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Unethical governance: capacity legislation and the exclusion of people diagnosed with dementias from research

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Abstract

This paper considers the potential for the Mental Capacity Act (MCA) of England and Wales to incentivise the exclusion of people with dementia from research. The MCA is intended to standardise and safeguard the inclusion of people with cognitive impairments in research. This entails various procedural requirements, which in pressurised research contexts can lead researchers to exclude people with dementia as a means of simplifying bureaucratic constraints. I consider the risks of an ‘unethical ethics’, wherein procedural ethics indirectly causes the exclusion of people with dementia from research, undermining historic successes toward increased inclusivity. I suggest several solutions, including enhanced sensitivity to impairments and shifting the burden of proof from justifying inclusion to justifying exclusion. The paper responds to the ‘ethics creep’ tradition in procedural ethics, and critical appraisals of capacity legislation in dementia research. This approach recognises that institutional research ethics is itself a major ethical concern and can unwittingly beget unethical practices. Dementia researchers must be alert to such unethical ethics.

Keywords

Dementia, capacity, REC, exclusion, rights

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Introduction

The ethical credentials of a proposed academic research project are typically assessed by an officially recognised research ethics committee (REC). In British academia, RECs have become more numerous and substantial in remit over recent years, a process often described as ‘ethics creep’, within a broader political trajectory toward regulation and standardisation in the higher education sector (McAreavey and Muir, 2011; Monaghan et al., 2013). Over 75% of current RECs in the UK were established post-1990, indicative of the relatively recent proliferation of institutional governance (Hedgecoe, 2016) and potential for ethics creep. Today, RECs perform a critical gatekeeping role in institutional academic research because almost all major funders and publications stipulate that funded and published work must have received REC approval.

While the core concerns of research ethics are typically considered to be familiar issues of informed consent, confidentiality, data protection, etc., the institutional governance of research ethics is itself now a major ethical concern within research (Fletcher 2019a; McAreavey and Muir, 2011). The increasing prominence of RECs within academic research over recent years has generated substantial dissatisfaction among researchers – as evident in the somewhat derisory phrase ‘ethics creep’ – and has inspired various critiques (Burr and Reynolds, 2010; Walby and Luscombe, 2018). Some have argued that REC regulation stifles innovation in research through imposing blanket standards with insufficient scope for deviation (Snowden, 2014). Relatedly, critics from the social sciences have noted that RECs are grounded in biomedical epistemologies that are ill-suited to alternative methodologies (McAreavey and Muir, 2011). Some have contended that RECs typically prioritise the protection of the institution over that of researchers and participants (Hedgecoe, 2016). Other critical commentators have suggested that ethical over-governance discourages researchers from engaging with ethics in a productive manner and may even incentivise new types of ethically dubious practice (McAreavey and Muir, 2011).

In this paper, I build on the latter critique – that institutional ethics creep inadvertently incentivises unethical research practices. These new types of ethically dubious conduct are often intended to expediate the negotiation of procedural ethics processes, through regurgitating simplified copy-and-paste methodologies and treating ethics as a one-off administrative procedure (McAreavey and Muir, 2011). Here, I highlight the risks of an *unethical ethics* emerging in relation to mental capacity legislation, REC review procedures and the exclusion from research of people diagnosed with dementias.

This article stems largely from my own experiences and reflections. This includes conversations with various researchers over the past 5 years, particularly those working on ageing and care. During this time, I have repeatedly encountered

researchers who have excluded people with diagnosed cognitive impairments as a means of simplifying the ethical review process and expediting project completion. The article is also reflective of my own experiences of working in dementia research for the past 6 years, on both my own projects and as part of larger teams. Such exclusion practices are concerning for dementia research because they suggest that key governance mechanisms may inadvertently reverse some of the field's recent progress toward inclusivity.

Governing capacity

The Mental Capacity Act 2005 (MCA) is an important piece of legislation governing the conduct of much dementia research. It outlines legal decision-making processes in England and Wales for people above the age of 16 who have 'an impairment of, or disturbance in, the functioning of the mind or brain' (Mental Capacity Act, 2005). This definition is important for dementia research because it means that all people with a diagnosed dementia fall under the MCA's remit as they have an officially documented cognitive impairment (cognition typically being considered to be a function of the brain). Therefore, researchers who plan to conduct research that involves people with dementia are legally required to satisfy the MCA's relevant provisions, located in part 1, sections 30–34 of the Act.

The MCA was devised to regulate, standardise and clarify decision-making processes for people with mental, intellectual and cognitive impairments. This approach was intended to safeguard populations often considered vulnerable to exploitation and mistreatment. The MCA uses a concept of 'capacity' to delineate these people into two groups with different legal statuses. A person *with* capacity is able to make a decision on their own behalf without intervention. A person *without* capacity is unable to make a decision on their own behalf without intervention. In such instances, a set of 'consultee' procedures are invoked to ensure safeguarding. The MCA's capacity-based division of legal statuses has been critiqued. For example, capacity is an inherently subjective concept, being dissociated from cognitive batteries and neuropathology. It also seemingly contravenes international human rights conventions, differentiating people's legal statuses based on their impairments (Fletcher et al., 2019). However, in the context of research, this legislative approach aims to standardise the safe inclusion of people with cognitive impairments (McHale, 2009).

The MCA's detailing of standardised inclusion procedures is a response to historic ambiguity regarding the inclusion of people with dementia, which entailed substantial proxy decision-making and exclusion (Brown et al., 2009). The standardisation of relevant procedures is intended to replace proxy decision-making and exclusion with safeguarded inclusion. Under the MCA's research provisions, all prospective participants with a dementia diagnosis must

undergo a capacity assessment before being enrolled into a study. This assessment can be conducted by the researcher, who asks a series of questions to ascertain whether the person can: (1) understand information about the decision (in this case whether to participate in a study); (2) retain the information long enough to use it; (3) evaluate the information and appreciate the decision's consequences; (4) communicate the decision. If these four criteria are met, the person is deemed to have the capacity to make the decision and can progress to informed consent procedures. If they do not meet any one of the criteria, then consultee procedures are invoked (see Fletcher et al., 2019). Researchers wishing to recruit people with dementia must develop study protocols that satisfy these procedures and must act accordingly when subsequently conducting the research (Fletcher et al., 2019; Mental Capacity Act, 2005).

Most importantly in the context of this paper, research that falls under the MCA – that is, all those seeking to include people who have been diagnosed with a dementia – must undergo ethical review by an appropriate body. This body must be a 'committee (a) established to advise on, or on matters which include, the ethics of intrusive research in relation to people who lack capacity to consent to it; and (b) recognised for that purpose by the Secretary of State' (Mental Capacity Act, 2005). In practice, these bodies are RECs under the control of the Health Research Authority (HRA), which encompasses English and Welsh NHS RECs and the Social Care REC. University RECs are not recognised by the Secretary of State and therefore cannot legally review proposals that invoke the MCA (HRA, 2019). I am aware of instances in which university RECs have reviewed and approved research that falls under the MCA (for recent examples, see Griffiths et al., 2019, 2020; Orfanos et al., 2020; Pike et al., 2020; Shoesmith et al., 2020). This appears to arise due to an interpretation of the MCA as only applying to research involving participants who lack capacity, and therefore not applying to research involving people with a diagnosis who do not lack capacity. However, the MCA Code of Practice (Lord Chancellor, 2007: 41) specifies that capacity must be assessed if the prospective participant has 'an impairment of the mind or brain, or is there some sort of disturbance affecting the way their mind or brain works'. Indeed, dementia is cited as an example on page 44. While the MCA is ambiguous on this point, an interpretation of the MCA's procedures as only applying to those who lack capacity raises the following question: If the capacity of prospective participants with brain/mind dysfunction must be formally assessed, and such assessment is time and decision specific, then how can a study ensure continued capacity (of participants with dementia) throughout the study? The fact that capacity assessment is only applicable to the specific time at which it is conducted means that the result should not be extrapolated to future or ongoing research activities. In reality, this may lead to recruitment based on carer opinions about capacity, rather than time specific assessments. This is an issue that requires further investigation.

Excluding dementia

Thus far, I have outlined some of the ethical governance implications that apply automatically to research seeking to include people diagnosed with a dementia. I will now turn to the potential consequences of those implications for people with dementia and research. During several years working in research on dementia, ageing and care, several researchers have disclosed to me that they have excluded people with dementia from research because of capacity legislation and its procedural ethics requirements. Another area in which I have experienced the universal exclusion of people with dementia is in taught undergraduate and postgraduate dissertation research, because the length of time required to negotiate HRA ethics is incompatible with the timescales typically available to such researchers. Similarly, I have encountered several instances where the length of the HRA ethics review process has prevented short-term visiting researchers from including people with dementia in dementia-related work.

There is no dedicated data regarding the proportion of research projects that have excluded people with dementia due to MCA requirements. However, a recent review (Shepherd et al., 2019) of UK clinical trials relating to conditions typically affecting mental capacity found that less than 20% included participants who lacked capacity. Shepherd (2020) has also found that many studies report the exclusion of people lacking capacity in a ‘limitations’ section, but rarely attempt to justify this exclusion. In the studies that did provide some explanation of exclusion, Shepherd found that complex legislation and ethical review processes were among the major motivations. Regarding dementia specifically, Griffiths and colleagues (2019) have called for increased awareness of the exclusion of people with dementia who lack capacity in research, which they claim is commonplace but under-explicated. They have documented the difficulties of developing tools to include people with dementia who lack capacity in research in the context of MCA and REC constraints. As such, a small but growing body of literature is beginning to expose the danger of capacity-based exclusion. That said, it is notable that Alzheimer’s Europe’s (2019) recent report on ethical challenges in inclusive dementia research discussed capacity extensively but did not consider the REC implications of legislation or the potential for incentivising exclusion.

Researchers who have spoken to me about excluding people with dementia have typically expressed regret. However, they point to the additional concerns that would be introduced into already complex projects, particularly in areas such as care home research. The negotiation of REC approval can be a daunting task, especially for junior researchers or for those working on complex and sensitive issues such as dementia. Given the (rightfully) strict requirement that invasive research should undergo institutional ethics scrutiny and receive official approval prior to commencement, time- and resource-limited researchers can be anxious to

satisfy the REC as quickly as possible (Fletcher, 2019a). Snowden (2014) notes that the online IRAS forms needed to file for REC review, contain 80 sections on general information even before entry of site-specific details. The procedural ethics process can be the most difficult part of conducting research. Indeed, I have witnessed colleagues enter 2-year-long negotiations with some RECs during what should have been 3-year-long projects. In this context, devising protocols to satisfy the requirements of the MCA can pose additional challenges for dementia researchers, and may therefore appear undesirable.

There are two additional procedural ethics challenges that are introduced if the intended research falls within the MCA remit. The first is the designation of specific RECs. The aforementioned legal requirement for dementia research to automatically progress through an HRA REC rather than a university equivalent is important because researchers often view HRA review as being particularly difficult to navigate. Irrespective of whether this perception is justified, studies have found that researchers will actively seek to avoid NHS RECs (Richardson and McMullan, 2007). The second procedural ethics complication is the need to satisfy the aforementioned capacity assessment and consultee regulations. Researchers must familiarise themselves with these regulations so that they can devise protocols that respect legal requirements and develop competency in assessment and consultation. Given these two substantial stipulations, it is understandable that time- and resource-limited researchers can be keen to avoid having to comply with the MCA, and thus develop projects that exclude people with diagnoses that automatically invoke capacity legislation.

The danger here is that the MCA's procedural requirements for research unwittingly incentivise the exclusion of people with dementia from research that is relevant to them, as a means of making that research easier (and sometimes possible) to conduct. Such exclusion is concerning, having been widely regarded as an unethical practice in dementia research for many years (see Murphy et al., 2015; Sherratt et al., 2007). The inclusion of people with dementia in research is now widely regarded as an ethical and methodological imperative (Alzheimer Europe, 2019).¹ Indeed, one of the MCA's foundational rationales was to tackle the historic disenfranchisement of people with cognitive impairments (Fletcher et al., 2019). Of course, the issue is not limited to the MCA. Critics of the expanding role of RECs in academic research have noted that the difficulties of negotiating institutional governance can create unhealthy research cultures in which ethics becomes a challenge to overcome rather than a key issue to remain constantly engaged with throughout research (McAreavey and Muir, 2011). The exclusion of people with dementia to circumvent MCA stipulations is an extreme example of this problem, and one that has unfortunate ramifications for people with dementia specifically.

Potential solutions

The purpose of this paper is not solely to draw attention to the risk that the MCA encourages unethical research practices that disenfranchise people with dementia. It is also intended to stimulate discussion and inform the development of solutions. To this end, I will conclude with some potential solutions to MCA-based exclusion in research. First, given that a major incentive to exclude people with dementia from research is the desire to avoid HRA REC review and to instead progress through a university REC, it is worth considering whether university RECs could be officially sanctioned to review proposals that fall under the MCA. This expansion of remit would address perceptions that the MCA entails a more difficult review process. One danger with this suggestion is that such sanctioning may be contingent upon bringing university RECs in line with levels of NHS scrutiny, potentially intensifying other procedural requirements within the university system. Additionally, this would entail a substantial legislative undertaking, which may prove particularly unpopular given the recent difficulties of amending the liberty safeguards, another contentious area of the MCA (Series, 2020). One helpful solution could be to refine the Code of Practice (now under the Ministry of Justice's remit) to specify how, if possible, studies can recruit people with dementia who have capacity, while complying with requirements to evidence capacity through a time- and decision- specific formal assessment. Of course, the danger here is that such a clarification incentivises further exclusion of people who lack capacity. An alternative approach could be the simplification of HRA REC processes, though this is already a continual HRA aim.

A second suggestion is that the governance of mental capacity could be more sensitive. The current MCA approach to cognitive impairment is absolute. A diagnosis of a relevant condition automatically invokes MCA requirements, irrespective of the person's particular circumstances. In practice, this means that a researcher seeking to work with people newly diagnosed with Mild Cognitive Impairment (MCI), a group of people who are largely assessed as having decision-making capacity (Lui et al., 2013), must still negotiate the same governance requirements as a study that seeks to recruit people with advanced Alzheimer's disease. This is because capacity cannot be assumed and must be formally assessed in all potential participants with a diagnosis, ensuring that procedures are standardised, equitable and capture all cases. Unfortunately, this means that MCA regulations are applied even to dementia research that is unlikely to involve people who lack capacity. If procedural ethics were more sensitive to such cases, then these types of research could theoretically be exempted, or at least subject to simpler regulation. Of course, such sensitivity would be difficult to implement and would risk instances whereby people who lacked capacity were recruited into studies that had not undergone appropriate review. One compromise could be to

develop a list of carefully selected exemptions from full MCA governance, for example, for research recruiting people with MCI diagnoses.

The issue of an absolute approach, predicated on any neurocognitive diagnosis, speaks to broader tensions between capacity-based and rights-based approaches to dementia. That additional barriers to research participation are put in place by virtue of a diagnosis rests on a legal assumption that people with dementia are inherently vulnerable (Barry, 2018; Patterson and Block, 2019). This problematic assumption is increasingly difficult to sustain in contemporary contexts of early diagnosis and pre-symptomatic expansion (Fletcher, 2019b). Many people diagnosed with dementia may be as capable of making decisions as the researchers and ethics committee members who are assessing their status, yet capacity legislation casts them as inherently in need of institutional protections. The automatic filtering of people with dementia into a more arduous institutional process, based on diagnoses and assumed vulnerabilities, can be interpreted as breaching the human right to equal legal treatment outlined in the United Nations Convention on the Rights of Persons with Disabilities (2008). This sits among various other rights issues that emerge from capacity legislation (see Fletcher, 2020; Flynn, 2018; Shakespeare et al., 2019). This overarching tension is a key area in which the perspectives of people living with dementia should inform debate and potential change.

Finally, adopting a rights-based perspective on the MCA's ethical governance implications draws our attention to the issue of burden of proof in research with people who lack capacity. Currently, the MCA dictates that people who lack capacity can only be included in research that necessitates their specific involvement. Researchers must provide adequate justification for why people who lack capacity should be included, and why the research would be worsened by their exclusion. Though a slightly different issue from the blanket exclusion of all people with dementia, there is here another incentive to automatically exclude a certain population because of cognitive impairment that undermines inclusivity. To encourage inclusion, the burden of proof could be reversed so that researchers who propose to exclude people who lack capacity are required to justify this choice.

I will end with some caveats. I do not wish to argue that people with dementia should be recruited into research projects without appropriate ethical governance. Instead, I suggest that the automatic, absolute and disproportionate governance implications of the MCA in its current form risk incentivising unethical research practices, namely the exclusion of people because of their impairments. While I have focused on ethical concerns in this paper, there are also a range of related methodological problems, particularly regarding sampling. For example, 70% of the population living in care homes lack capacity under the MCA (Shepherd et al., 2019), raising serious questions about the representativeness of care home research that excludes those lacking capacity. Finally, I do not wish to attribute

the exclusion of people with dementia from research to the MCA entirely. It is well-reported that people with dementia are often excluded from research for a variety of reasons, or indeed, for seemingly little reason at all (Taylor et al., 2012). Instead, I wish to point out that, in its current form, the MCA, and its implications for ethical research governance, provides an added incentive for excluding people with dementia from research.

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Note

1. Though not the focus of this paper, the involvement of people living with dementia as co-researchers is also an increasingly important characteristic of contemporary dementia research. Co-research may be similarly disincentivised by current MCA provisions, and additional problems may arise when procedures pertain to researchers as well as participants.

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