overcome both consumer and producer lobbies."[10]

Similar arguments have been developed by Mechanic, who worries that explicit rationing might jeopardise the stability of the political process surrounding health care. He speaks of the "many disaffected people" created by the knowledge of why resource decisions are being made about them and others; whose responses would not be "conducive to stable social relations and a lower level of conflict; and who are likely to confront government and the political process with unrelenting agitation for budget increases."[11] Much better for people to believe—even if it is false—that rationing decisions are inevitable for purely clinical reasons. Then clinicians, managers, and politicians can get on with the job of making decisions in what they believe to be are the best interests of patients. Explicit rationing "will inevitably result in acrimony difficult to manage politically." [11]

Clear criteria for explicit rationing do exist

It is hard to believe that anyone really thinks that we should not at least try to understand the criteria which should be used in rationing decisions—to make them explicit in this sense and to compare them with criteria actually used. Refusing to make this attempt is tantamount to giving up the possibility of evaluating either the justice or the efficiency of the rationing process, of accepting that healthcare resources should be

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distributed in ways which might do as much harm as good.

Against the background of the explicit moral foundations of the NHS, such pessimism is curious. For in general terms, nothing could be clearer than the ethical principles at the heart of the health service. The most well known and important of these principles is that there should be equal access to health care within the NHS based on equal need.[12] The first group of critics might be claiming that there is something inherently confused about the equal need-equal access equation. Conversely, they could be claiming that even if the formulation is clear in principle, in practice it is so bereft of organisational and procedural content that it is of little use to those who must work in the real world of managerial, economic, and moral expediency. Both of these claims are false.

"Rationing should take place within rather than between different areas of healthcare need"

As regards the first claim, suppose that we define the need for health care as the requirement for specific clinical intervention in order to avoid or to minimise sustained and serious disability.[13] What would it mean to suggest that we have no clear understanding of what this means in practice? It is what occurs in the delivery of health care at its best on a daily basis throughout the world. To be sure, there are disagreements about the appropriateness or efficacy of some interventions, diagnoses, and prognoses.[2] But this does not detract from the clarity of what we do know or the success of the service that is often delivered. Those who like to emphasise the uncertainty of medicine will no doubt change their tune when they contract serious and treatable illnesses.

There is similar clarity associated with moral arguments for providing access to appropriate health care on the basis of need. Our potential to flourish as individuals in whatever cultural environment depends on our ability either to participate within or to struggle against it. We require the help of others if we are to discover what we are capable of doing and becoming. Sustained and serious disability inhibits our capacity to interact with and learn from others and is thus in the interests of everyone to avoid if possible.[13]

But this is just another way of underlining how vital it is for those so disabled that appropriate health care be distributed on the basis of need and on no other individual attribute.[14] On a macro level this means that healthcare resources should be allocated to local populations on the basis of the most accurate needs assessments of which we are capable. This means that generally speaking, resources should be divided proportionally between the different types of disabling and treatable illnesses represented within such populations. Specific types of illness should not be discriminated against on the grounds of popularity or estimations of social worth. Rationing should take place within rather than between different areas of healthcare need.[15]

"Any benefit derived from deception will be sustained only while patients are kept in ignorance"

On the one hand, disabling disease may strike any of us without warning and if health care is distributed on any other basis, most of us cannot know for sure whether or not we may individually qualify for it. On the other hand, it is in our interests that those known and unknown persons on whom we socially depend for our potential to flourish will also be kept as healthy as possible. Rationally, therefore, we should want for others what we desire for ourselves.[15]

The concepts of equality of need and of access to health care based on it are also reasonably straightforward. Once it is accepted that the focus of any definition of healthcare need should be associated disability and that the macro allocation of resources should take place accordingly, the issue of equality on the level of micro allocation partly reduces to what levels of disability can coherently be deemed to carry with them the same moral entitlement to health care. It also partly concerns how we can ensure that those who are believed to be in such equal need can be assured an equal chance of benefiting from whatever clinical resources are available for its satisfaction.

Triage is the procedural embodiment of the belief that some levels of disability caused by illness are morally similar enough to warrant the same priority of access.[16] When triage is linked to a system of waiting which ideally gives each person within each category of urgency an equal chance of treatment—one based on a first come first served basis—then equal access to available resources will be seen in principle to be provided on the basis of what is accepted to be equal need.[15] A trip to any well run accident and emergency department will provide ample practical illustration.

Of course, people may accept such principles in theory yet argue that in practice they become so muddled as to reduce to confusion. Such arguments

confuse substantive and procedural moral issues.[17] Moral principles must be interpreted to apply them to specific problems, and unless there are procedures to optimise the rationality of such interpretation, confusion and injustice can indeed follow. For example, the assessment of healthcare need is often based on questionable methods, including ad hoc extrapolations from prior levels of clinical demand.[18] Further, the traditional organisation of surgical waiting lists tells us more about the clinical preferences of surgeons and strategies for queue jumping than the just distribution of treatment to patients.[19]

Thus confused organisational practices do not necessarily entail confusion within the moral principles which are supposed to inform them. They can also reveal the inability or unwillingness of rationers to take clear principles seriously, or to recognise the rights of patients in whose interests they are supposed to be acting. We should direct our energies to correcting this problem rather than wringing our hands about the inevitability of methodological and administrative chaos.

Of course, further effort is required to show how theory and practice can be better integrated, and the clarity of theory will benefit as a result. This is the aim of current attempts to create uniform guidelines for clinical diagnosis and treatment, and similar research should be undertaken on various aspects of rationing—for example, triage and fair waiting patterns for different conditions, the non-provision of life saving treatment, the determination of clinical futility.[20] Those who support implicit rationing rightly argue that it will be a difficult task.[2] However, theoretical clarification and consistent practice will continue to elude us unless decision makers are encouraged to make explicit and publicly defend the criteria for rationing which they do use.

The disutility of ignorance: microrationing should be explicit

The second argument made against explicit rationing embraces the utilitarianism of traditional health economics. Thus it suffers from the same blindness to issues of equity as other attempts to reduce rationing decisions to the aggregate calculation of preference—for example, QALYS (quality adjusted life years).[15] The key argument is the same: explicit micro rationing will ultimately create more unhappiness—less utility—on the part of both patients and doctors than implicit rationing.

There is nothing new about the idea that because patients may find certain types of information distressing, they should not be told it. Yet any benefit derived from deception will be sustained only while patients are kept in ignorance. If they discover that they have been deceived, their sense of betrayal will probably far outweigh any distress from being told the truth.[21] Therefore, it can just as convincingly be argued that utilitarian clinicians should pretend that they take seriously the right of patients to be told the truth, even if in reality they do not. Indeed, evidence suggests that this is precisely what patients wish, including those who are terminally ill.[22]

Similar arguments apply to the suggestion that patients will be less distressed if they are not told about the real reasons why they are denied treatments. Such a discovery could again lead to considerable unhappiness when the deceit is discovered; we cannot calculate the utilitarian outcome of deceit with any certainty. Of course, if we take seriously the right of patients to protest against rationing decisions then such deception will be unjustifiable in any case.

That clinicians will be happier if they keep patients in the dark about the realities of rationing is just as questionable. This argument works only if it is assumed that the deception will always be successful. Yet, because we cannot be sure of the outcome, sustaining deception over time can itself be distressing, especially if patients begin to ask more direct questions about why they are not receiving care which they have heard is available to others. Also, because their professional guidelines so consistently emphasise the duty to respect the autonomy of patients, good clinicians are increasingly taught to feel uneasy about any form of deception not invited by patients in advance. In any case, to base a decision on the well being of the clinician rather than the best interests of the patient would be unacceptable.

Macro rationing should be explicit

Within a democracy an informed public can undoubtedly give administrators and politicians a hard time. Yet citizens should have explicit information about any policies which can dramatically affect their lives.

Firstly, as JS Mill saw so clearly, unless citizens are given at least the potential for such influence, their own moral development will be damaged: they will not have the same personal stake in either learning about or conforming to the rules of their culture. More specifically, their moral commitment to democracy itself will be undermined. If we accept that democratic participation in public and political life is a good worth pursuing then it follows that the citizenry should be educated about the matters on which their participation is sought.[23]

Secondly, informed democratic feedback can improve the effectiveness of public policies through allowing policy makers more accurately to assess the results of their labour. It also helps to make them more reflective, knowing that they may be held to account by those whose interests they are supposed to serve. Such accountability is particularly important in the light of the tendency for vested interests to dominate the formation and implementation of policy.[13]

More informed public understanding and participation should aid rather than impede the efficiency, accuracy, and equity of healthcare rationing through enabling more accurate needs assessments, more effective audit, and more representative research.[24] This will help to ensure that macro policy aims are being achieved and that the moral boundaries of acceptable rationing are not being exceeded in the name of expediency. Reasonable levels of understanding and participation will also help to minimise distress in the face of non-treatment. This is because the degree of scarcity and the reasons for it will be explicit, along with the knowledge of how and when resources are being distributed between different areas of clinical demand.

The fact that the public has been oblivious to healthcare rationing in the past may well explain some traditional allegiance to the NHS. Such ignorance undoubtedly made the work of health care much easier than it would otherwise have been. Yet it also has led to

injustices—for example, ageism and arbitrariness in the construction and management of waiting lists.[19 25] That cat is now out of the bag, and the media will see that it is not put back. The argument for implicit macro rationing on the grounds of bureaucratic and political stability is just unrealistic.

The same argument is also paternalistic, illegitimately conflating a professed concern with the public welfare with bureaucracies' love of secrecy. The key premise is that the public will not be able to understand and therefore not be able to accept the degree of indeterminacy and inaccuracy which necessarily accompanies decision making about healthcare rationing.

As regards health care, there seems little convincing evidence that this is so. When anger and frustration do occur, it is usually in the face of the harm caused by what is perceived to be a mistake falling outside the boundaries of what is regarded as acceptable error. Citizens in the United Kingdom have traditionally drawn such boundaries generously. Mistakes and inaccuracy in themselves have usually been tolerated provided that they are publicly acknowledged and that serious attempts are made to detect why the problems arose and how they will be avoided in future.[26]

Conclusion

I have argued that none of the arguments against explicitness in healthcare rationing are convincing. Attempts to clarify the moral principles on which rationing should be based are not doomed to failure. We already know what these principles are: we must now have the moral courage to develop them further to ensure that they form the explicit basis for rationing decisions at both micro and macro levels. There is too much secrecy in British public life already. It should be reduced rather than sustained within the NHS.

I thank Lesley Doyal.

1 Maxwell R, ed. *Rationing health care.* London: Churchill Livingstone, 1995.
2 Klein, R, Day P, Redmayne S. *Managing scarcity.* Buckingham: Open University Press,1996:83-93;102-8.
3 House of Commons Health Committee. *Priority setting in the NHS: purchasing.* London: HMSO, 1995:57.
4 Klein R. Dimensions of rationing: who should do what? *BMJ* 1993;307:309-11.
5 Hunter D. Rationing health care: the political perspective. In: R Maxwell, ed. *Rationing health care.* London: Churchill Livingstone,1995:877-84.
6 Coast J. The utility of ignorance: could implicit rationing be preferable to explicit rationing? *BMJ* 1997;314:1118-22.
7 Hoffenberg R. Rationing in action. *BMJ* 1993;306:198-200.
8 Mooney G, Lange M. Ante-natal screening: what constitutes benefit? *Social Science in Medicine* 1993;37:873-8.
9 Fuchs V. The "rationing" of medical care. *N Engl J Med* 1984;311:1572-3.
10 Klein R. Dilemmas and decisions. *Health Management Quarterly* 1992;14:2-5.
11 Mechanic D. Dilemmas in rationing health care services: the case for implicit rationing. *BMJ* 1995;310:1655-9.
12 Davey B, Popay, J. *Dilemmas in health care.* Buckingham: Open University Press, 1993:27-42.
13 Doyal L, Gough I. *A theory of human need.* London: Macmillan, 1991:49-75; 297-312.
14 New B, LeGrand J. *Rationing in the NHS.* London: King's Fund, 1996:63.
15 Doyal L. Needs, rights and equity: moral quality in health care rationing. *Quality in Health Care* 1995;4:273-83.
16 Winslow G. *Triage and justice.* Berkeley: University of California Press, 1982.
17 Doyal L. Medical ethics and moral indeterminacy. *Journal of Law and society* 1990;17:1-16.
18 Curtis S, Taket A. *Health and societies.* London: Arnold, 1995:138-80.
19 Frankel S, West R. What is to be done? In: Frankel S, West R, eds. *Rationing and rationality in the National Health Service.* London: Macmillan, 1993:115-31.
20 Grimshaw J, Hutchinson, A. Clinical practice guidelines - do they enhance value for money in health care. In: Maxwell R, ed. *Rationing health care.* London: Churchill Livingstone, 1995.
21 Beauchamp T, Childress J. *Principles of biomedical ethics.* New York: Oxford University Press, 1994: 395-406.
22 Davis H, Fallowfield L. *Counselling and communication in health care.* London: Wiley, 1991:3-24.
23 Gutman A. *Liberal equality.* New York: Cambridge University Press, 1980:48-63.
24 Pfeffer N, Coote A. *Is quality good for you?* London: Institute for Public Policy Research, 1991:45-58.
25 Grimley Evans J. Health care rationing and elderly people. In: Tunbridge M, ed. *Rationing health care in medicine.* London: Royal College of Physicians, 1993.
26 Audit Commission. *What seems to be the matter: communication between hospitals and patients.* London: HMSO, 1993:1-75.

The case against

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Rationing should be made explicit at all levels of NHS decision making

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This paper must begin with some definitions. Implicit rationing of health care occurs when care is limited and where neither decisions about which forms of care are provided or the bases for those decisions are clearly expressed.[1] Hence it is the unacknowledged limitation of care. Explicit rationing is, unsurprisingly, the opposite: decisions about the provision of health care are clear, as are the reasons for those decisions. Nevertheless, the term explicit has been used in various ways, from Klein's version of explicit rationing as rationing by exclusion[2], to a more general concern with honesty and openness surrounding the context of healthcare rationing.[3]

Both types of rationing decision can be made at different levels. Various taxonomies have been used, but this paper will assume four distinct levels of priority setting: across whole services; within services but across treatments; within treatments; and between individual patients.[1] It is at the last level, particularly, that explicit rationing may be most troublesome.

Currently, rationing in the United Kingdom at all levels is predominantly implicit.[4 5] It is carried out by doctors who are aware of the resources available and who ration by telling patients that they cannot help them, rather than explicitly stating that resources are not available.[4 6-9] The denial of care is instead made to seem optimal or routine.[4 10] Hence there is little sense among the public that healthcare rationing takes place on a daily basis. Indeed, on those occasions when explicit rationing is perceived (particularly at the level of the individual patient)—for example, in the case of child B[11 12]—there tends to be public outcry about the introduction of rationing.

The proposition put forward, that rationing should be made explicit at all levels of NHS decision making is very much "today's topic." An impetus in favour of explicit rationing has built up among both academics and healthcare policy makers. The assumption seems to be that explicit rationing is a wholly good

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thing—implying openness and honesty, and consequently paving the way to a more equitable, efficient, fairer service in which the public can also democratically influence the process and outcome of rationing.

There are, however, problems with this view, which tend to fall into one of two categories. Firstly, the assumption is that the path towards explicit rationing is one which it is practical and possible to follow. Many commentators have, however, questioned this, arguing that implicit rationing may be preferable to imperfect explicit rationing.[2-14] Secondly, there are some levels of healthcare decision making at which it may be intrinsically undesirable to make rationing explicit. This is because explicitness in rationing may cause various members of society to experience disutility (see later section). I will concentrate mainly on the second of these two broad areas of difficulty although I will first cover briefly the arguments relating to the practicality of explicit rationing.

Is explicit rationing practical?

The challenges to explicit rationing on the grounds of practicality fall into two broad areas. One relates to the possibility of developing explicit rationing schemes, the second to the practicalities associated with implementing and sustaining such schemes.

Advocates of explicitness are particularly concerned that the principles on which rationing is based should be established, yet it may not be possible to obtain consensus about such principles. Klein and colleagues suggest there is no obvious set of ethical principles or methodologies on which to base rationing, given the large number of objectives that health care is required to pursue simultaneously.[2 15] Indeed, "it is positively undesirable (as well as foolish) to search for some set of principles or techniques that will make our decisions for us."[2]

Further, it may be impossible to sustain explicit rationing given the potential impact on the stability of the healthcare system.[10] Individual strength of preference for health care is not accounted for by explicit rules, and disaffected individuals with a strong preference are unlikely to accept easily explicit rationing not in their favour.[10] This argument is associated with Mechanic, who states that such challenges will weaken the resolve of health authorities to continue with explicit rationing of health care and will, instead, force them to return to more flexible, implicit means of rationing care. The work of Redmayne *et al*,[15] which shows that UK purchasing authorities who attempted to rule out certain procedures have since relaxed such exclusions, is used to illustrate this problem.[13] Hunter, too, points out that, by increasing the visibility of the decision process, the potential for conflict among decision makers is likely to increase, resulting ultimately in a conservative approach in which current patterns of provision would be preserved.[14]

Disutility associated with explicit rationing

Utility is an economist's term, representing the idea of preference for a particular state—for example, we are likely to have a higher preference for a treatment that leaves us mobile and pain free than for one that leaves us walking with a stick and in severe pain. Economists would say that the former treatment provides higher utility than the latter. Disutility is merely the opposite of utility.

Economists traditionally associate utility only with the purchase of goods and services. Similarly most economists working in the area of health care have conventionally associated utility only with the outcome of treatment and not with the process by which either the treatment or the healthcare service is provided. The concern here is that there may be aspects of disutility associated with the process of explicit rationing that are not associated with implicit rationing.

> *"With openness and public debate, inevitably responsibility follows"*

Let us first clarify some of the important aspects which might characterise explicit rationing.

The citizenry as a whole would be aware that the rationing is taking place. They would essentially be either colluding with some form of technical rationing scheme—for example, based on combining information about cost with that about treatment outcome—or be directly involved in rationing through some form of public consultation process. Whichever the alternative, the citizenry would inevitably feel some of the responsibility for the denial of particular forms of treatment. Ultimately this means denial of treatment to particular individuals. (With openness and public debate, inevitably responsibility follows: if the citizenry knows about rationing and the principles on which it is based then it has the choice over whether to collude with these principles or to oppose them. With any rationing scheme some individuals will be denied care: the choice of individual will depend on the particular rationing scheme.)

In order to have explicitness at the doctor-patient level, general practitioners would be obliged to explain to patients not being referred for treatment that the reason for lack of referral is lack of resources, and for some reason (lower need, lower effectiveness, high cost, reduced "deservingness," age) they are the patients who will not receive treatment. Similarly, hospital doctors would have to explain to emergency patients (and their friends and relatives) that resources are not available for treatment and (as above) that this particular patient is the one who will not receive treatment. In some cases patients will subsequently die. Given the emergency nature of some illnesses, appeals may not be possible because of time constraints.

"The benefits of explicitness may be less than expected"

Explicit rationing may therefore give rise to two particular sources of disutility. Firstly, citizens becoming involved in the process of denying care to particular groups of individuals or particular individuals may experience disutility (denial disutility). Secondly, disutility may result when particular individuals are informed explicitly that their care is being rationed (deprivation disutility). The important question here is whether such disutility could potentially outweigh any increases in utility associated with beneficial changes in who is treated which might result from explicit rationing.

Disutility associated with denial

Denying treatment to patients who are sick and who may die or live years with disability might be expected to cause a considerable amount of disutility to those having to make this decision. Under implicit rationing, the doctor will make the decision about which of two individuals should receive treatment. Aaron and Schwarz, in their examination of implicit rationing in the UK, show that doctors deal with resource limits by seeking medical justification for their decisions.[4] In fact: "Doctors gradually redefine standards of care so that they can escape the constant recognition that financial limits compel them to do less than their best."[4]

Currently the disutility that results from denying patients is experienced primarily by doctors but is minimised by the doctor's ability to justify, both personally and to the patient, the absence of treatment on medical grounds. The decision can then be conveyed to the patient by a variety of means. Options for treatment can just not be mentioned, or they can be stated to be inappropriate for particular reasons. If patients are not referred, they will not be rejected from care, and the doctor will not then have to face the rejected patient.[4]

Contrast this with explicit rationing. Whatever the form of explicit rationing, the citizenry are now aware that they have some responsibility for denying treatment to some individuals and there is some evidence that such treatment may cause the citizenry disutility. As Callahan states: "This anguish will be all the greater when the victims are visible and when the accountability for their condition cannot be evaded." [16]

Those conducting explicit priority setting exercises have often found a general reluctance to specify services to be denied. For example, attempts at programme budgeting and marginal analysis have shown that, while happy to decide what should go on an incremental wish list, groups are much more unwilling to identify services for explicit disinvestment.[17-19] Similarly, reluctance to deny services was noted during initial consultation on core services in New Zealand.[20] Instead: "There is considerably more support for alternative approaches to expenditure constraint.... High technology treatments and pharmaceuticals expenditure are usually cited as examples."[20]

Although increases in denial disutility felt by the citizenry could be expected to be offset by reductions in disutility on the part of the doctor, this is unlikely to be the case. With explicit rationing doctors would still be responsible for informing patients that they were unable to receive treatment, and would be unable to justify this denial on medical grounds. The disutility associated with denying the patient could actually be much greater for the doctor: "For physicians to have to face these trade-offs explicitly every day is to assign to them an unreasonable and undesirable burden."[21]

Disutility associated with deprivation

Rationing of health care, whether implicit or explicit, inevitably means that some individuals will receive treatment and some individuals will not. Let us imagine two patients, A and B, who could each receive equally beneficial treatment. Rationing, however, means that only one patient can receive treatment within the resources available.

First assume the current system of implicit rationing. Patient A is treated and patient B is not. Patient B is told that there is nothing that can be done for her. A receives an improvement in health, and therefore an increase in utility, and B's utility does not change. Neither A nor B is aware that a rationing decision is being made: they do not have perfect knowledge about the availability of medical technologies and are unaware of the possibilities for treatment. B may feel pleased that A has received care and is left with hope that treatment for her condition might be developed.

Now assume an explicit rationing system. Patient A again receives treatment at patient B's expense, but now this fact is known to both individuals. As before, A receives utility from treatment and B's utility related to treatment does not change. Is there a difference between implicit and explicit rationing? Conventionally the answer to this question would be no: the outcome is the same in both scenarios. But B now knows that a treatment exists which is not being provided to her. She is likely to feel resentful, as well as being aware there is no hope. It is quite believable that B will experience a feeling of deprivation and hence disutility.

This notion of deprivation disutility was first developed by Mooney and Lange in relation to antenatal screening.[22] They discuss deprivation disutility in terms of women ineligible for a screening programme who subsequently bear a child with the disability for which screening was available. These women may well experience a loss in utility compared with women bearing a healthy child, but this loss in utility may be

greater because they know that the screening test could have informed them about the disability, allowing them to choose how to proceed at an earlier stage.

The essence of deprivation disutility is that it derives from knowing that something could have been done, but was not. As Evans and Wolfson point out: "It is easier to bear inevitable disease or death than to learn that remedy is possible but one's personal resources, private insurance coverage or public programme will not support it."[23]

The notion of explicitly informing patients that their care is being rationed has been considered inhumane. For example, Hoffenberg has stated that where doctors have to treat some patients with a particular illness at the expense of others he would prefer to see implicit rationing, "not through a belief in medical imperialism or paternalism but through a concern about the anguish that patients and their relatives might feel if they knew that they are being denied services that other patients had received explicitly because of cost."[24]

The advocates of explicit rationing have ignored the potential for disutility"

In practice, the fact that patients are seldom informed that they will not receive treatment because resources are not available provides the main indication for the existence of deprivation disutility. (The main exception to this is where elective patients are told that if they wish to receive treatment of a particular type then they must pay for it, the most obvious example being in vitro fertilisation for infertile couples.) Instead, denial of treatment is made to seem routine or optimal, for example (italics added): "By not referring the patient, the doctor spares the *nephrologist* from having to say no *and the patient and family a painful rejection*."[4]

Deprivation disutility resulting from implicit rationing may extend beyond the patient directly involved, to the population more generally. Individuals may feel deprivation disutility not only for themselves but also altruistically on behalf of others, particularly close friends and family. When care is explicitly rationed, particularly potentially life saving care for young children, donors often provide the required funding for the treatment to go ahead—for example, a single donor paid for the required treatment in the child B case.[12] This is the case even when charitable donations made more generally could be expected to provide much greater benefit to society as a whole and hence would appear to be more efficient. Deprivation disutility felt on behalf of others could explain such donations.

Discussion

Arguments for explicitness in healthcare rationing, as with the arguments against, are many and varied. Some are ideological and relate to the intrinsic benefits of honesty and openness—for example, the development of individuals' moral commitment to democracy and the discouragement of vested interests.[25] Others are more closely linked to the notion that explicitness will lead to an improvement in decision making[25] and ultimately a healthcare system that provides a greater total benefit to society. Economists, particularly, have placed a strong emphasis on explicit rationing techniques which aim to maximise the benefit available from healthcare resources.

Those advocating explicit rationing would generally expect an improvement in decision making to result, at least indirectly, from such explicitness. This is essentially equivalent to saying that the utility to society as a whole would be increased as a result of explicit rationing. There is no evidence, however, that this would be the case. For practical reasons, the benefits of explicitness may be less than expected. Explicitness may be unable to generate the sets of principles which lead to improved decision making. Even if such principles can be generated, it may not be possible to sustain the explicit decisions which follow. Further, the advocates of explicit rationing have ignored the potential for disutility arising from this very explicitness. Such disutility may affect both those making the decisions to ration care and those being denied. In particular, explicitness at the level of the individual patient is likely to lead to substantial disutility, which may itself outweigh any potential benefits in terms of improved outcomes or improved equality.

Greater total utility may therefore result from the equivocation associated with implicit rationing than from the openness and honesty of explicitness. It is questionable whether decisions about rationing should be made explicit at all levels of NHS decision making (unless this position is held on purely ideological grounds). In fact, whether rationing should be explicit (particularly at the level of the individual doctor-patient consultation) is an empirical question, the answer to which must ideally be determined on the basis of considering the various utilities associated with implicit and explicit rationing. It is important to determine the extent of increased utility which could, in practice, be expected to result from explicitness (via improved decision making). Furthermore, it is important to estimate whether such increased utility would be substantially offset by the disutility associated with deprivation and denial, the magnitude of which may be significant and has still to be determined. Researchers and health authorities should be exploring these issues rather than jumping on the fashionable bandwagon of explicit rationing.

1 Coast J, Donovan JL, Frankel SJ, eds. *Priority setting: the health care debate.* Chichester: Wiley, 1996.
2 Klein R. Dimensions of rationing: who should do what? *BMJ* 1993;307:309-11.
3 New B, Le Grand J. *Rationing in the NHS. Principles and pragmatism.* London: King's Fund, 1996.
4 Aaron HJ, Schwarz WB. T*he painful prescription. Rationing hospital care.* Washington, DC: Brookings Institution, 1984.
5 Grimes DS. Rationing health care. *Lancet* 1987;i:615-6.
6 Dean M. Is your treatment economic, effective, efficient? *Lancet* 1991;337:480-1.
7 Klein R. Rationing health care. *BMJ* 1984;289:143-4.
8 Parsons V. Rationing: at the cutting edge. *BMJ* 1991;303:1553.
9 Smith R. Rationing: the search for sunlight. *BMJ* 1991;303:1561-2.
10 Baker R. The inevitability of health care rationing: a case study of rationing in the British National Health Service. In: Strosberg MA, Weiner JM, Baker R, Fein IA, eds. *Rationing America's medical care: the Oregon plan and beyond.* Washington DC: Brookings Institution, 1992:208-29.
11 Price D. Lessons for health care rationing from the case of child B. *BMJ* 1996;312:167-9.
12 Toynbee P. Did the NHS cheat Jaymee? *Independent* 1995;27 Oct: 23.
13 Mechanic D. Dilemmas in rationing health care services: the case for implicit rationing. *BMJ* 1995;310:1655-9.
14 Hunter D. *Rationing dilemmas in healthcare.* Birmingham: NAHAT, 1993.
15 Redmayne S, Klein R, Day P. *Sharing out resources. Purchasing and priority setting in the NHS.* Birmingham: NAHAT, 1993.

16 Callahan D. Ethics and priority setting in Oregon. *Health Affairs* 1991; Summer: 78-87.
17 Cohen D. Marginal analysis in practice: an alternative to needs assessment for contracting health care. *BMJ* 1994;309:781-4.
18 Donaldson C. Commentary: possible road to efficiency in the health service. *BMJ* 1994;309:784-5.
19 Donaldson C, Farrar S. Needs assessment: developing an economic approach. *Health Policy* 1993;25:95-108.
20 The Bridgeport Group. *The core debate. Stage one: how we define the core. Review of submissions.* Wellington: Department of Health, 1992.
21 Fuchs VR. The "rationing" of medical care. *New Engl J Med* 1984;311:1572-3.
22 Mooney G, Lange M. Ante-natal screening: what constitutes benefit? *Soc Sci Med* 1993;37:873-8.
23 Evans RG, Wolfson AD. *Faith, hope and charity: health care in the utility function.* Vancouver: University of British Columbia, 1980.
24 Smith R, ed. *Rationing in action.* London: BMJ Publishing Group, 1993.
25 New B, on behalf of the Rationing Agenda Group. The rationing agenda in the NHS. *BMJ* 1996;312:1593-601.

Socioeconomic determinants of health

Children, inequalities, and health

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Summary

This article describes a growing body of evidence showing the adverse effects of the widening income gap on the health and welfare of children and young people. The effects of this go well beyond morbidity and mortality and can also be seen in the areas of crime, violence, and educational attainment. There is a need for evidence based policy in this area, but meanwhile there is scope for intervention in pregnancy and the early years, and good evidence that this is effective. A number of well evaluated interventions not necessarily directly related to health, such as early learning programmes and social support for parents, promise to have beneficial health effects.

In the early 1940s, on the publication of Richard Titmuss's *Birth, Poverty and Wealth*,[1] newspapers reported "Poor folks' babies stand less chance" and "Babies beware of poor parents." Titmuss's work showed that children's deaths were related to the occupations of their fathers and that the gap between the life chances of working class and middle class infants had increased since 1914. Some commentators found his conclusions unpalatable: an *Evening Citizen* reviewer wrote that the book ignored "the criminal ignorance and neglect of many mothers" who were inclined to give their babies "fish and chips, pickles, strong tea, lollipops, chocolate biscuits and toffee apples."[2]

Half a century later, when Barnardo's published *Unfair Shares: the Effects of Widening Income Differentials on the Welfare of the Young*,[3] favourable press coverage urged that it should inform evidence based policy,[4] but the inequalities debate continues to attract other interpretations. A *Daily Mail* article in 1996 concluded: "Rich or poor, life is getting better ... the vast majority are doing well and don't need welfare."[5] Now as in the 1940s, mothers—the main caretakers of children—continue to attract adverse press comment, with suggestions that the main need for change lies with them: their children suffer when they go out to work; their diets are not sensible; their discipline is lacking; their morality is in need of attention; and their family structures are suboptimal. This is despite evidence that the majority of mothers living in poverty successfully bring up their children and protect and promote their health under the most unpromising conditions.[6 7]

BARNARDO'S PHOTOGRAPHIC AND FILM ARCHIVE

Fig 1 How effective was this early intervention?

Unfair shares

The health index least susceptible to interrater variation, or other kinds of reporting bias, is death. The postwar period has seen a decline in perinatal and infant mortality—indeed, in the United Kingdom mortality under the age of 20 years has fallen by over 90% during the 20th century.[8] But this masks continuing (and in some cases increasing) problems facing young people. Before housing costs are taken into account, an estimated quarter of all children live in poverty[9]; when housing costs are allowed for, this rises to almost one in three.[10] In Britain, as in the United States, patterns of poverty reflect and reinforce the wider inequalities between black and white communities. To a large extent, the health effects of poverty have been measured quantitatively and indirectly, but there is an important seam of qualitative work describing the texture of the lives of mothers and children living in poverty.[11] Poverty involves social exclusion, which itself has adverse psychosocial effects. Emotional problems

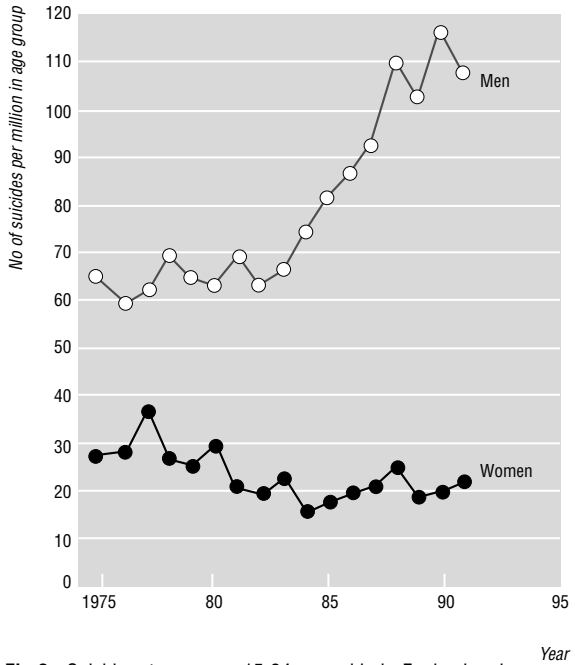

Fig 2 Suicide rates among 15-24 year olds in England and Wales.[3] Source: OPCS mortality statistics

in childhood can cast a long shadow forward, affecting many aspects of health and behaviour in adult life.

Relative poverty has absolute effects. Data from the 1970 birth cohort show that hyperactivity and conduct disorder, and to a lesser extent anxiety, increase with decreasing social class. Moreover a child in the lowest social class is twice as likely to die before the age of 15 as a child in the highest social class.[8] The social class gap in child deaths from accidents has widened over the past decade.[12] If this trend persists, the Health of the Nation target on accidents is likely to be met for children in the non-manual classes but not for those from the manual classes.

What is it that links adverse social, psychological, and economic conditions in childhood with adult morbidity, mortality, and other undesirable outcomes? And given that children are not simply trainee adults, with childhood no more than a preparatory period for later outcomes, what is it like to be a child in a society where the income gap is widening? In 1994, it was observed[3] that:

- Total reported crime, including juvenile crime, increased by almost 80% and violent crime by 90% during 1981-91[13]
- The number of drug offenders between the ages of 17 and 29 doubled between 1979 and 1989[14]
- The suicide rate among young men aged 15-24 increased by 75% from 1983 to reach a peak in 1990 (fig 2)[15]

Widening income differentials and relative poverty are not the whole story, but the statistical links between increasing relative deprivation and growing psychosocial problems among young people are compelling.

Early events and later outcomes

Probably the best sources of data on a link between early childhood events and later outcomes are the cohort studies which collect both health and social data from children at intervals, often from shortly after birth into adulthood, and studies that link poor intrauterine growth with later health.[16] Substantial social class differences in birth weight may be expected to generate inequalities in health in the future.[17] The new health variations programme of the Economic and Social Research Council will be exploring these influences.

From the cohort studies we know that risks of death and serious illness are greatest for people brought up in the lowest social classes, and so are the chances of relatively high blood pressure, poor respiratory health, obesity, and shortness of stature.[18-20] Work derived from the Swedish level of living surveys similarly describes the effects of adverse childhood conditions on illness and mortality in adulthood. Childhood adversity in this study included family breakdown and—with a stronger impact—family dissent.[21] This accords with British findings.[22 23] Work based on the youngest cohort of the west of Scotland twenty-07 study looks at the ways in which different aspects of the family lives of young people relate to a range of outcomes chosen as broadly representative of lifestyle, health related behaviours, delinquency, and contact with the police.[24] The authors considered both family structure (intact, reconstituted, or single parent), and reasons for family breakdown and distinguished between parental separation and death, and two aspects of family life: family centredness (a measure of time spent in joint family activities) and conflict (frequency of arguments between young people and their parents). Of the four aspects of family life, family centredness showed the strongest and most consistent relation with outcomes for both males and females. The distinction between family structure and family process is useful in helping to understand why simple policy solutions, such as penalising single mothers, are unlikely to be helpful. Outcomes for children in single parents families are, of course, heavily influenced by the fact that such families, usually headed by women, subsist on low incomes.

Can anything be changed until everything is changed?

There are several competing explanations for health inequalities.[25] Among these are the importance of psychosocial pathways in understanding the corrosive effect of the growing gap between the haves and the have nots.[26] But some things can only be done by governments, and narrowing the income gap is one of these. There is evidence that this strategy works. A randomised controlled trial on income maintenance shows that a guaranteed a minimum income to pregnant women in low income families (by using negative income tax) was associated with a significant increase in birth weight in the intervention group.[27 28]

In the absence of political and policy change, is there anything which practitioners—health professionals, educationalists, and those delivering child welfare services—can do, or which people and communities can do for themselves? Are more studies of baboons and civil servants needed, or can we take forward, and use creatively, some of what is already known? Given the plausibility of psychosocial pathways, it would be ironic if all solutions were seen as beyond the grasp of

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Fig 3 Highscope in action

ordinary people, who can only wait passively for the powerful to act.

The link between early events and later outcomes—and the recognition that interventions at crucial points may affect this—has long been understood: the Book of Daniel describes an experiment in which children were given pulses to eat and water to drink, rather than the king's wine and meat. While present day nutritionists might be surprised to know that after only 10 days the countenances of the experimental group "were fairer and fatter in flesh than all the children which did eat the portion of the king's meat," good nutrition as a helpful early intervention policy was clearly established.[29]

More recently, data from the cohort studies have indicated what might be protective. Parental interest in, and enthusiasm for, education offers the best protection in the long term from the disadvantages of a start in poor socioeconomic circumstances.[18 30] Children fortunate enough to have this help tended strongly to do better in cognitive tests and in educational attainment.[31] In due course, such children as adults were more likely than were others to be enthusiastic about their own children's education.[18 32] The importance of educational attainment is seen in all aspects of the findings on adult life. Those who gained qualifications at A level (or training equivalents) or above had much better chances in health[33 34] as well as in occupation and income.[18]

Early interventions which show promising effects include Highscope, a preschool intervention that incorporates an active learning curriculum, trained staff, and parental participation.[35] Highscope shares many of the elements of other good quality preschool interventions, but some aspects of the curriculum, concerned with encouraging the child to "plan, do, review" as part of a daily routine are seen as distinct. For the child, adult acknowledgement that she can make sensible decisions is important; the child is encouraged to be independent and seek solutions within the context of a secure and consistent daily routine.

A well conducted follow up study indicates that at age 27, children who had been randomised to the programme had higher monthly earnings, a higher proportion of home ownership, and fewer arrests including for crimes of drug taking or dealing than those not randomised to the programme (see box).[36] What is as important as the later outcomes is the enhanced experiences in childhood and the enjoyment which children gain from these early encounters.

In terms of health interventions, one promising social support intervention is the child development programme developed in Bristol; its fundamental goal is to help support and encourage parents in their task.[37] Considerable emphasis is laid on the health and wellbeing of the mother as a woman with her own interests and future as well as being the mother of children. This programme offers monthly support visits to new parents, antenatally and for the first year of life. Most of the visits are undertaken by specially trained health visitors. Perhaps the most radical development of this programme is the community mothers intervention, in which mature mothers were recruited to provide support to younger mothers. A randomised controlled trial showed that children in the intervention group were more likely to have received all of their primary immunisations, to be read to, and to be read to daily. They were less likely to be given cows' milk before 26 weeks. Mothers in the intervention group had a better diet than the controls and at the end of the study, they were less likely to be tired or feel miserable.[38]

There is good evidence that early interventions effect change. While risks for poor later outcomes are cumulative, the benefits of early intervention cannot be underestimated, as an important paper by Power and Hertzman which pulls together evidence on the early years makes clear.[19] These authors also make the point that such interventions cannot fully overcome socioeconomic disadvantage. Providing opportunities for improved cognitive and emotional functioning to socioeconomically disadvantaged children will improve their life chances, but this will not put them on an even playing field with their more advantaged young friends.

Where once the state's welfare apparatus stood as a clear statement of our mutual responsibilities to our fellow human beings, its decline now stands as a denial of that responsibility.[3] Evidence based, redistributive social welfare policies would be the best option, not only for children living in poverty but for the rest of us, who live with the corrosive effects of a divided society.

Meanwhile, intervention at practice level, and in particular education in the early years, is clearly worthwhile in affording children and young people the opportunity to experience a good childhood. Just as

Later effects of Highscope

At age 27, graduates of the Highscope programme, a preschool intervention, had:

- Significantly higher monthly earnings (29% *v* 7% earned $2000 or more per month)
- Significantly higher percentage of home ownership (36% *v* 13%)
- A significantly higher level of schooling completed (71% *v* 54% completed 12th grade or higher)
- A significantly lower percentage receiving social services at some time in the last 10 years (59% *v* 80%)
- Significantly fewer arrests (7% *v* 35% with five or more arrests)

early trauma may have long terms effects, early interventions enable children and young people to accrue some of the capital needed for good long term outcomes.

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1 Titmuss R. *Birth, poverty and wealth.* London: Hamish Hamilton, 1943.
2 Oakley A. *Man and wife: Richard and Kay Titmuss; my parents' early years.* London: Harper Collins, 1996:190. (Quoting *London News*, Dec 1943-January 1944 ; *Daily Herald*, 20 Sept 1943; *The Evening Citizen*, 5 Jan 1944.)
3 Wilkinson RG. *Unfair shares: the effects of widening income differences on the welfare of the young.* Barkingside: Barnardo's, 1994.
4 Wounds in a sick society [editorial]. *Guardian* 1994 July 28:12.
5 Smith R. Keeping the bad news from journalists. *BMJ* 1996;314:81.
6 Roberts H, Smith S, Bryce C. *Children at risk? Safety as a social value.* Buckingham: Open University Press, 1995.
7 Kempson E. *Life on a low income.* York: York Publishing Services, 1996.
8 Woodroffe C, Glickman M, Barker M, Power C. *Children, teenagers and health: the key data.* Buckingham: Open University Press, 1993.
9 Oppenheim C. *Poverty: the facts.* London: Child Poverty Action Group, 1993.
10 Department of Social Security. *Households below average income, 1979-1993/4.* London: HMSO, 1996.
11 Graham H. *Hardship and health in women's lives.* Brighton: Harvester Wheatsheaf, 1993.
12 Roberts I, Power C. Does the decline in child injury mortality vary by social class? A comparison of class specific mortality in 1981 and 1991. *BMJ* 1996;313:784-6.
13 Home Office. *Criminal statistics for England and Wales 1991.* London: HMSO, 1993.
14 National Children's Homes. *The NCH factfile: children in Britain, 1992.* London: NCH, 1992:64.
15 Office of Population, Censuses and Surveys. *OPCS mortality statistics.* London: HMSO, 1993.
16 Barker DJP. *Mothers, babies and disease in later life.* London: BMJ Publishing Group, 1994.
17 Phillimore P, Beattie A. *Health and Inequality: the Northern Region 1981-1991.* Newcastle: Department of Social Policy, University of Newcastle upon Tyne, 1994.
18 Wadsworth MEJ. *The imprint of time: childhood history and adult life.* Oxford: Oxford University Press, 1991.
19 Power C, Hertzman C. Social and biological pathways linking early life and adult disease. In: Marmot M, Wadsworth M, eds. Fetal and early childhood environment. *Br Med Bull* 1997;53:210-21.
20 Power C, Manor O, Fox AJ. *Health and class: the early years.* London: Chapman and Hall, 1991.
21 Lundberg O. The impact of childhood living conditions on illness and mortality in adulthood. *Soc Sci Med* 1993;36:1047-52.
22 Wadsworth MEJ, Kuh D, Rodgers B. Children of divorced and separated parents. *Family Practice* 1981;7:104-9.
23 Holterman S. *All our futures: the impact of public expenditure and fiscal policies on British children and young people.* Barkingside: Barnardo's, 1995.
24 Sweeting H, West P. *Young people and their families: analyses of studies from the twenty-07 youth study cohort.* Glasgow: MRC Medical Sociology Unit, 1995. (Working paper No 49.)
25 Davey Smith G, Egger M. Understanding it all—health meta-theories and mortality trends. *BMJ* 1996;313:1584-5.
26 Wilkinson R.G. *Unhealthy societies: the afflictions of inequality.* London: Routledge, 1996.
27 Arblaster L, Entwistle V, Fullerton D, Forster M, Lambert M, Sheldon T. *A review of the effectiveness of health promotion interventions aimed at reducing inequalities in health.* York: NHS Centre for Reviews and Dissemination (in press).
28 Kehner BH, Wolin CM. Impact of income maintenance on low birthweight: evidence from the Gary experiment. *Journal of Human Resources* 1979;14:434-62.
29 *Holy Bible.* Authorised version, 1611. Daniel i, 10-16.
30 Pilling D. *Escape from disadvantage* Brighton: Falmer Press, 1990.
31 Douglas JWB. *The home and the school.* London: MacGibbon and Kee, 1986.
32 Wadsworth MEJ. Effects of parenting style and preschool experience on children's verbal attainment: a British longitudinal study. *Early Childhood Research Quarterly* 1986;1:237-48.
33 Mann SL, Wadsworth MEJ, Colley JRT. Accumulation of factors influencing respiratory illness in members of a national birth cohort and their offspring. *J Epidemiol Community Health*1992;46:286-92.
34 Kuh DJL, Wadsworth MEJ. Physical health status at 36 years in a British national birth cohort. *Soc Sci Med* 1993;37:905-16.
35 Macdonald G, Roberts H. *What works in the early years? Effective interventions in health, social welfare, education and child protection.* Barkingside: Barnardo's, 1995.
36 Schweinhart L, Weikart D. *A summary of significant benefits: the Highscope Perry pre-school study through age 27.* Ypsilanti, MI: High Scope Press, 1993.
37 Barker WE, Anderson RM, Chalmers C. *Child protection: the impact of the child development programme.* Bristol: Early Development Unit, Department of Social Work, 1994. (Evaluation document No14.)
38 Johnson Z, Howell F, Molloy B. Community mothers' programme: randomised controlled trial of non-professional intervention in parenting. *BMJ* 1993;306:1449-52.

The benefits of foward planning

Flicking through some back copies of the *BMJ* the obituary of Air Vice Marshal David Davison (*BMJ* 1994;309:1510) triggered memories of a spell in the mid 1970s spent assisting him on a field surgical team. We were in the Middle East, and due to poor ventilation the doors of our operating theatre hut were often left open. On this particular night, we snipped and stitched to the soothing sounds of distant music carried in on the sluggish breeze.

Sadly, on the table, things were less comforting, and the latest mine injury from the local conflict was not doing so well. A deep pelvic bleeder was proving hard to silence and against David's previous expectations, more blood would certainly be needed. All hands were busy preparing the next case and being the "boy" of the team I was dispatched to organise six more units as quickly as possible. The laboratory technician, already busy cross matching the last stored bottle, pointed to the empty refrigerator, shrugged his shoulders, and remained glued to the microscope. Clearly, this was not viewed as his problem.

Outside, the sounds of music grew louder as the visiting services entertainment team struggled to overcome heckling from a lively audience. Time was pressing, so there was little choice but to tap into this reservoir in the hope that the donations would contain more blood than alcohol.

The sergeant compere was briefed and half way through "Anyone who had a heart" he leapt on to the makeshift stage. Pushing aside a mature Cilla Black look-a-like, he called for five B positive volunteers and handed back the microphone to the startled performer. Seats scraped on the hard packed sand and the donors, beer cans in hand, followed to the technicians' hut for bleeding. The first three were quickly attached to the collecting sets, but, strangely, the remaining two had vanished.

Swaying by the open doors of the theatre hut, holding each other for support, were the missing volunteers. They stared, wide eyed, at the red puddle next to the portable operating table, turned, and started to move off—in the wrong direction. Explaining their mistake, I joined them at the theatre doors and pointed to the laboratory.

"You gotta be joking Doc," slurred the larger one "We ain't giving our blood so you can chuck it on the floor." Ignoring my protests, they tottered off into the warm dark night singing their own version of "Anyone who had a heart." David Davison looked up from the table and using various RAF idioms of that time suggested that I might like to go away and apply my limited resources to researching a more suitable route to the laboratory for the next two volunteers.

I did. Through David's endeavours and perhaps in spite of mine, the casualty survived. The next morning he probably felt rather better than my two failed donors, while that evening over a beer or two David and I both reflected on the benefits of forward planning.

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We welcome filler articles of 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.