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Inclusion of adults with conditions that have the potential to affect capacity and or communication in research: triangulation from a mixed-methods study of current practice and values across multiple stakeholders

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ABSTRACT

Objectives We aimed to: (A) describe researcher decision-making when including or excluding adults with conditions that have the potential to affect capacity and/or communication in research and (B) explore the underlying values and reasoning of stakeholders in research which falls under the provisions of the Mental Capacity Act, 2005.

Design The mixed-methods design included semistructured interviews with adults with conditions that have the potential to affect capacity and/or communication, supporters, researchers, research ethics committee members and an online survey with researchers. Triangulation was used to integrate the data and examine the complementarity of the findings.

Setting England and Wales.

Participants There were 61 participants who took part in semistructured interviews, of which 39 were adults with conditions with potential to affect capacity and/or communication, 6 were in support roles for adults with conditions with potential to affect capacity and/or communication (including family members and professionals in advocacy organisations), 8 were members of research ethics committees flagged under the Mental Capacity Act to review research where there could be issues of mental capacity and 8 were researchers with experience of working with adults with conditions that have the potential to affect capacity and/or communication. The online survey had 128 participants, researchers with experience of working with adults with conditions that have the potential to affect capacity and/or communication.

Results All stakeholders were supportive of the genuine inclusion of adults with conditions that have the potential to affect capacity and/or communication in research, and exclusion was seen as a form of discrimination. Many researchers were daunted by meeting the threshold within the legislation for including participants who may lack capacity.

Conclusion Further training, expertise and resources are required to promote the successful inclusion in research of adults with conditions that have the potential to affect capacity and/or communication.

STRENGTHS AND LIMITATIONS OF THIS STUDY

⇒ The study was conducted with strong representation from key stakeholder groups throughout all stages of the research.

⇒ The multidisciplinary approach to a medicolegal problem combined pertinent disciplinary expertise from communication, law, clinical psychology and research experience in the fields of developmental disabilities, aphasia and dementia.

⇒ The study triangulated mixed-methods data from five sources using a tested approach (Tonkin-Crine *et al*).

⇒ Data concerned the experiences and values of participants; not all participants had experiences of participation in research to draw on.

⇒ While previous research has examined the outputs of research, this project brings a new perspective based on data from key stakeholders.

INTRODUCTION

Adults with conditions that have the potential to affect capacity and/or communication are frequently excluded from health-related research.[1] This includes both research about commonly occurring conditions,[2] and condition-specific research such as post-stroke aphasia.[3] This presents an issue for the external validity of the research where the participant population ceases to represent the target population.[4] Healthcare practices developed from evidence where such groups are under-represented are unlikely to account for and meet their needs, compounding a lack of representation and discrimination.[5]

Barriers to the inclusion of adults lacking capacity to consent within research can be classified as methodological, structural and systemic[6] although these interrelate. Methodological issues are receiving more attention, with funders commissioning work to examine how to improve inclusion of underserved groups within clinical research.[5] However, there is as yet no significant change in exclusion rates evident in published trials.[2] Structural issues include inadequate research infrastructure, for example a lack of sustained researcher involvement in research settings necessary for inclusion. Systemic barriers include the processes of ethical review and underpinning legislation.

In England and Wales, legal participation in research of adults lacking capacity is governed by the Mental Capacity Act (MCA), 2005,[7] which is supplemented by a Code of Practice.[8] Scholars have previously exposed some of the shortcomings of the legislation. In the MCA, 2005, intrusive research is defined as research that would be unlawful if it were carried out with 'on or in relation to a person who had capacity to consent to it' but without that person's consent, but there is a degree of confusion as to how this test might be applied to research using observation methods of data collection.[9] Further, under the terms of the Act, for research to be lawful, it has to be connected to an impairing condition affecting the participant, ruling out the possibility of a person lacking capacity taking part in research related to conditions other than the condition affecting their capacity.[9]

Where these conditions are met, the involvement of a person lacking the capacity to give informed consent for the research could be legal. A consultee is defined by the MCA, 2005, as someone caring for, or interested in the welfare of, a potential research participant, who is not acting either in a professional capacity or for remuneration.[7] If this person is prepared to be consulted, they are provided with information about the project by the researcher and asked to advise the researcher on what the likely wishes and feelings of the potential participant about taking part if they had capacity. Where a consultee cannot be identified the researcher can nominate a consultee (who may be acting in a professional capacity or remunerated but have no connection with the research project).

A systematic review of studies that used the MCA, 2005, found limited use of consultees, regular exclusion of adults with capacity and communication difficulties and insufficient use of accommodations in research which could support inclusion.[10] Accommodations in this context are alterations of the environment, communication, materials or processes, or use of additional materials or equipment with the aim of supporting the inclusion of a person who lacks capacity and who may have communication difficulties. These findings were consistent with those of a documentary survey investigating applications to approved research ethics committees (RECs) where the MCA, 2005, was invoked.[11]

In order to examine how barriers to inclusion are currently operating or mitigated, using mixed methods and triangulation, we aimed to explore and understand the current practice and values of a variety of stakeholders (ie, adults with conditions that have the potential to affect capacity and/or communication, members of National Health Service (NHS) RECs, supporters and practitioners, and researchers) about the inclusion of adults with conditions that have the potential to affect capacity and/or communication within research studies.

Our specific aims were to: (A) describe researcher decision-making when including or excluding adults with conditions that have the potential to affect capacity and/or communication within research and (B) explore the underlying values and reasoning of all stakeholders in research falling under the provisions of the MCA, 2005.

METHODS

Design

A triangulation protocol[12] was applied to integrate data from a survey of researchers and from qualitative interviews with key stakeholders (adults with conditions that have the potential to affect capacity and/or communication, carers and supporters of such adults, gatekeepers, researchers, members of RECs). The data were drawn from a mixed-methods project[13] investigating the ethicolegal landscape and current practice in relation to research under provisions of the MCA, 2005. The mixed-methods design was defined in three core stages. Stage 1 used documentary analysis and literature review to investigate the legal, ethical and regulatory frameworks governing capacity and consent under the MCA, 2005 and accompanying Code of Practice (2007). Stage 2 investigated contemporary research practice with a review of studies, analysis of information sheets, an online survey of researchers and qualitative interviews. In the third stage, we developed and piloted guidance to promote inclusion in research. Within the current study, we report the findings of our online researcher survey and interviews with stakeholders.

An on-line survey was used in order to capture research practice regarding the inclusion of adults with capacity and communication difficulties in ethically sound research from a sample of experienced principal investigators to represent a range of practices. We aimed to describe researcher decision-making and find out the strategies, resources and accommodations used by researchers to support the involvement of this population. We used qualitative semistructured interviews in order to investigate the reasoning and values underlying the decision-making, and to provide context for data collected in the survey.

The triangulation protocol was used to integrate data in order to examine the complementarity of findings.[12] We incorporated triangulation of both methods (survey and qualitative interviews) and of data (participants from different stakeholder groups) which allowed examination of shared and contrasting perspectives.

Setting and participants

The research was carried out in England.

Online survey: sample

As part of the overall programme of which this study forms a part a prospective survey of research applications to, RECs under the research provisions of the MCA, 2005, was conducted[11 13] with the Health Research Authority (HRA). This involved the HRA extracting data from targeted fields in the Integrated Research Application System.[11] Principal investigators of the research applications identified by the HRA were invited to take part in an on-line survey, as researchers with experience of working with adults with capacity affecting conditions and/or communication difficulties. There were 128 researchers who agreed to take part in our online survey. Demographic information about the participants is presented in table 1.

Semistructured interviews: sample

Sixty-one participants (34 male, 27 female, age ranged from 18–24 to 75+, see table 2) were interviewed. Of these, 39 were adults living with conditions that have the potential to affect capacity and/or communication (aphasia after stroke, 9, autistic spectrum disorder, 8, acquired brain injury, 7, dementia, 5, learning disability, 8, mental ill health, 2) and 6 were gatekeepers, supporters or practitioners. Eight interviewees were REC members and 8 were researchers. For inclusion, participants needed to be able to communicate verbally, either through spoken or written words, signing or other communication aid, and have the capacity to consent to take part in this research. The sample was made up of people from groups considered to have an interest in the topic of research inclusion (stakeholders).

Semistructured interviews: recruitment

Adults living with conditions that have the potential to affect capacity and/or communication, gatekeepers, supporters and practitioners were all recruited through support organisations and community groups. Presentations about the research were given in accessible formats and people were invited to take part. Researchers for interviews were recruited from the principal investigators who took part in a survey of research applications to flagged RECs[11] and from universities while REC members were recruited via the HRA who disseminated information about the project to RECs and encouraged REC members to contact us.

Data collection and analysis: online survey

The research team and working group constructed a bespoke online survey, drawing on their findings from earlier stages of the wider project.[9–11 14] Demographic information about each participant was collected, along with information about their experience of working within research and with adults with conditions that have the potential to affect capacity and/or communication. We asked questions about their experience of using the MCA, 2005, within research, and about the reasons for including or excluding adults with conditions that have the potential to affect capacity and/or communication within research. A series of further questions were presented which aimed to capture a range of communication supports used within research to accommodate the involvement of this population. 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 MCA, 2005, within research settings. The survey was delivered using online surveys (https://www.onlinesurveys.ac.uk/).

Descriptive data from the closed questions were summarised and reported. Data generated from the open-ended questions and free-text boxes were summarised using summative content analysis[15] completed by two members of the research team (HR and PL) using NVivo V.12. This analytical method was chosen as it allows for flexibility when analysing text data, and the aim was to identify data relevant to researcher decision-making, reasoning and values. 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 on 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.

Data collection and analysis: qualitative interviews

Semistructured interviews were conducted using a topic guide (online supplemental appendix A) coproduced with a working group made up of people representing affected user groups (intellectual disabilities, autism, aphasia after stroke, dementia, acquired brain injury and mental illness). Interviews were conducted as appropriate to the needs of the participant (which included face to face at a location convenient for the participant, or over the telephone). Communication approaches used were tailored to participant needs including supported communication techniques[16] as needed. Interviews were recorded using audiorecording, or in the case where supported communication techniques were used or a person used multimodal communication, by use of video and audiorecording. Interviews were transcribed and transcriptions on word documents imported into NVivo V.12 (https://support.qsrinternational.com/) data management software.

We asked about people's experience of research, their views on the inclusion or exclusion of adults with impairments in capacity and/or communication in research and their views on the consultee process.[7] Researchers and REC members were additionally asked about their experience of using the Code of Practice[8] which accompanies the MCA, 2005.

Table 1 Descriptive statistics summarising participant demographics and responses to the closed questions within the research survey

	n	%		n	%
Gender			Research experience		
Male	41	32	0	8	6
Female	85	67	1–2	16	13
Transgender	1	1	3–5	22	17
			6–10	16	13
Ethnicity			>10	65	51
White—English/Welsh/Scottish/Northern Irish/British	100	78			
White—Irish	3	2	Knowledge and understanding of the MCA		
Asian/Asian British—Indian	6	5	Excellent	23	18
Asian/Asian British—Pakistani	1	1	Very good	51	40
Asian/Asian British—Chinese	2	1.5	Good	33	26
Black/African/Caribbean/Black British—African	2	1.5	Fair	13	10
Black/African/Caribbean/Black British—Caribbean	1	1	Poor	8	6
Other	13	10			
Experience working with AwICC			I feel confident working with a consultee		
0	11	9	Strongly agree	52	42
1–2	11	9	Agree	48	38
3–5	17	13	Neither agree/disagree	13	10
6–10	21	17	Disagree	8	6
>10	67	52	Strongly disagree	5	4
Age					
25–34	21	16			
35–44	28	22			
45–54	37	29			
>54	42	33			
Method			Setting		
Qualitative	33	26	Hospital	64	29
Quantitative	31	24	Residential care home	36	16
Mixed	63	50	Participant home	50	23
			Community	25	12
Design			University	25	12
Laboratory experiment	15	7	Laboratory	4	2
Field experiment	14	6	Other	13	6
Interview study	66	29			
Questionnaire	46	21	Location		
Observational	49	22	North East England	17	7.5
Case study	8	4	North West England	28	12
Case series	5	2	Yorkshire and the Humber	18	8
Other	20	9	East Midlands	18	8
			West Midlands	12	5
Public involvement			East of England	17	7.5
Coproduction	62	34	London	33	15
User group engagement	71	39	South East England	30	13
Community engagement	44	24	South West England	21	9

Continued

Table 1 Continued

	n	%		n	%
Other	6	3	Scotland	9	7
			Wales	16	4
			Northern Ireland	4	2
			Other	4	2

AwICC, adults with impairments of communication and/or capacity.

Data generated from the qualitative interviews were initially analysed in two separate analyses: (A) adults with impairments in capacity and/or communication, their supporters and gatekeepers (completed by HR and AK) and (B) researchers and members of REC committees (completed by MR). These analyses used a thematic approach.[17 18] First, complete transcripts, in each group of participants, were read to become familiar with the discourse. Key ideas and concepts were noted to identify recurrent themes within and between participant groups. Transcripts were then reviewed in NVivo V.12, and these recurrent themes identified in each transcript through use of 'nodes'. These themes were then reviewed for interconnections and grouped under organising themes. Commonalities and differences between the separate analyses were examined at the level of both recurrent and organising themes to achieve complementary interpretations. The analysis took an experiential rather than critical orientation and was both top-down in that it was driven by the research question, with an inductive element introduced by the initial identification of key ideas and concepts from data familiarisation.[19]

Analysis: triangulation

Our initial analyses of our interviews and survey resulted in key findings from five sources:

i. Adults with conditions that have the potential to affect capacity and/or communication (interview data).
ii. Supporters and practitioners of adults with conditions that have the potential to affect capacity and/or communication (interview data).
iii. Researchers working in health/care research with these groups and REC members (interview data).
iv. Researchers working in health/care research with these groups (survey data free text).

Table 2 Demographic characteristics of interview participants

	Adults living with conditions that have the potential to affect capacity and/or communication	Gatekeepers, supporters or practitioners	REC members	Researchers
Gender—male	26		6	2
Gender—female	12	6	2	6
Gender not recorded	1			
Age 18–24	5			
Age 25–34	4	1		4
Age 35–44	3			
Age 45–54	8	3		2
Age 55–64	6	1	3	2
Age 65–74	2		1	
Age 75 or over	3		1	
Age not recorded	8	1	3	
Ethnicity White—English/Welsh/Scottish/Northern Irish/British	32			
Ethnicity Black/African/Caribbean/Black British—Caribbean	2			
Ethnicity Black/African/Caribbean/Black British—African	2			
Ethnicity British Mixed/multiple ethnic group	1			
Ethnicity not recorded	2	6	8	8
Total	39	6	8	8

REC, research ethics committee.

Table 3 Number of key findings in each data source

Adults with conditions that have the potential to affect capacity and/or communication (interview data)	Supporters and practitioners of adults with conditions that have the potential to affect capacity and/or communication (interview data)	Researchers working in health/care research related to these groups and REC members (interview data)	Researchers working in health/care research related to these groups (survey data closed questions)	Researchers working in health/care research related to these groups (survey data free text)
12	6	12	19	21

REC, research ethics committee.

v. Researchers working in health/care research with these groups (survey data closed questions).

Using the triangulation approach devised by Tonkin-Crine *et al*[12] for data from mixed-methods studies key findings for each data set were identified and presented as statements to aid comparison, for example, 'Participation in research offers benefits to the individual such as sense of achievement, feeling useful, increasing confidence' (adults with conditions that have the potential to affect capacity and/or communication), 'Some researchers felt discouraged to include participants who lack capacity within research studies' (Researcher survey free text). These key findings were identified as follows. For the findings from interviews (data sources i–iii above), AK reviewed coding and subcoding along with coded sections of data in context and identified 30 key findings. The findings from the survey-closed questions were differentiated into 19 key findings and the findings from the content analysis of free text into 21 key findings by PL. This resulted in a total of 70 initial key findings from the 5 sources of data.

Next, we compared each finding from each data set to every other key finding in the other data sets to create a 'convergence coding matrix'.[12] In this process, key findings were collapsed into one finding where there were data in at least two data sets that agreed. This resulted in 43 independent key findings across our 5 data sources (table 3).

We grouped these 43 key findings into topics (table 4): quality of research; equality and rights; MCA (2005); and research practice.

Each key finding was compared with every other key finding, and the level of agreement, partial agreement (PA), dissonance and silence for each comparison was identified. Relationships were categorised as agreement (A) where the finding from another source was consistent with the comparator. PA was used to describe a complementary relationship, while dissonance (D) was used to describe conflict between findings. Silence (S) was used to indicate that there was no related finding in a particular data source. In table 4, the five columns on the right are for the five original data sets. Each row of the table represents 1 of the 43 key findings. The letters and numbers in the right-hand columns indicate how many findings in the individual data sets relate to the key finding in that row.

For each of these stages, two researchers (AK and PL) worked collaboratively, challenged each other and negotiated for consensus. A third researcher who was part of the initial analyses across all data sources (HR) performed sense-checking on the preparation of the convergence coding matrix, by ensuring that all key concepts in the total of 70 key findings were contained in the 43 key findings in the convergence matrix.

Patient and public involvement

A project advisory group made up of key stakeholders met at 6-monthly intervals through the project. The membership included adults with autism, intellectual disabilities, acquired brain injury, aphasia, family carers of people living with autism, aphasia or dementia, a supporter of people with intellectual disabilities, an REC member, a researcher and representatives from the Office of the Public Guardian. A working group of adults with lived experience of capacity and communication difficulties and project researchers met 11 times to ensure the voices and perspectives of these groups were central to the research project. The group coproduced the participant information sheets, consent forms, recruitment process for the interview study and contributed to the development of the survey and evidence-based guidance. Roles and responsibilities of group members and working group processes were decided collaboratively at the start of the project.

RESULTS

The initial findings from our interviews and research survey are reported separately within (online supplemental appendix B), and these key findings were first converged from 70 to 43 key findings and then these 43 key findings triangulated.

Results of triangulation

To carry out the triangulation, 43 independent key findings were compared with each other key finding and the relationship categorised for agreement, PA, dissonance or silence.

For 8 of the key findings, there were data in each separate data set, for 5 findings, data were found in 4 of the data sets, for 14 findings there were data in 3 data sets, for 7 findings there were data in 2 of the data sets, while for

Table 4 Key findings and relationship to data sets

	Data set				
	Qualitative interviews			Researcher survey	
	Adults with conditions that have the potential to affect capacity/ communication	Supporters	Researchers	Closed questions	Open questions
Key finding					
Quality of research					
1. Adults with conditions that have the potential to affect capacity and/or communication should be included in research to ensure that research is of high quality, comprehensive and representative of the lived experience and needs of this population.	A=1	A=1	A=1	A=2 PA=1	A=2
2. Exclusion means it is it not possible to do high quality research about the impairing condition.	A=1	A=1	PA=1	A=1	A=2
Equality and rights					
3. Inclusion in research promotes advocacy, autonomy and gives people a voice.	A=1	S	A=1	A=2	PA=2
4. Participation in research offers benefits to the individual such as sense of achievement, feeling useful, increasing confidence.	A=1	S	S	PA=1	PA=1
5. Exclusion from research is discrimination, leading to a lack of recognition of needs and issues.	A=1	A=1	A=1	A=1 PA=2	A=2 PA=4
6. People who cannot communicate are thought not to understand and not noticed.	A=1	S	S	S	PA=1
7. Including adults with impairments of capacity or communication in research is important to reduce discrimination and is an ethical issue.	A=1 PA=1	S	PA=1	A=1	PA=3
8. Researchers excluded adults with impairments of capacity or communication as they could not provide responses needed.	D=7	D=4	D=1	A=1	D=4 PA=1
9. Having communication difficulties does not mean someone lacks capacity.	PA=1	S	S	S	A1
10. Some researchers felt discouraged to include participants who lack capacity within research studies.	S	S	S	PA=1	A=1
11. Some researchers said they felt uncomfortable if they had to exclude adults with impairments of capacity or communication from research studies.	PA=1	S	S	PA=1	A=1
Mental Capacity Act (MCA) (2005)					
Consultee process					
12. Researchers, supporters and gatekeepers, and adults with conditions that have the potential to affect capacity and/or communication were concerned about consultees speaking for someone else. They should not engage in direct decision-making.	A=1	A=1	S	S	A=1
13. If the consultee process is used, the participant should be involved as much as possible in the process.	A=1	S	PA=1 D=1	S	S
14. If the consultee process is used the consultee should be someone who knows the participant very well.	A=1	S	S	S	S
15. The consultee process could be beneficial if it leads to more inclusion of adults with conditions that have the potential to affect capacity and/or communication.	A=1	D=1	PA=1 D=1	S	D=3
16. Finding a consultee is burdensome, time-consuming and may cause delays.	S	PA=1	A=1	PA=1	A=1
Code of practice					
17. The code of practice is not much used by researchers.	S	S	A1	S	S
Exclusion					

Continued

Table 4 Continued

	Data set				
	Qualitative interviews			**Researcher survey**	
	Adults with conditions that have the potential to affect capacity/ communication	**Supporters**	**Researchers**	**Closed questions**	**Open questions**
18. Those who lack capacity to give consent for particular studies continue to be excluded from research because research is often focused on those who have capacity.	D=4	D=2	D=1	A=1	A=1 D=4
19. Adults with conditions that have the potential to affect capacity and/or communication are excluded because researchers cannot meet the requirements of the MCA. Research cannot be carried out successfully with those who have capacity.	D=2	D=2	D=1	A=1	A=2 D=2 PA=1
Research practice					
Gatekeeping					
20. People in gatekeeping roles do not necessarily see themselves as having this role.	S	A=1	S	S	S
Researcher knowledge					
21. More must be done to make sure that adults with conditions that have the potential to affect capacity and/or communication can participate in research. Researchers must be knowledgeable in order to adapt processes, methods and communication appropriately.	A=1	A=3	A=1	A=2	S
22. Some researchers were both familiar and confident with the consultee process.	S	S	A1	PA=1 D=1	A=1 D=2
23. Researchers were aware that potential research participants should be supported to make autonomous decisions about taking part in research.	S	S	A=1	S	S
24. Some researchers were confident about including people with conditions that have the potential to affect capacity and/or communication in research. Those that were confident tended to have had experience of working with adults with conditions that have the potential to affect capacity and/or communication in research.	PA=1	S	S	S	A1
25. Researchers indicated that it was important to work within an MDT inclusive of clinical and research staff to support the inclusion of adults with conditions that have the potential to affect capacity and/or communication in research.	S	S	S	S	A1
MCA					
26. A majority of researchers rated their knowledge of the MCA as good or excellent.	S	S	D=2	A=1	D=4 PA=1
27. Health-related research is a diverse activity, and researchers in different fields have varying levels of understanding of the MCA.	S	S	A=1	PA=2	PA=4
28. It was not generally understood that under the MCA people should be actively supported to make autonomous decisions.	S	S	A=1	S	S
29. Researchers were aware that under the MCA capacity is decision specific.	S	S	A1	S	S
30. It was not generally understood that under the MCA people judged to lack capacity to give consent should still be actively involved in the decision-making process where a consultee is used.	D=1	S	A=1	S	S
31. There were some researchers who were confident about their ability to work with a consultee.	S	S	PA=1	A=1	A=1 D=2

Continued

Table 4 Continued

	Data set				
	Qualitative interviews			**Researcher survey**	
	Adults with conditions that have the potential to affect capacity/communication	**Supporters**	**Researchers**	**Closed questions**	**Open questions**
32. Some researchers had a poor understanding of the MCA.	S	S	A=1 PA=1	A=1	A=2 D=1 PA=2
33. Some researchers were not confident in their ability to work with a consultee. They did not understand what a consultee was and what role they had in research. They confused this with other roles such as making treatment decisions, mediation, advocacy and translation.	S	S	D=1	A=1	A=2 D=1
34. Some researchers said they understood the MCA in clinical settings better.	S	S	PA=2	PA=1	A=1
35. Researchers had learnt about the MCA in teaching and personal study. They said that training in the MCA was important.	S	S	S	PA	A=1
36. Researchers who were less confident said that they were concerned with how to assess capacity and would seek support from others.	S	S	S	S	A1
Health research authority approval processes					
37. Applying for an ethical opinion when including participants who lack capacity is difficult.	S	S	PA=1	A=1	
38. Researchers are concerned that the HRA is too focused on written information and the use of signatures.	S	S	A=1	S	S
Research methods and engagement					
39. Researchers tended to use observational research designs with adults with conditions that have the potential to affect capacity and/or communication, which supporters and gatekeepers thought were more engaging.	PA=1	A=1	S	A=1	S
40. A range of methods were used to engage the public in research including coproduction, user group engagement and community engagement.	PA=1	PA=1	S	A1	S
Resources					
41. Researchers exclude adults with conditions that have the potential to affect capacity and/or communication because they do not have enough time to include them.	D=2	D=2	D=1 PA=2	A=1	A=1 PA=3 D=4
42. Researchers excluded adults with conditions that have the potential to affect capacity and/or communication due to a lack of funding.	D=2	D=2	D=1	A=1	D=3 PA=2
43. Researchers excluded adults with conditions that have the potential to affect capacity and/or communication due to a lack of training or resources.	D=3	D=2	D=1	A=1	D=5 PA=1

A, agreement; D, dissonance; HRA, Health Research Authority; MDT, multidisciplinary team; n, number of key findings; PA, partial agreement; S, silence.

9 of the key findings there were only data in 1 of the data sets. This indicated that use of two different data collection methods and four different groups of informants allowed useful interrogation between the data sets. Key findings were grouped thematically as presented in table 4, which shows the nature of the relationship of each finding to data from each of the five original data sets. The themes related to the quality of research, equality and rights, the MCA, 2005, and research practice. Examining the key findings and the relationship with the data sets revealed areas of shared values between stakeholder groups but, where there was dissonance around key findings, pointed to compromises that are made in practice where values cannot be enacted.

Agreement across databases: shared underpinning values

There were only two findings where there was agreement among all five data sources. These findings were in the areas of quality of research and equality and rights. They focused on the need for inclusion of adults with conditions that have the potential to affect capacity and/or communication for research to be of high quality and outlined the dangers of exclusion. There was evidence from all our data sources that a high value was placed on research which is comprehensive, advances our understanding of conditions related to impairments, and reflects lived experience. Exclusion was seen to be discriminatory and to lead to a failure to recognise the needs of this population. A third finding, although having only PA from the data from qualitative interviews with researchers, was consistent with the other four data sources, including the other two data sources generated with researchers. This was that the exclusion of participants with conditions that have the potential to affect capacity and/or communication negatively affects the quality of research.

Dissonance across databases: putting values into practice

When looking at how these values are enacted in research processes, the analysis revealed dissonance, indicating that while there may be shared values between stakeholder groups about principles of inclusion in research, it is problematic to be consistent with these values when undertaking research. For example, the finding 'researchers excluded adults with conditions that have the potential to affect capacity and/or communication as they could not provide responses needed' was categorised as dissonant with seven key findings originating from the interviews with adults with conditions that could lead to such impairments, such as 'People who can't communicate are thought not to understand and are not noticed.' While both statements indicate the knowledge or belief that people are excluded, the dissonance was in relation to the differing implied values and principles. This finding from the researcher closed questions was also dissonant with the findings from open questions in the researcher survey. A finding from the survey was that researchers said it was important that adults with conditions that have the potential to affect capacity and/or communication should be afforded the opportunity to take part in research just like those without such conditions because of their specific lived experience which was needed for effective research. This indicated a gap between the values and intent of researchers and how these are applied in the research process. Such a gap was revealed again under the theme of research practice, where in the closed questions of the researcher survey we found that researchers excluded adults with conditions that have the potential to affect capacity and/or communication because of a lack of time, funding, training or other resources.

Silence across databases: contrasting reasoning about implementation of inclusion

Examining silences between the databases gives a striking indication of how far there is to go to reconcile the difference of perspective between adults with conditions that have the potential to affect capacity and/or communication and researchers. Our participants with conditions that have the potential to affect capacity and/or communication were clear that participation in research, in addition to being important for the quality of the research and the knowledge generated, was also important because of the potential benefits for the individual. These included a sense of achievement, increased confidence and feeling useful. On this point, two data sources were silent (interviews with supporters and practitioners, and with researchers) while the other two (researcher survey; closed questions and open questions) each offered a single complementary finding.

Adults with conditions that have the potential to affect capacity and/or communication thought that the consultee process could be useful if it resulted in more inclusion but emphasised that a consultee should know the potential participant really well, and also that the participant should be involved as much as possible in the process. This is what the MCA, 2005, and Code of Practice[8] require, but there was largely silence on this point from the researchers in this study. Our data were conflicting with some researchers aware that potential participants should be supported to make autonomous decisions while others seemed unaware. This is consistent with the findings that some researchers had a poor understanding of the MCA, 2005. Some did not understand what a consultee was and the role they had in research, confusing this with other roles such as making treatment decisions, mediation, advocacy and translation. We found researchers in the qualitative interviews showing awareness that a judgement about capacity is decision specific as defined within the MCA, 2005, but again there was silence on this point in the researcher survey.

Findings from the qualitative interviews with researchers indicated that the Code of Practice is not much used. The silence on this point from the other data sources including the researcher survey, with none of the other data sources having a finding about the Code of Practice, is consistent with a lack of its use.

Researchers responding to the open questions in the survey reported that working in multidisciplinary teams with clinicians supported the inclusion of adults with conditions that have the potential to affect capacity and/or communication in research, but the other data sources were silent on this point.

DISCUSSION

Main findings

The paper provides evidence that there are shared values between adults with conditions that have the potential to affect capacity and/or communication, supporters, practitioners and researchers about the inclusion of research participants who have impairments of capacity and/or communication. The data from all of the data sources were in agreement that such inclusion is as a matter of rights, and also imperative for sound research.

The provisions within the MCA, 2005, governing the inclusion of adults with conditions that have the potential to affect capacity and/or communication within research, with a set of tests that must be met to gain approval, have a potentially chilling effect[9] on inclusive research as researchers manage tensions between the accommodations appropriate for potential participants and fulfilling the ethicolegal requirements for a favourable ethical opinion.[11] Although accommodations and the consultee process can work effectively, as indicated by the finding that researchers are using a range of approaches to engage participants, there are a proportion of researchers in the field who are not confident or knowledgeable about these provisions, or about constructing a case for their deployment when applying for ethical review. The full range of accommodations and supports that many people with impairments need in order to be included in research are rarely deployed. Researchers are not confident that ethical review will support accommodations they wish to enact to support inclusion. Lack of time, funding, knowledge and training were reported by researchers and lead to the decision to exclude adults with conditions that have the potential to affect capacity and/or communication from research.

Strengths and limitations

This study was conducted with strong representation from key stakeholder groups throughout. The multidisciplinary approach to a medicolegal ethical problem combined pertinent disciplinary expertise from communication, law, clinical psychology and rehabilitation and research experience in the fields of developmental disabilities, aphasia and dementia. This paper triangulated mixed-methods data from five sources using a tested approach.[12] Previous research has examined the outputs of research[1 2 4 10 20] and recruitment and ethical review processes,[11] while this project brings a new perspective based on data from key stakeholders. It is a limitation that, while all participants were asked both about experience of research activity and about values, there was more direct experience among participants in the researcher and REC member groups. Key findings drew on both values and experiences, and the triangulation process included interpretation where values-based key findings were related to those based on experiences.

Implications

Inclusion of adults with conditions that have the potential to affect capacity and/or communication in ethical research requires considerable knowledge and skill in the principles and requirements of the MCA, 2005, and in the use of adaptations and accommodations that support inclusion throughout the research process. We established that researchers are wary of attempting to meet the requirements of the MCA, 2005, and there are clear associated training requirements, while adults with conditions that have the potential to affect capacity and/or communication want to be included in research. Tailored, informed, evidence-based resources are needed to support researchers and those who review research proposals in order to promote inclusion. There was evidence that some researchers were familiar with the MCA, 2005, as applied to clinical and related decision-making, but they lacked clarity about the provisions governing research. The guiding principles of NHS England include an aspiration to maintain the highest standards of excellence through research with a 'commitment to innovation and to the promotion, conduct and use of research to improve the current and future health and care of the population' and an associated pledge to inform all patients about research studies in which they are eligible to participate.[21] Our 'NHS services must reflect and should be coordinated around and tailored to the needs and preferences of patients, their families and their carers'[21] and our findings clearly demonstrated a key commitment across stakeholders to include adults with impairments in capacity and/or communication in research. To allow for this, the necessary time, expertise (such as in the application of the MCA, 2005, in research and in appropriate communication), and resources (such as training material for researchers about accommodations) must be developed and implemented to allow researchers and adults with conditions that have the potential to affect capacity and/or communication to work collaboratively when undertaking research studies which will provide evidence for improved health and social care practice.

CONCLUSION

Adults with conditions that have the potential to affect capacity and/or communication are being excluded from research, with implications for evidenced-based practice to meet the health and care needs of these groups of people. This paper demonstrates that there is agreement from all stakeholders that this is wrong, but that researchers lack knowledge, skills and confidence to include such adults. Some researchers are not confident they can achieve what they perceive as the challenges of meeting the requirements of ethical review, or struggle with a lack of resources to make their research accessible. To continue to exclude based on impairments in capacity and/or communication is inequitable and discriminates against people. It perpetuates the inequity in evidence base, which is not informed by the experiences or needs of those with impairments in capacity and/or communication, and hence inequities in provision.

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Contributors AK and PL drafted the manuscript, AK, PL and RH conducted the triangulation, PL and RH analysed survey data, RH, AK and MR analysed qualitative data, KB, AK, PL and RH conceived the study, CS, RH and AK facilitated involvement of adults with capacity affecting conditions, KB, RH, CS, AK, OFJ and PL designed and completed data collection. All authors were involved in critical review of the manuscript and interpretation of the findings. KB acted as guarantor.

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