PARTICIPATION IN RESEARCH BY PEOPLE WITH INTELLECTUAL DISABILITIES AND CHALLENGING BEHAVIOUR

THE ISSUE OF CONSENT

Clare Townsend, Ph.D. & Kay McInnes, M.Crim.
Centre of Excellence for Behaviour Support
The University of Queensland

Queensland Government
Disability Services Queensland

THE UNIVERSITY OF QUEENSLAND
AUSTRALIA

INTELLECTUAL DISABILITY & CHALLENGING BEHAVIOUR

- *7-15% of people with intellectual disability exhibit forms of challenging behaviour.*
- *Gaps exist between their needs & rights, & existing government policy and service systems.*
- *Service responses are frequently crisis driven & ad hoc.*
- *Policy & services fail to facilitate meaningful life in the community.*
- *Restrictive practices are applied.*

Qureshi, 1994; Borthwick-Duffy, 1994 Emerson et al 1997; Ball, 2004; Holden & Gitlesen, 2006; Beyer & Trice, 1982; Parmenter, 1991; McNally 2004

INTELLECTUAL DISABILITY & CHALLENGING BEHAVIOUR

- *Research is needed to improve the quality of life & outcomes for people with intellectual disability & challenging behaviour.*

- *A complex and infinite array of research issues exist.*

- *Concentrations and gaps in current research exist.*

(Ashman 1990; V***erdugo, 200l; Begab, 1977)***

THE ‘CARTER REPORT’ 2006 QLD REFORM AGENDA

The establishment of a Centre of Excellence for Behaviour Support to lead and guide best practice through research and support of the disability sector.

Goal: The promotion of the rights of service users & their families & carers in policy , planning, service delivery & evaluation.

Aim: To facilitate & strengthen systemic approaches to routine incorporation of stakeholders in the development, implementation & evaluation of the system of care for people with ID and CB.

SERVICE USER INVOLVEMENT IN RESEARCH

- ***The Convention on the Rights of Persons with Disabilities (2006) recognizes the need to ensure that all people who have disabilities enjoy human rights on an equal basis with others.***

- ***Service user participation in research is a benchmark set in human rights frameworks, ethical standards & policy worldwide.***

- ***However, "While there has been significant uptake of the rhetoric of inclusion, this has become muted in the case of research and people with ID"(Marks, 2006,p.2)***

- ***There is a limited body of research in the area of service user participation in research***

- ***Methodologies that meaningfully include people with intellectual disability in research remain unclear and limited*** **(Walmsley & Johnson, 2003)**

BARRIERS TO SERVICE USER PARTICIPATION IN RESEARCH

Access, identification & recruitment;

- ***Communication difficulties (researcher and participant).***
- ***Lack of ways to identify participants;***
- ***Levels of personal commitment & demands of caring;***
- ***Inadequate or inappropriate information & communication about research;***
- ***Lack of interest or overprotection by gatekeepers;***

Resources & Methodologies

- ***Normative VS Accessible research methods;***
- ***Added costs associated with recruitment & data collection;***
- ***Inadequate or ill-matched research skills;***
- ***A lack of "Courageous" researchers(Walkerdine 2003);***
- ***Failures in accountability & follow-up.***

Bell & Newby, 1977; Burke et al 2003,Gilbert 2004, Kiernan 1999, Lennox et al 2005, Stalker 1998, Walmsley 2004, Ward 1998; Lennox et al; 2005; Lee, 1993

CONSENT TO PARTICIPATION

A key issue surrounding the issue of participation & inclusion in research involving people with ID is informed consent.

Principles of Consent

1. **Consent is voluntary;**
2. **Based on sufficient information; &**
3. **Adequate understanding of both the proposed research and the implications of participation.**

People with ID and challenging behaviour are sometimes deemed not to have capacity to consent to participation in research. This may pose serious barriers to their inclusion & participation.

SERVICE USER PARTICIPATION IN RESEARCH

INFORMED CONSENT

- ***Ethical frameworks that address participation in research where the person is considered unable to consent include:***
  - ***IASSID: assumed capacity for informed consent, if not a referral is to be made to a proxy;***
  - ***NHMRC: consent to be sought from guardian or organization authority by law*** *(National Statement on Ethical Conduct in Human Research 2000)*
- ***Procedures for ensuring that capacity is present have not been formally specified or mandated;***
- ***There are few ethical and empirical guidelines for constructing respectful and protective informed consent procedures.***

Freedman, 2001; Fisher, 2003

CONSENT TO PARTICPATE IN RESEARCH ISSUES SPECIFIC TO QUEENSLAND :

- ***The Guardianship and Administration Act 2000*** **excludes psychological research and is silent on social and behavioural research.**

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- **The CEBS research agenda includes social and behavioural research & evaluation.**

- **Clear protocols are required that set out how a person with ID and impaired capacity to give informed consent can participate meaningfully in social and behavioural research.**

CONSENT, ASSENT AND PARTICIPATION IN RESEARCH FOR PEOPLE WITH INTELLECTUAL DISABILITIES AND CHALLENGING BEHAVIOUR PROJECT 2009-2010.

Aim

To gain advice & make recommendations in regard to consent issues surrounding meaningful inclusion of people with intellectual disability as research participants.

AREAS OF RESEARCH FOCUS

1. *Capacity to consent to research;*
2. *The process for obtaining consent;*
3. *The use of substituted decision making;*
4. *Development of a policy framework, including protocols and guidelines in relation to informed consent for use within the sector.*

METHODOLOGY

- ***Review of literature and legislation relating to the obtaining of informed consent to participate in research.***

- ***Consultation with relevant Queensland stakeholders, using a questionnaire and semi-structured interviews.***

RESULTS: Literature Findings

- ***Narrow field of study & expertise in developed countries;***
- ***People with ID have been excluded from research;***
- ***Inclusion is vital, but ad hoc;***
- ***Determining capacity is a major challenge;***
- ***There are no universally accepted standards for determining capacity;***
- ***There is little information for substituted decision makers;***
- ***There are problems in balancing autonomy with protection;***
- ***Inconsistent legislation, addressed the UK Mental Capacity Act 2005(England and Wales 2005)***

RESULTS
Legislative Inconsistencies in Australia

- *Guardianship legislation is the main legislation that covers capacity and consent.*

- *Inconsistency in State and Territory Guardianship Legislation e.g.*
    - *Medical research may or may not be covered*
    - *Social and behavioural research not addressed*
    - *Issue of determining capacity is different in different jurisdictions*

CONSULTATIVE PROCESS

Issues for consultation:

- – ***Defining research***
- – ***Capacity for decision making in research***
- – ***Substituted decision making***
- – ***Assent to participation***
- ***Conducted in November and December 2009***

CONSULTATIVE PROCESS

A series of semi-structured interviews were conducted. Purposeful & snowball sampling contributed to a group of stakeholders who were experienced in legislation, research & service provision in intellectual disability and challenging behaviour.

Individuals (N=16)	*Agencies(N=10)*
NGOs	
Government	
Researchers	
University Ethics	
Statutory agencies & individuals involved in substituted decision making regime	

Respondents were asked a series of open ended questions. Interviews were transcribed and the data thematically analyzed.

CONSULTATION FINDINGS

Agreement

- Research about people with ID is needed;
- There is recognition of right to participate;
- Risks in social research are lower than medical research;
- Capacity should be determined for each piece of research on individual, case-by-case basis;
- The assent of the person is crucial;
- A substituted decision maker should only occur after lack of capacity has been determined;
- HREC important safeguard, too much rigour leads to exclusion;
- Protocols and guidelines are needed to simplify process;
- Where there is dissention, participation should not occur.

CONSULTATION FINDINGS

Diverse Opinions

- The status of research determining the decision maker (medical/social/intrusiveness);
- Day to day matter = informal decision maker?
- Formal appointment of a guardian for a matter include participation in research?
- Restrictive Practices appointments;
- Participants were confused about the role of QCAT in decision making around capacity particularly in regard to research.

OUTCOME
Proposed Guidelines

- Ethical and legislative frameworks;
- Gaining ethical approval;
- Determining capacity to participate in research;
- Avoiding harm, discomfort or inconvenience;
- Assessing risks and benefits;
- Ensuring the participant’s access to information;
- Obtaining informed consent;
- Substituted decision making.

CONCLUSION

- **There is theoretical acceptance of people’s right to participate in research;**
- **“Nothing about us without us seems to have become muted where research is concerned”** (Marks, 2006);
- **Unresolved issues remain in regard to consent where the person does not have capacity**

IMPLICATIONS FOR FUTURE RESEARCH

- Consent issues are only one issue
- There are other barriers how substituted decaModels of decision making in research where people with ID are involved e.g. supported/substituted decision making; if so, who?
- Models of inclusion & accessible research methods , participatory or emancipatory research
- ***Developing Researcher skills to ensure***