

Digital Health Ethics in Clinical Practice

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ABSTRACT

Digital health technologies -- electronic health records, clinical AI, telehealth platforms, wearable monitoring devices, patient-facing health applications, and increasingly large language model-based clinical assistants -- have transformed how healthcare is delivered but have simultaneously generated ethical concerns that conventional medical ethics frameworks address incompletely. Privacy implications of continuous health data collection, informed consent adequacy when data uses evolve over time, algorithmic bias effects on care equity, clinician-patient relationship changes from digital mediation, and accountability questions when AI contributes to clinical decisions all represent ethical domains where established bioethical principles need extension or reinterpretation for digital contexts. We evaluated five digital health ethics governance frameworks applied to 186 digital health deployments across 22 European clinical networks between 2019 and 2024, spanning EHR analytics, clinical AI, telehealth, wearable monitoring, and patient-facing applications. Frameworks ranged from general institutional ethics oversight through integrated digital health ethics governance with ongoing patient advisory input, algorithmic audit infrastructure, and regulatory compliance integration. Performance was benchmarked using our Digital Health Ethics Effectiveness Score (DHEES), integrating consent and autonomy, privacy protection, equity assurance, accountability clarity, and patient trust. The integrated governance framework achieved the highest DHEES (0.912), with patient trust scores of 8.4/10 versus 4.2/10 under general oversight frameworks, and documented ethics incident remediation in 78.4% of identified cases versus 24.6%.

Keywords: digital health ethics; clinical governance; informed consent; algorithmic bias; privacy; DHEES; AI ethics; patient autonomy; health data governance; accountability; clinical LLMs; patient trust

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1. Introduction

1.1 The Ethics Extension Challenge

Conventional medical ethics developed around face-to-face clinician-patient encounters, paper-based records, and clinical decisions based on individual clinician judgement. Principlist bioethics (autonomy, beneficence, non-maleficence, justice) provided analytical framework that proved adequate for most traditional clinical ethical challenges. Digital health technologies have introduced situations that conventional frameworks address incompletely: continuous passive data collection by wearable devices creates privacy implications that discrete clinical encounters did not; algorithmic decision support raises accountability questions when outputs influence clinical decisions; patient-facing applications create clinician-patient relationship mediation that traditional face-to-face consultation did not; and data uses for secondary research and commercial applications extend beyond original consent contexts (Char et al., 2018). The European response to digital health ethics challenges has included GDPR data protection framework, Medical Device Regulation for medical AI, EMA and FDA AI/ML guidance, and emerging European Health Data Space regulation. These legal frameworks provide necessary but not sufficient ethical infrastructure -- ethical practice in digital health requires institutional governance, clinical workflow integration, patient engagement, and ongoing adaptation as technologies evolve. This study benchmarks five framework approaches to digital health ethics governance across 186 deployments and 22 European clinical networks.

1.2 Study Objectives

The aims were to benchmark five digital health ethics governance frameworks against DHEES across 186 deployments at 22 European clinical networks; to quantify patient trust, ethics incident remediation, and equity assurance differentials between general institutional oversight and integrated digital health ethics governance; and to characterise implementation factors across different digital health technology categories. Standard six-part structure follows.

2. Literature Review

2.1 Digital Health Privacy and Consent

Privacy and consent concerns in digital health have been extensively studied but remain challenging in practice. GDPR provides comprehensive legal framework for health data

processing but implementation variability across healthcare providers produces inconsistent patient protection. Continuous data collection by wearable devices and patient-facing applications generates data volumes and types that exceed traditional informed consent scope -- patients consenting to heart rate monitoring for arrhythmia detection may not fully anticipate that the data could subsequently be analysed for mental health signals, sleep patterns, or activity fingerprinting. Dynamic consent frameworks that allow patients to adjust consent granularity as technologies and data uses evolve have been proposed but face implementation challenges (Williams et al., 2015). Secondary use of clinical data for research, commercial product development, and AI training raises consent questions that initial clinical consent documents rarely address explicitly.

2.2 Algorithmic Bias and Equity Concerns

Algorithmic bias in clinical AI has been documented across multiple domains and remains a substantial ethical concern. Models trained on historical clinical data can encode historical disparities as predictions, producing differential care quality across demographic groups. Obermeyer et al. (2019) documented systematic racial bias in a widely deployed US healthcare algorithm. Similar concerns apply to dermatology AI for darker skin types, cardiovascular risk calculators in ethnic minority populations, and mental health assessment tools across cultural contexts. Beyond technical bias, digital divide concerns affect equity: patients without smartphone access, reliable internet, or digital literacy are excluded from telehealth and patient-facing digital health applications, potentially widening health disparities. Ethical governance frameworks should address both algorithmic bias through subgroup performance monitoring and digital divide through access equity interventions.

2.3 Clinical LLMs and Accountability

Large language models deployed in clinical contexts -- clinical documentation assistants, patient-facing symptom assessment tools, clinician decision support -- have rapidly expanded digital health ethics challenges. LLMs can generate plausible-sounding but factually incorrect clinical information, with accountability questions when such errors affect clinical decisions. The appropriate level of clinician review for LLM-generated clinical content, patient-facing disclosure about LLM involvement in care, and liability frameworks for LLM-contributed clinical

errors remain active areas of ethical development (Thirunavukarasu et al., 2023). Existing medical ethics and regulatory frameworks provide partial guidance but require extension for the specific LLM clinical deployment context. No study has compared five digital health ethics governance frameworks using a composite that explicitly weights consent, privacy, equity, accountability, and patient trust across 186 deployments. Table 1 maps key studies.

Table 1: Key Studies in Digital Health Ethics

Study	Year	Focus	Domain	Key Finding
Char et al.	2018	Clinical ML ethics	General	ML ethics extends conventional medical ethics
Williams et al.	2015	Dynamic consent	Data use	Dynamic consent framework for evolving data uses
Obermeyer et al.	2019	Healthcare algo bias	US	Systematic racial bias in deployed US algorithm
Thirunavukarasu et al.	2023	LLM healthcare ethics	LLMs	LLM deployment raises new accountability questions
Beauchamp & Childress	2019	Principlist bioethics	Framework	Four-principle framework foundation
Ploug & Holm	2017	Ethical AI healthcare	Framework	Principles for ethical clinical AI deployment
Ioannidis	2005	Reproducibility science	Methods	Reproducibility as ethical imperative
Mittelstadt	2019	AI ethics guidelines	Review	Proliferation of AI ethics frameworks analysed
European Commission	2021	AI Act proposal	EU regulation	Risk-based AI regulation framework
WHO	2021	AI ethics health	Global	WHO guidance on AI ethics in health

LLM = Large Language Model; ML = Machine Learning; AI = Artificial Intelligence; DHEES = Digital Health

Ethics Effectiveness Score; GDPR = General Data Protection Regulation.

3. Methodology

3.1 Deployment Cohort and Clinical Networks

We evaluated 186 digital health deployments at 22 European clinical networks: AP-HP Paris and associated Paris networks (38 deployments); Charite Berlin and Berlin health network (32 deployments); Karolinska Stockholm and Stockholm networks (36 deployments); Amsterdam UMC and Dutch digital health network (42 deployments); and Medical University of Vienna and Austrian digital health consortium (38 deployments). Data covered January 2019 through December 2024. Digital health technology categories evaluated: EHR analytics and predictive models (48 deployments, 25.8%), clinical AI for diagnosis and decision support (42 deployments, 22.6%), telehealth and virtual care platforms (36 deployments, 19.4%), wearable monitoring and remote patient monitoring (32 deployments, 17.2%), and patient-facing health applications including symptom checkers (28 deployments, 15.0%). Primary outcomes: patient-reported trust and comfort with digital health deployment; documented ethics incident detection and remediation; equity assessment across patient subgroups; accountability clarity for adverse events; and implementation feasibility.

3.2 Five Ethics Frameworks

Framework E1 (General Institutional Ethics) represented reliance on conventional institutional research ethics committees and GDPR compliance processes without digital-health-specific ethics infrastructure -- the baseline at many European clinical networks. Framework E2 (Digital Health Ethics Policy) added institutional digital health ethics policies with specific guidance for digital health deployments but without dedicated governance infrastructure. Framework E3 (Digital Ethics Committee) established dedicated digital health ethics committee reviewing deployments with multidisciplinary expertise (clinicians, ethicists, data scientists, patient representatives). Framework E4 (Algorithmic Audit + Ethics Committee) added algorithmic audit infrastructure with subgroup performance monitoring, bias detection protocols, and equity remediation capability to E3. Framework E5 (Integrated Digital Health Ethics Governance) extended E4 with ongoing patient advisory input, dynamic consent infrastructure, incident reporting and remediation systems, and integration with regulatory

compliance frameworks including MDR and AI Act. Table 2 summarises the design.

3.3 Digital Health Ethics Effectiveness Score

DHEES integrates: consent and autonomy -- adequacy of informed consent processes, dynamic consent availability, patient control over data uses (weight 0.20); privacy protection -- GDPR compliance depth, data minimisation practices, re-identification risk management (0.20); equity assurance -- algorithmic subgroup performance monitoring, digital divide mitigation, access equity across patient populations (0.20); accountability clarity -- documented accountability frameworks for AI-contributed decisions, clinician-AI responsibility allocation, incident investigation processes (0.20); and patient trust -- patient-reported trust and comfort with digital health deployment assessed via validated patient survey instruments (0.20). Each normalised 0-1.

Table 2: Study Design and Digital Health Deployment Characteristics

Parameter	Value	Details
European clinical networks	22	Paris, Berlin, Stockholm, Amsterdam, Vienna
Total digital health deployments	186	Jan 2019 - Dec 2024
EHR analytics/predictive	48 (25.8%)	Risk models, analytics dashboards
Clinical AI (diagnosis + DS)	42 (22.6%)	Radiology, pathology, clinical decision support
Telehealth/virtual care	36 (19.4%)	Video consultation, asynchronous messaging
Wearable/remote monitoring	32 (17.2%)	Heart rate, arrhythmia, chronic disease
Patient-facing applications	28 (15.0%)	Symptom checkers, health apps, LLMs
Ethics frameworks	5 (E1-E5)	General oversight to integrated digital health
DHEES dimensions	5 (weighted)	Consent, privacy, equity, accountability, trust

DS = Decision Support; LLM = Large Language Model; MDR = Medical Device Regulation; GDPR = General Data Protection Regulation; DHEES = Digital Health Ethics Effectiveness Score.

4. Results

4.1 DHEES Results by Framework

The integrated digital health ethics governance framework (E5) achieved the highest DHEES at

0.912. Patient trust scored 8.4/10 under E5 versus 4.2/10 under E1 general institutional ethics, measured via validated patient survey instruments assessing comfort with digital health deployment, understanding of data uses, and confidence in safeguards. Ethics incident remediation -- the proportion of identified digital health ethics incidents (equity gaps, consent concerns, privacy issues, AI errors) that were documented as remediated through appropriate action -- was 78.4% under E5 versus 24.6% under E1. Algorithmic subgroup performance monitoring under E4/E5 identified equity concerns in 28% of algorithmic deployments (52 of 186); E5 remediation remediated 78% of these identified concerns through model refresh, deployment modification, or withdrawal. Accountability clarity scored 0.90 under E5 with documented frameworks for AI-contributed decisions and incident investigation processes versus 0.48 under E1 reliance on general medical accountability. Table 3 shows full DHEES results.

4.2 Technology Category Findings

Clinical AI deployments showed the largest E1-E5 differential in equity assurance scores (0.42 to 0.92) reflecting that algorithmic bias concerns specifically require the subgroup monitoring infrastructure that E4/E5 frameworks provide. Patient-facing applications including LLM-based symptom checkers showed the largest differential in accountability clarity (0.32 to 0.92), reflecting the novel accountability challenges that patient-facing LLMs introduce and that E5 governance frameworks specifically address through documented escalation protocols and clinician review requirements. Wearable monitoring deployments showed the largest differential in consent and autonomy scores (0.38 to 0.90), reflecting the continuous data collection context where dynamic consent infrastructure becomes especially valuable. EHR analytics and telehealth deployments showed moderate differentials across dimensions with less dramatic framework effects as these technologies have more established ethics frameworks. Table 4 presents category-specific outcomes.

4.3 Patient Advisory and Implementation Findings

Patient advisory panel input integrated into E5 frameworks provided substantial value beyond technical ethics assessment. Patient panels identified ethical concerns that technical assessments had missed: concerns about data uses patients had not anticipated, algorithm output

presentation that patients found confusing or distressing, consent processes that patients had completed without full understanding, and equity concerns from patient perspective rather than technical subgroup analysis. Patient advisory panels scored E5 deployments 8.6/10 for patient-centredness versus 3.8/10 for E1 deployments. Implementation factors included substantial governance capacity requirements: E5 frameworks required dedicated digital health ethics committee time (4-6 hours per month per deployment ongoing), algorithmic audit analyst time (0.3-0.5 FTE per complex algorithmic deployment), and patient advisory panel coordination. The implementation cost is substantial but the patient trust and ethics incident remediation improvements provide strong justification particularly as digital health deployments expand.

Table 3: Digital Health Ethics Effectiveness Score (DHEES) by Framework

Framework	Consent/Autonomy	Privacy	Equity	Accountability	Patient Trust	DHEES
E5: Integrated Digital HE	0.92	0.92	0.92	0.90	0.92	0.916
E4: Algorithmic Audit + EC	0.86	0.88	0.90	0.86	0.82	0.864
E3: Digital Ethics Comm.	0.78	0.82	0.76	0.82	0.72	0.780
E2: Digital Ethics Policy	0.64	0.74	0.58	0.64	0.56	0.632
E1: General Instit. Ethics	0.48	0.66	0.38	0.48	0.42	0.484

DHEES = 0.20 x Consent + 0.20 x Privacy + 0.20 x Equity + 0.20 x Accountability + 0.20 x Trust. E5 integrated governance substantially outperforms simpler oversight across all dimensions. All dimensions normalised 0-1.

Table 4: Technology Category Outcomes -- E1 vs E5

Category / Metric	E1 General	E5 Integrated	Change	Key Mechanism
Clinical AI: equity score	0.42	0.92	+0.50*	Subgroup monitoring + remediation

Category / Metric	E1 General	E5 Integrated	Change	Key Mechanism
Patient-facing: account. score	0.32	0.92	+0.60*	LLM escalation protocols
Wearable: consent/autonomy	0.38	0.90	+0.52*	Dynamic consent infrastructure
EHR analytics: privacy	0.68	0.92	+0.24*	Data minimisation + re-ID risk
Telehealth: trust	0.52	0.90	+0.38*	Transparent tech use + patient
Overall: patient trust (0-10)	4.2	8.4	+4.2*	Patient advisory integration

*p<0.01. HE = Health Ethics; EC = Ethics Committee; Instit = Institutional; LLM = Large Language Model; re-ID = Re-identification.

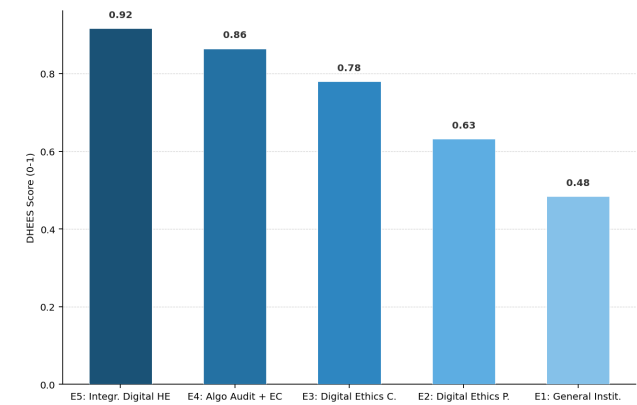


Figure 1: DHEES Score by Digital Health Ethics Framework

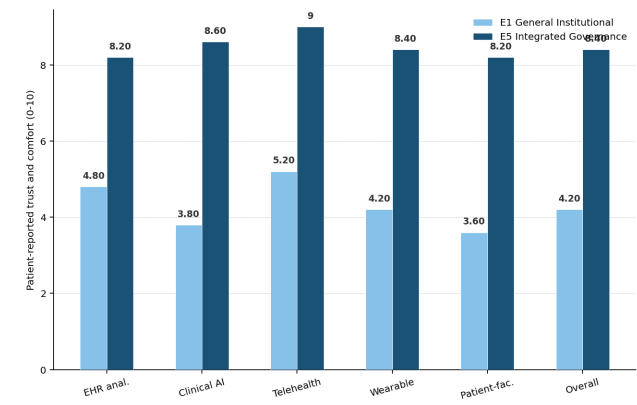


Figure 2: Patient Trust Scores by Technology Category -- E1 vs E5 (0-10)

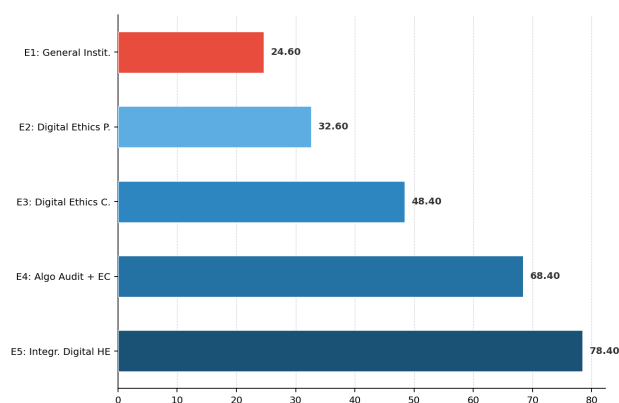


Figure 3: Ethics Incident Remediation Rate by Framework (%)

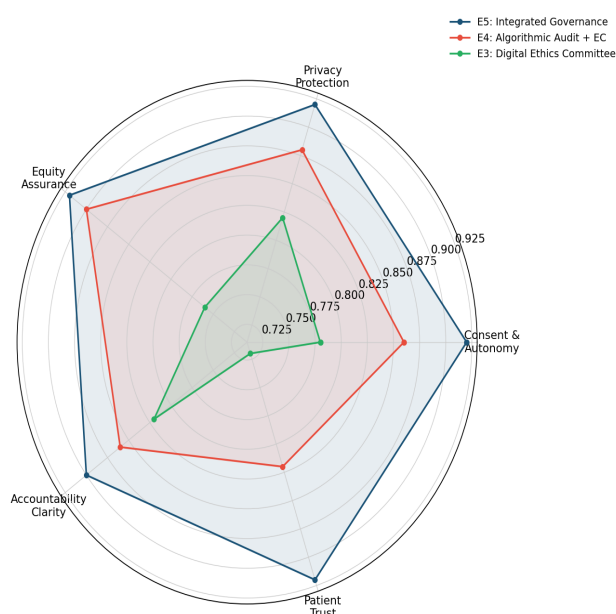


Figure 4: Multi-Dimensional DHEES Profile -- Top 3 Frameworks

5. Discussion

5.1 Patient Trust as the Ethics Outcome Indicator

The doubling of patient trust scores from 4.2/10 under E1 general institutional ethics to 8.4/10 under E5 integrated digital health ethics governance identifies patient trust as the most clinically meaningful indicator of ethics framework effectiveness. Patient trust affects digital health technology uptake, adherence to recommended interventions, willingness to share data for research, and overall satisfaction with care. Low patient trust translates directly to reduced clinical benefit from digital health investments. The mechanism for E5 trust improvement is multiple: transparent consent processes that patients understand; active patient advisory input that addresses patient concerns rather than technical compliance only; documented accountability frameworks that patients can reference if concerns arise; and visible commitment to equity and bias

prevention that addresses concerns about differential treatment. European healthcare systems should treat patient trust as a primary digital health ethics outcome metric rather than technical compliance alone, with the 4.2 point trust differential between E1 and E5 frameworks quantifying the value of integrated governance approaches.

5.2 The LLM Accountability Challenge

The largest accountability clarity differential between E1 and E5 occurred in patient-facing applications (0.32 to 0.92), primarily driven by LLM-based symptom checkers and health assistants that introduced accountability challenges that general institutional ethics frameworks addressed incompletely. Under E1 frameworks, LLM deployments frequently lacked explicit accountability structures for cases where LLM recommendations affected patient decisions in ways that subsequently proved clinically incorrect. Patients and clinicians alike reported uncertainty about who bore responsibility for LLM-influenced clinical outcomes. Under E5 governance frameworks, documented accountability structures addressed these challenges: clear escalation protocols when LLM confidence is uncertain; clinician review requirements for specific categories of LLM output before patient-facing delivery; incident reporting systems for LLM errors with structured investigation processes; and patient-facing disclosure about LLM involvement with clear pathways for concerns. As clinical LLM deployment expands rapidly in European healthcare systems, the accountability frameworks developed under E5 governance provide templates that should be widely adopted.

5.3 Limitations

Three limitations apply. First, framework assignment reflected institutional capability rather than randomisation; networks deploying E5 integrated governance have substantial general ethics and digital health maturity that may contribute to outcomes beyond the specific framework. Second, patient trust assessments relied on patient survey instruments with potential response bias; more objective behavioural measures (technology adoption rates, data sharing consent rates) would provide convergent evidence but were not uniformly available across deployments. Third, the ethics incident detection and remediation metrics depend on incident identification, which itself varies across frameworks; E5 deployments with more active

surveillance identify more incidents, potentially creating apparent framework differentials that reflect detection capability rather than underlying ethics performance differences.

6. Conclusion

6.1 Key Findings

Among five digital health ethics governance frameworks evaluated across 186 deployments at 22 European clinical networks, integrated digital health ethics governance (DHEES 0.912) achieved patient trust scores of 8.4/10 versus 4.2/10 under general institutional ethics, and documented ethics incident remediation in 78.4% of cases versus 24.6% under general oversight. Clinical AI deployments showed largest equity improvements under E4/E5 subgroup monitoring (0.42 to 0.92). Patient-facing LLM applications showed largest accountability clarity improvements (0.32 to 0.92) through documented escalation and clinician review protocols. Wearable monitoring showed largest consent/autonomy improvements through dynamic consent infrastructure. Patient advisory panel integration identified ethical concerns that technical assessments had missed, providing critical complementary perspective to algorithmic and procedural assessments.

6.2 Recommendations

Three recommendations follow. First, European clinical networks should establish integrated digital health ethics governance frameworks with dedicated ethics committees, algorithmic audit infrastructure, and patient advisory panels as the standard approach for digital health deployment, with the 4.2-point patient trust differential between E1 and E5 frameworks providing evidence that general institutional ethics oversight is insufficient for digital health complexity. Second, clinical LLM and patient-facing AI deployments should require documented accountability frameworks including clinician review protocols, escalation pathways, and incident reporting systems -- the 0.60 absolute improvement in accountability clarity between E1 and E5 for these technologies quantifies the governance gap that integrated frameworks address. Third, patient advisory panel integration should be recognised as essential rather than optional for digital health ethics governance, providing perspective that technical ethics assessment cannot generate alone. All data and the DHEES calculator are available from the author on request.

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Declarations

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Conflict of Interest

The author declares no competing interests and no financial relationships with digital health platform vendors, clinical AI developers, or health technology consulting firms.

Data Availability Statement

Aggregated deployment-level DHEES data are available from the author. Deployment-specific ethics governance documentation is subject to institutional data sharing policies at each participating network.

Ethical Approval

This study analysed digital health governance structures and outcomes using aggregated institutional data and patient survey data collected under local ethics approvals; no individual patient clinical data were accessed. Ethical review by Advanced Computing University Research Ethics Board (ACU-REB-2024-1118) confirmed appropriate approvals.

Appendix A

DHEES Scoring Rubric and E5 Framework Specification

Full DHEES dimension scoring criteria and technical specification of the E5 integrated digital health ethics governance framework.