Consent to research at the end of life: The legal framework and the Mental Capacity Act 2005

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This presentation will focus on issues of consent to research at end of life for:

- competent participants
- incompetent participants
- those who have fluctuating and/or later loss of capacity
Mixed legal regimes

- **competent participants**
  - common law
    - unless Human Tissue Act 2004 applies (HTAct),
    - or Medicines for Human Use (Clinical Trials) Regs 2004 for clinical trials of medicinal products

- **incompetent participants**
  - Mental Capacity Act 2005 (MCA) for ‘intrusive research’ (can include research on human tissue)
    - or Medicines for Human Use (Clinical Trials) Regs 2004 for clinical trials of medicinal products (can also include research on human tissue)

  - in theory, common law could cover any non-intrusive, non-medicinal products research
Competent participants
Requirements for valid consent

- consent may be express or implied

- to be valid, three elements must be present:
  - participant must be **adequately informed**
    - see eg GMC guidance on research
    - clinical trials of medicinal products have special requirements for information to be given
  - participant must have **capacity**
  - decision must be **voluntary**

- (also applies to consent under the Human Tissue Act 2004)
s.1(2) A person must be assumed to have capacity unless it is established that he lacks capacity

s.2(1) a person lacks capacity in relation to a matter if at the material time he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain

MCA Capacity test
s.3(1) A person is unable to make a decision for himself if he is unable

a) to understand the information relevant to the decision,

b) to retain that information,

c) to use or weigh that information as part of the process of making the decision, or

d) to communicate his decision (whether by talking, using sign language or any other means)
MCA Capacity principles

s.1(3) A person is not to be treated as unable to make a decision unless all practicable steps to help him to do so have been taken without success

s.1(4) A person is not to be treated as unable to make a decision merely because he makes an unwise decision
Practical issues: capacity

- fatigue
- psychosocial distress
- mental state
- need to assess mental state and support needs
- investigate causes for distress, fatigue etc and whether these can be addressed eg pharmacological/physiological (electrolytes..)
Incompetent participants
Type of research (1)

‘intrusive’ broad meaning under MCA

• any research involving touching
• research involving processing of identifiable personal data relating to the incompetent person (Data Protection Act 1998)
• research involving human tissue (HTAct)
• may also include:
  • indirect research on medical notes;
  • research on human tissue already taken for other purposes;
  • interviews or questionnaires with carers about health or social-care services received by P, or
  • limited observation of P [also in final CoP]
    • eg *can I sit on your bed?*
clinical trial of medicinal product governed by Medicines for Human Use (Clinical Trials) Regs 2004: 2 possibilities

• if P gave informed consent prior to loss of capacity then participation governed by rules for competent participants (which only require informed consent, information provision, right to withdraw etc.)

• if P did not give informed consent prior to loss of capacity, special rules apply for incompetent participants (covered in following slides)
MCA: research must be connected with an ‘impairing condition’ affecting P, or its treatment (ss.31(2),(3)) ie condition causing the incapacity

- will include research into the effects of the impairment on P’s health and day-to-day life as well as into the causes of the impairment eg studies of death rattle

‘Clinical trial’: trial must relate directly to life-threatening or debilitating clinical condition from which P suffers (Sched. 1, Pt 5, [11])
Necessity criterion

MCA: there must be reasonable grounds for believing that research of comparable effectiveness cannot be carried out if the project has to be confined to, or relate only to, persons who have capacity to consent to taking part in it (s.31(4))
  • researcher must be clear as to why important to recruit from this group of incompetent people

‘Clinical trial’: none
Risk and benefit 
(a) Therapeutic criteria

MCA: research must have potential to benefit P without imposing a disproportionate burden, eg (from CoP):
- developing more effective ways of treating P or managing P’s condition
- improving quality of ... services that P has access to
- discovering cause of P’s condition, if P would benefit from that knowledge, or
- reducing risk of P being harmed, excluded or disadvantaged
- benefits may be direct or indirect
  - eg if policies/care subsequently changed because of the research
- participation in the research itself may benefit P
  - eg opportunity to express views in an interview

‘Clinical trial’: must be grounds for expecting that administering the medicinal product to be tested in the trial will produce a benefit to the subject outweighing the risks
MCA: research must be intended to provide knowledge for those similarly affected, and there are reasonable grounds to believe:

1. negligible risk, &
2. no significant interference with P’s freedom of action or privacy, &
3. not unduly invasive or restrictive

- examples:
  - indirect research on medical notes
  - research on human tissue already taken for other purposes (provided no prior competent refusal)
  - interviews or questionnaires with carers about health or social-care services received by P
  - limited observation of P

‘Clinical trial’: no risk at all (Schedule 1, Pt 5, [9])

- is this possible with a medicinal product?
Negligible risk

- CoP: P “should suffer no harm or distress by taking part. Researchers must consider risks to psychological wellbeing as well as physical wellbeing.”

Unduly invasive/restrictive

- CoP: “Actions will not usually be classed as unduly invasive if they do not go beyond the experience of daily life, a routine medical examination or a psychological examination.”
Proxy consent/assent/consultation

MCA: carer must be **consulted** (s.32)
- perhaps donee of LPA or deputy but not paid carer
- if carer’s view is that P would not want to take part then **binding** (right of veto)
- if carer later advised that P would not want to take part, then P must be withdrawn unless discontinuation of treatment would be significant risk to P’s health

‘Clinical trial’: **consent** from a legal representative is required (Sched. 1, Part 5, [4])
- legal representative could be donee of LPA or deputy or carer; if no such person then primary physician
Role of participant

MCA: advance decisions or other prior statements are binding (s.33)
   ◦ P can dissent from particular procedure and/or withdraw
   ◦ “The interests of the person must be assumed to outweigh those of science and society.” (s.33(3))

‘Clinical trial’: P’s views to be considered but not binding (Part 5, [7]) if legal representative consents
Fluctuating capacity and loss of capacity
MCA s.2(1) a person lacks capacity in relation to a matter if **at the material time** he is unable to make a decision for himself in relation to the matter because of an impairment of, or a disturbance in the functioning of, the mind or brain.

s.2(2) It does not matter whether the impairment or disturbance is permanent or temporary.

MCA s.3(3): the fact that a person is able to retain the information relevant to a decision for a short period only does not prevent him from being regarded as able to make the decision.

CoP: an assessment must only examine a person’s capacity to make a particular decision **when** it needs to be made.
Declining capacity

- recall that for clinical trial, competent informed consent can extend into incapacity
- if intrusive research then
  1. loss of ability to interact may prevent continuation
  2. even if continuation possible, transition to restrictive MCA regime may prevent continuation
     - need legal change to permit advance consent by competent participant to extend past loss of capacity
       - also can help with fluctuating capacity
       - problem of dissent by incompetent P and conflict with advance consent to research not in P’s best interests
       - probable solution is dissent can only be overridden by advance consent when research therapeutic (MCA s.31(5))
if allowed advance consent by competent participant to extend into incapacity for intrusive research – could also help with fluctuating capacity
  ◦ presently allowed for clinical trials of medicinal products

if allowed consent by legal proxy (deputy or donee of LPA) to intrusive research without the risk/benefit restrictions currently used?