Children's competence to consent to medical treatment or research

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Citation for published version (APA):
Hein, I. M. (2015). Children's competence to consent to medical treatment or research. Amsterdam: Amsterdam University Press.
10 Summary and future perspectives in research on children’s decision-making competence

Background

In this study, we have explored the issue of children’s abilities to meaningfully decide on complex and important medical options, of which, until recently, little was known except that it often proved difficult to assess a child’s competence in some clinical settings. Nor was there empirical evidence on children’s competence to consent to treatment or clinical research to underpin these problematic areas. Yet problems did arise, when, for instance, pediatric patients did not agree with a recommended treatment. Or, when, in a research context, it remained unclear how to do justice to children’s vulnerable population status while attempting to optimize their research participation.

As it stands, patients’ competence to consent is usually assessed implicitly within the context of daily pediatric practice. However, lacking a gold standard, children’s competence has continuously been assessed in an unstructured way, which has led to inconsistencies. As we have shown, age standards prescribed by law may have had too much influence in clinicians’ assessments. To complicate matters further, these legal age standards have varied widely between countries. In addition, competence assessments were often influenced by the clinicians’ idea of what was in the child’s best interest.

With our project we aimed at developing a standardized tool for assessing children’s competence to consent and to offer empirical evidence to underpin age limits for alleged competence in children in order to optimize policies regarding children’s decision-making in clinical situations.

Best Practices for Children’s Competence Assessment

Having charted the latest developments in children’s competence assessment in chapter 2, we concluded that little progress was achieved over the last decades. Partly, because the discussion on children’s competence to consent to medical issues had been concentrated around complex normative concerns, a consensus over a clear operationalization of children’s
decision-making competence was far from being reached (chapter 2). Consequently, little empirical research had been conducted on competence assessment in children. We suggested a possible empirical research agenda to make way for advancements. Moreover, we recommended that research data are needed to underpin theories and guidelines and advance regulations concerning children’s decision-making competence in the medical context.

Assessment Instruments for Competence to Consent

As a starting point, the accuracy of existing tools for assessing competence to consent used in clinical populations were examined (chapter 3). Although many different instruments were described, few were tested in a systematic way. We concluded that studies on the MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR)(3) show clear indications of reliability and validity in adult populations. Used alongside the MacArthur Competence Assessment Tool for Treatment (MacCAT-T), the MacCAT-CR often proved to be the best assessment tool available.

A study protocol on how to assess children's competence to consent to clinical research was developed in chapter 4. The MacCAT-CR was translated and adjusted for use in children aged 6 to 18,(4) which included the use of simple language to be understood by elementary school-aged children, and additional questions on the influence of relationships with parents and peers. Research was implemented by using a sample of 161 pediatric patients visiting inpatient and outpatient clinics of pediatric departments of allergology, gastroenterology, oncology, ophthalmology and pulmonology. Clinical research projects on offer included 3 observational studies and 10 randomized clinical trials.

Results of this study (chapter 5) showed that children’s competence to consent to clinical research can be assessed validly and reliably using the MacCAT-CR. In the same study, the 4 domains representing competence in most jurisdictions (understanding, appreciation, reasoning, and expressing a choice) appeared to constitute a single trait or continuum of competence in children. Hence, a cutoff score on the MacCAT-CR above which competence was likely could be estimated.

Age Limits for Competence to Consent in Children

Our research showed that age limits for children to be deemed competent to decide on research participation could be estimated as follows: children
of 11.2 years and above generally appeared to be competent, whereas children of 9.6 years and younger were generally not competent (chapter 5). A change-over occurred between 9.6 and 11.2 years, and the cross-over point was estimated at 10.4 years.\(^{(150)}\)

For treatment decisions, a preliminary study using MacCAT-T on decisions about predictive genetic testing, revealed that most children above the age of 11.8 were competent to consent (chapter 7). The results from these studies in the research and in the treatment context show that MacCAT-scales modified for children are practicable in both settings and offer a preliminary indication that age-limits for competence do align.

**Factors Affecting Children’s Competence to Consent**

Out of all the factors that were considered to influence children’s competency, the key determining factor was age (chapter 6). Intelligence, on the other hand, was of little influence, its contribution to competence was small and inconsequential. The theory-based assumptions that risk and complexity of the decision would be related to a competence classification could not be confirmed with empirical data,\(^{(130)}\) meaning that for radical decisions that imply a higher level of competence a more mature age is not necessarily required. This may indicate that children of a certain age who are able to make less complex/low risk decisions could possibly also make high complex/high risk decisions at that same age. A possible explanation for this may be that children at a certain age possess the required capacities, and that competent decision-making is then possible when the information they receive is of good quality. For the other potential determining factors for competence shown by previous studies, like gender, the influences of social relationships, disease experience, ethnicity, and socio-economic status, no clear relationship with competence could be demonstrated either. Interestingly, parents judged their child more readily competent than experts did.\(^{(130)}\)

**Considering Implications of Empirical Knowledge for Policymaking**

Ethics, law, and clinical practice can benefit from these research data, even though assessment of children’s competence has a normative character (chapter 9). The research results may help validate the capacities of children when they face treatment and research decisions.\(^{(171)}\) Since age is an efficient proxy for competence, it is conceivable to use a fixed age-limit as cutoff for competence. Our research outcomes thus offer scientific input
for setting a reasonable and just age-limit; as far as we currently know the age-limit that presents closest accordance with children's competence is 11 or 12 years. However, fixed age-limits bear the disadvantage of an all or nothing character, meaning that relevant differences between individuals are not taken into account. If a more precise case-by-case assessment of children's competence is required, the MacCAT-CR would be an appropriate instrument for this purpose in the research context.\(^{(171)}\)

Assessment of all pediatric patients' competence on a case-by-case basis with an instrument would impose a heavy burden on patients, professionals, and the medical system, and will therefore be untenable and unsuitable. Although, dismissing a case-by-case assessment out of hand is inadvisable. A selective implementation of a standardized competence assessment in exceptional cases would be preferable.\(^{(171)}\)

Considering the research context, children were generally found competent from the age of 12 years and above, and incompetent under the age of 10, thus individual assessment in these age groups would be undesirable. For a case-by-case assessment of competence to have considerable value, the children in the change-over period between 10 and 12 years, whose competence is unresolved, should be focused on. Likewise, in special research populations of mentally compromised patients, and in case of children older than 12 years when there are reasons to doubt their competence, a case-by-case competence assessment can be recommended. Preliminary findings indicate similar age-limits for the treatment context; however, further research is needed to confirm those results. In the treatment context, individual competence assessment might create an opportunity in exceptional cases to allow a competent child under the age of twelve to co-decide over significant medical interventions.

In any case, where children are concerned we also need to take into account the developmental aspects. On the one hand, we have the research results showing that children of 11.2 and above have comparable decision-making capacities to adults concerning research participation, but on the other we need to consider their possible immaturity in decisions of a managerial or supervisory nature. It might be possible that children are able to decide with careful deliberation to participate in research, but are less able to responsibly respond to, for example, unforeseen traffic situations or coinciding agendas of other family members. Children, even competent ones, may still need the dyadic relationship they have with their parents, who give them the direction they need and who set limits that provide them with the necessary structure and security that, in turn, could help facilitate the decision-making process.\(^{(171)}\)
In addition, the research results must especially be interpreted against a background where parents are generally provided with the legal authority to raise their children; that is, by law they have rights and responsibilities to ensure the well-being of their child. To achieve an equable consideration between the legal position of the child and that of the parents, a double consent procedure (child and parent) is recommended for minors from the age of 12 until majority. Even if we were to establish a child's decision-making competence regarding a clinical decision, a double consent procedure would take into consideration the potential developmental aspects of children, the specific characteristics of the parent-child dyad, and the position of the parents.

Non-participation of Children in Research

As we revealed, there is a dire need for more pediatric drug trials since currently an alarming percentage of drugs (36-90%) prescribed to children are not being tested in their age group. Whereas specific pediatric regulations warrant children's safety, their recruitment for these trials remains one of the main difficulties. For this reason we investigated potential determining factors of children's non-participation in clinical research, in order to optimize their research participation by recommending improved recruitment strategies (chapter 8). We performed a qualitative and quantitative analysis of reasons why participation rates of children in clinical research are problematic.

In our sample of 161 pediatric patients eligible for clinical research participation, we ascertained that 60% did not participate (39% decided not to participate, 21% was indecisive). Factors that predicted non-participation were lower age, less disease experience, and less complex research with lower risk. Decisive reasons for non-participation expressed by children were time constraints and extra burdens brought about by the research procedures. We discussed that strategies to optimize research participation should be aimed at younger children and their families, who are logistically challenged, and unfamiliar with health care and research. Recommendations for optimizing children's research participation, we argued, would involve informing pediatric patients and their families of the value of research; coaching of children and parents in order to minimize logistic burdens; and improving accessibility.

Future Perspectives

Although our present empirical research provides substantial data to consider in debate and practice, many aspects of children's decision-making...
competence are still to be studied. We will consider some possible areas of future research, concerning the medical context as well as the forensic context.

Children's Competence to Consent to Treatment

In the treatment setting, more extended research on reliability and validity of the MacCAT-T in children is needed. There are several pediatric and psychiatric settings where children's competence can be an issue of importance. One of those settings might be the specialized gender dysphoria clinic for children, where competency issues play a significant role.

The rise in awareness about gender dysphoria (GD) in youth we are currently experiencing in the media and general population is leading to an increase in referrals to specialized clinics, not only in the Netherlands but also in the rest of Europe and the United States. Leading evidence suggests that puberty suppression that relieves the acute distress of physical puberty typical for GD seems to offer these youths the possibility of a healthy psychological development.\(^{172,173}\) Medical interventions that occur after puberty may be accompanied by irreversible physical changes and less favorable psychological outcomes. This implies that a complex medical treatment decision needs to be made by families and children around the age of 12 or younger, especially in natal females, with a mean age of 11 years at the start of puberty. Although puberty suppression implies, in principle, a reversible intervention, the start of treatment with cross-sex hormones (CSH) includes irreversible changes and consequences for fertility. Taking into consideration the possible side-effects of a prolonged puberty blocking of more than 3 years, like for instance lowered bone density (Klink et al, unpublished data), decisions to intervene with cross-sex hormones should be made at an earlier age than 16 years. Both intervention and nonintervention may carry risks to the welfare of the child.\(^{174}\)

We have shown that local jurisdictions, which determine the age limits for children's alleged competence, vary widely between countries.\(^{26}\) In the Dutch situation, two age limits apply: 12 years for deeming a child competent to consent to treatment together with parental consent, and 16 years for deeming a child competent to give independent consent. To date, these fixed age limits have been a leading principle in medical interventions for GD. However, they do not seem to be applicable in case of medical intervention with puberty blockers or CSH, because puberty often starts before the age of 12, and consequently, CSH should be started before 16 years.\(^{175}\)

Because no methods are yet available to establish medical decision-making competence in children, such competence is judged in intuitive
rather than standardised ways, leaving many developmental, ethical, and legal issues uncertain. Future research is needed on developing an instrument that assesses children's competence to consent to medical treatment. By extension, it is vital that research on the extent of children's competence to consent to medical interventions and on empirical evidence for estimating age limits for children's alleged competence is being realized.

Forensic Psychiatry and Children's Decision-Making Competence
The importance of children's decision-making competence is not confined to the medical context alone but may be of significance to adjacent fields as well: it could benefit, for instance, the competency assessment in criminal adjudication or civil procedures, which requires further research.

Recently, interesting similarities between assessments of criminal responsibility and assessments of competent decision-making within the context of informed consent were observed, whereby some authors conceived the assessment of criminal responsibility in terms of a decision-making process.(176) In both contexts, autonomy and decision-making would be central factors. Accepting this basic similarity would indicate that research on criminal responsibility could be directly informed by research on competent decision-making.(177) Although there are certain similarities between competence and criminal responsibility, we must realize that there are considerable differences as well.(36)

In child and adolescent forensic psychiatry, a broad assessment of the child's capacities is conducted in order to advise the court on his/her accountability in unlawful acts. This is done because adolescents in the criminal setting might be exposed to typical factors that influence decision-making: lower intelligence, higher rates of psychiatric disorders and brain trauma's, higher prevalence of prenatal exposure to alcohol and drugs, exposure to violence and abuse, dysfunctional family backgrounds, and substance abuse.(167)

Internationally, determining the age-limits for deeming a minor able to stand trial differ between jurisdictions. Some countries might require an assessment of adjudicative competence to deem the defendant capable to stand trial, others might only assess criminal responsibility, while others still might apply both. Nonetheless, these assessments are to take into account the maturity of the minor's decision-making capacities as well as possible psychopathology. In adults, decision-making competence and criminal responsibility are, although related, still considered to be two separate concepts.(36) Future research may elicit if and how decision-making competence and criminal responsibility intertwine in minors and if the
concepts should be regarded separately or concomitantly. Considerable differences between legal systems regarding the criteria for legal insanity will have to be considered carefully. Since some juvenile justice systems seem to move from a rehabilitative model to a more punitive model, it is vital to satisfactorily resolve questions on juvenile’s decision-making competence and criminal responsibility.

Neuroscience and Children’s Decision-Making Competence
Furthermore, new developments in neuropsychiatry may contribute to the understanding of the functioning of specific brain regions or connections that promote competent decision-making. For instance, currently, extensive neuroscience research is being done on the impact of mental disorders on specific components of decision-making; for example, decision-making deficits in addiction and in impulse-control disorders. Neurolaw is an example of such a developing interdisciplinary area of research that investigates the significance of the neurosciences in relation to the law from different perspectives. Now that the role of neuroscience for adult law is increasingly being studied, the perspectives that neuroscience could offer for juvenile law also come into sight. Research is needed to examine the possibilities – and pitfalls – of using neuroscientific methods (e.g. fMRI or spect) to inform the judge in juvenile court cases on the development of brain areas relevant for decision-making.

Conclusion
Empirical research on children’s competence to consent has yielded significant knowledge to be considered for policymaking. The present studies showed that children’s competence to consent to clinical research can be assessed validly and reliably using the MacCAT-CR, and feasibility of the MacCAT-T for assessing children’s competence to consent to treatment was confirmed. Using the MacCAT-CR, age limits for children to be deemed competent to decide on research participation could be estimated: children of 11.2 years and above generally appeared to be competent, whereas children of 9.6 years and younger were generally not competent. The key determining factor, out of all the factors that were considered to influence children’s competency, was age. Considering the implications of these empirical findings for law, ethics and clinical practice, we recommended that 12 years would be a just age-limit for asking children’s consent to clinical research. We argued that a double consent procedure, including both parent and child, would seem advisable for minors from the age of 12 until
majority, taking into consideration the potential developmental aspects of children, the specific characteristics of the parent-child dyad, and the position of the parents. Furthermore, in special research populations or when there are reasons to doubt a child's competence, case-by-case assessment is now possible in a standardized manner. In order to optimize children's research participation, we suggested improved recruitment strategies, which would involve informing pediatric patients and their families of the value of research, and coaching of children and parents in order to minimize logistic burdens.

Still, many aspects of children's decision-making competence are to be studied. For instance, in the treatment setting, more extended research on reliability and validity of the MacCAT-T in children is needed, especially in some pediatric and psychiatric settings where children's competence can be an issue of importance. One of those settings might be the specialized gender dysphoria clinic for children, where it is vital that research on the extent of children's competence to consent to medical interventions is being realized, even as on empirical evidence for age limits for children's alleged competence. Furthermore the similarities and differences between decision-making competence and criminal responsibility should be studied, and the possible opportunities offered by the developing field of neuroscience for assessment of decision-making competence should be explored.