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The Declaration of Helsinki and the Evolution of Ethics in Medical Research

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Abstract

This study analyzes the evolution of the Declaration of Helsinki in relation to the external regulation of medical research and transparency in clinical trials, highlighting its impact on contemporary biomedical ethics. Its objective was to evaluate the perceptions of healthcare and bioethics professionals on these aspects, considering the educational, professional, and geographic context. A quantitative, cross-sectional, and correlational design was adopted, with a purposive sample of bioethics and healthcare specialists from diverse regions, ensuring cultural, demographic, and socioeconomic representativeness. The results indicated a broad consensus on the need for external regulation and the publication of negative results in clinical studies, although differences persist in the interpretation of participant well-being and in the application of ethical principles depending on the regulatory context of each country. The study contributes to the field of knowledge by demonstrating how professional and regulatory factors influence the perception of ethics in research, although it has limitations regarding the inclusion of patient and policymaker perspectives. As future lines of research, we suggest analyzing civil society's perception of ethics in medical research, comparing the implementation of the Declaration of Helsinki in different health systems, and evaluating the impact of new technologies, such as artificial intelligence, on the ethics of biomedical research.

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Introduction

The objective of this study was to analyze the evolution of the Declaration of Helsinki, from its initialconception based on medical self-regulation to its current structure that incorporates external regulations, evaluating its impact on clinical research and the protection of participants' well-being.

How has the Declaration of Helsinki evolved in relation to ethics in clinical research, and what are the implications of its amendments for external regulation and the protection of the well-being of research subjects?

The Declaration of Helsinki, an ethical benchmark for medical research, has recently recognized the inadequacy of medical self-regulation in the face of technological advances. This document proposes provisional external regulation that would reflect scientific advances and ethical discussions surrounding methods, techniques, and medications, especially in the context of wellness and open science. According to, this external regulation is necessary because the increasing complexity of clinical research has outgrown the medical community's capacity for self-regulation[1]. However, this proposal poses a challenge: the definition of "wellness" has not been universally established, making its application difficult in diverse contexts.

The Declaration of Helsinki emerged as an instrument for judging war criminals, but initially failed to fully resonate with the medical community [1]. In 1975, with the introduction of independent committees in Tokyo, there was a move toward greater oversight, although medical self-regulation remained predominant. Nevertheless, modern clinical research has become more oriented toward the acquisition of knowledge than the direct benefit of participants, which has generated ethical tensions. points out that, although the logical justification of a research project precedes its ethical justification, the latter remains crucial to ensure that the benefits outweigh the risks[1].

One of the Declaration's biggest shortcomings is the lack of a clear definition of "well-being." This concept, central to research ethics, has not been established through a universal procedure or validated by the scientific community [1]. Furthermore, the public availability of protocols and access to negative study results are issues that have yet to be fully resolved. This poses a dilemma: if what constitutes the well-being of participants is not defined, how can we ensure that the best available treatment is truly ethical?

The Declaration of Helsinki reflects the current state of ethical and bioethical discussion surrounding medical research, but it suffers from inconsistencies and volatility. criticizes the document for not clearly distinguishing between research and experimentation, nor for considering the different designs that might or might not follow its guidelines[1]. Furthermore, the author points out that the Declaration appears to be a decalogue of good practices for a specific group of professionals, without a solid philosophical basis to support its principles. For example, although the text mentions the tension between internal and external self-regulation, it does not elaborate on this discussion, which limits its applicability.

The Declaration of Helsinki is an important advance in medical research ethics, but it still has significant limitations. The lack of a clear definition of well-being, the absence of a deep philosophical discussion, and the inconsistency of its principles highlight the need for a more thorough revision. As points out, "the Declaration of Helsinki is a necessary revision, but not a sufficient one"[1].

The Declaration of Helsinki has been a key reference in the ethics of medical research; however, its evolution has generated debates about the effectiveness of self-regulation versus the need for external oversight. The vagueness of the concept of well-being and its application in diverse socioeconomic contexts raises questions about equity in research.

Furthermore, the growing demand for open access to study results puts the interests of the pharmaceutical industry and the scientific community at odds [2].

Since its inception, the Declaration of Helsinki has sought to balance the acquisition of knowledge with the protection of research participants. However, revisions to the declaration have reflected tensionsbetween medical self-regulation and the need for ex ternal regulation. Currently, the lack of a universal framework for defining the well-being of research subjects and the gap in access to optimal treatments in developing countries remain critical issues [1]. In this context, it is essential to analyze whether the principles established in the declaration respond to contemporary challenges in bioethics and medical research.

Various studies have analyzed the evolution of the Declaration of Helsinki and its impact on the ethics of medical research. According to, revisions of the declaration have attempted to address criticisms regarding its applicability in different healthcare systems and socioeconomic contexts [1]. However, the lack of a uniform criterion for assessing participant well-being remains a challenge. Furthermore, the emphasizes the need for transparency in clinical studies, which has prompted changes in policies regarding the publication of negative results. Likewise, authors such as have pointed out the importance of integrating bioethical principles into the regulation of clinical trials to ensure equity in access to treatments [2,3].

The evolution of the Declaration of Helsinki has tended toward greater external regulation due to the inadequacy of medical self-regulation in protecting research participants.

The lack of a universal definition of well-being in medical research has led to inconsistencies in the application of the ethical principles of the Declaration of Helsinki in different socioeconomic contexts.

The requirement for public access to research protocols and results has increased transparency, but has also generated conflicts with commercial interests in the pharmaceutical industry.

Method

The study adopted a quantitative approach, with a descriptive and correlational design. A cross-sectional methodology was used to analyze the evolution of the Declaration of Helsinki over different periods and its impact on the ethical regulation of medical research. The design structure allowed for an assessment of the perceptions of bioethics and public health-experts regarding changes in ethical regulation [4].

The sample consisted of 150 healthcare, bioethics, and clinical research professionals, selected using non-probability convenience sampling. Participants from diverse cultural and socioeconomic backgrounds were included to ensure diverse representation. Demographically, participants ranged in age from 30 to 65 years, with an even gender distribution. Economically, most were in the middle and upper echelons of society, and educationally, all had postgraduate training in areas related to healthcare and medical ethics [3].

The instrument used was a questionnaire previously validated in studies on bioethics and medical regulation. It was based on the work of and adapted to the local context to assess participants' perceptions of the evolution of the Declaration of Helsinki [3]. The instrument's reliability was determined using Cronbach's alpha coefficient ($\alpha = 0.89$), which indicated high internal consistency. Construct validity was verified using exploratory factor analysis.

The Study was Carried out in Three Phases:

Preparation phase: The questionnaire was designed and pilot tested with 20 participants to fine-tune its wording and clarity.

Data collection phase: The questionnaire was administered digitally and in person at bioethics conferences and forums.

Analysis phase: Data was processed using statistical software, ensuring the confidentiality of the information.

The inclusion criteria were: being a professional in health, bioethics, or clinical research and having at least five years of experience in the field. Ethical principles such as informed consent and confidentiality were respected, in accordance with the Declaration of Helsinki [2].

Descriptive analyses were performed to characterize the sample, and Pearson correlation tests were used to assess the relationship between perceptions of changes in the Declaration of Helsinki and demographic variables. ANOVA was also used to identify significant differences between groups. The significance level was set at $p < 0.05$.

Results

The results indicated that 72% of participants perceived that the evolution of the Declaration of Helsinki has promoted stricter regulation of medical research. A significant correlation ($r=0.68$, $p<0.05$) was identified between the perception of increased regulation and participants' educational level. Furthermore, 65% of respondents considered that the lack of a clear definition of well-being has led to inconsistencies in the application of ethical principles across contexts.

Regarding transparency, 78% of participants supported mandatory publication of negative results, although 40% indicated that this could affect the competitiveness of the pharmaceutical industry. The ANOVA showed significant differences in perceptions of regulation based on respondents' geographic region ($F=4.27$, $p<0.05$).The first and third hypotheses are accepted, given that the data show progress in external regulation and transparency of results. The second hypothesis is rejected, as no consensus was found on a universal definition of well-being in medical research.

Discussion

The study's findings reflect significant differences in perceptions of the evolution of the Declaration of Helsinki depending on sample characteristics, such as participants' educational level, professional experience, and geographic context. Overall , external regulation has been viewed as a necessary step forward, but challenges persist in defining well-being and in consistently applying ethical principles.

Regarding external regulation versus self-regulation, 72% of participants considered that the Declaration of Helsinki has fostered greater oversight in medical research. Furthermore, a positive correlation ($r=0.68$, $p<0.05$) was found between the perception of greater regulation and educational level, suggesting that professionals with postgraduate degrees or training in bioethics tend to view external oversight as a necessary mechanism in the face of technological advances in medicine. Given that all respondents had training in areas related to health and medical ethics, this perception may be influenced by academic and professional bias.

Regarding the concept of well-being in research, 65% of respondents believed that the lack of a universal definition of well-being leads to inconsistencies in the application of ethical principles. However, analysis of variance (ANOVA) revealed no significant differences between groups with different educational levels or experience in bioethics on this topic. This indicates that, despite the participants' backgrounds, there is noclear consensus on what well-being means in medical research, which explains why the second hypothesis was rejected. Another relevant aspect was the perception of transparency in research and its conflict with the pharmaceutical industry. 78% of participants supported mandatory publication of negative results in clinical studies, believing this would strengthen research ethics. However, 40% warned that this could affect the competitiveness of the pharmaceutical industry, revealing an ethical dilemma in professional practice. While bioethics and public health experts favor transparency, researchers with ties to the pharmaceutical industry may perceive risks in terms of innovation and funding. This finding suggests that participants' professional and economic background influences their stance on transparency.

The analysis also revealed significant differences in perceptions of regulation based on respondents' geographic region ($F=4.27$, $p<0.05$). Participants from countries with stricter regulations displayed more favorable perceptions of external oversight, while those from countries with less developed regulatory systems tended to be more skeptical. This suggests that the sociopolitical and economic context influences how the evolution of ethics in medical research is valued, indicating that the Declaration of Helsinki, although global in scope, is subject to diverse interpretations depending on the regulatory infrastructure of each country.

In conclusion, the results show that the sample, composed of highly specialized professionals, favors external regulation and transparency, but does not reach a consensus on the concept of well-being. Furthermore, geographical differences and ties to the pharmaceutical industry affect perceptions of transparency and oversight in medical research. This suggests that, although the Declaration of Helsinki has evolved, its application remains heterogeneous depending on the context of the researchers and the healthcare system in which they operate.

The findings of this study contribute to our understanding of the evolution of the Declaration of Helsinki within the framework of external regulation of medical research and transparency in clinical trials. In terms of scope, the study provides evidence on the perception of health and bioethics professionals regarding the oversight of medical research and the publication of negative results. It also confirms that external regulation has been accepted as a necessary

mechanism in the era of evidence-based medicine [5]. Furthermore, the results suggest that the educational and professional context influences the interpretation of ethical principles, underscoring the need to develop ongoing bioethics training strategies to standardize criteria across different regions [6].

However, the study presents certain limitations that must be considered when interpreting the results. First, the sample consisted solely of professionals with training in health and ethics, which could have generated bias in the perception of external regulation. Previous research has indicated that the public and patients may have different views on ethics in medical research, particularly in terms of informed consent and access to treatments [7]. Second, although the study identified regional differences in perceptions of regulation, it did not delve into the cultural or political factors that may influence these differences, suggesting the need for qualitative studies to explore these nuances in greater depth. Finally, the lack of consensus on the definition of well-being in medical research highlights a conceptual gap that was not addressed in this study but that could have significant implications for bioethical policymaking.

Based on these findings, future lines of research are identified that could expand knowledge about the application of the Declaration of Helsinki in different contexts. One would be to explore the perceptions of patients and communities regarding ethics in medical research, in order to contrast their opinions with those of healthcare professionals. Previous studies have shown that patients' expectations regarding clinical trials can differ significantly from the ethical concerns of researchers [8]. Another relevant line of research would be a comparative analysis of the implementation of the Declaration of Helsinki in different healthcare systems, to identify whether the regulations adopted in each country have generated differences in the protection of clinical trial participants. Finally, an emerging line would be to assess the impact of artificial intelligence and new technologies on medical research, given that these innovations present unprecedented ethical challenges in terms of privacy, informed consent, and data transparency [9].

Conclusion

This study has shown that perceptions of external regulation and transparency in medical research are influenced by educational level, professional context, and geographic region. However, fundamental debates remain regarding the definition of well-being and the adaptation of bioethics to new technologies. Future research should address these challenges to consolidate an ethical framework that guarantees the protection of participants and the quality of medical science in the 21st century.

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