

Chapter 2

A Canadian Perspective on a Child's Consent to Research Within a Context of Family-Centred Care: From Incompatibility to Synergy

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2.1 Introduction

The recent development of paediatric bioethics has seen two dominant trends evolve simultaneously:

1. the framework of family-centred care and
2. recognition of the emerging autonomy and rights of children.

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The former led to the development of a “family-centred” care healthcare delivery model while the latter is consistent with a “patient-/child-centred” care model. Both healthcare delivery models are fundamental to caring for children in Canadian hospitals and each is accordingly increasingly pursued as a vehicle for guiding the delivery of healthcare in the best interests of children. While these recent trends have resulted in a kind of hybrid model of care on a functional level, they hold an inherent tension in establishing the ultimate decision-maker in health-related issues. This tension is particularly relevant in obtaining consent for participation in paediatric research.

In the last 25 years, family-centred care has become a familiar component of paediatric clinical practice in North America. Children in early paediatric hospitals were often kept apart from their parents, who had little to no say in the care given to their children; eventually simple moves, like allowing mothers to stay with their breastfed infants, expanded into a wider recognition of the importance of parents in paediatric healthcare. The family-centred care movement, as we know it today, emerged post-World War II and crystallized after the 1970s (Shields 2011). Today, many healthcare executives view patients and families as important decision-making partners and many healthcare institutions include family participants at the executive meeting level (Conway 2008). The movement is located in multiple, distinct disciplines. In the academic world, it has been ingrained in children’s nursing and therapy curricula in particular (Carter 2008). Its bases however, can also be found in social work, and it “fits well with a social work perspective that understands individuals in the context of their family system and greater environment” (Kovacs et al. 2006, p. 13).

The traditional triad has the parent(s) in the role of substitute decision maker, reflecting that the parent(s) is in the best position to appreciate what is in the child’s best interests. The language of family-centred care, while intended as a vehicle for bringing benefit to the child, considers the interests of those beyond the triad-focused patient.

Along with the rise of family-centred care, paediatric bioethics has also seen the rise of a framework that emphasizes the development of children’s autonomy and rights. This model of healthcare, focused on the unique needs and wishes of the patient, is often referred to as “patient-centred.” In a paediatric context, this approach is often referred to as “child-centred.” Paediatric clinical research now requires recognition of children’s developing capacity and eventual respect for their assent or dissent. Recognition of children’s developing capabilities has grown such that Canadian policy recently began to explicitly recognize that children’s assent and dissent should be determinative in the research consent process as well as in the context of care. Canadian ethics and law have thereby entrenched a patient-centred model of care that emphasizes respect for the autonomy of individual patients and the developing autonomy and rights of children in the context of treatment decision making.

Prima facie, these two perspectives may conflict in their designation of the primary ethical locus of decision-making. According to some interpretations, family-centred care can emphasize the full family unit as the primary focus of ethical consideration, while the children’s emerging autonomy/rights perspective clearly puts ultimate authority in the hands of the child. The existence of conflict may in-

crease risk to patients, physicians, and the institutions in which they work. Should physicians fall short of certain duties when giving priority to other duties and/or undermine the integrity of clinical care, this may result in compromised trust in the physician-patient or physician-family relationship. While one could argue that the different foci of patient/child-centred care and family-centred care do not have normative significance that would justify having a physician deviate from his or her primary fiduciary duty to the patient, the lack of clarity on how these distinct models are to be integrated in practice, finds the practical application of the models threatened by inconsistency or destined to only offer purely theoretical value.

This chapter explores the compatibility of these perspectives, and offers a guide as to how these views may be integrated in the context of consent to research (Sheahan et al. 2012).

2.2 “Family-Centred Care”

Family-centred care acknowledges “the importance of family participation in healthcare” (Williams 2006, p. 203). Although there are many broad definitions and conceptualizations of family-centred care, one used as the basis of a systematic review of the effectiveness of family-centred care describes it as “a way of caring for children and their families within health services which ensures that care is planned around the whole family, not just the individual child/person, and in which all the family members are recognized as care recipients” (Shields et al. 2006, p. 1318).

A formal role for parents in their children's health really only began to emerge in the 1950s and 1960s (Palmer 1993; McGonigel 1998). The concept of family-centred care in North America emerged through a strong advocacy movement in the late 1960s led by parents of children with special healthcare needs (MacKean et al. 2005). The movement argued against the dominant expert model, with parents advocating for more involvement in their child's healthcare and for the healthcare system to recognize the influence of the family on a child's health and wellbeing. Throughout the next 40 years, family-centred care began to influence health policy in the North American paediatric setting. For instance, paediatric hospitals changed their visiting policies from a very restrictive set of visiting hours each day to an open visiting policy allowing parents to stay with their children 24 h a day (MacKean 2005).

Recent bioethics literature suggests family-centred care only received a “nominal definition” that does not touch the “real nature” of what is being described to date (Shields 2011, pp. 144–145), but some preliminary features still prove useful. Fostering family-friendly environments, along with acknowledging parental expertise in providing care and encouraging collaboration between parents and the healthcare team emerged as key elements of family-centred care (MacKean 2005). Indeed, more recent definitions give “all the family members” of a paediatric patient the status of care recipients (Shields et al. 2006, p. 1318). This arguably gives all family members a sense of ethical concern that could be translated to the research context with the possible aforementioned implication of multiple family members having a sense of authority in their own right rather than as individual proxies for individual patients.

Contrasted with the medical professional-centred care model, a merging of competing interests into a hybrid “patient- and family-centred care” model, which recognizes the perspectives of both children and their families, has developed (IPFCC 2011). This hybrid “is an approach to the planning, delivery and evaluation of healthcare that is governed by collaborative partnerships among healthcare providers, patients and families” (Sodomka 2006, p. 7). The paediatric hybrid approach of “child- and family-centred care” reflects a simultaneous commitment to the focus on patients and recognition of the fact that a paediatric patient is generally embedded in a family unit. It is described as an “equal partnership” between providers and recipients of healthcare (Sodomka 2006, p. 7). In the research context, the principles of patient- and family-centred care require designing, conducting and evaluating research in collaboration with parents as well as respecting the diversity and privacy of families (Johnson et al. 1992; McGonigel 1998). Such collaborative research programs have been widely successful, with programs at schools like the University of Kansas, Stanford University and others proving productive in the domain of evidence-based research (Johnson 2008).

Unfortunately, broad concepts and a lack of empirical evidence make further development and evaluation of family-centred care difficult. Although family-centred care is widely accepted in children’s healthcare, little work has been done to evaluate its effect on child and family outcomes (Shields et al. 2006; Franck and Callery 2004). This leads some to suggest more research is needed to ensure family-centred care is “being properly implemented” (Shields et al. 2006, p. 1317). Others argue that it is not obvious that family-centred care is “intrinsically good and therefore worthwhile pursuing and getting right” (Carter 2008, p. 2092). Some authors suggest that improvements to the concept are required, and that the voice of the child is notably missing in the debate (Lambert 2009).

One area where effectiveness may be questionable is in relation to the tensions between the interests of children and of the family. As Franck and Callery note, “there may be important differences between the perspectives and objectives of children and of their families...[P]arents may not be best placed to assess symptoms and quality of life from their children’s point of view” (Franck and Callery 2004, pp. 268–269). Semantically, family-centred care and patient-centred care clearly identify different parties as holding the ultimate position of privilege. Just as there can only be one true centre of a circle, there can only be one ultimate position of privilege. Family-centred care developed due to an understanding that “a child’s illness has the ability to impact all aspects of family life” (Locsin 2003, p. 203). It does not in any way minimize the fact of the child’s illness, nor does it explicitly denigrate their decision-making capability. Placing the family at the semantic ‘centre’, however, could result in considerations relevant to family members taking priority. So, in relation to paediatric research, family-centred care potentially opens the possibility of research being done on a patient based primarily on the interests of his or her family, while not being held to a strict standard upholding the individual’s interests. This risk is of particular concern in a research setting where the benefits to the patient are often less obvious to define.

A strict model of patient-centred care, however, would view the patient as the primary focus of ethical consideration. Inclusion of the child at each stage of the

research process and giving the child ultimate authority to at least decide not to participate in a study would be necessary. A strict reading of patient-centred care could be taken further such that a capable child could participate in a research program without parental permission.

One may wonder if an increased role for children's decision making is desirable; some parents may wish for their consent to be determinative regardless of a child's viewpoint presuming that as adults they will likely have a greater understanding of a given research program. In addition, parents are held legally responsible for their children. They must provide them with both education and the necessities of life (Criminal Code, R.S.C. 1985). It may seem inconsistent to allow children to act in a manner that would undermine parents' ability to provide that which they are statutorily obligated to provide.

Currently, clinicians and researchers accept a kind of ill-defined hybrid model for making decisions in paediatric medicine. A hybrid position does not provide us with adequate answers. The Institute for Patient- and Family-Centered Care's core concepts (dignity and respect, information sharing, participation and collaboration) include both patients and family members at each step of the process, but do not clearly articulate who the ultimate decision-maker should be (IPFCCND 2011). Amongst equal partners, it is difficult to find an ultimate decision-maker. A strict family-centred approach would make the third party permission determinative, but such an approach appears incongruous with our increased recognition of the importance of child's rights and developing capacity, including an explicit recognition that children's assent or dissent could be determinative of their participation in a research study.

Franck and Callery suggest that "the difference between 'child-centered' and 'family-centered' care is one of emphasis: neither term can exclude the other, because child-centered care must take account of the social environment in which children live and FCC [family-centered care] must be primarily concerned with the health of children" (Franck and Callery 2004, p. 269). Under this rubric, there is no merger or hybridization, only an important relationship between related positions. This may not solve the problem entirely. Where one places his or her *primary* emphasis can nevertheless still lead to substantial differences. While the hybrid model does encourage one to consider the values underpinning each model, it offers little guidance on how to balance the interests or perspectives of the patient/child with the family and how to balance the range of clinical duties that flow from each model, especially in the context of dispute and/or differences between the perspectives of patients (children), legal guardians (families) and/or physicians about what should be done.

2.3 Children's Rights to Consent Under the Tri-council Policy Statement

The increased importance of the child's rights and child's developing capacity framework for the Canadian paediatric research consent context can be best observed by examining Canada's primary research standards document, the Tri-Council Policy Statement (TCPS) (Canadian Institute of Health Research et al. 2010).

In the absence of statutes devoted to research ethics or common law standards, guidelines, regulations and policy statements are often the best resources for determining the standard of conduct in a given area. Outside of Quebec, where at least research consent standards are proscribed within the *Civil Code*, the TCPS is the leading research ethics resource in Canada. Canada's three main research funding agencies, the Canadian Institutes of Health Research, the Natural Sciences and Engineering Research Council of Canada, and the Social Sciences and Humanities Research Council of Canada, originally adopted the TCPS in 1998. The TCPS serves a soft law function in Canadian jurisprudence and helps to establish standard of care for Canadian research.

Under the original TCPS, children were recognized as vulnerable persons (Canadian Institute of Health Research et al. 1998). Their participation was contingent on their assent or dissent (Simpson 2003). While children still needed to reach a certain lower capability threshold in order for their assent or dissent to be relevant (i.e., newborns could not give their assent to research), *prima facie*, respect for children's assent or dissent was an important component of an ethically permissible research study. Whether a valid parental consent would lead to research participation in the presence of a patient's dissent was questionable. Even where assent and dissent were seen as determinative, the lack of definition of these terms and the lack of clarity on when one is capable of giving determinative assent or consent were problematic. Accordingly, Christy Simpson recommended expanding the role of the child in decision-making about research, clarifying the language surrounding this role and outlining the respective roles and responsibilities of parents, researchers, and Research Ethics Boards in the decision-making process (Simpson 2003).

Children's roles in the TCPS-mandated consent process changed with the December 2010 adoption of its 2nd draft, also known as the "TCPS 2" (Canadian Institute of Health Research et al. 2010). Recognition of the fact that consent is an ongoing process now explicitly entails recognition of the developing capacity of children. Where third party proxy consent is initially given, researchers must gain valid consent from someone who either:

- a. reaches the age of consent (in the case of children) or
- b. acquires or regains capacity (in the case of all incapable individuals, including incapable children) (Canadian Institute of Health Research et al. 2010, p. 30, art. 3.9(e)).

The TCPS 2 notes that "the determination of capacity in research is not a static determination" (Canadian Institute of Health Research et al. 2010, p. 41).

Under TCPS 2, a child is either capable of consent or of assent/dissent only. However, the TCPS 2 does suggest that individuals with "diminished capacity [may] still be able to decide whether to participate in certain types of research" (Canadian Institute of Health Research et al. 2010, p. 41). One wonders if a developing child may be able to consent to some types of research, even if he or she is only capable of giving assent or dissent elsewhere.

Researchers now have a responsibility to seek a child's assent or dissent. The TCPS remains in an assent-dissent framework for those who are incapable of giving

fully valid consent on their own, but the necessity of assent or dissent from a child capable of giving it as a component of a valid consent is now explicit:

Where children have not yet attained the capacity to consent for themselves to participate in research, researchers shall seek consent from an authorized third party while ascertaining the child's assent or dissent.... While their assent would not be sufficient to permit them to participate in the absence of consent by an authorized third party, their expression of dissent or signs suggesting they do not wish to participate must be respected. (Canadian Institute of Health Research et al. 2010, p. 42, 50)

The threshold for when a child's assent or dissent is determinative is difficult to parse. Article 3.10 requires "some ability to understand the significance of the research" (Canadian Institute of Health Research et al. 2010, art. 3.10). Emphasizing the word 'some' suggests a low standard. If, however, one focuses on 'significance', what one needs to understand may be rather robust; it may approximate an appreciation standard. Clinical assent, by contrast, only requires understanding what is being proposed, not appreciating it (Diekema et al. 2011).

In either case, the explicit recognition of the importance of a capable child's assent or dissent brings the TCPS closer in line, in spirit if not in consequence (given the potentially different standards), with the Ontario *Health Care Consent Act's* capacity-based analysis. This consistency is desirable given that it can be difficult to draw a sharp divide between clinical care and clinical research in certain circumstances. While the trend in paediatric research practice may reflect the notion that child assent/dissent is required for participation in paediatric research, most regulations make it possible for a child to be in a study entirely against their expressed wishes.

both U[nited] S[tates] and ICH [International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use] regulations specifically allow for a child's participation in a study, against their [meaning the child's] wishes, if it provides them some benefit (which is related to their health). The E[uropean] U[nion], on the other hand, requires only that the dissent be 'considered'. Thus, all three regulations make it possible for a child to be in a study against their wishes. It presents itself as what is sometimes colloquially called an "orphan". (Blake et al. 2011, p. 73)

2.4 Seeming Incompatibility?

The trends in paediatric bioethics of family-centred care and recognition of emerging autonomy and child rights focus on two different values and can lead to different results in a given decision-making process. It has been argued that the ethical underpinnings of family-centred care are insufficiently grounded; consequently, the model has failed and "it is ethically untenable to continue to apply it when caring for children and their families" (Shields 2011, p. 152). The basic underlying (pragmatic) argument for its value nonetheless appears to be rooted in the simple suggestion that a child is, generally speaking, embedded in a family that will have the best sense of what is in the child's best interests. Of course, critics argue against this point. For instance, some suggest that the movement is based on a neoliberal,

idealized understanding of the family (Breen 2009). It is possible that family-centred care developed on the basis of, and in conjunction with, recognition of the importance of the value of beneficence. Increased recognition of children's rights and the wider patient-/child-centred care model, by contrast, partially developed as increased respect for children's autonomy.

While a hybrid approach to paediatric research most often results in acceptable outcomes in terms of patient and family interests, it nonetheless fails to give patients and families a clear and coherent understanding of their roles and responsibilities. Researchers thus require a clear model for obtaining consent in paediatric research. The model needs to be broadly applicable, and based around clearly delineated values and principles which clarify the relative weights of potentially conflicting values. An example would be where parental autonomy comes into conflict with the emerging autonomy of an individual child.

According to Richard Miller, the distinctive feature of the paediatric model of medical ethics is that the norm of beneficence has general priority to the norm of respect for autonomy (Miller 2003). Prioritizing beneficence essentially means acting in a child's 'best interests'. The beneficence standard has a number of unique components in paediatrics. Most importantly, a child's 'best interests' are intimately tied to his or her social unit, and we must therefore recognize the importance of the family unit. This value or right is not synonymous with the value or right of patient autonomy, and is therefore accorded a different status in the decision-making process.

The importance of the family unit, as is enshrined in family-centred care, thus elevates the idea of parental autonomy, where parents may be considered the ultimate locus of decision-making. The obligation to recognize the significance of parental autonomy is contingent on parents fulfilling their obligations toward children. Where parents fail to act in the best interests of their children, outsiders may justifiably intervene in a family's domestic affairs to ensure that healthcare decisions are made in accordance with the child's best interests and where children may be in need of protection. The focus of ultimate ethical consideration may be the child in a beneficence model, but a substitute decision-maker, often a family member, is the ultimate ethical decision-maker. While consideration of the interests of the child is to be the focus of the family's decision-making rights, care decisions are centred on what the parents decide.

The first question for the researcher in paediatrics, therefore, becomes: 'Can this child give autonomous consent to participate in this project?' For the purposes of consent to research in paediatrics, autonomy can be seen as having two essential components: decision-making autonomy and executional autonomy. Decision-making autonomy refers to the ability and freedom to make decisions without external coercion, and executional autonomy refers to the ability one has to implement decisions made (Collopy 1988). In both research and treatment models for adults, decision-making autonomy tends to 'trump' all other relevant values.

The TCPS 2 marks an important moment in which children's autonomy is increasingly recognized. Children develop capacity for self-determination in decision-making as they mature. This creates an obligation to respect both the developing autonomy of young people, and their full capacity and independence when it is

reached. Paediatric patients, therefore, should gradually accrue the rights accorded to adults in light of their full capacity for self-determination. In the research context they develop a right to dissent even prior to the full right to consent accorded to capable persons in the clinical context. Unlike in the previous TCPS, this dissent is now clearly determinative.

Different foci of ethical consideration (family interests vs. children's rights) can lead to different conclusions in a given decision-making process. It is not enough to say that which is good for a patient is good for his family and vice versa. Parents and children do not always agree about what is best for a child.

2.5 Privacy: A Third Concern?

A further logistical problem arises when initially gaining consent: Who does one approach first and what can one share with the other party? Respect for autonomy entails respect for children's decisions as to what medical information is shared with others. Under Canadian law, capable youths have a right to have their information kept private (Personal Health Information Protection Act 2004). For the competent child who is thinking about research, approaching parents about the research may result in a lack of respect for this position. Approaching parents with information about a study may violate privacy if inclusion/exclusion criteria are included in the discussion. Study information provision would thereby give away medical information children may want to keep private. Approaching parents about the theoretical idea of a study only, however, is less than adequate information provision for making a third party proxy decision.

On the other hand, asking children for permission may require explaining the research purpose to the children prior to telling their family about it. Family-centred care demands the inclusion of parents in the decision-making process. It is understandable that recruiters may feel uneasy about discussing research with children without parental presence. In order to ascertain permission to share information, however, such a discussion will need to take place. Discussing consent to disclosure of information without knowing what the disclosure is all about runs into the same theoretical problems as the theoretical discussion of a study mentioned above. Operationalizing both autonomy and family-centred care will accordingly require consideration of how to work around related privacy concerns.

2.6 An Analogous Case?

TCPS 2 does provide another example of synergy between group interests and individual interests within a TCPS 2 research context. The TCPS 2 devotes a chapter on how to promote such synergy in Aboriginal communities. Chapter 8 of the TCPS 2 is identified by the Tri-Council funding agencies as a "*significantly changed*

chapter” (Interagency Advisory Panel on Research Ethics 2010, p. 3). Drawing on public consultations, Chapter 8 “serves as a framework for the ethical conduct of research involving Aboriginal peoples, premised on respectful relationships and encouraging collaboration between researchers and research participants, and community engagement” (Interagency Advisory Panel on Research Ethics 2010, p. 3). Community leaders must be consulted before research is conducted in Aboriginal communities, though the leaders do not necessarily recruit individuals for the research program.

The example of Aboriginal communities has many parallels with the concept of consent in the paediatric context, and can provide instruction on how to integrate family-centred care with the patient-centred care in a paediatric research setting. Just as community for this group has a heightened significance around consent to research, family should be recognized as serving a similar role for children. The family member’s permission is important, but so too is the individual patient’s decision not to participate in something of which the parent approves. Additionally, just as article 9.6 states that there are diverse interests in a community, such that a certain leader’s decision is not dispositive (Canadian Institute of Health Research et al. 2010), so too is there a wide breadth of interests in a family, such that a parent’s view is important, and whereby other family interests remain relevant. This is not an instance of individual consent waiver, but of an acknowledgment that cultural sensitivity is a prerequisite for even seeking it. Relatedly, one may wish to acknowledge the importance of a family context when seeking and examining the legitimacy of consent.

Community engagement is one aspect of the Aboriginal research context that demonstrates that model’s ability to meet the demands of both individuals and the groups of which they are members. It is “a process that establishes interaction between a researcher or research team, and the Aboriginal community relevant to the research project” (Canadian Institute of Health Research et al. 2010, p. 108). Article 9.12 states that it is a collaborative process where even the nature of engagement is determined through collaboration and Article 2.9 states that:

The nature and extent of community engagement in a project shall be determined jointly by the researcher and the relevant community, and shall be appropriate to community characteristics and the nature of the research. (Canadian Institute of Health Research et al. 2010, p. 111)

Community engagement is also highly contextual:

[T]he engagement may take many forms including review and approval from formal leadership to conduct research in the community, joint planning with a responsible agency, commitment to a partnership formalized in a research agreement, or dialogue with an advisory group expert in the customs governing the knowledge being sought. (Canadian Institute of Health Research et al. 2010, p. 108)

All research, however, must be relevant and respond to the community’s needs and priorities:

The research should benefit the participating community... as well as extend the boundaries of knowledge. (Canadian Institute of Health Research et al. 2010, p. 124)

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