

Children and Decisionmaking in Health Research

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Introduction

In March 1998 the Office of Bioethics Education and Research at Dalhousie University hosted a multidisciplinary workshop, "Assent and Dissent in Research Involving Children."¹ The overall objectives for the meeting were: first, to promote and protect the health and well-being of children² by ensuring that potentially beneficial biomedical and health research involving children was not inappropriately precluded; and second, that when such research did proceed, it was appropriately respectful of children. For the purposes of the discussion, appropriate respect included both protection from harm and promotion of the capacity for independent decision-making. Particular attention was focused on the roles and responsibilities of children and their parent(s) or legal guardian(s) in decisionmaking about research participation.

At the outset, it was hoped that workshop participants would generate a consensus statement clearly identifying substantive points of agreement and disagreement. In retrospect, that goal was overly ambitious. A more modest goal informs this discussion document—namely, to provide a public record of important contributions made to the debate about research involving children in an attempt to advance the discourse on this important issue.

The Issue

Research guidelines the world over recognize the importance of respect for persons.³ This principle requires that research involving humans not proceed without appropriate authorization. For persons with decisionmaking capacity,⁴ this authorization is their informed consent to research participation. For persons without decisional capacity (and this typically includes most children), this authorization is the permission to proceed granted by a legally recognized surrogate decisionmaker. For children, the legal surrogate decisionmaker is most often their parents.

In recent years it has been thought, in some jurisdictions, that authorization by a surrogate decisionmaker is insufficient in some instances, and that persons with developing decisional capacity must also be involved in the decisionmaking process. In the United States, as early as 1977 the National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research held that:

Parental permission normally will be required for the participation of children in research. In addition, assent of the children should be required when they are seven years of age or older. The Commission uses the term "assent" rather than "consent" in this context, to distinguish a child's agreement from a legally valid choice.⁵

The Commission further proposed that a child's dissent should be binding in most circumstances. In Canada, this view was incorporated into the 1987 Medical Research Council (MRC) *Guidelines for Research Involving Human Subjects*:

A concept has developed that a child incapable of giving legally and ethically acceptable consent may give an "assent" which is significant in respecting a level of autonomy. Related to this concept is the recognition that a child, whose consent or assent to participate in research is questionable, may nevertheless have the power to decline invasive involvement with conclusive effect. Parental consent may be a necessary condition of engaging the child in research, but it is not necessarily sufficient; the child's negative preferences in such cases should be respected.⁶

In the fall of 1998 these research guidelines were replaced with the *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans*. The new guidelines make this point more forcefully still,

Where free and informed consent has been obtained from an authorized third party, and in those circumstances where the legally incompetent individual understands the nature and consequences of the research, the researcher shall seek to ascertain the wishes of the individual concerning participation. The potential subject's dissent will preclude his or her participation.⁷

Persons capable of dissent include "those whose competence is in the process of development, such as children whose capacity for judgement and self-direction is maturing."⁸

As suggested by the excerpts above, it is widely accepted that in principle children's expressed wishes regarding research participation should be respected.⁹ In practice, however, the involvement of children in decisions about research participation is neither routine nor standardized. One reason for this difference between principle and practice is a general reluctance on the part of the research community and parents to recognize mature children and adolescents as persons with decisionmaking capacity who are fully capable of providing an independent consent or refusal to research participation. The Declaration of Helsinki illustrates the problem. It is stipulated therein that,

In case of legal incompetence, informed consent should be obtained from the legal guardian in accordance with national legislation.... Whenever the minor child is in fact able to give consent, the minor's consent must be obtained in addition to the consent of the minor's legal guardian.¹⁰

Note, the requirement here is that the child's consent be obtained in addition to, not in lieu of, the consent of the legal guardian.

A second reason for the difference is concern about liability. The problem here is the lack of clarity in the law about decisionmaking authority for mature minors with respect to research, as well as the lack of clarity in its interpretation, particularly by investigators and research review committees (in Canada, research ethics boards [REBs], in the United States, institutional review boards [IRBs]).

A third reason for the difference between principle and practice is the general confusion about the moral weight and basis of an assent or dissent provided by children with developing decisionmaking capacities. The tendency is to conflate consent with assent and dissent with refusal. For example, if a parent's legal and morally valid authorization can be overridden by a child's dissent, then it appears that a dissent by a person with developing decisionmaking capacities has the same moral force as a refusal by a person with decisionmaking capacities. This is perplexing, for while it is undeniably important to heed a child's objections, it is not clear these objections should be authoritative in the same way and for the same reasons that a refusal by a person with

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decisionmaking capacity is generally regarded as authoritative.

To allow a child's dissent to function as the moral equivalent of a refusal by a person with decisionmaking capacity, without first having determined that the child has decisional capacity, is to seriously

undermine parental responsibility for promoting children's interests. Parents who are not neglectful, exploitive, or abusive of their children are generally deemed responsible for making decisions on behalf of their children as they mature. For most activities of daily living, as children's capacities for decisionmaking develop, a fine-grained assessment of the balance between the parent's role and the child's role in decisionmaking occurs. Typically this assessment is at the parent's discretion. For some, a critical question then is, "Why the difference with respect to research participation?"¹¹ Considered from another perspective, the key question is, "Are the notions of assent and dissent, as they are currently understood and applied, the best way of recognizing and promoting children's developing autonomy and independence?"

It is clear that children should be involved in decisions about research participation to the extent that they are capable. It is much less clear, however, what the nature of that involvement should be. More generally, what should be the role and responsibility of children, parents, researchers, and communities in decisionmaking regarding children's research participation? Further, what factors should be considered in determining these various roles and responsibilities?



Children as Embedded in Context

With research involving children, it is important to attend to the context of each child for at least three reasons. First, context affects a child's capacity for involvement in decisionmaking about research participation. Second, context affects the perceptions by others of a child's capacity for such involvement, i.e., the context may affect the range of interests taken into account in assessing the child's capacity. Third and more generally, context affects what might be appropriate involvement of children in decisionmaking about research participation.

Not surprisingly, there are significant variations among the multitude of contexts within which children are raised.¹² At the very least, individual, familial, and social factors must be considered when trying to understand a particular child's context. For example, one must explore the child's physical, emotional, and developmental status; unique personality; life experience; social and moral maturity; and cognitive capacities. One must also seek to understand the religious, cultural, racial, and economic features of the familial context as well as such social factors as patterns of positive and negative bias within the society.

Finally, attention must also be paid to the complex and diverse context of research, which is not itself homogeneous; there is research on disease prevention, health promotion, risk assessment, and innovative practice. In addition, in some circumstances the researcher may have conflicting research, caregiving, and health promotion responsibilities. As well, there can be research on children of varying health status ranging from those who are basically healthy to those with a chronic, life-threatening illness.

To elaborate briefly on this last point, research involving children with chronic, life-threatening illness¹³ must carefully attend to an expanded range of contextual issues including, for example, the child's likely ongoing (and possibly long-term) relationship with persons in the health care setting. The nature of this relationship may engender unique responsibilities on the part of caregivers and researchers given the increased potential for role blurring. Second, there is the risk of overexposure to research; this risk is particularly acute for those with rare diseases or disorders. Finally, there is the need for renewed authorization for research conducted over a long period of

time and the possibility that in certain instances the responsibility for providing (or withholding) this authorization might shift from the parents to the child in recognition of the child's changing role in the decisionmaking process as she matures.

A Decisionmaking Process That Is Interactive and Iterative

Respectful involvement of children in decisionmaking about research participation requires, at the very least, an assessment of: (1) what the child *wants* to know; (2) what the child can understand; (3) what the child's decisionmaking capacity is; and, (4) what the child *needs* to know in order to exercise her decisional capacity. In turn, this requires a decisionmaking process involving children that is both interactive and iterative. These characteristics of the process are essential for addressing some of the relevant substantive issues (e.g., what the child wants or needs to know), and some of the procedural issues (e.g., how the communication should take place).

Meaningful interaction with children requires that those providing them with information listen and respond to the concerns they identify. It is only in talking with, and attentively listening to, children that researchers and parents can learn what information is important to a particular child, and then in conversation with that child gauge her ability to understand more or less complex answers to her questions. Differences between the sorts of things that individual children want to know about their research participation and the information that researchers typically provide in their carefully constructed information sheets and consent forms can be quite striking.¹⁴ An interactive process is also important for allowing researchers and parents to assess a particular child's developing capacity for independent decisionmaking. For example, whereas one child with a serious chronic illness "with all its attendant experiences and choices, may have been challenged to develop increased capacity,"¹⁵ another child with a similar illness may have been raised in a very protective environment and as a result may have limited decisionmaking experience and capacity. The latter child may be uniquely harmed by the disclosure of too much (or inappropriate) information, whereas the former child might be uniquely harmed by the nondisclosure of information.

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The decisionmaking process also needs to be iterative so that parents, children, and researchers can have a full understanding of the relevant issues. Initial discussions may be clouded by fear, insecurity, mistrust, or illness. An iterative process is also particularly relevant for research that spans a period of time (for example, long-term follow-up studies) where the child's decisionmaking capacity may change with life experience and maturation.

At present there are very limited data on how to communicate effectively with children about participation in research. Given the central role of communication in respectful involvement of children in the decisionmaking process, it is essential that further research be done on: (1) how to disclose information in a manner that is sensitive, informative, and noncoercive; and (2) how to check for adequate understanding.

Children and Decisionmaking About Participation in Research

Debates about the proper role of children in discussions concerning research participation often focus narrowly on decisional authority: "Is the child capable of *making the participation decision*?" If so, it is argued that the appropriate role for the child is that of decisionmaker. If not, then the appropriate role for the child is that of absent or silent, uninvolved audience. More recently, the key question about decisional authority has been reformulated in broader terms: "Is the child capable of *participating in the decisionmaking*?" This reformulation, which essentially entails a reordering of the relevant concepts, has introduced a third category of children and a corresponding new role description where the child is neither decisionmaker nor uninvolved audience. If the child is not capable of making the decision, but capable of participating in the decisionmaking, then the appropriate role for the child is that of assenter or dissenter.

In discussing the concepts of assent and dissent, workshop participants suggested that children can have a role in decisionmaking about research participation that is unrelated to decisional authority. That is, there may be reasons for involving children in discussions about their possible involvement in research that have nothing to do with seeking their authorization or assent. With this in mind, four broad categories of children were described:

1) children with no language comprehension (e.g., neonates);

- 2) children with some language comprehension but no decisional capacity;
- 3) children with good language comprehension and developing decisional capacity; and
- 4) children with good language comprehension and sufficient decisional capacity ("sufficient decisional capacity" being defined as "the capacity of an adult considered capable of making decisions")

Next, the role of children in decisionmaking about research participation was explored in each of these categories.

First, it was agreed that there is no role for children with no language comprehension. These children have no decisional capacity and no useful purpose is served in explaining the research to them since they cannot understand even the simplest of explanations. It was also agreed that there is a receptive but not a decisional role for children with some language comprehension but no decisional capacity. If children can understand at least some language, then what is going to happen to them should be explained to them, albeit sometimes in very simple terms, by their parents and the researchers. There are two reasons for this. First, there is the obligation to limit the potential harms of research. Children can be seriously harmed by having something done to them without their knowledge or understanding. An explanation appropriate to the child's comprehension level of what is likely to happen to her or him as a result of their participation in research can help to reduce this potential harm. Second, there is the obligation to help children develop decisionmaking skills, and early involvement in discussions that require decisionmaking by their parents is an important step in this learning process.

Now while there was agreement about the appropriate role for children in categories one and two, there was disagreement about their role in categories three and four. Some participants felt that children in category three should have the same role in discussions about research participation as those in category two, i.e., receptive but not decisional. The decisional role hinged on capacity for decisionmaking and accountability. Children in this category, by definition, were not yet capable and should not be held accountable for their choices.¹⁶ Others felt that developing decisional capacity supported a more decisional role for children in this category, and some suggested that a child's dissent should be authoritative when her views were not being weighed by her parents in their assessment of the harms and benefits of research participation.

Finally, all participants agreed that children in category four have a decisional as well as a receptive role. Disagreement arose, however, over the moral weight of the decisional role.

Some suggested (largely by analogy to authorization for an adult's participation in research and on the basis of the principle of autonomy), that authorization by a child with sufficient decisionmaking capacity, by definition, was sufficient for research to proceed and conversely that such a child's decision not to participate in research should preclude her participation. Others suggested that in addition to considering a child's decisional capacity, the nature of any underlying illness, the nature of the proposed research, and parental wishes needed to be considered.¹⁷ On this alternative view, in certain instances the parents' role in decisionmaking with respect to research participation should remain authoritative. It was emphasized, however, that parents have an obligation to weigh their child's preferences in assessing the harms and benefits of research participation and they ought not to authorize research they believe may be harmful to their child.

In sum, there was not agreement on an appropriate role for children in categories three and four. More work is needed on the significance of developing decisional capacity, the relevance of any underlying illness, the nature of the proposed research, parental wishes, and parental responsibilities as relevant factors in determining the proper role of children in decisionmaking about participation in research.

The Responsibility of Parents for Decisions about Children's Research Participation¹⁸

The law requires of parents that they safeguard the interests of their children until such time as children are capable of making independent decisions for themselves. Arguably, this legal obligation grounds parent's authority to make decisions for their children regarding research participation. Respect for the law, however, is not the only (or even the most important) moral reason for conferring on parents decisionmaking authority regarding children's participation in research.

Society entrusts parents with responsibility for protecting their children from harm and for promoting their children's interests. This parental responsibility typically requires decisionmaking on behalf of children regarding issues that range from the mundane to the very complex; at the complex end of the spectrum is decisionmaking regarding participation in some kinds of research. The general responsibility for decisionmaking on behalf of children is conferred on parents for several reasons. First, it is widely believed that parents are the persons most likely to know

their children's interests and thus be in a position to promote them.¹⁹ This belief about parents having privileged knowledge of their children's interests, coupled with the belief that parents invariably care the most about their children, provides a firm foundation for the claim that parents are the legitimate decisionmakers.²⁰ A further moral claim that might be advanced by parents (or on their behalf) concerns the fact that parents (in addition to their children) may bear some of the consequences (ranging from inconvenience to serious harm) of a decision regarding their child's participation in research.

Two other ways in which legitimate parental authority for decisionmaking regarding research participation may be established relate to expectations of, and decisions by, potential child research participants. Decisionmaking authority may come from legitimate expectations a child may have of her parents that they will care for her by making appropriate decisions on her behalf. In the alternative, that authority may be conferred on parents by their child in an overt manner, as when a child with (some) decisional capacity expressly delegates authority to her parents.

Legal Limits on the Parents' Role in Decisions about Children's Research Participation

What are the limits on parents' authority to have their children participate in research? At present there are conflicting interpretations of Canadian law with regard to at least two related issues concerning children's participation in research.²¹ The first issue is whether the law permits parents to authorize participation in any research with no potential for direct medical benefit. The second, more specific, issue is whether the law permits parents to authorize participation in research with no potential for direct medical benefit where the research involves venepuncture. Since the second issue revolves around differing interpretations of a particular provision of the Canadian *Criminal Code* and has no relevance beyond Canada, it is not discussed here.²² And while the prior concern involves a Supreme Court of Canada decision, it is discussed below because it rests on a distinction that is relevant beyond Canada.

In short, the debate about the first issue revolves around differing interpretations of the Supreme Court of Canada decision in *E. (Mrs.) v. Eve*.²³ One interpretation of *Eve* takes the Court to have implied that parents cannot authorize research of no potential medical benefit for their children. Another takes the Court to have implied that parents cannot

authorize research of no potential benefit for their children, with benefit understood broadly as including medical, psychological, social, and religious benefit. On this latter view, parents can authorize research with no potential for direct medical benefit as long as there is the potential for direct benefit. The former interpretation obviously has a more restrictive impact on research involving children than the latter.

Workshop participants were not in a position to resolve these interpretive disagreements. However, they did agree that the confusion about the law with respect to each of these two issues has probably had a chilling effect on research involving children in Canada. Some participants speculated that important research involving children is not being done in Canada because of fear that the research falls afoul of the law. They also speculated that some such research is being done by researchers who live in the fear of liability but with the hope that the first interpretation of the law would not be sustained by the courts. Unless the law is clarified, it is feared that important research will not be done or, if done, will be done by researchers having to live with the stress of acting under the threat of criminal liability. Workshop participants agreed that the law needs to be clarified.

Conclusion

As stipulated at the outset, this is not a consensus document; nonetheless, it is worth noting that agreement emerged on a few significant points. Respectful involvement of children in decisionmaking regarding research participation at the very least involves attention to the following: children are embedded in their own context; they should be included in discussions about their potential research participation for informational and/or decisional purposes once they have some language comprehension; and, these discussions should be interactive and iterative. Finally, assent and dissent are difficult concepts to interpret; further reflection on their content and moral relevance is required.

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1. Workshop participants, in addition to the authors, included: Rona Abramovitch, University of Toronto; Dorothy Barnard, IWK Grace Health Centre; Dan Brock, Brown University; Paul Dick, The Hospital for Sick Children; Bernard Dickens, University of Toronto; Carl Elliott, University of Minneapolis; Conrad Fernandez, British Columbia's Children's Hospital; Kathleen Cranley Glass, McGill University/The Montréal Children's Hospital; Christine Harrison, The Hospital for Sick Children; Mabel Horton, Aboriginal Services Manitoba; John Lantos, La Rabida Children's Hospital and Research Centre; Abbyann Lynch, Ethics in Health Care Associates; Michael Moffatt, Community Health Services Manitoba; Kathleen Oberle, University of Calgary; and Barbara Sourkes, Montréal Children's Hospital/McGill University.

2. For the purposes of this discussion the term "children" applies to individuals below the legal age of majority, usually eighteen.

3. For example, the *Nuremberg Code*, reprinted in Office for Protection from Research Risks, *Protecting Human Research Subjects: Institutional Review Board Guidebook*. (Washington, D.C.: U.S. Government Printing Office, 1993) at A6-1; Council for International Organizations of Medical Sciences, *International Ethical Guidelines for Biomedical Research Involving Human Subjects* (Geneva: Council for International Organizations of Medical Sciences, 1993).

4. The terms "competence" and "incompetence" are not used in this document in an effort to avoid potential problems of equivocation between the moral and legal constructs. Instead, typically, there is reference to persons with or without decisionmaking (or decisional) capacity as well as persons with developing decisional capacity.

5. National Commission for the Protection of Human Subjects of Biomedical and Behavioural Research *Research Involving Children: Report and Recommendations* (Washington, D.C.: U.S. Government Printing Office, 1977).



6. Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects* (Ottawa: Minister of Supply and Services Canada, 1987) at 29.

7. Medical Research Council of Canada, Natural Sciences and Engineering Research Council of Canada and Social Sciences and Humanities Research Council of Canada, *Tri-Council Policy Statement: Ethical Conduct for Research Involving Humans* (Ottawa: Public Works and Government Services Canada, 1998) at 2.10. These guidelines replace the Medical Research Council of Canada, *Guidelines on Research Involving Human Subjects*, *ibid*.

8. *Ibid*.

9. See, W.G. Bartholome, "Hearing Children's Voices" (1995) Winter Bioethics Forum 3; Committee on Drugs, "Guidelines for the Ethical Conduct of Studies to Evaluate Drugs in Pediatric Populations" (1995) 95:2 Pediatrics 286.

10. World Medical Association, *Recommendations Guiding Physicians in Biomedical Research Involving Human subjects (Declaration of Helsinki)*, 18th Assembly, June 1964, as amended by the 48th General Assembly, Somerset West, Republic of South Africa, October 1996.

11. This question was advanced by John Lantos in his paper for the workshop. J. Lantos, *Assent and Dissent in "Therapeutic" Research for Children* (La Rabida Children's Hospital and Research Centre, 1998) [unpublished].

12. Workshop papers by Mabel Horton and Michael Moffatt directly addressed these issues in a Canadian context: M. Horton, *Assent, Dissent, and Children in Cultural Communities or Other Collectivities* (Aboriginal Services Manitoba, 1998) [unpublished] and M. Moffatt, *Assent and Dissent in Research in Children's Health: Examples From the Real World* (Community Health Services Manitoba 1998) [unpublished].

13. Conrad Fernandez raised many of the relevant concerns in a workshop paper. C. Fernandez *Assent and Dissent to Research in Children with Chronic, Life-threatening Illnesses* (British Columbia Children's Hospital 1998) [unpublished].

14. Various examples were provided by Barbara Sourkes and Rona Abramovitch and colleagues. B. Sourkes, *The Medical Encounter: A Child's Eye View* excerpted from B. Sourkes, *Armfuls of Time: The Psychological Experience of the Child with a Life-Threatening Illness*, (Pittsburgh: Pittsburgh University Press, 1995) 31-44 and 53-60; and R. Abramovitch *et al. The Development of Assent Forms: Maximizing Children's Understanding of Biomedical Research* (McGill University) [unpublished].

15. Society for Adolescent Medicine, "Guidelines for Adolescent Health Research: A Position Paper of the Society for Adolescent Medicine" (1995) 17:5 J. Adolescent Health 270 at 272.

16. It may be suggested that a child with developing decisionmaking abilities is capable of expressing a preference but, for a number of reasons, should not be held accountable for her choice. A paper written by Carl Elliott for the workshop led to a discussion about the ability of mature children and adolescents to appreciate and be held accountable for-not simply understand-the consequences of choices they are being asked to make. C. Elliott, *The Competence of Children* (University of Minneapolis, 1998) [unpublished]; see also, C. Elliott "Competence as Accountability" (1991) 2 J. Clin. Ethics 167.

17. *Supra* note 11.

18. Many of these points are made by Dan Brock. D. Brock, *What is the Moral Authority of Parents to Make Decisions for Their Children Regarding Research Participation* (Brown University, 1998) [unpublished].

19. In many (if not most) cases this is likely a true belief because parental values typically inform the context in which potential harms and benefits are construed and evaluated in assessing what is in the child's "best interests."

20. Of course, if either of these beliefs is not true in a particular instance, then the foundation is eroded and the parental authority is compromised.

21. These conflicting interpretations were brought out in the discussion of Bernard Dickens's workshop paper. See B. Dickens, "The Legal Challenge of Health Research Involving Children" (1998) 6 Health L.J. 131.

22. For a complete discussion of this debate, see F. Baylis & J. Downie, "An Ethical and Criminal Law Framework for Research Involving Children in Canada" (1993) 1 Health L.J. 39; and B. Dickens, "Substitute Consent to Participation of Persons with Alzheimer's Disease in Medical Research: Legal Issues" in J.M. Berg, H. Karlinsky & F. Lowy, eds., *Alzheimer's Disease Research: Ethical and Legal Issues* (Toronto: Carswell, 1991).

23. *E. (Mrs.) v. Eve*, [1986] 2 S.C.R. 388.

