MORECare Capacity - Mental capacity and processes of consent for research on end-of-life care

Expert Think-Tank

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On behalf of MORECare Capacity
Expert Think–tank overview

• Introduction to MORECare Capacity and MORECare
• Debate three areas to provide solutions and guidance on best research practice
• Format of brief presentation (whole group), structured group work (two groups) and feedback (whole group)
MORECare Capacity

**Aim:** To determine how best to include individuals near to death in research on end of life care by identifying solutions and developing best practice guidance on processes of consent for people with impaired mental capacity

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MORECare

• MORECare Capacity came to life as the daughter of MORECare – Methods of research and evaluating end of life care (funder: MRC/NIHR)

• MORECare provided much needed guidance on developing and evaluating services and treatments in palliative and end of life care (Higginson et al 2013 BMC Medicine)

• MORECare Capacity intended to provide more detailed examination on capacity and consent
Why is this important?

• A major barrier to improving the evidence base on EoLC is how to include people near to death and their families in research studies that aim to innovate and test better treatments and models of care.

• It is essential to include those at the end of life if we are to understand how to provide the best care and treatment.
Why is research on end-of-life care important?

Science is not for the sake of piling up miscellaneous information or curious facts, but for the sake of saving life and increasing health and comfort

(Florence Nightingale)
MORECare Capacity: research methods

**Systematic literature appraisal** asking ‘What solutions to processes of consent have research studies incorporated to enable the inclusion of individuals with declining mental capacity?’

**Consensus exercise**: a face-to-face consultation with stakeholders (e.g. research ethics committee members) on needs and views to involving ALC in research using Nominal Group to generate recommendations, then an online consensus survey to ascertain level of agreement and identify areas of contention/uncertainty.

**Electronic survey** to national and international leading academics on best practice to involve adults lacking capacity (ALC) in research, particularly participants towards the end of life.

**Preliminary synthesis of the research findings compiled as the 1st draft of the methods guidance on processes of consent for adults lacking capacity**

**Expert ‘think tank’ workshop** to debate areas of contention or uncertainty identified in the preliminary synthesis and critically discuss proposed solutions.

**Final synthesis of the research findings published as methods guidance on processes of consent for adults lacking capacity. Guidance publication and disseminated**
MORECare Capacity is funded by Marie Curie Cancer Care.
Think-Tank aims....

1. To present and debate the contentious issues from the consensus exercise and systematic literature appraisal on how best to include individuals near to death in research on end-of-life care

2. To help understand the narrative and debates underpinning the main areas of contention or uncertainty
Three main areas of contention

1. The involvement of consultees in the consent process
2. Training and education on consent and ethical considerations; the challenges and solutions
3. Legislative frameworks; incorporation into practice and limitations
Contention/uncertainty

• Generated 29 recommendations, online scoring on level of agreement (1-9, low to high)

• Contention/Uncertainty indicated by:

1. Average score (median) between:
   – 4-6 recommendation equivocal
   – 1-3 recommendation not indicated
   – 7-9 recommendation indicated

2. Score spread (inter-quartile range IQR)
   – IQR in any three-point range broad agreement
   – IQR in one region strict agreement for recommendation

(Jones and Hunter 1999)
Area 1

The involvement of consultees in the consent process
Adults lacking capacity

- A person is unable to make a decision for himself if he has impairment of, or disturbance to, the mind or the brain (long-term condition e.g. Dementia or temporary loss e.g. Emergency medicine).

- Assessment of capacity: decision-specific AND time specific
  - Understand the information related to the decision
  - Retain the information (even if for a short time)
  - Use or weigh the information
  - Communicate decision (by any means)

- Preparations for losing capacity e.g. Lasting Power of Attorney

Mental Capacity Act 2005
Adults lacking capacity - Online toolkit
https://connect.le.ac.uk/alctoolkit
Involvement of consultees; an area of greatest contention/uncertainty

The findings from our research highlighted the involvement of consultees as an area of contention leaving the research team with a central question:

*How can we enable consultees’ involvement as surrogate decision makers for adults lacking capacity in research on end-of-life care in ways that minimise the burden of participation?*
Area 1: Involvement of consultees

Recommendation 27: Establishment of a nationally recognised body that provides support and information to family members and carers acting as consultees and/or proxies Median 5, IQR 3-6
Comments highlighted a general disagreement with this recommendation (n = 13) as the role could be taken on by existing charitable groups.

Recommendation 17: Health and social care practitioners to act as advocates for both participants, their consultee and/or proxies to support decision making on taking part in a research study. Median 5, IQR 4-6
Comments highlighted unease with the recommendation with participants citing a conflict of interest as the main issue of contention (n = 5) and how clinicians could accommodate (n = 5).
Area 1: Involvement of consultees

Recommendation 15: Carers or professional consultees are encouraged to indicate to researchers their availability to act as a consultee on behalf of an individual. Median 5, IQR 4-6
Participants divided between the recommendation reinforcing the importance of involving the consultee early in the research process (n = 4) and strong disagreement from others that coercive and impractical (n = 3).

Recommendation 6: Researchers to make available to patients and/or carers a patient advocate or public representative to support them to decide if they wish to participate in a research study and in the consent process. Median 5, IQR 3-6.25
Participants ambiguous with a research link seen as helpful, but not framed in terms of an advocate (n = 6), others disagreed as paternalistic (n = 3).
Consultees; literature findings

• 17 studies on involving personal consultees in the decision-making process
• Disparity between participants’ responses to hypothetical scenarios on acting as a consultee and engagement of consultees in research.
  • Hypothetically most agree to participate, but in research studies engagement ranged from 3.6% to 51% (unable to identify or engage, functionally unable, or refused)
• High number of eligible participants excluded
• Use nominated (‘professional’) consultee
Limitations of the research

• Only 3 papers involved those adults nearing the end-of-life and were situated in care home

• The majority of papers concerned Alzheimer’s patients in early to late stages

• The sample sizes in the vast majority of studies was small and population specific meaning the data could not be generalised

• There was often recruitment bias through those willing to engage in discussions with researchers

Evidence based solutions to involving consultees

1) Time given to identify in advance a consultee for research purposes

2) Support given to staff to help identify appropriate consultees and minimise the burden of the research process

3) Researcher flexibility to arrange and accommodate interviews with consultees at a time and place most convenient to them

4) The use of a professional consultee (a nominated consultee) when a personal consultee cannot be contacted to give an opinion on participation
How can we enable consultees’ involvement as surrogate decision makers for adults lacking capacity in research on end-of-life care in ways that minimise the burden of participation?
Area 2

Training and education on consent and ethical considerations; the challenges and solutions
Our research findings showed limitations in researchers and clinicians knowledge of consent for adults lacking capacity and the potential impact of training on the process of research.

What are the best ways to provide education and support for researchers and clinicians on approaching patients at the end-of-life and their families on participating in research, assessing capacity and seeking consent from a patient with impaired capacity or surrogate decision-maker for patients lacking capacity?
Area 2: Education and training

Recommendation 16: Researchers to attend advanced communication training to increase their sensitivity and confidence when seeking to consent a patients to participate in a research study. Median 7, IQR 5-8

Some (n = 6) queried who would approve and provide the training, others (n = 5) disagreed as all researchers should be equipped with communication skills, and some (n = 4) considered this is essential.
Area 2: Training and education

Recommendation 3: *Increased support and training for clinicians is required to improve their skills in discussing research with patients during routine clinical contact.* Median 7.5, IQR 6.75-9
Many agreed (n = 4) but queried who provided the training and clinicians availability.

Recommendation 19: *Researchers to have timely access to experienced members of the research team to provide supervision on the consent process, particularly when an individual’s level of capacity is uncertain or fluctuating.* Median 8, IQR 7-9
Participants’ indicated consistent concern about the feasibility of ensuring researchers’ availability to an experienced team member.
Education and training; literature findings

- Seven studies on clinicians’ and/or researchers’ knowledge of the ethics of consent for adults lacking capacity and legislative frameworks, and the impact of training on the research process.
- Two papers found that clinicians’ and researchers’ had poor knowledge of the legislation governing the process of assent for adults lacking capacity. The authors of both advocated greater efforts to be made to educate researchers and clinicians on the ethical issues involved in assent.
Limitations of the research

• Only 2 papers involved adults nearing the end-of-life

• Surveys detailing hypothetical scenarios may not be representative of researcher/physician behaviour in real world scenarios

• The sample sizes in the vast majority of studies was small and population specific meaning the data could not be generalised

• Inability to determine whether respondents differ in any significant way from non-respondents

Studies reported methods of improvement in researchers and clinicians knowledge through training

1) Education sessions for palliative health clinicians’ enabling an increase in clinicians’ engagement and interest in a study

2) Researchers liaising closely with clinical staff

3) Researchers and research nurses undertaking a two training session on informed consent and assent

4) Training on interviewer techniques to improve recruitment and retention
Question Area 2

What are the best ways to provide education and support for researchers and clinicians on approaching patients at the end-of-life and their families on participating in research, assessing capacity and seeking consent from a patient with impaired capacity or surrogate decision-makers for patients lacking capacity?
Legislative frameworks; implementation into research practice and limitations
The findings from our research and the MORECare work examined the implementation and limitations of the Mental capacity Act 2005 (MCA). A key question raised from the synthesis of both the MORECare Capacity and MORECare work is:

What are the strengths and limitations of legislative frameworks, notably the Mental Capacity Act 2005, to enable the inclusion of adults lacking capacity in research on end-of-life care?
Area 3: Legislative frameworks

Recommendation 25: The Mental Capacity Act 2005 to be amended allowing paid professional carers to act as a consultee for individuals who lack capacity to give advice on whether the individual would have wanted to participate in the research study had they had capacity to indicate this. Median 5, IQR 3-6

Comments highlighted the ambiguity of the recommendation due to conflicts of interest, time limitations, and the issue of a formal carer not knowing the individual when they had capacity.

MORECare Recommendation 14: Seek to change the law, so that advance consent is legally effective for all research and not limited to Clinical Trials of Investigational Medicinal Products (CTIMPs). Median 7, IQR 5–8.25
Area 3: Legislative frameworks

MORECare recommendation 15; When obtaining consent from a competent participant for a non-CTIMP study, anticipate the potential loss of capacity and fulfil the requirements of the Mental Capacity Act 2005 by obtaining assent from a carer and meeting the risk/benefit criteria for non-therapeutic projects. Median 7, IQR 5-8.25

Recommendation 26: The Mental Capacity Act 2005 to be amended to simplify the provisions on Lasting Powers of Attorney. Median 7, IQR 5-8
Participants (n = 3) queried who would draft the new version of the law and how would it be implemented to meet everyone’s needs
Findings from the systematic literature appraisal

- Six studies examined implementation of the Mental Capacity Act 2005 in research, and its limitations. All the studies were undertaken in the UK after the implementation of the MCA 2005.
- Five studies discussed the implementation of the MCA 2005 to guide the inclusion of adults lacking capacity and the limitations of the legislation. The findings indicate further requirement to enable participation for adults lacking capacity and complex consent procedures to ensure adherence to the MCA 2005.
Limitations of the research

• Studies concerned end-of-life care, but not care in the last days and hours of life

• Although there are a variety of tools to assess capacity there is little consensus on the best ways in which to assess a patient's capacity

• Selection bias is often present in these studies

• Procedures used may only be suitable for the particular population under study

Requirements to enable participation for adults lacking capacity in accordance to the MCA 2005

• Higher research costs to ensure researcher time for preparatory work to access adults lacking capacity and identification and engagement of consultees

• Lack of research resource and preparation may compromise recruitment of adults lacking capacity and accrue only a small increase in trial recruitment

• Continuing ongoing consent for adults with impaired capacity and assent for adults lacking capacity

• Advanced consent for adults with anticipated declining capacity with identification of consultee at initial consent stage

• Use of a nominated or professional consultee in the absence of a personal of consultee
Question Area 3

What are the strengths and limitations of legislative frameworks, notably the Mental Capacity Act 2005, to enable the inclusion of adults lacking capacity in research on end-of-life care?
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