MENTAL CAPACITY AND CONSENT FOR RESEARCH

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BACKGROUND
Mr Huw Morgan has severe dementia and lives in a care home near his son. He is admitted to hospital with a fractured femur following a fall. He is eligible to take part in an observational study the hospital is conducting to investigate post operative pain management for people with dementia, but lacks capacity to consent.

Who is legally authorised to decide on his behalf whether Mr Morgan participates or not? (tick all the answers you think apply) Why?

a) No-one
b) His son
c) His consultant
d) Multi-disciplinary team following a Best Interests meeting
e) The researcher
f) I don’t know
g) Other (please specify)
2+ million people in UK

Critical illness

Dementia

Palliative care

Mental illness

Learning disability

Complex care – need for research
SHOULD WE BE INCLUDING PEOPLE WHO LACK CAPACITY IN RESEARCH?

‘Protection’ by exclusion……

‘The afflicted should not be called upon to bear additional burden and risk [involved in medical research], …they are society’s special trust’

……..exclusion through lack of knowledge

Survey of health and social care professionals showed very low levels of knowledge and understanding of legal frameworks
IMPORTANCE OF INCLUSION IN RESEARCH

- Equity of access
- Inequalities in care
- Conditions under-researched

Mental capacity and research
We believe it is important not to exclude people who lack capacity from taking part in research, in the same way that they should not be excluded from services and medical treatment.

People with a learning disability are in fact under-represented in all types of research.

a ‘knowledge shadow’.....we have almost systematically excluded the very old from our research.
A TALE OF TWO REGULATIONS

Consult ‘consultee’ for advice

Informed consent from ‘legal representative’
PRINCIPLES OF MENTAL CAPACITY ACT

1. Must be **assumed to have capacity** unless it is established that they lack capacity

2. Not to be treated as unable to make a decision unless **all practicable steps** to help have been taken

3. Not to be treated as unable to make a decision merely because makes an **unwise** decision

4. An act done, or decision made, must be in the person’s **best interests**

5. Must be achieved in a way that is **less restrictive** of the person’s rights and freedom of action

**except decisions about research**
Mental Capacity Act 2005 - Research

- Applies to all adults over 16 years, sections 30-34 cover research.

- Assessment of capacity required **ONLY IF** concerns that the person may not have capacity.

- Pertains to all 'intrusive' research i.e. research 'of a kind that would be unlawful if it was carried out
- (a) on or in relation to a person who had capacity to consent to it, but
- (b) without his consent'
MENTAL CAPACITY ACT 2005 - RESEARCH

Decision and time specific – relates to whether the person is able to make that particular decision at the required time.

May have capacity to make some decisions, but not others, or may fluctuate over time.

All attempts must be made to maximise the ability of the person to make their own decision (if temporary loss of capacity – can the decision wait, provision of information tailored to their needs, language etc.)
MENTAL CAPACITY ASSESSMENT
ASSESSMENT OF MENTAL CAPACITY

Capacity is absent if, at the time of decision making:

- The person in question has impaired functioning of their mind or brain
- This impairment makes the person unable to decide whether to participate in this particular research
ASSESSMENT OF MENTAL CAPACITY

A person is deemed unable to decide whether to take part in research if they cannot:

**Understand** the information relevant to the decision (information should be given in a way that is appropriate to the particular person)

**Retain** that information for long enough to make the decision (this may be for a relatively short time)

**Use** or weigh that information as part of the process of making the decision

**Communicate** their decision (by any means)
Mr John Davies attends a stroke outpatient clinic with his wife who is his carer.

Pre-screening of his notes reveals that he is eligible for a study looking at a new quality of life measure. You also note a diagnosis of vascular dementia.

When you meet him, it appears that he has aphasia. His wife answers questions on his behalf.
CONSULTATION PROCESS
WHO DECIDES – MENTAL CAPACITY ACT

- Someone who is engaged in caring, or interested in the person’s welfare is consulted.
- Consultee advises what, in their opinion, the person’s wishes and feelings about taking part would be.
- Decision whether to enrol lies with the researcher.
- If no personal consultee is available and willing, a professional may be nominated.
WHO DECIDES — CLINICAL TRIAL REGULATIONS

- Someone who by virtue of their relationship is suitable
- Legal representative provides informed consent based on presumed will
- If no personal legal representative is available and willing, a professional may be approached
- Usually medical professional responsible for their care
ETHICAL RESEARCH
ETHICAL REVIEW

- **Justification**
  Must be connected to an impairing condition, or its treatment, affecting participants who are unable to consent, and could not be carried out as effectively if it was confined to participants able to give consent.

- **Risk vs benefit**
  Either the research is (a) of potential benefit to participants without imposing a disproportionate burden, or (b) is intended to provide knowledge of the causes/treatment/care of the condition affecting the participants or of a similar condition (the risk to participants must be negligible, not significantly interfere with their freedom of action or privacy, and not unduly invasive or restrictive).
ETHICAL REVIEW

- **Consultee arrangements**

  Arrangements are in place to consult consultee/legal representative for advice. Appropriate information will be provided about the project and their role and responsibilities, including possible consultation throughout the project.

- **Protection of participants**

  Nothing will be done to which participants appear to object, or would be contrary to an advance decision or statement made by a participant.

  The participant will be withdrawn if the consultee advises or the participant indicates they wish to be withdrawn.
Mrs Mary Williams is living with severe dementia. Since her husband died she has been living in a care home. Her daughter lives far away but visits regularly.

A researcher is hoping to conduct a study in the care home looking at links between urinary tract infection and agitation in people with dementia using GP and care records and validated agitation scales.
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Who is legally authorised to decide on his behalf whether Mr Morgan participates or not? Why?

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\[\text{e) The researcher}\]
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INVOLVING PEOPLE WITHOUT CAPACITY

- Research as relationship
- Tailored information
- Fluctuating capacity
- ‘One–off’ act of consent inadequate
- Anticipate loss of capacity during study