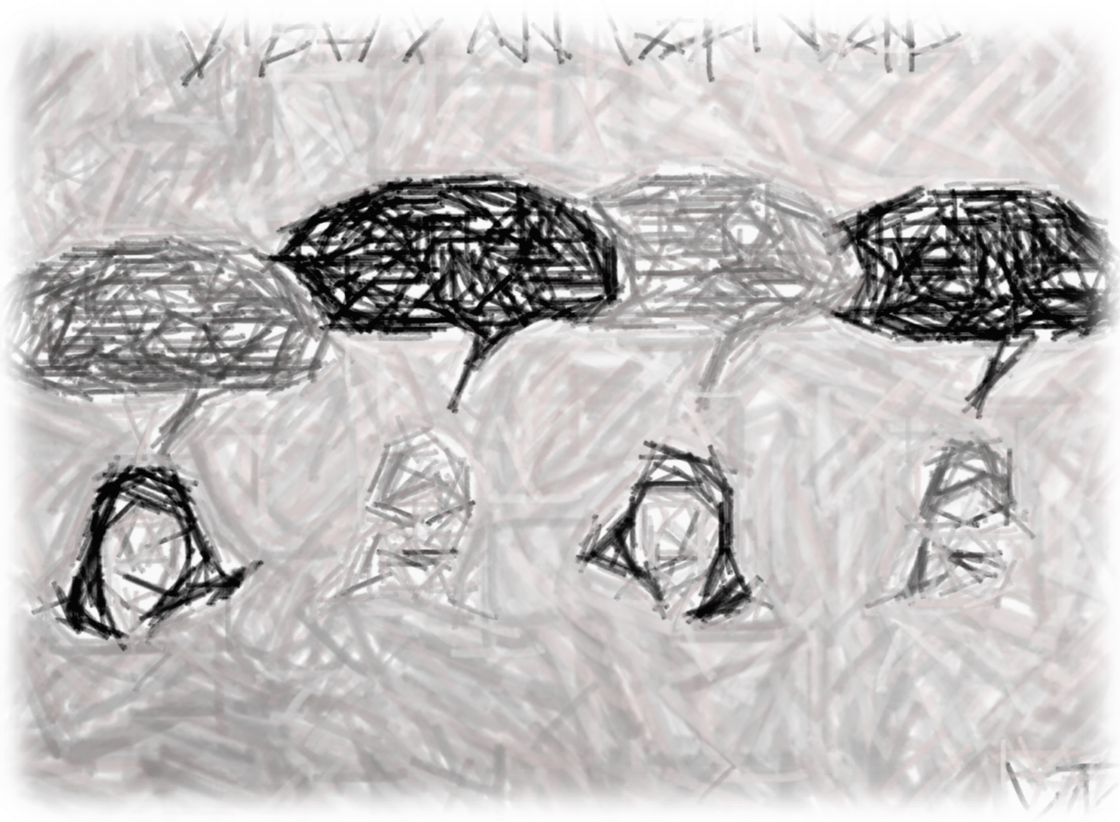
assent

Final Report

Including adults with capacity and communication difficulties in ethically-sound research



Including adults with capacity and communication difficulties in ethically-sound research

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Centre of Research Excellence in
Aphasia Recovery and Rehabilitation

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- Professor Tom Shakespeare, OBE: London School of Hygiene & Tropical Medicine/Nuffield Bioethics committee; expertise in disability research and ethics.
- Craig Spary: Asperger's East Anglia; expertise through lived experience.
- Liz Lund: Asperger's East Anglia/Research Ethics Committee (REC) member; expertise in working with people who have autistic spectrum conditions and as current REC member.
- Dan Kipper: Norwich Age UK; expertise in older people and dementia.
- Linda Watson: Norfolk Conversation Partners (people with acquired language disorder after stroke); expertise through lived experience.
- Kevin James: Mental Health service Users, Norwich; expertise through lived experience.
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- Ann Tunley: Head of Research Ethics Service (England)

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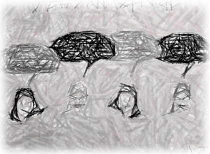


Executive Summary

This is the Executive Summary report of a three-year, multi-disciplinary project about the inclusion of adults with capacity and communication difficulties in ethically-sound research in England and Wales (2018-2021). It provides an overview of the project in terms of the background and aims; the methods, approaches and activities; the findings; the conclusions and recommendations.

Overview of Project

Gaining consent is a fundamental prerequisite for involving human participants in ethical research. Founded on the principle of respect for autonomy, it formally recognises people's interest in making decisions, acting voluntarily, and understanding and processing information relating to these decisions. However, our society also includes people who lack mental capacity that may be associated with communication difficulties. This includes adults with: learning disabilities, autism, language disorder after stroke, acquired brain injury, mental health disorder, and dementia.

As people live longer, so the number of people who have dementia or who have had strokes rises. Improved neonatal care means that premature babies are also surviving in greater numbers, with an associated risk of developmental disability. Thus, the proportion of people who require support in decision-making is increasing. There are ethical questions about whether it is appropriate to include such people in research. Researchers and ethics committees may find it easier to err on the side of caution and exclude people who seem unable to give informed consent. This results in the under-representation of these groups in research, which negatively impacts the development of medical, educational, and social interventions.

This project was conducted with the aim of defining a way through the complexities of including adults with capacity and communication difficulties in ethically-sound research.

Methods, Approaches & Activities

We adopted a mixed methodology that was defined variously across three stages.

Stage 1. Ethico-legal Landscape

We investigated the legal, ethical and regulatory frameworks governing capacity and consent under the Mental Capacity Act (MCA, 2005) and its accompanying Code of Practice (COP, 2007). This was completed across three sources of data:

1.1 The Law

We reviewed a number of primary and secondary legal sources in order to construct an in-depth critical legal analysis of the research provisions of the Mental Capacity Act 2005 (MCA). In terms of primary sources, we analysed the legislative provisions of the MCA and also reviewed some relevant legal cases. In respect of secondary sources, we analysed the Hansard Reports in the build-up to the implementation of the MCA and also reviewed accompanying policy documents, such as the MCA Code of Practice (MCA COP, 2007).

1.2 Policy Guidance

We surveyed the content of the research-focused Chapter 11 of the MCA COP (2007) and advisory documents that were publicly available on the Health Research Authority (HRA) website. We looked at the vocabulary used as an initial indication of the subject matter being addressed, before carrying out a summative content analysis.

1.3 Applications in research

We carried out a systematic review of the literature (with narrative synthesis), focusing on research involving adults with capacity and communication difficulties published since the implementation of the MCA (2005).

Stage 2. Current Practice

We explored research practice around the inclusion of adults with capacity and communication difficulties in ethically-sound research in England and Wales. This was completed across four sources of data:

2.1 Review processes

Firstly, we carried out a retrospective survey of studies carried out in England and Wales, featuring the provisions of the MCA (2005). The targeted period was from 2007 (the year of implementation). Data were collected using the publicly available HRA database (http://www.hra.nhs.uk/news/research-summaries/). Secondly, we conducted a prospective survey of research applications to MCA-flagged Research Ethics Committees (REC) in England and Wales over a 12-month period.

2.2 Adapted resources for participant recruitment

We analysed the design features and linguistic content of a sample of participant information sheets devised and used by researchers for people with communication difficulties and/or capacity-affecting conditions.

2.3 Researcher reasoning

We were particularly interested in researcher decision-making in relation to the inclusion/exclusion of people with capacity and communication difficulties. We surveyed researchers using a questionnaire devised for the purpose.

2.4 Stakeholder views and opinions

We carried out structured interviews with four stakeholder groups: a. REC members; b. researchers; c. practitioners, supporters, and carers; d. adults with communication and/or capacity difficulties. The last group included adults with: learning disabilities; autism; acquired language disorder after stroke; acquired brain injury; dementia; and mental health disorder.

Stage 3. Strategic Guidance

Within the context of existing legislation, and drawing on the evidence from our investigations, we developed and piloted structured guidance to promote inclusion in research.

3.1 Synthesis of data from stages 1 and 2.

We mapped our findings on the ethico-legal landscape to those arising from our review of current practice, identifying points of convergence and divergence across the data sets.

3.2 Development of evidence-based guidance.

We organised the key messages from the data into practical information and guidance within a navigable learning object.

3.3 Evaluation of guidance.

We piloted the guidance by inviting researchers, REC members and commissioners of research to try out the digital learning object and to complete an evaluation questionnaire.

Data Summary

Table 1. Summary of data across all project stages

Stage	Activity	Sample	
1. Ethico-legal landscape	1.1 Review of MCA (2005)	Primary sources Secondary sources	31 54
	1.2 Review of COP (2007) & policy guidance	Policy guidance documents COP	14 1
	1.3 Systematic review of the literature	Full text review Final sample	134 29
2. Current Practice	2.1 Survey of REC review of research applications	Retrospective survey Prospective survey	1617 83
	2.2 Adapted resources for participant recruitment	Participant Information Sheets	25
	2.3 Survey of researcher reasoning	Questionnaires	128
	2.4 Values and opinions of stakeholder groups	Interviews	60
3. Strategic Development	3.1 Data synthesis	N/A	
	3.2 Development of guidance	N/A	
	3.3 Evaluation	E-questionnaire	31

Findings

Stage 1. Ethico-legal Landscape

The Law

We identified some problems that stem from the fact that the MCA is mainly focused on treatment, welfare and financial decisions as opposed to research. Insufficient time seems to have been devoted to identifying clear aims and objectives to the research provisions of the MCA and to creating an effective legislative regime that would adequately meet them. Establishing a separate set of substantive tests that must be met in order to gain approval for research involving incapacitated participants does not, in reality, achieve a fair balance between protection and empowerment. The additional measures introduced that require the appointment of a consultee and the final approval from an approved Mental Capacity Act Research Ethics Committee (MCA REC) are also of questionable effectiveness. The idea that a third-party consultee can act as an effective advocate and thus empower an incapacitated participant by ensuring that her voice is heard is frustrated by its impracticalities. A system that promotes cooperation between a researcher and a participant, with a renewed emphasis on seeking positive assent from a participant, may be a more desirable method of guaranteeing greater emphasis on supported decision-making. Similarly, very little is known about how an approved MCA REC actually forms its opinion and about what is at the forefront of the minds of its members when making a decision on a given project. Significant variation in interpretation of the requirements for approval could lead to a pattern of inconsistency between MCA RECs, which has the potential to undermine the perceived value of the system. What is clear, however, is that the manner in which the research requirements have been drafted creates the impression that the researcher, the consultee and the MCA REC are subject to differing obligations which all potentially overlap, but which may not necessarily be viewed in that way. This sense of confusion may cause researchers to become disillusioned with the system of approval and therefore reluctant to consider incapacitated participants in the future.

Policy Guidance

Capacity and communication difficulties were referred to in both the HRA documents and the COP (e.g. aphasia; learning disability; autism; dementia). The semantic category inclusion in research was largely determined in terms of ‘risk’, ‘benefit’ and ‘protection’. In contrast, terms associated with ‘empowerment’ and ‘autonomy’ were far less frequent. Vocabulary associated with media to facilitate participant understanding of research was present only in the HRA documents.

The content of the surveyed documents (14 multi-authored guidance documents and the COP) was attributed to three organising themes: Ethics; Capacity & Decision-making; and Accommodations. Ethics and Capacity & Decision-making appeared to be connected, with Ethics focusing on the moral principles governing actions and decisions in relation to research, and Capacity & Decision-making describing the procedures used to include people in research. Accommodations focused on considerations for people with capacity and communication difficulties participating in research.

Whilst Capacity & Decision-making was dominant in the research guidance, Ethics occupied the greater content of the COP (2007). Both of these themes corresponded to governance procedures under the MCA (2005). They included references to ‘protection’ and ‘risks & benefits’ in both the research guidance and the COP (2007), with the latter promoting the importance of ‘research value’. In the policy guidance documents, Accommodations included references to ‘context’; ‘language’; and ‘media’. Typically, they were presented as isolated position statements with no obvious connection to the other two domains. The COP (2007) contained just one generic statement on the need for support.

Applications in Research

We reviewed primary research studies carried out in England and/or Wales from 2007, which included participants aged 16 years and above, with capacity and communication difficulties (e.g. autism; stroke; mental health, dementia, acquired brain injury and learning disabilities). Reports of clinical trials were excluded. Twenty-eight studies met the inclusion criteria.

Table 2. Summary of studies included

Conditions	n	%
Learning disability	12	42.9
Dementia	9	32.1
Autism	3	10.7
Mental health disorder	2	7.1
Aphasia after stroke	2	7.1
Acquired brain injury	0	0

Participants deemed to lack capacity were included in 15 studies (54%) based on consultee advice and excluded from 7 studies (25%). Of the remaining 6 studies, one study made provision for consultee advice but in fact all the participants were able to give informed consent. The participants in the remaining studies (n=5) were able to give informed consent

Despite report of a range of adapted materials and information sharing procedures to support the recruitment of potential participants, relatively few studies included adults with communication and/or capacity-affecting conditions. Existing regulations appear to be interpreted variably. Sporadic use of consultees and the exclusion of individuals on the basis of incapacity indicated that this group continue to be under-represented in research.

Stage 2. Current Practice

Representation & Accommodation

Review Processes

We conducted a retrospective survey of research recorded on the public database of the Health Research Authority (HRA) between 2012-2017. We retrieved 1617 records featuring people with communication difficulties and/or capacity-affecting conditions. The majority of research applications focused on people with mental health conditions (n=521; 32.2%) and dementia (n=514; 31.7%), followed by people with acquired brain injury (n=248; 15.3%) and people with aphasia after stroke (n=229; 14.2%), then people with learning disabilities (n=136; 8.4%) and autism (n=107; 6.6%). We classified the research using the International Classification of Functioning framework (World Health Organisation, 2001). The majority of studies were focused on 'activities & participation' either as a single focus (n=389) or connected to some form of intervention (assigned to the category of 'environment') (n=622). A focus on 'body function & structure' either singly (n=152) or in combination with some form of intervention ('environment': n=177) or 'activities & participation' (n=120) was less frequent. Reported opinions by Research Ethics Committees were similar across all groups with capacity and communication difficulties with 7% receiving an unfavourable opinion and less than 1% after further information; 30% receiving a favourable opinion and 63% after further information.

We carried out a prospective survey of research applications made to MCA-flagged Research Ethics Committees in England and Wales over a 12-month period. Data were collected by the Health Research Authority and focused on the following sections of Integrated Research Application Systems (IRAS):

- IRAS A 17.1 Population-types targeted for recruitment
- IRAS A 17.2 Exclusion criteria relating to communication and/or cognitive difficulties affecting capacity
- IRAS A 33.1 Information sheets -used as source of information to identify key provisions made to communicate project information with prospective participants.

As shown in table 3., just over half the applications focused on adults with dementia.

Table 3. Summary of applications by associated condition

Adults with:	n (%)
Dementia	42 (50.6%)
Acquired brain injury	21 (25.3%)
Learning disabilities	6 (7.2%)
Aphasia after stroke	5 (6%)
Mental health disorders	5 (6%)
Autism	4 (4.8%)

Around 50% did not identify any exclusion criteria in relation to communication and/or capacity. Of the cited exclusion criteria cited in applications, 18 related to a lack of capacity; 5 to communication difficulties; 11 to lack of a consultee; 17 to limited English language skills.

Accommodations for recruiting participants were various, and featured adaptations to the format and content of the Participant Information Sheet (PIS) (n=46; 55%), e.g. using pictures/images; large print typography. Twenty-one applications highlighted the mode of delivery for project information, e.g. interacting with potential participants offering verbal explanations, using a slow rate of speech, simple phrases, repetition was identified in 21 applications (25%). Extra support from the family, carers and others was considered in 25 applications (30%). Use of a consultee was only reported in 5 applications, although procedures to check the assent or dissent of incapacitous participants featured in 15 applications (18%).

Adapted Resources for Participant Recruitment

Of the 30 Participant Information Sheets (PIS) we received, 5 were excluded because the content was not aimed specifically at adults with communication difficulties and/or capacity affecting conditions population. Of the 25 PIS included in the sample, just less than half were prepared for people with dementia (n=12); 8 were for people with aphasia after stroke; 2 for adults with learning disabilities; and 2 for people with mental health disorders. No PIS were received for people with autism and acquired brain injury. The majority were prepared as Microsoft word documents with just 2 using a PowerPoint format. The number of pages of the PIS ranged 1-24 (*Median*=4; *Mean*=5).

Use of pictures featured in 56% of the sample. The location of pictures in relation to text varied across the sample with 50% placing the pictures on the right and the left of the text, or immediately below. A font point size greater than12 was use by 60% of the sample. Sub-headings were used in all but 1 PIS and other space organising devices were used less frequently, e.g. bullet points (28%); numbered lists (20%). The content of the PIS varied broadly across the sample in terms of quantity of words and sentences. Vocabulary used in the PIS looked at the indices of: familiarity *(how familiar a word seems to an adult, which relates to ease of processing)*; its concreteness (*how concrete or non-abstract a word is, which relates to the sense the word evokes)* and imageability (*how easy it is to construct a mental image of the word)*. The vocabulary in use achieved a level of reasonable familiarity generally, although values for concreteness and imageability were lower. The median reading ease score for information sheets was 67.7 on a scale of 0-100 – difficult to easy) although this varied across the sample.

Researcher Reasoning

Of the 127 researchers who responded to our online survey about their use of the Mental Capacity Act within their studies, just over 50% of the respondents reported having worked with people who have difficulties with communication and/or capacity for more than ten years. Just over 50% of the sample also reported having more than ten years of experience working in research, and just over 80% reported that they thought their knowledge of the Mental Capacity Act was good to excellent, with 78% agreeing that they felt confident when working with a consultee.

The majority of the researchers stated that they included people who have difficulties with communication and/or capacity within research because their project was specifically about this population. They also reported that inclusion was to improve the quality of research and to give this group a voice. A variety of communication aids and accommodations to meet the needs of participants were used by researchers, including using increased hand and body gestures, easier to read text, being flexible and offering breaks, and making sure to ask participants about their needs. Around 35% reported that they did not make use of any communication aids within their research projects.

Analysis of the answers given to free text boxes using content analysis revealed that some were knowledgeable about the Mental Capacity Act as used within a clinical context, and the analysis suggested a degree of confidence in the assessment of capacity within this specific context. Surprisingly, there was evidence to indicate that researchers appeared unclear about some aspects of the application of the Mental Capacity Act within research settings. This included some confusion about the role of a consultee, where some confused the role with that of an advocate, or with a best interest assessment within a clinical setting. Some researchers were unsure as to whether the assessment of capacity was their responsibility or the responsibility of those involved in the provision of care.

Stakeholder Views and Opinions

Adults with capacity-affecting conditions and communication difficulties: Participants thought people with these difficulties should be included in research to improve understanding of the impact of various conditions, for research to be more comprehensive and to give a voice to these groups. Participants identified benefits to individuals from taking part in research, including feelings of altruism, a sense of achievement and feeling useful. Anger was expressed that people with capacity and communication difficulties would be excluded from research. This gave rise to a sense of being ‘disregarded’, ‘locked out’, of discrimination and that their issues would not be recognised, contributing to invisibility associated with some disabilities. Some participants were concerned about the MCA (2005) consultee process, but others thought it beneficial if it meant more people could be included. Participants said they would want to be involved as much as possible in the process and that the consultee should be someone who knew them well. Participants expressed the view that people who can’t communicate are thought not to understand and are not noticed.

Supporters and practitioners: Most participants thought it was wrong to have left groups of people out of research as then assumptions are made about their experiences which are not accurate. There should be more attempt to make research participation accessible. For example, research approaches could be more engaged and make more use of observation of people's everyday lives. One to one support helps people to take part. Some participants were not familiar with the MCA consultee process. Several supporters felt they wouldn't want to speak for someone else. There was a view that researchers were inclined to err on the side of caution. Not all 'gatekeepers' saw themselves as such but made judgements about research that is 'badly run' or 'using' participants and not passing on information to service users. Others were proactive in seeking research opportunities for their group. Researchers assessing capacity should have the communication skills to be able to adapt the information to the individual.

Researchers and ethics committee members: Respondents viewed it as morally good to involve adults with capacity and communication difficulties in research. Ethics committee members thought that research applicants understood the main principles of the MCA, although ethics committee respondents themselves had weaker understanding in some areas of the Act, including distinguishing between personal and nominated consultees. Some felt the HRA was overly focused on written information and signatures although respondents agreed that information sheets should be "easier to read". Less evident was a commitment to the full range of methods for supporting people to make autonomous decisions. Only a minority of respondents appeared to understand that under the MCA people should be actively supported to make autonomous decisions and that a person judged to lack capacity should still be involved in the decision-making process, even where a consultee is involved.

Conclusions from Stages 1 and 2

The ethico-legal landscape for research in England and Wales is informed by the MCA (2005) and its accompanying Code of Practice (2007). The MCA's concern for people who lack capacity is largely focused on treatment, welfare and financial decisions, with additional provisions for research. We found the research provisions to be poorly drafted and lacking an appropriate balance between protection and empowerment. The MCA COP (2007) provides some elucidation of the technical aspects of the MCA, including formal governance procedures related to protection and risk management. However, the ethical approval process appears to place contrasting obligations and expectations on different parties (e.g. MCA REC members, researchers, consultees), which may blur the allocated responsibilities and the formation of ethical opinions. Generally, there was a noted lack of strategic and practical guidance to support the execution of responsibilities. We found relatively few studies linked to the MCA and featuring adults with communication difficulties and/or capacity-affecting conditions. Sporadic use of consultees and the stated exclusion of adults with capacity and communication difficulties indicates that this group continue to be under-represented in research. The complexities of balancing protection with empowerment may cause researchers to err on the side of caution and exclude incapacitous individuals.

Our review of current practice revealed that, intrusive research under the MCA appears to be most commonly focused on participant ‘activities and participation’ and/or interventions, with a lesser focus on ‘body functions and structure’. Although incapacitous individuals were included in research because of their presence in the target population, exclusions continue to be made on the basis of a lack of capacity. Where participants with capacity and communication difficulties are included, researchers use a range of materials, resources and procedures to support their understanding of the planned research. However, the majority of recruitment procedures seem to involve the use of some form of documentation to convey project information. Furthermore, the accessibility value of such resources in terms of the language content and presentational features to augment meaning is inconsistent. The use of consultees is variable across our populations of interest, i.e. adults with learning disabilities, autism, dementia, acquire brain injury, aphasia after stroke and mental health disorders, and a source of some confusion to researchers regarding the responsibilities and obligations of the role. Where a consultee is involved in giving advice on the individual’s likely wishes and feelings about participation, there appears to be minimal recognition and report of the active involvement of incapacitous participants in decision-making as far as their abilities allow.

Recommendations from Stages 1 and 2

1. Promotion of researcher-participant cooperation

The system for developing, reviewing and conducting ethically-sound research that includes adults with capacity and communication difficulties would benefit from redefining. This requires promotion of cooperation between a researcher and a participant such that empowerment is recognised within a system that protects. A renewed emphasis on seeking positive assent from a participant, may be a more desirable method of guaranteeing greater emphasis on supported decision-making.

2. Support for participant autonomy

There is a strong and enduring need for guidance that focuses on the researcher's efforts to promote the autonomy of the participant as far as possible, regardless of their assessed capacity, and even where a consultee is involved, with specific attention to strategic adaptations and accommodations that enable people with capacity and communication difficulties to have a voice in research.

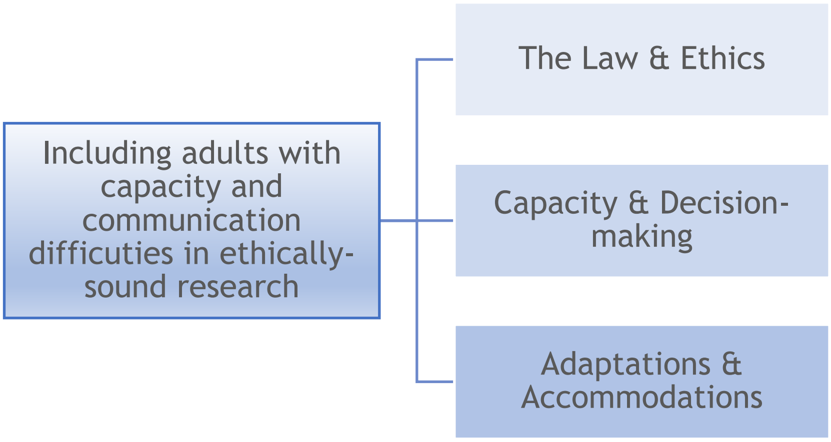
3. Use of a full range of adaptations & accommodations

Researchers and ethics committee members need to be better informed about the full range of methods to support people to make autonomous decisions so they can advise applicants seeking ethical approval for their research. The researcher needs to make sure that the conditions are right for a person to use their available skills as far as possible, to understand information, to retain and weight it up, and finally, to communicate their decision. Traditional ways of obtaining informed consent are not appropriate for all, and there is a need to consider alternative processes.

Stage 3. Strategic Development

The final stage of the project focused on the strategic development of guidance to address the recommendations emerging from stages 1 and 2 of the project: promotion of researcher-participant cooperation; researcher-participant cooperation; support for participant autonomy; and use of a full range of adaptations and accommodations. Accordingly, the content was defined in correspondence to the findings and organised in three key domains as shown in Figure 1.

Figure 1. The three domains for strategic development



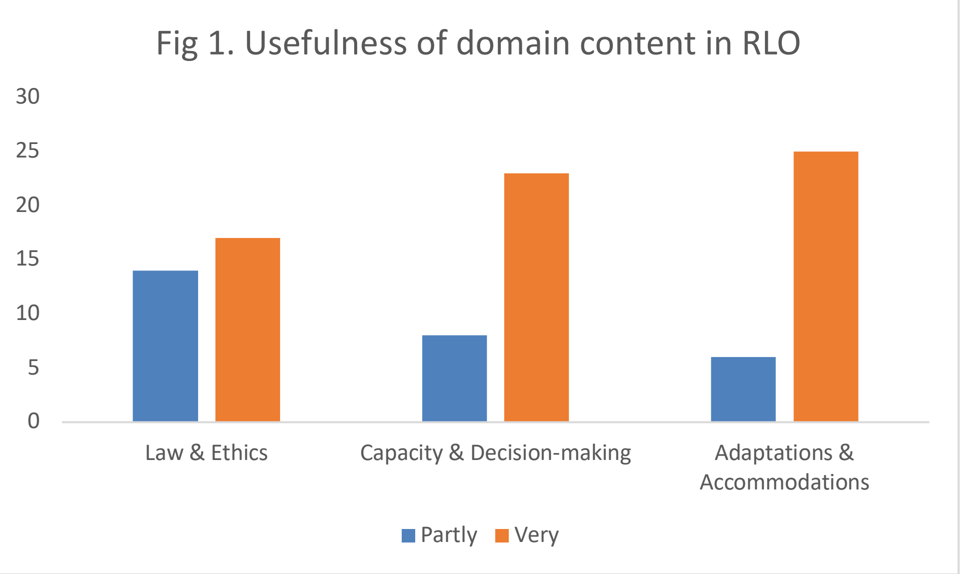
The aim was to develop a Reusable Learning Object (RLO) containing guidance that would be of interest to a wide range of users/stakeholders including: researchers, reviewers of research proposal serving on ethics committees, and service user-focused organisations as potential consumers of research. A first draft of the content was completed in PowerPoint format and was accompanied by a narrative describing the proposed navigation, visualisation and animation of the RLO. At this stage, the proposed content was shared with representatives of the Working Group who had the opportunity to make comments and suggestions, which in turn fed into the development process.

The PowerPoint and narrative information were used as the basis for constructing the digital entity. The work was carried out by an independent digital learning company. Work samples were sent out for review by the project team at regular intervals and feedback was given. An e-questionnaire was developed to solicit feedback from parties interested in field-testing the RLO.

Researchers and Research Ethics Committee (REC) members were invited to evaluate the Re-usable Learning Object (RLO), developed from the research outcomes of stages 1 and 2 of the project. Although not part of the target population, adults with capacity and communication difficulties, who have been part of the project since inception offered to provide their feedback.

We received 31 completed evaluation questionnaires on the RLO (19 below our target of 50 questionnaire returns). Most participants were female (67.7%), over 54 years (48.4%), predominantly white (90.3%) and worked as researchers (64.5%). Others were stroke survivors with aphasia (n=4), a student (n=1) and a recently stepped down Lay Plus member of a REC (n=1).

Participants were asked to rate the usefulness of each domain within the RLO according to the following response options: very useful; partly useful; not useful. The domain 'Adaptations & Accommodations' was rated the highest (Partly=6; Very=25), followed by 'Capacity & Decision-making' (Partly=8; Very=22). The Law & Ethics domain showed a fairly even distribution between 'partly' and 'very' (Partly=14; Very=17).



Feedback and suggestions included:

- Worked case examples: greater diversity in the scenarios needed; more examples needed of how to involve participants, make language accessible and work with consultees; how to evidence participant responses; use of audio file/narrations could be supplemented with practical examples and definitions.
- Structure: A navigational route to be presented visually and for the user to track their journey through the RLO with a 'back' button; introduce

more sub-headings and sections; greater clarity from the start about the target audience would be helpful.

- Presentation: review language content for acceptability; review text superimposed on a pictorial background with a screen reader; indicate when a sound file is playing.

Recommendations from Stage 3

The numbering of recommendations from Stage 3 follows on from the those articulated for Stages 1 and 2.

4. Enhance the relevance and usability of the ASSENT RLO

In order that the content of the RLO may be refined for optimal relevance and usability, feedback needs to be solicited from a wider and more representative sample. Drawing on the feedback established thus far, case-based scenarios that capture real-life communication processes and exemplify expressions of assent and dissent would serve to enhance the continuum of decision-making that is featured in the ASSENT RLO.

Chapter 1. Introduction

Gaining consent is a fundamental prerequisite for involving human participants in ethical research. It has emerged from the development of ethical principles for research involving human beings (e.g. World Medical Association Declaration of Helsinki, 1964; Council for International Organisations of Medical Sciences). Founded on the principle of respect for autonomy (Simpson, 2008), it formally recognises people's interest in making decisions, acting voluntarily, and understanding and processing information relating to these decisions.

However, our society also includes people who lack mental capacity and people with communication difficulties, either as separate impairments or in combination. This includes people with: learning disabilities, autism, language disorder associated with aphasia after stroke, head injuries and dementia. The prevalence of such cases is likely to increase over the coming decades, as greater numbers of people live with dementia and other capacity-affecting conditions (Prince et al. 2014). Similarly, a 14% increase in prevalence rates, for adults with learning disabilities (also known as 'learning disabilities) in England was forecast for 2001-21 (Emerson & Hatton, 2008) with a rise in the proportion of individuals with more severe to profound and multiple disabilities (Emerson et al. 2009; Hatton et al. 2016). Improvements in medical interventions mean that people are surviving life-threatening conditions throughout the life course, from birth prematurity (Costeloe at al. 2012), to stroke and head injury (Townsend et al. 2012).

Regulatory Framework

Project Assent was concerned with the provisions for research in England and Wales under the Mental Capacity Act (MCA: 2005). Of particular interest was the inclusion of adults with communication and/or capacity difficulties who are not well represented in research (Age UK, 2013; Allmark, 2004; Hamilton et al. 2017; Shepherd, 2020). Researchers may be reluctant to recruit such individuals because of the complexity of the relevant legal, ethical and regulatory frameworks governing capacity and consent.

Article 12 of the Convention on the Rights of Persons with Disabilities (CRPD: UN, 2006a) asserts there should be 'equal recognition before the law'. However, differing legislation applies to different types of research. The Medicines for Human Use (Clinical Trials) Regulations (DoH, 2004) governs research in England and Wales involving investigation of medicinal products. The law requires that a legal representative must give written consent for any participant who lacks capacity. For all other kinds of research, the MCA (DoH, 2005) applies. Based on a binary model, the MCA upholds the rights of individuals deemed to have capacity to make their own decision regarding participation in research. For those individuals judged to lack capacity, a familiar other is asked to advise on the person's likely views on participation (Case, 2016).

In the context of research, these protocols require participants to be clearly categorised: either they have capacity to agree to take part in the research, or they do not (see Keene, 2017). As reviewed by Lock (2015), the area between capacity and incapacity is unclear. Furthermore, capacity will vary according to the complexity of information and over time (Warner et al. 2008). Other aspects of the MCA (2005) recognise that in everyday life, people may have capacity for some decisions and not others. Protocols in supported decision-making may be invoked, as elaborated in the CRPD (UN, 2006b), where the individual's interest in exercising choice is accommodated. However, this does not necessarily filter through to the research context. Because research is treated in this exceptional way, it increases the sense that participating in research is a risky endeavour, and both researchers and consultees may be unsure as to how or whether an individual's participation can be ethically justified. Certainly, House of Lords select committee review of the MCA identified a culture of 'protection and paternalism' amongst professionals working in clinical settings with people who may lack capacity in the (2014; p.51).

Culture of Choice

Those individuals who do not possess capacity as per the requirements of the MCA (2005) may still, nevertheless, have views about their participation or non-participation in research. The Code of Practice (MCA COP: DfCA, 2007) accompanies the MCA (2005) providing guidance for persons required to interpret the legislation (Nicholson et al. 2008). For example, paragraph 11.29 (MCA COP, 2007) stipulates that even where a consultee agrees that a person can take part in the research, the researcher must still consider the patient's wishes and feelings. However, in practice this may cause difficulty. The culture of choice, history of decision-making, individual perceptions and the power relations that characterise the person's life are relevant here (Masty & Fisher, 2008). Eliciting the views of the individual requires recognition that the person has views, and that they are relevant. However, depending on the level of capacity and/or communication, different strategies and communication techniques may be required. Some new possibilities are offered by protocols, such as the 'Consent Support Tool' (Palmer & Jayes, 2020), which is designed to facilitate research inclusion of adults with communication disorders associated with a variety of conditions (Jayes & Palmer, 2014). Others argue against the reliance on printed information in favour of a detailed conversation to support the decision-making process, which is then documented (Williamson & Martin, 2010). Regardless of approach, it is the case that people are most likely to engage with and understand information that requires the least cognitive effort (Wilson & Sperber, 2012).

Seeking assent is already widely acknowledged to be best practice in research involving children (Kodish, 2005; Miller et al. 2017), and is an emerging concept in dementia research (Batchelor-Aselage, 2014; Diener et al. 2013; Petryk & Hopper, 2009; Slaughter et al. 2007; Sorrell & Cangelosi, 2007; 2009). Assent has been described as an individual's agreement to participate in research where parental permission or consultee affirmation has been established. In contrast, supported decision-making is about enabling 'the individual to exercise his/her legal capacity to the greatest extent possible, according to the wishes of the individual' (UN, CRPD, 2006b; Chapter 6). The 'Partnership of Consent Protocol' was developed for people with dementia in the USA (Aselage et al. 2009) and recently modified (Batchelor-Aselage et al. 2014). The protocol defines assent as the verbal agreement expressed by the person, as well as 'not demonstrating verbal or nonverbal behaviours' indicative of dissent (p.18). Seeking assent requires that researchers communicate with the prospective participant and respond to his or her views. Mere absence of dissent is not enough to infer assent. However, a positive communication of assent, i.e. 'engaged assent' (in addition to the formal legal requirements for a consultee) could be regarded as an ethical prerequisite for the involvement of People with capacity and communication difficulties in research, and as enabling the recognition of the person's self-expression. This would involve direct communication with the prospective participant, supporting engagement with research information that is responsive to the individual's cognitive and communicative capacities (see Miller et al. 2017). Frost et al. (2016) described assent as an 'expansive, educational and multimodal' process that is adaptable to individual needs. For example, video has been used to support young people with severe to profound learning disabilities to engage in research information (Bunning et al. 2012; 2016).

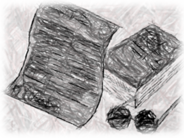
Inclusion in Research

The Research Governance Framework for Health and Social Care (DoH, 2011; 2005) requires that research participants reflect the diversity of the population and advises against routine exclusion of under-researched groups, including those with disabilities. Yet, adults with capacity and communication difficulties continue to be under-represented in research (Age UK, 2013; Allmark, 2004; Hamilton et al. 2017; Shepherd, 2020). It is possible that researchers and ethics reviewers interpret the legal frameworks too narrowly (Dixon-Woods & Angell, 2009). Under-representation of people with capacity and communication difficulties in health and social care research may lead to a systematic knowledge deficit concerning the views and experiences of this client group and the efficacy and impact of new interventions (e.g. Diener et al. 2013).

The current situation is that, whilst the MCA COP (DfCA, 2007; paragraph 11.29) urges consideration of the individual's wishes and preferences, how to seek out and evidence them with People with capacity and communication difficulties is usually left to local interpretation. Sibley et al. (2016) draw a distinction between 'respecting a decision' and 'encouraging a decision'. The former acknowledges the rights of an individual and attributes value to their involvement in decision-making. The latter focuses on the pedagogical process whereby an individual actively engages with the options presented. Both dimensions were considered on the current research.

Project Aim

The concept of assent and its operationalisation remain poorly defined and require further elucidation and analysis. The relevance is clear, not only to research, but also to the medical, educational, and social interventions that a person may require over the life course. The over-arching aim of the current project is to develop an ethically-sound, legally-robust strategy for including adults with communication and/or capacity difficulties in research within the context of existing legislation. It is envisaged that the guidance will enhance the current Code of Practice that accompanies the MCA (2005) and help to define a way through the complexities of working with adults with communication and capacity difficulties by recognising personal autonomy in all its gradations and defining practical strategies and resources that serve to endorse their greater agency.



Chapter 2. Project Design

The project adopted a mixed methodology defined in three stages.

Stage 1 focused on assessing the ethico-legal landscape for research conducted under the Mental Capacity Act (2005) in England and Wales.

- We conducted a comprehensive review and discourse analysis of the provisions for research in the Mental Capacity Act (2005) and the accompanying Code of Practice (2007).
- To examine how the needs of people with communication and/or capacity difficulties are supported, we carried out a documentary survey of publicly-available, guidance documents published by the Health Research Authority (www.hsa.nhs.uk) that provide additional advice to the Code of Practice.
- To ascertain how the regulatory frameworks had been applied to research involving adults with communication and/or capacity difficulties post-implementation of the MCA Code of Practice (2007), a systematic review with narrative synthesis of the published literature was conducted.

Stage 2 focused on current practice regarding research with adults who have communication and/or capacity difficulties in England and Wales.

- To determine how adults with communication and/or capacity difficulties are represented within the review process by MCA-flagged Research Ethics Committees (RECs) in England and Wales, a survey of applications processed by RECs was conducted in two parts: 1. a retrospective survey of relevant studies using the publicly available Health Research Authority (HRA) database (http://www.hra.nhs.uk/news/research-summaries/). http://www.hra.nhs.uk/news/rec/). 2. A prospective survey of research applications reviewed by MCA-flagged RECs in England and Wales during a 12-month period.
- To determine the accommodations put in place for including People with capacity and communication difficulties in research, specifically the informed consent procedure, we gathered a sample of participant recruitment resources developed and used by researchers for seeking informed consent.
- To establish the reasons behind decisions of whether to include/exclude people with capacity and communication difficulties, we surveyed researchers using an e-questionnaire.
- To explore the underlying values, views and opinions of our main stakeholder groups about participation in research under the provisions of the MCA (2005), we interviewed a purposive sample of key informants including: members of MCA-flagged RECs; researchers; supporters, gatekeepers and practitioners;

and adults with communication and/or capacity difficulties with learning disabilities, autism, dementia, aphasia after stroke, acquired brain injury, mental health disorder.

Stage 3 focused on strategic development in terms of practical guidance on including adults with communication and/or capacity difficulties in ethically-sound research based on the findings from the previous two stages of the project.

- To determine the extent and nature of data convergence/divergence around the ethical governance frameworks in England and Wales, stage 1 and 2 data were triangulated.
- To establish a continuum of decision-making that incorporates the spectrum of ability for self-determination from informed consent/refusal (the decision made by a person deemed to have legal capacity), through degrees of engaged assent or dissent (the person's active dis/agreement to something through a process of interaction), to passive dissent (lack of observable response or extreme passivity), the critical factors and accommodations that support the inclusion of adults with communication and/or capacity difficulties in ethically-sound research were identified and defined.
- A digital entity comprising prepared content was constructed to facilitate and support guidance for stakeholders in research.

Assent Project Groups

Working Group

The Working Group was set up at the beginning of the project in order to work collaboratively with representatives of the service user groups at the centre of the concerns of Project ASSENT. Members were recruited to represent the following groups; people with autism, people with aphasia following stroke, people with learning disability, people living with dementia, people with mental health difficulty. The objectives for the Working Group were to co-produce the participant information sheets, consent forms, recruitment process for the interview study and contribute to the development of the questionnaires and evidence-based guidance.

Process

The Working Group's perspectives were essential in ensuring that the voices and perspectives of the service user groups were central to our research processes. By working collaboratively with researchers on the project, the different experiences and expertise could be brought together to ensure that this research project would be appropriate, acceptable and accessible to those living with communication and cognitive difficulties. The Working Group worked collaboratively with researchers at initial meetings to decide on their roles and responsibilities within the project, when and how often and how we would work together (e.g. establishing ground rules), and how their involvement in the process could be supported (e.g. meeting agendas and minutes sent in advance in a variety of accessibility formats; meeting in an accessible location, with a quiet room available).

The Working Group met for blocks of three meetings at key points in the research process, with interim meetings at approximately 3-monthly intervals to maintain the relationship between Working Group members and the project. The decision to meet more regularly for interim meetings came from the Working Group, who felt that this was integral to them keeping engaged with the ASSENT Project and remembering project goals and their roles and responsibilities. The working group met for a total of 11 meetings face to face at the University between July 2018 and February 2020. ASSENT team members attended the meetings so that there could be discussions in small groups. The agenda and the minutes for each meeting were produced in a range of formats (standard text, Easy Read, Easy Text and audio). Contact with working group members was maintained through their preferred route (email, text, audio message). Processes for the working group were co-produced with working group members, including the time of day and length of the meetings, provision of a break and the language and terms used to discuss the project activities. Examples of language used that working group members found more understandable included ‘research checking group’ for research ethics committee and ‘asking questions’ or ‘ASSENT conversations’ for qualitative research interviews. One person attended the working group meetings with a supporter. Two members of the working group were family carers. In each meeting the ASSENT staff gave information about the aims and activity of the project, and answered question, then the group discussed the implications of the topic from their point of view and with the needs of People with capacity and communication difficulties in mind. Verbal information was supported with easy read information on visual aids. Where appropriate verbal communication was supported with the use of topic cards using text and images. Table 2.1 on the next page summarises the topics discussed at the working group meetings.

Pandemic restrictions

The team planned to reconvene the Working Group once the draft RLO was created in order to get their input on this. Shortly after the last face to face meeting of the working group COVID-19 restrictions came into force. Members of the working group were contacted to ask their views on potential virtual means of conducting the group. One person preferred to no longer be involved if not meeting face to face, one person was not contactable as people supporting them, the preferred contact route, were furloughed. Two people were happy to meet through video call. This process was therefore used for a final discussion of the draft RLO. Discussion over video link was assisted with an accessible PowerPoint presentation comprising explanation, examples from the RLO and closed questions. Further feedback was provided via email.

Table 2.1 Summary of topics discussed at working group meetings

Working Group	Topics
1.	Working together, information sheets
2.	Working together, information sheets, questionnaires, interviews
3.	Questionnaires, asking questions
4.	Questionnaires, asking questions
5.	Project update
6.	Project update, project website, asking questions
7.	Law paper, project recruitment, project website
8.	ASSENT learning pack, interview process
9.	ASSENT learning pack, findings from stage 1.
10.	ASSENT learning pack, information from ASSENT conversations
11.	ASSENT learning pack, information from ASSENT conversations
On line meeting	Consultation on draft Reusable Learning Object

Art Group

A local art group was commissioned to create pictures of some of the key concepts associated with including adults with capacity and communication difficulties in research. The idea was for the group to come up with visualisations for the relevant terms associated with the ASSENT project during scheduled sessions with the resident art tutor. Payment was offered for pictures selected for use in project outputs for dissemination purposes. The members of the group had autism and learning disabilities. Information about project ASSENT was initially presented to the group and there was the opportunity to ask questions of the researcher. To help the group with their work, the researcher presented the communication cards that had been devised and used in the interviews with people who have capacity and communication difficulties. The group reviewed the pictures and conversations about the content followed. In addition, pictures were gathered that were associated with some core concepts connected to inclusion and taking part in research. The aim was to stimulate the groups ideas for their artwork. The pictures were drawn from a variety of sources and compiled in a handout that was given to the art group. This provided the focus for their decisions concerning the subject matter of their artwork. Table 2.2 (over the page) summarises the core concepts presented to the art group.

Table 2.2 Summary of concepts used to stimulate artwork

Core Concepts	Examples
Research	Making decisions Saying yes or giving consent Saying no or refusing Taking part or being included Being left out or exclude
Feelings	Nervous or worried Comfortable or relaxed Confused or not understanding
Communication	Understanding Talking Support Time Asking questions
Information formats	Written information Film or DVD Communication Signing and gesture Communication charts and electronic devices
Mental Capacity Act	Documentation People with disabilities

The group worked together over a period of 6 months with variable attendance and contributions by the members. During this period 5 visits were made by the researcher to review the work and to provide feedback and encouragement. Participation in the art groups varied over the period with one member in particular attending each session, whilst others attended infrequently depending on their personal well-being. Usually there were around four members per session. The artwork varied from illustrations based on the stimuli presented to 'bubble' writing of key words. A review of the artwork was completed by the researcher and art tutor at the last session and the final set of pictures was selected.

Chapter 3. Ethico-legal Landscape (Stage 1)

The objective was to establish a comprehensive overview of legal, ethical and governance frameworks, with specific identification of the ways adults with capacity and communication difficulties are recognised and accommodated at the levels of policy and implementation. Our research questions were:

1.1 How are impairments of capacity and/or communication associated with adult participants recognised and represented in research governance in England and Wales?

1.2 How does the Mental Capacity Act Code of Practice, as the operational document, build on the provisions contained in the MCA (2005)?

1.3 What perspectives about the inclusion/exclusion of adults with capacity and communication difficulties in research emerge from a systematic review of the academic literature on this topic?

The Law

The first component of the project involved an investigation and review of the current legal provisions governing the inclusion of individuals who lack capacity in research. Typically, legal research methods are doctrinal in nature and involve a textual analysis of key cases and legislation. Cases and legislation are the primary legal resources, upon which legal researchers develop critical insights. Judgments and legislation are read and analysed, with a view to generating observations about the strengths and weaknesses of the law, where the law has worked, what has been missed and where matters could be improved by way of reform. Two members of the team thus embarked upon an initial doctrinal legal analysis of the legal sources that were relevant to research involving participants who lack capacity. The main source we focused on was the Mental Capacity Act 2005, which is the principal piece of legislation governing this area. We scrutinised each provision of the Act forensically and generated critical reflections pertaining to how the different sections may operate in practice. During the course of our investigation, we discovered that the nature of the research provisions meant that there would be a paucity of case law to consider, because research related matters in the Mental Capacity Act 2005 tend not to be referred to court. Thus, to buttress our analysis, we further embarked upon a thematic analysis of the Code of Practice, which accompanies the Mental Capacity Act 2005. Here we forensically dissected the relevant research sections of the Code of Practice by comparing and contrasting them to the substantive provisions of the primary legislation. We were then able to discern that the Code of Practice is not always helpful in translating the terms of the Mental Capacity Act 2005 into a workable model that researchers will be able to read, understand and gain assistance from in practice when considering whether or not to include participants who lack capacity in a project. The language of the Code of Practice was unclear and some of the guidance therein did not altogether correspond with the terms of the Mental Capacity Act in a clear and coherent manner. We also carried out a similar analysis on other policy documentation from the Health Research Authority and again concluded that it was not necessarily a useful accompaniment to the legislation.

Given the lack of relevant case law in the field, we then decided to adopt another legal research technique, which is to analyse the Hansard debates that take place prior to the implementation of a piece of legislation. These Parliamentary debates often provide an insight into the main intentions underpinning the relevant Act and highlight its aims and objectives. Hansard debates are thus a useful source of information as they reveal the points of contention in the build-up to a new piece of legislation and assist legal researchers in identifying controversial aspects of a proposed law that that were given suitable attention in terms of debate and discussion and, equally, they allow researchers to spot issues that were overlooked or given insufficient attention. We thus located and collected the relevant Hansard debates in relation to the Mental Capacity Act 2005 and undertook a thematic analysis of these documents using a qualitative software package. We sought to identify common and recurring themes from within the text and placed relevant passages from the text into each of these thematic headings. From here we were thus able to generate a number of observations, such as the fact that most of the debates centred on how the Mental Capacity Act 2005 applied to treatment, and research seemed very much marginalised in the discussion. Best interests, for example, was another theme we identified, but again most of the discussion centred on how this ought to apply to the treatment aspects of the Mental Capacity Act 2005. Similarly, much of the discussion focused on the Mental Capacity Act 2005 as an instrument to provide protection to those who lacked capacity, but not much attention was given to the importance of empowerment within research. It therefore became clear from our thematic analysis of the Hansard debates that the research provisions of the Mental Capacity Act 2005 were not given a significant amount of airtime, which led us to conclude that more emphasis should perhaps have been placed on the research provisions during the early debates which, in turn, may have positively influenced the final drafting of the research sections.

Sections of this aspect of the report have been extracted from the following published article, which provides a more thorough analytical discussion of our findings: Rob Heywood, Hayley Ryan, Anne Killett, Peter Langdon, Yvonne Plenderleith, Ciara Shiggins and Karen Bunning (2019). Lost Voices in Research: Exposing the Gaps in the Mental Capacity Act 2005. *Medical Law International* 19 (2-3), 81–112.

For the first stage of the project, we reviewed a number of primary and secondary legal sources in order to construct an in-depth critical legal analysis of the research provisions of the Mental Capacity Act 2005 (MCA). In terms of primary sources, we analysed the legislative provisions of the MCA and also reviewed a number of relevant legal cases. In respect of secondary sources, we analysed the Hansard Reports in the build-up to the implementation of the MCA and also reviewed accompanying policy documents, such as the Code of Practice and HRA guidance.

Due to incapacitated research participants being unable to consent for themselves, and because any research findings may often only benefit others, the research provisions of the MCA are set apart from other aspects of the legislation. The intention behind this was to provide a suitable balance between appropriate protection on the one hand, and the need to maintain sufficient sCOPe for participant inclusion and empowerment on the other.

Sections 30 to 33 of the MCA allow intrusive research to be lawfully carried out on, or in relation to, a person who lacks capacity. The legislation does not, therefore, completely prohibit research. Rather, it purports to adopt a permissive approach, seeking to recognise the potential value that incapacitated participants can bring to answering particular research questions. Nonetheless, given that often research may be conducted not for the benefit of an individual, but only for the benefit of others, the MCA remains sensitive to the enhanced vulnerability of incapacitated participants and inserts additional measures of protection. First, a project will only be deemed lawful under the MCA once an appropriate independent body, which is now defined as an approved MCA Research Ethics Committee (MCA REC), has authorised it. Secondly, before researchers can proceed with MCA REC sanctioned research, a personal or nominated consultee needs to be appointed who must offer an opinion about the willingness and likely wishes of any potential incapacitated participant.

The MCA operates from the basis that research involving incapacitated participants can ordinarily proceed, unless the activities in question fall with the Act’s definition of intrusive research. Where research falls within the definition, it will be prima facie unlawful unless it adheres to additional requirements stipulated by the legislation. These additional requirements state that any research must be connected with an impairing condition affecting the proposed participant, or its treatment. An approved MCA REC must also consider from the outset whether or not there are reasonable grounds for believing that research of comparable effectiveness could be carried out on persons who have capacity to consent to taking part in it. Finally, the best interests test, which is used to render lawful an array of other decisions under the broader terms of MCA, does not apply to research. This is replaced by a set of conditions that demand an assessment of the potential benefit to risk ratio that an incapacitated research participant may be exposed to and, in cases where there may be no value whatsoever to that individual, of the potential benefits that may conferred on persons affected by the same or similar condition.

This stage of our project revealed that the research provisions of the MCA are obscure and that their misinterpretation could lead to an overly restrictive attitude, which is damaging to notions of inclusivity and empowerment. First, it is not entirely clear what type of research should fall within the purview of the Act, and an apparent focus on medically-intrusive research causes some key areas to be overlooked. Quite apart from that, in initially calling for some consideration as to whether or not more effective research could be carried out on a capacitous individual, the MCA begins by making a dangerous comparison that could undermine the value and status of an incapacitated participant's involvement in research.

We concluded that some of these problems may have stemmed from the main thrust of the MCA being focused on treatment, welfare and financial decisions. This may signify that research was very much an afterthought. Insufficient time seems to have been devoted to identifying clear aims and objectives and to creating an effective regime that would adequately meet them. The research sections do not appear to sit comfortably with the other aspects of the MCA and, in places, appear to have been drafted rather awkwardly.

Imposing a separate set of substantive tests that must be met in order to gain approval does not, in reality, achieve the objective of providing a fair balance between protection and empowerment. This goal could arguably have been better achieved by assessing the existing objective and subjective factors that must be considered under a traditional section 4 MCA 'best interests' assessment. The additional measures introduced that require the appointment of a consultee and the final authorisation from an approved MCA REC are also of questionable effectiveness. The idea that a third-party consultee can act as an effective advocate and thus empower an incapacitated participant by ensuring that her voice is heard is frustrated by its impracticalities. Similarly, very little is known about how an approved MCA REC actually forms its opinion, and about what is at the forefront of the minds of its members when making a decision on a given project. Significant variation in interpretation of the requirements for approval could lead to a pattern of inconsistency between MCA RECs, which has the potential to undermine the perceived value of the system. What is clear, however, is that the manner in which the research requirements have been drafted creates the impression that the researcher, the consultee and approved MCA RECs are subjective to differing obligations, which all potentially overlap, but which may not necessarily be viewed in that way. This sense of confusion may cause researchers to become disillusioned with the system of approval and therefore reluctant to consider incapacitated participants in the future. If the research provisions of the MCA are having this effect, they are arguably impeding the very type of activity that they should be seeking to promote and this ought to be recognised as a problem that needs resolving.

Alongside the MCA, a Mental Capacity Act Code of Practice (COP) also exists, which is supposed to act as an accompaniment to the primary legislation. However, in analysing the COP, it became evident that the guidance contained therein was somewhat disjointed from the substantive legal provisions contained in the Act. It is not unusual for primary legislation to remain sufficiently broad so as to allow sCOPe for development and adaptation and relying on Codes of Practice to develop more detailed operational guidance is often an effective way of constructing a permissive regulatory regime. Delegating finer points to supplementary guidance from the COP therefore has the potential to confer a number of benefits on the MCA in the sense that the COP is supposed to not only complement, but also to elaborate upon, the more general framework provided by the legislation. Nevertheless, if the guidance contained in the COP is opaque, inaccessible and remains somewhat under the radar, little will be done to obviate some of the problems encountered by those involved in research practice.

It seems likely that researchers will look first to the COP in order to better understand their obligations in respect of dealing with participants who lack capacity. The attraction of consulting such guidance is that it should work as the outward looking document that aims to translate the technical provisions of the law into practical frontline advice. Whether the COP actually operates as such though is questionable. We therefore suggest that sections of the COP need to be redrafted in order to provide greater clarity for researchers. As the COP is currently due to be revised, the overall findings from our project could not be more perfectly timed.

Given some of the MCA's research-targeted provisions do not sit comfortably with the growing emphasis on supported decision-making promulgated by Article 12 of the United Nations Convention on the Rights of Persons with Disabilities (UNCRPD), we concluded at the end of Stage One that perhaps more thought should be given to a system that promotes greater co-operation between a researcher and a participant, with a renewed emphasis on seeking positive assent from a participant. This may be a more desirable method of guaranteeing greater emphasis on supported decision-making than is currently achieved by the problematic consultee scheme.

Policy Guidance

Sections of this aspect of the report have been extracted from the following published article, which provides a more thorough analytical discussion of our findings: Hayley Ryan, Rob Heywood, Oluseyi Jimoh, Anne Killett, Peter Langdon, Ciara Shiggins and Karen Bunning (2020). Inclusion under the Mental Capacity Act

(2005): A review of research policy guidance and governance structures in England and Wales. *Health Expectations* 00,1–13.

As part of our investigation into the ethico-legal landscape, we had questions around how researchers are supported to include people with capacity and communication difficulties in their research. The Health Research Authority (HRA) website (www.hra.nhs.uk) provides a central repository of information for researchers, which includes supplementary guidance to the MCA (2005) and the COP (2007). We retrieved 14 guidance documents for the documentary survey. Using the criteria below, we collated a comprehensive sample of e-documents (www.hra.nhs.uk, 2019) (N=14).

Table 3.1 Sample criteria for survey

Inclusion	Exclusion
Reference to: • MCA (2005) and/or the COP (2007)	Separate provisions for: • Clinical trials; research with children; emergency settings
Addresses: • Capacity, informed consent and support for people with CCD	Text exclusions: • General operational principles, rules and regulations

Firstly, we carried out a survey of surface-level vocabulary to establish how people with CCD were represented in the language of the guidance. A list of key word referents relating to: communication difficulties; decision-making and capacity; and inclusion in research was generated through several iterations. The documents were uploaded as files in NVivo-12 and a search of word frequency was conducted. Using the list, we then searched the results for each document to determine frequency of word referent occurrence.

Secondly, we carried out a summative content analysis (Hsieh & Shannon, 2005) on all documents. This included latent content analysis to explore meanings within text. Two researchers performed close reading of the documents and identified content themes, which were then grouped into organising themes according to their homogeneity. We conducted a team review of coding decisions until consensus on coding was achieved. Any inter-connections amongst the thematic content were identified as a final step in the content analysis.

Finally, we reviewed the findings and searched for points of corroboration between the hierarchy of themes and the summary of word referent frequencies.

Findings

Surface level vocabulary

As shown in Table 2, word referent frequency is rank ordered (high-low) in the three semantic categories: 'people with communication difficulties'; 'decision-making & capacity'; and 'inclusion in research'.

A range of conditions was identified in association with 'people with capacity-affecting conditions and associated communication difficulties' (n=264). As perhaps expected in guidance documents supplementary to the MCA COP, 'inclusion in research' had the highest frequency word referents overall, with risk dominating (n=532), followed by benefit (n=365) and protect+ (n=158). The latter featured in all 14 sources. In contrast, the combined referents equality, accessibility+, autonomy, inclusion, enable+, and empower+, yielded a frequency of 141. The combined frequency of assent and decision-making was relatively small (n= 30). Choice of media to support inclusion referenced 'easy read' (n=63) four times higher than other media types, *e.g.* audio, DVD+, combined (n=16). The second most frequent word referents fell within 'decision-making & capacity' (n=643), with capacity+ dominating (n=396), followed by consultee (n=122), which referred to the recommended procedure for people lacking capacity.

Table 3.2 Frequency of word referents in documentary sources: R(S)

Semantic Category	Word Referents	HRA documents: R (S)
People capacity-affecting conditions and associated communication difficulties	*Aphasia+; autism+; attention+; dementia+; brain injury+; Brain disturbance; learning+; mental health+; communication+ disable+; impair+;*	264 (14)
Decision-making & capacity	*Capacity+*	396 (9)
	Consultee	122 (3)
	Cognition+	95 (12)
	Assent	21 (3)
	Decision-making	9 (2)
Inclusion in research	*Risk+*	532 (11)
	Benefit+	365 (10)
	Protect+	158 (14)
	Equality	55 (8)
	Accessibility+	39 (8)
	Autonomy	20 (5)

	Inclusion	16 (6)
	Enable+	9 (4)
	Empower+	2 (2)
	Easy Read	63 (1)
	Audio	9 (4)
	DVD+	7 (2)

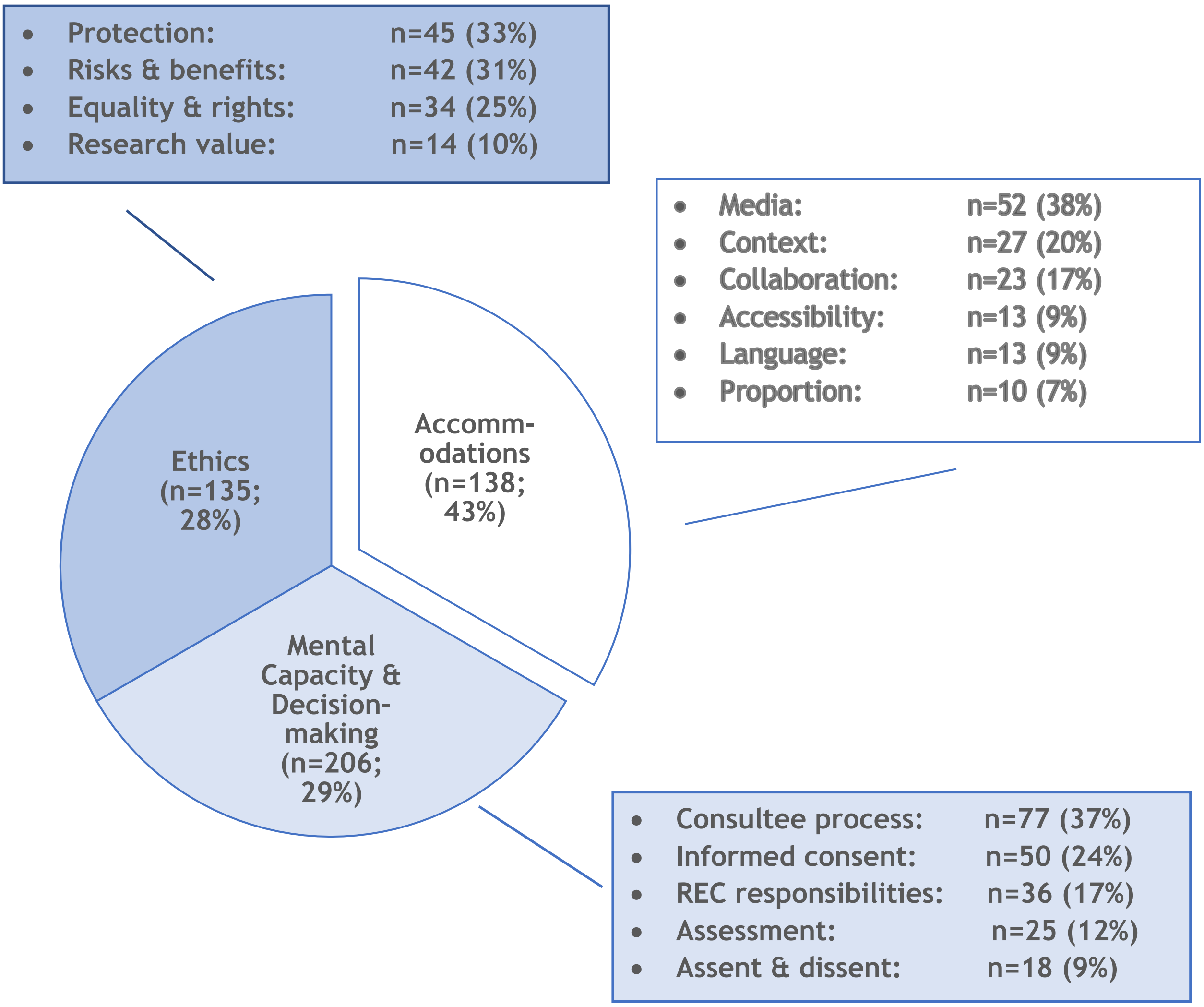
Key: '+' after word referents in each semantic category indicates a 'multi-stem' phrase, which includes related terms, e.g. autism+ included autistic spectrum disorder/condition/ASD/Asperger's syndrome/AS.

Summative content analysis

Three organising themes emerged: Ethics; Capacity & Decision-making; and Accommodations. Ethics focused on the moral principles governing actions and decisions in relation to research, and was linked to Capacity & Decision-making, which described the enactment procedures. The third organising theme, Accommodations, focused on considerations for people with capacity and communication difficulties participating in research.

As shown in Figure 3.1., 'Mental capacity & decision-making' occupied the greatest content in the HRA guidance (n=206 references; 43%), with similar weightings for 'Ethics' (n=135; 28%) and 'Accommodations' (n=138; 29%). For the COP (2007), 'Ethics' (n=51 references; 64%) represented the major content, followed by 'Mental capacity & decision-making' (n=28 references; 35%), with 'Accommodations' barely mentioned (1%).

Figure 3.1 Organising themes and sub-themes from content analysis: number (%) of references indicated



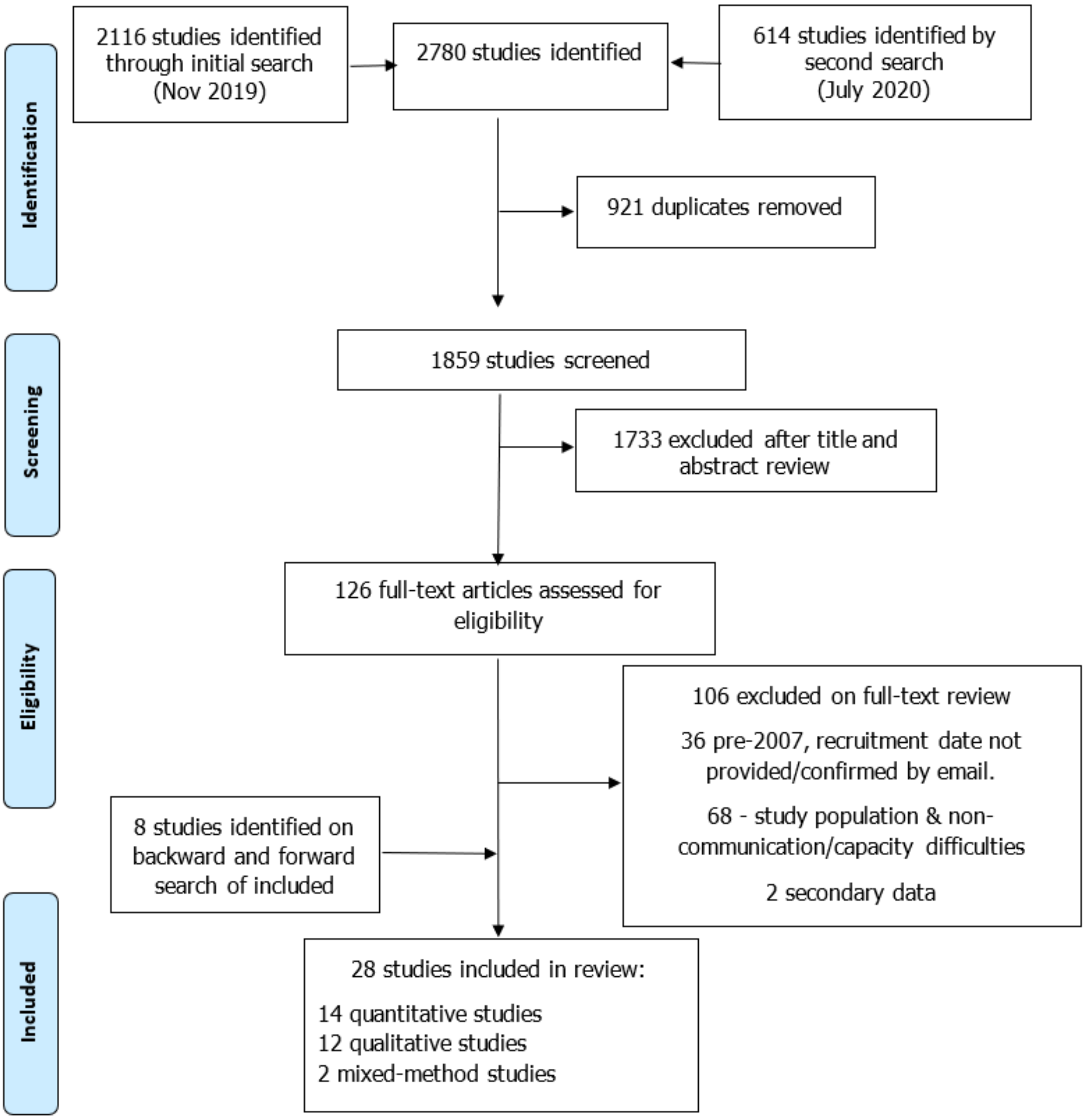
Applications in Research

To examine how the regulatory frameworks have been applied in research involving people with capacity and communication difficulties, we conducted a systematic review of the literature. Searches were carried out on the following databases: Academic Search Complete, ASSIA, MEDLINE, CINAHL, PsycArticles, PsycINFO and Science Direct. Using the criteria below (table 3.3), we included 28 papers [see Figure 3.2 for the search results].

Table3.3 Sample criteria for review

	Inclusion	Exclusion
Population	• Participants aged 16yrs+. • Capacity and communication difficulties associated with autism; stroke; mental health; dementia; acquired brain injury; and learning disabilities.	• Clinical trials • Research using tissue sample. • Secondary data
Intervention	• Invoking the provisions for research under the MCA (2005).	
Outcomes	• Demographic data • Recruitment procedures • Accommodations supporting research participation.	
Study designs	Quantitative, qualitative, mixed study design	
Publication types	*Primary empirical studies from peer-reviewed literature	
Publication year	2007 to 2019	
Language	English language	
Notes	*The year the study was conducted indicated when participants were recruited. When the date was not provided, clarification was sought by sending an email to the corresponding author and searching the publicly available Health Research Authority (HRA) database. Finally, where this could not be established, we back-tracked three years from publication data on the basis that majority of studies are published within 30 months post the live period of a study (i.e., from 2010) (1).	

Figure 3.2 PRISMA Flow diagram of studies included



Included participants were said to have learning disabilities (n=12; 42.9%); dementia (n=9; 32.1%); autism spectrum disorders (n=3; 10.7%); mental health disorders (n=2; 7.1%); and aphasia after stroke (n=2; 7.1%). None were said to have acquired brain injury. Study designs included quantitative (n=14; 50.0%); qualitative (n=12; 42.9%) and mixed methods (n=2; 7.1%). Samples were drawn mainly from hospital in-patients or attending outpatient services (n=13; 46.4%). Others were in receipt of social care services, prisoners, or part of national databases or ongoing studies (n=15; 53.6%).

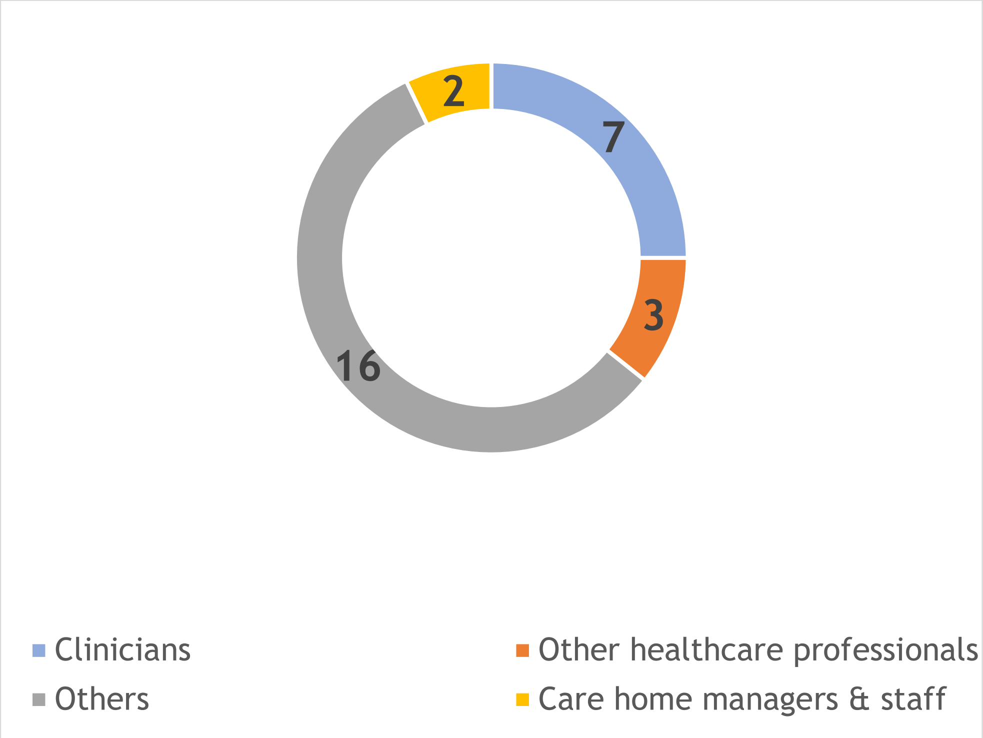
The Mixed Methods Appraisal Tool (MMAT) (2), for concurrent critical appraisal of quantitative, qualitative and mixed-methods primary research was applied (3) to included studies. Twelve (85.7%) of the fourteen quantitative studies, were evaluated as high-quality, one (7.1%) as moderate-quality and one (7.1%) as low-quality; all qualitative studies (n=12, 100%), were evaluated as high-quality and both mixed-methods studies (n=2, 100%) were evaluated as moderate quality. To account for methodological diversity and sample variability, we employed narrative synthesis in the report of results (4,5).

Findings

Access to and identification of participants

In all studies, access to participants was managed through designated gatekeepers, who also identified potential eligible participants. Where specified, the role was fulfilled by clinicians, other healthcare professionals, care home managers and staff, staff of participating institutions (e.g. prison services), support staff as well as a researcher working closely with staff and relatives of people living in a residential home with dementia.

Figure 3.3 Designation of persons acting as gatekeepers



*

**NHS Trust, social care services, ongoing studies, charities, community services, private service providers etc.*

Inclusion and exclusion criteria of participants

Those lacking capacity were included in most studies (n=15) based on consultee advice but excluded from some (n=7). Although one study made provision for consultee advice, this was not needed as all participants were able to provide informed consent. In the remaining studies (n=5), all participants were able to give informed consent. Furthermore, some studies (n=3) excluded those with capacity and communication difficulties or inability to speak English language, if they were deemed unable to take part in data collection process such as interviews.

Study information format

Reporting on study information format was varied and frequently lacked detail (n=11/28). Where information was provided, it was typically written text combined with verbal explanations, especially for those living with aphasia. Adaptations to written text included the use of 'aphasia friendly' format for people with aphasia post-stroke, 'easy read' for those living with learning disabilities and 'accessible information for those living with learning disabilities and dementia. Study information was sometimes provided in multiple formats (n=9). For example, one study provided full information sheet, abbreviated version, and accessible formats for those living with dementia. There was also report of the use of picture cards and images to supplement text. Collaboration between researchers and service user group representative was reported in two studies, which influenced the volume of information presented to potential participants.

Further support for decision making process

The decision-making process was further scaffolded by: support from familiar others such as family members, carers, and healthcare professionals; allowing extra time for participants to process information as well as providing question and answer opportunities. In addition, researchers put in place a range of accommodations, including the use of familiar places to minimize any anxiety affecting understanding, meeting in private places to control for distraction, and flexibility to research activities to accommodate participants' preferences. For example, flexibility with when to meet, where to meet and how to meet. Although there was limited report of tailored approaches to support adults with capacity and communication difficulties, a role for experts with lived experience was reported for those living with psychosis. In this case, the collaboration between researchers and patient group representatives led to the development of study information suitable for participants. Engaging the expertise of professionals such as Accessible Information Officer, Language Therapist and professional advocates at interviews was also reported.

Capacity assessment procedures

Capacity assessment procedures were often not described in detail (n=13/28). However, seven studies (n=7) referred to the Mental Capacity Act functional test

(MCA 2005)[1], using various procedures. Some studies (n=4) used a formal approach, e.g. closed questions, checklist of items, standardised questions, structured assessment and in an instance, the Competence Assessment Tool for Clinical Research (MacCAT-CR), which assesses understanding, appreciation, reasoning, and expression of choice. Some studies (n=4) used informal approaches, for example, checking capacity during conversations with prospective participants through detailed observation of behaviour reflexively for understanding and consent or observations coupled with guidance from those how know potential participants well, e.g. family members and those working closely with them.

Informed consent procedures

For studies which provided some details (n=19/28), informed consent was still predominantly through written methods (n=16), while in some studies (n=3), it was accepted orally as part of an interactive process. For example, four studies (n=4) involving adults living with dementia and learning disabilities, used an enhanced process consent model that monitored ongoing consent through verbal and non-verbal signs. Another researcher assessed consent in adults with learning disabilities, with a supporter in attendance, capturing the process on video to document non-verbal cues. The video was then checked by the supporter for non-verbal cues to either confirm or refute capacity and a decision free of coercion. A single study used the Consent Support Tool with adults with aphasia post-stroke to determine the requirements for support and the recommended communication strategies. Another study, which recruited from a population case register, reported the use of either an ‘opt-out consent procedure’ whereby researchers made contact with prospective participants by phone or an ‘opt-in consent procedure’ where participants contacted the study team directly if they were interested in the study. Adaptations to the informed consent procedures were designed to support participants’ autonomy.

Support for data collection

A range of communication tools and strategies were used to facilitate research-related activities. It included the use of Talking Mats (https://www.talkingmats.com), a tool that allow the placement of graphic symbols on a visual rating scale displayed on a carpet mat. It was used to help participants with aphasia express their views. Similarly, ‘culturegram’ (www.Toolsfortalking.co.uk; 6), a talking tool, developed to provide a visual map or prompts for exploring preferences and identification relating to key elements of culture, such as family, language or religion, facilitated discussions around the experiences of Asian women with learning disability.

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[1] ability to understand, retain and weigh the information provided and communicate decision

For qualitative studies, data collection was mainly through observation and semi-structured interviews. Interviews followed informal or unstructured conversational formats, one-to-one or group discussions, and used a variety of open-ended questions, prompts, probes, visual cues, topic guide and supplementary questions. These methods were often combined and, in some instances, were created during collaboration[2] between researchers and participant groups, carers, family members or professionals. The use of supported conversation, incorporating short sentences with high frequency words, repetition and paraphrasing helped with comprehension during interviews with those with aphasia. Flexibility of the process allowed the use of note taking with participants with learning disability, who were not comfortable with audio-recorded interviews. Similarly, adults living with dementia were given options (e.g. email; post; in situ support) for completing study documents; in another study, shorter times and staged interviews were used to accommodate participants' preference, concentration, and time constraints. Participants could also attend interviews on their own, accompanied by a supporter (fellow participant, carer, family member) and sometimes in a group.

Points of corroboration

The review provides evidence that adults with capacity and communication difficulties can take part in ethically sound research [See Figure 3.4]. Adaptations and accommodations have been used variously to support both the assessment of capacity and participant decision-making in the recruitment process. Through these approaches, the autonomy of adults with capacity and communication difficulties and the route to research participation are enhanced. However, there was considerable variation in the researchers' interpretation of the provisions of the MCA (2005) and the accompanying guidance of the COP. For instance, the report of capacity assessment was inconsistent, with some studies adopting formal measures and others making it part of conversations during extended observation of potential participants. This would seem to indicate that there is no standard way of assessing capacity. The gatekeeper is attributed a pivotal role in gaining access to participants, which can facilitate or impede recruitment. Their interpretation of mental capacity for decision-making appeared to have influence over the recruitment of potential participants. Therefore, early engagement, information sharing and relationship-building with gatekeepers is important for researchers. There is evidence that a lack of capacity is used in exclusion criteria, when recruiting adults with capacity and communication difficulties, without appropriate assessments or adaptations in necessarily being in place.

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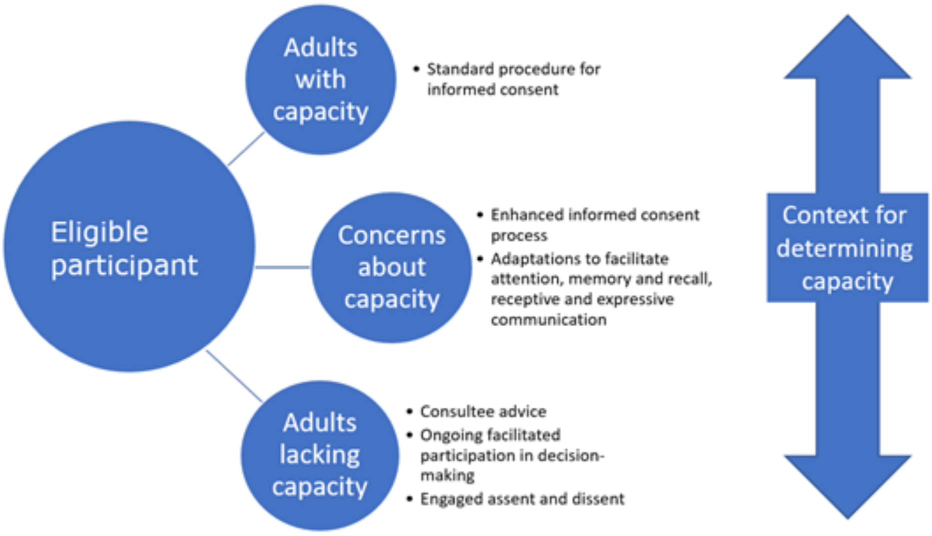
[2] ability to understand, retain and weigh the information provided and communicate decision

Figure 3.4 Including adults with capacity and communication difficulties in research



Ethico-legal Landscape: Conclusions

Protection of individual rights under the law through the relevant governance procedures formed the major content of the research guidance provided by the HRA, which is consistent with our findings on the COP, the operational document of the MCA (Heywood et al. 2019; Ryan et al. 2020). The law is sensitive to the enhanced vulnerability of adults who lack capacity for informed decision-making. Conversely, empowerment is addressed infrequently within the research guidance, which resonates comments from the House of Lords select committee (HL Deb 01.02.2005). In accordance with the legal test for capacity, a binary approach to mental capacity assessment is recommended, whereby a person is assessed to either have capacity or not (DfCA, MCA COP, 2007; Heywood et al. 2019; Keene, 2017; Jackson, 2013). However, fluctuations in capacity and how these affect an individual's eligibility to participate in research also requires consideration. The need for support is recognised in the MCA COP and some accommodations are advised in the supplemental HRA guidance. Exactly how they might serve the principles of determining and supporting an individual's capacity and communication is not explored (Heywood et al. 2019). Thus, the idea of joining efforts with others in order to achieve understanding, which is consistent within an empowering process (Rigaud, 2020) is largely neglected.

Although there was mention of capacity assessment within the COP (2007) in relation to decisions to take part in research, practical guidance to support researchers in this endeavour was absent. Furthermore, it neglected to discuss accommodations to support the assessment of capacity. As the outward-facing document of the MCA, the aim is to translate the technical provisions of the law. However, the COP's lack of practical guidance might explain why it has been poorly implemented (HL, 2004).

The HRA research guidance provides additional information on research under the MCA to support researchers dealing with participants who have capacity difficulties. However, the major emphasis is on formal governance procedures related to protection and risk management. The inclusion of incapacitous participants in research appears to be mainly linked to procedural aspects of the consultee process, with limited practical strategies for facilitating engagement and decision-making that is evidenced in the emerging use of assent in some areas of research, e.g. dementia (Batchelor-Aselage et al. 2014; Diener et al. 2013; Petryk & Hopper, 2009). More generally, within the research guidance, there was encouragement for providing a supportive context for delivering information by considering time, place and the development of dialogue with the individual. This suggests a more collaborative enterprise to information presentation where setting factors are considered in the promotion of individual understanding.

The question of how to empower potentially vulnerable research participants whilst also providing adequate protection remains. The connection between protection and empowerment of people with capacity and communication difficulties might possibly be served by general accommodations and tailored adaptations, which enable optimal understanding by participants whatever their capacity. Although the use of multiple media for presenting information was considered in the research guidance, such as 'Easy Read' for people with learning disabilities, little attention was given to the critical factors in language processing (Wilson & Sperber, 2012. Accordingly, advice provided on reasonable adjustments and practical ways of conveying information tended towards surface level features, e.g. making sentences simpler, and neglected deeper level features of vocabulary and meaning and the functions of communication.

Adults with capacity and communication difficulties can take part in ethically sound research but continue to be excluded based on a lack of capacity. If research with human participants is to move towards a more inclusive base for such individuals, there needs to be a deliberate, relevant and consistent approach to adaptations and accommodations in support of both the assessment of capacity and the decision-making process. For the researcher, this means engaging with participants, as well as the gatekeepers and familiar others in their lives who are possible sources of information and support to them. Traditional ways of obtaining informed consent are not appropriate for all, and there is a need to consider the non-traditional ways such as the process model of consent. Capacity is relative to a spectrum of decisions, exercise of capacity can be supported, and its assessment is context- and time-specific. While consultees can facilitate participation in research for those lacking capacity, autonomy through partial participation is possible and should be encouraged. Therefore, including people with communication and capacity difficulties in ethically-sound research is attainable, but requires a deliberate approach to devising ways of assessing true capacity and presenting study information.

The ethico-legal landscape for intrusive research in England and Wales points to a strong and enduring need for guidance that focuses on the researcher's efforts to promote the autonomy of the participant as far as possible, regardless of their assessed capacity. This includes skilful use of language for meaning construction and communication strategies for information retention and processing; deliberately addressing setting factors for promoting understanding and recall; and the use of a variety of media for representing and conveying information. These strategic accommodations might serve to mediate the apparent disconnect between protection and empowerment, enabling people with communication and understanding difficulties to have a voice in research.

Chapter 4. Current Practice (Stage 2)

The objective was to capture characteristics of the ethical review process by MCA-flagged Research Ethics Committees (RECs) and the views of key stakeholders, including members of Research Ethics Committees (RECs), researchers, adults with capacity and communication difficulties and their carers/supporters. The research questions were:

2.1 How are adults with capacity affecting conditions associated with communication difficulties represented and accommodated in research proposals?

2.2 How do current stakeholders in research evaluate ethical, legal and regulatory priorities in including/excluding adults with capacity and communication difficulties in research?

Representation & Accommodation

Aim

Our aim was to explore how people with capacity and communication difficulties are represented and included in research. With this in mind, we conducted a survey in three parts focusing on:

(i) Retrospective studies registered to the public database for the Health Research Authority in England and Wales since the implementation of the MCA (2005);

(ii) Prospective research applications to MCA-flagged Research Ethics Committees (RECs) in England over 12 months (September 2018-August 2019);

(iii) Participant information sheets (PISs) used with adults with capacity and communication difficulties.

Method

Retrospective survey

To overview the ethical review process since the implementation of the MCA COP (2007), a retrospective survey of studies was conducted.

Table 4.1 Study criteria

Studies were included that:	Studies were excluded that:
• focused on capacity affecting conditions including autism, Asperger, autistic spectrum condition or disorder; stroke, aphasia; learning or learning disability; dementia, Alzheimer's; mental health condition or disorder; acquired head or brain injury; • qualified as intrusive research; • were carried out in England and Wales.	• focused on significant others (e.g. carers, partners) associated with people with capacity-affecting conditions; • involved participants below 16 years of age; • qualified as clinical trials.

We used the public database of the HRA (https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/), which contains summaries of studies that have been carried out under the HRA research regulations. Keywords associated with capacity-affecting conditions were filtered using the following setting:

Research type:	Research Study
REC opinion:	All opinions
Date:	01/10/2007- 01/10/2017

The information was summarised in a prepared excel spreadsheet detailing: study titles, research summary, REC opinion (favourable, unfavourable, further information favourable, further information unfavourable) and duration of study. The studies were then organised according to the main research populations of interest: autism; learning disability; acquired brain injury; aphasia after stroke; mental health disorder; dementia. Percentage scores were calculated by population group, REC opinion and year of application.

Prospective survey

To capture ethical review processes of MCA-flagged RECs in England and Wales, we carried out a prospective survey (September 2019 to August 2020). The Health Research Authority (HRA) for England collated the data centrally using targeted fields in the online form of the Integrated Research Application System (IRAS) as shown in table 4.2.

Table 4.2 Targeted fields drawn from IRAS

Source	Content	Information Extracted
IRAS A 17-1	Inclusion criteria	Population types targeted for recruitment
IRAS A 17-2	Exclusion criteria	Exclusion criteria in relation communication and/or capacity
IRAS A 33-1	Information sheets	Provisions made to communicate project information with prospective participants
IRAS B10	Information & recruitment	Methods used with people deemed to lack capacity.
REC decision	• Favourable opinion with no additional conditions • Favourable opinion with additional conditions (further information) • Unfavourable opinion	
Additional conditions & recommendations	Relevant excerpt from REC feedback to applicant that details further requirements in the form of conditions to be met for a favourable opinion and advice to improve the research.	

Information for IRAS sections labelled A 17-1 and A 17-2 was entered into the Excel spreadsheet. Textual information under sections A 33-1 and B 10 was entered into a separate Excel spreadsheet and reviewed by a researcher. Summative content analysis was carried out (Hsieh & Shannon, 2005). Categorical themes associated with exclusion criteria and provisions made for people with capacity and communication difficulties were generated through review of the displayed content. The categories were then applied across the data. To manage any potential bias, all codings were reviewed by a second researcher. Any points of query were discussed until consensus was achieved. The listed 'additional conditions and recommendations' from RECs were inspected and categorised in a similar way.

Participant Information Sheets (PISs)

To establish practices in relation to the development and use of PISs, we analysed the presentational and linguistic features of an opportunistic sample. We contacted Chief Investigators who had completed an e-questionnaire on researcher reasoning (see p. 50), asking them to share their participant information sheets (PISs). This resulted in 31 PISs, of which 6 were excluded: 3 targeted parents or carers; 2 targeted people without capacity and communication difficulties; and 1 targeted a population of unclear determination. The final sample comprised 25 PISs (learning disabilities = 2; aphasia post-stroke = 8; dementia = 8; mental health disorder = 2; acquired brain injury = 1; autism = 0).

We reviewed each PIS and recorded key *presentational features* in a prepared Excel spreadsheet:

- the format (e.g. word document or PowerPoint);
- number of pages;
- images (use of pictures, source and use of colour, placement in document);
- typography (font point size and keyword highlighting);
- and layout (background features and textual organisation).

We assessed the *linguistic properties* using automated linguistic analysis software (Coh-Metrix) on all the PISs. This involved extracting and COPying the text content into MS Word documents initially. To ensure that the same automated rules were applied to all texts, we removed:

- all titles and sub-headings;
- information on contact details and REC approval;
- pictures;
- bullet points and numbering outside the text;
- proper nouns;
- use of extra spacing and indentations to text;
- columns;
- and inverted commas.

Descriptive statistics were extracted from the Coh-Metrix output, focusing on: quantity of words and sentences, vocabulary attributes (familiarity, concreteness, imageability) and readability scores. The readability statistics were then compared to the national reading age equivalent of the Flesch-Kincaid reading level.

Findings

Retrospective survey

The final sample comprised 1605 studies from 2007-17 with no studies identified prior to 2012. As shown in table 4.3, the number of studies on populations with capacity-affecting conditions rose incrementally each year. The highest number of studies focused on dementia (32%) and secondly on mental health (27%). REC opinions were largely favourable with 30% achieving approval after a first application and 65% after addressing REC recommendations. Around 5% received an unfavourable opinion with only 2 studies (0.1%) receiving an unfavourable opinion after address of REC recommendations.

Table 4.3 Retrospective survey (2012-2017): Summary of REC opinions and year of application by population group

Population Group	REC Opinion				Year of Application						No. of studies
	Favourable	Unfavourable	Further Info-Favourable	Further Info-Unfavourable	2012	2013	2014	2015	2016	2017	
Stroke & Aphasia	78	6	145	0	1	13	16	15	17	167	**229 (14%)**
Learning Disability	46	9	81	0	4	25	24	37	27	19	**136 (8%)**
Autism	32	8	66	1	0	16	24	32	20	15	**107 (7%)**
Dementia	160	24	329	1	2	80	100	124	123	85	**514 (32%)**
Mental Health	105	24	298	0	0	46	73	102	123	83	**427 (27%)**
Acquired Brain injury	58	4	130	0	1	31	37	51	39	33	**192 (12%)**
Sum	**479 (30%)**	**75 (5%)**	**1049 (65%)**	**2 (0.1%)**	**8 (0.5%)**	**211 (13%)**	**274 (17%)**	**361 (22.5%)**	**349 (22%)**	**402 (25%)**	**1605**

Note. Favourable: research approved; Unfavourable: approval dependent on address of conditions and recommendations subject to further review; Further information-favourable: satisfactory address of recommendations – research approved; Further Info-Unfavourable: Unsatisfactory address of recommendations – research not approved.

Prospective survey

After applying exclusion criteria, the final sample comprised 83 research applications to MCA-flagged RECs in England and Wales (September 2018 to August 2019). There was an increase in applications in September, November, December, and February. Of the total applications, 76 (91%) were first-time applications; 3 were re-submissions; 1 was an appeal against an unfavourable opinion; and 5 applications were unspecified.

The range and type of exclusion criteria in relation to capacity and communication difficulties cited in the proposals are summarised in Table 4.4. Capacity and communication were used either singly or in combination as exclusion criteria, with 41 proposals (49%) containing no exclusions in relation to capacity and communication difficulties. Of the identified exclusion criteria, a 'lack of capacity' was most frequently cited (25%) and attributed most frequently to dementia studies (n=14). Exclusion through 'limited English' was identified in 20% of the studies.

The use of consultees was low (n=5; 6%). However, procedures identified for checking the assent/dissent of participants was higher (n=15; 18%). This would seem to indicate that assent/dissent procedures were invoked, not only to supplement the consultee's role, but also on an ongoing basis with participants who were able to give informed consent.

The provisions put in place for the recruitment of participants with capacity and communication difficulties varied. Adaptations to information format and content of Participant Information Sheets (PIS) and consent forms were identified in just over half of the proposals (n=48; 58%) and included: simplifying the language content, adding pictures or graphic symbols, adoption of formats particular to the population such as 'aphasia-friendly', 'dementia-friendly', 'easy read', use of an audio version, use of proportional summary of information and augmented typographic prints (use of large font point size). The *mode of delivery* was identified (n=21; 25%), and included adopting a conversational manner, speaking slowly, using clear simple phrases, repeating information, using verbal and non-verbal expressions commensurate with the individual's style of talking. Use of *visual augmentation* (e.g. photographic and pictorial images as guides, magnification of visual information, use of colour and personalised pictures) was specifically identified in 7 proposals (8%). Procedural *flexibility* was cited in 12 proposals (14%) and covered increased time to process information, multiple and repeated explanations, use of a familiar setting for conveying information, communication with participant via telephone, use of different tools to support the presentation of information. In addition, flexibility regarding consent was identified in 4 proposals (3 dementia studies and 1 ABI study), which referred specifically to the need to reassess the individual's capacity for informed consent due to changes in condition. *Significant other support* referred to the involvement of persons familiar with the individual and included family members, carers and others (n=25; 30%). *Experienced personnel/specialist skills* was an identified asset in 17% of the studies (n=14) and referred to support from a clinician - well-versed in patient communication, an experienced researcher or one with bilingual skills, a speech and language therapist for people with specific communication difficulties or advice from a specialist day service. *Collaboration* included all forms of patient-public involvement that draw on the lived experiences of the study population through advisory and working groups (n=4; 5%). No specific provisions were identified in 6 of the studies (7%).

Table 4.4 Prospective survey: Characteristics of research applications (2018-19)

	Population-types						
	Aphasia (n=5; 6%)	Dementia (n=42; 51%)	Acquired Brain Injury (n=21; 25%)	Learning Disability (n=6; 7%)	Autism (n=4; 5%)	Mental Health (n=5; 6%)	**Total (N=83)**
Exclusion criteria relating to capacity and communication							
None	2	17	12	5	2	3	**41 (49%)**
Lack of capacity	2	14	3	0	0	2	**21 (25%)**
Communication difficulties	1	3	1	0	0	0	**5 (6%)**
Lack of consultee	1	8	1	0	0	1	**11 (13%)**
Limited English	2	13	0	0	1	1	**17 (20%)**
Other diagnosis	0	5	4	1	1	1	**12 (14%)**
Other	0	1	3	0	1	0	**5 (6%)**
Use of consultee and assent/dissent procedure							
Use of consultee	0	1	3	1	0	0	**5 (6%)**
Assent/dissent procedure	0	4	8	0	2	1	**15 (18%)**
Provisions made to support capacity and communication							
PIS format/ content	9	24	7	6	2	0	**48 (58%)**
Mode of delivery	0	3	14	2	2	0	**21 (25%)**
Visual augmentation	0	5	0	0	2	0	**7 (8%)**
Interpreters/ translators	2	19	17	4	0	2	**44 (53%)**
Significant other presence	3	18	2	2	0	0	**25 (30%)**
Flexibility	0	7	1	0	2	2	**12 (14%)**
Specialist support	3	7	0	0	3	1	**14 (17%)**
Collaboration	1	2	1	0	0	0	**4 (5%)**
Not reported	0	2	3	0	0	1	**6 (7%)**

There were 666 separate REC recommendations related to studies involving people capacity and communication difficulties. These were majorly concentrated on participant-facing documentation (PIS: n = 262, 39%; consent form: n = 52, 8%; consultee information sheet: n = 63, 9%). Recommendations focused on the PIS content and format, e.g. making the language simpler for the target audience, providing missing information, specific rewordings of segments and using an Easy Read format. A single reference was made to running a readability score on the text. ‘Procedures & Protocols’ accounted for 248 (37%) recommendations and related to content of study protocols, data collection tools and specific content of IRAS sections. There was a single recommendation for a procedure for participant oral consent. Collaboration with individuals who have lived experience (i.e. Patient & Public Involvement: 6; 1%) featured mainly in recommendations for acquired brain injury and dementia studies. ‘Editorial’ recommendations referred to proof reading of study documents. ‘No recommendations’ were given for 17 applications (3%).

Table 4.5 Prospective survey: Recommendations given by RECs on research applications (2018-19)

	Population-types						
	Aphasia (n=5; 6%)	Dementia (n=42; 51%)	Acquired Brain Injury (n=21; 25%)	Learning Disability (n=6; 7%)	Autism (n=4; 5%)	Mental Health (n=5; 6%)	**Total (N=83)**
Participant Information sheet	18	124	67	28	14	11	**262 (39%)**
Consent form	3	24	12	5	6	2	**52 (8%)**
Consultee Information Sheet & Declaration	3	29	21	5	5	0	**63 (9%)**
Procedures & Protocols	9	115	71	18	17	18	**248 (37%)**
Patient & Public involvement	1	1	2	0	0	2	**6 (1%)**
Editorial	1	5	9	1	1	1	**18 (3%)**
No recommenda-tions	1	10	5	0	0	1	**17 (3%)**

Participant Information Sheets (PISs)

Twenty-five PISs were collected from studies carried out between 2014-2019. The PISs focused on people with: dementia (n = 12); learning disabilities (n = 2); aphasia post-stroke (n = 8); mental health (n = 2); acquired brain injury (n = 1). People with autism were not represented in the sample. The majority of the PIS used an MS Word format (n = 22) with 3 using PowerPoint. Volume of pages ranged from 1-24 *(mdn = 4; mean = 5.3; SD = 4.6)*.

In terms of *presentational features*, images were present in just over half the documents (n = 14; 56%) and drawn from various sources. Of those displaying pictures, photographic images were most frequently used (n = 12; 86%) with line drawings used in 57% of the documents. Colour in images was favoured by the majority (n = 12; 86%). The placement of the images in the document varied both across the sample and within separate documents. Typography in use also varied in terms of font point size (less than 12: n = 10, 40%; more than 12: n = 15, 60%). Different techniques were used to highlight keywords including highlighting, emboldening, capitalising, and colouring. Layouts varied with some adopting tabular formats or a frame for the textual information or using block colours as backgrounds. The majority used sub-headings to break up the text (n = 23; 92%) with some also adopting organisational devices such as bullet points (n = 7; 28%) and

Table 4.6 Summary of presentational characteristics of PISs

Category	Item	Descriptors	n	(%)
Format	MS Word	Printed text	22	88
	PowerPoint	Slides	3	12
Images	Pictures	Present	14	56
	Type	Photos - unknown source	12	86
		Photo-symbols	1	7
		Line drawings	8	57
	Colour	Yes	12	86
		Black & white	1	7
		Mixed	1	7
	Placement	Right	0	0
		Left	6	43
		Bottom	1	7
		Mixed	7	50
Typography	Font point size	<12	10	40
		>12	15	60
	Keywords	Keywords highlighted	11	44
		Bold keywords	5	45
		Capitalised words	2	18
		Colour keywords	4	36
Layout	Background	Tabular	4	16
		Frame	2	8
		Colour	1	4
	Text organisation	Sub-headings	23	92
		Bullet points	7	28
		Numbers	5	20

Linguistic properties of words, vocabulary and readability revealed wide variations in the quantity of words used (*mean = 7542.2; mdn = 618.5; SD = 565; min = 48, max = 2396*). The length of sentence, (surface indicator of syntactic complexity), was also variable

(*SD=4.5; min* = *5.3, max* = *22.3*) with a central tendency towards 15-16 words per sentence (*mean* = *15.3; mdn* = *16.2*).

<u>Vocabulary</u> attributes showed less variation across the documents generally with closer Mean and Median scores. The attributes of 'concreteness' (words relating to things you can hear, taste, or touch) and 'imageability' (how easy it is to construct a mental image) achieved moderate scores (Concreteness: *mean* = *361.3; mdn* = *361.4*; Imageability: *mean* = *392.5; mdn* = *390.3*). 'Familiarity' (how recognisable vocabulary seems to an adult which aids speed of language processing) achieved high central tendency scores (*mean* = *573.9; mdn* = *573.7*).

<u>Readability</u> scores indicated a moderate level generally (reading ease: mean = 65.5; mdn = 67.7), which is roughly equivalent to scores of UK tabloid newspapers, e.g. the Daily Star (n = 66) (Williamson & Martin, 2010). Variation in scores indicates the presence of outliers (*min* = *2.3, max* = *85; SD* = *17*). The Flesch-Kincaid Grade Level scores (conversion of the Reading Ease Score to a U.S. grade-school level) was around 7 (*mean* = *7.6; mdn* = *7.3*) which corresponds approximately to a school-aged child of 11-13 years.

Table 4.7 Summary of language properties of PISs

Category	Attributes	Mean	Median	SD	Min - Max
Words & Sentences	Number of words (sum)	754.2	618.5	565	48-2396
	Number of sentences (sum)	45.6	41	29	7-123
	Words in sentences (mean)	15.3	16.2	4.3	5.3-22.3
Vocabulary [a]	Familiarity (100-700: unfamiliar-familiar) [b]	573.9	573.7	8.5	547.3-589.8
	Concreteness 1(100-700: highly abstract-highly concrete) [c]	361.3	361.4	12	338.7-381
	Imageability (100 -700: low imageability-highly imageability) [d]	392.5	390.3	11.3	373.4-415.5
Readability	Flesch Reading Ease (1-100: low-high reading ease)	65.5	67.7	17	2.3-85
	Flesch Kincaid (mean grade score) grade range=age range in yrs: 5=5-10yrs; 6-8=11-13yrs; 9-12=14-18yrs.	7.6	7.3	2.5	3.5-12

[a] *mean rating for each word derived from MRC Psycholinguistic database*

[b] *based on ratings for 3488 words*

[c] *based on ratings for 4293 words*

[d] *based on ratings for 4825 words*

Researcher Reasoning

As part of our endeavour to capture research practice regarding the inclusion of adults with capacity and communication difficulties in ethically-sound research in England and Wales we completed an online survey of researcher decision making involving this population.

Aims

Our specific aims were to: (a) describe researcher decision making when including or excluding adults with capacity and communication difficulties within research, and (b) outline the strategies, resources and accommodations put in place by researchers to support the involvement of this population within research (e.g. information presented via adapted text; pictorial support; video demonstration).

Method

Researchers, with experience of working with adults who live with capacity and communication difficulties, were identified as part of the prospective survey by HRA, followed up and invited to take part in the survey. One hundred and twenty-eight researchers from the United Kingdom agreed to take part in our online survey, delivered using Qualtrics. Sixty-seven percent of respondents identified as a woman. The majority of participants reported that they were white British/Irish (81%). Seven percent were Asian (Indian, Pakistani, or Chinese), and 2% reported they were Black (African or Caribbean). Finally, 10% said they were of another ethnicity. Sixteen percent of participants were aged between 25 and 34 years, 22% were aged between 35 and 44 years, 29% were aged between 45 and 54 years, while 33% were aged older than 54 years.

The research team constructed a bespoke online survey, drawing upon their findings from earlier stages of this project. Demographic information about each participant was collected, along with information about their experience of working within research and with adults with communication difficulties and/or capacity-affecting conditions. Questions about research experience with using the Mental Capacity Act were also presented, along with questions about the reasons for including or excluding adults with capacity and communication difficulties within research. A series of further questions were presented which aimed to capture a range of communication tools and accommodations used within research to support the involvement of this population within research. Finally, a series of open-ended questions and free text boxes were presented where researchers were asked for their further views and opinions about their use of the Mental Capacity Act and the inclusion of adults with capacity and communication difficulties within research settings.

Descriptive data from the closed questions were summarised and reported. Data generated from the open-ended questions and free text boxes were analysed using summative content analysis completed by two members of the research team (HR and PL) using NVivo Version 12. This analytic method was chosen as it allows for flexibility when analysing text data, and the aim was to generate further data to help address our aims. Both researchers independently read the answers provided which were initially categorised according to the topic associated with each question. Further categories were generated by each researcher independently based upon an understanding of key concepts. These were discussed together by the researchers over a series of three meetings until consensus was reached which involved combining and organising the categories further. The number of references within each category was reported.

Results

Fifty-two percent of the participants reported they had more than 10 years of experience working with adults with capacity and communication difficulties and/or capacity-affecting conditions, and 51% said they had been working in research for more than 10 years. The majority (50%) reported that they made use of mixed methods research, while 26% reported mainly using qualitative methods, and 24% reported that they used quantitative research methods. The most commonly used research designs were reported as an interview study (29%), followed by observational (22%), and questionnaire-based studies (21%). Laboratory (7%) or field (6%) experiments were reported as being used less frequently, followed by case study (4%) and case series (2%) designs. Nine percent of participants said they used other types of research designs. Considering public engagement in research, 34% reported that they had made use of co-production, while 39% engaged with service user groups, and 24% had made use of some community-based engagement. The most frequently indicated location of research activity was reported as within hospitals (29%), followed by the participants' own home (23%) or residential home (16%), the community (12%), university (12%) or other (6%).

Researchers reported that they targeted participants with dementia (38%) most frequently within their programme of research, followed by other conditions (17%), those with post-stroke communication difficulties (16%), mental illness (13%), learning disabilities (8%), autism (5%) and head injury (4%). Considering the nature of the capacity-affecting conditions or communication difficulties amongst those participants who had been included within research studies, dementia was again this most frequent (34%), followed by those with post-stroke communication difficulties (18%), other conditions (15%), mental illness (14%), learning disabilities (8), head injury (6%) and autism (5%).

Researcher Decision-Making about Inclusion and Exclusion

Considering the rationale for the inclusion of adults with capacity and communication difficulties within research, the most commonly reported reason (25%) given by researchers was that this group were the target population within the actual research study. The next most common reason for inclusion was to give this group a voice (16%) or to improve the quality of research (16%). Researchers also reported that they included this population for ethical reasons (12%), only those with capacity and communication difficulties could provide the data needed (11%), or to help ensure autonomy (6%) or for advocacy (4%). Seven percent of the responses to the question about the rationale for the inclusion of adults with capacity and communication difficulties were “not applicable” suggesting that some researchers did not have experience of including this population within research studies.

Considering the rationale for the exclusion of adults with capacity and communication difficulties, the vast majority of researchers (64%) indicated that the question was ‘non-applicable’ suggesting that they did not have a previous rationale for excluding this population from research. For those who had excluded this group from research, the most frequently indicated reason was because adults with capacity and communication difficulties were unable to provide responses to questions (10%), followed by research participants being unable to provide consent (8%), another reason not listed (7%), being unable to meet the requirements of the MCA (4%), or due to a lack of funding, training, resources or time (combined at 7%).

Knowledge, Strategies, Resources, and Accommodations

Fifty-eight percent of participants agreed that their knowledge and understanding of the MCA was very good or excellent, while 26% thought it was good, 10% thought it was fair, and 6% considered it to be poor. Eighty percent agreed or strongly agreed that they were confident working with a consultee, while 10% neither agreed or disagreed, and 10% either disagreed or strongly disagreed that they were confident working with a consultee.

Considering the use of communication tools when working with adults with communication difficulties and/or capacity-affecting conditions, 24% of responses were that these were not used by researchers, followed by the use of easy read information (21%), or other types that were not listed within our survey (21%). Sixteen percent of the responses indicated the used of hand and body gestures as a communication tool, while 13% indicated the use of easy text. The responses indicating the use of audio, British sign language, video, translators and interpreters ranged from 1 to 2%. No one reported that they used Braille. The most frequently endorsed accommodation used by participants was being flexible (23%), followed by enquiring about the needs of research participants (22%), offering regular breaks (19%), giving the participant the choice of location when arranging to meet (18%), making use of alternative communication (14%) or another accommodation not listed within the question (4%).

Summative Content Analysis

The findings from our further analysis of open-ended questions and free text boxes using summative content analysis are found in Table 4.8. There were six key semantic categories: (a) knowledge and understanding the Mental Capacity Act, (b) confidence including adults with capacity and communication difficulties in research, (c) confidence in working with a consultee, (d) understanding of the role of a consultee, (e) confidence in assessing capacity within research, and (f) other comments.

- *Knowledge and Understanding of the Mental Capacity Act*

Researchers most frequently referred to the use of the Mental Capacity Act within clinical settings. There was reference to learning about the Mental Capacity Act within training and personal study, and several instances where participants referred to having received teaching about the Act, including its use within research settings. There were seven references to having a limited knowledge about the Mental Capacity Act. There were further references to having learned about the MCA from working with others who are experienced in the use of the MCA.

- *Confidence Including Adults with Capacity and Communication Difficulties in Research*

The most frequent references were about experience of having included this population within research studies, and there were seven instances where participants indicated that they felt confident working with this population, while a few indicated that they felt they required training, or had limited confidence. Some participants indicated that they drew on the support of a multidisciplinary clinical team to help support inclusion, while there were other references about having to exclude this population from research, including comments about barriers associated with inclusion (e.g. it is extremely difficult to get an ethical opinion). There was one instance where it was mentioned that it was important consider that communication difficulties are not the same as difficulties with capacity.

- *Confidence in Working with the Consultee*

Participants indicated that they were confident in working with the consultee within the open-ended questions and free text boxes, but at the same time, others indicated that they were inexperienced or did not understand the question, suggesting that some of our respondents were not experienced with working with a consultee. There were two references to difficulties with identifying a personal consultee, and one instance where the researcher stated that they did not work with a consultee because participants who lacked capacity were excluded from their study.

- *Role of the Consultee*

There were 46 references within the responses to the open-ended questions and free text boxes indicating that the role of the consultee was understood correctly. However, there were also 26 references indicating that this was not correctly understood and 8 references to suggest that the role was confused with advocacy or a best interest meeting. Other examples indicating the role was misunderstood included comments that the role of consultee was to improve communication, work on co-production, make decisions about treatment, or to act as an independent arbitrator. There were 12 references to indicate that the role was partially understood. This included giving advice to researchers about what might be in the best interests of a person without explicitly taking their wishes and feelings into account about taking part in a study as if that person had capacity to make such a decision.

- *Confidence in Assessing Capacity within Research*

There were 15 references indicating confidence with assessing capacity in clinical settings. Notably, there were seven references to indicate that researchers did not see the assessment of capacity as their responsibility, and this was something decided by clinical staff. Some mentioned the importance of making use of the multidisciplinary team when assessing capacity. Some of the participants who responded to the open-ended and free boxes indicated that they felt confident, while at the same time, there were two references to being not confident. Some noted that the assessment of capacity is meant to be decision-specific, and there are sometimes difficulties with translating the principles of the Mental Capacity Act into practice.

- *Other Comments*

The most frequent references within this key semantic category were comments about the importance of working to support the inclusion of adults with capacity and communication difficulties in ethically-sound research, along with references to some of the barriers to inclusion. This included challenges of gaining a favourable ethical opinion which was discouraging, a sense that the MCA discourages the inclusion of those who lack capacity from research studies, excessive paperwork, and difficulties with sourcing a consultee in good time. Several references were categorised as focused upon exclusion of this population from research due to participants lacking capacity to decide to take part in research, while others commented about their personal experience related to the inclusion of this population within research. There were also some references to the importance of further training and support about the Mental Capacity Act. There was a single referent that the current guidance about the use of the MCA in research is clear.

Table 4.10 Summary of content analysis (n = number of references)

Nodes	n	Nodes	n
Knowledge and understanding of the MCA		**Confidence working with a consultee**	
Within Clinical Settings	27	Has experience of consultee process	7
Within Research	11	No experience of consultee process	6
Training and personal study	10	Did not understand our question	2
Teaching others about the MCA	4	Difficulties identifying a personal consultee	2
Clinically	4	Not relevant to research project	2
Research-focussed	2	Worked with consultees in clinical practice	1
Personal experience with family member	1	People lacking capacity were excluded	1
Rarely use the MCA	1		
Level of knowledge and understanding		**Role of the consultee**	
Limited	7	Unable to answer our question	7
Good	1	Consultee process is challenging	3
Familiar with research provisions	1	*Description of consultee role*	
Has improved over time	1	Correctly described	46
Worked with colleagues who know the MCA		Incorrectly described	26
Clinical settings	4	Sees consultee as an advocate	8
Legal settings	1	Partially described	
		Partially describes role correctly	12
Confidence including adults with CCDs in research		Confused with best interests meeting	9
Inclusion of adults with CCDs is important	10		
Work with and seek advice from an MDT	5	**Confidence assessing capacity within research**	
Common to exclude adults with CCDs	4	Seen as part of clinical role	15
There are barriers to inclusion	3	Other’s responsibility, usually clinical staff	7
Communication impairments does not mean impaired capacity	1	Would seek Support from MDT	4
Broad range of impairment	1	Tools to support assessment (e.g. checklist)	3
Experience working with adults with CCDs		Confident because of training	2
Experienced in clinical settings	4	*Confidence*	
Experienced in research settings	1	Confident	7
Confidence		Limited confidence	2
Confident	7	Dependent on individual being assessed	2
Required training	3	*Assessment issues*	
Limited confidence	3	Assessment is decision-specific	2
		Translating MCA principles is unclear	2
Any other comments			
Support for inclusion	14		
Barriers to inclusion	14		
Exclusion of adults with CCDs	6		
Personal experience of relative who lacks capacity	5		

Importance of training, research experience and appropriate support	2
Multifaceted methods of communication	1
Current guidance is clear	1

Note. capacity and communication difficulties = CCDs

Stakeholder Views and Opinions

We carried out qualitative semi-structured interviews of stakeholders in research in order to explore their underlying values and reasoning in relation to research, and to provide context for data collected in the questionnaire survey. The stakeholder groups were Research Ethics Committee (REC) members (Chair, professional and lay members), researchers from health and social science disciplines, practitioners, gatekeepers and supporters of adults with capacity and communication difficulties, and six different service user groups that live with capacity and communication difficulties (people with learning disabilities, autism, aphasia after stroke, head injury, dementia, mental health disorder).

Methods

Within the target stakeholder groups, we recruited a purposive sample, using maximum variation sampling. Particularly within the service user group, we wanted to ensure that the voices of each of the service user groups was represented. Therefore, we intended to recruit 8 from each of the stakeholder groups, and 8 from each of the service user groups.

Topic guides for semi-structured interviews were developed through collaboration between the research team and the Working Group. The interviews asked people's experience of research, their views on the inclusion or exclusion of adults with impairments in capacity and or communication in research, their views on the consultee process (Mental Capacity Act (MCA) 2005). Researchers and REC members were additionally asked about their experience of using the MCA Code of Practice.

Participants were recruited in the following ways: REC members were recruited through the publicly available contact details for RECs. Members of REC committees were sent a letter of information inviting them to contact the project. Researchers were recruited from among the Principal Investigators whose studies were reviewed as part of the prospective survey. Practitioners, gatekeepers, and supporters of people with capacity and communication difficulties were recruited through the organisations advising Project ASSENT and their networks. People with capacity and communication difficulties were recruited through organisations supporting people from the different service user groups. Once permission had been given by support organisations, Project ASSENT team members attended group meetings to provide information about the project in accessible formats. This included a presentation and an opportunity for discussion about the project and for the groups questions to be answered. People could ask to speak to a member of the research team to have their questions answered in a way that was accessible for them, for example, using supported communication techniques with people with aphasia. The Project ASSENT team made it clear that not everyone who expressed interest in being part of the project, would be able to take part, as we wanted a varied sample. Variation sampling using a sample matrix took into account age, gender, role on committee (REC members), discipline (researchers, practitioners). Those who expressed interest in taking part in the study were provided with written information about the project which was prepared in a range of versions including easy text, easy text with pictures and audio. Potential participants picked the version that best suited their communication and / or cognitive needs. Project ASSENT team members then went through the information sheets with potential participants using supported communication techniques as needed, before consent was provided.

Interviews were conducted as appropriate to the needs of the participant and the participant had the opportunity to choose what would support their inclusion and participation in the interview, including what would support their communication and make them feel most comfortable (for example, having an interview face to face, over the telephone, or held in premises used for services to the service user groups). Consent was confirmed at the start of the interview and time was taken to discuss what helped the person to communicate, for example, if it was useful for key words to be written throughout the interviews. These were then used throughout the interview. In addition, interview materials were prepared in different formats which could support participant's needs, for example pictures of key concepts, key words on pieces of card or interview questions written. Interviews were recorded using audio recording or when needed, interviews were video recorded, so both verbal and non-verbal communication and communication aids could be captured.

Interviews were transcribed and transcriptions on word documents imported into NVivo data management software in preparation for analysis. Thematic analysis (Braun & Clarke, 2013; 2012) was conducted by two researchers. Whole transcripts were read to become familiar with the discourse and to identify key ideas and concepts, which were noted at this point. The two researchers met to compare and agree recurrent themes from which were developed the basic themes. In NVivo 'nodes' were created for these themes. Transcripts were reviewed and relevant content assigned to the nodes. The content of each node was reviewed. The two researchers further negotiated until consensus was reached on categorisation. The themes were reviewed for interconnections and grouped under organising themes.

Table 4.8 Summary of stakeholder groups and participants

Stakeholder group	Number of participants
REC members	8
Researchers	8
Practitioners, gatekeepers or supporters	6
Aphasia after stroke	9
Autism	8
Head injury	7
Dementia	5
Learning disability	8
Mental ill health	2
Total	61

Adults with capacity and communication difficulties

Participants were clear that they should be included in research for the quality of the research, in order for research to have a more comprehensive picture and range of opinions, and for research to improve understanding of the various conditions. There was a clear sense that talking to people with the actual condition/experience relevant to the research would give a better picture of the experience. A number of participants expressed the view that research not involving people with capacity and communication difficulties would be flawed or partial. The potential of research participation to give a voice to groups of people was also seen as an important reason to involve them as research participants.

As well as improving the research, there were also perceived benefits for individuals themselves taking part in research. Many participants spoke about the altruistic feeling of helping others and being pleased to do so. For many taking part in research was a positive experience including feeling a sense of achievement and of being useful, increasing confidence and for two participants an improvement in their condition directly attributed to taking part in the activities associated with a research project. Those participants who had previously taken part in research had been motivated by the importance of the research and their interest in the research topic.

Participants asked about the impact of excluding adults with capacity and communication difficulties from research expressed anger, a sense of being ‘disregarded’, ‘locked out’ and that their issues would not be recognised. It was described as ‘discrimination’. There was a sense that to be left out of research increased invisibility associated with some disabilities, with one person going so far as to equate this with a lack of democracy.

Adults with capacity and communication difficulties participants expressed the view that people who can’t communicate are thought not to understand, and also are not noticed.

There was a view that there is discrimination against people with autism. Some participants thought researchers might assume that it would be much more difficult to involve adults with capacity and communication difficulties and so would exclude them. Alternatively, they may think adults with capacity and communication difficulties would not want to be involved because research would be ‘boring’ whereas this would often not be the case. There were challenges to participation related to particular conditions, such as depression or fatigue following stroke. One person also spoke about the potential hurt of remembering difficult experiences and ‘going over things’. Others talked about the challenges of taking part in light of understanding difficulties and the need to ‘work harder to really get to the nub of what you’re about’.

About half of the participants had not heard of the MCA (2005). For those who had there was more familiarity of it in relation to health and care rather than research. Participants had views about the consultee process. Around a third of participants were not comfortable with the process, but for others it was seen as beneficial if it meant more adults with capacity and communication difficulties could be included in research. Participants said they would want to be involved as much as possible in the process and that the consultee should be someone who knew them well, although this was not necessarily straightforward.

A key message from adults with capacity and communication difficulties participants is that researchers should not assume they don’t want to take part in research, for many it is important to have the opportunity to be altruistic. The enterprise of research will be flawed if Adults with capacity and communication difficulties are excluded and their needs and experiences not reflected.

Participants had a lot of advice on accommodations that could support the participation of adults with capacity and communication difficulties in research, and these are shown in table. 4.9.

Table 4.9 Suggested positive practice for optimal inclusion

Including and/or supporting adults with capacity and communication difficulties in research participation
Check in on participants throughout participation
Consider individual needs
Delivery of information *Breaking down words* *Concise information* *Explain the information* *Having the information read out loud to me* *Information in plain English* *Sign language* *Speaking clearly* *Speaking slowly* *Use of communication cards or pictures* *Use of 'Easy Read'* *Use of gestures, body language* *Use of hand-outs* *Use of technology* *Text to speech technology* *Use of PowerPoint to break information into smaller chunks*
Early intervention speech and language therapy
Environment *Be aware of distractions* *Flexibility with location* *Making the participant feel comfortable*
Feedback from previous participants
Interpersonal skills *Being friendly and welcoming* *Check you have understood what the person is trying to say* *Eye contact* *Gaining rapport* *Listen* *Patience*
Involvement of supporter *Different perspective from supporter* *Involvement of multiple supporters*
Remembering additional information about the participant
Research 'buddy'

  - *Support with paperwork*
  - *Supporting communication*
  - *They know the participant*
- *Meetings*
  - *Group setting*
  - *Helpful to know others in the group*
  - *Important to engage all members of a group*
  - *Meeting in person*
  - *Meeting one-to-one*
  - *Pre-meet and de-brief*
- *Researcher experience and training*
- *Time*
  - *Flexible with time and date*
  - *Flexible with time of day*
  - *Giving the participant extra time*
  - *Giving the participant notice about the research*

REC members and Researchers

Interview respondents were required to combine and articulate their understanding: i) of the law as it applies to the participation in research of adults judged to lack capacity; with ii) research design and methodology and iii) contemporary ethical standards.

There was variation in the ability of REC and researcher participants to reflect upon their experiences and articulate the views on the inclusion of adults with capacity and communication difficulties in research, the laws and ethical standards that govern this and the accommodations that need to be put in place support the inclusion of this group in research. Moreover, some respondents had a fuller and more accurate understanding of section 30-33 of the MCA, than others. In general, however, respondents understood the notion that capacity is decision specific, and that where a person lacks the capacity to make an autonomous decision, a consultee should be involved in the process.

Both the MCA and the COP give little consideration to just how diverse an activity research is. Variously, research we found, could be focused on bio-medical outcomes as opposed to service (re)design and the patient experience. Research might involve a single intervention or multiple interventions over time; be based in a hospital or in the community; it might be well-funded or undertake as a student project. All these variations were thought to have a significant impact on how sections 30-33 of the MCA were being implemented.

REC Member respondents tended to think that applicants had grasped the fundamentals of the MCA, although their own understanding of the MCA was weak in some instances.

Areas of weakness included responses to fluctuating capacity; difference between personal and nominated consultees and provisions for urgent decisions.

The COP was not a well-used resource. The inclusion of persons in research who lacked the capacity to give or withhold consent was seen as a morally good. Only a minority of respondents appreciated that the MCA's criteria for their involvement, turns, in part, on the belief that research of comparable effectiveness cannot be carried out without their involvement (s.31 (4)).

The views of the researchers were very much tied to their own sphere of research. As a group they had a understood the fundamentals of the MCA with respect to decision specific capacity and the use of consultees. Where experience and understanding varied, this was due to whether their research tended towards the biomedical as opposed to services and/or the patient experience. Bio-medical researchers working in hospitals seemed to have both a better understanding of the MCA and an easier time recruiting personal consultees who could be approached at a patient's bedside. In contrast, researchers investigating services and/or the patient experience, appeared to have a harder time with ethics committees – disagreements over the (in)capacity to consent and (in)capacity to participate – and recruiting consultees in residential community settings where support staff might have little understanding of either research or the MCA.

There was general presumption that adults with capacity and communication difficulties should be included in research. This presumption was based upon the belief that such populations had something of value to contribute; they could broaden the relevance of the research and being involved brought with it psychological benefits. There was widespread commitment to the idea that information sheets should be presented in an easy read format. Less evident was a commitment to the full range of methods, outlined in the COP, for supporting people to make autonomous decisions. Similarly, there was little awareness that even where a consultee is involved, the person concerned should be supported to take part in the decision-making process. The idea that information sheets should be made "easier to read" was well understood by all respondents, although there was some criticism of the HRA for being overly focused on written information and the use of signatures. Only a minority of respondents appeared to understand that under the MCA people should be actively supported to make autonomous decisions (all practicable efforts) and that where a person is judged to lack capacity he or she should still be involved in the decision-making process.

Opinion was divided on the degree to which an assessment of capacity should be undertaken by clinicians, possibly using a standardised instrument, or whether it was a less formal process, a "quick chat" and did not require those performing it to have a clinical background.

The MCA's four prong definition of capacity came-in for some criticism for not being an accurate representation of how people really made decisions.

Practitioners, supporters and gatekeepers

Most participants thought it was wrong that adults with capacity and communication difficulties were excluded from research as then assumptions are made about their experiences which are not accurate. There should be more attempt to make research participation accessible. For example, research approaches could be more engaged and make more use of observation of people's everyday lives. One to one support helps people to take part.

Some participants were not familiar with the MCA consultee process. Several supporters felt they wouldn't want to speak for someone else. There was a view that researchers were inclined to err on the side of caution. Not all 'gatekeepers' saw themselves as such but made judgements about research that is 'badly run' or 'using' participants and not passing on information to service users. Others were proactive in seeking research opportunities for their group. Researchers assessing capacity should have the communication skills to be able to adapt the information to the individual.

Current Practice: Conclusions

The inclusion of adults with capacity and communication difficulties in ethically-approved research has risen incrementally in the period since the introduction of the MCA (2007). This suggests a growing confidence amongst researchers navigating the requirements of the review system, although people with capacity and communication difficulties continue to be excluded. There is a possible tension between meeting the ethico-legal requirements necessary for a 'favourable opinion' and accommodating the processing capacities of potential participants effectively. Currently, accommodation of capacity and communication difficulties is defined mainly by objects that can be reviewed, such as informational documents to support decision-making. The implication of such a narrow view is that critical strategies that support inclusion are neglected. A more nuanced approach to the recognition and accommodation of capacity and communication difficulties is needed, both for the researcher and the reviewers, that moves beyond participant-facing documentation towards the real-world context for information sharing and decision-making.

Researchers responding to our questionnaire recognised the importance of people with capacity and communication difficulties having a voice in research and certainly there appeared to be a willingness to include them in research. Whilst over half of our respondents felt they knew and understood the MCA (2005) well and were confident in working with consultees, despite some confusion between the consultee's role and use of 'best interests'. Most references were made to the clinical setting and not research provisions. The need to gain a favourable ethical opinion and the challenges this presented were clear. In addition, a need for training in relevant approaches to support and accommodate people with capacity and communication difficulties was identified.

There was agreement across stakeholder groups that adults with capacity and communication difficulties should be included in research. It is notable however that adults with capacity and communication difficulties themselves prioritise not only the benefits for sound research that is built on accurate understandings of the needs of adults with capacity and communication difficulties, but also the opportunity for altruism, making a contribution to society, that research participation offers. This was not raised by other stakeholder groups, even though there was some recognition that taking part in research could be a positive experience that adults with capacity and communication difficulties should not be excluded from.

It appears the extent to which the provisions of the MCA (2005) act as facilitators, or indeed barriers to involving persons at risk of lacking the capacity is open to question. How is the ratio of potential benefit to risk assessed and managed for persons with capacity and communication difficulties? Obscurity in the provisions might possibly lead to an overly restrictive attitude in considering whether or not to include people with capacity and communication difficulties, which might affect researchers, REC members and significant others performing the roles of gatekeeper or supporter.

Chapter 5. Conclusions & Recommendations (Stages 1 & 2)

The ethico-legal landscape for research in England and Wales is informed by the MCA (2005) and the Code of Practice (2007). The MCA's concern for people who lack capacity is largely focused on treatment, welfare and financial decisions, with additional provisions for research. We found the research provisions to be poorly drafted and lacking an appropriate balance between protection and empowerment. The COP (2007) provides some elucidation of the technical aspects of the MCA, including formal governance procedures related to protection and risk management. However, the ethical approval process appears to place contrasting obligations and expectations on different parties (e.g. MCA REC members, researchers, consultees), which may blur the allocated responsibilities and the formation of ethical opinions. Generally, there was a noted lack of strategic and practical guidance to support the execution of responsibilities. We found relatively few studies linked to the MCA and featuring adults with capacity and communication difficulties. Sporadic use of consultees and the stated exclusion of adults with capacity and communication difficulties indicates that this group continue to be under-represented in research. The complexities of balancing protection with empowerment may cause researchers to err on the side of caution and exclude incapacitous individuals.

Our review of current practice revealed that, although incapacitous individuals were included in research because of their presence in the target population, exclusions continue to be made on the basis of a lack of capacity. Where participants with capacity and communication difficulties are included, researchers use a range of materials, resources, and procedures to support their understanding of the planned research. However, the majority of recruitment procedures seem to involve the use of some form of documentation to convey project information. Furthermore, the accessibility value of such resources in terms of the language content and presentational features to augment meaning is inconsistent. Researchers recognise that people with capacity and communication difficulties need to be represented in research. However, despite growing confidence levels in researcher understanding of the MCA, insecurities persist. There is confusion around the different provisions for research as opposed to those applied to the clinical setting. Furthermore, researchers express perceived difficulties in getting an ethical opinion on their research, which might be attributed to apparent inconsistencies in the review process conducted by MCA approved RECs. The use of consultees is variable across our populations of interest, i.e. adults with learning disabilities, autism, dementia, acquire brain injury, aphasia after stroke and mental health disorders, and a source of some confusion to researchers regarding the responsibilities and obligations of the role.

Where a consultee is involved in giving advice on the individual’s likely wishes and feelings about participation, there appears to be minimal recognition and report of the active involvement of incapacitous participants in decision-making as far as their abilities allow.

Ultimately, for people with capacity and communication difficulties to be represented in ethically-sound research, it requires consideration of:

1. How well the Act is understood by researchers and REC members;
2. The willingness of researchers to implement the Act in the field;
3. The ability of researchers to manage uncertainties over who can undertake and what constitutes a capacity assessment;
4. The ease with which consultees can be identified and approached;
5. How personal autonomy is recognised in all its gradations, from informed consent/refusal (the decision made by a person deemed to have legal capacity), through degrees of engaged assent or dissent (the person’s active dis/agreement to something through a process of interaction), to passive dissent (lack of observable response or extreme passivity).
6. A wide range of practical strategies and resources that serve to endorse the greater agency of individuals;
7. Access to training and practical resources to support inclusive practice in research for all stakeholders in research.

Recommendations from Stages 1 and 2

1. Promotion of researcher-participant cooperation

The system for developing, reviewing and conducting ethically-sound research that includes adults with capacity and communication difficulties would benefit from redefining. This requires promotion of cooperation between a researcher and a participant such that empowerment is recognised within a system that protects. A renewed emphasis on seeking positive assent from a participant, may be a more desirable method of guaranteeing greater emphasis on supported decision-making.

2. Support for participant autonomy

There is a strong and enduring need for guidance that focuses on the researcher's efforts to promote the autonomy of the participant as far as possible, regardless of their assessed capacity, and even where a consultee is involved, with specific attention to strategic adaptations and accommodations that enable people with capacity and communication difficulties to have a voice in research.

3. Use of a full range of adaptations & accommodations

Researchers and ethics committee members need to be better informed about the full range of methods to support people to make autonomous decisions so they can advise applicants seeking ethical approval for their research. The researcher needs to make sure that the conditions are right for person to use their available skills as far as possible, to understand information, to retain and weight it up, and finally, to communicate their decision. Traditional ways of obtaining informed consent are not appropriate for all, and there is a need to consider alternative processes.

Stakeholder Implications

The recommendations from Project ASSENT are interlinked. Combined, they have implications for the different stakeholder groups who are brought together in a planned series of actions and interactions in research endeavours.

Researchers

During the various phases of proposal development, community engagement, participant recruitment and research administration, the researchers need to:-

- Dedicate time to the advancement of researcher-participant cooperation. Early engagement with potential sites and populations support orientation to and familiarisation with the places where potential participants live and work. The researcher is afforded opportunities to understand the rhythm of everyday life in the settings such that researchers and research can be introduced with minimal disruption. This process of orientation and familiarisation is critical to a research culture of cooperation.
- Be open to learning from the main actors in the research setting. By observing, asking questions and listening the researcher is helped to develop materials and interaction skills that are useful with potential participants. Conversations with significant others (e.g. carers, support staff, marital partners and other family members) may serve to inform the researcher of the optimal ways of communicating with individuals.
- Recognise the agency of all participants. Regardless of an individual’s capacity for informed consent and the deployment of consultees during recruitment procedures, the researcher’s actions need to support the participant’s self-expression. This means the early recognition of an individual’s particular form of expression to indicate their assent or dissent to a proposition. Furthermore, if agency is to be recognised it needs to be recorded and responded to appropriately. Thus, a participant’s negative response to the start of a data collection session might prompt its cessation at this point in time.
- Develop and use an array of adaptive resources and accommodating participant needs. In order to develop and carry out research that is inclusive of people with capacity and communication difficulties, the researcher needs to have access to a comprehensive set of augmentative and alternative communication methods. This should include accommodations that go beyond adapted textual information on paper. The starting point needs to be the co-construction of communication to which both researcher and participant contribute so that meanings are developed and shared. This demands consideration of: contextual factors; language to be used (e.g. vocabulary, sentence structure); media for carrying messages; and their authenticity (e.g. consultation with persons with lived experience).

REC Members

During the review of IRAS forms, research proposals and protocols submitted by researchers, the members of the assigned REC need to:-

- Consider how the engagement and communication needs of people with capacity and communication difficulties are accommodated. This applies to potential participants who are able to understand and retain project information, weigh up the implications of participation, and communicate an autonomous decision, as well as those who are considered to lack capacity for this purpose. Such considerations depend on the availability of adaptations and accommodations to understand and weigh up the research and any implications for themselves. It is incumbent on REC members to check that appropriate provisions are in place such that recruitment strategies feature a range of adaptations and accommodations, and participant autonomy is upheld.
- Check arrangements for supporting a continuum of decision-making. In circumstances where a personal or nominated consultee is involved to give advice on the person's likely wishes and feelings regarding participation, there needs to be a plan for engaging the actual person. This needs to run throughout the relevant research period providing opportunities for: engagement with the research being proposed; self-expression of their wishes and feelings; and recognition of the person's expressed assent and dissent.
- Draw on relevant expertise for addressing capacity and communication needs. RECs may wish to consider having a member with recognised expertise in order that adaptations and accommodation may be reviewed effectively. Of course, people with lived experience may offer some insights. However, there is a potential place for expert knowledge that might implicate certain professional roles, e.g. speech & language therapists; clinical psychologists.

Supporters, Practitioners and Gatekeepers

Significant others, e.g. someone who is known to the person, may be a source of relevant and useful support. Indeed, they may act as gatekeepers – permitting access to potential participants and facilitating opportunities for sharing project information. The gatekeeper needs to:-

- Facilitate meetings between the researcher and potential participant(s). This demands neutrality in terms of any personal agendas that might be held by the gatekeeper in relation to the proposed research. The gatekeeper works to ensure that the autonomy of the individual is upheld and that suitable opportunities are arranged for the person to receive information about the research and to express their wishes and feelings.
- Consider how best to help people to engage with research. This requires facilitation on a practical level so that information about a project may be shared using

communication resources that support the individual’s understanding. In addition, ongoing opportunities may be arranged for participants to re-engage with project information and to be reminded of what research participation means.

Adults with Capacity and Communication Difficulties

The partnership between researcher and participant is at the centre of research participation. Regardless of their capacity and communication difficulties, and whether or not a consultee is involved, the person needs to:-

- Experience meaningful communication opportunities. These are the offer of interactions that enable individuals to use their available skills. This means that adaptations and accommodations are in place. Much as the use of ramp enables a person in a wheelchair to access a building with steps at the entrance, so the use of communication ramps provides entry points to a conversation about a project. Meaningful communication opportunities mean there is consideration of contextual factors, language content, media for conveying messages; and the authenticity with which adaptations and accommodations are developed. Thus, project information needs to move beyond text and pictures on paper towards a range of resources used in supported conversation
- Have a voice in decision-making about their research participation. A consultee’s advice on the likely wishes and feelings of an individual should not be an end in itself. The person’s self-expression in relation to project information, is the real test of their ‘likely wishes and feelings’. Ultimately, the more opportunities there are for adults with capacity and communication difficulties to engage with researchers and participate in research, the better chance there is of having their voices heard.

Chapter 6. Strategic Development (Stage 3)

The objective was to establish a structured, evidence-based guidance on involving adults with capacity and communication difficulties in ethically-sound research. We aimed to develop guidance that is of relevance to the research community and wider society, and also enhances the existing MCA COP. The research questions were:

3.1 How, if at all, can the COP be enhanced at a functional level to encourage participation of adults with capacity and communication difficulties in research?

3.2 Could an assent-based approach that is conceptualised on the basis of structured evidence, resolve ethical and practical barriers to the inclusion of adults with capacity and communication difficulties in research?

3.3 How useful is a Re-usable Learning Object in helping RECs and researchers to adopt an assent-based process to accommodate adults with capacity and communication in research?

Method

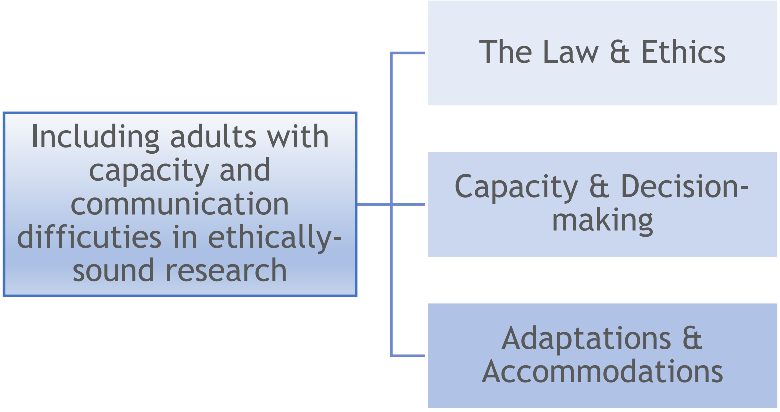
Based on a synthesis of the findings (objectives 1 & 2), we conceptualised a continuum of decision-making. To this end, we adopted a contextualist grounded theory approach (Braun & Clarke, 2006), whereby the findings arising from Stage 2. Current Practice were mapped to the findings emerging from Stage 1. Ethico-legal Landscape. We identified the critical factors considered to support the inclusion of adults with capacity and communication difficulties. Our target audience was defined to include researchers at all stages of their career and members of research ethics committees.

The strategic development of guidance was underpinned by key recommendations that emerged from the data analyses in Stages 1 and 2, namely:

- promotion of researcher-participant co-operation;
- researcher-participant cooperation; support for participant autonomy; and
- use of a full range of adaptations and accommodations.

Accordingly, the content was defined in correspondence to the findings and organised in three key domains as shown in figure 6.1.

Figure 6.1 The three domains for strategic development



The content of the three domains was defined in correspondence with the MCA COP as shown in table 6.1. We identified sections in the COP that mapped onto the main findings from stages 1 and 2 of the project.

Table 6.1 Indicative content of RLO domains with correspondence to the MCA COP

Domain	Indicative Content *Consideration of:*	MCA COP Reference
The Law & Ethics	The need for appropriate support so that an individual might exercise their own decision-making or indeed, participate as far as they are able in the decision-making process.	1.11.13-14
	The need to minimise risk whilst also optimising potential benefits	11.12-18
	The particular circumstances of an individual participant such that the benefits of participation can be articulated whilst also assessing and managing risk	11.12-19
Capacity & Decision-making	The amenability of conditions for person to use their available skills as far as possible, to understand information, to retain and weight it up, and finally, to communicate their decision.	*11.4*
	The role of consultee in advising on the individual’s likely wishes and desires regarding participation in research.	11.11

	The individual's wishes and feelings regardless of their capacity for deciding about their own research participation.	11.29; 11.9
Adaptations & Accommodations	Sensitivity to the participant's own repertoire of communication skills and available capacities.	11.4
	Organisation of resources to support the person to participate in their own decision-making as far as possible, by focusing on key factors implicit in the decision-making process.	11.4

A first draft of the content was completed in a PowerPoint format and was accompanied by a narrative describing the proposed navigation, visualisation, and animation of the RLO. At this stage, the proposed content was shared with representatives of the Working Group who had the opportunity to make comments and suggestions, which in turn fed into the development process.

The PowerPoint and narrative information were used as the basis for constructing the digital entity (http://www.marshallacm.co.uk/ClientScorm/UEA/Assent/story.html). The work was carried out by an independent digital learning company. Work samples were sent out for review by the project team at regular intervals and feedback was given. An e-questionnaire was developed to solicit feedback from parties interested in field-testing the RLO.

Findings of ASSENT RLO Evaluation

Aims

To evaluate the potential usefulness of the RLO and the accommodations recommended for including adults with capacity and communication difficulties in research, an e-questionnaire, co-produced with the working group was used. The questionnaire which used a mixture of fixed-choice, Likert-type scale and free text questions. The latter was focused on individual evaluations of the RLO in terms of the: information and key messages in the guidance; accessibility of language used; readability and functionality of graphics; navigation of the RLO; overall satisfaction and suggestions for amendments.

Method

The web-based survey was delivered via the academic survey provider 'onlinesurveys.ac.uk' and was available for six weeks (from 01/06/2021 to 16/08/2021). An opportunistic sample of participants comprising Researchers, Organisations and Research Ethics Committee (REC) members who had shown interest in Project ASSENT completed the evaluation. Although not part of the target population, adults with capacity and communication difficulties, who had been part of the project also offered to provide their feedback. Potential participants were contacted using email, with reminders sent half-way through the survey and in the last 7 days to closing date.

Results

We received 31 completed evaluation questionnaires on the RLO, 19 below our target of 50 questionnaire returns. The characteristics of participants is shown in Table 1. Most participants were female (67.7%), over 54 years (48.4%), predominantly white (90.3%) and worked as researchers (64.5%). Others were stroke survivors with aphasia (n=4), a research student (n=1) and a recently stepped down Lay Plus member of a REC (n=1). The sample was not representative of the different roles in research, ethnicity and age.

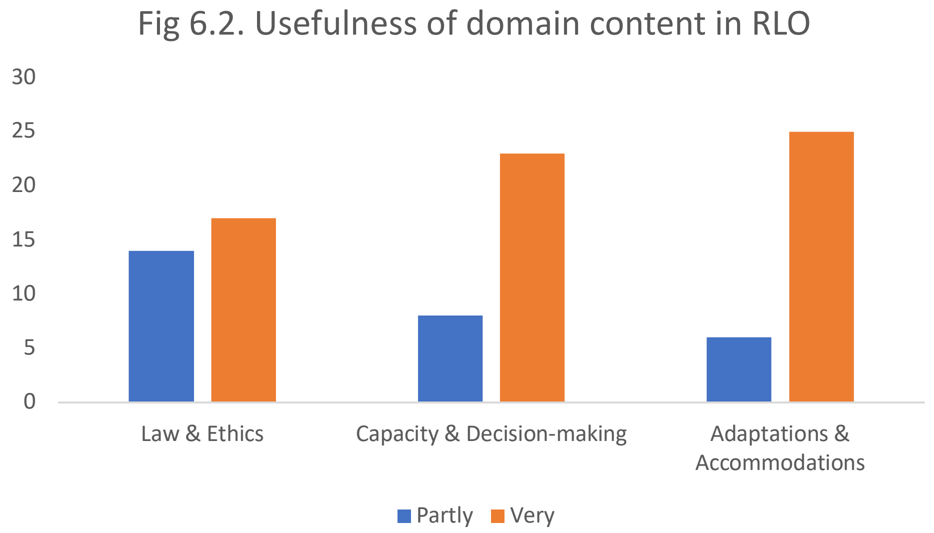
Table 6.2: Characteristics of participants

Variable	N (%)
Gender	
Male	10 (32.3)
Female	21 (67.7)
Age range	
25-34	4 (12.9)
35-44	4 (12.9)
45-54	8 (25.8)
Over 54	15 (48.4)
Ethnicity	
Prefer not to say	1 (3.2)
White (Irish)	2 (6.5)
White (UK)	28 (90.3)
Role in research	
Other	6 (19.4)
Researcher	19 (61.3)
Researcher and reviewer	2 (6.5)
Researcher and other	2 (6.5)
Professional body	1(3.2)
Reviewer	1(3.2)

Usefulness

Participants were asked to rate the usefulness of each domain within the RLO according to the following response options: very useful; partly useful; not useful. The domain ‘Adaptations & Accommodations’ was rated the highest [Very = 25/31(80.6%); Partly = 6/31 (19.4%)], followed by ‘Capacity & Decision-making’ [Very = 23/31(74.2%); Partly =

8/31(25.8%). The Law & Ethics domain showed a fairly even distribution between 'partly' and 'very' [Very =17/31 (54.8%); Partly = 14/31 (45.2%)].

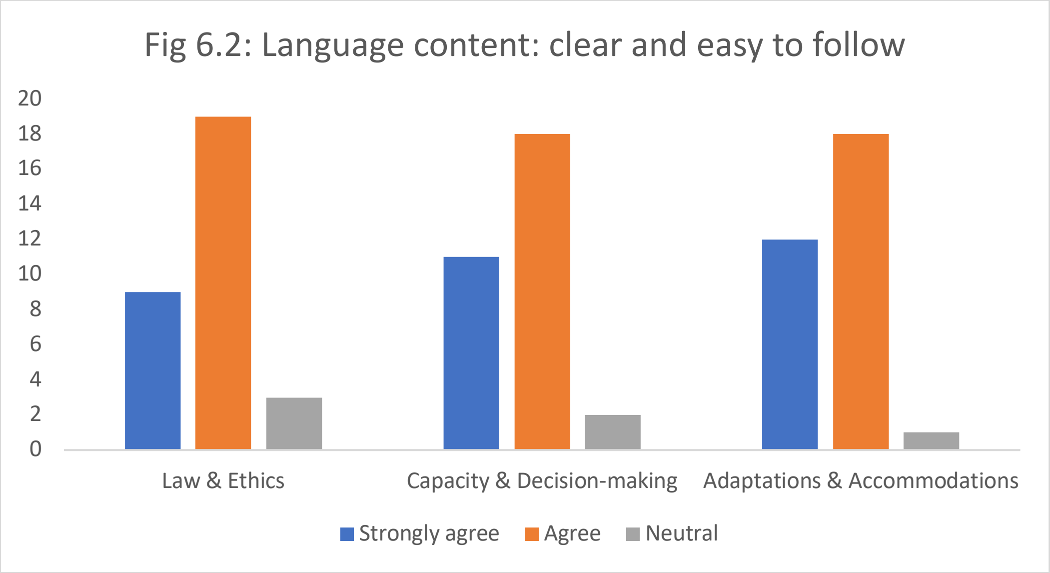


The free-text responses provided additional insight into the ratings. Feedback and suggestions included:

- *Law & Ethics*: the 'Law and Ethics' section was viewed as informative as it provided relevant legislation in clear and accessible formats (i.e. 'bite size'); the scenarios served as useful reminders of key considerations to be addressed; highlighting the Code of Practice (COP) within the RLO was seen as likely to boost researchers' confidence about the legalities of including adults with capacity and communication difficulties in research. However, one researcher viewed the RLO as e-learning rather than guidance for use by researchers.
- *Capacity & Decision making*: the usefulness of this section was associated with clear case studies, easy navigation, clearly expressed information, e.g. diagrams and visuals which reinforced previous knowledge. However, one participant found the flow through this section of the guidance hard to understand, whilst another found it repetitive. Suggestions included further explanations of: capacity assessment, e.g. when, how, who, with links to further resources; types of research ('intrusive'); and how to produce documentary evidence of participant understanding of research information.
- *Adaptations & Accommodations*: this section was rated high because it contained very helpful tips, real life scenarios, useful information, which was well presented, with various considerations for adaptation, scenarios, and opportunities to think 'outside the box'.

Language content

Participants were asked to rate if the language used in each domain within the RLO was clear and easy to follow according to these response options: strongly agree; agree; neutral; disagree; strongly disagree. All the sections were highly rated, with agreement or strong agreement indicated by over 90% of participants (Fig 6.2). The domain ‘Adaptations & Accommodations’ was rated the highest [Agree or Strongly agree = 30/31(96.8%); Neutral = 1/31 (3.2%)], followed by ‘Capacity & Decision-making’ [Agree or Strongly agree = 29/31(93.6%); Neutral = 2/31 (6.4%)]. For the ‘Law and Ethics’ section, over 90% (90.3, 28/31) agree or strongly agree that the language used was clear and easy to follow, whilst 9.7% (3/31) remained neutral.



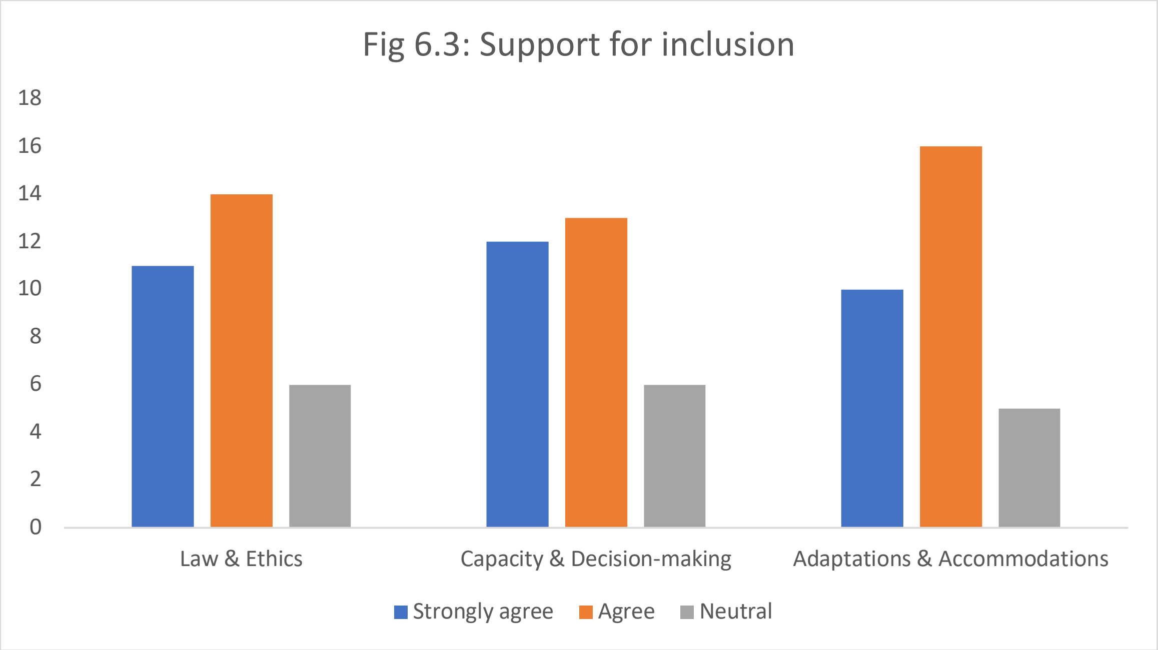
Feedback and suggestions included:

- *Law & Ethics*: participants agreed that it was clear and well written; one participant liked the use of excerpts directly from the MCA/COP, whilst another saw it as legalistic. They suggested that terminologies should be further defined or described, e.g. the consultee process, and abbreviations should be avoided.
- *Capacity & Decision-making*: feedback for this domain was mostly positive: very clear, lacking jargons, contained the description of consultee, and bite-size information which prevented participants from becoming overwhelmed. Participants suggested that the technical language should be avoided, and the section should be checked for typos.
- *Adaptations & Accommodations*: participants found the information in this section to be clear and easy to understand. The combination of text with video, and scenarios were particularly useful. They suggested that the language could be made

more accessible, especially when describing adaptations and accommodations, with examples of how to make language or vocabulary more accessible.

Support for inclusion

Participants were asked to rate how each domain within the RLO has helped them to consider the inclusion of adults with capacity and communication difficulties. Results for all the domains were similar and showed that over 80% of participants agreed or strongly agreed that each of the RLO domains helped them to consider the inclusion of adults with capacity and communication difficulties in research (Fig 6.3). The domain 'Adaptations & Accommodations' was rated [Strongly agree & Agree = 26/31(83.9%); Neutral = 5/31 (16.1%)], The domains 'Capacity & Decision-making' [Strongly agree & Agree = 25/31(80.6%); Neutral = 6/31 (19.4%)] and 'Law & Ethics' [Strongly agree & Agree = 25/31(80.6%); Neutral = 6/31 (19.4%)] were also rated as shown.



Feedback and suggestions included:

- *Law & Ethics*: the scenarios enabled consideration of issues surround inclusion and made researchers feel better informed. It was suggested that the RLO could be more inclusive and consider fluctuating capacity as well as scenarios for hospital, community and care home.
- *Capacity & Decision-making*: the scenarios, advice about sharing information in accessible ways, and the continuum of decision making were viewed as useful. This

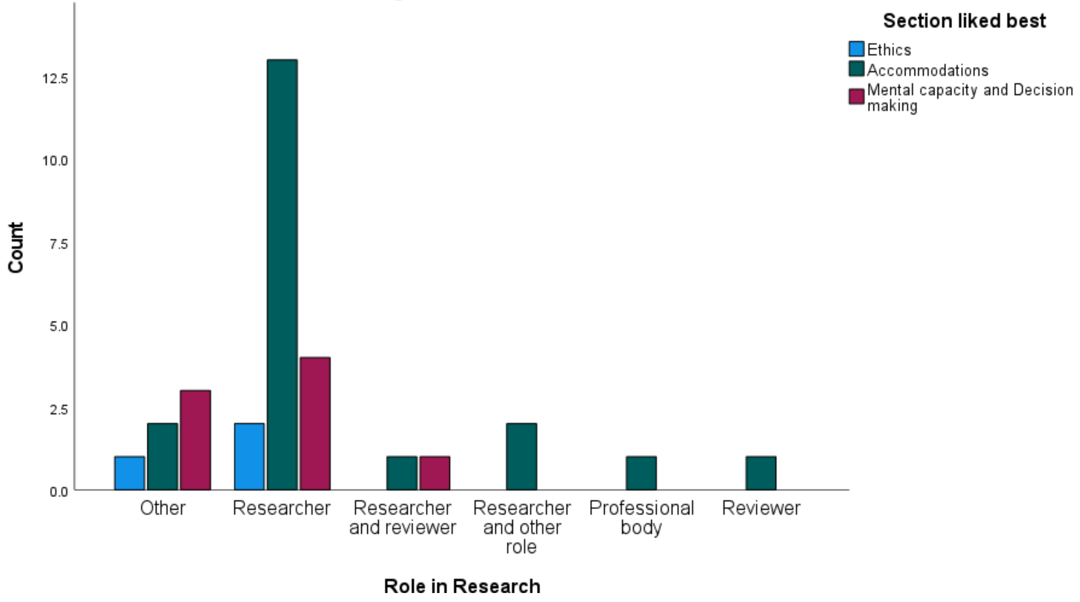
section improved thinking around capacity and reinforced decision to include adults with capacity and communication difficulties in research.

- *Adaptations & Accommodations*: participants reported that this domain provided guidance on making information accessible; personalising resources released them from "habitual approaches" and raised their awareness to the validity of different ways of including people with capacity and communication difficulties in research. Case studies needed to be more diverse also.

Most preferred domain

Participants were asked to rate the most preferred domain within the RLO. The domain 'Adaptations & Accommodations' was most preferred (64.5%, 20/31) as reflected by participants across all research roles [Fig. 6. 4]. This was followed by 'Capacity & Decision-making' (25.8%, 8/31). 'Law & Ethics' domain was the least preferred (9.7%, 3/31). In the qualitative survey data result, respondents reported that the 'Adaptations & Accommodations' domain provided useful ideas and practical tips on adapting information for adults with capacity and communication difficulties. As an area that researchers can struggle with, the information was information was seen to be precise and new in an instance. It had a good layout and encouraged them to think differently. Those who preferred 'Capacity & Decision-making' attributed it to a clear flow chart, good clinical-reasoning, with clear relevance to their work in the future. 'Law & Ethics' was selected by some because of its relevance to the researcher's area of research.

Fig. 6.4: Preference for the RLO domains



The impact of media on learning and understanding

Participants were asked to rate how the media (e.g. animations, talking heads, images) used in the RLO helped their learning and understanding according to the following response options: strongly agree; agree, disagree; strongly disagree. All respondents agreed (74.2%, 23/31) or strongly agreed (25.8%, 8/31) that the media used in the RLO helped their learning and understanding.

Feedback and suggestions included:

- Participants reported that the media used was engaging; the use of both written and audio-visual supported learning; and the case video or scenarios provided a real-world aspect to the text.
- Improvements suggested: addition of more text narrations to reduce the amount of reading; diversification of cases (e.g. addition of case scenarios of people living at home in addition to care homes scenarios already explored); ensuring that all terms are defined and checking text with screen reader to ensure that it is clear.

Ease of navigation

Participants were asked to rate the ease of navigation through the RLO according to the following response options: strongly agree; agree, disagree; strongly disagree. 74.2% (23/31) agree or strongly agree that they were able to navigate the RLO with ease while 25.8%, 8/31) strongly disagree or disagree.

Feedback and suggestions included:

- *Ease of navigation:* simplicity of the navigation system for some participants, so they could move through different parts of the RLO. Some participants found the 'pop up boxes' confusing and it was not easy to know which sections had been completed.
- *Improvements suggested*: the layout needs improvement as it was confusing for some participants and the instructions about navigation were not always clear. The absence of the 'back button' function meant that some participants had to go back to the main menu before accessing other sections of the RLO. The 'Menu' section could benefit from the addition of more sections e.g. indentation of sub-topics. A system that allows the tracking of progress through the RLO was suggested, e.g. fading out completed sections.

Recommend the RLO?

Participants were asked if they would recommend the RLO to fellow researchers according to the following response options: strongly agree; agree, disagree; strongly disagree. Nearly all participants (96.8%, 30/31) would recommend the RLO to fellow researchers whilst one participant (3.2%, 1/31) said they would not.

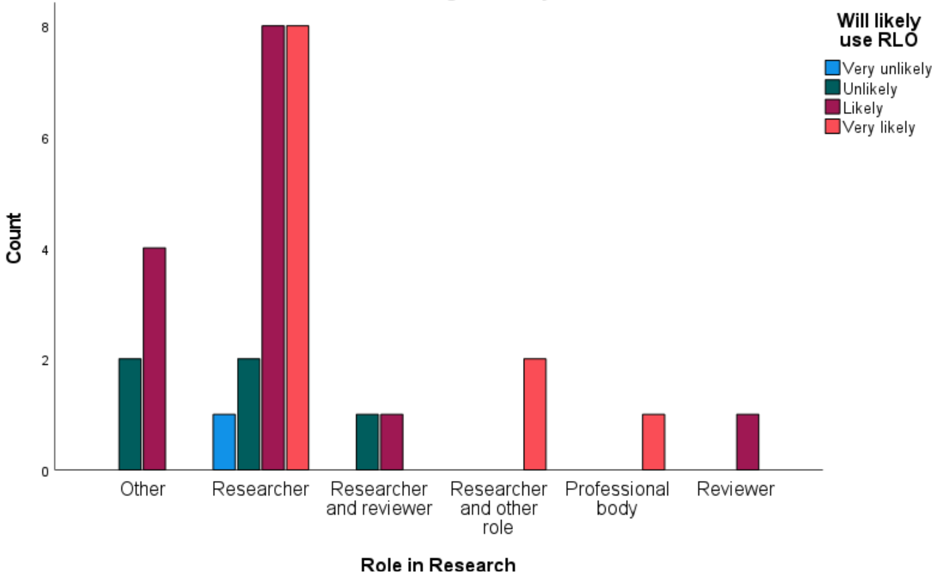
Feedback and suggestions included:

- Positive recommendation of the RLO was based on: its higher level of engagement potential than the MCA or COP; the clarity and practicality of its content; and the detailed content and case studies. The RLO was recommended for training purposes by some participants. One researcher identified the training potential of the RLO for researchers, "….. and used by the HRA for advising researchers on consent processes". Another said, "case studies good for team discussions and to reflect on current practice". One participant identified it as "thought provoking, tradition challenging, accessible resource". The need for such a resource like the RLO was voiced by one researcher: "absolutely I have been looking for something like this in a package".
- The only participant (a researcher) that disagreed with recommending the RLO felt that there was a lot to work through in the RLO (i.e. Law and Ethics, Capacity and Decision making) before getting to 'potentially novel and useful guidance' with examples of accommodations. This participant suggested adding more examples of accommodations with images for further explanation.

Likely to use the RLO?

Participants were asked if they would recommend the RLO to fellow researchers according to the following response options: very likely; likely, unlikely; very unlikely. 80.7% of participants (25/31) stated that they were likely to use the RLO in their role, whilst 19.3% (6/31) were not likely to use it. Those who were likely to use the RLO found it useful and a valuable resource. This included researchers, researchers acting as reviewers, researchers in other roles, and members of a professional body (Figure 6.5). Participants also reported that it provided practical guidance on adaptations and accommodations. However, those who considered themselves unlikely to use the RLO reported that it was time-consuming or that they were already aware of the topics discussed within the RLO. One participant who was unlikely to use the guidelines was a retired REC member.

Fig. 6.5 Likely to use RLO



Content

Participants were asked if there was anything to be left out from the RLO. There was no specific mention of items recommended for removal. Instead, they suggested modifications to the RLO, including shortening the section on ‘Law & Ethics’ and review of language content for acceptability. For example, phrases and words used within the RLO should correspond to MCA wordings with particular reference to ‘next of kin’. It was also suggested that ‘childless’ should be replaced with the phrase 'the couple did not have children' and 'agitated' with 'distress'.

Participants were asked for ideas for anything else they wanted to see added to the RLO. Suggested ways to enhance the RLO included:

- Information on the time required to go through the RLO at the beginning;
- Simplifying the RLO by reducing its length and density;
- Provision of links within the RLO to other resources, such as https://sites.google.com/nihr.ac.uk/pi-standards/standards/Support-and-Learning, the Mental Capacity Act (MCA) and COP;
- Including actual testimonies from researchers or research participants;
- Additional information on how to record consent or assent. For example, the use of verbal agreement, circling a happy face or recording a spoken agreement; specific mention of the process consent in dementia (e.g. the Dewing Process consent: a person-centred, relationship-based approach to consent);
- More examples of how to involve participant representatives from the beginning of projects, i.e. true participatory research;
- Making sections of the RLO printable so that it can be printed if required;
- More elaboration of the consultee’s role. One way might be to include a protocol of prompts for the researcher, containing questions to ask, such as 'how do you think an individual would like to be involved?’. It needs to be made clear that a

consultee can also ask for the participant to be removed from the study after they have given their assent.

- Examples of different media for recruitment materials would also be helpful.

Follow up

Further development work on the ASSENT RLO is indicated. In order to enhance the relevance and usability of the RLO, project ASSENT will be extended over a period of 12 months with support from the Nuffield Foundation. The primary objective is to produce a refined version of the ASSENT RLO that is responsive to stakeholder views and opinions. This will be achieved by:

1. Soliciting and using targeted feedback from our key stakeholder groups on the three domains that make up the ASSENT RLO: the law & ethics; capacity & decision-making; adaptation & accommodations. This is so that the content of the RLO may be refined for optimal relevance and usability.
2. Establishing a collection of authentic case-based scenarios that capture real-life communication processes and exemplify expressions of assent and dissent. Typically, these will be communications taking place between practitioners/researchers/carers and people with capacity and communication difficulties, where adaptations and accommodations are invoked to support understanding.

The extended period is from 1st October 2021 to 30th September 2022.

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Annex: Project Outputs

In order to communicate key messages from Project ASSENT, we have contributed a range of platform presentations and seminar papers to university-based, national and international research dissemination events. These are summarised below.

Conferences

Details	Platform presentation
Annual Conference of the Royal College of Occupational Therapists **Date**: Thursday 1st July 2021 **Venue**: Online	**Title**: Including adults with communication and understanding difficulties in ethically sound research. **Presenter(s):** Anne Killett
End of Project ASSENT Conference 2021 LOST VOICES IN RESEARCH: The development of a continuum of decision making for adults with communication and/or capacity difficulties in ethically sound research. **Date**: Friday 25th June 2021 **Venue**: Online	Presentations: **Title**: Introduction to project ASSENT **Presenter**: Karen Bunning **Title**: Inclusive approach to project ASSENT (Working Group) **Presenter**: Ciara Shiggins **Title**: The Law (Mental Capacity Act, 2005) **Presenter**: Rob Heywood **Title** Application of MCA in research (Systematic review) **Presenter**: Florence Jimoh **Title**: Researchers' reasoning of inclusion/exclusion of adults with capacity and communication difficulties **Presenter**: Peter Langdon **Title:** Assent guidance **Presenter**: Karen Bunning **Further details**: Registered - 140 Attended - 60 Interested in evaluating the RLO – 23

International Aphasia Rehabilitation Conference; June 2020; University of British Columbia (accepted for poster presentation but cancelled due to COVID-19)	**Title:** Lost voices in research: supporting the inclusion of adults with communication and/or capacity difficulties in ethically-sound research – the case of adults with aphasia (Project ASSENT). **Presenter(s)**: Shiggins, C., Ryan, H., Killet, A., Langdon, P., Heywood, R. & Bunning, K
International Association for the Scientific Study of Intellectual and Developmental Disabilities (IASSIDD) Conference; August 2019; Glasgow	**Title:** Supporting the inclusion of adults with communication and/or capacity difficulties in ethically-sound research: the current situation for people with intellectual disabilities in England and Wales **Presenter(s):** Karen Bunning; Hayley Ryan; Yvonne Plenderleith; Rob Heywood; Anne Killett; Pete Langdon & Ciara Shiggins.
British Aphasiology Society Clinical Symposium; 10th September 2019; University of East Anglia	**Title:** Supporting the inclusion of adults with communication and/or capacity difficulties in ethically-sound research: the current situation for people with aphasia in England and Wales. **Presenter(s)**: Shiggins, C., Ryan, H., Plenderleith, Y., Heywood, R., Killett, A., Langdon, P. & Bunning, K
Health Sciences Festival; Tuesday 4th June 2019; University of East Anglia	**Title:** The Mental Capacity Act 2005: Whose business is it anyway? **Presenter**: Hayley Ryan
3MT Project ASSENT; 2019; University of East Anglia wide research conference	**Title:** Lost voices in research: The current climate of evidence-biased practice **Presenter(s):** Yvonne Plenderleith and Hayley Ryan **Further details**: Best Presentation Award.

Seminars

Details	Platform presentation
HSC Seminar Series; Wednesday 21st July 2021; University of East Anglia	**Title:** Lost voices in research: Including adults with capacity and communication difficulties in ethically-sound research **Presenter(s):** Bunning, K; Killett, A.
Qualitative Research Forum; Wednesday 26th June 2019; University of East Anglia	**Title:** Semi-structured interviews to explore stakeholder priorities & views on in/exclusion of adult with communication and/or capacity (AwICC) difficulties in ethically-sound research.

	Presenter(s): Ryan, H., Bunning, K.
Title: Qualitative research methods seminar talk **Date**: 17th January 2019 **Venue**: University of East Anglia	**Title:** Co-production in research: Facilitating a Working Group with ‘Experts by Experience’. **Presenter(s):** Hayley Ryan & Yvonne Plenderleith

Journal Papers

Published

Heywood, R., Ryan, H., Killett, A., Langdon, P., Plenderleith, Y., Shiggins, C. & Bunning, K., (2019). Lost Voices in Research: Exposing the Gaps in the Mental Capacity Act 2005. *Medical Law International* 19(2-3): 81-112

Ryan, H., Heywood, R., Jimoh, O., Killett, A., Langdon, P.E., Shiggins, C. & Bunning, K. (2021). Inclusion under the Mental Capacity Act (2005): A review of research policy guidance and governance structures in England and Wales. *Health Expectations* 24(1):152-164.

Jimoh, O.F., Ryan, H., Killett, A., Shiggins, C., Langdon, P.E., Heywood, R. & Bunning, K. (2021). A systematic review and narrative synthesis of the research provisions under the Mental Capacity Act (2005) in England and Wales: Recruitment of adults with capacity and communication difficulties. *PLOS One*

Under review

Bunning, K., Jimoh, O.F., Heywood, R., Killett, A., Ryan, R., Shiggins, C. & Langdon, P.E. (2021). Survey of ethical review and recruitment processes under the research provisions of the Mental Capacity Act (2005) for England and Wales, with reference to adults with capacity-affecting conditions and communication difficulties.

In preparation

There are a number of other papers planned. Currently in preparation is:

Langdon, PE, Killett, A et.al. Current practice and values across multiple stakeholders about the inclusion of adults with impairments of capacity and/or communication within research: triangulation from a mixed methods study. *Target journal: TBA;* Target submission: September/October 2021.