Developing Inclusive Practices around Consent and Mental Capacity in Palliative Care Research

18th November 2025

NIHR ARC Palliative and End of Life Care National Leadership Forum

Dr Caroline Barry

Dr Victoria Shepherd

Kathy Jeays-Ward

Outline

11.05 - 11.15 Kathy Jeays-Ward

11.15 - 11.30 Dr Caroline Barry

11.30 - 11.45 Dr Victoria Shepherd

11.45 Q&A

Research Inclusion – Setting the Context

The importance of inclusion in research

Dr Kathy Jeays-Ward

Research Lead

Transformation Directorate, NHS England

18 November 2025

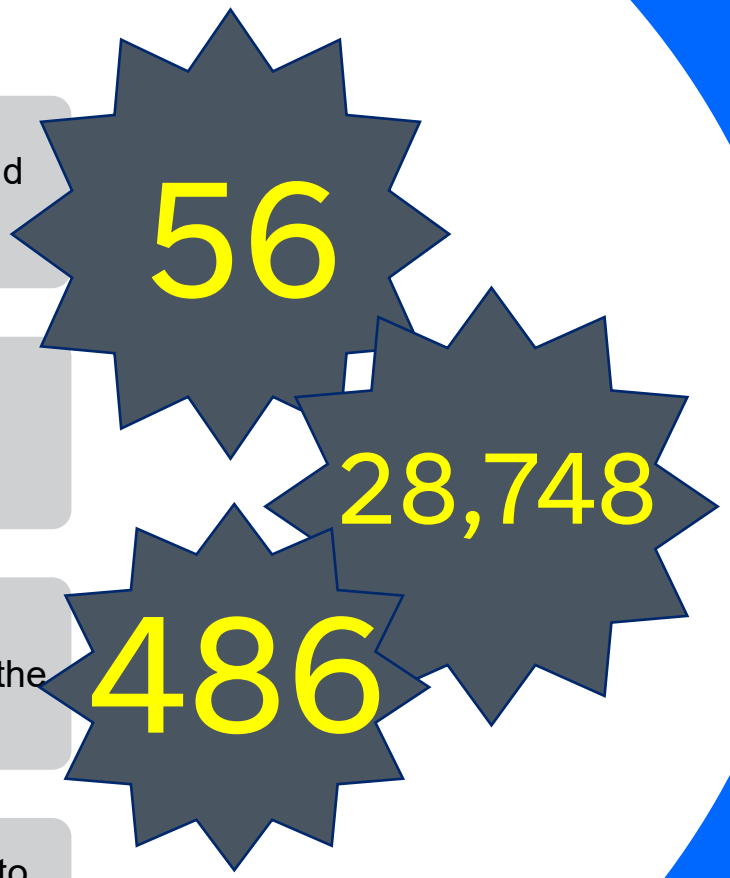
Why is research inclusion important?

Health difference across ethnicity may reflect **different disease pathologies** and **response to treatments (**Hussain-Gambles et al., 2004; Nazha et al., 2019).

Differences in effective doses of treatments: lower doses of *Warfarin* are required to be effective in Asian patients(3.4mg) compared to white (5.1mg) patients.

Culture and behavioral norms can shape **people's experience of navigating a complex healthcare system**. Patients from an Asian background were among the least satisfied with aspect of care (Race Disparity Audit,2019)

Implications: National evidence- based guidelines may confer greater benefits to particular communities, particularly those who have helped shape the underpinning research.



Courtesy of Professor Azhar Farooqi, LLR REN

UK Clinical Research Delivery Inclusion Group: towards a roadmap of national priority actions

"Despite often having the highest levels of need, older adults are frequently left out of research that directly affects their care. This exclusion can lead to gaps in evidence, less effective treatments, and care that isn't properly tailored to those who use services the most. As the population ages, it's essential that research reflects the people it aims to serve."

– CMO Professor Chris Whitty

	Domain of activity to improve research inclusivity
1	Requirements and expectations **Statement of intent about including older people in research – 43 signatories**
2	Trial participation and access
3	Workforce diversity
4	Data
5	Community engagement
6	Public awareness and communication
7	Sharing best practice and learning

Barriers to research inclusion

Language Barriers

Accessibility

Mistrust

The Research Engagement Network (REN) programme

NHSE/DHSC-funded programme to increase diversity in research participation by engaging with underserved communities around research:

1. **NHS**
2. **NIHR**
3. **Voluntary, Community, Faith and Social Enterprise (VCFSE) or charity**

We recognise that local experts drive this activity. Each team determines their local activity to deliver against nationally-determined aims, and the programme supports the rapid spread of effective practices.

REN teams 24/25

47 partnerships across **41** Integrated Care System areas

400 team members including **248** community research champions

435 community organisations became ‘community ready’

29,000+ people attended **700+** public-facing events

23,000+ people invited to join research studies

27,000+ people signposted to research registries

38 successful funding awards including REN teams, totalling **£7.5M**

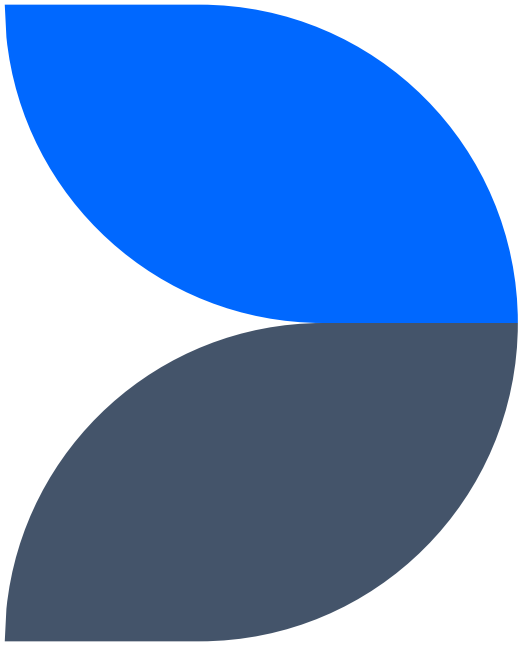
Addressing systemic barriers to research inclusion (REN Cohort 3)

Addressing English literacy as a barrier to participation in clinical trials: working with communities and stakeholders to co-develop a modifiable accessible patient information leaflet (MAPLE)

Exclusion by age to clinical trials for young people with cancer: a multi-stakeholder approach to lowering age eligibility of current and planned adult cancer trials.

No Voice, No Choice? Reducing system factors that form a barrier to research for those with impaired capacity nearing the end of life across care settings.

Understanding the structural barriers to adults with impaired capacity to consent to palliative care research



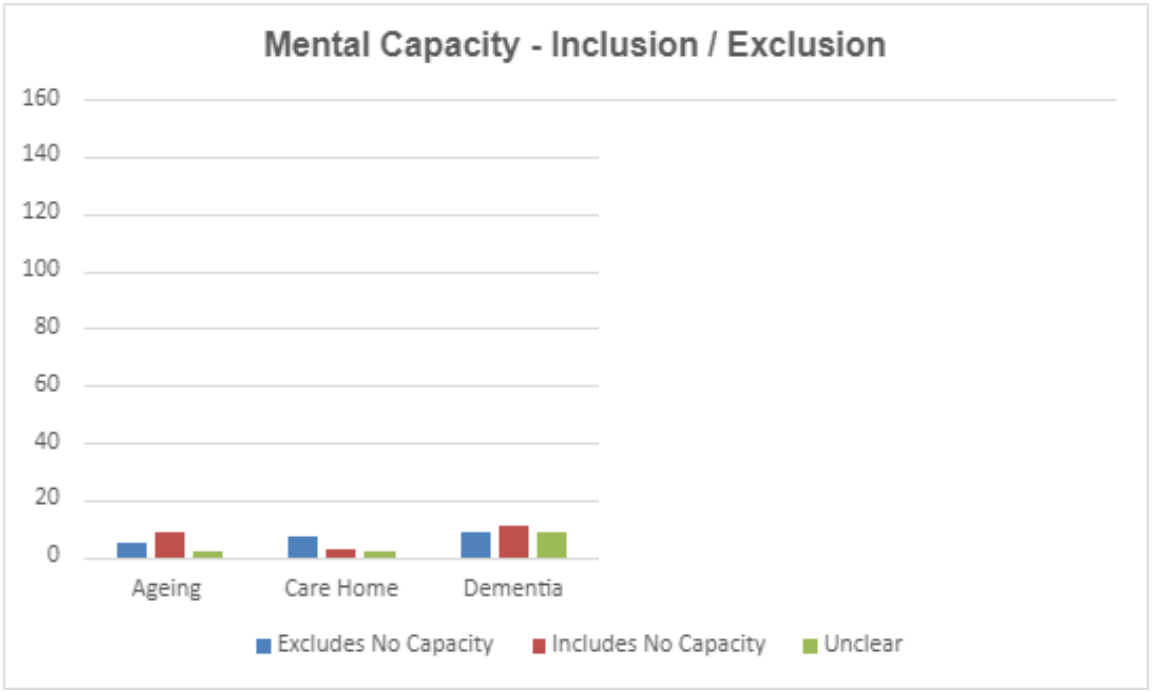

DO NOT ATTEMPT CARDIOPULMONARY RESUSCITATION
Universal Form of Treatment Options
Attempt CPR and refer to DCC if patient deteriorates

What proportion of NIHR portfolio studies relevant to palliative and end of life care enable participation of adults with impaired capacity?

Answer – not many!

Results

Speciality	Studies (n=)
Ageing	344
Care Home	172
Dementia	911
Hospice	144
Palliative	388
Total	1959



Only 7% of dementia studies relevant to palliative & end of life care

Only 5% of palliative care studies included people with impaired capacity

What challenges do palliative care clinicians and academics face?

Palliative Care Professionals Survey: What improvements do you believe would improve the inclusion of people with impaired mental capacity approaching end of life in research?

Please rate your level of knowledge on the following.	None	Slight	Moderate	Extensive
The ethical considerations in research involving patients with impaired capacity	3	6	14	4
The legal framework governing research with vulnerable populations	3	11	10	3
Research opportunities for patients with impaired capacity (in your area of work)	9	9	5	3
Developing and adapting research protocols to include palliative care patients with impaired mental capacity	11	9	0	1

Improving lives together
Norfolk and Waveney Integrated Care System

Pallaborative North West
UPSKILLING PALLIATIVE CARE TOGETHER
Quality Improvement | Guidelines | Training | Research | Digital | Patient & Public Partnership

NHS
Norfolk and Waveney

UCL

music mirrors

mnda
motor neurone disease association

Priscilla Bacon
Hospice Charity

UNIVERSITY OF CAMBRIDGE

UNIVERSITY of STIRLING

Conversations(n = 46)

Law Commission
Reforming the law

NHS
Health Research Authority

Marie Curie
Care and support through terminal illness

ENRICH
Enabling Research In Care Homes

Alzheimer's Society

CARDIFF UNIVERSITY
PRIFYSGOL CAERDYDD
Centre for Trials Research
Canolfan Ymchwil Treialon

NIHR | Clinical Research Network East of England

UNIVERSITY OF OXFORD

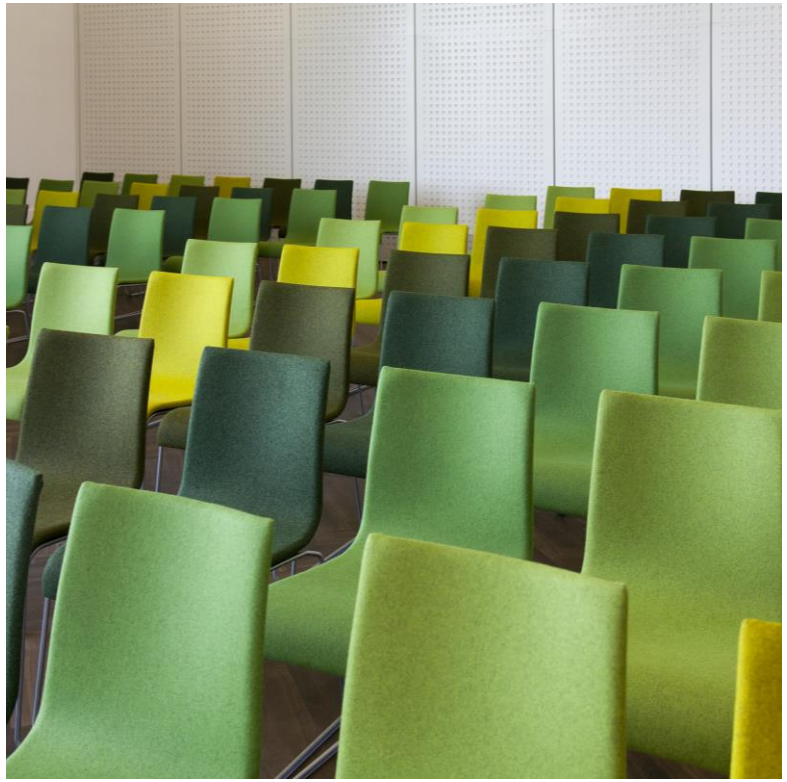
Trinity College Dublin
The University of Dublin

NNUH TOGETHER

University of Kent

Stakeholder Conversations

- Palliative Care Specific Challenges
- Policy, governance & Infrastructure
- Uncertain legal landscape
- Research Relationship / Role of voluntary sector



What about people with lived experience?

Public Survey (n = 52)

How do you feel about involving people who are in the last weeks of life in research?

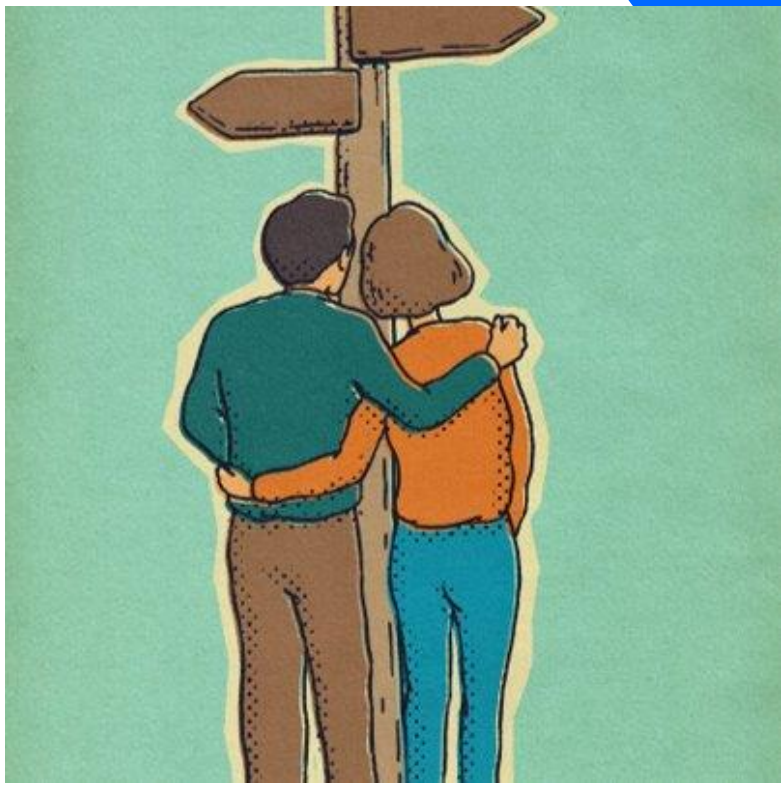
Proxy Decision-Making about Participation in Palliative Care Research: A Scoping Review

- **Who** should act as a proxy for a person unable to consent to participation palliative care research?

- What constitutes '**best practice' f**or the use of proxies in supporting the involvement of adults with impaired capacity in research

- What roles do **volunteers/independent advocates** play in supporting ethically-sound research for those with impaired capacity?

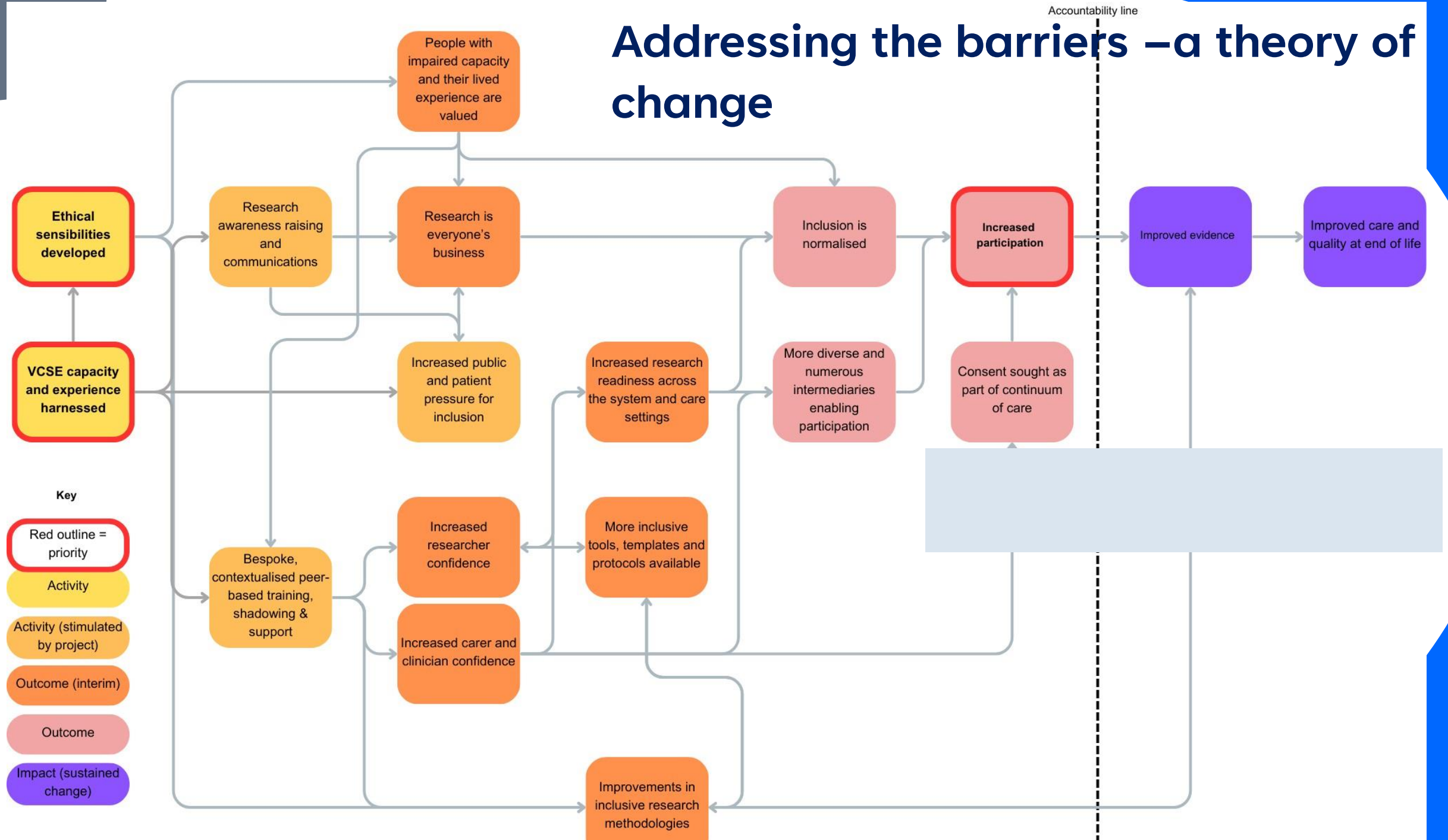
- What **support** or preparation do all potential proxies require to support involvement of adults with impaired capacity in ethically-sound research?



Narrative Themes

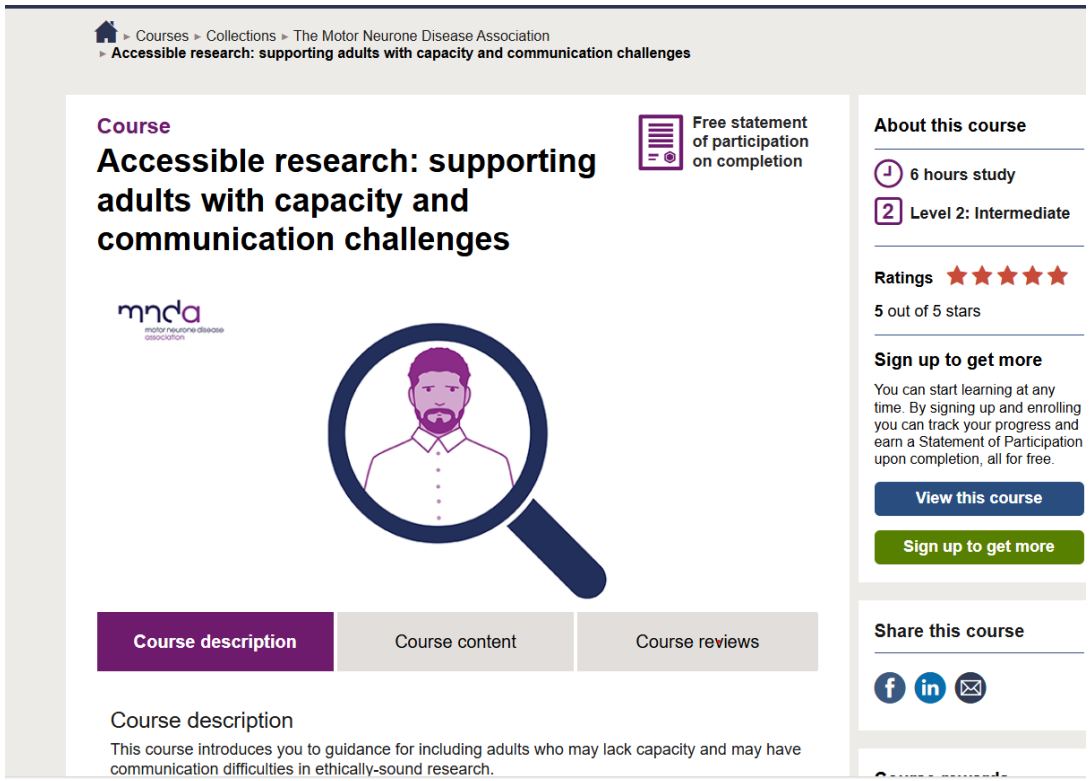
- **Communicating Value:** Understanding the role, importance and relevance of research
- **Respectful Responsiveness:** Getting the timing right
- **Trust and Connection:** Ensuring that the right people are involved
- **Balancing Power and Reciprocity** in decision making
- **Navigation of uncertain legal, ethical and policy contexts**

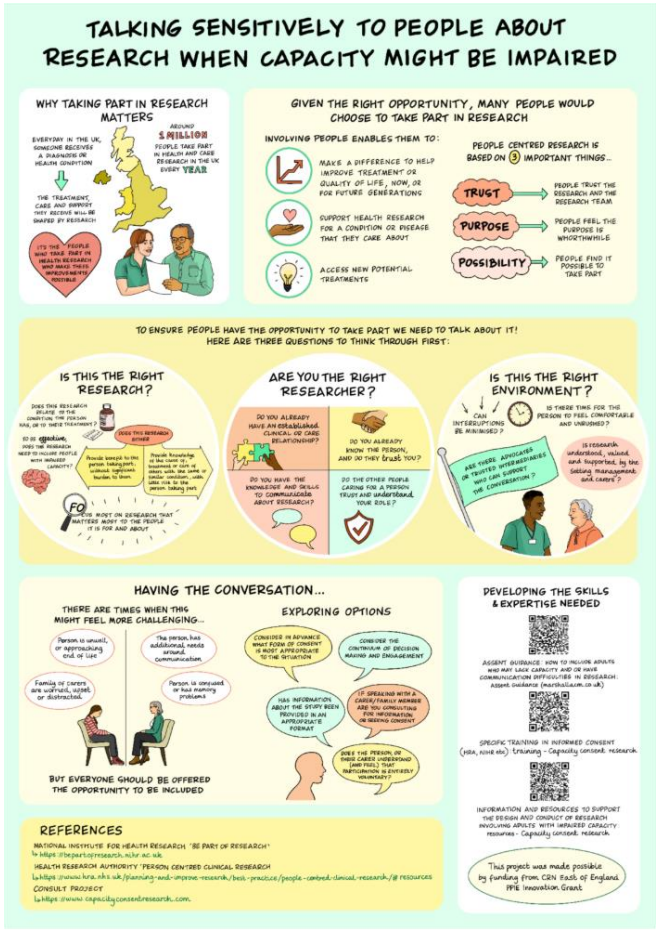
Addressing the barriers –a theory of change

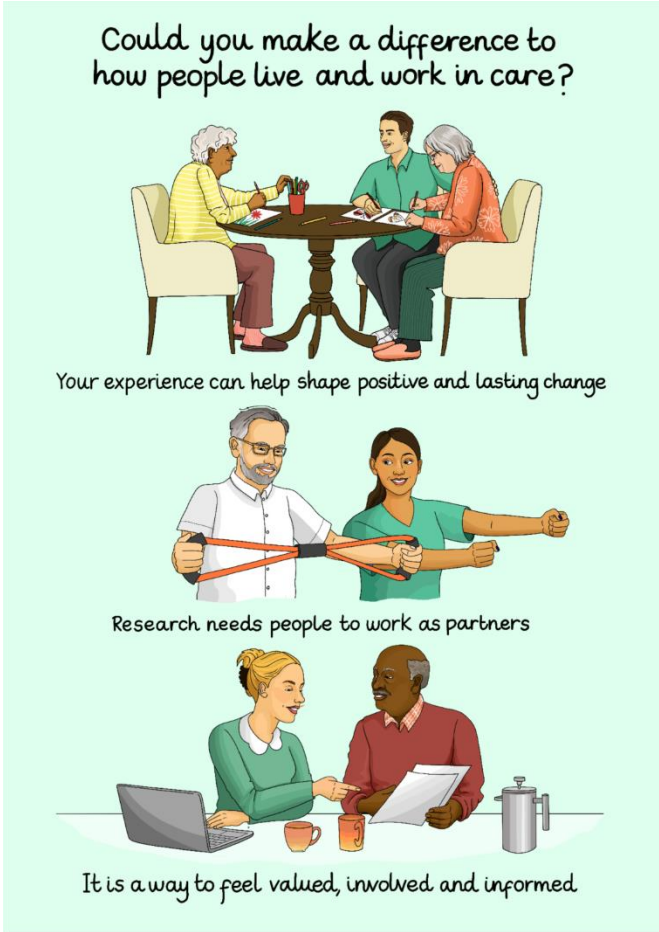


Recommendations

- Bespoke, Contextualised **Peer Based Training and Support**
- More inclusive **tools, templates and methodologies**
- Prioritising **rapport** between proxy and researcher. Opportunities for VSCE partnerships to improve this relationship
- **Advance Research Planning** and **Community Awareness** initiatives in research are likely to be particularly pertinent in palliative care
- **Protocol development** – must consider both psychosocial (e.g. burden) and practice (e.g. travel and time) impact of research involvement for proxies




TALKING SENSITIVELY TO PEOPLE ABOUT RESEARCH WHEN CAPACITY MIGHT BE IMPAIRED
WHY TAKING PART IN RESEARCH MATTERS
AROUND 1 MILLION PEOPLE TAKE PART IN HEALTH AND CARE RESEARCH IN THE UK EVERY YEAR
GIVEN THE RIGHT OPPORTUNITY, MANY PEOPLE WOULD CHOOSE TO TAKE PART IN RESEARCH
INVOLVING PEOPLE ENABLES THEM TO:
MAKE A DIFFERENCE TO HELP IMPROVE TREATMENT OR QUALITY OF LIFE, NOW, OR FOR FUTURE GENERATIONS
SUPPORT HEALTH RESEARCH FOR A CONDITION OR DISEASE THAT THEY CARE ABOUT
ACCESS NEW POTENTIAL TREATMENTS
PEOPLE CENTRED RESEARCH IS BASED ON 3 IMPORTANT THINGS...
TRUST
PEOPLE TRUST THE RESEARCH AND THE RESEARCH TEAM
PURPOSE
PEOPLE FEEL THE PURPOSE IS WORTHWHILE
POSSIBILITY
PEOPLE FIND IT POSSIBLE TO TAKE PART
TO ENSURE PEOPLE HAVE THE OPPORTUNITY TO TAKE PART WE NEED TO TALK ABOUT IT! HERE ARE THREE QUESTIONS TO THINK THROUGH FIRST:
IS THIS THE RIGHT RESEARCH?
ARE YOU THE RIGHT RESEARCHER?
IS THIS THE RIGHT ENVIRONMENT?
HAVING THE CONVERSATION...
THERE ARE TIMES WHEN THIS MIGHT FEEL MORE CHALLENGING...
EXPLORING OPTIONS
BUT EVERYONE SHOULD BE OFFERED THE OPPORTUNITY TO BE INCLUDED
DEVELOPING THE SKILLS & EXPERTISE NEEDED
REFERENCES
This project was made possible by funding from CRN East of England PPIE Innovation Grant


Could you make a difference to how people live and work in care?
Your experience can help shape positive and lasting change
Research needs people to work as partners
It is a way to feel valued, involved and informed

A Guide for UK-Based Research Ethics Committees Assessing Health and Care Research with People with Impaired Capacity

Introduction

This guide is designed to support RECs in England and Wales to evaluate research proposals involving people with impaired capacity. It provides areas for REC members to consider when ethically and legally reviewing research proposals involving individuals with limited mental capacity. It offers practical advice to ensure research practices uphold ethical standards when working with individuals and groups who face communication and / or cognitive challenges to ensure ethical and inclusive research practices.

The concept of mental capacity can perhaps best be defined as **a person being able to make informed decisions about their life and wellbeing**. Someone with mental capacity has the ability to understand information (with varying levels of complexity) and its implications, remember it long enough to make decisions based on their understanding and consideration of that information, and then communicate their decision to others verbally through their preferred mode, including spoken and written words, sign language, pictorial symbols or computer-aided devices.

In research, people are deemed to lack capacity if, at the time a decision needs to be made that impacts their health or wellbeing, they are unable to: understand, retain or use/weigh up the information relevant to the decision-making process, and to effectively communicate their decision to others because of an impairment of, or a disturbance in the functioning of, the mind or brain **(Mental Capacity Act 2005)**.

UEA CONSULT

NIHR | Applied Research Collaboration East of England

Building Inclusive Practices around Mental Capacity & Consent in Palliative Care Research

Interdisciplinary Research Workshop

We are inviting researchers, clinicians and others with an interest in palliative care research to join us to share and consolidate knowledge

Workshop Objectives:

- Hear and discuss key findings from our work to improve research engagement for adults with impaired capacity to consent
- Identify current research gaps and set priority areas for future research.
- Foster inter-disciplinary collaboration to address system and practical challenges.
- Opportunities to contribute to programmes of research in this area

Event Details:

- 17th October 2025
- 10.30 - 15.00
- Royal College of Physicians, London
- In Person Event, Lunch provided

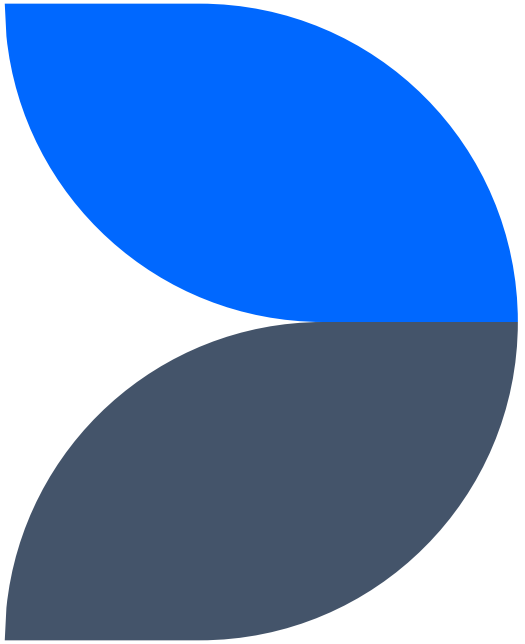
Contact for information:
Dr Caroline Barry
caroline.barry@uea.ac.uk

capacityconsentresearch.com/palliative-care

Travel bursaries may be available where cost would be a barrier to attendance (please contact before booking any travel)

Understanding the challenges & creating solutions

Victoria Shepherd

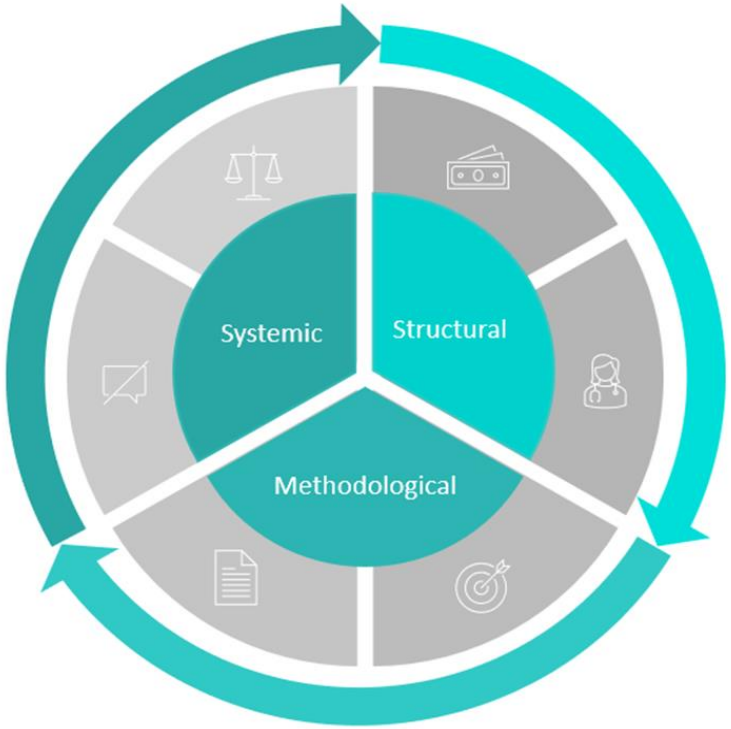


Understanding system-wide challenges

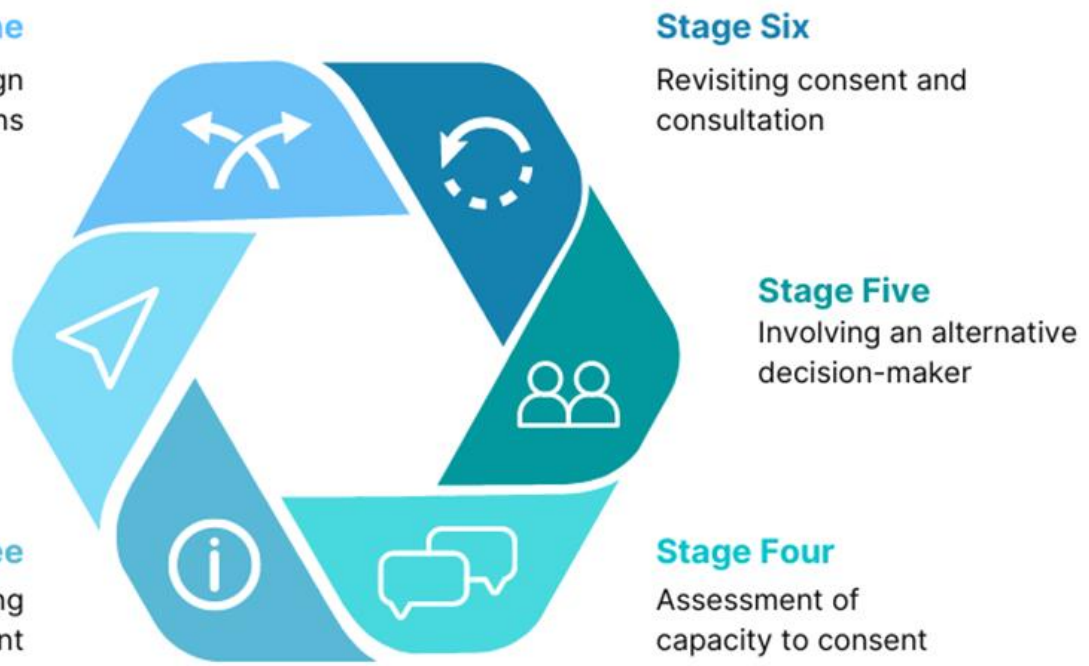
Systemic - complex legal frameworks, ethical review processes, paternalistic protection

Structural - resource requirements, research infrastructure, lack of support

Methodological - restrictive eligibility criteria, alternative consent pathways



Challenges across research lifecycle



Ethical, legal, & practical challenges

Complexity of trials involving adults with impaired capacity

> It feels like an **insurmountable black box of horrendousness** that I dare not go. It feels very much [that] if you get this wrong you will be **illegal** ….. and the **ethics police** will come for you!

Inadequate support and resources

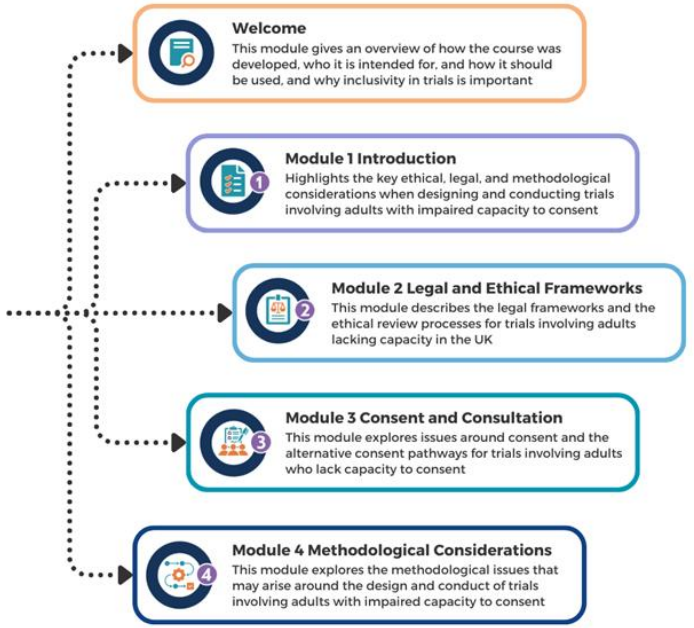
> I've been stabbing in the dark like '**where should I look for reliable information**'? A lot of it was potluck Googling …. it still took the thrashing at the REC meeting for them to go **you've not interpreted that correctly** or not thought about this

Lack of knowledge affects confidence

> We need **better support and guidance**, particularly around the correct terminology, who needs to give consent, and how it varies between different countries, to give people **more confidence** to set up this sort of study

Shepherd et al 2022 https://bit.ly/3deBnyX

Addressing the knowledge gap



www.capacityconsentresearch.com/training

Supporting inclusive study design

Q1	Who should my trial results apply to?	People with particular types or severity of conditions or disabilities
Q2	Are they likely to respond to the intervention in a different way?	**Worksheet A** - condition/disability related factors, other factors
Q3	Will my intervention make it harder for them to respond?	**Worksheet B** – intervention/comparator (who, what, how, where, when)
Q4	Will my trial design make it harder for them to take part in or remain in the trial?	**Worksheet C** – eligibility, recruitment **Worksheet D** – data collection **Worksheet E** – analysis (subgroup etc) **Worksheet F** – reporting, dissemination
	Summary of actions and resources needed	**Worksheet G** – key factors, actions, costs/resources

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Using the framework

Research teams should use the framework as part of a collaborative process

Most useful at earliest opportunity - and revisit during the design and conduct stages

Public involvement (that is inclusive) is essential throughout

Review the relevant legal frameworks before considering the framework questions

Useful for all populations who experience impaired capacity – for all types of studies

Set aside time to address inclusivity, and include any associated costs in the funding application

'Designing in' more inclusive consent

LANGUAGE

FORMAT

TIMING

DESIGN

ENVIRONMENT

CONTENT

SUPPORT

Launch webinar 1st Dec 2-3pm

Challenges of proxy decision-making

- Family members **often unprepared** to make research decisions
- May not **know the person's wishes**
- Experience emotional and decisional **burden**
- More likely to **decline** participation
- Concerns that decisions may not be in accordance with the person's wishes

> "I think if my dad had....at any time discussed it, or given any indication then maybe my decision would have been different. But he didn't, it felt that it's my decision I am doing it because I think that's the best....whether it's the right decision or not I don't know, only time will tell I suppose"

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> It felt that it is my decision, I am doing it because I think that's the best. Whether it's the right decision or not who knows

Supporting proxy decision-making

- Decision aid to **support families** to make more informed and preference-based decisions
- Encourages families to **consider** what participation involves, risks and benefits
- **Supports** them to make values-based decisions – option that best aligns with person's preferences
- Effectiveness being evaluated in CONSULT SWAT; primary outcome **decision quality** (CONCORD scale)

Role for advance research planning?

A voluntary process that involves **thinking about, discussing and documenting preferences** for taking part in research in the future.

May include making an advance research directive and naming trusted people to be involved in research decisions.

May be tailored to a **specific research project** where it is anticipated that participants may experience cognitive changes during the study (‘advance consent’) or **general views** about taking part in research during future periods of incapacity

ARP best viewed as a continuum

Example of 'advance consent' in a palliative care trial:

- Patients admitted to palliative care unit given information about types of studies there
- During next ward round, consultant informed all potentially eligible patients about the ‘noisy breathing’ study and **asked if they would be prepared to enter the study** if they were to develop difficulty breathing because of retained secretions
- Patients who provided consent (supported by carers and relatives) had medication prescribed as PRN (highlighted in red, labelled as a research study)
- If subsequently developed noisy breathing needing treatment, then randomised

Promising – but questions remain

- **Legal complexities** – introducing research into established legal planning arrangements may lead to misunderstandings
- Can it be **sufficiently informed** to be considered ‘advance consent’?
- **Practical questions** - implementation, uptake, and usability of advance research directives – especially given low uptake of other advance planning activities and research is less foreseeable
- An advance research directive would require **careful interpretation**

Exploring feasibility of ARP in the UK

- Survey of members of the public (n=277), researchers and healthcare professionals (n=50) and semi-structured interviews (n= 27)
- **High levels of support** for advance research planning, differing views about how binding an ARD should be depending on context (e.g benefit-risk profile)
- Identified **barriers** to implementation e.g informational needs, and **facilitators** e.g embedding ARP in processes such as ACP

Opportunities for engaging with ARP

Conclusions

- **Ethical and legal challenges** impact research involving this population – need to address in order to improve opportunities for research inclusion
- **Solutions include designing and conducting** studies that are more inclusive and responsive to peoples' communication/capacity needs aided by **resources** (e.g CONSULT Training, INCLUDE framework, OPTIMISE)
- **Support families** and others acting as proxy decision-making – including through decision support and **encouraging conversations**
- **Exploring advance research planning** - identify priority populations, develop interventions, learn from international experiences
- **Further research** - implementation of legal frameworks (ACCORD, 2026)

Acknowledgements

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