

Introduction

People with cognitive impairments, such as those with profound learning disabilities or dementia, are frequently excluded from research despite having the highest care needs. As a result, the health and social care provided for these populations is less evidence-based than others in society. An ageing population is expected to see an accompanying rise in people living longer with cognitive impairments, however, research involving those who lack capacity to consent presents ethical, legal, and practical challenges.

In England and Wales, when a person is unable to provide consent a family member is approached to act on their behalf.^{1,2} However, the ethical and legal frameworks can be difficult to navigate for families, health and social care professionals, and researchers who are involved in making decisions about research participation.³ The ethical basis for these decisions, and what support is required by families through a complex decision-making process, have not previously been investigated empirically.

Aims & Objectives

This project forms part of an NIHR Fellowship. The aim is to enhance understanding of the ethical, legal, and practical issues involved in research involving adults who lack capacity to consent, and to develop a Decision Support Instrument (DSI), set within ethical and legal frameworks, to support informed decision-making by representatives of adults with cognitive impairments.

It is hoped that this intervention, together with further work to improve knowledge, understanding, and attitudes more generally, will begin to address the current exclusion of those with cognitive impairments from research.

Methods

This project is comprised of a number of studies:

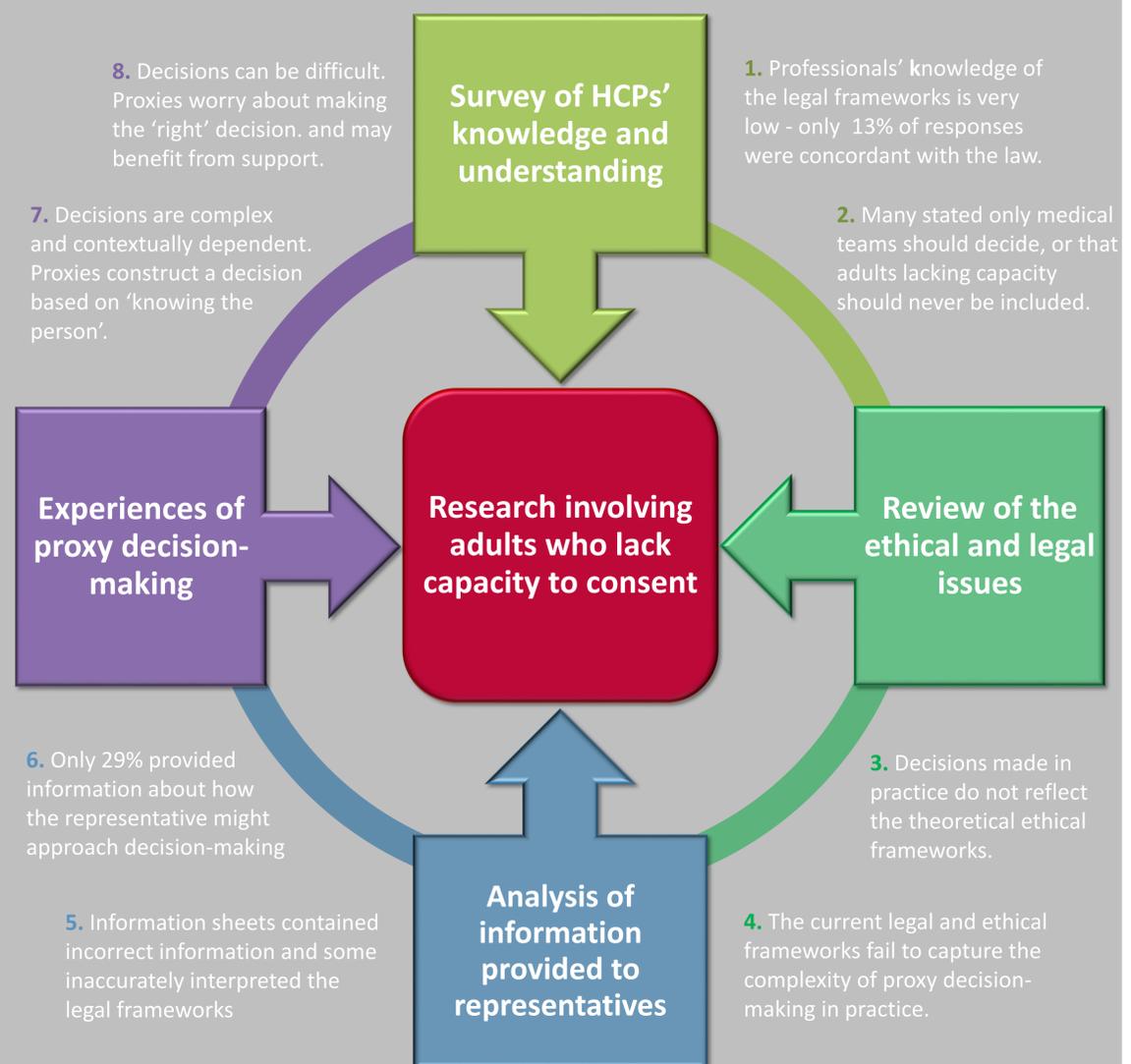
- > An **online survey** explored how the frameworks governing research involving adults lacking capacity in England and Wales are understood by health and social care professionals involved in their care.
- > A **systematic review** and a critical literature review analysed the ethical and legal issues involved in proxy decision-making.
- > A **content analysis** of Participant Information Sheets examined what information is currently given to families and health professionals about their role as a consultee or legal representative.
- > **Qualitative interviews** have explored how family members make proxy decisions about research in a range of practice settings.

Findings

The legal frameworks governing research involving those who lack capacity are not well understood by professionals, families, or researchers.⁴

Proxy decisions about research are a complex process with inter-woven layers of decision-making.⁵ Family members balance a number of different factors (the person's values, preferences and interests) within the specific decision context, to construct a decision that is 'authentic' and in line with what the person would have wanted. However, decisions can be problematic for family members, and they may benefit from decision support.

Findings (cont'd)



Conclusions

This is the first project to explore the ethical, legal, and practical issues encountered in research involving adults who lack capacity to consent. The findings suggest that greater training for health and social care professionals, resources for researchers who design and conduct trials with these populations, and support for families, are needed in order to address the exclusion of adults with cognitive impairments from research.

The findings are being used to develop a decision support intervention that may help families make more informed decisions about research in the future. The acceptability and feasibility of the intervention will be assessed, prior to a future evaluation of the intervention.

References

1. Mental Capacity Act 2005, HMSO
2. Medicines for Human Use (Clinical Trials) Regulations 2004
3. Shepherd V. Research involving adults lacking capacity to consent: the impact of research regulation on 'evidence biased' medicine. *BMC Medical Ethics* (2016) doi 10.1186/s12910-016-0138-9
4. Shepherd V, Griffith R, Sheehan M, Wood F, Hood K. 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) 44:632-637
5. Shepherd V, Hood K, Sheehan M, Griffith R, Jordan A, Wood F. Ethical Understandings of Proxy Decision Making for Research Involving Adults Lacking Capacity: A Systematic Review (Framework Synthesis) of Empirical Research. *AJOB Empirical Bioethics* (2018) doi 10.1080/23294515.2018.1513097

This study forms part of an NIHR Doctoral Research Fellowship funded by the Welsh Government through Health and Care Research Wales

For more information:

Victoria Shepherd, Division of Population Medicine, Cardiff University



ShepherdVL1@Cardiff.ac.uk
@VickyLShepherd