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Regulatory Trends and Governance Gaps in CRISPR-Cas9 Frameworks Across Developing Countries: A Comparative Policy Analysis

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ABSTRACT

Background: CRISPR-Cas9 has rapidly transitioned from a laboratory tool to a globally implemented technology with applications in human therapeutics, agriculture, disease control, and environmental engineering. While high-income countries have established clear regulatory pathways and ethical guardrails for gene editing, governance mechanisms in low- and middle-income countries (LMICs) remain inconsistent, outdated, or absent. This regulatory asymmetry raises critical concerns related to biosafety, biosecurity, ethical compliance, research integrity, and equitable access. Understanding current governance trends and identifying structural gaps is essential to inform responsible CRISPR adoption in LMICs. **Methods:** A qualitative comparative policy analysis was conducted using a systematic literature review (2018–2025), legal document mapping, and evaluation of CRISPR-related national policies. Data were extracted from governmental regulatory repositories, WHO and UNESCO guidance documents, peer-reviewed scientific literature, institutional review frameworks, and regional biotechnology governance reports. Policies were assessed against six analytical dimensions: regulatory clarity, ethical oversight mechanisms, biosafety infrastructure, biosecurity preparedness, dual-use governance, and public engagement. Countries included represented Africa, Asia, and Latin America. **Results:** Findings revealed substantial cross-country variation and persistent governance gaps. Most LMICs lacked explicit regulation for germline genome editing, gene drives, or CRISPR-based clinical trials. Ethical oversight was often limited by inadequate domain expertise, uncertain enforcement power, and absence of standardized review criteria. Biosafety capacity was restricted due to insufficient accredited BSL-2/3 facilities, inadequate training pipelines, and weak environmental monitoring mechanisms. Biosecurity provisions including DNA synthesis screening and dual-use review were largely absent. Public engagement processes were minimal, with limited transparency or community consultation for sensitive applications. **Conclusion:** CRISPR governance in LMICs remains fragmented and insufficient to address emerging ethical, biosafety, and biosecurity challenges. Without coordinated policy reform, LMICs risk scientific inequity, misuse, and loss of public trust. The analysis underscores the need for flexible, scalable, and context-adaptive regulatory models aligned with international standards but tailored to LMIC realities. These findings provide the evidence base for a harmonized CRISPR governance framework proposed in the companion paper.

Keywords: CRISPR-Cas9; Governance; Bioethics; Biosafety; Genome Editing Regulation; LMICs; Policy Analysis; Gene Drives; Dual-Use; Global Health Ethics.

1. Introduction

Genome editing has undergone a paradigm shift with the emergence of CRISPR-Cas9, a programmable RNA-guided nuclease system that enables precise, efficient, and cost-effective modification of genomic sequences. The technology has accelerated scientific advances in therapeutics, diagnostics, vaccine design, agricultural biotechnology, ecological engineering, and functional genomics. Compared to earlier editing platforms such as Zinc Finger Nucleases and TALENs, CRISPR-Cas9 offers unparalleled scalability, accessibility, and adaptability resulting in steep global adoption across academic, industrial, and clinical sectors. However, the rapid pace of CRISPR development has produced governance challenges, particularly as applications shift from controlled laboratory settings into clinical, agricultural,

and environmental domains. While high-income countries (HICs) have proactively implemented structured regulatory regimes including restrictions on human germline modification, oversight of dual-use risks, and ethical review mechanisms low- and middle-income countries (LMICs) exhibit fragmented or incomplete governance structures. Existing biosafety and biotechnology laws in many LMICs predate genome editing and often fail to address CRISPR-specific concerns, such as gene drives, embryo editing, transboundary ecological effects, pathogen engineering, and genomic data protection. The regulatory asymmetry between HICs and LMICs raises concerns regarding scientific safety, ethical compliance, cross-border risk management, and equitable access to technology. Without updated regulatory architecture, LMICs risk:

- Unregulated or premature clinical experimentation,
- Weak oversight of germline and embryo editing,
- Insufficient biosafety containment for genetically modified organisms,
- Inadequate preparedness for dual-use or biosecurity threats,
- Lack of community consultation for environmental CRISPR applications (e.g., mosquitoes, crops),
- Dependence on external entities for policy direction and technology governance.

At the same time, LMICs face disproportionate burdens of infectious disease, food insecurity, and agricultural vulnerability areas where CRISPR-based innovations may have the greatest benefit. Yet without contextualized oversight structures, these innovations may widen rather than close equity gaps.
Several global bodies including WHO, UNESCO, NASEM, and the International Summit on Genome Editing have issued guidance emphasizing responsible research conduct, prohibition of premature germline embryo use, and the necessity of public engagement. However, these frameworks were developed primarily within high-regulation contexts and are not directly transferable to LMIC sociopolitical systems, cultural norms, or infrastructural realities.

Therefore, there is a pressing need to systematically map the regulatory landscape of CRISPR governance across LMICs, identify systemic gaps, and propose actionable policy strategies tailored to capacity constraints, ethical pluralism, and regional priorities.

This study addresses that gap by conducting a cross-national comparative policy analysis of CRISPR governance frameworks across LMICs representing Asia, Africa, and Latin America. By examining regulatory clarity, ethical oversight, biosafety infrastructure, biosecurity preparedness, public engagement mechanisms, and alignment with international standards, this work seeks to:

1. Characterize existing governance models in LMICs,
2. Highlight systemic weaknesses and risks, and
3. Lay the groundwork for harmonized, capacity-appropriate regulatory reform.

2. Methods

This study employed a qualitative policy analysis design supported by a systematic literature review (SLR) and comparative regulatory assessment. The methodology was developed to evaluate the governance landscape of CRISPR technologies across selected low- and middle-income countries (LMICs), using standardized criteria aligned with global regulatory and ethical norms.

2.1 Study Design

A multi-phase methodological approach was used, consisting of:

1. Systematic Literature Review
2. Regulatory Document Mapping and Extraction
3. Comparative Policy Analysis (CPA)
4. Thematic Synthesis and Interpretation

This mixed qualitative approach enabled the integration of legal, ethical, biosafety, and policy dimensions into a cohesive analytical framework.

2.2 Data Sources

Data were collected from five primary sources:

- Government and Institutional Regulatory Repositories (e.g., biosafety acts, clinical trial regulations, GMO laws, research ethics guidelines)
- International Governance Frameworks including WHO (2021), UNESCO Universal Declaration on Bioethics and Human Rights, NASEM reports, and the International Commission on Genome Editing
- Peer-reviewed Literature indexed in PubMed, Scopus, Web of Science, and Google Scholar
- Regional Governance Bodies (African Union biosafety guidelines, ASEAN biotechnology framework, SAARC regulatory data)
- Policy Briefs, Gray Literature, and NGO Reports

The review period was restricted to January 2018-December 2025, capturing the most relevant regulatory developments following major CRISPR clinical milestones.

2.3 Search Strategy

A structured Boolean search strategy was applied using keywords and controlled vocabulary (MeSH terms):

("CRISPR" OR "Genome editing" OR "Gene drives") AND ("Regulation" OR "Policy" OR "Governance" OR "Biosafety" OR "Ethics") AND ("LMIC" OR "Developing countries" OR "Global South"). Additional customized regional searches (e.g., "India gene editing guidelines," "Brazil CRISPR regulation") supplemented the core dataset.

Table 1: Search Strategy and Inclusion Criteria (Systematic Literature Review)

Category	Details
Databases searched	PubMed, Scopus, Web of Science, Google Scholar
Search period	January 2018 – December 2025
Search string	("CRISPR" OR "Genome editing" OR "Gene drives") AND ("Regulation" OR "Policy" OR "Governance" OR "Biosafety" OR "Ethics") AND ("LMIC" OR "Developing countries" OR "Global South")
Document types included	Peer-reviewed articles, regulatory documents, national biosafety frameworks, WHO/UNESCO/NASEM guidelines, policy briefs

Language restrictions	English (translated documents included when available)
Inclusion criteria	Documents addressing CRISPR governance, ethics, biosafety, policy development, public engagement in LMICs
Exclusion criteria	Experimental laboratory studies, non-policy-oriented reviews, editorials without regulatory relevance

Table 1: Search Strategy and Inclusion Criteria Used for the Systematic Literature and Policy Review. *This table summarizes the databases searched, inclusion/exclusion criteria, search terms, document types, and eligibility filters applied in the screening phase.*

Figure 1: PRISMA Flow Diagram Showing Document Selection Process in the Systematic Review. *The figure illustrates the screening and eligibility pathway from initial identification (n = 1,243 documents) to final inclusion (n = 62), detailing steps for duplicate removal, title/abstract screening, full-text review, and final inclusion.*

2.4 Country Selection Criteria

Countries were included based on:

1. Active or emerging CRISPR research capacity
2. Availability of biotechnology or biosafety policy documentation
3. Representation of diverse LMIC regions

Final selected countries:

- **Asia:** India, Pakistan, Bangladesh, Nepal
- **Africa:** Kenya, South Africa, Nigeria
- **Latin America:** Brazil, Argentina

These regions reflect varying levels of technological maturity and regulatory evolution.

Table 2: Countries Included and Rationale for Selection

Country	Region	Rationale for Inclusion	CRISPR Policy Status
Brazil	Latin America	Active CRISPR research; developed regulatory structure	Established
Argentina	Latin America	Emerging CRISPR regulation; agricultural applications	Partial
South Africa	Sub-Saharan Africa	Advanced biotechnology governance	Established
Kenya	Sub-Saharan Africa	Ongoing CRISPR agriculture and gene drive trials	Emerging
Nigeria	Sub-Saharan Africa	Active GMO regulation but minimal genome editing policy	Undefined
India	South Asia	Active clinical and agricultural CRISPR research	Partial
Pakistan	South Asia	Limited ethical regulation; agricultural research increasing	Undefined
Bangladesh	South Asia	Agricultural focus, no CRISCR-specific regulation	Undefined
Nepal	South Asia	Very limited policy infrastructure	Undefined

Table 2: Countries Selected for Comparative Analysis and Rationale for Inclusion. *This table details the geographic distribution, inclusion justification, and CRISPR regulatory status among the nine LMICs evaluated.*

Figure 2: Geographic Distribution of LMICs Included in the Comparative CRISPR Governance Analysis. *This map visualizes the nine countries assessed in the study, grouped into three regional clusters: Latin America (Brazil, Argentina), Sub-Saharan Africa (South Africa, Kenya, Nigeria), and South Asia (India, Pakistan, Bangladesh, Nepal).*

2.5 Data Extraction and Coding Framework

A standardized extraction matrix was used to evaluate six governance dimensions:

Dimension	Indicators Evaluated
Regulatory clarity	Laws, enforcement structures, CRISPR-specific language
Ethical oversight	Research ethics systems, germline guidance, informed consent
Biosafety capacity	Facility accreditation, training, laboratory standards
Biosecurity readiness	DURC review, sequence screening, data protection
Dual-use safeguards	Restrictions, penalties, oversight bodies
Public engagement	Consultation mechanisms, transparency, communication

Documents were independently coded by two reviewers using NVivo qualitative software to minimize interpretation bias.

2.6 Comparative Policy Analysis

Country policies were comparatively assessed using:

- Alignment scoring with global governance standards
- Regulatory readiness index ranking
- Gap identification across domains
- Policy maturity classification:
    - *Undefined*, *Emerging*, *Partial*, or *Established*

This enabled cross-national benchmarking and identification of systemic trends.

2.7 Quality Control and Validation

To ensure rigor:

- Duplicate screening and independent coding were performed.
- Disagreements were resolved through consensus with a third reviewer.
- PRISMA methodology guided the literature screening process.
- A validation check was conducted against WHO Genome Editing Governance Framework domains.

2.8 Ethical Considerations

As this research analyzed publicly accessible documents and published literature, ethical committee review was not required. However, the study adhered to principles of transparency, neutrality, and responsible handling of policy-sensitive data.

2.9 Methodological Limitations

The method may be influenced by:

- Uneven document availability across countries
- Rapidly evolving regulatory landscapes
- Variable transparency of biotechnology governance systems
- Language-based accessibility constraints in non-English policy archives

3. Results

This section presents findings from the comparative policy analysis across the selected LMICs. Results are organized according to the six analytical dimensions defined in the Methods section: (1) regulatory clarity, (2) ethical oversight capacity, (3) biosafety infrastructure, (4) biosecurity and dual-use risk governance, (5) public engagement and transparency, and (6) alignment with global standards. Cross-country differences, converging themes, and structural gaps are highlighted to contextualize governance maturity levels.

3.1 Regulatory Clarity and Policy Status Across Countries

The analysis revealed wide variation in the extent to which CRISPR-specific governance frameworks exist across LMICs. Countries such as **Brazil and South Africa** have developed explicit regulatory frameworks addressing genome editing across biomedical, agricultural, and environmental sectors. Brazil, for example, differentiates gene-edited organisms from transgenic GMOs, enabling faster approval pathways for CRISPR-modified crops. South Africa integrates CRISPR oversight under established biosafety and biotechnology regulations, ensuring clearer enforcement authority.

Conversely, countries like **Pakistan, Bangladesh, Nepal, and Nigeria** lack legislative language specific to CRISPR, relying instead on outdated biosafety or genetic engineering statutes originally constructed for GMO regulation. These laws do not address germline modification, off-target genomic effects, gene drives, or genome editing applied to human embryos.

India occupies an intermediate position: multiple policy documents and draft regulations reference CRISPR and gene editing; however, implementation pathways, enforcement authority, and sector-specific guidelines remain inconsistent across ministries. Differences between the Department of Biotechnology, the Indian Council of Medical Research, and national biosafety authorities illustrate regulatory overlap and fragmentation.

Figure 3: Regulatory Readiness Comparison Across LMICs. *Bar chart displaying aggregate governance performance scores across six regulatory domains, demonstrating the variation between countries with established frameworks (Brazil, South Africa), partial frameworks (India, Argentina, Kenya), and minimal or undefined systems (Pakistan, Bangladesh, Nepal, Nigeria).*

Key Patterns Identified Include:

- Somatic clinical trials are permitted conditionally in only three countries (Brazil, India, South Africa).
- Germline editing remains unregulated not explicitly banned nor permitted—in most LMICs, creating legal and ethical ambiguity.
- Agricultural CRISPR regulation diverges sharply, with regulatory leniency in Latin America but restrictive or unclear frameworks in South Asia and Sub-Saharan Africa.

Overall, only 22% of the analyzed LMIC regulatory documents contained CRISPR-specific terminology, indicating governance lag relative to technological advancement.

Table 3: Evaluation Framework Used for Comparative Policy Analysis

Governance Dimension	Indicators Scored	Score Scale	Source Type
Regulatory clarity	CRISPR-specific laws, somatic/germline distinction, enforcement	0–5	National regulatory documents
Ethical oversight	IRB strength, genome editing guidelines, informed consent mechanisms	0–5	Ethical review frameworks
Biosafety infrastructure	Facility accreditation (BSL-2/3), waste and containment policies	0–5	National biosafety standards
Biosecurity & dual-use	DNA sequence screening, DURC governance, cyberbiosecurity	0–5	Biosecurity regulation
Public engagement	Consultation processes, transparency, community involvement	0–5	Public-facing policy statements
Alignment with global frameworks	WHO/UNESCO/NASEM compliance	0–5	Cross-referenced analysis

Table 3: Governance Assessment Framework Used for Policy Coding and Comparative Scoring. *The table outlines the six analytical dimensions (regulatory clarity, ethical oversight, biosafety capacity, biosecurity protections, public engagement, and alignment with global frameworks) alongside scoring indicators.*

Table 4: Comparative Regulatory Readiness Scores Across Countries

Country	Regulatory Clarity	Ethical Oversight	Biosafety Infrastructure	Biosecurity Measures	Public Engagement	Global Alignment	Total Score /30	Readiness Level
Brazil	5	5	5	4	4	5	**28**	High
South Africa	5	5	4	4	3	5	**26**	High
India	4	4	4	3	3	4	**22**	Medium
Argentina	3	3	4	2	2	3	**17**	Medium
Kenya	3	3	3	2	2	3	**16**	Medium
Nigeria	2	2	2	1	1	2	**10**	Low
Pakistan	2	2	2	1	1	2	**10**	Low
Bangladesh	1	2	2	1	1	2	**9**	Low
Nepal	1	1	1	0	0	1	**4**	Very Low

Table 4: Comparative Regulatory Readiness Scores Across Selected LMICs. *This table presents cross-country scoring based on regulatory maturity and oversight capacity, categorizing each nation into readiness levels (high, medium, low, very low).*

3.2 Ethical Oversight Capacity and Review Pathways

Ethical oversight structures exist in all countries; however, their capacity to address genome editing-specific issues varies significantly. National ethics committees or IRB systems are established in all cases, but only three countries explicitly incorporate genome editing considerations into ethical review processes (Brazil, South Africa, India).

Challenges identified include:

- Limited local expertise in genomic ethics, population genetics, and privacy ethics.
- Absence of standardized criteria for evaluating risk–benefit ratios in gene-editing proposals.
- Informed consent frameworks not adapted to low-scientific-literacy populations, especially where collective or community consent models are culturally dominant.

In Sub-Saharan Africa, ethical review systems rely heavily on externally supported research ethics training programs, creating dependence on international institutions. In South Asia, ethics oversight remains uneven across public and private institutions, with private biotechnology research often falling outside mandatory review pipelines.

A notable gap across all LMICs is the lack of genome editing–specific genetic counseling infrastructure, which limits ethically sound clinical deployment.

3.3 Biosafety Infrastructure and Laboratory Readiness

Biosafety infrastructure emerged as a major challenge across LMICs. All countries possessed some BSL-2 laboratory capacity, but the availability, accreditation, and functionality of BSL-3 facilities were extremely uneven.

- Brazil, India, and South Africa maintain relatively robust high-containment laboratory networks, partially due to infectious disease research and vaccine infrastructure.
- Kenya and Argentina demonstrate emerging readiness but lack nationwide containment networks.
- Nepal, Pakistan, Bangladesh, and Nigeria face severe infrastructural shortfalls, limited funding mechanisms, and absence of CRISPR-specific biosafety protocols.

Training gaps were pervasive: only four countries required genome-editing-specific biosafety training for laboratory approval, and only two (Brazil and South Africa) maintained national registries of CRISPR research facilities. Waste management, environmental monitoring, and containment protocols for live gene drive organisms were universally inadequate, raising concerns for malaria-vector gene drive research proposed in Africa. These disparities align with heatmap patterns reflected in Figure 4.5 (Biosafety Readiness Index), showing high variability and low preparedness in several LMIC regions.

3.4 Biosecurity Governance and Dual-Use Risk Management

Biosecurity governance was the weakest domain across all countries. Only South Africa had a formal framework addressing dual-use research of concern (DURC). India demonstrated partial DURC consideration, mostly influenced by BSL-3 pathogen work.

Across the remaining LMICs:

- No regulations mandated DNA sequence screening for synthesis orders.
- Cyber-biosecurity protections for genomic sequencing data were extremely limited.
- Export control policies on gene editing reagents lacked enforcement clarity.

The lack of oversight poses significant risks, especially as CRISPR democratizes access to viral engineering, antimicrobial resistance pathways, and population-level ecological manipulation. In alignment with **Figure 4.6 (Biosecurity Threat Spectrum)**, this regulatory vacuum represents a high-risk governance vulnerability.

Figure 4: Governance Maturity Radar Visualization for LMICs. *A radar chart comparing six governance dimensions regulatory clarity, ethical oversight, biosafety capacity, biosecurity preparedness, public engagement, and alignment with global standards highlighting strengths and deficiencies across countries.*

3.5 Public Engagement, Trust, and Transparency Mechanisms

Public engagement was identified as an emerging but underdeveloped governance dimension. Countries with active scientific communication cultures (Brazil, India, South Africa) had higher levels of public awareness and structured science communication programs.

However, in most LMICs:

- Public engagement was reactive rather than proactive.
- Civil society involvement in decision-making was minimal.
- Misinformation (e.g., CRISPR equated to "designer babies" or "population control") remained unaddressed.

No LMIC maintained a publicly accessible CRISPR research registry, limiting transparency and accountability.

3.6 Alignment with International Governance Standards

Alignment with WHO, UNESCO, NASEM, and OECD frameworks varied widely:

Alignment Category	Characteristics	Countries
High Alignment	CRISPR-specific policy language + enforcement mechanisms	Brazil, South Africa
Intermediate Alignment	Draft guidelines + partial implementation	India, Argentina, Kenya
Low Alignment	General GMO or biosafety laws with no CRISPR provisions	Pakistan, Bangladesh, Nepal, Nigeria

The divergence underscores the absence of harmonized governance pathways and reinforces the need for adaptive frameworks.

3.7 Cross-Domain Structural Themes

Three structural governance themes emerged:

1. Policy fragmentation and technological lag dominate CRISPR oversight across most LMICs.
2. Infrastructure readiness does not match research ambition, especially regarding biosafety and biosecurity.
3. Ethical and public engagement systems lack specificity, risking social resistance and regulatory instability.

Table 5: Key Governance Gaps Identified in LMIC CRISPR Regulation

Category	Observed Gap	Impact Severity	Example Regions
Legal clarity	No law distinguishing germline vs. somatic editing	High	South Asia, West Africa
Oversight expertise	Ethics committees lack genome editing knowledge	High	All LMIC regions
Biosafety	Limited BSL-3 capacity and waste management protocols	Very High	Nepal, Nigeria, Pakistan
Biosecurity	Lack of dual-use governance and DNA synthesis screening	Very High	All LMICs except South Africa
Community engagement	No structured consultation models	High	Africa and South Asia

Table 5: Key Gaps Identified in CRISPR Governance Across LMIC Contexts. *The table lists critical regulatory, ethical, biosafety, and public governance deficiencies alongside expected impact severity and regional patterns.*

4. Discussion

The findings of this comparative analysis reveal substantial governance gaps across CRISPR regulation in LMICs, driven by uneven policy development, insufficient ethical oversight, limited biosafety infrastructure, weak biosecurity preparedness, and minimal public engagement. Although CRISPR adoption is accelerating globally, the capacity of LMICs to regulate, monitor, and ethically implement genome editing remains significantly underdeveloped. This discussion interprets these findings in relation to global regulatory discourse, theoretical frameworks in emerging biotechnology governance, and the practical realities of institutional readiness in LMICs.

Table 6: Comparison of LMIC Policies with Global Governance Standards

Standard	Brazil	South Africa	India	Kenya	Pakistan	Bangladesh	Nepal
WHO Genome Editing Guidance	✓	✓	Partial	Partial	✗	✗	✗
UNESCO Bioethics Framework	✓	✓	✓	Partial	✗	✗	✗
NASEM Germline Guidelines	✓	✓	Partial	✗	✗	✗	✗
OECD Responsible Biotechnology	✓	✓	✓	Partial	✗	✗	✗

Table 6: Alignment of LMIC Regulatory Frameworks with International Standards (WHO, UNESCO, NASEM, OECD). *This table highlights the extent to which participating countries comply with global genome-editing governance principles.*

4.1 Regulatory Lag and Fragmentation: A Systemic Pattern

A key theme arising from the results is the widening gap between scientific innovation and regulatory preparedness often referred to as the **"innovation=regulation lag."** While CRISPR research and application have expanded rapidly, regulatory systems in many LMICs remain anchored in frameworks originally designed for GMOs or conventional biomedical research.

This misalignment presents multiple risks:

- Regulatory ambiguity may allow unmonitored or premature experimentation, particularly in clinical or germline contexts.
- Policy fragmentation across ministries creates bureaucratic uncertainty, slowing responsible innovation but *not* necessarily preventing unethical activity.
- Lack of CRISPR-specific language creates enforcement loopholes, enabling research without formal oversight even where ethical guidelines exist.

The pattern observed mirrors governance trajectories seen during earlier biotechnology waves (e.g., transgenics, stem cell research), but CRISPR's dual-use potential and irreversible ecological impacts amplify the consequences of delayed governance.

Figure 5: Conceptual Model Illustrating Determinants of CRISPR Governance Readiness in LMICs. *The figure integrates ethical, institutional, socio-political, infrastructural, and international alignment factors into a unified framework explaining systemic drivers of governance strength or weakness.*

4.2 Ethical Oversight Limitations and Contextual Challenges

Ethical governance emerged as another significant weakness, reflecting limited domain expertise, unclear review criteria, and inadequate adaptation to sociocultural realities. Genome editing intersects with deeply embedded beliefs about identity, reproduction, disability, inheritance, and nature meaning ethical oversight cannot rely solely on universal bioethical principles.

Two challenges are particularly salient in LMICs:

1. Low genomic literacy among both ethics boards and populations compromises informed consent and risk reasoning.
2. Collectivist decision-making norms in many African and South Asian contexts conflict with Western individual-centered ethical models.

The absence of trained genome-editing counselors, standardized guidelines for embryo research, or mechanisms for community-based deliberation suggests that ethical governance is reactive rather than anticipatory. Without expansion of ethical capacity, LMICs risk repeating mistakes seen in unregulated reproductive and stem cell markets.

4.3 Biosafety and Biosecurity Gaps: Risks to Health and Security

Biosafety infrastructure and dual-use governance gaps represent one of the most urgent findings. CRISPR enables rapid editing of pathogens, self-propagating genetic constructs such as gene drives, and high-consequence genomic alterations with ecological reach. Conducting such work without adequate containment or monitoring systems risks accidental release, environmental disruption, or malicious exploitation.

Weak biosecurity frameworks including absent DNA synthesis screening, poor genomic data security, and limited dual-use oversight mirror vulnerabilities identified by global health security assessments. These gaps place LMICs at heightened risk of being:

- Unregulated testing sites for foreign-funded projects, or
- Targets for illicit technology transfer or misuse.

This emphasizes the need for coordinated biosecurity governance integrated with national security, public health systems, and international databases.

4.4 Public Trust and Social License: The Missing Governance Element

A recurring pattern across LMICs is the absence of structured public engagement. Public trust is foundational for emerging biotechnology governance, particularly when interventions affect communities rather than individuals—as in **gene drive malaria control**, **CRISPR crops**, or **population-wide genetic screening programs**.

Without transparency mechanisms or participatory consultation, CRISPR risks triggering public backlash similar to resistance seen in GMO adoption, stem cell research, or vaccination in certain regions.

Building a **social license to operate** requires:

- Accessible science communication
- Community-based consent frameworks
- Public advisory committees
- Transparent research registries

Countries with emerging engagement structures (Brazil, India) demonstrate comparatively higher public acceptance, indicating scalability.

4.5 Alignment with International Guidance: Gaps and Opportunities

Although most LMICs express commitment to global governance norms, alignment is inconsistent. The absence of regulatory harmonization presents barriers to:

- International research collaborations
- Cross-border clinical trials
- Regulatory recognition of CRISPR-based therapies
- Shared monitoring of ecological risks

Yet, this also presents policy opportunity space: LMICs can develop adaptive frameworks that learn from regulatory evolution in HICs rather than repeating fragmented governance cycles.

4.6 Moving from Reactive to Anticipatory Governance

Current governance in LMICs is largely **reactive**—responding to visible ethical controversies or scientific milestones rather than anticipating risks. A shift toward **anticipatory, dynamic governance** is essential. Such governance includes:

- Scenario-based risk planning
- Periodic technology reviews
- Flexible regulatory triggers
- Built-in mechanisms for scaling oversight with innovation maturity

This aligns with WHO recommendations for iterative, evidence-based governance of genome editing.

4.7 Implications for Policy, Research, and Capacity Building

The findings suggest that harmonizing CRISPR regulation in LMICs requires:

- Institutional coordination across ministries
- Dedicated genome editing regulatory authorities
- Investment in biosafety infrastructure and workforce development

- Ethical capacity-building including genomic counseling
- National and regional research registries
- Multi-stakeholder public engagement initiatives

5. Conclusion

This study provides the first systematic comparative analysis of CRISPR governance across selected low- and middle-income countries and demonstrates that the regulatory environment surrounding genome editing technologies in LMICs remains fragmented, inconsistent, and underdeveloped. While scientific interest and early-stage CRISPR research activity are increasing across biomedical, agricultural, and environmental domains, the policy systems required to govern this technology safely and ethically have not evolved at the same pace.

The findings reveal that most LMICs lack explicit legislation addressing key dimensions of CRISPR governance, including somatic and germline editing boundaries, gene drive oversight, biosafety containment standards, and dual-use mitigation strategies. Even where ethical review structures exist, they often lack the technical specificity, interpretive frameworks, or genomic literacy required to assess genome-editing research proposals rigorously. Similarly, biosafety and biosecurity infrastructures remain insufficient in many countries to ensure responsible laboratory practice, safe deployment, or environmental stewardship, particularly for high-risk applications such as pathogen engineering or gene drives. Public engagement and transparency emerged as a critical missing pillar. Without accessible communication strategies, community consultation frameworks, and mechanisms for democratic oversight, LMICs risk generating mistrust and resistance—outcomes that have historically undermined other biotechnology-driven public health and agricultural initiatives. The observed disconnect between scientific innovation and public perception underscores the importance of relational governance, cultural contextualization, and societal consent in emerging genetic technologies. Despite these gaps, the results indicate meaningful opportunity. Countries such as Brazil, South Africa, and India demonstrate emerging regulatory readiness and could serve as regional models or anchors for policy harmonization. Furthermore, the alignment between LMIC needs and international frameworks—including WHO's 2021 Genome Editing Governance Recommendations—provides a strong starting point for structured regulatory development.

Collectively, these findings underscore the urgent need for harmonized, context-sensitive governance that balances innovation with ethical responsibility and societal protection. Establishing clear regulatory pathways, strengthening biosafety and ethical oversight capacity, and embedding public engagement within policy design are foundational steps to ensuring that LMICs can adopt CRISPR responsibly rather than reactively.

6. Limitations

This study has several limitations that should be acknowledged when interpreting the findings. First, the analysis relies on publicly accessible policy documents, national guidelines, and published literature; therefore, internal or unpublished regulatory drafts, institutional practices, and informal governance mechanisms may not have been captured. Second, regulatory environments in emerging technologies evolve rapidly, and policies may have changed or expanded during or after the review period. This temporal limitation is especially relevant given the acceleration of CRISPR clinical research and agricultural applications since 2022.

Third, although efforts were made to include diverse LMIC regions, the selected countries may not fully represent all sociopolitical, cultural, or regulatory contexts in the Global South. Variations in administrative structures, federal versus centralized governance models, and local implementation capacity could influence applicability of findings. Fourth, some policy sources were available only in national languages, creating potential interpretive constraints despite cross-verification with translated and secondary sources.

Finally, this study did not include stakeholder interviews, regulatory enforcement audits, or on-ground laboratory assessments. As a result, the gap between *policy-as-written* and *policy-in-practice* often significant in LMICs remains outside the analytical scope. Future research incorporating mixed methods including expert consultation, implementation evaluation, and regulatory impact assessment would deepen and validate these insights.

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