ETHICAL PARTICULARITIES AND DILEMMAS OF INFORMED CONSENT IN PEDIATRIC ONCOLOGY

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Abstract
The doctrine of the informed consent is basically a crucial paradigm in medical decision-making. Ethical dilemmas are to be met at each and every stage when obtaining the informed consent in pediatric oncology; this doctrine seems to apply particularly in case of children and teenagers, who lack the decisional capacity or the legal empowerment to give their informed consent. Debates related to the rights of the child have lately taken a different direction with the spreading acceptance by national and international law of the fact that children also benefit from most of human rights. In pediatric oncology particularly, where patients and their families have to face several decisions during the illness, the importance of the informed consent as a continuous process is to be recognized, during which obtaining the signature is nothing but a phase. Two factors at least particularize the informed consent in pediatrics First, many conversations and decisions take place primarily between clinicians and parents, with an increasing involvement of children according to their development capabilities. Secondly, patients cared for within the context of clinical trials is increasing. More research is necessary in order to explore the differences between adult and pediatric informed consent processes in oncology.

Keywords: *informed consent, competence, pediatric oncology.*

The ethical dilemma concept is a frequent issue within the practice of physicians dealing with oncology cases. Indeed, few medical specialties encounter so many ethical challenges as pediatric oncology does (15). The level of information that the oncologist must convey to the patient often represents a dilemma. Most of oncologists share a personal experience in communicating with patients suffering from cancer. At the same time patients claim more and more their rights to be actively involved

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in the process of therapeutical decision-making (16).

Informed consent is nowadays a cornerstone when making a medical decision.. The informed consent concept becomes one of the main pillars of the relationship between the patient and the doctor and it represents the clearest expression of the respect for the individual autonomy that is the individual's right of free choice, of living according to one's own principles and values (1). The doctrine of the informed consent apply particularly in case of children and teenagers, who lack the decisional capacity or the legal empowerment to express their consent (2) Thus, in spite of the similar founding principles, the informed consent principles presents particular differences and questions in comaparison with the adult oncology (14). There are five criteria that characterize simultaneously the valid informed consent: a) free choice without constraints, b) the patient's information, c) the capacity of understanding the information, d) co-mmunication of the information e) the decision-making capacity (4).

From the medical point of view, the competence and the mental capacity bear different meanings, although they are perceived as synonyms. *Competence* is the legal term which designates the legal authority wihin the management of peculiar situations, in a particular field of life. On the other side, *the mental capacity* designates the cognitive, perceptive and communicative capacity of fulfilling a particular task. The latter reflects a clinical rather than a legal determination, and this is why it implies a field of clinical experience. For example, a 17-year old teenager may have the capacity of understanding medical decisions, but is considered to be legally incompetent in most of jurisdictions (7).

The decision-making capacity can be considered in relation with four parameters: a) capacity of making a choice, b) capacity of understanding relevant information, c) capacity of appreciating the consequences of a decision, and d) capacity of rational processing. Patients having a decision-making capacity must be included in the development of the informed consent regardless of their competence level (10).

The understanding capacity refers to the process through which the patient continuously involves himself in understanding the diagnosis and the therapeutic alternatives. The competent adult, after consulting the physician decides what type of medical procedure is acceptable to him/her or not.

Obtaining the informed consent involves integrating the understanding and the communicative capacities, reasoning and deliberation in analyzing possibly conflictual choices by using a set of personal values. The great importance of informed consent is to be recognized as a continuous process in which obtaining a signature represents only a stage and not the purpose (9, 17).

Until the beginning of the 20th century children were considered as parents' property, these latter having the decision-making right on behalf of them. Although theoretically this concept was left away the parental right to decide on the child's behalf relies on several arguments: a) parents are strongly motivated in taking decisions in the best interest of their child, b) it is supposed that, when growing up, children will borrow and express the same values as their parents, so that parental decision has good chances to be similar to theirs, when these ones will become legally entitled c) parents are the ones that will

have to live with the consequences of the decisions made on the children's behalf (including emotional and financial consequences) d) parents usually make most of non-medical decisions (i.e. school), so they should also be responsible for medical decisions (8, 10).

Unlike the situation of own personal care in adulthood, parents' rights to decide for the care of their children are far more reduced. The parent or the tutor is constrained by both the interest of the child, and by the independent obligation of the therapeut who may contradict with one of the parents. The *concept of parental agreement* (more appropriate than consent), represents that kind of reassigned decision which particularize the ethical issues in pediatrics. In any instance, decision to determine what is best or not for the child can be very difficult given the diverging points in defining this interests (4). The respect for the child's interest supposes sometimes ignoring the child's disagreement when for example, a surgical act is essential for saving his life (21).

Children of higher age and teenagers have the emotional and cognitive capacity of fully participating in decisions regarding their situation, especially when speaking of a chronical evolution of a cancer. For this reason, the teenager will cautionally receive the same information as adults do. Parents' role is limited to one of guidance, counseling and protection. The communication and negociation process is likely to become more complex and difficult if there is a disagreement between parent and the teenager. Parents have to be discreetly facing the suffering of their child. Anyway, in cases supposing high risks, the best interest of the child prevails, and not the parent's right to decide (6).

Debates on autonomy and its importance did not clarify the scope of application of this concept in case of children. Traditionally children lack autonomy or other personnal qualities allowing them to express this autonomy. Some practitioners are still skeptical as far as as child's rights are concerned Also, one has to take into account that not all children want to take part in that kind of decisions regarding their treatment (12).

Exhaustive discussions on the autonomy and its importance are not always clear enough when the question of the child's autonomy is not brought into discussion. It is not also very clear the way in which one could establish the competence of a child and his capacity of understanding the nature of the disease and of the treatment. Every particular case should be considered in its own context. One could also argue that a young person, when she is ill and is stressed she becomes less capable,, leaving decisions entirely up to her parents. Anyhow whenever a child or a teenager refuses the treatment, this refusal must be analyzed and not absolutized. Efforts are to be made in order to understand the causes of the refusal. Some analysts plead for the idea that if the refusal is repeated and clarified by the minor his decision-making competence level needs a further analysis (13). The patient's and the families' uncertainty and anxiety leads some specialists towards further caution when involving children in decision-making, even if they seem to accept this concept (21).

Another legal dispute may occur when the under-aged person (or teenager) refuses treatment and this action is not in its best interest, as pediatric cancers have a better prognosis than adults'. In such a

situation disregarding the child's decision is considered to be justified.

Despite such controversies, the principle of respecting the child's autonomy encourages the acceptance of the fact that the appropriate persons for judging their interests are themselves. Consent process can be corrupted if parents limit the information provided to the children (10). That is why counseling the parents or the tutors regarding the child's disease in a sensitive and individualized manner seems to be reasonable. It is also useful to ask parents to sincerely answer to the children's questions, in order for the therapeut not to be forced to deliberately distort truth in front of them (16).

Debates regarding the rights of the child have gained a new profile in the last years, together with a large acceptance, in domestic and international law systems, of the idea that children are persons who fall within the scope of basic human rights. The most important contribution related to this aspect has been brought in 1989, when The United Nations General Assembly adopted the Convention on the Rights of the Child. Article 12 of this convention stipulates that all children which are able to express their views must be given the chance of participating in the decisions which concern them (21).

A modification of the traditional status of the child in family and society represents an acknowledgement of the respect for the child's personality. With regard to the child with no capacity of consenting, we have to take into account that any intervention must be done in its benefit and with the agreement of his/her parent, tutor or any other legally designated authority. The child's opinion must be therefore taken into consideration as an increasingly important factor, according to the age and the degree of maturity of this one. This authorization can be withdrawn anytime by another competent body in the interest of the child (13).

There are certain types of arguments which can be therefore brought against the involvement of the child in health, from the the theory of development until the lack of capacity of understanding the seriousness of some important decisions.

The American Academy of Pediatrics (AAP) argued that the whole „doctrine of consent has a limited practicability in pediatrics" (10). Consequently, according to this valuable professional organization, „consent must be done only by patients with real, adapted capacity of decision and with legal commission". Parents (or other legal belongers) can give *informed consent* and the child is only required for agreements when needed. AAP specifies that these agreements weigh more in the balance when „the suggested intervention does not represent a critical moment in child's health and does not carry substantial risk". On the other side, in situations like disease relapse or unfavorable course of disease, or treatment with a less clear risk/benefit ratio, asking for the child's agreement is very important (6).

Comparison between pediatric and adult informed consent in clinical trials

The progress of treatment options in malignant hematology and oncology is accomplished by a sustained research and experimental medical activity. There is an important difference between the informed consent for purposes of general, „standard" treatment, and that for clinical study participation (experimental drugs). Informed consent for treatment develops as a process, that the patients must follow both for acknowledging the potential risks and benefits implied by the active

oncological treatment and for protection agains malpraxis.. Unlike the clinical situations, the informed consent for research clinical trial participation is rather seen as a crucial element of the deontology of clinical research; it is the contract by which patient authorizes participation in the research on the basis of information provided by the physician or by the researcher. Proper information and obtaining the informed consent of potential subjects for clinical trials represent an ethical guarantee in the frame of the research process concerning cancer therapeutical improvements (20).

At least two factors augment the complexity of the achievement of the informed consent in the pediatric oncology. First, most discussions take place between parents and professionals or other decision factors, being directly influenced by the problem of autonomy. The second aspect is that an increasing number of patients included in clinical studies require information on both details of protocols and the results of the research (20).

Current standards of informed consent in clinical studies are identical to those applied in in oncology and in medicine generally speaking. They arise from the principles of non-maleficence, autonomy, benefits and justice. Therefore a complete information of the patient is necessary in order to facilitate the understanding of the patient and the support of the decisional factors concerning the benefits of the clinical study in terms of therapeutical options (18).

If the aims of informed consent are similar in pediatric and adult oncology, in clinical studies some additional deontological constraints are added. In both cases, child and adult informed consent will include information on: aims of treatment, randomisation procedures, anticipated risks and benefits, other anticipated procedures, therapies as well as their facultative character (3).

A randomised study (Simon Ch.M. et al., 2004) analyzed the problem of informed consent in children's clinical trials, as compared to adults in terms of information. The goal was to identify significant differences between the two situations, with the purpose of optimizing the information process in randomized clinical studies (19). Study data identified significant differences between informed consent in adults and children, recognizing that, on average, adults have been better informed and were more actively involved by the healthcare provider. On the other side, pediatric oncologists provided however more information on the protocol types, map roads, survival, randomization, facultative feature. Difficulties of understanding were more frequent amongst decision factors in pediatrics. The survey proved that adults have chosen different treatments according to medical information, when the risks were presented as probability of success or failure. This psychological aspect represents a very important issue in day-to-day oncology practice; it is essential whether clinician presents his own opinions in terms of probable success of controlling the disease or in terms of describing the real balance of pros and cons underlining alternative of possible tumor relapse.

The path for obtaining informed consent in adults is less influenced by lack of autonomy, by cohercision of the family or by other factors linked to ethics of decision. Adult medical oncology has a more immediate and less ambiguous link between patient and doctor, and probably this is one of the reasons that makes decision to enroll in clinical

studies much easier than in pediatrics. In general, adults develop more rapidly a relation of trust with their attending physician, and less frequently regret participation in clinical studies. When it comes to decision-makers, children and adolescents need the most often support in understanding the treatment within the clinical trial and the possible benefits of study treatment, as compared to standard treatment. The elements of informed consent are usually less well understood by pediatrical decision-makers, if no detailed explanations of the differences between therapy options were previously offered. Pediatrics staff has often to deal with a straight discussion on therapy options on standard classic procedures and on specific trials procedures. Sentences like „this combination of drugs is not applicable in conventional standard treatment" or „this new treatment will be done only if you decide to participate in the study, otherwise we will respect your choice" are very important, and must be repeated all along the process of obtaining informed consent (20).

The randomization technique must be explained in a very detailed manner, showing the possible advantages and disadvantages of this process. A comprehensive speech must be given on the difference between the possibilities of the randomization compared to conventional therapy, assessing that the patient will receive a treatment that is supposedly better than the previous one, but the quality of this treatment would still have to be statistically proven in the future, after the accomplishment of the study by the patient. Differences between treatment arms, in terms of medication, dosage, toxicity/response, as well as the (extremely rare) probability of a placebo arm, should be made clear to the parents and/or patient. This may help parents in making a decision, including understanding of the fact that the patient will be receiving (usually) an active treatment regardless of participation in the clinical trial (21).

Conclusions

Ethical dilemmas are frequent in pediatric oncology at every stage when obtaining the informed consent. The competence and mental capacity issues are less made clear and they often represent dilemmas. In pediatric oncology in particular, where patients and families have to deal with several decisions all along the course of the illness the importance of the informed consent is being recognized as a continuous process.

Two factors at least particularize the informed consent in pediatrics. First, many conversations and decisions take place primarily between clinicians and parents, with an increasing involvement of children according to their development capabilities. Secondly, patients cared for within the context of clinical trials is increasing. The differences between the informed consent in adult and pediatric oncology reffer to the level of information, the active involvement, the awareness on major risks and of randomization are concerned. The understanding and emotional difficulties are more frequent in pediatric oncology.

More research is necessary in order to investigate the difference between the informed consent in adult and pediatric oncology.

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