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Healthcare Innovation and Bioethical Challenges in Emerging Digital Health Systems

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Abstract

The pace of development of innovations in digital health is accelerating in emerging economies, while the associated bioethical risks (privacy, consent, equity, accountability of algorithms, and commercial manipulation) are rarely assessed in comparison with healthcare systems having varying levels of governance. This paper addresses the evolution of bioethical risk in the process of maturation of digital health systems and whether the protection provided by governance affects this pattern. A synthetic dataset consisting of 60 emerging digital health systems (20 with high, 22 with moderate, and 18 with weak governance) observed for ten years (2015-2025), i.e., 660 system-year observations, is examined through line-trend comparisons, domain-specific comparisons, cross-sectional trust scatter analysis, and system fixed-effect regressions. While the index of bioethical risk increases from 26.0 to 41.6 points in systems with weak governance, it increases only from 17.6 to 22.1 points in systems with strong governance. Public trust increases with maturity levels only under strict controls (interaction effect of 0.212), while privacy and consent are the governance aspects with the largest gaps (approximately 29 points). The numbers presented above just represent the way the framework was applied, without any attempt to make any estimate for any particular country. It can be concluded from the analysis conducted that innovation and ethics are complementary only when deployed together.

Keywords: Digital Health, Bioethics, Healthcare Innovation, Emerging Health Systems, Governance Safeguards, Patient Trust, Health Equity.

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Introduction

In the digital era, the application of mobile applications, health information technology, telemedicine, connected devices, and the use of AI in healthcare is changing the way in which health services are conceived, delivered, and experienced. Such innovation offers the potential to broaden access and provide personalized care; however, it also places information and decisions into entirely new realms of technology and business. The issue of public trust provides the first measure of this transition: a cross-sectional study conducted on the general population of Sweden sought to explore public perceptions and trust of electronic health data, considering digital privacy as an ethical issue (Belfrage et al., 2022). A second ethical concern is that of responsibility. Davies identifies how mobile health can become an act of personal health surveillance and a means for the responsibilization of individuals regarding their health (Davies, 2021).

Ethics and safety concerns exist at all levels of technology. A narrative review provides an overview of ethical and safety considerations associated with digital health technologies (Grosman-Rimon & Wegier, 2024), whereas a mapping review highlights the ethical concerns related to digital twins in personalized healthcare services (Huang et al., 2022). At the program level, there is a scoping review that looks into the challenges involved in the development of digital public health interventions and the possible solutions (Iyamu et al., 2022). Empowerment remains contentious. A systematic review explores the role of online communities as an empowerment mechanism (Johansson et al., 2021), while Kapeller and Loosman explore the idea of empowerment in the health self-testing applications context (Kapeller & Loosman, 2023).

Equity and risk considerations then arise. Koehle et al. consider that there are three issues to consider for digital health equity, which include power, usability, and trust (Kepper et al., 2024), while Landau et al. address the relevant ethical concerns when using machine learning to assist in the identification of child abuse and neglect (Landau et al., 2022). On a larger scale, Maeckelberghe et al. address the ethical concerns related to personalized digital health (Maeckelberghe et al., 2023).

Three research gaps drive this research. First, most of the research reviewed above is conceptual, literature-driven, or focused on a particular technology, which means that there is a lack of empirical evidence concerning the relationship between changes in ethical risk levels and digitalization of systems as a whole. Second, the issue of governance has been examined only as a recommendation and not as a moderating variable in the relationship under consideration. Third, the relationship between trust and digitalization maturity has not been explored empirically. Key contributions of this research are:

- Presents comparative evidence on the dynamics of development of a bioethical risk index in relation to digital maturity with strong, moderate, and weak levels of governance.
- Measures the impact of governance protection factors on the associations between maturity and risk, and maturity and trust.
- Breaks down bioethical risk into six areas in order to highlight where governance is lacking the most and bioethical risks persist despite strong governance.
    - Quantifies the amount of ethical risk that could have been mitigated had the weaker systems been allowed to develop under the protection of more strongly governed systems using a hypothetical approach.

The research questions are: RQ1 – How does bioethical risk develop along with the evolution of digital health systems, and does governance influence this development process? RQ2 – What ethical domains cause the differences between governance levels? RQ3 – Is digital maturity reflected in trust, and under what circumstances?

The current paper deviates from the usual sequence of first presenting the framework and then reporting. Following the review of literature, the paper introduces the evidence and methodology used, presents the findings, and then provides their interpretation in the context of the ethical domain framework.

Literature Survey

Current research has also found that the data-driven technologies bring up ethical questions that transcend any single product. Research has been done on the ethical questions surrounding democratizing digital phenotypes and machine learning in the next generation of digital health technologies (Mulvenna et al., 2021), and also mapping the literature on artificial intelligence in good health through a scoping review (Murphy et al., 2021). Such research has established

that algorithmic technologies give rise to new issues regarding data usage, fairness, and accountability that are not covered by current clinical ethics.

A second set of literature connects digital health with issues of justice and organization of care. Current literature discusses justice and empowerment in the context of digital health, laying out ethical issues and possibilities (Nickel et al., 2023). Some literature has traced the past, present, and future of digitally enabled primary care, a setting where most of the digital systems currently being developed are first used (Pagliari, 2021). Some research has even outlined frameworks for digital health equity (Richardson et al., 2022). Together, such research sees equity as an issue of design.

Thirdly, the incentives and relationships are under investigation. Literature dedicated to the analysis of commercial health applications investigates the optimization goals of those applications and defines them as a digital environment with the potential to manipulate people (Sax, 2021). Another research deals with the notion of trust and the transformations of relationships between doctors and patients Segers & Mertes, (2022), while sociotechnical framework expands the approaches of bioethics (Shaw & Donia, 2021).

Fourthly, there is a literature mapping the variety of challenges. Reviews of literature discuss ethical, legal, and social issues of digital phenotyping as the future remedy for current problems Tomičić et al., (2022) as well as ethical challenges to the deployment of digital healthcare technology (Zarif, 2022). Common message is that challenges become more numerous with the use of a technology and its institutional context. However, systematic comparison across systems how the risk grows along with the level of maturity of technology and how governance affects this process is still lacking. It will be provided below.

Evidence Base and Analytical Approach

Sample and Data Construction

Unit of analysis is the digital health system at the national or regional level. The sample consists of 60 emerging systems ranked on a governance safeguard index (0-100), which represents the degree of regulation, supervision and participation: 20 systems are strong (index of 70 and above), 22 are moderate (between 45 and 66) and 18 are weak (below 45). Observations on an annual basis between 2015 and 2025 result in a well-balanced panel consisting of 660 system-years. Since there are no available time series of the bioethical risk in comparable countries, the panel is artificial. The data generation process in the panel conforms to the theoretical propositions discussed in the literature review and features an emergency deployment shock between 2020 and 2021. Thus, the findings provide information about the characteristics of the model and not of any real country.

Variables and Specification

There are four indexes (0-100). The Digital Health Maturity Index (DHMI) measures the depth and extent of digital service provision. The Bioethical Risk Index (BRI) is calculated from the average of six domain indexes: privacy and data management, informed consent and autonomy, equity and accessibility, algorithmic accountability and bias, manipulative commerce and surveillance, and responsibilization and trust in clinicians and patients. The Trust Index indicates the level of public trust in digital health in 2025, while GOV is the governance safeguard index. Log of health expenditure per capita is the control variable. Two models are estimated:

$$\mathrm{BRI}_{it} = \alpha_i + \lambda_t + \beta \mathrm{DHMI}_{it} + \delta(\mathrm{DHMI}_{it} \times \mathrm{GOV}_i) + \varepsilon_{it} \quad (1)$$

$$\mathrm{TRUST}_i = \gamma_0 + \gamma_1 \mathrm{DHMI}_i + \gamma_2 \mathrm{GOV}_i + \gamma_3(\mathrm{DHMI}_i \times \mathrm{GOV}_i) + \gamma_4 \ln \mathrm{EXP}_i + u_i \quad (2)$$

Equation (1) uses system fixed effects (α_i) and year fixed effects (λ_t) with standard errors clustered by system; DHMI and GOV are centred, and the interaction is scaled per 10 governance points. Equation (2) is a 2025 cross-section estimated by OLS with heteroskedasticity-robust standard errors. In the tables, three stars denote significance at 1%, two at 5% and one at 10%.

Table 1 shows the way in which each variable is included in the analysis. Since the six domain indices are equally weighted to create the BRI, such that one unit change in any domain will bring about a change of one-sixth of a unit in the overall index, DHMI is a system year index, while GOV is fixed by system across the panel, while the Trust Index and health expenditure are recorded only in the 2025 cross-section. This is important because equation (1) makes use of within-system variation, while equation (2) uses between-system variation.

Table 1: Definition and Measurement of Study Variables

Variable	Definition	Scale / unit	Role in the models
DHMI	Depth and extent of digital service provision	Index, 0–100	Main regressor (system-year)
BRI	Equal-weighted mean of six domain risk indices	Index, 0–100	Dependent variable, Eq. (1)
Domain indices (6)	Privacy; consent; equity; algorithmic accountability; commercial manipulation; responsibilisation	Index, 0–100	Components of BRI; domain gaps
TRUST	Public trust in digital health, 2025	Index, 0–100	Dependent variable, Eq. (2)
GOV	Regulation, supervision and participation safeguards	Index, 0–100	Moderator; tier classification
ln EXP	Log of health expenditure per capita	Log units	Control, Eq. (2)
Tier	Strong (GOV ≥ 70); moderate (45–66); weak (< 45)	Categorical	Grouping and tier slopes
Emergency shock	Telehealth deployment surge, 2020–2021	Calendar window	Robustness exclusion

Table 2 presents descriptive statistics. The pooled panel covers a very broad range of maturity (DHMI 8.1 to 92.4) and risk (BRI 9.8 to 52.4), giving enough within-system variance to the fixed effects model. The governance index shows a standard deviation of 20.9 points, equal to the standard deviation of DHMI, thus neither moderating nor regressing variable is restricted. The 2025 Trust Index has an average of 58.0 points with a standard deviation of 12.0 points.

Table 2: Descriptive Statistics of Study Variables (Synthetic Panel)

Variable	N	Mean	SD	Min	Max
DHMI (system-year)	660	46.9	19.6	8.1	92.4
BRI (system-year)	660	26.8	9.7	9.8	52.4
GOV (system)	60	56.8	20.9	14.2	94.1
Trust Index, 2025	60	58.0	12.0	38.6	86.2
ln EXP, 2025	60	5.90	0.80	4.20	7.60

Ethical Considerations and Reproducibility

Since the analysis does not employ any patient-level information, there is no problem regarding ethical clearance for the information involved. In view of the theme, it is essential that the evidence base be transparent; that is why the fact that the panel was synthetically created is mentioned in the abstract, in the method, in the limitations and in the conclusion, and the tables cannot be cited as evidence about actual countries. The panel is constructed using a fixed random seed, and each table and figure is calculated from it; that means that the analysis can be replicated and re-estimated on observed data without changing the specification.

Results and Discussion

Sample Details and Trajectories

Table 3: Sample Composition and Tier Averages

Tier	Systems	Mean GOV	DHMI 2015	DHMI 2025	BRI 2015	BRI 2025	Trust 2025 (SD)
Strong governance	20	81.4	30.1	81.0	17.6	22.1	72.5 (7.5)
Moderate governance	22	54.9	25.4	66.4	23.8	33.9	53.2 (5.1)
Weak governance	18	31.9	16.6	56.4	26.0	41.6	47.7 (4.3)
All systems	**60**	**56.8**	**24.3**	**68.3**	**22.4**	**32.3**	**58.0**

DHMI = Digital Health Maturity Index; BRI = Bioethical Risk Index; GOV = governance safeguard index; all on 0–100 scales. Source: synthetic panel.

Table 3 indicates that there has been substantial digitalisation among all three tiers between 2015 and 2025. DHMI increased by 50.9 points in the strong, 40.9 in the moderate, and 39.7 in the weak. Risk, however, does not go up hand-in-hand with maturity. The BRI increases by 4.5 points in the strong, 10.0 in the moderate, and 15.6 in the weak, hence the most digitally backward tier becomes the one with the most ethical decline. In 2025, trust stands at 72.5 in the strong and 47.7 in the weak, a difference of 24.8 points.

Table 4 translates these differences into rates. One point of maturity growth is linked to 0.088 points of additional risks in robust systems, 0.245 in moderate systems, and 0.393 in weak systems; thus, the difference in endpoints

between weak and strong tiers is estimated at 4.5 times. Fig. 1 is larger than the ratio of the slopes of 3.6 (see table 9 below) since endpoint difference takes into account the common shocks to all countries in a given year, including the increase in 2020. The gap in risks compared to robust systems is larger in both weak and moderate tiers: from 6.2 to 11.8 points in the moderate tier and from 8.4 to 19.5 points in the weak tier. Fig. 1 illustrates this trend visually: weak tier made the least progress in maturity and absorbed the largest part of risk.

Table 4: Decomposition of Change in Maturity and Risk by Governance Tier, 2015–2025

Tier	ΔDHMI	ΔBRI	ΔBRI per DHMI point	BRI gap vs strong, 2015	BRI gap vs strong, 2025	Trust gap vs strong, 2025
Strong	50.9	4.5	0.088	—	—	—
Moderate	40.9	10.0	0.245	6.2	11.8	19.3
Weak	39.7	15.6	0.393	8.4	19.5	24.8

Note: Source: computed from the tier means in the sample composition table. Gaps are tier mean minus strong-tier mean; for trust the gap is strong minus tier mean.

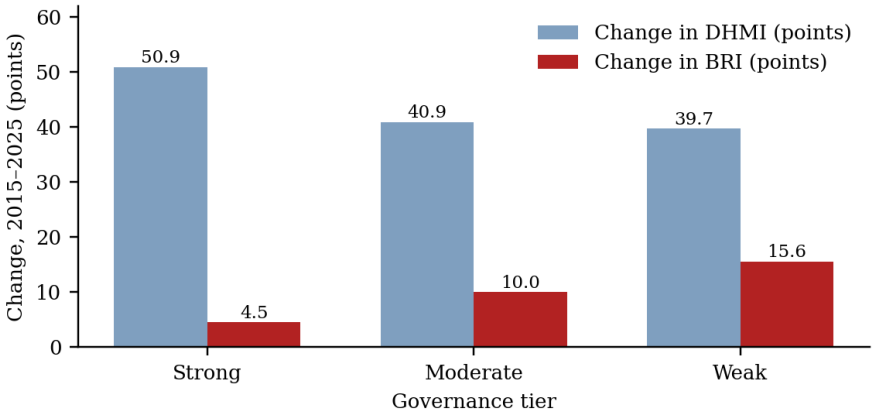


Fig. 1: Change in Digital Maturity and Bioethical Risk by Governance Tier, 2015–2025

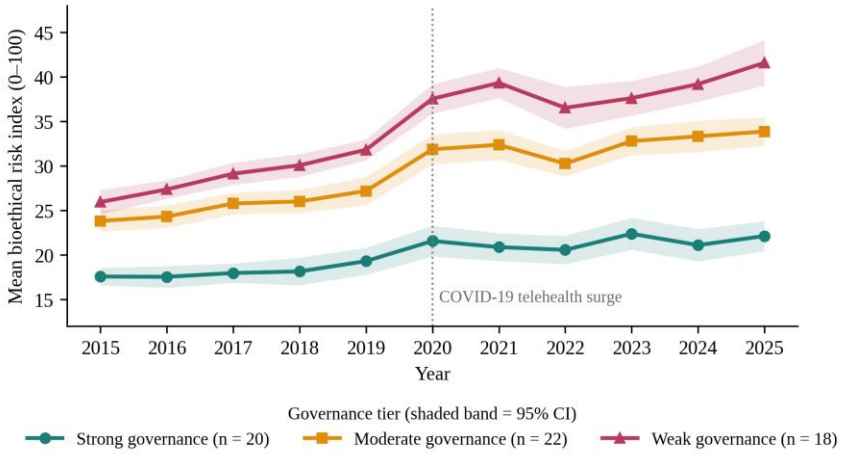


Fig. 2: Bioethical Risk Index by Governance Tier, 2015–2025

Fig. 2 presents the evolution of mean BRI at different governance tiers from 2015 to 2025, where the shaded area represents the 95% confidence interval and the dashed vertical line marks the spike in telehealth services in 2020. Initially, the differences in risk levels between the three tiers of governance are quite comparable; however, the differences become extremely large over time, and the gap between weak and strong governance becomes 8.4 points in 2015 and grows to 19.5 points in 2025. Risk increases in 2019-2020 by 2.3 points in the case of strong governance, 4.7 points in the case of moderate governance, and 5.7 points in the case of weak governance, which means that emergency deployment was almost 2.5 times more harmful in the case of weaker safeguards. While the risk of digital health declines after 2021 in the case of moderate and weak tiers, it increases again later on, while strong governance remains relatively unchanged.

Domain-Level Ethical Exposure

Table 5: Bioethical Risk by Domain and Governance Tier, 2025, Mean (SD)

Domain	Strong	Moderate	Weak	Weak − Strong	p-value (Welch t-test)
Privacy and data governance	18.6 (4.8)	33.7 (4.7)	47.2 (6.1)	28.6	< 0.001
Informed consent and autonomy	18.7 (4.0)	34.9 (4.2)	47.5 (6.1)	28.7	< 0.001
Equity and access (digital divide)	27.6 (4.5)	38.3 (4.5)	45.2 (6.0)	17.6	< 0.001
Algorithmic accountability and bias	25.1 (5.3)	34.6 (5.2)	38.2 (5.9)	13.1	< 0.001
Commercial manipulation and surveillance	22.5 (4.5)	36.0 (4.2)	44.2 (6.5)	21.7	< 0.001
Responsibilisation and clinician–patient trust	20.3 (4.9)	25.7 (4.8)	27.2 (6.4)	6.9	< 0.001

Table 5 dissects the 2025 risk. Privacy and data governance (28.6 points) and informed consent and autonomy (28.7 points) have the largest difference between weak and strong scores. Commercial manipulation and surveillance (21.7) and equity and access (17.6) follow, respectively. This means that the importance of regulation, enforcement, and monitoring is greatest in these areas. Responsibilization and trust in clinicians (6.9 points, $p = 0.001$) have the smallest difference between the two scores, since it is less dependent on regulation and more so on practice and culture. The area of equity and access is important, as it has the highest strong-governance score among all other areas (27.6).

As shown in table 6, privacy and consent comprise 49.1% of the total weak-strong gap of 116.6 domain points, while responsibilisation only makes up 5.9%. In addition, the ratio columns reveal the same ordering pattern – weak systems have about 2.5 times the strong level of risk for privacy and consent but just 1.3 times for responsibilities. The final two columns identify where the gains are made – in algorithmic accountability (9.5 out of 13.1 points) and responsibilisation (5.4 out of 6.9 points), most of the gap is already bridged through moving from weak to moderate governance, and thus the advantage of intermediate governance is highest in those areas. The relationship between weak and strong tiers for privacy and consent is almost linear, with about half of the gap bridged by each level of governance, which suggests that these areas need all the strong safeguards. Fig. 3, the domain level bioethical risks scores for the year 2025 have been calculated for six ethical domains under three types of governance such as strong governance, moderate governance, and weak governance. Weak governance produces high risk scores in all ethical domains, which includes privacy and data, consent and autonomy, equity and access, algorithmic accountability, manipulation, and responsibilisation.

Table 6: Decomposition of the Governance Gap by Ethical Domain, 2025

Domain	Weak − Strong	Share of total gap (%)	Weak / Strong ratio	Moderate − Strong	Weak − Moderate
Privacy and data governance	28.6	24.5	2.54	15.1	13.5
Informed consent and autonomy	28.7	24.6	2.54	16.2	12.6
Equity and access	17.6	15.1	1.64	10.7	6.9
Algorithmic accountability	13.1	11.2	1.52	9.5	3.6
Commercial manipulation	21.7	18.6	1.96	13.5	8.2
Responsibilisation and trust	6.9	5.9	1.34	5.4	1.5
Mean / total	19.4 (116.6)	100.0	1.88	11.7	7.7

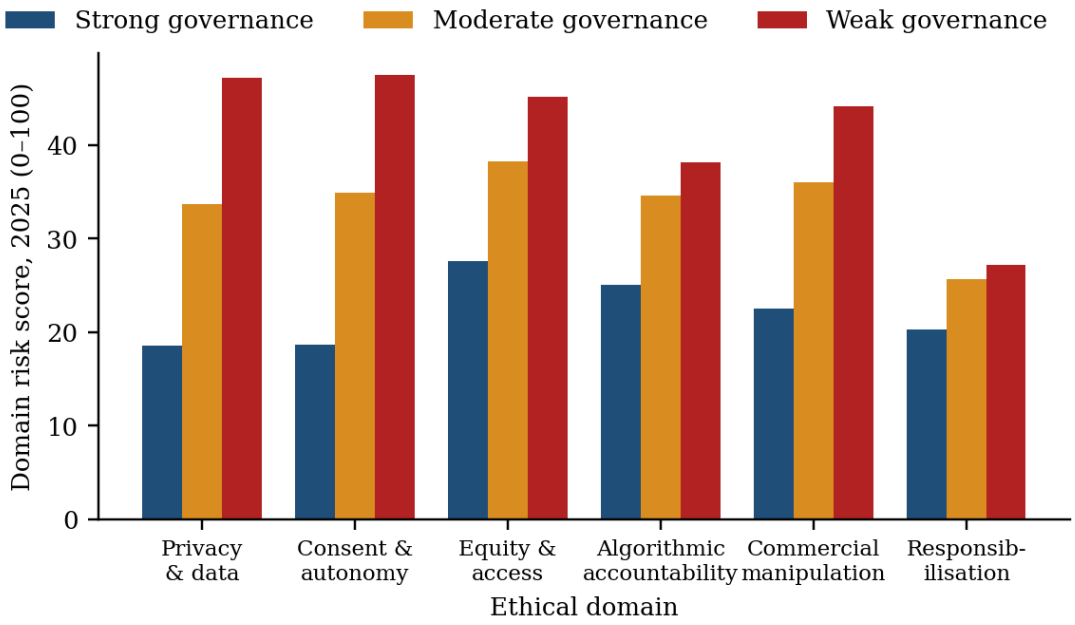


Fig. 3: Domain-Level Bioethical Risk Scores by Governance Tier, 2025

Digital Maturity, Governance and Public Trust

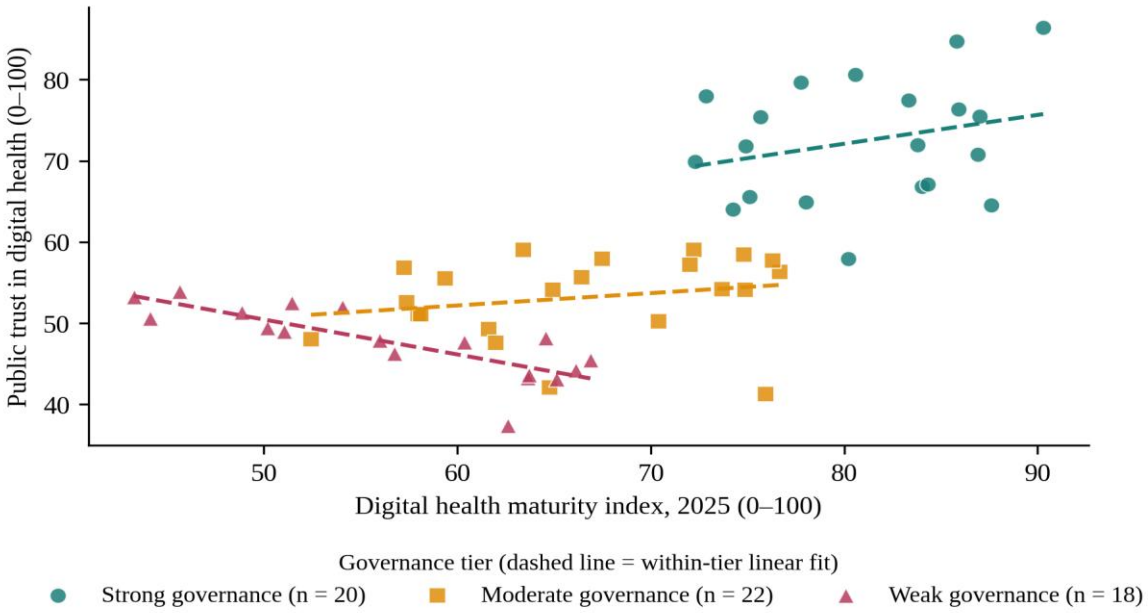


Fig. 4: Digital Health Maturity and Public Trust across 60 Systems, 2025

Fig. 4 illustrates the scatter diagram of 60 systems in 2025. In this figure, the x-axis represents the DHMI, the y-axis represents the Trust Index, the shape and color of the markers denote the governance tier while the dashed lines indicate the within-tier linear fit for each tier. Clearly, the three clouds are distinctively separated vertically, and there is a pooled correlation between maturity and trust at 0.70. Yet, within-tier correlations have different signs, with 0.36 for the strong tier, 0.15 for the moderate tier and −0.43 for the weak tier. In other words, with more mature digital services, higher levels of trust will be observed when safeguards are strong, but constant when moderate, and lower when weak.

Table 7: Determinants of Public Trust, 2025 Cross-Section (Dependent Variable: Trust Index)

Variable	(1)	(2)	(3)
DHMI (centred)	0.687***	0.090	0.099
	(0.091)	(0.102)	(0.066)
GOV (centred)		0.469***	0.443***
		(0.052)	(0.037)
DHMI × GOV (per 10 points)			0.212***
			(0.019)
Log health expenditure			0.870
			(1.579)
Constant	57.963***	57.963***	49.588***
	(1.127)	(0.735)	(8.086)
R-squared	0.483	0.784	0.918
Observations	60	60	60

Note: Heteroskedasticity-robust standard errors in parentheses. *** p < 0.01, ** p < 0.05, * p < 0.10.

This test is provided in table 7. Maturity alone is positively correlated with trust (0.687) and accounts for 48% of variation in the latter in column (1). As governance is included in the regression equation in column (2), the coefficient of maturity drops to 0.090 and becomes statistically insignificant but governance stays significantly positive (0.469). This means that most of correlation observed initially can be explained by the fact that mature institutions are well governed. The interaction term turns out to be statistically significant and positively correlated with trust (0.212), which means that each one extra point of governance increases the marginal effect of maturity on trust by 0.21 at any given level of governance. For a score of governance equal to 85 the coefficient of maturity will be 0.70, for 30 it will be −0.47. Health spending is insignificant, and the value of R-squared increases to 0.918.

Panel Evidence on Risk Escalation

Table 8: System Fixed-Effects Estimates for the Bioethical Risk Index

Variable	(1)	(2)	(3)
Specification	**System FE**	**System + year FE, interaction**	**System + year FE, tier slopes**
DHMI	0.222***	0.237***	
	(0.019)	(0.027)	
DHMI × GOV (per 10 points)		−0.057***	
		(0.002)	
DHMI × Strong governance			0.113***
			(0.031)
DHMI × Moderate governance			0.279***
			(0.037)
DHMI × Weak governance			0.406***
			(0.041)
System fixed effects	Yes	Yes	Yes
Year fixed effects	No	Yes	Yes
R-squared (within)	0.563	0.449	0.407
Observations	660	660	660

Table 8 focuses on the panel. The slope is 0.222 in the first column, indicating that a one-unit increase in DHMI in the same system increases the BRI by 0.222 units. The second column introduces the effect of the year and the effect of the interaction between governance and year, whereby the slope is 0.237 and decreases by 0.057 units for each 10 units increase in the governance level. The third column includes tier-specific slopes where the values are 0.113, 0.279, and 0.406 for strong, moderate, and weak governance levels respectively. The weak-governance slope is 3.6 times that of the strong-governance slope. Over the 39.7 points of maturity increase in weak-governance systems, this implies an increase of 16.1 points of risk, compared to 5.8 points of 50.9 points of increase in strong-governance systems.

Risk at Equivalent Maturity

Table 9: Mean Bioethical Risk at Equivalent Digital Maturity Levels

DHMI band	Governance tier	System-years	Mean BRI
50–60	Strong	38	20.8
50–60	Moderate	55	32.1
50–60	Weak	21	40.8
60–70	Strong	37	20.8
60–70	Moderate	26	34.2
60–70	Weak	11	44.3

Table 9 presents risk at the same level of maturity, eliminating any influence of varying development speeds. Mean BRI values when DHMI values are between 50 and 60 are 20.8 for strong, 32.1 for moderate and 40.8 for weak systems, and 20.8, 34.2 and 44.3, respectively, for levels between 60 and 70. Weak governance systems are hence 2.0 times more risky than strong systems at levels 50-60 and 2.1 times more risky at levels 60-70. The groups passed the maturity level 50 barrier at different times too: 2020 for strong, 2022 for moderate and 2024 for weak groups. Later digitalisers face the challenge of catching up, having the least protection in place, which is consistent with issues of power and usability in digital health equity.

Robustness Checks

Table 10: Robustness of Tier-Specific Risk Slopes (Dependent Variable: BRI)

Slope of DHMI	(1) Baseline	(2) Excl. 2020–21	(3) Excl. 2015–17	(4) DHMI lagged one year
Strong governance	0.113***	0.118***	0.149***	0.083**
	(0.031)	(0.033)	(0.037)	(0.037)
Moderate governance	0.279***	0.281***	0.317***	0.237***
	(0.037)	(0.040)	(0.051)	(0.043)
Weak governance	0.406***	0.406***	0.410***	0.357***
	(0.041)	(0.043)	(0.048)	(0.049)
System and year FE	Yes	Yes	Yes	Yes
R-squared (within)	0.407	0.488	0.278	0.310
Observations	660	540	480	600

Table 10 indicates that the tier-specific slopes are robust. Omitting the surge in 2020-21 reduces the strong, moderate, and weak slopes to 0.118, 0.281, and 0.406, which are very close to the benchmark values, and thus, the findings cannot be attributed to the period of emergency. Omitting the early periods increases the slope values, whereas lagging the DHMI variable by one year reduces them, but the order weak>moderate>strong is found in all the columns. The weak/strong slope ratios vary between 2.7 and 4.3 in the four estimates.

Table 11: Summary of Results by Research Question

RQ	Key finding	Evidence
RQ1	Risk rises with maturity; the slope is steepest under weak governance	Slopes 0.406 / 0.279 / 0.113
RQ2	Privacy and consent show the widest gaps; equity persists under strong governance	Gaps 28.6 and 28.7; strong-tier equity score 27.6 (Table 2)
RQ3	Maturity builds trust only with strong safeguards	Interaction 0.212***

Table 11 summarizes the conclusions drawn from all three experiments conducted. All three together confirm that digital health innovation and bioethical risk do not necessarily clash with each other but their connection depends on institutions. The less regulation, oversight, and involvement there is in some place, the more ethical risk grows with each step forward taken and trust becomes correspondingly lower.

Relation to the Existing Literature

The pattern of findings is compatible with a number of arguments from the literature, despite the fact that, given that it is synthetic data, the findings neither support nor refute any of the claims. The discovery that the level of ethical exposure increases with adoption is compatible with the finding that ethical issues arise due to the widespread adoption of digital health technologies. The dependence of trust on maturity is consistent with the argument that trust is associated with new doctor-patient relations and also with the sociotechnical argument that the ethics of digital health must be considered in light of institutional context. The huge gap in commercial manipulation is related to concerns

about for-profit health applications, while the persisting risk of inequity even in high governance levels is consistent with the idea that digital health equity requires consideration of power and usability along with governance. Finally, the dominance of privacy and consent gaps reflects ongoing public concern about the use of electronic health records.

Interpreting the Results through an Ethical-Domain Framework

Fig. 5 shows how the findings can be summarised in a framework which relates digital innovations to six challenge areas in bioethics and then to consequences, while governance safeguards are the moderating variables evaluated. The innovations listed to the left, such as health applications, digital phenotyping, machine learning-based decision support, digital twins and online communities, are those that have been discussed in the literature. These innovations lead to exposure in the six areas in the middle box, and depending on how well the safeguard variable moderates this process, the result can either be distrust, inequity, autonomy loss and clinical risks, or trust, access, empowerment and safety.

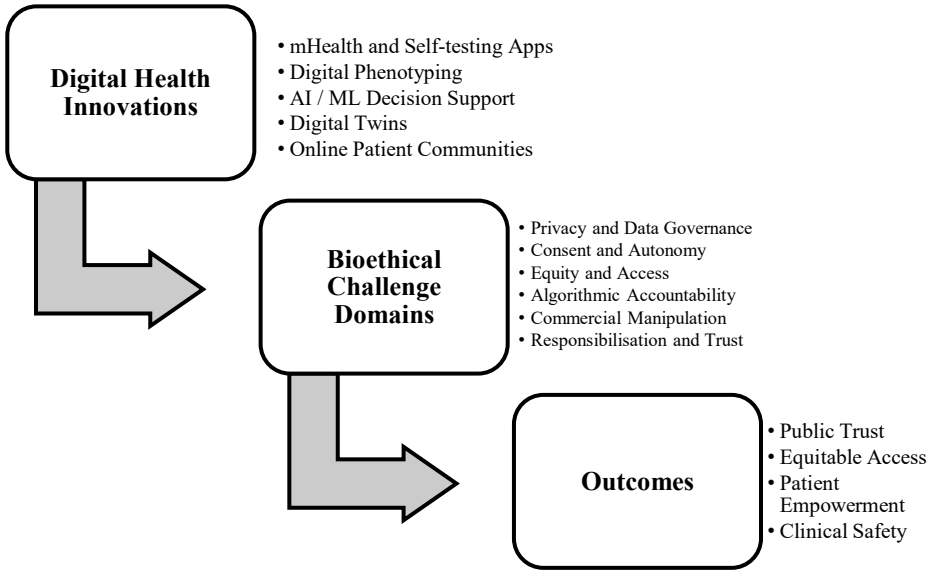


Fig. 5: Ethical-Domain Framework for Emerging Digital Health Systems

Table 12: Mapping of Ethical Domains to Literature and Empirical Signals

Domain	Concern raised in the literature	Empirical signal in this study	Refs.
Privacy and data governance	Trust and attitudes towards uses of electronic health data; surveillance	Widest gap with consent (28.6 points)	Belfrage et al., (2022); Davies, (2021); Maeckelberghe et al., (2023)
Consent and autonomy	Empowerment as a process; personalised digital health; digital phenotyping	Gap of 28.7 points	Kapeller & Loosman, (2023); Mulvenna et al., (2021); Tomičić et al., (2022)
Equity and access	Power, usability and trust; justice; digital health equity framework	Highest domain score under strong governance (27.6)	Kepper et al., (2024); Nickel et al., (2023); Richardson et al., (2022)
Algorithmic accountability	Ethical challenges of machine learning, AI ethics, digital twins	Gap of 13.1 points	Huang et al., (2022); Landau et al., (2022); Murphy et al., (2021)
Commercial manipulation	For-profit apps as manipulative digital environments	Gap of 21.7 points	Sax, (2021)
Responsibilisation and trust	Responsibilisation of individuals; trust in changing doctor–patient relationships	Narrowest gap (6.9 points)	Davies, (2021); Segers & Mertes, (2022)

Each empirical signal in table 12 has a literature equivalent. The domains showing the largest governance gaps – namely privacy and consent – are linked to the concern over data usage and autonomy. The persisting existence of an

equity risk in the presence of strong governance systems reflects the claim that equity requires power and usability and trust and not just regulation. The narrowness of the governance gap for trust and responsibilisation reflects the fact that trust is contingent upon shifting doctor-patient relations and not just regulations.

Implications for Policy and Practice

Data governance and consent need to be considered the primary form of safeguard since these are the areas where there is the greatest need for governance. Oversight of the use of health data, compulsory breach notification, and remedies in case of problems would be more beneficial in low governance contexts than new technology initiatives. Ministries need to prepare an ethics review mechanism for emergencies as well.

Equity impact assessment and clinical governance of algorithmic technologies must be built into procurement and deployment of the tools. Even the most governed systems remain at their greatest risk in matters of equity and access, which means that mere compliance isn't sufficient: testing and offline provision for underserved populations have to be budgeted as part of the service. Clinicians require training to speak about technology, because trust rests upon the quality of the doctor-patient interaction just as much as on governance.

Adoption of privacy by design, bias auditing, and moderation of engagement-driven design should be encouraged in the developer and industry circles. The commercial manipulation gap in table 2 indicates that profit motives are some of the significant drivers of ethical vulnerabilities where there is a lack of oversight, a problem noted in the literature concerning for-profit health applications. Participants like patients and civil society can help in the process through participatory design and community oversight; online communities, for instance, could help in the process of empowering patients and providing avenues for raising red flags. International partners could help in strengthening systems with weak ethical safeguards by capacity building and connecting assistance with minimum governance requirements.

Limitations and Potential Biases

The following limitations can be mentioned. First, the panel itself is artificial, so the magnitudes and the levels of significance obtained should not be interpreted as metrics of actual systems. Second, composite indicators reduce complex ethical phenomena to a single number, while the weight of each of the six domains being equal is a value judgment. Third, there are rather coarse categories of governance and a relatively small number of 60 cases for cross-sectional models. Fourth, causal conclusions cannot be drawn from the cross-sectional analysis of trust, since governance is assumed to be constant over the time period considered. The interpretation of ethical risks as scalar indicators does not take into account any context-specific tradeoffs, like that between privacy and public health surveillance.

Conclusion and Future Directions

The purpose of this paper was to explore how bioethics issues develop over the course of development of new digital health infrastructures, as well as what kind of effect does the development of governance safeguards have on such development. Risk increased with maturity across all domains, although it increased from 17.6 to 22.1 for well-governed systems and from 26.0 to 41.6 for poorly governed ones; the increase per point was 3.6 times higher in the latter case. In well-governed systems privacy and consent were found to be the most vulnerable domains, while equity turned out to be the most stubborn regardless of the governance. Trust develops alongside with the maturity only if the system is well-governed. The takeaway from these findings is that innovation, ethics, and governance need to occur simultaneously rather than in sequence: governance safeguards, equity assessment, and accountable governance need to go hand-in-hand with infrastructure deployment. Future research should rely on actual measures of the panel based on population survey data, audit results, and health event data; consider the perspectives of patients and communities when developing ethical index criteria; investigate other moderating factors such as digital literacy, health finance, and market concentration; and employ long-term or agent-based modeling approaches to follow the interplay between protective and innovative measures. Case studies of particular technologies, including digital twins, digital phenotyping, and machine learning to protect children, could illustrate how the six fields manifest in practice.

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