

State of the art digital health projects build on existing evidence, and normative guidelines, frameworks, and tools in various areas, ranging from software development to financing and equitable programing. In the context of the GIZ Digital Innovation in Pandemic Control (DIPC) Initiative, the Robert Koch Institute, Germany, has conducted a comprehensive analysis on key digital public health definitions and concepts, and on 75 normative resources for digital health programing across 11 digital health topics, published between 2012 and early 2024 [\[link\]](#). Findings from the report have been summarized in form of 20 easy to use Factsheets.

The current factsheet (10/20) summarizes the findings on the identified **Guidelines, Frameworks, and Tools for Regulation, Strategy & Policy Formation** and covers resources that support the creation of cohesive digital health policies and strategies.

Factsheet 10

Guidelines, frameworks and Tools for Regulation, Strategy & Policy Formation



Target Audience

Primary Users: Government health sector leaders in Ministries, Departments and Agencies who manage the development of digital health strategies

Secondary Users: Technology developers, Donors

Relevance

Developing policies and strategies for digital health (DH) is essential for governments as DH can significantly enhance the accessibility and quality of healthcare services.

Government policies, strategies, and regulations in DH are crucial for ensuring that digital technologies are integrated into healthcare systems in a secure, efficient, and equitable manner, enhancing healthcare delivery and outcomes while fostering innovation and addressing broader public health goals.

As digital health evolves, it is crucial to have a regulatory framework in place to manage emerging issues such as the ethical use of AI in healthcare, telemedicine practices, and digital health equity.

Findings

Number of resources identified: 7

The WHO released the “Global Strategy on Digital Health 2020-2025” to globally guide the development and adoption of digital health solutions that are appropriate, accessible, affordable, scalable, and sustainable. This strategy is built on four core principles:

- Institutionalizing digital health within national systems,
- Developing cohesive digital strategies,
- Promoting beneficial technology use,
- Addressing adoption barriers in least-developed countries.

Only one guideline specific to supporting governments in developing a national eHealth vision has been identified: “WHO’s National eHealth Strategy toolkit”; despite being over a decade old, remains relevant due to its adaptable framework and fundamental principles such as stakeholder engagement, strategic planning, and governance. It is complemented by resources like the WHO’s Digital Implementation Investment Guide (DIIG), which provides detailed guidance on financial planning for digital health initiatives.

Health data governance is crucial, with data privacy and security posing significant challenges. The Health Data Governance Principles offer globally accepted guidelines for developing robust data protection policies. Compliance with diverse regulations is essential for digital health providers to balance innovation with strong security measures, enabling sustainable use of health data for the public good.

Other resources are available that focus on guiding government actors on selected aspects of DH development. However, these can be considered as complementary to the eHealth Strategy Toolkit as they zoom in on particular areas.

Guidelines

Global Strategy on Digital Health 2020-2025

To guide the development and adoption of DH solutions that are appropriate, accessible, affordable, scalable, and sustainable, based on four core principles.

Published by: WHO

Year: 2021

Language: English, French, Arabic, Russian

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA establishes Privacy and Security Rules for handling protected health information in USA.

Published by: U.S Department of Health & Human Services

Year: 2021

Language: English

The General Data Protection Regulation (GDPR)

GDPR is a crucial law within the EU, affecting any organization worldwide that processes personal data of EU/EEA residents.

Published by: EU

Year: 2016

Language: All the languages of EU

Guide to Privacy and Security of Electronic Health Information

To provide practical compliance support for healthcare professionals and aims to empower providers in safeguarding health information and preserving patient confidence.

Published by: The Office of the National Coordinator for Health Information Technology

Year: 2015

Language: English

Framework

Framework for Improving Critical Infrastructure Cybersecurity

Provides detailed guidelines to help private sector organizations improve their cybersecurity.

Published by: National Institute of Standards and Technology

Year: 2018

Language: English

Toolkits

National eHealth Strategy Toolkit

Provision of assessment framework

Published by: WHO & ITU

Year: 2012

Language: English, Arabic, Chinese, French

Principles

Health Data Governance Principles

These principles, aim to protect individuals and communities, promote health value through data sharing, and ensure equitable benefits distribution. They guide global health data policies and serve as advocacy tools for fair governance.

Published by: TransformHealth

Year: 2023

Language: English



This is based on "[Navigating the Digital Health Ecosystem: A Review of Key Guidelines, Frameworks, and Tools](#)"

Read the full report [here](#) or scan the QR code

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