

# Capacity and Consent in Care Homes: Focus on Clinical Trials

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# Dementia National Initiatives

- **National Dementia Strategy:**
  - Improved care in care homes
- **Ministerial Advisory Group on Dementia (MAGD report)**
- **Prime Minister's Dementia Challenge:**
  - 1. Driving improvements in health and care
  - 2. Creating dementia friendly communities
  - 3. Better research
- **NIHR/Wellcome/MRC Themed Call for Dementia research**
- **ESRC Themed Call for Dementia**
  - Dementia: prevention, intervention and care


# Top level – support for dementia research

Health Secretary Andrew Lansley said “As part of our £4 billion investment in Research and Development, we have committed £800 million for translational research. Dementia research also features strongly in the programme of funding announced today. Dementia is one of the most important issues that we face as our population ages.




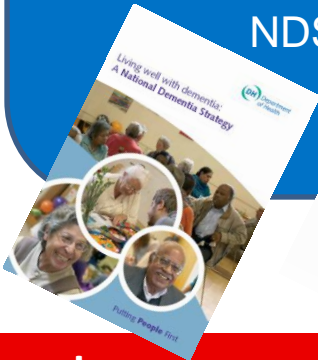
**NHS**  
*National Institute for  
Health Research*

DeNDRoN  
BRUs & BRCs  
CLAHRC



**DH** Department  
of Health

Dementia Themed Call  
MAGDR report  
NDS



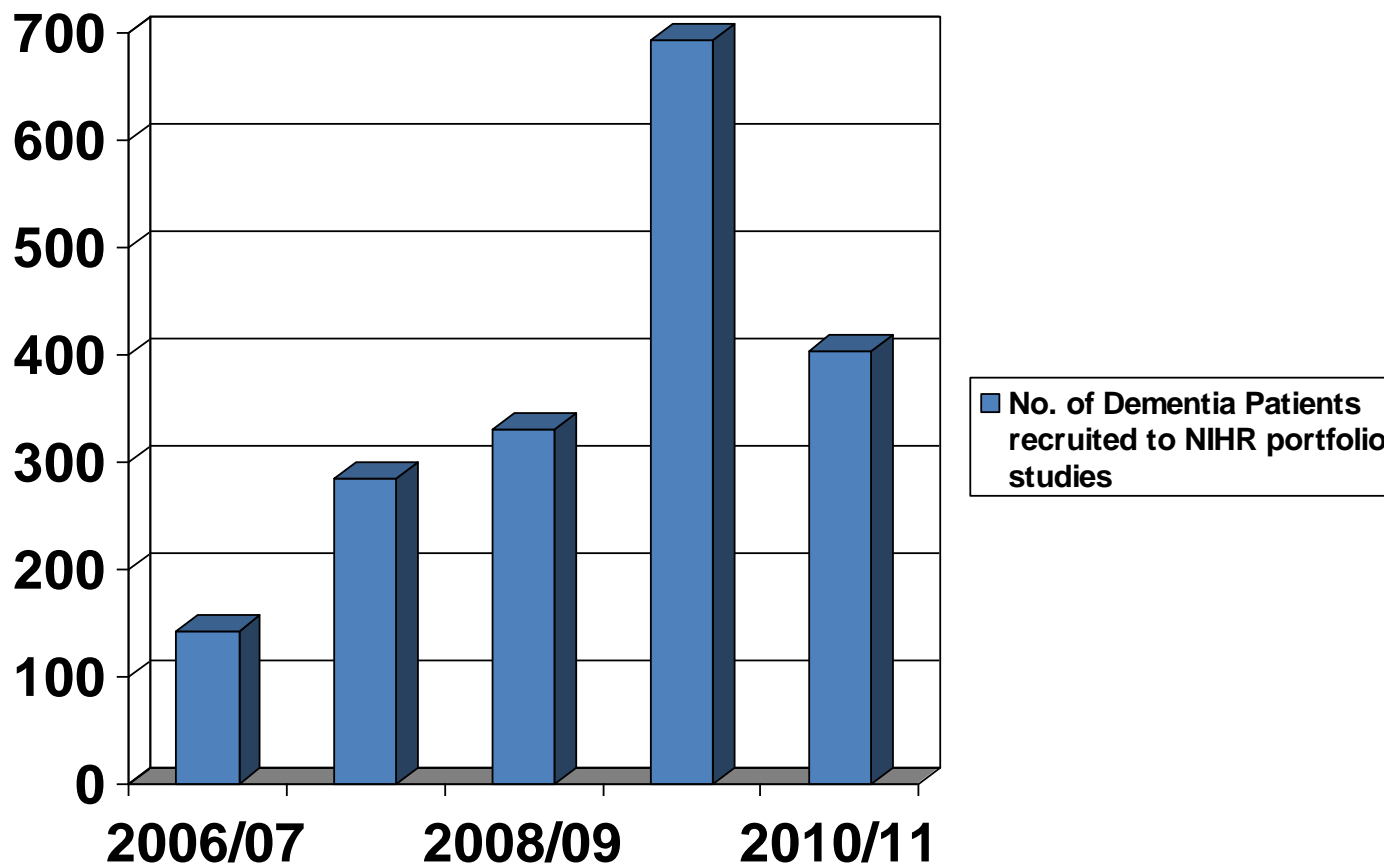
## North West Dementia Picture

- **750,000 people in the UK with a form of dementia (NW figures\_Alzheimer's society )**
- **Northwest Population-6.9 million: 87, 500 people with dementia**

## DeNDRoN NW

- DeNDRoN-NIHR Dementias and Neurodegenerative Diseases Research Network
  - One of seven Local Research Networks in England
  - Provide infrastructure to facilitate research-both commercial and non commercial- in the NHS
  - **1855 dementia patients recruited to commercial and non commercial studies (March 06-March 11)**
  - 29 projects-8 commercial studies (March 06-March 11)
- Supported by 3 Comprehensive Clinical Research Networks
  - Cheshire & Merseyside
  - Cumbria & Lancashire
  - Greater Manchester

# Dementia Patients Recruited to NIHR Portfolio Studies



# Why do research in people with dementia who lack capacity?

- "It is important that research involving people who lack capacity can be carried out, and that it is carried out **properly**. Without it, we would not improve our knowledge of what causes a person to lack or lose capacity and the diagnosis, treatment, care and needs of people who lack capacity"
- (MCA 2005, Code of practice, 2007). and

# Why do research in people with dementia who lack capacity?

- "To exclude [adults who lack mental capacity to consent] from any research would...prevent researchers making progress in the understanding of many disorders that can affect the brain, and in the **care** and **treatment** of those who have such disorders. (MRC Ethics Guide: medical research involving adults who cannot consent (2007))



# Where are the people who lack capacity due to dementia?

- "One-third of people with dementia live in Care homes and at least two-thirds of all people living in Care homes have a form of dementia."
- DH, Living well with Dementia"
- National Strategy (2009)[www.dh.gov.uk](http://www.dh.gov.uk)

# Reasons for working with Care homes

- **1. The environment and population in Care homes**
  - vulnerable group, often lacking an effective voice due to dementia and other communication difficulties.
  - risk that their health and social care rights are neglected.
- **2. Provides evidence**
  - We have relatively little research evidence from Care homes
  - Care home residents are under-represented in research studies.
- **Raises the standards**
  - The research evidence we have has been instrumental in helping raise the standards of care in Care homes.

# Reasons for working with Care homes

- **4. Improves quality of life**
  - People in Care homes and their families want to be involved in research to improve quality of life and quality of care.
  - It is important to ensure that there is equal and open access and opportunities to participate in research studies.
- **5. Guides best practice**
  - Research provides an opportunity to develop the evidence base to guide best practice in Care homes.
  - **“We also found that participants wanted to be involved, enjoyed the process and enhanced our understanding of their situations.”**
  - Increasing the Voice, Choice and Control of Older People with High Support Needs, Gillian Granville et al, May 2011 [www.cpa.org.uk](http://www.cpa.org.uk)

# Support for doing research in care homes

- MAGD Report: recognised that more research is needed to improve the quality of life of people with dementia in care homes.
- The National Institute for Health Research (NIHR) Dementia & Neurodegenerative Research Network (DeNDRoN) has been working to increase the volume, quality and impact of dementia research.
- **Enabling Research in Care Homes (ENRICH)**
  - launched to provide a central information point for care home staff, residents and relatives seeking information and advice about research.
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# ENRICH Toolkit

The toolkit has been produced in collaboration with the NIHR School for Social Care Research (SSCR).

The SSCR is keen to increase research in social care settings including the care home sector.

We need evidence of what works to improve the quality of care staff provide and the quality of life for residents.

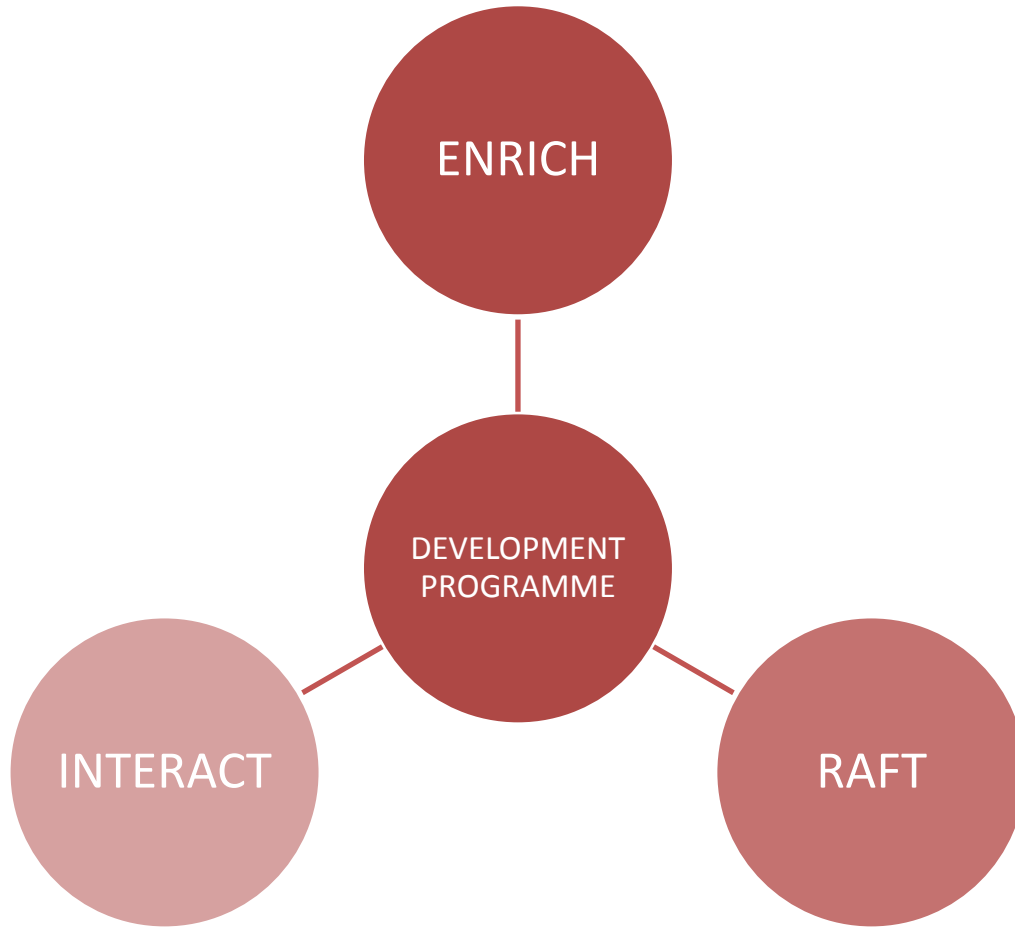
The SSCR argues that is not simply a matter of increasing research in volume but that the findings have to be useful to the sector, its staff and residents.

Resource: The ENRICH Toolkit website is available now at [www.dendron.org.uk/enrich](http://www.dendron.org.uk/enrich)

# ENRICH Project



# What are DeNDRoN Projects?



# ENRICH objectives

- Build on existing systems and best practice to deliver three objectives:
  1. Agreement on funding sources for the different component of research in care homes
  - 2. A tool kit to support researchers developing and delivering research in care homes**
  - 3. A network of “research enabled” care homes**



# A network of “research enabled” care homes

Initial focus is to:

- Understand what could / does motivate Care homes to support research.
- Agree a definition of a ‘research active / network of care homes.
- With three LRNs define a ‘pilot’ of the network, to test how a network can be established, how it could work, and what will be the challenges to delivery.



# ENRICH

Enabling Research In Care Homes

**ENRICH toolkit is a resource to support researchers, care home staff, residents & relatives deliver research in care homes.**



**Visit: [www.dendron.org.uk/enrich](http://www.dendron.org.uk/enrich)**

# Toolkit launched

Available at: [www.dendron.org.uk/enrich](http://www.dendron.org.uk/enrich)

It includes;

- Tariff clarifying the funding arrangements for each component of the research process
- **Practical guidance on ethics, consent, recruitment, and undertaking a study**
- Practical tips
- Case studies
- Templates for readers to take away
- Signposts to important websites

N.B It will not attempt to replicate existing information but rather signpost people to the existing standards of research governance and best clinical practice.

# Guidelines on care home research from the ENRICH project:

- 1. Specific advice to care homes about what to expect from researchers
- 2. Advice about ethical research in dementia
- 3. Advice on how to protect residents

# What care homes and their residents can expect from researchers

- Residents, their family and friends and Care home staff should expect researchers to:
- Build a good relationship with the manager and staff, and get to know the home.
- Ensure that someone explains the study to the staff as well as the manager.
- Allow plenty of time for questions to be asked about the study before any research starts.
- Make sure the researchers give enough information to staff and residents without bombarding them.

# What care homes and their residents can expect from researchers

- Ensure that material for residents takes account of possible problems with sight or hearing. Further information can be found in the [Research with d/Deaf people guidance](#).
- Provide a simple leaflet on who the researchers are, where they are from and what they will be doing.
- Be honest with the manager and staff at the beginning about the amount of time, resource and involvement required.
- Be respectful of people's time.
- Highlight the benefits but also the expectations of being involved.

# Information for Researchers

- It combines the main themes from NIHR School of Social Care Research (SSCR) Methods Reviews
- advice from those undertaking research in Care homes and people who work and live in them.

# Advice for Researchers

- The toolkit identifies the **over-arching principles** that should guide research in Care homes and signposts researchers to other, more detailed sources of information.
- It does not describe the details of the Mental Capacity Act 2005, however it highlights its importance and **signposts** you to more information.



# Five key issues to understand about doing care home research

- **Understanding** the benefits of research to Care home residents, staff, and families;
- Knowing what is **different** about doing research in Care homes;
- **Planning** research in Care homes;
- **Carrying out** research in Care homes;
- **Feeding back** the results of your research to Care homes

# Advice on preparing research studies

- It is important that researchers take time preparing research studies and properly [understand the care home sector](#).
- There is considerable **variation** between individual Care homes in terms of culture, management and delivery of care.
- Researchers are advised to spend time understanding the overall sector, how it works and the challenges it faces.
- This will ensure that appropriate consideration can be made when discussing support for studies.

# Advice on preparing research studies

- Researchers should consider the how the variance can be accommodated, how study delivery can be integrated into normal care and activities, and how the setting and variance could influence research findings.
- ***A major reason research bids fail is the ability of applicants to show that their recruitment strategy is feasible. Identify the Care homes you will work with as early as possible, plan and test feasibility together***

# Ethics, Research Governance and Consent

- All research undertaken in the NHS or through local government social care services and in Care homes must be approved by ethics committees and meet the legal requirements outlined in the Mental Capacity Act 2005.
- Any work that is conducted within either NHS or social care settings in England must be presented to a Research Ethics Committee (REC) operating under the umbrella of the National Research Ethics Service (NRES) ([www.nres.npsa.nhs.uk](http://www.nres.npsa.nhs.uk)).

# Why have regulation?

- These processes are designed to protect the dignity, rights, safety and well-being of Care home residents and those participating in research.

# Governing Bodies for Research in the UK

- Must comply with the Department of Health's Research Governance Framework all such research activities must be formally approved by **NHS R&D Trust management**.
- Research Governance Framework (2005): The Department of Health Research Governance Framework for Health and Social Care - Second Edition (2005)
- Department of Health Website: Research Governance
  - NIHR Regulatory and Governance Advice
  - NHS R&D Forum: Research Governance Documentation and Information Guide (Oct 2008)

# Protection under the Mental Capacity Act (MCA) 2005

Residents of Care homes in England and Wales are also protected by the [Mental Capacity Act \(MCA\) 2005](#) if they are unable to make decisions, for example, if they have severe dementia.

This sets out how an individual's capacity to understand and give consent must be decided.

It requires those with care responsibilities to always act in the individual's best interest if they lack the capacity to make the decision to take part in the research.

It also allows for opinions to be given, by people who know the resident – 'consultees'.

# Principles of the Mental Capacity Act 2005

- **5 key principles (Section 1, MCA)**
- Principle 1: A presumption of capacity
- Principle 2: Individuals being supported to make their own decisions
- Principle 3: Unwise decisions
- Principle 4: Best interests
- Principle 5: Less restrictive option



# Does the person have capacity to consent?

## Steps in Assessing Capacity

- 2-stage process
- 1. Is there an impairment of disturbance that may impact on the person's ability to make decisions?
- 2. If yes: Does this disturbance affect their ability to make decisions



Do the capacity test

# A person may lack capacity due to

- A lack of mental capacity could be due to:
  - a stroke or brain injury
  - a mental health problem
  - dementia 1
  - a learning disability 2
  - confusion, drowsiness or unconsciousness because of an illness or the treatment for it
  - substance misuse.

# Assumption of the Mental Capacity Act (2005)

- “A person must be **assumed** to have capacity unless it is established that he lacks it capacity”
- Capacity must be assessed in terms of a person’s ability **to make a decision** at the point at which it is required

# Assessing the ability to make a decision (MCA 2005): The capacity test

- 1. Does the person have a **general understanding** of what decision they need to make and why they need to make it?
- 2. Does the person have a general understanding of the likely **consequences** of making, or not making, this decision?
- Is the person able to **understand, retain, use and weigh** up the information relevant to this decision?
- Can the person **communicate their decision** (by talking, using sign language or any other means). Would the services of a professional (such as SALT) be helpful?

# Guidance on Informed Consent

- **Informed Consent: Incapacitated Adults**
- • The Medicines for Human Use (Clinical Trial) Regulations (SI 2004/1031) Refer Specifically to:
  - **Schedule 1, Part 3: Provides a Definition of Informed Consent**
  - **Schedule 1, Part 5: Conditions and Principles Which Apply in Relation to An Incapacitated Adult**

# 3 possible scenarios for capacity in research

- 1. The person has capacity
  - Can voluntarily confirm his willingness to participate once fully informed (ICH GCP 1.28)
- 2. The person does NOT have capacity and the study is a CTIMP
  - CTIMP: trial of an interventional medicinal product or device
- 3. The person does NOT have capacity and the study is a non-CTIMP
  - Guidance: **Clinical Trials in the UK: Governance, Regulations and Guidelines**

# Person does NOT have capacity

- Voluntary consent is a fundamental principle underpinning the ethical conduct of all clinical research
- When a person is unable to volunteer for themselves it is essential that their **presumed will** informs any decisions made on their behalf – would they volunteer to participate if they were able to make decisions for themselves?
- CTIMP processes are different from Non-CTIMP processes

# CTIMP: Person does not have capacity

- **Legal representative:** consents on behalf of the person
- Must ensure all the information has been given at the level the person might be able to understand (risks, benefits)
- All possible steps have been taken to enable understanding and communication
- Any indication that the person DOES NOT wish to participate be respected



# Legal representatives for CTIMPS

- 2 types: makes a decision on the **presumed will** of the person
- ***Personal legal representative***: suitable, available, willing
- ***Professional legal representative***:
  - If personal legal rep cannot be found
  - May be doctor responsible for the person's care (but is not involved in the study)
  - May be nominated by the relevant health provider (IMCA, medical director, PALS, voluntary organisation)

# Non-CTIMP: Person does not have capacity

- Consultee will represent the **presumed will** of the person:
- **Role:** to provide advice as to whether the person should take part based on their opinion whether it is what the person wishes
- Does **NOT consent** on behalf of the person
- 3 types:
- Personal consultee: involved in caring (no remuneration)
- Professional consultee:
- Nominated consultee: if not personal; has no connection with the project (IMCA, SW, care home director...)

# Useful Links

<http://www.dendron.org.uk/enrich/research-community/ethics-governance-consent.html> - consent

<http://www.dendron.org.uk/enrich/research-community/practical-advice.html> - practical advice

<http://www.dendron.org.uk/enrich/care-home-staff/protecting-residents.html> - what to expect from researchers

# Useful Links

- [School for Social Care Research Methods Reviews](#)
- [National Research Ethics Service](#)
- [British Geriatric Society: Quest for Quality](#)
- [Cochrane Report](#)
- [National Institute for Clinical Excellence – Dementia Guidelines](#)
- [National Institute for Health Research \(NIHR\)](#)
- [NIHR DeNDRoN](#)
- [DeNDRoN Portfolio of Studies](#)
- [Social Care Institute for Excellence – Living in care, a positive outcome](#)