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Regulatory Frameworks for Human Gene Editing: A Systematic Literature Review

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Abstract

Human gene editing technologies, especially CRISPR-Cas9, have advanced rapidly, raising complex regulatory, ethical, and scientific issues. This study reviews 47 peer-reviewed articles published between 2015 and 2025, following PRISMA 2020 guidelines. The analysis reveals major empirical, theoretical, methodological, and practical gaps in governance. It notes a lack of global harmonisation, weak ethical oversight, and inconsistent national policies that obstruct responsible innovation. Developing countries often lack enforceable guidelines, while developed nations use varied regulatory frameworks, leading to fragmentation. The study recommends a shared, participatory regulatory model, stronger international cooperation, and better integration of bioethics into policy-making. These steps are vital to ensure fair access, protect human dignity, and build public trust as gene editing moves into clinical and societal applications.

Keywords: Gene Editing, CRISPR-Cas9, Human Genome, Regulatory Framework, Bioethics, Germline Modification

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I. Introduction

Gene editing is a ground-breaking technology that enables scientists to modify DNA sequences within living organisms. This tool, especially through techniques like CRISPR-Cas9, (Farasat & Salis, 2016) TALENs, and zinc finger nucleases, has rapidly transitioned from theoretical concepts to practical applications. Gene editing has the potential to cure genetic diseases, increase agricultural yields, and propel biomedical research. However, the use of gene editing in humans also raises unprecedented potential and profound ethical issues about human identity, justice, and risk.(Saluja & Khushi, 2024) As these technologies transition from the lab to clinical trials, global regulatory frameworks struggle to keep pace with the rapidly advancing science, creating a complex and dynamic regulatory environment.

Do we have the authority to alter the very nature of what it means to be human? This question sits at the heart of the gene editing technologies controversy, posing essential questions about what is scientifically possible versus what is ethically permissible. Gene editing may revolutionise medicine, but it raises significant ethical issues, most notably with the possibility of "designer babies," eugenics, (Van Beers, 2020) and widening the gap between those who will have access to gene therapy and those who will not. Moreover, as the technology advances, concerns about the consequences of unforeseen genetic modifications, and above all, the ethical implications of editing the human genome, are growing.

Regulations for human gene editing vary significantly around the world. Countries like the EU, U.S., and China have different standards in terms of germline and somatic editing, with stricter controls on germline editing.(De Miguel Beriain, 2017; Mahalatchimy et al., 2021) While regulatory systems exist in developed nations, they are mostly absent in many developing countries, and privately financed research can capitalise on loopholes in the law. Such heterogeneity at a global level results in serious ethical issues surrounding the use of gene editing technologies.(Millett et al., 2023) Much of the research has focused largely on the technical aspects of gene editing for example, the technologies themselves (e.g., CRISPR) and not adequately addressing their governance issues and the ethics of their use, particularly in the context of somatic versus germline editing. What happens when some nations advance at the expense of others, creating an uneven playing field? The regulatory failures in these areas are a pressing concern.

The objective of this literature review is to critically evaluate global regulatory regimes for human gene editing. With innovations like CRISPR evolving rapidly, the world requires more reliable regulation and ethics to ensure the safe and responsible use of such technology. (Nelson et al., 2021) This review identifies loopholes in prevailing governance and proposes effective, harmonised steps toward filling these gaps. The focus is on the regulatory requirements of somatic and germline editing, particularly in advancing precision medicine, ensuring equity, and preserving

international ethical standards.

Furthermore, this review considers the global imbalance in gene editing regulation. The majority of the literature that has been produced is from Western countries, leaving a significant gap in terms of research and regulation for regions such as Africa, Asia, and parts of Latin America.(Nekoteneva & Ponomareva, 2023) The lack of a consolidated global framework for governing gene editing technologies results in ethical regulation mismatches and unequal access to therapy, which can adversely affect vulnerable populations who may face exposure to improper or unsafe experimental practices.

This review emphasizes the urgent need for effective governance in the stewardship of the international environment surrounding human gene editing. With a focus on ethical integrity, public trust, and enabling responsible scientific advancement, it highlights the importance of international cooperation to safeguard human dignity while promoting therapeutic applications of gene editing technologies.(Mourby & Morrison, 2020) By providing practical guidance on global regulatory approaches, the review aims to shape harmonised policies that discourage non-therapeutic enhancements while fostering innovation. It supports researchers, clinicians, and policymakers by clarifying governance expectations and ethical concerns, ensuring equitable access to safe therapies. Additionally, it helps families affected by inherited diseases understand the balance between preserving natural DNA and accessing beneficial treatments. Ultimately, this review promotes legislative transparency, responsible innovation, and the development of balanced frameworks that protect the most vulnerable and guide future research.

A. Problem Statement

Gene technology progress has unparalleled potential for treating genetic diseases and enhancing human traits. (Berlincourt et al., 2024) However, there exists a significant gap in consolidated regulatory mechanisms that balance innovation with ethical and human rights assurances. Current regulations remain fragmented across various jurisdictions, with most of the focus placed on therapeutic applications, often neglecting broader social impacts such as long-term genetic modifications and non-therapeutic enhancements. These regulatory loopholes create opportunities for misuse, inequality, and ethical violations. This review critically assesses global regulatory frameworks, highlighting the intersection of science, ethics, and law. It aims to support responsible innovation, protect human dignity, and guide the development of equitable and inclusive gene editing governance.

B. Research Questions

- What are the existing gaps in the regulatory frameworks governing human gene editing?
- Which authors and journals have made the most significant contributions to this area of research?

- What are the most frequently occurring keywords in the literature on the regulation of human gene editing?
- Which researchers and institutions demonstrate the highest levels of collaboration in this field?

C. Research Objectives

- To examine and identify existing gaps within current regulatory approaches to human gene editing.
- To highlight the most influential contributors and leading journals in the domain of gene editing regulation.
- To analyse recurring keywords and thematic trends within the scholarly literature.
- To map collaborative networks among researchers actively engaged in regulatory studies on human gene editing.

D. Significance of the Study

This study is of critical value to addressing the urgent need for a coherent, ethical, and globally harmonized regulatory framework for human gene editing technologies. As CRISPR-Cas9 and similar technologies rapidly transition from experimental science to clinical application, the lack of steady regulatory guidance raises serious questions about safety, equity, and moral integrity. This systematic review of a decade of research is a foundational contribution to reducing the expanding gap between scientific innovation and governance.

For regulators and policymakers, the study provides precious perspective on existing legislative fragmentation and regulatory lacunae. Most countries, especially in the developing world, lack enforceable legal frameworks to guide the use of gene editing. This absence of regulation provides fertile ground for unethical experimentation, exploitation, and the potential for irreparable harm. By identifying where these lacunae are and offering recommendations for harmonised international cooperation, the study facilitates the creation of proactive, rather than reactive, informed policy. It encourages the adoption of inclusive, binding norms that balance innovation with public safety and human rights.

The study offers bioethicists, legal scholars, and philosophers a far-reaching overview of the ethical and legal issues of human genome editing. While bioethics and human rights principles are among the theoretical frameworks that do indeed exist, they are fragmented, undertheorized, or weakly operationalized at the international level. This research illustrates the inadequacy of current ethical frameworks in the face of complex, multicultural realities and emerging biotechnologies. It calls for a more integrated, interdisciplinary approach to regulation that draws on legal, philosophical, and ethical dimensions in a way that is applicable worldwide.

For medical practitioners and clinical researchers, the article outlines the regulatory landscape within which they must work when engaging with gene editing

technologies. As clinical applications of somatic and germline editing expand, practitioners require access to concise, evidence-based information to ensure that their activities are not only fulfilling scientific requirements but also ethical obligations. This review provides them with a map of governance frameworks worldwide, specifying best practices, areas of conflict, and the implications of conducting research under regimes with varying degrees of regulation.

For universities, funders, and global health authorities, the study emphasizes the need for cross-border and interdisciplinary collaboration. The lack of coordinated global research to date has led to duplication and fragmentation of knowledge on regulation. By emphasizing geographical and methodological diversity in the literature, this study calls for institutions to promote collaborative research, capacity building in underrepresented regions, and policy dialogue that is commensurate with the global scale of biotechnology governance.

To the public at large and to patient communities, particularly those afflicted with inherited genetic disorders, this study serves an advocacy role. It emphasizes the necessity of ethical safeguards to prevent misuse and guarantee that gene editing technologies are utilized to promote human welfare and not reinforce social inequalities. Through creating a public appreciation of regulatory matters and highlighting the need for fair access, the research inspires trust in scientific advancement and educates public debate on the future of human therapy and enhancement.

II. Methodology

This systematic literature review (SLR) examines the regulation of gene editing on human beings by searching, evaluating, and combining published studies from 2015 to 2025. The review is conducted according to the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 to ensure transparency, consistency, and credibility in the process. The overall research goal is to examine how regulatory frameworks have changed in response to advances in gene editing tools such as CRISPR, and determine gaps, theoretical foundations, and the ethical considerations that shape global regulatory regimes. The process of review was conducted through three levels of significance: data mapping, wherein crucial literature was selected and picked through keyword searching across a set of databases; data refining, through which studies were screened and sorted on the basis of such inclusion criteria as relevance, language, and accessibility; and end appraisal, through which selected articles were read to understand how scientific progress and ethical debate have influenced the establishment of current and developing human gene editing regulations.

A. Stage 01: Data Mapping through Keyword Search

This systematic literature review sought to map and identify the research published between 2015 and 2025 that is associated with the current regulatory

frameworks of human gene editing technologies. With the PRISMA 2020 guidelines, there was a structured keyword search strategy employed in ensuring that the literature selection was not biased and was comprehensive. Boolean terms such as "human gene editing," "regulatory framework, "CRISPR," and "genome editing" were used to identify studies that were directly relevant to the purview of this review. Five academic databases (PubMed, Semantic Scholar, ResearchGate, ScienceDirect, and Emerald Insight) were selected based on their credibility and relevance in biomedical, scientific, and policy-related research. Among them, PubMed yielded the highest number of results, which is reflective of its strong focus on genetics and clinical research. This stage allowed the screening of a wide range of sources so that the review reflected varied perspectives from scientific, ethical, and policy-making areas of human gene editing.

B. Stage 02: Refining Results

After the initial mapping of data, 89 records were screened in this stage in order to determine their applicability to the study question. At screening, 14 records were excluded as outside the scope of the study domain, and 12 were excluded because full texts were not available. Of 63 reports that were requested to be retrieved, 8 could not be obtained. The other 55 articles were subsequently assessed for inclusion. Of these, 5 articles were excluded because of the cut-off date for publication, and 3 articles were excluded because they were published in languages such as Chinese, Russian, and German. Lastly, 47 valid and appropriate articles remained and formed the final review process, providing clear evidence of the regulatory issues, ethical concerns, and evolving governance mechanisms surrounding human gene editing technologies.

C. Stage 03: Review Summary and Article Evaluation

A total of 130 records were initially identified in five academic databases: PubMed, Semantic Scholar, ResearchGate, ScienceDirect, and Emerald Insight. After the inclusion and exclusion criteria were applied, 83 records were removed due to issues like irrelevance to the topic, non-English language use, full-text unavailability, and unsuitable document types. The remaining papers were reviewed scientifically for applicability to the purpose of the studies, in connection with the control mechanisms, ethics, and attitudes of scientists concerning human gene editing. Using PRISMA 2020's flow diagram in the review procedure, 47 thematically well-matched high-quality papers that contributed to creating a comprehensive base of knowledge in relation to global regulatory frameworks, ethics, and governance models towards the application of gene editing techniques in humans were chosen.

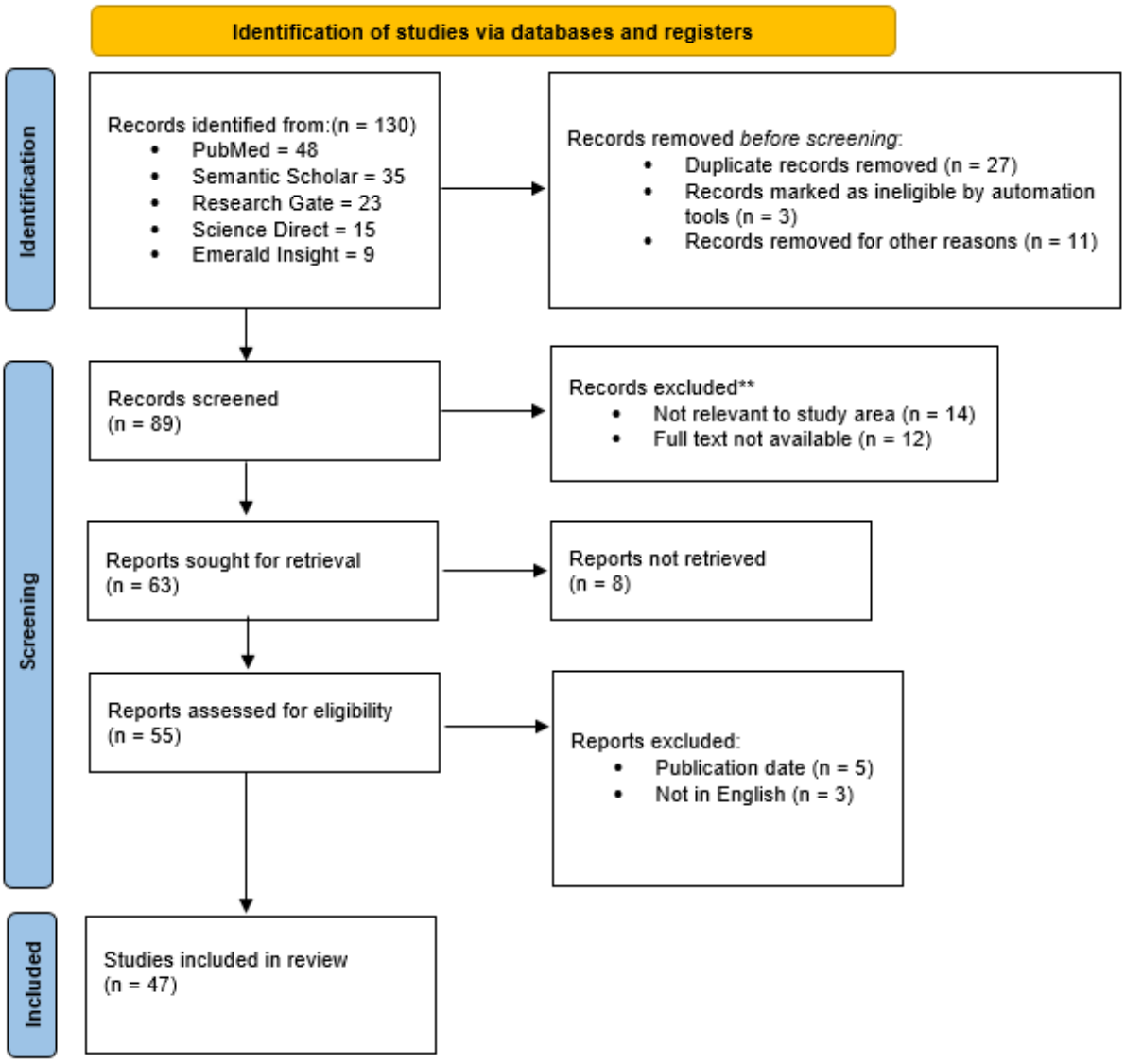

Figure 01: PRISMA Flow Diagram

III. Results

47 full-text papers were chosen to be included in this systematic review of the literature following a thorough screening process. The visual representations of data presented in this review are an informative depiction of important bibliographic patterns and trends. Figure 2 presents a dramatic increase in publications starting from 2018 and coinciding with the infamous gene editing scandal of He Jiankui and the birth of the first ever gene-edited twins in China. Figures 3 and 3.1 show the geographical distribution of the selected studies both in a bar chart and world map, highlighting the international scope of studies in this area. Figure 4 explains the methodology frameworks employed across the studies, demonstrated in the form of a pie chart to show the diversity of approaches. Table 1 depicts the most influential

authors who have contributed to the subject. Table 2 summarises the top academic journals on which these studies were published. Figure 5 presents keyword co-occurrence as a cluster map to provide an overview of overarching themes. These are further segmented into ten thematic clusters of legal frameworks, ethical implications, stakeholder opinions, and new genome editing technology. Figure 6 presents the co-author occurrence map, depicting collaboration among researchers in this discipline.

A. Bibliometric Analysis

1. Growth of publications

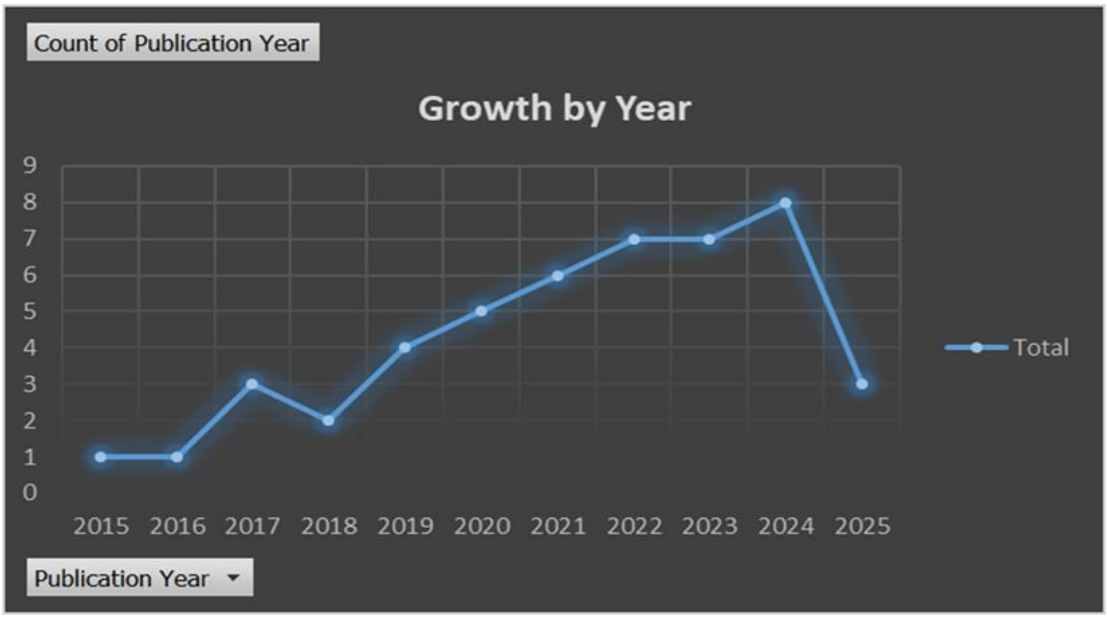

Figure 02: Growth of Publications

The publication trends from 2015 to 2025 show a clear evolution in academic interest surrounding human gene editing. Between 2015 and 2016, research in this field remained minimal. However, in 2016, the controversial birth of a "three-parent baby" sparked ethical debates that drove a noticeable increase in publications. A sharper rise occurred in 2018, coinciding with the global uproar over He Jiankui's gene-edited twins, which intensified scrutiny on human genetic modification.

Despite the COVID-19 pandemic, momentum continued. There was high interest, partly due to the promise of gene-targeted therapies for the virus. Publication volume was highest in 2024, a sign of ongoing interest in both the scientific and ethical aspects of gene editing.

Between 2022 and 2023, publication numbers plateaued, showing ongoing but steady interest. A further rise in 2024indicated fresh momentum in the industry. A single decline in 2025 might how a shift in focus or tightening up of regulation.

These trends highlight the imperative necessity for a strong regulatory framework. With gene editing technologies evolving at a fast pace, regulation

is necessary to ensure responsible application, avoid ethical breaches, and safeguard human dignity and health for generations to come.

2. Geographical publication distribution

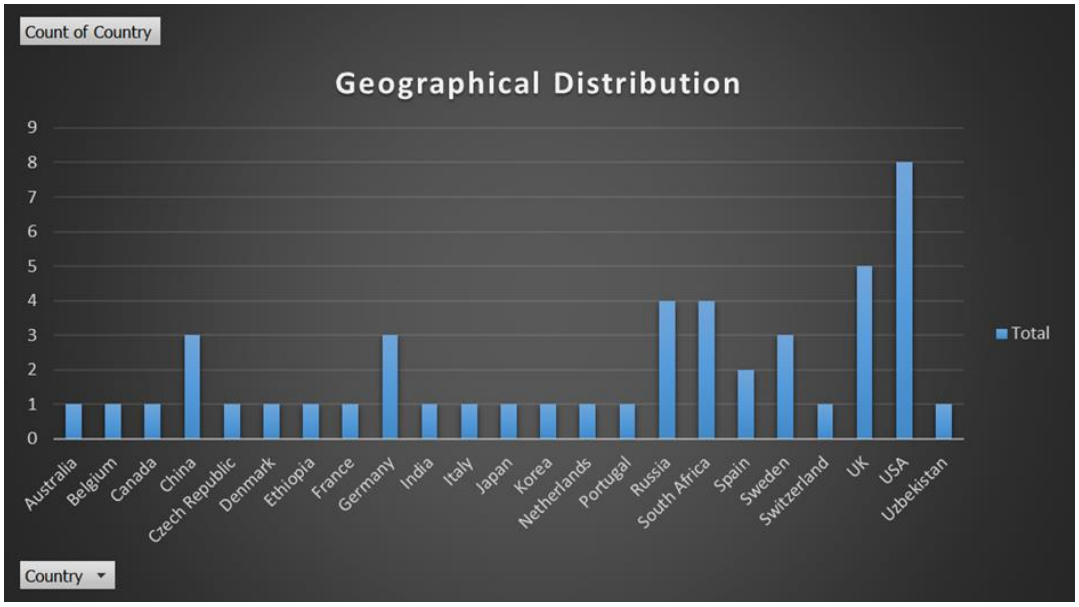

Figure 03: Geographical Distribution (Countries)

The country-wise publication graph in the form of a bar chart reflects a total count of 47 research articles published in 23 countries. The United States stands out with 9 publications, the maximum in regulation of human gene editing. The United Kingdom ranks second with 5 publications, South Africa and Switzerland with 4 publications each, reflecting moderate but good representation. Sweden and the Czech Republic had 3 articles each, while China, Spain, and Portugal had 2 articles each, which represents a middle-level contribution.

At the opposite end of the scale, there were several nations like Australia, Belgium, Canada, Denmark, Ethiopia, France, Germany, India, Italy, Japan, Korea, Netherlands, Russia and Uzbekistan that reported a single publication each, which speaks to extremely low participation. These figures attest that while some nations have emerged as the hegemonic players in regulatory discourse, others are weakly represented or only marginally involved.

Figure 03.1: Geographical Distribution (Universities)

Scholarly Contributions by Universities (Geographical Map Analysis) The map below shows the global distribution of universities conducting research in human gene editing regulation. As can be seen, North America and Europe takes the lead with a dense clustering of research organizations in the United States, Canada, United Kingdom, Germany, France, Switzerland, and the Netherlands. This indicates strong research capacity, sound funding, and institutional dedication to the ethical and legal dimensions of gene editing.

Asia is representative of selective but remarkable inputs, especially from China, India, Japan, South Korea, and Uzbekistan. All these countries, even though having strong scientific power, still exhibit fairly dispersed academic contribution, often limited to prestigious universities. Australia and South Africa also possess a few signature institutions engaging in this field, showing increasing awareness on the Southern Hemisphere.

However, vast regions such as South America, large parts of Africa, and Central Asia remain poorly represented on the map of research. These underdeveloped or new world regions are making little or no scholarly contribution owing to limited infrastructure, poor funding, and weak institutions of governance. Such a lack of presence is troubling since where there is weak governance, privately funded groups may exploit regulatory loopholes to carry out unregulated gene editing experiments with safety and ethical consequences. Therefore, the uneven

global academic engagement firmly supports one and the same international regulatory framework. Such a framework would prevent any region of the world from being treated as a guinea pig for unregulated gene editing, thereby upholding global bioethics and human rights.

3. Methodological analysis

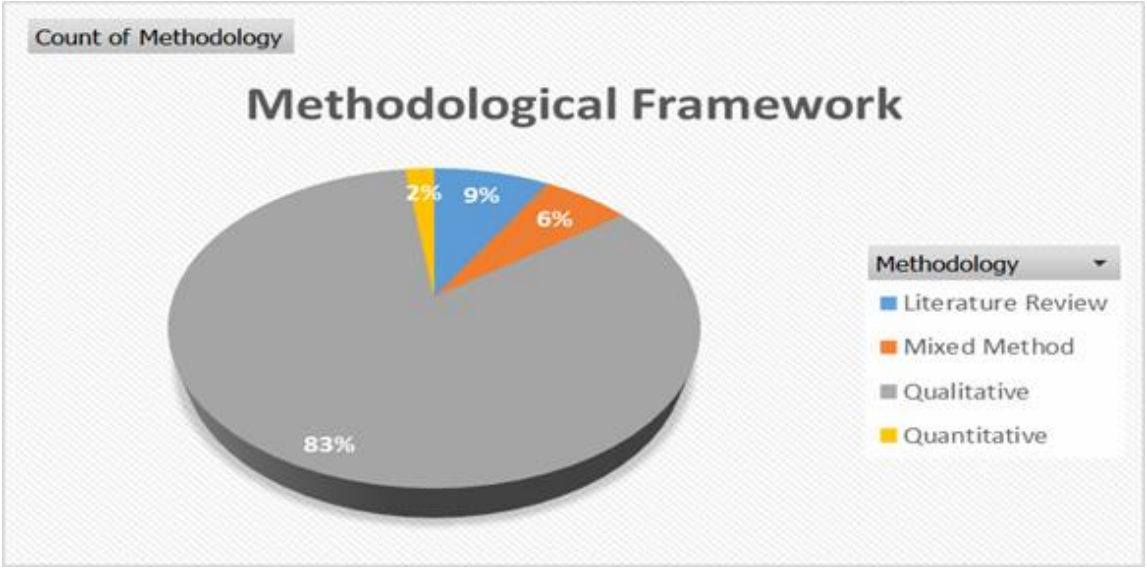

Figure 04: Methodological Analysis

Looking at the methodological landscape of the 47 studies spanning the regulatory landscape of human gene editing, there is an imbalance. Eighty-three percent (39 of 47) are grounded in qualitative methodologies, including expert interviews, policy analyses, and stakeholder focus groups. These approaches illuminate ethical dilemmas, legal ambiguities, and cultural contexts, yet their findings often resist broad generalisability.

By contrast, there are just four studies (≈8.5%) that are SLRs, which synthesise existing regulations, international standards, and scholarly debate to map emerging policy trends. The fewer instances of SLRs reveal that not many scholars have yet summarised the growing body of studies into comprehensive overviews.

Mixed-methods designs are used in three articles (≈6.4%), integrating qualitative findings with quantitative starter indicators, such as numbers of regulations passed or levels of compliance to bridge contextual depth and measurable outcomes. Purely quantitative investigations are even fewer, with a single article (≈2.1%) employing numerical data and statistical analysis in mapping policy uptake and trial submissions. This paucity reflects the nascent state of clinical trials and the lack of standardised datasets in human gene-editing governance. This methodological skew reflects a field still building foundations before widespread application yielding robust data. To build a truly evidence-based regulatory policy, research in the future must diversify methods: more SLRs will consolidate current knowledge; more mixed-method studies will span in-depth investigation and

measurement; and, as data accumulates, targeted quantitative studies will be invaluable in experimentally examining causal links between discrete regulatory interventions and observed impacts. A multi-disciplinary effort is required to supply policymakers with the robust evidence that they require to regulate human gene editing for efficient, equitable governance.

4. Most influential authors

Author	H-Index	Number of Citations	Institute
a) **Glenn Cohen**	48	11273	Harvard Law School
b) **Heidi C. Howard**	42	10019	Lund University
c) **Sarfaraz K. Niazi**	34	6985	University of Illinois
d) **Mara Almeida**	30	2932	Universidade Estadual de Ponta Grossa
e) **Thorben Sprink**	20	2124	Julius Kuehn Institute
f) **Michal Koscik**	12	1339	Masaryk university
g) **Jon Rueda**	14	689	Spanish National Research Council
h) **Miranda Mourby**	14	683	University of Oxford
i) **Donrich Thaldar**	14	669	University of KwaZulu-Natal
j) **Santa Slokenberga**	12	654	Uppsala University

Table 01: The Most Influential Authors

Of the 47 selected articles, 138 authors were identified. The most influential 10 were ranked based on citation count, H-index, and gene editing regulation contribution. Glenn Cohen (Harvard Law School) is number one with 11,273 citations and an H-index of 48, renowned for his work in legal and ethical issues in biomedicine. Heidi C. Howard (Lund University) ranks second with 10,019 citations and an H-index of 42, recognized for her work in genomic governance.

Sarfaraz K. Niazi of the University of Illinois has 6,985 citations and an H-

index of 34 under biopharmaceutical regulation. Mara Almeida, Thorben Sprink, and Michal Koscik are others cited for scholarly contributions. Authors like Jon Rueda, Miranda Mourby, Donrich Thaldar, and Santa Slokenberga link law, bioethics, and public policy.

The composite nature of these authors and prevalence of single-publication authors indicate the multidisciplinary and dynamic character of human gene editing regulation research.

5. Credibility of journals

Name of the Journal	Articles number	Impact Score	h-Index	SJR	Overall Ranking
Clinical and Translational Medicine	1	5.69	18	2.424	986
PLOS Computational Biology	1	3.65	217	1.652	1898
npj Regenerative Medicine	1	5.95	37	1.575	2074
European Journal of Human Genetics	2	3.04	142	1.538	2168
Journal of Responsible Innovation	1	5.04	37	1.531	2180
BMC Medical Ethics	1	3.37	60	0.975	4631
Biomedicines	1	4.05	67	0.962	4744

Journal of Medical Ethics	2	2.42	87	0.952	4842
Frontiers in Bioengineering and Biotechnology	1	4.25	101	0.893	5316
Journal of Law and the Biosciences	1	2.46	29	0.892	5324

Table 02: The Most Influential Journals

To assess the credibility of journals in this study, some well-indexed and highly ranked publications were chosen based on bibliometric indicators such as Impact Score, H-index, SJR, and world ranking. npj Regenerative Medicine was ranked number one with an Impact Score of 5.95 and an SJR of 1.575. Clinical and Translational Medicine followed closely behind, with Impact Score of 5.69, SJR of 2.424, and global rank 986. They are exemplars of high academic calibre in biomedical and regenerative science. PLOS Computational Biology was also highly ranked with an H-index of 217, reflecting consistent high-impact output. Others were the European Journal of Human Genetics and the Journal of Responsible Innovation, both from prestigious publishers. Whereas others, like BMC Medical Ethics and Journal of Law and the Biosciences, are ranked lower but provide domain-specific, relevant content, the overall utilization of the journals lends considerable academic weight and helps in ensuring reliability for the study.

6. Keyword occurrence analysis

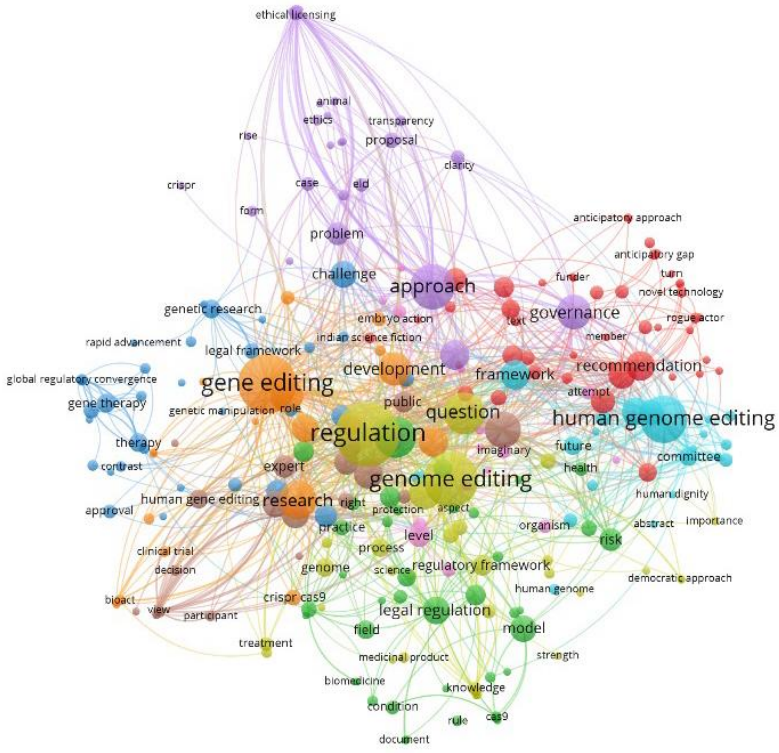

Figure 05: Keyword Occurrence

This map, constructed via VOSviewer, represents the interconnected topics within the literature on the regulation of gene editing technology on human subjects. Plotting common keywords among selected studies between 2015 and 2025, the figure illustrates landmark domains of inquiry, conceptual relationships, and shared concerns across the field.

The most frequent keywords are "regulation," "gene editing," "genome editing," "human genome editing," and "legal regulation." Their prominence on the map signals the growing interest of the academic and regulatory communities in establishing ethical, legal, and policy frameworks for new gene-editing technologies, particularly those in use in human applications.

Emphasis of "regulation" underscores the supreme importance of governance over the management and application of genetic technologies. Conversely, words like

Cluster	Number of items	Keywords	Category

“gene editing” and “genome editing” acknowledge the technological nature of the field, emphasizing how literature brings to the fore not only scientific development but also the need to apply it responsibly. Repeated use of "human genome editing" reaffirms the specific issue of human DNA editing, which raises unique ethical and social concerns.

Furthermore, "legal regulation" also occurs extremely frequently, indicating that legal issues are a prominent strand of discussion about developing responsible oversight mechanisms. This co-occurrence map therefore clearly illustrates the field's main areas of interest and constitutes the foundation for an understanding of how debates relating to governance, ethics, and safety are intricately embedded with the scientific developments in gene editing.

	26	• EU framework • Law • National legislation • Regulatory framework • Rule	Legal Governance Framework
Cluster 6	24	• Care • Human dignity • Risk • Saftey	Ethical and Societal Implications
		• Legal challenge • Legal framework • Regulatory challenge • Policymaker	Considerations
Cluster 3	32	• Cas9 • DNA • Eugenic • Gene • Genome editing	Scientific Foundations of Gene Editing
Cluster 4	29	• Advisory committee • Critical assessment • Decision making • Ethical licensing approach • Patenting	Regulatory Strategies and Tools

This table organizes thematic groups investigating the regulatory context of human gene editing technologies. Within each cluster, salient keywords revolve around key aspects of this emerging field, including new biotechnology, legal and policy responses, ethics, and actors. Together, these clusters lay open the multidimensional nature of gene editing regulation and react to scientific advancements, public discourses, and demands for internationally harmonized governance strategies.

		• Tension	
Cluster 7	23	• Area • Europe • National level • Position • Regional level	Geopolitical Levels of Regulations
Cluster 8	20	• Lawyer • Participant • Public • Scientist • Stakeholder	Stakeholder Perspective
Cluster 9	16	• CRISPR Cas9 • Embryo • Germline • Human • Somatic gene editing	Human Application of Gene Editing
Cluster 10	4	• Democratic approach • Elitist • Face • Importance	Philosophical and Democratic Debates

Table 03: Keyword Occurrence

Cluster 1 addresses the advent of new biotechnologies like human germline genome editing and heritable genome editing. It stresses the novelty of such technologies, playing them up as scientific advancements. They offer hopes of avoiding genetic disease but concurrently invite careful scrutiny due to their capability to alter generations to come.

Cluster 2 captures the growing legal and regulatory challenges that encircle gene editing. With "guideline," "policymaker," and "legal framework" as keywords, emphasis is on the complexity of developing uniform and use full legislation. It stresses how difficult it is to develop policies which balance innovation with safety, fairness, and ethical responsibility.

Cluster 3 delves into the technical aspect of genome editing, right down to tools like Cas9 and the fundamental parts such as genes and DNA. It does touch on contentious ideas like eugenics. This indicates proper consideration of both the promise and risk that come with the science of genetic engineering.

Cluster 4 examines mechanisms used to govern genome editing. Use of

phrases such as "ethical licensing approach" and "patenting" manifests an interdisciplinary blend of ethical analysis and intellectual property regulation. It lingers on the role played by advisory committees and formal decision-making in shaping responsible model regulation.

Cluster 5 focus on international and national legal frameworks; this cluster addresses the official legal standards that govern gene editing. Descriptions like "EU framework" and "national legislation" Imply the need to produce explicit, harmonized laws. It highlights the need for coordinated rule-making in addressing risks across borders.

Cluster 6 cluster focuses on the social and ethical concerns on a broader scale about gene editing. Phrases like "human dignity" and "risk" reflect concerns about security, fairness, and values. The inclusion of "tension" shows dialogue being had about finding a balance between innovation and social and moral responsibilities.

Cluster 7 Emphasizing the multi-layered nature of regulation, this cluster considers the differences in gene editing policies at regional, national, and local levels. Utilizing keywords like "Europe," "national level," and "position," it shows how regulatory strategies and moral stances are influenced by geographic and political considerations.

Cluster 8 recognizes the different stakeholders influencing the debate like scientists, lawyers, the public, and policymakers. It emphasizes ensuring inclusive debate and multi-stakeholder engagement to ensure that ethical, legal, and scientific insights are all accounted for in policy-making.

Cluster 9 highlights direct gene editing in human individuals, e.g., embryos and germline editing. The inclusion of "somatic gene editing" is a reflection of responsiveness to less hereditary but significant interventions. It reflects the pragmatic consequences and ethical resonance of genetic modification in human individuals.

Cluster 10 is the smallest group debates general questions about who gets to decide the future of gene editing. Terms like "democratic approach" and "elitist" setup public engagement versus command-and-control decision-making. The group also challenges fairness, governance, and moral authority in regulating such potent technology.

7. Co-author occurrences analysis

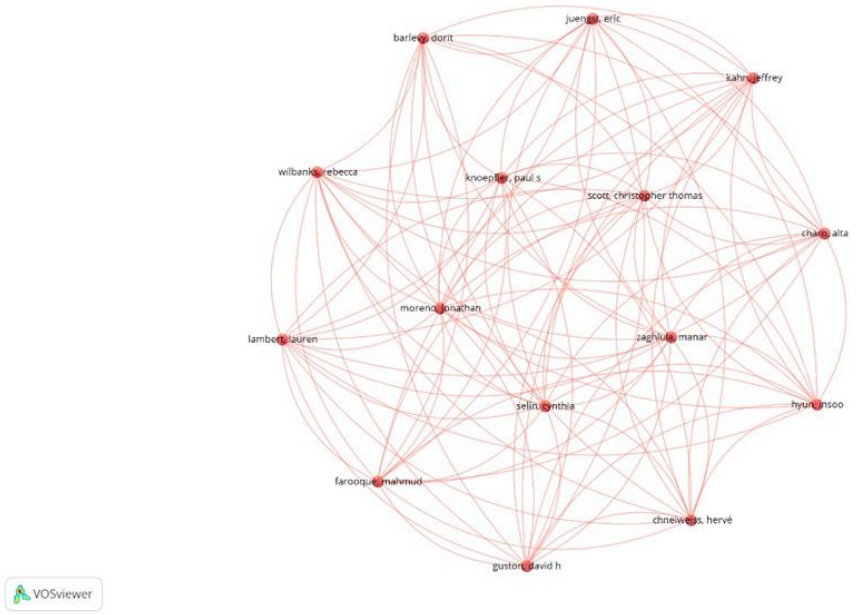

Figure 06: Co Author Occurrences

In this systematic review of literature, 138 authors were identified from the included studies, but there was only one loosely networked cluster in a VOSviewer analysis, indicating weak collaboration among researchers. The trend of fragmented authorship aligns with a larger issue which shows, significantly reduced scholarly coordination and inefficient information sharing within the field. Such seclusion not only delays innovation but also indicates a principal challenge: the inability to build a unified, worldwide regulatory scheme for gene editing in humans. Without strong cooperative networks, scientists cannot synchronize ethical norms, legal boundaries, and security protocols among regions. This directly impacts the development of my research topic, which analyses the regulatory scheme of gene editing in humans. A more homogeneous academic community to reconcile various schools of thought and create globally adopted standards is a necessity. Interdisciplinary collaboration, co-authored studies, and worldwide conferences could enhance the quality of research as well as the setting of uniform global policies in this new area exponentially.

8. Identification of research gap

Empirical gaps within the literature on regulation of gene editing technology on human subjects exist. Whereas theoretical discourse and normative argumentation are increasing, insufficient empirical evidence exists to support policy-making. Gene editing, particularly of human embryos, remains under researched due to ethical restrictions and regulatory barriers in most countries. Though some nations permit therapeutic trials, implantation is in general prohibited and the long-term impact remains not investigated. In addition, inequality in research equipment and regulation between developing and developed nations contributes to variability. Slowness in empirical research coupled with the problem of evaluating long-term

effects has obstructed the process of formulation of large, comprehensive regulatory standards to be adopted across the board. This lack of information undermines decision-making and disrupts the development of solid international standards.

There is a lacuna in theoretical terms in human gene editing law, as contemporary ethical and philosophical theories are scattered and insufficient. While ideologies like Transhumanism promote human upgrading and Bioconservatism advises against altering the nature of humanity, both are lacking in terms of pragmatic regulative guidelines. Moral theories such as the Principles of Biomedical Ethics, Procreative Beneficence, and Rawlsian Justice are morally informative but fail to take into account gene editing's global, legal, and societal complexities. These theories fail to fully capture the asymmetries between therapeutic and enhancement applications, nor do they guide policy in multicultural and economic environments. This disconnect highlights the necessity of a cohering, cross-disciplinary theory that can bridge ethical, legal, and scientific methods like giving responsible, equitable, and globally harmonised regulation of human gene editing technology.

There is a visible methodological gap in current studies of regulation of human gene editing. Among the 47 studies reviewed, more than an 80% dominance by qualitative methods for example, expert interviews and policy analysis that dominates them. Though rich descriptions of ethical and legal complexities, they are limited in generalisability and therefore impede broader policy application. Purely quantitative studies, which could offer statistical evidence of regulatory impacts, are hardly present with only a single one identified. In addition, systematic reviews and mixed-method studies are not fully utilised, offering lacunas in synthesis and quantifiable evidence. This imbalance reflects a still-infant discipline. To construct a balanced, evidence-based regulatory system, future studies will have to employ more diverse methodologies, especially mixed-method and quantitative approaches to enable stronger, data-driven policymaking that can better meet the demands of regulating human gene editing across global contexts.

There is a broad practice gap in the regulation of human gene editing technology. Ethical concerns, legal reasoning, and policy recommendations are well discussed in the literature, but their practical implementation is limited. As gene editing technologies like CRISPR are rapidly advancing, regulatory systems fall behind. The majority of countries lack enforceable guidelines, and where there are systems, they are largely theoretical or incomplete, giving little direction to clinical or research practitioners. Without systems in check, scientists may develop technology without restraint, only to trigger policy reaction to abuse afterwards. Second, the lack of codified international practice makes healthcare professionals uncertain about what is considered acceptable. Contrasting with case-based or outcome-based research, much of the literature today is not seen to offer a discussion of how to apply ethical precautions practically or adhere to interventions. Closing this gap is required to support responsible innovation, global consistency, and

protection of public trust in gene editing applications.

IV. Discussion

The past decade has shown us just how ill-equipped we were for the genetics revolution. Researchers, ethicists, and policymakers have been playing catch-up since 2015, trying to understand a world where the editing of human DNA has gone from science fiction to scientific fact.

This systematic literature review examines how gene editing in humans has been legislated globally between 2015 and 2025. Based on a synthesis of high-quality research articles, the review will critically compare how regions and governments worldwide are developing legal and ethical frameworks to address the challenges posed by human gene editing. The findings refer to broad trends, regional heterogeneity in policy development, and the difficulty of devising a harmonised global regulatory system. As such, this study contributes to the literature by outlining current perspectives, delineating deficits in global collaboration, and offering a glimpse into the evolving landscape of human gene editing governance.

Our survey finds this regulatory landscape is as messy and patchwork as you might expect. The research really picked up pace after 2018 – no surprise there. When a Chinese scientist announced he'd created the world's first gene-edited babies by altering the CCR5 gene in twin embryos, it was like someone had thrown a hand grenade into the scientific community (Conditi, 2022). Suddenly everyone was talking about what boundaries shouldn't be pushed and who gets to decide. This event also unearthed a more unsettling truth: not all countries had the infrastructure or foresight to manage such developments. China, for one, lacked comprehensive legal guidelines for human gene editing then. It was only after this incident that China, and the rest of the world for that matter, truly valued the significance of having legally accepted frameworks.

The inequality between countries is discomfiting. In fact, developed nations have established regulatory frameworks to oversee gene editing in humans, but a number of developing or underdeveloped countries have not. This is sometimes because their scientific communities quite simply haven't yet achieved the same level of technological advancement, and the necessity for regulation is not yet so obvious. However, this perceived irrelevance becomes dangerous when private entities choose to conduct experiments in these regions, bypassing government regulation completely. Without explicit jurisdictional policies, such experiments could lie beyond ethical and legal oversight entirely, with vulnerable populations at risk and local authorities powerless to intervene.

Even COVID did not manage to slow down this debate. If anything, it added fuel to the fire as scientists thought about how gene editing might be utilised in fighting the pandemic. Crisis tends to test our moral boundaries, and gene editing technologies were revisited for vaccine studies and antiviral applications (Niazi,

2023).

The US and the UK are publishing the most on this topic, and this raises a fascinating question: who gets to write the rulebook? The European Union has become a sort of gold standard with its thoughtful, integrated approach, but do regulations crafted for Brussels apply in Brasília or Bangkok? Probably not without significant adaptation (Yu et al., 2021). This is a growing need for a shared framework. A shared set of ethical and regulatory principles that can serve as a global reference. Yet, the challenge lies in the diversity of cultures, religions, and public opinions. While an underlying ethical concept can be the same everywhere across the globe, concrete regulations must be adapted and localised to fit the specific legal, cultural, and social tissue of a country.

Most egregious is the absence of global coordination we're seeing. Researchers are working in silos, publishing locally when what we really need is global conversation. Gene editing knows no national boundaries. Its implications are global. This sort of fragmentation means missing opportunities to develop shared ethical standards and harmonise regulations in diverse global contexts (Minari et al., 2022).

The field remains dominated by qualitative analyses rather than hard data, reflecting both the ethical complexities and the early stage we're at in this journey. We're still figuring out what questions to ask, let alone what the answers might be. Ethical debates are already well underway, but this issue needs to be tackled from multiple dimensions. Regulatory efforts must involve not just scientific and legal contributions, but also cultural sensitivities, public opinion, and religious values. These are some of the forces behind each country's response to new biotechnologies and why one size won't fit all.

What's for sure is that we need more voices at the table – particularly from countries that are currently underrepresented at this debate. These disparities are reflective of infrastructure, policy commitment, and research funding inequalities that undermine equitable participation in the governance of gene editing (Millett et al., 2023). The technology is evolving faster than we are able to govern it, and without inclusive, multilateral approaches, we will be left with a patchwork of policies that either stifles innovation or is unable to protect human dignity.

A. Limitations

This systematic literature review has several limitations that may affect the accuracy and generalisability of its findings. First, the inclusion of only English-language peer-reviewed journal articles may introduce language and publication bias, excluding valuable research published in other languages or as books, book chapters, or grey literature (e.g., conference proceedings, technical reports). As a result, insights from countries with significant cultural and regulatory differences may have been overlooked, especially in non-Western contexts.(Saluja & Khushi, 2024)

Furthermore, the study was limited to the period between 2015 and 2025. While

this timeframe was selected to reflect current regulatory trends, it may have inadvertently excluded foundational or historical studies that have shaped today's regulatory discourse.

Although the review aimed to examine both somatic and germline gene editing, the majority of available literature heavily emphasised germline editing, especially after the 2018 controversy involving Chinese scientist He Jiankui's CRISPR-edited babies (Berlincourt et al., 2024). This incident shifted global attention toward heritable gene editing, leading to an imbalance in the representation of regulatory discourse.

Another limitation is the dominance of ethical discussions in the literature, with relatively little focus on the legal and policy frameworks. Key topics such as the distinction between gene therapy versus enhancement were also often under explored or poorly addressed. Additionally, qualitative and empirical clinical research in this area remains limited likely due to the scarcity of clinical trials and the high ethical and regulatory barriers to conducting human gene editing studies.

Geographical concentration of research in countries like the UK and USA introduces potential regional bias, while diverse cultural, religious, and societal values that influence regulation may not be adequately reflected. The lack of international collaboration among authors further limits the possibility of a harmonised global framework, as most countries currently rely on jurisdiction-specific guidelines without a unified international policy (Olaghere et al., 2025).

B. Future Research Directions

In order to optimise the regulatory governance of human gene editing, future research must address some important gaps. First, quantitative, mixed-method, and literature review studies must be investigated further. Quantitative studies, by way of quantifiable data and statistical significance, can improve the validity and generalisability of regulatory findings. Mixed-method approaches offer a compromise between statistical validity and rich comprehension of social, ethical, and legal nuances, and literature reviews synthesize what is known in order to identify trends and contradictions. Such combined methodologies would give policymaking a more holistic and evidence-based foundation.

Second, regulatory frameworks have unfairly given greater emphasis to germline editing over comparatively few studies on somatic cell editing. This is a serious oversight because somatic editing albeit less ethically nuanced is medically, legally, and safely impactful enough to require systematic regulation. Follow-up studies must remedy this imbalance, exploring ethical boundaries, risk-benefit analysis, and long-term monitoring protocols for somatic procedures.

Interdisciplinary cooperation, institutional cooperation, and nation-state cooperation must be the priority. Decentralization of modern governance impedes the creation of international consensus standards. International alliances to develop coherent, equitable, and enforceable regulatory regimes must be explored by future

generations of researchers. International coalitions can share information, harmonise ethical principles, and resolve emerging biotechnology issues as a single entity.

Furthermore, regulatory language has to actively take on board the perspective of developing nations. Empirical inquiry must look into what these nations perceive gene editing to be and what infrastructural, cultural, and political issues they face in their adoption of regulations. This precludes Western bias and promotes inclusive, worldwide models.

Lastly, there needs to be greater research in cultural, religious, and ethical spheres since all these have a great impact on the acceptance of gene editing by the public and policy formation. The regulation should aim at safeguarding the natural human gene pool by restricting gene editing application to therapeutic purposes alone and not allowing enhancement or eugenics ends. These value-based policies will ensure that the technologies are responsibly being utilised.

Conclusion

Despite the promise of gene editing to transform the treatment of genetic disorders, the literature reveals that there are a number of issues: overemphasis on technical advance, underrepresentation of developing countries, lack of emphasis on regulating somatic cell editing, and minimal interdisciplinary research. Most of the studies are from Western countries, supporting a narrow regulation strategy and ignoring cultural, ethical, and regional differences that are important in creating diverse and inclusive policy settings.

Although germline editing has attracted significant ethical attention, the regulatory void surrounding somatic editing is not well explored, even though its clinical use continues to increase. In addition, the absence of global harmonisation in regulatory strategies has created loopholes that can be exploited, particularly in countries with weak or non-existent governance frameworks. Unless policymaking is collaborative and inclusive, these inconsistencies have the potential to worsen global health inequities and public distrust of gene technologies.

Later research has to employ higher quantitative, mixed-method, and systematic review-style approaches that deliver higher reliability, statistical power, and larger-scale studies. Also, a concurrent need for cooperation among international, multidisciplinary scientists, ethicists, lawmakers, and global health international officials is needed for setting agreed standards of ethics. Moreover, Third World perspectives should be brought forth to render model regulations more representative of international dynamics and less one-sided with an overemphasis stemming from Western perspective.

In conclusion, the review emphasizes that gene editing technologies need to be regulated not only for efficacy and safety but also to protect the natural gene pool, human dignity, and the common good. Regulations should favour enabling

therapeutic applications while excluding non-therapeutic enhancements that attempt to redefine human beings. As we move along, ethical prescience and wise governance ought to be at the root of all scientific advances, so that gene editing favours humankind overall, without sharpening inequality and ethical erosion.

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Author Bio / Cover Letter

Authors are Advanced Diploma in Nursing student at the Australian College of Business and Technology, Colombo. The research interests include gene editing, therapeutic gene editing, somatic and germline modifications, and their implications within nursing practice. In the development of this systematic literature review, she has applied a range of academic research tools and frameworks, including Zotero for reference management, VOSviewer for bibliometric analysis, PRISMA guidelines for literature screening, and APA 7th edition referencing. This paper represents her first academic publication and reflects a growing commitment to integrating scientific and ethical perspectives within modern nursing research.

Conflict of Interest Statement

We, the author, hereby declare that there are no conflicts of interest regarding the publication of this article. I have no financial or personal relationships with individuals or organizations that could inappropriately influence this research or its interpretation. This research was conducted with the highest ethical standards, and I have complied with all relevant guidelines for publication. I have read and understood the journal's policies on conflicts of interest and have provided full disclosure in accordance with those policies.

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