

Cover Page



Universiteit Leiden



The handle <http://hdl.handle.net/1887/44738> holds various files of this Leiden University dissertation

Author: Grootens-Wiegers, P.

Title: Targeted informed consent : empowering young participants in medical-scientific research

Issue Date: 2016-12-06

CHAPTER 8

Recognizing the Capacities of Minors in Medical Decision-Making:
Not Tokenism but Engaging and Empowering

Grootens-Wiegers, P., Van den Broek, J. M., & De Vries, M. C.
(manuscript in preparation)

Abstract

The weight of children's voices in medical decision-making is a controversial topic. The aim of this paper is to identify the underlying presuppositions in the discussion, which are related to the way we view children, and discuss how the debate can be advanced by recognizing the potential of children. A common view is the child as not-yet-adult, incompetent and in need of protection by adults who act in its best interest. Contrary to this view and based on research evidence, it is more appropriate to view children as individual persons, with their own characteristics and perspectives. However, even those in favor of involving children commonly appear to hold the first view, as they discuss the role of children without inquiring children's perspectives or evidence from research that does so. In order to advance insights, we need to adopt the view of the child-as-person and make an effort to understand their perspectives, i.e. not merely talk *about* them, but engage *with* them. We therefore plea to increase the extent of meaningful participation of minors in research and policymaking.

Conclusion: Only by truly engaging with minors can we further the debate on their role in decision-making about medical treatment and research participation.

Introduction

The weight of children's voices in medical decision-making is a controversial topic. It is increasingly discussed in guidelines, (inter)national laws and regulations and scientific publications (De Lourdes Levy et al., 2003; EU, 2001; Committee on Bioethics, 1995). In this discussion there are two opposing opinions: some argue that we should allow children a bigger role in decision-making about treatment and research participation (e.g. Moeller, 2003), whereas others disagree and claim that children should be protected from undue influence in decision-making (e.g. Joffe, 2003). In light of this discussion, a recent amendment of the Dutch law on medical research with children is noteworthy. This amendment contains a reduction in the age to independently decide upon research participation from 18 to 16 years old, alongside with the possibility to make more risky research possible with children. This amendment was executed based on a report from a national committee (the "Doek Committee"), in which a number of experts provided an overview of medical, pharmacological, psychological, ethical and juridical aspects of research with minors (Doek Committee, 2009). Most notably in this report is the recommendation that participation of minors in research should be increased, because a child should, 'besides being an object of care and protection, be viewed as a subject with its own conceptions and feelings' (Doek Committee, 2009, p. 26). Scientific evidence is said to conclude that underestimating decision-making competence of children 'does not do justice to the child as a moral subject' and the child is rather put away as 'a moral object that is not or insufficiently capable of making decisions based upon personal insights' (Doek Committee, 2009, p.33). Until now a view of protection was taken in the Dutch law, after recommendations of an earlier advisory committee, the "Meijers Committee" (1995).

The main evidence that is provided to support the statements by Doek is the study of Sokol et al. (Sokol et al., 2004). In this study an analysis is presented of children's moral judgements, demonstrating that children initially have an *objective* view of moral responsibility (i.e. actions are either 'good' or 'bad' in itself), which then during development changes into a *subjective* notion of responsibility (i.e. the intention of an action is also considered when judging an action as 'good' or 'bad'). The cited study does not mention the concept of a moral subject or object, but discusses the type of morality that children possess.

The shift in thinking about children as ‘vulnerable and in need of protection’ towards ‘moral actors’, that is presented in the national committee report is thus not supported by a body of sound scientific evidence in the report. This is remarkable, since this advice is responsible for an amendment on the Dutch law on Medical Research and thus has a huge impact on research regulations and practice. It appears that the national committee has based her rather radical recommendations mostly on expert opinion, without presenting extensive research evidence on children and their capabilities or characteristics. Hardly any evidence seems to be leading to this big shift in thinking about children; it is rather based on an intuitive conviction of people involved in pediatric care and regulations.

The intuitive way in which this conclusion was drawn is illustrative for a major part of the discussion on the weight of children’s voices, where adults often consider how competent children are and whether they should or should not be granted a role in decision-making (Hein, Troost, Broersma, et al., 2015). The discussion is characterized by adults talking *about* children and drawing conclusions for best practice of dealing with children in healthcare and research contexts, without looking at empirical evidence and – more importantly – without engaging with children to increase understanding about their competences and characteristics (Hein, Troost, Broersma, et al., 2015). When the discussion on the role of children in medical decision-making remains at the level of talking *about* children instead of talking *with* children, a valuable way to advance insights is neglected: looking at the perspectives and potential of children themselves. We argue in this chapter that in order to move forward our insights on children in medical decision-making, we need to look at the underlying presuppositions in the discussion on children’s capacities to participate, namely: the way we view children. Children are often viewed as *on their way to adulthood, but not yet there*, which leads us to talk about children and draw conclusions without actually consulting them. We argue that we can advance our insights by recognizing and respecting children as *persons with potential*. Only when we engage with children and learn about their perspective, will we be able to adequately and ethically empower them in their role in medical decision-making.

The way children are viewed

The issue of children and competence

The discussion of involving minors in decision-making revolves around a specific period in human development. It is quite obvious that at one point, humans are incapable of being involved in decisions, as they can hardly communicate and thus cannot understand what is at stake, nor express a choice. At a certain later stage in life, humans are deemed competent to make decisions and act on it, in and outside a medical context, such as obtaining a driver's license or getting married. This competence is generally based on age, but even for these seemingly straightforward decisions there are different cutoff values: in the USA one may drive from 14-17 years old (state-dependent), but not drink until 21, whereas in Europe it is allowed to drink already when 18, sometimes 16 years old and to drive from 15-18 years old (country-dependent). In medical decision-making there is also variation: in the Netherlands people may independently decide upon research participation from the age of 18, but children from the age of 12 are allowed shared consent together with their parents, whereas in the USA the legal age to consent is 18 years old and informal assent can be sought from a minimum age of 7 years old.

As there is no consensus on when humans enter full competence, there is even more confusion about how to deal with those that are not officially deemed competent. Minors, or children from hereon, are attributed with a developing competence and autonomy, as stated by various laws and guidelines (De Lourdes Levy et al., 2003; EU, 2001; Committee on Bioethics, 1995). In general, these laws and guidelines state that children should be involved in (medical) decision-making, according to their capacity, while at the same time stating that children need some form of protection.

These two aspects (capacity and protection) are also key elements in the Convention on the Rights of the Child (CRC; Unicef, 1989); Article 12.1 states that the child "who is capable of forming his or her own views [shall be assured] the right to express those views freely in all matters affecting the child, the views of the child being given due weight in accordance with the age and maturity of the child.". Yet Article 3.1 mentions "In all actions concerning children [...] the best interests of the child shall be a primary concern", and Article 18.1 states that "[...] Parents or [...] legal guardians, have the primary responsibility for the upbringing and development of the child. The best interests of the child will be their basic concern." (Unicef, 1989). Children should be involved in matters that affect them, while at the same time they should be protected by adults who

handle in their *best interests*, indicating that the child may not be able to act according to its own best interests itself and therefore needs protection by adults. The CRC in a sense presents two opposing perspectives on children: that of the vulnerable child in need of protection vs. that of the capable child attributed with agency. Which view is adopted, is dependent upon what people want to achieve. An example of the agency perspective is the use of the CRC by the Dutch charity Plan Nederland, which aims to combat poverty in developing countries, and for that adopts a 'child centered community development', which is a prerequisite for working in societies in which adults are underrepresented (Plan Nederland, 2016). An example of the protection perspective is The Netherlands Institute for Human Rights, which is fiercely against the discussed amendment to enable more research with children, and in order to convince the government has expressed a statement heavily relying on the view of the child as vulnerable and in need of protection, again using the CRC as justification (College voor de Rechten van de Mens, 2013). These two examples demonstrate that the CRC does not provide unequivocal direction in how to approach children. Are children vulnerable, an object of protection, or are they agents, capable of forming and expressing opinions and making decisions? The discussion on whether minors should participate in medical decision-making and to what extent, evolves around these two elements of protection vs. agency. Towards which end we shift depends on the way we view children: as not-yet-adult or the child-as-person in itself.

The child as not-yet-adult

The first view relies on the idea that children are developing towards adulthood, but they are *not yet there*; the child as 'not-yet-adult' view, which relates to Article 3.1 and 18.1 of the CRC on the 'best interests' of children. According to this view, children are defined by vulnerability, because they lack insight and power and are dependent upon adults to guide them in this world (Dedding, 2009; De Vries, 2015). Adults are responsible for this vulnerable child and are obliged to handle in its best interests. When it concerns the capacity to be involved in decision-making, adults decide when a child passes the threshold to competence. This competence is mostly measured based on how much of adult capacities are present in the child. The child has agency only when this is allowed or supervised by adults. Illustrative for this view in clinical practice is evidence that minors are generally deemed competent when their decision coincides with what adults (parents/doctors) would decide, but when the child decides otherwise, it is quite often automatically considered incompetent (Alderson, 1993). It is also demonstrated

in competence assessment tools: children are generally considered incompetent unless they prove otherwise, which is much harder than proving incompetence, being already suggested by a few mistakes or misunderstandings (Alderson, 2007). Furthermore, usually an adult-like competence and adult-like characteristics are sought in order to deem the child decision-making competent (Alderson, 2007; Kuther & Posada, 2004). In other words, when a child looks like an adult, it can make decisions like an adult.

Surprisingly, the child as not-yet-adult, and thus incompetent, is even found in the advice of the Doek advisory committee on amending the Dutch medical research law. The fact that this committee decided that a child is a moral subject instead of object, paradoxically demonstrates the view of the child as vulnerable: a team of adult experts has formed an opinion and advice on how to view minors, without actually consulting children and hardly referring to research that has done so. Would this be talking about an advisory report on how to deal with an adult group in the hospital, without actually consulting them, the authors would be criticized for not taking into account the adults' needs and preferences. Why is this not the same when it concerns minors? There is abundant talking *about* their needs without talking *with* them, as if they are incompetent to talk, express desires, or understand their own best interests: even in the Doek advice they are considered not-yet-adults after all.

The child-as-person

The second perspective on children is related to Article 12.1 of the CRC, in which children are attributed with agency. When we assume that children, lacking competence according to adult standards, are therefore completely incompetent in all aspects (of medical situations), we do not do justice to the potential that they possess. Competence is not an all-or-nothing concept and by dismissing children's developing competence, we deny the capacities, strengths and possibilities that children do have (De Vries, 2015). Research demonstrates that children, even very young ones, want to be informed and consulted about matters that affect them; that they are capable of identifying problems and providing solutions; and that they are capable to think about the future of their situation (Alderson, 1993; Dedding, 2009; Kuther & Posada, 2004; Schalkers et al., 2015; Staphorst, Hunfeld, Van de Vathorst, Passchier, & Van Goudoever, 2015). By approaching the child as not-yet-adult we miss out on the opportunity to meaningfully involve them, to consult them about their preferences and questions, to listen to what they have to say about their personal situation, and to act upon their input (Dedding, 2009; De Vries,

2015; Ganzini et al., 2004). Moreover, when we respect their (developing) autonomy, we might find that children have far more potential than we realized (Kuther & Posada, 2004). Children's potential to play a meaningful role in decision-making depends in part upon how well they are informed and the support and respect that they receive to be involved in the process of decision-making (Alderson, 1993, 2007; Kuther & Posada, 2004; Martenson & Fagerskiold, 2008). In order to bring out the potential of children, we need to change the way we view them.

We argue that, instead of intuitively discussing the role and capacities of children, we need to adopt the view of the 'child-as-person'. This view recognizes that children are not in an inferior stage towards adulthood, but that they are persons with their own characteristics and perspectives towards the world.

'Childhood must not be defined as a passing phase of impaired maturity [...] .rather it should be recognized as a unique, yet equally significant part of human development' (Benporath, 2003).

In order to understand and respect children, we cannot only talk about them, make guidelines about them and change laws about them, without consulting them (De Vries, 2015). To understand children's perspectives and potential, we need to engage with them and empower them and we need to recognize children as persons.

Respecting children and looking for their potential does not necessarily mean that they should be considered fully decision-making competent in all medical situations. However, it does mean that we respect their personhood and developing autonomy, and act accordingly by recognizing that they have their own desires and opinions and want to make choices based on their personal values and goals in life (Ganzini et al., 2004; Hein et al., 2012; Kuther & Posada, 2004). It also means that we respect their needs by answering their questions (even if they seem irrelevant to adults) and by offering support where they need it.

The child-as-person: the need to engage and empower

In order to know how we can support children, we need to engage with them to understand their potential and needs. Whereas there is an abundance of writing about children by (adult) experts, there is a lack of scientific evidence coming directly from research on the perspectives of children. Research about children often uses parents as informants, but they appear to not always reliably represent the child's perspective (C. Hart & Chesson, 1998; Lipstein et al., 2015; Staphorst et al., 2015). Also, most research in which children

are consulted is no more than that: children are used as consultants, informants, to provide some information or insight. However, after consultation it is quite often the case that children's opinions are not used in decisions, or that the adult researchers analyze the collected data and interpret the results without evaluating this interpretation with children (De Vries, 2015). There is a substantial risk that this type of research does not yield a true children's perspective, but rather an adult interpretation of children's opinions.

Moreover, involvement of children in research often does not lead to child-based insights or actions, as the extent to which children are involved is based on good intentions rather than on the actual will and preparedness to allow children substantive participation and influence. Different levels of children's participation in research are described in a model of an 8-stage ladder by R. A. Hart (1992); each level describes an increasing involvement of children, starting with level 1–3 of manipulation, decoration and tokenism; these reflect non-participation, i.e. children do not have a significant role, as in the above mentioned type of research in which children are only consulted without further consequences. An often encountered form of non-participation is 'tokenism' (level 3), when researchers or decision-makers pretend to consult children, but in reality do not have the intention to include children's input in decisions and policy execution. Level 4 on the ladder is informing children, and at level 5 children are consulted about their perspective and experiences. Levels 6–8 reflect increasing levels of involving children, even in formulating the research question and study design. According to this model, the highest attainable level of involving children is 'shared decision-making', meaning that adults are still to some extent involved in the decision-making process.

In spite of the current emphasis on involving children in matters that concern them, levels of 'non-participation' are often encountered, even in recent literature. A striking example is a recent publication in which it is argued that children could be involved in decision-making, but based on moral worth, rather than on capacities (Sibley, Pollard, Fitzpatrick, & Sheehan, 2016). The authors conclude that there is 'a distinction between respecting and encouraging a decision', and that the value of participation 'lies not in the child's response, but the fact that his views were solicited in the first place' (Sibley et al., 2016, p.6). In other words, the authors state that indeed children should be involved, but that we do not need to listen to what they have to say, or even base our subsequent actions upon their input. When comparing this to the ladder of Hart, this view demonstrates pure tokenism: there is no intention to follow-up on children's input in the decision-making process.

Thus, although it appears that involving children in research is already being done sufficiently, there is still a widespread lack of awareness on how to meaningfully involve children and do justice to their capacity and developing autonomy. We plea for increased participation and higher levels of participation of children in research, as this is essential if we want to further our insights on the role of minors in medical decision-making. In order to illustrate this, a number of examples will be provided on how we can engage and empower children.

Research showing the potential of engaging with children

Children are the experts when it comes to their personal situation, personality, preferences and goals (Dedding, 2009; C. Hart & Chesson, 1998). When we engage with children, we can learn from their expertise and gain insights in how they can be involved in decision-making. There are various ways to engage with children: Clavering and McLaughlin (2010) divide these ways into research *on* children; research *with* children; and research *by* children. Each type of research has a different level of participation from children, and each level can yield insights in children's perspectives (Clavering & McLaughlin, 2010). Research *on* children means that adults (e.g. parents) provide information about the child. As mentioned, this can be helpful, but not always reliable. Research *with* children means that children are the respondents; research *by* children is when children are involved in the research process itself, for example the main research question and goal.

Research *with* and *by* children demonstrates that engaging with children can lead to unexpected findings. For example, in a hospital evaluation study, children were asked to take pictures of things they did and did not like. Children indicated that current hospital practice did not meet their need for privacy, sleep and nutrition, all important aspects of well-being and recovery. As an example children took pictures of their hospital room window that had no curtains, showing that everybody could look inside and they could not sleep because of the light coming in. It appeared that the hospital rooms were designed by adults who had overlooked this issue (Schalkers et al., 2015). In another study, children were consulted about the discomforts of clinical research (Staphorst et al., 2015). Children indicated not only what was uncomfortable to them, but also provided solutions. They mentioned that not knowing what to expect made them anxious, and that this could be addressed by providing age-appropriate information on the procedures. Also, as a solution to the discomforts that can come with lengthy or painful procedures, they said that distraction in the form of television or games would alleviate the discomfort

significantly (Staphorst et al., 2015). Notably, the study demonstrated that children's discomforts were often over- or underestimated by adults, e.g. the parents or research nurses, confirming the lack of reliability of proxy reporters. In another study on research participation, it appeared that children were positive about being asked to participate in research, far more than researchers expected (Luchtenberg, Maeckelberghe, Locock, Powell, & Verhagen, 2015). Children indicated that they wanted to be encouraged to be involved in decision-making about research participation.

A third example of research that involves children is the evaluation of research information material in this thesis (Chapter 3, Grootens-Wiegers, De Vries, Vossen, et al., 2015). Information texts for minors that were approved by the Institutional Review Boards of academic medical centers were judged by the children to be too hard to read. Whereas it is custom to provide children with plain text information, children indicated to prefer a combination of text and visuals and said that the use of visuals would make it more likely that they would actually read the information and that it could help them understand complicated concepts.

These examples demonstrate how engaging with children can lead to insights that were otherwise overlooked, even, or especially so when adults were convinced that they were actually considering the child in issues such as hospital design, research practice, or information provision. When we engage with children, both in research and in the clinic at a personal level, we will come to a better understanding of the role that children can and want to play in medical decision-making. It will offer us ways in which we can empower children in the medical context. Empowering children means finding the right balance between involvement in the decision-making process and the need for protection and support. This empowerment is necessary, because children find themselves in an adult-dominated environment. Even when we recognize the potential of children, we need to be aware that children may still be in need of protection, both because of their developing autonomy and because all research participants (even adults) need some level of protection (Coyne & Harder, 2011; Lipstein et al., 2015). However, instead of assuming this need of protection, as is done in the child as not-yet-adult paradigm, we should base the ways in which we provide protection upon engagement with children. In order to do so, and to understand how we can empower children, we need to increase the amount of scientific evidence on the potential, perspectives and needs of children (Clavering & McLaughlin, 2010) and also approach each child as an individual, who can have different needs in different situations (Coyne & Harder, 2011).

Discussion

The role of children in medical decision-making is increasingly receiving attention in medical practice, clinical guidelines, and (inter)national laws and regulations. However, the debate about decision-making competence of minors is often held quite intuitively and not based upon peer reviewed research on this subject (Hein, Troost, Broersma, et al., 2015), as illustrated by the proposed change in the Dutch law on medical research described in the intuition-driven Doek report (Doek Committee, 2009). The aim of this chapter was to identify the presuppositions underlying the competence-debate, which relate to the way we view children, and discuss how the debate can be advanced by recognizing children as persons.

A common view on children in the competence debate is that of the child as 'not-yet-adult'. In this view, children are considered as developing towards adulthood and all its competences, but they are *not yet there*. This might imply that they are 'less' than an adult, incapable of understanding, forming and expressing opinions or making decisions. According to this view, children should be protected by adults, who should act on their behalf and in their best interest. In the context of medical decision-making, this means that adults (parents, doctors, and researchers) are informed and make a decision. Consulting the child is not considered necessary, or may be done as an attempt towards respect, but when opinions of the child are overridden by adults, this consultation turns out to be mere tokenism (R. A. Hart, 1992). Contrary to this view and based on research evidence (Dedding, 2009) it is more appropriate to view children as individual persons, with their own characteristics and perspectives. The child as not-yet-adult view does in no way correspond to experiences in research truly involving children, which show that even very young children can form and express opinions and have the desire to be involved in medical decisions (Dedding, 2009; Kuther & Posada, 2004).

In spite of the current attention for increased participation of minors in medical decision-making, we have demonstrated that the discussion on how to involve children is still not entirely based upon respecting the child as a person with potential. A tell-tale sign is the example of the Dutch advisory report in which a child view is based on mere intuition instead of solid evidence and insights in children, meaning that the report draws a conclusion *about* children *without* children. Although we do agree with this report that focusing on the protection of children leaves no room for children to make a choice based on personal views and values, we plea that any further discussion on this topic should be

performed based on consultation with children, recognizing the child as a person who has something to say. Only when we engage with children, will we be able to move forward our insights how to empower children by finding a proper balance between empowering them to participate in decisions that affect them and protecting them when needed.

