

Informed Consent from the Doctrine of the Mature Minor in Biomedical Research

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Abstract

It is necessary to recognize the child as an active moral subject in making decision process related to his health or his participation in research. The taking of informed consent as a communication process should tend to respect the autonomy and dignity of the child considered mature or not, taking their decisions seriously and not just an assent as a normative principle of mere legal aspect. It describes theoretical elements that can be used as tools to have an approach to the moral development of the child from the principle of responsibility according to the degree of emancipation. The objective is to provide a description of the most relevant aspects about the informed consent process in the mature child and their right to be informed to agree or consent. We searched the databases such as: Proquest, Medline, Lilacs and Pubmed, analyzing 51 articles. It was concluded that the ability to assent or consent of the child considered mature or not should be evaluated under objective parameters and not simply under the perception of the clinician or researcher. Finally, it is necessary to design strategies to promote the autonomy, respect and dignity of the child from the same practices at the time of informed consent.

Keywords: Competency • Clinical trials • Children • Capacity • Autonomy • Pediatricians

Introduction

The analysis carried out in this article, allows us to think about the moral system that encompasses the underage person to consider him as a subject of rights at the time of taking the informed consent. The minor who shows maturity to make a decision regarding their participation in research or treatment, could mean an ethical issue for those who take informed consent, which requires the clinical professional or researcher prudence not to underestimate the autonomy of the child [1], but also, the obligation to apply the regulations of each country that describes when the child becomes an adult. To consider that a underage person is mature, he must verify an understanding of the scope and meaning of his actions [2].

Aristotle says that "young people can be geometers and mathematicians and wise in things of that nature, and instead, do not seem to be prudent" [3,4]. That is, moral virtue par excellence and prudence is reached late. Although it also describes, that young people by their ability to be geometers and mathematicians come to understand situations, and be responsible for their own actions [3].

It is for this reason that it is necessary to clarify the idea of the minor from the doctrine of the mature minor, as well as the main elements to take into account when taking informed consent for clinical and for research, considering their right to be informed regardless of age, socio-cultural context or legal aspects, to achieve active participation of the child with a deliberative approach, free of extreme paternalism with a high ethical and moral responsibility on the part of the one who takes the informed consent as a process of real communication.

Literature Review

Methods

A review was made in different high scientific impact databases such as: Proquest, Medline, Lilacs and Pubmed. The search was systematized

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in English and Spanish languages, mediated by the impact of the articles (citations) as by the use of keywords such as: biomedical research, mature minor, children and informed consent as main inclusion criteria, then sort them according to the number of words.

Consent from the doctrine of the mature minor recognition of his autonomy

According to [5], "you cannot confuse moral maturity with moral and legal capacity" that is, the moral maturity of a person must be measured by their formal abilities to judge and assess situations, not by the content of the values that assumes or manages [6-8], refers the word consent as a communication process in which basic information is given to the child about a research study or treatment, likewise they are asked to participate in the decision making, taking as primary principles the autonomy and non-maleficence, which would lead to consider the child in the decision making from 12 years old, keeping in mind the elements of analysis proposed by the Royal College of Pediatricians of England which could be summarized in the need to communicate to the child about the medical or research aspects in the most appropriate way, keeping in mind their level of understanding, helping to the child to feel as a central character in the actions taken related to his/her health. For this, it is necessary to listen to the minor to diminish his fears, doubts and worries, but also to consider his/her observations or opinions regarding what it is important and make him/her comprehend that will be taken into account according to the degree of responsibility for the treatment or investigation, and thus consider him/her as an active and morally competent subject. The proposed study [9], indicates other levels of participation, such as providing information about the illness, treatment and medical procedures to the minor, as well as making the decision as a whole (trinomial: medical personnel-minor-family). On the other hand Drane proposes a methodology whose observation criterion is the proportionality between the severity of the decision and the degree of moral competence, which must be taken into account when evaluating the ability to make or not a decision by the mature minor or adult [10]

The study proposed by [11] Peter formulates 5 criteria which can be summarized as the rational understanding of the facts and the consequences of decisions beyond what Appelbaum proposes as "appreciation of the nature of their situation"[12] which can be simplified as "the understanding of the facts", that is to say; a factual compression.[11]

Moral capability of the minor considered mature

The ability of the mature minor to decide, as mentioned, is not equal to the legal aptitude, but does not exempt the clinician or researcher from their moral duty to assess the child's moral ability for making a decision [13].

The Presidential Commission for the Study of Ethical Problems and in Biomedical and Behavioral Research, mentions that the ability or competence lies in the fact that the person despite whether is an adult or underage must also have a set of values and goals, the ability to communicate and demonstrate understanding of information, as well as the aptitude for reasoning and deliberation about decisions [10,14].

According to [15], respecting the autonomy of the minor is a moral duty rather than a legal one. That is to say, that the decision making ability of the minor can vary in relation to the age [13], therefore he should not be exempt from his right to agree [16].

Health sciences professionals and researchers may presume a priori that children and adolescents have limited capability to make moral decisions, arguing that they are in a stage of development of their autonomy and therefore their ability to agree should be related to their degree of moral maturity [7].

In the same way, other studies mention the ability of children to understand issues related to the research or procedure that will be carried out, as long as it is informed to the minor with a simple and appropriate language, for example: children with ages of 6 years old showed a reasonable understanding to the clinical or investigative procedures, although it is emphasized that the logic of understanding is greater as older the child is [17,18]. Legally in many Latin-American and European countries the minor's legal ability to consent depends a lot on the degree of emancipation and the age, where countries like Colombia and France consider it from the age of 18 [19].

The informed consent in the minor subject of biomedical research: Deliberate or decide?

Between the child and the clinicians there must be an articulated dialogue where the child is considered as a recognized moral subject to assent even consent, when moral maturity is proven in the decision-making process with a high degree of responsibility in relation to its own self-care [20], that is to say; a relation of deliberative power articulated to a rational communication model contextualized to socio-cultural aspects between the doctor, minor and legal guardian [21,22].

The scope of biomedical research has expanded greatly, in relation to studying populations considered vulnerable such as pregnant women and children [23], by this means more attention should be paid in relation to topics related to methodological aspects related to recruitment and withholding of participants, instrumentation and data collection, [24] as well as certain aspects of the individual being present in the child, such as: confusion feelings, fear, apprehension of the unknown, loss, sadness, anxiety and stress, among others [25].

The research carried out at the present time in children and adolescents extends from the simple clinical observation of epidemiological data collection, to genetic studies to analyze the molecular mechanisms, as well as the evaluation of therapeutic interventions effects by clinical trials [3,26,27].

It has been demonstrated that the problem of taking assent does not lie only in a lack of academic training in bioethics, since most clinicians and researchers have it, but in a lack of acknowledgement of the child subjected to clinical trial as it is exposed by [28,29], definitively, to encourage the minor to make a free, autonomous and competent decision, and not simply consider him/her incapable of making decisions, transgressing his autonomy and dignity simply because of his/her age [5].

Ethical considerations with regard to biomedical research with children must be approved by an ethics committee, which must ensure, among other things, the application of assent, with the exception of over 16 years old emancipated people, it must be explained to the minor what it is intended to be done and finally, it must be justified the importance of the benefit that the child will receive [30].

It should be noted that the main idea of the regulations and the doctrine of the mature minor is to keep in mind that regardless of the minor's age, they have the right to be informed [31].

In the United States of America, the Academy of Pediatrics asked the

FDA to implement measures to generate scientifically supported information, which allows them to prescribe with more accuracy and less legal risks when researches are carried out with children [32]. The Directive 2001/20/EC of the European Union states that: "People who are not in a position to give their consent to participate in a clinical trial must receive special protection"... ". These people should not be included in trials if the same results can be obtained with people capable of giving their consent "[33].

The informed assent as a process should help to provide the elements to assess whether a minor is mature or not to agree or consent, when appropriate information is provided and in the most correct manner [34,35] which is an element of ethical responsibility on the researcher or clinician side, due until now international regulations do not have a consensus when the child has the full right to give their autonomous consent [36]. It could be said that the assent is the approval, but consent is an agreement between parties [32]. Physicians and researchers have a moral obligation to listen carefully to the opinions and wishes of children who cannot give their full consent and should strive to obtain their assent, as well as the responsibility to determine the child's ability and competence to give his/her consent or assent; therefore, promote and protect the dignity, privacy and confidentiality of the child and the family [37-49].

Conclusion

In the last century a great importance has been given to the subject of the minor's capacity to make moral decisions in relation to their health and to participate in biomedical research studies, there are even multiple methodologies with an ethical basis from the moral and practical point of view as an approach in the measurement of the minor's capability to be consider as mature when assenting or consenting. Possibly the practices of the clinicians focus more on their perception regarding the autonomy of the child or his degree of emancipation.

The informed consent as inclusive process must enact the development of autonomy and self-determination of the minor, where bioethics has been offering a framework for analysis, for a real communication process that recognizes the minor as a moral subject worthy of information and respect, beyond legal formalism.

It is important that the proposed researches in children should be evaluated and adjusted to national and international protocols, in addition to researchers and clinicians to promote child's autonomy, respect and dignity from the same practices when referring or requiring informed consent.

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