

Understanding consent in paediatric research: The ethical issues

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Overview of presentation

- Setting the scene – some examples of the issues
- “Understanding consent in paediatric research”: A study addressing these issues
- Discussion of scenarios
- Take – home messages

1. Setting the scene

Scenario 1

You are approached to recruit your 14 to 17 year old CF patients into a questionnaire and interview- based study of transition to adult care.

According to the protocol, consent will sought from the young people only, not their parents.

Setting the scene

Scenario 2

You are an investigator on a clinical trial of new drug regimen for leukaemia. Your own patients are involved.

The parents of 10 year old Jake are very keen for him to be on the trial, but Jake appears unhappy with their decision, which is made with him present.

At first administration of the trial drug, Jake is unco-operative, and fiercely resists even being touched.

Consent in research involving children is complex and difficult issue for:

- Researchers in the paediatric setting
- Paediatricians who are approached to recruit their patients
- Reviewers of research

2. The Study: Understanding consent in paediatric research: The ethical issues

[funded by the Alfred Felton Bequest]

The central aims of this project are to:

- Generate more clarity about consent in research involving children

- Develop an educational resource on consent for
 - members of Human Research Ethics Committees
 - Researchers who conduct research involving children.

The outcomes of this project will assist in the facilitation of vital research in which the public has confidence

Baseline data:
The current areas
of concern and uncertainty

- 2 rounds of submissions to the *National Statement*.
- Key informant interviews with researchers and HREC members

Some background:
Standard ethical and legal
considerations
in research involving children

- Informed consent
- Competence
- Autonomy
- Beneficence/best
interests of the child
- Justice

National Statement on Ethical Conduct in Research Involving Humans (1999)

Definitions (Appendix 3)

- **Child** - Subject to law in the relevant jurisdiction, a minor who lacks the maturity to make a decision whether or not to participate in research.
- **Young person** - Subject to the law in the relevant jurisdiction, a minor who may have the maturity to make a decision whether or not to participate in research.

(1999) Chapter 4: Research involving children and young people: CONSENT

4.2 Consent to a child's or young person's participation in research must be obtained from:

- (a) the child or young person whenever he or she has sufficient competence to make this decision; and either
- (b) the parents/guardian in all but exceptional circumstances; or
- (c) any organisation or person required by law.

(1999) Chapter 4 continued:
BEST INTERESTS AND REFUSALS

- 4.3 An HREC must not approve, and consent cannot be given for, research which is contrary to the child's or young person's best interests
- 4.4 A child or young person's refusal to participate in a research project must be respected.

Unclear and contentious issues in the *1999 National Statement*

- What constitutes maturity?
- Who consents?

- How do we measure competence?
- What does competence mean in terms of consent?
- Who ought to be measuring competence?

- What is an 'exceptional circumstance'?
- How do we know what is in a child's 'best interests' and who assesses that?
- Can a parent consent to their child's involvement in non-therapeutic research?

- What constitutes refusal to participate in research? What constitutes refusal at different ages?

Revision of the 1999 *National Statement*

- Call for submissions
- 359 received
- 253 authors gave permission to go on www
- Over 100 commented on children in research
- Submissions: mostly researchers and reviewers of research but also consumer and community based organisations and private individuals

Submissions

1. Provision of information
2. Dissent – taking refusal seriously
3. Competence to consent
4. The requirement for parental consent
5. A conflation of issues

1. Provision of information to children and young people

- Importance was given to the provision of 'comprehensive information' for participants 'whether or not' they are 'deemed to have the capacity to consent for themselves or not'.
- The 'all or none approach to children's and young people's role in research decisions' in which they are 'either considered capable of consenting or they are given no formal role' was perceived as problematic in the sense that it fails to demonstrate respect.
- 'Children do not need to understand the background or aims of a study to express an opinion' on whether they want to take part in a research study 'that is not for their personal benefit'.

2. Dissent – taking refusal seriously

- 'Like any other potential research participant', the child's right to refuse should be respected.
- A submission from the Cancer Council NSW refers to research that is purely research as opposed to research that includes treatment. It makes the claim that in the first instance a competent child's decision whether to participate or not should be 'considered final' whereas 'the parent's decision becomes more important' in the second instance.
- Does a temper tantrum in a one year old mean that the child should be excluded or withdrawn?

3. Competence to consent

- Unless there is guidance on how competence to consent is to be determined 'a child of five may well be judged capable of giving consent.'
- 'Capacity to consent' should be explained as 'not usually being true for children under 10-12 years of age'.
- 'The attempt to ascertain whether a person lacks/has capacity to consent' could be 'more intrusive (and have more serious consequences) than the research itself'.
- 'In cases where children or young people will provide consent without the involvement of their parents or guardians', responsibility for determining capacity to consent seems to be with individual researchers.

4. Requirement for parental consent

- Consent from both parents
 - Conflicting views.
- Research to which only the child or young person consents
 - It 'could create risks for the minor and invalidate the research'.
 - Children who are separated or estranged from their parents should be regarded as 'particularly vulnerable'.

5. A common conflation of issues

An entanglement of ideas:

competence to consent, 'mature minors', emancipated minors, estranged/separated young people, homeless kids, decisional authority, assent and autonomy.

The things being conflated are:

- The basis of consent and assent
- Homelessness is being conflated with competence.
- Estrangement or conflict with parents is also being conflated with competence.

*The National Statement
on Ethical Conduct in Human
Research
2007*

Chapter 4.2: Children and young
people

(guidelines specific to consent)

Levels of maturity and implications for consent

(2007 Ch 4.2 intro)

- (a) Infants, who are unable to take part in discussion about the research and its effects
- (b) Young children, who are able to understand some relevant information and take part in limited discussion about research, but whose consent is not required.
- (c) Young people of developing maturity, who are able to understand the relevant information but whose relative immaturity means that they remain vulnerable. The consent of these young people is required, but is not sufficient to authorise research; and
- (d) Young people who are mature enough to understand and consent, and are not vulnerable through immaturity in ways that warrant additional consent from a parent or guardian

(2007) Research merit and integrity

4.2.2 In the research design researchers should:

- (a) Specify how they will judge the child's vulnerability and capacity to consent to participation in research;
- (b) Describe the form of proposed discussions with children about the research and its effects, at their level of comprehension; and
- (c) Demonstrate that the requirements of this chapter will be satisfied

(2007) Respect

4.2.6

Researchers should be attentive to the developmental level of children and young people when engaging them in understanding the nature and likely outcomes of research, and when judging their capacity to consent to the research.

(2007) Respect cont...

- 4.2.7 Except in the circumstances described in paragraphs 4.2.10 and 4.2.11, *specific consent* to a child's or young person's participation in each research project *should be obtained from*:
 - (a) *the child or young person* whenever he or she has the capacity to make this decision;
 - and
 - (b) either
 - (i) *one parent*, except when, in the opinion of the review body, the risks involved in a child's participation require the consent of *both parents*; or where applicable
 - (ii) the guardian or other primary care giver, or any organisation or person required by law.

(2007) Respect cont...

- 4.2.8

An ethical review body may approve research to which only the young person consents if it is satisfied that he or she is *mature enough to understand and consent*, and *not vulnerable through immaturity* in ways that would warrant additional consent from a parent or guardian.

(2007) Respect cont...

4.2.9 A review body may also approve research to which *only the young person consents* if it is satisfied that:

- (a) he or she is *mature enough* to understand the relevant information and to give consent, although vulnerable because of relative immaturity in other respects;
- (b) the research involves *no more than low risk* (see paragraph 2.1.6, page 18);
- (c) the research aims to *benefit the category of children* or young people to which this participant belongs;

and

- (a) either

.. And, either:

- (i) the *young person is estranged* or separated from parents or guardian, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5).

(In this case, although the child's circumstances may mean he or she is at some risk, for example because of being homeless, the research itself must still be low risk);

Or ...

...or

(ii) it would be *contrary to the best interests of the young person to seek consent from the parents*, and provision is made to protect the young person's safety, security and wellbeing in the conduct of the research (see paragraph 4.2.5).

(2007) Best interests of the child

4.2.14

A *child or young person's refusal* to participate in research *should be respected* wherever he or she has the capacity to give consent to that same research

(see levels of maturity (c) and (d) in the Introduction to this chapter).

Where a child or young person *lacks this capacity*, his or her *refusal may be overridden* by the parents' judgement as to what is *in the child's best interest*.

Does the new *National Statement* address the ethical concerns in the submissions?

- Provision of information ✕
- Dissent – taking refusal seriously ✕
- Competence to consent
 - *Tries to*
- The requirement for parental consent
 - *Tries to address but in a very convoluted way*

(2007) Additional unclear and contentious issues

- What is 'capacity to consent'? How do we measure it and what does it mean in terms of consent to research?
- What constitutes vulnerability and what constitutes immaturity?
- How do we measure vulnerability and immaturity?
- Who should measure capacity to consent, vulnerability, and immaturity?
- If parents' judgment can override a child's refusal (4.2.14), can an unwilling child be coerced or forced into participating?

Discussion of scenarios

Scenario 1

You are approached to recruit your 14 to 17 year old CF patients into a questionnaire and interview- based study of transition to adult care.

According to the protocol, consent will sought from the young people only, not their parents.

1. Would you be prepared to be involved in this project?
2. What more would you need to know about the project?
3. Would you want any changes to the protocol?

Scenario 2

You are an investigator on a clinical trial of new drug regimen for leukaemia. Your own patients are involved.

The parents of 10 year old Jake are very keen for him to be on the trial, but Jake appears unhappy with their decision, which is made with him present.

At first administration of the trial drug, Jake is unco-operative, and fiercely resists even being touched.

1. Would you decide not to include Jake in the trial at that point?
2. What would you say to Jake?
3. What would you say to his parents?

Take home messages related to this discussion

Critically evaluate approaches to be involved
in a study:

- Do I think this research is being conducted appropriately?
- Do I think it is appropriate for my patients to be involved?

How to critically evaluate – some questions to ask

Apart from

1. Good study design
2. Appropriate balance of risks and possible benefits

→ **Are the consent processes appropriate?**

- Should the child be involved in the decision?
 - At all
 - Fully
 - Parents not needed
- Can the child refuse?
- Is suitable information being given to child?

Project outcomes

Your input, comments, suggestions invited

Educational resource

- Handbook for researchers and HRECs containing important ethical concepts and key questions which should track an actual ethics application.

Website – supported by the handbook

- annotated select bibliography
- Cases

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