The Mental Capacity Act 2005 and research

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What is the MCA about?

The MCA is about people over the age of 16 who cannot make decisions for themselves because of an impairment or disturbance in the functioning of the mind or the brain (i.e. they lack capacity).

It provides a framework for making decisions in their best interests while protecting them from harm.
Scope of the Act

• The Mental Capacity Act applies in England and Wales only

• The Adults with Incapacity (Scotland) Act 2000 applies in Scotland

• Separate legislation is expected to be introduced in Northern Ireland following a wide-ranging review of mental health and capacity issues
People who may lack capacity to consent because of:

• Dementia
• Serious mental illnesses
• Significant learning disabilities
• Physical conditions causing confusion, drowsiness or loss of consciousness, e.g. concussion, stroke, heart attack, epileptic fit, serious accident, delirium
• Drug overdose / withdrawal
Temporary loss of capacity

- The Act applies to temporary loss of capacity (e.g. emergency medicine, drug withdrawal) as well as long-term conditions.

- Some people may have conditions where their capacity fluctuates, e.g. schizophrenia, vascular dementias.
Loss of capacity in future

The Act also applies to making preparations for losing capacity in future. In particular, a person with capacity can:

• Create powers of attorney

• Make advance decisions to refuse treatment or participate in research, but, in general terms in English law, consent does not survive loss of capacity.
Assessing capacity (s.3)

A person is unable to make a decision for himself if he is unable to:

- understand the information relevant to the decision
- retain the information
- use or weigh the information
- communicate his decision (by any means)
Capacity may depend on the type of decision

- People with a duty of care must assess capacity to make each particular decision – not assume a person cannot make any decisions, e.g. because of their diagnosis, age, appearance or behaviour.

- Researchers must be able to assess capacity when recruiting participants - or seek expert advice / input from other professionals where necessary.
Helping people make decisions

- Best time of day
- Best location
- Right amount of detail
- Pacing the information
- Simple language
- Check understanding
- Repeat if necessary
- One decision at a time

- Non-verbal communication, e.g. DVD, signing, pictures
- Recognise language and cultural differences
- Involve others
- Involve an advocate
- Delay until capacity recovered?
- Address underlying difficulties, e.g. hearing
The MCA and research
Scope of research provisions

- England and Wales only

- Any “intrusive research” wherever it takes place (i.e. both NHS and non-NHS)

- People aged 16 and over (Note: position of children unclear at present.)

- Clinical trials of medicinal products are specifically excluded & fall under the 2004 Medicines for Human Use - Clinical Trials Regulations
Possible research settings

- NHS Trusts (including special hospitals)
- Private hospitals
- Private residential care homes / nursing homes
- Local authority social services accommodation
- Drug and alcohol treatment units
- Social research (e.g. major censuses and surveys)
- Prisons and police cells
- Armed services (including battle zones)
The research provisions

- Sections 30-33 make it lawful to carry out intrusive research involving people without capacity

  s.30 – Intrusive research
  s.31 – Requirements for approval
  s.32 – Consulting carers
  s.33 – Additional safeguards
Section 30

- Intrusive research involving a person who lacks capacity is unlawful unless it is approved by an appropriate body ("Section 30 approval")

- ‘Appropriate body’ to be specified in Regulations
What is ‘intrusive research’?

• Research is ‘intrusive’ if it would normally be unlawful to do it without consent

• Not limited to interventional studies

• For example, any research involving access to personal data, questionnaires/interviews or observations which infringe the right to privacy requires consent and is intrusive.

• Asking carers about those they care for is likely to be intrusive.
Is consent legally required?

• Consent is not a legal requirement and therefore MCA does not apply where research is limited to use of:
  • Non-identifiable data
  • Identifiable data with approval of the National Information Governance Board (NIGB) to process without consent
  • ‘Existing holdings’ of tissue (prior to 1 September 2006)
  • Non-identifiable tissue from the living
What is an appropriate body?

- Appropriate body is a REC recognised by the Secretary of State or Welsh Ministers

- All NHS RECs in England and Wales are recognised but NRES has ‘flagged’ certain committees to review studies on adults lacking capacity.

- The Social Care REC has also been granted MCA recognition.

- University ethics committees are not recognised
Section 31 – approval criteria

1. Research must be connected with an impairing condition affecting P or its treatment.

2. Research of equal effectiveness cannot be carried out if confined to participants with capacity.

3. (a) Research must have the potential to benefit P without imposing a disproportionate burden, or
(b) Provide knowledge of the causes or treatment of others with same condition, and involve negligible risk to P, not interfere significantly with freedom of action or privacy, or be unduly invasive or restrictive.

4. Arrangements are in place to comply with s.32 and 33.
Section 32 – consulting carers

• Researcher must seek advice from a carer or another person (‘consultee’) on whether P should take part and what P’s wishes and feelings would be.

• The consultee gives advice not consent or assent & the research takes place on the authority of the authorising REC.

• Under the MCA there is no ‘consent’ representing the presumed will of the participant in law – the MCA preserves the tradition of English law that one adult cannot consent for another.
Identifying a consultee

- Researcher must take reasonable steps to identify a personal consultee

- A “personal consultee” means a person who is (a) engaged in caring for P (not professionally or for payment) or is interested in his/her welfare, and (b) is prepared to be consulted

- If no personal consultee can be found, the researcher may consult a nominated consultee, i.e. a person independent of the project appointed in accordance with DH guidance.
Possible consultees

**Personal consultees:**
- Usual carer
- Other close relative/friend
- Person with Lasting Power of Attorney
- Court-appointed deputy

**Nominated consultees:**
- Independent Mental Capacity Advocate
- Participant’s usual doctor or other paid carer (if not connected with research)
- Other nominated person
Respecting the consultee’s advice

• Researcher must respect the advice of the consultee

• Consultee should be kept informed during the study and may advise at any time that P should be withdrawn, unless this would significantly harm his/her health

• Good practice for consultee to attend during research procedures
Research involving emergency treatment

• Some research may involve administering emergency treatment and it is not possible to identify and consult a consultee beforehand.

• Section 32(9) allows P to be treated with the agreement of an independent doctor or in accordance with a procedure agreed with the REC.

• Advice of consultee on whether P should continue in the study should be sought as soon as possible after initial treatment.
Section 33 – additional safeguards

1. Nothing must be done to which P appears to object unless it is to protect him from harm, or reduce or prevent pain or discomfort.

2. If P indicates he/she wishes to be withdrawn, this must be done without delay unless there would be a significant risk to health.

3. Any advance statement by P must be respected.

4. Interests of P must be assumed to outweigh those of science and society.
UK-wide issues

• Research conducted in England/Wales and Scotland requires separate approval from a REC in England/Wales and the Scotland A REC

• Consultation between the two committees is encouraged to agree a common approach to generic ethical issues

• Where two approvals are in place, substantial amendments must be submitted to both committees

• Northern Ireland will accept the opinion of the England/Wales REC or Scotland A. But a HSC REC should be consulted about the information sheets and assent forms to be used in NI.
Berkshire REC Experience (1):

Berks REC one of the first MCA flagged RECs, initially roughly:

• 1/3 rd - MCA applications – Unconscious, emergency or critically ill patients
• 1/3 rd - Dementia
• 1/3 rd – Learning Disabilities

Now, studies involving unconscious or critically ill patients predominate - ? An effect of the Social Care REC taking MCA studies?.
Berkshire REC Experience (2):

The very first MCA study we reviewed was a social care study of the effects of a large scale re-organisation of local authority housing on its residents.

We haven’t reviewed any studies which fall under the MCA by virtue of potential participants having a psychosis or other serious mental illness.
KEY ISSUES FOR SOCIAL CARE RESEARCH (1)

MCA – Criminal offence to conduct intrusive research on adults lacking capacity without the appropriate ethical approval – applies in all settings, not just health care.

University RECs not recognised – NRES not aware of any plans to recognise university RECs

MCA has brought into the National Social Care / NRES system studies that would previously not have been subject to the same level of scrutiny if any scrutiny at all.
KEY ISSUES FOR SOCIAL CARE RESEARCH (2)

The MCA may place a particularly onerous burden on large cohort studies where substantial numbers of participants may or will lose capacity.

Steep learning curve for researchers unfamiliar with the NHS Research Ethics system.

.................but the MCA has created a firm legal basis for conducting research involving adults who lack capacity where previously no such clear legal basis existed.
Researchers & RECs both growing in knowledge and expertise about the MCA and the quality of applications has markedly improved.

Hopefully, the quality of ethical review of MCA studies is also improving
Thanks for listening

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