PARTICIPATION IN RESEARCH BY PEOPLE WITH INTELLECTUAL DISABILITIES AND CHALLENGING BEHAVIOUR

THE ISSUE OF CONSENT

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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; Verdugo, 2001; Begab, 1977)
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.
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.

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.
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.

- 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.

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<td>Statutory agencies &amp; individuals involved in substituted decision making regime</td>
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Respondents were asked a series of open ended questions. Interviews were transcribed and the data thematically analyzed.
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 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 meaningful inclusion of people with ID.