Reification and assent in research involving those who lack capacity

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ABSTRACT

In applied ethics, and in medical treatment and research, the question of how we should treat others is a central problem. In this paper, I address the ethical role of assent in research involving human beings who lack capacity. I start by thinking about why consent is ethically important, and consider what happens when consent is not possible. Drawing on the work of the German philosopher Honneth, I discuss the concept of reification—a phenomenon that manifests itself when we fail to observe or respond to our fellow humans' need for recognition. I suggest that assent is a way of responding to this moral need for recognition, which exists independently of cognitive capacity. I will look at the circumstances in which consent cannot be obtained from human beings, and ask whether some of the same ethically important considerations that underpin the need for consent might be achieved through seeking assent. I discuss the ways in which this might be beneficial for researchers, for prospective research participants and for society at large.

INTRODUCTION

In the UK and many other jurisdictions, there is a legal requirement that research participants should reflect the diversity of the population, including in terms of age and disability. However, adults with impairments of capacity to give informed consent (AWIC) are often excluded from research. This presents a problem, since AWIC have medical, educational and social needs which could be identified and met through research. Some of these needs may relate specifically to their capacity impairments—and in turn, this may affect how they respond to certain treatments.[1] If AWIC are routinely excluded from research, their capacity to benefit is diminished. Their response to newly developed procedures will not be fully understood, meaning that they are at risk of unforeseen adverse consequences, or that their doctors are reluctant to prescribe new treatments as they are unsure of the results. It is well established that AWIC have a shorter lifespan than those who have capacity.[2] This is not invariably due to intrinsic factors related to their cognitive impairment, but is a product of the way in which they are treated. The exclusion of AWIC from medical research serves to increase the likelihood that AWIC will not benefit from biomedical advances to the same degree as others.

Even where research protocols do not specifically set out to exclude AWIC, in practice, they may not be recruited because their involvement is regarded as being too complex by researchers, is blocked by gatekeepers or is thought to be morally suboptimal. Researchers' reluctance to recruit AWIC may be related partly to the complexity of the relevant legal, ethical and regulatory frameworks. The Medicines for Human Use (Clinical Trials) Regulations (2004), which governs research in England and Wales involving investigational medical products, requires that a legal representative must give written consent for any participant who lacks capacity. For all other kinds of research, the Mental Capacity Act (MCA) (Department of Health, 2005) applies and requires that a 'consultee' must advise as to the person's likely views on participation, if they lack capacity.

These protocols rely on a crisp legal dividing line: participants either have capacity or they do not. But it is more plausible to think of capacity as something that lies on a spectrum. This makes it difficult for those who are tasked with determining capacity, and it is not surprising that mistakes are made. There is a wealth of literature on the unreliability of capacity assessments, and strategies for improving them. For example, Warner *et al* found that 76% of their sample of people with mild-to-moderate dementia was unable to give informed consent, but this could not be predicted from cognitive test results.[3] Gaps in clinician knowledge about informed consent have also been reported.[4] However, even if capacity assessments were perfect, we would still have a problem about how to improve the representation of AWIC in research.

There are good reasons to think carefully about whether, why and how vulnerable populations should be included in research. Researchers are sometimes advised by ethics committees to avoid recruiting people who cannot give informed consent.[5] This is largely to forestall any danger of exploiting vulnerable populations. In what follows, I will argue that the current approach to including AWIC in research is flawed and that the ethical constraints designed to protect subjects from abuse, harm or exploitation, may in some cases have counterproductive effects. I will consider whether adopting an assent-based approach might offer a way of accommodating AWIC in research. I will argue that adults who cannot give informed consent may nevertheless have the ability to assent and dissent, and that these capacities are morally important in the context of research. Drawing on the concept of reification, as employed by Honneth, I show that the urge to protect 'vulnerable' people through exclusion from research, may entrench a reifying attitude towards them, whereas the act of seeking assent necessitates a degree of recognition. We have justice-based reasons for pursuing an assent-based approach, but (as I demonstrate in the last sections of the paper) this will demand significant changes to recruitment and communication strategies in clinical research.

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Unethical medical research

In thinking about the ethics of research involving people who cannot consent, it is useful to think about what it is that we are trying to *avoid*. There are two major ways in which medical research—and perhaps any kind of research—can be inherently morally challenging. First, medical research can be risky to life and health. Second, medical research often involves a significant power imbalance which opens up the possibility for exploitation.

The risks involved in research may be greater than those involved in clinical practice, because the participants (unlike patients) often stand to gain nothing in medical terms, so the harm/benefit balance is already skewed towards harm. This distinguishes medical research, at least in theory, from innovative treatment: the latter is generally defined as the use of a novel intervention in response to a particular patient's condition and motivated by the potential benefit to that patient. Medical research, on the other hand, is 'directed towards the production of generalisable knowledge in the interests of future patients/medical science.'[6] If protection from harm is not the only, or even the most important consideration here, we need to think carefully about what other moral concerns might be connected with medical research. And we need to think what we are trying to protect AWIC from, if not necessarily from harm specifically.

The clearest examples of harmful research are the notorious Nazi medical experiments, in which human beings were treated as disposable, replaceable objects whose subjective interests and experiences were of no concern to the researchers. Following the Nuremberg Trials and the Declaration of Helsinki, strict protocols have been employed to prevent such abuses from happening again. One of these protocols is that medical research involving human participants 'may only be conducted if the importance of the objective outweighs the risks and burdens to the research subjects.'[7] This balancing of risks to participants against potential benefits to science and society is, however, insufficient for research to be ethical; the declaration further states that 'Participation by individuals capable of giving informed consent as subjects in medical research must be voluntary.'[8]

This brings us to the second moral challenge: power imbalance. As suggested, greater regulatory oversight has restricted the degree to which researchers can exercise their power. However, even in closely regulated medical research environments, power imbalances are still operational. Science and medicine are high status professions[9]; doctors and scientists commonly have many more years of education than the average research participant; they often come from the most privileged and powerful sectors of society. The risks of exploitation may be exacerbated by the fact that doctors and scientists are expected to relate to the world, and to other people in a very specific kind of way, in connection with their profession. Medical researchers specifically must observe without permitting their own human responses to affect the outcomes of their observations. A good biomedical researcher in effect has to assume a set of behaviours and dispositions that are similar to those displayed by psychopaths.[10] Finally, our medical and scientific frameworks specifically reward ambition and innovation. Any clinician or researcher who attempts a new approach is likely to be motivated both by concern to improve the field, and by the wish to benefit patients. We cannot require that scientists must never be motivated by self-interest, the wish to 'further science' or the compulsion to make their mark through new innovations and procedures. However, we can perhaps say that when these motivations entirely eclipse other concerns, problems are likely to arise.

We might think the primary aim of medicine should be to benefit individual patients, but this is not, and cannot be the primary aim of research. Unlike innovative treatment, research aims to provide generalisable answers to specific scientific questions. These may ultimately serve to improve medical outcomes, but this happens through the use of research participants, rather than any benefit being directed towards them. The use of plants, animals, chemicals or objects in research may not raise ethical concerns, depending on one's view of the moral status of the entities being so used. But to use a human being in any context tends to be regarded as being problematic.

Kant insists that we should never treat other human beings as mere means to our own ends, but always as ends in themselves.[11] It may appear that the use of human participants in research is inherently at odds with Kant's injunction; however, many bioethicists have noted that this injunction is qualified. That is, Kant specifies that we must not use people *merely* as a means. To use people partially as a means is not necessarily a moral problem. Deciding exactly how to distinguish between fully and partially using people as a means is not easy. However, one way of making life easier is to focus on consent. Many philosophers place heavy weight on the idea of informed consent as a sufficient indication that a person is not being used as a mere means. Accordingly, the research ethics framework and the dominance of informed consent have significantly shaped the landscape of medicine and medical research over the past decades. The upshot of this is that we seem to end with a situation in which those who cannot consent, must not be included in research. Arguably, then, what we are protecting AWIC from by excluding them from participation in research, is being used as a mere means to someone else's ends.

Autonomy and consent

The 'four principles' approach to medical ethics centres on respect for autonomy, beneficence, non-maleficence and justice. The principles of beneficence—benefiting the person—and autonomy—that of respecting their will—often come into conflict. Informed consent is a mechanism for dealing with this conflict; one that prioritises a person's interests in making his own decisions over the importance of another person deciding what those interests are or ought to be. Informed consent has thus become a symbol of respect for autonomy, a shortcut to ethical practice and a crucial part of medical ethics. We; therefore, face proportionally harder questions when we have to make decisions without the possibility of appealing to this ethical 'get-out' clause. What principles or values should guide our practice when informed consent is not a possibility? Should we jettison our concern for autonomy, or are there alternative ways of recognising and respecting autonomy in people who cannot give informed consent? If not, it might be argued that our ethical priority is to protect these people from harm, given that the difficulty in giving consent also renders such people vulnerable to exploitation, abuse and harm.

In legal terms, informed consent is the domain of patients who have capacity. Yet as medical technology has advanced, and social, economic and political circumstances have changed, larger numbers of people are surviving traumatic births and medical problems at the start of life, devastating accidents and illnesses during their adult years, and living into old age with conditions such as Alzheimer's disease. The ageing population alone brings with it a wave of new patients and research participants: those who either lack capacity to consent, or who suffer impairments that prevent their communicating consent. The default patient is not necessarily one who can consent, given

that medical needs are most intense towards the start and end of life. Do we have reasons to respect the autonomy of research participants who are unable to consent? It may seem provocative to speak of respect for the autonomy of those who lack capacity. In the Kantian sense referred to above, autonomy is intrinsically linked with capacity to reason. Clearly, therefore, in the strictest Kantian terms we cannot have duties to respect the *autonomy* of those who lack the ability to reason, even though we may have other duties towards them. Onora O' Neill remarks that '[p]atients too impaired to give any consent evidently cannot be treated as persons […] Paternalism may then seem permissible, even required, for those who are, if temporarily, only patients.'[12] O'Neill's statement does indeed reflect a common assumption about what should happen in situations where a person lacks capacity.

However, in much of life, and certainly in much of medical practice and medical research, we do not apply such a strictly Kantian understanding of autonomy. If we think about a weaker form of respect for autonomy as entailing attention to preferences, it seems less clear that those who lack capacity must automatically be excluded from autonomy-based systems.[13] Instead of lurching towards a paternalistic approach, perhaps we can and should accommodate a greater degree of flexibility in our understanding of autonomy than a simple binary distinction allows for.

Much research suggests that patients and research participants often do not understand the information they are given. Many scarcely bother to read the patient information leaflets that are painstakingly drawn up by researchers and on which Research Ethics Committees (RECs) expend a huge amount of interest and energy. Their willingness and motivation to participate in research is not always based on a rational weighing of risks and benefits, or a careful analysis of the information provided. It is based on trust—trust in doctors, in researchers, in the structures within which research is regulated. It is also based on a very basic and fundamental misapprehension. We know that many research participants falsely believe that they will benefit from participating in research, even when they are explicitly told otherwise.[14 15] All this seems to suggest that the link between informed consent and autonomy in medical research is not altogether clear. This being the case, O'Neill's statement begins to look problematic. It implies (A) that there is a clear distinction between those who have and who lack, capacity to consent and (B) that those who lack capacity to consent cannot be treated as persons!

I would suggest that consent operates as a kind of moral shorthand for things that we believe are important. That is, that a recognition of people's preferences, and responsivity to their choices has a prima facie moral value; to respond to this is to treat them as persons, in O'Neill's sense. We have established that AWIC may not be able to give informed consent – but they may well have preferences and the capacity to make choices. To fail to respond to this is to fail, again in O'Neill's words, to treat them as persons. For O'Neill, this is not morally worrying because these preferences and choices simply do not matter, as they do in fully autonomous patients.

Yet, as I have shown, such perfect autonomy seldom, if ever, obtains in research involving fully capacitous adults either. Rather, what we have is consent as a codified form of recognition. That is, the fundamental requirement that Honneth believes is a necessary part of human interactions. If this recognition is connected with capacity at all, it is only in a symbolic sense. It is not clear then why those who lack capacity should be excluded from such systems. One answer to this is, of course, that people who lack capacity are vulnerable in ways that capacitous adults are not. Another answer is that, as O'Neill claims, we are simply responding appropriately to different values in different contexts. One locus in which these discussions have been fruitfully explored is that of paediatric research.

The trajectory of assent in paediatric research

Over recent decades RECs have increasingly afforded to children an interest in deciding whether or not to participate in medical research. In the UK, children's legal rights in the medical context were clarified in law in 1986 (Gillick v West Norfolk and Wisbech AHA). While this case referred to medical treatment rather than to participation in medical research per se, it is relevant for the issues we are discussing here. Gillick competence refers to a child's ability to understand a medical procedure well enough to consent to it. Significantly, there is no lower limit to the age at which a child can be deemed Gillick competent. It is purely a capacity-based assessment. After 1986, the term 'Gillick competence' quickly entered medical practice, and became a familiar phrase in ethics and law teaching in medical schools in the UK. It is perhaps not surprising that the phrase then started to appear in the deliberations of British RECs.[16] If a child is competent to decide whether to receive treatment, perhaps children could be competent to decide whether to participate in research. Indeed, it seems almost perverse to insist that parents should provide or withhold informed consent for children who in another medical context would be making their own decisions.

Growing attention to children's agency led to questions about children who were not Gillick competent, but might still be deemed to have an interest or concern in their involvement in research. The RECs responsible for ethical approval of research involving human subjects in the UK began to suggest that researchers should provide age-appropriate information for children, rather than simply informing the parents. Importantly, this was not to facilitate 'informed consent' since the children involved were not Gillick competent. Rather, the necessity of communicating effectively with children had been recognised as a significant moral concern independently of the issue of consent. The importance of respecting children's views, regardless of legal capacity to give consent, has also been codified elsewhere: Article 12 of the United Nations Convention on the Rights of the Child states that 'States Parties shall assure to the child who is capable of forming his or her own views the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.'[17]

Moreover, the possibility of a dissonance between parent's and child's willingness to participate was recognised. A system-based solely on the parents' consent will in theory justify the coercion of a reluctant child. But with increasing focus on children's engagement, RECs decided there was a better way of doing things: parents' consent would in most cases be a necessary, but not sufficient component for paediatric research. Researchers would need to communicate with, and gain the assent of, the children involved.[16] The requirement for assent makes a significant change to research involving children, increasing the onus on researchers to recognise and respond to children's preferences, choices and agency. This is significant since it seems to represent a move away from the idea that cognitive capacity is the primary moral concern in our treatment of others. Given this, it is worth thinking about why the same trajectory has not been evident in the context of AWIC. Many of the same issues apply: there is a wide spectrum of cognitive capacity among adults; there are difficult legal and ethical issues in recruiting

adults who lack capacity into medical trials, and frequently, such potential participants are under the protection of others who make decisions on their behalf. Yet although assent is now regarded as a matter of best practice for many RECs in the context of paediatric research, it is not routinely sought in the context of research involving adults who lack capacity.[i] Nor has it been much discussed in the literature.

One reason for this may be that people regard assent as a step towards developing autonomy and independent decision making in children. To the extent that deciding whether to participate in medical research can help to further this, it is valuable. However, people whose capacity is irrevocably lost cannot improve their quality of life, or their chances of future flourishing by being offered opportunities to exercise capacities that they will never develop. As a reason for discriminating between the value of assent in children and in adults who lack capacity, this is misguided. The idea that assent in children is justified with regard to their future autonomy, is also worrying, in that it fails to recognise and acknowledge children for what they *are*. In focusing too exclusively on future acquisition of capacity and autonomy, we may fail to appropriately recognise and respect the needs, interests and preferences of the subject who actually is the object of our medical or moral concern. My suspicion is that many of those who currently advocate a future-oriented approach to recognising the value of autonomy in children and/or adults who lack capacity, do not fully realise the implications of their approach for the current moral status of those who lack capacity. However, part of the problem here is the concept of moral status itself. Those who are moral agents have moral reasons to recognise the interests and preferences of others, whether or not those others are also moral agents. Thus, we should recognise whatever ability others have to communicate their interests and preferences, and ascribe value to these current phenomena that comprise the primary focus of the person's life and interests.

Assent and recognition

The injustices endemic in our societies may encourage us to separate those who lack capacity, into conceptual or actual reservations. In doing so, we tell ourselves that we are protecting them. But we also protect ourselves. We ensure that we rarely have to think about how we relate to these groups or how society's norms affect them. Special people look after them. We do not have to communicate with them. If our societies are unjust towards them, we are seldom confronted with this, and their status becomes entrenched. There is an alternative approach to understanding how we might relate to AWIC—one which incorporates assent as part of an attempt to communicate and interact with others. This involves an assumption that it is important to include and incorporate, rather than isolate and separate the vulnerable from the powerful. I base my argument on a loosely adapted version of reification drawn from the work of Axel Honneth. The German term used by Honneth is 'verdinglichung', commonly translated as 'reification'. In his somewhat portentous way, Honneth writes: 'Like a philosophically unprocessed nugget, the category of 'reification' has re-emerged from the immense depths of the Weimar republic and retaken centre-stage in theoretical discourse.'[18] But although Honneth suggests that reification is again taking 'centre stage', it has not made an appearance in the bioethics literature.

For Honneth, the tendency to treat another person as a mere thing—to reify—is morally problematic, and is something to which we are particularly prone. This resonates with Kant's injunction never to treat humanity as a mere means, but always as an end in itself. If, like Kant, we regard the important thing about humanity as being the capacity for rationality, Kant's injunction may not apply to some of the people that we are talking about. However, from Honneth's perspective, the wrongness of reification does not depend so obviously on the nature of the being that is reified, but on the fact that the moral agent—the person who has the power to do otherwise—is choosing to reify rather than to recognise. Recognition of non-thingness in others requires effort and consideration. It is not a discrete action, in the way that obtaining informed consent is. Rather, it is a relationship and a disposition. When we seek assent from prospective research participants, we include them in our moral sphere. We understand that they may have interests and preferences to which we should respond. We reduce the separation between them and us. We engage with them. The fact that they cannot simply sign a consent form, and that we need to work to communicate with them means that our attention is focused directly on them, in ways that it would not be otherwise. Instead of being invisible and unnoticed, they are participants in what happens to them, and decision-makers, to the extent that this is possible. Assent, therefore, offers possibilities to researchers—and to society in general, to exercise their capacity to recognise, in Honneth's terminology.

Part of the point here is that respect for autonomy—in the weak sense I have outlined, rather than the strong Kantian sense—is not just valuable to those who have capacity, but also to those who do not have the cognitive ability to give informed consent, and never will have this ability. Autonomy in the strongest Kantian sense is exclusive; in my usage, it is *inclusive*. The frustration and distress caused by having one's view ignored, one's wishes overridden, or one's agency denied, is a source of suffering in itself for those who lack capacity, aside from the loss of whatever good the person was hoping to obtain. The current approach seems to deny this. Those who lack capacity are supposed to have decisions made for them and not to suffer from this. But since the very process of treating people paternalistically is itself a source of suffering[19] this gives us a compelling reason to find better ways of minimising its effects. Assent, based on recognition, is one such way of incorporating the views and preferences of those who might otherwise be relegated, in O'Neill's terms, to purely paternalistic treatment.

As I mentioned at the start of this paper, there are two key moral problems associated with medical research. One is that it may be risky, and harmful to participants' health. The other is that the power imbalance between researcher and participant increases the risk of exploitation, or abuse. The former risk is relatively straightforward; we do not need complex moral theory to understand that people may be harmed or killed in the course of medical experimentation. However, the second category of

[i]It is difficult to provide conclusive evidence of this; in the author's personal experience of working with Research Ethics Committees over a period of 8 years, not a single research project proposed to employ an assent-based approach to recruitment, where participants included adults who lack capacity; in contrast, an increasing proportion of projects involving children did explicitly state a plan to use assent. Again, as time went on, the committee's default position became one of requiring assent in paediatric research. It is also worth noting that in the UK's Health Research Authority guidance for researchers who want to recruit adults who lack capacity, consent forms are provided for consultees, guardians, friends or relatives of the adult who lacks capacity. But there is nothing specifically designed to use with the adult him or herself who lacks capacity (http://www.hra-decisiontools.org.uk/consent/examples.html). In contrast, the same authority gives examples of forms for use with children – which seek the child's agreement, though the word 'assent' is not used explicitly.

risk requires careful attention. In attempting to protect those deemed vulnerable from the most obvious causes of harm by excluding them from research, we may inadvertently increase their susceptibility to this second category of risk. In excluding those who cannot consent from research, we perpetuate their reification. Reification in medical research comes in two kinds. First, there is the overt view that the population being studied can and should be treated merely as a means to an end. The research subject's subjectivity is viewed as being unimportant; the sole value of the research subject lies in their utility to the researcher. In theory at least, it should be possible to regulate fairly simply against this kind of unethical research, by enforcing strict constraints on what researchers are able to do. Every jurisdiction that supports research regulation adheres to some variant of this principle. The question is, do we need some additional principle to protect those who lack capacity?

In systems that already exercise harm-based restrictions in medical research, it seems that we are not really protecting AWIC from harm by excluding them from participation in research. At least, not from harm that could legally be inflicted on a person with capacity. Rather, when we exclude AWIC from research, we are taking their incapacity to be their defining feature. The default move to exclude AWIC does indeed protect them from research-based exploitation, but it also serves to reify them in a variety of different ways. First, exclusionary policies entrench the notion that society is composed of 'reasonable people' who can give informed consent. Their concerns and preferences are attended to, and responded to, while those of the excluded population are not. But more significantly, they are communicated with while the excluded population are not. Those within the favoured group speak for themselves, while those without are spoken for by others. Finally, and perhaps most significantly, the drugs, interventions and insights are of uncertain relevance or benefit for those within the excluded groups. Increasingly, it is being shown that AWIC receive less optimal care, are more at risk of being undertreated for their medical problems, and are more likely to die prematurely than those who have capacity.[20]

Since the preferences of people who lack capacity are neither sought nor ascertained in the research context, there is a risk that the degree of cognitive or communicative ability that they have—wherever it may be on the spectrum—may atrophy. Being always protected, they may be institutionalised, infantilised. This is not to say that we should jettison all attempts at protection, but at least that we should acknowledge that protection is a double-edged sword. There is a danger in categorising people or groups as 'vulnerable'. As Szasz says, this can be a way of depriving people of their agency.[21] Further, we need to think carefully about who we are protecting when we seal off certain parts of the population from participation in research.

To exclude those deemed vulnerable from activities that others participate in is of course not as bad as directly abusing, neglecting or exploiting them. Nevertheless, perhaps we could do better. The exclusion of AWIC from research is part of a bigger picture in which we marginalise a particular population and simultaneously tell ourselves that we are morally admirable for doing so. This is in itself a form of reification. We are cementing the exclusion of this population which is to be defined by its lack of capacity, while at the same time evading opportunities to communicate with them, and condemning them to a life of second-rate medical care.

Communicating preferences and interests

This—one might argue—is begging the question. Some of these people simply have nothing to communicate; no preferences, or perhaps nothing that they are able to communicate. It is not uncommon to hear healthcare professionals make statements such as 'there is nothing there' in reference to patients who have suffered a stroke, or babies with brain damage. I would concede that this may be the case in some situations. However, I suggest that these are far less frequent than we might think. A person who is able to move or vocalise, to any degree at all—even a single eyelid, as in 'locked-in syndrome'—may signify preferences or dislikes through even very limited movements. These are extreme cases, but how many instances may there be where a person's capacity to express preferences is ignored, overridden or dismissed?

When we bear in mind that it is not consent we are speaking of here, but assent, it is far less clear to me that people who might be dismissed as having 'nothing there' are fundamentally unable to assent or indeed dissent. The person who struggles against the ventilator, who rejects the feeding tube, who writhes in distress expresses at a very basic level what the person is feeling and experiencing. Those who spend a long time caring for such individuals may become expert in recognising and interpreting these movements. There is nothing mystical in any of this. We have to be able to recognise and respond to non-verbal communication. We do this without thinking about it, with babies, children, our pets, with people who are profoundly disabled or incapacitated and with the elderly, the demented and the unconscious. If we could not do this, our species would die out.

Undoubtedly, the ability to communicate preferences or antipathies is far removed from the ability to understand complex information, to form future-oriented goals, or to hold abstract values. It is specifically because of this that assent is important. The importance of accommodating and communicating with people who have impairments is well recognised in the disability literature.[22] And there are many reports of inaccuracies or inconsistencies in the performance of capacity assessments. Many papers that discuss these questions focus on looking for better ways to measure capacity or ascertain capacity rather than to explore ethical recruitment possibilities for those whose incapacity is not in question. While I acknowledge the force of these and similar criticisms of capacity assessments, my argument goes further: those who do not have capacity on any legal measure, should also be recognised.

Researchers need to make the leap of faith to recognise that there is something relevant that could be communicated by the dementia patient, the neonate, the aphasic person. These leaps of faith have to be made all the time by those who live with and care for those who lack capacity. Assent is a way of bringing recognition into the domain of medical research, to accommodate rather than exclude those of us whose means of communication is restricted, or whose capacity is impaired. Assent functions as a way of enabling researchers to respect the preferences of research subjects who lack capacity.[23] These preferences are informed by trust. Participants may prefer not to participate in research with a person they do not know or trust. They may prefer to spend time with someone whom they do trust. Since trust is a key component of research ethics, it is important to acknowledge that those who lack capacity may also be able to form trusting relationships, and conversely, to be mistrustful.[24] Gaining assent is more burdensome than gaining consent, as it requires a more intersubjective communication with the prospective research subject. But this in turn is part of what is necessary for the development of a trusting relationship.[24]

The term 'leap of faith' sits uneasily in the context of biomedical science. Not only this, but it may seem unacceptably risky. What is to keep researchers' ambitions in check? If researchers

cannot point to a signed document, how can those around them be satisfied that the AWIC recruited into the research are indeed willing participants? Yet these risks also apply to the question of assent in relation to paediatric research. Paediatric assent applies across a wide spectrum of capacity. Some individuals can express their views and preferences fairly clearly. However,when verbal communication is not possible, it becomes more important to attend to the ways in which potential participants can communicate. This will involve spending time with them, and with those responsible for them, who may have specialised knowledge of their communication needs. There is an increasing array of communication devices designed specially to facilitate interactions in such contexts as these.[25] Even so, if we are to minimise the risk of coercion or exploitation, careful thought will have to be given to the ways in which AWIC assent is sought and documented. I do not attempt to give a full account of this here. My argument is a more preliminary one: that we acknowledge the moral importance of assent, and then begin the work required to make it an integral part of good medical research.

Legalities and practicalities: UK legislation

It is important to think about how these suggestions fit with current legislation and how they might be implemented in practice. Here, I will focus on the situation in the UK. The MCA 2005 states that research involving people who lack capacity

> 'must be connected with (a) an impairing condition affecting P, or (b) its treatment'. A researcher carrying out research on people who lack capacity must: identify someone who NOT IN A PROFESSIONAL CAPACITY OR RELATED TO THE RESEARCH is engaged with P's welfare and willing to be consulted. If no such person is available, then R can appoint someone but they must not be associated with the research.

There is a parallel here to Independent Mental Capacity Advocates (IMCAs), who have a legal role in law to contribute to complex medical decisions when no next of kin are available and a patient lacks capacity to consent to medical treatment. However, the use of IMCAs in medical practice in the UK is extremely rare. And despite many years' involvement in RECs, I am unaware of any case where IMCA—type input has been associated with a person's participation in medical research. Rather, those who lack capacity are simply excluded from research.

There may be a further inconsistency in the law. Although research must represent the diversity of the population in theory, in practice, it seems almost impossible that it could do so, since the legal protections for those who lack capacity are far more stringent than for those who are able to give informed consent. However, it is also possible that the law is interpreted as being more restrictive than it need be, by potential researchers and by RECs. For example, in section 31 5 of the MCA, it is stated that either (A) the research must have the potential to benefit P (the person who lacks capacity) or (B) it must be intended to provide knowledge about the condition, or causes, or treatment, or care of people affected by this or a similar condition. This is generally understood to mean that there needs to be direct personal benefit for P, but in fact this interpretation does not necessarily follow from the wording of the law. Research involving P may well be beneficial to other people who lack capacity in a general sense, since by including such populations, we increase our knowledge about their needs and treatment. Thus in a very general sense, any research involving P benefits those members of society who share P's lack of capacity.

The law also makes particular mention of the requirement that risks to participants who lack capacity should be 'negligible'. In the case of research subjects who can give informed consent, on the other hand, the balance between risk and prospective benefit is entirely different. Those who have sat on RECs will be aware that many research trials involve burdensome, painful and sometimes risky interventions. In what I have argued so far, I have suggested that some of the differences between our treatment of research subjects with and without capacity are not justified, and can even be detrimental to those whom we are trying to protect. The question of whether this implies that we should embrace greater research-related risks in our inclusion of people who lack capacity in medical research is challenging.

Here, there may be differences to be made between different kinds of negative experience in research. Pain and discomfort are immediate. The willingness of a person who cannot form complex long term projects and goals to undergo procedures whose immediate effects are unpleasant or painful is likely to be more limited. We see this all the time in the case of small children, who regard injections with fear, whereas many adults are able to offset the immediate and transient discomfort against the future gains they expect to accrue. Risk of future health problems may be worrying, but only for those who are able to appreciate that such risks exist. Because of this, those with capacity may find it easier to bear immediate pain, knowing that it is transient, and that it is for a worthy purpose and that they can choose to leave the study at any time. How should we deal with this from a recognition-based assent perspective? My suggestion here is that the very lack of capacity in itself forms an internal self-limiting mechanism, and indeed, that parts of the law almost seem already to endorse this kind of approach.

Section 33 of the Act includes additional safeguards that specify: nothing can be done to P during the course of research 'to which P appears to object'. Here, it appears that something approaching assent—or at any rate, dissent—is already embedded in the law. To the extent that this is the case, it is not the law itself that needs to change, but the habits and practices of researchers and RECs. However, the focus of the law here is problematic. Apathy or indifference appears to be an acceptable basis on which to involve the participant. From a recognition-based perspective, I would argue that a more engaged and active assent should be sought from the participant, in line with their abilities, and that in the absence of such active assent, the research should not proceed.

Provided we pay close attention to their preferences, and especially to dissent, we should be able to ensure that participants only take part as long as they are happy to do so. Participants are highly unlikely to assent to research that causes them extreme discomfort and suffering. Researchers in turn will have reasons to design research in ways that minimise such interventions. For longer-term risks, it may be harder to see how the assent-based approach could be operationalised. In this instance, it seems to me that there is justification for a paternalistic approach whereby others—perhaps RECs—determine whether research can go ahead.

CONCLUSION

In this paper, I have shown that the efforts we make to 'protect' those who lack capacity in the context of medical research may ultimately contribute to a world in which such people are systematically disadvantaged. The moral frameworks that govern medical research are geared towards 'reasonable' people who can give informed consent. Yet, as I have indicated, this is an

idealistic vision which bears little resemblance to the day-to-day reality of medical treatment and research. Informed consent has become a perfunctory exercise which neither serves to respect autonomy, nor to dispel the misconceptions that many research participants have. We are too hasty to regard informed consent as the cornerstone of ethical research, and too rigid in our understanding of the relationship between consent, rationality and autonomy. It is undeniable that medical research can be harmful to participants, and that biomedical researchers can be dangerous people. However, if we place effective limits on the powers of researchers to inflict harm on research participants, it is not clear that we have additional grounds to think that those who lack capacity should be excluded from research.

Paying attention to people's preferences and interests offers a way of engaging with those who lack capacity. Gaining assent, and respecting dissent in these groups offers greater scope for researchers to recognise their needs. In contrast, to exclude such groups by default is to define them solely in terms of their incapacity, and risks entrenching a reifying disposition that creates boundaries between us and them. While there are many legal and ethical complexities involved in medical research with those who lack capacity, there are ways in which the current status quo could be improved. The recognition/reification dichotomy offers a way of conceptualising the relationships that we can have with those who cannot give informed consent.

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