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Autonomy and individuals without the capacity to consent: the case of minors

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Abstract

The *Universal Declaration on Bioethics and Human Rights* (2005) contemplated autonomy in three articles among its 15 principles: autonomy and individual responsibility (article 5); consent (article 6); and, persons without the capacity to consent (article 7). In view of the complexity of the matter, this paper analyzes Article 7 of the Declaration, specifically focusing on children. Because of children's lack of competence to freely and autonomously provide their consent, this authorization is passed on to their legal guardians, usually parents or relatives. The absence of legal provisions to legitimize the decision of minors leaves room for paternalistic actions by professionals and legal representatives, who act, based on their own perspectives, for the benefit of children. Bioethics is responsible for stimulating a discussion on possible ways and mechanisms for the real protection of minors, legally regarded as unable to provide their own consent.

Keywords: Bioethics. Personal autonomy. Informed consent. Comprehension. Minors.

Resumo

Autonomia e indivíduos sem a capacidade para consentir: o caso dos menores de idade

A *Declaração Universal sobre Bioética e Direitos Humanos* (2005) contemplou a autonomia com três artigos entre seus 15 princípios: autonomia e responsabilidade individual (artigo 5º); consentimento (artigo 6º); indivíduos sem a capacidade para consentir (artigo 7º). Diante da complexidade do tema, este trabalho analisa o artigo 7º da Declaração, com foco especificamente na questão das crianças. Por causa da ausência de competência para que crianças consintam de maneira livre e autônoma, essa autorização é repassada aos responsáveis legais, geralmente pais ou familiares. A inexistência de dispositivos legais que legitimem a decisão dos menores abre espaço para atuação paternalista de profissionais e dos responsáveis legais, que agem visando ao benefício da criança, a partir de perspectivas próprias. A bioética é responsável por estimular a discussão sobre as possíveis formas e mecanismos de proteção real dos menores de idade, considerados legalmente incapazes de fornecer o próprio consentimento.

Palavras-chave: Bioética. Autonomia pessoal. Consentimento livre e esclarecido. Compreensão. Menores de idade.

Resumen

Autonomía e individuos sin la capacidad para consentir: el caso de los menores de edad

La *Declaración Universal sobre Bioética y Derechos Humanos* (2005) incluyó a la autonomía, con tres artículos, entre sus 15 principios: autonomía y responsabilidad individual (artículo 5); consentimiento (artículo 6); y personas sin capacidad para consentir (artículo 7). Frente a la complejidad del tema, este trabajo analiza el artículo 7 de la Declaración, centrándose específicamente en la cuestión de los niños. Debido a la ausencia de competencia para que los niños presten consentimiento de manera libre y autónoma, esta autorización es desplazada a sus responsables legales, generalmente los padres o familiares. La inexistencia de dispositivos legales que legitimen la decisión de los menores, abre espacio para acciones paternalistas de parte de los profesionales y de los representantes legales, quienes actúan en beneficio de los niños desde sus propias perspectivas. La bioética es responsable de estimular la discusión sobre las posibles formas y mecanismos de protección real de los menores de edad, considerados legalmente como incapaces de proporcionar su propio consentimiento.

Palabras clave: Bioética. Autonomía personal. Consentimiento informado. Comprensión. Menores de edad.

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The discussion and the creation of the key international mechanisms to protect human rights and the rights of the participants in research with humans has introduced principles that guide biomedical practice. Among the first principles established, used as a reference throughout the world, are those proposed by Beauchamp and Childress [1]: autonomy, beneficence, non-maleficence and justice.

During the development of bioethics, however, it was realized that these principles are morally insufficient for ethical discussions that go beyond the field of biomedicine. With the approval of the *Universal Declaration on Bioethics and Human Rights* (UDBHR) of the United Nations for Educational, Scientific and Cultural Organization (UNESCO) [2], the participation of autonomy in the international academic context was expanded, and its representation was broken down into three items: autonomy and individual responsibility (article 5), consent (article 6) and persons without the capacity to consent (article 7).

Autonomy comes from the Greek words *autos*, meaning "self" and *nomos*, which translates as "law," "rule" or "government", indicating therefore the notion of "self-government". The principle of autonomy is therefore the ability to decide and act in view of what is best for oneself [3]. It is a central principle in the bioethics of principlism, based on the individual. Depending on the author or era, this idea has received several denominations including the "principle of respect for a person," "the autonomy principle", and "the principle of consent", which is used as a moral basis for the elaboration of public policies for the defense of the vulnerable.

Even with the various interpretations of literature, there is a consensus that, for the principle of respect for autonomy to occur, two conditions are essential: freedom and the status of being an agent. Regarding the freedom of choice, the absence of controlling influences and coercive forces is required; in other words, in a clinical context, professionals involved in care should not impose conditions or exercise influences on the decision of an individual. The other aspect, the ability to act intentionally, requires an understanding of the situation, so that the action truly is autonomous, imposing an obligation of the professional/researcher to ensure access to all the information and options available in that situation to ensure the autonomy of choice [4].

An autonomous person is therefore an individual with the capacity to decide on personal matters and act consciously. Respecting the autonomy of a person means considering their values, positions and options, not impeding their freedom of action (except when it brings harm to others) and providing all the information necessary for them to use their own judgment [1].

The expression of the principle of autonomy in biomedical practice is known as informed consent, which consists of the full knowledge, on the part of the individual, of the therapeutic possibilities, so that they can choose in a free and informed way, as best they see fit. Consent implies the extension of autonomy, as it includes both the obligation of the researcher/professional to inform the subject properly and the effective understanding and consent of the patient/subject of the care or research. The premise is established, in scientific circles, that informed consent has as its main function and justification the protection of individual autonomous choice [5].

Article 6 of the *Universal Declaration on Bioethics and Human Rights*, which deals with consent, states in one item that: *Any preventive, diagnostic and therapeutic medical intervention is only to be carried out with the prior, free and informed consent of the person concerned, based on adequate information. The consent should, where appropriate, be express and may be withdrawn by the person concerned at any time and for any reason without disadvantage or prejudice* [2].

The UDBHR also requires that both professional care and scientific research is carried out with the express consent of the individual involved, previously provided in a free and informed manner. For this, the information should be provided in an understandable way, but with the inclusion of mechanisms to ensure the withdrawal of consent at any time and for any reason, without prejudice to the participant [2].

In the case of people with reduced autonomy (such as institutionalized individuals and the mentally ill), or who are unable to consent (unconscious people and children), responsibility is transferred. Special protection is guaranteed for such persons, so that permission for health care or research is granted in the best interests of the affected individual, and should, whenever possible, be based on the consent and/or withdrawal of the participant, where applicable [2].

Given the complexity of the subject and its many ramifications, the present study provides a brief reflection on the topic of individuals without

the capacity to consent, with a specific focus on children and adolescents.

Limitations of autonomy

Established as a response to the countless abuses that occurred in clinical trials with humans, the principle of respect for autonomy is the empowerment of the individual regarding him or herself. While the other principles proposed by Beauchamp and Childress - beneficence, non-maleficence and justice - depend primarily on the professional/researcher, autonomy is focused, primarily, on the perspective of the individual patient/research participant [1].

According to Garrafa [6], through the strong influence of Anglo-Saxon culture in bioethics, the principle of autonomy was maximized at the expense of others, contributing, in some countries, to the individual perspective becoming the only legitimate and decisive aspect in conflict resolution. According to the author, *the danger of the maximalist use of autonomy is – out of the healthy structure of respect for individuality and passing through individualism in its various nuances – ending up at the opposite extreme, with an exaggerated egoism, able to set aside any opposing, collective and indispensable viewpoint, which are essential to confront the tremendous social injustices related to social exclusion, which occur today more than ever before* [7].

For Fabbro [8], who described the legal constraints of autonomy, the main limit is the right to the body itself, guaranteed only by a partial or controlled availability, with individual autonomy restricted to therapeutic or restorative health purposes, according to current Brazilian law. Also according to Fabbro, these limitations should be primarily derived from the Civil Code and the Criminal Statute. In criminal law, the patient suffers from two limitations: direct, which prohibits certain conducts against the individual; and indirect, which determines vetoes against the health professional. To validate these acts in civilian life, Brazilian law requires that the agent is in full enjoyment of their rights, since *civil legislation establishes conditions or assumptions that, once met, recognize individual rights or the possibility of personally exercising these rights.* (...) *people older than twenty-one years shall be fully capable* (...) *those under the age of sixteen, the mentally ill of all kinds, the deaf-mutes who cannot express their will are absolutely incapable, according to the law, for the valid practice of their rights, which will be represented* [9].

One of the obstacles to autonomy is paternalism. Here, the professional, motivated by a desire to protect the patient and to offer the treatment he deems most suitable according to his point of view, knowledge and responsibility is ultimately considered the most appropriate person to make a decision. And he does so without the consent of the patient or by coercion. In this case, even if the motivation is for the "good" of the patient, there is disrespect to their autonomy [10].

Just as there is an individual paternalism in the biomedical field, where the professional understands what is best for the patient and acts from the perspective of "doing good", there is also paternalistic action by the State. In the context of public policy, the State limits or imposes certain conducts, subject to penalties of direct punishment (for non-compliance with some regulation) – such as in traffic law, the mandatory use of seat belts – or the limitation of rights, such as in non-adherence to vaccination campaigns, which may result in refusal of access to certain localities, or the need for forced isolation for serious infectious diseases. In such cases, the premise is that the collective interest supersedes the individual. The boundary between the two, however, is not well defined [1,3,10].

These limitations, arising from public policies and administrative or legal guidelines, legitimately imposed, are defined as objective limits and understood as *limitations inflicted on the whole community, regardless of individual subjectivism*. On the other hand, actual subjective limits are due to *errors caused by a lack of adequate information or the action of an illegitimate co-acting force that requires the patient to decide in a certain way*, preventing the free expression of their autonomy [11].

Consent

Biomedical practice establishes the principle of individual autonomy by informed consent. This is the full knowledge of the subject, based on the information provided by the professional/researcher, of the expected effect of the action on him or her, with the consequent freedom to make a decision from this position. The individual, therefore, can only consent after obtaining, from the person responsible for the research or clinical procedure, all information concerning the possibilities, risks and treatment alternatives.

A study by Biondo-Simões et al [11] argued that the informed consent that is the moral right of

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patients implies moral obligations upon physicians, and that its exercise is effective *after the conjunction of autonomy, ability, willingness, information, clarification and consent itself.* In their study on the understanding of patients of informed consent, and the factors that change their understanding, the authors concluded that the appropriate subjects for research *are better-educated*, *with the habit of reading, with ease of access to the internet and who earn more*, since Brazilian law provides the formal requirement of so-called consent in writing [8].

Another recent study indicates the failure to communicate information in an assisted reproduction service. According to the authors, the term of free and informed consent (TFIC) was not drafted in totally appropriate language, nor did it address all the aspects needed to decide on the best treatment to be adopted [12].

The massive, horizontal, compulsory and indiscriminate use of "informed consent forms" (ICFs), that occurs in many countries (particularly in the area of research with human beings), irrespective of the specific cultural factors and socioeconomic status of the population addressed, provides for Garrafa [6] a distortion of its historic goal. ICFs, according to the author, had as their initial purpose the protection of individuals, especially the most vulnerable, in medical and hospital care and research with human beings; however, in their application and in actual practice, they merely subvert – often – the order of things, *as in a few years, the new theory proved to be a double-edged sword, as universities, corporations and industries began to train their professionals to create ICFs suitable for each situation. This, in a way, obstructed, in practice, the initial and historical objectives of the measure to protect the most vulnerable, at least in countries with great numbers of people excluded from a social and economic perspective* [13].

The inversion of ethical parameters for the protection of the vulnerable has been studied critically by Latin American authors, who report the attempts of the attempts of researchers – particularly in clinical trials sponsored by the multinational pharmaceutical industry – to introduce an ethical double standard in research. In other words, this premise indicates the application of one methodological research standard for rich and developed countries, where most of the population possesses the social and educational conditions required to understand and make decisions about the study in question; and the use of another, "more flexible" (in other words, "looser"), standard, aimed at poor or developing countries, where people are not enough educationally or economically empowered enough to truly make decisions regarding the acceptance – or not – of the trial [4].

Individuals unable to consent: minors

Although the concept of autonomy is polysemic, there is a consensus that two basic conditions are necessary for its expression: the freedom and the capacity to act intentionally. Freedom of action is understood as the independence from any kind of control. However, no individual can be considered completely free of external influences, such as those exerted by family, social groups, the institution to which he or she is linked professionally or the culture to which he or she belongs. Various everyday situations can constitute the limitation of autonomy. There are, however, more extreme cases, such as individuals with restricted freedom [3].

Because of the enormous complexity and uniqueness present in the question of individuals with reduced autonomy, and those who lack the capacity to provide consent, the focus of this study is related to the autonomy of minors – children and adolescents – who are considered legally incapable. According to Hostiuc [15],

(...) for informed consent to be valid, five requirements must be met: 1) the patient is informed; 2) understands the information; 3) acts by his or her own will (independently) when agreeing to sign the informed consent form; 4) has the legal authority to agree; 5) authorizes the procedure. Of these five requirements three mainly depend on the patient (2, 3, 5), one depends mainly on the health professional (1), and one is a legal requirement (4). (...) In pediatrics, patients who meet requirements 1, 2, 3 and 5 can give autonomous authority to regularize the work of the doctor (...) but this is generally not valid in a court of law, as informed consent must be signed by a person legally competent to sign an official document [16].

With specific regard to consent in pediatrics, two terms stand out: the capacity and the competence to make decisions. It is necessary to distinguish that "capacity" is the *psychological term that describes a set of mental skills that people require in their daily lives (logical memory, ability to care for oneself etc.), while competence refers to the legally established ability to create a legal norm (or legal effect) through and according to statements (legal acts or dispositional statements) in this regard* [16].

Because of the absence of the legal competence of children and adolescents to provide their consent freely and autonomously, this authorization is passed on to their legal guardians, usually parents or relatives. However, Teixeira [17] points out that minors accounted for one third of patients who were the targets of research into new drugs made by foreign laboratories in Brazil in 2001. These children, especially in developing countries, are subject to exploitation by researchers or even parents and family members, who sometimes do not even inform the individual about their participation in the trial [17].

In a study on cochlear implants in deaf children, Miziara et al [18] highlighted the vulnerability of wards, as the decisions of parents about such procedures are often geared more towards themselves than towards the child. This finding is verified both in the case of hearing parents, who carry with them the anguish of the difficulty in communicating with their children, and so may desire the implant, and deaf parents, who may not see disability as a problem, and so are more likely to reject the procedure. However, the authors do not seem to consider that children have a participatory role, however limited, in this decision-making process.

Munhoz [19] defends the participation of the child in this process, through consent. In such cases, they should be informed about the purpose of the treatment in question, in a manner that is clear and appropriate to their condition, so that they can agree to the procedure or otherwise.

Discussion

In the current Brazilian context, the minimum age considered appropriate for the legal validity of consent is between 16 and 21 years. Considering, only this factor initially, it is clear that minors under 16 years of age will not have any kind of autonomy over their medical situation in legal terms.

In these situations, the consent to carry out treatment or procedure will have to come from the parents or guardians responsible for the child or adolescent, which creates a conflict. Although, legally, guardians have the necessary autonomy to allow or deny a medical act, there is no guarantee that their decision truly seeks the best for the child. Without a voice or legal capacity, the patient in question would have no right to enforce his or her will. The child would, therefore, to submit to the heteronomy of his or her guardian, since, although there are cases of joint decision-making, they are rarely seen in current decisions in Brazil, mainly due to a lack of consistent legal support.

The lack of legitimating legal provisions regarding the effective participation of children and adolescents in decision-making and paternalism – parents, health professionals and even lawyers – are huge obstacles to ensuring the autonomy of these individuals. When there is conflict between parents and children about the continuity of the therapeutic process, medical professionals usually respect the decision of parents over children. The exception, based precisely on paternalistic logic, usually occurs when there is disagreement about a procedure considered beneficial by health professionals – a situation in which the legal system is usually triggered to intervene, based on the doctrine of *parens patriae*, according to which the state can intervene to protect those who need it [20,21]. In other words, minors are heard and are considered competent when they consent to a medical procedure recommended by health professionals, but are not thought to be able to refuse a procedure that is "clearly beneficial" [15].

However, one should remember that the exercise of autonomy is *also revealed in the free choice of the patient to refuse treatment* [22]. The refusal to treatment or a health procedure has many motivations and should be as respected as assent. The complexity of situations related to the participation of children and adolescents in decision-making processes that affect them directly shows one of the problems of principlism. Likewise, it shows the weakness arising from a heightened emphasis on the autonomy of the individual, which does not consider the specifics of each case and other factors related to each particular situation.

The training of working health professionals is based on action, aimed at promoting and restoring health. There is therefore an inherent difficulty in accepting the refusal of treatment by patients. In the case of children, who are culturally a target group requiring greater protection and care, acceptance becomes even more complex because health professionals feel they are overlooking their professional and human responsibilities. Allied to this, there is a fear of legal liability in the event of a possible disagreement between the decision of the child and his or her legal guardian, or even when there is no consensus among those responsible.

A recent example of a situation that involved the inclusion of children in the decision-making process took place in 2014 in Belgium where, in an unprecedented manner, legislation was amended,

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extending to children the right to request euthanasia in cases of terminal illness, and removing any reference to age restrictions. In the Netherlands, for example, to make such a decision, individuals must be aged over 12 years. The law provides that the child should be in a position of constant and unbearable physical pain that is impossible to relieve and may result in the short term in his or her death. While there is a requirement that the child has consciousness, and that his or her understanding of the decision is subjective and not clearly described in the law, the need for certification of these conditions by a child psychiatrist or psychologist, as well as the support of the decision by one of the parents or legal guardians, provides a role for those involved and represents a pertinent solution [23].

While it is of paramount importance to ensure that there are instruments that preserve the autonomy of children and adolescents in clinical decision making, their participation is justified not only by respect for the principles of the autonomy and consent of these individuals, but also by the fact that the refusal of their participation will diminish and nullify their presence in decision-making. In addition to using the three principles described earlier in this article, other principles of the UNESCO UDBRH, such as: human dignity and human rights (Article 3), benefit and harm (Article 4) and respect for human vulnerability and personal integrity (Article 8) should be considered. These principles, combined with those of autonomy, individual responsibility, consent and those unable to consent, can provide concrete means to explore these issues more deeply, based on Article 27 of the same Declaration, which refers to the interrelationship and complementarity of its principles.

Final considerations

The fact that autonomy is limited by paternalism is widely known in the case of individuals who are subject to the care of health professionals. The "duty to do good" of the health professional finds strength in the fear of legal consequences, which can be mitigated through an instrument of informed consent. However, this protective step for patients/research subjects – on many occasions and in various situations – is also a protection mechanism of professionals and researchers, to exempt them from legal responsibility.

The absence of legal provisions to legitimize the decisions of children and adolescents on the clinical procedures they are to undergo opens a huge space for the paternalistic role of professionals and legal guardians who act for the benefit of the patient, but based on their own perspectives. It is important to think, in the future, of instruments that provide progressive respect for the autonomy of children and adolescents, a situation that – if crafted with care and participation – poses no threat to professionals and guardians.

Bioethics must discuss, with greater vigor and courage, possible real mechanisms and forms of protection for individuals considered legally unable to give their consent. In current clinical practice, multidisciplinary health teams, and clinical/hospital bioethics committees, appear to be the best alternative available to ensure the autonomy and protection of these subjects.

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Raylla Albuquerque, a master's student, created and wrote the original article. Volnei Garrafa, as study advisor, participated in its design, monitoring and review.

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