COMMENTARY

Obtaining assent for research involving children in Malaysia: a position statement from the Academy of Medicine of Malaysia College of Paediatrics

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SUMMARY

The Academy of Medicine of Malaysia College of Paediatrics acknowledges the role of children in research and this position statement explores the ethical considerations in obtaining assent from minors in the Malaysian context. It highlights the importance in respecting children's agency and navigating cultural complexities. The College proposes flexibility in the minimum age for assent of at least nine years old, while emphasising the need for a tailored assent procedure. Addressing language and cultural diversities and expanding local empirical research on a formal assent process are some building blocks in developing a standardised nationwide process in obtaining assent from children.

INTRODUCTION

The Academy of Medicine of Malaysia College of Paediatrics (the College) recognises the importance of involving children in research conducted within Malaysia. This acknowledgment serves to not only ensure inclusive representation but also to bolster the applicability of study findings across all age groups. Traditionally perceived as a vulnerable population, the exclusive reliance on research outcomes from adult studies, for example, is now deemed insufficient for establishing the essential evidence required to support the safe prescription of therapies or justify off-label drug use in children. Despite this imperative shift, responsibly engaging minors in research presents distinctive challenges, with one notable aspect being the process of obtaining assent.

In delineating this relationship between researchers and child participants, it is crucial to clarify the distinction between consent and assent. While informed consent is a well-established process requiring capacitated participants to voluntarily agree to take part in research after being fully informed about the study's objectives, procedures and potential risks; assent, by convention, pertains specifically to minors. Assent is the affirmative agreement from a child who may not have the legal capacity to provide full consent. Furthermore, children's cognitive capacity is not fixed but rather develops with age. As such, assent cannot be similarly applied to adults with impaired capacity.[1,2] Unlike informed consent, which is legally binding, assent is a more nuanced concept, recognising the evolving cognitive and decision-making abilities of children. It serves as a process through which researchers engage with minors, respecting their agency (the right to express themselves and influence decisions that concern them) and ensuring they understand the research to the extent of their developmental capabilities. The incorporation of assent requirements in research involving children marks a significant shift in research ethics, emphasising researchers' responsibility to acknowledge and respect children's preferences, choices and agency. This departure from the sole focus on children's cognitive capacity represents a broader consideration of moral concerns in our interactions with others. Although the concept of assent is theoretically clear, its ethical underpinnings and practical application remain less defined.

The College acknowledges that researchers may obtain assent merely as a procedural formality, prompting a call for a deeper and committed standard of practice. This concern has been amplified by the focused discussions on the challenges inherent in seeking assent, a key theme during a workshop led by Steven Joffe in the Third National Paediatric Bioethics Symposium, an event organised by the College.[3] The authors of this position statement, who are experts actively involved in paediatric research, clinical management and contributions to relevant guidelines, participated in the workshop and are integral to the Academy of Medicine of Malaysia's Ethical Professional Practice or Executive Council Members of the College.

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By appreciating the evolving capacity of minors in decision-making and the need to facilitate their comprehension of the research they are partaking in, this position statement aims to describe the challenges and articulate the essential elements needed to ensure the development of best practices in obtaining assent from children involved in research in Malaysia.

CHALLENGES

One of the primary challenges is determining the appropriate age for seeking assent, as specified by the Malaysian Research and Ethics Committee guidelines, which range from seven to 18 years old.[4] While the age of majority is 18 in Malaysia, the rationale behind the age of seven probably stems from the significant cognitive shifts that occur around this point.[5] At this age, children exhibit less egocentrism, display an ability to consider perspectives of others, and comprehend the consequences of their actions on others. However, differing perspectives exist. Grisso and Vierling[6] argued that minors only start to demonstrate competency comparable to that of adults at the age of 15. They even suggested caution for those between 11 and 14 years, proposing a need for careful consideration of their capacity to understand treatment complexities; and clearly states that those below 11 years old lack the intellectual capacity or tend to defer authority and self-determination, potentially falling short of legal standards for competent consent. Empirical data also lends substantial support to these considerations. For instance, while a study reveals that 14-year-olds exhibit no significant disparity from adults in their capacity to comprehend and reason about treatment information, 9-year-old demonstrate comparatively lower proficiency when compared to adults in their ability to grasp and rationalise the provided treatment information.[7] In a separate analysis focusing on children's assent in clinical anaesthesia or surgery studies, it was observed that those under the age of 11 displayed limited comprehension of disclosure elements and their role as research participants.[8] Additionally, Ondrusek et al concluded that the majority of children below nine years old lack the cognitive capacity to provide meaningful informed consent or assent to participate in clinical research.[9] With such diverse reported findings and recognising the lack of concrete studies to establish the most appropriate age threshold for assent, it appears reasonable to select the option that minimises the potential resulting harms. Until instruments are developed to assess the assent capacity reliably, it has been proposed that the threshold be fixed at the age of 14.[10,11] Collectively, the requirement for assent documentation in children also varies among research ethics committees. Kimberly et al.,[12] observed that while certain committees required assent from children as young as 6, others did not mandate assent documentation for children under 15 years, even when utilising the same research protocol. Correspondingly, a scoping review[13] of 116 articles conducted until November 2020 revealed that the reported minimum age for obtaining assent ranged between 5 and 13 years, with a median of 7.5 years. Only a handful of studies provided a rationale for their decision; some proposed a “school-age threshold”, highlighting the “considerable capacities of five- to seven years old children”, while others contended that children under 11 years possess a limited comprehension of research information.[10]

Recognising the language diversity in our country, the College acknowledges a second challenge related to literacy and potential communication barriers. Malaysia has a multi-ethnic population with speakers of 137 distinct living languages,[14] although only a fraction of them are inhabitants in Peninsular Malaysia. Even among the three major ethnic groups—Malay, Chinese and Indian—there are notable dialect variations that hold considerable influence as children communicate in their mother tongues. This linguistic complexity further highlights the importance of considering factors such as intellectual development, life experiences and proficiency in each language. These elements significantly impact a child's comprehension during the process of obtaining their assent in research. It is imperative to address these linguistic subtleties to ensure effective communication and a thorough understanding of the research context across diverse language communities.

Cultural differences in Malaysia extend beyond language and literacy, delving into complex cultural dynamics deeply rooted in tradition. The third challenge arises from the diverse socio-cultural and religious practices within each ethnic group, exerting a profound influence on decision-making and lifestyle choices. These factors amalgamate into established social hierarchies, defining specific roles for children within society. An even greater challenge is the involvement of underprivileged children as research subjects in a conservative society that requires cultural humility and proper assent practices.[15] In understanding and differentiating the roles of mothers and fathers, particularly in a predominantly patriarchal society, navigating these dynamics becomes even more critical. The process involves balancing the values of dignity, autonomy and family integrity, considering the aspects of respect, family connections and social relationships. Some decisions are influenced by the collective actions of people, rather than by individual choices. Collective agency, which refers to the ability of people to act together for a common purpose, provides a nuanced explanation for these decisions, challenging the traditional understanding and operationalisation of 'autonomy' in bioethics, which focuses on the rights and preferences of each person.[16]

Adding to these challenges is the discordant decision-making process in consenting and assenting to research participation. The issue of whether a researcher should proceed with enrolment when a parent or guardian consents but the child dissents, raises an ethical dilemma in the local setting. Conversely, situations may also arise where a child assents, but the parent or guardian does not consent. These are unsettled issues and warrant continued conversation. In any case, effective communication becomes crucial to address concerns and misconceptions, fostering a shared understanding and trust among all parties involved. Obtaining assent within the context of a complex network of family, community and culture structures will help researchers support the process of value-concordant and culturally appropriate decision-making for parents, guardian, and child.

RECOMMENDATIONS

Considering the challenges associated with obtaining ethical and effective assent for research involving children in Malaysia, the College proposes several recommendations to address these issues towards best practice.

1. Recognising the importance of respecting children as individuals with their own rights, the College suggests a flexible approach to the minimum age for assent. Specifically, the College recommends raising the minimum age to at least nine years old, guided by current available evidence. Additionally, this flexibility should be applied with consideration for the complexity of the research, ensuring that the assent process is age appropriate. Such an approach not only acknowledges the child's agency but also aids in the development of decision-making skills crucial for adulthood, contributing to the cultivation of trust in an era of evolving healthcare systems.
2. The College emphasises the need for tailored assent procedures that account for varying educational levels among children. To enhance comprehension, the College suggests customising assent procedures by integrating visual aids, multimedia resources, verbal explanations and open question sessions. Innovative methods, such as combining images with text or utilising multimedia, can further ensure the development of its best practice.
3. The College calls attention to the dynamic nature of the assent process, emphasising that obtaining assent is a dialogue. While the College advocate for researchers documenting a child's assent for accountability, the process is not a one-time signature on a form, that could all the more so place a burden on the child to engage in a significant act they might not fully comprehend. Recognising assent as an ongoing and dynamic process, continuous evaluation is desirable.
4. The College addresses the diverse linguistic landscape of Malaysia by recommending proactive language accessibility. This includes addressing translation needs to ensure inclusivity. Furthermore, the College advises granting sufficient time and privacy for consultations with parents, guardians and children. Additionally, extending this process to include discussions with extended family members or community members, as applicable, is deemed crucial. Cultural nuances that may influence the assent process should be acknowledged and navigated accordingly.
5. Given the absence of data on the appropriate age for obtaining assent in Malaysia, the College recommends and supports the conduct of local empirical research in this area. This research aims to better understand the cultural contexts within Malaysia and subsequently formulates the basis for developing assent practices nationwide. Such an approach stresses the importance of tailoring assent procedures to the unique cultural diversity present in Malaysia.

CONCLUSION

Addressing the challenges of obtaining assent from minors in Malaysia requires a multifaceted approach. This position statement by the College not only delineates its challenges but also outlines a path forward, emphasising the importance of respecting children's developing capacity and ensuring effective communication, while navigating Malaysia's socio-cultural landscape. Establishing local policies and guidelines must be dynamic and responsive to evolving research and societal norms. Advocating for best practices at a local level will deepen understanding and inform the formulation of standardised nationwide assent practices.

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DISCLAIMER

The recommendations in this position paper are based on the expert opinion of the authors, after seeking the best available and current evidence on assent from children. These may change when more studies are conducted in the future and new evidence emerges.

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