



Practical & Ethical Issues in Research with Older People

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What is Ethics?

- Basically, Ethics is the study of what *should* be done
- Includes - morals, moral questions, critical study of right/wrong, good/bad
- Framework for making moral judgements - decisions about difficult moral problems
- Requires: discussion, argument, reasoning, thinking - to understand **your** beliefs/values and the **authority** for those

Main Ethical Principles in Western Thinking

- **Autonomy** - Respect for Individual Rights
- **Nonmaleficence** - Do No Harm
- **Beneficence** - Do Good
- **Justice** - Treat all Equally (but may sometimes need to treat unequally to “level the playing field”).
 - May be divided into 3 areas:
 - distributive justice -fair distribution of scarce resources
 - rights-based justice - respect for the rights of all
 - legal justice - respect for morally acceptable laws

Human Research Ethics Principles

NRMRC National Statement (NS)

- The NS sets out values & principles that underlie good research behaviour and good practice. It includes “rules” relating to:
- Research merit– is it worth doing? How do you know? (e.g., gaps in literature?); and integrity – can the methodology you are proposing to use actually answer the research question? (If it’s bad science, it’s bad ethics – waste of resources and waste of participants’ time).
- Respect your participants: how you speak to them (no jargon; don’t patronize them); listen to them; has the interview time and place been set for your convenience or theirs? Will you cover cost of travel (e.g., bus far from town to campus?) & provide refreshment? Ensure privacy/comfort for interviews.

HRE Principles & the NS (2)

- Risk – to either participants or the researcher: there is always risk, e.g., distress or fatigue, or more serious outcomes.
 - Acknowledge any possible risk and say how you will try to minimize it; e.g., remove a question that might cause distress; modify a test; provide support for distress
- Benefit – (incorporates the general ethical principles of beneficence (do good) and non-maleficence (do no harm): may not be direct benefit to participants but may benefit similar people in the future but must not harm these participants. May benefit the wider community and increase knowledge
- Justice/fairness: sample selection – possible participants not excluded without good reason, especially if the results of the research might apply to them
- Informed Consent: not just a signature on a piece of paper.

Informed Consent - Impact of Legislation

- Sometimes it takes a Court case to change behaviour, e.g., surgical procedures, pre 1992, junior doctor or nurse gets all patients due for surgery to sign a piece of paper agreeing to operation. (That was NOT informed consent)
- Case in High Court of Australia: *Rogers v. Whitaker* (1992) 175 CLR 479.
- Mrs Whitaker, lost sight in one eye from riding accident; Dr Rogers offers elective eye surgery. Mrs Whittaker asks if there is any risk to her “good eye”; Dr Rogers said no (1 in 14,000 chance of damage to “good eye”). Damage occurs and she is blind.
- Dr Rogers’ defense - the *Bolam Principle*; (he did what any competent doctor in his profession would do); Court rejects defense, awards Mrs Whittaker \$800,000

Post *Rogers v. Whitaker*

- Practitioner (or researcher) has duty to warn patient (participant) of **material** risk.
- Risk is material if
 - a reasonable person in the patient's position, if warned of the risk, would attach significance to it; and
 - the medical practitioner (or researcher) is, or should reasonably be, aware that the particular patient, if warned of the risk, would be likely to attach significance to it.
- General & specific information, as required

Informed Consent for Research

- Participant has been given all relevant information, including risks/benefits – in a form that is accessible to them, e.g. right language level. Consider eyesight, literacy; CALD/ATSI (may need interpreter to read consent form, even if the person speaks English)
- Participant has capacity to make decision
- Participant freely agrees (no pressure/coercion) to take part in research (incl. where relevant all procedures involved)
- Consider person in RACF, hospital, prison – how free can consent be?
- Having someone sign a consent form does not, of itself, constitute “informed” consent.
- Informed consent is a process, not an event – and the person is free to change their mind and withdraw.

When Does A Person Have Capacity To Make A Decision/Consent to Participate?

- Person must understand *the nature* and *the effect* of the decision to be made (example);
- Person must be able to communicate their decision in some way - not necessarily by speaking or writing - body language may be adequate, e.g. nodding/ shaking head
- (Case study)

Evaluating Capacity To Consent and/or to Continue Involvement in Study

- **Assume capacity** - UN Declaration of Human Rights
- Major depression, early dementia, - patient may still have capacity to consent
- Family/RACF staff may say “not competent” – but may be
- Beware the Mini-Mental State Test - better to provide information and check comprehension

Who has Legal Authority to Consent for Person who Lacks Capacity to be in Research?

- Each state/territory has different legislation: responsibility of researcher to check.
- Qld: Depends on level of “research”
 - if non-invasive study – e.g. collecting verbal or written information only – EPoA (personal/health) or SHA could consent;
 - EPoA/SHA could also consent for “audit” of use of various routine treatments (for which consent has already been obtained);
 - New, experimental, invasive trials/studies on people who cannot consent (e.g. those with dementia); consent for trial comes from Adult Guardian; when that is obtained, consent for participation comes from EPoA/SHA

Practical Implications of Moral Principles for Research

- Justice
 - duty to share knowledge, disseminate information, i.e. publish research findings – even those that don't confirm your hypothesis or strongly-held beliefs
 - resource allocation – OK to discriminate – as long as it is in favour of the least advantaged – but age **may be** a legitimate consideration
 - protection of the individual (above interests of researcher, profession, society). May mean loss from study

Examples of Poor Ethical Research Practice

1. Specialist applying to Adult Guardian for consent to conduct trial with patients with dementia, which included attaching electrodes to their heads. Was asked, “How will you deal with distress if it occurs”
 - Replied: “Oh you just treat them like children, give them a lolly”.
2. Researcher interviewing older person, family member present; family member answers all questions on behalf of the older person; researcher does not ask family member to allow older person to answer (sometimes you can ask but family member still answers – ethical issue then is, can you use the data?)

Competing Ethical Principles

- Sometimes principles compete with each other, e.g.
 - screening - test lots of healthy people, possibly create anxiety/stress, to potentially benefit a few
 - researcher has given assurance of confidentiality but realises there is possible elder abuse occurring
 - a competent patient refusing treatment, may challenge a doctor's training or personal ethical values (and possibly religious beliefs)
- (Note: a competent patient has a legal right to refuse any treatment, even life-saving treatment, as well as food/fluid)

Ethical Issues in Research with Older People

- Autonomy/Justice - treat all equally
 - competent person's right to consent to or refuse to participate, does not diminish with age
- Beneficence – do good /Non-maleficence- do no harm
 - can harm someone by not providing opportunity to participate in research – miss benefits of participation

Ethical Issues in Research with Older People -2

- Beneficence – do good /Non-maleficence- do no harm
 - great care needed in talking about death & dying, e.g. with carers, may cause anguish if too soon after bereavement; may be poor recall of issues, emotions if too long after (whose needs are paramount?); often people want to talk about deceased person and no one “lets them”
 - Time taken to conduct interview – is older person becoming tired? Do they know they can take a break, or stop the interview? (May disappoint researcher – “push” boundaries)

Paternalism – “Older People don’t want to think about/talk about end-of-life issues”

- E-O-L study with Qld community – 8 groups
 - Men 60-69; 70-79; 80+
 - Women 60-69; 70-79; 80+
 - General community members – 18-29, 30-59
- 38-page questionnaire covering range of end-of-life issues, including causes of distress, advance care planning, pain management, palliative care, euthanasia
- Highest response rates – men 70-79, 60-69, 80+; then women 60-69; 70-79, 80+; then 30-59, 18-29

Issues re: Data Analysis & Interpretation

- Older people often not included in RCT; results often applied to them but may not actually apply, e.g. drug trials: older people metabolise drugs at different rates to younger people
- Where older people are included, they should not be considered one homogenous group – often analysis by age group puts all 65+ together; may be 3 distinct groups (e.g., 65-74; 75-84; 85+), having very different perspectives and even clinical reactions
- For longitudinal studies, risk of loss to study by death of participants must be identified/controlled for (as far as possible) in proposal

Why Older People Take Part in Research

- Most reasons same as anyone else:
 - interest in topic because of personal/family experience
 - My research: several respondents had witnessed bad deaths and felt that “the system” needed to change
 - altruism – want to help others in community
 - My research: “while I don’t think I would ever want euthanasia for myself, I think it should be available to those who do”; “if my experience helps one other person I’ll feel as if I made a contribution”
 - sense of obligation
 - My research: “The Blue Nurses did so much for my wife, if this research can help them, then I’m happy to do it”.
 - need to be heard/anger
 - My research: Very elderly man, extremely angry over poor treatment of his wife by GP – “I only agreed to this interview because it might save someone else going through what we did”

Why Older People Don't Take Part in Research

- Family objections
 - Family believe it would upset the person – despite the person themselves thinking it would not
 - my research: appointment made, arrived at house, “my daughter said I’m not to be involved in this”
 - Some family members “afraid” of what the person will say
 - my research, guilt over low level of support; or family believes a person was assisted to die (mostly not so).
- Distress
 - “I can’t – it was all too hard and it will just bring it all back”
 - “My doctor said it would probably be good for me to do it but I just can’t, it’s too soon” (12+ months post husband’s death)

In summary....

- Issues are similar to doing research with any age group but more consideration should be given to issues of physical, mental and emotional capacity
- Most older people are happy to be involved in research and want to know that they are making a contribution to others
- Older people have a right to be included in research, particularly if the outcome is likely to be applied to them