Advancing governance for digital transformation in health: insights from Georgia's experience

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ABSTRACT

Enhancing digital health governance is critical to healthcare systems in low-income and middle-income countries. However, implementing governance-enhancing reforms in these countries is often challenging due to the multiplicity of external players and insufficient operational guidance that is accessible. Using data from desktop research, in-depth interviews, focus group discussions and three stakeholder workshops, this paper aims to provide insights into Georgia's experience in advancing digital health governance reforms. It reveals how Georgia has progressed on this path by unpacking the general term 'governance' into operational domains, where stakeholders and involved institutions could easily relate their institutional and personal roles and responsibilities with the specific function needed for digital health. Based on this work, the country delineated institutional responsibilities and passed the necessary regulations to establish better governance arrangements for digital health. The Georgia experience provides practical insights into the challenges faced and solutions found for advancing digital health governance in a middle-income country setting. The paper highlights the usefulness of operational definitions for the digital health governance domains that helped (a) increase awareness among stakeholders about the identified domains and their meaning, (b) discuss possible governance and institutional arrangements relevant to a country context, and (c) design the digital health governance architecture that the government decreed. Finally, the paper offers a broad description of domains in which the governance arrangements could be considered and used for other settings where relevant. The paper points to the need for a comprehensive taxonomy for governance domains to better guide digital health governance enhancements in low-middle-income country settings.

INTRODUCTION

One strategic objective of the WHO's Global Strategy for Digital Health is to strengthen digital health governance at national levels. This objective proposes that countries strengthen digital health governance by leveraging existing structures and creating robust governance arrangements, including regulatory frameworks and the capacity to

SUMMARY BOX

⇒ Proper governance arrangements for digital health systems are needed to facilitate developments and seize the value of digital health data.
⇒ While enhancing governance for digital health is strongly advocated internationally, more clarity and guidance on what this means in practical terms and on how to implement/operationalise it on a country level are needed.
⇒ Georgia's experience reveals governance domains and their functional elaboration, which helped engage stakeholders and identify national institutions/organisations ascribed to carry out the specific tasks under each domain.
⇒ While Georgia's experience could help other countries enhance digital health governance, a collaborative effort of a multicountry, multidisciplinary research network is needed to elaborate a comprehensive taxonomy for the functional domains of governance.

implement evidence-based digital health solutions.[1] While WHO advocates for enhanced governance, current guidance on how this has to be operationalised at a country level is rather general, lacking the operational details that countries need, particularly in low-income and middle-income countries (LMICs).[2–4] Therefore, this paper focuses on learning how WHO's guidance on enhancing digital health governance can be operationalised before global guidance emerges.

We use WHO's definition of digital health, which is 'the field of knowledge and practice associated with developing and using digital technologies to improve health… The following areas are commonly understood as part of or related to digital health: artificial intelligence (AI), big data, blockchain, health data, health information systems, the infodemic, the internet of things, interoperability and telemedicine'.[5] Consequently, digital health encompasses integrating digital technology and data into all areas of life and health. It involves changes and advancements

brought by this integration, significantly impacting how we live and work.[6] Digital health requires governance grounded in core Health for All values of democracy, equity, solidarity, inclusion and human rights. This will help ensure digital technologies enable health benefits, improve universal coverage and access to quality health services, and effectively prevent and manage public health crises.[2]

The digital transformation in the healthcare of LMICs heralds a great promise. It could help improve service delivery quality and health outcomes. Yet, this promise has been harmed by systemic inefficiencies and numerous misalignments. Namely, decades of investment in multiple donor-funded projects focused on singular health issues without aligning with (or without) a broader digital health development strategy has often resulted in isolated and/or siloed information systems and frequently caused investment waste.[7] The fragmented nature of these digital systems poses a significant barrier to capitalising on the transformative potential of digital health data due to a pervasive need for interoperability. Such systemic isolation hinders the holistic management of health services and impedes the strategic pooling of data critical for advanced analytics.[8–10] Moreover, the proliferation of multiple stand-alone isolated systems, data collected that is not used and the increasing administrative burden at the health facility level demand more streamlined and holistic approaches to planning and managing digital health transformation.[11–13]

Compounding this issue is the inadequate focus on cybersecurity and data privacy, which are foundational to the integrity and trustworthiness of digital health data. As LMICs begin to explore the burgeoning field of AI—with its vast potential to leverage digital data for predictive analytics and tailored health interventions[12 14 15]—these inadequacies in data protection amplify the risk to patients and undermine trust. Moreover, the inability to interoperate within the digital ecosystem severely limits the possible benefits of AI for public health.[10 15] Thus, the challenges for developing digital health systems of the future are numerous, but their weak governance lies at the nexus of these challenges.[1 16]

There is a need to transition from the landscape characterised by predominantly project-driven, externally financed and isolated initiatives towards sustainable, integrated digital health systems that are locally owned and managed.[3] For this to happen, a more practical, actionable approach to establishing and institutionalising digital health governance arrangements informed by the evidence emerging from the literature and experiences of other settings is needed.

Confronted with Georgia's weak digital health governance, we sought practical solutions. Our work focused on advancing the governance arrangements by regulating institutions in the digital health ecosystem. This practice paper elucidates our experience of seeking digital governance solutions in a middle-income country—Georgia, with a setting that features similarities with the global digital health landscape for developing countries. By describing the operationalisation of the governance mechanisms in this country, we aim to contribute actionable insights to inform and support governance enhancement for digital health in LMICs.

METHODS
The study combined qualitative methods with participatory research[17] to develop this practice paper. The desk research focused on two domains: (a) the study of country-specific papers (including grey literature) looking at national information systems and (b) a purposeful search of international peer-reviewed journals for articles on governance functions in digital health or reform experiences, using previously recommended search terms.[3]

Desk research was complemented with in-depth interviews (IDIs) and focus group discussions (FGDs). On securing written informed consent, IDIs were conducted with purposefully selected individuals representing providers, technical and expert institutions, the policy-making field and patients. Similar groups were involved in FGDs to validate the findings.

Three stakeholder workshops were conducted to present documented weaknesses of Georgia's digital governance arrangements and system deficiencies, share evidence and experiences emerging from the literature and develop solutions for Georgia, described later in this paper, with the help of the cocreation workshop.[18]

CHALLENGES OF GEORGIA
Recent assessments of the digital health system of Georgia carried out by WHO and the Asian Development Bank revealed numerous weaknesses (similar to many LMICs) along with some significant strengths. They include a lack of patient-centricity and provider medical needs consideration in data collection modules, where managerial imperatives prevail; an absence of feedback loops to providers to support improvements in quality of care; the existence of about 90 siloed digital modules with little integration or interoperability; focus on data collection versus analysis, largely reinforced by limited integration across the data modules and constrained by data access limitations; multiple and often duplicated data entries negatively affecting data quality, limited data quality assurance and data protection mechanisms, imposing a significant burden on healthcare providers with 'useless' data collection requirements, and inadequate data use for public health and policy-making. The greatest importance is placed on meeting management needs in data collection versus meeting patients', providers' or public health needs.[19] Thus, Georgia ended up in a similar place, with challenges similar to those faced in many developing countries.[7] While this is not an exhaustive list of challenges, it is sufficient to reveal the need for a call to action. Finally, the system evolved with inadequate regulations because regulatory frameworks face challenges in

keeping up with the rapidly evolving digital transformation. Consequently, Georgia lacks necessary regulations and requirements for data or exchange standards, and critical registries necessary for a digital system are either missing or not adequately developed; service quality monitoring regulations are also missing, to name a few other regulatory shortcomings.[20]

Several factors explain the noted challenges, and they include (1) a lack of appropriate governance arrangements compounded by weak (or lack of) coordination across entities involved in digital health, (2) unclear roles and responsibilities concerning functions essential for adequate governance, (3) inadequate legal and regulatory framework governing data collection, storage, exchange, access and use of personal health data for primary and secondary processing and (4) lack of adequately trained human and shortage of financial resources, hampering further development necessary for the system. This paper will reveal how aspects under (1) and (2) were addressed in Georgia.

SEARCH FOR SOLUTIONS

In general, digital health governance involves establishing and deploying authority in political, administrative and technical spheres to oversee the entirety of a digital health information system within all sectors of a nation's health framework.[21] This governance structure includes a variety of methods, procedures and organisations through which stakeholders express their interests, perform their legal responsibilities and monitor the information system's functionality.[22] To operationalise the governance arrangements in Georgia, we embarked on a four-step process.

Identified digital health governance domains

First, with the help of a literature review, we identified the list of domains that collectively could be termed as governance domains for digital health. The identified list is detailed in figure 1; while for some settings, this list may not be exhaustive, indeed, for Georgia, it served the purpose. Unfortunately, there is no global agreement on this list, which would have been highly instrumental, but based on the literature review, the team created this list and used it for the next steps described later.

Next, we tried to find a description of each domain to understand better the specific functional areas they embody.

Domain for formulating policy and strategic plans usually assigned to the Ministry of Health (MoH), entails creating clear, actionable policies that outline digital health goals, principles and standards within a healthcare system or organisation.[3] These policies set the foundation for decision-making, prioritising initiatives, guiding the ethical use of digital health data and technologies, and developing strategic plans that detail the objectives, strategies and actions required to achieve the digital health vision. This includes identifying key digital health initiatives, setting timelines, allocating resources and defining metrics for evaluating progress. This domain also entails establishing a regulatory framework supporting digital health policies and strategic plans. It includes creating regulations for data privacy and security, standards for interoperability and guidelines for the ethical use of digital technologies in healthcare.

Health information security and privacy is primarily concerned with safeguarding patient data privacy and ensuring the protection required by national laws. This includes establishing data privacy, security standards, patient consent procedures and security requirements for interoperability to ensure that digital systems can communicate and exchange information securely and efficiently across different healthcare providers and settings without infringing on individual rights.[2 23 24]

Figure 1 Digital Health Governance Domains.

Patient summary, according to the available literature,[14 25–27] a patient summary (also frequently called an electronic health record) is a means to exchange digital information about the patient's health and care that is provided primarily between providers, including, if necessary, across borders and importantly with the patient her/himself. The current version of patient summaries encompasses several mandatory, recommended and optional components.[26] Therefore, it seems important to define which elements to mandate in the patient summary, which obviously would need to be exchanged and, subsequently, how data for each component have to be collected per government-established data standards and shared. Several possibilities exist for making these decisions. For example, to adopt 'Business Requirements for Health Summary Records,' described in ISO/TR 12773-1:2009, which provides a framework to support the effective use of health summary records in various healthcare settings, or alternatively, to refer to European Commission Guidelines.[27] In any case, patient summary development requires determining which national authorities are tasked to define mandatory elements of the patient summary and the data standards to be used, such as, for example, International Classification for Diseases codes for recording diagnosis, or Systemized Nomenclature of Medicine–Clinical Terms for standardising a core set of clinical terminology used in digital health records, or International Classification of Health Interventions that can be used as a tool for collecting information on what services is being provided to a patient by various providers of the healthcare system, or the ISO Identification of Medicinal Products for standardising medicinal products prescribed to a patient, etc. Due to the broad diversity of the listed standards that require different expertise, knowledge and skills, the organisations responsible for the standard setting are expected to be different. Therefore, charging one entity with standard-setting responsibility seemed not feasible, and it was recommended that the roles and responsibilities be ascribed and delineated, depending on organisational mandates and capacity/expertise.

Health information exchange and interoperability standards require a designated institutional authority. Several standards exist, which were included in the workshop materials for government consideration, and they included Consolidated Clinical Document Architecture standards that provide a framework for creating electronic clinical documents, allowing the capture, storage and exchange of structured and unstructured information. Health Level Seven is a set of international standards that allows the transmission and sharing of data between various healthcare providers and healthcare systems. Also, the Fast Healthcare Interoperability Resources (FHIR) standard enables the electronic transmission of healthcare information across modern web-based exchanges. In recent years, FHIR has gained significant traction and is widely adopted for patient access to medical records, interoperability initiatives and healthcare application

development. Under proper governance arrangements, defining a national entity responsible for deciding and regulating which standards to use and how they must be enforced in a marketplace where both public and private actors operate seemed critical.

Telehealth and remote monitoring are critical components of digital health that leverage technology to provide healthcare services and monitor patients' health status from a distance. In digital health governance, these elements require a comprehensive framework to ensure they are used effectively, ethically and securely. Without adequate security and privacy protections for underlying telehealth data and systems, providers and patients will lack trust in the use of telehealth solutions.[28 29] Furthermore, the COVID-19 pandemic has highlighted the importance of regulating payments for telehealth services that would be required to broaden the availability and access to these services.[29] Thus, entities under the MoH are required to elaborate and develop the regulatory requirements addressing these important aspects covered under this domain,

Infrastructure and connectivity should either be the responsibility of a single entity or be a collaborative effort among various public and/or private stakeholders, necessitating clear designation and coordination.

Finally, health analytics and insights need a clear definition of the data access rules. Therefore, identifying entities authorised to grant these access rights to state institutions, universities or research entities, civil society, etc, seemed necessary to ensure that collected data delivers value to patients, providers, policy-makers and society. Such clarity would guarantee that health analytics and insights from the data are effectively used primarily during care provision to a patient and then in decision-making and serve the nation's best interests.

Ascribing the institutions to governance domains

After identifying and defining the domains, we mapped the institutions under the MoH that are (or should be) involved in digital health governance to the identified functions. This entailed a detailed review of the institutional bylaws to understand the mandates assigned to each entity under the national legislation. Next, we looked at how these mandates align (or do not) with the identified domains. This mapping exercise was instrumental in uncovering gaps, duplications and/or inconsistencies, or instances of inadequately defined roles and responsibilities in the bylaws.

The insights gained from the literature review and institutional mapping were then used as inputs in cocreation workshops. Through these workshops, conducted in an inclusive and participatory manner, we determined or refined the responsibilities of specific institutions within the identified governance domain. We also discussed how coordination among these entities should be structured to ensure efficient governance in the future. The discussions and agreement on the role definition and distribution across the entities under the MoH were eventually

embodied in a ministerial decree (a regulatory act within Georgia's legal system).

Regarding institutional arrangements for digital governance, Georgia, guided by the Broadband Commission for Sustainable Development[30] and national legislation, positioned digital health governance within the MoH rather than opting for a separate digital agency. This led to the formation of a steering group within the MoH for a unified digital health strategy. However, this model is not universally applicable, as the best arrangement for each country will depend on its specific laws and needs.

While establishing and clearly delineating institutional roles and responsibilities is a crucial initial step, it alone is insufficient. These institutions must also implement mechanisms and tools to fulfil their roles effectively. This includes designing the data flow and exchange system, developing regulations for setting and enforcing standards with the help of incentives and sanctions, and fostering collaboration and coalition-building within the health sector and with other sectors and external partners. As a next step, adequate governance will also necessitate establishing an accountability framework and structure(s), rules and mechanisms for independent oversight to allow for transparency and scrutiny by political representatives and civil society. Unfortunately, in Georgia, we did not yet succeed in creating such an oversight mechanism requiring a lengthy legislative process. However, these actions could be taken as subsequent steps over the coming years.

CONCLUSIONS

Countries are expected to enhance their digital health governance, but more international guidance is required to do this effectively. Therefore, breaking down the broad concept of digital governance into specific operational domains has proved highly beneficial for Georgia. It allowed stakeholders to grasp their roles, responsibilities and place in the digital ecosystem more clearly, fostering active participation in cocreation discussions, connecting their roles to specific areas and offering pertinent solutions. This approach significantly aided the national consultation process by engaging stakeholders constructively and promoting consensus.

Furthermore, the detailed definitions of governance domains facilitated a targeted search for evidence, illuminating the scope of each area. Despite the challenge of scant published research in this field, the effort in Georgia moved forward under these limitations. It is important to view the identified governance areas not as fixed domains but as starting points for further exploration. Developing a comprehensive taxonomy for governance areas will be instrumental for countries to better address operationalisation challenges, and most likely, this will demand a collaborative effort to pool experiences from various countries and disciplines, suggesting the creation of a multicountry, multidisciplinary research network to delve into best practices of digital health governance and produce practical/operational guidance for states to use.

LIMITATIONS

The paper acknowledges certain limitations. It concentrates on digital health governance, not encompassing the broader governmental and cross-sectoral involvement due to resource and time constraints. Under the MoH, the focus is on the health sector to solidify governance and link with external entities as needed. The study does not assess the outcomes or effectiveness of governance reforms, noting that substantive impacts will be observable after several years and further systemic changes. It details immediate outputs like defining roles and responsibilities, updating regulatory documents and enhancing stakeholder awareness about digital governance. Lastly, it does not evaluate the institutional strength, as decisions were based on existing institutional bylaws and relevant national laws.

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REFERENCES

1. World health organization. Global strategy on digital health 2020-2025. World health organization; 2021. Available: https://apps.who.int/iris/handle/10665/344249
2. WHO Regional Office for Europe. Guidance for health information system governance. guidance for health information system governance. 2021. Available: https://iris.who.int/handle/10665/342572
3. Frost MJ, Tran JB, Khatun F, *et al*. What Does It Take to Be an Effective National Steward of Digital Health Integration for Health Systems Strengthening in Low- and Middle-Income Countries? *Glob Health Sci Pract* 2018;6:S18–28.
4. Mehl G, Labrique A. Prioritizing integrated mHealth strategies for universal health coverage. *Science* 2014;345:1284–7.
5. Digital health EURO. 2023. Available: https://www.who.int/europe/health-topics/digital-health
6. Kickbusch I, Piselli D, Agrawal A, *et al*. The Lancet and Financial Times Commission on governing health futures 2030: growing up in a digital world. *The Lancet* 2021;398:1727–76.
7. Akhlaq A, McKinstry B, Muhammad KB, *et al*. Barriers and facilitators to health information exchange in low- and middle-income country settings: a systematic review. *Health Policy Plan* 2016;31:1310–25.
8. Aerts A, Bogdan-Martin D. Leveraging data and AI to deliver on the promise of digital health. *Int J Med Inform* 2021;150:104456.
9. Hall CS, Fottrell E, Wilkinson S, *et al*. Assessing the impact of mHealth interventions in low- and middle-income countries--what has been shown to work? *Glob Health Action* 2014;7.
10. Lehne M, Sass J, Essenwanger A, *et al*. Why digital medicine depends on interoperability. *NPJ Digit Med* 2019;2.
11. Wang Q, Su M, Zhang M, *et al*. Integrating Digital Technologies and Public Health to Fight Covid-19 Pandemic: Key Technologies, Applications, Challenges and Outlook of Digital Healthcare. *Int J Environ Res Public Health* 2021;18.
12. Raghupathi W, Raghupathi V. Big data analytics in healthcare: promise and potential. *Health Inf Sci Syst* 2014;2.
13. Agrawal R, Prabakaran S. Big data in digital healthcare: lessons learnt and recommendations for general practice. *Heredity (Edinb)* 2020;124:525–34.
14. Jensen PB, Jensen LJ, Brunak S. Mining electronic health records: towards better research applications and clinical care. *Nat Rev Genet* 2012;13:395–405.
15. Murdoch TB, Detsky AS. The inevitable application of big data to health care. *JAMA* 2013;309:1351–2.
16. Michelsen K, Brand H, Achterberg P, *et al*. *Promoting better integration of health information systems: best practices and challenges*. Copenhagen: WHO Regional Office for Europe, 2015. Available: http://www.ncbi.nlm.nih.gov/books/NBK379469/
17. Jagosh J, Macaulay AC, Pluye P, *et al*. Uncovering the benefits of participatory research: implications of a realist review for health research and practice. *Milbank Q* 2012;90:311–46.
18. Mager B, Oertzen AS, Vink J. *Co-creation in health services through service design*. Springer Books, 2022. Available: https://ideas.repec.org/h/spr/sprchp/978-3-030-87273-1_24.html
19. Health information system assessment in Georgia: full assessment report. Geneva World Health Organization; 2022.
20. Georgia: support to health sector enhancement program: digital health assessment. Asian Development Bank; 2023. Available: https://www.adb.org/projects/documents/geo-56069-002-tacr
21. Carnicero J, Serra P. Governance for digital health: the art of health systems transformation. IDB Publications; 2020. Available: https://publications.iadb.org/en/governance-digital-health-art-health-systems-transformation
22. Smith AL, Bradley RV, Bichescu BC, *et al*. IT Governance Characteristics, Electronic Medical Records Sophistication, and Financial Performance in U.S. Hospitals: An Empirical Investigation. *Dec Sci* 2013;44:483–516.
23. Voigt P, Dem Bussche A. *The EU general data protection regulation (GDPR)*. Cham: Springer International Publishing, 2017. Available: http://link.springer.com/10.1007/978-3-319-57959-7
24. Tiffin N, George A, LeFevre AE. How to use relevant data for maximal benefit with minimal risk: digital health data governance to protect vulnerable populations in low-income and middle-income countries. *BMJ Glob Health* 2019;4.
25. IPS and the EHDS – a call for global collaboration – the international patient summary. 2023. Available: https://international-patient-summary.net/ips-and-the-ehds-a-call-for-global-collaboration/
26. International patient summary implementation guide - international patient summary implementation guide v1.1.0. 2024. Available: https://build.fhir.org/ig/HL7/fhir-ips/
27. Guidelines on patient summary - European Commission. 2024. Available: https://health.ec.europa.eu/publications/guidelines-patient-summary_en
28. Hall JL, McGraw D. For telehealth to succeed, privacy and security risks must be identified and addressed. *Health Aff (Millwood)* 2014;33:216–21.
29. Shachar C, Engel J, Elwyn G. Implications for Telehealth in a Postpandemic Future: Regulatory and Privacy Issues. *JAMA* 2020;323:2375–6.
30. Digital health: a call for government leadership and cooperation between ICT and health. International Telecommunication Union; 2017. Available: http://www. broadbandcommission.org/Documents/publications/