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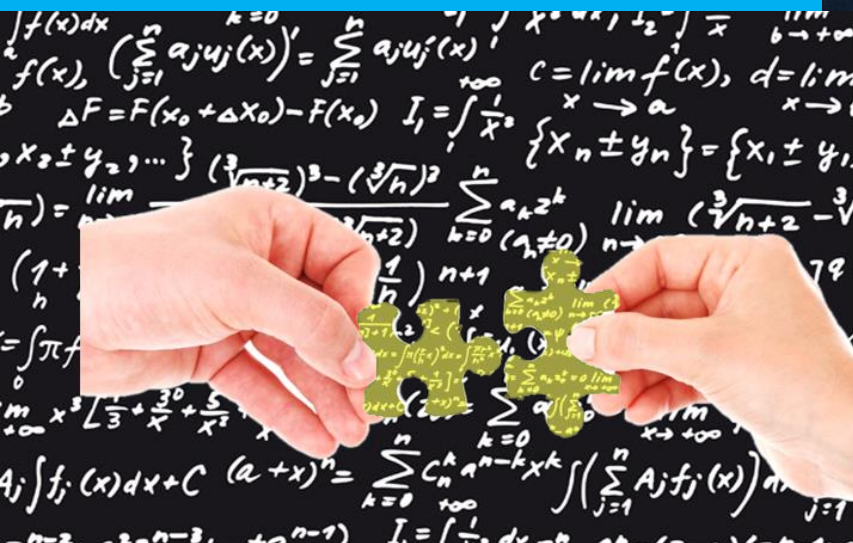
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ESCAP
Economic and Social Commission
for Asia and the Pacific

Regulatory Barriers in Implementing Digital Health Interventions



Antonio Postigo

ASIA-PACIFIC RESEARCH AND TRAINING NETWORK ON TRADE

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WORKING PAPER

Regulatory Barriers in Implementing Digital Health Interventions

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Abstract

The integration of digital technology into healthcare systems holds promise for improving services in developing countries, especially in remote and underserved regions. However, different types of challenges can impede the implementation and sustainability of digital health initiatives. Technical issues in remote areas, political instability leading to policy-related challenges, and inadequate government support are obstacles to progress. Regulatory barriers can create challenges for the effective implementation of digital health interventions. Inconsistent regulations, outdated guidelines, and legal ambiguities can stifle innovation and escalate costs. Weak or absent regulations on insurance coverage for telemedicine and digital health services further limit financial accessibility. To overcome these challenges, recommendations include the introduction of regulatory sandboxes, pre-certification schemes, and increased international collaboration. These approaches aim to strike a balance between robust regulation and fostering innovation in digital health. The accelerated growth of digital health interventions, exacerbated by the COVID-19 pandemic, underscores the urgent need for proactive and continuous regulatory frameworks. These frameworks play a critical role in ensuring safety, maintaining quality, and promoting equitable access. While some countries have temporarily eased regulations in response to the pandemic, achieving a balanced regulatory approach is essential to address new challenges, potential risks, and disparities in healthcare delivery arising from the evolving digital landscape.

Keywords: Digital health interventions, Health regulation, Regulatory barriers

JEL Codes: I18, Q01

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1. Introduction

The integration of digital technology into healthcare systems offers significant opportunities to enhance healthcare services. The adoption of digital health interventions has the potential to improve healthcare accessibility and use in hard-to-reach regions, and bring about healthcare cost savings. However, the implementation of digital health initiatives in low- and middle-income countries and, particularly, their long-term sustainability are frequently hindered by a set of common challenges (Al Meslamani, 2023; Kaboré and others, 2022; Leslie and others, 2023). These obstacles encompass **technical issues**, such as network connectivity and the reliability of power supply, which are common in remote areas with limited infrastructure (Al Meslamani, 2023; , Ittefaq and Iqbal, 2018; Macariola and others, 2021; Parajuli and others, 2022; Zharima and others, 2023). **Policy-related challenges** originating from political instability and insufficient government support, lack of sustainability of programs once donor support diminishes, financial constraints and a limited IT operational skills and literacy among stakeholders (healthcare professionals, administrators, patients) create additional hurdles. Independent of the level of economic development, persuading both healthcare providers and patients of adopting digital health solutions and establishing trust between healthcare professionals and patients in virtual consultations are also common concerns.

The rapid growth of digital health interventions demands the parallel establishment of **strong regulatory frameworks** that facilitate responsible and secure utilization of digital technologies for prevention, diagnostics, and therapeutics. These frameworks must ensure that digital health interventions are ethically, safely, and reliably deployed while promoting equity and sustainability. However, crafting regulatory frameworks that harmonize these objectives while fostering digital health innovation is a complex balancing task. Beyond the need of ensuring the free, secure, and safe handling of personal health data, which is discussed in detail in the accompanying paper (pages 4-5), various other aspects within regulatory frameworks can become significant barriers to the effective implementation and adoption of digital health solutions.

2. Regulatory Barriers to Digital Health Interventions

Regulatory frameworks can pose obstacles to the implementation and utilization of digital health interventions through various mechanisms. Digital health interventions differ from traditional medical devices and drug therapies, requiring **fit-for-purpose regulations** that do not necessarily apply to conventional health services and solutions. Technological advancements often outpace regulatory bodies, resulting in outdated guidelines and legal ambiguities. In many developing countries, there is either a lack of specific regulations for digital health solutions or existing regulations

lack the necessary comprehensiveness, clarity and consistency (Al Meslamani, 2023; Jain, 2023; Parajuli and others, 2022; Parums, 2021; Zhong and others, 2013). This ambiguity pertains to what qualifies as a digital health intervention, software, mobile application, or device, as well as the necessity for regulation and the predictability of its implementation. Fragmented regulations in many developing countries also hinder the effective use of digital health solutions and potentially create health risks. For example, in several ESCAP countries (e.g., India, Bangladesh) have multiple organizations regulating digital health with overlapping responsibilities that lead to inefficiencies (Ahmed and others, 2023; Al Meslamani, 2023; Chandwani and Dwivedi, 2015; Hoque and others, 2014; Jain, 2023; Merten and others, 2020; Parajuli and others, 2022; Parums, 2021; Patel and others, 2021). While ASEAN countries are making strides in removing regulatory obstacles, the absence of a comprehensive digital health policy framework, which includes data protection and considerations in clinical, ethical, legal, and operational domains, hinders the adoption and effective use of digital health solutions (Cascini and others, 2023; Macariola and others, 2021; Merten and others, 2020; Resilience Development Initiative, 2023). According to the Global Digital Health Index, several ASEAN states are trailing behind in establishing and consistently enforcing telemedicine regulations. Stringent or unclear regulations, which place the onus of determining compliance on the stakeholders developing or adopting digital interventions, can delay or impede innovation and/or inflate the costs of new digital solutions. Consequently, during the COVID-19 pandemic, some countries eased or eliminated regulatory barriers to the adoption of digital services across various sectors, notably in healthcare (Parums, 2021). Given that digital health interventions can potentially transcend national borders, countries should address not only challenges related to technical compatibility and interoperability but also establish consistent and predictable regional regulatory frameworks (bilateral, regional, global) for cross-border digital health interventions.

In certain instances, governments have incorporated IT into their public health services and overseen the collection and management of personal health data (as discussed separately in the accompanying paper). However, efforts to **guide or oversee the private sector development and/or implementation of digital health solutions** have been less proactive. Weak or absent regulations concerning insurance coverage for telemedicine and digital health services can make these services financially out of reach for many individuals. For example, in Bangladesh, digital health regulations delineate the roles and responsibilities of government agencies, but regulatory gaps persist regarding the types of services a company can offer, the qualifications required for health professionals offering advice, company ownership, and pricing policies. Interestingly, while regulators in Bangladesh have addressed these issues in the context of digital financial services, similar regulations are still lagging in the realm of digital health.

Innovations in digital health technology necessitate **innovative and risk-based approaches in regulation and policymaking** that can, in turn, foster continued

innovation (Al Meslamani, 2023; Parums, 2021). Conventional methods for assessing and authorizing medical devices are inadequate when dealing with digital health solutions that involve ongoing adjustments of devices and software. As used in other regulatory realms, regulatory sandboxes can help balance robust regulation of digital health interventions and health professionals with promoting technology innovation (Leslie and others, 2023). The incorporation of new digital health solutions into healthcare systems can be tested in limited pilot schemes using regulatory sandboxes before being implemented more widely. Some countries have introduced pre-certification schemes to evaluate and oversee digital health software and allowing faster regulatory review and market entry. National regulations for digital health devices and software should safeguard each country's autonomy to oversee the integration of digital health solutions into their healthcare systems. However, inconsistencies in approval and regulatory systems can create non-technical barriers and deter innovation and the adoption of new digital solutions by health professionals and patients. The *International Medical Device Regulators Forum* encompasses medical device regulators from Australia, Brazil, Canada, China, the European Union (EU), Japan, Russia, Singapore, and the US has issued recommendations for international regulation on digital health solutions, which proved useful during the COVID-19 (Parums, 2021).

The healthcare service landscape has rapidly evolved, particularly during the COVID-19 pandemic, with the widespread adoption of virtual care and telemedicine services. This transformation has ushered in new challenges, potential risks, and disparities in healthcare delivery. In virtually all countries, **healthcare providers are subject to rigorous regulation**, defining required professional competencies, registration and/or licensure requirements, and practice standards for virtual healthcare (Leslie and others, 2023). These standards must evolve with technology, requiring healthcare regulatory authorities to continually monitor and adapt them. This proactive and continuous regulatory approach is essential to ensure safety, quality, equitable access and affordability in virtual healthcare. Regulation should also address those aspects that are particularly salient in digital health interventions like privacy, security, and confidentiality. Naturally, the establishment of robust regulatory frameworks designed to safeguard the public from professional negligence, unethical behavior, and incompetence in virtual healthcare is just the first step. Health authorities must create systems to actively and efficiently monitor and enforce those standards.

Regulation of professional practice has been often ideologized and viewed by some as barriers to free market competition and driven by the private interests of the providers of those services rather than the public good (Leslie and others, 2023; Parums, 2021). In many countries, the COVID-19 pandemic prompted the issuance of waivers on certain healthcare provider regulations, expanding access to healthcare. As in most cases this occurred without negative impacts on safety or effectiveness, which led some to question the necessity of many of these regulations in the first place. However, regulators must escape such ideological debates and regulate healthcare

providers to ensure safe and effective healthcare, while avoiding creating barriers to equity in healthcare access and use.

In countries with multiple jurisdictions overseeing healthcare provision, subnational regulation can allow each local authority to establish its own standards according to its specific local conditions and needs. Digital technologies facilitate **cross-jurisdictional healthcare practice**, but requirements for subnational registration and licensure can create impediments to free competition. Once again, in response to the increased and geographically diverse demands for virtual healthcare during the COVID-19 pandemic, some counties temporarily eased or eliminated the need for multiple subnational licensures and established regulatory consortiums and compacts for cross-jurisdictional virtual healthcare services (Parums, 2021).

In the realm of digital health, varying regulations across jurisdictions pose challenges in data protection, privacy, and healthcare practices. Distinct requirements in different legal systems further complicate cross-jurisdictional (within and between countries) data sharing, especially concerning breach notification and liability determination in case of disputes or malpractice events. Legal responsibility may differ based on the location of healthcare providers, patients, and where digital health services are accessed. Licensing healthcare professionals involves navigating diverse legal requirements. The ethical dimensions of digital health, such as obtaining consent for data sharing and respecting patient privacy, require thoughtful consideration that accommodates cultural and legal disparities across subnational or national jurisdictions. Protecting patient rights, encompassing access to health information and control over its use, is a fundamental aspect of both cross-jurisdictional and cross-border digital healthcare. Addressing these complexities calls for policymakers to develop and regularly update regulations specifically tailored to the challenges of cross-jurisdictional digital health. This involves creating frameworks for data governance, liability, and patient rights that can be consistently applied across different legal systems at national and subnational levels. International collaboration is imperative in the realm of cross-jurisdictional healthcare in digital health to establish shared standards, guidelines, and agreements. Harmonizing legal frameworks is essential in facilitating smoother interactions and diminishing legal uncertainties in the global landscape of digital health.

List of references

- Ahmed T, Bloom G, Iqbal M, Lucas H, Rasheed S, Waldman L, Khan AS, Islam R, Bhuiya A. (2014). *E-health and M-Health in Bangladesh: Opportunities and Challenges*. Brighton, United Kingdom: Institute of Development Studies. (last accessed on September 15, 2023 at <https://opendocs.ids.ac.uk/opendocs/handle/20.500.12413/3613>).
- Al Meslamani AZ. (2023). Technical and regulatory challenges of digital health implementation in developing countries. *J Med Econ*. 26(1):1057-1060
- Cascini F, Gentili A, Causio FA, Altamura G, Melnyk A, Beccia F, Pappalardo C, Lontano A, Ricciardi W. (2023). Strengthening and promoting digital health practice: results from a Global Digital Health Partnership's survey. *Front Public Health*. 11:1147210.
- Chandwani RK, Dwivedi YK. (2015). Telemedicine in India: current state, challenges and opportunities. Transform Gov People. *Process Policy*. 9(4):393–400.
- Hoque MR, Mazmum MFA, Bao Y. (2014). e-Health in Bangladesh: current status, challenges, and future direction. *Int Technol Manag Rev*. 4(2):87–96.
- Ittefaq M, Iqbal A. (2018). Digitization of the health sector in Pakistan: challenges and opportunities to online health communication: a case study of MARHAM social and mobile media. *Digit Health*. 4:1–13.
- Jain D. (2023). Regulation of Digital Healthcare in India: Ethical and Legal Challenges. *Healthcare (Basel)*. 11(6):911.
- Kaboré SS, Ngangue P, Soubeiga D, Barro A, Pilabré AH, Bationo N, Pafadnam Y, Drabo KM, Hien H, Savadogo GBL. (2022). Barriers and facilitators for the sustainability of digital health interventions in low and middle-income countries: A systematic review. *Front Digit Health*. 4:1014375.
- Leslie K, Myles S, Schiller CJ, Alraja AA, Nelson S, Adams TL. (2023) Protecting the public interest while regulating health professionals providing virtual care: A scoping review. *PLOS Digit Health*. 2(4): e0000163.
- Macariola AD, Santarin TMC, Villaflor FJM, Villaluna LMG, Yonzon RSL, Fermin JL, Kee SL, AIDahoul N, Karim HA, Tan MJT. (2021). Breaking Barriers Amid the Pandemic: The Status of Telehealth in Southeast Asia and its Potential as a Mode of Healthcare Delivery in the Philippines. *Front Pharmacol*. 12:754011.
- Merten M, Roth S, Allaudin FS. (2020). *Public Health Innovations for COVID-19: Finding, Trusting and Scaling Innovation*. Manila, Philippines: Asian Development Bank. (last accessed on September 15, 2023 at: <https://www.adb.org/publications/public-health-innovations-covid-19>).

Parajuli R, Bohara D, Kc M, Shanmuganathan S, Mistry SK, Yadav UN. (2022). Challenges and opportunities for implementing digital health interventions in Nepal: A rapid review. *Front Digit Health*. 4:861019.

Parums DV. (2021). Editorial: Global Initiatives Support the Use and Regulation of Digital Health Technology During the COVID-19 Pandemic. *Med Sci Monit*. 27: e935123.

Patel SA, Vashist K, Jarhyan P, Sharma H, Gupta P, Jindal D, Venkateshmurthy NS, Pfadenhauer L, Mohan S, Tandon N. (2021). A model for national assessment of barriers for implementing digital technology interventions to improve hypertension management in the public health care system in India. *BMC Health Serv Res*. 21(1):1101.

Resilience Development Initiative, Diana A (2023). Transforming the digital health landscape in ASEAN. ASEAN Socio-Cultural Community (ASCC) Research and Development Platform. Policy Brief #6. (last accessed, September 15, 2023 at: <https://asean.org/serial/asean-socio-cultural-community-policy-brief-transforming-the-digital-health-landscape-in-asean/>).

Zharima C, Griffiths F, Goudge J. (2023). Exploring the barriers and facilitators to implementing electronic health records in a middle-income country: a qualitative study from South Africa. *Front Digit Health*. 5:1207602.

Zhong D, Kirwan MJ, Duan X. (2013). Regulatory barriers blocking standardization of interoperability. *JMIR Mhealth Uhealth*. 1(2): e13.



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