Bioethics and scientific integrity in assessing the quality of clinical research data: Scoping Review

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INTRODUCTION

During the Nazi period, experiments on vulnerable human subjects led to the Nuremberg Trials in 1947, resulting in the establishment of the Nuremberg Code to safeguard patients in clinical trials. The Helsinki Declaration, crafted by the World Medical Association years later, incorporated ethical principles from the Code. Since then, the "International Ethical Guidelines for Biomedical Research Involving Human Subjects" by WHO and CIOMS have been regularly updated to ensure research ethics. In Brazil, ANVISA and CECP/CONEP regulate clinical research, ensuring participant protection. Adherence to Good Clinical Practice is essential for the validity of clinical trials. Bioethics plays a crucial role in safeguarding participant rights and evaluating result reliability. Scientific integrity, linked to research ethics, underscores researcher impartiality, data legitimacy, and consideration of participant vulnerability, while also avoiding conflicts of interest. Regulatory agencies and trial sponsors conduct audits and monitoring to ensure data integrity, applying concepts like ALCOA and ALCOA+ to uphold data quality.

METHODOLOGY

This study conducted a scoping review using the JBI Manual for Evidence Synthesis (2020 version) to investigate how researchers ensure data integrity and adhere to bioethical principles in clinical trials. Comprehensive searches were performed on PubMed, Scopus, Web of Science, BVS, SCiELO, and Google Scholar databases, followed by the application of eligibility criteria. The analysis encompassed studies from various countries and contexts, addressing ethical issues in science. The study selection process was manual, followed by meticulous data extraction from the included studies. The results were synthesized, including quantitative analyses of the characteristics of the reviewed articles and a detailed analysis of the diversity of research approaches in ethics and integrity in science.

RESULTS

This scope review analyzed 25 original articles published between 2018 and 2023, focusing on ethics and integrity in science. The United States led in article count, followed by Canada, the Netherlands, Switzerland, and the United Kingdom. Studies used various methodologies, including cross-sectional analyses and qualitative studies, reflecting a global interest in ethical issues in science. Participants were diverse, and data covered areas such as clinical research, drug regulation, and stakeholder engagement. Results highlight the increasing importance of addressing ethical concerns in contemporary scientific research through multidisciplinary approaches.

The temporal distribution of articles revealed a gradual increase in publications over the years, this pattern suggests a growing awareness and interest in ethics and integrity in science over time. (Chart 1).

The research spanned a variety of countries, with the United States of America leading in number of contributions (Chart 2), reflecting the international breadth of interest in ethics and integrity in science.

A variety of analyzes were incorporated, providing a comprehensive understanding of the scenario (Chart 3), addressing different aspects and perspectives within the field of scientific ethics.

Chart 1.

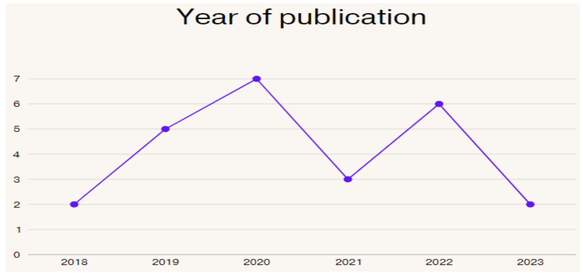


Chart 2.

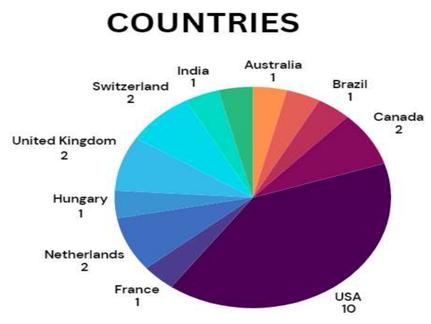
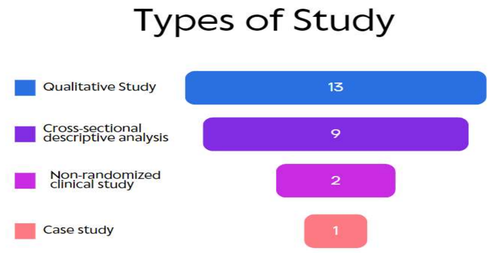


Chart 3.



A meticulous analysis of 25 articles revealed a wide range of population and sample data across multiple spheres of research. The study included European participants, members of ethics committees, Hungarian researchers, patients from oncology studies in the USA, among others. In addition, clinical trials, clinical study completion reports in India, interviews with academics from Big Data projects, drug authorizations by the EMA, interviews with investigators in the USA, patients in clinical studies in Brazil and participants in a study of obstetrics (Table 1)

Table 1

Demographic profile of studies

Participant Group	Number of Participants
European Researchers	5,321
European Research Ethics Committees	2,598
American Research Ethics Committees	130
Hungarian Researchers	2,557
Participants in Oncology Research Studies in the US	334
Participants from the United Kingdom	22
European Research Participants	59
Sub-Saharan African Participants	46
Participants in a Study in Singapore	81
Authors	104
Clinical Research Coordinators in the US	625
Phase III Clinical Trials (ClinicalTrials.gov)	94
Completion Reports of Clinical Studies in India	193
Warning Letters Issued by Biological Research Monitoring Program	300
Semi-Structured Interviews with Academics in Big Data Projects	39
Participants in the PRINTEGER European Project	1,126
Marketing Authorizations by the EMA	64
New Drugs Approved in 2015 (Based on US Clinical Trials)	674
Principal Investigators Interviewed in the US	52
Participants in an Oncology Clinical Study in Brazil	94
Researchers Funded by the National Institutes of Health (NIH)	203
Participants in an Obstetrics Study	31

CONCLUSION

The integrity, ethics, and robustness in conducting clinical studies are interconnected. Local and international regulations ensure ethical and scientific standards to protect participants and data. Agencies like ANVISA, FDA, and EMA oversee this. Rigorous measures, such as ALCOA tools, are essential to ensure data integrity. Ethics committees safeguard participants' rights. Collaboration among researchers, teams, and monitors is crucial. In summary, the integrity of clinical studies relies on regulations, ethical conduct, data integrity, and teamwork to advance medical science safely.

REFERÊNCIAS

•World Health Organization and Council for International Organizations of Medical Sciences. International Ethical Guidelines for Health-related Research Involving Humans. CIOMS; 2017.

•Pan American Health Organization. Good Clinical Practices: Document of the Americas. Washington: PAHO; 2005.

•ICH Harmonised Guideline Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). Current Step 4 version dated 9 November 2016.

•Mandrioli M. Genome Editing among Bioethics and Regulatory Practices. Biomolecules. 2021;12(1):13.

•Peters MJD, et al. Updated Methodological Guidance for Conducting Scoping Reviews. JBI Evidence Synthesis. 2020;18(10):2119-26.

•Angela De Pretto-Lazarova, et al. “Defining Clinical Trial Quality from the Perspective of Resource-Limited Settings: A Qualitative Study Based on Interviews with Investigators, Sponsors, and Monitors Conducting Clinical Trials in Sub-Saharan Africa.” PLOS Neglected Tropical Diseases, vol. 16, no. 1, 27 Jan. 2022, pp. e0010121–e0010121. [DOI: 10.1371/journal.pntd.0010121]

•Antes, Alison L., et al. “The Lab Management Practices of ‘Research Exemplars’ That Foster Research Rigor and Regulatory Compliance: A Qualitative Study of Successful Principal Investigators.” PLOS ONE, vol. 14, no. 4, 24 Apr. 2019, p. e0214595. [DOI: 10.1371/journal.pone.0214595]