



**Ethics, Bioethics, and Law: Legal Boundaries in Contemporary
Medical Practice**

**Ética, bioética y derecho: límites legales en la práctica
médica contemporánea**

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Resumen

La integración entre ética, bioética y derecho constituye uno de los mayores desafíos de los sistemas de salud contemporáneos, especialmente en contextos donde convergen transformaciones legales, tecnológicas y sociales. El objetivo de este estudio fue evaluar el grado de cumplimiento ético y legal en instituciones de salud de Ecuador, México y Colombia, considerando los ámbitos de consentimiento informado, protección de datos, funcionamiento de comités de ética y mecanismos institucionales de rendición de cuentas. Se realizó un diseño transversal y descriptivo con la participación de 612 profesionales de la salud y miembros de comités de ética, aplicando cuestionarios estructurados que abordaron los principales dominios de gobernanza ética. Los resultados mostraron un cumplimiento general moderado a alto (67%), con variaciones significativas entre los países y dimensiones evaluadas. Las mayores tasas de adherencia se observaron en la documentación del consentimiento informado y la revisión de protocolos por comités de ética, mientras que las áreas más débiles correspondieron a la auditoría interna, la transparencia institucional y los mecanismos de responsabilidad. Solo el 54% de las instituciones reportó contar con sistemas correctivos formales y menos de la mitad publica informes anuales de ética o cumplimiento. A pesar de la existencia de marcos legales como la Ley Orgánica de Protección de Datos Personales (2021) en Ecuador, su implementación práctica aún es parcial e inconsistente. Los resultados reflejan que las estructuras éticas formales existen, pero operan de forma reactiva más que preventiva. La madurez ética requiere trascender el cumplimiento normativo e incorporar el compromiso moral, la transparencia y la formación continua. Este estudio propone el desarrollo de un modelo regional de gobernanza ética integrada, capaz de articular derecho y filosofía moral para fortalecer la dignidad humana, la responsabilidad profesional y la justicia en la práctica médica en América Latina.

Palabras clave: bioética; derecho sanitario; gobernanza ética; consentimiento informado; protección de datos; responsabilidad institucional.

Abstract

The integration of ethics, bioethics, and law represents one of the most critical challenges facing modern healthcare systems, particularly in regions undergoing legal, technological, and social transitions. This study aimed to assess the degree of ethical and legal compliance within healthcare institutions in Ecuador, Mexico, and Colombia, focusing on informed consent, data protection, ethics committee functioning, and institutional accountability. A cross-sectional and descriptive design was conducted with 612 healthcare professionals and ethics committee members from the three countries. Data were collected through structured questionnaires addressing key domains of ethical governance, and statistical analyses included descriptive measures and cross-country comparisons to identify compliance patterns and institutional differences. The findings revealed moderate-to-high overall compliance (67%) with significant variability across domains. The strongest adherence was observed in ethics committee oversight and informed consent documentation, while internal auditing, transparency, and accountability mechanisms showed weaker implementation. Only 54% of institutions reported having formal corrective systems, and fewer than half published annual ethics or compliance reports. Despite the existence of advanced legal frameworks such as Ecuador's Ley Orgánica de Protección de Datos Personales (2021), practical enforcement remains partial and inconsistent. These results indicate that formal ethical structures are in place but often operate reactively rather than proactively. True ethical maturity requires moving beyond procedural compliance toward sustained moral commitment, transparency, and continuous professional education. This study proposes the development of a regional model of integrated ethical governance that aligns law



and moral philosophy to strengthen human dignity, professional accountability, and justice in healthcare practice across Latin America.

Keywords: Bioethics; Health law; Ethical governance; Informed consent; Data protection; Institutional accountability.

1. Introducción

Ethics, bioethics, and law constitute the triad upon which contemporary medical practice is built. These three domains intersect at the core of clinical decision-making, biomedical research, and public health policy, shaping how societies define and protect human dignity. As medicine evolves alongside technological innovation, particularly in fields such as artificial intelligence (AI), genomics, and end-of-life care, the ethical and legal implications of medical decisions have grown increasingly complex (Floridi et al., 2018; Mittelstadt, 2019). The challenge lies not only in defining what is “ethical” but also in ensuring that ethical principles are consistently applied through legal mechanisms that safeguard patient rights and professional accountability.

Globally, medical ethics has transitioned from a paternalistic model to a framework centered on patient autonomy and human rights. International documents such as the Universal Declaration on Bioethics and Human Rights (UNESCO), the Declaration of Helsinki (World Medical Association), and the CIOMS Guidelines have established a shared foundation for ethical practice. However, despite their normative value, these instruments face serious implementation challenges in low- and middle-income countries, where resource constraints, legal ambiguity, and cultural factors limit their effective adoption (Pratt & Hyder, 2016; De Castro & Garrafa, 2021). This tension between principle and practice has made the integration of ethics and law a pressing issue for the Latin American region.

In Ecuador, the evolution of bioethics has gained visibility in the last decade through judicial decisions and regulatory reforms. The decriminalization of euthanasia by the Constitutional Court in 2024 represented a historic turning point, aligning Ecuador with nations such as Colombia and Spain in recognizing the right to die with dignity (Associated Press, 2024; Ortiz-Prado et al., 2024). Complementing this, the Ley Orgánica de Protección de Datos Personales (2021) introduced a legal framework to protect the confidentiality and proper use of personal and medical information (Asamblea Nacional del Ecuador, 2021). These legal milestones demonstrate how ethical debates are increasingly shaping public policy and the broader conception of health as a fundamental human right.

However, the incorporation of ethical reasoning into daily medical practice remains uneven. Recent studies suggest that while the presence of ethics committees in hospitals and universities has increased, their operational effectiveness is limited by insufficient training, lack of enforcement mechanisms, and a weak integration between ethical oversight and legal compliance systems (González et al., 2024; Hagedorff, 2020). For example, the emergence of AI-driven diagnostic tools raises questions about data ownership, algorithmic transparency, and informed consent in digital environments (Floridi et al., 2018; Mittelstadt, 2019). These challenges illustrate the fragility of ethical governance when technology advances faster than regulation.

The problem guiding this research emerges from this dissonance: How effectively are ethical and legal standards being implemented in contemporary medical institutions? Despite the existence of regulatory instruments and ethical declarations, disparities in compliance persist among different healthcare systems in Latin America. This study therefore aims to evaluate the integration of ethical principles and legal norms in clinical and research settings across Ecuador, Colombia, and Mexico. By doing so, it seeks to identify structural gaps, patterns of good practice, and opportunities for harmonization across countries.



Previous scholarship provides a solid foundation for this inquiry. Ortiz-Prado et al. (2024) analyzed the ethical dilemmas surrounding euthanasia in Ecuador, advocating for a model in which bioethical committees mediate between moral judgment and constitutional law. Floridi et al. (2018) and Hagedorff (2020) emphasized that ethical principles alone are insufficient to guarantee accountability in AI applications unless embedded within a legal structure that enforces them. Pratt and Hyder (2016) highlighted how regional bioethics initiatives, particularly those funded through international collaborations, have strengthened training and research capacity but still fall short of establishing systematic oversight mechanisms. Collectively, these works underscore the need for empirical evidence on how ethics and law interact in real-world institutional contexts.

The present study employs a cross-national, descriptive, and analytical design. Surveys were conducted among physicians, nurses, and members of ethics committees in hospitals and universities in Ecuador, Colombia, and Mexico. The instrument focused on three domains: informed consent, protection of patient data, and ethical review of research protocols. This methodological approach allows for identifying not only compliance rates but also perceptions of ethical governance and legal awareness among professionals. The results will be interpreted in light of international frameworks and national regulations to assess both strengths and vulnerabilities of current ethical oversight systems.

This research thus contributes to an ongoing global dialogue: How can countries balance medical innovation, human rights, and social justice within coherent ethical and legal structures? By comparing three health systems and situating Ecuador as a case study, the article seeks to propose a pragmatic model of ethical governance that integrates moral philosophy, legal responsibility, and institutional accountability. Ultimately, the study aspires to reinforce bioethics as a bridge between abstract principles and everyday medical realities—one that ensures that medical progress continues to serve humanity rather than compromise its values.

2. Metodología

Study Design

This study employed a **cross-sectional, descriptive, and comparative design** to assess the integration of ethical and legal principles in clinical and research practices among healthcare institutions in Ecuador, Colombia, and Mexico. The research followed the international standards for bioethical evaluation established by the *Council for International Organizations of Medical Sciences (CIOMS)* and aligned with the *Declaration of Helsinki* and the *UNESCO Universal Declaration on Bioethics and Human Rights*.

The design was non-experimental, focusing on the identification of existing practices rather than manipulation of variables. The purpose was to describe current ethical and legal compliance patterns, identify institutional gaps, and compare governance mechanisms among the three participating countries.

Participants

A total of **612 professionals** participated voluntarily in the study, distributed as follows: **Ecuador (n = 218), Mexico (n = 238), and Colombia (n = 156)**. Participants were recruited from **public and private hospitals, medical faculties, and bioethics committees** officially registered within each country.



Inclusion criteria encompassed:

1. Healthcare professionals (physicians, nurses, psychologists, dentists, and public health specialists).
2. Members of institutional research ethics committees.
3. Individuals with a minimum of two years of professional or academic experience in health-related fields.

Exclusion criteria included professionals who were currently under administrative investigation, had participated in less than one year of institutional activity, or declined to sign the informed consent form.

The demographic distribution indicated an average age of **38.5 years (SD = 8.4)**, with **59% women and 41% men**. Approximately **67%** of respondents held a postgraduate degree, and **74%** worked in urban healthcare centers. A total of **44%** of the participants were affiliated with public institutions, while **56%** belonged to private or mixed entities.

Sampling Procedure

A **stratified sampling strategy** was adopted to ensure representation from different healthcare sectors (academic, hospital-based, and research-oriented). Each stratum was proportionally allocated according to the number of active healthcare institutions recorded by national directories in 2024.

Sample size was calculated using a 95% confidence level, a 5% margin of error, and an estimated population variance ($p = 0.5$). The minimal required sample size was 600 participants; therefore, 612 valid responses were included in the final analysis.

Data collection was conducted between **January and June 2025** through a combination of **online questionnaires and on-site interviews** in institutional facilities. Regional coordinators in each country supervised data gathering to maintain consistency and standardization in the process.

Data Collection Instruments

The study utilized a **structured, self-administered questionnaire** designed to evaluate perceptions, practices, and institutional policies regarding bioethical and legal compliance. The instrument contained **36 items** divided into four domains:

1. **Informed consent practices** – adequacy, documentation, and patient understanding.
2. **Data protection and confidentiality** – compliance with national privacy laws and security protocols.
3. **Ethical review procedures** – existence, frequency, and transparency of committee evaluations.
4. **Institutional corrective actions** – follow-up, monitoring, and accountability mechanisms.

Each item used a **5-point Likert scale** ranging from “Never” (1) to “Always” (5). The questionnaire’s internal consistency was confirmed through **Cronbach’s alpha = 0.89**, indicating high reliability.



Validation of the instrument was based on previous studies addressing ethical governance in healthcare (De Castro & Garrafa, 2021; Pratt & Hyder, 2016) and adapted to the legal context of each country. A pilot test was conducted with 30 participants (10 per country) to refine wording and assess comprehension before the main study.

Procedures

After obtaining institutional authorization, participants received detailed instructions about the purpose and confidentiality of the research. Data were collected anonymously to preserve participant privacy and comply with local regulations on personal data protection (*Ley Orgánica de Protección de Datos Personales*, Asamblea Nacional del Ecuador, 2021).

Data were cleaned and encoded in SPSS v.28 for quantitative analysis. Descriptive statistics (means, frequencies, and standard deviations) were calculated for demographic and categorical variables. Comparative analyses between countries employed chi-square tests and analysis of variance (ANOVA) to identify statistically significant differences in ethical compliance indicators.

To ensure validity, **triangulation** of data sources was applied, combining responses from healthcare providers, administrators, and ethics committee members. Institutional policy documents were also reviewed to corroborate reported practices in consent management, data protection, and research governance.

Ethical Considerations

All procedures adhered to the ethical principles of autonomy, beneficence, non-maleficence, and justice. Participation was voluntary, and written informed consent was obtained from all respondents. The research protocol received prior approval from the national bioethics committees of each participating country and was registered in the institutional research system under the corresponding ethics code.

The study maintained strict compliance with international standards on human subjects research, ensuring confidentiality, anonymity, and the right to withdraw at any stage without consequence.

3. Resultados

This section presents the main findings derived from the comparative analysis of ethical and legal compliance in medical and research practices across Ecuador, Mexico, and Colombia. The data summarized below reflect the degree to which healthcare professionals and institutions align with international bioethical principles—particularly in domains related to informed consent, data protection, and ethical committee oversight.

Overall, results indicate a moderate-to-high level of awareness of ethical obligations among healthcare professionals, yet persistent variability in institutional adherence and regulatory application. The comparative approach allowed for identifying cross-national patterns of compliance, as well as contextual differences shaped by each country's legal framework and organizational culture.

The following figures provide a structured overview of the results, combining quantitative and qualitative dimensions. Each figure highlights an essential aspect of ethical governance: (1) the profile of participants, (2) adherence to ethical and legal standards, (3) operationalization of informed consent, (4) data protection practices, (5) functioning of ethics committees, and (6)



institutional corrective mechanisms. Together, these findings form the empirical foundation for the interpretations and implications that will be discussed in the next section.

A total of six figures are included in this section. Each figure is followed by a concise description summarizing its content and relevance.

Figure 1. Demographic and professional characteristics of participants

Variable	Ecuador (n = 218)	Mexico (n = 238)	Colombia (n = 156)	Total (n = 612)
Mean age (years)	39.2	37.8	38.6	38.5
Most frequent age range	31–40 years (44%)	31–40 years (42%)	31–40 years (46%)	31–40 years (44%)
Gender distribution	61% female / 39% male	58% female / 42% male	59% female / 41% male	59% female / 41% male
Highest educational level	Bachelor's 28% / Postgraduate 72%	Bachelor's 35% / Postgraduate 65%	Bachelor's 31% / Postgraduate 69%	Bachelor's 31% / Postgraduate
Type of institution	Public 48% / Private 52%	Public 44% / Private 56%	Public 40% / Private 60%	Public 44% / Private 56%
Average years of professional experience	9.8	9.1	8.9	9.4
Participation in ethics committees	32%	29%	30%	30%

Figure 1 presents the demographic and professional characteristics of the 612 healthcare professionals and bioethics committee members who participated in the study. The overall sample shows a balanced distribution among the three countries—Ecuador, Mexico, and Colombia—representing diverse institutional, educational, and professional backgrounds.

The mean age of participants was 38.5 years, with the most frequent range between 31 and 40 years (44%), indicating that most respondents are in the active phase of their professional development and occupy decision-making positions within their respective institutions. This demographic aligns with prior regional studies emphasizing that mid-career professionals tend to be more involved in ethical and administrative responsibilities (Pratt & Hyder, 2016).

Gender distribution revealed a predominance of women (59%), reflecting the growing feminization of the health workforce across Latin America and globally. This pattern not only highlights demographic shifts but also illustrates a broader transformation in leadership and participation within ethics committees and research management (De Castro & Garrafa, 2021).

Regarding educational attainment, 69% of respondents held postgraduate degrees, suggesting a high academic qualification and a strong potential for critical reflection on bioethical and legal issues. Similar proportions across countries indicate consistent efforts to strengthen ethics and health law education among healthcare professionals (González et al., 2024; Pratt & Hyder, 2016).

The distribution by institutional type showed a near balance between public (44%) and private (56%) sectors, suggesting that ethical and legal compliance concerns extend beyond governmental structures and include private healthcare networks and universities (Asamblea Nacional del Ecuador, 2021). This balance enhances the generalizability of the findings by incorporating different operational and policy contexts.

Approximately 30% of participants reported active involvement in institutional ethics committees, which represents a significant proportion in relation to the general professional population. However, this figure also points to an opportunity for broader participation in ethical governance structures to ensure systematic oversight across institutions (De Castro & Garrafa, 2021; Ortiz-Prado et al., 2024).

In summary, the data in Figure 1 depict a well-qualified and demographically diverse participant pool, suitable for comparative ethical analysis across national contexts. The consistency in age, education, and professional engagement enhances the reliability of cross-country comparisons



and provides a strong empirical foundation for assessing ethical and legal practices in healthcare governance.

Figure 2. Overall ethical and legal compliance by country

Domain of Evaluation	Ecuador (%)	Mexico (%)	Colombia (%)	Average (%)
Informed consent properly documented and explained	76	74	70	73
Existence of institutional data protection policies	65	67	61	64
Research projects with prior ethics committee approval	83	85	80	83
Regular monitoring or internal audits of ethical compliance	55	52	50	52
Transparency and disclosure of conflicts of interest	58	61	57	59
Ethics training or continuing education in the last 12 months	71	69	68	69
Average overall compliance rate	68	68	64	67

Figure 2 illustrates the overall ethical and legal compliance levels among healthcare institutions in Ecuador, Mexico, and Colombia across six key domains: informed consent, data protection, ethics committee approval, internal monitoring, transparency, and ethics training. The results reveal a generally moderate-to-high adherence to ethical standards, though with notable variability across countries and domains.

The highest compliance rates were observed in research governance. Specifically, 83% of projects reported prior approval by ethics committees, indicating strong institutional mechanisms for oversight and evaluation. This finding aligns with global bioethical frameworks that emphasize ethical review as the cornerstone of responsible research (De Castro & Garrafa, 2021; Pratt & Hyder, 2016). It also reflects regional progress in strengthening the structure and recognition of bioethics committees within hospitals and universities, particularly following regulatory updates in Latin America.

Regarding informed consent, an average of 73% of respondents confirmed that consent procedures were properly documented and adequately explained to participants. This result suggests satisfactory adherence to the principles of autonomy and transparency but also highlights that nearly one in four cases may still present weaknesses in documentation or comprehension processes (González et al., 2024). Consistent consent practices remain a challenge in emergency or high-pressure clinical environments, where time constraints often limit thorough patient communication.

Data protection and confidentiality showed more heterogeneous outcomes, with an average compliance rate of 64%. Although Ecuador and Mexico have recently implemented or updated comprehensive data protection laws—such as Ecuador’s Ley Orgánica de Protección de Datos Personales (2021)—the operational enforcement of these laws remains partial and uneven across institutions (Asamblea Nacional del Ecuador, 2021). The results reveal that formal policies exist but are not always accompanied by continuous monitoring or staff training, leading to implementation gaps similar to those described in prior ethical governance studies (Floridi et al., 2018; Mittelstadt, 2019).

The lowest-performing domains were internal auditing (52%) and conflict of interest disclosure (59%), indicating limited mechanisms for sustained ethical accountability. This pattern suggests that, while ethical approval and training are relatively strong, post-approval oversight remains inconsistent (De Castro & Garrafa, 2021). The establishment of independent audit structures or



mandatory annual ethics reports could enhance institutional transparency and align practices with international expectations.

Encouragingly, 69% of professionals reported having participated in bioethics or legal training sessions within the past year, reflecting a regional commitment to continuous professional development. This figure is in line with international recommendations advocating for ongoing ethics education as a prerequisite for effective governance and compliance (Pratt & Hyder, 2016).

In summary, the findings in Figure 2 demonstrate that the three participating countries exhibit comparable overall compliance rates—averaging 67%—but with persistent challenges in operational transparency and auditing. The data underline the need to move from formal compliance toward a culture of active ethical responsibility, integrating both legal enforcement and moral awareness in daily medical practice.

Figure 3. Implementation of informed consent procedures

Indicator	Ecuador (%)	Mexico (%)	Colombia (%)	Average (%)
Written consent systematically obtained before any procedure	82	80	78	80
Verbal explanation provided in understandable language	79	76	74	76
Patient comprehension verified before signing	68	70	65	68
Consent form includes data privacy and confidentiality clauses	74	72	70	72
Use of updated institutional consent templates	71	73	69	71
Availability of translated consent forms for linguistic minorities	48	52	50	50
Average compliance with informed consent standards	70	71	68	70

Figure 3 presents the analysis of how informed consent procedures are implemented in clinical and research contexts across Ecuador, Mexico, and Colombia. The results reveal a generally high level of compliance with written and procedural standards, though significant differences persist in the depth of patient understanding and inclusivity for linguistic minorities.

Across all three countries, the systematic use of written consent before any medical or research procedure demonstrated the highest adherence (80%), indicating a solid institutional commitment to documentation and legal protection. This practice aligns with international guidelines such as the Declaration of Helsinki and national frameworks that define informed consent as an ethical and legal obligation rather than a mere administrative formality (Asamblea Nacional del Ecuador, 2021; González et al., 2024).

However, while verbal explanations were reported in 76% of cases, only 68% of professionals verified patient comprehension before signing. This gap between information delivery and understanding suggests that the consent process often prioritizes legal compliance over true patient autonomy. Similar findings have been documented in Latin American studies emphasizing the need for consent dialogues that go beyond technical language and legal jargon (De Castro & Garrafa, 2021; Ortiz-Prado et al., 2024).

Another relevant dimension concerns the inclusion of data protection and confidentiality clauses, present in 72% of the consent forms reviewed. This result reflects growing awareness of the intersection between ethical and legal responsibilities, especially following the enactment of data protection laws such as Ecuador’s Ley Orgánica de Protección de Datos Personales (2021).



Nevertheless, the lack of uniform templates and insufficient institutional monitoring continue to hinder comprehensive compliance (Mittelstadt, 2019).

The use of standardized institutional templates was reported by 71% of respondents, indicating that most institutions have developed official consent forms based on national or local regulations. Yet, only half of the surveyed institutions (50%) provided translated versions of consent forms for linguistic minorities—a significant shortcoming considering the multicultural and multilingual contexts of Latin America. The exclusion of indigenous and minority-language populations raises ethical questions about equity and accessibility in health communication (Pratt & Hyder, 2016).

Overall, the average compliance with informed consent standards (70%) demonstrates encouraging progress but also underscores the need for continuous training and patient-centered practices. Future institutional strategies should focus on strengthening communication skills, cultural adaptation, and routine evaluation of consent processes to ensure that ethical and legal obligations genuinely translate into respect for patient autonomy and human dignity.

Figure 4. Data protection and confidentiality practices

Indicator	Ecuador (%)	Mexico (%)	Colombia (%)	Average (%)
Existence of institutional data protection policy	68	70	63	67
Regular staff training on data privacy and confidentiality	61	64	59	61
Use of encrypted or password-protected patient databases	72	74	70	72
Implementation of internal audits on data handling	54	56	52	54
Patient data shared only with authorized personnel	77	79	75	77
Inclusion of data confidentiality clauses in consent forms	74	72	70	72
Average compliance with data protection standards	68	69	65	67

Figure 4 summarizes the degree of compliance with data protection and confidentiality standards among healthcare institutions in Ecuador, Mexico, and Colombia. The results show that, although all three countries demonstrate progress in formalizing data governance policies, their implementation remains inconsistent, reflecting the ongoing challenges of aligning ethical, technical, and legal dimensions of data handling in medical practice.

Overall, average compliance across all indicators was 67%, which can be interpreted as a moderate level of adherence. The most consistent practice across countries was restricting patient data access exclusively to authorized personnel (77%), reflecting a shared recognition of confidentiality as a fundamental ethical principle. This finding aligns with the Universal Declaration on Bioethics and Human Rights and national laws such as Ecuador's Ley Orgánica de Protección de Datos Personales (2021), which explicitly establishes data confidentiality as a patient right and a legal duty for healthcare providers (Asamblea Nacional del Ecuador, 2021).

The use of encrypted or password-protected databases (72%) emerged as another area of strong performance, indicating that most institutions have adopted at least basic digital security measures. However, the data also reveal that only 54% of institutions conduct regular internal audits of data management practices. This gap suggests that compliance tends to rely on technological safeguards rather than systematic oversight or continuous evaluation mechanisms (Floridi et al., 2018; Mittelstadt, 2019).



Staff training on data privacy, reported by 61% of respondents, represents a crucial area for improvement. Despite the existence of national data protection frameworks, consistent education and professional updating remain limited, especially in smaller hospitals and academic centers. This observation echoes international concerns about the ethical implications of data misuse and the need to foster a “culture of digital ethics” that extends beyond compliance checklists (Pratt & Hyder, 2016; De Castro & Garrafa, 2021).

Interestingly, confidentiality clauses within consent forms (72%) were moderately implemented, illustrating that many institutions integrate legal language into patient documentation but may not ensure comprehensive understanding or operational follow-up. Moreover, internal audits (54%) continue to be one of the weakest domains, underscoring that institutional accountability mechanisms are not yet standardized across the region (González et al., 2024; Ortiz-Prado et al., 2024).

Collectively, the data reflect a transitional stage in Latin America’s healthcare systems—where ethical awareness and legal mandates coexist but are not yet fully operationalized. To strengthen compliance, regional institutions should prioritize training, transparency, and routine evaluations of digital data management. Ethical oversight must evolve from policy creation to continuous verification, ensuring that patient information remains secure, confidential, and used solely for legitimate clinical or research purposes.

Figure 5. Functioning and performance of institutional ethics committees

Indicator	Ecuador (%)	Mexico (%)	Colombia (%)	Average (%)
Existence of a formally accredited ethics committee	84	86	81	84
Regular meetings (at least once per quarter)	68	72	66	69
Availability of written operational procedures (SOPs)	71	74	69	71
Inclusion of multidisciplinary members (medical, legal, community)	77	79	75	77
Timely review of research protocols (within 30 days)	63	66	62	64
Public disclosure of committee resolutions or summaries	41	44	39	41
Ethics committee members receiving periodic training	58	61	57	59
Average performance of ethics committees	66	69	64	66

Figure 5 presents the assessment of the structure, performance, and operational transparency of institutional ethics committees in Ecuador, Mexico, and Colombia. The results indicate a generally solid formal framework but highlight persistent gaps in procedural consistency, transparency, and ongoing member training.

The existence of formally accredited ethics committees was reported by 84% of participants, demonstrating that most healthcare and academic institutions in the three countries have established a recognized ethical oversight body. This figure represents significant progress compared to the early 2000s, when many institutions in Latin America lacked institutionalized ethical review structures (Pratt & Hyder, 2016). It reflects the maturation of national regulatory frameworks, such as Ecuador’s Reglamento de los Comités de Ética de Investigación en Seres Humanos (2015), which formalized accreditation processes and committee composition standards (Asamblea Nacional del Ecuador, 2021).



The inclusion of multidisciplinary members (77%)—spanning medical, legal, and community representatives—further underscores the shift toward integrative governance models. These diverse perspectives strengthen ethical deliberation by incorporating not only biomedical reasoning but also human rights, legal, and social dimensions (De Castro & Garrafa, 2021). However, the study also found that regular committee meetings occur in only 69% of institutions, indicating that ethical oversight remains reactive rather than proactive in some contexts.

Operational documentation, including written standard operating procedures (SOPs), was available in 71% of committees. While this proportion suggests an increasing degree of institutional organization, it also reveals that nearly one-third of committees still operate without clear procedural guidelines—raising concerns about consistency and accountability (González et al., 2024).

The timely review of research protocols (64%) was identified as a critical area for improvement. Delays in protocol review can negatively affect both scientific progress and participant protection, often due to administrative overload or insufficient human resources. This issue parallels observations in global analyses of bioethics governance, which emphasize the need for workflow optimization and digital management systems (Floridi et al., 2018).

The weakest domain across all three countries was public disclosure of committee resolutions (41%). Limited transparency undermines public trust and impedes the creation of an open ethical culture within institutions. Publishing anonymized summaries or annual reports of committee activities, as recommended by international bioethics standards, could enhance accountability and social legitimacy (Ortiz-Prado et al., 2024).

Finally, only 59% of committee members reported receiving periodic ethics training, underscoring a critical need for capacity building. Continuous education is essential to ensure that committees remain aligned with evolving international guidelines, emerging technologies, and local legal reforms (Mittelstadt, 2019; Pratt & Hyder, 2016).

In summary, Figure 5 demonstrates that institutional ethics committees in the participating countries have achieved substantial formalization and multidisciplinary integration. Nonetheless, challenges persist regarding transparency, regularity of operations, and professional development. Strengthening these areas is vital to advance from structural compliance toward substantive ethical governance capable of fostering accountability, social trust, and moral leadership in healthcare.

Figure 6. Institutional corrective and accountability mechanisms

Indicator	Ecuador (%)	Mexico (%)	Colombia (%)	Average (%)
Existence of internal ethical auditing or review units	52	55	49	52
Written procedures for reporting ethical violations	61	63	58	61
Anonymous reporting systems for misconduct or malpractice	46	49	45	47
Application of disciplinary measures in confirmed violations	58	60	56	58
Publication of annual ethics or compliance reports	39	43	37	40
Collaboration with external legal or oversight bodies	64	67	62	64
Existence of institutional ombudsman or ethics officer	55	59	53	56
Average institutional accountability performance	54	57	51	54



Figure 6 presents the comparative results on institutional corrective and accountability mechanisms implemented in healthcare and academic organizations across Ecuador, Mexico, and Colombia. The findings reveal that while most institutions have established formal procedures for reporting and addressing ethical misconduct, the overall effectiveness and transparency of these systems remain limited, with an average compliance rate of 54% across all indicators.

The presence of internal ethical auditing or review units (52%) and written procedures for reporting ethical violations (61%) indicates that a majority of institutions recognize the need for structured oversight. However, their limited operational frequency and reactive nature suggest that many mechanisms remain procedural rather than preventive. This pattern has been observed in prior analyses of Latin American bioethics frameworks, where accountability systems often exist “on paper” but lack consistent monitoring or sanctions (De Castro & Garrafa, 2021).

Anonymous reporting systems, crucial for protecting whistleblowers and maintaining institutional integrity, were reported by less than half of respondents (47%). The absence of robust confidentiality protections may discourage staff from reporting unethical practices, thus perpetuating a culture of silence rather than transparency (Floridi et al., 2018).

Similarly, the application of disciplinary measures following confirmed ethical violations was observed in 58% of cases, revealing that almost half of the institutions either do not enforce sanctions or manage them internally without documentation. This lack of procedural follow-up undermines the deterrent power of ethical regulation and may weaken public trust in medical institutions (Mittelstadt, 2019).

The publication of annual ethics or compliance reports (40%) was one of the lowest-scoring indicators. Limited public disclosure restricts institutional accountability and obstructs the creation of an ethical performance culture. In line with international bioethics and transparency standards, the regular publication of anonymized summaries of ethical violations and resolutions could strengthen public confidence and inter-institutional learning (Ortiz-Prado et al., 2024).

By contrast, collaboration with external legal or oversight bodies (64%) scored relatively higher, demonstrating a growing willingness among institutions to align with external accountability frameworks. Partnerships with ministries of health, academic councils, and national bioethics commissions play a vital role in reinforcing ethical governance structures and ensuring impartiality (Asamblea Nacional del Ecuador, 2021; González et al., 2024).

Finally, the existence of institutional ombudsmen or ethics officers (56%) shows emerging recognition of the importance of mediation and ethical counseling mechanisms. These positions are becoming increasingly common within universities and large hospitals, serving as key actors in conflict resolution and preventive ethics (Pratt & Hyder, 2016).

Overall, Figure 6 underscores that accountability structures in Latin American healthcare systems are evolving but remain underdeveloped. The results suggest a transition from declarative compliance to the gradual construction of a more active culture of ethical responsibility. Sustainable progress will depend on institutional commitment to transparency, regular auditing, and capacity building—transforming ethical governance from an administrative requirement into a cornerstone of professional integrity.

4. Discusión

The present study explored the intersection between ethics, bioethics, and law in the operational reality of healthcare institutions across Ecuador, Mexico, and Colombia. By analyzing informed consent, data protection, ethics committee functionality, and institutional accountability, the findings reveal a regional landscape marked by gradual progress toward formal ethical



compliance, yet hindered by persistent structural and cultural limitations. The results contribute to the broader global discussion on how developing countries can institutionalize ethical governance frameworks that not only comply with regulations but also embody the moral principles underlying medical practice (De Castro & Garrafa, 2021; Pratt & Hyder, 2016).

Ethical Awareness and Professional Composition

The demographic profile (Figure 1) demonstrates that healthcare professionals in Latin America increasingly possess the academic preparation necessary to engage with ethical and legal frameworks. The predominance of postgraduate education (69%) and the growing participation of women (59%) reflect an evolving professional landscape that prioritizes ethical literacy and inclusivity (González et al., 2024). Comparable to trends in Europe and North America, the feminization of healthcare correlates with stronger ethical accountability and patient-centered approaches (Pratt & Hyder, 2016). Nonetheless, regional disparities in access to continuing education persist, which may account for inconsistent interpretations of ethical norms among practitioners (De Castro & Garrafa, 2021).

Legal-ethical Integration and Compliance

The analysis of overall compliance (Figure 2) reveals that institutions across the three countries maintain moderately high levels of adherence to ethical and legal principles—averaging 67%—particularly in areas such as ethics committee approval and informed consent documentation. These findings reflect regional efforts to harmonize national legislation with international frameworks, including the *Declaration of Helsinki*, the *CIOMS Guidelines*, and the *Universal Declaration on Bioethics and Human Rights*. Ecuador's *Ley Orgánica de Protección de Datos Personales* (Asamblea Nacional del Ecuador, 2021) exemplifies this shift toward rights-based governance, emphasizing the patient's autonomy and informational self-determination. However, the relatively low compliance in areas such as internal auditing and conflict of interest disclosure indicates that ethics often remains formalized but not fully operationalized (Floridi et al., 2018; Mittelstadt, 2019).

The Persistent Challenge of Informed Consent

As shown in Figure 3, the implementation of informed consent protocols demonstrates encouraging, yet incomplete, adherence to ethical standards. Although 80% of professionals reported consistent written documentation, only 68% verified patient comprehension prior to signature. This discrepancy underscores a recurring ethical issue: the tendency to equate consent with paperwork rather than genuine communication. According to De Castro and Garrafa (2021), this “proceduralization of ethics” reduces a moral dialogue to an administrative step, thereby weakening the principle of autonomy. The limited availability of translated consent forms (50%) further restricts access for indigenous and linguistic minority populations, revealing a critical equity gap. True ethical practice requires culturally sensitive approaches that transcend literal compliance and empower patients as active agents in medical decision-making (Ortiz-Prado et al., 2024).

Data Protection and Digital Ethics

Figure 4 illustrates that the average compliance rate for data protection standards (67%) reflects partial success in institutionalizing privacy frameworks. The introduction of personal data protection laws in Ecuador (Asamblea Nacional del Ecuador, 2021) and Mexico, along with



hospital-level policies, marks a significant legal milestone. Nevertheless, practical enforcement remains limited by weak monitoring mechanisms and insufficient staff training (61%). As Floridi et al. (2018) emphasize, the ethical handling of data requires a dual focus: technological security and moral responsibility. Mittelstadt (2019) similarly warns that compliance-based models often fail to address deeper questions of digital trust and power imbalance. The regional data indicate that while encryption and restricted access are widely adopted, ethical data governance must evolve to include regular audits, transparency, and proactive oversight.

Ethics Committees: Strengths and Gaps

The results from Figure 5 show that ethics committees are well established in most institutions (84%), signaling the consolidation of formal ethical governance structures across Latin America. Their multidisciplinary composition (77%)—involving legal, medical, and community representatives—reflects a positive alignment with international standards (De Castro & Garrafa, 2021). However, the limited frequency of meetings (69%) and inconsistent availability of written procedures (71%) indicate that many committees still operate reactively. This situation mirrors prior regional studies that identified insufficient funding, limited autonomy, and over-reliance on a few active members as recurring barriers (Pratt & Hyder, 2016).

Moreover, the low rate of public disclosure of committee resolutions (41%) raises concerns about transparency. In a field that demands accountability and public trust, the secrecy surrounding ethical deliberations undermines legitimacy. Ortiz-Prado et al. (2024) emphasize that ethical committees must serve not only as internal regulators but also as moral beacons within their communities. Their effectiveness depends on consistent operation, proper documentation, and open communication about ethical decision-making processes.

Institutional Accountability and Ethical Culture

Figure 6 reveals the weakest dimension of ethical governance: institutional corrective mechanisms. Despite the existence of written procedures for reporting misconduct (61%) and collaboration with external bodies (64%), the absence of anonymous reporting systems (47%) and low publication of annual ethics reports (40%) indicate limited transparency. Ethical accountability, as noted by González et al. (2024), requires not only institutional will but also social legitimacy. The public's perception of ethical integrity depends on the visible enforcement of standards and equitable disciplinary actions.

In this context, the role of the institutional ombudsman (present in 56% of cases) emerges as a promising innovation. Ombuds offices serve as mediators and educators, promoting preventive ethics and resolving conflicts before escalation. Their growing presence in hospitals and universities suggests a shift toward more participatory and human-centered governance models. Still, as Floridi et al. (2018) argue, ethical governance must move beyond reactive measures to cultivate moral resilience—a continuous process of ethical reflection integrated into organizational culture.

Regional and Global Implications

The cross-country comparison underscores that Latin America is undergoing a transitional phase in bioethical institutionalization. Ecuador, Mexico, and Colombia share comparable compliance levels and challenges, suggesting that structural and cultural factors, rather than purely legislative differences, shape ethical performance. These nations exemplify the global struggle to



balance regulatory enforcement with moral intentionality (Mittelstadt, 2019). In contrast to the centralized oversight typical of high-income countries, Latin American systems rely heavily on institutional initiative, which results in variable outcomes across regions and institutions.

From a global perspective, these findings contribute to the ongoing discourse on ethical pluralism. As Floridi et al. (2018) and De Castro & Garrafa (2021) suggest, universal ethical principles must be interpreted through local social and cultural contexts. In Latin America, where inequalities and historical mistrust of authority persist, the legitimacy of ethical governance depends on participatory inclusion, fairness, and transparency. These elements are crucial for bridging the gap between legal compliance and moral conviction.

Toward a Model of Integrated Ethical Governance

The convergence of findings from all six figures supports the need for a regional model that integrates law, ethics, and institutional accountability. Such a model should rest on four pillars:

1. **Education and capacity building** – ensuring continuous training in bioethics, data protection, and human rights (Pratt & Hyder, 2016).
2. **Transparency and communication** – promoting public reporting and inter-institutional learning (Ortiz-Prado et al., 2024).
3. **Regulatory harmonization** – aligning national frameworks with global standards while preserving local relevance (Asamblea Nacional del Ecuador, 2021).
4. **Moral leadership** – encouraging ethics committees and ombuds offices to act as proactive agents of institutional culture rather than passive reviewers (De Castro & Garrafa, 2021).

By embedding these principles into the daily operations of healthcare institutions, ethical governance can evolve from formal compliance to genuine accountability. As Mittelstadt (2019) and Floridi et al. (2018) highlight, the future of medical ethics lies not merely in developing new regulations but in fostering moral ecosystems capable of self-correction, transparency, and adaptability.

5. Conclusión

The findings of this study highlight the dynamic and evolving relationship between ethics, bioethics, and law within the healthcare systems of Ecuador, Mexico, and Colombia. Through a comparative and multidisciplinary lens, the research demonstrates that these countries have made notable progress in institutionalizing ethical oversight mechanisms, developing national data protection frameworks, and establishing functional ethics committees. However, the results also underscore that such progress remains fragmented, unevenly implemented, and primarily reactive, revealing a need for a more integrated, proactive, and participatory model of ethical governance.

Across all dimensions analyzed – informed consent, data protection, committee functioning, and accountability – a recurring theme emerges: formal compliance does not always translate into ethical integrity. Informed consent, while largely documented, often fails to ensure full patient comprehension or cultural adaptation. Data protection policies exist in most institutions but lack systematic auditing and continuous staff education. Ethics committees have gained formal recognition, yet many still lack transparency, regularity, and adequate training for their members. Accountability structures, though present, remain limited by bureaucratic inertia and insufficient public reporting. These patterns suggest that the ethical landscape in Latin America



is characterized not by absence, but by partial maturity – an intermediate stage between regulatory development and full ethical operationalization (De Castro & Garrafa, 2021; Pratt & Hyder, 2016).

The integration of ethical and legal frameworks has advanced through national reforms such as Ecuador's Ley Orgánica de Protección de Datos Personales (Asamblea Nacional del Ecuador, 2021), which reflects a regional trend toward recognizing data privacy and autonomy as fundamental rights. Nonetheless, the mere existence of legal instruments is insufficient. True bioethical governance requires that these norms be embedded into the organizational culture and daily routines of healthcare professionals. As Floridi et al. (2018) and Mittelstadt (2019) argue, ethical regulation must evolve from static rules into dynamic systems capable of learning, adaptation, and accountability.

The study also highlights the central role of ethics committees as bridges between theory and practice. Their multidisciplinary composition represents an essential safeguard for pluralism and impartiality in medical decision-making. Yet, their limited visibility and lack of standardized procedures weaken their potential impact. Establishing continuous education programs, promoting regional collaboration among committees, and creating open-access databases for anonymized resolutions could significantly strengthen ethical transparency and inter-institutional trust (González et al., 2024; Ortiz-Prado et al., 2024).

A similar logic applies to institutional accountability mechanisms, where the findings revealed a modest average compliance rate of 54%. The creation of internal ombuds offices and formal reporting channels marks a promising direction, but genuine progress requires cultural change: from punitive control to ethical prevention, from secrecy to transparency, and from individual responsibility to collective integrity. As observed by De Castro and Garrafa (2021), institutional ethics must transcend procedural correctness and embrace moral reflection as a continuous process – a defining characteristic of mature bioethical systems.

From a regional perspective, the data suggest that Latin America is positioned at a critical juncture. While significant legal and structural advances have been achieved, the consolidation of a robust ethical culture demands stronger collaboration between state agencies, academic institutions, and healthcare organizations. Regional bioethics networks could play a transformative role by promoting shared guidelines, standardized training, and inter-country evaluation frameworks. The ultimate goal should be the construction of a Latin American model of ethical governance – one rooted in universal principles but sensitive to cultural diversity, social inequality, and historical context.

Finally, at the global level, this research reinforces the idea that bioethics cannot be detached from law, nor law from ethics. The moral legitimacy of healthcare systems depends on their ability to protect human dignity not only through legal compliance but through sustained moral commitment. As Mittelstadt (2019) emphasizes, ethical governance is not a destination but an evolving practice – a dynamic interplay between principles, people, and institutions. The transition from formal compliance to moral responsibility represents both a challenge and an opportunity for the region: to redefine healthcare not merely as a technical service, but as a profoundly human endeavor governed by compassion, justice, and respect for life.

Referencias Bibliográficas

Asamblea Nacional del Ecuador. (2006). Ley Orgánica de Salud. Registro Oficial Suplemento No. 423. <https://www.salud.gob.ec>

Asamblea Nacional del Ecuador. (2021). Ley Orgánica de Protección de Datos Personales. Registro Oficial Suplemento No. 459. <https://www.registroficial.gob.ec>



- Associated Press. (2024, febrero 7). Ecuador's high court decriminalizes euthanasia, following a lawsuit by a terminally ill patient. <https://apnews.com/article/7fff5e69f99ec573e13396a31b037d74>
- De Castro, P., & Garrafa, V. (2021). The negative impact of ad hoc committees for ethical evaluation in Latin America. *Developing World Bioethics*, 21(2), 89–96. <https://doi.org/10.1111/dewb.12277>
- Floridi, L., Cowls, J., Beltrametti, M., Chatila, R., Chazerand, P., Dignum, V., ... Vayena, E. (2018). AI4People—An ethical framework for a good AI society: Opportunities, risks, principles, and recommendations. *Minds and Machines*, 28(4), 689–707. <https://doi.org/10.1007/s11023-018-9482-5>
- Fors, M., Falcón, K., Brandão, T., López, M., & Mena-Tudela, D. (2024). Investigating obstetric violence in Ecuador: A cross-sectional study spanning the last several years. *Healthcare*, 12(15), 1480. <https://doi.org/10.3390/healthcare12151480>
- Gobierno del Ecuador / Ministerio de Salud Pública. (2015). Reglamento de los Comités de Ética de Investigación en Seres Humanos (Acuerdo Ministerial 4889). https://www.gob.ec/sites/default/files/regulations/2018-10/Documento_Reglamento%20Comit%C3%A9s%20%C3%89tica%20Investigaci%C3%B3n%20Serres%20Humanos.pdf
- González, A. F. M., León Pineda, C. F., & León Martínez, F. M. (2024). Revisión bioética acerca de la legalidad de la muerte asistida en el Ecuador. *Revista Bioética*, 32, e3630ES. <https://doi.org/10.1590/1983-803420243630ES>
- Hagendorff, T. (2020). The ethics of AI ethics: An evaluation of guidelines. *Minds and Machines*, 30(1), 99–120. <https://doi.org/10.1007/s11023-020-09517-8>
- Human Rights Watch. (2020, septiembre 9). Ecuador's Assembly approves bill furthering the right to health. <https://www.hrw.org/news/2020/09/09/ecuadors-assembly-approves-bill-furthering-right-health>
- Instituto Nacional de Investigación en Salud Pública (INSPI). (2017). Reglamento interno del Comité de Ética de Investigación en Seres Humanos (CEISH). <https://www.investigacionsalud.gob.ec/webs/ceish/wp-content/uploads/2017/05/Reglamento-CEISH.pdf>
- Jobin, A., Ienca, M., & Vayena, E. (2019). The global landscape of AI ethics guidelines. *Nature Machine Intelligence*, 1, 389–399. <https://doi.org/10.1038/s42256-019-0088-2>
- Macpherson, C. (2022). Global bioethics: Its past and future. *Global Bioethics*, 33(1), 1–18. <https://doi.org/10.1080/11287462.2021.2011009>
- Ministerio de Salud Pública del Ecuador. (2013). Acuerdo Ministerial 3557: Creación de la Comisión Nacional de Bioética en Salud (CNBS). <https://www.controlsanitario.gob.ec/wp-content/uploads/downloads/2017/01/A.M.-3557-CREA-LA-COMISION-NACIONAL-DE-BIOETICA-EN-SALUD-CNBS.pdf>
- Ministerio de Salud Pública del Ecuador. (2014). Normativa nacional en relación a comités de bioética en Ecuador. <https://www.salud.gob.ec/wp-content/uploads/2014/11/2.-CI-Comit-%C2%AEs-de-bio-%C2%AEtica.pdf>
- Mittelstadt, B. (2019). Principles alone cannot guarantee ethical AI. *Nature Machine Intelligence*, 1(11), 501–507. <https://doi.org/10.1038/s42256-019-0114-4>



Ortiz-Prado, E., Vásquez-González, J., & Izquierdo-Condoy, J. S. (2024). The difficult path to euthanasia in Ecuador: A call for actions for other nations. *Developing World Bioethics*, 24(2), e12449. <https://doi.org/10.1111/dewb.12449>

Peña, R. M. (2025). Argumentos bioéticos y jurídicos de la eutanasia como derecho a una muerte digna. *Revista Médica Militar*, 78(2), 45-58. <https://doi.org/10.23857/pc.v8i6>

Pratt, B., & Hyder, A. A. (2016). Twelve years of Fogarty-funded bioethics training in Latin America: Achievements and challenges. *Journal of Empirical Research on Human Research Ethics*, 11(5), 478-484. <https://doi.org/10.1177/1556264616662060>

Public Services International. (2025, abril 3). Ecuador approves law guaranteeing human right to care. <https://publicservices.international/resources/news/ecuador-approves-law-guaranteeing-human-right-to-care?id=14010&lang=en>

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