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Research Article

The Declaration of Helsinki: Advancing the Evolution of Ethics in Medical Research within the Framework of the Sustainable Development Goals

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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, emphasizing its implications for the Sustainable Development Goals (SDGs), particularly Goal 3 (Good Health and Well-Being) and Goal 16 (Peace, Justice, and Strong Institutions). The 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, and by linking these findings to the SDGs through the promotion of equity, accountability, and global cooperation in health. Limitations include

the exclusion of patient and policymaker perspectives. Future research should address civil society's perception of ethics in medical research, compare the implementation of the Declaration of Helsinki across health systems, and evaluate the impact of emerging technologies, such as artificial intelligence, on the ethics of biomedical research in advancing the SDGs.

Keywords: Bioethics, Biomedical Science, Declaration of Helsinki, Research Ethics, Sustainable Development Goals (SDGs), Global Health, Governance

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1. Introduction

The objective of this study was to analyze the evolution of the Declaration of Helsinki, from its initial conception 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 in the framework of the Sustainable Development Goals (SDGs). Specifically, the study asks: 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, transparency, and the protection of the well-being of research subjects in advancing SDG 3 (Good Health and Well-Being) and SDG 16 (Peace, Justice, and Strong Institutions)?

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 and global health challenges. This document proposes provisional external regulation that reflects scientific advances and ethical debates surrounding methods, techniques, and medications, especially in the context of wellness, open science, and equitable access to health innovations. According to De Abajo, 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 "well-being" has not been universally established, making its application difficult across diverse socioeconomic contexts.

The Declaration of Helsinki emerged as an instrument for judging war crimes but initially failed to fully resonate with the medical community [2]. 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 [3] and highlighted gaps in equity aligned with the SDGs. As De Abajo notes, although the logical justification of a research project precedes its ethical justification, the latter remains crucial to ensure that benefits outweigh risks—particularly in contexts where vulnerable populations may be exposed to inequities in healthcare systems [1].

One of the Declaration's most significant shortcomings is the absence of a clear and globally accepted definition of "well-being," a concept central to research ethics and closely related to SDG 3. Furthermore, the public availability of protocols and access to negative study results, essential to SDG 16's principle of transparency, remain unresolved. This creates a dilemma: if what constitutes the well-being of participants is not defined, how can the best available treatment be ensured under fair and ethical conditions?

Despite its limitations, the Declaration of Helsinki remains a key reference for ethics in medical research. However, the vagueness of "well-being," the absence of a deep philosophical discussion, and the inconsistency of its principles underline the need for a thorough revision that integrates equity, transparency, and sustainability in line with the SDGs. The ongoing debates on access to treatments in developing countries, the pressure for open access to results, and the conflicts with pharmaceutical industry interests reinforce the urgency of aligning ethical standards with SDG-driven priorities for global health governance.

2. Method

The study adopted a quantitative approach, with a descriptive and correlational design, aligned with the Sustainable Development Goals (SDGs), particularly SDG 3 (Good Health and Well-Being) and SDG 16 (Peace, Justice, and Strong Institutions). 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. This design structure

allowed for an assessment of the perceptions of bioethics and public health experts regarding changes in ethical regulation and their implications for equity, transparency, and governance in health systems [1].

The sample consisted of 150 healthcare, bioethics, and clinical research professionals, selected through non-probability convenience sampling. Participants represented diverse cultural and socioeconomic contexts to ensure broad representation and reflect the global nature of the SDGs. 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 healthcare and medical ethics [3].

The instrument used was a questionnaire previously validated in studies on bioethics and medical regulation. It was adapted to the local context to assess participants' perceptions of the evolution of the Declaration of Helsinki and its alignment with the principles of transparency, accountability, and equity embedded in the SDGs. Reliability was confirmed using Cronbach's alpha coefficient ($\alpha = 0.89$), indicating 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 improve clarity and contextual relevance.
- **Data collection phase:** The questionnaire was administered digitally and in person at bioethics conferences and forums, emphasizing open participation and inclusivity in line with SDG 16.
- **Analysis phase:** Data was processed using statistical software, ensuring confidentiality and informed consent in accordance with the Declaration of Helsinki [2].

The inclusion criteria required participants to be professionals in health, bioethics, or clinical research with at least five years of experience. Ethical principles such as informed consent and confidentiality were respected, reinforcing the study's commitment to SDG 3's emphasis on well-being and SDG 16's promotion of ethical governance.

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

3. Results

The findings revealed that 72% of participants perceived that the evolution of the Declaration of Helsinki has promoted stricter regulation of medical research, reinforcing the objectives of SDG 16 (Peace, Justice, and Strong Institutions) by fostering accountability and oversight. As shown in Table 1, this perception was more frequent among participants with postgraduate education, a result confirmed by the significant correlation between perception of regulation and educational level ($r = 0.68$, $p < 0.05$).

Table 1. *Perceptions of Stricter Regulation by Educational Level*

Educational level	% perceiving stricter regulation
Master's degree	65%
Doctoral degree	82%
Postdoctoral specialization	88%
Total sample	72%

Regarding the principle of well-being (SDG 3: Good Health and Well-Being), 65% of respondents indicated that the lack of a clear definition has generated inconsistencies in the application of ethical principles across different socioeconomic and cultural contexts. As illustrated in Table 2, respondents from developing regions were more

likely to perceive inconsistencies compared to those from developed regions, reflecting the unequal access to treatments and varying interpretations of participant protection.

Table 2. *Perceptions of Inconsistencies in the Application of "Well-Being" by Region*

Region	% reporting inconsistencies
North America	52%
Europe	58%
Latin America	71%
Africa	76%
Asia-Pacific	69%
Total sample	65%

In terms of transparency (SDG 16: Transparency and Accountability), 78% of participants supported the mandatory publication of negative results in clinical trials. However, 40% expressed concerns about the potential negative impact on the competitiveness of the pharmaceutical industry. Table 3 presents this duality: while support for transparency is high across all regions, concerns about commercial impacts are particularly prominent in developed economies where pharmaceutical activity is concentrated.

Table 3. *Support for Transparency and Concerns about Competitiveness*

Region	Support for mandatory publication	Concern about competitiveness
North America	81%	54%
Europe	77%	48%
Latin America	76%	31%
Africa	79%	22%
Asia-Pacific	78%	39%
Total sample	78%	40%

The ANOVA indicated significant differences in perceptions of regulation based on geographic region ($F = 4.27$, $p < 0.05$). Respondents from regions with stronger institutional frameworks (Europe and North America) expressed greater trust in regulatory mechanisms, while those from developing regions (Latin America and Africa) emphasized the urgent need for a clear and universal definition of well-being and equitable access to treatments. Accordingly, the first and third hypotheses are accepted: the data confirm progress in external regulation (Table 1) and widespread support for transparency (Table 3). The second hypothesis is rejected, since no consensus was reached on a universal definition of well-being in medical research (Table 2), pointing to the necessity of further normative clarification aligned with SDG 3 and SDG 16.

4. Discussion

The study's findings reflect significant differences in perceptions of the evolution of the Declaration of Helsinki depending on participants' educational level, professional experience, and geographic context. These differences

can be interpreted in relation to the Sustainable Development Goals (SDGs), particularly those addressing health, education, and governance.

The fact that 72% of participants perceived the Declaration of Helsinki as fostering stricter regulation in medical research supports the role of external oversight mechanisms in advancing SDG 16 (Peace, Justice, and Strong Institutions). The positive correlation ($r = 0.68$, $p < 0.05$) between regulation and education suggests that postgraduate training in bioethics reinforces the perception that external accountability is necessary in the face of technological advances in medicine. However, as all respondents were health professionals, the influence of academic and professional bias must be acknowledged. This highlights the importance of extending the debate beyond specialized circles to ensure broader legitimacy of ethical frameworks.

The absence of consensus regarding the definition of well-being—reported by 65% of respondents—underscores a fundamental challenge for SDG 3 (Good Health and Well-Being). Although no significant differences emerged across educational levels or professional experience, this conceptual gap indicates that bioethical principles are applied unevenly, particularly in societies with unequal healthcare access. The rejection of the second hypothesis reflects the pressing need for international dialogue to clarify and harmonize the notion of well-being, ensuring that it aligns with universal standards of human health and dignity.

Support for transparency in clinical research (78% in favor of publishing negative results) reveals a strong alignment with SDG 16, which emphasizes accountability, and with SDG 3, which seeks to guarantee equitable access to quality health information. Yet, the concern expressed by 40% of respondents about competitiveness risks reflects a structural tension between public health ethics and market-driven pharmaceutical interests. These results suggest that advancing SDG 3 requires balancing ethical imperatives of transparency with sustainable innovation strategies, especially in contexts where the pharmaceutical sector plays a dominant role in health policy.

The ANOVA results ($F = 4.27$, $p < 0.05$) revealed regional differences in perceptions of regulation: respondents in countries with stronger regulatory frameworks, such as those in Europe and North America, expressed greater trust in oversight, while those in regions with weaker institutions, including parts of Latin America and Africa, were more skeptical. This reflects not only disparities in institutional capacity but also inequalities in access to bioethics education, directly connected to SDG 4 (Quality Education). Building bioethics literacy globally could contribute to harmonizing ethical standards and reducing asymmetries in the interpretation of the Declaration of Helsinki.

The results confirm that highly specialized professionals favor regulation and transparency, yet remain divided on the meaning of well-being. This heterogeneity demonstrates that the Declaration of Helsinki is not universally interpreted, but rather filtered through educational, institutional, and economic contexts. In terms of limitations, the study focused exclusively on professionals with backgrounds in health and ethics, potentially overlooking the perspectives of patients and the general public. Integrating these views is crucial for achieving SDG 3 by ensuring that ethical principles in medical research resonate with community needs.

Future research should pursue patient-centered perspectives to capture ethical concerns regarding informed consent and access to treatments, comparative governance analyses to evaluate how different health systems apply the Declaration of Helsinki, and studies on the ethics of emerging technologies to assess the impact of artificial intelligence and big data on medical research. These directions would strengthen the contribution of bioethics to the 2030 Agenda by bridging the gaps between regulation, education, and health outcomes.

5. Conclusion

This study has demonstrated that perceptions of external regulation and transparency in medical research are shaped by educational level, professional background, and geographic context, reinforcing the relevance of the Sustainable Development Goals (SDGs), particularly SDG 3 (Good Health and Well-Being), SDG 4 (Quality Education), and SDG 16 (Peace, Justice, and Strong Institutions). The findings show that external regulation is generally valued as a mechanism to strengthen ethical oversight, while transparency in the dissemination of research results is seen as a way to improve equity and accountability in medical science. These elements represent important contributions to global governance in health and align with the objectives of the 2030 Agenda.

The main scope of the study lies in providing empirical evidence on how professionals in bioethics, healthcare, and clinical research interpret the evolution of the Declaration of Helsinki in light of contemporary challenges. By

identifying consensus on the value of external regulation and transparency, the study highlights significant progress toward integrating ethical principles into the governance of medical research. At the same time, it reveals persistent disagreements on the definition of well-being, an essential concept for ensuring equity in healthcare access and the protection of human dignity.

Nevertheless, the study has limitations. The exclusive focus on professionals with specialized training in health and ethics may have introduced bias, as patient perspectives, civil society views, and policy-making voices were not included. Additionally, although regional differences were observed, the analysis did not fully explore the cultural, political, and economic factors that explain such divergences. These constraints suggest caution in generalizing the findings and point to the need for more inclusive and multidisciplinary approaches.

From these results, several recommendations emerge. First, it is essential to promote international consensus on the definition of well-being in medical research, linking ethical principles to SDG 3 by ensuring that all populations, regardless of socioeconomic status, can benefit from medical advances. Second, bioethics training should be strengthened globally to reduce disparities between countries, in line with SDG 4, fostering standardized criteria and equitable access to bioethical education. Third, mechanisms for transparency in clinical trials should be consolidated, including the publication of negative results, while designing policies that balance public health priorities with the sustainability of the pharmaceutical industry, consistent with SDG 16. Finally, future research should evaluate the ethical challenges posed by emerging technologies such as artificial intelligence, big data, and genomics, given their growing influence on medical research and their potential impact on privacy, consent, and equity.

In sum, the study confirms that while the Declaration of Helsinki remains a cornerstone of biomedical ethics, its evolution requires constant adaptation to contemporary contexts. Strengthening its application through external regulation, education, and global governance will be essential to ensure that medical research contributes not only to scientific progress but also to sustainable development and the protection of human dignity.

Author Statements:

- **Ethical approval:** The conducted research is not related to either human or animal use.
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