A problem with inclusion in learning disability research.

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Abstract

People with severe learning disability are particularly difficult to include in the research process. As a result, researchers may be tempted to focus on those with learning disability who can be included. The problem is exacerbated in this field as the political agenda of inclusion and involvement is driven by those people with LD who are the higher functioning. To overcome this we should first detach the notion of consent from ideas about autonomy and think instead of it as a way to avoid wronging others; this fits the original historical use of consent in research. This allows us to think in terms of including participants to the best of their abilities rather than in terms of a threshold of autonomy. Researchers could then use imaginative ways to include the least able and to ensure they are not wronged in research or by exclusion from it.

Introduction

We claim that mechanisms of research ethics have evolved from an emphasis on research protection to incorporation of consent, ethical review by committee and, finally, inclusion of participants in the research process. Whilst this is positive for most research participants, we shall argue that it has potentially negative outcomes for the least able of those with learning disability. We go on to suggest ways nurse researchers might overcome the problem. We shall begin by setting out the evolution of research ethics in more detail.

Evolution of three research ethics mechanisms: review

The ethics of research involving humans has developed primarily in the realm of medicine. The earliest research ethics code was Prussian, written in response to dangerous research performed by doctors on human subjects at the end of the 19th Century [1]. Despite this code, the period of Nazi dictatorship before and during the Second World War was one in which horrific experiments were performed on inmates of concentration camps; the researchers were generally medics and the experiments usually had a quasi-medical goal. The Nuremberg trials followed this period and led to the development of the Nuremberg Code which drew on the earlier Prussian one.

In this context, it is unsurprising that the primary purpose of the Code was the protection of human subjects. In the Nuremberg Code, the main mechanism for this protection was voluntary consent, the underlying belief being that people would not consent to harmful research. There are two problems with this, however. First, people might consent to such research if they are vulnerable in some way, for example, unable to understand what is happening. Second, some people who would benefit from research might never be able to consent to it; for example, babies or those with severe mental illness.

The Helsinki Code developed in response to these and other problems. It was written by the World Medical Association and a version of it is still in place today and forms the basis for all other medical research ethics codes.[2] It allows research to be performed on those without capacity to consent provided certain protective criteria are met; one of these is the review of research by independent committees, another is the notion of informed consent rather than simply voluntary consent.

This gives us two mechanisms in research ethics: consent and ethics review. Both have developed to protect health care research subjects (or participants as they are now usually known) from harmful research. Since the publication of the first Helsinki Code, the need for such protection has been underlined by the coming to light of many cases of harmful research. Two key publications from 1966 and 1967 were those of Beecher and Pappworth which set out hundreds of examples of unethical research performed by reputable clinicians and published in reputable journals [3, 4].

This emphasis on protection, however, has resulted in a different type of problem: exclusion. One way in which ethics committees and researchers have protected people perceived as vulnerable is by excluding them from research. Pregnant women, children and people with learning disabilities are examples of groups excluded in this way. The result is that health care has a gap in the evidence for the care of such groups. Thus we have the following statement in the *Research Governance Framework* [5].

> 'Research and those pursuing it should respect the diversity of
> human culture and conditions and take full account of ethnicity,

gender, disability, age and sexual orientation in its design, undertaking, and reporting. Researchers should take account of the multi-cultural nature of society. It is particularly important that the body of research evidence available to policy makers reflects the diversity of the population'.

One response to this is the development of the notion of inclusion in research. This is particularly so in the field of disability research, which has been much influenced by social model thinking. This is the idea that disability is more a social creation than a biological fact. In line with this, early commentators such as Oliver [6] and Zarb [7] argued for an emancipatory model which framed research as an activity controlled by disabled people rather than by professional researchers.

Thus we now have three mechanisms of research ethics: consent, review and inclusion. We now turn to how these mechanisms work both for and against the interest of some people with learning disability.

Inclusion

The three mechanisms, it will be recalled, developed out of the need to protect participants from harmful research. In the field of learning disability the population was seen as 'vulnerable' and with the long-lasting influence of eugenics and the asylum programme their care was thought to be best carried out away from public scrutiny and under medical control [8, 9]. The need to challenge the dominance of such a clinical approach was highlighted by a disabled man, Paul Hunt, who, with colleagues experienced at first hand the intrusive effects of research into their residential living experience at the Le Court Cheshire Home in England in the1960s. They had invited researchers from the Tavistock Institute to explore their situation and were disappointed with the outcomes [10]. Rather than condemn the management of the homes the researchers merely reported that 'the cripples' who lived in these conditions would inevitably experience 'social death'. This sparked a movement for inclusion by disabled people within all research which affected their material and social circumstances.

At roughly the same time in the US Becker's question 'Whose Side Are We On?' [11] challenged those working in social research to consider siding with the oppressed and abandoning any pretence of the brand of scientific objectivity which marked

the investigation carried out in the Tavistock Institute, England. Later, and with specific reference to the struggles of disabled people, the disabled activist, writer and commentator Michael Oliver applied a political perspective to the idea of participation in research. He was explicit about what he saw as a potentially divisive split between the researchers and the researched. Where Becker asked a general question Oliver was more direct. With clear echoes of Hunt's earlier situation he asked[6]

> '.......do researchers wish to join with disabled people and use their
> expertise and skills in their struggles against oppression or do they
> wish to continue to use these skills and expertise in ways in which
> disabled people find oppressive? (p. 102).

Walmsley [12] notes that inclusive research as practised with a learning disabled populations is a product of the late twentieth century (2001:188). She cites Edgerton [13] who was the first to attempt to include the voices of individuals with learning disability in research in any meaningful way. In the late 1960s he interviewed former patients of state institutions to find out how they were coping with life 'in the community. His seminal work *The Cloak of Competence*' was highly influential in subsequent enquiry.

It was in the same year that the first ever UK White Paper 'Better Services for the Mentally Handicapped' was published [14]. In this document the government responded to criticism of conditions inside long-stay institutions and outlined plans for more community based care. It was only with the subsequent development of the principle of normalisation [15, 16] and its application to support services that the learning disability population gradually became visible to social science researchers. With a higher profile people with learning disability gradually became more involved in research as academics and practitioners on both sides of the Atlantic became convinced of the need to include them in research [17-19].

For those living with learning disability this movement towards inclusion in research grew in parallel with academic commentary and culminated with the publication of

Nothing About Us Without Us [20] which acted as a rallying point for those professionals, academics, clinicians and individuals who saw value in sharing research agendas. The arguments were subsequently taken up by others in an effort to establish some direction to the trend [21-23].

Thus, inclusion has arguably been more central in the development of ethics in LD research than other areas. With this, however, comes the need to examine the assumption that LD is incompatible with informed consent.

Consent and review

The mechanism of consent has been less to the fore in the development of ethics in relation to LD. The underlying notion seems to have been that people with LD were there to be looked after and cared for. The research process merely mirrored this attitude. The research agenda was set by researchers; and research was performed on people with LD with, at best, their nominal agreement rather than consent. Whilst the inclusion agenda has developed, it is nonetheless the case that obtaining consent to participate in research can be difficult when the mental capacity of the participant is impaired or otherwise open to debate, as is the case for many individuals who have some learning disability. This detail can be enough to prevent the process from even beginning. As Valentine observes,

> 'The moral pressure to get inclusionary research 'right', without an acknowledgement or recognition that it is an imperfect process, can also be a deterrent to some researchers even trying' [24](2003: 378).

Alison Cocks [25] moves the debate on when she juxtaposes the idea of 'informed consent' with the notion of a 'right to be heard'. Her examples are taken from scenarios involving children with learning disability but the principle remains: disadvantaged, underrepresented and potentially vulnerable groups exist in social circumstances we interpret as being in need of 'research'. However the rules of enquiry make it very difficult to engineer the circumstances for researchers to obtain the necessary levels of consent. Cocks suggest that 'assent' might be a way of circumventing this dilemma (249) which she sees essentially as being founded in an overly formal definition of 'consent' (253) that is outside the scope of many 'lay' participants . This is corroborated by Cook and Inglis who suggest that the design of information sheets and related paraphernalia are part of the problem with consent

rather than being a solution (56). Truman certainly found that the public were largely ignorant about what they were consenting to when signing documents for the authorities at Alder Hey Hospital.

Consent then can be unpacked to reveal three problems for research conducted in this area:

- the capacity of the participants to give consent
- the value of consent as an indicator for participation
- the discrepancy apparent between expert and lay understandings of what consent actually entails

The protection that can be afforded to potential participants by securing their consent comes at a cost. For as long as consent remains in place as an artificial construct designed to protect the probity of academic research these issues will remain problematic for parties who are engaged in the process. This cost may be considered too high if it results in a reduction in learning disability research due to risk-averse attitudes from researchers which effectively prohibit individuals from participating in research that directly affects their quality of life and overall participation in society. A further consideration then needs to be given to the potential diminution of knowledge that will result from such a position.

Implications of review, consent and inclusion: a paradox

The development of review, inclusion and consent in LD research is clearly positive. However, there is a paradox. The problem is that people with intellectual disability, as noted by [26] 194, form a heterogeneous population and within this grouping many sub-groups cluster around all the typical socio-demographic divides such as class, ethnicity and gender. Some of these individuals will have few problems understanding the purpose of a research project and their potential contribution to it. They will be able to make a judgement about their involvement and give or withhold their consent. But people with intellectual disability who live with the highest levels of impairment and whose impairments and associated needs demand the highest levels of continual support and care challenge our understanding of how to facilitate their inclusion in research. They are also those least equipped to understand their own situation and furthest from being able to articulate their sense

of self. This causes difficulties for researchers, their potential participants and those in support roles who might mediate.

This position can polarise thinking as the political aspects of research are emphasised. Barnes [27](1996) for example divided the field into 'for and against' where a researcher who is not 'disabled' must share the values of the 'researched' in any collaboration or else his research is exploitative.

These two issues of exploitation and exclusion lie uneasily together in research ethics. In the field of disability research the tension has been tackled through the adoption of an emancipatory model of research in which research is viewed as an activity controlled by disabled people rather than by professional researchers. Using this approach, the risks of both exploitation and exclusion seem to be minimised. The approach itself, though, gives rise to a further problem particularly when it is applied to learning disability research.

There is of course a sliding scale of disability and impairment and the continuum is not necessarily a smooth linear progression from total dependency to full autonomy. And this is precisely where the dilemma appears. The dilemma exists primarily for researchers and it is whether to abandon those who cannot readily contribute to research due to issues around capacity, consent and capability and instead to secure partnerships only with those who are functionally able to make the commitment. A cursory examination of the research topics reported on in the literature suggests that the majority of researchers have found this to be a more pragmatic solution, if not a more satisfying option. It follows that the interests of those unable to be included in "inclusive" research programmes may be overlooked.

For researchers operating in LD research the danger in ignoring the contributions of those who constitute the LD community should be readily apparent. Academics have an important contribution to make themselves but this is only ever a partial account. It will be further compromised if it cannot find a way to include other voices, some of which are being silenced through the application of ethical review.

A way forward

We are concerned that the conduct of research within learning disability circles might at best maintain the hegemony of current academic hierarchies and at worst replicate some of the mistakes made in the past [28, 29]. The problem for researchers is whether to follow closely the inclusion and consent requirements for research in LD at the cost of excluding those unable to meet those requirements. We suggest that at present this seems to be what is happening. If so, the body of research evidence will not reflect the needs of the whole population of people with LD. What solutions are available?

One element might be a rethink of what consent is for. Currently, it tends to be justified in terms related to an individual's autonomy; we get consent because people have a right to choose what happens to their selves and data. This autonomy model, which is almost universally accepted, is problematic in that autonomy itself is problematic; there is no widely agreed definition. Some definitions are demanding such that few individuals or actions are deemed autonomous. Others are undemanding such that most individuals or actions are autonomous but where it is hard then to understand why such autonomy deserves respect.

Manson and O'Neill [30] say that the function served by consent is not (or not primarily) to respect autonomy; it is rather to make permissible an otherwise wrongful act. The nature of this wrong varies, however. Sex without consent is rape; a tattoo without consent is criminal assault; taking money without consent is theft. The wrong when consent is not obtained for treatment or research is different (here we assume the research itself is otherwise ethically sound). It lacks an obvious descriptor, but words like impertinence suggest themselves. To undertake research on individuals without getting the best possible involvement and consent from them is rude, impertinent, unkind, and so on. If we use this model of consent, it becomes clear that we should be less troubled about whether or not an individual has capacity to consent and more concerned that we have not wronged them; that we have included them to the best of their and our abilities.

In practice, including to the best of our joint abilities will require imagination. We should try out different methods of communication with different groups. But the

model itself means that the idea of inclusion and consent no longer becomes one that threatens exclusion of those unable to give an autonomous or ideal consent.

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