Consent

Consent for emergency care research: the Mental Capacity Act 2005

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Mental Capacity Act (2005) versus Clinical Trial Regulations (2004)

Researchers in emergency medicine will face another major change in the law when the provisions of the Mental Capacity Act 2005 come into force in England and Wales in April 2007. This act gives a framework for consent for emergency care research in cases where patients are incapacitated and cannot consent themselves.¹ Research in Scotland has a different set of regulations contained in the Adults with Incapacity (Scotland) Act 2000.

The new law

There will now be two major legal frameworks for emergency medicine research. The Mental Capacity Act will be applied if the research involves non-drug interventions, procedures, devices, investigations or service organisation. Within the Act, sections 30–34 relate to research. This Act does not apply if a “medicine” is being studied, in which case the research must be conducted under the Medicine for Human Use (clinical trials) Regulations 2004 (the UK implementation of Directive 2001/20/EC of the European Parliament).² Despite the difference in the name, the Medicines Regulations and the Mental Capacity Act have the same status in law.

A number of circumstances within the Mental Capacity Act have to be fulfilled to be able to carry out medical research on incapacitated patients. Firstly, there should be no potential to answer the research question in patients who possess capacity. Secondly, the research must be connected with the condition that underlies the mental incapacity (trauma research on patients with trauma, stroke research on patients with stroke, etc). Thirdly, the research should have “the potential to benefit the patient without imposing on the patient a burden that is disproportionate to the potential benefit”. This means that only small risks will be tolerated with interventions that have small potential benefit, but that large risks can be tolerated if there is potential for a large benefit. Fourthly, if there is no potential benefit to the individual patient (eg, research on the underlying mechanisms of the

disease), then the research should involve little risk.

Trial entry under the Mental Capacity Act

Wherever possible, consent must be obtained from the patients themselves. If this is not possible at the time, consultation should be carried out with a relative or friend, defined in the Act as a person who “is engaged in caring for the patient or is interested in the patient’s welfare”, with a specific exclusion that does not permit paid carers to act in this role. It is clear that this relative or friend is being “consulted” but is not giving legal consent. This has parallels with the “personal legal representative” role in research on medicines under the 2004 Clinical Trials Regulations.

If there is no relative or friend who can be consulted (not present or insufficient time to go through the consent process), the researcher should identify a “person” (third party) who is unconnected with the research project and is willing to be consulted (a) for advice on whether the patient should take part in the project and (b) what, in his opinion, the patient’s wishes and feelings about taking part in the project would probably be if the patient had capacity in relation to the matter. This independent role is not named (the term “professional consultee” is likely to be used) and the characteristics (professional background, training and seniority) of the person who can carry it out are not defined (guidance is awaited from the Secretary of State for Health (England) and the National Assembly of Wales). This role seems similar to the “professional legal representative” role for research on medicines under the 2004 Clinical Trials Regulations.

If it is not possible to consult with an independent person and the trial intervention is urgently required, a third option is available. The researcher may “take action” (ie, enter the patient into the trial) with the permission of a “registered medical practitioner who is not involved in the organisation or conduct of the research project”. In emergency medicine

this would presumably be a doctor caring for the patient, who is not part of the research team (or under the influence of the research team).

Finally, if it is not possible to consult with a “registered medical practitioner” and the trial intervention is urgently required, the researcher may “take action” (ie, enter the patient into the trial) in “accordance with a procedure approved by the appropriate body”. The “appropriate body” will probably be the research ethics committee (REC), but the procedure to be followed is not specified, leaving the REC free to approve the patient’s entry without consent in a way that is commensurate with the procedure under study. This is likely to be based on strict trial inclusion criteria, and is in fact very much like a “waiver of consent” system. This will be required for many emergency care studies (for example, a pre-hospital study to answer the question “In patients in cardiac arrest do chest compressions before defibrillation give better long-term survival?” could never be carried out with consent or even consultation for each patient).

Analysis

It seems as though many of the provisions of the Mental Capacity Act (2005) have been designed to parallel the provisions of the Clinical Trial Regulations (2004) (table 1). However, the terminology is different, which is a potential source of confusion. The Mental Capacity Act uses the term “consultee” for the patient’s advocate, which seems to be a better name for the role than the “legal representative” terminology used in the Clinical Trials Regulations (which at first brings to mind a solicitor rather than its actual meaning of a relative or friend).

An important difference is that for research on medicines there is still no provision for research to be conducted without consent from someone (the patient or a legal adviser); so in the UK it is currently impossible to conduct a research project involving a drug that has to be given so rapidly that the consent process cannot be achieved. For example, there is currently no way to legally conduct a trial involving a cardiac arrest drug or a pre-hospital drug. In 2005 there was a consultation on an amendment to the Clinical Trial Regulations to allow emergency medicines research, in response to which the College of Emergency Medicine argued strongly that such research was vital to the future development of emergency care, but no change in the law has yet occurred.

Under the Mental Capacity Act, consent in the legal sense is not given by one person on behalf of another—the researcher is allowed to “take action”

(ie, enter the patient into the study) without consent as long as the appropriate "consultation" has taken place, as approved by the ethics committee. This is in keeping with longstanding UK practice (where the principle had always been that one person cannot consent on behalf of another), but is different from the Clinical Trials Regulations under which the "legal representatives" are actually giving consent on behalf of the patient.

There is no requirement in either the Medicines Regulations or the Mental Capacity Act that the person consulted should be at the bedside; so it seems acceptable for a telephone consultation to take place. It is probably a good thing that little detail is given in this respect, as the individual circumstances may vary. For example, it is more likely that an accurate impression of the patient's wishes will be obtained from a telephone conversation with a relative or friend than from a person nominated to act on behalf of the patient who does not know him or her. However, in many emergency situations, it is inappropriate to give distressing information over the telephone. The individual researcher will have to make (and may be asked to justify) a decision about which type of consent to use for each patient. Consent forms or other trial documentation may need to be altered to record the reasons for the decision.

There is still a "fudge factor" involved if consultation is taking place with someone who does not know the patient (as there is with the professional legal representative role for medicines research). When no friend or relative is able to represent the patient, the Act requires a "consultee", who does not know the patient, to guess what the patient's wishes would be if he or she had the capacity to make a decision. This is obviously impossible. The "consultee" will simply reason that most people wish to improve medical treatment and for most trials, most of the patients approached agree to participate in research projects. Therefore, the incapacitated patient would probably agree to be included in the trial. Without any prior knowledge of the patient the "consultee" will therefore always agree to patient entry, which in effect seems very much like a "waiver of consent", but dressed up in politically correct clothes.

The Act talks of an "appropriate body" approving the entry process for a research study. The appropriate body will be designated by the Secretary of State, and has not been named in the Act, as the wider system of RECs in the UK is going to be reformed and names may change. The REC will probably be designated as the "appropriate body", and a small number of RECs specially trained to deal with issues of consent in these special circumstances. This system would be a major

Table 1 Comparison of hierarchy of consent for medicines and other research

Research on medicines (Medicine Regulations 2004)	All other research (Mental Capacity Act 2005)
Patient consent wherever possible	Patient consent wherever possible
Consent from a relative or friend acting as a personal legal representative	Trial entry after consultation with a relative or friend
Consent from an independent person (designated by the NHS Trust) acting as a professional legal representative	Trial entry after consultation with an independent person nominated by the researcher.*
	Trial entry after consultation with a registered medical practitioner who is independent of the research.
	Trial entry after a procedure agreed by the research ethics committee.

*The system for regulating who can be nominated is awaiting guidance to be issued by the Secretary of State for Health (England) and the National Assembly of Wales.

improvement, as emergency care researchers will not be submitting to their local REC, but will be talking to an REC whose members are experts in emergency consent.

Future requirements

Despite The Mental Capacity Act giving the broad framework of law surrounding future research in incapacitated patients, this by itself is insufficient. Much of the detail of the practical implementation of these systems has not been specified in the Act, and will be contained within more detailed Department of Health guidance, a draft version of which has been published for consultation.⁴ Further details will have to be established by "case law" from individual NHS research and development departments and RECs. When the 2004 Clinical Trials Regulations were introduced, insufficient guidance was given by the Department of Health and the Medicines and Healthcare products Regulatory Agency, resulting in a paralysis within the system that, more than 2 years later, continues to have an adverse effect on emergency care research. It is encouraging to see that attempts are being made to avoid a repetition of this mistake.

Expertise in consent in emergency care research needs to be built up within the UK research and development community. This will be best achieved with co-operation from the Confederation of Research Ethics Committees (COREC), the NHS R&D Forum, the Department of Health and the College of Emergency Medicine. This has not happened in the past, but there is now an opportunity to create a strong and effective system for the future. The College could play a central role by collecting together the "case law" that will be built up through the decisions of individual RECs.

The Research and Development Department of every NHS trust will need to develop its own trust policy for consent under the Act. Unfortunately, this is likely to take some time and may be the stage

that provides the biggest barrier to emergency care research. Experience from the implementation of the 2004 Clinical Trials Regulations is not encouraging as in most NHS Trusts these Regulations have not yet been implemented.³ As an example, the CRASH1 trial (before 2004) had 10% of patients entered from the UK compared with 1% for the CRASH2 trial (after 2004).⁴ There is no actual requirement that individual NHS trusts implement a system for research in incapacitated patients, and it seems that many are, whether by default or intention, choosing not to undertake this type of research.

Summary

The Mental Capacity Act gives what could be an effective basis for future emergency care research, and has the potential to clarify a currently difficult area for researchers. However, the accompanying detailed guidance from the Department of Health needs to be applied by RECs in a pragmatic manner and individual National Health Service trusts need to take action to implement the new legislation if some of the current barriers to emergency care research are to be removed.

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