Problem or safeguard? Research ethics review in social care research and **the Mental Capacity Act 2005**

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Abstract

The Mental Capacity Act 2005 (MCA) introduced safeguards to protect people who lack capacity from intrusive research. Whilst these safeguards stemmed from predominantly medical ethical review concerns and developments aimed at protecting people from physical and psychological damage and harm, the Act relates to all forms of research. The implications of the requirements of the Act for the conduct of social care research and the identification of helpful approaches or development of new knowledge concerning people who may lack capacity are as yet unknown but there are some worries that the Act does not fully account for social research, recognise its importance to and differences from health-related research and may even hamper such research from taking place. This paper describes the findings and implications from a Social Care Institute for Excellence (SCIE)/Department of Health (DH) funded research project[?] that considered the impact of the Mental Capacity Act 2005 on the ethical scrutiny and development of social care research. The particular focus of the study was processes relating to university research ethics committees (URECs). The study was undertaken in two stages beginning with an on-line survey of UREC policies and procedures and followed by interviews with social care researchers working in areas in which people may lack capacity according to the terms of the Act. Recommendations for research ethics review are made that will be of importance to practitioners, policy-makers and researchers

Key words

Mental Capacity Act, research, ethics

Introduction

The draft Mental Incapacity Bill lacked reference to research, which the Joint Committee of Parliament (Dimond, 2008) considered might potentially restrict beneficial research for people who have incapacitating conditions. The debate which followed suggested that inclusion of statutory provision governing research would establish ethical safeguards whilst facilitating research into incapacity and its treatment. However, the focus of ethical scrutiny is taken predominantly from medical ethics as are the standards from which the wider provisions of the Act were drawn (Johns, 2007).

The conditions outlined in sections 30-34 of the Act for carrying out research with people lacking the requisite mental capacity to make decisions to take part in a research project include:

- The research is part of a research project
- The research is approved by an 'appropriate body' (NHS and the Social Care Research Ethics Committees, both of which are accessed through the Integrated Research Application System [IRAS] https://www.myresearchproject.org.uk/)
- The research concerns an impairing/incapacitating condition which

- can only be carried out with people who lack the capacity to consent
- must have potential benefits to the person or wider society and not impose a disproportionate burden
- is intended to provide knowledge of causes and treatment of the condition
- carries negligible risks, maintains freedom of action and privacy, and is not unduly invasive

• The research complies with the requirement to consult with carers or a third party

Dominelli and Holloway (2008) state that social care research ethics and governance have lagged behind health and medicine. They propose the adoption of appropriate ethical scrutiny to bring social care 'into the fold' but also consider the process of engaging with people who use services which they believe reflect different ways of knowing and being to those promoted within medical and health professions. From little and generally informal regulation in social care research, wide changes have been brought about by the introduction of the Department of Health Research Governance Framework for Health & Social Care (DH, 2005). Social care research in the UK has always engaged with National Health Service (NHS) ethical review to gain access to participants within those settings but differences in ways of understanding and in types of research militated against the wholesale adoption of NHS governance processes. However, the DH Framework broadly reflects issues in health research. The MCA states that the capacity to make a decision to take part in a research project is central (Johns, 2007). This capacity relates to understanding information relating to the decision, being able to retain that information and to evaluate and communicate the decision (see s.3). Consent is decision-specific and so assessment is necessary for subsequent decisions where capacity may be deemed to be impaired or lacking. Johns (2007) believes that the requirements of the MCA concerning intrusive research applies to almost all social research, interpreting s.30 as referring to any research that normally requires informed consent. The Department of Health has subsequently issued a clarification of the meaning of 'intrusive research' under s.30 (2) of the Act as:

> "wide ranging and covers all primary data collection, apart from that which involves the collection of anonymised, or effectively pseudonymised, data where there is no breach of the Data Protection Act (DPA) or the common law duty of confidence. **It is not limited to medical or biomedical research that is physically invasive** (e.g. the collection of tissue samples)." (DH, 2009, p1)

This has great implications for the ethical scrutiny of social care research because of its substantial breadth.

Rising emphasis on ethical review in social science

However, increased ethical review and research governance has been criticised by medical researchers (Wald, 2004; Walley, 2006), psychologists (Malouff and Schutte,

2005) and social scientists who believe ethical scrutiny has been transported from bio-medical research and developed insidiously as a form of 'ethics creep' (Haggerty, 2004), or represents a fundamentally flawed and anti-democratic attack on social research (Dingwall, 2006; 2008).

Questions of potential harm, to participants and researchers, and the protection of vulnerable people from abuse are at the centre of research ethics scrutiny. However laudable these aims are at first glance, not all social researchers recognise these as issues in social research settings. Dingwall (2008) argues that ethical scrutiny is fundamentally wrong in respect of social research because of its damage to knowledge production and the lack of harm caused by humanities and social research.

Dingwall's (2008) position does not take into account the power relations that exist in relationships between researcher and researched, potential harm (Aldred (2008) nor the aspects of decision-making ability and vulnerability of prospective participants which the MCA seeks to address. Neither does this acknowledge that, with the implementation of the MCA, certain forms of research are unlawful unless approved by an 'appropriate body'. However, his views are important. The development of ethical scrutiny in universities has been politically and economically driven by the need to address research council requirements, insurance and funding issues. In health and social care research, it has also been driven by the Department of Health's research governance framework with its associated governance arrangements and operating procedures.

Calvey (2008) adds to the concerns about ethical scrutiny. He suggests that the focus on informed consent as a touchstone in ethical review marginalises covert methods which could have an important role within social science research. Aldred (2008) states further that how open and transparent researchers should be needs to be more fully debated and believes a simplistic approach may put researchers at risk. Calvey (2008) calls for dialogue with university RECs to ensure that social research is not damaged by a focus on biomedical approaches to regulation, suggesting that in much social research the engagement with ethics is an on-going and often a situated process that continues throughout the life of a project and is not simply undertaken on a single occasion, for example at the beginning of a study.

Hedgecoe (2008) acknowledges that an increase in emphasis on ethical review has led to concern amongst some social scientists. However, his research suggested that social scientists were not considered differently to medical researchers when RECs reviewed proposals.

Dixon-Woods et al. (2007) analysed NHS REC letters to gain insights into the ways in which they operated, finding that letters conferred a degree of authority on what was deemed to be ethical practice; functioned as a kind of institutional display and specified the nature of the relationship between researchers and a REC. RECs fixed the meaning of what might be deemed ethical in two ways: by identifying the features of a proposal which constitute ethical areas of concern and actively or passively prescribing what ethical conduct is required in relation to these areas of concern. The REC letter has the power to ascribe a favourable opinion which constitutes whether an application is ethical or not. Dixon-Woods et al. believe that what is needed for successful passage through

ethical review is the competence to make appropriate displays of docility, deference, submission and acting as a supplicant to the REC.

The area of ethical review is contentious and ongoing with the introduction of the MCA. Debates indicate that there is a potentially huge area for review that requires consideration. However, the differences between social research and biomedical research appear to have been largely skirted over and inadequately considered, with potentially problematic consequences.

Study

Methodology

Our research was undertaken in two stages during 2008. Ethical approval for the study was obtained from the lead university's REC. Firstly, we undertook a survey of 30 university RECs using a diverse sample of universities in England and Wales[?] engaged in social care research in order to determine the practices of the REC in each university. The second stage concerned 12 semi-structured interviews which were undertaken with social care researchers involved in research with people who may be vulnerable and who lack decision-making abilities to give consent to involvement in research. Most of these interviews were conducted by telephone, although there was one face-to-face interview and three further responses by email. Interviews were recorded and transcribed. Wherever possible, respondents were sent a copy of the guiding protocol for the interview prior to the interview in order to familiarise themselves with areas for deeper exploration. The research aims were outlined by researchers prior to each interview and the confidentiality of respondents and anonymity of data provided was assured.

A qualitative approach to the thematic analysis of primary themes, identification of sub-themes and interconnections was undertaken in respect of the interview data collected.

Findings

It was quite illuminating that none of the researchers contacted as part of this research and who, because of their research interests, background and publication histories, might be thought to be key social care researchers had submitted recent proposals in areas in which capacity and decision-making abilities were central since the implementation of the Act. There was also some degree of misunderstanding and a lack of clear knowledge amongst researchers about the implications of the Act for social care research. One respondent highlighted some of the tensions between the Department of Health research governance requirements, local authority governance procedures and the demands arising from the MCA. There was a consensus about the need for additional clarity and simplicity in respect of requirements for the ethical scrutiny of non-NHS research.

Internal university processes and research ethics

Universities approached the process of research ethics review in broadly similar ways, although those institutions which are less research intensive offered less formal guidance about their practices and the organisational structure of university RECs

differed. The MCA was rarely mentioned explicitly within the documentation obtained/gathered. However, this did not necessarily imply that universities were not equipped to scrutinise research proposals effectively and appropriately or to refer researchers to an 'appropriate body' where capacity may be an issue. Most universities in our sample had advice, policy or procedures to signpost researchers to NHS ethics committees, which seemed to anticipate the requirement to refer proposed research with people who lack capacity under the Act to a designated 'appropriate body'. Further work may be necessary to determine how university RECs will refer proposals to the Social Care Research Ethics Committee (SCREC), established in 2009 as an 'appropriate body' under the Act.

There were differences in UREC composition and where ethical scrutiny sat within the university structures but most respondents indicated that review was undertaken at a high level as indicated by the following quotation:

> *(the university) has some very clear and detailed procedures about gaining ethical approval and research that will be using human subjects. In addition it has some further guidance as to whether or not that research involves subjects who may not be able to give consent.*

One respondent described an interesting addition to the UREC by including a service user representative that had been brought about by commitment to a policy designed to enhance inclusion. This innovation took place prior to the implementation of the MCA but suggests a commitment to capacity, consent, safety, inclusivity and human rights.

However, the NHS review process was considered the gold standard for research ethics where potential participants might lack capacity, reflecting a perception concerning the lack of rigour of university RECs amongst some respondents:

> *I think there is a perception that university processes are very much easier to get through than NHS committees. I would never think about going through the university systems if participants may not have the capacity to consent…*

One social researcher who appeared rather more positive about university RECs expressed a belief that UREC processes have been tightened appropriately as a result of the implementation of the MCA. Another university had developed its own ethical review process in order to help students and staff develop high quality proposals that would be able to progress through the NHS review; a system of peer review and advice that anticipated later NHS scrutiny.

Explicit reference to the MCA within UREC policies and procedures was not common, though with the passing of time since implementation it may now be more prevalent; however, there was mention of cognate ethical issues. One respondent indicated that

there was always consideration of 'special cases' and 'vulnerable' people at the School's REC but that there was no explicit mention of the MCA. Others indicated that they would have to check their documentation to be sure the MCA was mentioned. One participant reported that the MCA had not made an explicit impact on the ways in which consent and decision-making were scrutinised within their university REC.

Of the minority who stated the MCA was referred to in their ethical scrutiny processes, training and guidance was mentioned as important in determining when an application should go to external research ethics scrutiny with a need for both aspects to assist researchers to establish the point at which a REC submission should be made.

Many university RECs still expected to scrutinise research proposals where external ethical review was required and or expected as part of their quality assurance processes. Diverse practice was found across universities. One respondent indicated that part of the ethics review form of the university asks whether the research proposal has been the subject of any other form of ethical scrutiny. One university committee:

> *would want to know if you've got NRES (approval) and they would be minded to accept that. In a hierarchical sense we would generally start with health and use that with local authorities as a sort of indicator of* bona fide *research.*

Another university researcher said, however, that their committee would not be involved if a proposal had been through NRES and that they would not want duplication of scrutiny to happen. A question arises as to whether duplication of scrutiny helps meet the requirements of the MCA or whether it might slow the progress and development of research.

Diverse practices remained in relation to the dual scrutiny of research proposals by university RECs where proposals were externally reviewed. This may be because universities have moral, insurance and legal responsibilities for the research conducted by them and in their name. As such university RECs have developed an expertise in assuring the ethical, as well as scientific, propriety of research, together with the risks and benefits that may accrue. We assume that audit of ethics approval at least will continue, even when external approval is required. This could help to ensure research proposals are of the highest quality prior to submission for external ethical review thus reducing the workload of those committees in filtering out any proposals which are not of the right calibre.

We asked if a 'policy implementation gap' was apparent from the documentation given that the MCA was rarely referred to explicitly. This may demonstrate a need for policy, procedure and guidance up-dating and not necessarily a lack of awareness of changes affecting research ethics. Indeed, the documentation, and our experience of university research ethics committees, indicates that committees and chairs were well aware of external as well as internal responsibilities in respect of proposal scrutiny.

Positive perceptions of the MCA

Increased regulation and review was considered, by some, as useful and positive for both participants and for researchers. One respondent found the experience of dual process of review extremely valuable in safeguarding participants. Internal scrutiny was believed by another respondent to assist in determining capacity to take part. An additional interviewee indicated that the MCA requirements would assist her/him to look more closely at issues of informed consent and capacity, how this might change for participants over the course of the research and how informed consent might be given and facilitated in different and possibly more creative ways.

One respondent described a developing research project concerning people with Alzheimer's disease. The question of determining the decision-making capacity of participants was a clear focus of this researcher:

> *…there is the issue that not all people with dementia lack capacity to decide whether or not to take participate…and indeed nobody is quite sure, dementia being what it is, when a person loses capacity or whether they have it. So, we will go through the appropriate channels and we're quite pleased there are specialist committees for consideration of these issues.*

> I*'m a person who's very much inclined to believe there's a spectrum of decision-making abilities and that people have the right to participate in research rather than always trying to exclude them.*

The definition of capacity and tensions between health and social care views – right to protection from harm and right to participate – is central. For this researcher the principle of presumption of capacity, which in any event is a legal requirement under the MCA irrespective of whether the research is located within the NHS, held sway and added an interesting perspective to non-NHS based social research and determining the capacity of potential participants to make decisions. A different interviewee also considered how external scrutiny:

> *forced me to go back and do a lot more work and think about vulnerable people's capacity to make decisions and to demonstrate in a very transparent way how I thought about groups of people who may be vulnerable; how I'd come to a judgement about what they were consenting to.*

Barriers to research resulting from the MCA

Not all respondents were so positive about the MCA and some believed the prescriptions of the Act might be detrimental to research proposals being submitted:

> *My own recent application about the MCA did not specifically involve service users, but included professionals. On reflection, I think I specifically avoided (including service users), which is an interesting observation, and I think that such research may be becoming seen as difficult. I think that researchers may think there are obstacles to doing this type of research and could see this area as too difficult in terms of gaining approval and so may avoid this type of research.*

Others saw problems in the ways in which university RECs looking at research with people who may/might lack consent under the Act might/could consider issues of consent and capacity in 'narrow' ways, which could militate against research. A perception of a medical orientation of the MCA in relation to research ethics was highlighted by respondents. One consequence of the Act is that no research which involves people who lack capacity to give informed consent can be approved by a UREC unless it is also approved by an 'appropriate body'.

The concept of informed consent is a complex issue and one which the Act brings to the fore. A respondent exemplified this by stating that:

> *…someone may lack the capacity to be involved in a research programme but may be perfectly able to answer research questions. Capacity to take part in a research project is very abstract whereas capacity to answer questions may be clearer to individuals.*

The same respondent identified concerns that these complexities will not be fully developed and worked out when social care operates in the context of health research processes, which are seen generally as 'more risk averse' and potentially damaging to social care research. The respondent believed that social researchers have the capacity to engage with an inclusion agenda that seeks ways of facilitating participation and engagement in research. Another researcher championed a staged approach to informed consent in which consent was sought for a stage of the research that was (in many ways) different from other aspects of the research. On reaching a further stage, participants would be approached again for a kind of 'on-going informed consent': a kind of 'Gillick competence' approach to consent. According to one participant, whilst the MCA has increased ethical scrutiny, the level of ethical review in social science research has become much more rigorous over the last few years. However, this did not detract from a concern that the Act could prevent valuable research concerning people who lack capacity:

> *Getting ethical approval for complicated situations, for example involving capacity, is complex and time-consuming so it may be that researchers could decide only to do work that does not include service-users.*

Guidance and information

There is, as yet little guidance on the implications of the Act for social care research (Brown and Barber, 2008). Dimond (2008) offers a number of case scenarios to assist researchers through the implications of the MCA. However, these examples focus on health-related research and they do not address the presumption of capacity in detail. Simple, clear and accessible one-page guidance is provided in the Welsh Assembly Government/Department of Health (2007) training set for the MCA. The Department of Health (DH, 2009) has issued a fact sheet for social scientists which does provide a number of non-health related case examples. The most comprehensive guidance is contained within the Code of Practice which provides more cogent advice in respect of social care research (para 11.14). Potential benefits to individuals involved in research may include improving social care and services, reducing risks of harm, exclusion and disadvantage and also consider the effects of the incapacitating condition on everyday life.

Suggestions for guidance, made by respondents to the interviews, included seminars where specific examples, such as defining vulnerability, determining capacity to consent, what to do when a potential participant seems to lack capacity to consent and the need for someone independent of the research who knows the person giving their view are used to facilitate discussion about core issues that might arise. Briefing papers detailing guidance were also mentioned and web-sites from specific bodies also using case examples were highlighted, such as the Alzheimer's Society. Another respondent suggested that a critical philosophical discussion concerning issues of autonomy and power and participation and benefit was needed.

Some respondents drew attention to the large amount of disciplinary guidance for various operations and processes and identified the dangers of too much information, although, again, referred to health rather than social care guidance:

> *I think everybody's awash with guidance and I don't think there should be more. The [MCA] Code of Practice is quite clear. If issues are coming up through NRES then they should be dealt with before starting. One thing we're not short of is guidance by everybody about absolutely everything and the more you get the less it's read.*

One respondent drew attention to the potential uses of observational and covert research and how different ethical scrutiny and understanding would be required to that currently offered by NHS committees. One interviewee cogently expressed the concerns raised about research being constrained:

> *I would hate the outcome of MCA implementation to be a framework in which people/researchers felt that they could not do this type of research because of the interpretation of the MCA. Speaking personally, guidance would be most helpful in terms of how best to construct a case* re: *service user research (and) how to undertake such work successfully and ethically. I think this would also assist*

researchers to be more ethical in their practice.

Rather than looking at guidance, some universities have developed training within their RECs. This model could perhaps be extended to provide training for the community of researchers at university-level, as arguably it is not just REC members who require training about this area. This was thought to be especially useful around issues of consent and determining capacity to make decisions. One respondent made the suggestion that 'appropriate bodies' under the Act, should be in dialogue with university RECs.

Analysis and discussion

The small, purposive sample limits the research and its findings, as does its focus on researchers and university research ethics policies and processes. However, the lack of proposals put forward at the time of the study in 2008 indicates a need to address any concerns social researchers may have if we are to prevent potential damage to social care research where capacity is or may be an issue.

There were some limitations to the first phase of the study. Many universities placed their policies, guidelines and procedures in the public domain. However, at times we found that web pages were password protected for access and use by internal staff only and this may have prevented access to important ethical scrutiny material. It is also possible, given the potential for human error, that we did not identify all available material. Indeed, our pilot trawl of our own institutions highlighted the identification of different data by different researchers. However, theoretical saturation (in which no new findings were seen) was reached within the sample. Further, there was evidence that the difference between some aspects of research governance, for example the needs of local authority hosts to be satisfied that the presence of researchers would present no unacceptable risks, and the specific focus of research ethics was not always clearly understood. Similarly there were some views that the MCA prevented legitimate research from being undertaken and that, as a piece of legislation, it was risk averse.

Notwithstanding the intention to reduce duplication of ethical review (see Dominelli and Holloway, 2008), universities are likely to continue to scrutinise research proposals despite external review. This may enhance the safety of human participants involved in the research and identify core areas that could have been missed by one committee before approval was given, although it adds time and bureaucracy to the research process.

It is important to acknowledge that implementation of the MCA is in its infancy. The Act's implications for social care research are only now being explored and further work needs to be undertaken on how this develops and is played out. Since the completion of the study, the national Social Care REC (SCREC) has become operational. Resulting from extensive consultations lead by the Department of Health, and involving a wide range of

stakeholders, it works to standards set by the general governance arrangements and operating procedures of the National Research Ethics Service and is recognised as an 'appropriate body' under the MCA. Its aim is to deliver a national research ethics review service, for England, and to complement, not replace, other RECs by addressing gaps in provision, and taking on some specialist roles (www.screc.org.uk; Stanley, 2009).

Some researchers appear to privilege the NHS review system, partly because of its long-standing development and partly because of its presumed or perceived rigour (see Dixon-Woods et al., 2007). This has led to practice that sees the submission of proposals to an NHS committee as a precursor or alternative to university scrutiny. Protection from harm and seeking authentic participation is important to social care researchers, although health and biomedical researchers may understand this differently. The two do not need to be subject to the same processes of scrutiny as they represent different aspects of human research and may require different criteria to judge potential harm, benefit and necessary safeguards: the notion of proportionality must therefore be a key principle when arriving at ethical opinions. Some believe that research may be stifled by the Act if a medical bias is adopted by those scrutinising proposals, mirroring concerns raised by Haggarty (2004) and Dingwall (2006; 2008). This should be acknowledged when reviewing social care research so that potentially life-enhancing and important research is not halted or retarded.

The question of guidance, however, raised diverse and strongly held views from those who wanted to be taken, step-by-step, through the process, to those who did not wish for any more guidance believing that it would complicate matters still further. The dominant focus on health issues in many ethical review processes makes the assumption that this translates easily into situations of social research and is made without question. The tensions between health and social research lead to differences in understanding issues of capacity and consent (see Aldred, 2008; Holland, 2007). The focus in social care research appears to concern facilitation for participation, where appropriate, and seeing capacity 'at the time' as being paramount. However, the Act does make it clear that consent is context specific and must be assessed by a competent person, always provided that the proposal meets the required criteria. The respondent who suggested a type of 'Gillick competence' approach to consent perhaps captures the different nature of social research. This form of process consent would generally be seen as good practice in social care and much social science research. The DH Research Governance Framework states unequivocally that 'The dignity, rights, safety and well-being of participants must be the primary consideration in any research study.' (DH, 2005, p7). It is difficult to imagine that any social care researcher would disagree with such a statement. Similarly, as we engage with the provisions and implications of the Mental Capacity Act, social care researchers must ensure that inclusion, involvement and participation lie at the heart of proposals and their ethical base.

Recommendations for practitioner-researchers and researchers

1. There is a need for clarity regarding the implications of the MCA for developing social research and its ethical scrutiny. Equally there is a need for researchers to understand the duties the Act places upon them and the legal principles which underpin it. Both of these needs would be helped by more widely promoting the role of the national Social Care REC and clarifying the place of university RECs in preventing social research with potentially vulnerable participants from being stifled.

2. Attention should be given to university RECs' potential to assist in scrutinising social research that requires Social Care REC review.

3. Consideration should be given to promoting a greater understanding of the role of the 'appropriate body' such as the Social Care REC and, together with University RECs, the scope for developing guidance and case study exemplars for social researchers

4. University and ethical review bodies need to work together to ensure duplication is minimised, that due recognition of the need for prior planning is factored into research scrutiny and commissioning and that time delays for ethical review do not prevent research being undertaken. In support of this aspiration, a document 'Securing research ethics approval - a route map for social care researchers' has been issued jointly by the Economic & Social Research Council, the Department of Health, the Social Care Institute for Excellence the Association of Research Ethics Committees and the Association of Directors of Adult Social Services. Further work now needs to take place in order to embed these aspirations in practice.

5. Safety issues for participants in social care research need to be explored in more depth. This includes developing further clarity about issues relating to consent for those participants who might be vulnerable but deemed able to consent (or to answer questions) under 'normal circumstances'.

6. The implications of the MCA for social care research need to be further explored and made more explicit, especially within the university sector and issues relating to ethical approvals and non-NHS settings appear in need of some clarification.

7. Social care research has the potential to develop and promote exciting, innovative and ethical approaches to inclusion, drawing on its value-bases. Research that facilitates inclusion and participation, rather than exclusion, should be explored and the contribution of social care research to understanding and promoting the rights of people who may lack capacity under the Act requires further (careful) consideration.

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[1] The focus is on universities in England and Wales to represent the scope of the Mental Capacity Act.

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