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A Framework for Evaluating a Minor's Involvement in Medical Decision Making

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Olszewski and Goldkind's (2018) article on pediatric decision making in the clinical care setting is articulate and well written. The authors understand the challenges in ensuring that pediatric patients can participate in decisions regarding their care. The authors present a stepwise approach or framework to assess the child's readiness to participate in the assent process, including an evaluation of the context in which assent will be obtained, and suggest a series of questions to ascertain the child's understanding of the clinical situation. The authors recognize that some factors that must be considered, such as age, are fixed, but that other factors, such as the maturity of the child, are child dependent. The authors use the regulatory requirement for research assent under subpart D (21 CFR 50 and 45 CFR 46), approaches to consent in cognitively impaired adults, and case studies where clinical care has been refused, to inform their approach.

Discussions of assent in pediatric research originated after the post-World War II Nuremberg trials. Until the early 1970s, it was thought acceptable to enroll children only in clinical trials for therapeutic purposes. Some argued that proxy consent by the parent for participation in therapeutic trials without child assent was acceptable because children, if given a choice, would choose life and health because of the desire for self-preservation (McCormick 1974). Bill Bartholome, in his 1977 essay for the National Commission for the Protection of Human Subjects of Biomedical and Behavioral Research, proposed that child assent must be obtained for nontherapeutic research where there was no prospect of direct benefit, stating, "No child should be allowed to participate in non-therapeutic research unless serious effort was made to obtain his/her consent" (Department of Health Education and Welfare 1977). Bartholome's continued work on parental decision making and child assent resulted in the development of a 1995 policy statement by the American Academy of Pediatrics (AAP) Committee on Bioethics: "Informed Consent, Parental Permission, and Assent in Pediatric Practice" (American Academy of Pediatrics Committee on Bioethics 1995). This policy statement did not differentiate between therapeutic and nontherapeutic procedures, but stated that "patients should participate in decision-making commensurate with their development; they should provide assent to care whenever reasonable."

One of the premises of Olszewski and Goldkind's article is that a structured approach for assessing a pediatric patient's understanding of relevant aspects of a proposed (clinical or research) intervention had not been considered in the past. The 1995 AAP policy statement does contain a structured approach and includes a list of considerations for obtaining child assent. These considerations included the following:

1. "Helping the patient achieve a developmentally appropriate awareness of the nature of his or her condition."
2. "Telling the patient what he or she can expect with tests and treatment(s)."
3. "Making a clinical assessment of the patient's understanding of the situation and the factors influencing how he or she is responding (including whether there is appropriate pressure to accept testing or therapy)."
4. "Soliciting an expression of the patient's willingness to accept the proposed care. It is noted that no one should solicit a patient's views without intending to weigh them seriously. In situations in which the patient will have to receive medical care despite his or her objection, the patient should be told that fact and should not be deceived."

Although not identical to the questions proposed by Dr. Atul Gawande, these considerations address similar concerns regarding the understanding of the illness by the child, what the expected outcomes may be, and how the treatment or intervention may impact the decision. The 1995 AAP policy statement also includes a discussion on the importance of shared decision making that involves the parents, the child, and the health care provider.

The AAP Committee on Bioethics expanded their policy statement in 2016. The updated AAP policy statement "Informed Consent in Decision-Making in Pediatric Practice" includes the same considerations listed in the preceding and a thorough discussion of specific aspects of child assent, such as a requirement to include information on the nature of the illness or condition, that consent is voluntary, that the decision-making capacity of the child should be assessed, and that there should be an appropriate balance between the developing autonomy of the child and the responsibility of the parent to protect the child and the child's interests (American Academy of Pediatrics 2016). The policy statement also describes the various standards for surrogate decision making (in its Table 3, reproduced here).

Standards for surrogate decision making in pediatrics

Best-interest standard	Surrogate should aim to maximize benefits and minimize harms to the patient, while using a holistic view of the patient's interests
Harm principle	Identify a harm threshold below which parental decisions will not be tolerated
Constrained parental autonomy	Parents may balance the best interest of the patient with the family's best interest if the patient's basic needs are met
Shared, family-centered decision making	Process that builds on collaborative mechanism between families and clinicians

The emphasis in Olszewski and Goldkind's article is clearly on the child's involvement in medical decision making; the concept of decision making in the context of the family unit is largely left unexplored. It appears that the authors favor a best-interest standard for the child that maximizes the benefit to the child and minimizes harms. However, there are other family-centered approaches, as noted in the preceding, where the decision for the child is balanced against the needs of the family if the child's basic needs are met (American Academy of Pediatrics 2016; Ross 1998). Mary's choice to not know her diagnosis and leave decisions in the hands of her parents is consistent with a family-centered decision-making model and is perfectly acceptable. Her decision likely is impacted by her relationship to her parents and her perceived role within the family (Miller, Reynolds, and Nelson 2008). Although the medical staff members are concerned that her impending death is being kept from Mary, it is likely that she is aware that she is dying and chooses not to discuss the situation with her parents. Myra Bluebond-Langer in her book *The Private Worlds of Dying Children* reports that children often understood they were dying without needing to be told directly (Bluebond-Langner 1978). Children maintain the pretense of not knowing their diagnosis with their parents and health care providers to maintain hope within the family that they might recover from their illness and to remain "treatable" in the eyes of their physicians (Bartelt 1998). When these children interact with their peers, they may be willing to talk openly about their diagnosis. Of note, the authors were unable to ask Mary Dr. Gawande's five questions because of her unwillingness to know her diagnosis. Consequently, the authors' framework may not be applicable in situations where the child does not want to actively participate in medical decision making.

Olszewski and Goldkind include a discussion of the regulatory requirements for research assent in their review. They state that "if the research poses the potential for direct benefit for a life-threatening illness, assent can be waived by the IRB." However, this waiver of assent requires that the treatment is only available in the research setting and not elsewhere. Consequently, this criterion for waiving child assent would not apply in the clinical setting. However, parents are responsible for ensuring that their child receives appropriate care for life-threatening illnesses. There may be cases where the parent may override the child's refusal of treatment because the treatment is in the best interest of the child. Hopefully, when this happens, the child is informed of the parents' concerns and does not feel coerced to accept the treatment.

The framework proposed by Olszewski and Goldkind provides guidance on how to assess a child's ability to participate in medical decision making and the factors to consider when discussing a medical care plan with a minor. However, the ideas presented are not new; all the concepts in this article are found in the 2016 AAP policy statement. Nevertheless, the framework may provide a different perspective to practitioners when assessing a child's ability to assent to treatment and the tool may be more user-friendly, since all the considerations are included on a single page. The framework's value may be limited by the child's willingness or cognitive ability to answer the five questions.

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