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Contiguous Governance of Synchronic and Diachronic Changes for the Use of Genome Editing Technologies

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Genome editing technologies are increasingly coming under scrutiny, based on various social value judgments in biomedical research, clinical care, and public health. A central cause of this sociotechnical tension is that these technologies are capable of precisely and easily creating genome-modified organisms and human cells and tissues. To exemplify a general framework for a national governance system of genome editing technologies, we first look at the regulatory dynamics in Japan. Second, we expose the potential tension between national and international debates and directions for the global harmonization of genome editing technologies. Third, underpinning these two perspectives, we propose *contiguous governance* as a novel model of the governance of emerging biotechnologies from both synchronic and diachronic perspectives. These perspectives, derived from genome editing technologies, can contribute to a better understanding and consideration of future regulations and governance systems.

Keywords: governance, syncronicity, diachronicity, genome editing, future generations

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INTRODUCTION

Compared to conventional methods, current genome editing technologies enable handy and precise genetic control over a broad range of organisms and human cells. While this new power is a boon to medical research, clinical care, public health, and the economy, using these technologies can also lead to various ethical, legal, social, and policy tensions. In particular, their uncertain and possibly irreversible influence on not only present generations but also future generations has prompted investigations into proper regulations and governance systems. Many international institutions and organizations are addressing these emerging challenges. For instance, the World Health Organization (WHO) has significantly contributed to the creation of key documents aimed at managing human genome editing and genetically modified mosquitoes (World Health Organization, 2021a,b,c). This international approach is effective in encouraging scientific development and assessing its ethical and social impacts such that key stakeholders in many countries can reach a consensus on the development of related governance systems. To revisit and foster the harmonization of related regulatory and governance systems, we first explore a case study of the impacts of Japanese regulations on genome editing technologies in biomedical fields. We then consider potential challenges in the development of a global governance framework. Ultimately, we suggest a *contiguous governance* model that focuses on the synchronic

and diachronic aspects of using emerging biotechnologies. Here, the synchronic aspects represent national and international regulations and governance systems over a limited time span, which can be interpreted as a way to highlight the spatiality of governance at a particular time. On the other hand, the diachronic aspects reflect time-course regulations and governance systems bridging the past, present, and future. Instead of individually addressing the current challenges in regulations and governance, we discuss three major initiatives for implementing contiguous governance to spur further fundamental debates and measures in the management of emerging biotechnologies.

PART 1: JAPANESE REGULATION OF GENOME EDITING TECHNOLOGIES

In Japan, the emergence of genome editing technologies has resulted in three key regulatory impacts in the biomedical field. The first concerns the interpretation of the *Japanese Cartagena Act* (formally, the *Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms)*, which was enacted in 2003 to observe the *Cartagena Protocol on Biosafety to the Convention on Biological Diversity*. This act is deeply associated with research, care, and public health, as it governs the use and related biosafety issues of living modified organisms (LMOs). In fact, the Japanese government recently ruled that genome-edited end products should be classified as LMOs unless they have "no remnants of inserted nucleic acid or its replicated product" (Tsuda et al., 2019).

The second impact concerns the handling of somatic genome editing for clinical applications, which is associated with three key regulatory considerations. The regulatory considerations for the marketing authorization and approval of genome editing products have already been addressed by the Science Board of the Pharmaceuticals and Medical Devices Agency of Japan (Yamaguchi et al., 2020). Moreover, the *Act on the Safety of Regenerative Medicine*, which regulates *ex vivo* genome editing for clinical research and care, was partially revised in 2020 to reclassify the use of gene-edited cells as a high-risk category, as these cells are relatively novel, along with induced pluripotent and embryonic stem cells (Takashima et al., 2021). Furthermore, the *Guidelines for Gene Therapy Clinical Research*, which cover *in vivo* genome editing for clinical research (but not for clinical care), were amended in 2019 (Uchida, 2020) to redefine their scope and definition (e.g., to include genome editing without gene transfer) and to align them with the *Clinical Trials Act*. It should be noted that these non-legally binding guidelines prohibit germline genome editing for clinical applications. Attempts are underway to bridge the gap between the regulatory pathways of *ex vivo* and *in vivo* genome editing (Takashima et al., 2021).

The third impact is related to the nature of human germline genome editing for basic research. In 2019, the *Guidelines for Research Using Gene-Altering Technologies on Human Fertilized Embryos,* were established. While these guidelines originally regulated studies that used genome editing for assisted reproductive technology (ART), their 2021 revision also allowed for research with genome editing for hereditary or congenital diseases. Another set of guidelines, *Ethical Guidelines for Assisted Reproductive Technology Studies Involving Production of Human Fertilized Embryos,* included the use of genome editing technologies through a 2021 revision. This indicates that research using genome editing for the production of human fertilized embryos for ART is allowed. Furthermore, governmental papers suggest that these guidelines are likely to be revised to allow for research with genome editing for hereditary or congenital diseases. While various debates have arisen on the handling of human embryos (Nakazawa et al., 2018), these regulations have paved the way for applying genome editing for human embryos, albeit with limited purposes and relevant conditions.

These impacts show that, even with rapid and proactive regulatory responses to genome editing technologies in Japan, three challenges remain in improving the current regulatory system. First, there is no comprehensive perspective on the regulation of genome editing. In other words, to date, regulatory attention has been limited to their specific and segmented elements: LMOs, somatic and germline genome editing, basic research and clinical applications, *ex vivo* and *in vivo* genome editing (somatic genome editing for clinical applications), and pre- and post-embryo editing (germline genome editing for basic research). Second, there are many overlapping regulations. For example, *in vivo* somatic genome editing (clinical research) can be governed by three different regulations: *Guidelines for Gene Therapy Clinical Research*, *Clinical Trials Act*, and *Japanese Cartagena Act*. Third, the coverage/scope and forms (i.e., legally binding or non-legally binding) of the regulations are not yet optimized in the context of biomedical research and clinical care.

While these challenges likely arose due to the conventional approach to formulating specific regulations in response to the emergence of new technologies, the continuous emergence of new technologies can necessitate more regulatory efforts. This can result in an administrative burden and a maze of regulations (Minari et al., 2021). In this scenario, while *ad-hoc* regulations are important short-term solutions, fundamental regulations must be established over time. Moreover, we must constantly re-evaluate the fundamental regulations in light of the new *ad-hoc* regulations introduced over time to ensure they remain relevant. At the same time, *ad-hoc* regulations must be framed on the same principles as fundamental ones; in essence, both regulation types must be compatible with each other. In the case of genome editing, these initiatives should include a comprehensive consideration and review of relevant fundamental elements, that is, of the implications of genetic editing, the handling of organisms and human cells, the significance of biosafety, potential limitations for basic research, and the social meaning of unproven therapies. This integrative perspective can contribute to the formation of systematic and robust regulations and governance systems.

PART 2: CHALLENGES FOR THE GLOBAL GOVERNANCE OF GENOME EDITING TECHNOLOGIES

The notion of governance, with its references to power, actor networks, and decentralization, comes from modern social and institutional settings, which have reached a global scale. Despite the ambiguous and variable nature of global governance, it has increasingly become the focus of attention as an approach to dealing with the complexities of a dynamic, interactive, and international society and developing specific and feasible solutions for sociotechnical issues. However, given the robust interoperability of genome editing technologies, the absence of clear global laws poses a potential challenge for implementing global governance. While a nation can control and adjust its specific regulations to some degree, no single authority can manage global regulations and governance. Although having such an authority would entail various advantages and disadvantages, reflecting on the nature of the current international governance system can provide a better solution.

In the current governance structure, at least three key approaches can be identified for developing mutual trust and shared responsibility between states. The first approach is to conclude international conventions, such as the *Oviedo Convention* and the *Convention on Biological Diversity*. The second is to issue recommendations and guidelines through representative international organizations, such as the WHO, the United Nations Educational, Scientific, and Cultural Organization (UNESCO), and the Organization for Economic Co-operation and Development (OECD). For instance, the WHO highlighted the importance of better global governance and called for a monitoring system with a human genome editing registry (World Health Organization, 2021a,b). The third approach is to shape the statements and reports of national academies or independent organizations on bioethics and academic communities (Marchant, 2021). These approaches are vital to the formation of an international framework beyond national boundaries and the rapid integration of expert knowledge from different angles. However, they do not necessarily ensure effective global governance.

The limitations of the current governance structure include its non-conforming, gradual, and asymmetric elements. First, international conventions can provide a common stable regulatory and normative space for robust action, but they inherently create loopholes for non-member states and global corporations. Moreover, consensus among several actors is not always achievable; thus, it is not surprising that, in an international context, regulations on germline genome editing for clinical applications are inconsistent and have differing degrees of control (Araki and Ishii, 2014). Second, while international organizations and institutions provide some degree of professional consensus, they not only have an indirect influence on the regulatory initiatives of individual states but also tend to adopt stepwise measures in response to the progress of science and technology. These can be regarded as deliberate approaches to the gradual expansion of genome editing technology use without prior restrictions and prohibitions. Finally, there can be an asymmetric relationship between relevant actors in terms of whether and how genome editing technologies should be handled. For instance, as a premise, some major actors are keen on the broad and rapid use of such new technologies rather than conventional and alternative ones.

In fact, the current global governance of genome editing technologies aims to establish a common, well-defined framework for a harmonious mindset and shared understanding without adopting strong international initiatives, as in the case of human cloning. However, given the current decentralized governance system, global and synchronic prohibited issues related to genome editing technologies are not regulated in a clear or unified manner. From a governance perspective, even minimal levels of prohibition should be universally identified, shared, and agreed upon. In this sense, a promising governance system would be neither centralized nor decentralized, but polycentric, involving a broad range of stakeholders, such as players, intermediaries, regulatory agencies, and/or funders. Such a system would also be tolerant of divergent and ambiguous values and views aimed at "opening up" governance commitments on these technologies (Stirling, 2008). This governance perspective can also be employed to adjust relationships between science and technology policies, public funding and market mechanisms, and ethico-legal regulations.

Viewed through the lens of genome-editing technologies, the governance of emerging biotechnologies *over time* has two potential challenges. The first is closing the growing gap between the emergence and accelerating application of technology and traditional regulatory action timelines (Bennett Moses, 2007; Marchant, 2011). One practical approach to this pacing problem is a technological slowdown (Linstone, 1996; Woodhouse, 2016). Yet, moratoriums—an oft-used tactic for sensibly suspending scientific development by leaving the future open and taking time to consider the optimal decision (Chesneaux, 2000)—may not necessarily be a viable measure and may be criticized as empty gestures or pure public relations, as was the case of dual-use research on the H5N1 bird flu (Malakoff, 2012; Engel-Glatter, 2014). Moratoriums may even be rejected outright by technology-friendly countries for gene drives (Callaway, 2018). The other approach is regulatory speedup. This has already emerged in the modern governance context, as national and international stakeholders, who are generally impatient by nature, demand immediate action, rapid conformity, fast concordance of norms, and short-term convergence of practices (Halliday, 2017). In addition, national governments generally tend to concentrate on topical problems over future ones (Hoogerwerf, 1990). However, such fast policy solutions may increasingly disrupt and obliterate long-term decision-making cycles, institutional memory, and efforts to anticipate future difficulties and policy failures (Jessop, 2002). To extend beyond the two approaches of "technological slowdown" and "regulatory

speedup" described above, a possible remedy is to cautiously set minimum levels of restrictions and limit the scope of application of the technology and appropriately revise or redefine this scope through continuous monitoring and intervention. In other words, social applications of the technology must be carefully promoted, while the minimum restrictions are identified and maintained.

The second challenge is to reconcile or accommodate different time perceptions to shape future visions and perspectives based on cultural backgrounds and psychological presuppositions (Das, 1991; Hofstede, 1993; Meyer-Sahling, 2007). The subjective recognition of time has non-uniform and elastic characteristics and leads to differing visions for the future. For instance, a Japanese public survey on genome editing technologies has shown that the adoption of different scopes and ranges of the future is deeply associated with different (often ambiguous) decisions and attitudes toward such technologies (Hibino et al., 2019). Similarly, a policy study on synthetic biology has demonstrated that even analytical future-oriented discourses are socioculturally and institutionally bounded, and options for present and future generations remain limited (Yoshizawa, 2019). Notably, the future is often discounted by the subjectivity, ambiguity, and contextuality of time perceptions.

DISCUSSION: THREE INITIATIVES FOR CONTIGUOUS GOVERNANCE

Traditional approaches to managing genome editing technologies are primarily synchronic and spatial in scope. Thus, the lack of diachronic perspectives on regulations and governance is increasing. This article diverges from academic debates centered on discourse and rhetoric and demands more fundamental and viable action to improve future regulations and governance systems for emerging biotechnologies. We propose a contiguous governance approach that focuses on both geopolitical landscape and diachronic perspectives. This approach comprises three complementary initiatives: improvement of historical literacy, empowerment of future generations, and development of a sustainable material culture.

When scientific progress is closely related to economic growth, high stakes gradually undermine the precautionary approach to the development and use of emerging biotechnologies. However, memorable events can always bring us back to our ethical basics. Our first proposed initiative is the improvement of historical literacy, that is, remembering and reinterpreting some watershed events or historical tipping points. These tipping points include the Asilomar Conference on Recombinant DNA in the U.S., the first baby born through *in vitro* fertilization in the UK, and the first babies born with edited genomes in China. Promoting and developing historical literacy illuminates ways to offer a softer and less direct form of regulatory coordination than with substantive law. Such coordination may then provide a firm legal foundation for co-regulation, or "regulated self-regulation," as hybrids between state regulation and self-regulation, through institutionalized legal procedures and organizational norms (Scheuerman, 2001). It also leaves a regulatory margin for future responses to temporal changes by accepting systematic and functional redundancy in any governance.

While people exhibit differences in their perceptions of time and tend to discount the future in favor of the present, our second proposed initiative is the empowerment of future generations who are keener to face and tackle the planetary crisis than incumbents. Due to their longer life expectancy, young people can become more far-sighted and responsible. Besides the necessity of providing civic youth science engagement projects (Mayhew and Hall, 2012; King et al., 2021), a direct and plausible political action would be to lower the voting age (Leece, 2009) or introduce a new voting system in which parents are allowed to vote as proxies for their children (Demeny, 1986). A more feasible and softer solution may include establishing a training grant program for the youth to enable them to gain scientific knowledge, learn its social implications, and have a more articulate voice in policymaking and social decision making.

Our third proposed initiative is based on a more ontological and longer-term perspective: the establishment of sociotechnical objects or materials and related public spaces for remembering, reflecting on, and connecting the dynamics of norms from the past, present, and future. It makes little sense for an object or material to simply exist in which human norms and values are embedded in some design approaches, such as "value sensitive design" (Friedman and Hendry, 2019) and "ethics by design" (Dignum et al., 2018). This is because it deprives us of opportunities to regularly review what is ethical in the interaction between humans and objects. Such design approaches also entail the risk of inviting technological fixes. Some recent examples of technological fixes are restricted gene drives (Noble et al., 2019; Bier, 2022) and genetically engineered apples that never turn brown (Maxmen, 2017), which may be durable and environmentally friendly but are less respectful of natural products and processes. In addition, our relentless pursuit of convenience through objects and organisms must be questioned. Such an engineer- or user-oriented solutionist approach is shortsighted and suboptimal and lacks functional redundancy and dynamic capabilities for sociotechnical change.

An alternative idea is the development of a sustainable material culture. The Future Library is a public artwork project in which a forest was planted in Norway to supply the paper for a special anthology of books to be printed in 100 years. The forest's existence is subject to whatever has happened to the environment over that century (Paterson, 2014; Mickiewicz, 2016). A similar but more sustainable project is the millennium-long ritual of rebuilding and renewing a Japanese Shinto shrine every 20 years to maintain a sacred place and foster technical skills as "everlasting youth" by cultivating timber and human resources across the country (Lopes, 2007). Similarly, the governance of genome editing technologies and other emerging biotechnologies must be based on a culture of continuous human intervention in

society through which the ecological and social resources and systems necessary for the technologies become more sustainable. This requires continual awareness that governance policies must be geopolitically and diachronically contiguous. All of this depends on how we envisage the kinds of apples we will need in the distant future and in what environments.

DATA AVAILABILITY STATEMENT

The original contributions presented in the study are included in the article/supplementary material, further inquiries can be directed to the corresponding author/s.

AUTHOR CONTRIBUTIONS

JM and GY conceived and drafted the study. NS and KT revised the manuscript. All authors made key contributions to the development of the final manuscript and approved its publication.

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