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Artificially Engineered Carcinogenesis as a Biosecurity Threat: A Policy Review and Call for Inclusion in National and International Governance Frameworks

Geoffrey Mutale[1*], Sandra Matinyi[1], Amadile Lawrence[2], Janessa Sochima Aneke[1], Babigumira Peter[1], Pamela Kajumba[1]

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ABSTRACT

Rapid advances in gene editing, synthetic biology and related biotechnologies have significantly expanded the range of biological interventions available for medical research and clinical practice. These innovations have contributed to major improvements in disease diagnosis, treatment, and prognosis worldwide. However, the same technological capabilities that enable therapeutic progress also introduce novel biosecurity challenges. Existing biosecurity and biosafety frameworks have historically prioritized infectious agents and transmissible pathogens, with comparatively limited attention given to non-communicable biological threats. One emerging but underexplored concern is the potential for carcinogenesis to be intentionally or unintentionally induced through engineered biological interventions, including genome editing platforms such as CRISPR-Cas9 systems, viral vectors, and synthetic regulatory elements. This policy review critically examines scientific evidence, ethical analyses, and governance literature to identify plausible pathways through which advanced biotechnologies could contribute to oncogenic risk. The review further evaluates existing international and national policy discussions that call for expanded oversight of dual use research of concern and emerging biotechnologies, highlighting gaps in current regulatory and surveillance mechanisms. This paper calls for the explicit recognition of artificially engineered carcinogenesis as a potential biosecurity threat. It proposes targeted policy measures to strengthen governance, including risk assessment frameworks, enhanced ethical review processes, and integration of oncogenic risk considerations into biosecurity strategies. Incorporating these measures into national and international biosecurity frameworks is essential to ensure responsible innovation while safeguarding public health and global security.

INTRODUCTION

Genome editing technologies, particularly CRISPR-based systems, together with rapid advances in synthetic biology, have fundamentally transformed biomedical research and therapeutic development. These tools enable precise, efficient, and cost effective manipulation of genetic material, accelerating innovation in areas such as cancer therapy, gene correction, regenerative medicine, and functional genomics (Doudna & Charpentier, 2014). As a result, biotechnology has become a cornerstone of modern medicine, offering unprecedented opportunities to improve diagnosis, treatment, and long-term disease outcomes globally.

Alongside these benefits, the expanding accessibility and technical sophistication of genome editing technologies have raised significant dual-use concerns. CRISPR-Cas systems, viral vectors, and synthetic regulatory elements can be repurposed or misused beyond their intended therapeutic applications, either unintentionally through inadequate oversight or deliberately for harmful purposes (of Sciences & National Academies of Sciences, 2017). Existing biosecurity and biosafety frameworks, however, have historically focused on infectious disease threats, particularly those involving high-consequence pathogens and pandemic potential. While this emphasis is justified, it has limited the recognition of emerging biological risks that are non-communicable yet potentially engineered (Lewis *et al.*, 2020).

One such underexamined risk is the potential induction of carcinogenesis through engineered biological interventions. Genome editing has been shown to cause off-target mutations, insertional mutagenesis, activation of oncogenes, and disruption of tumor suppressor pathways, including p53 mediated DNA damage responses (Ihry *et al.*, 2018). Although these risks are widely discussed within research ethics and clinical trial governance, they are rarely framed as biosecurity concerns or explicitly incorporated into national and international security policies. The possibility that oncogenic outcomes could be deliberately engineered, or introduced at scale through negligent or poorly regulated applications, represents a critical governance gap.

Furthermore, the convergence of synthetic biology with automation, artificial intelligence, and globalized research infrastructures has lowered technical barriers to advanced biological manipulation, increasing the potential for misuse by non-state actors or inadequately regulated institutions (DiEuliis & Giordano, 2018).

Disparities in regulatory capacity across regions may further amplify these vulnerabilities. Addressing these challenges requires a broader conceptualization of biosecurity one that explicitly includes no-communicable, engineered biological harms such as artificially induced carcinogenesis (World Health Organization, 2023).

[1] Nuo Bioscience, Uganda
[2] Muni University, Uganda
[*] Corresponding author's e-mail: mutalegeoffrey@gmail.com

This paper argues that biosecurity policy must evolve to reflect the changing technological landscape. By integrating engineered carcinogenesis into biosecurity frameworks, policymakers can strengthen risk assessment, ethical oversight, and global governance, ensure responsible biomedical innovation while safeguarding public health and security.

Objectives

General Objective

To examine the current biosecurity policy framework safeguards to artificially engineered carcinogenesis as an emerging biosecurity risk and assess whether current biosecurity governance frameworks adequately address oncogenic risks arising from genome editing and synthetic biology.

Specific Objectives

- To analyse how oncogenic risks associated with advanced biotechnologies are currently addressed within ethical, safety, and dual-use governance frameworks.
- To assess the extent to which existing national and international biosecurity policies recognise non communicable, engineered biological harms.
- To identify gaps in regulation, oversight, and surveillance relevant to the prevention and attribution of engineered carcinogenesis.
- To propose policy options for integrating oncogenic risk into biosecurity governance while supporting responsible biomedical innovation.

Policy Review Guiding Questions

- What mechanisms have been identified through which genome editing and synthetic biology could plausibly contribute to oncogenic risk?
- How are oncogenic risks framed within current ethical guidelines and dual-use research governance related to gene editing technologies?
- To what extent do existing biosecurity and biosafety frameworks address non-communicable, engineered biological harms such as carcinogenesis?
- What gaps exist in current governance and surveillance systems for detecting, regulating, and attributing engineered oncogenic risks?
- What policy approaches could strengthen biosecurity frameworks to better address oncogenic risks without constraining responsible biomedical research?

MATERIALS AND METHODS

Policy Review Framework

This study is a narrative policy review. A systematic review approach was not undertaken because the objective was to synthesize scientific, ethical, and governance literature on an emerging biosecurity issue for which empirical evidence is heterogeneous and limited. The review, therefore, aimed to identify conceptual gaps and policy implications rather than to provide a quantitative synthesis of outcomes.

Literature was drawn from peer reviewed journals, policy reports, and expert assessments addressing biosecurity, gene editing, and synthetic biology governance. The review was designed to synthesize scientific, ethical, and governance perspectives rather than to conduct a systematic meta-analysis of experimental outcomes. Priority was given to sources recommending policy review or adaptive governance in response to emerging biotechnologies.

Search strategy

A comprehensive literature search was conducted across PubMed, Scopus, Google Scholar, and other relevant academic databases. Additional records were identified through grey literature searches, including policy reports, international governance documents, and manual screening of reference lists. The search covered publications from June 2010 to October 2025. Key search terms included combinations of biosecurity, biosafety, dual-use research, genome editing, CRISPR, synthetic biology, biosecurity governance, and policy review.

Eligibility criteria

Publications were eligible for inclusion if they:

- Addressed biosecurity, biosafety, or biosecurity governance;
- Discussed dual-use implications of biotechnology, genome editing, or synthetic biology; or
- Examined regulatory, ethical, or policy frameworks relevant to biological risk management.

Articles were excluded if they were unrelated to biosecurity, focused exclusively on clinical outcomes without policy relevance, or lacked substantive discussion of governance or oversight mechanisms.

Study selection

The search identified 86 records from electronic databases and 24 additional records from other sources, yielding 110 records in total. After removal of 35 duplicates, 75 records underwent title and abstract screening. Sixteen records were excluded for lack of relevance to biosecurity. The remaining 59 full text articles were assessed for eligibility, all of which met the inclusion criteria and were included in the final qualitative synthesis.

Data extraction and synthesis

Relevant information was extracted on study focus, biosecurity themes, governance frameworks, and identified policy gaps. A thematic synthesis approach was used to organize findings into key domains, including scientific plausibility, dual-use governance, surveillance limitations, and international policy gaps. The synthesis emphasized policy relevance rather than quantitative effect estimation.

Study Flow Chart

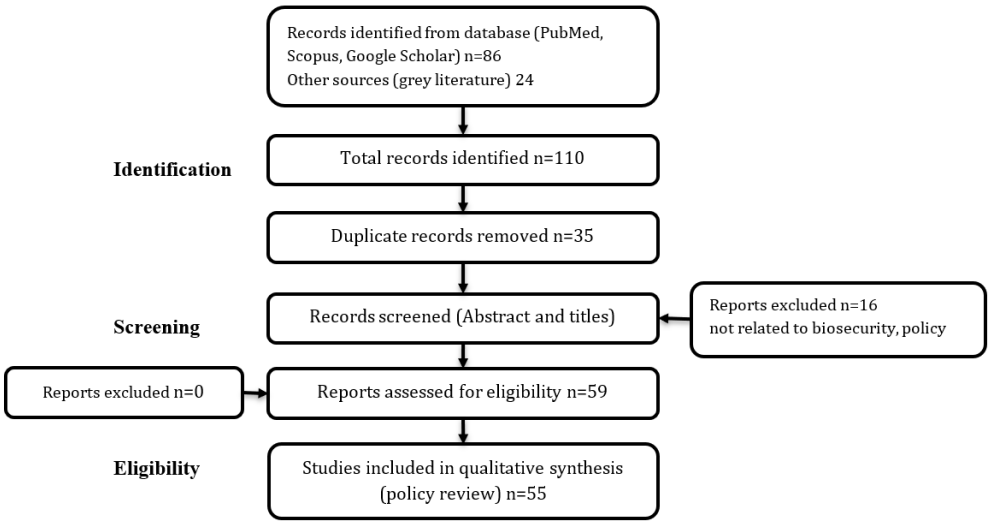

Figure 1: Study Flow Chart

Analytical Framework

An inductive thematic analysis was applied to identify recurring concepts and policy gaps. Literature was examined across three analytical domains:

- Scientific pathways of oncogenic risk, including off target effects, insertional mutagenesis, and dysregulation of oncogenes and tumor suppressor genes;
- Ethical and dual use considerations, focusing on responsible research and innovation, misuse potential, and accountability;
- Governance and policy responses, assessing the extent to which existing biosecurity frameworks recognize non communicable engineered harms.

Policy Synthesis

Findings were compared against existing international biosecurity instruments, including the Biological Weapons Convention (BWC), World Health Organization (WHO) guidance, and national biosafety regulations. Gaps were identified where engineered carcinogenesis is insufficiently addressed. Based on this synthesis, policy options were developed to support explicit incorporation of oncogenic risk into biosecurity governance frameworks.

RESULTS AND DISCUSSION

Table 1 highlights engineered carcinogenesis as a credible but under addressed biosecurity risk within current policy frameworks. The findings show that the scientific basis for inducing cancer through genome editing is well established, with known risks such as oncogene disruption and chromosomal instability.

Table 1: Thematic analysis of engineered carcinogenesis as a biosecurity threat

Theme	Core Findings	Biosecurity & Policy Implication
Scientific Plausibility	Oncogene disruption, insertional mutagenesis, and chromosomal rearrangements are documented risks of genome editing.	Risks are currently managed only as clinical safety issues; there is no framework for managing them as intentional threats.
Dual-Use Governance	Governance focuses on pathogen enhancement (e.g., gain-of-function). Induction of non-communicable diseases (NCDs) is largely ignored.	Tools like CRISPR are not adequately screened for their potential to induce delayed onset harms in target populations.
Policy Framework Gaps	International instruments (BWC/WHO) prioritize communicable, acute agents. DNA screening ignores oncogenic sequences.	A blind spot exists for non-transmissible harms, leaving engineered cancer outside the scope of global health security monitoring.

Thematic analysis of the policy

However, these risks are treated solely as clinical safety concerns rather than as potential intentional threats. The analysis also reveals weaknesses in dual-use governance. Existing biosecurity oversight focuses primarily on infectious disease threats, particularly pathogen enhancement, while the deliberate induction of non-communicable diseases like cancer is largely overlooked. Consequently, powerful tools such as CRISPR are not adequately assessed for their potential to cause delayed, population-level harm.

Finally, the review identifies major policy gaps in international frameworks. Instruments such as the Biological Weapons Convention and global health security mechanisms prioritize acute, communicable

agents and exclude non-transmissible harms. This creates a significant blind spot, leaving engineered cancer outside routine biosecurity monitoring and response systems.

Table 2: Comparison between the traditional Pathogen centered model and the proposed oncogenic framework

Feature	Traditional Pathogen Model	Proposed Oncogenic Framework
Primary Threat	Infectious agents (e.g., Anthrax, Ebola).	Engineered mutations and oncogenic sequences.
Detection Signal	Acute symptoms, rapid spread, high mortality.	Delayed onset, chronic progression, no contagion.
Surveillance Method	Syndromic & epidemiological monitoring.	Cancer registries & genomic sequence screening.
Focus of Oversight	Physical containment (Biosafety Levels).	Functional genetic screening (DURC).
Attribution	Relatively clear via molecular epidemiology.	Extremely difficult due to different pathways of tumorigenesis.
Regulatory Scope	High consequence pathogen lists.	Functional risk lists of tumor suppressors and oncogenes.
Primary Goal	Preventing outbreaks and mass casualties.	Safeguarding genomic integrity and long term public health.

Comparison of the traditional framework with the proposed framework

This Table:2 shows comparison and illustrates a fundamental shift between traditional biosecurity models and a proposed oncogenic framework. Conventional pathogen-based models are designed to detect and control infectious agents that cause acute disease, rapid transmission, and high mortality. Surveillance systems therefore rely on syndromic reporting, epidemiological patterns, and physical containment measures such as biosafety levels, with attribution often achievable through molecular epidemiology.

In contrast, the proposed oncogenic framework addresses threats arising from engineered genetic alterations and oncogenic sequences. These threats are characterized by delayed onset, chronic disease progression, and the absence of contagion, making them largely invisible to traditional surveillance systems. Attribution is significantly more challenging due to the complex and heterogeneous nature of tumorigenesis and lack of a forensic signature biomarker. Overall, the primary regulatory goal shifts from preventing outbreaks to protecting genomic integrity and long term public health, highlighting the need for expanded biosecurity concepts beyond infectious disease paradigms.

Discussion

This policy review identifies artificially engineered carcinogenesis as a plausible yet insufficiently recognized biosecurity risk emerging from advances in genome editing and synthetic biology. While CRISPR-based systems and related tools have transformed biomedical research and clinical care, the same mechanisms that enable therapeutic gene modification can, under certain conditions, compromise genomic integrity and promote malignant transformation. Evidence reviewed highlights multiple pathways of oncogenic risk, including off target genome edits, insertional mutagenesis, epigenetic dysregulation, and disruption of tumor suppressor pathways. For instance, the deliberate targeting of the TP53 tumor suppressor gene or the epigenetic upregulation of MYC oncogenes via synthetic transcription factors represents a plausible pathway for engineered carcinogenesis (Koblentz, 2010). Although these risks are well documented in scientific and clinical governance contexts, they remain largely absent from formal biosecurity discourse, these interventions may lack an immediate epidemiological, forensic and diagnostic signature markers, making detection and attribution exceptionally difficult.

Unlike viral pathogens, this slow motion biothreat bypasses current biosensors and syndromic surveillance systems designed to catch rapid outbreaks.

A key finding is the structural mismatch between contemporary biotechnological capabilities and existing biosecurity frameworks. As illustrated in Table 2 above, current governance remains anchored in a pathogen centered model focused on transmissibility, acute disease, and rapid detection. This model is poorly suited to non-communicable, delayed onset harms such as engineered carcinogenesis, which may lack clear epidemiological signals and evade traditional surveillance systems. Framing biological threats solely in terms of infectious potential overlooks functional genomic harms that may have profound long-term population health consequences.

Ethical and dual-use governance mechanisms similarly exhibit limitations as indicated in Table 1 above. This compartmentalization constrains anticipatory governance and weakens accountability, particularly as genome editing technologies become more accessible, automated, and globally distributed.

Policy implications

Addressing these gaps does not require redefining cancer as a weapon, but rather expanding biosecurity frameworks to reflect functional biological risk. At the international level, instruments such as the Biological Weapons Convention should clarify that synthetic genetic constructs capable of inducing chronic disease fall within their remit. Precautionary governance is justified given the irreversible nature of genomic harm and the pace of technological change.

In conclusion, evolving biosecurity beyond infectious paradigms to include engineered, non-communicable harms such as carcinogenesis is essential for safeguarding public health while enabling responsible biomedical innovation.

Strengths and limitations

This policy review integrates scientific, ethical, and governance literature to examine artificially engineered carcinogenesis as an emerging biosecurity concern. A key strength is its interdisciplinary approach, which bridges biomedical risk assessment and biosecurity policy an area that has been insufficiently explored. By situating oncogenic risk within existing international frameworks, including the Biological Weapons Convention and WHO guidance, the review offers policy-relevant insights applicable across regulatory settings.

However, the review has limitations. It employs a narrative rather than systematic methodology, which may introduce selection bias and limits reproducibility. Empirical evidence of deliberate misuse of genome editing technologies to induce carcinogenesis remains limited; therefore, some conclusions rely on plausibility and precautionary reasoning. Additionally, the analysis focuses on high-level governance and may not fully capture national level regulatory variability. Despite these limitations, the review provides a timely contribution to expanding biosecurity discourse beyond infectious disease paradigms.

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Conflict of Interest Statement

The authors declare no competing interests.

CONCLUSION

Advances in genome editing and synthetic biology have ushered in a new era of biomedical innovation, offering transformative potential for disease prevention, diagnosis, and treatment. However, these same technologies also introduce emerging risks that challenge traditional biosecurity paradigms. This policy review has demonstrated that artificially engineered carcinogenesis represents a plausible yet underrecognized biosecurity threat, one that falls outside the conventional focus on infectious agents and transmissible pathogens.

The capacity of genome editing platforms to induce genomic instability, disrupt tumor suppressor pathways, or activate oncogenic mechanisms underscores the need to reconsider how biological harm is defined within security and governance frameworks. While oncogenic risks are well acknowledged within research ethics and clinical oversight, their exclusion from explicit biosecurity discourse creates a critical governance gap. As biotechnological tools become more accessible, automated, and globally distributed, the potential for misuse whether deliberate or inadvertent will continue to increase.

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