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How are adults with capacity-affecting conditions and associated communication difficulties included in ethically sound research? A documentary-based survey of ethical review and recruitment processes under the research provisions of the Mental Capacity Act (2005) for England and Wales

Karen Bunning ,[1] Oluseyi Florence Jimoh,[1] Rob Heywood,[2] Anne Killett,[1] Hayley Ryan,[1] Ciara Shiggins,[1,3] Peter E Langdon [4,5,6]

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For numbered affiliations see end of article.

Correspondence to
Professor Peter E Langdon; Peter.Langdon@warwick.ac.uk

ABSTRACT

Objectives This study aimed to determine the characteristics of ethical review and recruitment processes, concerning the inclusion of adults with capacity-affecting conditions and associated communication difficulties in ethically sound research, under the provisions of the Mental Capacity Act (MCA, 2005) for England and Wales.

Design A documentary-based survey was conducted focusing on adults with capacity-affecting conditions and associated communication difficulties. The survey investigated: (1) retrospective studies during the implementation period of the MCA (2007–2017); (2) prospective applications to MCA-approved Research Ethics Committees (RECs) during a 12-month period (2018–19); (3) presentational and linguistic content of participant information sheets used with this population.

Setting Studies conducted and approved in England and Wales.

Sample Studies focused on adults with the following capacity-affecting conditions: acquired brain injury; aphasia after stroke; autism; dementia; intellectual disabilities; mental health conditions. The sample comprised: (1) 1605 studies; (2) 83 studies; (3) 25 participant information sheets.

Primary and secondary outcome measures The primary outcome was the inclusion/exclusion of adults with capacity-affecting conditions from studies. The secondary outcome was the provisions deployed to support their inclusion.

Results The retrospective survey showed an incremental rise in research applications post-MCA implementation from 2 (2012) to 402 (2017). The prospective survey revealed exclusions of people on the bases of: 'lack of capacity' (n=21; 25%); 'communication difficulties' (n=5; 6%); 'lack of consultee' (n=11; 13%); and 'limited English' (n=17; 20%). REC recommendations focused mainly on participant-facing documentation. The participant information sheets were characterised by inconsistent use of images, typography and layout, volume of words and sentences; some simplified language content, but variable readability scores.

Conclusions People with capacity-affecting conditions and associated communication difficulties continue to be excluded from research, with recruitment efforts largely concentrated around participant-facing documentation. There is a need for a more nuanced approach if such individuals are to be included in ethically sound research.

Strengths and limitations of this study

- ► The progressive survey focuses on marginalised groups of people with capacity-affecting conditions in its examination of the period post implementation of the Mental Capacity Act (2005), both retrospectively and prospectively.
- ► Quantitative and qualitative data are combined in the results in order to address the research question.
- ► The survey focus is confined to six main capacity-affecting conditions (acquired brain injury; aphasia after stroke; autism; dementia; intellectual disabilities; mental health conditions).
- ► The retrospective and prospective surveys were limited to available information on the Health Research Authority database and the researcher completed fields of the Integrated Research Application System, respectively.
- ► The sample of participant information sheets was small and unevenly distributed across the different population groups and therefore not representative.

INTRODUCTION

Informed consent, as a prerequisite for human participation in research, emerged from the ethical principles in the Declaration of Helsinki.[1] It formally recognises people's interest in making decisions and acting voluntarily.[2] However, society also includes people for whom autonomous decision-making is problematic. These are individuals who lack mental capacity and have communication difficulties, either as separate impairments or in combination. This paper uses the term 'capacity and communication difficulties' (CCDs) to refer to this population. The prevalence of people affected by such difficulties is increasing and includes those with dementia,[3] acquired brain injury including non-superficial head injuries, stroke and other pathologies,[4] mental health conditions,[5] autism and intellectual disabilities.[6] There is a need to advance the science associated with such conditions and to develop effective interventions. Yet, adults with CCDs continue to be under-represented in research.[7–9]

The Mental Capacity Act (MCA)[10] and its accompanying Code of Practice[11] were introduced primarily to protect the rights of people who may lack capacity for informed decision-making (ch11.1; ch2.1).[11] The Act addresses provisions for treatment, welfare and finance, with separate provisions for intrusive research.[12] Underpinned by the assumption of individual capacity (ch1.2),[11] there is nevertheless the requirement to determine categorically whether an individual has capacity or not.[13] The distinction between capacity and incapacity, however, is not always clear.[14] It is affected by the complexity of information related to the decision and its cognitive load,[15] the setting and timing of the procedure,[16] and the availability of opportunities to exercise decision-making.[17] For the purposes of research, when a person is deemed to *have* capacity, usual informed consent procedures apply; when a person is deemed to *lack* capacity there is reliance on another person, the consultee, who advises on the likely wishes and feelings of the individual regarding their research participation.[11] In both situations, researchers consider how to support the individual's understanding and expressive needs (ch11.4).[11]

Prior to accommodating individual capacity, the researcher needs to defend the intrinsic value of including incapacitous participants, or indeed those with fluctuating capacity[12 18] (ch11.12).[11,] The question of whether the research could be equally satisfied with capacitous participants only needs to be answered.[11] As a result of research being treated in an exceptional way, it increases the sense that participation is a risky endeavour. This consideration extends to the Research Ethics Committees (RECs),[19] operating under the Health Research Authority (HRA), which has devolved responsibilities for research from the UK government's Department of Health and Social Care. Ethical approval is based on their scrutiny of research applications[19 20] (s31.1).[10] In particular, proposals involving people with capacity difficulties are referred to MCA-approved RECs. Navigation of the ethicolegal framework demands secure knowledge of the law by the various stakeholders (eg, researchers and REC members). However, deficits in researcher understanding of the law have been reported.[21]

It has been argued that the MCA is weighted towards protection of the individual,[8] with minimal consideration of the individual's agency.[12 22] It does, however, encourage support for decision-making under its research provisions (s1.3),[10] and in the context of 'best interests' decisions for treatment[23] (s4.6-7).[10] More broadly, supported decision-making has been advocated as a means of accommodating the individual's interest in exercising choice.[24] However, this has not filtered through to the research context. Some new possibilities are offered by resources, such as the 'Consent Support Tool',[25] which is designed to facilitate the inclusion of adults with communication disorders in research.[26] Others have argued against the reliance on printed information in favour of a detailed conversation to support the decision-making process, which is then documented.[27] Regardless of approach, it is the case that people are most likely to engage with and understand information that requires the least cognitive effort.[28]

The current study, part of a larger scale investigation, aimed to determine the characteristics of ethical review and recruitment processes under the research provisions of the MCA for England and Wales,[10] with particular reference to adults with CCDs. The research question was: how are adults with capacity-affecting conditions and associated communication difficulties included in ethically sound research?

METHODS

Design

A documentary-based, progressive survey of research in England and Wales was conducted in three parts: (1) a retrospective survey of studies since implementation of the MCA, to discover the proportion focused on capacity-affecting conditions; (2) a prospective survey of research applications to MCA-approved RECs over 12 months (September 2018–August 2019), to capture study recruitment processes and their ethical review; (3) a content survey of participant information sheets (PISs), to investigate practices in relation to the recruitment of people with CCDs.

Retrospective survey

Data were collected from the public database of the HRA (https://www.hra.nhs.uk/planning-and-improving-research/application-summaries/research-summaries/), which contains summaries of approved research studies that have been completed. Keywords associated with capacity-affecting conditions and communication difficulties were entered into the database (eg, autism, Asperger, autistic spectrum condition/disorder; stroke, aphasia; intellectual/learning disability; dementia, Alzheimer's; mental health condition/disorder; acquired head/

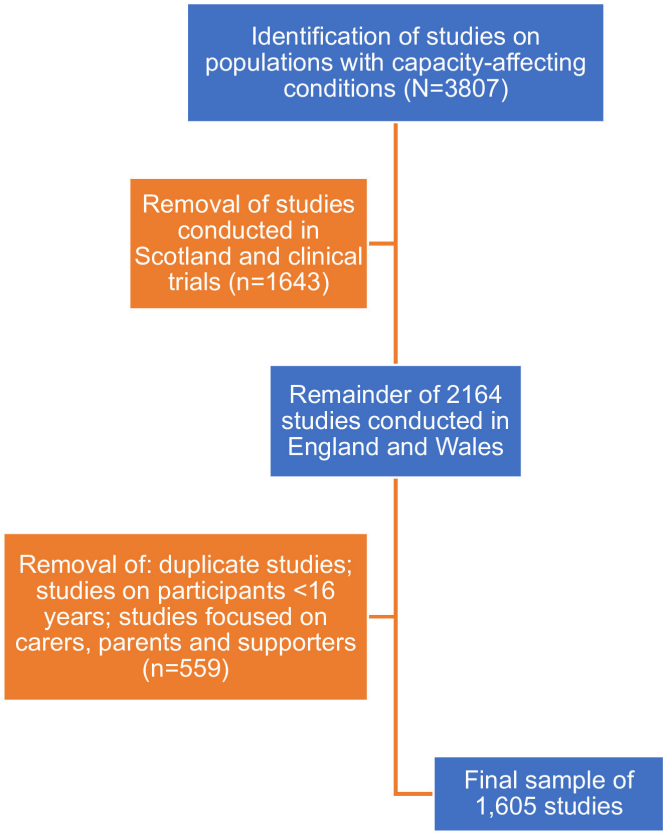

Figure 1 Sampling process for retrospective survey.

brain injury). Each keyword search was filtered using the following settings:

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

An initial search yielded 3807 studies, as shown in figure 1. Studies conducted in Scotland and clinical trials were identified and removed (n=1643) leaving 2164 studies. Information was extracted and summarised in a prepared excel spreadsheet detailing: title of study, research summary, REC name/reference, REC opinion and date (favourable, unfavourable, further information favourable, further information unfavourable) and study duration. The studies were then organised according to six main capacity-affecting conditions: autism; intellectual disability; acquired brain injury; aphasia after stroke; mental health condition; dementia. At this stage, all duplicates, studies that included individuals below 16 years of age, and studies focused on healthcare professionals or significant others (eg, family members, and carers) were removed (n=559). This left a final sample of 1605 studies. Percentage scores were calculated by population group, REC opinion and year of application.

Prospective survey

The HRA collated data for targeted fields in the Integrated Research Application System (IRAS) as shown in table 1. This is an online form used by researchers applying for study ethical approval in England and Wales.

Over the 12-month period (2018–2019), 184 studies were recorded. Studies carried out in Scotland (n=82) and those that did not include adults with CCDs (n=19) were identified and excluded from the final sample (N=83).

Information for IRAS sections A 17-1 and A 17-2 was reviewed initially. Textual information under sections A 33-1 and B 10 was entered into a prepared spreadsheet and organised according to population types associated with capacity-affecting conditions. Summative content analysis was carried out on the data.[29] The textual information was inspected and coded initially by the second author (OFJ). To manage any potential bias, the first author (KB) reviewed all codings, identifying any points of query, which were discussed with OFJ until consensus was achieved. The codes were then aggregated into overarching themes. The number of thematic references was presented by population group and as percentages for the entire dataset. Analysis of the listed 'additional conditions and recommendations' from RECs was managed in a similar way.

Table 1 Sections used for data extraction from IRAS (created by authors)

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 and 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 and 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.	

IRAS, Integrated Research Application System; RECs, Research Ethics Committees.

Participant information sheets

Survey of presentational and linguistic features was conducted on a small opportunistic sample. Chief investigators who had participated in a related study on researcher reasoning were invited to share PISs from their studies involving people with CCDs. Of the 31 PISs received, those that included individuals below 16 years of age, focused on significant others (eg, family members and carers) rather than people with CCDs were removed (n=6). The final sample comprised 25 PISs (intellectual disabilities=2; aphasia post stroke=8; dementia=8; mental health disorder=2; acquired brain injury=1; autism=0).

First, the key presentational features for each PIS were reviewed and recorded in a prepared Excel spreadsheet using the headings of: format (eg, 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). Second, an automated linguistic analysis was applied to all the PISs using the open-source software Coh-Metrix (http://cohmetrix.com). This involved extracting and copying the text content into MS Word documents initially, removing all titles and subheadings, information on contact details and REC approval, pictures and proper nouns. Each document was then 'cleaned' as recommended,[30] by removing bullet points, any numbering outside the text, extra line spacing, indentations to text, columns and inverted commas. All other punctuation was retained. This ensured that the same automated rules were applied to all texts, avoiding erroneous computational interpretation of such conventions as bullet points and inverted commas. Descriptive statistics in the Coh-Metrix output were extracted for: 'words' (quantity of words and sentences; sentence length), 'vocabulary' (familiarity; concreteness; imageability) and 'readability' (reading ease; reading age equivalence).

Patient and public involvement

Representatives from our key stakeholder groups (adults with intellectual disabilities, aphasia after stroke, autism and their supporters), REC members, voluntary organisations and the HRA were involved variously in the project advisory and working groups. They contributed to the design of the original research, the development of recruitment materials, project reports and dissemination activities.

RESULTS

Retrospective survey (2007–2017)

The final sample comprised 1605 studies with no studies identified prior to 2012. As shown in table 2, studies on populations with capacity-affecting conditions rose incrementally each year, with the highest number addressing dementia (32%) and second mental health conditions (27%). REC opinions were largely favourable: 30% achieved approval after a first application; and 65% after addressing REC recommendations. Around 5% received an unfavourable opinion. Only two studies (0.1%) received an unfavourable opinion after addressing REC recommendations.

Prospective survey

There were 83 applications to MCA-approved RECs in England and Wales from September 2018 to August 2019. Of the total applications, 76 (91%) were first-time applications; 3 were resubmissions; 1 was an appeal against an unfavourable opinion; and 3 applications were unspecified.

The range and type of exclusion criteria in relation to CCDs cited in the proposals are summarised in table 3. Exclusions based on lack of capacity or presence of communication difficulties occurred either singly or in combination, with 41 proposals (49%) containing no exclusions in relation to either. Of the identified exclusion criteria, a 'lack of capacity' was most frequently cited (25%) occurring most frequently in dementia studies (n=14). Exclusion through 'limited English' affected 20% of the studies.

The use of consultees was minimal (n=5; 6%). However, procedures identified for checking the assent–dissent of participants was higher (n=15; 18%), possibly to supplement the consultee's advice, but also to monitor the wishes and feelings of participants who were able to give informed consent.

Provisions used for the recruitment of participants with CCDs varied. Adaptations to information format and content of PISs 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* (eg, 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 four proposals (three dementia studies and one acquired brain injury 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;

Table 2 Retrospective survey (2012–2017): summary of REC opinions and year of application by population group (created by authors)

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 and aphasia	78	6	145	0	1	13	16	15	17	167	229 (14%)
Intellectual 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 conditions	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

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. Created by authors.
RECs, Research Ethics Committees.

Table 3 Prospective survey: characteristics of research applications under ethical review (2018–2019) (created by authors)

	Population types						
	Aphasia (n=5; 6%)	Dementia (n=42; 51%)	Acquired brain injury (n=21; 25%)	Intellectual disability (n=6; 7%)	Autism (n=4; 5%)	Mental health (n=5; 6%)	Total (N=83)
Exclusion criteria relating to CCDs							
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 CCDs							
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%)
REC recommendations related to inclusion of adults with CCDs							
Participant information sheet	18	124	67	28	14	11	262 (39%)
Consent form	3	24	12	5	6	2	52 (8%)
Consultee information sheet and declaration	3	29	21	5	5	0	63 (9%)
Procedures and protocols	9	115	71	18	17	18	248 (37%)
Patient and public involvement	1	1	2	0	0	2	6 (1%)
Editorial	1	5	9	1	1	1	18 (3%)
No recommendations	1	10	5	0	0	1	17 (3%)

CCDs, capacity and communication difficulties.

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%).

There were 666 separate REC recommendations in relation to studies involving people with capacity-affecting conditions and associated 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, for example, 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 concerning the 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 (ie, patient and 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%).

Participant information sheets

The sample of 25 PIS documents focused variously on people with: dementia (n=12); intellectual disabilities (n=2); aphasia post stroke (n=8); mental health condition (n=2); acquired brain injury (n=1). People with autism were not represented in the sample (see table 4). The majority of the PISs used an MS Word format (n=22) with 3 using PowerPoint. Number of pages ranged from 1 to 24 (*Mdn*=4; *Mean*=5.3; *SD*=4.6).

Images were present in just over half the documents (n=14; 56%). 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 emphasise keywords including highlighting, emboldening, capitalising and colouring. Layouts varied with some adopting tabular formats, others framing textual information or using block colours as backgrounds. The majority used subheadings to break up the text (n=23; 92%), with some also adopting organisational devices such as bullet points (n=7; 28%) and numbered lists (n=2; 20%).

As shown in table 5, 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).

'Vocabulary' attributes showed less variation across the documents 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 language processing speed) achieved high central tendency scores (*Mean*=573.9; *Mdn*=573.7).

'Readability' scores indicated a moderate level generally (reading ease: *Mean*=65.5; *Mdn*=67.7), which is roughly equivalent to scores of UK tabloid newspapers, for example, the Daily Star (n=66), and the BBC primary schools website (n=73).[27] 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 Summary of presentational characteristics of PISs (created by authors)

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 and 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	Subheadings	23 (92)
		Bullet points	7 (28)
		Numbers	5 (20)

PISs, participant information sheets.

DISCUSSION

The retrospective survey focused majorly on studies involving people with dementia, followed by people with mental health conditions. The number of studies rose incrementally in the post-MCA implementation period, with most receiving a favourable opinion after

Table 5 Summary of language properties of PISs (created by authors)

Category	Attributes	Mean	Median	SD	Range
Words and 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*	Familiarity (100–700: unfamiliar–familiar)†	573.9	573.7	8.5	547.3–589.8
	Concreteness 1 (100–700: highly abstract-highly concrete)‡	361.3	361.4	12	338.7–381
	Imageability (100–700: low imageability-highly imageability)§	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 years: 5=5–10 years; 6–8=11–13 years; 9–12=14–18 years.	7.6	7.3	2.5	3.5–12

*Mean rating for each word derived from Medical Research Council Psycholinguistic database.
†Based on ratings for 3488 words.
‡Based on ratings for 4293 words.
§Based on ratings for 4825 words.
MRC, Medical Research Council; PISs, participant information sheets.

making revisions in accordance with REC conditions and recommendations. The prospective survey revealed, of the applications undergoing ethical review, around half focused on people with dementia, followed by acquired brain injury (25%). Studies on the other populations ranged from 5% to 7%. Around half of all applications contained exclusion criteria in relation to CCDs. Use of consultees was fairly minimal (6%), but with a greater number of studies monitoring participant assent–dissent (18%). REC recommendations largely focused on participant-facing documentation with minimal attention to alternative communication approaches. The PIS sample was unevenly distributed across the population groups. Presentational features and language properties varied, with readability attaining an average level roughly equivalent to 11–15 years.

Inclusion of adults with CCDs

The increase in proposals submitted for ethical review during the post-MCA implementation period may be attributable to growth in researcher's familiarity with the research provisions of the MCA and the ethical review process using the online system IRAS. However, deficits in knowledge and understanding of the ethico-legal framework have been observed.[21] Alternatively, this might reflect trends in targeted funding for particular population groups in response to rising prevalence and an increased need for research, for example, people with dementia.[3]

Despite rising applications featuring people with capacity-affecting conditions, exclusion criteria around CCDs revealed in the prospective survey are consistent with previous reports.[7–9] It is possible that the extra demands of the consultee process for incapacitous participants may be off-putting for some researchers.[21] The challenge of soliciting a consultee's knowledge of the wishes and feelings of another individual about proposed research may affect their decision-making around sample inclusion.[8 9] Furthermore, insecure understanding of the MCA research provisions may cause confusion around the intrinsic value of research participation for incapacitous individuals, indicating a narrow interpretation of legal frameworks.[20] Ultimately, the weighting of MCA provisions towards protection of the individual, as opposed to empowerment, may influence a cautious approach to inclusion.[8 12 22] Thus, to avoid the complexities of the legal provisions for research, it may be expedient to exclude people with CCDs.

The majority of accommodations to support recruitment of people with CCDs focused on *format and content* of participant-facing documentation.[9] This was also reflected in the REC recommendations. The need to check for compliance with informational standards for ethical research may underpin the emphasis on documentation. Participant-facing documentation possibly represents a more tangible artefact for both the RECs conducting ethical reviews of research applications, and the researchers demonstrating they have met the requirements for ethical approval. Beyond the documentation, various communication strategies were referred to, although infrequently, such as supported conversation and procedural flexibility.[27]

Informational compliance versus participant needs

The tension between informational compliance and meeting the needs of prospective participants is borne out in the surveyed PIS sample, with some documents providing comprehensive levels of information with word volumes to match, and others displaying proportional levels of information with a commensurate low cognitive load.[28] Variable use of images (type, colour and placement) and typographic features may be accounted for by the different processing needs of the focal population types. However, despite attempts to use familiar vocabulary to accommodate participants with CCDs, lower levels of concreteness, imageability and readability persisted.

The different skillsets and professional backgrounds of the researchers devising the resources might be factors here.[31] In some cases, resources were the result of collaboration with people with relevant lived experience bringing authenticity. However, this does not necessarily assure a suitably reduced cognitive load for prospective participants.[28]

Strengths and limitations

The progressive nature of the survey covers the post-implementation period of the MCA (2005) both retrospectively and prospectively, and extends to an analysis of participant-facing information deployed in studies. The retrospective survey was limited to available information on the HRA database. Information extracted from the IRAS forms possibly affected the level and type of information available for the prospective survey and may be a commentary on the variable way researchers completed the required fields. Address of the question on how adults with CCDs are included in ethically sound research was supported by combining quantitative and qualitative data in a summative content analysis. The survey of presentational and linguistic features of PISs provided further detail on how information is configured for prospective participants. However, it was a small, opportunistic sample and unevenly distributed across the different population groups. It can therefore only provide an illustration of how the understanding of people with CCDs is accommodated. Principles of retention and weighing up of information, communication of the decision, and issues around temporary loss of capacity, were not considered.

CONCLUSIONS

The incremental rise in research including people with CCDs in the post-MCA implementation period,[10 11] suggests a growing confidence among researchers navigating the requirements of the ethical review system in England and Wales. However, exclusions still happen. Balancing the protection of incapacitous persons against support for their inclusion in research is an ongoing consideration for researchers. A further possible tension exists between accommodating the processing capacities of potential participants and meeting the ethicolegal requirements necessary for a 'favourable opinion'. One possible outcome is for accommodations to be defined by tangible 'objects' that can be uploaded to the online system (IRAS) for ethical review, for example, PISs. Despite attempts to render materials accessible to people with CCDs, there is insufficient attention to language content to match the processing needs of potential participants, and on how to support the retention and weighing up of information, and communication of the actual decision (ch4.12).[11] The implication of such a narrow view of recruitment materials is that critical strategies to support inclusion, for example, supported conversation and management of fluctuating capacity, are overlooked. A more nuanced approach to the recognition and accommodation of CCDs is needed, that moves beyond participant-facing documentation towards the real-world context for information-sharing and decision-making. The continued exclusion of people with CCDs from research will ultimately constrain both the availability and relevance of knowledge about conditions, and interventions with proven efficacy. Through executing deliberate strategies to support their inclusion, individuals with CCDs can be enabled to exercise their voices in ethically sound research, contribute to science and look forward to more effective treatments.

Author affiliations
[1]Faculty of Medicine and Health Sciences, University of East Anglia, Norwich, UK
[2]University of East Anglia Norwich Law School, Norwich, UK
[3]Queensland Aphasia Rehabilitation Centre, The University of Queensland, St Lucia, Queensland, Australia
[4]Centre for Educational Development, Appraisal and Research, University of Warwick Centre for Educational Development Appraisal and Research, Coventry, UK
[5]Rainbow Unit, Brooklands Hospital, Coventry and Warwickshire Partnership NHS Trust, Marston Green, Birmingham, UK
[6]Herefordshire and Worcestershire Health and Care NHS Trust, Worcester, UK

Twitter Karen Bunning @BunningKaren and Peter E Langdon @p_langdon

Collaborators Project ASSENT and collaborating authors Team: Karen Bunning, Oluseyi F Jimoh, Rob Heywood, Anne Killett, Hayley Ryan, Ciara Shiggins, Peter E. Langdon.

Contributors KB was involved in drafting of manuscript, data analysis and data interpretation. OFJ was involved in critical review of the manuscript, data analysis and data interpretation. RH, AK, CS and PL were involved in critical review of the manuscript. HR was involved in data analysis and critical review of the manuscript. KB accepts full responsibility for the work and/or the conduct of the study, had access to the data, and controlled the decision to publish.

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ORCID iDs
Karen Bunning http://orcid.org/0000-0002-7396-9205
Peter E Langdon http://orcid.org/0000-0002-7745-1825

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