cognizancejournal.com
Mohammed Al Amin Ali Alsharawy *et al*, Cognizance Journal of Multidisciplinary Studies, Vol.5, Issue.9, September 2025, pg. 236-241
(An Open Accessible, Multidisciplinary, Fully Refereed and Peer Reviewed Journal)
ISSN: 0976-7797
Impact Factor: 5.183
Index Copernicus Value (ICV) = 92.57

The Global Policy Vacuum: Regulating CRISPR after Japan's Breakthrough in Deleting Trisomy 21 from Down Syndrome Cells

Mohammed Al Amin Ali Alsharawy*; Alaa Ali Alsharawy; Motassim Kamran Baig; Mohammad Kaif Shamsuddin; Miysaa Ali Al Abri; Bashair Nasser Al Adawi; Atheer Nasser Al Jahwari; Atheer Abdullah Al Amri; Ayaat Ali Alsharawy

National University of Science & Technology, College of Medicine and Health Sciences,
P.O. Box 620, PC 130, Muscat, Oman
Emails: mohamed210084@nu.edu.om, alaa200011@nu.edu.om, motassim210040@nu.edu.om, mohammad220584@nu.edu.om, miysaa200288@nu.edu.om, bashair200137@nu.edu.om, atheer200196@nu.edu.om, atheer200483@nu.edu.om, ayat220591@nu.edu.om
Corresponding Author:
Mohammed Al Amin Ali Alsharawy*
Email: mohamed210084@nu.edu.om
Contact number: +968 91752715

DOI: 10.47760/cognizance.2025.v05i09.018

Abstract: In a major scientific development, researchers at Japan's Mie University have successfully used CRISPR gene editing technology to delete the extra chromosome 21 from lab grown cells of individuals with Down syndrome. The edited cells demonstrated improved cellular function and normalized gene expression, marking a key milestone in the path toward potential genetic therapies for chromosomal conditions. Though not yet applicable to embryos or clinical treatment, the study raises urgent ethical and regulatory questions. This article explores the global policy gaps surrounding CRISPR's use for conditions like Down syndrome, comparing national regulatory frameworks and ethical norms. It calls for an inclusive, internationally harmonized governance model that balances scientific progress with disability rights, reproductive autonomy, and anti-eugenics protections.

Keywords: CRISPR gene editing, Down syndrome, chromosome 21, genetic therapies, gene expression, ethical questions, regulatory frameworks, global policy gaps, disability rights, reproductive autonomy.

©2025, Cognizance Journal, ZAIN Publications, Fridhemsgatan 62, 112 46, Stockholm, Sweden, All Rights Reserved

cognizancejournal.com
Mohammed Al Amin Ali Alsharawy *et al*, Cognizance Journal of Multidisciplinary Studies, Vol.5, Issue.9, September 2025, pg. 236-241
(An Open Accessible, Multidisciplinary, Fully Refereed and Peer Reviewed Journal)
ISSN: 0976-7797
Impact Factor: 5.183
Index Copernicus Value (ICV) = 92.57

Introduction:

In mid-2025, scientists at Mie University in Japan announced a breakthrough: for the first time, they used CRISPR to successfully remove the extra copy of chromosome 21 from lab grown cells taken from individuals with Down syndrome. The altered cells not only survived but exhibited normalized gene expressions and signs of restored cellular function. Though the study did not involve embryos or clinical applications, it signaled a turning point in the use of CRISPR for chromosomal abnormalities [**1**].

This development catalyzed international debate, not just within the scientific community but across bioethics, disability rights, and public policy spheres. If germ-line editing ever enables the targeted deletion of trisomy 21 in embryos, society must grapple with critical questions. Is Down syndrome a disease to be cured or a human variation to be accepted? Who has the moral authority to decide which lives are worth preventing, and which are worth preserving? What protection exists to prevent the misuse of such powerful technology?

This article argues that Japan's CRISPR milestone illuminates a major global policy vacuum. At present, no comprehensive international framework governs how, when, or why CRISPR should be used to alter human chromosomes particularly when those changes intersect with disability, identity, and reproductive autonomy. This policy forum examines the current ethical and legal gaps, analyzes cross cultural regulatory models, and offers a blueprint for more inclusive and globally harmonized governance.

Scientific Promise and Ethical Peril:

CRISPR-Cas9 has revolutionized genetic science by making it possible to edit specific genes with precision. While most CRISPR experiments to date have focused on correcting point mutations, trisomy 21 presents a qualitatively different challenge, it is a full chromosomal aneuploidy. The Mie University study proved that, under laboratory conditions, entire chromosomes can now be deleted in vitro. The potential clinical impact of this is both staggering and deeply fraught.

Down syndrome has long been at the center of debates about selective reproduction. In many countries, prenatal testing allows for detection of trisomy 21, and in some jurisdictions, leads to termination in over 90% of cases [**2**]. Critics argue that this practice reflects implicit societal bias against people with disabilities and reinforces a eugenic mindset. If CRISPR eventually enables embryo editing to remove trisomy 21 preimplantation, the moral terrain becomes even more

©2025, Cognizance Journal, ZAIN Publications, Fridhemsgatan 62, 112 46, Stockholm, Sweden, All Rights Reserved

cognizancejournal.com
Mohammed Al Amin Ali Alsharawy *et al*, Cognizance Journal of Multidisciplinary Studies, Vol.5, Issue.9, September 2025, pg. 236-241
(An Open Accessible, Multidisciplinary, Fully Refereed and Peer Reviewed Journal)
ISSN: 0976-7797
Impact Factor: 5.183
Index Copernicus Value (ICV) = 92.57

complex. Rather than aborting a fetus with a disability, we would be editing it into nonexistence or into a different kind of person entirely.

Ethically, the central question is whether Down syndrome should be framed as a disorder needing correction, or a form of neurodiversity deserving of protection. Advocates within the disability rights community often argue for the latter, emphasizing the rich lives, contributions, and unique perspectives of people with Down syndrome [**3**]. Conversely, some bioethicists contend that if a condition predictably causes intellectual disability and medical complications, parents should have the freedom to prevent it [**4**]. This tension between reproductive autonomy and disability justice lies at the heart of CRISPR policy.

A Global Policy Vacuum:

Despite rapid scientific advances, international regulatory bodies have not kept pace with the implications of germ-line editing for chromosomal conditions. National laws and ethical guidelines differ widely, leading to what some scholars call "CRISPR tourism," where prospective parents or researchers travel to jurisdictions with fewer restrictions.

In Japan, CRISPR research involving embryos is restricted to non-reproductive purposes, but there is no explicit legal ban on future clinical applications. The Japanese government issued bioethics guidelines in 2019 discouraging germ-line editing, yet enforcement is largely voluntary. The Mie University study stayed within legal bounds by using in-vitro somatic cells, but it revealed the slippery slope toward embryo manipulation [**5**].

In contrast, the United States does not allow federal funding for research involving embryo editing, but private funding is not subject to the same limits. The U.S. lacks comprehensive legislation regulating CRISPR in embryos, creating a regulatory grey zone. Meanwhile, in the European Union, the Oviedo Convention explicitly prohibits heritable genome editing, reflecting a more precautionary approach rooted in human rights and postwar eugenics sensitivities [**6**].

These divergent regulatory postures create not only ethical confusion but also legal and geopolitical risk. If one country permits trisomy 21 deletion via CRISPR and others prohibit it, the technology may flow to less restrictive jurisdictions, bypassing ethical scrutiny and public debate. This fragmented system also undermines trust in scientific governance and leaves vulnerable populations, particularly people with disabilities, without a meaningful voice in shaping the technologies that may affect their future.

©2025, Cognizance Journal, ZAIN Publications, Fridhemsgatan 62, 112 46, Stockholm, Sweden, All Rights Reserved

cognizancejournal.com
Mohammed Al Amin Ali Alsharawy *et al*, Cognizance Journal of Multidisciplinary Studies, Vol.5, Issue.9, September 2025, pg. 236-241
(An Open Accessible, Multidisciplinary, Fully Refereed and Peer Reviewed Journal)
ISSN: 0976-7797
Impact Factor: 5.183
Index Copernicus Value (ICV) = 92.57

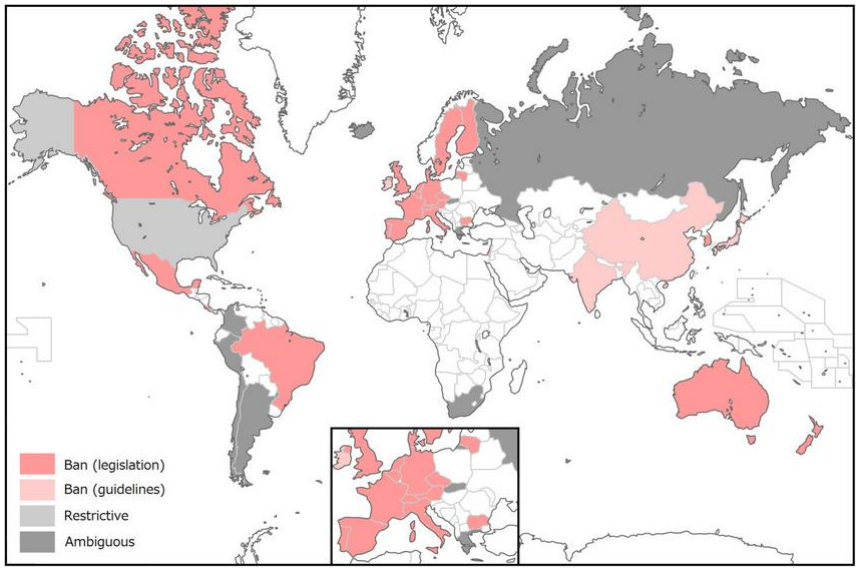

Figure 1: An international regulatory landscape regarding human germ-line gene modification. Thirty-nine countries were surveyed and categorized as "Ban based on legislation" (25, pink), "Ban based on guidelines" (4, faint pink), "Ambiguous" (9, gray), and "Restrictive" (1, light gray). [**7**]

In addition to regulatory divergence, there is a notable lack of coordinated oversight at the global level. While the World Health Organization issued broad ethical recommendations in 2021 regarding human genome editing, these remain non-binding and lack enforcement mechanisms. UNESCO's Universal Declaration on the Human Genome and Human Rights offers general guidance, but its scope predates CRISPR and does not address the technology's transformative capabilities [**8**].

Scholars have also pointed to the need for an international genome editing governance body, like the International Atomic Energy Agency, that could monitor, inspect, and advise on high stakes genomic interventions. Without such infrastructure, societies risk making irreversible changes to human germ-line without shared consent or accountability [**9**].

Reproductive Autonomy and Disability Rights: A False Binary?

At the ethical core of this debate is the potential clash between reproductive freedom and disability justice. Defenders of germ-line editing argue that prospective parents should have the right to prevent what they perceive as suffering in their children. Yet this framing assumes that life with Down syndrome is necessarily undesirable, a claim disputed by many individuals with the condition and their families.

©2025, Cognizance Journal, ZAIN Publications, Fridhemsgatan 62, 112 46, Stockholm, Sweden, All Rights Reserved

ISSN: 0976-7797
Impact Factor: 5.183
Index Copernicus Value (ICV) = 92.57

Indeed, research shows that most people with Down syndrome report high levels of happiness and life satisfaction [**10**]. Parents of children with Down syndrome often describe their lives as enriched by the experience. When society promotes technologies that seek to eliminate trisomy 21, it risks devaluing those already living with it and undermines the principle of equal moral worth.

Some ethicists argue that this tension is a false binary. It is possible, they say, to respect reproductive autonomy while also fostering a culture that affirms disability as part of human diversity. This would require decoupling technological possibility from social desirability and ensuring that families are not pressured implicitly or explicitly into genetic "corrections" based on stigma rather than informed choice.

Policy Recommendations: Toward Global Harmonization

Considering these challenges, this article proposes five concrete policy recommendations to address the global CRISPR governance gap and ensure ethical use of the technology, particularly for chromosomal conditions like trisomy 21.

First, national and international bioethics committees should include individuals with lived experience of the conditions under consideration such as Down syndrome in review processes. This disability informed oversight would help counteract implicit bias and broaden the moral lens.

Second, all countries should require preclinical safety and social impact assessments before authorizing any clinical trials involving germ-line chromosomal editing. These assessments should be interdisciplinary, incorporating genetics, disability studies, law, and ethics.

Third, UNESCO or the World Health Organization should convene a binding treaty or regulatory framework on germ-line genome editing, similar in structure to the Framework Convention on Tobacco Control. Such an agreement would outline permissible uses, safeguard against eugenic abuses, and provide dispute resolution mechanisms.

Fourth, a public deliberation infrastructure citizen assembly, stakeholder panels, or national ethics commission should be established to foster transparent dialogue on genome editing's implications. These forums would ensure that regulatory decisions are not left solely to scientists or industry stakeholders.

©2025, Cognizance Journal, ZAIN Publications, Fridhemsgatan 62, 112 46, Stockholm, Sweden, All Rights Reserved

Fifth, global funding bodies such as the NIH, European Research Council, and Japan's AMED should prioritize ethical research and cross border collaboration on genome editing governance, thereby encouraging convergence rather than competition.

Conclusion:

The Mie University breakthrough marks a scientific leap but also an ethical fork in the road. CRISPR's ability to delete an entire extra chromosome in Down syndrome cells suggests that interventions previously thought impossible may soon be within reach. Whether these possibilities become realities, however, should depend not only on what is technically feasible, but on what is ethically justifiable and socially desirable.

As we stand on the brink of editing conditions tied not just to health, but to identity and human variation, we must ensure that policy does not lag progress. Only through anticipatory, inclusive, and globally coordinated regulation can we safeguard the future of genome editing while honoring the dignity of all forms of life edited or not.

References

1. Hashizume, R. *et al.* (2025) 'Trisomic rescue via allele-specific multiple chromosome cleavage using CRISPR-Cas9 in trisomy 21 cells', *PNAS Nexus*, 4(2). Available at: https://doi.org/10.1093/pnasnexus/pgaf022.
2. Mansfield, C., Hopfer, S. and Marteau, T.M. (1999) 'Termination rates after prenatal diagnosis of Down syndrome, spina bifida, anencephaly, and Turner and Klinefelter syndromes: a systematic literature review. European Concerted Action: DADA (Decision-making After the Diagnosis of a fetal Abnormality)', *Prenatal Diagnosis*, 19(9), pp. 808–812. Available at: https://pubmed.ncbi.nlm.nih.gov/10521836/.
3. Crissman, B.G. *et al.* (2006) 'Current perspectives on Down syndrome: Selected medical and social issues', *American Journal of Medical Genetics Part C: Seminars in Medical Genetics*, 142C(3), pp. 127–130. Available at: https://doi.org/10.1002/ajmg.c.30099.
4. de Wert, G., Dondorp, W. and Bianchi, D.W. (2017) 'Fetal therapy for Down syndrome: an ethical exploration', *Prenatal Diagnosis*, 37(3), pp. 222–228. Available at: https://doi.org/10.1002/pd.4995.
5. Jennings, V. (2015) *Genome Editing: A Slippery Slope? - The Prindle Institute for Ethics*, *The Prindle Institute for Ethics*. Available at: https://www.prindleinstitute.org/2015/09/genome-editing-slippery-slope/ (Accessed: 5 August 2025).
6. *Heritable Genome Editing* (2017) *www.ncbi.nlm.nih.gov*. National Academies Press (US). Available at: https://www.ncbi.nlm.nih.gov/books/NBK447263/.
7. Araki, M. and Ishii, T. (2014) 'International regulatory landscape and integration of corrective genome editing into in vitro fertilization', *Reproductive Biology and Endocrinology*, 12(1), p. 108. Available at: https://doi.org/10.1186/1477-7827-12-108.
8. World Health Organization (2021) *Human genome editing: a framework for governance*, *www.who.int*. Available at: https://www.who.int/publications/i/item/9789240030060.
9. DiEuliis, D. and Giordano, J. (2017) 'Gene editing using CRISPR/Cas9: implications for dual-use and biosecurity', *Protein & Cell*, 9(3), pp. 239–240. Available at: https://doi.org/10.1007/s13238-017-0493-4.
10. Skotko, B.G., Levine, S.P. and Goldstein, R. (2011) 'Self-perceptions from people with Down syndrome', *American Journal of Medical Genetics Part A*, 155(10), pp. 2360–2369. Available at: https://doi.org/10.1002/ajmg.a.34235.

©2025, Cognizance Journal, ZAIN Publications, Fridhemsgatan 62, 112 46, Stockholm, Sweden, All Rights Reserved