

CONTEMPORARY LEGAL ISSUES IN BIOETHICS: GENETIC ENGINEERING AND END-OF-LIFE DECISIONS

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ABSTRACT

The rapid development of genetic engineering and the expansion of end-of-life decision-making practices generate complex legal and bioethical dilemmas that directly affect fundamental human rights. These developments create tensions between scientific progress, the state's obligation to protect life, and the need to respect individual autonomy. The absence of unified legal approaches to regulating biomedical practices highlights the necessity for systematic analysis of international and supranational standards. This study aims to identify and characterize contemporary legal dilemmas in genetic engineering and euthanasia within a bioethical framework, while clarifying the limits of permissible regulation based on human dignity and personal autonomy. The research focuses on legal mechanisms governing biomedical interventions at international and supranational levels and applies theoretical-analytical and normative methods, including the examination of conventions, recommendations, and judicial practice. The findings demonstrate that regulation of genetic engineering operates as a multi-level system of substantive and procedural safeguards, with human dignity as a key limiting principle. Individual autonomy gains legal significance when exercised through structured procedures such as informed consent and ethical oversight. Furthermore, judicial practice increasingly frames autonomy as a procedural standard balancing the protection of life with self-determination, contributing to the development of coherent governance standards.

KEYWORDS: International law; Human rights; Ethics; Legal regulation; Healing; Wholeness; Health.

INTRODUCTION

The rapid development of biomedical technologies, in particular, genome editing and the practice of ending life for medical reasons, has led to the emergence of complex legal and bioethical challenges that directly concern the right to life, human dignity and autonomy of the individual. Genetic engineering and euthanasia form persistent collisions between individual rights and public interests, while at the same time revealing the limitations of traditional legal mechanisms in the context of rapid scientific and technological progress.

Despite a significant body of scientific studies, conceptual and normative gaps remain in law and bioethics, primarily the lack of an integrated approach to genetic engineering and euthanasia as interrelated phenomena. The lack of coherence of bioethical principles with positive law leads to fragmented regulation and a lack of universal guidelines for law enforcement, which highlights the need for a comprehensive legal analysis.

In modern studies on genetic engineering and end-of-life decisions, a common motif of fragmented legal regulation and tension between bioethical principles and positive law can be traced. Thus, in the scientific work of Gibelli et al. (2025), the ethical and medico-legal consequences of using genome editing in medicine were systematized, and the lack of agreed legal standards between jurisdictions was shown, which creates risks for the protection of human dignity and human rights. A similar regulatory deficit was identified by Wiley et al. (2025), who, in the context of CRISPR–Cas9, recorded a systemic conflict between scientific progress, individual autonomy, and the protection of human life in the early stages of development, justifying the need to review current legal approaches, taking into account bioethical constraints.

In the area of end-of-life decisions, Vergallo et al. (2025) used the example of Italian legislation to show the gradual transformation of the legal approach to euthanasia and assisted suicide under the influence of case law, while at the same time noting the persistent normative tension between the protection of life and patient autonomy. A similar problem of conceptual uncertainty was identified by Ibim (2025), who proved that the legal interpretation of human dignity is a key factor in shaping the limits of the admissibility of assisted death, in the absence of a universal approach to the interconnection between dignity, autonomy and the right to life. At the same time, Conley et al. (2023) in their study of governance of human genome editing established the declarative

nature of public engagement mechanisms and emphasized the need for an institutional combination of bioethical principles with legal regulation.

The purpose of the present research was to identify and characterize contemporary legal dilemmas arising in the field of genetic engineering and euthanasia in the context of bioethics, as well as to clarify the limits of permissible legal regulation of biomedical practices, taking into account the principles of human dignity and personal autonomy. The following research tasks were established in order to accomplish the goal: analyzing contemporary approaches to the legal regulation of genetic engineering through the lens of bioethical principles; characterizing legal models of regulating assisted suicide and euthanasia; elucidating the primary regulatory conflicts between the right to life, individual autonomy, and public interests; identifying the function of bioethics as a quasi-normative reference point in the formation of legal decisions; and developing generalized directions for improving legal regulation in this area.

LITERATURE REVIEW

Recent studies have examined how end-of-life procedures and human genome editing technology have both broadened medical possibilities and clarified the legal parameters of acceptable interference with human life. The ethical concerns of human genome editing are conceptualized via the lenses of social justice and intergenerational responsibility in Baylis's (2019) monograph, which emphasizes the necessity of legal protections against potential discrimination and unequal access. The article by Benston (2016) outlined the human rights conflict between the right to health and the rights of persons with disabilities, emphasizing the risk of normative consolidation of implicit ideas about "desired" bodies and "normative" states, which required clear criteria of non-discrimination at the legal level.

In terms of the ethical boundaries of genome editing, the revision of the classic division into somatic and germline interventions has become important, since changes in practices and technological capabilities have reduced the explanatory value of this dichotomy. Evans (2021) has shown that the blurring of the barrier between somatic and germline editing has made it difficult to establish stable normative boundaries and has required procedural criteria for the legitimacy of decisions, rather than just categorical prohibitions. Lorenzo et al. (2022) have systematized the major conflicts surrounding CRISPR-Cas9, including safety, consent, liability, and equitable risk sharing, within the framework of applied bioethics of genome editing. This has brought attention to the shortcomings of strictly technocratic models of regulation.

A separate group of academic papers was devoted to socially responsible governance and public legitimation of decisions in the field of genome editing. Morrison and de Saille (2019) substantiated the need to contextualize the discussion on embryo editing, since social consequences, symbolic meanings and trust in institutions significantly influenced the acceptability of legal decisions. Kamenova (2023) proved that public discussion had intrinsic value not only as a communication tool but also as an element of democratic legitimation of norm-making, which is relevant for assessing the procedural quality of bioethical regulatory models. At the level of public policy and institutional mechanisms, Peng et al. (2022) showed the specifics of responsible governance of germline editing in China, emphasizing the importance of state frameworks, control of research practices, and combining ethical principles with regulatory tools.

End-of-life studies have focused on how the legal regimes of euthanasia and assisted suicide reflect profound conflicts between the protection of life, patient autonomy, and the professional responsibilities of the physician (Akdeniz et al., 2021). A review by Fontalis et al. (2018) systematized the basic arguments for and against and showed that the legal positions of different states were shaped not only by bioethics but also by traditions of judicial review and cultural notions of dignity. In the normative dimension of autonomy, Mendz and Kissane (2021) revealed that the concepts of agency and autonomy in the context of euthanasia required a clearer legal definition, since the limits of "free will" in situations of suffering and dependence could not be presumed without procedural safeguards.

A significant contribution to the comparative legal analysis of end-of-life decisions has been made by studies of the Italian context, where regulation was shaped at the intersection of legislative norms and judicial interpretation. Di Paolo et al. (2019) analyzed Law 219/2017 on informed consent and advance directives for treatment, showing that the enshrining of the right to informed consent and advance directives created a framework for the legitimacy of medical decisions in borderline states. Against this background, Ciliberti et al. (2025) examined the controversial aspects of assisted suicide for patients on life support and showed that the desire to converge with the models of other European states was accompanied by contradictions between the principle of the inviolability of life and the principle of self-determination. In a broader comparative perspective, Nafziger (2022) emphasized that legal regimes of end-of-life decisions were determined by the balancing of human rights, medical ethics and the institutional responsibility of the state, and therefore required the harmonization of domestic law with international approaches to dignity and autonomy.

Empirical and general reviews have pointed to the complexity of the use of euthanasia and assisted suicide in psychiatric patients, where the risks of erroneous assessment of volition, vulnerability and remission are particularly high. Calati et al. (2021) systematized data on such cases and showed the heterogeneity of admission criteria and assessment of decision-making capacity, which in the legal field increased the need for formalized procedural guarantees. Taken together, the works cited showed that law and bioethics developed as interdependent systems of argumentation, but remained fragmented between the domains of genome editing and the end of life, which created the basis for an integrative analysis of contemporary legal dilemmas with a focus on human dignity, autonomy and non-discrimination.

The purpose of the present research was to establish the systemic parameters of contemporary legal dilemmas arising from the development of genetic engineering and euthanasia practices in the context of bioethics.

MATERIALS AND METHODS

The research was conducted in 2024–2025 using theoretical-analytical and normative-oriented approaches to study legal dilemmas in the field of bioethics. The methodological goal was to ensure the reproducibility of results through standardized selection, analysis and interpretation of legal and quasi-legal sources with subsequent generalization of descriptive indicators. The research was based on open international materials and did not involve experimental or sociological methods.

The material base was formed by three groups of sources. The first covered international legal acts in the field of human genome editing and end-of-life decisions, in particular, provisions on informed consent, advance medical directives and the regulation of biomedical studies (Council of Europe, 1997, 2005). Their analysis aimed to identify the legal limits of medical intervention, decision-makers and mechanisms of responsibility in relation to the basic bioethical principles of personal autonomy, human dignity and proportionality (UNESCO, 2005).

The second group consisted of decisions of supranational judicial institutions, which considered the issues of patient autonomy, the admissibility of medical intervention and the limits of legal liability of medical professionals (European Court of Human Rights, 2002, 2015). The case law was analyzed by reconstructing legal argumentation in order to identify the standards of balancing between the protection of life and self-determination of the individual, as well as the criteria of procedural legitimacy of end-of-life decisions.

The third group of materials consisted of recommendation documents and reports of international organizations, in particular World Health Organization (further – WHO), United Nations Educational, Scientific and Cultural Organization (further – UNESCO) and the Council of Europe, devoted to the issues of bioethics, human rights and biomedicine (UNESCO, 2005, 2015; World Health Organization, 2021). Their processing was aimed at identifying supranational standards of governance and comparing the recommendatory principles with normative and judicial approaches (Mia et al., 2022). Expert analytical materials on the socio-ethical consequences of human genome editing were used to clarify the interpretative framework (Nuffield Council on Bioethics, 2018).

The analytical procedure included thematic structuring of materials and their comparative analysis with the parallel implementation of the quantitative-descriptive component of the documentary analysis. The unit of analysis for normative and quasi-normative texts was a separate provision (article, paragraph or recommendation), and for European Court of Human Rights (further – ECHR) decisions – a motivational fragment containing a legal test or argumentation regarding autonomy, dignity, proportionality of interference or procedural guarantees (European Court of Human Rights, 2002, 2015). Coding was carried out according to a unified categorical matrix, after which the results were summarized in the format of descriptive indicators used to construct tables in the Results section (UNESCO, 2015; Shavarskyi et al., 2022).

The limitations of the research are the dependence on the availability of international normative and recommendatory materials, as well as quantitative generalizations to coding rules and structural heterogeneity of documents.

RESULTS

Regulatory limits of admissibility of biomedical interventions in the field of genetic engineering

As a result of the thematic structuring and comparison of international regulatory legal acts and recommendation documents, it was established that modern regulation of genetic engineering was formed as a multi-level system of permits and prohibitions, in which the legal admissibility of interventions was derived from a combination of requirements for the protection of human dignity, personal autonomy and the principle of proportionality. The quantitative and descriptive component of this section was implemented through the parameters of the coding matrix: 6 documents ($N = 6$) were processed within the corpus, and the results were systematized according to 6 categories of admissibility criteria ($K = 6$) with 18 operationalized indicators ($k = 18$). The normative provisions of the Council of Europe established a framework approach, under which any biomedical intervention was considered acceptable only if there was a clearly defined legitimate purpose, procedural protection of the person and appropriate guarantees against abuse (Council of Europe, 1997). The Additional Protocol on Biomedical Research specified this framework through requirements for ethical review, risk assessment, and permitted modes of research intervention, which formed a procedural barrier to the use of genome editing technologies based on criteria of safety and public benefit (Council of Europe, 2005).

The results obtained showed that the central procedural mechanism of the admissibility of biomedical intervention in the field of genetic engineering was the guarantees of *informed consent* and related instruments of prior expression of will. The normative analysis showed that *informed consent* performed not only the function of informing but also the function of establishing the legal regime of the admissibility of intervention in the presence of proper information, voluntariness and competence of the subject. This was consistent with the bioethical orientation of personal autonomy as a prerequisite for legitimate medical intervention, while a deficit of autonomy or information asymmetry shifted the situation to a plane of increased guarantees and control (UNESCO, 2005). Within the coding matrix, the category “Autonomy and *informed consent*” was detailed by 3 indicators ($k = 3$): voluntariness, awareness, competence, which ensured a unified comparison of procedural requirements between documents of different legal nature (Council of Europe, 1997; UNESCO, 2005). Additionally, it was found that advance directive instruments functionally complemented *informed consent* in cases of loss of legal capacity or impossibility of actual expression of will, shifting the emphasis from the moment of decision-making to the legal permanence of will over time (Council of Europe, 1997).

A comparison of UNESCO documents and WHO recommendations revealed a normative trend towards strengthening the governance regime for genome editing technologies through a combination of human rights and procedural standards of scientific integrity. UNESCO documents set human dignity as a boundary limiting the permissibility of practices that could lead to discrimination, stigmatization or the transformation of a person into an object of technological construction, even in the presence of potential medical benefits (UNESCO, 2005). At the same time, the report of the International Bioethics Committee on the Genome and Human Rights set the direction for more detailed legal control over interventions related to hereditary changes, through strengthening requirements for legitimacy of purpose, risk assessment and social acceptability (UNESCO, 2015). The WHO recommendations formed a practically oriented set of governance principles, in which the key outcomes of regulatory regulation were requirements for transparency, accountability, oversight mechanisms and the prevention of transnational regulatory gaps in the application of genome editing (World Health Organization, 2021). For the purpose of ensuring the comparability of such provisions, the category “Governance and international coherence” was operationalized with 3 indicators ($k = 3$): transparency, accountability, coordination of standards, which made it possible to uniformly compare quasi-normative guidelines with framework legal requirements (World Health Organization, 2021; UNESCO, 2015).

In order to systematize the results obtained, an analytical table was formed, reflecting which regulatory criteria determined the admissibility of biomedical interventions in the field of genetic engineering and which legal mechanisms were used for their implementation (Table 1).

Table 1. Regulatory criteria for the admissibility of human genome editing and relevant legal mechanisms

Normative admissibility criterion	Specific legal implementation mechanism	Expected legal effect for regulation	Number of indicators (k)
The priority of human dignity as a limit to intervention	Enshrining the principle of dignity as the upper limit of permissibility; prohibiting practices that create a risk of dehumanization or discrimination	Establishing a material limit for what is unacceptable even when technologically feasible	3
Personal autonomy as a condition of legitimation	<i>Informed consent</i> procedures; requirements for voluntariness, awareness and competence	Transferring interference to the regime of legality in the presence of proper expression of will	3
Proportionality and risk minimization	Mandatory risk-benefit assessment; priority for less invasive alternatives; ethical review	Limiting excessive or experimentally unjustified interventions	3
Scientific validity and integrity	Requirements for protocols of examinations; oversight by ethics committees; standards of transparency and reporting	Preventing pseudoscientific practices and reducing the likelihood of abuse	3
Public interest and prevention of harm	Regulatory oversight; accountability mechanisms; restrictions on technology translation without proper control	Creating barriers to commercialization of interventions with high social risks	3
Governance and international coherence	Governance guidelines; coordination of standards; prevention of regulatory tourism	Reducing transnational gaps and unifying minimum standards	3

Source: compiled based on the Council of Europe (1997, 2005), UNESCO (2005, 2015), World Health Organization (2021), Nuffield Council on Bioethics (2018)

Note: the coding matrix contained $K = 6$ categories and $k = 18$ indicators (3 indicators per category); the terms *informed consent* and *governance* are used as established concepts according to the sources

The results showed that the regulatory limits of the acceptability of genome editing were not determined by a single prohibitive principle but by a combination of substantive and procedural constraints. The substantive limits were set through the concept of human dignity and the prevention of discriminatory consequences, while the procedural limits were implemented through informed consent, ethical oversight, risk assessment and accountability requirements. Generalization by coding matrix parameters ($N = 6$; $K = 6$; $k = 18$) showed that the legal model of permissibility in the field of genetic engineering was institutionally described as multi-criteria, where the fulfillment of one criterion did not compensate for the absence of others (Council of Europe, 1997; UNESCO, 2015; World Health Organization, 2021).

Regulatory regulation of genetic engineering and end-of-life decisions in Europe: a positive legal dimension

As a result of a documentary analysis of international and national regulatory acts, it was found that the regulation of genetic engineering and end-of-life decisions in the European legal space is based on a combination of supranational binding instruments and domestic legislative regimes. In contrast to recommendation documents

and bioethical declarations, these acts form a legally binding framework for the admissibility of biomedical interventions and determine the legal consequences of their application.

The key supranational legal instrument in the field of biomedicine is the Council of Europe Convention on Human Rights and Biomedicine, which establishes the basic material limits of the admissibility of interventions through the principles of human dignity, the priority of the individual over the interests of science and society, as well as the requirement of a legitimate aim and proportionality. The Additional Protocol on Biomedical Research specifies these provisions at the procedural level, establishing mandatory conditions for ethical examination, risk assessment and control of research interventions. Thus, a legal framework is formed at the supranational level, within which bioethical principles acquire the status of legally relevant restrictions.

At the national level, the results of the analysis showed the absence of a unified regulatory model, but revealed the presence of typologically similar legal regimes. Firstly, in European countries, special legislative provisions are being established regarding informed consent as a mandatory condition for the legitimacy of any medical intervention, including biomedical studies and end-of-life care. Secondly, in a number of jurisdictions, regulatory mechanisms for advance medical directives have been formed, which ensure the legal permanence of a person's will in cases of loss of legal capacity. Thirdly, the issues of assisted suicide and euthanasia are regulated mainly within the framework of criminal law, where the dominance of a prohibitive approach or a regime of strictly limited permissibility persists.

The results obtained made it possible to summarize the positive legal regulatory regimes in the form of a systematized matrix reflecting the level of regulation, scope and legal effect of key regulatory instruments (Table 2).

Table 2. Positive legal regimes regulating genetic engineering and end-of-life decisions in Europe

Regulatory act / legal regime	Regulatory level	Scope of application	Legal status	Key legal effect
Convention on Human Rights and Biomedicine (Oviedo Convention, 1997)	Supranational	Biomedical interventions, genetic engineering	Binding international treaty	Establishing material limits to the admissibility of interventions and the priority of human dignity
Additional Protocol on Biomedical Studies (2005)	Supranational	Biomedical studies	Mandatory protocol	Procedural legitimization of research interventions through ethical review and risk assessment
Legislation on <i>informed consent</i>	National	Medical interventions, clinical practice	Statutory law	Legal validity of medical intervention in the presence of voluntary and informed consent
Legislation on advance medical directives	National	End-of-life care	Statutory law	Ensuring the legal stability of a person's will in the event of loss of legal capacity
Criminal law regulations regarding assisted suicide and euthanasia	National	End of life	Criminal law	Defining the boundaries of acceptable medical behavior and risks of legal liability

Source: compiled based on the Council of Europe (1997, 2005) and the results of the documentary analysis and coding of the research categories (European Court of Human Rights, 2002, 2015)

Note: National-level positions are presented as typological legal regimes identified within the framework of the documentary analysis and coding of the categories "informed consent", "advance directives" and "limits of liability", without detailing individual jurisdictions

The results of the analysis showed that positive law in the field of genetic engineering and end-of-life decisions does not function as a system of direct permissions, but as a multi-level construction of boundaries and procedures. Bioethical principles are embedded in legal regulation through substantive prohibitions and procedural guarantees, while national legislation implements these restrictions in forms adapted to domestic legal systems. This structure creates a normative basis on which judicial standards of autonomy and responsibility, analyzed in the next section, are subsequently formed.

Judicial standards of patient autonomy and responsibility of healthcare professionals in ECHR decisions

As a result of the reconstruction of the argumentation of the European Court of Human Rights, it was established that the judicial standard of patient autonomy in cases of termination of life was formed not as a “right to euthanasia”, but as a procedure for legal balancing between the protection of life, the private sphere of the individual and the obligations of the state to ensure effective protection of vulnerable groups. The quantitative and descriptive component of the section was implemented through the parameters of the coding matrix of judicial decisions: 2 decisions of the ECHR were analyzed (N = 2), 5 categories of judicial standard (K = 5) and 15 indicators (k = 15; 3 indicators per category) were identified, which ensured the reproducibility of the comparison of procedural guarantees and limits of liability. In the judgment in *Pretty v. the United Kingdom*, the Court recognized that the question of a person’s self-determination in the context of the end of life was a matter of private life, but it was not transformed into a positive right to require the State or third parties to assist in the termination of life (European Court of Human Rights, 2002). The result was to establish an approach in which autonomy was recognized as a legally significant category only if the normative limits established for the protection of life and the prevention of abuse were maintained, and the State retained a wide “margin of appreciation” in relation to criminal law prohibitions (European Court of Human Rights, 2002).

The analysis of the case *Lambert and Others v. France* showed that the ECHR distinguished between “active deprivation of life” and the termination or failure to provide supportive treatment under a procedurally secured medical assessment and consultation mechanism. The judicial standard of admissibility of end-of-life decisions was formulated as a set of procedural guarantees: the presence of a legislative basis, an independent medical assessment, a documented decision-making procedure, the involvement of close persons in the process and the possibility of judicial control (European Court of Human Rights, 2015). Within the coding matrix, the category “Procedural guarantees” was operationalized by 3 indicators (k = 3): legislative basis, documented medical procedure, availability of judicial control, which unified the comparison between cases with different factual configurations. Patient autonomy in this logic was not interpreted as the only decisive criterion, but was integrated into the model of “procedural legitimacy”, where the decisive question was whether mechanisms were applied that could minimize errors and ensure proportionality of the intervention (European Court of Human Rights, 2015).

The results obtained provided grounds for distinguishing two interrelated blocks of judicial standards that determined the limits of liability of medical professionals. The first block concerned the requirements for the legality of medical professionals’ actions in situations of termination of treatment: compliance with the procedure prescribed by law, compliance with professional standards, collegiality in assessing the patient's condition, and documentation of the reasons for the decision (European Court of Human Rights, 2015). The second block concerned the limits of criminal legal risk for medical professionals: the Court did not establish universal “immunity”, but in fact linked the reduction of the risk of prosecution to the demonstrable presence of procedural guarantees and good faith compliance with the regulatory order (European Court of Human Rights, 2002, 2015). This was quantified through 2 categories directly relevant to liability (K = 2 out of K = 5), for which 6 indicators (k = 6 out of k = 15) were applied, which allowed separating the “procedural” grounds of legitimacy from the “substantive” arguments regarding the protection of life. Thus, the liability of the doctor in the judicial logic of the ECHR depended on whether a normatively defined decision-making process was ensured, and not only on the fact of death occurring as a result of the cessation of the intervention (European Court of Human Rights, 2015). In order to summarize the established results, a comparative table was formed, reflecting the key elements of the autonomy standard and the criteria for the legal liability of medical professionals in the two basic decisions of the ECHR (Table 3). The quantitative indicators in the table are given as parameters of the coding matrix (k) for each element of the standard; frequency counts of the recurrence of motives in the paragraphs of the decisions require separate coding information, which should be added as additional material if required by the editors.

Table 3. Judicial standards of autonomy and limits of responsibility of medical professionals in the practice of the ECHR

Element of the judicial standard	<i>Pretty v. the United Kingdom (2002)</i>	<i>Lambert and Others v. France (2015)</i>	Legal significance for admissibility and liability	Number of indicators (k)
Legal status of autonomy	Autonomy was linked to privacy, but did not create the right to request assistance in suicide	Autonomy integrated into the medical decision-making process and assessment of the patient’s interests	Autonomy was recognized as relevant but not absolute; its implementation depended on normative boundaries	3
The role of the state	The state retained the right to criminalize assisted suicide	The state was responsible for creating procedural guarantees and control mechanisms	The “margin of discretion” approach: assessing national models through the quality of guarantees	3

Type of intervention/situation	Request for assisted suicide	Discontinuation/withholding of supportive treatment	Distinguishing “actively causing death” and “withdrawal of treatment” as different regimes	3
Procedural guarantees	Focus on the legitimacy of the ban and the protection of vulnerable individuals	Focus on the procedure: medical assessment, consultations, documentation, judicial control	Procedure has become a key criterion for the legitimacy of end-of-life decisions	3
Implications for medical liability	High risk of liability for aiding suicide under prohibition	Reducing liability risk while adhering to legal procedures and standards	The limits of responsibility were determined by compliance with procedure and professional integrity	3

Source: compiled based on the European Court of Human Rights (2002, 2015)

Note: The coding matrix contained N = 2 decisions, K = 5 categories and k = 15 indicators (3 indicators per category); the elements of the standards were summarized by reconstructing the legal argumentation and operationalizing the procedural criteria

The results obtained showed that the case law of the ECHR formed a “procedural” standard of autonomy, in which the key was not the proclamation of a universal right to end life, but ensuring the proper order of decision-making and minimizing the risks of abuse. Within this standard, patient autonomy was recognized as legally relevant, but was subject to balancing with the state’s duty to preserve life and protect vulnerable persons (European Court of Human Rights, 2002, 2015). Generalization by coding matrix parameters (N = 2; K = 5; k = 15) showed that the “process” of making a medical decision was a system-forming criterion for assessing admissibility, while the issue of medical professionals’ liability was derived from the evidentiary fixation of procedural guarantees and professional integrity.

Supranational governance guidelines: convergence of recommendations of WHO, UNESCO and the Council of Europe

As a result of comparing the guidelines of WHO, UNESCO and the Council of Europe, supranational governance guidelines: convergence of WHO, UNESCO and the Council of Europe guidelines is observed. As a result of comparing the WHO, UNESCO and the Council of Europe guidelines, it was found that supranational governance guidelines in the field of genome editing and end-of-life decisions were formed as a convergent system of principles, combining human rights, procedural and institutional requirements. The quantitative and descriptive component of the unit was implemented through a coding matrix of supranational documents: 6 sources (N = 6) were analyzed, representing 3 institutional blocks (m = 3) and 6 convergent principles (K = 6). UNESCO documents set a “normative center” through the concept of human dignity and the prohibition of practices that can generate discrimination, commodification of humans or instrumentalization of biomedical technologies beyond socially acceptable goals (UNESCO, 2005; UNESCO, 2015). The Council of Europe framework has reinforced this approach by requiring the protection of the individual in biomedical interventions and setting limits on acceptability through criteria of legitimate aim, proportionality and procedural guarantees, including ethical review of biomedical studies (Council of Europe, 1997, 2005). WHO recommendations have provided institutional and practical substance to governance, focusing regulatory guidelines on transparency, accountability, oversight and the prevention of transnational “regulatory gaps” in the application of genome editing technologies (World Health Organization, 2021).

The results of the analysis showed that the convergence of supranational documents was manifested not in the identity of formulations but in the coincidence of functional requirements for the regulatory process. In order to ensure a formalized comparison, a two-point coding of institutional support for principles was applied: 2 points meant “explicit regulatory consolidation”, 1 point meant “mediated support”, 0 points meant “absence of direct prescription”; the maximum sum for one principle was 6 points (2×m, where m = 3). Firstly, all three institutional blocks prioritized human protection over technological expediency, but implemented it through different instruments: UNESCO – through human rights principles, the Council of Europe – through legally defined guarantees, and WHO – through governance mechanisms focused on implementing standards in practice (UNESCO, 2005; Council of Europe, 1997; World Health Organization, 2021). Secondly, a common element was the principle of procedural guarantees, which in the supranational logic served as a “regulatory minimum” for the admissibility of interventions: independent ethical assessment, institutional oversight, documentation of decisions, transparency and accountability (Council of Europe, 2005; World Health Organization, 2021). Thirdly, a shift was identified from declarative principles to managerial requirements, in particular, towards the formalization of risk control mechanisms, public accountability of research practices, and the need for international coordination,

consistent with the transnational nature of biomedical technologies (World Health Organization, 2021; UNESCO, 2015).

Additional analytical materials from the Nuffield Council made it possible to clarify that supranational governance guidelines were insufficient without mechanisms for social legitimation and assessment of public acceptability, since regulatory decisions in the field of genome editing have a high potential for long-term consequences and conflicts of values. Within the matrix, “social legitimation and public control” was highlighted as a separate principle (1 out of $K = 6$), for which institutional support turned out to be asymmetric: UNESCO and WHO provided only indirect guidelines (1 point each), while the detailing of public acceptability mechanisms required the involvement of an external analytical source (Nuffield Council on Bioethics, 2018). This has highlighted that the convergence of supranational instruments forms a framework of minimum standards, the application of which depends on the institutional capacity of the state and the quality of legal control, including whether national systems are able to ensure transparency and accountability of regulatory decisions (World Health Organization, 2021; Council of Europe, 1997). As a result, recommendatory frameworks have functioned more effectively as “soft law” instruments when they have been integrated into legislative or judicial standards and complemented by public accountability procedures (Nuffield Council on Bioethics, 2018).

For the purpose of capturing the results, a table was created that reflected the convergent governance principles, the institutional sources of their support, and the generalized regulatory effect (Table 4). Additionally, the table presented a “convergence index” (CI), calculated as the fraction of the points scored out of the maximum possible 6 ($CI = S/6$), which provided a compact numerical comparison between the principles.

Table 4. Convergence of supranational governance guidelines in WHO, UNESCO and the Council of Europe documents

Convergent governance principle	UNESCO	The Council of Europe	WHO	Total points (S, 0–6)	Convergence Index (CI = $S/6$)	Regulatory effect in the legal field
Priority of human dignity and non-discrimination	2 (UNESCO, 2005)	2 (The Council of Europe, 1997)	1 (World Health Organization, 2021)	5	0.83	Material limits of the acceptability of technologies and practices
Procedural guarantees of the legitimacy of interventions	1 (UNESCO, 2005)	2 (The Council of Europe, 2005)	2 (World Health Organization, 2021)	5	0.83	Moving from declarations to a procedural standard of admissibility
Risk management and proportionality	1 (UNESCO, 2005)	2 (The Council of Europe, 1997)	2 (World Health Organization, 2021)	5	0.83	Minimizing abuse and increasing application security
Transparency and accountability	1 (UNESCO, 2005)	1 (The Council of Europe, 1997)	2 (World Health Organization, 2021)	4	0.67	Strengthening trust and oversight of examinations and clinical practices
International coordination of standards	2 (UNESCO, 2015)	1 (The Council of Europe, 1997)	2 (World Health Organization, 2021)	5	0.83	Reducing transnational gaps and unifying minimum standards
Social legitimization and public control	1 (UNESCO, 2015)	0	1 (World Health Organization, 2021)	2	0.33	Increasing the acceptability of regulatory decisions; the need for external detail (Nuffield Council on Bioethics, 2018)

Source: compiled based on the Council of Europe (1997, 2005), UNESCO (2005, 2015), World Health Organization (2021), Nuffield Council on Bioethics (2018)

Note: 2 points meant explicit regulatory support, 1 point meant indirect support, 0 points meant no direct prescription; the table reflects the functional overlap of regulatory requirements, not the identity of formulations; matrix parameters: $N = 6$, $m = 3$, $K = 6$, the number of comparison cells was $N \times K = 36$

The results showed that supranational governance in the field of genome editing and end-of-life decisions was constructed as a system of minimum standards, where human dignity, non-discrimination and autonomy set the material limits of acceptability, and transparency, oversight, accountability and risk management ensured the procedural legitimacy of practices (UNESCO, 2005; Council of Europe, 1997; World Health Organization, 2021). The numerical comparison showed uneven convergence between the principles: CI varied in the range of 0.33–0.83, and the average index value for 6 principles was 0.69 $((0.83+0.83+0.83+0.67+0.83+0.33)/6)$. The

convergence of the documents of WHO, UNESCO and the Council of Europe was manifested in the transition from general principles to standardized governance requirements, which can be used as quasi-normative guidelines for lawmaking and judicial interpretation, with the exception of the block of social legitimation, where additional specification of public control procedures is required.

DISCUSSION

In the context of analyzing global regulatory approaches to end-of-life decisions, Grove et al. (2024) systematically reviewed international practices of voluntary-assisted dying, euthanasia, and physician-assisted suicide. The authors showed that the key factor in the legitimacy of such practices was not material permissions but the presence of extensive procedural guarantees, including multi-stage medical assessment and judicial review. The results obtained in this research correlated with this conclusion, since the established model of regulatory and judicial standards also demonstrated the superiority of procedural legitimacy over declarative recognition of autonomy.

In the framework of legal problems of genetic engineering, Heyderova Senan (2025) emphasized that modern law does not keep up with the pace of development of genetic modification technologies. The author argued that the lack of clear legal boundaries strengthens the role of ethical declarations as temporary regulators. The results of this research clarified this position, demonstrating that supranational documents actually perform the function of quasi-normative filters that structure the admissibility of interventions even in the absence of special positive regulation.

From a historical-comparative perspective on the development of euthanasia, Picón-Jaimes et al. (2022) traced the evolution of approaches to assisted suicide and euthanasia from moral-religious prohibitions to modern legal models. The authors showed that the transition to regulated forms was associated with a gradual strengthening of procedural guarantees. The results obtained were consistent with this conclusion, since the judicial standards of the ECHR also witnessed a shift in emphasis from assessing the consequences to assessing the quality of the decision-making procedure.

In the studies of sociocultural factors of attitudes towards euthanasia, Sabriseilabi and Williams (2020) found that religious beliefs significantly influence perceptions of the permissibility of ending life. The authors emphasized that even in legal systems with formalized procedures, societal values remain an important regulatory context. This was consistent with the findings of this research, which showed that supranational guidelines only function effectively if they are socially legitimized and integrated into national legal and cultural frameworks.

In the field of human rights and genome editing, van Beers (2020) raised the question of transforming the concept of human dignity in the era of CRISPR technologies. The author argued that human rights can undergo a “rewriting” along with the rewriting of the genome. The results obtained partially confirmed this thesis, since the revealed normative model did not change the concept of dignity itself, but expanded its functional load as the limits of the acceptability of biomedical practices.

In the context of implementing international principles in the field of biomedicine, Wang et al. (2022a) analyzed the application of the UN Guiding Principles on Business and Human Rights to genome editing. The authors noted that the lack of clear accountability mechanisms reduces the effectiveness of human rights standards. The results of this research complement this conclusion, showing that it is the combination of human rights principles with institutional oversight mechanisms that forms real regulatory capacity.

In a comparative analysis of national euthanasia models, Wang et al. (2022b) demonstrated significant differences between the Dutch and East Asian approaches to the regulation of assisted dying. The authors concluded that even with similar ethical arguments, legal decisions remain dependent on institutional design. This was consistent with the results obtained, which showed that supranational standards do not unify the law, but only set a minimum procedural horizon within which states implement their own models of balancing autonomy, protection of life and public interest.

CONCLUSIONS

The research showed that the modern legal regulation of genetic engineering and end-of-life decisions is not formed as a set of individual prohibitions or permissions but as a multi-level system of material and procedural boundaries. The results showed that the key role in determining the admissibility of biomedical practices is not the proclamation of the autonomy of the person per se, but the institutionally ensured procedure for its implementation, which minimizes the risks of abuse and errors. It was expected to reveal the dominance of ethical arguments in supranational documents; however, the research showed their transformation into quasi-normative guidelines that can directly influence judicial interpretation and lawmaking. The novelty of the results lies in the identification of a convergent model of governance in which human dignity serves as a material boundary, and procedures as a tool for legal legitimation of biomedical interventions. The practical significance of the research lies in the possibility of using the formulated criteria to evaluate national regulatory models and judicial decisions in the field of bioethics. The limitation of the research is its dependence on available international documents and judicial practice, which does not allow for full coverage of the diversity of national approaches. Further studies should be directed to a comparative analysis of the implementation of supranational standards in the domestic law of individual states, as well as to studying the role of public trust and public participation in the formation of legitimate models of regulation of biomedical technologies.

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