Consent in paediatric research: an evaluation of the guidance provided in the 2007 NHMRC *National statement on ethical conduct in human research*

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ABSTRACT

- In 2007, the National Health and Medical Research Council (NHMRC) released a revised *National statement on ethical conduct in human research.*
- Public submissions in the review process leading to the 2007 statement highlighted four main areas of concern: children's competence to consent, mature minors and the requirement for parental consent, whether children can refuse to participate, and the provision of information to children.
- A useful addition to the statement is the concept of levels of maturity, which help determine whether a child or young person's consent is necessary and/or sufficient for participation in research.
- Changes in terminology ("capacity" instead of "competence" and introduction of the term "vulnerability") have the potential to create confusion, as the new terms are not clearly defined, and capacity is used in several senses.

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New Australian research ethics guidelines became available in April 2007. Compliance with the 2007 National Health and Medical Research Council (NHMRC) *National statement on ethical conduct in human research*[1] commenced on 1 January 2008. This article focuses on significant changes in the chapter on children and young people as they relate to biomedical research. We evaluate the 2007 statement in the light of issues raised during the consultation phase of its development.

In 2003, the Australian Health Ethics Committee, a principal committee of the NHMRC, established a working committee to review the previous guidelines, the 1999 *National statement on ethical conduct in research involving humans*.[2] The review became a joint venture by the NHMRC, the Australian Research Council, and the Australian Vice-Chancellors' Committee. The review process included submissions from the public in response to two consultation drafts of the guidelines.

One hundred and two submissions commented on children in research. Most were from researchers and ethics committees, but some were from consumer and community-based organisations and private individuals. In relation to consent for paediatric research, the main areas of concern and uncertainty were:

- children's competence to consent;
- mature minors and the requirement for parental consent;
- dissent (non-competent children's refusal to participate); and
- provision of information to children and young people.

Here we consider whether the 2007 statement adequately addresses these issues.

Competence to consent

The concern with competence to consent was mostly about whether formal assessment of a child's competence is required, and if so, by whom. Many submissions indicated a desire for more specific guidance. According to one, without guidance "a child of five may well be judged capable of giving consent" (Australian Catholic University [ACU], second round submission). Another made the point that "capacity to consent" should be explained as "not usually being true for children under 10–12 years of age" (Royal Australasian College of Physicians [RACP] Working Group, first round submission). There was concern that determinations of competence are being made by individual researchers without "suitable guidance" (Princess Margaret Hospital for Children Human Research Ethics Committee [HREC], second round submission). On the other hand, at least one submission warned about making formal assessment of children's competence a uniform requirement: "[t]he attempt to ascertain whether a person lacks/has capacity to consent" could be "more intrusive (and have more serious consequences) than the research itself" (Professor Susan Dodds, University of Wollongong, first round submission).

Evaluation of provisions in the 2007 statement

The new statement tries to address the concerns about competence to consent with extra guidance about levels of maturity. The aim is to assist in determining when a young person's consent is necessary, in addition to parental consent, or as sole authorisation without a requirement for parental consent (Box). This clarification may assist researchers and ethics committees. It provides a framework for thinking, without being too rigid. Researchers can expect ethics committees to use these categories, and can frame their research proposals accordingly.

Unfortunately, this improvement may be undermined by a change in terminology, which may have unintended ramifications. Throughout the 2007 statement, the term "capacity" has replaced "competence". There is no acknowledgement of or explanation for this change. There may be a good reason, but without a definition of its meaning we cannot know. In the 1999 statement, "competence" referred to the ability to give consent.[2] Competence was understood as shorthand for competent to consent. In the revised statement, "capacity" is used in more ways: for example, it includes "capacity to understand" and "capacity to be involved in the decision", as well as "capacity to consent". Hence, we cannot use the term "capacity" without specifying precisely what it refers to. The significance of capacities to understand, to be involved in discussions and decisions, and to consent to give full and valid sole consent are different (see Box, levels of maturity). This is likely to lead to confusion.

The 2007 statement still does not address whether *formal* assessments of children's competence or capacity should be carried out by a person with particular expertise, or whether the researcher's own

Significant changes to consent for paediatric research in the 2007 *National statement on ethical conduct in human research*[1]

- A child's refusal can be overridden by parents' judgement about the child's best interests (section 4.2.14). Previously, all refusals by a child had to be respected.

Addition

- Levels of maturity which help determine whether the child's consent is necessary and/or sufficient to authorise participation (chapter 4.2 Introduction)
  - ➢ Infants: parent/guardian consent required.
  - ➢ Young children: parent/guardian consent required.
  - ➢ Young people of developing maturity: consent of both young person and parent required.
  - ➢ Mature young people: consent of young person only.

Changes in terminology

- "Capacity" replaces "competence". All reference to decision-making competence has been replaced with "capacity". "Capacity" is used in different senses; eg, "capacity to understand" and "capacity to be involved in the decision", as well as "capacity to consent".
- New term: "vulnerability". Competence is now defined in terms of a lack of vulnerability. Having "sufficient competence" to make a decision (1999) has become "mature enough to understand and consent and not vulnerable through immaturity" (section 4.2.8).

Additional tasks for researchers

In the research design researchers should:

- Specify how they will judge the child's vulnerability and capacity to consent to participation in research;
- Describe the form of proposed discussions with children about the research and its effects, at their level of comprehension;
- Demonstrate that the requirements of chapter 4.2 will be satisfied (section 4.2.2). ◆

intuitive judgement is sufficient. This is presumably to be left to the judgement of individual ethics committees, which could result in different requirements at different research sites. In addition, no guidance is provided to ethics committees on what factors to consider when deciding about assessments of competence or capacity. It does not identify the potential conflict of interest involved when capacity is assessed by researchers wanting to recruit research participants, let alone suggest how to resolve it. Nor is guidance given on whether the intrusiveness or potential harms involved in determining a child's capacity to consent should be considered a valid ethical reason for not doing a formal assessment in some circumstances.

The requirement for parental consent

On the question of who should consent, there were opposing perspectives, indicating that it is not always clear whether consent is required from only the young person or whether additional consent from a parent or guardian is required. One submission claimed that it is not always appropriate to obtain parental consent and that a distinction should be made between young people and older young people (ie, mature minors such as "street kids"), because parental consent "could create risks for the minor and invalidate the research" (University of Western Australia, first round submission). From another submission, we get the view that "most, if not all, parents would prefer to have oversight of the decision-making to ensure that their child has made an appropriate decision" and that "this will be so even for older children". According to this submission, the fact that children are separated or estranged from their parents is a practical problem to overcome rather than an ethical justification for not seeking parental consent, and so these young people should be regarded as "particularly vulnerable" (ACU, second round submission).

Evaluation of provisions in the 2007 statement

"Vulnerability" is another new term that has been introduced (Box). The presence of vulnerability appears to be another way to assess a child as lacking competence, indicating that the child's consent is not sufficient to authorise participation. This is a potentially helpful concept, as well as an ethically important one. However, the lack of explanation as to what the child can be vulnerable to means that it is likely to cause confusion.

The 1999 statement dealt with sole authorising consent from the young person in terms of "exceptional circumstances" that would permit parental consent to be omitted. No specific description of what counts as exceptional circumstances was given. The 2007 version uses levels of maturity and the concept of vulnerability. The provisions are presented as a set of conditions, which are presumably an attempt to spell out the idea of exceptional circumstances. The conditions are complex, which may cause difficulties in interpretation. In addition, the concept of vulnerability seems to get lost, because it is permissible to have sole authorising consent from a vulnerable young person when these conditions apply. There is likely to be quite a settling-in period as researchers and ethics committees work their way through this.

Dissent

"Dissent" refers to a refusal to participate in research made by a person who would not be competent to consent. The weight which should be given to such refusals is in dispute. According to the 1999 statement, "[a] child or young person's refusal to participate in a research project must be respected".[2] The second consultation draft[3] listed some exceptions where a child or young person's refusal need not be respected. This provoked considerable criticism and some authors of submissions were adamant that a child's right to refuse should be taken seriously (University of Newcastle, second round submission). "Like any other potential research participant", the child's right to refuse "should be respected at all times" (La Trobe University HREC, second round submission).

Two specific aspects of the dissent issue were raised: (i) dissent in therapeutic research, and (ii) how to recognise an expression of dissent. One submission referred to research that is "purely research" as opposed to research that includes "treatment of the child's illness" and claimed that, in the first instance, a competent child's decision whether to participate should be considered final, whereas "the parent's decision becomes more important" if research includes treatment (The Cancer Council NSW, second round submission).

Another submission asked whether a temper tantrum in a 1-year-old child meant that the child should be excluded or withdrawn (RACP Working Group, first round submission), highlighting the issue of how to determine whether resistance of some sort counts as dissent, especially in young children.

Evaluation of provisions in the 2007 statement

Children's refusal is not taken as seriously in the 2007 statement as it was in the 1999 statement (Box). This could be ethically problematic,

as it raises the prospect of an unwilling child being forced into participating in research (eg, research involving an experimental drug for a child for whom all else has failed). Despite lack of capacity to consent, a child might reach a point where he or she wants nothing more to do with hospitals, medications and medical procedures. Arguably, these children should not be forced to take part in research which involves additional procedures and hospital visits done primarily for the sake of research.

Provision of information to children and young people

Submissions from leading organisations gave particular importance to the provision of "comprehensive information" for participants whether they are "deemed to have the capacity to consent for themselves or not" (Australian Nursing Federation [ANF], second round submission). It was thought that "children and young persons may be capable of receiving information about what is going to happen to them even where their ability to decide to participate is questionable" (RACP Working Group, first round submission).

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. It was argued that "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 study "that is not for their personal benefit" (Princess Margaret Hospital for Children HREC, second round submission).

According to one submission, informing children in an appropriate way about the nature of the research demonstrates respect and allows children to express an opinion about whether they want to participate (ANF, second round submission).

Evaluation of provisions in the 2007 statement

The idea of levels of maturity goes some way to addressing this matter. It recognises the developing capacity of children and young people to be involved in decisions about research participation, which goes beyond the all or none approach. However, it does not sufficiently capture the idea that providing information to children demonstrates respect and has value in itself apart from its role in consent. This might be because the word "consent", which emphasises decision making, is used to refer to both the actual informed consent of mature minors and children's mere involvement in discussions.

Use of the term "assent" might help distinguish these different senses of consent and help show that there are different values at stake. Although a child's assent does not have the moral authority of informed consent, it does have a different kind of value. Children benefit from being involved in discussions and from being given information about what will happen if they participate even when they do not have decision-making authority. "Assent" or a similar term may assist in providing recognition for the value of and the role for children that lies between no involvement in discussions and full decisional authority.

One submission did suggest consideration be given to including "assent" or a similar term in the guidelines, but noted that some people find "assent" confusing because "most dictionaries regard it as a synonym for consent" (RACP Working Group, first round submission). However, it could hardly be worse than using the word "consent" to mean two different things. "Assent" is widely referred to in the research community and is established in the literature. It is referred to in United States, United Kingdom, New Zealand and Canadian research ethics guidelines.[4-7] It would make sense for those who conduct and review paediatric research in Australia to be using this internationally recognised term, providing of course that its meaning and application are well defined.

Conclusion

The 2007 statement will be helpful for ethics committees in some ways. For example, it will help in deciding whether a young person's consent alone is required or if consent from a parent or guardian is also required. However, it also creates more complexity and potential for confusion and divergence of interpretation, by introducing new terms, especially "vulnerability" and "capacity to consent" rather than "competence".

Researchers and ethics committees will have to work out how to interpret and apply these terms and may encounter difficulties. Introduction of the concept of assent into the next iteration of the national statement (which is subject to statutory review every 5 years) may help resolve some of these difficulties. It is important to get research ethics guidelines for children right. Children need protection, but they also need research, as that will protect them from drugs and devices that have only ever been tested formally in adults. It is vital that complexity and lack of clarity in guidelines do not dissuade researchers from pursuing research that would actually be ethically acceptable.

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Competing interests

None identified.

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