Ethical Challenges in Intellectual Disability Research

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ABSTRACT

Involving individuals with intellectual disability in research can be difficult, researchers often focus on those with a mild/moderate disability as they are often more accessible. However, there is a drive politically and socially to include and involve all persons with intellectual disability in research. Researchers must address the notions of consent, autonomy and consider best practice rather than a threshold of autonomy to avoid wronging participants and enabling persons with intellectual disability to be involved in research to the best of their ability. Thereby enabling all people with intellectual disability including those least able to participate in research through using creative and imaginative ways to support them through the research process.

KEYWORDS

Ethics; Inclusion; Intellectual disability; Participation; Research.

INTRODUCTION

There has been great strives over the years for individuals with intellectual disability to live in their own community, or move towards least restrictive environments to support inclusion. However, this has resulted in an inconsistent emancipation for individuals with intellectual disability within healthcare and research. This inconsistency is evident in the increased health disparities among individuals with intellectual disability [1, 2] and the fact most research has relied on a proxy voice, with the voice of individuals with intellectual disability less evident [3]. Movement towards self-advocacy promises to empower individuals with intellectual disability to challenge these inequities, particularly around health and wellness goals [3-5]. However, accomplishing these goals requires engagement with individuals with intellectual disability in research, not only for the benefit of findings and outcomes, but also for the emancipatory value of hearing their voice [6]. In so doing, health care professionals, family carers and researchers can be informed of ways to improve health and well-being of individuals with intellectual disability through an increased understanding, knowledge and awareness.

Involving individuals with intellectual disability in research is essential, as health is considered beyond that of a dominant bio-medical cultural paradigm, which adopts freedom from disease and disability as the ideal. This presents a theoretical challenge in contextualising health and wellness as there is an absence of consistent and authentic voices of individuals with intellectual disability. Failing to engage people with intellectual disability in research and using proxy voice assumes that understanding of perceptions, meanings, and indeed the construct of reality are within the range of experience and thought of the proxy. Embedded in this approach, is that knowledge of best practices for personal health and wellness is a nexus situated within the sole possession of proxy that can be shared on behalf of the individual with intellectual disability [6]. Moving beyond proxy voice places the person with intellectual disability in a position of power by enhancing their knowledge and understanding of the world and their place in it, and valuing them as expert witnesses [7]. This article presents ethical aspects of consent, inclusion, and review and access of people with intellectual disability in research.

INTELLECTUAL DISABILITY RESEARCH AND ETHICS

The earliest research ethics code was Prussian, which developed because of dangerous research conducted by doctors on human subjects at the end of the 19th Century [8]. However, during the World War II the Nazi performed horrific experiments in the concentration camps resulting in the Nuremberg trials and development of the Nuremberg Code [9] with its primary function of protecting human subjects. Protection would be maintained through voluntary consent, freedom from coercion and appropriate risk benefit ratio [10]. However, vulnerability and benefit remained an issue for concern as individuals may consent to research if they are vulnerable or do not understand what is happening, or individuals who may benefit may never be able to consent; for example, babies [10]. In response to these concerns the Declaration of Helsinki [11,12] was developed allowing research to be conducted with those who may not have the capacity to consent provided the criteria of; been reviewed by an independent committee, informed rather than voluntary consent were met and the notion of legal guardians was addressed. Building on these codes The Belmont Report [13] introduced the three rights of; respect for autonomy, beneficence and justice. In addition, to protect these three rights the Belmont Report identified the three practices of; informed consent, risk-benefit assessment and fair-selection process.

In the field of intellectual disability, the population has often been seen as 'vulnerable' and this may be due to the long history of institutional care that was often located away from public scrutiny, with an underlying notion that individuals with intellectual disability were to be looked after and cared for. However, the development of the principle of normalisation [14, 15] and its application to service provision saw individuals with intellectual disability gradually becoming visible in society and research. The emphasis on protection of individuals often resulted in exclusion of individual with intellectual disability as a means for ethics committees and researchers to protect individuals perceived as vulnerable [16, 17]. This perceived vulnerability and/or overestimation of vulnerability has often led to the exclusion of people with intellectual disability in research [18, 19]. Due to the concerns regarding vulnerability, where research with people with intellectual disability has occurred it has tended to focus on those with mild to moderate intellectual disability leading to an under representation of a large proportion of the intellectual disability population [4]. This under representation particularly of those with severe to profound level of intellectual disability may be in part due to exclusion and in part due to the hesitancy of ethics committees to grant approval for the intellectual disability population grouping. To engage individuals with intellectual disability in research, ethical approval is required which places an emphasis on research protection and incorporating consent. In response to this issue, the aspect of inclusion in research has arisen for individuals with intellectual disability, facilitated by social model thinking [20]. Early commentators such as Oliver [21] and Zarb [22] argued for an emancipatory model, framing research as an activity decided by intellectual disabled people rather than by professional researchers. Thereby, creating three aspects of research ethics: consent, inclusion, and review and access all of which work for and against the interest of some individuals with intellectual disability.

CONSENT

Gaining informed consent from persons with intellectual disabilities can be challenging, as there is nothing ordinary about informed consent, either conceptually or procedurally for people who have intellectual disability [23]. Valid consent 'requires a person to appreciate the current situation, possess sufficient information, understand the information given, be able to weigh up the pros and cons, communicate a choice voluntarily and free from coercion' (p.58) [24]. Thereby obtaining consent from participants with intellectual disability presents particular ethical challenges for researchers [25]. Difficulties with attention, memory and ability to transfer recently learned material creates tension between, ensuring people with intellectual disability understand the purpose and implications of their participation in research and at the same time avoiding any coercion [25]. Iacono and Murray (p.49) [26] further emphasis the difficulty and tension that exists when stating 'there is a need to protect potential vulnerable participant groups, while ensuring that demands placed on researchers are not so restrictive as to preclude valuable research'. Thereby there is a concern that to overcome these difficulties researchers may exclude people with an intellectual disability from research or include them without their consent. Generally, consent can be unpacked to reveal three issues for research undertaken in this area; the capacity of the participants to give consent, the value of consent as an indicator for participation, and the discrepancy between expert and lay understandings of what consent actually entails.

To determine the capacity of an individual to freely provide consent, one should focus on a person's ability to engage in everyday decision-making. Consideration must also be given to those areas of functioning where individuals retain competency and the ability to consent should not be presumed [23]. When conducting a study, the researcher should remain focused on other indicators of the clients general well-being, including facial expressions to assist in identifying their capacity to consent [27]. In addition, at various points during

data collection the researcher should stop to reconfirm the participants wish to continue, as their initial agreement to participate is insufficient [28] and to acknowledge that consent is not a one-off event [27, 29]. Having family member or staff members well known to participants present during data collection, acting as third parties or validator is important for identifying signs of discomfort or stress should they transpire [27, 29]. Participant should have the capacity to provide consent of their own volition and without coercion [30] and it must be recognised that both the participant and the family or staff member must give consent to participate [31]. However, difficulty arises in reaching a balance between ensuring that people with intellectual disability understand the purpose and consequences of their participation in research and ensuring at the same time they are not coerced to participate [25, 32]. Often proxy consent from a next of kin/family member or a care worker working closely with the person with intellectual disability is used [33, 34].

Jenkinson [35] identify factors that affect an individual's decision making such as; who has control over decisions and the organisational structures that exist in the individual's environment. Others may relate to the researcher's attitude to consent and the significance of ensuring that participation in research is an ongoing practise and not just something that is ascertained at the onset of contact. The greater control the individual with intellectual disability has in each decision point within the research process the less probable it would be that the research infringes on the rights of people with intellectual disability [36]. Thereby careful planning by the researcher on issues such as; access to participants, consent by participants, content and appropriateness of information (written and verbal), nature and duration of data collection, support required by participants, accessibility and transport arrangements need to be considered [37]. The researcher should clearly identify him/herself, establish a good rapport with the participant, use incidental conversation to break the ice before embarking on the data collection proper, thereby encouraging the participant to trust and share accurate information on the topic to be discussed [38]. The researcher should explain the purpose of the research, address and explain terms such as; consent, confidentiality and that there are no right or wrong answers.

What must be considered is that people with intellectual disability are a heterogeneous population and within this population many sub-groups exists [39]. Some individuals with intellectual disability will have few problems understanding the nature of a research project and the implications of their involvement. They will be able to make a decision about their participation and provide or withhold their consent. However,

people with the higher degrees of disability and whose disability and associated needs require the highest levels of continual support and care challenge our understanding of how best to support their participation in research. This group are also least equipped to understand their own situation and being able to articulate their sense of self. However, participation should reflect the importance of capacity rather than lack of capacity and should be engaging rather than preventive in nature, thus safeguarding that it complies with relevant constitutional and human rights standards. Finding that a person lacks capacity leads to the restriction or removal of fundamental rights and in this sense, the issues of capacity and rights are intricately interrelated. Thereby, consent should be evaluated from the point of view of research participants, and the possible stress or harm caused to them. This wider more holistic approach to informed consent entails a greater focus on the wellbeing of research participants as the major concern during research and researchers need to plan their practice accordingly and continually evaluate participants' wellbeing [6].

INCLUSION

It was not until the 1980s that people with intellectual disability were involved even as interviewees in research that was about them, or their views sought in evaluations of the services they received [40]. Policy requirements promoting 'client involvement' led to a range of clients, including people with mild and moderate intellectual disability participating in health and social care service planning and research [41, 42]. Most people with intellectual disability now live in community settings but are among the most disadvantaged in our society [43, 44]. In addition, the perceptions and viewpoints of people with intellectual disability who lack capacity (and indeed others with cognitive impairments) may therefore be 'missing' from research and this in itself is an ethical issue [45]. The benefits of carrying out research with persons with intellectual disability includes; helping others to better understand their reality [30], gain insight into the experiential nature of quality of life [46], understanding the embodied experience of intellectual disability [47], getting the perspectives of those underrepresented in public policy [48], and discovering positive experiences of care [49].

The movement towards inclusion in research developed in parallel with academic discourse and culminated with the publication of Nothing About Us Without Us [50] and unified professionals, academics, clinicians and individuals who valued sharing research agendas. Inclusive research encompasses two methodological approaches, participative research and emancipatory research [51, 52]. Participative research enables

alliances or partnerships to develop between the researcher and the participants used to differentiate between situations where people with disability participate, but have no control of the research process. Where as emancipatory research enables people with intellectual disability control the whole research process thus leading to empowerment, social change and the emancipation of people with disabilities [37, 40]. The participatory model, to date has been more commonly used promoting partnership working by professionals and clients, while the aim of the emancipatory approach is for clients to have control by been involved in all decisions throughout the process [37].

Walmsley [53] distinguishes between participative and emancipatory approaches, suggesting that participative approaches are concerned with the experiences of people with intellectual disabilities, and are influenced by normalisation theory, phenomenological approaches or the social model of disability. In participatory approaches, researchers work in conjunction with the participants, while employing qualitative methods with the aim of interpreting and explaining the experiences of people with intellectual disability. In contrast, emancipatory approaches are based on the social model of disability and can utilise either qualitative or quantitative methods in the research process where the researchers expertise is available for people with disability. Emancipatory research is dedicated to changing the conditions of the relationship between the researcher and the researched [54]. This approach highlights a shift from doing research on and about populations, to conducting research with populations and involving relevant service-users, carers or their representative groups in the design, conduct, analysis and reporting of research [55]. Through such processes, researchers can be better informed on how to frame their research questions, test the validity and acceptability of the research methodology, and assist in interpretation of the findings. In these ways, inclusive approaches enhance the efficacy of research and in today's research environment many funding agencies require an inclusive approach. In addition, the United Nations (UN) Convention on Rights for Persons with Disabilities challenges researchers to find ways to include people with intellectual disability in the development of research about them and to collect data and statistics which can inform policy and practice [56].

Including people with intellectual disabilities in research about their lives is widely endorsed [57] and progress is evident with the promotion of inclusive research [58, 59]. To support the inclusion of people with intellectual disability in research a variety of approaches and forms of involvement have arisen [60-62]. Utilisation of supports are evident across the research literature such as; McCleery [63] high-technology devices and supports, Manning [64] story-telling, Cannella-Malone et al.,[65] video-recording, Darewych et al., [66] art medium and Akkerman et al.,[67] photovoice. In addition, people with intellectual disability have been involved in; acting as an adviser [68], data collection and analysis [69, 70], provision of research education and training [57,71,72], dissemination of research findings [73], identification of research questions [74], being a member of an ethics committee [75] and being involved at each step of the research process [69,70,76]. Thus the opportunity to take part in research is increasing for many people with intellectual disability [58, 77].

REVIEW AND ACCESS

The structure and knowledge available to enable the ethical review and approval of proposed research projects varies from country to country. Therefore, it is imperative to draw upon a number of internationally accepted principles to guide the development, ethical review and implementation of research. Consequently, the IASSID have drawn up a statement developed with reference to a number of internationally accepted documents, including: Nuremberg Code [9], Universal Declaration of Human Rights [78], Declaration of Helsinki [11, 12], International Ethical Guidelines for Biomedical Research Involving Humans [79, 80] and the European Union Directive on the Conduct of Clinical Trials [81]. Prior to research proceeding rigorous ethical safeguards must be in place to promote and protect the health, safety and human rights of participants; and to prevent their exploitation. The ethics process involves the researcher explaining to an independent and competent authority what they aim to do; why such an inquiry is important; possible benefits to society; dangers involved; how they intend to proceed; safeguards to protect the participants' rights and safety; and how they will make their findings available. Ethics committee/institutional review board normally consist of men and women, who provide expertise in research processes from different disciplines, as well as lay persons from the general community, and wherever possible people with intellectual disability. In the case of institutional-based ethics committees, there will usually be at least one person who is independent of the institution or the organisation from which the ethics application originates. Ideally, there should be at least one committee member who can represent and advocate for the interests of those persons identified as potential participants for the study. Such representation or advocacy is particularly important where the proposed research involves participants who could be considered vulnerable or disadvantaged in some way or from a cultural background different from that of those proposing the research.

An ethics committee/institutional review board, or equivalent local committee, has the authority to approve, propose modifications or reject an ethics application. Such committees also have a right to request regular progress reports regarding any research activities they have approved and the authority to withdraw approval for research that fails to comply with an agreed protocol or local regulations. When evaluating the ethical merit of a proposed research project, and conducting research involving people with intellectual disability as participants or research that is intended to affect their lives. The three fundamental ethical principles [80] should apply; respect for persons, including their autonomy and right to self-determination, and beneficence for participants and the community. Thereby maximizing benefits and minimising risks, and justice, both legally and morally for those involved in research and the communities to which the participants belong.

There is a need for ethics committees to move away from protectionism and acknowledge the empowering potential of inclusive research [82]. To do this it may be helpful to differentiate between procedural ethics (what happens in research design and in research ethics committees) and ethics in practice (what happens in the interactions between researcher and participants and in the way data is interpreted, communicated and used). Ethics in practice is enhanced by procedural ethics and the underlying values are the same [83]. Dalton and McVilly [84] offer a guide for ethics in practice when conducting research with people with intellectual disability (see table 1).

Table 1: Ethics in practice guide [84].

• how the research is to be explained to the participants
• how participant consent (and/or proxy consent) is to be obtained
• how participants are to be treated during the research
• what safeguards are in place to minimize any potential harm to participants
• what mechanisms are in place to respond to any adverse events
• how participants' personal information and research results pertaining to them as an individual are to be kept private and confidential
• what mechanisms are in place to report findings to the participants and allow for peer review by the scientific community
• what mechanisms are in place to maximize any benefit to participants (and their community) of research findings

Gaining access to participants almost always involves going through gatekeepers or facilitators and a hierarchy of gatekeepers [18, 85] or tiers of management [86, 87] can exist. Using gatekeepers usually involves the additional stage of providing the gatekeeper with information about the study and asking them to suggest or contact potential participants. This requires building rapport and trust with the gatekeeper before doing so with potential/actual participants. For gatekeepers to assist, they will need to be convinced of the benefits for the people they often regard as in need of their protection. It is acknowledged that while there is, a need to include individuals with intellectual disability in research there remains a potentially negative outcome (exclusion) for the least able through the over-protection and gatekeeping roles taken by service providers. Gatekeepers are faced with a difficult decision of trying to decide to grant access and may actually block access [49, 88] rendering the person with intellectual disability silent [38] and this protective power can be seen as oppressive [89]. This difficult position placed upon gatekeepers may be alleviated by them having access to the ethics committees review comments and letter of approval to support their decision making and abate their concerns.

Having to negotiate access to the client group's reveals the importance of gatekeepers when it comes to conducting research with people with intellectual disability [90]. The directors of the agency, acts as initial gatekeeper, granting access to their facilities to conduct the study. The second layer of gatekeepers are staff members on whom researchers rely, to approach care recipients and inquire if they are interested in being involved, and to ensure that potential participants understands the researchers explanation of why the researcher wishes to involve them, what the research will involve and that they could withdraw at any point during the process. Gatekeepers may also facilitate access and have a significant role in carefully explaining to participants how research is different from intervention with different purposes and timelines [91]. Moreover, staff are often required to remain with clients during data collection and are often too busy and tired or too suspicious of the research to want to become involved [87, 92]. Although staff members do not have the power to deny permission because the director would already have granted authority, they have "power to block access" (p.8) to clients [93]. The power of gatekeepers can also be explicit in their ability to make determinations about which clients may be more eligible to participate in the research than others [49, 94]. In addition, self-advocacy organisations supporting people with intellectual disability can become overwhelmed by the increasing volume of opportunities to participate in research and reject approaches from some researchers.

CONCLUSION

Research is conducted to expand knowledge, discover the truth and provide evidence for practitioners, policy-makers and legislators. Research involving people with intellectual disability is important to; uncover relevant issues, inform policy, evaluate programmes and services, and identifying

the affects of social and economic change. The importance of research and data related to intellectual disability is recognised in the Convention on the Rights of Persons with Disability [56]. The problem for researchers is whether to follow closely the inclusion and consent requirements for research in intellectual disability at the cost of excluding those unable to meet those requirements. If we do this, the research evidence will not be reflective of the needs of the intellectual disability population. We need to try different methods of communication with different groups so as inclusion and consent do not threaten exclusion of those unable to give an autonomous or ideal consent. While there is a need to protect vulnerable participant groups, researchers also must ensure they are not placing restrictions to preclude valuable research and exclusion of people with intellectual disability [26] or including them without their consent [95]. This article identifies ethical challenges and possible action for the inclusion of people with intellectual disability in research (Figure 1).
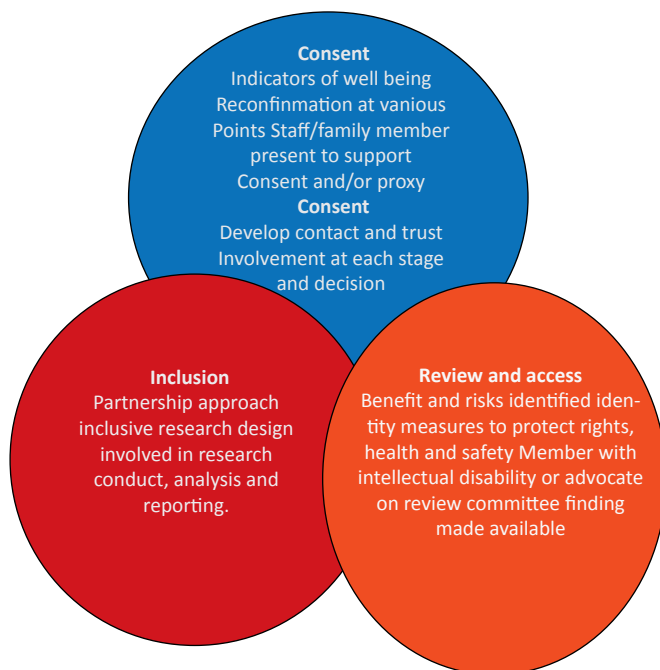
Figure 1: Ethical challenges and possible action for the inclusion of people with intellectual disability in research.

The omission of people with intellectual disability results in skewed sampling and the decision to include people with intellectual disability is influenced by those who have control over decisions and the organisational structures that exist in the individual's environment [35]. Others relate to the researcher's attitude to consent and the necessity to ensure that participation in research is an ongoing process and is not something established only at the beginning of contact. Researchers need to adopt a research approach that involves people with intellectual disability at each stage of the research process,

including the development of research agendas, commissioning, overseeing, conducting and evaluating research as well as supporting the use of the emerging evidence base in policy and practice. The influences of normalisation theory and the social model of disability have been key influencers in changing the research environment for people with intellectual disability [53]. However, a number of challenges exist regarding the inclusion of people with intellectual disability been included in mainstream research affecting their lives [96]. The challenges include; attitudes of professionals, diversity and complexity of lay groups, knowledge, power relationships, resources (both personal and financial), and values [97].

One way in which ethics committees and researchers have protected people perceived as vulnerable is by excluding them from research [32]. However, people with intellectual disability should not be excluded (discriminated against) as potential participants in research and every effort should be made to include their perspectives, priorities and needs in research activities. Tuffrey-Wijne et al., [88] argues that it is unethical to exclude people with more severe intellectual disability from studies that could provide insight into their experiences and help to shape sensitive care in the future. A positive development with many funding bodies is that they now insist on the participation of people with intellectual disability as a condition of research funding [53, 97].

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