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Informed consent in scientific research: what should we know?

Consentimento informado em pesquisa científica: o que devemos saber?

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Palavras-chave
Bioética; Consentimento informado; Ética clínica; Deontologia.

Resumo

O consentimento informado é um dos pilares da investigação e considerado imperativo numa perspetiva ética. Atendendo aos respetivos princípios e ao processo de investigação cada vez mais rigoroso, responsável e complexo, torna-se desafiante a reflexão sobre a sua validade na perspetiva ética e deontológica.

Assistimos ao rápido desenvolvimento do conhecimento na biomedicina e, associado a uma inovação tecnológica sem precedentes, verifica-se uma maior complexidade dos estudos e, consequentemente, do consentimento informado. Considera-se, portanto, a simplificação e validação das informações a serem transmitidas ao participante, a possibilidade de prorrogação do prazo para esclarecimento de possíveis dúvidas, a utilização de ferramentas de apoio e a otimização da comunicação por parte dos pesquisadores. Outros aspetos a ter em linha de conta pelos investigadores são os termos excessivamente técnicos, as informações de difícil interpretação, esclarecimento resumido, culturas diferentes e as ideologias sociopolíticas.

Dadas as várias dimensões jurídicas do consentimento, demonstra-se a relevância do exercício livre e informado dos direitos previstos na lei, no desenvolvimento científico em saúde. Além de ser uma oportunidade de comunicação efetiva, o consentimento informado deve ser baseado numa relação de confiança entre o investigador e o participante, baseada em princípios éticos. Estes são essenciais para o desenvolvimento de investigações racionais e robustas, orientando de alguma forma o trabalho a ser desenvolvido pelos investigadores, baseando-se nos princípios da beneficência, não maleficência, justiça, autonomia e precaução. Assim, o participante assume um papel ativo no sucesso ou inviabilidade da investigação, cabendo aos investigadores respeitar uma decisão livre e esclarecida.

Keywords
Bioethics; Informed consent; Clinical ethics; Deontology.

Abstract

Informed consent is a pillar of the research and imperative in an ethical dimension. Given its inherent principles in an increasingly rigorous and responsible investigation, this process is complex, making it challenging to reflect on its validity from an ethical and deontological perspective.

We are witnessing the fast development of knowledge in biomedicine intrinsic to unprecedented technological innovation, with increased complex studies and repercussions on consent. Among them, the simplification and validation of information to be transmitted to the participant, the possibility to extend the period for clarifying possible doubts, the use of support tools, and optimization of the communication by researchers. Overly technical terms, difficult interpretation of the information, little explanation, different cultures, and sociopolitical ideologies affect the researchers' differentiation.

Given the several legal dimensions of consent, the relevance of free and informed exercise of the rights provided by law for scientific development in health was demonstrated. In addition to an opportunity for effective communication, informed consent must be based on a trust relationship between the investigator and the participant, based on ethical principles. These are essential to the development of rational and robust research, somehow guiding the work to be carried out by researchers, including the principles of beneficence, non-maleficence, justice, autonomy, and precaution. Therefore, the participant assumes an active role in the success or suspension of the investigation, and the investigators are responsible for respecting the informed and free decision.

Introduction

The informed consent process in scientific research is fundamental for developing knowledge in health in a transparent, credible, rigorous, and reliable way, leading us, in certain circumstances, to ethical-deontological dilemmas. Currently, this is a challenge with a certain degree of complexity, and it is essential to reflect on the validity of informed consent in an increasingly rigorous and responsible investigation.

It is essential to reflect on informed consent in scientific research, addressing the ethical and deontological perspectives. We will not focus on the legal perspective as adaptations are specific to each country.

In an increasingly global society, with scientific evidence assuming a central element in the development of communities, the transparency of processes and the consent of stakeholders is undoubtedly one of the themes discussed universally.[1]

One of the essential points in an investigation considered ethically robust is the consent obtained by all parties, that is, the process where the person investigating ensures awareness of the risks and benefits, rights, the possibility of not wanting to participate or simply giving up on the inclusion in the study. The participant's decision must be voluntary, having the capacity to receive the information, the alternatives, understand them, having the ability to decide.[2]

The ethical principles of biomedicine provide robustness to prior, free and informed consent in scientific research, especially the principle of autonomy, which reflects respect for individual decision throughout participation in a given clinical study, even in a position of a possible vulnerability in relation to the consequences of the respective decision.[3]

1. Imperative conduct in scientific research: current challenges

The development of knowledge in biomedicine has been exponential with increasingly complex studies and sometimes with repercussions on the consent itself due to information that is difficult to interpret or terms too technical for the participant. This process can be a challenge in specific populations or in underdeveloped countries where literacy is very low and, in some cases, illiteracy, forcing researchers to look for other strategies so that understanding on the part of the participants is obtained.[4]

Informed consent is one of the parts of the process that supports a given scientific investigation. It must contribute to a participant's decision based on their autonomy to be part of the study and understand the information provided to them.[5]

This decision-making is not linear, given the complexity of the information, the participant's literacy level, and the understanding of the benefits and acceptance of the associated risks.[4]

Understanding is one of the components of informed consent, which includes knowledge of different clinical situations and various therapeutic possibilities.[6] Informed consent must be in a language accessible to the participant's cultural level, adapted as much as possible to their linguistic or cognitive limitations.[6] As researchers, it is crucial to reflect on understanding, ensuring conditions for a decision based on the assumptions of self-responsibility and freedom in the choice made.[6]

2. Strategies for the informed consent process

According to several authors and scientific entities, there are several strategies for understanding the information inherent to participating in a study and allowing a more understandable and valid decision.[4,7,8] Among them are the simplification of informed consent, the use of communication strategies by the researcher and tools to support the information transmitted, the evaluation of the information provided to the participant, and the possibility of extending the period for clarification of the information.[4,7,8]

Regarding the first strategy, the simplification process, this is an asset in explaining what is intended by scientific research and the assimilation and subsequent decision of the person to participate. The information to be transmitted must be clear and accessible through verbal communication and, whenever possible, accompanied by ancillary material, without value judgments on the researcher's part.[5,8] The participant must receive sufficient knowledge to make a good decision, verifying if the information was enlightening through a participatory and continuous communication process.[4,5,8] It should be noted that structuring the informed consent process in a logic of simplification makes it possible to reflect and qualitatively evaluate the information transmitted as recommended by appropriate ethical conduct.

Another of the strategies to be adopted by the researcher, and reported by other authors, is related to successful communication. Effectively, participants better understand the potential risks and benefits when researchers learn communication strategies.[7,9] Ineffective communication negatively influences the ethical integrity of consent, compromising the informed decision to participate in the study.[9] That is why the communication process is essential: identifying the audience, the most appropriate information channels, and the exposition of the message clearly and objectively. By reading or explaining the risks and benefits by the researcher,[5] based on a summary and highlighting of certain important information from the study, it allows the participant to pay attention to what is most important or most likely.[9] In addition, it is also essential to use simple language, with transparent and objective forms of reduced size that contain only the most relevant or necessary information.[10] Although scientific knowledge has evolved regarding the various strategies to improve the informed consent process, with published recommendations, it may be through the development of skills inherent to effective communication to overcome some obstacles.[11]

Other strategies and tools are used to optimize the informed consent process that facilitates the evaluation of the information transmitted. The use of auxiliary technology, the creative approach in presenting information, the improvement of scientific vocabulary, and the participation of trusted family members/friends throughout the consent and decision-making process stand out.[7] One such example is the “take it home” approach, which has already been adopted in several contexts.[9] It is allowed to take a copy of the consent home, allowing for multiple readings and opinions.[9] This type of strategy, in which the process is more integrative and dynamic, may imply an extension of the period for reflection and clarification of possible doubts of the person participating in the study.[4] It may also be essential to update the consent of the investigator, reformulating the main elements of the form at a given moment in the study.[10] Therefore, these strategies and continuous efforts allow bringing different realities and cultures closer together in achieving informed consent.

3. Ethical-deontological perspective

Given the Convention on Human Rights and Biomedicine, human beings are protected in their dignity and identity, guaranteeing respect for their integrity, rights and freedoms in the application of biology and medicine.[3] Respecting principles, the well-being of each human being must prevail over the benefits of society or the development of science. In this context, before any intervention, the respective free and informed consent must be provided, based on credible and perceptible information, with knowledge of the individual consequences/risks and benefits.

Consequently, the researcher may face ethical problems that are difficult to resolve. Reflection based on principles and values, ethical principles and deontological duties can be the key to a good solution in developing the process,[12] being the solution to an ethical dilemma based on ethical principles. It is essential to mention the distinction between an ethical dilemma and an ethical problem.[13] In an ethical dilemma, the solutions go through ethical principles or duties linked to a particular position of the person.[13] In the face of an ethical problem, responsibility is mentioned; however, it does not place the person at the centre of the decision but the common problem or ethical axis on which it must be addressed.[13] The identification of ethical problems in developing a particular clinical study and its categorization can guide the solution on the assumptions initially defined in the implementation of that same study.

Scientific research is based on different principles inherent to its integrity, guiding the work to be carried out by researchers, on which we will reflect.

Considering that beneficence corresponds not only to the researcher’s point of view but also to what is advocated by the person himself, what is seen as beneficial for himself, the person has the right to decide what is best for him by participating in a free.[2] The autonomy of the person to decide to participate in a scientific study reflects the quality of the methodology used, ensuring respect for the recognition of each person’s abilities in the decisions throughout their health process, with the respective integration in a plan of sharing knowledge to what is proposed.[5,14]

However, given the context of scientific research, the participant is exposed to varying degrees of risk.[5,11] It is impossible to guarantee direct benefit, so weighing the risks and benefits is crucial.[5,11] Therefore, it is essential to prevent participation in studies where the risks of taking part are more significant than not participating. In managing possible risks associated with research related to life sciences and the inherent technologies, it is implicit in the Universal Declaration on Bioethics and Human Rights in its article 20.[15] Being conditioned by identifying potentially harmful effects, by evaluating available scientific knowledge and by the dimension of possible uncertainties related to the investigation, it is essential to attend to the imminence of potential risk or damage. Adequate ethical conduct makes it possible to safeguard and promote the interests of current and future generations following article 2 of the Universal Declaration on Bioethics and Human Rights.[15]

Access to innovative healthcare or the possibility of participating in a particular clinical study should not differ depending on the individual characteristics of each person, ethnicity, geographic location, socioeconomic status or gender.[14] The European Code of Conduct for Research Integrity also addresses respect for participants in the research process and, in a broader perspective, respect for society, ecosystems, cultural heritage and the environment.[14] The respective commitment to the current challenges is based on present generations' responsibility to ensure the needs and interests of future generations,[15] with a solid commitment to training, supervision, and guidance in scientific research.[14]

3.1. Participant vulnerability

In addition to the primary principles mentioned above, integrating vulnerability into the ethical dimension reinforces the integrity of scientific research. Article 8 of the Universal Declaration on Bioethics and Human Rights considers the vulnerability and integrity of people, referring to the protection (and not exclusion) of individuals/groups in light of the current development of scientific and technological expertise.[15] An ethically responsible society must protect the most vulnerable, using scientific and technological knowledge to promote information within the limits of the rights of the enlightened will of each person in favor of human dignity.[16]

Exemplary ethical conduct requires special attention to certain vulnerable groups: children, the elderly, people with disabilities, and the terminally ill. Scientific research is not morally justifiable when facing high-risk conditions for the participants and the nature and degree of risk given the exposure. The involvement of these vulnerable groups should be justified, with the respective expected benefits in documents and procedures, such as the detail of the informed consent process.[2] Scientific research is fundamental for developing knowledge in health, allowing for a better quality of life and well-being for each person, safeguarding the individuality, vulnerability, dignity and voluntariness of all those who contribute to it.[16] In this sense, communication, information, and ethical principles are the pillars that can allow free and informed consent to participate.

Conclusion

The imposition of protection of human beings in their dignity and identity guarantees respect for rights and freedom. This paper reflects the importance of informed consent in scientific research, which ethics committees currently support; researchers face some challenges for its entire validity. It should be noted that, in scientific research and particularly in the clinical area, informed consent obtained explicitly is an essential but complex process, given the specificity of the information, which is sometimes too technical and challenging to interpret.

In the ethical-deontological context, the principles of beneficence, non-maleficence, justice, autonomy and precaution are fundamental. In the field of ethics, there are the rights of people in their condition as human beings, understood by their dignity, physical and psychosocial well-being, and autonomy in their own decisions. Deontology entails the duties of researchers to respect the decisions of people//participants in a given scientific study, providing adequate information on possible risks and benefits, ensuring autonomy for their consent. Communication is essential for the informed consent process, with the need to resort to strategies and skills on the part of the researcher/professional in adapting the information to each participant.

Each Member State of the European Union adopts or ensures the necessary measures to maximize the protection of each person who participates in given scientific research, seeking to defend their rights and values.

In public health policies and scientific health research, the autonomy and individuality of each person's must be respected to make the best decisions to achieve a specific objective. The success of the development of knowledge through science largely depends on the conduct adopted by researchers in compliance with ethical-deontological and legal principles.

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