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Informed consent and competence in pediatrics: opinions from a sample of Romanian physicians in training

Sorin Hostiuc*

Abstract

Objectives: To assess the views of physicians in training regarding the informed consent as autonomous authorization in pediatrics and to discuss the limiting effects of the competence norm in this field.

Methods: We conducted a multi-institutional survey with 158 medical residents in order to assess the views of physicians in training regarding the informed consent as autonomous authorization in pediatrics. The study was conducted with volunteer participants, from a limited geographical area (Bucharest and surrounding areas).

Results: Most respondents strongly agreed that a patient aged 16-18 years should make informed medical decisions regarding any type of procedures (including reproductive choices), whilst those aged 14-16 should be allowed to take informed medical decisions regarding minor procedures only. Most participants agreed that transplant procedures involving bone marrow should be allowed between siblings if they approve, whilst most disagreed allowing solid organ transplantation. The involvement of children in clinical studies should only be allowed if the children agree.

Conclusions: The responses obtained in our study regarding the informed consent put it closer to the autonomic authorization sense than the effective authorization sense. Therefore, respondents' moral intuition is more bioethical and less legal, which, even if maximizing the patient's benefit, is associated with an increased liability risk. However, since the newer generations become more and more precocious, a reanalysis of the classical competence dogmas should be conducted.

J Pediatr (Rio J). 2012;88(6):518-23: Informed consent by minors, parental consent, third-party consent, competence.

Introduction

Informed consent in medicine entitles a person to exercise their decision-making rights in regard to their medical status.¹ To be valid, it must fulfill five conditions²:

- 1) the patient is informed;
- 2) understands the information;
- 3) acts free-willed (autonomously) in agreeing with the informed consent;
- 4) is legally competent to agree;
- 5) consents to the procedure.

Of these five conditions, three are mainly dependent on the patient (2, 3, and 5), one is mainly dependent on the physician (1), and one is a legal requirement (4). Faden & Beauchamp gave two main senses to informed consent – informed consent as autonomous authorization and informed consent as an effective authorization,² the main difference for clinical practice being the absence of condition 4 (legal competence) in the first sense. In pediatrics, the patient who fulfills conditions 1, 2, 3 and 5 is able to give an autonomous authorization for the physician to act; it may

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respect the right of the patient to make decisions on their medical status (respects the autonomy of the patient), but it is usually not valid in a court of law, since the informed consent must be signed in by a person which is legally competent to sign an official act.

Legally, a person is competent to sign an official act if (1) they have the proper age (which varies, usually from 16 to 21 years, and may be dependent upon the type of medical act) and (2) there are no conditions which may limit this right (like severely diminished decision-making ability).

Competence and capacity are two terms that are partially overlapped with informed consent, which often leads to errors and to the misuse of the informed consent in clinical practice. Competence is a legally established ability to create a legal norm (or legal effects) through and in accordance with enunciations (acts-in-the-law or dispositive declarations) to this effect.³ In order for an informed consent to be valid, it has to create legal effects (the authorization by the patient/proxy for the physician to perform a medical procedure), which is inextricably linked with the right to sign a legal act.⁴⁻⁷ Capacity is a psychological term that describes a set of mental skills needed by people in their everyday life (memory, logic, the ability to take care of oneself, etc.). There are two main types of capacity from a bioethical point of view – global capacity, which is superimposable with the psychological definition, and decisional capacity, defined as the ability of a person to make decisions in regard to themselves. If the global capacity is severely affected, that person becomes incompetent to sign legal acts and therefore the informed consent signed by them has no legal validity. Decisional capacity refers strictly to the ability of the patient to understand and analyze medical information and to make an informed decision. If the patient does not have decisional capacity, the informed consent is not valid (the patient is unable to consent to the procedure). The lack of global competence is usually assessed by a committee of physicians (one or more psychiatrist and sometimes other types of physicians, such as a legal medical physician) and psychologists, which drafts a set of conclusions that must be validated in a court of law, with the direct consequence upon the patient being the loss of legal competence. Decisional capacity must be assessed by the curing physician, for each case, while the patient is informed regarding their medical condition, or afterwards, when the patient must analyze their options or make a decision.

The purpose of this study is to assess the views of physicians in training regarding the informed consent as autonomous authorization in pediatrics and to discuss the limiting effects of the competence norm in this field.

Methods

We conducted a multi-institutional survey in order to assess the views of physicians in training regarding the

informed consent as autonomous authorization in pediatrics by using an online questionnaire, which was open to be filled in by each respondent during the Bioethics module at the Carol Davila University of Medicine and Pharmacy. The physicians in training were informed about the questionnaire during the Bioethics module, and invited to take part in the survey. In Romania the residency training has a variable period (from 3 to 7 years), and a two-week Bioethics module is mandatory. The respondents had their base position in all major hospitals in the Bucharest area, and also in private and public clinics. A distribution of the respondents according to their base position was not assessed, since it could be used to identify the respondents (especially if the respondent came from small private clinics), which was not recommended, because the completion of the questionnaire was supposed to be optional and anonymous. A total of 158 medical residents completed the questionnaire (out of a total number of 362 which participated in the Bioethics modules in December 2010). The questionnaire consisted of items covering five main areas – age when the child should have the right to sign the informed consent, age when the child should have the right to make reproductive choices, involvement of children in clinical studies, transplant-related competence, and conflicts between parents and physicians; each item consisted in a clinical case-like scenario. Respondents were asked to grade each one on a scale from 0 to 10 and informed that 0 means strongly disagree, and 10 means strongly agree (therefore having options corresponding to a classical 10-point Likert scale); in our analysis, the intermediary values were considered as follows: 1-3 = moderately disagree, 4-6 = neutral, and 7-9 = moderately agree.

Due to the type of sample (convenience sample), standard error and confidence intervals could not be calculated; therefore, the results cannot be projected to the general population of interest with a specific degree of confidence, which can lead to a selection bias, both considered to be limitations of this study.

The Institutional Review Board approved the study, the consent was presumed (filling up the questionnaire was optional), and the study was anonymous. The questionnaires were built using Moodle CMS 2.0, exported in a .csv file and then imported in a .sav database. Statistical analysis was conducted using SPSS v.19 and charts were created using Microsoft Excel 2011.

Assessment of mean values was done using the Frequency function. Difference between paired variables was analyzed using the paired samples *t* test in SPSS v.19. Correlation tests were conducted using bivariate analysis (Kendall's tau).

A *p* value below 0.05 was considered significant and a value below 0.01 was considered highly significant.

Results

The age when the child should have the right to make informed medical decisions

Most respondents strongly agreed that a patient aged 16-18 years should make informed medical decisions (median of 10.00) (Table 1) for minor procedures; even when the lower age limit was decreased to 14 years, most respondents agreed and moderately favored this option (median of 8.00).

When respondents were asked about patient competence regarding any type of procedure, the values were significantly lower – a median of only 7.00 for patients aged 16-18; when the lowest age limit was decreased to 14 years, the majority disagreed – 23.41% strongly disagreed, 18.5% moderately disagreed, and only 13.9% strongly agreed. The differences were highly significant both between any type of medical procedure and minor procedures and between the two age ranges (14-18 and 16-18), $p = 0.000$.

The right to make reproductive choices

Most respondents considered that a patient aged 16-18 has the right to take informed medical decisions regarding reproductive matters (mean score of 8.21 and median of 10.00), whilst if the age range increased to accommodate the 14-16 year group the mean value was significantly lower (5.20). Moreover, a very high score was obtained when the respondents were asked if the physician should keep reproductive matters secret from patient's parents in minors aged 16-18 (mean score of 8.20). The difference between age groups in reproductive matters was highly significant ($p = 0.000$) whilst we found a highly significant correlation between informed consent and confidentiality (Kendall's tau = 0.173, significant at a 0.001 level).

Involvement of the child in clinical studies

When respondents were asked if parents should be allowed to include their children in a clinical study regardless of their age, the responses have a mean value of 5.08. When respondents were asked if the parent should be able to include their children below 14 years in clinical studies against their will, the mean value dropped to 2.84.

Transplant-related competence

Respondents strongly agree that a minor should be able to donate bone marrow to a sibling if they and both their parents agree (mean value of 9.03). When asked if a minor should be allowed to donate a solid organ (e.g. a kidney), they responded mostly in a negative manner (mean value of 4.52); the difference was highly significant ($p = 0.000$).

Conflicts between parents and physicians

When asked whether the duty to care should prevail over the autonomy of the parents, the respondents moderately

agreed (mean value of 8.36); when asked if they should respect a decision from a parent who does not want their child to have access to treatment, even if the physician considers it beneficial, the value was much lower (5.29). The respondents strongly disagreed with the fact that a physician should hide medical facts from a parent (mean of 2.37) and moderately agreed on acting without parental consent in emergencies (mean of 8.09).

Discussion

From a purely bioethical point of view, informed consent should be age independent - its main purpose is to respect patient's right to freely take informed medical decisions. If the patient complies with conditions 1, 2, 3, and 5, their mental status should permit them to take the decision. Competence, however, is obtained in most countries after a certain age, usually 18. Therefore, even if the patient has the mental ability to sign an informed consent, their signature is not valid unless a parent/guardian signs it too (except for legally empowered minors). The physician should then obtain two informed consents – an autonomous one from the patient and an effective one from the parent; as the level of understanding may be significantly different between parent and child, the physician must practically do the same thing twice, once for medical purposes and once for legal purposes. This in turn leads to many problems, such as an increased time spent on each case (a very serious problem, especially in underdeveloped countries where there is an increasing shortage of physicians), divergent therapeutic opinions between parents and child, an artificially decreased autonomy for the patient, etc. If a conflict regarding the way the therapeutic process must continue appears between parent and child, physicians almost always respect the parental decision (except in cases where this side is obviously detrimental to the child), as (1) any other attitude may lead to judicial consequences and (2) a more paternalistic approach to the physician-patient relationship prevails in pediatrics.⁸ There are countries in which the legal framework now gives priority to the patient instead of the parent if the child has decisional capacity,⁹ but this is usually an exception. Our opinion is that, if the medical procedure is a major one, the parent should indeed be involved, as the patient would probably need a lot of after hospital care, and their capacity to rationalize future consequences is often limited; if, however, the procedure is minor, the patient should be allowed to decide themselves and the parents should be involved only by request. Our study shows that physicians mainly consider this attitude to be correct (a significantly higher score for minor medical procedures).

The exact age when a person becomes competent is still a subject of debate. Some authors consider that a person may be able to take informed medical decisions

Table 1 - Questionnaire. Descriptive statistics

Questions	Mean value	Median value	Strongly disagree (0) n (%)	Strongly agree (10) n (%)	Most selected value (%)
Minors aged 14-18 should have the right to give their informed consent for any type of procedure	4.47	5.00	37 (23.4)	22 (13.9)	0 (23.4)
Minors aged 16-18 should have the right to give their informed consent for any type of procedure	5.99	7.00	21 (13.3)	39 (24.7)	10 (24.7)
Minors aged 14-18 should have the right to give their informed consent for minor procedures	7.08	8.00	16 (10.1)	61 (38.6)	10 (38.6)
Minors aged 16-18 should have the right to give their informed consent for minor procedures	8.21	10.00	6 (3.8)	82 (51.9)	10 (51.9)
Minors aged 14-18 should have the right to give their informed consent in reproductive issues	5.20	5.00	31 (19.6)	32 (20.3)	10 (20.3)
Minors aged 16-18 should have the right to give their informed consent in reproductive issues	8.20	9.00	6 (3.8)	76 (48.1)	10 (48.1)
Parents may consent to the inclusion of their child in clinical studies at any age	5.08	5.00	35 (22.2)	34 (21.5)	0 (22.2)
Parents may consent to the inclusion of a child < 14 years in clinical studies even if the child disagree	2.84	1.00	70 (44.3)	13 (8.2)	0 (44.3)
The physician may hide certain medical information from a parent if the child and the other parent want this	2.37	1.00	76 (48.1)	11 (7.0)	0 (48.1)
Confidentiality of the medical act with a child should not include the parents	6.78	8.00	18 (11.4)	59 (37.3)	10 (37.3)
The duty to care is more important than the autonomy of the parents if the physician and the parents disagree on a certain medical act	8.36	10.00	6 (3.8)	85 (53.8)	10 (53.8)
If parents refuse a certain medical procedure, the physician should respect their decision	5.29	5.00	26 (16.5)	25 (15.8)	5 (25.9)
Bone marrow donation should be permitted between siblings if the donor and the parents agree	9.03	10.00	2 (1.3)	108 (68.4)	10 (68.4)
Kidney donation between minor siblings should be permitted	4.52	5.00	49 (31.0)	30 (19.0)	0 (31.0)
After reaching 16 years of age, a girl should decide whether to continue the pregnancy without parental involvement	7.80	10.00	17 (10.8)	89 (56.3)	10 (56.3)
A physician may perform emergency procedures on a child if they agree and their parent/legal guardian does not	8.09	10.00	12 (7.6)	96 (60.8)	10 (60.8)

before reaching adulthood, especially in specific areas like oncology or familial issues (maternal use of drugs, domestic violence).¹⁰⁻¹⁵ Shaw¹⁶ for example, separated minors into two age groups – 16 and 17 years old and below 16 years old; he concluded that a minor with decisional capacity aged over 16 should be able to give their competent consent for a medical procedure but should not be able to refuse a clearly beneficial procedure. Minors below 16 years should be informed regarding the medical procedure, but the consent should be co-signed by a parent/guardian; they cannot refuse a clearly beneficial procedure. Our study revealed that physicians consider that patients over 16 are significantly more capable of taking medical decisions, both minor and major. There are a few other factors that may influence decisional capacity more than age; for example Alderson¹⁷ found that children who have previously been subjected to surgery, when asked “How old do you think you were or will be when you’re old enough to decide?” gave a mean value of about 14 years, whilst when a similar question was asked to minors not previously subjected to surgeries, they gave a mean value of 15-17 years. Another study, conducted by Borry et al. in order to analyze the attitudes of clinical geneticists regarding the age at which minors could undergo carrier tests found that age is not the only decisive element in decision making by adolescents, since there are also other crucial factors, such as cognitive, emotional and sexual maturity.¹⁸

Reproductive medical issues in adolescents are usually associated with abortion contraception and its consequences¹⁹⁻²¹; some studies revealed that, in reproductive matters, minors (over 14 years) may equal adults in their decisional capacity; any potential differences are most likely caused by the different roles of adolescents in family and society²¹; however, the consideration of future risks and vested interests of advice givers has a tendency to increase during adolescence,²¹ motivating a potential limitation of medical reproductive decisions, at least in the first years of adolescence. Therefore, an intermediary age limit may be permissible from a bioethical point of view; this argumentation is supported by the views of our study group, which gave a significantly higher approval score for allowing minors over 16 to take reproductive decisions compared to patients below 16 years. Other reasons, non-medical, limiting the adolescent’s capacity to take medical decision, like those regarding a potential decrease in abortion rate,^{20,22-24} must be carefully balanced with the fact that pregnancy is associated with a much greater psychological, physical and economic burden for the adolescent than an abortion.²¹ If the law states an age-dependent limitation to the adolescent’s medical decision capacity, it not only diminishes the self-determination of the patient but also may significantly alter their life, limit some choices like education, relationships, etc. The issue is still in debate as other studies

have identified a decreased competence level even in young adults, especially in reproductive matters,²⁵ most likely caused by deficiencies in the educational process.

Children’s involvement in clinical trials should be limited as they are a vulnerable population, with developmental, psychological and physiological differences from adults.²⁶ Our study reveals very low scores in questions regarding the involvement of children in clinical trials, especially if the subjects do not agree. Therefore, the physicians mainly agree that involving a child in a clinical trial is a very delicate task and should only be done when absolutely needed. In the case of clinical trials, our opinion is that an age limit for the capacity to refuse should be completely eliminated; however, due to the increased complexity of the informed consent in clinical trials, and the fact that beneficence is mainly directed toward others, a high minimum age limit for being able to consent to the inclusion should be reinforced.

The question regarding the donation of regenerative tissue had a very high score, suggesting a very high acceptance for this procedure if it is in favor of a sibling. Interesting, a higher than anticipated value was also obtained when participants were asked if they agree with the donation of a solid organ, a technique forbidden in most countries.²⁶ The physicians in our study agreed with both transplant procedures mostly because they considered that a patient, even if minor, should have the right to make informed medical decisions if they have decisional capacity. Potentially negative future consequences should however limit the use of solid organ transplantation from living persons and especially children, even if the organ is in pair (like the kidney) or has an increased regenerative capacity (like the liver).

The last set of items in our study analyzed a potential conflict between parents (their right to authorize a medical intervention on their children) and physicians (duty to care). Our respondents strongly agreed that the duty to care should prevail over the autonomy of the parents, but only if the parental act is clearly against the patient’s best interest. This attitude is somewhat in contradiction with recent legislative developments, which tend to increase the role of the minor in the decision making process,⁹ through shared decision-making (SDM). In SDM the physician informs all interested parties (in pediatrics the minor and their parents), and the treatment plan is decided together. Even if SDM seems a very attractive option in pediatrics, there are not many studies analyzing its efficiency²⁷; moreover, there are a few challenges which makes it difficult to implement SDM at a larger scale. These challenges include the following: the minor needs at least an intermediary literacy skill to properly analyze and interpret medical information and the shared decision process, there is the expectancy of a more paternalistic approach to the physician-patient relationship in pediatrics, high levels of stress are found in parents

with children with special needs, some parents will take a decision based not upon medical data but as a mean to minimize their guilt if the selected treatment does not lead to the expected favorable outcome, some clinicians are not comfortable with this process, differences may arise between parents and children regarding the best alternative option, etc.²⁸

The responses obtained in our study regarding the informed consent put it closer to the autonomic authorization sense than the effective authorization sense. Therefore, respondents' moral intuition is more bioethical and less legal, which, even if maximizing the patient's benefit, is associated with an increased liability risk.

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