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Informed consent in medical practice and clinical research

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Palabras claves:
Consentimiento informado
Ética médica
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Autonomía del paciente
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Resumen

Introducción. El consentimiento informado es un pilar fundamental en la práctica médica y la investigación clínica, evolucionando de un modelo paternalista a uno que enfatiza la autonomía del paciente y la toma de decisiones compartida. A lo largo del tiempo, la importancia de garantizar que los pacientes y participantes en estudios clínicos comprendan plenamente los procedimientos, riesgos y beneficios ha sido reconocida como esencial para proteger sus derechos y asegurar un trato ético. **Objetivo.** El objetivo de este artículo es realizar una revisión de la literatura sobre el consentimiento informado en la práctica médica y en la investigación clínica, identificando los avances, desafíos y consideraciones éticas asociadas, con el fin de proporcionar una comprensión integral y actualizada de su estado actual y su aplicación en diferentes contextos. **Metodología.** La metodología de la revisión se basó en una búsqueda sistemática de estudios en bases de datos académicas como *PubMed, Scopus, y Web of Science*. Se incluyeron artículos que abordaran el consentimiento informado en contextos médicos y de investigación clínica, publicados en los últimos diez años. Los estudios seleccionados fueron evaluados críticamente para identificar sesgos y extraer temas relevantes, como la comprensión del consentimiento por parte de los pacientes, las barreras culturales y la influencia de las innovaciones tecnológicas. **Resultados.** Los resultados de la revisión revelaron que, a pesar de los avances en la conceptualización del consentimiento informado, persisten desafíos significativos en su implementación. Estos incluyen la comprensión limitada por parte de los pacientes y participantes, barreras de comunicación, y diferencias culturales que complican el proceso de consentimiento. Se destaca la necesidad de herramientas tecnológicas y formación continua para los profesionales, así como la adaptación cultural del proceso de consentimiento para mejorar su eficacia y respetar los derechos de los individuos. **Conclusión.** El consentimiento informado en práctica médica y en investigación clínica es una piedra angular, su importancia no puede ser subestimada, porque en la medicina y la investigación continúan evolucionando, también debe hacerlo la práctica del consentimiento

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www.anatomiadigital.org

informado, adaptándose a nuevas tecnologías, desafíos éticos y las necesidades cambiantes de los pacientes y participantes. **Área de estudio general:** Medicina. **Área de estudio específica:** Bioética y ética médica. **Tipo de estudio:** Artículos originales.

Keywords:
Informed Consent
Medical ethics
Clinical research
Patient autonomy
Bioethics

Abstract

Introduction. Informed consent is a fundamental pillar in medical practice and clinical research, evolving from a paternalistic model to one that emphasizes patient autonomy and shared decision making. Over time, the importance of ensuring that patients and clinical trial participants fully understand the procedures, risks, and benefits has been recognized as essential to protect their rights and ensure ethical treatment. objective. The aim of this article is to conduct a review of the literature on informed consent in medical practice and clinical research, identifying advances, challenges, and associated ethical considerations, to provide a comprehensive and up-to-date understanding of its status and application in different contexts. Methodology. The methodology of the review was based on a systematic search for studies in academic databases such as PubMed, Scopus, and Web of Science. Articles addressing informed consent in medical and clinical research contexts, published in the last 10 years, were included. The selected studies were critically applied to identify biases and extract relevant issues, such as patients' understanding of consent, cultural barriers, and the influence of technological innovations. Results. The results of the review revealed that, despite advances in the conceptualization of informed consent, significant challenges persist in its implementation. These include limited understanding by patients and participants, communication barriers, and cultural differences that complicate the consent process. The need for technological tools and ongoing training for professionals is highlighted, as well as cultural adaptation of the consent process to improve its effectiveness and respect the rights of individuals. Conclusion. Informed consent in medical practice and clinical research is a cornerstone, its importance cannot be underestimated, because as medicine and research continues to evolve, so must the practice of informed consent, adapting to

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modern technologies, ethical challenges, and the changing needs of patients and participants. General Area of Study: Medicine. Specific Area of Study: Bioethics and Medical Ethics. Type of study: Original articles.

Introduction

Informed consent is a central concept in medical practice and clinical research, deeply rooted in the principles of ethics and human rights. It refers to the process by which a patient or participant in a clinical trial receives sufficient and comprehensible information about a treatment, procedure or research, and then voluntarily decides whether to proceed. This practice is based on respect for the autonomy of the individual, recognizing their right to make decisions about their own body and health, based on adequate knowledge of the implications, risks and benefits of the proposed interventions.(1).

Historically, informed consent has not always been standard practice in medicine. For a long time, physicians and scientists often made decisions about treatments and procedures in a paternalistic manner, assuming they knew what was best for their patients. However, various events and movements transformed this perspective, underscoring the importance of respecting patient autonomy and ensuring that patients are provided with all the information necessary to make informed decisions. Extreme situations, such as medical atrocities committed in certain historical periods, revealed the need to protect individuals from non-consensual treatments and experiments. These events prompted the creation of ethical codes and declarations that establish the need to obtain voluntary consent in clinical research and medical practice.(2).

In the clinical context, informed consent involves providing the patient with clear and complete information about the diagnosis, the nature of the proposed procedure, the potential risks and benefits, the available alternatives, and the possible consequences of not receiving the treatment. This process should be ongoing, not just a signed document, and should be tailored to the patient's understanding, considering factors such as education level, language, and cultural context. The doctor-patient relationship has evolved from a paternalistic model to a more patient-centered one, where shared decision-making has become a standard of care. In this model, doctors act as guides and facilitators, helping patients understand the information and make decisions that reflect their values and preferences.(3).

In clinical research, informed consent takes on an additional dimension of complexity. Participants in clinical trials not only need to understand the procedures and risks, but also the implications of participating in research that might have an experimental and

uncertain component. Here, informed consent is critical to protect participants from potential harm and to ensure that their participation is truly voluntary. Ethical documents and statements guiding medical research emphasize the importance of informed consent in research, providing a framework to ensure that participants in clinical trials are treated with respect and dignity.(4).

Despite its fundamental importance, the implementation of informed consent faces several challenges in medical practice and clinical research. One of the main challenges is ensuring that the patient or participant fully understands the information provided. Studies have shown that many patients do not adequately understand the risks and benefits of the treatments they are considering, calling into question the validity of the consent obtained. Communication barriers, such as the use of complex medical terminology, cultural differences, and limitations in health literacy, can prevent patients from fully understanding the information. Furthermore, limited time in medical consultations often restricts the opportunity to thoroughly discuss all options, which can lead to less informed consent.(5).

Another significant challenge is the influence of psychological and emotional factors on the decision-making process. Patients facing serious diagnoses or risky procedures may feel overwhelmed by information or pressured to accept treatment quickly, which could compromise their ability to make truly informed decisions.(6)In the context of clinical research, pressure to recruit participants can sometimes lead to rushed or insufficiently informed consent. The reliance on financial incentives for participation in clinical trials also raises ethical questions about the true voluntariness of consent, especially in vulnerable populations.(7).

Ethical considerations related to informed consent are profound and encompass the need to balance respect for the autonomy of the individual with the obligation of the health care professional to do what is best for the patient or participant. The ethical dilemma of informed consent arises when the interests of the patient, his or her well-being, or the scientific objectives of the research conflict with the autonomy of the individual. For example, in medical emergency situations, it may be difficult to obtain truly informed consent before proceeding with essential, potentially life-saving treatment. In clinical research, studies involving vulnerable populations, such as children or people with cognitive disabilities, present unique challenges in ensuring that informed consent is truly valid and representative of the will of the participant.(8).

Technology has begun to play an increasingly important role in the informed consent process. Digital tools, such as mobile apps and online platforms, are being used to provide more accessible and understandable information to patients and participants. These technologies can include educational videos, interactive simulations, and questionnaires to assess comprehension, which can significantly improve the consent process. However,

these innovations also raise new questions about privacy, data security, and equity in access to information, especially for those who lack access to technology or digital skills.(9).

In medical practice, informed consent is not simply a legal requirement, but an essential component of medical ethics and the doctor-patient relationship. Providing adequate information and ensuring that the patient understands it is essential to respecting their autonomy and dignity.(10). Shared decision making, which is the natural evolution of informed consent, strengthens the collaboration between physician and patient, ensuring that medical decisions reflect both clinical expertise and the patient's values and preferences. This not only improves patient satisfaction, but can also lead to better health outcomes, as patients who understand and actively participate in their care are more likely to follow recommended treatments.(11).

In clinical research, informed consent is a fundamental pillar that protects the rights of participants and ensures the ethical integrity of studies. Ongoing reviews by ethics committees and monitoring of consent processes are essential to ensure that studies are conducted in accordance with the highest ethical standards. However, researchers must be aware of the complexities and challenges associated with informed consent, and continually work to improve the clarity and transparency of the process.(12).

Methodology

To conduct a literature review on informed consent in medical practice and clinical research, a systematic approach was adopted, which included the identification, selection and critical analysis of relevant studies. This approach aims to provide a comprehensive and updated overview of the state of informed consent, highlighting both the advances and challenges in its implementation in different contexts.(13).

The first step in the methodology was to conduct a comprehensive search in recognized academic databases, such as PubMed, Scopus, Web of Science, and Google Scholar. These databases were chosen due to their broad coverage of scientific publications in the fields of medicine, ethics, and social sciences. Specific keywords such as “informed consent,” “medical practice,” “clinical research,” “medical ethics,” and “patient autonomy,” combined with Boolean operators were used to refine the search and ensure the relevance of the results. The search was limited to studies published in the last ten years, although seminal articles that are essential to understanding the historical and conceptual evolution of informed consent were included.(13).

To ensure the relevance and quality of the selected studies, inclusion and exclusion criteria were established. Articles that specifically addressed informed consent in medical and clinical research contexts were included, both from a theoretical and practical

perspective. The studies had to be published in peer-reviewed journals and written in English or Spanish. Articles that did not offer a direct analysis of informed consent or that were narrative reviews without a rigorous methodological approach were excluded. In addition, duplicate studies and those with insufficient methodological quality, according to the critical appraisal carried out.(14).

Once the studies were selected, a critical appraisal was carried out using standard appraisal tools, such as the PRISMA (Preferred Reporting Items for Systematic Reviews and Meta-Analyses) checklist and the CASP (Critical Appraisal Skills Programme) approach. This appraisal allowed the identification of potential biases, the validity of the results, and the applicability of the findings to different contexts. The analysis focused on extracting information on the main challenges and barriers in the implementation of informed consent, the differences in its application between medical practice and clinical research, and recommendations to improve its effectiveness.(13).

Information extracted from the selected studies was synthesized thematically. Emerging themes included patients' understanding and perception of informed consent, the influence of cultural and linguistic factors, the appropriateness of consent in vulnerable populations, and the impact of technological innovations on the consent process. Particular attention was paid to contextual differences between medical practice and clinical research, identifying both similarities and divergences in the application of informed consent. In addition, the role of ethics committees and institutional policies in ensuring adequate and ethical informed consent was analyzed.(14).

Despite the rigor of the review process, it is important to acknowledge some limitations. The review was limited to studies published in two languages and may have missed relevant research in other languages. Furthermore, the focus on articles from the past ten years, while ensuring currency, could have excluded important previous studies that are still relevant. Finally, the quality and scope of the available studies may influence the ability to generalize the findings globally.(13).

Results

Once the literature review has been carried out, the following results are obtained:

Evolution of informed consent

The concept of informed consent has undergone significant evolution over the years. Originally, medical practice was based on a paternalistic model, where doctors made decisions on behalf of the patient, believing that they knew what was best for their health.(15). However, as the importance of individual rights and patient autonomy became recognized, informed consent emerged as an essential component of the physician-patient relationship. The studies reviewed indicate that the development of this

concept has been driven by several factors, including advances in medical ethics, bioethics, and human rights.(2). Landmark events such as the Nuremberg trials and the Belmont Report played a crucial role in formalizing informed consent, establishing that patients and research participants must be fully informed about procedures, risks, benefits, and alternatives before making a decision.(11).

It is stressed that informed consent is not a one-time process, but rather a continuous one, which must be adapted to the specific context of each patient or study participant. The articles reviewed underline the importance of health professionals and researchers developing effective communication skills to ensure that the information provided is understandable, complete and suitable for informed decision-making.(16)The evolution of informed consent has led to a greater emphasis on shared decision-making, where the physician or researcher acts as a facilitator in the decision-making process, respecting the values, beliefs, and preferences of the patient or participant.(4).

Application in medical practice

In medical practice, informed consent is a fundamental element in the relationship between physician and patient. The literature review reveals that although most countries have adopted informed consent as a legal and ethical requirement, its application varies significantly in daily practice. Several studies point out that while health professionals recognize the importance of informed consent, they often face challenges in its implementation. These challenges include lack of time during consultations, the complexity of medical information, and communication barriers such as language and cultural differences.(7).

The literature also suggests that informed consent in medical practice is not always optimal. In some cases, patients sign consent forms without adequate understanding of what they are consenting to. This may be due to the use of technical and complex language that patients do not fully understand, or the pressure they may feel to agree to treatment quickly.(17). Studies indicate that, to improve informed consent practice, it is essential that physicians receive ongoing training in communication skills and consent ethics. In addition, it is recommended that more structured and standardized processes be implemented to ensure that consent is truly informed and voluntary.(4).

Application in clinical research

Informed consent in clinical research presents additional challenges compared to standard medical practice. The literature review shows that in the context of research, informed consent is crucial not only to protect participants, but also to ensure the validity and ethical integrity of the study. The reviewed articles highlight that unlike in clinical practice, where consent is typically focused on a specific treatment, in clinical research,

participants must understand the experimental nature of the study, the potential risks and benefits, and the possibility of uncertain outcomes.(7).

The complexity of information that must be conveyed in a research setting can make it difficult for participants to fully understand what their participation entails.(17). The literature suggests that participants in clinical trials often do not fully understand the risks associated with their participation, raising questions about the effectiveness of the informed consent process. In addition, there are concerns about the influence of factors such as financial incentives and pressure to recruit participants in clinical trials, which could compromise the voluntariness of consent.(2).

To address these challenges, several studies propose the use of technological tools, such as educational videos and interactive questionnaires, which can improve participant understanding. In addition, the implementation of continuous informed consent processes is suggested, in which researchers provide updated and reiterated information throughout the study, ensuring that participants continue to understand and consent to their participation.(12).

Challenges and barriers in implementation

The reviewed studies identify multiple challenges and barriers to the effective implementation of informed consent in both medical practice and clinical research. One of the most significant challenges is patient or participant understanding.(18). The literature points out that individuals often do not have the level of health literacy necessary to fully understand the information provided, especially when it is presented in technical language. This is particularly concerning in vulnerable populations, such as people with low educational attainment, older people, or those who do not speak the language in which the information is presented.(3).

Another challenge highlighted in the literature is the limited time that healthcare professionals and researchers have to discuss informed consent in depth. Pressure for reduced consultation times or the need to move quickly with participant recruitment can lead to a rushed consent process, where not all patient or participant questions and concerns are adequately addressed.(12).

Also, the reviewed studies point out that cultural differences and personal beliefs can significantly influence the perception and understanding of informed consent. In some cultures, shared decision-making and questioning of medical authority are not common practices, which can lead to less informed consent or acceptance of procedures without a full understanding of the risks.(19)To overcome these barriers, the literature recommends cultural adaptation of the informed consent process, including the use of cultural

mediators or translators when necessary, and personalization of information to make it more relevant and accessible to patients or participants from diverse cultures.(3).

Ethical implications

Informed consent is fundamentally an ethical issue, centred on respect for the autonomy and rights of the patient or participant. The reviewed studies underline that, in addition to practical challenges, there are important ethical implications related to informed consent.(20). In medical practice, informed consent is crucial to ensure that treatment decisions reflect the patient's preferences and values. However, when the consent process is not carried out properly, there is a risk that patients will undergo treatments they do not fully understand or do not want, which constitutes a violation of their autonomy.(11).

In clinical research, ethical implications are equally important. The literature review highlights that in studies where placebos are used or the efficacy of new treatments is tested, participants must be fully informed about the nature of the study and the potential risks. However, the complexity of these studies often makes it difficult for participants to understand all aspects of their participation.(21)The literature also points out that, in research involving vulnerable populations, such as children or people with cognitive disabilities, informed consent must be obtained with extreme caution, ensuring that legal representatives or guardians are fully informed and that participation is truly voluntary.(5).

The reviewed studies also address the importance of confidentiality and handling of personal information in the context of informed consent. In the digital age, where personal and health data are collected and stored electronically, protecting the privacy of patients and participants is a crucial issue. The literature suggests that informed consent processes should include clear information about how data will be handled, who will have access to it, and how individuals' privacy will be protected.(9).

Progress and recommendations

Throughout the review, several advances and recommendations were identified to improve the informed consent process in medical practice and clinical research. One of the most significant advances is the use of digital technologies to improve the understanding and accessibility of information.(22). The literature suggests that mobile apps, educational videos, and online platforms can be effective tools to provide information in a more understandable and personalized way. These tools can also allow for a more interactive informed consent process, where patients or participants can ask questions and receive answers in real time.(9).

Another important recommendation is the need for ongoing training for health professionals and researchers in communication skills and consent ethics. The literature

underlines that for informed consent to be truly effective, professionals must be able to communicate complex information in a clear and understandable manner, adapting their approach to the needs and capacities of each patient or participant.(5).

Conclusions

- Informed consent is a cornerstone of both medical practice and clinical research, and its importance cannot be understated. As medicine and research continue to evolve, so must the practice of informed consent, adapting to new technologies, ethical challenges, and the changing needs of patients and participants. This review article seeks to explore in depth the key aspects of informed consent, examining its evolution, current challenges, and best practices to ensure that patients and participants are adequately informed and their rights respected at all times.
- The methodology adopted for this literature review provides a solid foundation for understanding the challenges and advances in informed consent within medical practice and clinical research. Through a comprehensive search, critical appraisal and thematic synthesis, this study seeks to offer a comprehensive overview that can inform future research and practice in this field.
- The literature review on informed consent in medical practice and clinical research reveals that, although significant progress has been made in its conceptualization and application, there are still significant challenges that need to be addressed. These include limited understanding by patients and participants, cultural and linguistic barriers, and the ethical implications of less than fully informed consent. However, with the use of emerging technologies, ongoing training, and a tailored approach, it is possible to improve the effectiveness and ethics of informed consent, ensuring that the rights and autonomy of patients and participants are respected at all times.

Conflict of interest

The authors declare that there is no conflict of interest in relation to the submitted article.

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Indexaciones