Children's competence to consent to medical treatment or research

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Informed consent instead of assent is appropriate in children from the age of twelve

Policy implications of new findings on children's decision-making competence in the clinical context

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Submitted

Abstract

Background

For many decades, the debate on children's competence to give informed consent in medical settings concentrated on ethical and legal aspects, with little empirical underpinnings. Recently, data from empirical research became available to advance the discussion. It was shown that children's competence to consent to clinical research could be accurately assessed by the modified MacArthur Competence Assessment Tool for Clinical Research. Age limits for children to be deemed competent to decide on research participation have been studied: generally children of 11.2 years and above were competent, while children of 9.6 years and younger were not. Age was pointed out to be the key determining factor in children's competence. In this article we reflect on policy implications of these findings, considering legal, ethical, developmental and clinical perspectives.

Discussion

Although assessment of children's competence has a normative character, ethics, law and clinical practice can benefit from research data. The findings may help to do justice to the capacities and challenges children may face when deciding about treatment and research options. We discuss advantages and drawbacks of standardized competence assessment in children on a case-by-case basis compared to application of a fixed age limit, and conclude that a selective implementation of case-by-case competence
assessment in specific populations is preferable. We recommend the implementation of age limits based on empirical evidence. Furthermore, we elaborate on a suitable model for informed consent involving children and parents that would do justice to developmental aspects of children and the specific characteristics of the parent-child dyad.

Background

In clinical practice an accurate assessment of children's decision-making competence is needed to avoid two pitfalls: to impose complex medical decisions on children who are unable to make them, and to inadvertently exclude capable children who want to take part in decision-making.(106) For many decades, the debate on children's competence to give informed consent or assent in medical settings concentrated around ethical and legal aspects, with little empirical underpinnings.(150) In clinical practice many questions remained unanswered, for example which age span to evaluate, how to study the full range of abilities relevant to children's decision-making described in the literature, how to assess decision-making capacities regarding different types of medical decisions, and how to objectively assess children's competence. Progress was hard to achieve in debates on the subject and the lack of consensus on children's competence to consent was reflected by the restricted clinical implementation of the concept. There was a gap between recommendations regarding policies for children's involvement in the consent procedure and what had been documented in scientific research about children's competence assessment. The empirical approach emerged as a designated way to examine the dilemmas.

Recently, objective data stemming from empirical research on children's competence to consent became available, offering an opportunity to further the discussion. Research demonstrated in a sample of 161 pediatric patients that children's competence to consent to clinical research could be assessed in a valid and reliable way by means of an instrument, the modified MacArthur Competence Assessment Tool for Clinical Research (MacCAT-CR).(150) In the same study, the four 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, which allowed for estimating a cutoff score on MacCAT-CR above which competence was likely. This is in contrast with adult literature, stating that scores on subscales need to be weighted independently, and that failure in one domain could translate into an
incompetent assessment. In adults, because of this presumption, dimensionality was never tested.

Age limits for children to be deemed competent to decide on research participation were estimated: children of 11.2 years and above generally appeared to be competent, while children of 9.6 years and younger were not. Between 9.6 and 11.2 years, there was a change-over. For treatment decisions, a preliminary study using MacArthur Competence Assessment Tool for Treatment (MacCAT-T) on decisions about predictive genetic testing, revealed that most children above the age of 11.8 were competent to consent. 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 suggest that age-limits for competence align.

Furthermore age turned out to be the key determining factor in children’s competence, with a small additional contribution of intelligence. Theoretical assumptions that risk and complexity of the decision would be related to a competence classification could not be confirmed with empirical data. This demonstrated that more radical decisions, requiring a higher level of competence, could possibly be made by children as young as the group of children who were able to make lower impact decisions. An explanation might be that children at a certain age have the required capacities, and competent decision-making is possible when information provision is of good quality. For other potential determining factors for competence, like gender, systemic influences, disease experience, ethnicity and socio-economic status, no clear relationship with competence could be demonstrated either. Interestingly, parents appeared to judge their child more readily competent than experts would.

These recent empirical findings do not stand alone however, and need to be considered in view of their context. Since the age limits for asking children’s consent stated in many jurisdictions do not coincide with those demonstrated in our research, we need to evaluate whether it would be advisable to reset local statutory age-limits. Having the possibility to assess children’s competence individually in a standardized way, an alternative option (namely to let go of rigid age limits for alleged competence and switch to a case-by-case assessment) might be considered. For example, now that it is possible to establish a very intelligent eight-year old boy’s competence, we need to consider if it would be judicious to do so and to allow him an independent consent. Although our assessment instrument proved to be accurate, there might be possible drawbacks of the normative classification of children into groups of competent and incompetent ones.
Overall, we should evaluate whether the clinical assessment of children’s competence by an instrument is comprehensive, or that we miss out on important non-measurable factors. Finally, we need to consider if we are fully aware of the influence of developmental aspects affecting children’s competence, and if this makes children’s competence different from adults.

In this article we will reflect on possible implications of the recent empirical findings on children’s competence to consent considering normative, developmental, and clinical perspectives. Subsequently, we will derive recommendations for policies.

Discussion

Normative aspects
Considering children either competent or incompetent is a normative judgment. However, the fact that competence is a normative judgment does not mean that it cannot be informed by research data. Research shows that a competence assessment can be reliably performed using a structured tool like the MacCAT-CR. The MacCAT-CR’s total and sub-scores showed a good reproducibility and the overall accuracy of MacCAT-CR scores in correctly classifying children as competent against the reference standard was high as well.\(^\text{150}\) In addition, it was shown that using such a tool, three age groups could be distinguished: one in which children are most probably incompetent, one in which children are most probably competent, and a group in which probability of (in)competence is less clear (between 9.6 and 11.2 years). Such findings do not prescribe how ethics and law should deal with (in)competence and children. But, as we will discuss below, the findings may help to do justice to the capacities and challenges children may face when deciding about treatment and research options. For instance, for health care professionals, as well as parents, it is important to know that a structured and reliable tool for assessing competence in children is available. Performing such a structured competence assessment may clarify the capacities of an individual child in case professionals have doubt about the child’s competence. In addition, the findings concerning the age groups may support the development of guidelines dealing with informed consent in children. Still, clearly, the ethical and legal norm for competence in children cannot be directly derived from these research findings. For instance, establishment of cutoff scores for competence is after all based on normative judgments.
Ethical Aspects

Rational Reasons versus Emotions and Values
Some authors have raised doubts about the validity of competence assessment by MacCAT-scales, and argued that the MacCAT-assessment puts the main emphasis on rational reasoning. Ethicists and other commentators bring into the discussion the role of values and emotions in competence. In the case of patients with anorexia nervosa, Hope and colleagues(164) suggest that to develop a better understanding of competence, research needs to be expanded by factors of competences not covered by the four criteria that are commonly applied (understanding, appreciation, reasoning, expressing a choice). Charland argues that MacCAT-scales seldom sufficiently recognize emotive components and values in decision-making competence.(165) He states that “pathological values” may be present in patients with anorexia nervosa or substance abuse disorders, which are both mental disorders that effect competence. He proposes to incorporate a measure of emotional competence into a competence assessment instrument before considering it a valid measure. Appelbaum, author of MacCAT-T, agrees that emotions aid humans in processing information but suggests that the feasibility of adding emotional capacity to the list of capacities essential for decisional competence should be demonstrated first.(166) No consensus in this debate has been reached yet. It is conceivable that in children “immature values” might be present that are not covered by competence assessment using MacCAT-scales. The study on accuracy of MacCAT-CR in children was performed using a reference standard established by experts. In cases of anorexia nervosa and substances abuse disorders the pathological values might be recognized by clinical experts, in children we might expect the clinical experts to have recognized immature values when present in children. If not, the study might have missed out on an unmeasured component of children's competence. This would then have resulted in considering more children competent using the MacCAT-CR than actually justified.

Legal Aspects

Age-Limits versus Case-by-Case Assessment
It is widely recognized that the evolving capacities of children and adolescents are reflected by a gradual development of decision-making competence.(133) The use of a fixed age-limit as cutoff for competence is defensible, since age is an efficient proxy for competence with considerable practical advantages as an administrative and normative gauge. It can be
measured easily and offers a clear framework. However, the disadvantage of fixed age-limits is the all or nothing character, meaning that relevant differences between individuals are not taken into account. With a set age-limit, some incompetent individuals above the limit will unjustly be deemed competent and some competent individuals below the limit unjustly deemed incompetent.

An alternative for the fixed age-limit is a case-by-case assessment of decision-making competence. A recent study has shown that doctors and researchers tend to judge a child to be competent if the child's decision conforms to their own ideas of the child's best interest. This means that competence is gauged by the outcome of the decision rather than by the process of reasoning in deciding about participation. Data suggest that unstructured performance of competence assessments is often sub-optimal and hence the reliability of unstructured judgments has been poor. To avoid this bias, a case-by-case assessment would require an objective assessment instead of the currently used intuitive one. The MacCAT-CR would be an appropriate instrument for this purpose in the research context and there are indications that MacCAT-T is feasible for use in the pediatric treatment setting.

Reset Age-Limits
Age-limits for asking children's consent vary widely over nations and states. In Europe, domestic law determines whether or not people are competent to consent to healthcare interventions. In some countries autonomous decision-making is lawful only from 18 years onwards and in other countries minors are allowed to take healthcare decisions from a fixed age below legal majority, e.g., 12 years in the Netherlands and 15 years in Denmark. Another variant applied in most Canadian provinces and Switzerland is a flexible system stating that anyone who is capable can give informed consent, whereby competence is evaluated on a case-by-case basis. In the United States, generally speaking, it often falls to parents or legal guardians to provide informed permission for medical decisions and children under 18 are to give assent. Ideally, age-limits accomplish the goal of striking a proper balance in order to both protect children's interests when they are not fully able to do so themselves and to respect their autonomy when they can exercise it. So if a fixed age-limit is used, it must be generally in accordance with the developmental stages. Our research outcomes now 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 eleven or twelve years.
Informed Consent Instead of Assent

Children’s Decision-Making Competence in Civil Law and Criminal Law
The development of decision-making capacities in children is not solely of importance in health law, but also considered in other juvenile laws e.g., civil law and criminal law. In many jurisdictions the age of twelve constitutes a cardinal point, for example regarding adjudicative competence. The age of twelve is not very different from the ages for competence resulting from the studies with MacCAT-CR and MacCAT-T. However, there are arguments mentioned in literature to reconsider these age-limits for juveniles’ pre-adjudicative and adjudicative competence, and criminal responsibility, as adolescents in the criminal setting might show typical deficiencies in their decision-making due to additional risk-factors: for instance, 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. In addition, we should note that although there are certain similarities between competence and criminal responsibility, there are differences as well.

Developmental Aspects

Difference between Competence Assessment in Adults and Children
In adults, patients are deemed competent unless the clinician has reasons to believe otherwise. In children, it is generally the other way around, they are presumed not to be competent in most jurisdictions. Whereas in adults MacCAT-scales are merely used to ascertain incompetence in mentally compromised patients out of an overall competent population, in children it might be more important to discover competence in a mainly incompetent population. The application of MacCAT-scales in children puts higher demands on the specificity of the instrument; it serves to weed out the proportion of children that are correctly identified as competent from those (possibly incorrectly) identified as incompetent. In the MacCAT-CR study, specificity in children of 11.2 years and older was good: 90%.

Parent versus Professional
Research showed that judgments of incompetence by parents frequently coincided with the MacCAT-CR incompetent classification, however parents’ assessments of competence showed only moderate agreement with the MacCAT-CR standard. This might imply that parents express a higher expectation regarding their children’s competence, assigning them more voice and responsibility, than professionals do. In literature the opposite
was described: in a sample of 120 young people undergoing orthopedic surgery in 1993, health professionals recommended a much lower mean age for competence than parents did (10.3 vs. 13.9). The recent finding that parents judged their children more readily competent than clinicians, might be related to the specific dynamics of parent-child relationships. Parents are expected to inhibit their child's impulsive, risky, and sometimes harmful behavior and to substitute the child's ineptitude and inability to judge situations, appropriate behavior and actions with their superior judgment. Parents tailor their parenting behavior to the specific abilities of the child. Children who are raised in a warm and understanding atmosphere are often able to present their part in a joint decision-making process at an early stage of their development. An authoritative parenting style, which includes direction-giving and limit-setting, is positively related with an adolescent's capacity for autonomous decision-making. In the medical context children might be capable of autonomous decision-making, albeit, within the guiding environment set by their parents. Possibly parents assign their children more decision-making competence than professionals do, because parents shape the family context and professionals regard the child more independently.

Assessment Must Cover Developmental Aspects
Differences between children and adults regarding decision-making competence have been found in the ability to restrain impulsivity and in the ability to place a given decision in a larger temporal context. The inadequate capacity of children in risk assessment could be connected to the late full maturation of the frontal lobes that are essential for effective executive functions. Adolescents generally do not fully possess the capacity to appreciate the long-term consequences of their choices until the age of 21. Research demonstrated a difference between decision-making under low levels of arousal or in situations with low emotional upheaval (cold cognition), and thought processes under high levels of arousal and emotional valance (hot cognition). Hot cognition may result in intuitive responses rather than carefully considered, rational responses. Decisions on medical research participation involving information provision, rehearsal of information, time to consider, and reflection with parents, generally result in cold cognition decisions. Treatment decisions are more prone to hot cognition when involving time pressure or weighty risks. With the research results showing that children of 11.2 years and above have comparable decision-making capacities to adults concerning research participation, we need to consider their possible immaturity in decisions of a supervisory or
managerial nature normally made by their parents, for example overseeing the family agenda, or arranging transport to the hospital. Possibly, children are able to decide with cold cognition on research participation, but are less able to responsibly respond to, for example, unforeseen traffic situations and therefore need the dyadic relationship with parents who provide the necessary direction-giving and limit-setting.

Practical Aspects

From a practical point of view, 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. A selective implementation of a standardized competence assessment in exceptional cases would be preferable over a broad implementation (Table 8).

Table 8. Recommendations for Structured Assessment of Decision-Making Competence in Children in the Clinical Context

<table>
<thead>
<tr>
<th>Context</th>
<th>Proposal</th>
<th>Comments</th>
</tr>
</thead>
<tbody>
<tr>
<td>Treatment</td>
<td>Individual cases: strike proper balance between protecting and respecting the child's interests</td>
<td>General population: burden on medical system, not much better than age limits</td>
</tr>
<tr>
<td></td>
<td>Children &lt; 12 years: if competent in exceptional case with weighty decision</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Children &gt; 12 years: in case doubts exist on competence</td>
<td></td>
</tr>
<tr>
<td>Research</td>
<td>Individual cases: children between 10 and 12 years</td>
<td>General population: burden on medical system, not much better than age limits</td>
</tr>
<tr>
<td></td>
<td>Children &gt; 12 years: in case doubts exist on competence</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Feasible for research purposes at group level</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Feasible in special research populations (intellectual disabled, psychiatrically ill)</td>
<td></td>
</tr>
</tbody>
</table>

For the research context, under the age of 9.6 years children were generally incompetent to decide on research participation, so an individual assessment does not seem profitable. Children between 9.6 and 11.2 years were in the change-over period, an individual assessment of competence might be applicable in this age group. Children of 11.2 years and above can generally be considered decision-making competent, no individual assessment is needed unless there are reasons to doubt a child's competence. In special
research populations like intellectual disabled children or pediatric patients with a psychiatric disorder that diminishes competence, a research protocol could include a standardized competence assessment of participants in order to warrant the interests of incompetent patients.

In the treatment context, there are no conclusive age-limits for competence established empirically, yet preliminary findings indicate agreements with the research context. An age-limit that is generally in accordance with the age that children reach decision-making competence could be applied; derived from the studies on MacCAT-CR and MacCAT-T a preliminary appropriate age may be 11 or 12 years. In case of doubt, competence will have to be assessed in children older than 12 years as well. Individual competence assessment of all pediatric patients in the change-over period might possibly overburden clinicians. However, it may be valuable to create the possibility for clinicians to take into account exceptional cases, such as the assessment of a child under the age of 12, seemingly competent, who has to make a weighty decision. In these cases an individual standardized competence assessment contributes to substantiate the exception.

Parents are generally provided with the legal authority to raise their children, assigning them rights and responsibilities. To achieve an equitable 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 establish a child's decision-making competence regarding the medical decision at hand, a double consent procedure will do justice to developmental aspects of children and the specific characteristics of the parent-child dyad. The parental role is needed to offer extra protection by creating the context for the child's competent decision-making and by facilitating the child's long term autonomy.

Besides the advantages of a double consent procedure, there may be a disadvantage concerning possible disagreement between child and parent, which may require elaborated policies. In the Dutch situation experience has been gained with a double consent procedure and evaluation shows that disagreement between parent and child was not a concern.(168;169)

A double consent procedure is fundamentally different from a procedure of parental permission and child assent, and would imply a considerable shift regarding some current legislations. For instance, in the current Code for Federal regulations of the United States (13) by definition children are "persons who have not attained the legal age for consent to treatments or procedures involved in the research" (45CFR46.402(a)). The legal age of adulthood is a matter of local law, but is in a large majority of states 18 years.
Regulations state that some children might be able to give their assent, meaning an affirmative agreement. However, in research the institutional review board may still waive the assent requirement under certain circumstances (45CRF46.116). Some authors have proposed that children's assent should only be required from a fixed age of 14 years, based on theories of subject autonomy and child development. (170) The empirical evidence that children are generally competent not only to assent, but even to consent from the age of 12 offers a force opposing to these regulations and theories. There is no indication of a considerable difference in children's development between regions with widely varying policies regarding children's consent. These local variations in regulations may have evolved under the influence of historical, cultural, or emotional preferences, representing a local normative view. Empirical data now provide underpinnings for more evidence-based age limits in policies.

Limitations and Directions for Future Research

Although our recent empirical research provides substantial data to consider in debate and practice, many aspects of children's decision-making competence are still to be studied, of which we will name just a few. For instance, regarding medical decision-making, the age limits for reaching legal majority vary between countries and states from 16 to 21 years. Research does not show at what age a double consent procedure will no longer prove effective. In addition, more research is needed to demonstrate the validity of a cutoff score on a standardized assessment instrument for competence and the desirability of such a cutoff must be considered. In the treatment setting, more extended research on reliability and validity of the MacCAT-T in children is recommended. The importance of children's decision-making competence is not confined to the medical context alone but may be of significance to adjacent fields, for instance children's competence to proceed to criminal adjudication or to be consulted in civil procedures, which requires further research. Furthermore, new developments in neuropsychiatry may contribute to the understanding of the functioning of specific brain regions or connections that promote competent decision-making.

Summary

Research outcomes show that the legal concept of medical decision-making competence could be operationalized into a standardized assessment instrument for children in the clinical context. The MacCAT-CR proved
accurate for children’s competence assessment in clinical research, preliminary findings show feasibility of MacCAT-T in the treatment setting. Developmental aspects, especially the fine-tuning of decision-making within the parent-child dyad, including the broader family context, are of importance in addition to a standardized competence assessment.

Policy recommendations include a selective implementation of individual assessment of children’s competence in medical decision-making by a standardized tool in combination with practicable, generally appropriate age-limits. In the research context children can be deemed competent from the age of 12 and above, preliminary findings suggest the same age-limit for the treatment context. In the research context, case-by-case assessment of competence might be valuable in children in the change-over period between 10 and 12, in special research populations of mentally comprised patients, and in case of children older than 12 years when there are reasons to doubt their competence. In the treatment context, individual competence assessment might create an opportunity in exceptional cases to allow a competent child under the age of 12 to co-decide over significant medical interventions. A double consent procedure, including both child as well as parents, is recommended for children from the age of 12 until legal majority.