Research involving adults who lack capacity to consent

#WhyWeDoResearch tweetchat

16th May 2018 8pm GMT

Introduction

People may experience impaired decision-making capacity due to a sudden illness or accident, progressive conditions such as dementia, or an intellectual or learning disability. Research involving adults who are unable to provide consent raises ethical, legal, and practical challenges. Those who lack capacity are generally underrepresented in research, resulting in a lack of evidence base for their care. Greater understanding about how we can appropriately involve them in research, whilst protecting their interests and welfare, is needed.

Should we involve adults who lack capacity to consent in research?

Research is an important way for us to improve the care and support that people receive. This includes people living with a condition, such as dementia, that may affect a person's ability to make a decision for themselves about whether to participate in a research study, even when supported to make a decision. Sometimes the research can only be carried out with people who lack the mental capacity to provide informed consent.

For those who are unable to provide informed consent for themselves there are special legal arrangements for their involvement in research, although these vary according to the legal frameworks in different countries. Generally, legislation allows such research to take place but sets out strict rules to protect people who lack capacity to decide to take part in the research, and to make sure their current and previous wishes are considered.

What is the legal framework for research involving people without capacity in the UK?

There are separate laws governing research involving adults who lack capacity to consent in England and Wales, Scotland, and Northern Ireland: the Mental Capacity Act 2005 (MCA) covers research involving adults (aged 16 years and over) who lack capacity in England and Wales, which differs from Adults with Incapacity (Scotland) Act 2000, and Mental Capacity Act (Northern Ireland) 2016. All these Acts exclude clinical trials of investigational medicinal products which are regulated separately by the Medicines for Human Use (Clinical Trials) Regulations 2004 (CTR) in the UK.

The situation will be largely unchanged by the new incoming EU Clinical Trials Regulations (No 536/2014) expected to come into force in 2019.

Research that includes people who lack capacity to consent must be carefully reviewed by a Research Ethics Committee to ensure that the inclusion of adults who lack capacity is justified, and that appropriate arrangements are in place for consulting others on the person's behalf. It also considers any risks and benefits for participants, and that the safety of participants is ensured.

How can we ensure that people who lack capacity have the opportunity to be included in research?

A recent study published in the Journal of Medical Ethics has shown that health and social care professionals in England and Wales have a lack of knowledge and understanding about the legal situation regarding adults lacking capacity and research. This included those who are responsible for recruiting participants, as well as Principle and Chief Investigators. More training and education is needed about how to involve people who lack capacity in research, in order to provide better evidence about their treatment and care.

Where can I find more information (UK resources)?

Health Research Authority (HRA) information:

https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/ and http://www.hra-decisiontools.org.uk/consent/principles-ALC.html

Health and Care Research Wales guidance for researchers (download pdf):

https://www.healthandcareresearch.gov.wales/uploads/News/research_and_impaired_mental_capacity_in_adults-guidance_for_researchers.pdf

NIHR CRN Informed Consent with Adults Lacking Capacity online course:

This course is designed to provide an introduction to informed consent with adults lacking capacity. It explores the requirements of the Mental Capacity Act and Medicines for Human Use (Clinical Trials) regulations when involving adults who lack capacity in non-CTIMP and CTIMP research.

https://www.nihr.ac.uk/our-faculty/clinical-research-staff/learning-and-development/national-directory/good-clinical-practice/our-courses/introduction.htm

Online toolkit (University of Leicester and University of Bristol):

An on-line toolkit on research involving adults lacking capacity to consent for themselves, covering the provisions of the Mental Capacity Act 2005 and the Medicines for Human Use (Clinical Trials) Regulations 2004

https://connect.le.ac.uk/alctoolkit/

Further reading:

Shepherd, V. Research involving adults lacking capacity to consent: the impact of research regulation on 'evidence biased' medicine. BMC Medical Ethics, 2016, Volume 17 (1) https://doi.org/10.1186/s12910-016-0138-9

Shepherd, V et al. Healthcare professionals' understanding of the legislation governing research involving adults lacking mental capacity in England and Wales: a national survey. Journal of Medical Ethics, 2018 DOI: http://dx.doi.org/10.1136/medethics-2017-104722

NIHR Doctoral Research Fellowship: Informed consent and proxy decision making in research involving adults lacking capacity: development of an intervention to support proxy informed decision making, set within ethical and legal frameworks (PI V Shepherd, Cardiff University, funded by Health and Care Research Wales) https://www.researchgate.net/project/Informed-consent-and-proxy-decision-making-for-research-involving-adults-lacking-capacity

Any questions?

Email: ShepherdVL1@cardiff.ac.uk
Twitter: @VickyLShepherd @DECISION_Study
PRIME Centre Wales http://www.primecentre.wales/
Centre for Trials Research https://www.cardiff.ac.uk/centre-for-trials-research
Health and Care Research Wales https://www.healthandcareresearch.gov.wales/