

Ethical approaches to researching the mentally incapable patient

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Patients seen in psychiatric settings may, for a variety of reasons, be incapable of informed consent. The Mental Health Act allows for their treatment, but research into their pathologies is practically impaired (while their consent is a criterion for inclusion). Is it ethically unacceptable to perform research upon these patients? If so, then the prospects for therapeutic and conceptual advance seem remote. In this paper the competing ethical claims are examined. An approach is proposed which is humane yet permissive of research in this heterogeneous group of patients.

Can we perform research upon patients who are incapable of informed consent? There is neither legislation nor case law regarding this question. The issue is important, both for the protection of patients (from unwarranted and non-beneficial violation) and scientists (who may feel that research is necessary and justified).

The Mental Health Commission draft guideline (1985) stated that research involving a therapeutic procedure could be justified if it was of small risk and possible benefit to the patient. However, non-therapeutic research was not sanctioned. This issue is of public interest (Hirsch & Harris, 1988).

Every law has exceptions

English law works by setting down principles which are then modified case by case in a stepwise fashion; exceptions are the rule. An exception to the law of battery is the rule of necessity; that one should intervene when it is absolutely necessary to save life and limb. Lord Donaldson (1992) argued that everyone has a right to self-determination even if it is detrimental to his/her health, but that there is also a strong interest in preserving the life and health of citizens. Where there is doubt over whether or in which way an individual would exercise his right to self determination, the doubt must fall to be resolved in favour of the preservation of life (Lord Donaldson, 1992).

Treatment can be ethical without overt consent (as is the case under the Mental Health Act). Thus we have a necessary modification to the ideas of trespass and violation of the individual's integrity. We are in the area of value judgements.

We suggest, with regard to research, that the inviolability of the human body would have to be interpreted as follows.

That a violation of the person takes place when a procedure is against the person's will, not simply in the absence of his/her will. If it is otherwise consistent with or in his interest, and providing there is no real harm or disadvantage to the individual, the action would not be a violation.

Harris (1988) has argued that broadly, so long as there is a reasonable chance of research culminating in an advance in treatment and knowledge, there may be a moral obligation to undertake it, for a failure to do so would arguably damage society as well as the present and future interests of the individual. This is especially so for those individuals afflicted by the disease or condition in question.

Harris argues further that where there is a negligible risk of pain, discomfort or indignity to patients involved in research, which is independently found to be ethically and scientifically sound, it would be morally wrong to fail to undertake present research simply because the individual is incapable of indicating a knowing consent. We would add that where the individual refuses, either by verbal or non-verbal means, to comply or consent, then to proceed with the research would be unethical.

Harris reminded us (1988) that there are many instances in life when a person in control or authority undertakes risk involving others without their consent but with the interest of others in mind, implicitly balancing risks and benefits. A ship's captain who diverts his voyage in dangerous waters to attempt to rescue another distressed vessel is

one example. Would he not be culpable if he refused to do so in order to spare his passengers anxiety and fear? This illustrates that we do not in ordinary life expect to be free of the involuntary imposition of risk of harm.

We suggest that while usually the risk is negligible there are cases where the danger warranted by pursuance of research may be justified even if any beneficiaries will be in the future. Examples would be experimental treatments or investigations of the later stages of AIDS or cancer when the individual is unlikely to benefit, or investigations such as positron emission tomography or single photon emission computerized tomography, which are invasive and carry a real yet minimal risk. Should they be abandoned if the patient is conscious but cognitively incapable?

A difference between non-treatment and volunteer research

There is a possible confusion which may be useful to clarify at this point. There is an important distinction between research in volunteers, non-therapeutic research, and relevant research. Research which is not testing treatments *per se* but is, for example, investigating the mechanisms of the disease or its pathophysiology, has come to be called non-therapeutic research. Research on volunteers is usually not relevant to any condition that the subject has at present or can expect in the future. From the volunteer's perspective the research is not relevant. The crux of the issue is research involving subjects who suffer from diseases such as dementia, which have rendered them incapable of consenting, unable to consider their involvement, and where the subject will not suffer appreciable pain, discomfort or indignity from the latter which is necessary and relevant to their condition (and to the class of individuals who suffer from their condition). This situation is very different from that of unaffected volunteers asked to participate in research. It is, of course, axiomatic that such research (in affected subjects) be accompanied by all the usual safeguards of ethical committees, scientific integrity, and the agreement of available relatives or guardians where this is appropriate. There is a need to protect the vulnerable from violation, suffering and indignity, but there is also a need to

ensure that they get the best available care now and in the future (and that others in the future receive the same).

We must recognise that for many conditions which render patients unable to consent there may be no adequate alternative or animal model to push forward the frontiers of understanding. The mechanisms of such conditions as catatonic schizophrenia, the forward development of stroke after the initial insult, and dementia from AIDS are examples. The patients and those affected by their condition in the future should not be deprived of the benefits of harmless research, involving themselves, simply because they are unable to consent.

The law has not declared on this point and there are competing issues of trespass *v.* negligence and different moral principles which may be called upon. In philosophical terms these are value judgements which cannot be avoided. In the end we must choose what we think is the right course; there is no absolute principle on which to rely.

In their consultation paper number 29 the Law Commission (1993) made recommendations which seem commendable. In principle they would allow non-therapeutic as well as therapeutic research on incapable patients with a disorder which has incapacitated them if the following conditions were met.

That the research entail only an insubstantial and foreseeable risk to the subject's physical or mental health, had been approved by a local research ethics committee, had the consent of the medical treatment proxy or nearest relative of the patient (who had been fully informed of the purpose of the research and procedures to be used) and that the subject had not and did not in any way indicate his/her unwillingness to participate in the research.

If we do no research into states associated with lack of insight and inability to form consent, then we significantly handicap our future prospect as a caring society. We effectively demarcate a class of disease which will remain without cure. By avoiding the fine balancing act of weighing each procedure's potential cost to a subject against its potential benefit to a group of subjects we place perhaps inordinate value on the diminished autonomy of those suffering in the present, thereby consigning those of the future to a repetition of the same. If that future included ourselves then might we debate the issue more urgently?

The authors would welcome correspondence agreeing or disagreeing with the views expressed in this paper.

LAW COMMISSION (1993) *Mentally Incapacitated Adults and Decision Making Medical Treatment and Research*. Consultation Paper number 129. London: HMSO.

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