Protecting and empowering adults with capacity-affecting conditions to take part in health and health-related research

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Abstract:

Health research is essential if people are to enjoy the highest attainable standard of health and healthcare. Yet, persons with capacity-affecting conditions are routinely excluded from research, as they are often judged to lack the capacity to give consent. Focusing on the *Mental Capacity Act England and Wales 2005* (MCA), which regulates research involving adults judged to lack capacity, we outline the provision of the MCA and then describe the process of ethical review designed to ensure compliance with these provisions; 2) present findings from interviews with members of the committees responsible for ethical review and with researchers, who have experience of working with the MCA; 3) discuss the implications of these findings for the inclusion of adults lacking capacity in research as well as drawing conclusions about the effectiveness of the MCA.

Keywords:

Mental Capacity Act; research; equality; health; healthcare; inclusion; the Convention on the Rights of Persons with Disabilities

Points of Interest:

- Adults with adults with capacity-affecting conditions are often judged as unable to give or withhold consent and are routinely excluded from participating in biomedical and clinical research.
- Denying this group an opportunity to participate in research reduces the possibility of them benefiting from both new treatments and improvements in healthcare.
- The *Mental Capacity Act England and Wales 2005* provides a legal framework for involving adults with capacity-affecting conditions in research where consent is a legal requirement.

- Interviews with researchers and those responsible for ensuring the *Mental Capacity Act England and Wales 2005* revealed that it is poorly understood and that there are no reliable means of ensuring the *Act* is fully implemented.

Funding:
Nuffield Foundation, grant number: OSP/43239

Acknowledgements:
We are grateful to the Research Ethics Committee members and the researchers who agreed to be interviewed, and to the Nuffield Foundation for funding this research.

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Introduction

Article 25 of the United Nations' Convention on the Rights of Persons with Disability (CRPD) asserts the right of persons with disabilities "to the highest attainable standard of health and healthcare". This is not solely an issue of access (Redley, 2012). Improvements in health and healthcare also depend upon evidence of both effectiveness and efficacy generated through high-quality research. Persons with disabilities, especially those conditions which affect their capacity (such as, an intellectual disability, dementia, or a brain injury) are, however, routinely excluded from much biomedical and clinical research (Bunning et al., 2022; Prusaczyk, Cherney, Carpenter, & DuBois, 2017): a practice that indirectly denies them opportunities to benefit from both new treatments and improvements in healthcare (Shepherd, 2020), and is likely to be a breach of Article 25. The exclusion of people with capacity-affecting conditions turns on two interlinked ideas. Firstly, free, and informed consent is considered essential to all ethical research involving human participants (see World Medical Association Declaration of Helsinki) and secondly, many people with capacity-affecting conditions are seen as lacking the capacity to give such consent. Excluding this group, therefore, protects them from potential harm and abuse (Wertheimer, 2010), while also protecting researchers from accusations of conducting unethical, if not unlawful, research. This line of reasoning, however, is increasingly seen as disadvantageous and discriminatory (Capri & Coetzee, 2012). It is disadvantageous, in that this group are less

likely to have their health-related needs recognised and researched (Shepherd, Wood, Griffith, Sheehan, & Hood, 2019a) and discriminatory, in that, it creates a class of persons who are systematically excluded from research (Scholten, Gather, & Vollmann, 2021).

To give an example, epilepsy, is some twenty times more common among people with intellectual disabilities, a condition defined by difficulties with general intellectual functioning (American Psychiatric Association, 2013), than it is in the general population (Matthews, Weston, Baxter, Felce, & Kerr, 2008). Yet, while 70–80% of the general population achieve seizure freedom through anti-epileptic medications and other interventions, only 30% of people with an intellectual disability attain this outcome (Bell & Sander, 2001). Furthermore, standardised mortality rates for people with an intellectual disability and epilepsy are 5.0; among members of the general population with chronic epilepsy, they are as low as 2.05 (Hitiris, Mohanraj, Norrie, & Brodie, 2007). While these differences cannot be wholly attributed to the exclusion of persons with intellectual disabilities from health and health-related research, it is the case that within this population, polypharmacy and the use of older medication are more common (Fitzgerald & Ring, 2009). Were people with intellectual disabilities and epilepsy to be better represented in health and health-related research we could be sure they were receiving the highest attainable standard of health and healthcare.

In England and Wales, the *Mental Capacity Act 2005* (England and Wales) (MCA) and its accompanying Code of Practice (Department for Constitutional Affairs, 2007) include legal provisions enabling adults lacking the capacity to consent to be research participants. Focusing on these provisions, and drawing on interview data, this paper considers whether enough is being done in England and Wales to ensure adults who lack capacity can participate in research and therefore enjoy their right to the highest obtainable standard of health and healthcare. Divided into three parts, this paper, first, presents the MCA's framework for involving persons who lack capacity in research and describes the administrative infrastructure of Research Ethics Committees (REC) overseeing their implementation; second, to learn about the practical operation of the MCA, it presents findings from semi-structured interviews with REC members and researchers; and third, assesses whether more could be done to enable adults lacking capacity to participate in research, and thereby further their right to the highest attainable standard of health and healthcare.

Background

The *Mental Capacity Act 2005 (England and Wales)* and its *Code of Practice* (Department for Constitutional Affairs, 2007) establishes a framework for protecting the rights and dignity of adults lacking the capacity to make decisions for themselves. The MCA is based on the principle that a person has capacity until shown otherwise (s.1.2) and that capacity is always decision-specific (s.2.1). Before a person is judged to lack capacity it must be established: that the person has an 'impairment of, or disturbance in the functioning of, the mind or brain' (s.2.1); and concerning the decision in question, is unable to understand information relevant to it, retain and weigh-up that information and then communicate (by any means) their decision (s.3.1). However, before such a judgement is made, all practicable steps must be taken to support the person to make an autonomous decision (s.1.3). Chapter 3 of the Code of Practice provides an extensive list of what these steps might be: presenting information in a way that is easier for the person to understand; exploring different modes of communication, and involving different people such as family members, support workers or an advocate. Consideration should also be given as to whether the time of day or location could be affecting a person's capacity. Only when such efforts have proved ineffective, can a lawful substitute decision be made on a person's behalf. And even then, efforts must be made to promote the person's participation by considering their wishes, feelings, and values (s.4.6.b) as well as seeking the opinion of others interested in the person's welfare (s. 4.7.b). Furthermore, substitute decisions must be made in a person's 'best interests' (s.4) and made by the individual requiring that a decision be made. Chapter 5 of the Code of Practice to the *MCA* provides a checklist of factors that decision-makers should consider when determining what might be in a person's best interests. These factors, which cannot be exhaustively listed, include no discrimination; involving the person as fully as possible; not being motivated to bring about the person's death, and choosing the option least restrictive of the person's freedom. Significantly, however, the best interests principle does not apply to decisions about participating in research (s. 32.4).

Instead, sections 30-34 of the MCA, and Chapter 11 of the Code of Practice, which specifically addresses research participation, requires researchers to seek advice from a consultee (s.32). Provided with information about the research, the consultee advises the researcher on whether the person concerned should take part (s. 32.4.a) and what that person's wishes and feelings would be if they had capacity (s. 32.4.b). Only with favourable advice from a consultee can a person participate (s.32. 5), with the final decision remaining with the researcher. Ideally, a consultee's advice will be based upon personal knowledge of the person concerned, and the consultee will not be that person's paid carer. However, where

this is not be possible, advice may be sought from a nominated consultee (s.32.3), provided the nominated consultee is unconnected with the research (s.32.3.b). Where a research project is investigating emergency medicine, such that there may be insufficient time to involve a consultee, the MCA allows for urgent decisions (s.32.8). A researcher may lawfully decide to temporarily recruit a person lacking capacity, providing agreement is given by a medical practitioner not involved in the research (s.32.9a); or recruitment follows procedures agreed in advance with a Research Ethics Committee (s.32.9.b). Consent must be sought should the person regain capacity, or if the person continues to lack capacity, a consultee must be involved (s. 32.10). Suspending the best interests principle means that researchers are not in a position to decide it is in a person's best interests to be a participant in their research. It also allows for altruistic decisions: persons lacking capacity can participate in research where their involvement, while of no direct benefit to them, could benefit others (s. 31.5b; CoP ch.11, par.16). The MCA also has several additional safeguards: the research must relate to the condition, or treatment of the condition, causing the impairment or disturbance in the participant's mind or brain (s.31.2); research of comparable effectiveness could not be conducted without involving participants lacking capacity (s. 31.4); the research has the potential to benefit those affected by the same or similar condition (s.31.5.b); risks are negligible (s.31.6.a) and there is no significant interference in participants freedom or privacy (s.31. 6.b); nothing is done that a participant appears to object to (s.33.2); the interests of science and society do not outweigh the participant's interests (s.33.3). Finally, the research must be approved by an appropriate body (s. 30.4), namely, the network of ethics committees in England and Wales and overseen by NHS Health Research Authority (HRA).

Through its network of Research Ethics Committees (RECs), the NHS Health Research Authority (HRA) aims to ensure that health and social care is legal, ethical, and scientifically worthwhile. To expedite the review process RECs specialise; at the time of writing, there are 30 RECs in England and Wales specialising in research involving adults lacking capacity. Researchers applying for ethical review do so through an application process requiring not only comprehensive information on the research but also, where it is planned to involve adults lacking capacity, answers to questions specifically relating to sections 30-34 of the MCA. These questions, in section B of the Integrated Research Application System (IRAS) collect details on: the conditions impairing potential participants' capacity (Question 1); why the research would be less effective without their involvement (Question 2); the experience and training of the person(s) who will assess participants' capacity (Question 3); whether the research will directly benefit participants, or contribute to

knowledge of the causes, treatment or care of persons with the condition causing their incapacity, and the foreseeable risks or burdens of participation (Questions 4-6); how consultees will be identified and consulted, and if required, arrangements for urgent decisions (Questions 7-9); steps, for providing would-be participants with information about the research, and how their wishes and feelings will be considered (Question 10); how fluctuations in participants' capacity will be managed (Question 11); criteria for withdrawing participants from the research, steps for ensuring that nothing is done to which a participant objects, and what measure are in place for ensuring any advance decisions or statements are respected (Questions 12-14). Conspicuously absent, however, are questions concerning what steps will be taken to support would-be participants to make autonomous decisions. That said, applicants are required to submit copies of their public-facing documents, which will include participant information sheets written in an accessible or easy-read style. Research can only proceed once a REC has given a favourable opinion. Should a committee require changes to a proposed project, they will describe these in a letter. Such changes can range from minor modifications to the wording of public-facing documents, to methodological revisions. Only when the required changes are made and approved, will a favourable opinion be given.

Interviews with REC members and researchers:

The findings presented below contribute to a larger project, known as ASSENT, focused on adults who may lack capacity and have communication difficulties (www.uea.ac.uk/groups-and-centres/assent). A project aiming to ensure more adults with capacity-affecting conditions have opportunities to participate in research by ensuring researchers have a better understanding of the MCA and that would-be participants with capacity-affecting condition receive appropriate support to make an autonomous decision (Killett et al., 2023). The findings presented here focus specifically on provisions in sections 30-34 of the MCA relating to the participation of adults lacking capacity in research.

Method

Members of a REC were eligible to be interviewed if they sat on a committee "flagged" as reviewing research projects involving adults lacking the capacity to give consent. A pragmatically recruited sample of eight respondents from eight different committees was recruited. Researchers were eligible for recruitment if they had conducted health or healthcare-related research involving adults at risk of lacking capacity since 2007 when the

MCA came into force. Again, a sample of eight researchers from eight different universities in England was recruited pragmatically. Data presented below are based upon the REC members, and researchers, views and experiences on four issues: the principle of involving adults judged to lack capacity in research; the MCA's legal framework for involving such adults; the utility of the MCA's Code of Practice; and the process of using consultees. Interviews were conducted by telephone, audio recorded, and transcribed verbatim. The analysis involved collating and summarising respondents' views on these four topics. These summaries, essentially a content analysis (Hsieh & Shannon, 2005), took participants' views at face value (Silverman, 2001). As our interest is only in the practical operation of the MCA, rather than respondents' constructions of subjective experiences, we present no quotations from the interview data. The interviews were conducted in 2019 following a favourable ethical opinion from a NHS Research Ethics Committee (insert the REC assigned application number).

Findings

There was some variation in the ability of respondents to formulate their views on sections 30-34 of the MCA, research methodology, and research ethics. While some had a good knowledge of the MCA, even if their use of legal terminology was not always correct, others made factual errors. Findings from the interviews are structured around four areas: the issues involving adults judged to lack capacity in research; the MCA's legal framework for involving these adults in research; the helpfulness of the MCA's Code of Practice; and the process of involving consultees. Findings from REC members are reported first.

REC members

Our sample comprised respondents with several years of service on these committees to those with little experience. In addition, some respondents, because of clinical responsibilities, had a wider familiarity with the MCA.

Involving adults judged to lack capacity in research*:* all REC members endorsed the general principle that including people who lack capacity in research was morally good. Inclusion, we were told, enabled them to contribute to the greater social good, as well as making them feel valued. One respondent also observed that including people who lacked capacity led to better research, although precisely how, was not specified. Inclusion was described as dependent upon the provision of easy-to-understand information in an accessible format. This

was characterised as public-facing documents that avoided jargon and used diagrams. It was also suggested that researchers might use techniques developed for communicating with children, although what these techniques were was not elaborated on. One REC member believed A4 sheets (the standard format for patient information sheets) were overused, while another praised a project that had used video. Most information sheets and supporting documentation coming before RECs were said to be well written, although according to one respondent, '25-30 per cent' needed improvement. It was specifically observed that if information sheets did not adequately describe the consultee role, prospective consultees would not know what was expected of them. It was also reported that Public and Patient Involvement (PPI) groups had a role in supporting involvement and that some research methodologies such as ethnographic observations were more inclusive of people likely to lack capacity, although precisely why was not specified. Concerning research undertaken by graduate students, two respondents raised financial considerations as a constraint against involvement. Some respondents' enthusiasm for involvement was tempered, however, by an awareness that participants had to be protected from harm, an observation one REC member illustrated with reference to people with autism. Reportedly, an applicant to the REC had wished to involve people on the autistic spectrum. Members of that project's PPI group, however, advised against it, as being a research participant was thought to be 'upsetting'.

REC members also saw their role as one to challenge the 'unthinking' exclusion of persons who lack capacity, especially where applicants had little experience of working with speech and language therapists or using supported communication techniques. That said, none of the REC members described any actual occasion where they had challenged a researcher's use of eligibility criteria that excluded persons who lack capacity. Only two respondents mentioned the principle that the inclusion of persons lacking capacity had to be scientifically justified, i.e. that research of comparable effectiveness could not be undertaken without their involvement. One of these two suggested that PPI groups put pressure on researchers to include people who lacked capacity, because such groups were committed to social inclusion. Another commented that researchers with backgrounds in the social sciences, tended more often than clinicians, to see the MCA as promoting social inclusion, rather than as a means of protecting vulnerable adults from potential harm.

The MCA's legal framework for involving adults lacking capacity in research: REC members thought the MCA worked well where researchers assumed prospective participants could consent, supported them to make autonomous decisions, and did not confuse clinical

categories like ‘intellectual disability’ and ‘insight’ with the MCA’s legal definition of (in)capacity. REC members also told us that researchers: did not always appreciate that consultees did not give proxy consent; muddled their information sheets where consultees were also approached as potential research participants; and failed to appreciate that the inclusion of participants lacking capacity needed to be scientifically justified. There were REC members who thought applicants, especially student researchers, could benefit from training in sections 30-34 of the MCA. In the opinion of one such REC member, graduate students making REC applications were insufficiently supported by their academic supervisors. However, a contrary view held by a respondent was that the only way to understand sections 30-34 of the MCA was to go through the process of seeking and obtaining ethical approval. That said, it was clear that some REC members' own understanding of the MCA was hazy. One admitted having a poor grasp of the MCA and deferring to the opinions of others. Another suggested, erroneously, that the MCA failed to cover what should be done when a research participant unexpectedly loses capacity and suggested that he was happy to work with the idea of ‘enduring consent’ were capacity to be lost. A different REC member described the MCA's formulation of capacity as ‘clunky and haphazard’ because it did not map neatly onto medical understandings of capacity (*sic*). The principle that persons be able to retain information germane to a decision was seen as potentially problematic. Giving the example of a series of ethnographic studies, a respondent wondered if it was necessary to seek consent, or involve a consultee, if a participant was unable to recall the researcher’s previous visits. In sum, they queried how long a person might be expected to retain information about a decision for it to be seen as being made with capacity. Concerning the assessment of capacity, and contrary to exceptions in the Code of Practice, three committee members thought these assessments could only be made by people with clinical training. For one of these respondents that meant a psychiatrist or a clinical psychologist. Only one REC member formulated the general principle that sections 30-34 of the MCA were there both to protect people lacking capacity, as well as to facilitate their involvement in research.

The helpfulness of the MCA’s Code of Practice: when asked about their use of the Code of Practice, all but one committee member described its role as marginal. Rather, their knowledge of sections 30-34 of the MCA and Chapter 11 of the Code of Practice came from the questions REC applicants were required to answer when planning to involve adults lacking capacity (see above). The one respondent who did report reading the Code of

Practice, cited their absence of a legal background, saying he found it a useful guide to issues raised by the MCA.

The process of involving consultees: the respondent with little REC experience even likened adults lacking capacity to children's lack of capacity and described consultees as making 'best interests' decisions for them. This respondent's understanding of the consultee process was more accurate when he noted that nominated consultees should be unconnected to the research in question. Only one REC member observed that before involving a consultee, researchers should 'go the extra mile' to support would-be participants to make an autonomous decision. Moreover, this REC member, and one other, observed that what was asked of personal consultees was difficult: imagining a person as different (having capacity) from how they were. An exercise thought to be particularly difficult where a person had an intellectual disability and might never have expressed, or been able to express, views on participating in research. Committee members were aware of the distinction between personal and nominated consultees, with many preferring personal consultees as they were thought more likely to know a person's wishes. An exception to this was held by two REC members who reported that nominated consultees were preferable, as they could be contacted in the middle of the night or when an 'emergency decision' was needed. While another described personal consultees as 'flaky', observing that in stressful situations personal consultees could give their views without considering what the person concerned might want. Additionally, it was reported that there was no way of knowing if the person acting as a personal consultee would be the choice of the person concerned, a worry that was also raised about nominated consultees. It was variously suggested that nominated consultees might have insufficient knowledge of the person concerned, be biased either towards or against participating in the research, and not make a concerted effort to involve the person in the decision-making process. Although it was also reported that nominated consultees might be more objective when assessing the risks and benefits of participation. Finally, one respondent observed that since REC members never saw the consultee process in operation, they did not know how it worked in practice.

Researchers

Our sample of eight researchers comprised seven clinicians: three medical doctors; three clinical psychologists specialising in intellectual disability; and a speech and language

therapist. The eighth was a social scientist conducting research involving people with dementia.

Involving adults judged to lack capacity in research: respondents thought involving such adults was a moral good: participation was empowering, and inclusion led to better research. Two respondents attributed the exclusion of persons lacking capacity to worries about assessing capacity and difficulties associated with producing accessible participant-facing documentation. In the view of these researchers, people should only be excluded from research if they could not comply with the demands of an intervention or were unable to respond meaningfully to questionnaires or interview questions. In contrast, another researcher described, with evident frustration, how a REC would not allow him to recruit adults with intellectual disabilities because persons lacking the capacity to consent would also be unable to answer questions about their medical condition. Only three respondents cited the requirement that persons lacking capacity could only be participants if research of comparable effectiveness could not be conducted without their involvement. One of these went on to observe that participation should not interfere with the person's freedom and privacy, nor, idiosyncratically, be 'speculative'. All respondents understood the principle of informed consent and that potential participants should be supported to make an autonomous decision. While one respondent reported using Talking Mats (a proprietary aid, used with people experiencing communication difficulties: https://www.talkingmats.com), others described writing accessible or 'easy read' information sheets. 'Easy read' was described in terms of using large-size fonts with increased spacing, high contrast printing (black letters on yellow paper), pictures, and summary boxes. Two respondents observed that information sheets prepared using these techniques to enhance their value in communication, could potentially benefit all participants, not just those at risk of lacking capacity. One respondent thought more guidance on the preparation of such sheets would be useful. In contrast, another respondent thought that due to an 'audit culture' in the HRA, information sheets were becoming overly long: 'seven pages of legal waffle'. A view shared by three other respondents who expressed frustration with the HRA for stipulating that information sheets refer to the General Data Protection Regulations (GDPR). While communication issues underpinning support might be implied by the measures mentioned here, such issues were not addressed or their implications considered by these respondents.

The MCA's legal framework for involving adults lacking capacity in research: the idea that capacity is decision-specific was understood by all researchers, and most, with a little prompting, could name the four prongs comprising the MCA's definition of (in)capacity. Views differed, however, as to whether capacity assessments should be the outcome of a methodical process, or a judgement formed around a conversation. Researchers in the former camp thought that capacity should only be assessed by qualified clinicians and/or using a standardised instrument. Among respondents taking this stance, were requests for additional guidance when assessing the capacity of persons, hitherto, unknown to them, and what should be done when capacity had to be assessed by researchers lacking clinical skills. Concerns were also raised over how much detail a person had to retain, while three others thought that gauging a person's understanding was difficult. One of these respondents reported using a person's body language (orientation to the relevant parts of an information sheet) as a check on comprehension. Furthermore, when assessing a person's understanding these researchers said they were guided, in part, by the views of paid and family carers. This practice, raised for this respondent, the uncomfortable possibility of disagreeing with those providing care and support. Among those researchers who saw capacity assessments as a matter of judgement (as opposed to a formal assessment), one suggested that efforts to formalise the process would be too burdensome. Without much elaboration, another acknowledged that capacity assessments were a 'grey area' and that in clinical situations such assessments were used to intentionally limit people's freedom.

Two researchers raised conceptual concerns over the MCA's definition of capacity, suggesting that psychological factors like 'trust' and 'emotion' play an important part in decision-making. Neither respondent, however, described how these considerations might be incorporated into a legal definition of capacity. Only one of the eight researchers mentioned the importance of involving persons lacking capacity in the decision-making process by actively seeking to ascertain their views and wishes. He described this as the right thing to do, both ethically and pragmatically. Pragmatically, efforts to involve a person in the decision-making process were appreciated by family members who might subsequently be asked to act as personal consultees.

The helpfulness of the MCA's Code of Practice: rather than turning to the MCA's Code of Practice, respondents reported relying on the HRA's website and the materials garnered from *Good Clinical Practice training (GCP)*. Respondents were not asked to elaborate on the usefulness of either the HRA website or GCP training. That said, one respondent commented

that the HRA website provided useful templates for creating information sheets and consent forms.

The process of involving consultees: this appeared to be well understood. All researchers reported writing information sheets specifically targeted at consultees; yet all described consultees as giving consent, rather than advice. Among researchers recruiting participants from hospitals, the identification of personal consultees was said to be straightforward. Staff on wards were able to provide background information on patients and make introductions to family members who could be approached as potential consultees. We were also told by one of these respondents that her research protocols set a specific deadline after which, if a personal consultee had not been found a nominated consultee would be sought. Another respondent, recruiting patients in emergency departments, observed that family members often failed to understand what was expected of them as personal consultees. Rather than realising that they were being asked for advice on what the patient might want or wish, they heard a coercive demand for consent, which they refused to give. None of the researchers working in acute settings reported using the MCA's provisions for urgent decisions (s.32.8), although one did think these provisions were misused. Using the term 'retrospective consent', this respondent believed that patients admitted to emergency departments were judged as lacking capacity as they were thought unlikely (at that moment) to give consent, due to such patients being scared and/or in pain. Consequently, an urgent decision would be made to include them. Then, when their medical condition had stabilised, and they were thought more likely to give consent, were they approached. Concerning potential participants living with members of their families, we were told that identifying and approaching potential consultees was similarly unproblematic. Furthermore, family members were described as accustomed to making decisions on behalf of the person concerned. Where the identification and recruitment of consultees were reported to be more problematic, was when a person lived in a community residential service. Researchers described their reliance on the managers of these services to both identify and make initial contact with potential personal consultees as a time-consuming process beyond their control. For one respondent, the delays inherent in this process meant he discouraged doctoral students from undertaking research involving participants lacking capacity. Another researcher described staff working in these services as 'gatekeepers', with little or no knowledge of sections 30-34 of the MCA, and who arbitrarily determined that it was inappropriate for a person to be involved in research or suggesting (incorrectly) that it was necessary to arrange a 'best interests' meeting. Such

difficulties were resolvable, one researcher told us, once face-to-face contact was made with staff working in these services. Nevertheless, this respondent described some staff as 'deliberately obstructive', and suggested services should have policies that explicitly addressed residents' involvement in research. Such policies, it was suggested, could clarify the conditions under which staff members might act as nominated consultees (erroneously referred to as 'professional consultees'). Researchers appeared to favour personal over nominated consultees on the bases that personal consultees would have a better knowledge of the person concerned. One respondent even wondered if using a 'professional consultee' was 'within the spirit of the MCA'. This respondent thought personal consultees particularly important where the research involved an element of risk, giving the legally incorrect example of participating in 'drugs trials', which along with medical devices are regulated by the *Medicines for Human Use (Clinical Trials) Regulations 2004*. Another researcher believed the HRA's expectation that consultees give 'written consent' (sic), was unhelpful when conversations about participation often took place over the telephone. The possibility that participants' capacity might fluctuate during their involvement was a concern for three respondents. Two wondered if such participants would have to go through the consent process again. The third reported, anticipating the possibility that participants might lose capacity, that they asked participants in advance if they would wish their participation to continue. This respondent reported seeking advice from the HRA as to whether it was necessary to re-consult a consultee each time a participant lost capacity. After some 'to-ing and fro-ing' he was advised that it was not. This same respondent also wondered if the MCA should be brought in line with the *Medicines for Human Use (Clinical Trials) Regulations* where consent is presumed to endure should capacity be lost, and where consent can be given by a proxy. We were told by one researcher who wished to read patient records held by opticians, that advice from a personal consultee did not always secure access. Consequently, this respondent described only asking people with powers of attorney to act as a consultee. While holders of patients' records might respond by releasing the records to the consultee, the fact that the consultee had powers of attorney at least ensured the records could be accessed. This respondent thought the HRA needed to provide clearer guidance on access to patient healthcare records in circumstances like these.

***Experiences of ethical review*:** researchers' views on the MCA and the recruitment of participants lacking capacity were often entwined with experiences of ethical review. Three respondents expressed views on receiving unfavourable opinions. One of these thought REC

members could not 'disentangle' ethical issues, vulnerable adults engaged in criminal behaviour, from matters of scientific method. This respondent believed the *modus operandi* of RECs was to 'decline applications wherever possible'. The other two researchers, who appeared to understand the principle of 'comparable effectiveness', had been given unfavourable opinions because the REC ruled that research of comparable effectiveness could be carried out without involving participants who lacked the capacity. One of these acknowledged that RECs were there to protect vulnerable people but thought the REC had confused a scientific question, the necessity of including people with a capacity-affecting condition, with ethical concerns. When this respondent sought approval for a similar but larger project, he described applying to a different REC, which gave a favourable opinion.

Respondents also offered some general criticisms of RECs. We were told that: decisions varied between RECs; a 'one size fits all' approach was applied to all research projects; the process had lost touch with the realities of research; and that RECs, were becoming *de facto* arbiters of the law. In contrast, other respondents displayed an awareness of how to successfully navigate the process by anticipating and addressing the concerns of a REC. This involved: pointing out that while risks can be minimised, they cannot be eliminated; demonstrating compliance with the MCA; illustrating that you are a 'safe pair of hands' by showing that you have the skills to undertake the research and can explain the research to would-be participants and assess their capacity.

Discussion:

Despite the limitations of a small sample size, the descriptive account of our interviews presented here provide a unique set of materials to assess whether enough is routinely being done to ensure adults who lack capacity can participate in research.

First, both REC members and researchers held that people lacking capacity should have opportunities to take part in research. The case for their involvement was overwhelmingly based on a commitment to inclusion as a moral good. Additionally, some respondents thought that people with who lack capacity benefited from being involved and brought a unique perspective. This last claim assumes, however, that the persons concerned can formulate and communicate their perspective, something not all people who lack capacity are thought to be able to do (Vehmas, 2008). Some respondents suggested that involvement was contingent upon minimising risks, although it was not clear from the interviews whether the level of risk should be set at a lower threshold than that for persons with capacity. That said, it is a requirement of the MCA that risks should be negligible. While a few respondents

mentioned the principle that there must be grounds for believing research of comparable effectiveness could not be carried out without involving people lacking capacity, no one referred to the principle that the research must also benefit people affected by the same or a similar condition. In sum, while respondents appeared committed to the idea of inclusion and saw it as a key MCA concern, they seemed less aware that the MCA also sought to protect participants from abuse and exploitation. Absent from respondents' commitments to the value of inclusion was any critique of the pervasive exclusion of people with cognitive impairments from research (Prusaczyk et al., 2017). Notably, only one REC member mentioned having confronted the 'unthinking' use of exclusion criteria that prevented people with capacity-affecting conditions from being research participants. Unfortunately, our data do not reveal if this person was able to exert any influence over such criteria, and in any case the MCA was not written to challenge such exclusion (Shepherd, 2020). Nor are there any official figures reporting the proportion of trials where lacking capacity to consent to take part is used as an exclusion criterion. Although, a recent review concluded that 90% of UK-based randomised control trials excluded persons with intellectual disabilities (Feldman, Bosett, Collet, & Burnham-Riosa, 2014). It is also the case that the HRA's annual reports (see https://www.hra.nhs.uk), while reporting the total number of applications it receives, do not identify those where section B of the IRAS form has been completed. So, while the MCA seeks to include people with capacity-affecting conditions in research, little is being done to challenge their exclusion.

All respondents appeared well versed in the importance of 'easy read 'documentation and were able to characterise how these are written. Research suggests, however, that these documents, despite undergoing ethical review, contain legal errors (Shepherd, Wood, Griffith, Sheehan, & Hood, 2019b). Moreover, their presence is not synonymous with evidence of either their use or effectiveness. Strikingly absent from our data, save for one researcher, was any mention of practical steps having been taken to support people to make autonomous decisions. As such, it is worth also noting that few of those we interviewed reported using the MCA's Code of Practice, with its guidance on how people might be supported to make autonomous decisions. At the time of writing, the HRA's web pages (https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/mental-capacity-act/), which some researchers referred to, gives no guidance on supporting people to make an autonomous decision. Furthermore, the researchers we interviewed, rather than being concerned about promoting people's autonomy, for instance by modifying modes of communication, seemed overwhelmingly focused on the technicalities of

assessing a person's capacity. Many of them requested further guidance and/or a standardised instrument for making these assessments. This may imply that if researchers put more effort into supporting would-be participants to make autonomous decisions, they might be more confident judges of whether a person could make an autonomous decision. In keeping with anxieties over assessing capacity was the ubiquity with which respondents spoke of consultees giving 'consent'. If consultees are described as giving consent, this may call into question whether there exists any incentive for researchers to support would-be participants to make an autonomous decision or involve them in the decision-making process. The idea that consultees give consent, chimes with the preference of many respondents for personal consultees over a nominated consultee, as the former are presumed to have more knowledge of a person's wishes (Heywood et al., 2019). Furthermore, describing consultees as giving consent obscures the practical reality that it is the researcher - the person requiring that a decision be made - who has responsibility for finally deciding (after gaining favourable advice from a consultee) whether a person can participate. That said, neither Sections 30-34 of the MCA nor Chapter 11 of the Code of Practice, clearly state that it is the researcher who has this final responsibility. In sum, our data suggest that while researchers see the inclusion of people who lack capacity as a moral good, they are less inclined to actually involve them in the decision-making process. Instead, many researchers appear to want tried-and tested techniques for identifying would-be participants who lack capacity and then to speedily identify a consultee who will give consent (sic). In other words, while supporting a person to make a decision is an important safeguard within the MCA, any such support, beyond 'easy read' documentation, did not feature prominently among the concerns of the researchers we interviewed. As one of the REC members observed, he and his colleagues have little idea how the MCA is being implemented in practice. Moreover, there has been little independent scrutiny of sections 30-34. No cases concerning these sections have come before the Court of Protection, while the House of Lords Select Committee Report on the MCA does not mention them (House of Lords Select Committee, 2014).

The Code of practice to the MCA is currently undergoing revision (https://www.gov.uk/government/consultations/changes-to-the-mca-code-of-practice-and-implementation-of-the-lps). Those responsible for amending the Code of Practice might, therefore, wish to consider the following observations based on our findings.

The MCA's current provisions for including adults at risk of lacking the capacity to give or withhold consent in research, could be improved by ensuring any revised version of

Chapter 11 emphasises the importance of supporting adults who have difficulties with decision-making associated with a disability to make autonomous decisions about participating in research, and that where this is not possible because of the severity of a person's disability, that the person is still supported, as far as practicable, to participate in the decision-making process. Guidance on how best to support persons at risk of lacking capacity needs to be prominent and signposted. It needs to be clarified whether a person must be qualified or trained before assessing a person's capacity and if these are necessary, to use a structured assessment rather than simply having a conversation with the person concerned. The routine practice that consultees offer advice rather than consent by proxy needs to be highlighted and supported with an explanation as to why enacting this distinction is important. Finally, clarity is needed as to whether favourable advice from a consultee ensures that researchers have a right, should they require it, to access a person's healthcare records. Notwithstanding these suggestions, our research indicates that researchers and REC members make little use of the Code of Practice. Consequently, to ensure that the principles of the MCA are followed it may be necessary to ensure that the HRA's website includes guidance on supported decision-making, and that section B of the IRAS form asks researchers to describe what efforts, beyond the submission of accessible or 'easy read' documents, they will make to enable would-be participants to make autonomous decisions. It may also be important therefore to review in more depth what means of communication are being used and how, to engage potential participants in such decision-making.

Conclusion:

The MCA operates to protect those at risk of lacking capacity as much as to empower them. As such, it provides an important framework for involving adults with capacity-affecting conditions in research. What it does not do is challenge their routine exclusion (Bunning et al., 2022). To address the routine exclusion of adults with capacity-affecting conditions researchers should be required to explain to the REC reviewing their research, why it is methodologically or scientifically necessary to exclude adults who lack the capacity to give or withhold consent.

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