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Editorial

Research, consent, distress and truth

Important (and topical) problems are raised in this issue by Dr Peter Lewis in his paper on the drawbacks of research ethics committees and by his commentator Dr D J Weatherall. Their reminder that researchers sometimes illegitimately interpret the approval of a research ethics committee as a sort of permission to forget about ethical issues thenceforth, is timely and perhaps all committees should make a point of reminding researchers that this is not the case – that researchers must never delegate their personal moral responsibility towards their patients and research subjects. Whether or not members of ethics committees should take up Dr Weatherall's suggestion that 'medical members of the committee should not be averse to visiting research workers and watching them at work' will doubtless be hotly debated; but he points out that currently 'Animal inspectors are regularly seen in research departments; medical members of ethics committees rarely are'.

The proposals, from both authors, that written consent from patients for their participation in research studies should in some circumstances be dispensed with requires meticulous assessment. Each offers different reasons. Dr Lewis concentrates on the distress that the information in such written consent can evoke in cases where patients have fatal diseases. 'In some circumstances written consent can be distressing to subjects and hence in my view the antithesis of "ethical" ' he writes and he gives the example of a young leukaemia patient who may be treated either with 'the established treatment which emerged as best in the last comparative trial' or with 'a variant which it is hoped might be superior'. A controlled trial is in process comparing the two treatments by random allocation of appropriate patients and some form of sequential analysis will ensure that as soon as one regime proves superior to the other the trial 'will be stopped and the better treatment adopted for all the patients until the next trial is mounted'. However, the research ethics committee insists upon written informed consent and as a result 'the patient will be told by the document that he has leukaemia, that there is no entirely satisfactory treatment and that continuing experiment is necessary to determine which drugs are best. The patient will have to be told that his allocation to one or other treatment regime will be at random. Thus at a stroke, the patient is asked to sign a consent form with some very disturbing information on it. He does not have "serious anaemia" or "an abnormality of the white cells", he has leukaemia. Furthermore, however it is phrased, the patient will realise the treatment for his condition is unsatisfactory; experiment is necessary, outcome is being measured. There is a further implication. The ultimate outcome will not be cure but worse. His attendants intend to measure his progress to an end point.'

Moreover, Dr Lewis points out, if the patient exercises his right to refuse to participate he can still be offered only 'one of the two standard treatments. Hence all that has been achieved by presenting the research ethics committee's consent form to the patient is unnecessary distress and the delay of the comparative trial'. Instead Dr Lewis proposes that investigators of 'accepted therapies' for fatal diseases should 'be charged with sensitively and sympathetically explaining to patients that while they were being treated they were also participating in research. Patients would be told that their inclusion in research assessments would never be to their detriment and that they would receive the best treatment for their condition'.

It is not entirely clear from Dr Lewis's account what he means by 'standard' or 'accepted' treatments. It may be that he means both treatments are at the time considered on equally good grounds to be of equal efficacy (however small that efficacy may be). Such cases must be rare, and even in some of those the requirement for informed consent may be indicated because the patient may have personal preferences for one sort of therapy rather than another on the grounds for example of which side-effects he or she finds more objectionable. However, what Dr Lewis earlier *says* he is considering is a comparison of two treatments, one 'the established treatment which emerged as best in the last comparative trial' and the other 'a variant which *it is hoped* might be superior' (emphasis added). If this hope turns out to be unjustified and the variant treatment is shown to be inferior to the established treatment (for example by producing unexpectedly nastier

side-effects) then its use will have been detrimental to those patients who received it. Thus before the results of such a trial are available patients simply cannot *truthfully* be told that their inclusion in the trial 'would never be to their detriment and that they would receive the best treatment for their condition'.

Now it may be that Dr Lewis is arguing that it does not matter that such an assertion may be untruthful. He may believe, as many doctors do, that not to cause distress to his patients is more important than not to lie or to deceive them. This interpretation is certainly consistent with his assumption that if written consent is distressing to the subject it is 'the antithesis of "ethical" '. It is also consistent with his implicit indication that he tells patients with leukaemia that they have 'serious anaemia' or 'an abnormality of the white cells' rather than that they have leukaemia. Certainly many doctors do hold such a view. Even more believe that unless the patient positively indicates that he wishes to be told the truth, it should not be volunteered when the truth is ugly. Yet the requirement of informed consent (whether written or not) entails that the truth is revealed whether subjects wish it or not. What Dr Lewis *seems* to be advocating as a way out of this dilemma is that research ethics committees should in certain limited circumstances give permission for researchers to obtain verbal consent from patients based on the false information that research would never be to their detriment and that they would receive the best treatment for their condition – what might accurately be called 'mis-informed consent'.

The crucial moral issue here seems to be whether or not patients may be deliberately deceived or lied to about their medical condition in order to save them distress. If this is an acceptable aspect of medical ethics (and it is certainly a maxim of many doctors' actions) then presumably it should be acceptable for research ethics committees to sanction it, and the Declaration of Helsinki should be amended accordingly. On the other hand an opposing view, also common within the medical profession, is that doctors must *not* lie to or deliberately deceive their patients, even though they should be sensitive about not thrusting *unwanted* truths at patients who, having been given genuine opportunities to ask about their condition, make it clear that they 'don't want to know'. The moral obligation not to lie or deliberately deceive is a general moral norm and is linked with the moral obligation to respect other people as autonomous agents – a respect which also leads to the view that people have a right to obtain medical information they desire about themselves, even if obtaining it will lead to distress.

If this alternative view is accepted then the proposal that research ethics committees should sanction 'mis-informed consent' is untenable. Two alternative options are open. One is to exclude from research patients who, having been given the genuine opportunity to be told about their condition make it clear that they do not wish to be told. Such patients should be given the best established treatment – eg that 'which emerged as best in the last controlled trial'. The second option is to dispense with informed consent altogether, written or verbal, in such cases. This may even be happening in some centres already and at least seems preferable to requiring or encouraging 'mis-informed consent' – but it would be a step which would leave many people very uneasy, however benign its motivation.

Dr Weatherall's objections to signed consent are based on even more problematic examples. Thus it does indeed seem inappropriate in the circumstances he describes for a newly admitted coronary patient 'in severe pain drowsy with diamorphine' and so on, to be faced by a researcher babbling about beta-blockers and requesting signed consent to participation in a controlled trial. This may well add 'another burden to what is often an intolerable situation'. Of course, it does not follow that the research should therefore go ahead *without* obtaining informed consent; but the investigator may not be willing to try and obtain even verbal consent by sensitive and sympathetic explanation that the patient is to participate in a trial while being tested. Indeed there may be no time to do so, if the drugs to be tested are part of the immediate emergency treatment. And if the patient is unconscious or too distressed, too drugged, or in too much pain to be unable to make rational decisions should the researcher turn to the next of kin (also likely to be distressed and confused)?

The issue here seems to turn on whether or not the doctor in such circumstances intends to put that particular patient's interests before all other considerations. If he does, then he will treat the patient with whatever therapy he believes, on the basis of the best information that he then has, to be the best available therapy. Of course, he will not *know* which of the two being tested is the better therapy, but he will often have good reason to prefer one to the other. A useful way to find out whether or not he is indifferent at the time of decision as to which of the two treatments is preferable is to ask himself which he would use for a loved one who needed such treatment. If he would be happy to randomise the decision for a loved one then there seems little objection to randomising it for his patient. If not, and he accepts, as the Declaration of Helsinki enjoins, that 'concern for the interests of the subject must always prevail over the interest of science and society', then he must surely not enter the patient into a controlled trial without his informed consent. But clearly the disadvantage of such a view is that either the pace of therapeutic advance will be slowed, or, in this sort of case, that patients or their relatives will be distressed by being asked for informed consent in what are already highly distressing circumstances.

The issues raised by Drs Lewis and Weatherall are important and complex. They deserve thorough discussion.