SIIM CAIMI26 Conference on Artificial Intelligence in Medical Imaging
OCT 26-27 | University of Pennsylvania, Philadelphia, PA

Global Data Governance and Equitable Innovation in Medical Imaging AI: A Comparative Legal Analysis

Lars Lindgren, JD, Perelman School of Medicine, University of Pennsylvania; Shawn Lyo, MD
Tessa Cook, MD, PhD, CIIP, FSIIM; Abass Noor, MD

Introduction/Background
Diverse datasets are essential for medical imaging models that perform reliably across populations, yet privacy regulations limit the data sharing needed to build them. This study characterizes the regulatory landscape surrounding cross-border health data sharing across six jurisdictions, evaluates barriers that limit equitable AI/ML model development in radiology, and identifies regulatory and technical solutions that improve global data collaboration.

Methods/Intervention
A comparative legal analysis was performed across six jurisdictions representing distinct regulatory frameworks: the United States (HIPAA), Germany (GDPR/BDSG), China (PIPL/CSL/DSL), Brazil (LGPD), Nigeria (NDPA), and Botswana (DPA). Primary texts, administrative guidance, and secondary literature were reviewed across five domains: health data classification, restrictions on data processing, cross-border transfer requirements, data subject rights, and AI/ML-specific regulation.

Results/Outcome
Substantial regulatory heterogeneity was observed across the six jurisdictions. Health data classification criteria, lawful processing bases, cross-border transfer limitations, and data subject right protections differed meaningfully, generating stacking compliance obligations for prospective data aggregation initiatives. Four recurring barriers were identified: (1) variable de-identification standards that impede standardized data sharing; (2) unresolved implications of data subject rights, particularly the right to erasure, that present untested legal and technical challenges; (3) increasingly stringent AI regulation that further complicates compliance obligations; and (4) a lack of tested health data guidance from early-stage regulatory frameworks such as Nigeria's NDPA and Botswana's DPA. Partial solutions can be found in federated learning and international data-sharing agreements, but unresolved legal and technical challenges, especially around data subject rights and machine unlearning, are likely to persist.

Conclusion
Fragmented international data privacy frameworks impose compounding barriers to the cross-border data sharing necessary for diverse, representative AI/ML training datasets in radiology. Low-resource settings with the most to gain from innovation in radiology risk continued underrepresentation and exclusion from model development. International regulatory harmonization and official guidance on federated learning and machine unlearning are critical next steps.

Statement of Impact

Heterogeneous international health data privacy laws restrict global data sharing and limit the data diversity and generalizability of AI/ML models, disproportionately disadvantaging low-resource settings. Regulatory clarity and purposeful alignment are essential for equitable AI/ML innovation and implementation in radiology.

Country	Primary Regulation	De-Identification	Transfer Mechanisms	Key Data Subject Rights	Approach to Data Regulation	Key Barriers to Data Collaboration
United States	HIPAA	De-identified data is exempt (Safe Harbor or Expert Determination)	Largely unrestricted, transfer to "countries of concern" is restricted	Access and amendment	Sector-specific, risk-management, harm-based	"Countries of concern" restrictions, deregulation trends
Germany	GDPR, BDSG	Anonymized data is exempt (case-by-case); pseudonymized data is regulated	Adequacy, approved transfer instruments, or derogations; EHDS enables sharing across member states	Consent withdrawal and deletion	Rights-based	Strict enforcement of rights has uncertain consequences for trained models
China	CSL, DSL, PIPL	Anonymized data is exempt (national technical standards recommended); de-identified data is regulated	Government security assessments and contractual agreements	Consent withdrawal and deletion	Security and national sovereignty	Onerous transfer approvals; government audits and ongoing reassessment
Brazil	LGPD	Anonymized data is exempt (case-by-case, guidance pending); pseudonymized data is regulated	Adequacy (EU only), approved transfer instruments, or derogations	Consent withdrawal and deletion	Rights-based, maturing framework	Consent-free research route excludes commercial/foreign entities; bar on third-party transfer for public health research unsettled in adjacent domains
Nigeria	NDPA	Regulation depends on identifiability; de-identification is undefined and untested	Adequacy (no binding decisions currently), approved transfer instruments, or derogations	Consent withdrawal and deletion	Emerging, largely untested	De-identification undefined, no binding adequacy decisions
Botswana	DPA	Regulation depends on identifiability; de-identification is undefined and untested	Adequacy, approved transfer instruments, or derogations	Consent withdrawal and deletion	Emerging, largely untested	De-identification undefined, data localization and uncertain information technology infrastructure demands

Table 1. Comparison of key regulatory characteristics and barriers across six jurisdictions. HIPAA = Health Insurance Portability and Accountability Act; GDPR = General Data Protection Regulation; BDSG = Bundesdatenschutzgesetz (Federal Data Protection Act); EHDS = European Health Data Space; CSL = Cybersecurity Law; DSL = Data Security Law; PIPL = Personal Information Protection Law; LGPD = Lei Geral de Proteção de Dados (General Data Protection Law); NDPA = Nigeria Data Protection Act; DPA = Data Protection Act.

Keywords

Model Development; Regulation; Data Privacy; International Law; Global Health; Equity