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Children's competence to consent to medical treatment or research

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Publication date

2015

Document Version

Final published version

[Link to publication](#)

Citation for published version (APA):

Hein, I. M. (2015). *Children's competence to consent to medical treatment or research*. [Thesis, fully internal, Universiteit van Amsterdam]. Amsterdam University Press.

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1 Introduction

In the past, children were often excluded from participating in trials out of protection for their well-being, in light of their vulnerability and assumed incompetence. In addition, pharma industry did not want to invest in studies in infants and children as the profits were deemed to be small or even non-existing. This led to a lack of significant research data on the effects of drugs in children, which, inadvertently, places sick children in jeopardy. In daily pediatric practice, patients' competence to consent is usually assessed implicitly because of the assumption that children's ability to understand medical issues is limited.

Strictly speaking, competence to consent denotes a legal status, representing an informed, free, self-determined choice based on understanding and rational reasons.⁽¹⁾ Competence is task and context specific.⁽¹⁾ Incompetence should, in principle, be determined by a court; however, good pragmatic reasons exist to continue the traditional practice of having clinicians determine patients' competence.⁽²⁾ From a clinical perspective, competence is generally addressed as decision-making capacity,⁽³⁾ involving factors as developmental stage of children, influence of parents and peers, quality of information provision, life experience, and the type of medical decision to be made. However, law is established on a strong presumption that persons older than a certain age are competent, whereas younger persons are not.

Until recently, there was no empirical evidence on children's competence to consent to treatment or clinical research. The reliability of unstructured competence assessments up to now has been inconsistent, because clinicians possibly did not know which standard to apply,⁽²⁾ rendering age standards prescribed by law as the guiding principle in their assessments. To complicate matters further, the age limits of these standards for deeming a child competent to consent vary widely between countries.⁽⁴⁾ Also, absent a standard, clinicians tended to judge a child competent if the child's decision conformed to their own ideas of what was in the child's best interest.⁽⁵⁾

Therefore, more understanding of the issues involved in children's competence to consent in medical decision-making is needed. The aim of this research is to make recommendations for optimizing policies, in order to do justice to the capacities and challenges children face when deciding about medical treatment and clinical research options. If a fixed age-limit for alleged competence is used, it must be generally in accordance with children's developmental stages. In an ideal situation, statutory

age-limits must 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 are able to exercise it. Furthermore, for health care professionals as well as pediatric patients and parents, availability of a reliable standard for assessing competence is important.

We attempt to find answers to key questions. What are currently the most efficient practices for assessing children's competence to consent in pediatric practice? Are there any adequate test instruments available, and, if not, could we try to fill this gap? Having an assessment tool at our disposal, which age limits for competence to consent in children can be gathered? And which factors exactly affect children's competence to consent in medical decision-making? Taking into account that recruitment of children for clinical research remains one of the main difficulties, what strategies could optimize research participation of children? Furthermore, in what way could this empirical knowledge on children's competence contribute to policymaking?

The little progress achieved over the last decades in normative discussions on children's competence is dealt with in chapter 2, where we suggest a possible research agenda to make way for advancements. In chapter 3, we inventory the most adequate instruments for assessing competence.

Chapter 4 contains the research protocol of our study on children's competence assessment by a standardized tool. The results of this study are demonstrated in chapters 5 and 6, in which we describe our findings on the reliability and validity of the MacArthur Competence Assessment Tool for Clinical Research in pediatric patients of 6 to 18 years of age, and the age limits found for competence, followed by an analysis of determining factors for children's competence.

Chapter 7 examines our study on the MacArthur Competence Assessment Tool for Treatment in children and shows preliminary findings on feasibility. In chapter 8 we present a qualitative and quantitative analysis of reasons for the high rates of children's non-participation in research in order to derive strategies to optimize research participation of children.

The possible implications of the research findings for policymaking are discussed in chapter 9. The thesis concludes with a summary of the results and a reflection on future perspectives regarding research on children's decision-making competence (chapter 10).