The Practice of Informed Consent and Assent in Pediatric Care: A Multicenter Study

Danilo A. Ballesteros, MD, MBAH

The right of competent adult patients to consent is evident, but in pediatric care, the participation of patients still remains unclear and the issues are more complex. With the growing importance of informed consent and pediatric assent, this cross-sectional study aims to identify and analyze factors affecting the practice of informed consent and assent in pediatric care in four health institutions. Categorical data was summarized using percentage frequency distribution and quantitative data was analyzed with mean and standard deviation. Data from the two tertiary care training hospitals were compared utilizing Mann-Whitney Test and Fisher's exact test. In practice, 90% explain the diagnostic or therapeutic modality before the consent form signing. Seventy six percent responded that the objective of informed consent is to provide information to help patient understand the intervention. The percentage of procedures requiring informed consent showed a mean of 81.59±25.30 with no significant difference between the two training hospitals (P=0.743). Only 37% answered that all interventions require informed consent. In informed consent discussion, parents were "always" included at 97.8% compared with pediatric patients at 48.9%. Patient age is the most considered factor pegged at 13.71± 4.452, followed by maturity. Resident physicians are the front liners at 93.3%. Seventy one percent was not aware of the term pediatric "assent" with no significant difference in assent awareness between the two training institutions (P=0.195).

The respondents have good knowledge of informed consent which did not match up with pediatric assent awareness. Practice of informed consent and assent is concentrated on providing information. Children have limited roles and are minimally involved in decision making. Parents and resident physicians/medical officers are always involved in the discussion. A multidisciplinary, holistic and locally accepted approach is recommended consisting of strengthening Bioethics programs, establishing

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ethics committee, creating/reviewing hospital guidelines and policies and educating and advising parents and patients.

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Informed consent lies at the heart of physician-patient relationship. It is considered the most accepted bioethical principle. The right of competent adult patients to consent is evident, but in pediatric care, the participation of patients still remains unclear and the issues are more complex. Supported by international professional organizations, notable differences still exist such as national regulations, socio-cultural perspectives and religious dimension. A study is therefore needed to explore local perspectives on the practice of informed consent and assent in pediatric care. This cross-sectional study aims to identify and analyze factors affecting the practice of informed consent and assent in pediatric care in four health institutions: two tertiary care hospitals (private sectarian teaching/training and government training institutions), and, one secondary care and one primary care government hospitals. The study also aims to come up with recommendations on the practice of the said principle.

A 14-item pretested questionnaire consisting of eight open ended, three multipart multiple choice and three simple multiple choice items with questions ranging from theoretical items to clinical approach was utilized. Demographic profile of respondents was also included. Categorical data was summarized using percentage frequency distribution and quantitative data was analyzed with mean and standard deviation. Data from the two tertiary care training hospitals were compared utilizing Mann-Whitney Test and Fisher's exact test.

Thirty four of 45 (76%) respondents answered that the objective of informed consent is to provide information and to help the patient understand the diagnostic and therapeutic intervention. When asked to describe what they do to obtain informed consent, 37 of 41 (90%) responded that they explain the condition, diagnosis, need and risk and eventually signing of the form. The percentage of procedures that requires informed consent showed a mean of 81.59±25.30. No significant difference between the government training hospital and the private sectarian teaching/training institution (P=0.743) was noted. Only thirty seven percent (37%) answered that 100% or all procedures and interventions need informed consent. Parents/guardians were "always" included at 97.8 % in informed consent discussion compared with pediatric patients at 48.9%. Resident

physicians are "always" involved at 93.3% with the medical specialist/consultants at 51.1% and nurses at 35.6 %. Other family members are "sometimes" involved at 50% and identified by most respondents as the most involved family members are the grandparents. Comparing the two training hospitals, there is a significant difference as to involvement of medical consultants "always" in the private hospital and "usually" in the government institution (P=0.003). Age is the most considered factor in consent discussion, which was pegged at 13.71± 4.452, followed by patient maturity. There was no difference (P=0.584) between the two training hospitals with a median age of 15 and 16. Thirty-two out of 45 (71.1%) were not aware of the term pediatric "assent". There was no significant difference in assent awareness between the two training institutions (P=0.195). Respondents from the private sectarian institution considered allowing the patient to evaluate and choose the tests and treatments "always" than the "sometimes" response from the tertiary care government hospital (P=0.33). Two hypothetical scenarios were presented, one wherein a child refused to agree/give assent in an elective procedure, but the parents consented, 77% of the respondents mentioned that they would proceed. In another clinical situation when a child can be involved in the consent discussion, but the parents objected to involve him or her, 51% of the respondents would still include the patient.

The results showed that the respondents have good knowledge of informed consent which did not match up with pediatric assent awareness. Practice of informed consent and assent is concentrated on providing information. Children have limited roles and are minimally involved in decision making. Parents and resident physicians/medical officers are always involved in the discussion.

A multidisciplinary, holistic and locally accepted approach is recommended consisting of strengthening Bioethics curriculum/programs/modules, establishing consultative and advisory ethics committee, creating and reviewing hospital guidelines and policies, and educating and advising parents and surrogates. All of which are directed to support and respect a child's developing capacity and autonomy as health care providers aspire for the patient's best interest and full potential.■