Procedural Compliance and Relational Legitimacy in Sensitive Health-Data Governance: A Case Study of GDPR Alignment in Albania

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Abstract

Purpose: This study examines whether and under what conditions procedural compliance in sensitive personal-data governance becomes legitimacy-relevant during periods of regulatory transition. Focusing on Albania's regulatory convergence with the General Data Protection Regulation (GDPR) through Law No. 124/2024 "On Personal Data Protection" (Republic of Albania, 2024), the paper develops a mechanism-based explanation of how consent practices come to carry legitimacy within an organisational setting. Design/methodology/approach: The study adopts a qualitative case study design using process tracing and analytic generalisation (George and Bennett, 2005; Yin, 2018). A structured governance audit of consent and documentation artefacts is conducted across three analytically defined phases (pre-GDPR, transition, GDPR-aligned). Operational clinic records (N = 29; 2022–2025) are incorporated exclusively for descriptive contextualisation to illustrate the limitations of behavioural indicators within a sensitive and potentially stigmatised service environment. No statistical inference is undertaken in the present study; these records are used descriptively only, and analyses reported in Imeri and Prifti (2026) are not relied upon here. Findings: Documentation structures exhibited increased legal specification, standardisation, and traceability across successive phases, consistent with strengthened procedural legitimacy. Observable variation relevant to legitimacy formation, however, is primarily associated with records that also captured interactional detail, such as documented patient questions, clarification exchanges, and reassurance about confidentiality, rather than with template completeness alone. These patterns are interpreted through Relational Communication and Engagement Capacity (RCEC), proposed as a mediating mechanism linking compliance infrastructures with relational legitimacy. Originality/value: The study proposes a refinement of the Ethics → Compliance → Trust (ECT) framework by further developing RCEC as a candidate mediating mechanism. The findings aim to inform governance and public administration scholarship by illustrating how compliance reforms may translate into legitimacy dynamics under conditions of regulatory convergence.

Keywords: ***regulatory governance; procedural legitimacy; relational legitimacy; data protection; organisational compliance; GDPR alignment***

1. Introduction

Governance of sensitive health data is closely connected to legitimacy dynamics, particularly where trust depends not solely on regulatory safeguards but also on how governance practices are communicated and interpreted. HPV screening involves highly sensitive and potentially stigmatising information, carrying implications that extend beyond clinical outcomes to perceptions of confidentiality, autonomy, and procedural fairness. Under such conditions, trust and consent may operate as relational rather than purely procedural constructs, shaped by comprehension, dialogue, and perceived benevolence. Foundational trust frameworks identify competence, integrity, and benevolence as core antecedents of trust, with benevolence frequently enacted through communicative interaction (Gilson, 2003; Hall et al., 2002; Mayer et al., 1995). Research on shared decision-making similarly indicates that individuals engage more confidently with sensitive procedures when information practices are clearly explained rather than merely documented (Elwyn et al., 2012).

This study develops a mechanism-based explanation of how procedural compliance may become legitimacy-relevant when translated into patient-intelligible consent practices. Prior to 2024, the clinic under study relied on heterogeneous and internally developed documentation structures that often lacked explicit articulation of legal bases or data subject rights. Law No. 124/2024 (Republic of Albania, 2024) initiated Albania's regulatory convergence with the EU General Data Protection Regulation (GDPR), strengthening statutory obligations related to lawful processing, transparency, and accountability. While regulatory convergence and digitisation are frequently associated with improvements in governance quality, such expectations remain empirically contingent rather than institutionally guaranteed. Law No. 124/2024 (Republic of Albania, 2024) was adopted by the Albanian Parliament on 19 December 2024, published in the Official Gazette No. 9 on 17 January 2025, and entered into force 15 days after publication, with selected provisions subject to phased implementation timelines.

Regulatory convergence processes place distinctive pressures on organisational compliance capacity, particularly where legal reforms precede stabilised implementation routines. From a public governance perspective, compliance infrastructures are not self-executing; they require translation into operational practices through documentation systems, workflow adjustments, and frontline interpretive work. This translation process resembles forms of street-level governance in which professionals operationalise abstract regulatory requirements under conditions of informational asymmetry, audit exposure, and procedural accountability. Digitised consent systems, template standardisation, and traceability mechanisms therefore function not merely as technical artefacts but as instruments through which regulatory regimes become organisationally enacted and evaluated. Legitimacy outcomes, in this sense, depend not solely on formal legal alignment but on how compliance structures are rendered intelligible within operational encounters.

Prior research on digital health consent suggests that improvements in documentation and formal consent procedures do not necessarily produce corresponding gains in understanding or trust. This pattern is consistent with prior evidence from the Albanian private healthcare context, where GDPR-aligned compliance reforms were observed to improve documentation structures before corresponding changes in communication practices emerged, highlighting the conditional relationship between compliance and trust (Imeri and Prifti, 2026). Transparency effects appear more likely where information is presented in accessible forms and accompanied by opportunities for clarification and interaction (Kassam et al., 2023). These findings motivate an analytical distinction between procedural legitimacy, grounded in formal compliance structures, and relational legitimacy, emerging through interpretation and interaction (Suchman, 1995).

Against this background, the study examines how a private gynaecology clinic in Albania transitioned from internally developed consent documentation to GDPR-aligned practices between 2022 and 2025. As a single-provider organisational environment observable across the regulatory transition, the clinic constitutes a critical case suitable for mechanism-oriented analysis (George and Bennett, 2005; Yin, 2018). The central analytical objective is to explain how compliance practices acquire relational significance.

Observations from Clinic X suggest that procedural reforms alone were insufficient to generate stable legitimacy-relevant conditions. Instead, governance signals compatible with relational legitimacy mechanisms were observable primarily where records captured interactional detail beyond the standardised template, such as documented patient questions, clarification exchanges, and reassurance about confidentiality, rather than in the presence of a completed consent form alone. Within this study, digitisation refers specifically to the shift from paper-based consent and ad hoc documentation towards a more standardised and digitally supported consent workflow, including electronic documentation of consent artefacts, date/time stamping, template version control, and auditable record trails (Elhariry et al., 2025). These infrastructural changes redistribute work and accountability: clinicians and administrative staff must maintain template consistency, ensure traceability, document explanatory exchanges, and translate regulatory requirements into intelligible communication. Such activities represent forms of organisational "invisible work" that

become consequential for both auditability and perceived legitimacy.

Digitisation is therefore conceptualised as an organisational transformation rather than a neutral technical adjustment. While GDPR alignment and traceability infrastructures may strengthen procedural legitimacy by enhancing demonstrable conformity, they do not inherently guarantee that governance practices are experienced as legitimate. In sensitive and potentially stigmatised service environments, legitimacy may depend on whether individuals can interpret the purpose, implications, and protections associated with data-processing practices. Where organisational priorities emphasise record completeness without equivalent attention to explanation, compliance infrastructures risk becoming procedurally robust yet relationally opaque.

The analytical contribution is framed as a technology-to-work-to-legitimacy chain. Digitisation introduces documentation and traceability infrastructures that reshape organisational routines and boundary relations surrounding consent. Legitimacy outcomes become contingent on whether procedural safeguards are rendered intelligible through interaction. Within this context, Relational Communication and Engagement Capacity (RCEC) is developed as an analytically useful construct that captures the organisational capacity through which compliance practices become relationally meaningful.

2. Conceptual Framework and Literature Review

Governance of sensitive personal data in private clinical environments involves the interaction of compliance structures, organisational ethical arrangements, and relational conditions shaping consent encounters. To analytically clarify these dynamics, the framework is organised around three complementary strands:

1. agency–stewardship governance;
2. ethical infrastructure and record-keeping practices;
3. legitimacy under regulatory convergence.

These strands capture distinct yet interdependent governance dynamics: incentive and information asymmetries (agency theory), organisational routines and control systems (ethical infrastructure), and institutional evaluation processes (legitimacy). Together, they motivate refinement of the Ethics → Compliance → Trust (ECT) framework through the further development of Relational Communication and Engagement Capacity (RCEC) as a mediating mechanism linking procedural legitimacy with relational legitimacy.

2.1 Agency and Stewardship Governance in Clinical Settings

In private healthcare contexts, patients entrust clinicians with highly sensitive personal data, much of which becomes organisationally embedded and informationally opaque. Agency theory highlights how information asymmetries may generate governance vulnerabilities, particularly where monitoring, transparency, and accountability mechanisms are limited (Jensen and Meckling, 1976). Stewardship theory, by contrast, assumes that professionals are intrinsically motivated to act in the interests of those they serve (Davis et al., 1997).

However, stewardship-oriented conduct does not inherently guarantee that governance practices become intelligible to patients.

Foundational trust frameworks conceptualise trust as arising from perceptions of competence, integrity, and benevolence (Gilson, 2003; Mayer et al., 1995). In sensitive clinical domains such as HPV screening, benevolence is frequently enacted through communicative interaction, including explanation, reassurance, and responsiveness. From this perspective, GDPR-aligned compliance structures may strengthen procedural legitimacy by codifying lawful bases, transparency obligations, and accountability systems. Such mechanisms, however, do not automatically generate trust, which is more closely associated with relational legitimacy emerging through interpretation and interaction (Elwyn et al., 2012).

2.2 Ethical Infrastructure and Documentation Culture

Ethical infrastructure refers to the organisational arrangements, routines, and normative expectations sustaining ethical conduct within institutions. Within consent governance, documentation and record-keeping practices may perform analytically distinct roles:

- as legal artefacts signalling procedural conformity;
- as communicative instruments shaping patient interpretation.

To clarify variation in consent practices, this study treats documentation modes as heuristic analytical categories rather than normative classifications. Table I presents the analytical classification of consent documentation modes and their corresponding patient experience dimensions. These modes are not conceived as mutually exclusive empirical states, but as interpretive devices for examining governance practices.

Table 1: Modes of Consent Documentation and Patient Experience

Documentation Mode	Characteristics	Patient Experience
Administrative	Consent primarily as formal authorisation	Formal awareness with minimal engagement
Procedural	Standardised documentation emphasising compliance	Process clarity without the necessary comprehension of implications
Relational	Consent explained, contextualised, and dialogic	Opportunities for explanation and clarification

Empirical research on shared decision-making and digital governance consistently indicates that communication quality is strongly associated with trust-relevant perceptions, often exceeding the influence of formal documentation alone (Elwyn et al., 2012). Studies of digital consent similarly suggest that transparency effects depend on comprehension rather than procedural presence (Kassam et al., 2023).

On this basis, the study proposes that documentation reforms may strengthen procedural conformity while leaving relational practices largely unchanged unless explanatory mechanisms are institutionalised. This proposition underscores the analytical importance of distinguishing procedural from relational legitimacy.

2.3 Regulatory Convergence and Legitimacy

Albania's adoption of Law No. 124/2024 (Republic of Albania, 2024) represents a process of regulatory convergence with the EU GDPR framework. Such convergence is situated within a broader landscape of cross-jurisdictional data-protection governance, in which legislative frameworks for health-data processing have been examined comparatively across jurisdictions (Scheibner et al., 2020). Within governance discourse, such reforms are frequently presented as legitimacy-enhancing developments associated with accountability, transparency, and trustworthiness (Kickbusch and Gleicher, 2012; OECD, 2022).

Legitimacy theory, however, cautions that organisations may adopt compliance structures symbolically, generating procedural legitimacy without necessarily transforming interactional practices (Suchman, 1995). Empirical studies from other GDPR-transition contexts document instances where formal legal conformity did not automatically translate into perceived legitimacy or trust. Legitimacy within sensitive data-governance environments may therefore be more accurately conceptualised as comprising both procedural and relational dimensions.

Revising the Ethics → Compliance → Trust Model

The traditional Ethics → Compliance → Trust (ECT) framework implies a relatively linear progression in which ethical orientation produces compliance, which subsequently generates trust. Governance and organisational research complicate this assumption. Compliance infrastructures may strengthen procedural legitimacy without necessarily altering trust-relevant perceptions or behaviours.

This conceptual tension motivates examination of a candidate mediating mechanism linking compliance structures with relational legitimacy.

Relational Communication and Engagement Capacity (RCEC)

To address this gap, the study develops Relational Communication and Engagement Capacity (RCEC), a construct first outlined in Imeri and Prifti (2026) and defined here as the institutionally supported capacity through which consent practices become intelligible, contextualised, and responsive within interactional encounters. RCEC is conceptualised as an organisational capacity manifested through structured explanations, documentation of dialogue, and responsiveness to concerns.

Positioning this construct within established clinical communication traditions helps situate RCEC within recognised interactional models rather than as an ad hoc conceptual addition:

Ethical Orientation
↓
Compliance Quality
↓ (mediated by RCEC)
Relational Legitimacy
↓
Trust-relevant legitimacy perceptions
↓
Legitimacy dynamics

This expanded framework aims to contribute to multiple theoretical domains.

Table II summarises the theoretical contributions of the ECT–RCEC framework across governance, ethics, and trust domains.

Table 2: Theoretical Contributions of the ECT–RCEC Framework

Domain	Existing Understanding	Contribution of This Study
Governance Theory	Compliance as a legitimacy signal	Legitimacy conditioned by relational intelligibility
Organisational Ethics	Ethical culture shapes behaviour	Ethical meaning mediated through communicative enactment
Trust Theory	Ability, integrity, benevolence	Benevolence operationalised through RCEC practices

This framework positions consent not solely as a procedural requirement but as a relational governance process through which legitimacy is stabilised, negotiated, or contested.

3. Methodology

3.1 Research Design and Rationale

This study adopts a qualitative case study design drawing on process tracing and analytic generalisation to examine governance changes across regulatory phases (George and Bennett, 2005; Yin, 2018). The primary empirical material consists of a structured governance audit of consent forms, documentation structures, and communication-related annotations across three analytically defined governance phases.

Clinic records (N = 29) were incorporated exclusively for descriptive contextualisation rather than for statistical analysis or behavioural inference. Their purpose is to describe the screening pathway and to illustrate the limitations of behavioural indicators within a sensitive service environment. No statistical inference or causal estimation is undertaken in the present study; analyses of these records reported in Imeri and Prifti (2026) are separate from, and not relied upon by, the argument developed here. The analysis draws on all available clinical records within the study period (N = 29), alongside the associated consent artefacts and documentation materials available for those records.

A qualitative case study approach is appropriate for examining regulatory transitions because it enables mechanism-oriented analysis of sequential governance changes. Within this logic, qualitative evidence is prioritised for analytical interpretation, while quantitative patterns serve descriptive and contextual functions rather than statistical generalisation (Yin, 2018). Consistent with analytic generalisation principles, the study aims to develop theoretically informed explanations of governance dynamics rather than estimate behavioural prevalence.

Process tracing is applied to identify observable changes in documentation structures, legal specification, and communication-related annotations across governance phases (George and Bennett, 2005).

3.2 Study Setting and Data Source

The empirical dataset includes all cervical swab specimens collected for HPV molecular screening at a private gynaecology clinic (“Clinic X”) in Albania between December 2022 and April 2025. Each observation contains patient age, HPV test result (positive vs. negative), test type (first vs. repeat), timestamps, and governance-relevant documentation features derived from consent artefacts.

Unit of analysis. The dataset comprises 29 test records rather than 29 individual patients. Twenty-two records correspond to first tests and seven to repeat tests performed for women who also contributed a first test within the study

period, so that the 29 records represent 22 individual patients. The unit of analysis is accordingly the test record, and records are not independent at the patient level. This non-independence further constrains the descriptive use made of these records and reinforces the decision not to draw inferential conclusions from them in the present study.

The clinic was selected because it offers a bounded organisational environment observable across the regulatory transition period. Within the analytical scope of the study, the dataset constitutes a bounded organisational case, enabling comprehensive examination of governance practices without sampling variation.

3.3 Governance Phases

Observations are classified into three governance phases defined by calendar period and anchored to the regulatory timeline: a pre-alignment phase (2022–2023), a transition phase (2024) spanning the adoption of Law No. 124/2024, and a post-alignment phase (2025). Phase assignment is therefore determined by the date of each record relative to that regulatory milestone, independently of the documentation features analysed. Treating the phases as temporally rather than documentarily constituted avoids defining the periods by the same characteristics whose variation the audit seeks to examine. Within each phase, the audit then examines the following documentation characteristics as observed outcomes:

- presence or absence of explicit legal grounding;
- visibility of data subject rights;
- traceability markers (timestamps, version identifiers);
- evidence of explanatory annotations.

Table III outlines the analytically defined governance phases and their associated consent documentation characteristics.

Table 3: Governance Phases and Consent Documentation Characteristics

Governance Phase	Period	Consent Form Characteristics	Documentation Traceability
Pre-GDPR	2022–2023	Clinic-developed consent with limited legal specification	Low traceability; purpose not explicitly articulated
Transition	2024	Consent referencing Law No. 124/2024 with partial rights disclosure	Mixed documentation structure; moderate traceability
GDPR-aligned	2025	Standardised GDPR-based consent template with explicit legal grounding	Explicit legal basis, timestamps, and version identifiers

Note: Data for 2025 represent a partial year (January–April) and are interpreted descriptively. Governance maturity is conceptualised analytically as increasing visibility of legal specification, rights disclosure, and traceability structures rather than as a normative compliance assessment.

These indicators are treated as analytical descriptors rather than psychometric measures.

3.4 Variables and Measures

The study distinguishes between descriptive clinical variables, behavioural proxies, and governance-mechanism indicators. Table IV summarises the variables and measurement strategy employed in the study.

Table 4: Variables and Measurement Strategy

Variable	Type	Operational Definition	Analytical Role
HPV test result	Binary	Positive vs. negative	Descriptive clinical context
Patient age	Continuous (years)	Age at testing	Descriptive comparison
Test type	Binary	First vs. repeat screening	Behavioural proxy (non-inferential)
Governance phase	Categorical	Derived from the documentation audit	Compliance trajectory indicator
Consent/documentation features	Qualitative markers	Legal basis visibility, rights disclosure, traceability, explanations	Mechanism-relevant evidence

Behavioural indicators are not treated as direct measures of trust due to the confounding effects of clinical protocols, scheduling routines, and diagnostic pathways.

3.5 Analytical Strategy

The analytical strategy follows a mechanism-building logic consistent with process tracing and analytic generalisation (George and Bennett, 2005; Yin, 2018). No hypothesis testing, statistical inference, or causal estimation is undertaken in the present study; such analyses are reported separately (Imeri and Prifti, 2026). Quantitative clinic records are analysed descriptively to characterise observable patterns within the screening pathway.

Qualitative analysis applies reflexive thematic analysis (Braun and Clarke, 2019) using theory-informed coding. Structural codes capture observable governance features (e.g., legal bases, traceability), while conceptual codes examine relational and communicative dimensions (e.g., explanatory depth, responsiveness).

Interpretation follows a congruence logic in which observable implications of procedural compliance are compared with patterns compatible with relational legitimacy mechanisms. Process-tracing inference followed a structured observable-implications logic. Under a purely procedural compliance mechanism, expected observations include increased template standardisation, expanded legal specification, and strengthened traceability markers without systematic evidence of interactional documentation. Under a relational legitimacy mechanism, observable implications include documented explanations, patient-initiated questions, clarification entries, and narrative annotations reflecting communicative engagement. Explanatory weight is assigned primarily to records containing contemporaneous communication markers, as these constitute higher-specificity evidence of interactional processes compared to structural documentation features alone. To mitigate confirmation bias in single-researcher coding, analysis relied on a maintained audit trail, explicit coding rules, iterative memoing, and active examination of negative and ambiguous cases.

Establishing RCEC as a distinct construct. RCEC is operationalised through three observable documentary indicators that are analytically separable from procedural-compliance markers: (i) explanatory depth (contemporaneous notes recording that the purpose, retention, or withdrawal implications of processing were explained); (ii) relational tone (patient-oriented or reassurance language addressing confidentiality or stigma concerns); and (iii) responsiveness (logged patient questions together with a documented answer). These indicators were coded only where a contemporaneous interactional trace was present in the record; standardised template language, legal-basis statements, timestamps, and version identifiers were explicitly excluded from RCEC coding, as these evidence procedural rather than relational conformity.

Treating RCEC as distinct rather than as a descriptive relabelling of compliance rests on a dissociation criterion. If relational annotations were merely a by-product of documentation quality, they would be expected to increase monotonically with traceability and legal-specification markers across the three governance phases. The audit did not show this pattern: procedural markers strengthened consistently and uniformly following alignment with Law No. 124/2024, whereas interactional annotations appeared unevenly and were concentrated in a subset of records rather than tracking template standardisation. This divergence between structural and relational indicators is the primary evidence that RCEC captures organisational variation not reducible to procedural compliance. At this stage RCEC is advanced as a candidate mechanism for which theory-informed coding establishes content and face validity; formal construct validation, including inter-coder reliability and convergent and discriminant testing against procedural-compliance measures, is identified as a task for subsequent research.

3.6 Coding Framework

Coding combined deductive (theory-informed) and interpretive strategies.

Coding units consisted of consent documents and associated clinical record annotations. Table V presents the coding framework used for the qualitative analysis.

Table 5: Coding Framework

Code Type	Code	Definition	Example Extract
Structural	Legal basis present	Explicit articulation of legal grounds for processing	"Processing based on explicit consent under Law No. 124/2024 'On Personal Data Protection'."
Structural	Rights disclosure	Visibility of data subject rights	"The patient may request information."
Structural	Traceability	Presence of timestamps, versioning, and clinician identifiers	"v2.1 / [date redacted] / clinician identifier."
Conceptual	Explanatory depth	Evidence of a documented clinician explanation	"Explained the purpose of molecular testing."

Code Type	Code	Definition	Example Extract
Conceptual	Relational tone	Presence of supportive and patient-oriented language	"Discussed privacy concerns; reassured confidentiality."
Conceptual	Responsiveness	Documentation of patient questions or interaction	"Patient asked about result implications."

Interpretation: Relational indicators are treated as governance-relevant signals rather than psychological measures.

3.7 Reflexivity and Analytical Rigour

Although coding is conducted by a single researcher, analytic credibility is strengthened through iterative memoing, reflexive journaling, re-coding of ambiguous records, peer debriefing with an external domain expert familiar with health-data governance, and maintenance of a chronological audit trail. These procedures enhance interpretive transparency rather than inter-coder reliability.

3.8 Ethical Aspects

The analysis relies exclusively on retrospective operational records anonymised prior to examination. No direct identifiers are available to the researcher. The study involves no participant interaction and no clinical intervention.

4. Results

4.1 Descriptive Age Distribution Between Observations

Patient ages range from 18 to 43 years, consistent with the reproductive-age population typically associated with HPV screening pathways. Age variation is reported solely for contextual description and carries no inferential role. Table VI displays the distribution of first and repeat HPV tests across the 29 test records.

Table 6: Distribution of First vs. Repeat HPV Tests

Result	First Tests (n)	Repeat Tests (n)
Positive	12	5
Negative	10	2

Repeat testing is observable in both HPV-positive and HPV-negative cases.

4.2 Repeat Testing as a Behavioural Indicator

Repeat testing appears in both HPV-positive and HPV-negative cases. Within this bounded dataset, follow-up behaviour cannot be interpreted as a proxy for trust or governance perceptions. Behavioural continuity may reflect clinical routines, scheduling structures, or diagnostic pathways rather than legitimacy-related factors. Conversely, non-continuity may be influenced by anxiety, stigma management, cost considerations, or access constraints.

4.3 Transformation in Approval and Information Documentation

The governance audit identifies observable variation in consent documentation, legal specification, and communication-related annotations across governance phases. Table VII illustrates the evolution of consent documentation and communication practices across governance phases.

4.4 Pre-GDPR Phase (2022–2023)

Documentation during this phase was dominated by administrative forms of consent documentation. Illustrative phrasing extracted from consent artefacts typically resembled the following:

Excerpt (Pre-GDPR; clinic-developed consent form)

Patient agrees to the procedure; information provided verbally. Observed characteristics included:

- explicit legal basis not specified

- minimal articulation of withdrawal rights
- inconsistent traceability markers
- predominantly administrative language

4.5 Transition Phase (2024)

Consent artefacts displayed partial incorporation of statutory language:

Excerpt (Transition Phase; revised consent template)

"The clinic processes personal data in accordance with applicable legislation. The patient may request information as needed."

Observed characteristics:

- partial rights disclosure
- mixed documentation structures
- emerging explanatory annotations.

4.6 GDPR-Aligned Phase (2025)

Documentation structures exhibited greater legal and procedural specificity:

Excerpt (GDPR-Aligned Phase; standardised consent template)

"Processing is based on explicit consent under Law No. 124/2024 'On Personal Data Protection'. The patient has the right to withdraw consent at any time. The clinician explained data-storage duration and answered the patient's questions."

Observed characteristics:

- explicit legal grounding
- consistent traceability markers
- documented communicative annotations
- patient-oriented language.

Table 7: Evolution of Consent Documentation and Communication Practices

Governance Phase	Consent Form Structure	Legal Basis Visibility	Traceability	Communication-Related Annotations
2022–2023 (Pre-GDPR)	Clinic-developed; limited specification	Implicit	Low	Administrative
2024 (Transition)	Revised; legislation referenced	Partial	Moderate	Emerging explanatory elements
2025 (GDPR-Aligned)	Standardised; legally explicit	High	High	Patient-oriented / relational

Across governance phases, documentation artefacts exhibit increasing standardisation and traceability.

4.7 Summary of Empirical Findings: System-Level Governance Implications

Table VIII summarises the key empirical findings and their evidence base.

Table 8: Summary of Key Empirical Findings and Evidence

Finding	Evidence Base	Status
Consent documentation exhibited increasing legal specificity and traceability	Governance audit	Observed
Repeat testing patterns did not display a stable association with governance phases	Clinic records (descriptive)	Descriptively observed

Source: Authors' analysis of Clinic X screening records (2022–2025). All consent artefacts available for each governance phase were included in the audit.

Clinic records do not display stable behavioural variation across governance phases, whereas governance audit observations indicate increased documentation clarity, legal specification, and traceability structures following regulatory alignment under Law No. 124/2024.

5. Discussion

5.1 Interpretation of findings

Within this bounded dataset, clinic records do not display behavioural patterns permitting stable interpretation across governance phases. Observed variation is primarily located within documentation structures and communication-related annotations rather than behavioural indicators.

Importantly, these findings do not suggest that procedural compliance lacks governance relevance. A similar sequential pattern has been documented in prior work, where legal convergence first manifested in documentation and traceability improvements, followed only later by the internalisation of communication practices within clinical interactions (Imeri and Prifti, 2026). Rather, they indicate that compliance infrastructures alone may be insufficient to generate trust-relevant interpretations, particularly in contexts characterised by informational asymmetries and data sensitivity.

Alternative explanations, including template standardisation effects, organisational routine stabilisation, and inspection-driven documentation adjustments, are analytically plausible. However, the presence of documented patient questions and explanatory annotations is consistent with the operation of relational communication mechanisms.

These observations highlight a governance tension frequently noted in digitisation contexts. Improvements in auditability and traceability do not inherently imply corresponding changes in intelligibility or relational legitimacy. As documentation becomes more standardised, organisations may more easily demonstrate procedural conformity. At the same time, such infrastructures may create a false equivalence between formally valid consent artefacts and substantively intelligible consent processes.

This distinction becomes particularly salient in sensitive service environments. Digitised documentation systems may record that consent was obtained or rights were disclosed, yet remain unable to capture whether individuals understood the practical implications of withdrawal, retention, or downstream data processing. The differentiation between procedural legitimacy and relational legitimacy therefore reflects distinct organisational accountability regimes. Procedural legitimacy emphasises demonstrable conformity, while relational legitimacy concerns interpretability, comprehension, and interactional quality.

Digitisation may consequently reinforce compliance-oriented routines without automatically strengthening relational governance conditions. Where organisational priorities focus predominantly on documentation completeness, consent infrastructures risk becoming procedurally robust yet interactionally limited. These findings should be interpreted as analytically indicative rather than as direct measures of patient-level perceptions or trust.

5.2 Theoretical Contribution

The findings aim to extend governance and organisational theory by proposing a refinement of the Ethics → Compliance → Trust (ECT) framework. The further development of Relational Communication and Engagement Capacity (RCEC) specifies a theoretically proposed mediating mechanism through which procedural compliance may acquire relational significance.

Consistent with established trust models, the framework operationalises the benevolence dimension through observable communicative practices rather than abstract attitudinal constructs.

Three conceptual implications follow:

- Governance theory: Procedural compliance may signal conformity without necessarily generating legitimacy unless rendered intelligible through interaction.
- Organisational ethics: Documentation practices acquire ethical meaning when embedded in explanation, transparency, and responsiveness.
- Trust theory: Trust formation in sensitive environments appears closely associated with relational interpretation rather than structural compliance alone.

Under this interpretation, consent is more appropriately conceptualised as a relational governance process rather than solely a procedural artefact. The framework does not propose a new theory of trust, but rather specifies a proposed organisational mechanism through which compliance practices may acquire legitimacy-relevant meaning.

The analysis supports a mechanism-based refinement of the Ethics → Compliance → Trust (ECT) framework within sensitive data-governance environments. Observations from Clinic X indicate that regulatory alignment is associated with increased documentation clarity, legal specification, and traceability structures.

However, behavioural patterns do not display stable variation across governance phases. Procedural reforms alone appear insufficient within the observed organisational context to account for legitimacy-relevant dynamics.

Relational Communication and Engagement Capacity (RCEC) is proposed as a mediating mechanism linking compliance infrastructures with relational legitimacy. Under this framework, compliance structures establish procedural legitimacy, while relational legitimacy emerges through communicative practices enabling interpretability. Revised governance mechanism:

Table IX presents the theoretical positioning of the ECT–RCEC mechanism.

Ethical Orientation
→ Compliance Quality
→ (mediated by RCEC)
→ Legitimacy dynamics

Table 9: Theoretical Positioning of the ECT–RCEC Mechanism

Domain	Existing Emphasis in Literature	Mechanism-Based Refinement
Governance Theory	Compliance as legitimacy signal	Legitimacy conditioned by relational intelligibility
Organisational Ethics	Ethical culture shapes behaviour	Ethical meaning emerges through communicative enactment
Trust Theory	Ability, integrity, benevolence	Benevolence operationalised through RCEC practices

Source: Authors' analysis, based on the revised Ethics → Compliance → Trust model with RCEC mediation

Specifying RCEC re-specifies how compliance infrastructures may become legitimacy-relevant without displacing the role of procedural safeguards. Legitimacy dynamics are consequently conceptualised as contingent upon both structural conformity and relational interpretability.

5.3 Comparative Perspective

The mechanism identified here is compatible with observations from other GDPR-transition environments. Prior research indicates that improvements in documentation infrastructures do not automatically translate into stabilised trust perceptions, consistent with recent conceptualisations treating legitimacy as a form of social infrastructure emerging through organisational and relational dynamics (Howe et al., 2025). Albania's case is descriptively consistent with this broader governance pattern, supporting the analytical plausibility of relational communication mechanisms.

Analytical scope and transferability. The single-site design supports analytic and theoretical generalisation rather than statistical generalisation to a population of clinics. Clinic X is treated as a critical case of a broader class of settings, and the transferability of the RCEC mechanism is therefore framed through explicit scope conditions rather than sample representativeness. The mechanism is expected to be most salient where four conditions co-occur: (i) an active regulatory-convergence transition in which legal reform precedes stabilised implementation routines; (ii) sensitive or potentially stigmatised data that raise the relational stakes of consent; (iii) a documentation-led compliance culture in which auditability can advance ahead of communication practice; and (iv) resource-constrained or single-provider organisational settings where relational work is discretionary and unevenly recorded.

Distinguishing the Albania-specific features from the generic mechanism further clarifies scope. The recency and phased implementation of Law No. 124/2024, and the private single-clinic governance context, are particular to this case; the compliance-first sequencing in which documentation and traceability mature before relational practice is the portable element and is consistent with observations from other GDPR-transition environments. The findings should therefore be read as generating theoretical propositions about this sequencing, to be tested across settings, rather than as estimates that generalise directly to the Albanian health system or to clinics elsewhere.

5.4 Policy and practice implications

Several governance implications follow from the mechanism-based interpretation.

- Audit and compliance frameworks may benefit from incorporating evaluation of communication practices alongside documentation structures.
- Professional standards may emphasise competencies related to explanation clarity and verification of understanding.
- Regulatory supervision mechanisms may consider intelligibility as a complementary dimension of compliance assessment.
- Organisational governance systems may strengthen legitimacy by institutionalising attention to interactional practices.

Operationalising RCEC in governance and compliance audits. To move RCEC from an analytical construct towards routine practice, compliance audits can incorporate a small set of relational-intelligibility indicators alongside existing legal-basis and traceability checks. A practicable RCEC audit rubric includes:

- the proportion of consent records containing a documented explanation of processing purpose, data-retention duration, and withdrawal rights, rather than a legal-basis statement alone;
- the presence of logged patient questions together with a recorded response, as an indicator of documented responsiveness;
- plain-language and readability review of consent templates, verifying that statutory content is expressed in patient-intelligible terms;
- evidence of staff competency in explanation and verification of understanding, for example through periodic template-comprehension checks or brief training records;
- a simple maturity rating (administrative, procedural, relational) applied at record or template level, allowing organisations to track movement towards relational documentation over time.

Embedding these items within existing audit cycles allows relational intelligibility to be monitored as a complementary dimension of compliance without displacing procedural safeguards, and provides supervisory bodies with observable criteria for assessing whether consent practices are rendered meaningful rather than merely documented.

These implications do not diminish the value of compliance infrastructures, but clarify the conditions under which procedural safeguards begin to carry relational weight.

5.5 Limitations and future research

This single-site, small-N study supports analytic rather than statistical generalisation. The findings aim to illuminate governance mechanisms rather than estimate behavioural prevalence.

Sample size and evidentiary scope. Several limitations bound the robustness of these conclusions. The clinical dataset is small (N = 29) and is used solely for descriptive contextualisation; no prevalence, association, or causal claim is made from it, and the repeat-testing patterns reported are explicitly non-inferential. The governance conclusions rest on the documentation audit rather than on this record count, but the limited volume nonetheless constrains the range of interactional traces available for coding.

Absence of direct patient perspectives. The study infers relational legitimacy from documented organisational practice rather than from patients themselves. RCEC is therefore measured at the level of recorded institutional capacity, not at the level of patient-reported comprehension, trust, or experience, and the absence of interviews or surveys means the study cannot confirm whether documented explanations were understood as intended. Combined with the single-site scope and single-coder analysis, this bounds the claims to analytically indicative organisational-level interpretations that require patient-side validation before they can be treated as evidence of experienced legitimacy.

Future research may extend this analysis through:

- multi-site comparative designs;
- incorporation of validated trust measurement instruments;
- examination of digital consent systems as relational governance tools;
- analysis of organisational determinants of communicative practices;
- testing boundary conditions of the RCEC mechanism.

Designs for testing the RCEC mechanism and its boundary conditions. These directions can be specified more concretely. A multi-site comparative case design spanning clinics and countries at different stages of GDPR

transition would vary the proposed scope conditions and test whether the compliance-first sequencing recurs. A mixed-methods design pairing the documentation audit with validated patient instruments for comprehension and trust would test the core prediction that RCEC-rich records are associated with stronger patient-reported understanding, providing convergent validation of the mechanism. A dedicated construct-validation study could develop an RCEC index and assess inter-coder reliability and its convergent and discriminant relationship to procedural-compliance measures. Longitudinal within-site tracking would test the temporal claim that relational practice follows documentation maturity, while a vignette or field-based intervention introducing RCEC-oriented consent practices would allow legitimacy outcomes to be observed directly.

Boundary conditions worth probing include the degree of data sensitivity and stigma, organisational size and resourcing, the maturity of the regulatory regime, and the balance between digital and paper documentation. Comparing high- and low-sensitivity service domains, and public and private providers, would help establish the range across which relational communication remains legitimacy-relevant and identify the settings in which procedural compliance alone may be sufficient.

6. Conclusion

The preceding analysis examined how regulatory convergence and compliance infrastructures reshape consent governance within a sensitive health-data environment. The governance audit indicates that documentation practices evolved towards greater legal specification, explicit articulation of processing grounds, and strengthened traceability structures following alignment with Law No. 124/2024. These developments are consistent with maturation of procedural compliance mechanisms within the observed organisational setting.

Behavioural indicators drawn from clinic records remained stable across the three phases. Behavioural continuity within sensitive screening pathways cannot therefore be interpreted as a direct indicator of trust or legitimacy perceptions, as such continuity may be shaped by multiple structural and contextual factors, including access conditions, clinical routines, and risk perceptions.

The mechanism-based interpretation advanced here suggests that procedural compliance appears legitimacy-relevant primarily when translated into intelligible and interactionally supported consent practices. Documentation reforms, while procedurally significant, do not inherently guarantee relational legitimacy. Consent practices are more appropriately understood as relational governance processes in which communication mediates how regulatory safeguards are interpreted and experienced.

The revised ECT–RCEC framework offers a conceptual contribution by proposing Relational Communication and Engagement Capacity (RCEC) as a candidate mediating organisational mechanism linking compliance structures with relational legitimacy. This refinement clarifies how ethical orientation, procedural conformity, and communicative practices interact within transitional governance environments.

Future research may extend this analytical account through comparative multi-site designs, incorporation of validated trust measurement instruments, and examination of digital consent infrastructures as relational governance mechanisms. As healthcare systems continue processes of regulatory convergence, greater analytical attention to the intelligibility and enactment of consent practices may support more nuanced interpretations of legitimacy dynamics.

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