Short Communication

Clinical Pediatrics in the Philippines: Parental Assent and Consent

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Abstract:

The involvement of children in the acceptance or refusal of any proposed plan of management in the Philippinesis discussed. The practice of pediatrics includes patients who can already sign the informed consent form on their own and those patients that require a parent or legally authorized representative to provide the necessary consent for them. Assent from minors has always been required by Philippine guidelines for health and health-related researches. However, this same assent has never been mandatory in the clinical practice of health care in children until recently.

Keywords: Autonomy; Assent; Clinical Pediatrics; Parental Consent; Ethics; Parental Permission; Philippines

General Objective

Discuss ethical bases for decision-making in pediatric patients and considerations for the involvement of children in the acceptance or refusal of any proposed plan of management in the Philippines.

Specific Objectives

1. Review the moral principle of autonomy in the context of pediatric clinical practice;
2. Discuss the ethical foundations and ethical models for parental decision-making;
3. Elaborate on assent as a component of decision-making among pediatric patients;
4. Elaborate on the refusal of treatment by minors;
5. Discuss the ethical, legal, and sociocultural implications of consent, assent, and refusal in the clinical practice of pediatrics in the Philippines.

Scope and Limitations:

The discussion focuses on informed consent, assent, and refusal in the clinical practice of pediatrics. This does not elaborate on informed consent, assent, and refusal in the end-of-life care of children, or in the setting of health and health-related research involving pediatric subjects. The concept of medical futility is best addressed in a discussion devoted to the moral principle of justice.

Disclosures

None.

FRAMEWORK OF MEDICAL ETHICS

A commonly employed framework of moral principles reflecting the common morality is principle-based ethics as defined by Beauchamp and Childress. Four moral principles are considered when seeking options in patient care and professional behavior. These include respect for autonomy, nonmaleficence, beneficence, and justice. [1]

Respect for autonomy includes the key elements of liberty, defined as the capacity to live life according to one's own reasons and motives and agency, defined as the rational capacity for intentional action. Although many pediatric patients lack the agency required to act independently, this framework remains important in resolving ethical dilemmas. [1]

In the practice of pediatrics, most discussions regarding the direction of care are three-sided, and involve the physician, the patient, and the patient's surrogate. Most commonly, the parents will act as the patient's surrogate decision-maker within the framework of family autonomy and privacy. This allows decision-making within broad ethical boundaries that reflect family values. A parent's medical decision-making for their child can be framed as a responsibility, rather than a right, with the focus remaining on the child's best interests and freedom from undue harm, rather than the parent’s assertion of autonomy. [1]

The patient in this triad is expected, when capable, to provide assent. Assent from children aged seven years for medical examination and contemplated surgery can foster moral growth and developing autonomy. This contributes to empowerment and potentially even compliance with the treatment plan. [2, 3, 1]

The discussions regarding medical decision-making should be understood as a longitudinal process over time. It is important for physicians to recognize that many decisions are made for the duration of the illness as new information emerges. Throughout this process, it is very important that the child is not deceived and with certain limitations, the physician should allow the child as much control over the diagnosis and treatments as possible. [1]

INFORMED CONSENT

Informed consent is central to modern medicine. This incorporates concepts from the fields of sociology, ethics, and law. [2] The phrase ‘informed consent’ is adopted verbatim from a legal opinion filed by the American College of Surgeons in the United States Supreme Court. [1] The key elements of informed consent include [4, 5, 6]:

1. disclosure of information;
2. assessment of the decision maker’s capacity to make medical choices;
3. the process of obtaining consent in the form of a voluntary agreement from the patient without undo coercion or persuasion.

Informed consent, also known as *informed permission*, in pediatrics proceeds from a parent or guardian who makes decisions on behalf of the child. [1] In unique situations, this permission is not compulsory such as in emergency care where the anticipation of parental permission would cause unwarranted harm, or in other circumstances in which minors can provide their own consent. Among various jurisdictions, these circumstances might include situations covered in legislation on mature minors, emancipated minors, or a court determination of a mature minor’s status. Besides these, the process of obtaining informed consent generally requires parents acting as decision makers on their behalf. [2, 3, 5]

Informed consent in pediatrics is unique; decision making on behalf of minors is anchored on principles that diverge from those in adult medicine. While parents are often viewed as substitute decision makers for their children, the **standard of substituted judgment** used in the decision making of substitutes for previously self-sufficient mature patients does not apply, as most children are incapacitated to make their own choices. [2]

In the **best-interests standard,** utilized in minors, parents are generally regarded to be in the best position to determine their child's best interest. Parental decisions aim to maximize benefits for their children while minimizing harm. However, the determination of what is in children's best interest is often subjective and debatable. [3, 7]

The **harm principle** allows parents to choose the best decision for their children by allowing choices that does not cross below a clearly-defined minimum threshold—that is, any decisions or option is tolerated as long as it does not cause unwarranted injury. [8]

Constrained parental autonomy is another accepted principle and model where while parents are empowered to make decisions on behalf of their children, they are "constrained" in such decisions by balancing the best interests of each child and of other family members. [6]

Finally, there has been a trend toward **shared family-centered decision-making** with its emphasis on ongoing communication and decision making with the whole family and clinicians. The consideration of multiple viewpoints is valued in the decision making for children. [6]

ASSENT

A written or verbal informed parental permission may be enough for ethical and legal purposes, but it does not meet the requirements of the ethical concept of informed consent. A specific role has been advocated for older children and adolescents in their decision making. [3] The concept of pediatric assent was well articulated in 1982 by William Bartholome when he wrote that, "assent of the child is indeed an idea before its time. It is a fragile idea that can easily be crushed amidst the boulders of consent, autonomy, rights, and competence. It's an idea that is so foreign to adult reality that its central thrust is missed even by astute minds." [9, 10]

Including **assent** in medical decision-making allows children to express their interests. While, informed consent has been a cornerstone of clinical decision-making, the inclusion of children in the decision-making process and the solicitation of their assent is less widespread. [2, 3]

Multiple professional organizations, including the American Academy of Pediatrics (AAP) and the Confederation of European Specialists in Pediatrics (CESP), have endorsed and published statements calling for the solicitation of assent in practice. Consent and assent, while related concepts, substantially differ and are used differently. [5, 11]

The requirements for assent according to Katz include elements of [6]:

1. informing patients in a developmentally appropriate manner about the issues at hand and what to expect;
2. assessment of their understanding; and
3. soliciting agreement or acknowledgment of the decision.

Assent is not necessarily a contract and is individualized to their understanding. Obtaining assent and parental permission through informed consent affords minors a chance to contribute and partake in their healthcare. This broods an open and honest relationship between the family and healthcare team. [2]

While assent is now recommended for medical decisions involving minors and is backed by policy statements in most western countries, there have been no clear guidelines on the solicitation of assent in clinical practice. Ethicists and policymakers agree that **one should not attempt to obtain the child's assent if the treatment or diagnostic test is required**. [1, 5] Clinicians often struggle with determining the suitability of children in medical discussions leading most of them to not obtain assent. Though, children as young as the age of seven [3, 1, 5] to nine years [2] are able to provide some input on medical decisions and give assent, their inclusion in these discussions should be based on their developmental level, experience, and familiarity of their medical condition. Physicians differ in their perspective toward assent unduly hampering the widespread adoption of assent in clinical practice. [2, 3, 5]

When pediatricians view assent as an ideal rather than an obligation, more children are more likely to be involved in the decision-making process. Distinguishing assent from consent and contextualizing conversations to **how children should participate** in contrast to when they should contribute to the discussion have been proposed as ways to advance the acceptance of consent and assent in the clinics. [2]

Determinations of **capacity,** or the conditions that permit a child to give consent, are made by clinicians at the bedside. These are based on the ability to provide informed consent rather than being based on its quality. Patients should understand and appreciate the diagnosis and the options, decide, and understand the consequences. Similarly, these same requirements guide assessments on the ability to provide assent. [2, 5]

Although many minors reach the cognitive development that allows abstract thinking by mid-adolescence, recent studies on brain structure and function demonstrates slower development of executive function and judgment. Recall that executive function is key to the ability to balance risks and benefits and plan for long-term goals, skills that are necessary for meaningful informed consent discussions. While self-regulation and impulse control develops during young adulthood, reward seeking behavior is prominent during adolescence, resulting in the risky behavior often seen in this age group. There is evidence that, in general, **adolescents make decisions differently than adults**, and this slow neuromaturation may limit the adolescent's medical decision-making ability, despite good cognitive skills. [1, 3]

“Can the child understand at an age-appropriate level the proposed plan, provide or decline permission for the plan, and understand and appreciate the consequences of this decision?” If so, the child can provide assent. **The level of understanding necessary in categorically accepting or refusing a plan which has already been decided on by the parents is less than that used in considering all the risks, benefits, consequences, and alternatives as obligated by informed consent**. Thus, the provision of consent generally follows from the presence and exercise of a more robust level of executive function and judgment than that proceeding from the provision of assent. [2, 3, 4]

While those with neurologic and psychiatric conditions may not meet these prerequisites, they should be afforded the greatest extent of involvement possible and their lack of capacity reconsidered. It is imperative to provide care without a child’s assent, either due to age, or incapacity related to their illness, if he or she is unable to provide it in the same way that emergency healthcare is provided when it is essential. [5] However, if the illness has dampened the child’s capacity to decide, clinicians should repeatedly determine whether, with treatment, they could provide assent. Should they be capable of providing assent, the healthcare team must include the minor in the decision-making in an appropriate manner. [2, 3]

REFUSAL OF TREATMENT

A consequence of the discussion of assent by minors is refusal of treatment. In adult medicine, the refusal of treatment relies on the principle of autonomy. An able adult of adequate capacity with knowledge of the effects of a medical decision can recluse from any form of treatment. [2] In pediatric patients, however, decisions regarding refusal are multifaceted and problematic since as children grow and are consequently getting more involved in the process. [3] Although information should be provided, one must not solicit the child's assent if the treatment is required [1] and while the American Academy of Pediatrics recommends obtaining assent "whenever reasonable," the same policy statement also notes that "**assent should only be solicited in situations in which the healthcare team would be willing to honor, at least in part, a child's dissent**". [5]

Pediatricians must balance between advocating for the best interest of the child and conceding to patient and family autonomy. At times, the child and the parents may on differ on what is the right decision. Practices to help resolve these conflicts include the **arbitrative model** that places pediatricians as mediators that help resolve conflicts that foster shared decision making. [12]

In the model of **conditional autonomy**, adolescents are granted a greater a degree of involvement when the risks are less or when they are perceived to be making the right choices. [2] In a study [13] that looked into pediatricians' perspectives on refusals of treatment, pediatricians were more likely to respect the refusal for treatment if the prognosis for the patient was poor; if the prognosis appeared good, however, the best interest of the patient took precedence and refusals were easily rejected, particularly with younger patients.

Parents or guardians are supposed to avoid harm when deciding for their children. The **harm principle** has justified legal involvement in circumstances involving parents that refuse treatment deemed necessary. This is anchored on the concept that society has the duty to protect and care for those who cannot fend for themselves. [8] Indeed, clinicians and parents are required to override a child's dissent when a planned action is essential to the child's welfare. [2, 3, 5, 11]

In general, parental refusals of care, his parents, and his guardians, should begin with an investigation of the reasons for refusal, followed by a discussion their goals, and with a negotiation to reach an acceptable compromise. Legal action must always be the last resort. [2, 3]

ASSENT AND CONSENT ABROAD

There have been several, sometimes contradicting, cases cited by Lang about pediatric capacity and autonomy in making decisions in various jurisdictions:

The Tennessee Supreme Court case of Cardwell v. Bechtol established a **rule of sevens** in regard to capacity—"children less than the age of 7 are presumed to have no decision-making capacity; lack of capacity is assumed, but can be challenged, for children 7 to 14 years of age; and children 14 years or older are presumed to have capacity." [2] This judicial interpretation of capacity has permeated our textbooks [3] and has been adopted in the clinical practice of pediatrics in various jurisdictions.

In 2015, a 17-year-old girl with Hodgkin's lymphoma, had to receive chemotherapy after refusing treatment. The **mature minor doctrine** was cited, and the girl had to be sedated and restrained to receive chemotherapy. This called into question the balance between the ethical principles of respect for autonomy, beneficence, and nonmaleficence. [2]

Courts have occasionally compelled families to comply with treatment based on the determination of lack of capacity of the minor. This may prove challenging for clinicians and legal action to determine and interpret the extent of the mature minor exception when life-saving care is refused may be required. A consensus on an acceptable refusal of treatment in older children and adolescents remains to be seen. [2]

GRADUAL ADOPTION OF ASSENT IN THE PHILIPPINES

In as much as ethical principles, models, and cases serve to guide our approach in the care of children, every clinical setup must still be considered individually, taking into account the patient and the family. Clinicians should be cognizant of local regulations when dealing with difficult situations involving consent, assent, and refusal of treatment. [2]

In the Philippines, the term **minors** refer to persons under eighteen years of age and is synonymous with the term "children." Republic Act No. 6809 places the age of majority at eighteen years of age at which time the person is unbound by parental authority and is considered "qualified and responsible for all acts of civil life", and can enter into agreements on their own, or sign an informed consent form. [14, 15, 16] Pediatric practice in the Philippines on the other hand, has been delineated by various statutes such as Republic Act No. 10747 to patients zero to eighteen years old [17]; this includes patients who are more than eighteen years though under nineteen years old. This means that **the practice of pediatrics may include patients who can already sign the informed consent form on their own**, without requiring parental consent.

A **parent or legally authorized representative of each child shall provide the necessary consent for minors**. Aside from parents or judicially declared guardians, the line of succession to parental authority is as follows: grandparents, oldest sibling over twenty-one years of age, unless unfit or disqualified, and the actual custodian over twenty-one years of age, unless unfit or disqualified. Where the parents are both of minors or themselves unable to enter contracts, or give consent, the guidelines on medical treatment of such a child generally allows for a third party, or the state, to give the consent. [14, 15, 16, 18]

Assent from minors has been required by Philippine guidelines for health and health-related researches involving the pediatric population. [19] If the minor is under seven years-old, no formal assent, whether verbal or written, is needed if there is no manifestation of dissent. If the minor is seven to under twelve years-old a verbal assent is acceptable, and the documentation of the verbal assent is required. Documentation may be in the form of a written description of the process and witnessed. If the minor is twelve to under fifteen years-old, he or she shall sign a simplified assent form approved by the proper ethics committee that is different from the informed consent form which the parents or guardians sign. If the minor is fifteen to under eighteen years-old, he or she can sign on the same informed consent document signed by the parents.

However, in the clinical practice of health care in children, there is scarcity of national guidelines, legislation, or jurisprudence regarding assent. In the specific instance of screening, voluntary testing, and treatment for human immunodeficiency virus infection, Republic Act No. 11166 lowers the age of consent to fifteen years of age, legislates the mature minor doctrine, and requires the assent of the child to voluntary testing in those below fifteen years old or mentally incapacitated to protect the best interests of the child when the capability to give the same assent exists. [20]

Indeed, health care providers, which include hospital and clinics, have either not yet adopted the practice of obtaining assent, or have been obtaining assent based, entirely or in part, on the same guidelines used in health and health-related research and/or those called for in specific statutes.

CONCLUSION

In the care of children, the clinician–patient dyad faces the complexities of the inclusion of parents in the clinician–parent–patient triad. Though clinicians almost always turn to parents to make decisions for their very young children, as they mature, they become more capable of contributing to the decision-making process. [2, 3]

In the Philippines, the practice of pediatrics includes patients who can already sign the informed consent form on their own and those patients that require a parent or legally authorized representative to provide the necessary consent for them. Assent from minors has always been required by Philippine guidelines for health and health-related researches. However, this same assent has never been mandatory in the clinical practice of health care in children until recently.

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