

The Current Landscape of Guidelines, Frameworks and Tools for Digital Health Programing



Imprint

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Internet: www.rki.de
E-Mail: zentrale@rki.de
Twitter: [@rki_de](https://twitter.com/rki_de)

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Authors

Rita Dörner, Andrea Bernasconi, Dounia Iskandarani, Afrina Karim & Charbel El-Bcheraoui from the Unit for Evidence-Based Public Health, Centre for International Health Protection, Robert Koch Institute
Tessa Lennemann & Mariana Gonzales Carrillo from Digital Innovation in Pandemic Control Flagship, Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ)

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Diego Narrea Sheen

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PREFACE

It is a real pleasure to write a foreword for this very important and timely report, which, based on a large review of the peer-reviewed and grey literature, provides an excellent overview of a very dynamic and, in some areas, overwhelmingly rapidly developing area of research and implementation: digital health. By first defining digital health, the digital health system architecture and its components, this report provides the deep context in which the resources evaluated are placed. The report provides an excellent overview of the development - or rather evolution - of terms, concepts and definitions in the field of digital health over the last 20 years, from electronic health (eHealth) and mobile health (mHealth) to digital health. This systematic approach is the basis for understanding how guidelines and frameworks, as well as specific tools, fit into digital health systems and which stakeholders need to be empowered. In addition, the authors make a good distinction between digital health and digital public health, the latter being a more recent term. While digital health refers to the operational scope and impact of technology on individuals, digital public health targets communities and populations.

Key findings are that low- and middle-income countries will benefit most from the evolution of digital health, and that digital public goods for health have become indispensable. More importantly, they identify gaps that need to be addressed in the near future: the obvious challenge of harmonization, the plea for a more focused development of clear indicators for digital health, focusing on impact and economic value, as well as the issue of equity, gender and inclusion. It also clearly identifies the issue that, from my personal experience, is of paramount importance: addressing the digital health literacy of health workers. Based on their findings, the authors make six recommendations: (1) harmonize approaches, (2) fill gaps, (3) develop targeted guidelines for training programs, (4) align global standards, (5) embrace inclusive development, and (6) generate strategic evidence. It goes without saying that resources should be prioritized to serve these goals.

For all those working in the field of digital global and public health, this document will be a reference for all future efforts, as it takes into account the impressive work of so many stakeholders worldwide. The list of guidelines, frameworks and tool applications is itself an impressive reference. To the right, the authors refer to the coordination and leadership of the World Health Organization (WHO). Accordingly, the authors promote the WHO's definition of digital health: Digital health, a broad umbrella term encompassing eHealth (which includes mHealth) as well as emerging areas such as the use of advanced computer science in 'big data', genomics and artificial intelligence (AI). It encompasses the field of knowledge and practice related to all aspects of using digital technologies to improve health (WHO. Global Strategy for Digital Health 2020-2025. Geneva: World Health Organization, 2021).

This report is part of the Digital Innovation in Pandemic Control (DIPC) initiative, funded by the German Federal Ministry for Economic Cooperation and Development (BMZ) and implemented by the Deutsche Gesellschaft für Internationale Zusammenarbeit (GIZ). It was written by seven authors, five from the Centre for International Health Protection at the Robert Koch Institute (RKI) and two from GIZ - a good example of the inter-ministerial cooperation that is so urgently needed. Health-in-all policies are the foundation of policy frameworks that are the basis for a fruitful and prosperous development of digital health - we need more of them. Indeed, this document provides a comprehensive overview and assessment of the current landscape of digital health policies, frameworks and tools. I am pleased to have had the opportunity to provide a foreword to this report, as it will serve as a foundation for much future work for the common good of health.

Lothar H. Wieler, H
Potsdam, 31 July 2024

LIST OF ACRONYMS

AI

Artificial Intelligence

BMZ

Bundesministerin für Wirtschaftliche Zusammenar-
beit und Entwicklung

DAK

Digital Adaptation Kit

DH

Digital Health

DHA

Digital Health Atlas

DHEA

Digital Health Enterprise Architecture

DHI

Digital Health Intervention

DHP

Digital Health Platform

DICE

Digital Centre for Excellence

DIPC

Digital Innovation in Pandemic Control

DiPH

Digital Public Health

DLA

Digital Landscape Assessment

DPG

Digital Public Good

DPI

Digital Public Infrastructure

DPI-H

Digital Public Infrastructure for Health

GPGH

Global Public Goods for Health

DPPA

Digital Pandemic Preparedness Assessment Tool

EDIT

Early Stage Digital Investment Tool

EPI

Expanded Program on Immunization

FHIR

Fast Healthcare Interoperability Resource

GDHM

Global Digital Health Monitor

GIZ

Gesellschaft für Internationale Zusammenarbeit

HIC

High Income Country

HIE

Health Information Exchange

HIS

Health Information System

HL7

Health Level Seven International

HW

Health Worker

HWF

Health Workforce

ICT

Information and Communication Technology

IMCI

Integrated Management of Childhood Illness

IT

Information Technology

ITU

International Telecommunication Union

LMICs

Low-Middle Income Countries

LMMs

Large Multi-Modal Models

MAT

Maturity Assessment Tool

M&E

Monitor & Evaluation

MoH

Ministry of Health

NICE

National Institute for Health and Care Excellence

PAHO

Panamerican Health Organization

PATH

Program for Appropriate Technology in Health

SDGs

Sustainable Development Goals

SMART

Standards-based, machine-readable, adaptive, requirements-based, and testable

UN

United Nations

UNDP

United Nations Development Programme

USAID

U.S. Agency for International Development

UHC

Universal Health Coverage

WHO

World Health Organization

WP

Work Package

GLOSSARY

Artificial Intelligence. (AI) is the term used to describe the use of computers and technology to simulate intelligent behavior and critical thinking comparable to a human being¹.

Digital Health. A broad umbrella term encompassing eHealth (which includes mHealth), as well as emerging areas, such as the use of advanced computing sciences in ‘big data’, genomics and artificial intelligence (AI). It captures the field of knowledge and practice associated with any aspect of adopting digital technologies to improve health².

Digital Health Ecosystem. The combined set of digital health components representing the enabling environment, foundational architecture and ICT capabilities available in a given context or country³.

Digital Health Enterprise. The business processes, data, systems and technologies used to support the operations of the health system, including the digital health applications, point-of-service software applications, other software, devices, hardware, standards, governance and underlying information infrastructure (such as the digital health platform) functioning in a purposeful and unified manner. The Digital Implementation Investment Guide distinguishes between four different types of digital health enterprise system architectures along a continuum of maturity: siloed, ball of mud, integrated and exchanged³.

Digital Health Intervention. A discrete technology function designed to achieve a specific objective addressing a health system challenge in order to improve a health program process and help strengthen the overall health system⁴.

Digital Health Platform. A shared digital health information infrastructure (infostructure) on which digital health applications are built to support consistent and efficient healthcare delivery. The infostructure comprises an integrated set of common and reusable components that support a diverse set of digital health applications. The components consist of software and shared information resources to support integration, data definitions and exchange standards for interoperability and to enable the use of point-of-service applications across health program areas and use cases³.

Digital Health Programing. For the purpose of this review, “digital health programing” refers to the collective activities, projects, programs, or initiatives undertaken by governmental, non-governmental, private sector, or collaborative entities to advance information and communication technology (ICT) solutions in the health sector. In our definition, this encompasses strategic planning, development, implementation, and management of digital technologies within health systems aimed at enhancing healthcare and public health services. Digital health programing involves efforts to improve digital public infrastructure, ensure interoperability for seamless data exchanges, and establish robust digital health governance frameworks. Additionally, it includes ICT capacity building and the integration of gender, equity, and inclusion approaches into digital health initiatives.

Digital Public Health Intervention. addresses at least one essential Public Health function through digital means. Applying a framework for functional classification and stratification categorizes its interaction level with the user. The developmental process of a digital public health intervention includes the user perspective by applying participatory methods to support its effectiveness and implementation with the goal to achieve a population health impact⁵.

Digital Public Infrastructure for Health. Is conceptualized as the health-specific components of a country’s digital infrastructure that enable an ecosystem of inclusive, scaled, user-driven digital applications in a health system⁶.

Digital Public Goods. Are open source software, open data, open AI models, open standards and open content that adhere to the DPG Standard and are of high relevance for attainment of the [UN’s 2030 Sustainable Development Goals \(SDGs\)](#)⁷.

Electronic Health (eHealth). “The use of information and communications technology in support of health and health-related fields”⁸.

Enabling Environment. Attitudes, actions, policies and practices that stimulate and support effective and efficient functioning of organizations, individuals and programs. The enabling environment includes legal, regulatory and policy frameworks and political, sociocultural, institutional and economic factors³.

Global Goods. A refined category of Digital Public Goods (DPGs), characterized by their maturity in scale, diversified funding, and proven efficacy. A “mature” digital health software global good is typically identified as Free and Open Source Software (FOSS), backed by a strong community, governed by clear and structured rules, financially supported through various means, extensively implemented across multiple countries, proven effective in its applications, engineered for interoperability, and acknowledged as a standard application within its domain³.

Health Information Exchange. The mobilization of health care information electronically across organizations within a region, community or hospital system. Participants in data exchange are called in the aggregate Health Information Networks (HIN). In practice, the term HIE may also refer to the health information organization (HIO) that facilitates the exchange. The goal of HIE is to facilitate access to and retrieval of clinical data to provide to public health authorities in analyses of the health of the population⁹.

Health System Challenges. Are various needs and obstacles that hinder the optimal performance of health systems. It identifies broad issues that can be mitigated through the implementation of digital health interventions. Program planners can use this framework as a foundation to identify specific bottlenecks or pain points within a health program. This process helps in selecting the most suitable digital health interventions to address those challenges effectively⁴.

Implementation Research. Research that “seeks to understand and work in real-world or usual practice settings, paying particular attention to the audience that will use the research, the context in which implementation occurs, and the factors that influence implementation”¹⁰.

Indicators. A “quantitative or qualitative factor or variable that provides a simple and reliable means to measure achievement, to reflect the changes connected to an intervention or to help assess the performance of a development actor”¹¹.

Interoperability. The ability of two or more information systems or components to exchange information based on standards, and to use the information that is exchanged. Interoperability enables different Health Information Systems to work together in and across organizational boundaries to advance the health status of individuals and communities and the effective delivery of healthcare to them (Healthcare Information and Management Systems Society)¹².

Large Multi-Modal Models. LMMs (including large language models), which, for use in health care and medicine, are trained with highly diverse datasets, extending beyond text, and include biosensor, genomic, epigenomic, proteomic, imaging, clinical, social and environmental data (3). LMMs can accept more than one type of input and generate outputs that are not limited to the type of data entered. ¹³

Mobile Health (mHealth). The use of mobile and wireless technologies to support the achievement of health objectives¹⁴.

The “Know-Do” Gap. In implementation science, the “know-do” gap refers to the disparity between what is known from research and evidence-based practices (the “know”) and what is actually implemented and practiced in real-world settings (the “do”). This gap highlights the challenges and barriers that prevent the effective translation of knowledge into action, leading to a lack of application of proven interventions, guidelines, and best practices in everyday practice and policy. Addressing the “know-do” gap involves identifying and overcoming these barriers to ensure that scientific knowledge is effectively integrated into health systems and improves outcomes.

EXECUTIVE SUMMARY

Introduction

Healthcare systems are increasingly adopting digital technologies to enhance agility, operational efficiency, and patient experiences. This transformation, through tools such as unified digital platforms, mobile applications, and telehealth, offers significant benefits, particularly for Low-and Middle-Income Countries (LMIC). These include improved access to healthcare services, especially in remote areas, better safety and quality of care, increased health workforce productivity, and higher service uptake. Effectively designed and implemented digital technologies can also increase efficiency, reduce service delivery costs, enable swift public health information sharing, and improve program and health system monitoring. Additionally, digital health has the potential to address universal health coverage challenges by impacting various health system aspects.

The World Health Organization (WHO) recognizes the power of Information and Communication Technology (ICT) in accelerating advancements across health-related Sustainable Development Goals (SDG) as outlined in its “Global Strategy on Digital Health 2020-2025”. This strategy set the vision, objectives, and a framework for action and implementation of ICT to advance digital health globally and at national levels. The COVID-19 pandemic has notably accelerated digital health adoption, which highlights its importance in strengthening health systems, preventing disease, and enhancing global service delivery. However, challenges persist, such as the need for effective assessment and integration of new technologies, data unification in health care records, and the provision of adequate clinical support for digital tools².

Digital Innovation in Pandemic Control (DIPC) Initiative

This review has been conducted as part of the Digital Innovation in Pandemic Control (DIPC) initiative, funded by the German Ministry for Cooperation (BMZ) and implemented by the German Development Cooperation (GIZ). DIPC focuses on strengthening pandemic response and vaccine delivery systems in Ghana, Malawi, Peru, Sierra Leone, and Tanzania. Its four key work packages are 1) assessing the countries’ digital health ecosystems, 2) developing digital solutions to support vaccine delivery, 3) enhancing ICT and health workforce digital capacity, 4) project evaluation and evidence generation. DIPC is also involved in global efforts beyond its project countries, such as developing IT training curricula and advancing digital health standards. Integral to a broader strategy, it supports digital solutions for future pandemics and contributes to wider digital health knowledge.

Purpose of the Report

The review aims to provide a comprehensive overview and assessment of the current landscape of digital health guidelines, frameworks, and tools. By first defining digital health and the digital health system architecture and its components, the review seeks to provide the theoretical context in which the evaluated resources are positioned.

To provide specific findings on the landscape of resources relevant to digital health programing, alongside identified gaps and challenges, the review of guidelines, frameworks and tools is structured around eleven digital health programing-relevant

topics 1. Digital Landscape Assessments (DLAs), 2. Regulation, Strategy & Policy Formation, 3. Solution Design & Development, 4. Integration & Interoperability, 5. Scaling up, 6. Monitoring & Evaluation (M&E), 7. Sustainability & Financing and as well as 8. Gender, Equity & Inclusion, 9. Capacity Strengthening, 10. Technical Standards for Developers and 11. Digitizing Immunization Programs. This report also examines potential future scenarios related to Digital Health (DH) and the ethical issues that may arise with the adoption of ICT in healthcare.

Following this structure, this review aims to provide readers with an informative summary of available normative resources to encourage uptake and adoption of guidelines, frameworks and tools. This is to foster a more harmonized approach to digitizing health systems, which in turn would strengthen

the impact of DH at the national level and globally. At the same time, by highlighting gaps and challenges in the landscape of resources, this review seeks to encourage research for evidence-sparse topics, and the development of evidence-based guidelines, frameworks and toolkits for aspects of digital health development, that are currently lacking resources.

Target Audience

This review is relevant for policy makers, digital health planners and implementers, by providing an overview of resources that are available to them. It also holds relevance for researchers offering a detailed analysis of frameworks and toolkits that can guide practical implementation and research and by highlighting evidence-gaps, which can steer future study.

Methodology

The methodology employed a comprehensive search strategy relevant to digital health guidelines, frameworks and toolkits, spanning across the 11 topical areas of this review. Key sources of information included online search platforms (Google, Google Scholar), scientific journal repositories (PubMed, EMBASE), and websites, specialist blogs and publications from governmental and non-governmental organizations. This approach was designed to capture a broad spectrum of the digital health sphere, including peer-reviewed articles and grey literature.

The review process involved an initial screening of texts relevant to digital health at the public health or health system level. The focus was on literature that provided background on digital health, including definitions, development of terms, and the makeup of digital health systems. Guidelines, frameworks and tools aligning with global strategies, such as WHO's Global Strategy on Digital Health 2020-2025 were included. The emphasis was on resources fostering the digitization of health systems in LMICs, aligned with digital health development phases and system architecture.

The review and analysis process encompassed four stages: 1) Search, appraisal and selection of relevant resources, 2) Summarizing of each selected resource, 3) Evaluation of resources' fit into the wider

digital health development and health system context, and 4) Evaluation of the landscape of resources for each of the 11 topical areas.

Findings of the review are presented by first describing the relevant guidelines, frameworks and tools for the respective topic area, then a summary of the topic-area specific findings on the landscape of guidelines, frameworks and tools is provided and last, a synopsis of each resource reviewed is included in tabular format. More extensive descriptions and of the resources are given as part of the annex.

Results

Definitions and Concepts for Digital Health Systems

In this section, we provide definitions for digital health and explore the concept of digital public health. We discuss the architecture of digital health systems, including their commonly used components and frameworks in development of digital health systems. Additionally, we present the relevance of our findings from reviewing selected guidelines, tools, and frameworks according to thematic areas within digital health programing.

The evolution from electronic Health (eHealth) to digital health reflects the field's growing complexity and diversity. Initially focused on medical informatics and health data digitization, the scope expanded to include mobile Health (mHealth) and advanced areas like "big data" and Artificial Intelligence (AI). Today, digital health encompasses eHealth, mHealth, and emerging technologies, emphasizing the use of digital tools to improve health outcomes. However, precisely defining digital health is challenging due to its vast scope and countless circulating definitions of the term, which draws attention to the need for common language and comprehension. The review did show that the term increasingly focuses on using technology to enhance individual and population health, going beyond just disease treatment to include intelligent processing of clinical and genetic data.

In digital health, a key distinction lies in the operational scope and impact of technologies at either the individual user level or for advancing public health goals. While many tools focus on personal health management, like tracking physical activities or monitoring health parameters, they might not significantly impact community or population health. The review highlights that Digital Public Health (DiPH) has emerged as a distinct field, focusing on technologies that address public and community health needs, including Electronic Medical Records (EMR), disease surveillance, and vaccination reminders. DiPH, positioned at the population level, spans across eHealth and mHealth domains, encompassing prevention, health promotion, and healthcare management. Defining DiPH presents challenges, but Digital Public Health Interventions (DPHIs) were postulated as addressing essential public health functions through digital means, emphasizing user interaction and participatory methods to ensure effectiveness and population health impact.

The Architecture of Digital Health Systems

To allow for the positioning of guidelines, frameworks and tools for digital health programs into the structure of a digital health system, the review outlines its architecture and describes the relevant components essential for implementing effective digital health interventions (DHIs). The review summarizes several concepts, including DHIs, the composition of an eHealth system, including its seven building blocks, Digital Public Infrastructure for Health as well as the digital health enterprise and the corresponding system architectures of Siloed, Monolithic Unarchitected Software Distributions (MUD), Integrated, and Exchanged systems, each representing different stages of maturity in digital health implementation. Last, the review describes Digital Health Interventions and how they are positioned within the broader digital health system.

The review also describes the digital health architecture framework or blueprint for national Health Information Exchange (HIE) systems, and introduces OpenHIE as a modular approach to unify health information.

Digital Public Goods for Health

The review also emphasizes the role of Digital Public Goods for Health (DPGH) in health system digitization. These are accessible resources, such as open-source software and open data sets, meeting United Nations (UN) criteria for Digital Public Goods (DPGs), including SDGs relevance, open licenses, and privacy law adherence. Digital Square's Global Goods Guidebook classifies digital health applications as DPGs, highlighting the importance of e.g., open-source status and interoperability. However, the review also notes challenges in funding DPGH, for which the Peace Research Institute Oslo proposes a Global Public Investment Framework for more inclusive financing of these goods, focusing on collective responsibility and democratic governance to enhance contributions, crucial for achieving Universal Health Coverage (UHC) and the 2030 SDGs, particularly in LMICs.

Guidelines, Frameworks and Tools for Digital Health Programing

The review goes on to detail the critical role guidelines, frameworks and tools in directing the

development and application of digital technologies in health systems. A synopsis on the evolution of DH guidelines over the past decade is provided and reflects the rapid growth and transformation of the sector. Early efforts in guideline development focused on eHealth, initially aimed at digitizing health data and creating Health Information Systems (HIS). The period between 2012 and 2022 brought important achievements in digital health with the introduction of the Principles for Digital Development in 2012 and the release of advanced AI tools like ChatGPT4 in 2022.

The report provides a brief overview of universal principles such as standardization, quality and safety, interoperability, regulatory compliance and scalability and sustainability, which should form the foundation of resources for digital health development.

Following an introduction to the structuring of the review of resources according to 11 thematic areas relevant for digital health development, the review goes on to present the findings for each of these topics.

Digital Landscape Assessments

The review of guidelines, frameworks and toolkits for Digital Landscape Assessments (DLA) highlights DLAs as a critical first step for digital health projects and national initiatives to obtain a comprehensive overview of a nation's DH infrastructure challenges, existing policies, and integration into the healthcare system.

Fifteen resources guiding DLAs were reviewed and findings show that each tool brings a unique perspective and methodology, focusing on areas like infrastructure, interoperability, governance, and service delivery. Findings also highlight that the tools vary in scope considerably, from evaluating broader digital ecosystems to specific aspects like interoperability. A variety of methodologies are employed in DLAs, often blending different approaches to meet specific country needs. The review shows that while this flexibility can be helpful, it also raises the risk of non-harmonized outcomes. Thus, harmonizing DLA guidelines and tools is crucial for streamlining digital health efforts globally. Such efforts are underway, examples including the ongoing work of technical experts of the Digital Health & Interoperability Working Group – Maturity Model Small Working Groups (WHO-hosted Health Data Collaborative), and meta-instruments such as the Digital Health Profile and Maturity Assessment Toolkit (DHPMAT) and Digital Square's Navigator for Digital Health Capability Models. Alongside this challenge, the review

highlights the importance of country leadership for DLA and national ownership of assessment results, the need to build on existing national digital health landscape information and the value of adding DLA results to the evolving global digital health resource infrastructure.

Regulation, Strategy and Policy Formation

Developing digital health policies and strategies is essential for governments to enhance healthcare access and quality. Policies ensure the broader reach of digital health tools, promote equity, and increase the efficiency of healthcare delivery to only name some.

The review highlights the “WHO's National eHealth Strategy toolkit” as a key guideline for developing national eHealth strategies. Despite its age, the toolkit's principles of stakeholder engagement, clear vision, and strategic objectives remain relevant. It is adaptable to different contexts and technological changes, focusing on governance, comprehensive planning, and stakeholder inclusivity.

Solution Design & Development

The third topic relevant to digital health programing concerns guidelines for digital health solution design and development, which is crucial for creating effective, safe, user-friendly, and legally compliant tools. The review focused on three key resources that guide digital health design and development, emphasizing human-centered approaches: 1. UNICEF's “Interventions for Lasting Impact: A Human-Centered Guide to Digital Health Deployments”, 2. Collaborative Requirements Development Methodology (CRDM) - Essential for developing impactful digital solutions and 3. WHO SMART Guidelines. The application of these guidelines should be contextualized within broader frameworks targeting aspects like interoperability and regulatory compliance. WHO's “Digital Implementation Investment Guide” provides additional guidance.

WHO SMART guideline approach is particularly significant for converting clinical guidelines from paper to digital formats within national health systems, facilitating seamless information exchange across health sectors. Their role in the digitization of health systems is elevated, with potential impacts on clinical decision-making, public health planning, research, and population health outcomes.

Integration & Interoperability

The rapid digitalization in healthcare necessitates integrated and interoperable digital solutions to address challenges in data collection, quality, and system efficiency. Interoperability is key for seamless patient data exchange, enhancing care coordination, reducing errors, and supporting public health surveillance and decision-making.

Findings show that, in LMICs, fragmented digital health investments have led to siloed systems and there are several resources to address this issue. WHO's "Digital Health Platform Handbook" for developers, PATH/Digital Square's "Harmonizing Digital Health Assessment Tools" and MEASURE Evaluation's "Health Information Systems Interoperability Maturity Toolkit" and "Maturity Models and HIS Interoperability Toolkit Users Guide" evaluate health system interoperability and are crucial for national digital landscape assessments. Also, the Health Level Seven International (HL7) Fast Healthcare Interoperability Resource (FHIR) standard is increasingly used for healthcare data exchange, and supported by resources like the SMART guidelines.

Scaling up

Scaling digital health initiatives is key to enhancing healthcare access and equity, especially in underserved areas. It leads to improved health outcomes, cost reductions, and more comprehensive data for research. Scalable solutions are essential in public health emergencies and for integrating digital health into national policies. However, successful scale-up is challenging, with many initiatives not advancing beyond pilot stages.

The WHO/ITU's National eHealth Strategy Toolkit outlines essential conditions for scaling eHealth strategies, including conducive policy environments and adequate technology infrastructure. The WHO mHealth Assessment and Planning for Scale (MAPS) toolkit offers comprehensive guidelines for scaling digital health programs. As part of the review, key factors for scale-up were identified from the literature that are to guide DH stakeholders in the scale-up process. These include intrinsic program characteristics addressing practical needs, human factors involving stakeholder engagement and training, technical simplicity, interoperability, and adaptability, alignment with broader healthcare policies for sustainable funding and consideration of the extrinsic ecosystem, including infrastructure.

Monitoring & Evaluation

Monitoring and Evaluation (M&E) in digital health is essential for assessing whether digital health technologies meet their goals, identifying and resolving issues, and informing resource allocation for optimal impact. M&E ensures accountability and continuous improvement of digital health interventions. It also helps identify barriers to adoption, tracks user trends and satisfaction, and informs ongoing program success. Data from M&E activities fuel research and innovation in digital health. However, M&E in DH requires considerations distinct from non-digital projects due to the dynamic nature of digital health programs, which evolve through various stages of maturity. Initial phases focus on alignment with needs, technical functionality, and feasibility, progressing to user satisfaction, effectiveness, impact, and cost-effectiveness evaluation. Four key resources were identified from this review that can provide valuable suggestions for implementing evaluations and monitoring activities at different digital health development stages, aiding program planners, implementers, and monitoring teams in navigating digital health program cycles. However, one of the main challenges pertains to suitable indicators for DH, which is a topic of ongoing discussion and continued work.

Sustainability & Financing

Findings from this review highlight that financing digital health initiatives requires sustainable, long-term funding models, incorporating government support, private investments, and public-private partnerships. Understanding digital health investments' long-term value is key for justifying resource allocation. The review shows that a significant challenge lies in the lack of comprehensive economic evaluations, which makes evidence-based decision-making difficult for policymakers and funders, especially in LMICs where resources are limited. This gap also makes it difficult to develop guidelines that accurately reflect economic realities and potential returns on investment in digital health. Particularly in LMICs, strategic decisions on scaling are crucial due to substantial opportunity costs in a resource-limited environment. However, these gaps have been recognized and five resources have been identified to assist government, digital health planners, donors and investors.

Gender, Equity, Inclusion & Ethics

Digital health technologies risk reinforcing or creating disparities, which highlights the importance of integrating Gender Equity and Inclusion (GEI) into digital health planning, implementation, and scale-up.

The review emphasizes that digital inclusion, crucial for equitable healthcare access, involves creating culturally sensitive tools and providing resources in various languages and formats. Efforts to achieve digital inclusion encompass affordable internet, appropriate devices, digital literacy training, technical support, and inclusive online content.

The review identified nine key resources addressing various aspects of Gender, Equity, Inclusion & Ethics in digital health. These resources range from theoretical frameworks to practical design and implementation guidelines, including UNICEF's human-centered guide, but also WHO's Guidance on ethics and governance for artificial intelligence in Health. However, there is a notable lack of comprehensive resources that address GEI in digital health in its entirety, guiding policy makers and practitioners through evidence-based, user group-specific needs and the integration of the inclusion lens in digital health programing.

Capacity Strengthening

Empowering healthcare staff in all aspects of health ICT systems is crucial for the effective utilization, maintenance, and evolution of digital tools and systems. Capacity strengthening is essential for personnel to use digital tools effectively and integrate them into health systems, promoting sustainability and reducing reliance on external organizations. Capacity strengthening also addresses digital disparities, whilst offering targeted training to marginalized groups, which can contribute to economic growth and development in the healthcare sector.

Findings highlight that despite the recognized importance of strengthening digital knowledge and skills, there is a notable lack of targeted guidelines and frameworks for developing digital literacy and competency training programs for healthcare workers (HW) and ICT staff in the health care sector. This gap is particularly evident in LMICs, where developers and implementers of training programs need evidence-based guidance.

Only two resources were identified. These can be viewed as a starting point for future work and research on the topic. One aids in outlining the sparse evidence base around using digital modalities for medical training of health care staff and the other provides some insides from the European health workforce on digital and ICT training needs, which are in part transferable to LMICs.

The limited evidence base and challenges in digital education modalities complicate the formulation of robust guidelines for healthcare and ICT workers in

LMICs. Nevertheless, ongoing efforts are evident for addressing these gaps for example, in form of the GIZ's DIPC initiative's WP3, implemented by the Regenstrief Institute.

Technical Standards for Developers

The commercialization of digital health products in global markets requires adherence to specific standards to ensure user safety. Especially for complex digital solutions providing crucial health information, strict regulations are necessary to label these interventions as Software as a Medical Device.

Four resources have been identified as significant in regulating and standardizing digital health technologies. The review also highlights some challenges that may be difficult to overcome. These include, e.g., the challenge of different regions having varied frameworks, creating hurdles for developers releasing products in multiple markets, thereby potentially hindering global digital health technology accessibility. Also, keeping regulatory frameworks updated with technological advancements can be difficult, as this is risking outdated regulations that could stifle innovation or fail to address new safety concerns.

Having said that, the review emphasizes that standards are crucial in shaping the digital health technology landscape, providing structures for safety, efficacy, and reliability. The challenge lies in ensuring these frameworks adapt to the fast-paced nature of technological advancements, harmonize across regions, and balance rigor with flexibility to support innovation while safeguarding patient health.

Digitizing Immunization Programs

In the context of the DIPC initiative and its objectives, this review also covers resources specifically designed for the digitization of vaccination programs. Such guides are important as they provide structured approaches to address challenges such as costing, target population identification, vaccination delivery strategies, and human resource management. The review showcases eight documents that address the above-mentioned points and aid in selecting appropriate digital tools and technologies for immunization programs as well as help to address vaccine hesitancy, improve vaccine coverage, and ensure interventions are user-centered and context-specific.

Discussion

This comprehensive review of digital health program-relevant guidelines, frameworks, and tools reflects the significant evolution and diversification of digital health, and emphasizes the critical role of digital health as part of modern healthcare systems. This transformation is particularly vital for LMICs, offering numerous benefits such as improved healthcare access, safety, and efficiency. The COVID-19 pandemic has accelerated digital health adoption, which shows its potential in strengthening health systems and enhancing global service delivery. Yet, challenges in effective technology assessment, data unification, and clinical support for digital tools remain.

Findings from this review highlights the field's complexity and the need for common language and comprehension. Understanding the architecture and components of digital health systems is crucial for implementing effective digital health interventions. Concepts like DHIs, eHealth system building blocks, and digital health enterprise system architectures play a significant role and for digital inclusion and accessibility, Digital Public Goods for Health have become indispensable.

The landscape of resources, including guidelines, frameworks and tools has evolved considerably,

especially over the past 11 years. Many of the foundations exist to effectively guide decision-makers, planners, implementers and donors through the stages of digital health development for health systems. However, some gaps in the landscape were identified. As such, work on harmonizing tools and methods for DLAs needs to continue. For this, governments, donors and implementers should share field experiences and country use cases to build on and contribute to this field of work. In terms of M&E, there is a need for evidence on process, impact and on the economic value of DHIs. Thus M&E professionals need to adopt monitoring and evaluation methods that address this gap. Moreover, further work is needed to create useful indicators for digital health. Whilst the topic of Gender, Equity and Inclusion is increasingly mainstreamed into digital health programing and some resources exist, there is real need for further evidence on the topics and a unification of sources into a comprehensive guidance document for users. Even less evolved is the evidence-base for digital literacy capacity strengthening for health workers and ICT professionals in LMICs, and consequently, the guidance available on the topic is also sparse. There is a need for rigorous research in this area as well as the development of resources for digital health professionals.

Conclusion

This review sought to provide a comprehensive overview of the landscape of digital health program-relevant guidelines, frameworks and tools. Whilst a systematic strategy was adopted to ensure completeness, the selection of resources in this review should not be considered as finite. Instead, in the fast-evolving context of digital health, revisions of existing guidelines and development of new ones is likely to occur at parallel pace.

From this review a number of recommendations can be drawn for digital decision makers, planners, implementers, donors and researchers.

- 1. Harmonize Approaches:** Encourage the development of harmonized guidelines and frameworks to foster a more unified approach to digitizing health systems globally.
- 2. Address Gaps:** Focus research and development on evidence-sparse areas and create

comprehensive guidelines for aspects of digital health development currently lacking resources.

- 3. Develop Targeted Guidelines for Training Programs:** Develop specific guidelines and frameworks for digital literacy and competency training, particularly in LMICs, to enhance healthcare staff's capacity in utilizing digital tools.
- 4. Align Global Standards:** Work towards aligning technical standards across regions and ensure they are adaptable to rapid technological changes.
- 5. Adopt Inclusive Development:** Prioritize the inclusion of diverse user groups and stakeholders in developing and implementing digital health interventions.
- 6. Generate Strategic Evidence:** Continuously monitor and evaluate the processes, effectiveness and impact of digital health interventions and

share evidence widely. Guidelines and frameworks should be adapted accordingly.

By following these recommendations, stakeholders can harness the full potential of digital health solutions, thereby improving healthcare delivery, patient outcomes, and overall health system efficiency and effectiveness at the national and global level.

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1. INTRODUCTION

Healthcare systems are undergoing digital transformation, with the aim of providing agility that will enhance, complement, and refine operational processes and improve patient experiences and outcomes. The traditional model of medical charting, assessment, differential diagnosis, and treatment may be improved by tools such as unified digital platforms, mobile applications, and telehealth. Use of digital technologies for health has potential benefits like improving access to health care services¹⁵⁻¹⁷ especially for those in inaccessible or remote areas¹⁸⁻²¹, improvements in safety and quality of care²², enhanced knowledge and access to health information and communities leading to better productivity of the health workforce²³, and increased uptake of health services²⁴. Furthermore, if designed purposefully and implemented in a cost-effective way, digital technologies can increase efficiency and reduce the cost of service delivery^{25,26}, facilitate swift transmission of public health information for timely decision making and enhance the capacity for monitoring the performance of programs and the health system as a whole²⁷⁻²⁹. Other potential benefits include detecting and addressing sociocultural, physical, and financial barriers to equitable access to health and digitalization of health insurance schemes which could make them more efficient²¹. Digital health thus has the potential to become an engine for innovation to address challenges that hinder the establishment of universal health coverage (UHC)³⁰ by impacting on all the six health system building blocks once properly integrated^{1,2,31,32}.

The recent COVID-19 pandemic has accelerated the move towards digital health. It highlighted some of the major challenges within healthcare systems, the significance of digital health technology application to health and its potential to strengthen health

systems, prevent disease and enhance service delivery at the global, national and sub-national level. However, important concerns remain. These include ensuring that new technologies are assessed effectively and are introduced thoroughly, data are unified into care records, and, ultimately, digital tools are reinforced with appropriate clinical support³³.

The Digital Innovation in Pandemic Control (DIPC) initiative is a German Ministry for Cooperation-funded (BMZ) digital health project, that seeks to address country-specific and global challenges in health systems through digital solutions. Implemented by the German Development Cooperation (GIZ), DIPC focus is on pandemic response, in particular on strengthening vaccine delivery systems, in five LMIC countries: Ghana, Malawi, Peru, Sierra Leone and Tanzania. DIPC comprises four working packages:

1. Assessment of national digital health eco-systems
2. Development of a software suite for managing vaccination distribution based on the SMART Guidelines and/or enhance the interoperability of current solutions through Fast Healthcare Interoperability Resource (FHIR)
3. Strengthening of health and ICT workforce capacity
4. Project evaluation and evidence generation

Beyond the five target countries, DIPC also executes two global initiatives: the first is to develop a comprehensive training curriculum for IT professionals to support them in building and sustaining digital health systems; the second is to advance WHO SMART Guidelines Level 3 Software, utilizing the FHIR standards². DIPC collaborates with four

*The six building blocks are: governance and leadership, health systems financing, service delivery, health workforce, health information systems and access to essential medicines (including quality vaccines)

implementation partner organizations, namely Digital Square (DS), the Pan American Health Organization (PAHO), UNICEF, and Regenstrief Institute to create health system-level digital solutions in the five project countries. These initiatives are designed to bolster the preparedness and response of countries facing future pandemics through digitalizing vaccination delivery systems.

DIPC is an integral component of BMZ's broader global strategy. This strategy aims to provide structural support to alleviate poverty and hunger, combat the climate crisis, and foster a feminist development policy. Worldwide, the strategy advocates for the development of digital public goods and infrastructure, encourages fair regulation of the digital economy, and fosters digital skills. Additionally, it supports tech start-ups, NGOs, and social enterprises, empowering them to innovate, scale, and successfully accelerate the implementation of their solutions^{34,35}.

As the fourth work package of DIPC (WP4), the Evidence-based Public Health Unit (known for its German acronym as ZIG 2) at the Centre for International Health Protection of the Robert Koch Institute has been contracted by GIZ to conduct the process evaluation of the DIPC initiative and to generate evidence in digital health in form of knowledge products that inform not only DIPC, but the digital health community, including academia, public health, international donors, implementers and developers more widely. This report forms part of this work.

Purpose of the Review

In recent years, there has been rapid, dynamic, but also heterogeneous development of digital technology in the medical and wider Public Health Sector. Many DH tools now feature in everyday life whilst many more were rendered obsolete within a few short years after their development. The broad spectrum of tools and the rapid advancements in the sector demand a streamlined approach to development and implementation of technology, especially in the digital public health sphere. In parallel, a significant body of evidence has been and continues to be generated at considerable pace in form of scientific peer-reviewed publications.

This report aims to provide an overview of the current landscape of guidelines, frameworks & tools relevant for digital health programs and national digital health systems more widely and their application in LMICs. Whilst many of the resources and concepts presented here apply globally, the review is predominantly addressing LMICs.

The review begins by defining key terms in digital health and goes on to outline the theoretical architecture of digital health systems, which includes concepts such as the WHO's building blocks of a digital health system, digital health enterprise system and architecture, health information exchange, interventions.

The overview of the key terms and definitions in digital health and the descriptions of the architecture and the components of digital health systems serves as the theoretical foundation for the subsequent chapter, which aims to provide a synthesis of key resources (guidelines, frameworks and tools) designed to support and guide an integrated and systematic approach to development, implementation, and scale-up processes of digital health interventions, particularly in the public health sector.

For those working in the DH sphere, the large number and breadth of resources to guide DH solution development can be challenging to navigate, and the variety of different frameworks, postulated methods and tools can be difficult to review and evaluate. Thus, this report can be used to gain an overview of the most relevant guidelines, frameworks and tools for DH available today, and it provides an analysis of what these resources offer.

In addition, the purpose of the review is to serve as a repository (Annexes 1 to 12), enabling DH professionals to systematically select resources, according to the planning, development or implementation stages they find themselves at or according to the thematic area they wish to address.

This review has also identified gaps in the landscape of resources to guide DH. We found that in areas in which resources were lacking, the evidence base was often also sparse (e.g., capacity strengthening). In other areas, a considerable amount of evidence, as well as guidelines and tools existed, yet the available information requires further harmonization and practical learnings from implementation to optimize their utility and adoption (e.g., digital landscape assessments).

Consequently, this means that research, and well-documented best practice experiences and use cases are needed to generate evidence, and evidence is required to formulate guidelines. This document highlights some of these under-studied or under-documented areas, which can help researchers in defining research agendas. For those engaged in the development of normative resources, the identified gaps can help to orientate future efforts.

FHIR (Fast Healthcare Interoperability Resource): FHIR is a healthcare interoperability standard designed to facilitate the electronic exchange of healthcare data across different systems within the healthcare sector. It provides a simplified implementation for data exchange between healthcare applications without compromising data integrity. Designed to meet the growing complexity of healthcare data, user expectations, and the need for a modern, internet-based approach, FHIR enables communication between different discrete components.

Ideally, this review will encourage uptake and adoption of guidelines, frameworks and toolkits, and thereby foster a more harmonized approach to the digitization of health systems, which would then in turn strengthen the impact of DH solutions on the health status of the population at the national level and beyond.

Target Audience

The topics covered in this report are important to better collocate DIPC in a rapidly growing and evolving digital world, and to ascertain the most relevant guidelines to steer and accompany the implementation of DIPC.

Beyond DIPC, this report also holds relevance for policy makers, DH planners and implementers, DH implementation researchers, and those engaged in the development of normative resources for DH mostly in LMICs.

2. METHODOLOGY

2.1 Search Strategy

For the purpose of this review, which stretches across a wide spectrum of the digital health sphere, we accessed a variety of sources of information, including generic online search platforms such as Google and Google Scholar as well as scientific journal repositories including PubMed and EM-BASE. These repositories were accessed to obtain peer-reviewed articles, academic papers, and research studies published by experts and researchers in the field. The sample of keywords used for the search included: *'cellphone', 'smartphone', 'digital health', 'digitalization', 'mHealth', 'eHealth', 'mobile applications', 'decision support systems', 'software', 'electronic health records', 'algorithms' and 'artificial intelligence', 'guidelines', 'regulatory standards', 'tools and toolkits', and 'frameworks'.*

Additionally, we explored websites and publications from various governmental and non-governmental organizations (including business-oriented ones and developers) involved in healthcare, public health, and technology. These sources proved invaluable for obtaining information about the regulatory frameworks, policies, and strategic initiatives surrounding digital health implementation at national and international levels, with focus on LMICs.

The search strategy for grey literature on generic online platforms was based on seven focal topics, and three thematic areas relevant to digital health development (described in more detail overleaf), including permutations and variations in terminology of: 1) *'digital health landscape' or 'eco-system', 2) formation of 'regulations', 'strategies' & 'policies', 3) 'solution design and development', 4) 'integration' & 'interoperability', 5) 'scaling up', 6) 'monitoring & evaluation', and 7) 'sustainability and financing'.* Moreover, grey literature searches were performed on the thematic areas of *'gender, equity and inclusion', 'capacity strengthening', and 'technical standards for developers'* in the context of digital health. Lastly, given the DIPC Initiative's emphasis on the digital immunization delivery in LMICs, a specific search was performed to identify resources that pertain to the digitization of immunization programs.

There was a notable snowball effect in the search, as oftentimes the identification of one relevant resource, especially in the grey literature, lead to others. The way in which the existing guideline landscape has been built, lends itself to this approach, as especially for some of the key texts, one resource builds on the other, or integrates elements of a third and cross-references back. Moreover, when a more in-depth enquiry into a particular topic was needed, we actively engaged in direct exchanges with experts in the respective DH field.

It should be highlighted that multiple resources included in this review were published whilst this desk research was conducted, and another was published as a version 2.0 (WHO's Classification of digital interventions, services and applications in health, 2nd edition). This is characteristic of the fast-evolving realm of DH and thus, the resources included here must not be considered as finite. In addition, whilst we included the most relevant sources available to the best of our knowledge and as identifiable through the above described search strategy, we acknowledge that some resources may have been overlooked.

A practical format of a review like the present, which would account for the fast-evolving nature of the sector, would therefore be a **"living guide to guidelines for DH"**, which could be continually updated and extended to accurately reflect the landscape of available resources going forward.

2.2 Review and Analysis

An initial sighting of all identified texts was conducted and those considered relevant to DH at the public health or health system level were included for a more in-depth review. Literature on the background of DH, including definitions, the development of terms and information on the make-up of digital health systems were synthesized and summarized in the first part of the results chapter.

With regards to the review of available DH guidelines, frameworks and tools, resources were included if they aligned with the existing global strategies, for example WHO’s Global strategy on digital health 2020 – 2025 and the Digital Development Principles. Moreover, included in the review were resources that have been developed or are recommended by WHO and other key organizations as relevant for fostering the digitization of health systems in LMICs and that are in alignment with the DH development phases and DH-system architecture described in Chapter one.

The review and analysis of the guidelines, frameworks and toolkits was conducted according to the following stages:

1. Search, appraisal and selection of the identified resources by three of the authors
2. Writing of a descriptive summary of the selected resources’ contents, including reference to their objectives, target groups and intended method of application
3. Evaluation of how a respective resource fits into the wider context of DH development
4. Evaluation of the landscape of resources available for each of the eleven thematic areas for DH-programing

To provide a structured overview of guidelines, frameworks and tools relevant to DH-programing, the WHO has previously classified and mapped key resources on the basis of their utility for seven different phases of DHI development 3 (Figure 1). This map covers seven progressive phases useful to establish a DHI, starting with “an assessment of the current state and enabling environment” and ending with “implementing, maintaining and scaling”.

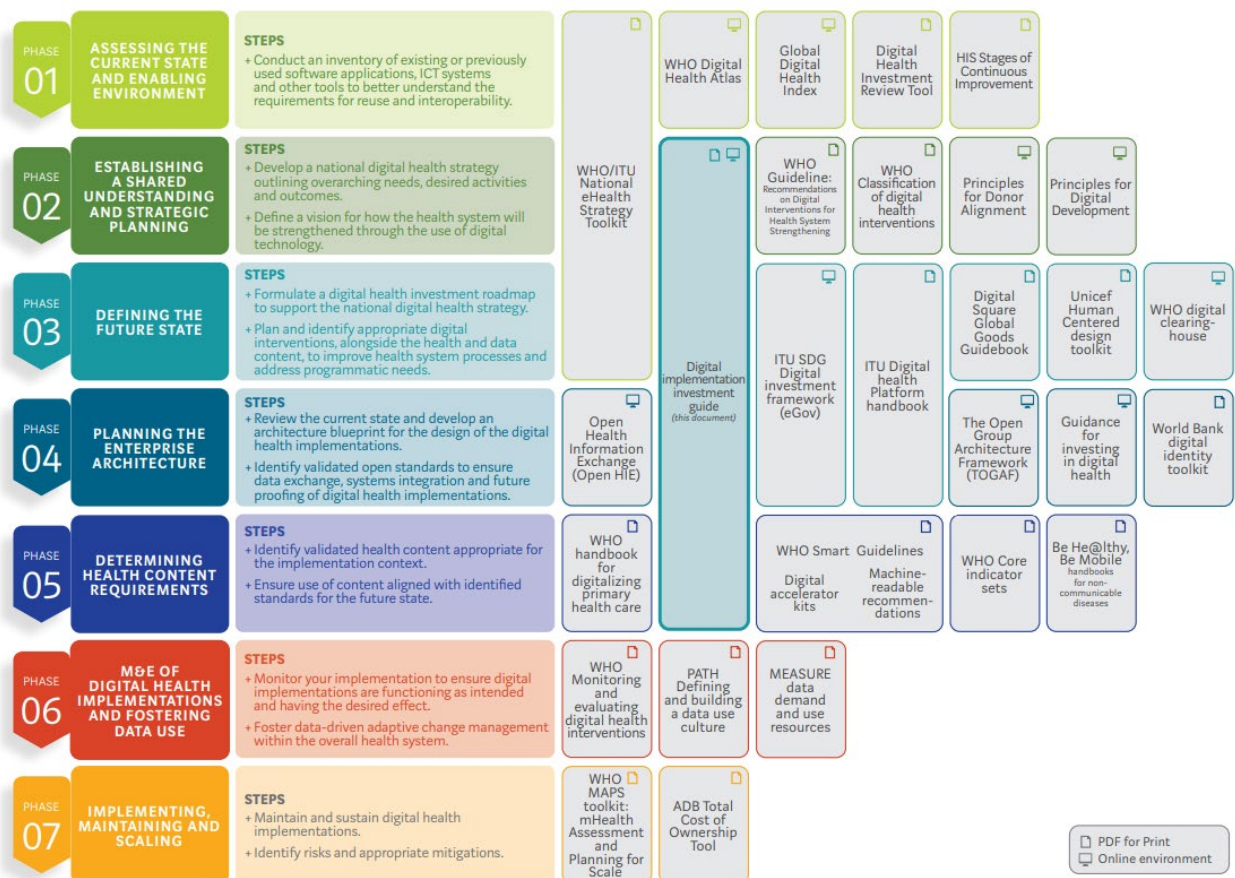


Figure 1. Mapping of the seven phases to establish an integrated digital health ecosystem and phase-specific guidelines, tools and frameworks (Source: WHO, 2020b)

For the purpose of this report, we adapted this 7-phase model. Our structure for analysis includes eleven components of DH-programing and implementation (Figure 2.), these are not consecutive phases as such, but rather thematic topics of relevance. The first seven topics are well-established focal areas for DH-programing and bear similarity to the WHO model.

1. Digital Landscape Assessments
2. Regulations, Strategy & Policy Development
3. Solution Design & Development
4. Integration & Interoperability
5. Scaling-up
6. Monitoring & Evaluation
7. Sustainability and Financing

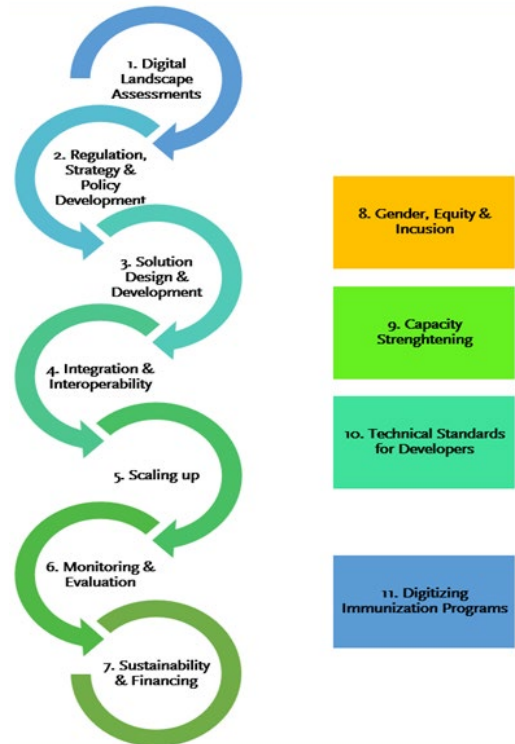
Topics 8 to 10 are topics that are rapidly gaining traction in the DH sphere given their importance (8 & 9).

9. Gender, Equity & Inclusion
10. Capacity Strengthening
11. Technical Standards for Developers

Finally, given the context of the DIPC initiative, we analysed the landscape of guidelines, frameworks and tools specific to immunization programing as an additional thematic area.

11. Digitization of Immunization Programs

The selected resouces are presented in Chapter 3 according to the thematic area they pertain to (Table 1. & Figure 12.).



For each of the above mentioned topics, a brief explanation is provided about the relevance of the topic and of the identified resources. Moreover, a findings summary about the landscape of available resources is given, alongside a tabular summary of each selected resource. In the appendix a comprehensive overview and analysis of all selected guidelines, frameworks and tools according to thematic area is provided.

Figure 2. Roadmap of the Chapter on Guidelines, Frameworks and Tools for Digital Health

3. RESULTS

In this section, we first present a number of definitions for digital health and elaborate on the concept of digital public health. We describe the architecture of digital health systems and its components and frameworks, as commonly used by those working on the development of digital health systems. This overview is to provide the blueprint on which many of the reviewed resources are based and onto which they are to be applied when adopted.

Second, the relevance of, and our findings from the review of selected guidelines, tools, frameworks are presented according to the DH-programing relevant thematic areas, they pertain to. This includes potential challenges and gaps that have been identified. In addition, a brief tabular overview is provided on the content, applicability and utility of the respective resources. More detailed descriptions of the guidelines, frameworks and toolkits are included in

a repository at the end of the document (Annexes 1 to 10).

We then discuss and reflect on the current landscape of existing resources for digital health programing, their importance as well as the challenges around standardized conceptual frameworks and definitions and conclusions are drawn by highlighting the main findings and key recommendations.

3.1 Definitions and Concepts for Digital Health Systems

The term “digital health programing”, as used in this review, refers to the collective activities, projects, programs, or initiatives undertaken by governmental, non-governmental, private sector, or collaborative entities to advance information and communication technology (ICT) solutions in the health sector. In our definition, this encompasses strategic planning, development, implementation, and management of digital technologies within health systems aimed at enhancing healthcare and public health services. Digital health programing involves efforts to improve digital public infrastructure, ensure interoperability for seamless data exchanges, and

establish robust digital health governance frameworks. Additionally, it includes ICT capacity building and the integration of gender, equity, and inclusion approaches into digital health initiatives.

Ambiguities in language and the lack of a precise and comprehensive definition of digital health can hamper effective collaboration between research, policy and practice, and consequently advancement. Especially in the public health sector, where perspectives, interests and needs of government, academia, scientific institutions, industry and individuals come together, there is need for a common language. As

such, achieving consensus between sectors and stakeholders is critical in order to reach individual and ultimately joint high-level goals and thus striving towards achieving the 2030 Sustainable Development Goals (SDG)².

The notion of capturing the field's diversity is reflected in the WHO **2020-2025 Global Strategy on Digital Health** which refers to “digital health” as *“the field of knowledge and practice associated with any aspect of adopting digital technologies to improve health, and incorporates the subdomains of eHealth, medical informatics, telemedicine, telehealth and mHealth, as well as data-analytics, big data, and artificial intelligence.”*²

3.1.1 From eHealth to Digital Health

The term “digital health” is rooted in eHealth, which originates in the 2000s. At the time, eHealth was an attempt to expand the focus from medical informatics to the use of technology in the business of health care delivery³⁶. eHealth was defined as *“the use of information and communications technology in support of health and health-related fields”*⁸. eHealth initially regarded digitalizing health data and creating health information systems (HIS). By 2008, the focus broadened to mobile health (m-health) when the term was introduced at “Making the eHealth Connection: Global Partnerships, Local Solutions (Bellagio Center, Italy)”³⁷. Mobile health (mHealth) was considered a subset of eHealth and defined as *“the use of mobile wireless technologies for health”*.

The term “digital health” was only recently introduced as *“a broad umbrella term encompassing eHealth (which includes mHealth), as well as emerging areas, such as the use of advanced computing sciences in ‘big data’, genomics and artificial intelligence (AI). It captures the field of knowledge and*

*practice associated with any aspect of adopting digital technologies to improve health”*².

Because “digital health” covers numerous technologies, systems and scientific fields based on ICT, it is challenging to group such a variety of disciplines in one standardized definition. To demonstrate the challenge, an analysis of “definitions of digital health” in a recent systematic review, was based on 95 individual definitions of digital health³⁸ which highlights the potential ambiguity in understanding and perspectives. The results of this study show that when it comes to digital health, the main focus is on the wellbeing and health outcomes of individuals, rather than diseases or technology or mechanisms implemented. This systematic review highlighted that digital health revolves around the proper utilization of technology to improve both individual and population health, as well as enhancing the care of patients receive by healthcare providers through intelligent processing of clinical and genetic data³⁸.

3.1.2 Digital Public Health

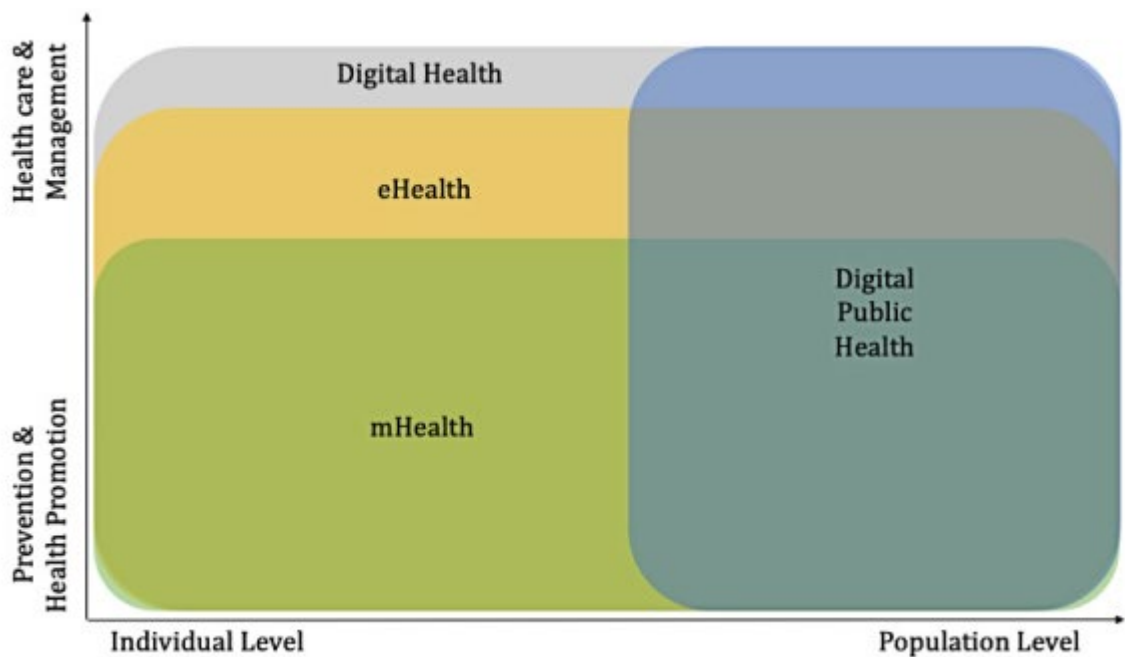
Within the wider realm of digital health, a distinctive field of practice, referred to as “**Digital Public Health (DiPH)**”³⁹ has emerged and gained traction. It distinguishes itself, because the focus is on integrating digital technologies in health services and the potential of these technologies to improve health outcomes of populations and communities, rather than on tools that, for instance, assist individual users to take better care of aspects of their health (e.g., tracking of physical activity, diet, weight, or sleep).

Instead, the development of technology in the public health space is based on public needs, which usually includes population or community health needs but also health system needs, with examples such as Electronic Medical Records (EMR), disease surveillance tools, vaccination reminders, medical imaging processing tools, or digital medical or laboratory logistics, which may include procurement or transport.

This distinction between “digital public health” and “digital health” has been shown both necessary and useful when conceptualizing and framing the field of

digital health as it is concerned with the operational scope and application of technologies and their level of impact at the individual user level or an integration of technology/technologies to advance public health goals and functions.

Figure 3. illustrates the core field of action and target group levels of mHealth, eHealth, digital health and digital public health and showcases the earlier mentioned considerable heterogeneity and interrelation between these commonly used terms in digital health⁵. Moreover, the figure demonstrates the potential position of DiPH within the broader context of DH terminology. The scope of DiPH is shown to span across the action fields of eHealth and mHealth, addressing prevention and health promotion as well as health care and management, whilst positioned at the population-level end of the user-spectrum.



The term DiPH is relatively new and as such, still little used in comparison to others, such as mHealth or eHealth. However, its distinction with regards to the focus on population, prevention, health promotion and a conscious analysis of health inequalities, may offer a clearer classification of the respective technology or area than some of the other, currently more prevailing terms⁴⁰.

There is also consensus in the literature that devising a comprehensive definition of this particular field is not without challenges. As such, a core obstacle in defining DiPH appears to be the seamless integration of digital advancement and technologies into existing public health frameworks, leveraging them to achieve public objectives, rather than completely redefining or reconceptualizing public health in response to technological progress^{40,41}.

Figure 3. Field of action and target groups of eHealth, mHealth, digital health and digital public health. (Adopted from Wienert et. al, 2022)

Wienert et al. defined a Digital Public Health Intervention as any intervention “addressing at least one essential Public Health function through digital means. Applying a framework for functional classification and stratification categorizes its interaction level with the user. The developmental process of a digital public health intervention includes the user perspective by applying participatory methods to support its effectiveness and implementation with the goal to achieve a population health impact.”⁵

3.1.2.1 DIPC: A digital public health initiative

DIPC is an example for DiPH initiatives, with its aim to establish interoperable digital vaccine delivery solutions in its five partner countries. In conformity with the definition provided by Wienert et al., 2022, DIPC’s objective is to provide population-based services that fall within the essential public health functions, cross-cutting (horizontal) functions, based roughly on the building blocks approach to health systems such as financing or work force development; and service-based (vertical) functions comprising the traditional public health services provided by modern health systems such as health protection and disease prevention.

Among the horizontal functions, DIPC is involved in health management information systems and terminology services. At this level, DIPC seeks to contribute to the advancement of digital ecosystems in its partner countries to help establish more resilient health systems, that have improved access to digital solutions. This is to be accomplished through the strengthening of existing digital solutions to improve vaccine distribution processes and pandemic prevention efforts. Furthermore, DIPC aims to improve interoperability between existing digital solutions for better data exchange and workflow. DIPC is also aiming to support the workforce in partner countries through a capacity strengthening component. Health and IT professionals in the health sector are to be offered training on the effective use of the strengthened digital tools on the one hand and access to an open-source e-learning course on the other hand.

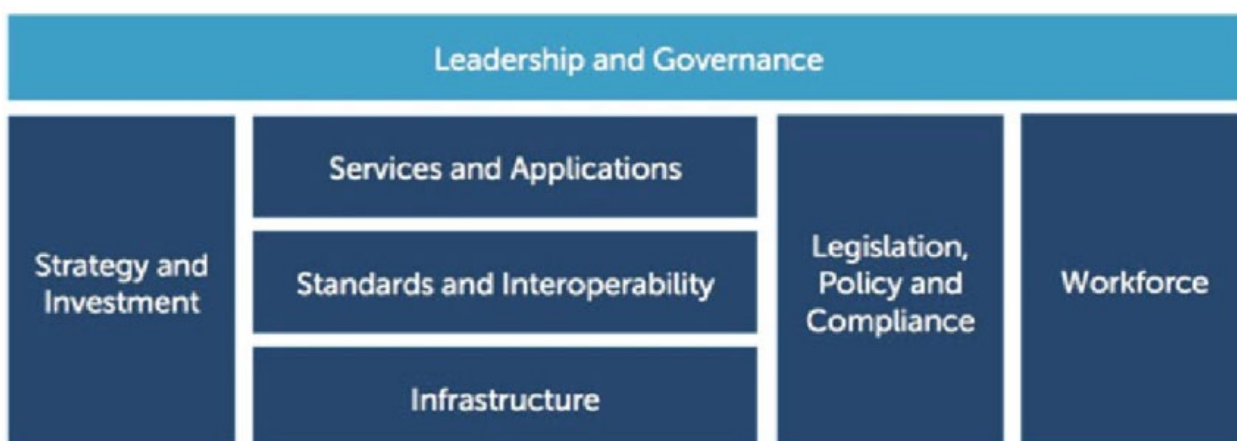
In addition to horizontal functions, DIPC is involved in vertical functions such as disease prevention targeting communicable diseases by facilitating vaccine

distribution and clinical services to allow for vaccination, contact-tracing and reporting. DIPC is also involved in health promotion through infodemics via intersectoral collaborations with different entities such as governments, institutions and implementation partners (Digital Square, UNICEF and Regensrief Institute). Accordingly, DIPC has the potential to play a major role in preparedness for public health emergencies. While DIPC does not necessarily take the lead role in managing these emergencies in respective countries, DIPC does play a role in implementing solutions that will assist in surveillance and consequently coordinated responses.

The concept of DiPH is by its very definition relevant to national health systems. In order to establish national digital public health systems, well-defined and interconnected structural models and concepts can assist governments, public health professionals, system developers and donor agencies to align their DH development strategies. In order for this to happen, WHO and other key actors have postulated theoretical concepts and architectural frameworks for DH systems and its components, which can serve as blueprints for DH developments and have been summarized in the following section.

3.1.3 The Architecture of a Digital Health System

3.1.3.1 Seven Building Blocks of the eHealth System³



First described in the **WHO & ITU “National eHealth Strategy toolkit** ⁴², a national eHealth system comprises seven components or building blocks, which should be strengthened through a national eHealth strategy. These seven components can be grouped into the “ICT environment” and the “enabling environment”, whereby 1) leadership & governance, 2) strategy & investment, 3) legislation, policy & compliance, 4) the workforce and 5) standards & interoperability fall within the “enabling environment”, whilst 6) infrastructure and 7) services and applications (where DHIs are situated) fall within the “ICT environment”⁸. Figure 5. (adopted from WHO & ITU, 2012) describes in more detail the individual components and strategies for strengthening them.

WHO & ITU (2012): National eHealth system toolkit describes national eHealth systems and environments as a collective system, which comprises mHealth and eHealth solutions and encompasses digital public health and individual digital health solutions, without further distinction as per Section 3.1.1 & 3.1.2.

Figure 4. Framework of the seven components of an eHealth System (Source: WHO & ITU, 2012)

Component	Role	Description
Leadership, governance and multi-sector engagement	Enabling environment	<ul style="list-style-type: none"> • Direct and coordinate eHealth at the national level; ensure alignment with health goals and political support; promote awareness and engage stakeholders. • Use mechanisms, expertise, coordination and partnerships to develop or adopt eHealth components (e.g. standards). • Support and empower required change, implementation of recommendations and monitoring results for delivery of expected benefits.
Strategy and investment	Enabling environment	<ul style="list-style-type: none"> • Ensure a responsive strategy and plan for the national eHealth environment. Lead planning, with involvement of major stakeholders and sectors. • Align financing with priorities; donor, government and private-sector funding identified for medium term.
Legislation, policy and compliance	Enabling environment	<ul style="list-style-type: none"> • Adopt national policies and legislation in priority areas; review sectoral policies for alignment and comprehensiveness; establish regular policy reviews. • Create a legal and enforcement environment to establish trust and protection for consumers and industry in eHealth practice and systems.
Workforce	Enabling environment	<ul style="list-style-type: none"> • Make eHealth knowledge and skills available through internal expertise, technical cooperation or the private sector. • Build national, regional and specialized networks for eHealth implementation. • Establish eHealth education and training programmes for health workforce capacity building.
Standards and interoperability	Enabling environment	<ul style="list-style-type: none"> • Introduce standards that enable consistent and accurate collection and exchange of health information across health systems and services.
Infrastructure	ICT environment	<ul style="list-style-type: none"> • Form the foundations for electronic information exchange across geographical and health-sector boundaries. This includes the physical infrastructure (e.g. networks), core services and applications that underpin a national eHealth environment.
Services and applications	ICT environment	<ul style="list-style-type: none"> • Provide tangible means for enabling services and systems; access to, and exchange and management of information and content. Users include the general public, patients, providers, insurance, and others. The means may be supplied by government or commercially.

Since the release of the WHO-ITU eHealth Strategy’s building blocks, the significance of data use and change management in the digital transformation of health systems has become increasingly recognized by countries and their partners. Adjusting operations and workflows to enhance data use is often necessary and capacity to manage these organizational changes is critical to successful implementation. Recognizing this, the Data Use Acceleration and Learning (DUAL) initiative’s model⁴³ proposed two new components to the WHO-ITU eHealth Strategy’s building blocks: change management and data use ecosystems as essential elements of advancing data use. The data use ecosystem encompasses all activities that facilitate better access to and utilization of data, including collection, quality assurance, demand generation, and analysis. The model stresses the importance of employing proven strategies to introduce and integrate new technologies, systems, and processes among health workers, ensuring smooth transitions and broad adoption. It advocates for nurturing a data-centric culture and supporting the workforce through the organizational changes required for sustainable digital transformation.

To fully capture a country’s ICT environment, we also need to understand several technical constructs and taxonomies designed to facilitate a digital transformation from the national system level down to the functional level of a digital health intervention itself. They serve as infrastructural, architectural and functional maps and have been summarized in the following section.

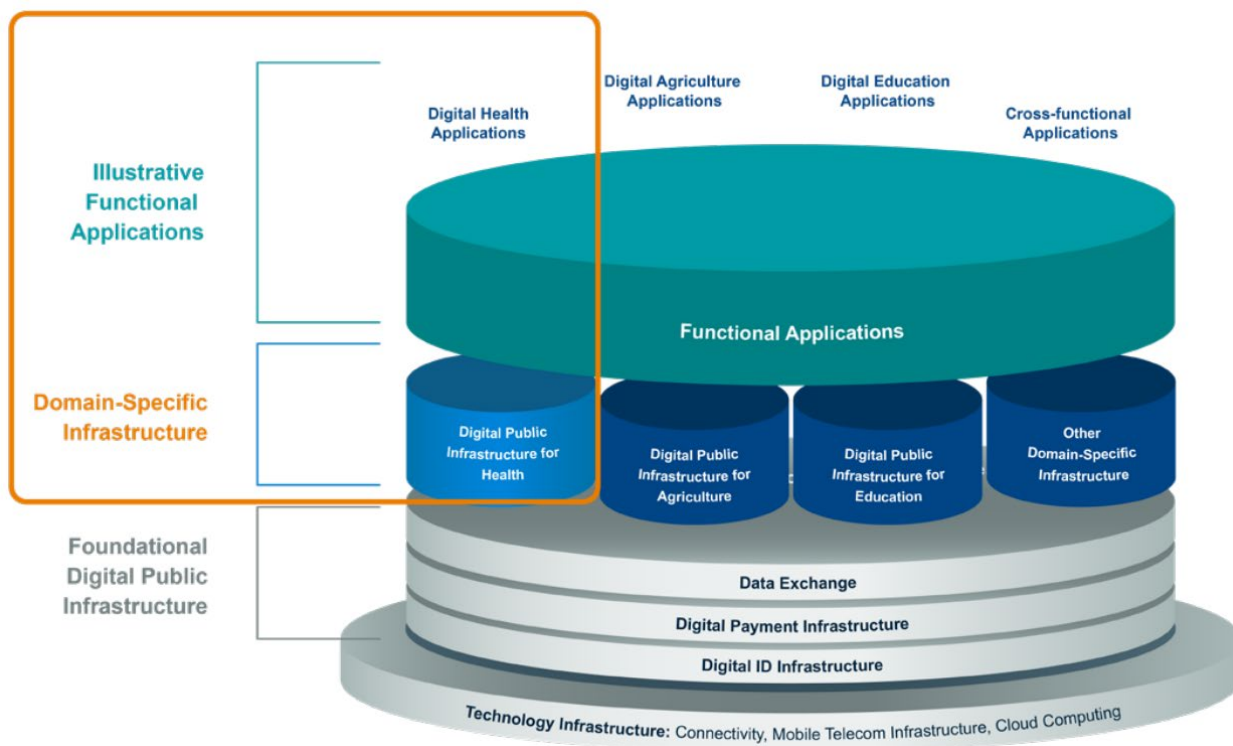
Figure 5. Description of the seven components of an eHealth System (Source: WHO & ITU, 2012)

3.1.3.2 Digital Public Infrastructure for Health

According to a 2023 UNDP compendium⁴⁴, Digital Public Infrastructure (DPI) refers to a collection of shared digital systems designed to be secure and interoperable, often based on open standards and specifications. These systems aim to provide equitable access to both public and private services on a large societal scale. They are governed by relevant legal frameworks and regulations and are designed to encourage development, inclusion, innovation, trust, and competition while upholding human rights and fundamental freedoms. These infrastructures go beyond isolated digital solutions⁴⁴, with examples of DPI including digital identity systems, payment

platforms, and data exchange frameworks. These infrastructures are designed provide scalability by minimizing physical and cost barriers to accessing services⁶.

Within the conceptualization, Digital Public Infrastructure for Health (DPI-H) plays a key role in enhancing healthcare delivery in low- and middle-income countries. DPI-H includes health-specific digital components such as client registries, health information exchanges, and central data repositories.



These components can collectively support a variety of digital health applications, intended to lead to improved health outcomes through better data management, enhanced service delivery, and more efficient health systems. DPI-H is designed to facilitate scalable and interoperable digital health systems, thereby creating an ecosystem that is conducive to innovation and widespread adoption, which is achieved through foundational digital functions like health information exchanges (more detail in a later part of this section) and client registries. However,

in order to successfully implement such systems, it is necessary to strengthen governance, build technical capacity, develop core infrastructure, ensure interoperability, coordinate investments, and engage stakeholders⁶, whilst there are persisting challenges, such as fragmented investments, e.g., focusing on specific disease rather than integrated platforms, technical and regulatory gaps, resource limitations, data governance, and interoperability, that must be addressed to fully realize the benefits of DPI-H.

Figure 6. Conceptual model for DPI and Health Domain-Specific DPI (Source: Vital Wave, 2023)

3.1.3.3 Digital Health Enterprise

Another important concept when defining the structure of a DH system is the “digital health enterprise architecture” (DHEA). **According to WHO’s Digital Implementation Investment Guide - DIIG³**, this term refers to a group, be it a single entity, an organization, or a consortium of organizations, that shares common health-related objectives and works together to deliver specific health services and products to their clients.

It encompasses the associated business processes, data, systems, and technologies that are essential for supporting the health system’s operations. This includes everything from software applications used at the service delivery point, to the devices and hardware employed, governance structures, and the fundamental information infrastructure (digital health platforms) that operate cohesively and deliberately. There are four distinct kinds of digital health enterprise system architectures according to the DIIG, each representing a stage in the maturity spectrum (Figure 7).

SILOED: This type of digital health enterprise system architecture is characterized by isolated applications. A digital health project under this category

is often a finite initiative focused on establishing a proof of concept using a siloed approach.

MUD (Monolithic Unarchitected Software Distributions): These systems are marked by their disorganized, expansive nature, formed through an ad hoc accumulation of functions without a pre-planned scope or design. They often carry significant technical debt due to their unplanned evolution.

INTEGRATED: In this architecture, at least two applications are directly connected (without a middleman for data exchange). The purpose is to tackle specific health system challenges and achieve health program objectives.

EXCHANGED: This architecture features multiple applications connected via a health information exchange using standardized methods. It addresses broader needs across the health system and functions in a synchronized way within a digital health architecture.

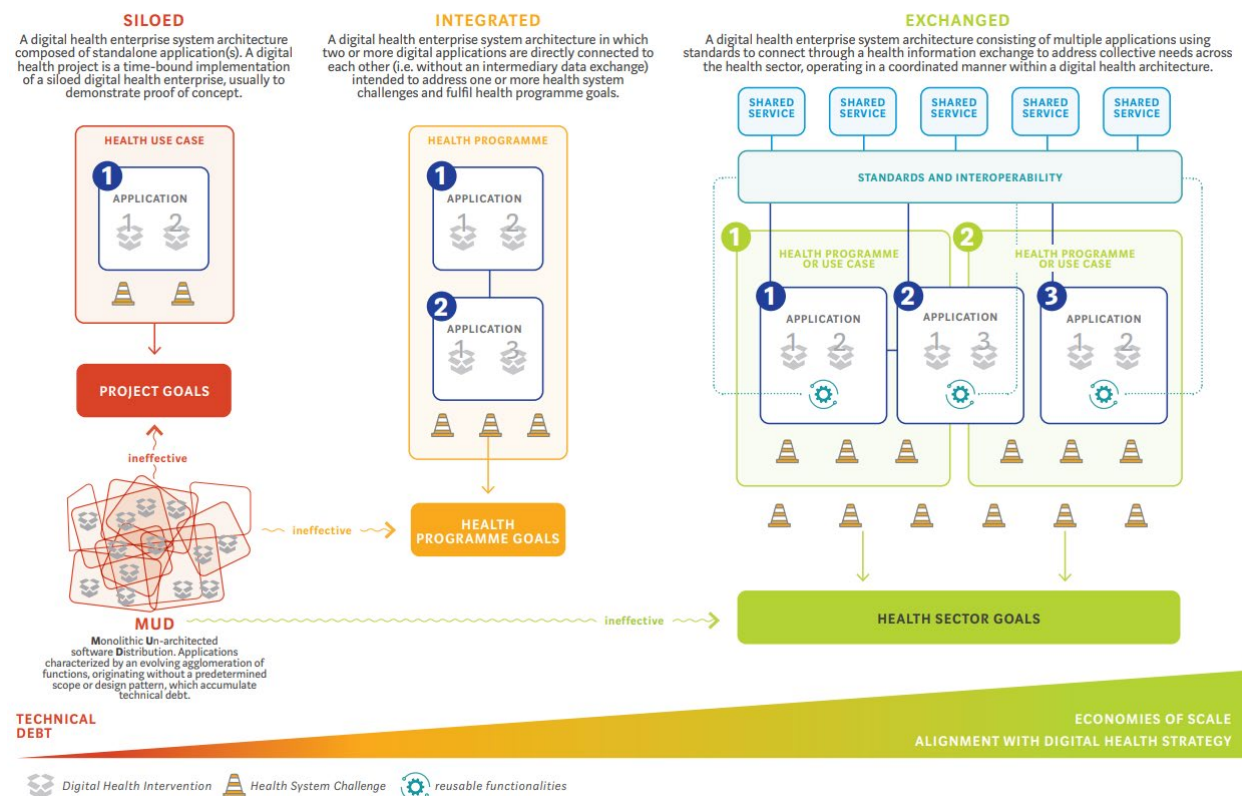
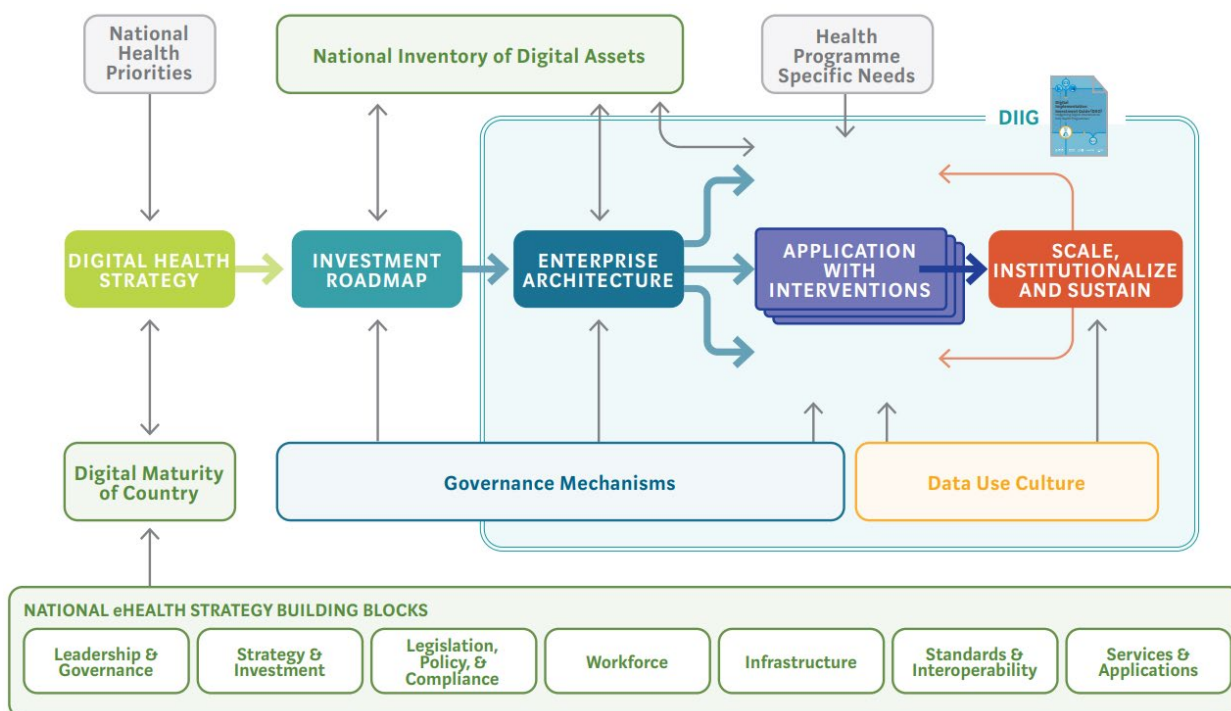


Figure 7. Digital Health Enterprise System Architectures (Source: WHO DIIG, 2020)

Developing a DHEA is a flexible and evolving process and the sequence and specifics of each phase may need to be adjusted according to a country's unique context, needs, and constraints (Figure 8).



As such, revisiting earlier stages can be part of the process to adapt to changing health needs and the evolving digital health ecosystem, which in turn would lead to new strategies and interventions.

The relationship between DPI-H and DHEA can be summarized as follows: DPI-H is a concept that encompasses the foundational digital systems required to support health services at a societal level. DHEA provides a blueprint for integrating various digital health applications, data flows, and processes to ensure they work together seamlessly. The relationship between DPI-H and DHEA is complementary. DPI-H provides the foundational infrastructure upon which DHEA can be built and operationalized, in the following ways:

1. **Foundation and Framework:** DPI-H serves as the foundational infrastructure that supports the broader digital health ecosystem. It provides the necessary digital systems, such as identification, payments, and data exchange platforms, that can be utilized by various digital health applications designed within the DHEA framework.
2. **Interoperability and Standards:** Both DPI-H and DHEA emphasize the importance of interoperability and the use of open standards.

DPI-H ensures that the underlying infrastructure supports interoperable systems, while DHEA applies these standards to ensure that different digital health applications can communicate and exchange data effectively.

3. **Scalability and Integration:** DPI-H enables the scalability of digital health solutions by providing infrastructure that can support large-scale implementations. DHEA utilizes this scalable infrastructure to integrate various health applications, ensuring that they can operate at a societal scale and provide seamless services across different health domains.
4. **Governance and Regulation:** DPI-H is governed by legal frameworks and regulations that ensure the secure and equitable use of digital infrastructure. DHEA aligns with these governance structures to ensure that digital health applications comply with legal and regulatory requirements, thereby ensuring data privacy, security, and trust.
5. **Innovation and Flexibility:** By providing a robust and flexible digital infrastructure, DPI-H allows for innovation in digital health solutions. DHEA leverages this flexibility to

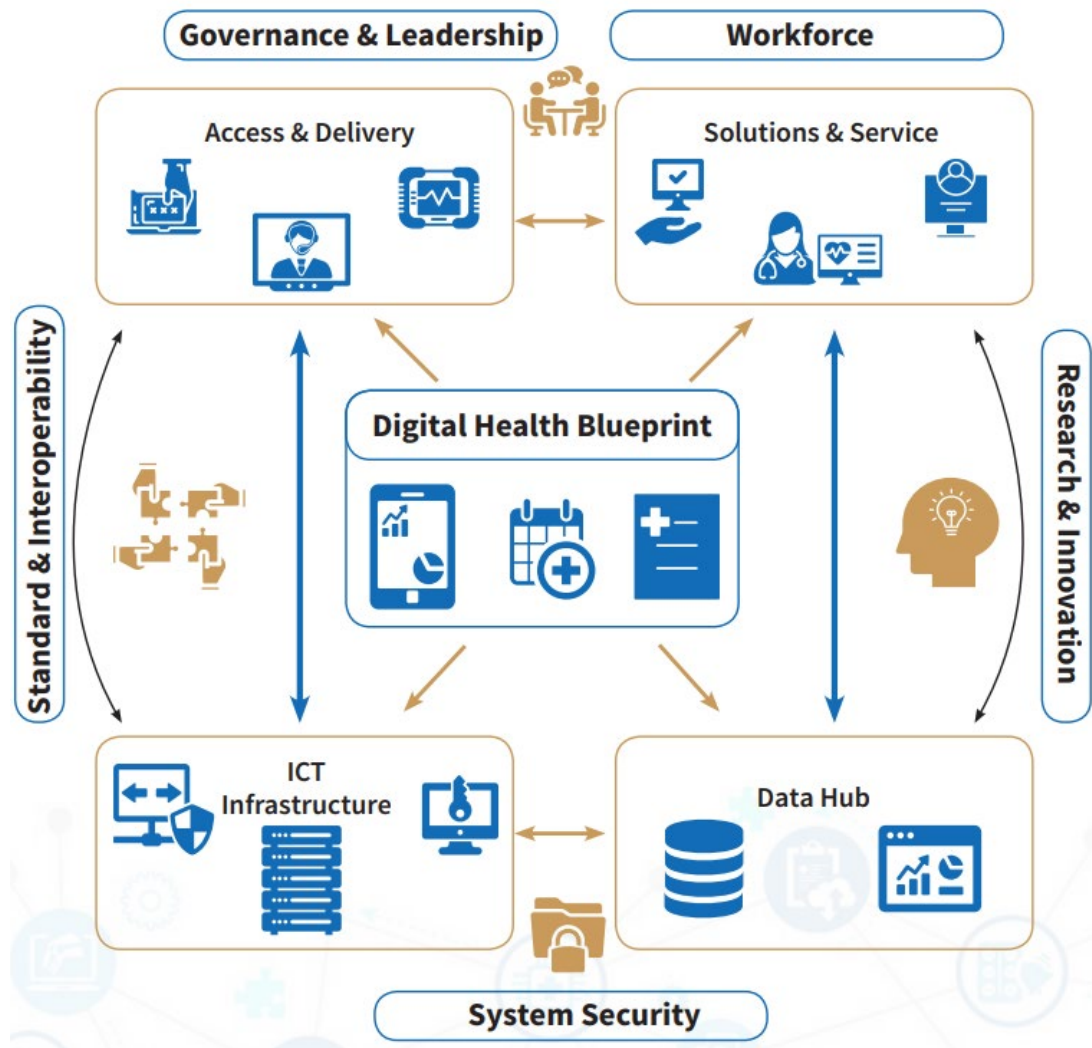
Figure 8. Essential processes of national digital health implementations (Source: WHO DIIG, 2020)

design and implement innovative health applications that can adapt to changing health needs and technological advancements.

As such, DPI-H provides the essential digital infrastructure that supports the implementation and scalability of digital health solutions designed within the DHEA framework. Together, they enable the development of a cohesive, interoperable, and efficient digital health ecosystem that can enhance healthcare delivery and outcomes.

In its entirety, digital health implementation should be based on a “digital health architecture” specific to the country context, national DH strategy and status

quo of its eHealth components. According to the WHO/ITU eHealth Strategy toolkit ⁴², governments are encouraged to develop their national strategies to strengthen the enabling environment and ICT environment (and their respective eHealth components or building blocks) and to devise a national digital health (and other programmatic) architecture framework or blueprint to demonstrate the interlinkages and interactions. Following these guidelines, numerous countries have developed such blueprints to guide the digitization of their health system, for example India and Ethiopia (Figure 9). The principle of the blueprint can also be applied to smaller organizational systems, such as regions, or DH program-level planning.

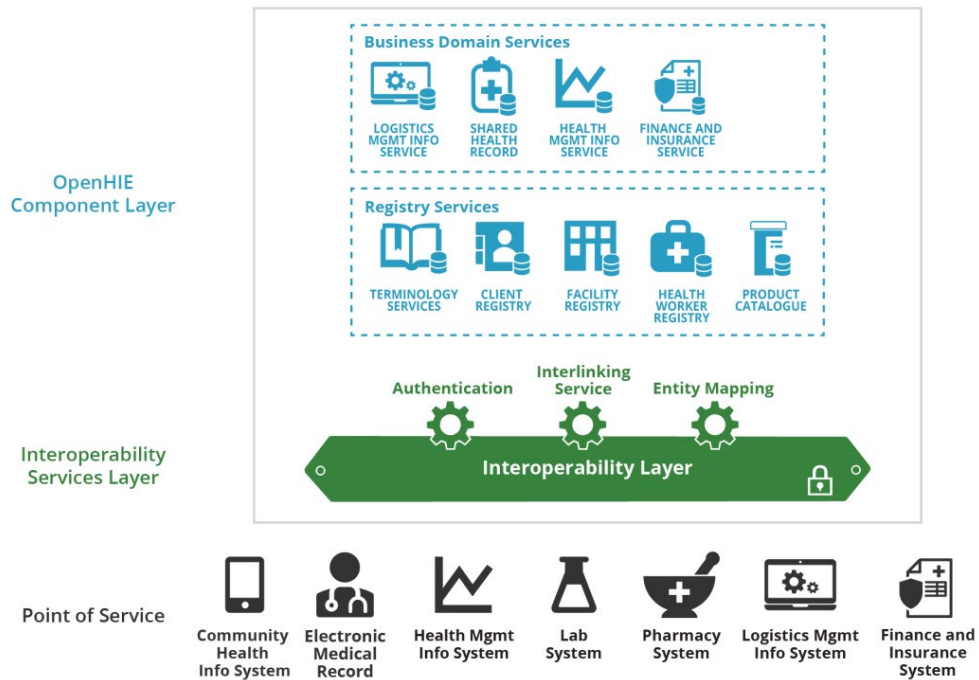


For components of the ICT environment and the building block for Standards and Interoperability (part of the enabling environment) the WHO/ITU toolkit highlights the importance of data accuracy and exchange of information. “Health Information Exchange” (HIE) is considered fundamental for DH system implementation as it makes sharing of health and other data across information systems possible.

As digital systems can differ substantially between countries and settings, setting up information exchange systems models can be accomplished by using a component-based framework approach, which is adaptable to the given environment and needs.

Figure 9. Ethiopian digital health blueprint
(Source: Ministry of Health Ethiopia, 2021)

As a proposed solution, the OpenHIE's Architecture ⁴⁵ is a modular framework based on a number of individual components and an interoperability layer. It employs patterns to unify health information from diverse external systems into a single HIE. This is achieved by normalizing the context of health information, focusing on the "for whom," "by whom," "where," and "what" aspects of different workflows or patient journeys and brings relevant information through an interoperability layer directly to the point of service.



OpenHIE, 2021-09-29; CC BY 4.0

Source: OpenHIE Architecture (10)

OpenHIE (Figure 10) integrates medical supply data, supporting decision-making, with the aim of enhancing care quality and safety, ensuring care continuity, and using information appropriately to improve population health.

The DIPC initiative developed their digital health blue print for vaccine delivery based on the OpenHIE framework and the GovStack framework (Figure 11).

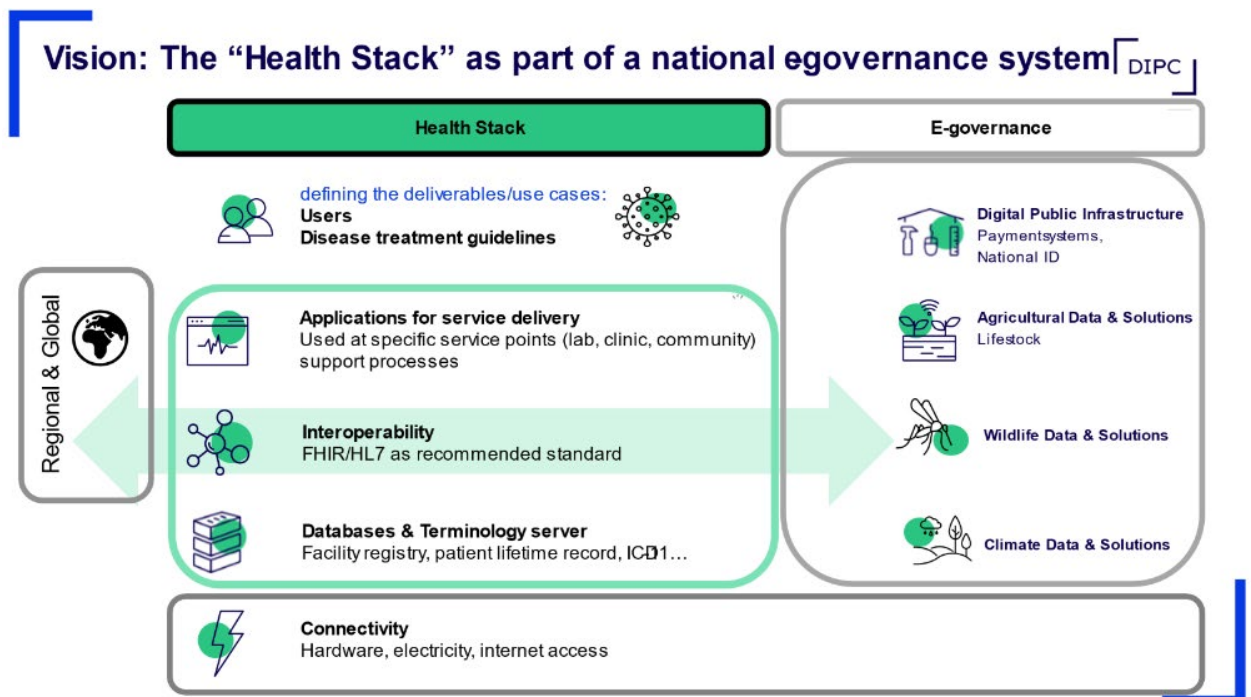


Figure 10. OpenHIE Architecture Framework (Source: OpenHIE, 2021)
Figure 11. DIPC "Health Stack"

There are efforts globally to streamline the establishment of such digitized health systems, which is critical as resources are limited, especially in LMICs. The digital sector offers enormous potential to develop technological solutions that can be adopted and adapted at the national level, rather than development efforts that take place in silos.

3.1.3.4 Digital Health Interventions

The term Digital Health Intervention (DHI) is frequently cited in the literature, but oftentimes used interchangeably to describe digital health application, technology, tools, initiatives, or even programs. We adopt the meaning for DHIs postulated by WHO 4, which positions DHIs as important functional components of the larger architecture of a digital health system. Accordingly, DHIs are:

“...discrete functionality of digital technology that is applied to achieve health objectives and is implemented within digital health applications and Information and Communication Technology (ICT) systems, including communication channels such as text messages, computers, software, the internet, telecommunication networks, mobile devices, and any other digital tools”⁸.



Figure 12. Digital Health Interventions for Health Care Providers according to the Classification of digital interventions, services and applications in health. (Source: WHO, 2023)

WHOs Classification of digital interventions, services and applications in health⁴ (see section 3.2.4.1 for further detail) outlines specific digital health interventions (DHIs) tailored to address particular health system challenges.

For example (Figure 13), eleven digital approaches have been identified for healthcare providers, each listing distinct DHIs. Under Health Care Provider Decision Support (2.3), there are three DHIs:

1. Provide prompts and alerts based on protocol (2.3.1)
2. Provide checklists according to protocol (2.3.2)
3. Screen clients by risk or health status (2.3.3)

The latter, DHI 2.3.3, would include tools for screening, risk assessment, triage, client prioritization, and supporting service delivery in alignment with care plans, guidelines, and protocols⁴.

This shows that whilst DHIs are considered as discreet units, their implementation and operation does not occur in isolation. Instead, DHIs are conceptually positioned within a country’s eHealth environment, which is made up of the aforementioned seven eHealth components (WHO & ITU, 2012). DHIs are, as part of the “Services and Applications” component (Figure 12), illustrating that DHIs and their level of impact is influenced by multiple surrounding and inherently related factors. (Figure 13, WHO, 2019).



FOUNDATIONAL LAYER: ICT and Enabling Environment



Key factors within the “Services & Applications” component that affect the impact of DHIs include: (i) the Health Content; (ii) the Digital Health Intervention itself and (iii) Digital Applications, including the hardware, software, and communication channels facilitating the digital health intervention;⁴².

This conceptualization illustrates that DHIs should integrate into an overarching digital health architecture, fostering a cohesive implementation approach where various interventions complement each other rather than functioning in isolation. The broader health system and enabling environment play a critical role in shaping the impact of DHIs. The evaluation of DH ecosystems is therefore an indispensable part of the process, given that without a robust ICT and enabling environment, there is a risk of disparate and disconnected systems, jeopardizing the effectiveness and sustainability of health interventions (more detail on DH landscape assessments is provided in section 3.2.4.1).

Figure 13. The seven components of an eHealth system, with focus on the “Service & Applications” component (Source: WHO, 2019)

3.1.4 Digital Public Goods and Global Goods

Digital Public Goods (DPGs) play a crucial role in the digitization of health systems. The UN defined DPGs as “open source software, open data, open AI models, open standards and open content that adhere to privacy and other applicable laws and best practices, do no harm”⁷⁷ and help attain the Sustainable Development Goals. DPGs are added to a specific registry when they meet nine-indicators⁴⁶:

1. Relevance to the Sustainable Development Goals
2. Use of Approved Open Licenses
3. Clear Ownership (Ownership of assets that the DPG produces must be clearly defined and documented)
4. Platform Independence
5. Documentation (Digital public goods require documentation of the source code, use cases, and/or functional requirements)
6. Mechanism for Extracting Data
7. Adherence to Privacy and Applicable Laws
8. Adherence to Standards & Best Practices
9. Do No Harm by Design

Highly relevant to countries’ DH architecture, DPGs can include open-source software, open data sets, educational resources, research publications, and digital infrastructure, among others. The idea behind DPGs is to provide access to valuable digital resources that can be used (and re-used) for various purposes, such as education, healthcare, economic development, and research, without imposing barriers or restrictions that limit their accessibility. Thus, DPGs are particularly important in the context of LMICs as they can help bridge the digital divide and promote equitable access to essential digital tools and information⁴⁶.

Because the nine Digital Public Goods standards do not evaluate aspects such as scale, funding sources, country deployments, or other indicators of the ‘maturity’ of the product, a new term was coined to address this gap: ‘Global Goods’. A Global Good should have the three following properties in addition:

1. It is non-rivalrous. Consumption of this good by anyone does not reduce the quantity available to other agents.
2. It is non-excludable. It is impossible to prevent anyone from consuming that good.
3. It is available more-or-less worldwide⁴⁷.

Digital Square has devised a maturity model that evaluates global goods. This model aims to delineate global goods as a refined category of Digital

Public Goods (DPGs), characterized by their maturity in scale, diversified funding, and proven efficacy. A “mature” digital health software global good is typically identified as Free and Open Source Software (FOSS), backed by a strong community, governed by clear and structured rules, financially supported through various means, extensively implemented across multiple countries, proven effective in its applications, engineered for interoperability, and acknowledged as a standard application within its domain³. The use of global goods is strongly encouraged by various stakeholders in the field, including UN agencies, large donor organizations and national governments themselves. To support them, Digital Square has recently updated its handbook concerning **Global Goods: Global Goods Guidebook Version 4.0**⁴⁸ and made available online an interactive guide to the digital health global goods ecosystem. These guidebooks compiles established digital health applications known for their use of open standards and backed by a solid developer community. The applications that have been included have been shown to be effective and are versatile enough to be tailored to various countries and scenarios.

A global overview of **Global Public Goods for Health (GPGH)** has recently been published by the Peace Research Institute Oslo⁴⁹. The paper highlights the growing yearly demand for GPGHs and the current lack of effective means to meet this demand. This under-contribution by countries is explained as a “participation trilemma”, which refers to a complex challenge in GPGs funding, particularly for health. As such, there appear to be conflicting interests and positions of 1) Existing Country Contributors (“Traditional Donors”), willing to fund, but reluctant to relinquish control over funding allocation, 2) Under-contributing Countries (“non-traditional Donors”) – inclined to increase contribution, but seeking more control before committing to higher contributions, and 3) non-contributing Countries (“Recipient Countries”), who are often excluded from decision-making.

Resolving this trilemma, as the paper argues, requires a deeper understanding of why countries choose to participate (or not) in supporting GPGHs and the various participation options available to them. This complex interplay of authority, contribution, and decision-making represents a significant challenge in mobilizing resources for global health needs. The paper provides data on country contributions to GPGH agendas and presents a set of strategic approaches that could help increase the volume and quality of such contributions in the future.

The Norwegian authors postulate The Global Public Investment framework, which offers an approach to finance GPG, such as health and education, shifting from the traditional donor-driven official development assistance model to a more inclusive, cooperative system. It emphasizes collective responsibility, engaging various countries in funding and decision-making. GPI aims for equity and inclusivity, allowing diverse nations, including middle-income ones, to contribute and benefit fairly. It advocates for democratic governance, ensuring all participants have a say in fund allocation. The framework also stresses transparency and accountability in fund use, and sustainability, seeking long-term contributions from a wide array of sources. GPI's goal is to create a more equitable, sustainable, and effective financing method for global public goods, ensuring equitable benefits for all nations.

Finding agreement to finance and streamline the efforts to accelerate the development of GPGH is critical, as the digitization of health systems, the strive towards UHC and the 2030 SDGs, especially in LMICs, is heavily dependent on GPGHs.

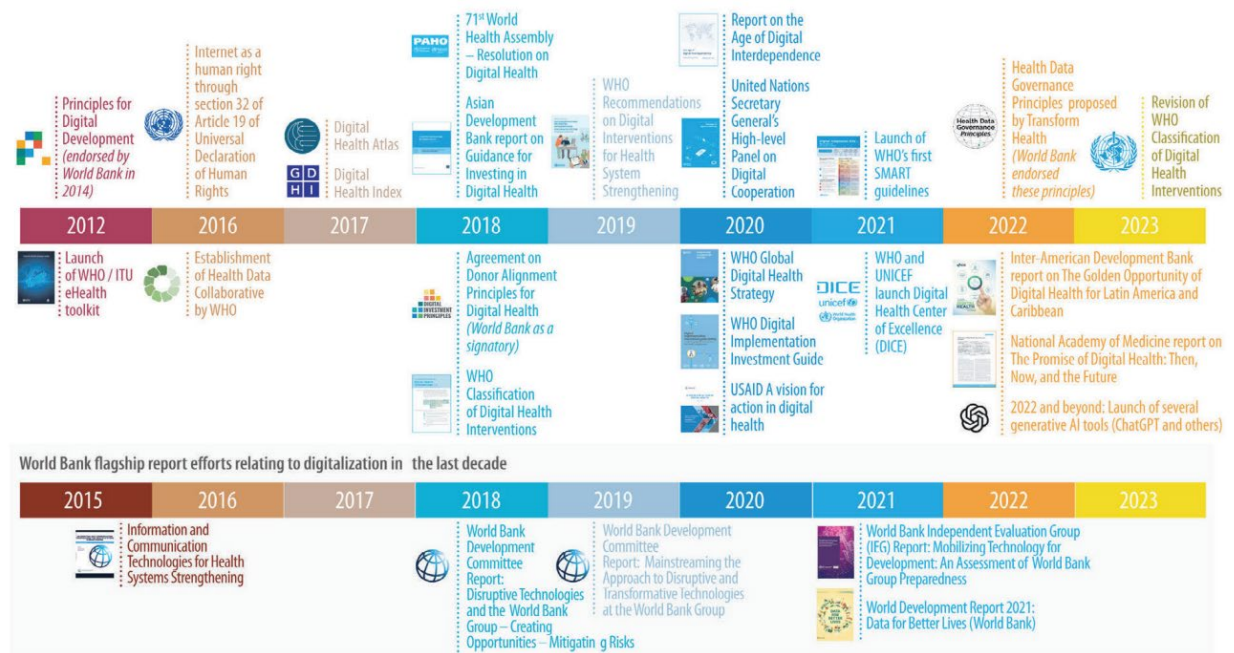
Streamlining the digitization of health systems is also dependent on clear guidance for DH stakeholders, including national governments, donors and implementers to manage the process in an evidence-based and feasible manner.

3.2 Resources to guide the digitalization of health systems

In this section, the history of DH guidelines development over the past 11 years is outlined, followed by a discussion on the needs and benefits for establishing and adopting guidelines, frameworks and tools for digital health programing.

Findings from the review of the most pertinent guidelines, frameworks, and tools relevant to digital public health that have emerged from our search are presented according to eleven thematic areas relevant to DH programing. Our findings are discussed and placed into the broader DH context.

3.2.1 A brief history of digital health guidelines development



Amid tight fiscal constraints, health systems are facing increasing pressures to offer enhanced, high-quality, and integrated services. ICT, which have rapidly expanded in recent decades to assist health systems, also constantly adapt to remain relevant amidst the ever-changing technological landscape. An initial regulatory effort to steer DH development began in 2005 when the first World Health Assembly encouraged member states to formulate a long-term strategic plan for the development and implementation of eHealth services⁵⁰. eHealth efforts initially focused on digitalizing health data and creating Health Information System (HIS) such as district information systems (e.g., DHIS 2), human resource information systems, logistics management information systems (to manage supply chains), and laboratory information systems. By the late 2000s, the spotlight had shifted to mHealth, considered as health care delivery via mobile devices⁵¹. As technology evolved, the scope expanded to digital health considered as an umbrella that today includes digital consumers, smart devices, the internet of things, Artificial Intelligence (AI) and big data⁵².

Today Digital Health plays an important role in supporting efforts towards UHC and in attaining the SDGs^{2,53}, and guidelines, frameworks, tools or any other regulatory mechanisms⁴, are essential for overseeing and steering this rapidly growing sector.

A recent World Bank report (2023) emphasized the timespan between 2012 and 2022 as a transformative period in digital health, characterized by increased recognition of the value of digital technology and data in healthcare. “Bookended” by two pivotal events: the introduction of the Principles for Digital Development in 2012 (described in more detail later) and the public release of generative AI tools like ChatGPT4 (Figure 14). Since 2012, landmark global cooperation agreements, resolutions and guidelines were developed to facilitate digital technology adoption for health systems and to provide guiding resources and frameworks for these otherwise oftentimes unregulated processes at both national and international level. Noteworthy milestones during this era include the launch of the **WHO/ITU eHealth toolkit** (2012), the **Digital Health Atlas** and the **Digital Health Index** (2017) and **WHO’s Global Strategy on Digital Health 2020–2025**².

DH guidelines and frameworks play a pivotal role in furthering the digitization of national health systems and global digital public health efforts. Many of the guidelines reviewed during the present research are based on the following guiding principles:

Standardization: Because the digital health landscape is rapidly evolving, guidelines, frameworks and tools help establish standards and best practices for the design, development, implementation, and evaluation of digital health solutions. This ensures

Definitions for Guidelines, frameworks and tools:
Guidelines consist of procedures that will prove useful in meeting the standards.
Frameworks are intended to connect inter-related core concepts.

Figure 14. Milestones in the development of digital health and guidelines (Source: Digital-In-Health, World Bank, 2023)

uniformity, interoperability, and high quality across various systems and platforms ⁵⁴.

Quality and Safety: DHI have the potential to improve healthcare outcomes, but they also come with inherent risks. Applying frameworks and guidelines helps address issues related to quality and safety by promoting evidence-based practices, usability standards, and risk management strategies ⁵⁵⁻⁵⁷.

Interoperability: Interoperability is a key challenge in DH. Different systems and technologies often operate in silos in the past. Frameworks and guidelines can promote interoperability by providing technical standards, data exchange protocols, and guidelines for integrating different DHI. This facilitates seamless communication and data sharing between different systems, enabling coordinated and holistic care for patients ⁵⁸⁻⁶¹.

Regulatory Compliance: DH technologies are subject to various regulatory requirements, such as data privacy and security regulations. Frameworks and guidelines assist developers and healthcare providers in understanding and complying with these regulations by following common standards as they provide guidance on ethical considerations, privacy protection, data governance, and security practices ^{56,62-64}.

Scalability and Sustainability: As DH continues to expand, scalability and sustainability become critical factors. Guidelines can provide guidance on factors such as technology infrastructure, business models, resource allocation, and evaluation methodologies, enabling long-term success and impact ⁶⁵⁻⁶⁸.

Knowledge Sharing and Collaboration: DH frameworks and guidelines foster knowledge sharing and collaboration among stakeholders. They provide a common language and framework for communication, enabling multidisciplinary teams to work together effectively. They facilitate the exchange of experiences, lessons learned, and best practices, fostering innovation and advancement in the field of digital health ⁶⁶.

Resource Allocation and Investment: Governments and donors play a crucial role in resource allocation and investment in DH. By underpinning guideline application, governments and donors ensure that their investments are directed towards projects that adhere to established standards and guidelines. This helps maximize the impact and sustainability of digital health interventions ⁶⁹.

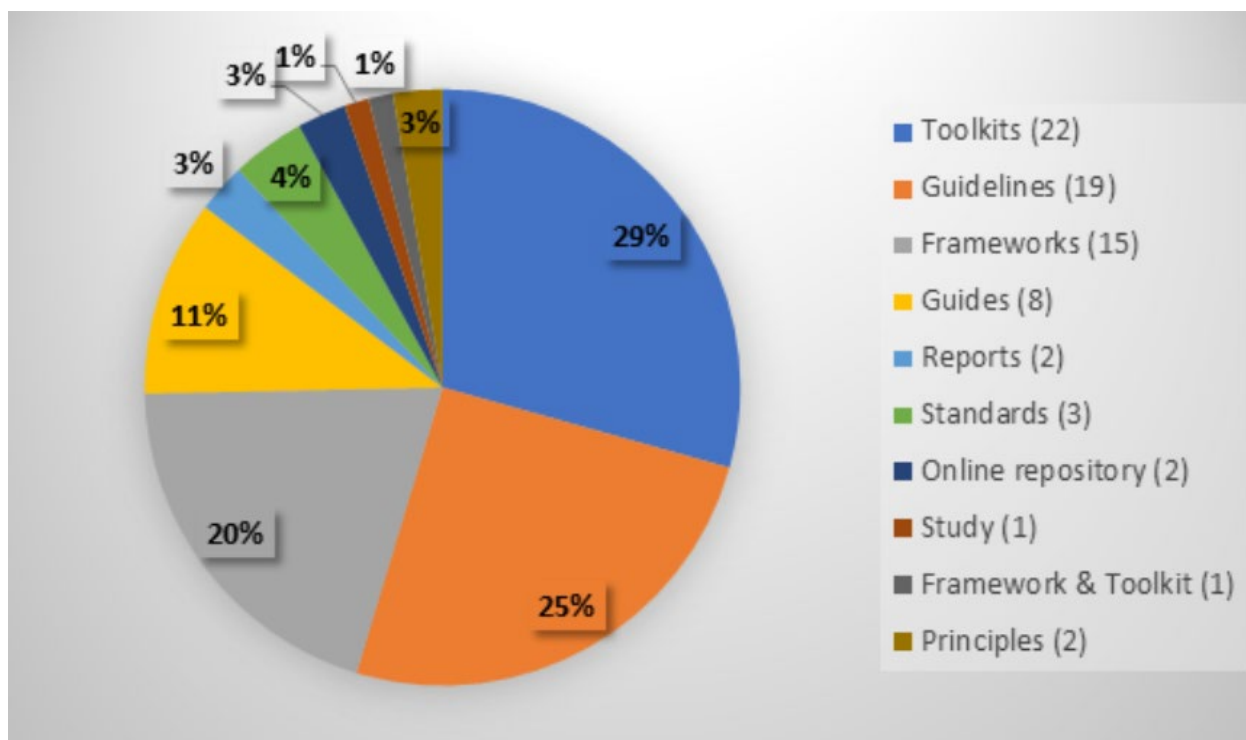
3.2.2 The need for guidelines, frameworks and tools in digital health

The adoption of guidelines is critical in Low- and Middle-Income Countries (LMICs), as they can serve as blueprints for governments, developers, researchers, implementers and donors to systematically address gaps in general infrastructure, the digital eco-system, and the development of regulations to only name a few areas needed for an integrated digitized health system.

In LMICs the development and adoption of guidelines saw a turning point following the so called “*pilotitis*” (Figure 15), a term coined in Uganda in 2010, when a proliferation of small, technically-driven pilots, often testing similar applications, created confusion in government health departments. The situation became so extreme that the Uganda government placed a moratorium on them. These pilots did not provide sufficient evidence of effectiveness or value to justify a scaling up or there were

challenges or barriers to implementation that were not addressed or resolved during the pilot phase, such as resistance from health care providers, lack of stakeholder engagement, or policy-level barriers ⁷⁰⁻⁷². Guidelines, toolkits and frameworks are to counteract such uncoordinated efforts by providing a systematic and structured orientation for government, developers, investors and other stakeholders alike ⁷³.

3.2.3 Classification of digital health guidelines, frameworks and tools



Although a large number of texts have been developed on this subject, we selected a sub-set of 75 resources, published between 2011 and 2024, as the most relevant resources to support the steering of DH-programing in LMICs, including the working packages of the DIPC initiative. This sub-set of guidelines, frameworks and tools are promoted to be widely adopted by implementers, donors, policy makers, developers and other DH experts. They are publicly available and those published by WHO followed the WHO handbook for guideline development⁸¹. The number of guidelines that are being released has been continuously increasing since 2011, with 62% of the selected sub-set (with publication dates) having been published in the past 5 years only. 21% were authored by UN-agencies including WHO, illustrating their efforts to encourage adoption of ICT to achieve the SDGs' targets.

As described in the methodology (Section 2.2) the review of normative resources is structured around 11 thematic areas:

1. Digital Landscape Assessments
2. Regulations, Strategy & Policy Development
3. Solution Design & Development
4. Integration & Interoperability
5. Scaling-up
6. Monitoring & Evaluation

7. Sustainability and Financing
8. Gender, Equity & Inclusion
9. Capacity Strengthening
10. Technical Standards for Developers
11. Digitization of Immunization Programs

The selected resources are presented according to the thematic area they pertain to (Tables 1 to 12 and Figure 2), with some having relevance to multiple topic areas. It should be noted that the number of reviewed resources per section differs considerably, which reflects the availability of guidelines, frameworks and tools identified and selected. In each section, information is provided on the primary and secondary target groups, a brief explanation on the relevance of guidelines on the topic or phase, a findings summary regarding the landscape of available resources and a tabular summary of the resources that have been selected as particularly relevant per thematic area.

Figure 16. Types of normative resources selected for inclusion.

Cross-cutting Principles & Guidelines				
1	Principles for Digital Development	Guideline	Digital Impact Alliance (DIAL) at the United Nations Foundation	2012
2	National eHealth Strategy Toolkit**	Toolkit	WHO/ITU	2012
3	Recommendations on digital interventions for health system strengthening	Guideline	World Health Organization (WHO)	2019

Table 1. Selected Resources: Cross-cutting Principles and Guidelines

Digital Landscape Assessments				
1	Digital Landscape Assessment Frameworks	Framework	UNDP	2021
2	Digital Ecosystem Country Assessment (DECA) Toolkit: A How-To Guide for USAID Missions	Toolkit	USAID	2022
3	National eHealth Strategy Toolkit (Assessment framework for DLAs) **	Toolkit	WHO/ITU	2012
4	The Digital Pandemic Preparedness Assessment (DPPA)	Toolkit	Digital Square/GIZ	2021
5	Early Stage Digital Health Investment Tool (EDIT)	Toolkit	DICE	2022
6	Map & Match Initiative (M&M)	Online Repository	USAID and collaborating partners	N/A
7	U.S. President’s Malaria Initiative Digital Community Health Initiative (PMI DCHI)	Toolkit	PMI, USAID, CDC	2020
8	Digital Health Assessment Toolkit Guide	Toolkit	World Bank	2021
9	HIS Interoperability Maturity Model (IMM) Toolkit	Toolkit	USAID, Health Data Collaborative & Measure Evaluation	2017
10	Health Information System Stages of Continuous Improvement (SOCI) Toolkit	Toolkit	USAID, Health Data Collaborative & Measure Evaluation	2020
11	The Information System for Health (IS4H) Toolkit	Toolkit	WHO/PAHO	N/A
12	Navigator for Digital Health Capability Models	Guide	PATH - Digital Square	2022
13	Classification of digital interventions, services and applications in health, second edition	Guideline	World Health Organization (WHO)	2023
14	Digital Health Atlas	Online Repository	World Health Organization (WHO)	N/A
15	Global Digital Health Monitor (GDHM) (former Global Digital Health Index (GDHI))	Toolkit	Health Enabled & the Global Development Incubator (GDI) & Partners	2022

Table 2. Selected Resources: Digital Landscape Assessments

**Marked resources pertain to more than one thematic area and are therefore listed multiple times.

Regulation, Strategy & Policy Formation				
1	Global Strategy on Digital Health 2020-2025	Guideline	World Health Organization (WHO)	2021
2	National eHealth Strategy Toolkit **	Toolkit	World Health Organization (WHO) and International Telecommunication Union (ITU)	2012
3	Health Data Governance Principles	Principles	TransformHealth	2023
4	Health Insurance Portability and Accountability Act (HIPAA)	Guideline	U.S Department of Health & Human Services	2021
5	General Data Protection Regulation (GDPR)	Guideline	European Union (EU)	2018
6	Framework for Improving Critical Infrastructure Cybersecurity	Framework	National Institute of Standards and Technology	2018
7	Guide to Privacy and Security of Electronic Health Information	Guideline	The Office of the National Coordinator for Health Information Technology	2015

Table 3. Selected Resources: Regulation, Strategy and Policy Formation

Solution Design & Development				
1	Designing Digital Interventions for Lasting Impact: A Human-Centered Guide to Health Deployments	Guide	Unicef	2018
2	Collaborative Requirements Development Methodology (CRDM)	Guide	PATH	2015
3	SMART Guidelines	Guideline	World Health Organization (WHO)	2021
4	Xcertia mHealth App Guidelines	Guideline	Various Authors	2019

Table 4. Selected Resources: Solution Design & Development

Integration and Interoperability				
1	Digital Health Platform Handbook: Building a Digital Information Infrastructure (Infostructure) for Health	Guide	World Health Organization (WHO) and International Telecommunication Union (ITU)	2020
2	HIS Interoperability Toolkit Users Guide	Toolkit	MEASURE Evaluation	2017
3	Digital implementation investment guide (DIIG): integrating digital interventions into health programmes**	Guideline	World Health Organization (WHO)	2020

Table 5. Selected Resources: Integration & Interoperability

Scaling Up				
1	The MAPS Toolkit	Toolkit	World Health Organization (WHO)	2015
2	Understanding scale of digital tools: a framework and triangulation tool to measure scale of digital deployments in the context of the COVID-19 pandemic'	Framework and Toolkit	Digital Square	N/A
3	The journey to scale – moving together past digital health pilots	Guide	PATH	2014

Table 6. Selected Resources: Scaling up

Monitoring & Evaluation				
1	Monitoring and Evaluating Digital Health Interventions	Guideline	World Health Organization (WHO)	2016
2	Monitoring the implementation of digital health	Study	World Health Organization	2022
3	The Evidence DEFINED framework	Toolkit	Various Authors	2023
4	Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth	Toolkit	Various Authors	2011
5	Framework for the Economic Evaluation of Digital Health Interventions	Framework	World Bank	2023
6	mHealth Evidence Reporting and Assessment	Toolkit	World Health Organization (WHO)	2016
7	iCHECK-DH	Toolkit	Various Authors	2023

Table 7. Selected Resources: Monitoring & Evaluation

Sustainability & Financing				
1	The Principles of Donor Alignment for Digital Health	Principles	Various Authors	2018
2	Digital Health Investment Review Tool to guide investment in digital health	Toolkit	Digital Impact Alliance (DIAL) at the United Nations Foundation.	2018
3	Digital implementation investment guide (DIIG): integrating digital interventions into health programmes**	Guide	World Health Organization	2020
4	SDG Digital investment framework (eGoV)	Framework	International Telecommunication Union (ITU) and Digital Impact Alliance (DIAL)	2019
5	A Framework for the Economic Evaluation of Digital Health Interventions	Framework	World Bank	2023
6	Total Cost of Ownership Tool; Digital Health Sustainability Calculator	Toolkit	Digital Square, USAID, Bill & Melinda Gates Foundation, PATH	2022

7	Closing the digital divide: More and better funding for the digital transformation of health	Guideline	Transform Health	2022
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Table 8. Selected Resources: Sustainability & Financing

Gender, Equity, Inclusion & Ethics				
1	Roundtable on Digital Inclusion	Report	UN	N/A
2	Bridging the digital gender divide	Report	OECD	2018
3	Digital Health Equity Framework (DHEF)	Framework	Academic paper	2020
4	National Institute on Minority Health and Health Disparities Research Framework Expanded for Digital Health Equity	Framework	Academic paper	2022
5	Why Gender Matters for Digital Health	Framework	GIZ	2021
6	Youth-centred digital health interventions	Framework	World Health Organization (WHO)	2021
7	UNICEF’s GenderTech Toolkit: Building digital solution for, with, and by girls	Toolkit	UNICEF	2020
8	WHO-ITU’s Global Standards for accessibility of telehealth services	Standards	World Health Organization (WHO) and International Telecommunication Union (ITU)	2022
9	WHO’s Ethics and governance of artificial intelligence for health	Guideline	World Health Organization (WHO)	2021
10	WHO’s Ethics and governance of artificial intelligence for health – Guidance on large multi-modal models	Guideline	World Health Organization (WHO)	2024

Table 9. Selected Resources: Gender, Equity, Inclusion & Ethics

Capacity Strengthening				
1	Digital education for building health workforce capacity	Framework	World Health Organization (WHO)	2020
2	Empowering the health workforce – Strategies to make the most of the digital revolution	Guide	OECD	2019

Table 10. Selected Resources: Capacity Strengthening

Technical Standards for Developers				
1	Evidence Standards Framework for Digital Health Technologies (ESF)	Framework	National Institute for Clinical Excellence (NICE)	N/A
2	ISO-82304-2	Standards	ISO	2021
3	Digital Health Applications (DiGA) process	Framework	DiGA	2020
4	FDA Digital Health quality regulations	Standards	Digital Health Centre of Excellence (DICE)	2020

Table 11. Selected Resources: Technical Standards for Developers

Digitization of Immunization Programs				
1	DICE Guidance on the use of digital solution to support COVID-19 national deployment and vaccination plans	Guideline	DICE	2021
2	Primer on Digital Solutions for COVID-19 Vaccination Service Delivery	Guideline	DICE	2022
3	Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines	Framework	WHO-UNICEF	2020
4	Digital Health Information Interventions for Immunization Demand Generation: A guide for selecting appropriate tools and technologies	Guide	GAVI	2022
5	Electronic Immunization Registries	Guide	Digital Square	2021
6	Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation	Guideline	PAHO	2018
7	Digital Applications and Tools Across an Epidemic Curve	Framework	Digital Square & GIZ	2021
8	Considerations for integrating COVID-19 vaccination into immunization programmes and primary health care for 2022 and beyond	Framework	WHO-UNICEF	2022

Table 12. Selected Resources: Digitization of Immunization Programs

Digital Public Goods				
1	Global Goods Guidebook Version 4.0	Guideline	Digital Square	2023

Table 13. Selected Resources: Digital Public Goods

It should be noted that many of the resources presented here are intended to be used in combination with one another by design, as they build on each other, and thereby establish an infrastructure of normative resources, that if applied correctly, are to facilitate the digital transformation of health systems.

3.2.4 Guidelines, Frameworks and Tools for Digital Health

3.2.4.1 Cross-cutting Principles and Guidelines

Some guidelines and principles are relevant across the DH-programing spectrum or pertain to more than one thematic area and are thus highlighted at various points throughout this chapter.

Among the guidelines we understand as cross-cutting, the **Principles for Digital Development** hold particular importance. The Principles for Digital Development is considered as a foundation for digital programing efforts in general. In 2014, these Principles were proposed by a group of international donors and multilateral organizations. Nowadays many normative resources for digital health are based on these principles. In 2015 USAID led a successful process to recruit 50 other agencies to endorse the Principles. They were updated in 2017 and a set of nine key principles for integrating best practices into technology-enabled development programs for international development and cooperation ⁸². The Principles are:

1. Design with User
2. Understand the Existing Ecosystem
3. Design for Scale
4. Build for Sustainability
5. Be Data Driven
6. Use Open Standards, Open Source and Open Innovation
7. Reuse and Improve
8. Address Privacy & Security
9. Be Collaborative

By adopting these nine Principles, policymakers, practitioners, and developers are more effectively positioned to work towards everyone benefitting from digital initiatives and partake in the wider digital society. Based on each principle, specific guidance is provided on how to address each phase of the project lifecycle (proposal, design, implementation, and evaluation). Furthermore, these principles were proposed as a form of “living guidelines”, able to change over time in order to remain relevant and useful. Principles like: “Use Open Standards and Open Source Software”; “Reuse and Improve”; “Address Privacy and Security”; “Design With The User and Be Collaborative” are still valid today. However,

areas which are increasingly recognized as critical issues in digital developments, such as challenges in terms of inclusiveness and the prevailing digital gender gap, were not adequately addressed ⁸³. Thus, in 2024, under the stewardship of the Digital Impact Alliance (DIAL), the Principles underwent a comprehensive update following consultations with over 300 stakeholders worldwide. The updated Principles maintain the essence of their original intention while more accurately mirroring the dynamics of the contemporary digital landscape. The revision emphasizes the importance of radical inclusion and local control, highlights the ethical considerations surrounding digital data generation and use, and speaks directly to its initial audience while also appealing to the broad spectrum of individuals and organizations influencing the design, deployment, and management of digital infrastructures and solutions. In essence, adopters of these Principles pledge to, at the very least, avoid causing harm, and at their best, ensure their initiatives enhance the autonomy of individuals and communities to shape their own progress ^{82,84,85}.

Furthermore, the Digital Principles community offers ongoing support for actors operating in the field of digital development and their website provides resources to apply each of the nine principles, including case studies, toolkits, and how-to-do guides.

Another resource, which acts as a foundation to many of those resources described over the following sections, is **WHO’s eHealth Strategy toolkit** ⁴². Even though we have categorized this resource within the topics of Digital Landscape Assessments (Section: 3.2.4.1), it serves as a framework for many of the subsequently developed resources for digital health. The toolkit guides users (target group is primarily DH planners and policy makers) through the process of developing a DH strategy and thus also pertains to many of the thematic areas that have been analysed in this review. As another cross-sectional resource, **WHO’s Recommendations on digital interventions for health system strengthening** ⁸ marked the inception of evidence-based guidelines for digital health. Following

the WHO’s evidence-to-decision framework, they systematically utilized existing peer-reviewed evidence and expert opinions across nine priority digital innovations (as reference, birth notification via mobile devices, digital provision of educational and training content to health workers and stock notification accessible via mobile devices) aimed at strengthening health systems.

The resource addresses not only the effectiveness of the reviewed interventions, but also highlights key considerations for acceptability, feasibility in varying contexts, considerations for gender, equity and rights, use of resources associated with the intervention and identify gaps in evidence to guide future research. Furthermore, these recommendations point out that health interventions are not a substitute for functioning health systems, and that there are significant limitations to what digital health is able to address. These recommendations have been considered as a milestone in global health as they provide a roadmap for governments and policymakers for introducing and scaling up digital health interventions to support population health outcomes in a feasible way ^{67,72}.

3.2.4.2 Digital Landscape Assessments

Target Audience

- **Primary Users:** Government bodies, ministries of health, donors, technology developers
- **Secondary Users:** Healthcare providers

Relevance

Digital health landscape assessments (DLAs) should be considered as a crucial first step when approaching digital health projects, programs or national initiatives. This view is reflected in the **Principles of Donor Alignment for Digital Health - Digital Investment Principles** ⁸⁶, in which many of the main global donor agencies committed themselves not to finance digital health investments unless an assessment has been undertaken.

DLAs are critical to develop a comprehensive understanding of the stakeholder environment, of a nation’s specific health challenges and priorities, existing policies and regulations and their integration into the healthcare system. DLA offers a systematic approach to review the existing DH infrastructure and any existing solutions, as well as to determine gaps in the current system and the potential role of DH to address them. Moreover, DLAs can be used

to establish or enhance national data standards to ensure interoperability across regions and health domains.

Whilst there is consensus that conducting DLAs is necessary, the methods by which these assessments are done vary, with a plethora of assessment tools and methodologies available, ranging widely in focus and scope. An overview of these resources will aid in navigating and selecting the most suitable frameworks and assessment methodologies, depending on the respective assessment needs.

Findings

For the purpose of this review, we analyzed and summarized 16 resources to guide DLAs, 14 of which are specific to the health sector. All are designed to be adaptable to the respective country context and assessment needs, which includes flexibility with regards to the assessment focus and depth.

These DLA tools and guidelines have been developed by various international organizations such as the World Bank, WHO, USAID, UNDP, PAHO, Digital Square, GIZ and others and they represent a significant effort in guiding the development and optimization of digital health systems.

While these tools share a common goal of advancing digital health infrastructures, each brings a unique perspective, methodology, and focus area. A commonality is that all resources reviewed provide a structured approach or frameworks for evaluating e.g., DH infrastructure, interoperability, governance, data management, and service delivery. These are primarily designed for health sector decision-makers, IT professionals, and program managers, as these tools guide are designed to support strategic planning, implementation, and scaling of digital health initiatives. The structured frameworks of these tools are accompanied by specific indicators or assessment criteria, through which systematic evaluation and strategic planning is facilitated.

The tools vary considerably in scope. As such, the **UNDP DLA Framework**⁸⁷ and the USAID DECA toolkit⁸⁸ are examples of non-health sector specific tools and designed to evaluate the wider digital ecosystem of a country. The **WHO/ITU National eHealth Strategy Toolkit**⁴² provides assessment methodologies for developing national eHealth strategies, whilst the **USAID HIS Interoperability Toolkit**¹² focuses specifically on the assessment of interoperability aspects of health information systems.

Each tool employs different methodologies; the **WHO/ITU National eHealth strategy toolkit**⁴² recommends a research approach that encompasses desk-based research, internal assessments and stakeholder consultation alongside a repository of possible questions that address the seven building blocks of the eHealth system. The UNDP's guide on the other hand is centered around a SWOT analysis, whilst the **Early Stage Digital Investment Tool (EDIT) tool**⁸⁹ is based on an indicator-based points system. The EDIT tool as well as the majority of the other tools reviewed here, e.g., the **World Bank's DH Assessment toolkit**⁹⁰, uses a maturity model approach.

Digital maturity models have been shown to be helpful for steering the development, adoption, adaptation, implementation, and maintenance of DH. In fact, the **WHO Global Strategy on Digital Health 2020 – 2025**² specifies as a key output “a continually evolving digital health maturity model assessment designed to direct the prioritization of national investments in digital health, promoting primary health care and universal health coverage.”

Maturity Assessment Tools (MATs) aid in evaluating a country's capability maturity for implementing and assessing a national DH program. and consequently, they need to be thorough and adaptable and should encompass the viewpoints of health systems, organizations, professionals, and consumers. Maturity

assessments can encompass an evaluation of the entire DH health system at the macro-level, or be specific to a health district or health facility levels. The choice of assessment is dependent on a country's assessment focus, needs and objectives.

The review of DLA resources has highlighted a number of key findings.

1. Systematic Approach and Country Leadership:

To ensure the success of a DLA, adopting a systematic approach tailored to the specific needs of a country is paramount. Ideally, DLAs should be led by the country itself or conducted in close collaboration with relevant ministries. This approach ensures alignment with the country's DH system vision or existing strategy. Moreover, countries leading DLA efforts can better maintain an overview of the existing digital landscape and can actively coordinate donors' and implementers' efforts. It has been known that partners conduct assessments, sometimes in parallel, when a DLA has already been conducted⁸⁷. Strong country leadership can avoid such scenarios, so that efforts can be streamlined and resources spent more efficiently.

2. Building on existing Digital Landscape Information:

The review has highlighted the importance of utilizing available country-specific resources and datasets from earlier assessments (e.g., Map & Match) or other existing sources. By doing so, duplication of work can be avoided, limited resources can be used more efficiently and progress can be accelerated through effective information use. In turn, results from newly conducted DLAs should be made widely available to stakeholders at the local, national, regional and global level, so that future assessments can build on them. Converting DLA findings into usable recommendations and making DH technology inventories available nationally and internationally (e.g., via the Digital Health Atlas) further strengthens the impact of assessments.

3. Country ownership of assessment results:

National governments should take ownership of assessment results, as this facilitates the coordination of ongoing and future DH development initiatives. Ideally assessments should be government-led, however, if DLAs are conducted as part of donor-funded DH initiatives and the relevant

ministers are not fully engaged in the process, international organizations should include a hand-over of the DLA findings and subsequent action points to the national government, including the necessary training as part of the project plan. This will facilitate continuity of efforts.

4. Methodological Flexibility and Integration of Tools:

A variety of assessment tools and methodologies exist for DLAs, addressing different stages or thematic areas of a DH eco-system. Assessors frequently integrate these tools, modifying and blending methodologies to gather the required information. This methodological flexibility allows users to tailor assessments according to specific country needs.

5. Integration of harmonized DLA results into the evolving DH Resource Infrastructure:

While the flexibility of methodologies allows for customized assessments, there is a risk of generating non-harmonized or even non-harmonizable DH ecosystem information, which constitutes a missed opportunity to contribute to global efforts towards better information use and learning, as well as more effective coordination of DH initiatives within and across countries. To enhance the impact of DLAs, it is therefore recommended to use DLA tools that align with global DH repositories and discourage the development of new tools that do not align with already existing taxonomies, data formats or thematic categorizations (e.g., WHO's eHealth strategy toolkits, WHO's classification for DHIs, the Global Digital Health Monitor or the Digital Health Atlas).

By referring to some of the tools and guidelines that are reviewed in this chapter (more detail is provided later), we can exemplify the broader impact of harmonizing elements of DLAs and showcase the interconnectedness of existing resources in the DH landscape. For example, the **WHO/ITU eHealth strategy toolkit**⁴² assessment framework for DLAs is based on the seven components of an eHealth system⁶, and those in turn are recommended to form the basis for national DH blueprints. These components also serve as the foundation for the **Global Digital Health Monitor** (GDHM)⁹¹, a web-based resource, designed to track, monitor, and assess the enabling environment for digital health throughout the world (more detail in the later part of this section).

The **Early Stage Digital Investment Tool (EDIT)**⁸⁹ adopted many of its indicators from the GDHM and is also an integral part of the GIZ's **Digital Pandemic**

Preparedness Assessment tool (DPPA)⁹². The utilization of DHIs as pre-defined units of digital functionality provides a basis for national digital health inventories. This enables the universal communication and understanding of information about existing DHIs at the national, multi-national, and global levels, which is then facilitated by tools like **WHO's Digital Health Atlas**⁹³.

Use cases developed through the USAID Map & Match Initiative⁹⁴ are intended to be used as baseline data for the completion of GIZ's Digital Pandemic Preparedness Assessment Tool⁹² and all findings from Map & Match are currently being integrated into the WHO's Digital Health Atlas⁹³, further enhancing the interoperability and comprehensive coverage of global digital health information.

6. Harmonization of DLA Guidelines & Tools:

The potential collective impact of DLA tools on global health is significant. They guide countries in making informed decisions about digital health investments, ensuring that digital transformations align with broader health goals and are responsive to specific regional needs. In LMICs, these tools are particularly crucial in leapfrogging developmental stages and adopting best practices in DH.

However, the growing number of DH assessment tools, each with its methodologies and focus areas also poses potential for problems. A mix and match approach of tools, whilst workable, fosters the development of disparate and siloed assessments, where different stakeholders may continue to develop and conduct assessments, resulting in duplication of efforts, and non-harmonized DLA results beyond, at the regional or national level.

This issue has been recognized in the DH community and there are ongoing efforts harmonize the landscape of existing resources.

A noteworthy effort is the development of a meta-model to unify various domain-specific maturity models. The **Digital Health Profile and Maturity Assessment Toolkit (DHPMAT)** was designed to assist Pacific Island Countries in DLAs⁹⁵. Based on the WHO/ITU **National eHealth Strategy Toolkit**⁴², the **Atlas of eHealth Country Profiles**⁹⁶ and the WHO's **Recommendations on digital health interventions for Health Systems Strengthening**⁸, the authors adopted a stakeholder co-creation approach for the DHPMAT, drawing on existing DLA maturity models⁷ to develop a list of Digital Health Profile (DHP) indicators to assess digital health maturity.

⁶According to WHO/ITU (2012), the seven components of an eHealth system are: 1) leadership and governance, 2) Strategy and Investment, 3) Service and Applications, 4) Standards and Interoperability, 5) Infrastructure 6) Legislation, Policy and Compliance and 7) Workforce.

Digital Square's **Navigator for Digital Health Capability Models**⁹⁷ offers a meta-perspective on assist in the selection of digital health maturity models. Described in more detail later (Appendix 2), this tool is a hands-on guide, including a step-by-step guidebook and Excel workbook to assist in identifying the maturity model-based tool(s) that align most closely with DH stakeholders' objectives for conducting an assessment and helps users understand how to leverage findings from any previous maturity model assessments.

Whilst not a resource in the traditional sense, an effective forum for advancing the streamlining and optimization of approaches is found, as so often in the digital development world, in a community of practice and expertise. The **Digital Health & Interoperability Working Group (DH&I WG)**⁹⁸, established in 2016, is a collaborative community of nearly 250 technical partners from various countries. Affiliated with the WHO-hosted Health Data Collaborative (HDC) and secretariat by Digital Square, the DH&I WG focuses on standardizing how governments describe their paths to operational national digital health systems and developing common digital health terminologies. The group has formed the smaller, and topic-focused **Maturity Model Small Working Group**, which is working towards harmonization of digital health assessment tools and

maturity models with the goal to harmonize them to prevent redundancy, improve clarity, and enhance the utility of these tools for various stakeholders, including policymakers, donors, and practitioners. One case study conducted by the group in 2019⁹⁹ focused on four main tools: the Global Digital Health Index, the Digital Health Atlas, the Health Information Systems Interoperability Maturity Toolkit, and the Health Information System Stages of Continuous Improvement Toolkit. By enabling close collaboration among organizations that developed these tools, the group were able to standardize language and frameworks, and thereby improve compatibility between tools.

Harmonization of DLA tools facilitates adoption of best practices, reduces redundancy, and fosters collaborative development of DH systems. While each tool may contribute uniquely to the DLA landscape, their collective strength lies in offering a multifaceted approach, which allows adaptability to country assessment needs and objectives. Harmonization of these tools can significantly enhance their effectiveness, leading to more coordinated, impactful, comparable data to further national and global DH efforts.

Reviewed Guidelines, Frameworks and Tools

UNDP Digital Landscape Assessment Framework

For the analysis of national digital landscapes in relation to SDGs, thus not health sector-specific. It encompasses: 1) Rapid Integrated, 2) Digital Maturity, and 3) Bottleneck Assessments to identify digital solutions to expedite progress towards the SDGs.

USAID Digital Ecosystem Country Assessment (DECA) Toolkit

To conduct assessments for digital development decision making (not health-sector specific), covering "Digital society, rights and governance," "Digital infrastructure and adoption," and "Digital economy," over three phases: 1. Desk research and planning (5 weeks), 2. Interviews (2–7 weeks), and 3. Analysis and report writing (10-15 weeks).

The WHO/ITU eHealth strategy toolkit

The toolkit provides an assessment framework (Chapters 10 & 11) that aligns with the seven building blocks of a digital health enabling environment for national digital health strategy development. It suggests a 3-stage research approach (desk-based research, internal assessment, stakeholder

⁹⁷Maturity Models included in the development of the DHPMAT: 1) Informatics Capability Maturity model, with focus on health organization, 2) Global Digital Health Index, with focus on national DH systems, 3) Health Information Systems Interoperability Maturity Toolkit, focused on health organizations – technical & operational aspects, and 4) Health Information System Stages of Continuous Improvement Toolkit, also focused on technical and operational aspects of health organizations; The elements of the DHPMAT are: 1) Country context (17 indicators), ICT infrastructure (21 indicators), 3) Essential digital health tools (39 indicators), 4) Readiness for information sharing (27 indicators), 5) Health system adoption (31 indicators) and Quality improvement, measurement, monitoring and evaluation (QUIMME) (number of indicators not specified).

consultations) with example questions addressing each eHealth strategy component, along with opportunities, gaps, risks, and barriers.

GIZ Digital Pandemic Preparedness Assessment Tool (DPPA)

The DPPA streamlines digital tool identification in a nation's ecosystem, aligning with EDIT and USAID Map & Match, and syncing with the Global Digital Health Monitor. The 5-stage, 3-phase assessment (3 weeks) 1) engages stakeholders, 2) analyzes the digital health ecosystem, 3) integrates map and match data, 4) maps DPP use cases, and 5) reports results with recommendations for digital health and pandemic preparedness, producing a report to inform budgetary decisions.

Early Stage Digital Health Investment Tool (EDIT)

A tabular toolkit for early-stage DH ecosystem assessments. It assesses DH readiness, fostering coordinated strategies for health digitization among key stakeholders. It integrates into the DPPA and Navigator for Digital Health Capability Models. The tool promotes dialogue on six essential building blocks (1. human capacity, 2. investment & funding, 3. data capture & use, 4. infrastructure, 5. standard & interoperability and 6. governance and policy) with indicator-based point-system ratings (1 to 5) for assessing a country's DH readiness.

USAIDs Map & Match Initiative (M&M)

M&M, not a formal guideline or framework, serves as a vital baseline resource for ecosystem mapping. Prioritizing repurposing digital tools for rapid disease information access, it is a 2-phase initiative documenting DH investments in LMICs. Outputs from M&M are: 1) a publicly accessible dataset for 130+ countries (Phase 1), 2) more detailed information on 22 M&M countries (Phase 2) and 3) Country briefs showcasing the identified tools. 4) M&M develops outbreak response use cases aligned with GIZ's DPPA and integrated into the DATEC framework. All M&M data are shared with the DHA in collaboration with WHO.

World Bank Digital Health Assessment Toolkit Guide

A toolkit guide to assess a country's digital health maturity, aiding in planning and prioritizing digital health strategies and investments. The toolkit includes a Digital Health Landscape Profile, a Maturity Scoring Tool, and in-depth interviews and workshops, offering a comprehensive view of a country's digital health infrastructure, workforce, and governance using 74 indicators.

HIS Interoperability Maturity Model (IMM) Toolkit

A toolkit that provides a maturity model to assess and enhance the interoperability of health information systems (HIS) across three domains: leadership and governance, human resources, and technology, intended for Ministry of Health officials and stakeholders in LMICs. This model categorizes HIS performance into five levels and includes an assessment tool for evaluating 18 subdomains. The process involves self-administration by health officials, aiming to guide improvements in HIS interoperability for more effective healthcare delivery and data management.

Health Information System Stages of Continuous Improvement (SOCI) Toolkit

A guide to evaluate and enhance Health Information System (HIS) effectiveness, designed for HIS stakeholders, including government and health program managers, It presents a structured method for assessing HIS, starting with forming a leadership team and setting the assessment scope. The toolkit assesses various HIS aspects, such as leadership, workforce, ICT, and data quality, using a five-stage maturity scale. It stresses stakeholder consultation for consensus on HIS status and future goals, leading to a roadmap for improvement with defined actions and responsibilities.

WHO/PAHOs The Information Systems for Health (IS4H) Toolkit

A toolkit designed to help national health authorities and stakeholders assess and improve their HIS. It features a maturity model with five levels, covering domains, including Data Management, Governance, Knowledge Management, and Innovation. The toolkit provides a structured method for evaluating these systems and the assessment process is meant to be carried out by health officials, forming teams to complete, analyze, and use the results to develop strategies for advancing their HIS.

Digital Square’s Navigator for Digital Health Capability Models

A guide designed to assist countries and organizations in choosing the most suitable digital health maturity models for their needs. It provides guidance on a range of maturity model-based tools for digital health systems, helping users understand which tools best fit their specific assessment goals and contexts. It was created through a collaborative process involving tool users, designers, funders, and decision-makers from national digital health entities. It offers a framework to understand individual tools, mapping specific indicators between them to leverage assessments used in the past and avoid duplication of efforts.

WHO Classification of digital interventions, services and applications in health, second edition.

An updated version of the “WHO Classification for Digital Health Interventions v1.0 (CDHI).”, this guideline is a taxonomy that provides a common language for stakeholders in the DH sector to assess and communicate the uses of DH and to identify program needs. It categorizes digital and mobile technologies to support individuals and health system requirements, based on the discreet unit of a “digital health intervention.” It is organized around three axes: Health System Challenges, Digital health interventions, and Digital Services and Application types. It groups interventions based on users: Persons, healthcare providers, health systems or resource managers, and data services. It is integrated into the WHO Digital Health Atlas.

WHO’s Digital Health Atlas

An open-source online-based platform designed to coordinate global digital health initiatives and designed to serve as a global digital health inventory, a solution finder, and an information resource on intervention maturity, functionalities, and standards. It aids governments, technologists, implementers, and donors by providing essential information for planning, coordination, and evaluation of digital health projects. The platform’s effectiveness depends on active engagement, with roles for implementors, government, and investors/donors.

Global Digital Health Monitor

An online resource designed to evaluate countries’ digital health maturity. Aligned with the WHO/ITU eHealth Strategy Toolkit, it supports progress tracking, weakness identification, and improvements in national digital health systems. As part of the WHO Digital Health Resolution, GDHM uses 23 indicators grouped into seven key components. Also includes areas such as AI, equity, gender, and UHC, with visualizations for year-on-year performance, country comparisons, and regional insights. Data sources include the GovTech Maturity Indicator, Network Readiness Index, and GSMA Mobile Connectivity Index.

U.S. President’s Malaria Initiative Digital Community Health

In 2020, the U.S. President’s Malaria Initiative, through USAID and the CDC, initiated the Digital Community Health Initiative to enhance healthcare quality in 27 African countries via digital health platforms. Aiming to optimize digital technology for malaria and community health, the initiative conducted a mixed-methods assessment through three phases: 1) ecosystem assessment of digital technology and malaria data. This phase involved a comprehensive assessment to understand community-level malaria data management, including ICT use. The assessment encompassed a desk review, surveys

on digital tools, and interviews with national and subnational stakeholders. Desk reviews were conducted in all countries, while surveys and interviews were tailored by country to address gaps and corroborate findings. 2) stakeholder engagement to refine digital health needs and priorities. 3) country-specific implementation of tailored strategies. This approach broadened its focus beyond malaria, providing insights for improving integrated service delivery.

3.2.4.3 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 is essential for governments as ICT can significantly enhance the accessibility and quality of healthcare services. With the right policies, and governance structures in place, governments can ensure that digital health tools reach a broader population, including remote or underserved areas, whilst safeguarding their citizens health and health information, thereby promoting equity in healthcare access and at the same time protecting confidentiality of information.

Digital health initiatives can increase the efficiency of healthcare delivery, reducing costs for both healthcare systems and patients. Policies and strategies are needed to guide the integration of these technologies in a manner that maximizes cost-effectiveness without violating the rights of the users and patients. The management of health data is a critical aspect of DH and governments need to establish policies that ensure data is handled securely and privately, complying with legal and ethical standards, and ensuring public trust in digital health systems.

To fully benefit from DH solutions, it is essential to have standardized systems that can interact seamlessly. Government policies can set the standards for interoperability, ensuring that different data can merge, which in turn allows public health planners and managers to measure comprehensive and reliable indicators for informed decision making. In addition, well-crafted policies can foster innovation in digital health, encouraging the development of new and improved technologies to achieve better health care outcomes. However, because digital health is

evolving fast, it is important to establish a flexible regulatory framework to manage emerging issues, such as the ethical use of AI in healthcare, telemedicine practices, and digital health equity. Also, DH can stimulate economic growth by creating new jobs and market opportunities within the health tech sector, a process which should be fostered and guided by policies and strategies.

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

Given the complexity of DH system development and the intricacies around this, guidelines can be helpful for governments to support the development of the legislative frameworks and thus, the landscape around this topic was investigated as part of this review.

Findings

The WHO released the **Global Strategy on Digital Health 2020-2025**² 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, and addressing adoption barriers in least-developed countries. It outlines four strategic objectives: fostering global DH collaboration, promoting national DH strategies, enhancing DH governance, and supporting people-centered health systems. The strategy also includes a framework for action focused on commitment, catalysis, measurement, and continuous improvement, accompanied by an action plan to achieve these objectives.

At national level, only one guideline was identified that specifically supports governments in developing a national eHealth vision: **WHO's National eHealth**

Strategy toolkit ⁴² and despite the fact that this guideline is more than 10 years old, it remains valid and highly relevant.

The toolkit is grounded in fundamental principles of healthcare and technology implementation that do not out-date. These include the importance of stakeholder engagement, the need for a clear vision and strategic objectives, and the recognition of the unique challenges and opportunities in health information management. Such principles are universally applicable and remain relevant as foundational guidelines.

Moreover, the toolkit provides a framework that is adaptable to different contexts and technological advancements. It focuses on strategic planning, assessment of the current state, vision setting, and implementation, which are steps applicable regardless of specific technology trends. This adaptability allows it to remain useful even as specific technologies evolve.

The toolkit emphasizes the importance of strong governance structures and policy frameworks for successful eHealth implementation. These aspects of health system strengthening are not tied to specific technologies and remain critical for any health initiative.

The toolkit stresses the importance of engaging a wide range of stakeholders, including government bodies, healthcare providers, patients, and technology experts. Such an approach to inclusive and participatory planning remains pertinent.

Also, the toolkit takes a comprehensive approach to eHealth implementation, covering aspects like infrastructure, human resources, financing, and monitoring and evaluation. This holistic view is essential for the success of any health initiative, regardless of technological changes. The toolkit allows for flexibility in its application, acknowledging that each country or region may have different needs, resources, and starting points. This flexibility makes it broadly applicable and enduring.

It may be argued that one guideline does not suffice for this critical phase of DH development. However, the **eHealth Strategy Toolkit** can be viewed as an overarching resource, which provides stakeholders with the tools to address the strategic planning each of the seven building blocks of an eHealth system (described in more detail in Section 3.1.3).

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.

For example, **WHO's Digital Implementation Investment Guide (DIIG)** ³ is relevant for integrating digital solutions into health systems and thus has been included in this review in Section 3.2.4.4. It also provides information on financial investment, assisting governments and technical partners in planning and implementing digital health initiatives that support national health system goals. Beyond the implementation guidance it provides, the DIIG also offers a step-by-step guidance through the planning and costing of DHIs within a digital health enterprise (see Section 3.1.3 for more detail). It advises on the planning and costing of digital health interventions, with a focus on identifying cost drivers at each phase of implementation and developing a comprehensive budget for the lifespan of the investment.

Similar to the DIIG, many of the resources reviewed in the sections have relevance for Regulation, Strategy and Policy Formation for government stakeholders, but also pertain to one or more specific phases. However, WHO's eHealth Strategy Toolkit remains the only tool, which assumes the macro-perspective across the process of developing of a DH system strategy at national level.

An important aspect concerning this thematic area is that of health data governance. Data privacy and security issues pose a significant barrier to the expansion of digital health tools. As healthcare systems increasingly adopt digital technologies to store, process, and transmit patient information, the risk of data breaches, unauthorized access, and cyber-attacks grows. These risks raise concerns among patients, healthcare providers, and policymakers, slowing the adoption and implementation of digital health solutions. These concerns are amplified by the sensitivity of the data as they include personal information about individuals' physical and mental health conditions, treatment plans, and medical history. Unauthorized access to this data can lead to privacy violations, discrimination, and even financial or reputational damage to individuals. Trust is a cornerstone of healthcare delivery as patients must have confidence that their personal health information is handled with the utmost care and confidentiality. Data privacy and security concerns can erode this trust, making patients reluctant to use digital health tools, fearing their personal information might be compromised. Thus, healthcare is among the most regulated sectors in some regions of the world, with stringent data protection laws, for example, the **Health Insurance Portability and Accountability Act (HIPAA)** in the United States or the

General Data Protection Regulation (GDPR) in Europe ¹⁰⁰. However, many countries still lack robust and equitable data protection regulations and data governance policies. The **Health Data Governance Principles** ¹⁰¹ have been designed to address this need as they present globally accepted principles for health data governance that are applicable at the regional and sectoral levels. This means that the principles can guide stakeholders in domesticating national and organizational policies, e.g., through the principles themselves and through the “Model Law on Health Data Governance”, which encompasses core elements, legislative guidance and reference legal text with the aim of strengthening national frameworks. Moreover, this consensus on high-level principles marks an important step towards the creation of a global health data governance framework that could support the use of digital technologies and data for the public good.

However, ensuring compliance with diverse and sometimes conflicting regulations in settings with existing robust governance structures can be challenging for digital health providers and developers alike. Non-compliance not only risks legal repercussions and fines, but also damages trust and credibility among users and stakeholders. Effective digital health solutions often rely on interoperability to aggregate, share, and analyze health data across

different systems and stakeholders. Data privacy and security concerns can limit these activities, hindering the development of interoperable systems that support comprehensive care management, research, and public health monitoring. The need to navigate data privacy and security concerns may slow innovation in the digital health space, nonetheless developers must balance the creation of user-friendly, accessible tools with the imperative to incorporate strong security measures. Whilst maintaining this balance can complicate design processes, increase development costs, and extend time-to-market for new solutions, it is ultimately the only sustainable way to enable the use of health data for public good.

Reviewed Guidelines, Frameworks and Tools

WHO’s Global Strategy on Digital Health 2020-2025

WHO’s aims to guide the development and adoption of DH solutions that are appropriate, accessible, affordable, scalable, and sustainable, based on four core principles: institutionalizing digital health within national systems, requiring cohesive strategies for digital health success, promoting beneficial digital technology use in health, and addressing the adoption barriers in least-developed countries. The strategy outlines four strategic objectives: enhancing global DH collaboration and knowledge sharing, supporting national digital health strategy implementation, improving DH governance, and fostering people-centered health systems through DH. It proposes a framework for action focused on commitment, catalysis, measurement, and continuous improvement, accompanied by an action plan outlining the necessary impacts, outputs, policy options, and actions for achieving these objectives.

The WHO/ITU eHealth strategy toolkit

This earlier described toolkit (see section on DLAs) is the fundamental guideline document to help governments develop a national eHealth vision aligned with their health and development goals, designed to facilitate the creation of an action plan reflecting country priorities, and to manage associated risks. It is a step-by-step tool, that addresses common challenges in digital health development,

such as misaligned agendas and ‘siloed’ technology investments. Divided into three parts—1) Establishing a National eHealth Vision, 2) Developing a National eHealth Action Plan, and 3) Monitoring and Evaluation—the toolkit aims to prevent stalled efforts and optimize return on investment by promoting a broader vision of health system development.

TransformHealth’s Health Data Governance Principles

A set of principles that have been developed through a collaborative bottom-up process, driven by civil society and stewarded by TransformHealth. They encompass three interconnected objectives, namely 1) Protect people – as individuals, as groups and as communities; 2) Promote health value – through data sharing and innovative uses of data; and 3) Prioritize equity – by ensuring equitable distribution of benefits that arise from the use of data in health systems. The Principles are designed for governments, technology companies, and other stakeholders involved in health data collection and use. They aim to guide national and organizational health data policies and contribute to a global governance framework. Additionally, they serve as a tool for advocating equitable, human-rights-based data governance and can function as an accountability mechanism.

Health Insurance Portability and Accountability Act (HIPAA)

HIPAA establishes Privacy and Security Rules for handling protected health information in USA. These rules require healthcare providers, insurers, and employers to protect patient data, allow controlled disclosure without consent under specific conditions, and give individuals rights over their health information. The aim is to protect patient privacy while ensuring necessary data flow for quality healthcare and public safety. Additionally, the Security Rule mandates safeguards for electronic data, and the Enforcement Rule specifies compliance, penalties for violations, and hearing processes.

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. Key provisions include obtaining explicit consent for data processing, granting individuals rights to access, erase, and transfer their data, and the right to object to data use for specific purposes. Organizations must implement data protection measures from the start, appoint Data Protection Officers for significant data processing activities, and promptly report data breaches. The GDPR also regulates the international transfer of personal data to maintain protection standards globally.

Framework for Improving Critical Infrastructure Cybersecurity¹⁰²

The National Institute of Standards and Technology’s Cybersecurity Framework provides detailed guidelines to help private sector organizations improve their cybersecurity. It helps entities prevent, detect, and respond to cyber threats by integrating standards, guidelines, and best practices for risk management. Notable for its adaptability, cost-effectiveness, and focus on protecting critical infrastructure, the last version includes a self-assessment section, expanded risk management for cyber supply chains, and improved guidance on authentication, authorization, and identity verification, along with clearer connections between its components and vulnerability disclosure considerations.

Guide to Privacy and Security of Electronic Health Information¹⁰³

This guide offers practical support for healthcare professionals, especially in smaller practices, to comply with HIPAA in the US. It includes advice on regulatory compliance, risk management strategies, staff training guidance, and how to handle and report health information breaches. It also features tools and resources to help providers assess their practice’s needs for the privacy and security of electronic health information, develop appropriate policies and procedures, and manage potential risks effectively. This comprehensive strategy aims to equip healthcare providers with the necessary tools to protect sensitive health information and maintain patient trust.

3.2.4.4 Solution Design & Development

Target Audience

- **Primary Users:** Developers, healthcare providers
- **Secondary Users:** Donors, government bodies, ministries of health

Relevance

Guidelines for digital health solution design and development ensure the creation of effective, safe, and user-friendly tools. They emphasize the importance of interoperability with existing health systems, guide ethical and legal compliance, particularly in handling sensitive health data, and standardize development practices. These guidelines are pivotal in making digital health solutions scalable, sustainable, and evidence-based, addressing both local and global health challenges.

Importantly, while providing structured approaches, these guidelines also foster innovation, encouraging developers to create novel solutions for unmet healthcare needs. They enhance collaboration among various stakeholders, including healthcare providers, patients, technologists, and policymakers. This holistic approach ensures the development of digital health solutions that are not only compliant and of high quality but also responsive to the complex needs and challenges of modern healthcare systems.

One area of solution design, which is current and of particular importance, is the need for guidelines to design DH solutions based on national paper guidelines. Their relevance is about ensuring accurate and evidence-based digitalization of national paper guidelines, adhering to international standards and best practices.

In terms of application, these guidelines allow for the creation of tailored digital health solutions that meet the specific needs and expectations of users. Such solutions can significantly enhance efficiency and automate various administrative tasks, reducing paperwork and leading to cost savings and improved healthcare delivery. Furthermore, incorporating clinical guidelines and evidence-based practices in solution design aids healthcare providers in making informed decisions regarding diagnosis and treatment.

Findings

The topic of “Solutions Design & Development” in DH is vast and encompasses a wide range of working

processes, technical phases, and perspective, which can all be explored at varying depths. For the purpose of this review, we opted to highlight three resources that guide design and development by focusing on the user.

As the first *Principle for Digital Development*, “Design with the User”, also referred to as “design thinking” or “human-centered design” is a critical consideration for the development of impactful digital solutions. As such, the first two resources included here, namely UNICEF’s **“Interventions for Lasting Impact: A Human-Centered Guide to Digital Health Deployments”**¹⁰⁴ and the **“Collaborative Requirements Development Methodology”** (CRDM) should be considered as fundamental for those on the DH field. The third guideline included, namely **WHO’s Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable (SMART[®]) guideline**¹⁰⁵, incorporates the CRDM in its methodology as part of the Digital Adaptation Kit (DAK) in Layer 2 to develop generic personas, user scenarios for functional requirements and to develop business processes and workflows for the respective health topics addressed (e.g., family planning, HIV or ANC).

Beyond its user-centered approach, the SMART guidelines are now viewed as a cornerstone for transforming paper-based clinical guidelines into digital solutions into fully functioning, interoperable and integrated digital solutions that form part of the wider DH architecture and HIE.

However, the success of such application hinges not only on the implementation of the five layers of the SMART guidelines, but also on other critical factors, such as scalability, interoperability, legislation and capacity strengthening. The application of these guidelines should therefore be contextualized within a broader framework of specific guidelines that target for example, technical approaches to interoperability or scalability or regulatory guidance for applications (e.g., Xcertia mHealth App guidelines described later) to enable integrated and impactful DH systems. **WHO’s Digital implementation investment guide (DIIG): integrating digital interventions into health programmes**³ provides further guidance on this.

DAKs (Layer 2 of the SMART guidelines) have been currently developed for ANC, family planning and HIV to only name some. This work is ongoing and continually extended, and WHO is working closely with countries to provide technical support for DAK and broader SMART guideline adoption.

The true value beyond this however, lies in the fact that the SMART guideline approach has the capacity to bring any clinical guideline in the health sector from paper-format into a national digital health system. In an integrated and interoperable environment, applications from different sectors of health and beyond can then begin to exchange information seamlessly. The impact this can have on clinical decision making, public health planning, research and population health outcomes could be tremendous. We consider the role of the WHO SMART guidelines for the digitization of health systems as elevated and have therefore gone into additional detail to describe tool and evidence of their adoption in Appendix 4.

Reviewed Guidelines, Frameworks and Tools

UNICEF's Designing Digital Interventions for Lasting Impact: A Human-Centered Guide to Digital Health Deployments

A toolkit that applies human-centered design (HCD) principles to DH program design, with focus on users and their context. This guide contains methodologies, tools, and templates, to direct decisions throughout the program cycle. Recognizing the importance of frontline workers and community insights, the toolkit emphasizes observation, interaction, and tailored design.

Collaborative Requirements Development Methodology (CRDM)

A human-centered requirement-gathering process for system development that emphasizes local ownership and collaboration. It creates workflows, develops user personas, uses visual representations like matrices and diagrams, redesigns processes, and defines functional requirements. Part of the technology life cycle, CRDM covers business modeling, requirement definition, system design, testing, training, implementation, management, and optimization.

WHO's SMART Guidelines

A comprehensive guideline and framework with five knowledge layers for the technical process of incorporating WHO health and clinical guidelines into digital systems. The five knowledge layers are: L1 - narrative (enhanced guidelines), L2 - operational (digital adaptation kits), L3 - machine-readable (coding for integration), L4 - executable (software applications), and L5 - dynamic (leveraging big data for precision health models). These layers enhance traditional guidelines, facilitate discussions, aid integration, ensure interoperability, and leverage advanced analytics for context-specific health outcomes.

Xcertia mHealth App Guidelines

A guideline for mobile health applications (mHealth apps), that addresses five key areas of design and development: privacy, security, operability, usability and content. Even though these guidelines are especially suited for the mHealth sector, topics such privacy and security are generally relevant for any software developer and this resource can be applied beyond mHealth.

3.2.4.5 Integration & Interoperability

Target Audience

- **Primary Users:** Developers, donors, ministries of health
- **Secondary Users:** Healthcare providers, government bodies

Relevance

The accelerating rate of digitization in the digital health ecosystem brings challenges, as numerous digital solutions compete without being fully integrated into the system for impactful results. Many of these solutions are standalone (siloed), created for specific needs or programs, leaving significant gaps in real-time digital data collection and analysis¹⁰⁶. This situation leads to decreased data quality and creates opportunities for errors, negatively affecting surveillance mechanisms¹⁰⁷. Siloed solutions also increase the burden on system users and contribute to errors in medical practice. As healthcare workers and administrators are forced to use multiple, disconnected digital applications. This duplication of effort leads to systemic confusion, data entry errors, staff burnout, and ultimately, impacts the overall quality of service delivery¹⁰⁷.

Seamless data exchange ensures the free flow of patient information and health records between systems, facilitating coordinated patient care across different healthcare providers. This enhances efficiency and accuracy by reducing duplication and errors, eliminating manual data entry, keeping healthcare information current and accurate, reduce the likelihood of medication errors and adverse events. In terms of continuity of care, interoperability ensures that patient health information is consistently available across various healthcare settings.

For public health surveillance, interoperable digital health systems enable timely data collection and analysis, crucial for tracking disease outbreaks and health trends with important resource optimization

Interoperability improves the creation and use of Electronic Health Records (EHR), data availability for decision-making, enhanced stock management, and quick access to lab results for clinicians, aiding in diagnosis and treatment. It supports population health management by aggregating data from various sources to identify and address at-risk groups, and public health initiatives like vaccination programs, and community health services with accessible patient data.

Findings

In LMICs any health investments, if vertical, partner-driven, and program-specific, may result in fragmented, siloed systems with limited end-user involvement. To combat inefficiencies in Africa's digital systems, the World Health Organization Africa Regional Office (WHOAFRO) recommends to apply the **ITU-WHO Digital Health Platform Handbook**¹⁰⁸ to adopt a Digital Health Platform (DHP).

Such DHP would unify disparate solutions into a cohesive system, promoting UHC and achieving progress towards the health-related SDGs¹⁹. To place a DHP into the context of the earlier described concepts of "digital health architectures or blue prints", the digital enterprise architecture is used to describe how the DHP components will interaction with each other, and specify how the DHP will interact with external applications and systems.

Early guidelines didn't focus specifically in integration and interoperability. Thus, the ITU-WHO **Digital Health Platform Handbook: Building a Digital Information Infrastructure (Infostructure) for Health**¹⁰⁸ was specifically developed to support developers and technician in guarantee integration & Interoperability of their DHI and fill this gap.

In addition, the **Health Information Systems Interoperability Maturity Toolkit**¹², **PATH/Digital Square's Harmonizing Digital Health Assessment Tools**⁹⁹ and **Maturity Models and HIS Interoperability Toolkit Users Guide**¹² can be used to measure the interoperability of a health system. They are based on a maturity model and can, depending on the digital infrastructure of a country, form an integral part of a national digital landscape assessments, as described earlier in this review (see Section 3.2.4.1).

Even if not specifically designed for interoperability, **WHO's Digital implementation investment guide (DIIG): integrating digital interventions into health programmes**³ is a highly pragmatic resource and targets implementers and public health officers. It is easy to use and provides a useful worksheet matrix to guide developers and implementers in the most important steps for implementing a DHI. Moreover, the DIIG model embodies a comprehensive approach and offers a compelling case study focused on the distribution of COVID-19 vaccines

In terms of the technical process to achieve interoperability, public institutions beyond the health sector globally recognize the significance of achieving

interoperability within their digital health systems (e.g., interoperable EHRs) and are actively working toward this goal.

The HL7 FHIR standard is one of the standards that has emerged as a prominent solution, and has been adopted in various countries to promote healthcare interoperability. This is also the case for the earlier mentioned SMART guidelines, which support and provide guidance on the FHIR standards within their L3 layer – machine-readable recommendations).

FHIRs popularity appears to be due to the standardized approach it provides for the exchange of healthcare data. Additionally, to facilitate the seamless implementation of the FHIR standard without posing a burden on healthcare stakeholders, the HL7 international organization has introduced a tool known as the **FHIR Implementation Guide**¹⁰⁹. However, a review of this tool is beyond the scope of this review and expertise of the authors.

Reviewed Guidelines, Frameworks and Tools

ITU-WHO's Digital Health Platform Handbook: Building a Digital Information Infrastructure (Infostructure) for Health

This guideline, intended for health sector planners and enterprise architects in early-stage digital maturity countries, focuses on building national health platforms for SDG support. It emphasizes developing a Digital Health Platform (DHP) as foundational infrastructure, unifying various digital health applications for consistent and efficient healthcare delivery. The DHP includes integrated, reusable components to enhance interoperability for supporting DH application. The handbook details tasks from context analysis to ongoing institutionalization efforts, outlining steps like designing DHP architecture, and implementing DHP with country case studies. The DHP serves as a horizontal base for connecting vertical siloed information systems within individual DH applications.

Measure Evaluation's Health Information Systems Interoperability Maturity Toolkit

This earlier listed toolkit (see also section on DLAs) aids Ministries of Health in evaluating Health Information System (HIS) landscapes for interoperability, hence it included here also. It utilizes the earlier defined maturity model across three domains: technology, leadership/governance, and human resources. Each domain has specific subdomains, evaluated on a 5-point scale. Results are visualized in radar graphs, offering a self-administered assessment to guide countries in strengthening HIS interoperability for more robust systems.

WHO's Digital implementation investment guide (DIIG)

This guide serves as a roadmap for integrating DHIs into health programs. Aligned with the 9 principles for digital development, DIIG complements the WHO guideline on digital interventions. It guides users through a 9-step process, covering identification, assessment, design, definition, linking to national

architecture, monitoring, evaluation, costing, and maintenance. The guide emphasizes needs-based investments, interoperability, and alignment with national goals. Additionally, it includes a process matrix worksheet for evaluating processes, outcomes, and potential bottlenecks, offering a holistic approach with a COVID-19 vaccine distribution case study and insights into OpenHIE architecture.

3.2.4.6 Scaling Up

Target Audience

- **Primary Users:** Developers, donors, ministries of health
- **Secondary Users:** Healthcare providers, government bodies

Relevance

Scaling up digital health initiatives enhances access to healthcare services, particularly in underserved and remote areas, and thereby contributes to improving healthcare equity and reaching vulnerable populations. The expansion of digital health programs enables a broader segment of the population to reap the benefits of digital health technologies, potentially leading to enhanced health outcomes, including reductions in morbidity and mortality rates.

Moreover, as digital health initiatives scale up, there can be a noteworthy decrease in the cost per patient due to economies of scale. This cost reduction holds the potential to make healthcare more affordable and sustainable, especially in resource-constrained settings. The scale-up also facilitates the collection of larger and more comprehensive datasets, offering invaluable resources for epidemiological research, disease surveillance, and evidence-based decision-making.

The advantages of scaling up digital health programs extend to the potential for attracting government support and funding, thereby fostering the integration of digital health into national healthcare systems and policies. Furthermore, the scalability of digital health initiatives acts as a catalyst for innovation in the field, encouraging the development of new technologies, applications, and approaches to address evolving healthcare challenges. Lastly, in times of public health emergencies, such as pandemics or epidemics, scalable digital health solutions provide a rapid and efficient means of delivering critical healthcare services and information to affected populations.

However, scale-up is no small feat and as described in the earlier chapter of this review, a majority of DH programs fail to move beyond the pilot stage. Also, evaluating the effective “scale-up” of digital health initiatives requires a nuanced understanding of what ‘scale’ means and in that to consider the perspectives of end-users, patients, healthcare policymakers, and investors. As proposed previously, successful scale could be when a digital solution is seamlessly integrated into the healthcare system, ceasing to be viewed as a separate activity ¹¹⁰. A 2014 report published by PATH ¹¹¹ offers a discussion around the need for an agreed goal for scale. According to findings from interviews with digital health thought leaders, some organizations adhere to a traditional understanding of scale, focusing on the coverage of a target population of patients or providers within a specific area (scaling up) or expanding across different regions (scaling out). The concept of “relevant scale” was described to also vary significantly depending on the type of digital product or service being implemented, such as medication adherence programs or national health management information systems (HMIS). This variation makes it challenging to establish a unified goal for scaling all digital health interventions. Whilst this report was published a decade ago, this discussion is likely still relevant today in many DH-programing contexts.

Findings:

The **National eHealth Strategy Toolkit** ⁴² describes ideal circumstances for scaling national eHealth strategies. These conditions encompass a conducive policy environment, along with requirements in human resources capabilities and technology infrastructure. While certain factors like the stability of the national electrical grid or cellular phone coverage are usually beyond the control of individual projects, project implementers play a crucial role as stakeholders in advancing this agenda at the national level.

This is one aspect covered in **WHO’s MAPS toolkit** ¹⁴, which is a comprehensive and targeted guideline

document for DH planners and implementers addressing program scale-up, and thus a “must-consult” for practitioners (described in more detail below). The earlier mentioned report by PATH, **The journey to scale – moving together past digital pilots**¹¹¹ introduces key aspirations for scale, emphasizing sustainability in terms of funding and defining institutionalization as the goal for successful scale, along with the capacity for replication, refinement, and continuous improvement over time¹¹¹.

In addition, a 2018 study on best practices in scaling digital health in LMICs¹¹⁰ outlines five key focus areas critical for successful scale-up: 1) Intrinsic program characteristics, 2) Human factors, 3) Technical factors, 4) the Healthcare Ecosystem and 5) the extrinsic ecosystem. Based on case study consultations of real-life implementation projects that went beyond the pilot phase, the authors concluded that:

- A DH program should inherently address a practical need with input from end-users and stakeholders need thorough engagement, training, and motivation for effective implementation.
- The technical profile of the initiative should prioritize simplicity, interoperability, and adaptability.
- The policy environment must align with broader healthcare policies, ensuring sustainable funding, potentially from the private sector.
- Consideration of the extrinsic ecosystem, including appropriate infrastructure, is vital for scalable digital initiatives.

Beyond that, the authors describe the critically important global collaborative efforts (e.g., the Health Data Collaborative, the OpenHEI community and others) that are ongoing to date, aiming towards a less-siloed approach for scaling and integrating digital health, facilitating innovative solutions for health-care workers and patients in LMICs. Those working in the field should engage with these collaborations. In a fast-evolving environment such as the DH sector, working groups and direct expert information sharing through such communities of practice, can be a highly effective way to obtain up-to-date best practice information.

Finally, to measure scaling up, Digital Square has introduced a triangulation tool, the **Understanding scale of digital tools: a framework and triangulation tool to measure scale of digital deployments in the context of the COVID-19 pandemic**¹¹². This approach emphasizes that utilizing, modifying, and implementing existing digital tools prevalent within a country serves as the most efficient, economical, and effective method for integrating ICT into national health systems. Functionally, this tool measures an intervention’s reach through three interconnected aspects: the volume of end-users, the level of tool engagement, and the depth of institutional adoption.

Reviewed Guidelines and Toolkits

WHO’s mHealth Assessment and Planning for Scale (MAPS) Toolkit

A self-assessment tool guiding project teams in scaling up innovations for DH. It employs an iterative process covering assessment, planning, and targeted improvements. MAPS helps to evaluate scaling-up progress through detailed self-assessment questions across six axes: 1) Groundwork, 2) Partnerships, 3) Financial Health, 4) Technology & Architecture, 5) Operations, and 6) M&E. The resulting scorecard provides insights for projects to enhance scale and sustainability. Acting as a decision tool, it helps overcome scale barriers, with iterative activities meant to be conducted throughout the project’s life.

Digital Square’s Understanding scale of digital tools: a framework and triangulation tool to measure scale of digital deployments in the context of the COVID-19 pandemic

This tool provides a way to evaluate scaling efforts by assessing an intervention’s scale through three dimensions: end-user numbers, tool usage breadth, and institutional adoption level. It addresses complexities such as the variable nature of “end users” (which could mean individuals or healthcare

facilities), the dynamic digital ecosystem and tool availability across countries, and a country's evolving capacity marked by digital literacy, infrastructure, and financial resources.

PATH's "The journey to scale – moving together past digital health pilots"

A report primarily intended for global health practitioners, policymakers, donors, and technology developers. It aims to provide these stakeholders with a clear understanding of the pathways and levers necessary for achieving large-scale, sustainable digital health interventions. It advocates for a deliberate, coordinated approach that aligns on a shared goal of institutionalization and identifies key factors that enable successful scale-up, including the importance of a strong case for action, effective leadership, viable economic models, and interoperability standards.

3.2.4.7 Monitoring & Evaluation

Target Audience

- **Primary Users:** Developers, donors, ministries of health
- **Secondary Users:** Healthcare providers, government bodies

Relevance

Monitoring and evaluation (M&E) activities in DH are critical for multiple reasons. They play a vital role in providing empirical evidence on whether ICT are accomplishing their intended goals, they allow for the timely identification and resolution of issues and contribute significantly to resource allocation decisions, allowing policymakers and organizations to make informed choices, thereby optimizing the allocation of resources for maximum impact. M&E also functions as a mechanism for accountability and the iterative nature of the different types of M&E activities allows for the identification of areas requiring adjustments or improvements in digital health interventions, promoting continuous refinement and optimization.

In addition to immediate impacts, M&E activities can be instrumental for identifying barriers to the adoption of digital health technologies, whether they are of a technical, cultural, or logistical nature. This insight is invaluable for overcoming hurdles and enhancing the overall adoption and impact of digital health initiatives. Moreover, by tracking usage trends, user satisfaction, and the continued achievement of desired outcomes, stakeholders can make informed decisions to ensure the enduring success of these programs. Beyond operational

considerations, the data collected serves as a valuable resource for research and innovation in the field of digital health. It contributes to the development of new technologies and approaches, fostering ongoing progress and advancements in the digital health landscape.

Findings

M&E in DH programing requires in part different considerations compared to "non-digital" projects or initiatives. In the complex realm of DH, the areas of program monitoring and impact evaluation remain areas that require well-developed guidance, DH programs usually undergo dynamic evolution, whereby they are progressing through various stages of maturity, which means that the M&E requirements are can also be in constant flux. Typically, these projects commence by addressing fundamental questions related to the intervention's alignment with identified needs, technical functionality, and feasibility. The subsequent phases involve evaluating user satisfaction and advancing towards the assessment of effectiveness, attributable impact, and, ultimately, the cost-effectiveness or "value for money" of the intervention.

Through this review, we identified seven key resources that can support DH program planners, implementers and the monitoring evaluation teams to navigate the DH program cycle.

WHO's Monitoring and Evaluating Digital Health Interventions²⁹ can be considered as the primary resource for undertaking M&E activities in DH. This resource user-friendly and provides the theoretical

foundations required. With a more technical and methods-oriented content, the **Evidence DEFINED Framework** ¹¹³, **CONSORT-EHEALTH 114** and **iCHECK-DH** ⁷³ are useful for planning and conducting effectiveness and impact evaluations of DHIs, whilst **WHO's Monitoring the implementation of digital health** ²⁹ has its focus on the process of implementation rather than effectiveness or impact. Even though this resource is not a guideline as such, it provides case evidence from M&E activities from eight different countries and places particular emphasis on the ongoing discussion around indicators in DH.

The **Recommendations on digital interventions for health system strengthening** ⁸ proposes some valid case studies and presents evidence on the impact of DHI. Whilst not designed for M&E practitioners may find the evidence helpful in guiding their efforts. Together with **Monitoring and Evaluating Digital Health Interventions** ²⁹, these two guidelines provide valid suggestion to implement evaluations and monitoring activities at the different stages of the development, adoption and use of the service ^{24,115}.

Reviewed Guidelines, Frameworks & Toolkits

WHO's Monitoring and Evaluating Digital Health Interventions

A guide specifically for enhancing M&E initiatives in Digital Health (DH), focusing on monitoring intervention deployment and evaluating outputs across user satisfaction, process enhancements, health outcomes, and cost-effectiveness. It covers value proposition development, indicator selection, evaluation design decisions, and offers techniques for assessing data accuracy and accessibility, along with directives for result reporting.

WHO's Monitoring the implementation of digital health

A study, which focuses on monitoring the implementation of digital health initiatives, consolidating information from WHO, the European Commission, the Nordic eHealth Research Network, OECD, and the Statistical Conference of the Americas. It reviews national digital health monitoring activities in eight countries, and highlights the need for evidence to shape healthcare system transformation. The study describes challenges in measuring governance, health data reuse, and system-wide interoperability, stressing ongoing efforts to adapt metrics to the evolving digital health landscape.

The Evidence DEFINED framework ¹¹³

A framework designed for practical use, which streamlines the assessment of DHIs in four steps. This evaluative protocol involves initial screening against fundamental requirements, adopting a recognized evidence assessment methodology, applying the 'Evidence DEFINED' supplementary checklist, and utilizing evidence-to-recommendation guidelines to provide adoption recommendations. The framework assesses the support for DHIs based on clinical evidence while considering additional crucial areas such as patient experience, cost, health equity, and more.

Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth ¹¹⁴

CONSORT-EHEALTH extends the established CONSORT statement, offering guidance on reporting trials for ehealth & mhealth interventions. It comprises 17 sub-items, with four addressing intervention attrition, user engagement, dosage, and adherence. The checklist is applicable beyond internet-connected scenarios but may require further research for adaptation. CONSORT-EHEALTH is to enhance transparency and consistency in reporting eHealth intervention research. mERA is designed for mHealth interventions, providing a framework for assessing and reporting evidence from these studies.

World Bank's Framework for the Economic Evaluation of Digital Health Interventions

A recent (2023) and specialized economic evaluation framework for scaling up DHIs (based on WHO's Classification) within limited health budgets. This tool helps assess the value of DHIs for evidence-based decision making, against the backdrop of lacking economic data on DHIs. The framework includes five steps: 1) determine the context, 2) determine the intervention type, 3) establish the level of complexity, 4) analytical principles, and 5) presenting the value proposition and aligns with the project maturity cycle as per WHO's Guide to Monitoring and Evaluating DHIs.

The mHealth Evidence Reporting and Assessment (mERA) Checklist ¹¹⁶

A checklist designed to improve the reporting of mHealth interventions. It outlines essential details for replicating mHealth interventions, including content, context, and technical features. It is to assist authors, reviewers, policymakers, and journal editors in synthesizing and critically evaluating mHealth research for transparency and completeness. The checklist is specifically designed for mHealth interventions, providing a framework for assessing and reporting study evidence.

iCHECK-DH⁷³

A 20-item checklist for reporting digital health implementations, covering areas such as claims, methods, sustainability, and budget planning. The primary goal of iCHECK-DH is to identify key information necessary for thoroughly defining DH implementations, helping to discern success and failure factors and enabling replication in various contexts. It further aims to standardize reporting quality and enhance implementation standards and best practices.

3.2.4.8 Sustainability and Financing

Target Audience

- **Primary Users:** Donors, government bodies
- **Secondary Users:** Developers, implementers

Relevance

There are several aspects that need to be considered when it comes to financing digital health initiatives. DH programming requires long-term funding models that go beyond initial grants or pilot project funds. This could include government funding, private sector investment, or innovative financing mechanisms, such as public-private partnerships. Part of this process is to understand the long-term value of digital health investments, justifying the allocation of resources, and ensuring that the benefits outweigh the costs. Ensuring policy and regulatory support can lead to more stable funding environments and government policies that prioritize DH can lead to more consistent and reliable funding.

Investments should focus on scalable solutions that can be expanded or adapted as needed. Relying on a mix of funding sources, including government, international donors, private sector, and non-profit

organizations, can help in spreading financial risks and ensuring sustainability. Also, integrating DH solutions into existing health systems can leverage current funding streams and infrastructure, making them more sustainable.

Financing models must also include budgeting for ongoing maintenance, updates, and operational costs, including staffing and training, is crucial. These costs often exceed initial development costs and are vital for long-term sustainability. Importantly, regular monitoring and evaluation help in demonstrating the impact of digital health systems, which is crucial for continued funding and support.

Findings

Through this review, we were able to identify numerous resources addressing the broad spectrum of issues around DH Financing and Sustainability. First and foremost, the **Digital Investment Principles** ⁸⁶ constitute principles, that have been endorsed by a number of major donor agencies with the aim to align investments with countries' digital health strategies, addressing issues of fragmentation, lack of

interoperability, and promoting collaboration, prioritization, quantification of costs, and strategic investments.

Critically however, there is still a dearth of evidence regarding economic evaluations of digital health interventions, which makes informed-decision making for policy makers and funders challenging and also the development of guidelines difficult. As such, the recent World Bank- commissioned **Framework for economic evaluations of DHIs**¹¹⁷ may prove particularly useful for the sector. In a resource-limited world, and especially LMIC-settings require strategic scaling decisions due to substantial opportunity costs. The paper introduces a five-step economic evaluation framework to enhance decision-making and investments in constrained health budgets, thereby promoting methodological transparency for improved utility in digital health interventions. **WHO's Digital implementation investment guide (DIIG)**³ provides guidance on financing and costing for digital health initiatives, focusing on identifying cost drivers at each implementation stage and developing comprehensive budgets for the entire lifespan of the investment.

The other guidelines like the **Digital Health Investment Review Tool**¹¹⁸ summarized below cover areas including how to align investments with national health priorities to ensure relevance and guiding procurement processes, whilst the **SDG Digital Investment Framework**¹¹⁹, even if not health-domain specific, provides a comprehensive approach for governments to invest in digital infrastructure aligned with the SDGs, simplifying the mapping of digital strategies and ensuring alignment with broader development goals. **Closing the digital divide: More and better funding for the digital transformation of health**¹²⁰ presents six strategic recommendations targeted at national governments, international donors, and the private sector.

Finally, to facilitate health managers Digital Square developed two simple tools: the **Total Cost of Ownership Tool**¹²¹ and the **Digital Health Sustainability Calculator**¹²². These tools provide preliminary inputs to help stakeholders comprehend the full financial scope of sustaining digital health efforts and to elaborate a budget.

Reviewed Guidelines, Frameworks & Toolkits

The Principles of Donor Alignment for Digital Health⁸⁶

These are 10 principles for donors to align their investments with national digital health strategies in LMICs. The goals are to integrate health system strengthening, enhance health service delivery, and improve data use for better health outcomes. These principles address the challenges of fragmentation and lack of interoperability in digital health systems and emphasize the need for progress in health outcomes and achieving the SDGs

Digital Health Investment Review Tool to guide the investment in DH¹¹⁸

A tool to support strategic investments in DH, that includes a country self-assessment of the ICT environment and readiness for eHealth, introduces a “process framework” for 12 eHealth components (i.e., Policy Landscape, System Users, Cost of Ownership, Privacy & Security). Each component includes a self-assessment worksheet and considers the developmental stage of the proposed system, ranging from nascent to optimized, to determine the emphasis on different aspects, such as Total Cost of Ownership, based on the system's scale and maturity.

WHO's Digital implementation investment guide (DIIG)

A Guide that aids governments and technical partners plan and implement digital health initiatives aligned with national health system objectives. Besides offering implementation guidance, it includes detailed step-by-step instructions for planning and budgeting DHIs within a digital health enterprise. The guide focuses on pinpointing cost factors at various implementation stages and creating a thorough budget that spans the entire investment period.

ITU's Sustainable Development Goals Digital investment framework (eGov) ¹¹⁹ A Framework to assist governments and partners in digital infrastructure investment and SDG programing enhancement. Using enterprise architecture planning (EAP) principles, the Framework connects SDG Targets to ICT Building Blocks, aligning technology investments with business strategies. It serves as a practical guide for developing digital strategies and investment plans, providing examples, cataloging use cases, workflows, ICT components, and outlining a process for organizational integration.

World Bank's Framework for the Economic Evaluation of Digital Health Interventions

An economic evaluation framework for scaling up DHIs (based on WHO's Classification) within limited health budgets. This tool helps assess the value of DHIs for evidence-based decision making, against the backdrop of lacking economic data on DHIs. The framework includes five steps: 1) determine the context, 2) determine the intervention type, 3) establish the level of complexity, 4) analytical principles, and 5) presenting the value proposition and aligns with the project maturity cycle as per WHO's Guide to Monitoring and Evaluating DHIs.

Closing the digital divide: More and better funding for the digital transformation of health

A framework that advocates for stronger and more unified funding support, both locally and globally, to advance equitable and sustainable digital health system development in LMICs. It offers six strategic recommendations for national governments, international donors, and the private sector: increased funding from various sources, improved investment coordination, a detailed digital health strategy with investment planning, a strong regulatory and policy framework, mechanisms for effective multi-stakeholder involvement, and enhanced digital connectivity.

Digital Square's Total Cost of Ownership Tool

An Excel-based tool, which serves as an interactive resource designed to aid health leaders in creating more accurate budgets for digital health initiatives. With built-in user inputs, the TCO Tool emphasizes the identification of common hidden costs, cost drivers, and variances, particularly focusing on the often-overlooked operational expenses.

Digital Square's Digital Health Sustainability Calculator

An Excel-based tool designed to estimate the total cost of implementing sustainable digital health systems at a national level. This tool is intended for informational, non-commercial purposes and not intended to be 100% accurate. Not to be used as a replacement for professional expert consultation, but rather as a starting place to estimate the total cost of digital health.

3.2.4.9 Gender, Equity, Inclusion & Ethics

Target Audience

- **Primary Users:** Developers, healthcare providers, ministries of health, donors
- **Secondary Users:** Government bodies

Relevance

Whilst digital technologies are becoming increasingly important for supporting health systems, we must acknowledge that they are not inherently neutral. On the contrary. Whilst there is compelling

evidence that DH can significantly improve access to healthcare, for example for populations living in remote areas, digital tools can also inadvertently reinforce existing inequalities or create new disparities by marginalizing the poorest, the less educated, or those simply less familiar with technology¹²³. The challenges are multifaceted, including, e.g., prevailing unavailability of electricity for charging mobile devices or poor network connectivity coverage in areas with poor mobile infrastructures. Also, the most expensive handsets may consume up to 54% of the poorest population's monthly income and rural adults are 33% less likely to use mobile internet compared to their urban counterparts, with women being 16% less likely to use it compared to men¹²⁴. A clear example of this issue can be seen in the use of reminders in immunization programs. Although there is significant evidence supporting their effectiveness, one cannot overlook that caregivers without a connection or a mobile device are excluded from these benefits. As such, it is imperative that Gender, Equity and Inclusion (GEI) considerations become an integral part of DH planning, implementation and scale-up.

Digital inclusion is considered a social determinant of health¹²⁵. Inclusivity in healthcare is crucial for reducing health disparities and ensuring access to services for everyone, regardless of socioeconomic status, location, or abilities. Digital inclusion activates community engagement and empowerment and is critical to the success of the SDGs.

In the realm of DH, inclusivity means creating user-friendly, culturally and socially sensitive digital tools with clear navigation and customizable options to suit diverse user groups. This includes providing educational materials and medical information in multiple languages and formats accessible to people with different health literacy levels and cultural backgrounds. Ensuring DHIs reach the most vulnerable is essential for equitable health service distribution, ultimately improving global health outcomes. The US-based National Digital Inclusion Alliance resumes in five points the efforts to reach digital inclusion, that should act as guiding posts for DH policy makers, planners and implementers¹²⁶:

1. affordable, robust broadband internet service;
2. internet-enabled devices that meet the needs of the user;
3. access to digital literacy training;
4. quality technical support;
5. applications and online content designed to enable and encourage self-sufficiency, participation and collaboration.

Implementing digital interventions also requires a thorough examination of ethical principles and practices within healthcare technology. This area is vast and intricate, and it encompasses a variety of issues, including health data governance, which was discussed in an earlier section (see section: 3.2.4.3). Moreover, ethical principles and practices may be governed by specific regulations on the one hand, but may also entail more nuanced ethical dilemmas. Ensuring equity and providing widespread access to healthcare services stand out as less obvious, yet critically important challenges.

For example, the adoption of algorithmic decision-making in healthcare pose the risk of introducing bias and the need for transparency in how algorithms are developed. Algorithmic bias occurs when algorithms produce systematically prejudiced results due to erroneous assumptions in the machine learning process or biases present in the data used to train them. If the data used to train health algorithms lack diversity, the algorithm might perform well for certain groups but poorly for others, potentially exacerbating health disparities. Algorithmic bias often occurs because certain populations are underrepresented in the data used to train algorithms or because pre-existing societal prejudices are baked into the data itself¹²⁷.

Furthermore, algorithms might be designed or deployed in a way that favors certain outcomes or interpretations, further entrenching existing clinical practices even when they may not be the most effective or equitable. Regularly assessing algorithms' performance across different populations and settings can identify and correct biases that may emerge over time¹²⁸.

Findings

We summarized nine key resources relevant to gender, equity, inclusion & ethics in the digital space. They cover a range of critical topics that pertain to GEI & ethics in digital health technology development and implementation and differ considerably in their format and intended application. The selection includes fundamental information on the principles of digital inclusion relevant beyond the health domain, outlined in the **United Nations Roundtable on Digital Inclusion**¹²⁹, theoretical frameworks that place health equity factors in the context of digital determinants of health, namely the **Digital Health Equity Framework**¹³⁰ and **National Institute on Minority Health and Health Disparities Research Framework Expanded for Digital Health Equity**⁷¹, a technical brief on gender-sensitive programing in digital health, **GIZ's Why Gender Matters for Digital Health**¹³¹, toolkits based on human-centered

design principles for particular populations, namely young people and girls, **WHO's Youth-centred digital health interventions**¹³² and **UNICEF's Gender-Tech Toolkit**¹³³ and **WHO-ITU Global standard for accessibility of telehealth services**¹³⁴, which are standards for improving accessibility to telehealth services for individuals with disability.

Moreover, we included two guidance documents for an increasingly critical topic, namely on ethics and governance of artificial intelligence for health. First, **WHO's Ethics and governance of artificial intelligence for health – WHO Guidance**¹³⁵ focuses on the ethical issues and risks associated with the use of artificial intelligence (AI) in healthcare. It outlined six key principles to ensure AI benefits all nations and provided recommendations to improve AI governance in healthcare, aiming to fully realize the technology's potential. Second, in response to governments' and individuals' unpreparedness for the rapid proliferation of Large Multi-modal models (LMMs), WHO produced an extension of WHO's 2021 guidance document on AI, **WHO's Ethics and governance of artificial intelligence for health – Guidance on large multi-modal models**¹³ to provide guidelines to ensure the ethical, legal, and effective use of these technologies in healthcare and digital health. Large multi-modal models, despite their novelty, are rapidly influencing healthcare and medicine. The nearly universal adoption of models like ChatGPT, which had 100 million monthly active users within two months of its launch¹³, illustrates their potential and popularity. However, the rapid integration of LMMs into applications by tech-companies and startups, often backed by significant investments, has raised concerns about the transparency, reliability, and ethical use of these models. Issues such as unpredictable outputs, data bias, and compliance with data protection laws highlight the need for clear guidelines and regulations, and these are being addressed in this first guidance document on the topic.

Whilst already described in the earlier the section: "Solution design & development", UNICEF's foundational guide on **Designing Digital Interventions for Lasting Impact: A Human-Centered Guide to Digital Health Deployments**¹⁰⁴ is a resource which should certainly also be considered in the GEI context as it allows planners, developers and implementers to focus their efforts towards their user groups and adapt technologies accordingly.

The resources presented in this section cover theoretical aspects as well as hands-on practical recommendations for design and implementation and should be consulted by policy makers, researchers and DH practitioners. However, the review also highlighted that there is a need for a resource, which

addresses the topic of GEI & Ethics in digital health in its entirety and guides policy makers and DH practitioners through the evidence base, the intricacies of different DH user groups and their needs, including step-by-step guidance on how to incorporate the "inclusion lens" throughout the entire project cycle of DH programing. The lack of such a resource is not surprising given that the evidence-base for addressing GEI in DiPH implementation is still in its infancy. Drawing on the existing, if limited body of evidence on GEI challenges in DiPH, some key considerations have emerged as relevant for GEI-programing in DH (Ladysmith: Rapid Review for DIPC on Gender Equity and Inclusion in Digital Health, 2023, unpublished):

Privacy and Ethical Data Use: One of the foremost concerns for GEI & Ethics involves privacy intricacies and ethical use of data. The potential for exploitation of health data, especially by third-party entities, highlights the need for robust protective measures. Thus, it is critical to strike that delicate balance between opt-in and opt-out mechanisms to ensure individual consent while upholding human rights standards. Also, rigorous efforts to maintain accountability and transparency in the handling of sensitive information are essential in fostering public trust and which in turn will facilitate the engagement of all population groups.

Digital Literacy and Access Disparities: A critical hurdle lies in the existing disparities in digital literacy, which affects especially marginalized populations' access to digital health services. Bridging this gap necessitates targeted support, user-friendly interfaces, and educational resources. Furthermore, considerations of affordability, local norms, and societal contexts need to be considered to enhance overall accessibility and inclusivity.

Inclusive Data Representation: Addressing the pervasive issue of underrepresentation and data gaps among marginalized groups has emerged as a key issue for GEI & Ethics in the literature. There is a need for diverse and representative datasets that not only reflect the broader societal landscape but also help mitigate existing health disparities. A multi-dimensional approach, encompassing eHealth literacy and an understanding of broader social conditions, is essential in crafting an inclusive digital health framework.

Human-Centered Design and Continuous Engagement: The quality and usability of digital health software stand out as pivotal aspects impacting effective healthcare delivery. The literature highlights the importance of a human-centered design approach, given the need to incorporate user perspectives and to integrate gender-sensitive design principles.

Users engagements should be done and checked on a continuous basis throughout the intervention life-cycle. This iterative process not only addresses the lack of standardization in software quality but also guarantees the alignment of digital health solutions with the evolving needs and contexts of users, which in turn fosters equitable and inclusive digital health programing.

The following resources on the topic of GEI & Ethics should be considered by policy makers, DH planners and implementers.

Reviewed Guidelines, Frameworks & Toolkits

UNITED NATIONS' Roundtable on Digital Inclusion

A key document covering digital inclusion's definitions and themes, emphasizing an intersectional approach to tackle challenges like racism, gender discrimination, and biases against marginalized groups. It addresses factors such as data disaggregation, infrastructure, connectivity, access, affordability, and participation and places them in the context of "inclusion" as a social determinant of health.

OECD's Bridging the Digital Gender Divide. Include, upskill, innovate

The OECD report aims to promote gender equality in the digital economy by addressing barriers like access, affordability, education, and socio-cultural norms. It offers policy recommendations for stakeholders to bridge the digital gender gap. Key challenges include limited access to technology, underrepresentation in STEM and ICT jobs, and online harassment. The report emphasizes the need for coordinated actions, such as raising awareness, enhancing digital literacy, and fostering an inclusive digital culture.

Digital Health Equity Framework (DHEF)

A theoretical framework (Crawford & Serhal, 2020), which integrates health equity with digital health determinants to address health disparities. It considers factors, including race, age, income, and geography, and extends beyond traditional health system roles by incorporating digital health equity. The framework examines interactions between digital access, literacy, and various health-related factors. It emphasizes equitable digital healthcare to mitigate disparities and highlights the role of socio-cultural contexts in health and technology use.

National Institute on Minority Health and Health Disparities Research Framework Expanded for Digital Health Equity

A theoretical framework (Safiya Richardson, 2022) on DH equity, which underscores the need to consider both digital determinants of health (DDoH) and social determinants of health, especially for those digitizing health solutions. It highlights the importance of community and societal-level interventions to address health inequities and advocates for multi-level approaches in digital health interventions, considering DDoHs to ensure equity and effectiveness.

GIZ's Why Gender Matters for Digital Health

A technical brief that focuses on gender-sensitive programing in DH and emphasizes that DH solutions should address differences and inequalities for empowering marginalized groups. The paper outlines challenges, such as the digital gender divide, violence risks, and algorithmic biases that DH planners need to consider and assesses gender-specific benefits and obstacles of DHIs. Concluding with seven key recommendations for enhancing gender sensitivity in DH initiatives, it provides a framework for integrating gender considerations in DH.

WHO's Youth-centred digital health interventions

A framework to guide the development and implementation of DH solutions for young people, targeting a range of professionals from designers to funders. It focuses on three key phases: planning, development, and implementation. It features real-life examples, insights from young people, best practices, and case studies. Each section includes relevant tools and resources, and the guide also offers lessons learned for future investment and expansion in youth-centered digital health interventions.

UNICEF's GenderTech Toolkit: Building digital solutions for, with, and by girls

A toolkit to aid digital innovators in creating solutions that cater to girls, with the aim to bridge the gender digital divide. This toolkit, applicable in various contexts including digital health, includes four distinct tools: 1) How to build digital solutions for girls' digital realities, 2) How to co-create digital solutions with girl, 3) How to include girls in digital product user testing and 4) How to conduct consultations with girls.

WHO-ITU Global standard for accessibility of telehealth services

A standard designed for governments, healthcare providers, telehealth platform manufacturers, and organizations advocating for people with disabilities. It addresses the "digital divide" that people with disabilities face, and offers a comprehensive set of technical requirements to enhance telehealth platforms' usability. These guidelines are designed to ensure that telehealth services are effective, safe, and inclusive, considering various impairments and offering specific solutions to make digital health services more accessible to everyone.

WHO's Ethics and governance of artificial intelligence for health

A guidance document for developers, ICT users, and regulators in the healthcare sector. It emphasizes the protection of human dignity, safety, and fairness by providing a framework for responsible AI development and implementation. This standard is a key text because AI's integration into healthcare raises significant ethical and privacy concerns, necessitating robust guidelines to prevent harm, bias, and misuse of data. The document offers guidance on maintaining transparency, ensuring informed consent, safeguarding privacy, and promoting equitable access to AI technologies.

WHO's Ethics and governance of artificial intelligence for health – Guidance on large multi-modal models

A guidance document for governments, healthcare providers, AI developers, and policymakers, focusing specifically on large multi-modal models (LMMs). Unlike the pervious WHO AI guidance (2021), it addresses the unique ethical, legal, and societal challenges of LMMs. The document provides a framework for the ethical development and governance of LMMs, emphasizing transparency, accountability, inclusiveness, and human rights. It offers recommendations to manage risks and promote best practices, aiming to maximize LMM benefits while ensuring patient safety, data privacy, and public trust in these advanced AI-driven healthcare solutions.

3.2.4.10 Capacity Strengthening

Target Audience

- **Primary Users:** Healthcare providers, government bodies, ministries of health
- **Secondary Users:** Developers, donors

Relevance

To harness the full potential of DH solutions, the empowerment of healthcare and other staff involved in any aspect of the health ICT system is the only paths to ensure effective utilization, maintenance and evolution of tools and digitized systems for the benefit of patients, the wider community and country as a whole.

Capacity strengthening is a key measure to empower personnel to effectively use digital tools and to foster their integration into the health system. Importantly, knowledge and skills required for digital health initiatives then become increasingly less reliant on external organizations, thereby promoting sustainability and long-term success.

Additionally, capacity building plays a key role in addressing digital disparities. Providing targeted training to women or other digitally marginalized groups, facilitates intervention scale-up and promotes work, and -economic possibilities, contributing to the overall growth and development of the healthcare sector and beyond. Moreover, strengthening workforce capacities helps to mitigate the risk of knowledge loss due to the high turnover of health workers (HWs) in LMICs, as creating standardized curricula could allow for the exchange of HWs with similar competencies.

Whilst the importance of strengthening digital knowledge and skills among the HWs is unquestionable, developers and implementers of trainings, especially in LMICs, would benefit from evidence-based guidance to steer the potential initiatives.

Findings

This review has shown that there is a distinct paucity of targeted guidelines, toolkits and frameworks to support the development of digital literacy and competency training programs for HW and health system ICT staff.

WHO's Digital education for building health workforce capacity¹³⁶ is the only "official" document we were able to identify, that addresses some of the basic questions around the implementation of digital

education for health sector worker in LMICs, but it should be emphasized that it is not a planning or implementation guideline. Instead, the paper outlines the global mandates to address workforce challenges and their intersection with digital health, it summarizes existing evidence on the effectiveness of education through digital modalities for the health workforce and proposes a possible framework that policy makers, planners and implementers may adopt to systematically identify the requirements and resources needed to address their respective health system outcomes. To emphasize, the resource primarily considers health workforce capacity strengthening through different digital means, and not capacity strengthening of HWs to be able to use digital tools and ICT for health care delivery.

One key learning from the paper (its contents is described in more detail below) is that there is a need for robust, context-specific research before evidence-based implementation guidelines can be formulated. As in any other context, the digital education for health workers also requires rigorous and critical evaluation and much of this evidence does not exist at this point.

According to the resource, while certain approaches show promise for delivering training to HWs via digital education modalities (e.g., offline digital education for medical students and doctors), many of the studies remain inconclusive or require more nuanced investigations. A number of concerns exist around the available evidence. First, there is the disproportionate focus of studies on medical students and doctors which is problematic because this skewed representation raises doubts about the generalizability of findings across other health care or ICT professions relevant for the functioning of digitized health systems.

Second, there is a lack of high-quality randomized controlled trials from LMICs and limited cost-effectiveness studies. Nevertheless, findings from a comprehensive review of 93 studies suggest a significant role for online digital education in training medical doctors, demonstrating enhanced learning outcomes compared to self-directed or face-to-face learning¹³⁷. The emphasis on blended learning appears suitable for healthcare training, addressing the need for a combination of practical hands-on, skill-based training, and self-directed digital education.

A second resource¹³⁸, although based on the HWs in the European regions provides to some extent applicable guidance for DH planners and implementers around HWs barriers and enablers to fully engage in

the digital transformation of health systems, including some recommendations for improving the process. Evidence from the health workforce of LMICs is still needed however to inform capacity strengthening initiatives.

Given this evidence landscape, crafting guidelines for training developers becomes a challenging task. The lack of clarity in the effectiveness of various digital education modalities, alongside little evidence on the challenges of the HWF in LMICs, raises skepticism about the feasibility and robustness of such guidelines.

However, efforts are ongoing, also as part of WP3 of the DIPC initiative. WP3, implemented by the Regenstrief Institute, is concerned with capacity strengthening activities and the ongoing work is addressing some of the questions that prevail on

this topic. For example, at the time this review was written, the Regenstrief Institute was compiling a repository of existing global goods training resources, including trainings on e.g., digital literacy, ICT skills and digital governance & leadership skills for professionals working as part of the health system to evaluate training development needs and avoid duplication or siloed publication of new resources. The global capacity strengthening activities for DIPC will then be designed and implemented, focusing on planners, researchers and developers in LMICs. At the same time, DIPC implementation at the country level will include capacity strengthening for users of the digital solutions, which means practitioners and providers.

Reviewed Guidelines, Frameworks & Toolkits

WHO's Digital education for building health workforce capacity

A guide to for integrating ICT in health education. It emphasizes digital education's role in addressing global health workforce challenges and covers themes, including enrollment, learning outcomes, remote access, educator skills, and lifelong learning.

The proposed framework considers external, system-level, institutional and individual factors to optimize digital education for the HWF. The report provides an overview of the existing evidence, and give practical tips, and guidance for effective digital health workforce education strategies.

OECD's Empowering the health workforce – Strategies to make the most of the digital revolution

A strategy document that discusses digital transformation challenges in European healthcare, focusing on HWs' experiences with digital tools. While Europe-centric, the findings offer insights for LMICs. The document's recommendations, relevant for global health contexts, include incorporating digital skills into health education, improving tool usability, and ensuring inclusivity in workforce planning.

3.2.4.11 Technical Standards for Developers

Target Audience

- **Primary Users:** Developers; DH planners
- **Secondary Users:** Donors

Relevance

Beyond these proposed guidelines, commercialization on the Western market of digital health products is required to fit into specific standards to guarantee the safety of the users. More complex digital solutions deliver precise health information upon which medical decisions are based. Thus, strict regulations are necessary to ensure patient safety once we can label our digital intervention a Software as a Medical Device ¹³⁹

Findings

We identified four resources as particularly relevant. These frameworks and standards, developed by various global entities, represents a significant advancement in the regulation and standardization of digital health technologies. They collectively contribute to enhancing the reliability, safety, and efficacy of digital health products. However, their impact and effectiveness are not without gaps or areas for improvement. These frameworks provide a structured approach to assessing digital health technologies, ensuring that products meet a certain level of reliability and functionality. The ESF's tiered approach, ISO 82304-2's self-certification model, DiGA's certification process, and the FDA's guidelines collectively establish a global benchmark for what constitutes a reliable and effective digital health technology.

The frameworks, particularly the FDA's DICE and DiGA's temporary registration option, encourage innovation by allowing developers to navigate regulatory landscapes more easily. This support is essential for fostering innovation in digital health. Moreover, these standards provide clear guidance for developers, helping them understand what is required for regulatory approval. This clarity is essential for streamlining the development process and bringing products to market more efficiently.

However, there are some gaps and challenges that should be highlighted. There is a lack of global harmonization in standards. Different regions have their own frameworks, which can create challenges for developers aiming to release their products in multiple markets. This fragmentation can hinder the global accessibility of digital health technologies. Also, DH is a rapidly evolving field, and keeping regulatory

frameworks up to date with technological advancements is challenging. There is a risk that regulations may become outdated quickly, potentially stifling innovation or failing to address new safety concerns. While these standards ensure safety and efficacy, they may inadvertently raise the barriers to entry for smaller developers due to the resources required for compliance. This could limit the diversity of innovations in the digital health space. Finding the right balance between rigorous standards and flexibility for innovation is a constant challenge. Overly stringent requirements might hinder rapid development and deployment of potentially beneficial technologies, especially in response to urgent health crises.

These guidelines and standards collectively play a crucial role in shaping the landscape of DH technologies, providing necessary structures for safety, efficacy, and reliability. However, the challenge lies in ensuring these frameworks can adapt to the fast-paced nature of technological advancements, are harmonized across regions, and strike a balance between rigor and flexibility to support innovation while safeguarding patient health.

Reviewed Guidelines, Frameworks & Toolkits

NICE's Evidence Standards Framework for Digital Health Technologies (ESF)

A tiered framework that categorizes digital health products based on functionality and specifies evidence requirements for developers. It represents a significant methodology in the field of digital health evidence.

ISO 82304-2

A European standard enabling developer self-certification and guiding assessment processes with accrediting bodies. It mandates varied evidence types for compliance, including observational studies or RCTs for specific uses.

The Digital Health Applications (DiGA) process

A process framework which mandates specific criteria for healthcare tools to qualify as medical products under the German Digital Healthcare Act. It requires evidence through comparative studies and allows innovators to register temporarily without an RCT, provided they complete one within a year, accommodating the development of emerging technologies.

Food and Drug Administration (FDA)

The U.S. FDA, responsible for public health safety, established the Digital Health Center of Excellence (DICE) in 2020 to support high-quality digital health innovations. The FDA focuses on efficient, low-burden regulatory approaches while maintaining safety and effectiveness. Detailed guidance on FDA digital health regulations is available online (FDA, 2023).

3.2.4.12 Digitizing Immunization Programs

Target Audience:

- **Primary Users:** Government bodies, Ministries of Health, DH implementers, health care providers
- **Secondary Users:** Developers, donors

Relevance

Guidelines for digitizing vaccination programs, are important because they can provide a structured approach to address the multifaceted challenges these entail. Immunization programs include key components, such as costing and funding, target population identification, vaccination delivery strategies, and human resource management. As many of these

digital tools exist and thus guidelines can be helpful for selecting the appropriate digital tool and ICT.

For example, successful immunization programing depends on communities' willingness to receive vaccines, highlighting the need for strategies that are tailored, evidence-based, and designed to build trust and bridge the knowledge-practice gap. Leveraging behavioral science to develop and implement interventions that can effectively increase the uptake of immunization services and is crucial in addressing vaccine hesitancy and improving vaccine coverage. Guidelines can be pivotal in guiding MoHs, donors, and implementers through the complex process of digitizing vaccination programs because a structured, evidence-based approach to understanding

and addressing immunization demand, selecting and implementing digital tools, and ensuring that these interventions are user-centered and context-specific is needed.

Findings

The COVID-19 pandemic prompted the largest vaccination campaign effort in history^{140,141}, as national governments, international organizations, nonprofits and the private sector sought to vaccinate the world's population. At the same time, the pandemic also accelerated the adaptation and adoption of DH tools in LMICs and numerous guidelines specifically targeting EPI⁹ were published.

For example, the Digital Centre for Excellence (DICE) initiative published their **Guidance on the use of digital solution to support COVID-19 national deployment and vaccination plans**¹⁴³. This guide was prepared by the COVAX working group in 2021¹⁴³ and focuses on assessing the national context in order to find facilitators and barriers to apply the most suitable and sustainable DH solutions. It helps also to prioritize activities such as regulatory preparedness, coordination and planning, delivery strategies, supply chain, human resource management and monitoring. It is a valuable manual that goes beyond the technical development of DHIs but focuses more on the governance of the whole vaccination delivery and its recommendations can be easily extrapolated to the EPI. A similar guideline, also published by DICE, **Primer on Digital Solutions for COVID-19 Vaccination Service Delivery**¹⁴⁴ proposed the same topic providing a comprehensive overview for any policy maker involved in the digitalization of an EPI. In addition, the **Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines**¹⁴⁵ provides a broad perspective on how a vaccination program should respond to a pandemic such as the COVID-19.

A useful guide to design and implement DH solutions in EPI is also GAVI's **Digital Health Information Interventions for Immunization Demand Generation: A guide for selecting appropriate tools and technologies**^{146,147} that can be used in conjunction with the Digital Square guidelines to build immunization registries: **Electronic Immunization Registries**¹⁴⁸, an important document to support digitalization in EPI. Another key text on this topic is the **Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation**, developed by PAHO¹⁴⁹.

In response to the COVID-19 pandemic. **Digital Square and GIZ published Digital Applications and Tools Across an Epidemic Curve**¹⁵⁰, a user-friendly

roadmap suggesting the best digital solutions that could be implemented to prevent, detect, respond to an epidemic¹⁵¹. With this publication Digital Square highlights the importance of interoperability between different software and to gain interoperability, it encourages the use digital public goods.

WHO has also recently published **Considerations for integrating COVID-19 vaccination into immunization programs and primary health care for 2022 and beyond**¹⁴¹. This document does not specifically address DHIs but it outlines crucial programmatic considerations necessary for transitioning from mass COVID-19 vaccination campaigns to the integration of COVID-19 vaccination into EPI, PHC, and other pertinent healthcare services. To operationalize the integration of COVID-19 vaccination at national and subnational level this document emphasizes four steps: 1) Initiating/building on the integration process; 2) Planning and preparatory phase: develop a country-level COVID-19 vaccination integration plan; 3) Implementation and monitoring; 4) Post-integration follow-up action. This is a living document and will be updated to reflect the changing context.

A valid guide to design and implement DH solutions in EPI is also **GAVI's Digital Health Information Interventions for Immunization Demand Generation: A guide for selecting appropriate tools and technologies**^{146,147} that can be used in conjunction with the Digital Square guidelines to build immunization registries: **Electronic Immunization Registries**¹⁴⁸, an important document to support digitalization in EPI. Another key text on this topic is the **Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation**, developed by PAHO¹⁴⁹. Specifically, as part of its **Digital Health Information Strategy 2022-2025**¹⁵², GAVI has provided a comprehensive collection of practical guides, case studies, and technical briefs on its website (<https://www.gavi.org/programmes-impact/our-impact/digital-health-information-dhi>). This resource is designed to assist health managers and developers in the implementation of DH solutions for immunization programs. A notable case study by the HISP Centre at the University of Oslo details how health workers in two districts of the DRC utilized DHIS2 for polio vaccination campaign management, achieving 96% coverage for children under age 5. This included addressing hundreds of "zero dose" cases where children had not previously received any vaccinations¹⁵³.

⁹**Expanded Program on Immunization (EPI):** The Expanded Program on Immunization (EPI) is a global public health program, initiated by WHO in 1974, with the goal to provide routine vaccinations to children and infants in order to protect them from vaccine-preventable diseases. The EPI aims to ensure that essential vaccines are accessible to all children, regardless of their socioeconomic status or geographical location, and to reduce the morbidity and mortality associated with these diseases 142 Keja K, Chan C, Hayden G, Henderson RH. Expanded Programme on Immunization. World Health Stat Q 1988; 41(2): 59-63.

Reviewed Guidelines, Frameworks & Tools

DICE's Guidance on the use of digital solution to support COVID-19 national deployment and vaccination plans

A guideline provides a framework to facilitate equitable access to and distribution of COVID-19 vaccines across countries, particularly in low- and middle-income settings. It is policy and strategy-oriented and offers an overview of various evidence-based digital innovations and practices that can be utilized in different stages of vaccine planning, distribution, and scale-up, intended to amplify efforts in vaccine deployment while generating actionable data, in alignment with strategic resources like the WHO Digital Implementation Investment Guide (DIIG) and UNICEF's digital health guidance for COVID-19 response.

DICE's Primer on Digital Solutions for COVID-19 Vaccination Service Delivery"

A practical guide to support those directly engaged in vaccination efforts with strategies for effectively using digital health tools and data to enhance vaccine distribution and administration beyond the COVID-19 pandemic. The document details an "adapt and scale" approach, using existing systems to support vaccination efforts rather than creating new ones. It includes real-world examples and case studies to illustrate the application of digital solutions in various contexts.

WHO's Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines

An interim guide aimed at assisting national and sub-national health authorities and immunization program managers in planning and executing COVID-19 vaccination strategies. Its primary purpose is to ensure effective, efficient, and equitable deployment of COVID-19 vaccines, addressing key aspects such as regulatory readiness, target population identification, vaccine delivery, supply chain management, and safety monitoring.

GAVI's Digital Health Information Interventions for Immunization Demand Generation: A guide for selecting appropriate tools and technologies

A guideline to assist national immunization program managers, social and behavior change specialists, and immunization implementing partners in selecting and planning digital technologies to increase the demand for routine childhood immunization using a step-by-step approach. It focuses on understanding the factors affecting immunization uptake and offers a categorization of various digital interventions based on their effectiveness.

Digital Square's Electronic Immunization Registries (EIRs)

A briefing guide to improve immunization data quality and use, exemplified on Tanzania and Zambia. Targeted at health professionals and policymakers involved in immunization programs, it demonstrates how EIRs can address data challenges in these programs. The guide details the CRDM, and includes a tailored approach to developing EIRs suited to each country's specific needs, with key contents including the step-by-step process of CRDM, practical aspects of EIR implementation, and lessons learned from the initiative's experiences, with a strong emphasis on user-centered design, sustainability, and effective data use.

PAHO's Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation

A guide to aid in the development, implementation, and evaluation of EIRs, aimed at health decision-makers and program managers in PAHO Member States. It covers all aspects of EIR systems, including technical, functional, and operational considerations and is structured into sections discussing the background, planning, design, development, and implementation of EIRs, with tools like checklists and case studies to assist in decision-making.

GIZ & Digital Square's Digital Applications and Tools Across an Epidemic Curve

A strategic guide for using digital tools in various stages of pandemics and outbreaks. It's designed for governments, health organizations, and investors, focusing on integrating digital technologies into epidemic responses. The framework, influenced by the COVID-19 pandemic, identifies 13 critical use cases and provides a visual mapping of these tools across different epidemic phases. It offers practical guidance on adapting existing digital tools for rapid deployment and effective management during health crises, aiming to improve response efficiency and data-driven decision-making.

WHO & Unicef's Considerations for integrating COVID-19 vaccination into immunization programmes and primary health care for 2022 and beyond

A guide to provide strategies for incorporating COVID-19 vaccination into existing health systems, designed for public health planners and immunization program managers. It outlines principles, benefits, risks, and operational steps for integration, drawing on experiences from various countries. The document emphasizes the need for a strategic, evidence-based approach to manage the pandemic while maintaining essential health services.

4. DISCUSSION

This review was conducted to provide an overview of the current landscape of normative resources—guidelines, frameworks, and tools—designed to steer and guide digital health programing. Additionally, it sought to identify existing gaps in this landscape and offer a repository of these normative resources. The findings are organized according to eleven DH programing-relevant thematic areas, enabling professionals to select appropriate resources based on their specific needs.

These thematic areas cover guidelines, frameworks and tools for 1) Digital Landscape Assessments, 2) Regulation, Strategy & Policy Development, 3) Solution Design & Development, 4) Integration & Interoperability, 5) Scaling-up, 6) Monitoring & Evaluation, 7) Sustainability and Financing, 8) Gender, Equity & Inclusion, 9) Capacity Strengthening, 10) Technical Standards for Developers and 11) Digitization of Immunization Programs.

This review of resources is supported by an initial synopsis of key terms and concepts in digital health, as well as a description of the architectural frameworks that are widely postulated to facilitate the digital transformation of health systems, with particular focus on LMICs.

Ultimately, this review aims to encourage the adoption of guidelines, frameworks, and tools, promoting a harmonized approach to health system digitalization, which in turn is expected to enhance the impact of digital health solutions on population health nationally and internationally. In the spirit of an evolving digital world, we acknowledge that digital health is a field of continuous growth and learning, and, as such, the normative resources assembled here present a cumulative stock of what has been developed

up to this point. As the field evolves, so should this review, as a “living guide of guidelines”, to be updated regularly to incorporate new or revised resources to help further the digital health transformation.

Our findings highlighted that over the past decade, an increasing number of guidelines, frameworks and tools have been developed to support governments, developers, investors, and donors. The resources produced to date have advanced in response to the expanding body of knowledge about the application of digital technologies in health. As ICT and its applications continue to progress, the evidence base also continues to evolve¹⁵⁴.

The eleven thematic areas and the selected corresponding resources reveal that existing guidelines, frameworks, and tools often address specific aspects of digital health, sometimes overlapping but more importantly, complementing each other. Our analysis indicates that the landscape of resources, created by organizations such as the WHO, World Bank, Gavi, and USAID, encompasses a broad spectrum of digital health efforts. This includes strategic initiatives at the macro level and various technicalities at the micro level. This evolving landscape aligns with essential phases and processes of digitalization, from developing national digital health visions and data governance structures to creating interoperable digital health infrastructures. It also includes guidance on technicalities, such as the HL7 FHIR standards for interoperability, technical standards for developers, monitoring and evaluation of digital solutions, and incorporating equity considerations into digital health programing. However, the review also highlighted significant variability in the quantity of available guidelines, frameworks, and tools across different topics. For example, numerous resources

are available for Digital Health Landscape Assessments, while areas such as ICT capacity strengthening for health workers remain less developed.

Overall, our findings indicate an ongoing need for further evidence to develop evidence-based resources in areas currently lacking guidance. For example, the observed gap in evidence for ICT capacity strengthening for health workers, emphasizes the need for more research, well-documented best practices, and case studies to generate initial guidelines. The under-studied or under-documented areas that have been identified, can help define research agendas and guide future resource development efforts. One notable example is the scarcity of cost-effectiveness studies and economic evaluations in digital health, as well as impact studies for DHIs to inform the development of sustainable funding models. Conversely, for areas with ample guidelines and tools, such as digital landscape assessments, there is a need for collaborative efforts to further harmonize these resources and provide practical insights from field implementations to maximize their utility and avoid duplication. Thus, implementation research and process evaluations are essential to accompany national or sectoral programs and report their findings for effective knowledge sharing.

The review showed that guidelines developed in the early days of DH often lacked the inclusion of the user, which is one of the most important principles in digital programing and development, according to the widely adopted “Principles for Digital Development”⁸⁴. The incorporation of a user-centered approach to ensure adequate attention towards, e.g., the prevailing gender digital divide, programing considerations for equitable digital access, as well as geographical factors, is critical and must also be reflected in guidelines. Overlooking such aspects can result in digital solutions lacking, for example, cultural sensitivity or relevance to certain populations, which in turn may lead to reduced adoption, effectiveness and impact, of the digital health solution.

However, the landscape of normative resources for DH-programing has evolved considerably and human-centered design and implementation approaches are today widely advocated for. In fact, the integration of GEI into DH programing is gaining traction, yet there is a still clear need for more comprehensive research on these topics. This is because it remains unclear, to which extent guidelines for GEI-programing are being adopted and translated into action. We understand that gender, equity and inclusion are critical to ensure “health for all” and various guidelines exist that target different population groups, e.g., DH-programing for girls or people living with disabilities. However, it remains

less clear, how this knowledge, and, in fact, existing normative guidelines, can be effectively translated for DH-programing.

Whilst a plethora of guidelines and frameworks has been published to date, there is only a small number of studies reporting on how and, to what extent, specific guidelines, tools, or frameworks were actually utilized¹⁵⁵. In general, there is still little evidence on how specific guidelines have been implemented, and most of the literature is based on wealthier healthcare systems. Implementation science approaches to address the “know – do” gap can be particularly useful. Nonetheless, there are ongoing concerted efforts to facilitate guideline adoption. For example, the Department of Digital Health and Innovation as well as the Department of Sexual and Reproductive Health and Research at the WHO are engaged in technical support and operational research to gather evidence for evaluating the impact of the SMART guidelines approach¹⁰⁵, particularly in enhancing adherence to the guidelines, improving data quality measurements and provide easy replicable blueprints.

The review also highlighted that the area of digital literacy and capacity strengthening for healthcare workers and ICT professionals, particularly in LMICs, is still in its infancy. This situation necessitates dedicated research efforts and the creation of educational resources tailored to the needs of digital health professionals. Also, whilst an array of tools exists to conduct DLAs, continuous efforts are needed to align and refine tools and methodologies. In this endeavor, sharing implementation experience and use cases from different countries among governments, donors, and implementers is crucial for enriching this domain.

Moreover, the issue of lacking robust health data governance has been growing more evident and is yet to be adequately addressed in most contexts and countries. DHIs, programs and systems generate a substantial volume of data, much of which is sensitive. Today, the challenge lies not in a lack of data, but in the capacity of governments, corporations, and individuals to comprehend and harness the wealth of available information for collective benefit (or commercial interest), whilst safeguarding individuals’ privacy and rights and upholding rigorous scientific and ethical standards. Hence, the imperative for establishing data governance to guarantee the secure and ethical utilization of health data, as well as to strike a balance between the commercial interests in data and the pursuit of the public good, has grown increasingly apparent, particularly following the 2018 Cambridge Analytica scandal¹⁵⁶.

“A lot of innovations in the health sector are being deployed without considering a rights-based approach. This creates huge risks when thinking about what happens to the data: How is it being collected, who is going to end up using it, particularly in contexts where there isn’t a legal framework?”

Alexandrine Pirlot de Corbion ¹⁵⁷

Further, compared to acquiring data manually and handling and transmitting paper-based data, digital data are more susceptible to being stolen, lost or hacked in large quantities, given that they can be accessed more easily on a large scale and without physical boundaries ¹⁵⁸. Cyberattacks involving personal health data could involve millions of patients’ records ¹⁵⁹ and have devastating consequences to vulnerable people, those close to them, and many other stakeholders ¹⁶⁰. Personal health data is now among the most valuable form of data on the dark web ¹⁶¹, and cybersecurity breaches in the healthcare sector continue to grow ¹⁶². In January 2021 alone, a total of 878.17 million data records were compromised worldwide, which is more than in all of 2017 ¹⁶³. This issue is believed to pose a significant challenge in this millennium ¹⁶⁴.

There are significant advantages to ensuring secure and transparent data utilization, for example more consistent and transparent data sharing, enhanced global disease surveillance, and better preparedness to respond to pandemics. A universally accepted approach to data generation, storage, and utilization should promote interoperability across jurisdictions and platforms, thereby also removing entry barriers for smaller developers, which in turn fosters diversity and innovation.

While the European Union’s General Data Protection Regulation ¹⁶⁵ is frequently regarded as a ‘gold standard,’ there is currently no universal global standard for the generation and utilization of digital health data. Each country maintains its unique governance framework, and regulations are patchy in many contexts, particularly LMICs, which poses challenges to effective data protection. The United Nations has voiced concerns regarding the potential of digital technologies to perpetuate sexism, racism, and other forms of discrimination ¹⁶⁶, which could be counteracted by strong governance structures. Transform Health, a global civil society coalition, has recently proposed “Principles for the Health Data Governance” ^{101,167}, which seeks to address the issue by providing stakeholders with the guidance needed to develop the legislative and regulatory frameworks at national and sectoral levels.

Further, AI is already playing a transformative role for the future of DH ¹⁶⁸, which is why “WHO’s

guidance on ethics and governance for artificial intelligence in health” ¹³⁵, as well as its compendium guidance for large multi-modal models¹³ are timely and much needed additions to the landscape of normative resources.

It is unquestionable, that digital health solutions hold unprecedented promise for health services delivery and public health planning, nationally and globally. However, in the context of health system strengthening, we must recognize that digital solutions are not a panacea, especially if the traditional paper-based systems are failing. Therefore, a thorough examination of the gaps in the existing paper-based processes is essential before transitioning to digital methods. Merely digitizing these processes without a comprehensive analysis of their inherent issues can lead to digital replicas of inefficiencies, rather than transformative improvements in healthcare delivery and public health. Thus, before embarking on digital transitions, a critical evaluation of the existing paper-based systems is indispensable. This involves identifying and understanding the specific challenges these systems face, such as data inaccuracy, accessibility issues, delays in information flow, and the potential for loss or damage. Such an evaluation not only highlights the areas in need of improvement but also provides insights into how digital solutions can be designed to address these specific gaps effectively.

Moreover, transitioning to digital methods requires careful consideration of the context in which these technologies will be implemented, including infrastructure readiness, digital literacy of health workers, and the accessibility of digital tools for all users. Implementing digital health solutions without addressing the underlying issues in the traditional system can exacerbate disparities, leading to solutions that are not sustainable or equitable.

Therefore, the shift from paper-based to digital health systems should be approached with a strategy that includes stakeholder engagement, needs assessment, and capacity strengthening. This holistic approach ensures that digital health solutions are not just technologically advanced, but also responsive to the specific needs of the healthcare system, ultimately leading to more effective, efficient, and inclusive health services.

Additionally, in this shift from paper-based to digital formats, it is anticipated that the SMART guidelines¹⁰⁵ may signify a major transformation in the digitalization of complex public health programs. Ideally, these operationally and technically critical guidelines will not only operationalize the translation of paper-based clinical guidelines into usable

digital formats, but will further encourage interoperability of solutions and systems. An example of interoperability would be that data collected during pregnancy and the child's birth should be available in the electronic immunization registry, and viewable at the time of the visit through an electronic version of Integrated Management of Childhood Illness. Furthermore, should the child be hospitalized, the attending hospital physicians should also be able to assess through an EMR, which vaccinations the child is missing. For all this to happen, the digital versions of four different programs (ANC, EPI, IMCI and EHR) should be able to communicate with each other.

We observed during this research that although guidelines, frameworks, and tools address many aspects of DH solution implementation, a rigorous public health approach is essential for leveraging DH to bridge the gap between private and public health services. Furthermore, it is crucial to ensure that the implementation of DH solutions does not create additional barriers for patients who lack access to ICT.

Despite a significant decline after the COVID-19 pandemic, the interest of donors and the attention of individual governments in Digital Public Health (DiPH) remains high. However, there is still a lack of a standardized and shared format to report the benefits and outcomes of the digital health revolution, likely due to the heterogeneity of interventions and the rapid evolution of technological solutions. Important platforms for collaboration among developers have been established, such as WHO's Digital Health Atlas⁹³, the Clearinghouse¹⁶⁹, OpenHIE 45, and the Health Data Collaborative¹⁷⁰. However, standardized DH-programing and DHI-specific indicators for thorough benchmarking processes are, to our knowledge, yet to be formally assembled and there is an apparent gap in understanding the processual, impactful, and economic aspects of DHIs. This absence of structured reporting hinders the harmonious development and governance of the digital health revolution, and is compounded by the strong influence of individual local contexts. Professionals in this field are thus encouraged to embrace or develop further M&E methods that fill this void and address the development need for practical and relevant indicators for digital health.

In the southern hemisphere, DH is becoming an increasingly large focus of countries' System Policy and Strategy Plans to reach the goals of SDGs and UHC²¹ even if gender equity is often not fully explored. Some countries are adopting a broader approach to articulate the digital transition, integrating it into a common framework that will improve not only the healthcare sector, but also e-commerce and administration. This highlights a strategic

commitment to a holistic digital transformation that can lead to significant benefits in various sectors.

Indeed, the current momentum surrounding DH in LMICs is promising, with several positive developments in place. Guidelines have matured significantly, providing valuable direction for implementation and strategic planning. Additionally, specific guidelines addressing planned costs have been released, contributing to better financial planning and management. Furthermore, impact evaluations of various DHI are increasingly conducted, with many successful projects reaching national scaling levels. This demonstrates the potential of digital health to positively transform healthcare delivery on a broader scale. Also, specific guidelines dedicated to Expanded Programs on Immunization reflect a focused effort to improve vaccination logistics, which is crucial for public health outcomes. Although the heightened donor attention during the COVID-19 pandemic might have subsided, there is still significant interest and support for digital health initiatives in LMICs.

Given the relatively recent introduction of the SMART guidelines and DAKs and the rapid deployment of digital health interventions during and after the COVID-19 pandemic, it is indeed too early to draw definitive conclusions about their impact and sustainability. Assessing the impact of the new guidelines and the sustainability these digital health interventions requires rigorous evaluation processes. Meanwhile, continuous monitoring and assessment of digital health initiatives are crucial to ensure that resources are directed effectively, to ensure that guidelines, frameworks and tools evolve based on evidence and that health system transformation aligns with the specific needs and contexts of the populations they aim to serve. Only through robust evaluation can we make informed decisions, refine strategies, and further enhance the role of digital health in driving positive healthcare outcomes in LMICs.

5. CONCLUSION

Over the last decade, we have witnessed an extraordinary transformation in the healthcare landscape, driven by the unprecedented advancement of digital technologies. Particularly in LMICs, digital health has emerged as a beacon of hope, promising to bridge the gap between limited resources (scarce funding, insufficient infrastructure, and shortages of skilled healthcare professionals) and burgeoning healthcare demands specially among the most remote and underserved communities. However, fully realizing the potential of digital health in LMICs is not without its challenges. Issues related to data privacy, security, interoperability, and digital literacy demand urgent attention to ensure a sustainable and equitable digital health ecosystem. Addressing these challenges is key to unlocking the full transformative potential of digital health and ensuring that no one is left behind in the pursuit of improved healthcare outcomes.

Guidelines, frameworks and tools for DH-programing play a critical role in facilitating the smooth implementation of ICT solutions as they provide standardized procedures and best practices to navigate and overcome common challenges. Normative resources in digital health have been developed gradually as more evidence became available on the benefits offered by ICT. Today, we have a large number of guidelines aimed at different users, from ministerial policymakers to developers and donors. These guidelines cover a wide range of topics, from how to plan a DH program at a legislative level, to budget planning, developing tailored interventions based on the country's needs, and monitoring progress. There is no one definitive guideline, as each of them is useful for different stages of development of DHIs, and at different levels of a country's technological maturity. However, the recently published SMART guidelines have been seen as a possible turning

point to speed up the digitalization of public health programs. In the wake of the COVID-19 pandemic, specific guidelines have been published regarding the digitalization of vaccination logistics too. These specific guidelines are particularly important as they address the complexity of Expanded Programs on Immunization.

The development of guidelines, frameworks and tools to support the digitalization of health systems has also evolved considerably since 2011 and there is now a well-established landscape of resources to guide digital health system development in LMICs. Whilst this landscape is by no means gap free, this review shows that the cornerstones have been set to guide country governments and digital health development partners.

However, also identified through this research are some areas that still require considerably work to ensure that countries and DH developers have the necessary resources to hand to plan, implement or expand their national DH strategies and aligned initiatives.

Areas requiring further attention are, in no particular order:

1. **Need for Harmonization of Digital Landscape Assessments (DLAs):** Despite the availability of tools for DLAs, there's a need to continue working towards their harmonization. Sharing field experiences of conducting DLAs and publishing use cases across countries and different DH stakeholders can significantly contribute to this effort. Governments, donors, and implementers should continue to collaborate, as exemplified by the work of

the HDC Digital Maturity Model Small Working Group⁹⁹ to refine tools, thereby ensuring their adaptability to diverse health system contexts and assessment needs.

2. **Need for Monitoring and Evaluation (M&E) and DH Implementation Evidence:** A significant evidence gap exists with regards to the process, impact, and economic value of DHIs. M&E professionals in the digital health sphere need to further develop and adopt methodologies that can effectively capture these dimensions. This includes creating and utilizing robust indicators that can accurately measure the performance and impact of DH initiatives. The development of such indicators is crucial for demonstrating the value of DH initiatives and benchmarking, and this can consequently guide future investments, and inform policy decisions.
3. **Need to address the Resource and Evidence Gap for gender, -equity, and inclusion-sensitive DH programing:** While GEI considerations are increasingly being integrated into DH programing, there is a pressing need for more comprehensive evidence on the impact of these interventions. There is also a need for unification of existing resources on guiding GEI programing into a comprehensive guideline that can be easily applied by DH professionals. Such a resource should not only provide theoretical insights, but also practical, actionable strategies for ensuring that DHI are inclusive and equitable.
4. **Need to address the Resource and Evidence Gap for Digital Literacy and Capacity Strengthening activities targeting ICT staff and HCWs:** The evidence-base for digital literacy and capacity strengthening, particularly for health workers and ICT professionals in LMICs, is still limited. This gap reflects the scarcity of guidance available for digital health professionals. Rigorous research in this area is urgently needed to inform the development of targeted training and capacity-strengthening programs, given that training programs can empower health workers and ICT staff to effectively utilize and manage DH tools and systems.
5. **Need for Economic Evaluation Data for Sustainable Financing of DH:** Financing DH initiatives remains a challenge, particularly in LMICs. The review points to the need for sustainable funding models that go beyond initial grants and pilot projects. This includes

exploring innovative financing mechanisms and ensuring long-term investment in DH infrastructure and programs, but more importantly rigorous economic data to inform investment decisions and help the formulation guidelines for sustainable DH financing.

6. **Need for up-to-date Technical Standards and Regulatory Frameworks:** The review also underscores the importance of technical standards and regulatory frameworks, particularly for complex digital health solutions. These standards and frameworks must be regularly updated to keep pace with technological advancements and ensure the safety and efficacy of digital health products.
7. **Need for Global Collaboration and Knowledge Sharing:** There is a need for increased global collaboration and knowledge sharing in the DH sector and beyond. This involves not only the sharing of resources and best practices but also joint efforts in research, development, and policy formulation. Incidentally, adopting existing resources for DH programing contributes to knowledge sharing and global collaboration as this is part of their core design.

At a more general level, the following recommendations have been formulated:

1. **Harmonize Approaches:** Encourage the development of harmonized guidelines and frameworks to foster a more unified approach to digitizing health systems globally. This is not to suggest a monolithic, one-size-fits-all approach, but rather an approach of country-tailored adoption of best practice evidence.
2. **Address Gaps:** Focus research and development on evidence-sparse areas and create comprehensive guidelines for aspects of digital health development currently lacking resources.
3. **Develop Targeted Guidelines for Training Programs:** Develop specific guidelines and frameworks for digital literacy and competency training, particularly in LMICs, to enhance healthcare staff's capacity in utilizing digital tools.
4. **Align Global Standards:** Work towards aligning technical standards across regions and ensure they are adaptable to rapid technological changes.

5. **Adopt Inclusive Development:** Prioritize the inclusion of diverse user groups and stakeholders in developing and implementing digital health interventions.
6. **Generate strategic evidence:** Continuously monitor and evaluate the processes, effectiveness and impact of digital health interventions and share evidence widely. Guidelines and frameworks should be adapted accordingly.

One undeniable reality of digital technologies is their continuous evolution, and this is as true for the health sector as for any other. This reality necessitates parallel efforts to keep normative resources to guide DH programing relevant and up-to-date, an undertaking which will need to be pursued at the same time as the advancements made in this field. Moreover, concerted efforts are required to engage governments and digital health stakeholders to contributing to, utilize, and apply existing resources while continuously generating high-quality, real-world evidence to address gaps in the landscape. The World Health Organization, as a global health leader, is called upon to continue to expand its coordination of these efforts and harness the catalytic power of digital health to accelerate progress towards the 2030 Sustainable Development Goals.

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ANNEXES

Annex 1. Cross-cutting Principles and Guidelines

1. Principles for Digital Development

Source: [Principles for Digital Development \(digitalprinciples.org\)](https://digitalprinciples.org)

The Principles for Digital Development guide sustainable and inclusive growth in the digital age. Endorsed by over 300 organizations, these principles have significantly influenced funding and program design since their inception in 2014. Updated in 2024 through broad consultation, they now emphasize radical inclusion, local ownership, and address the broader impact of digital ecosystems on all people, including those not yet using technology. The refreshed principles highlight the importance of handling digital data responsibly and ensuring that digital initiatives empower individuals and communities. They are designed to be mutually reinforcing, ensuring that no one is left behind in the digital transformation. Endorsers commit to minimizing harm and maximizing people's agency in their development, tailoring the principles to their specific contexts and initiatives.

2. WHO-ITU National eHealth Strategy Toolkit

Source: <https://www.who.int/publications/i/item/national-ehealth-strategy-toolkit>

The National eHealth Strategy Toolkit, developed by the WHO and ITU, is designed for governments, particularly health and IT ministries, to develop or enhance national eHealth strategies. It emphasizes eHealth's growing impact on healthcare delivery, making systems more efficient and responsive. The toolkit offers a comprehensive framework for creating a national eHealth vision, action plan, and monitoring framework, adaptable to various levels of eHealth advancement. It consists of three parts:

1. **Vision:** Establishes the strategic context, defining the role of eHealth in achieving health-sector goals and identifying necessary components.
2. **Action Plan:** Structures activities based on country priorities, laying a foundation for long-term development.
3. **Monitoring:** Provides a plan to monitor progress, manage risks, and secure long-term support.

Key activities include stakeholder engagement, establishing governance mechanisms, understanding the current eHealth environment, and identifying short-, medium-, and long-term goals. The toolkit's success relies on strategic planning, ongoing stakeholder communication, and adaptability to changes in strategic contexts, ensuring sustained momentum and support for eHealth initiatives.

3. WHO's Recommendations on digital interventions for health system strengthening

Source: [9789241550505-eng.pdf \(who.int\)](#)

This guideline aims to provide normative guidance for the adoption of evidence-based digital health interventions that strengthen health systems. Targeted primarily at decision-makers in ministries of health and public health practitioners, the guidelines also serve organizations investing in digital health systems. The document offers a framework for evaluating emerging digital health interventions by assessing their benefits, harms, feasibility, resource use, and equity considerations. It emphasizes that digital health interventions should complement rather than replace essential health system components such as workforce, financing, and governance. The guidelines review specific digital interventions, including mobile-based birth and death notifications, telemedicine, targeted client communication, health worker decision support, and digital tracking of health status. By providing comprehensive recommendations, the guidelines aim to support informed decision-making and encourage the integration of effective digital health solutions within health systems.

The guidelines offer a structured framework for implementing digital health interventions, primarily through mobile devices. Key Digital Health Interventions are:

- Birth and death notifications via mobile devices.
- Stock notification and commodity management.
- Telemedicine for client-to-provider and provider-to-provider interactions.
- Targeted client communication for health promotion and reminders.
- Health worker decision support and training via mobile devices.
- Digital tracking of patients' health status and services.

The guide emphasizes that digital health interventions should complement rather than replace traditional health system components. Moreover, the importance of assessing the local ecosystem's readiness and capacity to support digital interventions is highlighted, alongside an ongoing engagement with stakeholders to ensure the successful implementation and sustainability of digital health initiatives.

The guideline promotes a cohesive approach where digital interventions operate synergistically rather than as isolated implementations and encourages the use of established best practices and principles, such as those outlined in the WHO/ITU National eHealth Strategy Toolkit and other related resources. The guidelines emphasize that digital health interventions are part of a broader strategy to achieve Universal Health Coverage (UHC) and should be implemented thoughtfully to enhance health system performance without compromising fundamental health services.

Annex 2. Digital Landscape Assessments

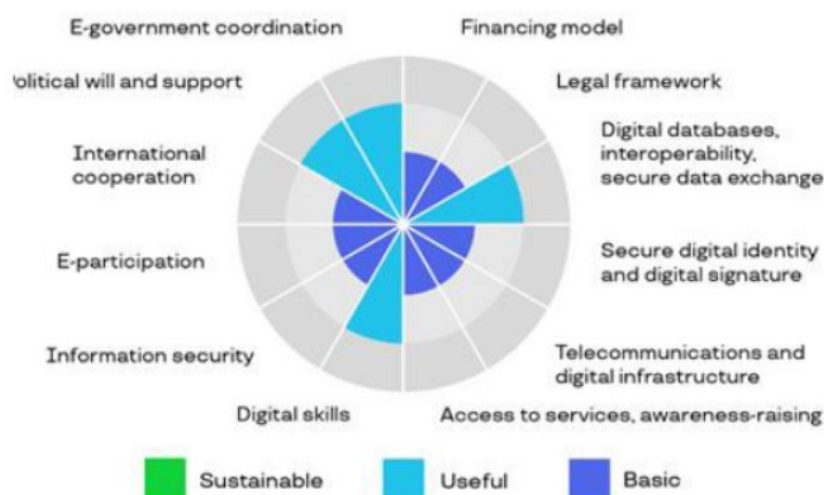
1. UNDP Digital Landscape Assessment Framework

Source: <https://www.undp.org/arab-states/publications/digital-landscape-assessment>

Developed by UNDP and the e-Governance Academy of Estonia, this framework facilitates the analysis of the digital landscape in the context of the SDGs and as such, is not a health domain-specific assessment. The framework instead covers the broad spectrum of national digital landscapes with the aim to pinpoint digital solutions to expedite progress towards the SDGs. The assessment is illustrated on the example of Palestine, and the framework consists of three components: a) Rapid Integrated Assessment, b) Digital Maturity Assessment, and c) Bottleneck Assessment. This tool is particularly valuable in settings in which there is no comprehensive overview of the digital landscape in general.

It serves as a comprehensive tool for evaluating the current state of digital development, with a focus on identifying strengths, weaknesses, opportunities, and threats (SWOT) in the digital sector. The guide is intended for a wide range of stakeholders including government policymakers, digital technology experts, development practitioners, and anyone involved in the digital transformation in Palestine. Its primary aim is to provide a thorough understanding of the digital environment, facilitating informed decision-making for future digital initiatives and investments.

The assessment process outlined in the guide involves various steps, starting with a preliminary assessment to understand the existing digital scenario. This is followed by a detailed analysis across several key areas such as infrastructure, governance, digital services, and human capacity. The guide emphasizes the importance of considering socio-economic factors and the role of different stakeholders in the digital ecosystem and the digital maturity of the public sector is assessed across 12 distinct e-government focus areas, as illustrated in Figure 17. for the State of Palestine.



By offering a structured framework for digital landscape assessment, this document plays a crucial role in guiding the strategic direction for digital development in Palestine. It aims to assist in crafting policies and strategies that promote digital inclusivity, innovation, and sustainable development, ultimately contributing to the broader goals of economic growth and societal advancement.

In essence, this guide is a strategic instrument for navigating and enhancing the digital landscape in Palestine, ensuring that digital transformation efforts are aligned with national priorities and international best practices.

Figure 17. e-Government maturity of the public sector of the State of Palestine (Source: UNDP Digital Landscape Assessment Framework)

2. Digital Ecosystem Country Assessment (DECA) Toolkit: A How-To Guide for USAID Missions

Source: <https://www.usaid.gov/digital-development/deca-toolkit>

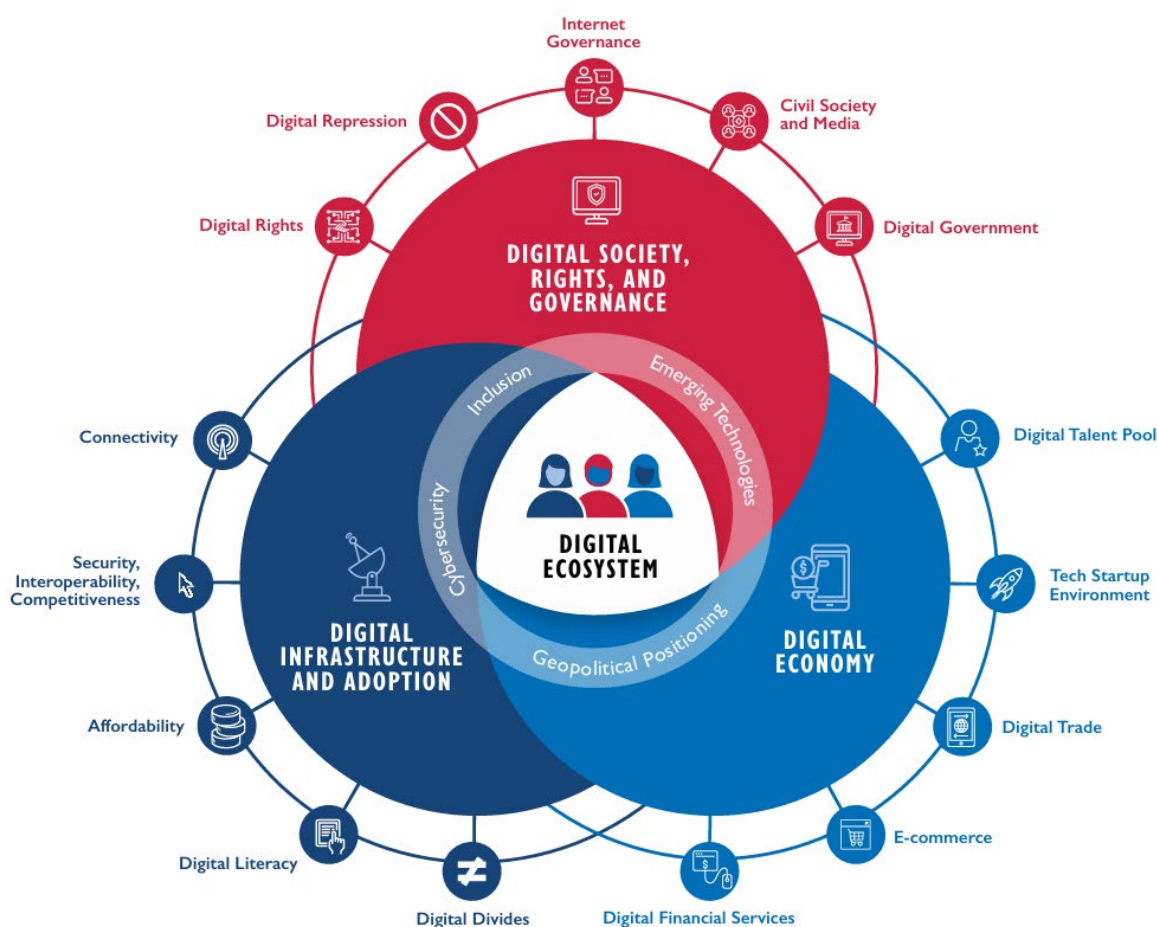
The DECA Toolkit is a step-by-step guide designed to assist USAID mission staff in independently conducting high-quality assessment. DECA findings and recommendations directly influences mission decision-making regarding digital development.

The Toolkit is structured into three main sections:

1. **Introduction:** This section provides an overview of the DECA’s purpose and process.
2. **Mission’s Guide to Managing a DECA:** It describes the recommended roles and responsibilities for the mission staff and offers guidance on how to plan, procure, and oversee a DECA.
3. **Research Guide:** This section provides detailed instructions on how to execute a DECA, including guidelines, best practices, and templates for each phase, which are as follows: a. Desk research and planning b. Interviews c. Analysis and report writing

The recommended assessment goes across three main areas: “Digital society, rights and governance”, “Digital infrastructure and adoption” and “Digital economy” (Figure 18) along three phases:

- Phase 1 (5 weeks) Desk research and planning lay the foundation for the DECA.
- Phase 2 (2–7 weeks) Interviews build on the desk research through conversations with stakeholders across the digital ecosystem.
- Phase 3 (10-15 weeks) Analysis and report writing



DECA Toolkit recommend to hire a specific Research Team to conduct the assessment. Additionally, the Toolkit includes user-friendly templates and a research checklist.

Figure 18. Elements of a digital ecosystem (Source: USAID, 2022)

3. National eHealth Strategy Toolkit ⁴²

Source: <https://www.who.int/publications/i/item/national-ehealth-strategy-toolkit>

The WHO/ITU eHealth strategy toolkit offers a digital landscape assessment framework (Chapter 10. “Gather information on the eHealth environment” & Chapter 11. “Assess opportunities, gaps, risks and barriers”) in alignment with the seven building blocks of a digital health enabling environment, which are considered the key components or building blocks for developing a national digital health strategy, (1. leadership and governance, 2. strategy and investment, 3. legislation, policy and compliance, 4. infrastructure, services and applications, 5. workforce, 6. standards and interoperability and 7. strategic investment).

Alongside general recommendations for a research approach to assess a DH eco-system (desk-based research, internal assessment and stakeholder consultations), the tool provides examples for potential organizations and stakeholders to be consulted during the research. Additionally, both chapters 10. And 11. contain a comprehensive set of example research questions that can be addressed. First (Chapter 10.), questions are proposed for each of the seven key eHealth strategy components, and second (Chapter 11.) for identifying three main elements of a digital landscape: 1. Re-use and sharing opportunities, 2. gaps, and 3. risks and barriers.

Overall the toolkit offers stakeholders, in particular those involved in the development of national digital health strategies, a generic, yet highly adaptable framework to obtain an overview of the existing national DH landscape, with which countries can develop their own tailored research protocol to gather data according to the context-specific assessment focus, depth and need. For example, the Federal Ministry of Health of Nigeria in collaboration with the United Nations Foundation ¹⁷¹ developed a two-stage research protocol, which encompassed a comprehensive Policy and Landscape & Inventory Review (Phase 1 – desk review) followed by a field assessment (Phase 2 – primary data collection) to appraise the current state and experience of relevant ICT for health implementation and capacity and multiple levels of the health system (Figure 19).



Figure 19. Nigeria DH landscape assessment structured around the WHO/ITU eHealth Strategy toolkit’s key components. (Source: FMoH Nigeria, 2015)

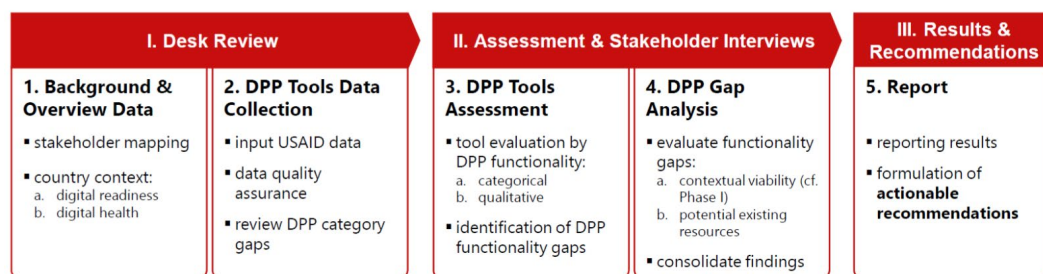
4. Digital Pandemic Preparedness Assessment Tool (DPPA)

Source: <https://digitalsquare.org/resourcesrepository/dppa-v2>

The Digital Pandemic Preparedness Assessment Tool (DPPA), which was produced by the GIZ, constitutes a structured approach for identifying the requirements for digital tools that can smoothly integrate into a nation’s current digital ecosystem. At the same time, it aims to enhance the country’s overall preparedness, response, and planning for vaccination during pandemics. The assessment’s intended output is in report format to inform decisions on budgetary allocations and future interventions.

The DPPA has been devised to fit into an existing infrastructure of tools and resources for digital eco-system assessments. The assessment process by design incorporates the Early Stage Digital Investment Tool (EDIT) and country-specific information from the USAID Map & Match initiative, whilst its data model aligns with data elements present in the Global Digital Health Monitor.

The DPPA proposes a linear assessment process in 5 stages divided in 3 phases (Figure 20) which allows for cross-referencing, semi-automated data transfer (Integration of data collected by USAID Map & Match) and color-coded gap identification. Overall, it is estimated to take a national consultant three weeks to complete the assessment exercise.



The data collection process involves five Work Packages (WPs)

- 1. Preliminary Work and Stakeholders’ Engagement (WP1):** Prior to initiating DPPA, the first step is to conduct a stakeholder mapping exercise, and to secure the support from the Ministry of Health and other key stakeholders.
- 2. Digital Health Ecosystem Analysis and EDIT Tool (WP2):** This step is to analyze the country’s digital health ecosystem using the EDIT tool, focusing on six key blocks. EDIT indicators are scored to gauge digital health readiness (see further detail below).
- 3. Map and Match Data and Existing Digital Tools (WP3):** Existing national data from USAID’s Map & Match initiative (see below for further detail), is to be integrated into the DPP tool to provide information about existing digital solutions at the country level. The Map & Match database serves as a baseline, but needs to be validated, and its contents probed for relevance and supplemented if needed. Stakeholder interviews are to provide indepth information on each identified tool and the DPP functionalities are evaluated categorically and qualitatively.
- 4. DPP Use Cases and Mapping (WP4):** Using the DPP tool, gaps are then identified and validated. For this purpose, DPP use cases are designed to align with USAID’s Map & Match framework, and break down into 64 sub-functionalities, which the tool aggregates into functionality gaps. In the pilot phase, the mapping process involves local validation with national stakeholders using a simple coding system. To note is also that the functionalities are aligned with the Digital Applications and Tools Across an Epidemiological Curve (DATEC) framework (see more detail section 3.2.4.11, Digitizing Immunization Programs).
- 5. Reporting Results & Recommendations (WP5):** Recommendations are divided into those influencing the digital health ecosystem and those for pandemic preparedness. For the former, suggestions aim to enhance digital health infrastructure and readiness. For the latter, recommendations guide leveraging existing software or deploying new packages based on identified gaps in functionality.

Figure 20. Landscape Assessment approach proposed by the DPPA (Source: GIZ, 2021)

5. Early Stage Digital Health Investment Tool (EDIT)

Source: <https://www.katicollective.com/tools>

Developed by the Kati-Collective, the Early Stage Digital Health Investment Tool (EDIT) is a global good and a toolkit in tabular format, designed for the early stages of DH eco-system assessments. It examines DH readiness and is intended to support the process of developing a more coordinated strategy for digitizing health between key stakeholders.

The EDIT tool has been widely adopted, e.g., its integration into the DPPA tool and the Navigator for Digital Health Capability Models. It is designed to foster dialogue between a country and its stakeholders around six building blocks that need to be firmly established prior to investing in and implementing a digital health solution. The building blocks are: 1. human capacity, 2. investment & funding, 3. data capture & use, 4. infrastructure, 5. standard & interoperability and 6. governance and police. For each building block, a set of indicators is provided within an excel spreadsheet, which the assessor rates according to a standardized point-system (1 to 5) to then gauge the country's DH readiness.

6. USAID Map & Match Initiative

Source: <https://digitalsquare.org/covid19-map-match>

Whilst the Map & Match initiative is not considered a guideline, toolkit or framework as such, it is unquestionably an invaluable baseline resource for countries looking to conduct comprehensive eco-system mapping exercises and has therefore been included in this review. More than a dataset, Map & Match has 22 country briefs and an array of other accompanying resources.

The West-Africa Ebola outbreak and the COVID-19 pandemic have shown that giving priority to repurposing and modifying existing digital tools is crucial for rapidly expanding access to time-sensitive disease information and data.

The Map & Match (M&M) initiative is an extensive 2-phase, multi-donor, collaborative project, led by Digital Square, aimed at documenting existing digital health investments in LMICs for this purpose. It sought to identify systems utilized for COVID-19 response and vaccine distribution, along with systems that could be modified to support these specific use cases.

The project's outputs are first, an openly accessible dataset of information gathered as part of a broad landscaping exercise in form of a desk review including over 130 countries (Phase 1) and in-depth M&M information on 22 Map & Match countries (included in Phase 2). Second, and in addition to the dataset, 22 country briefs have been developed which showcase the digital tools in use, identify those tools that have already been repurposed for COVID-19, and explore possibilities for adapting existing tools for COVID-19 scenarios, including vaccine planning, delivery, and monitoring. These 22 country profiles are based on information gathered through desk reviews, surveys, and, in several instances, interviews with key personnel from country Ministries of Health. Third, a set of use cases specific to outbreak response were developed in coordination between Digital Square, USAID and the GIZ. These are, on the one hand, in alignment with the GIZs DPPA tool and can be used to pre-populate the tool in preparation for stakeholder interviews. On the other hand, the M&M use cases are also integrated and further defined in the DATEC framework (see more detail section 3.2.4.11). It is also to note that in collaboration with WHO, all M&M data are to be shared to the DHA.

7. U.S. President’s Malaria Initiative Digital Community Health Initiative (PMI DCHI)

Source: <https://digitalsquare.org/community-health>

In 2020, the U.S. President’s Malaria Initiative (PMI) launched the Digital Community Health Initiative (DCHI) through USAID and the CDC, aiming to improve health care quality at the community level across 27 African countries by expanding digitally enabled health platforms. Partnering with Digital Square, PMI embarked on a mixed-methods assessment of malaria and digital health to tailor digital technology use in community health efforts.

The initiative unfolded in three stages:

1. **Ecosystem Assessment:** Understanding the landscape of digital technology and malaria data management at the community level. The assessment focused on community-level malaria data management, including ICT use. It encompassed a desk review, surveys on digital tools, and interviews with national and subnational stakeholders. Desk reviews were conducted in all countries, while surveys and interviews were tailored by country to address gaps and corroborate findings. Overall, the assessment reviewed over 600 documents from 27 countries and conducted more than 300 stakeholder interviews in 22 countries.
2. **Stakeholder Engagement:** Conducting workshops to validate findings, outline digital health needs, and set priorities based on Phase 1 insights.
3. **Country-Specific Implementation:** Focusing on actionable strategies tailored to individual country needs.

This approach not only addressed malaria but also offered insights into the broader digital health ecosystem to enhance integrated service delivery. The resulting Cross-Country Landscape Report synthesized findings and outlined recommendations for PMI, partners, and stakeholders to leverage digital tools in community health programs effectively.

8. The Digital Health Assessment Toolkit Guide (World Bank)

Source: [World Bank Document⁹⁰](#)

The World Bank’s Digital Health Assessment Toolkit is designed as part of its commitment to the Principles of Donor Alignment for Digital Health, which requires an assessment before financing digital health investments. The toolkit aims to reduce fragmentation and harmonize various digital health assessment tools.

It seeks to provide a comprehensive assessment of a country’s digital health landscape, maturity, and readiness for digital health interventions. It is intended for countries and organizations planning to invest in digital health, helping them understand their current state and plan future strategies. This toolkit uses a hybrid approach, integrating insights from different tools and methodologies, and it involves various stakeholders in a participatory process to ensure a comprehensive understanding of digital health readiness and maturity.

The toolkit proposes the following methodology:

1. **Digital Health Landscape Profile:** It includes quantitative indicators on socio-demographics, ICT coverage, digital health interventions, and workforce exposure to digital health.
2. **Digital Health Maturity Scoring Tool:** This tool assesses digital health maturity across four areas: Ecosystem and Governance, Architecture & Data, Applications, and Analytics, using 74 indicators.

3. **In-Depth Interviews and Workshops:** These collect primary and secondary information for a deeper understanding of DH topics.

The assessment process involves determining the need for assessment, defining its scope, establishing an oversight team, conducting desk reviews, assembling an assessment team, data collection, data analysis, and action planning based on the assessment results.

9. HIS Interoperability Maturity Model (IMM) Toolkit

Source: [Health Information Systems Interoperability Maturity Toolkit: Users' Guide – MEASURE Evaluation](#)

The USAID Health Information Systems (HIS) Interoperability Toolkit is a comprehensive guide designed to help Ministries of Health (MoHs), their implementing partners, and other stakeholders assess and enhance the interoperability of their digital HIS. Developed in 2017, it addresses the fragmentation of digital information systems in low- and middle-income countries. The toolkit is composed of three main components: an interoperability maturity model, an assessment tool, and a user guide, which includes scoring and maturity model worksheets.

The toolkit aims to help identify existing capacities, processes, and structures critical for HIS interoperability. It seeks to measure and improve the maturity of HIS interoperability, leading to more resilient and effective health systems.

The toolkit uses a self-administered assessment process, beginning with determining the need for an assessment and defining its scope. It involves forming two teams: an oversight team to lead the process and an assessment team to participate in the evaluation. The assessment involves data collection, analysis, and consensus-building on the maturity levels of various HIS components. This process includes evaluating subdomains, mapping them to a maturity model, and determining the overall HIS interoperability maturity level. Based on the assessment, an action plan is developed to address identified gaps and prioritize improvements. This includes defining actions, timeframes, necessary resources, and responsible entities.

10. Health Information System Stages of Continuous Improvement (SOCI) Toolkit

Source: [HIS Stages of Continuous Improvement Toolkit – MEASURE Evaluation](#)

The USAID HIS Stages of Continuous Improvement (SOCI) Toolkit is designed to assist countries and organizations in assessing and strengthening their Health Information Systems (HIS). It's particularly geared towards low- and middle-income countries but can also be adapted for high-income countries. The toolkit aims to provide a systematic way to measure the status of an HIS, set goals for progression, and inform the development of plans for continuous improvement.

A key feature of the toolkit is its assessment approach across stages. It uses a maturity model to assess HIS across five stages, identifying gaps and supporting the development of improvement roadmaps. It establishes a systematic basis for measuring HIS components, facilitating goal-setting and improvement planning. The toolkit is designed for national-level HIS planning and improvement, the toolkit is useful for ministries, HIS units, governing bodies, NGOs, and others involved in HIS assessment and strengthening at the national or subnational levels.

The guide provides step-by-step instructions for implementing the assessment, including stakeholder engagement, data collection, analysis, and roadmap development. It's meant for HIS and monitoring and evaluation managers, officers, or leaders responsible for the assessment and implementation of the tool.

11. WHO/PAHOs The Information Systems for Health (IS4H) Toolkit

Source: [IS4H Toolkit | Pan American Health Organization \(paho.org\)](https://paho.org)

The Information Systems for Health Maturity Model (IS4H-MM) is a reference framework designed by the Pan American Health Organization to guide the evolution of Information Systems for Health (IS4H). It helps countries and organizations develop their capabilities to operate, interact with, and benefit from information and knowledge advancements. The framework outlines five levels of maturity, demonstrating the progression of capabilities in health information systems

The IS4H-MM encompasses various components under Data Management and Information Technologies (DMIT):

1. **Data Sources:** Focuses on data collection mechanisms and technologies for both structured and unstructured data.
2. **Information Products:** Involves processing and openly publishing health data in various formats to meet the needs of IS4H constituencies.
3. **Standards for Quality and Interoperability:** Emphasizes the use of data standards, interoperability identifiers, and a national health information architecture.
4. **Data Governance:** Establishes a framework for sub-regional and national strategies, objectives, policies, standards, and tools for technical data management, supported by a legal framework.
5. **IT Infrastructure:** Addresses the availability and maintenance of tools, networks, hardware, and software to support IS4H, ensuring interoperability among platforms and integration of data repositories.

The framework's maturity levels describe the progression in the development and utilization of these components. For example, at Level 1, data collection may be minimal or reliant on external estimates, with limited enforcement of formal data standards by national health authorities.

This toolkit is intended for countries and organizations looking to improve their health information systems, providing a structured approach to assess and enhance their capabilities in managing health data and technologies. It serves as a guide for strategic planning and development in the field of digital health, catering to the evolving needs and challenges of managing health information in a digital age.

12. Digital Square's Navigator for Digital Health Capability Models

Source: [Navigator for Digital Health Capability Models \(digitalsquare.io\)](https://digitalsquare.io)

The "Navigator for Digital Health Capability Models" is a guide aimed at supporting the assessment and improvement of national-level digital health systems using maturity model-based tools. It is designed for health systems planners, implementors, evaluators, and funders.

It provides an overview of the value of using maturity models and introduces six specific models. This helps users understand how to select the best tool for their specific context and goals.

The Navigator is intended for digital health professionals with some level of experience in the field, including those working in ministries of health, and funders of digital health interventions.

The Navigator assists in informing strategic planning, identifying investment priorities, and benchmarking, monitoring, and evaluating digital health strategies. It is particularly useful for organizations ready to invest in strengthening digital health systems and can be used to inform the design and planning of new assessments based on past findings.

The six-maturity model-based tools included in the Navigator are:

1. **Early Stage Digital Health Investment Tool (EDIT):** Targets governments to help understand where to invest for successful digital health implementation.
2. **Global Digital Health Index (GDHI):** Assesses and tracks the use of digital technology for health across countries.
3. **Health Information System Interoperability Maturity Model (IMM) Toolkit:** Focuses on components essential for HIS interoperability.
4. **Information Systems for Health (IS4H) Toolkit:** Addresses key components of national health information systems.
5. **Survey Count Optimize Review Enable (SCORE) Essential Interventions:** Measures the status of a country's HIS and suitability for planning.
6. **Health Information System Stages of Continuous Improvement (SOCI) Toolkit:** Assists in assessing, planning, and prioritizing interventions to strengthen HIS

These tools are designed to assess different aspects of digital health maturity, from readiness for digital health investments to the interoperability of health information systems, thus providing a comprehensive view of digital health capabilities at the national level from multiple angles. The “Navigator for Digital Health Capability Models” aids in selecting the correct maturity models and tools by offering a systematic process:

The Navigator assists digital health planners, implementors, evaluators, and funders in identifying the maturity model-based tool(s) that align most closely with their objectives for conducting an assessment. This alignment ensures that the chosen tool is the best fit for the specific requirements of the assessment. It also helps users understand how to leverage findings from any previous maturity model assessments. It includes a Microsoft Excel-based Decision Support Workbook that guides users in choosing the most suitable tool or combination of tools for their assessment needs. This workbook is designed to match the goals of the assessment with the appropriate tools. The Navigator comes with a User's Guide that provides detailed information about each of the six maturity models included. This guide offers insights into the specific contexts and goals each tool is best suited for, enabling users to make informed decisions.

In essence, the Navigator streamlines the process of selecting maturity models and tools by providing a structured and user-friendly approach, aligning tools with specific assessment goals, and utilizing past assessments for continuous improvement in digital health capabilities.

13. Classification of digital interventions, services and applications in health (DISAH), 2nd edition

Source: <https://www.who.int/publications/i/item/9789240081949>⁴

The recently published “Classification of digital interventions, services and applications in health (CDISAH), 2nd edition” is the revised version of the “WHO Classification for Digital Health Interventions v1.0 (CDHI)”. Considering the advances made since the publication of the first version, CDISAH can be understood as a

taxonomy, that sets out to provide a mutually understandable language which allows stakeholders to assess and articulate the uses of digital health.

It categorizes the various ways digital and mobile technologies are employed with the aim to support individuals and health system requirements. Tailored for stakeholders in the digital health sector, including government and public health agencies, technologists, healthcare providers, donors, implementers, researchers, and academics, the framework offers a taxonomy, and thereby facilitates understanding and communication among health program planners and stakeholders, emphasizing the unit of a “digital health intervention” (see section 3.1.3) as a distinct functionality of technology to achieve health sector objectives. The classification is organized around three axes: 1) Health System Challenges, 2) Digital health interventions and 3) Digital Services and Application types.

The classification organizes interventions into four main groups based on their users:

1. **Interventions for Persons;** in which persons are members of the public who are potential or current users of health services, as well as caregivers of those receiving health services.
2. **Interventions for healthcare providers,** where healthcare providers are considered members of the health workforce who deliver health services.
3. **Interventions for health systems or resource managers who are involved in the administration and oversight of public health systems.** Interventions within this category reflect managerial functions related to supply chain management, health financing, and human resource management.
4. **Interventions for data services.** This consists of intersectional functionality to support a wide range of activities related to data collection, management, use, and exchange.

This resource should be considered fundamental for digital health planners, implementers and developers as it provides a common language to articulate program needs and offers a framework to systematically identify them. The Classification is also an integral part of the WHO Digital Health Atlas, as any registered item can be defined according to the Classification’s taxonomy. However, an assessment of the user uptake of the Digital Health Atlas highlighted that linkage of registered tools to the DHI is lacking and that there is a need to increase awareness around and knowledge of the DHI Classifications in order to maximize the benefits it can offer for DH planners, donors and implementers (HISP-PA, 2022), an area which is now being addressed by WHO (HELINA, 2023 – Presentation).

14. WHO’s Digital Health Atlas (DHA)

Source: [DHA \(digitalhealthatlas.org\)](https://digitalhealthatlas.org)

FormaThe Digital Health Atlas is an open source web-based platform and a global good hosted by the WHO. It has been designed to enhance global coordination of digital health initiatives, supporting and benefiting governments, technologists, implementers, and donors. It equips users with essential information for enhancing planning, coordination, and utilization of digital health information systems. Moreover, the DHA assists implementers in evaluating the advancement of their digital health projects and provides access to valuable global resources encompassing current best practices in the field of digital health, using a standardized way to access, record and share information.

The DHA has the potential to streamline health system digitization at the global level. The DHA can serve as a national and international digital eco-system map and evolve into a global digital health inventory. It functions as a digital solution finder for investors, health planners and governments. It can provide information on the existing interventions’ maturity levels, the incorporated functionalities (using the WHO Classification of digital interventions, services and applications in health version 2.0⁴, and interoperability standards. It also provides an overview about the donor and stakeholder landscapes and it allows governments, donors and developers to assess progress and solutions adopted in other countries, for example by

researching existing products to design a national immunization registry, as a possible use case. However, despite all these potentialities, the project submission is on voluntary basis, information/projects requiring government endorsement are not available. Moreover, there's a lack of curation, meaning outdated solutions that are no longer in use remain listed. Additionally, solutions are displayed on a country basis, leading to redundant listings for solutions used across multiple countries. Few DHIs progress beyond the pilot stage. This results in minimal or no documentation of these digital health interventions in peer reviewed journals, repositories, and gray literature ¹⁷².

Digital Health Atlas is a powerful tool in the global effort to digitize health systems. Reaching its potential, however, is dependent on countries actively engaging with the Atlas by registering any tools or applications, whether already operational or still under development. The platform provides access for three main roles: implementors, government, and investors/donors. Implementors have access to basic functionalities, while government and investors/donors are granted additional incremental functionalities.

Users can easily search for projects on the platform using keywords and filters, view a list of projects, and export them individually. They can add their DH projects to the platform through various means, including importing data, creating new projects on the platform, or evaluating the readiness of existing projects for scaling-up through a standardized framework presented as a yes-no questionnaire. The platform offers specific functionalities for government users, such as project endorsement, managing national health reference documents, user access approvals, customizing registration forms with country-specific questions, and updating country boundaries. Similarly, the investor/donor page provides functionalities like managing user access approvals and customizing registration forms with specific questions aligned with their requirements. By providing these features, the platform enhances user experience, fosters collaboration, and ensures efficient management of digital health projects for implementors, government, and investor/donor users (WHO Data Quality Guidebook) ¹⁷³.

However, it appears that certain countries and geographical regions are more engaged with the platform than others and that the DHA has not yet been universally adopted. An analysis of DHA engagement in Africa showed that, as of September 2022, 45 out of 47 African countries had registered an overall 469 projects on the platform ¹⁷⁴. Findings show that among the four African countries, in which the GIZ DIPC initiative is implemented, Tanzania logged considerably more DHIs overall (262) in accordance with the WHO Digital Health Interventions (DHI) classification than Malawi (115), Ghana (48) or Sierra Leone (36). Interventions for health care providers were the user groups for which most interventions were logged across these 4 countries (Figure 21).

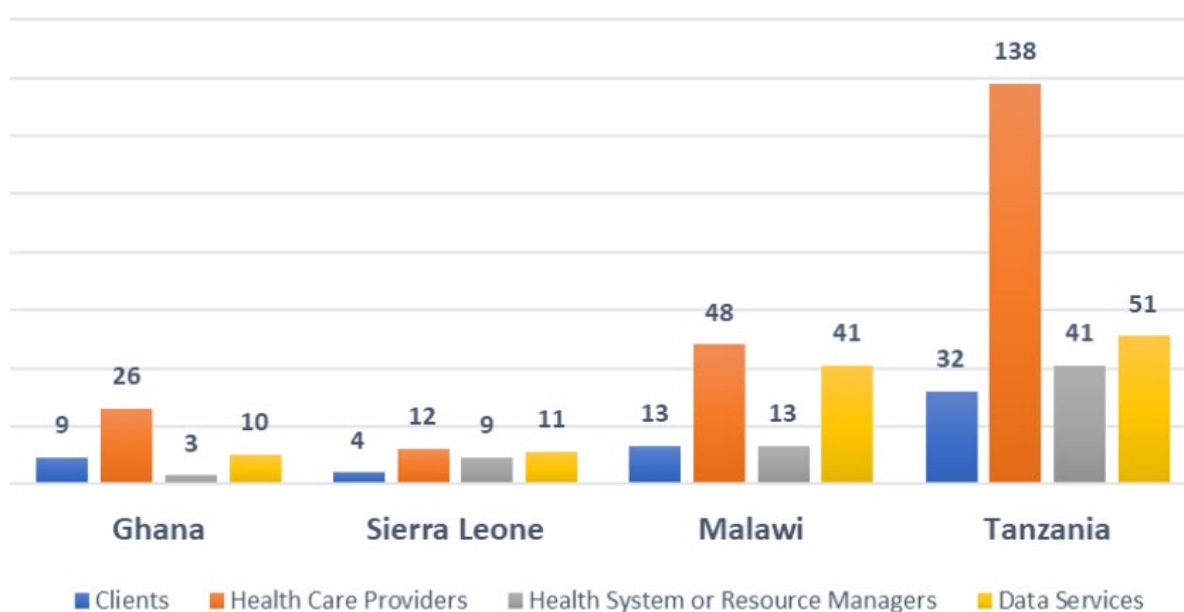


Figure 21. Number of Digital Health Interventions (WHO DHI Classification) registered on the Digital Health Atlas per DIPC project country (data used from WHO & HISP-AS report on Digital Health Atlas in Africa, 2022)

Countries from other regions of the world were not included in this analysis, however, a rapid examination of the DHA for the Latin-and South American region shows much lower levels of engagement and product registrations (DHA access data correct as off 27.07.2023).

For example, in Peru, Bolivia and Paraguay, there were no registered products on the DHA at the time this review was written. Even in the African region, it remains questionable, whether the number of products that have been logged represent an accurate reflection of the true digital eco-system.

The registration process is intended to be led by the national governments, which encourages country-leadership and ownership. The analysis of digital health products in Africa highlighted that even among the registered products, many do not link product information with DHI classifications or interoperability standards. For example, of 34 African countries that reported on COVID-19 projects, only 13 captured an interoperability standard linked to a project ¹⁷⁴.

The report highlights that whilst there is reasonable country-level uptake of the DHA in Africa (45/47 countries engaged), they are not extensively linked to DHIs. This means that digital technologies in countries are not registered in terms of the WHO Classification for DH interventions, described earlier. Only Eastern African countries show more connection with DHIs primarily focusing on DHIs for providers. Out of 45 countries, only 34 reported COVID-19 projects, and among them, only 30 linked their projects to a DHI. Additionally, only 13 countries linked their projects to Interoperability Standards.

To enhance the utilization of the DHA platform and promote compliance with interoperability standards, it was recommended ¹⁷⁴ to:

1. **Increasing Awareness** of the WHO Classification of DHIs guide and the integrated use of the DHA platform. This will encourage more countries to participate in the DHA platform.
2. **Providing strategic development and training** on the DHA platform will lead to better utilization and understanding of its features. This will facilitate effective use by countries and improve their compliance with interoperability standards.
3. **Implementing at the global scale:** Extending the WHO Classification of Digital Health Interventions guide and the use of the DHA platform on a global scale will add significant value. It will establish a shared language to describe the uses of digital technology for health, promoting standardized and comprehensive approaches worldwide.

Allocating time and resources into the registration process may not always seem like a priority especially in a dynamic and fast-moving environment such as health digitization. Nonetheless, the fact remains that the DHA grows in universal value and develops into a living and dynamic product only if populated with up-to-date country-based information about the digital tools that are implemented.

The DHA is a global public good, which once adopted universally may accelerate the health system digitization globally and thus enable us to move closer towards achieving health for all in a more cost-effective, coordinated and government-led manner.

15. Global Digital Health Monitor (GDHM)

Source: <https://monitor.digitalhealthmonitor.org>

The GDHM is an interactive digital resource, dedicated to evaluating the maturity of countries' digital health enabling environments. The vision behind the tool is to assist countries in tracking progress, identifying weaknesses and incentivizing improvements in national digital health systems, including more targeted investments, with benefits beyond national scope.

Based on the WHO/ITU eHealth Strategy Toolkit framework, the Global Digital Health Monitor (GDHM), formerly named the Global Digital Health Index, conforms to the WHO Digital Health Resolution and Global Strategy for Digital Health. As a complement to the WHO Digital Health Atlas, the GDHM tracks progress using 23 indicators, which are grouped according to the seven key components of the WHO/ITI eHealth Strategy. Since its revision in 2022, the GDHM also includes a focus on AI, equity, gender, and UHC and year-on-year performance monitoring country visualizations, regional visualizations, and country to country comparisons.

Data sources for GDHM included the GovTech Maturity Indicator (GTMI), the Network Readiness Index, and the GSMA Mobile Connectivity Index.

Annex 3. Regulations, Strategy & Policy Formation

1. Global Strategy on Digital Health 2020-2025²

Source : <https://www.who.int/publications/i/item/9789240020924>

WHO has defined a global strategy regarding DH, with clearly outlined objectives for between 2020 and 2025. Having acknowledged ICT's significant role in driving progress for health-related SDG, WHO recommends the adoption of DH for health systems in LMICs. Thus, since 2005 with the World Health Assembly's Resolution WHA58.28 on eHealth, WHO urges member states and stakeholders to synchronize their eHealth strategies with national health priorities and resources, formulate actionable plans, and set up frameworks for assessing eHealth initiatives and their advancement.

The strategic and innovative employment of digital and advanced ICT is key to achieving WHO's ambitious goals: expanding UHC to an additional one billion people, enhancing the protection of one billion more from health emergencies, and improving the health and well-being of another billion people (WHO's Thirteenth General Programme of Work, 2019–2023).

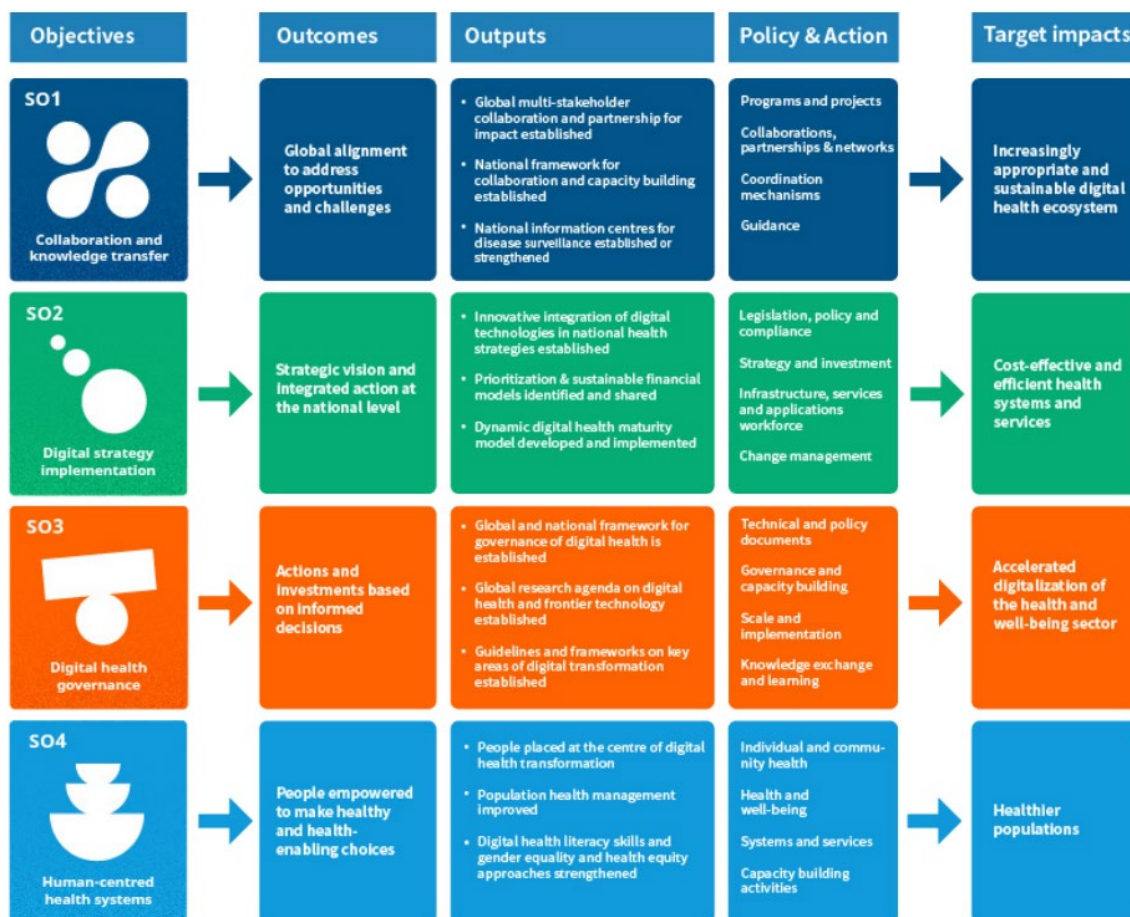
In pursuit of a global strategy for developing and adopting DH solutions that are appropriate, accessible, affordable, scalable, and sustainable, WHO released the **"Global Strategy on Digital Health 2020-2025"**. This strategy is founded on four core principles:

1. Recognition of the need for countries to decisively institutionalize digital health within national health systems.
2. Understanding that successful digital health initiatives demand a cohesive strategy.
3. Encouragement of digital technology use in health in a manner that is fitting and beneficial.
4. Acknowledgment of the critical need to overcome significant barriers faced by the least-developed countries in adopting digital health technologies.

These principles guide four strategic objectives:

1. Foster global collaboration and knowledge sharing in DH.
2. Promote the execution of national digital health strategies.
3. Enhance DH governance at all levels.
4. Support people-centered health systems through DH.

The strategy also presents a framework for action, structured around commitment, catalysis, measurement, and ongoing enhancement and iteration. Accompanying this framework is an action plan detailing the impacts, outputs, policy options, and actions required to achieve each strategic objective (Figure 22).



2. National eHealth Strategy Toolkit (WHO, 2012)

Source: <https://www.who.int/publications/i/item/national-ehealth-strategy-toolkit>

This overarching toolkit offers a comprehensive, step-by-step guide that aims to support governments to develop a national eHealth vision that responds to health and development goals, to produce eHealth action plan that reflects country priorities, to plan M&E and to manage associated risks. The toolkit tackles frequent challenges in DH development, such as the misalignment of ministerial agendas and timelines, which often result in crucial infrastructure components not being available when needed. It also addresses the issue of ‘siloed’ ICT investments that lead to system incompatibilities, requiring separate initiatives to resolve. By addressing these issues, the toolkit aims to prevent stalled efforts and maximize the potential return on investment for the health system. This toolkit is in three parts:

1. Establishing a National eHealth Vision
2. Developing a National eHealth Action Plan
3. Monitoring and Evaluation

This toolkit helps to avoid strategies that are narrowly focused, with an overemphasis placed on achieving technical outcomes. It emphasizes a broader vision of health system development and a firm commitment from partners¹⁷⁵.

Figure 22. Implementation stages of the action plans of the Global Strategy on Digital Health 2020 - 2025. (Source: WHO, 2021)

3. Health Data Governance Principles

Source: <http://healthdatapinciples.org/>

The Health Data Governance Principles emphasize human rights and equity in the management of health data, ensuring fair and inclusive data use within and across health systems. They support the development of sustainable and resilient public health systems and contribute to achieving Universal Health Coverage (UHC). This approach ensures that health data governance protects individual rights while promoting health equity and access to quality healthcare for all.

These principles developed through a collaborative bottom-up process led by civil society and stewarded by TransformHealth, these principles encompass three interconnected objectives: 1) Protecting individuals, groups, and communities; 2) Promoting health value through data sharing and innovative uses of data; and 3) Prioritizing equity by ensuring the fair distribution of benefits from health data use. Intended for governments, technology companies, and other stakeholders involved in health data management, these principles aim to guide national and organizational health data policies and contribute to a global governance framework. They also serve as a tool for advocating equitable, human-rights-based data governance and act as an accountability mechanism.

4. Health Insurance Portability and Accountability Act (HIPAA)

Source: <https://www.hhs.gov/hipaa/for-professionals/index.html>

The Health Insurance Portability and Accountability Act (HIPAA), enforced by the U.S. Department of Health & Human Services, outlines Privacy Rule standards that regulate the usage and sharing of protected health information by healthcare providers, health insurance plans, and employers. These standards also empower individuals with the right to comprehend and manage how their health information is utilized. A primary objective of the Privacy Rule is to ensure the safeguarding of individuals' health information while facilitating the exchange of data necessary for delivering and enhancing high-quality healthcare services and safeguarding public health and safety. The Privacy Rule is designed to balance the crucial need for information flow with the privacy rights of individuals seeking medical care by allowing certain uses of information under stringent protection measures.

- The Privacy Rule sets forth guidelines for the protection of individuals' medical records and personal health information, mandating adequate safeguards to maintain the privacy of this information. It also delineates the conditions under which such information can be disclosed without the patient's consent.
- The Security Rule details administrative, physical, and technical safeguards that covered entities must employ to ensure the confidentiality, integrity, and availability of electronic protected health information (ePHI).
- The Enforcement Rule outlines the procedures for compliance and investigations, establishes penalties for HIPAA violations, and sets forth the process for hearings.

5. General Data Protection Regulation (GDPR)

Source: <https://gdpr-info.eu/>

The General Data Protection Regulation (GDPR) is the data protection legislation within the European Union (EU). Its influence extends globally, affecting any entity that processes the personal data of EU residents, regardless of the organization's location. The GDPR introduces several critical principles and rights aimed at enhancing personal data privacy:

Individual Consent and Rights

- **Consent:** GDPR mandates explicit, informed consent for personal data processing, requiring it to be freely given, specific and clear.
- **Right to Access:** Individuals are entitled to access their personal data held by data controllers, including the right to receive copies.
- **Right to Erasure:** This right enables individuals to have their data deleted under specific circumstances.
- **Right to Data Portability:** This right allows individuals to receive their data in a structured, widely used format, facilitating the transfer between service providers.
- **Right to Object:** Individuals may object to the processing of their personal data for purposes like direct marketing, research, or statistical analysis.

Data Protection Measures

- **Data Protection by Design and Default:** From the outset of data processing activities, organizations must embed data protection measures, ensuring minimal data processing.
- **Data Protection Officers (DPOs):** Appointment of DPOs is mandatory for entities processing significant volumes of sensitive data or conducting extensive monitoring.

Furthermore, the GDPR requires prompt notification of data breaches to the relevant authority, and in cases where there's a significant risk to individual rights and freedoms, the affected individuals must also be informed. Additionally, the GDPR enforces stringent guidelines on the international transfer of personal data, ensuring that data protection standards are maintained outside the EU/EEA.

6. Framework for Improving Critical Infrastructure Cybersecurity

Source: <https://www.nist.gov/publications/framework-improving-critical-infrastructure-cybersecurity-version-11>

The National Institute of Standards and Technology (NIST)'s Cybersecurity Framework offers a comprehensive set of guidelines designed to assist private sector organizations in enhancing their cybersecurity measures. This framework enables entities to evaluate and augment their capabilities in preventing, detecting, and responding to cyber threats through a structured approach that integrates standards, guidelines, and best practices for managing cyber-related risks. Characterized by its prioritization, adaptability, and cost-efficiency, the framework aims to bolster the protection and resilience of vital infrastructure and sectors crucial to the economy and national security.

The latest edition, Version 1.1, includes a new section dedicated to self-assessment, an expanded discussion on the application of the framework in managing risks to the cyber supply chain, and improvements in addressing authentication, authorization, and identity verification. Additionally, it clarifies the interconnections between implementation tiers and profiles, and introduces considerations for coordinated vulnerability disclosure.

7. Guide to Privacy and Security of Electronic Health Information

Source: <https://www.healthit.gov/topic/health-it-resources/guide-privacy-security-electronic-health-information>

This guide is to support healthcare professionals, particularly those in smaller practices, in navigating and adhering to the US's HIPAA. It provides actionable advice for achieving regulatory compliance, strategies for managing risk, guidance on staff training, and protocols for addressing and reporting breaches of health information. Furthermore, the guide encompasses a suite of tools and resources aimed at assisting providers in evaluating their practice's requirements for the privacy and security of electronic health information. It aids in the development of policies and procedures that align with federal regulations and offers insights into identifying potential risks and effectively managing them. This comprehensive approach ensures healthcare providers are well-equipped to safeguard sensitive health information, maintaining the trust and confidence of their patients

Annex 4. Solution Design & Development

1. Designing Digital Interventions for Lasting Impact: A Human-Centered Guide to Digital Health Deployments

Source: <https://www.unicef.org/innovation/reports/designing-digital-interventions-lasting-impact>

This UNICEF toolkit applies the principles of human-centered design¹⁰ (HCD) to the design process of digital health programs. HCD is a problem-solving methodology anchored in understanding the users, their community and the context in which frontline workers, community members, caregivers, and prevailing systems operate.

This step-by-step guide offers a plethora of methodologies, tools and templates and provides clear direction for making decisions throughout the entire digital health program design, planning and implementation cycle, with a specific emphasis on end-users and communities, which is why it has been included in this section of the review.

As explained in the resource, a digital solution may perform well in theory, but its effectiveness is compromised if it fails to account for challenges encountered by frontline workers, community members, caregivers, and the surrounding systems. Community Health Workers or nurses possess invaluable insights into problem-solving within their domains, surpassing the expertise of health experts and digital strategists. The toolkit's methodologies recognize this reality by emphasizing observation, interaction, and design tailored to the people being served, in addition to considering technical constraints and specifications.

This toolkit is therefore an invaluable resource and its approaches can be adopted beyond the framework of UNICEF health initiatives to bring user-perspectives to the forefront of application and program design. It is health-domain specific, and thus should be considered as essential reading, for DH planners and implementers who are looking to strengthen participatory approaches.

2. Collaborative Requirements Development Methodology (CRDM)

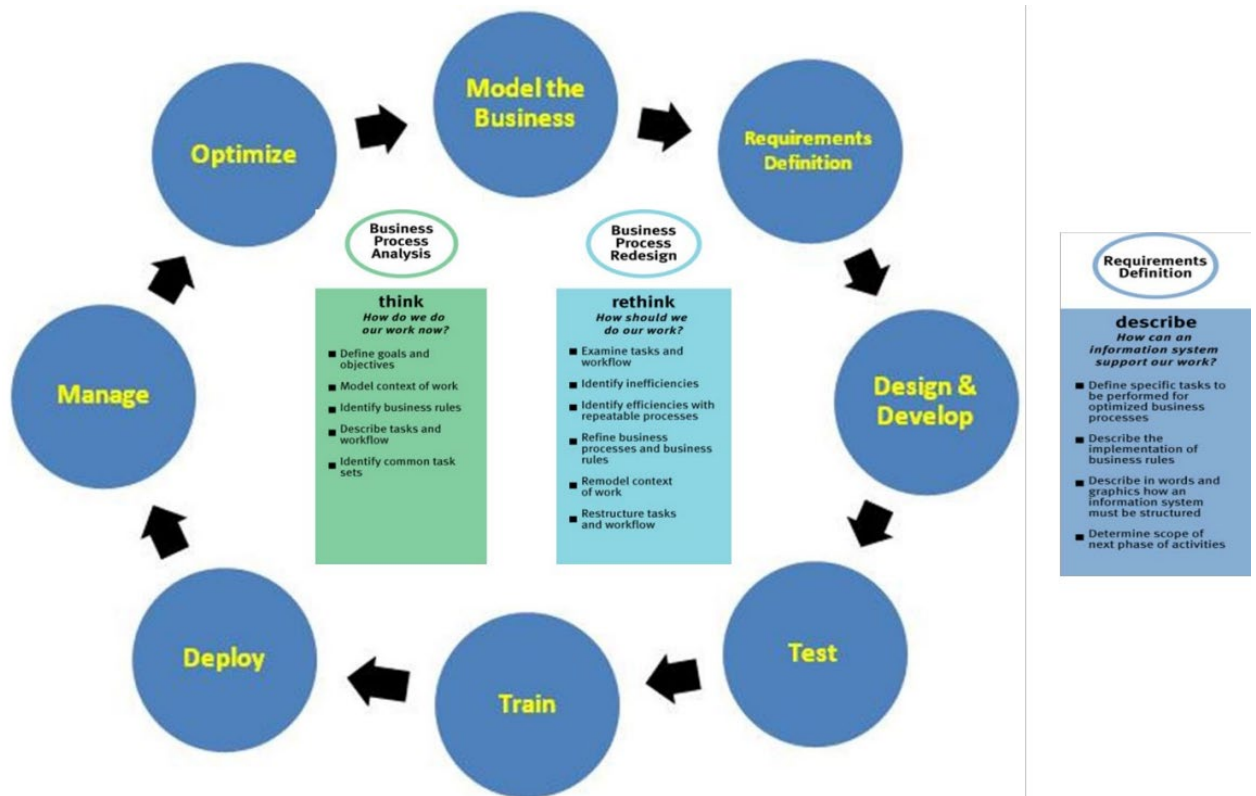
Source: [CRDM_Participants_Guide_Overview_1.pdf \(path.org\)](#)

Endorsed by PATH since 2015, CRDM¹⁷⁷ is a requirement-gathering process that centers on local ownership, buy-in, and context. This approach is based on collaboration with the stakeholders/users of the system to develop a shared understanding and agreement on what the system is supposed to do. Its primary purpose is to develop workflows using a human-centered approach.

¹⁰Human-centered design (HCD) is a versatile and structured approach to innovation, prioritizing people's aspirations and everyday experiences in the development of complex systems, services, or products. As defined by the International Standards Organization (2010), it encompasses six principles: understanding users, tasks, and environments; involving users throughout design and development; refining design based on user-centered evaluation; employing an iterative process; addressing the complete user experience and context; and engaging a multidisciplinary design team. This methodology has evolved through influences from diverse fields like human factors, human-computer interaction, anthropology, sociology, and design professions. Human-centered design emphasizes holistic consideration of human factors and values, facilitating a paradigm shift in design thinking 176 Holeman I, Kane D. Human-centered design for global health equity. Information Technology for Development 2019; 26(3): 477-505.. (Holeman & Kane, 2020).

This business process analysis is founded on a logical framework and focuses on core components. It includes: (1) the development of user personas that detail the demographics, environments, and principal challenges faced by various stakeholders in different countries who will use elements of the system; (2) the creation of a business process matrix and logical workflow diagrams as visual representations, with decision points prominently marked; (3) the initiation of process redesign by examining the current pain points of users and organizations, employing visual storytelling for clarity; and (4) the definition of functional requirements for the systems, ensuring they meet the needs of users and stakeholders. This model is part of technology life circle that include business modelling, requirement definition, design and developing of the system, testing, training, implementation, managing and optimization (Figure 23).

Digital Square applies CRDM. In DIPC, CRDM it is used to identify user personas for the respective tools and to then define workflows in accordance with the user personas. This model was already successfully used in Porto Rico during the Zika outbreak to enhance the informatics system that securely manages, stores, and transmits digital data ¹⁷⁸.



3. WHO SMART Guidelines

Source: <https://www.who.int/teams/digital-health-and-innovation/smart-guidelines>

The SMART guidelines (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable) were developed by the WHO in response to the challenges faced with digitization of existing guidelines. These challenges include slow and incomplete integration into practice, stretched resources during adaptation and scaling up into digital systems, difficulties in maintaining fidelity during digitization, and frequently neglected concerns regarding interoperability and indicator standards.

Figure 23. Collaborative requirements development and the information technology life cycle proposed by the CRDM (Source: CRDM, 2015)

In the past the process of incorporating health recommendations into digital systems has been unsystematic and error-prone, leading to concerns about transparency and traceability¹⁰⁵. Consequently, a number of key challenges have been identified that hamper the digitization of health systems according to accepted international and national guidelines and standards¹⁰⁵:

1. **Unsuitable Format:** Evidence-based guidelines from WHO are often in narrative format, making it difficult to be digitized and integrated into digital systems.
2. **Unsystematic Incorporation:** The process of translating and incorporating health recommendations into digital systems has been unsystematic, slow, and prone to errors, leading to poor transparency and traceability.
3. **Lack of Specific Guidance:** There is a lack of specific guidance at both technology and content levels, resulting in an abundance of digital solutions with unknown provenance and merit. This undermines confidence, hinders country localization, and prevents interoperability.
4. **Hard-Coded Solutions:** Many digital solutions are hard-coded, making it challenging to align them with an evolving evidence base.
5. **Limited Representation of Informaticians:** The guideline panels lack sufficient representation of health informaticians, which affects adherence to operational and terminology standards.
6. **Data Ownership and Ethics:** The use of big data and advanced analytics in dynamic health models raises ethical considerations and concerns about data ownership.
7. **Complexity of Change:** The systemic change needed for effective integration of SMART guidelines into digital health systems is comprehensive and complex.

To address these challenges, WHO has introduced the SMART guidelines as a comprehensive framework to facilitate the rapid and effective implementation of its recommendations in the digital age. These guidelines encompass documentation, digital health components, and procedures that guide developers, technologists, and countries in translating, integrating, and localizing recommendations into digital systems.

The SMART guidelines consist of five knowledge layers:

- L1 - narrative layer (enhanced guidelines)
- L2 - operational layer (digital adaptation kits)
- L3 - machine-readable layer (machine-readable recommendations)
- L4 - executable layer (reference applications and services)
- L5 - dynamic layer (precision health models).

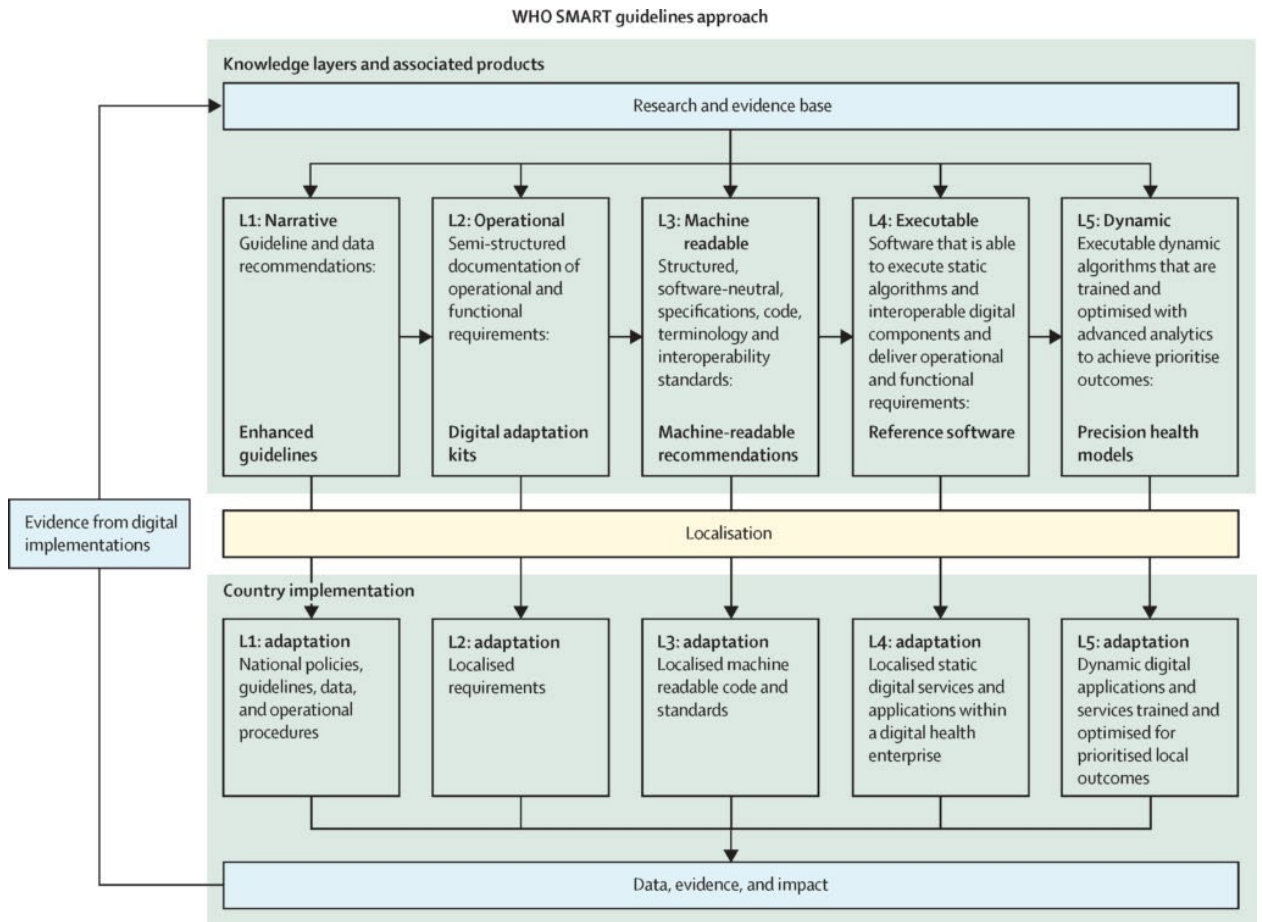
The first knowledge layer (L1: Narrative layer) enhances traditional guidelines to support digital transformation, emphasizing the need for living guidelines with unique identifiers and increased health informatician representation in guideline panels.

The second layer (L2: Operational) comprises digital adaptation kits (DAKs) that align with WHO data and health service recommendations, aiding discussions between health program managers and software developers. These kits cover a range of requirements, including health interventions, user scenarios, workflows, and standard terminology codes.

The third layer (L3: Machine-readable) provides code for software developers to integrate WHO guidelines into digital systems, ensuring fidelity to recommendations and standards. It involves mapping L2 content to value sets and FHIR standards for interoperability, and encoding logic into Clinical Quality Language (CQL) for consistent data extraction.

The fourth layer (L4: Executable) includes software applications which embodies WHO recommendations and supports interoperability and localization to specific operational contexts. It also encompasses terminology services and software libraries for seamless updates and integration.

The final layer (L5: Dynamic) leverages big data and advanced analytics for precision health models, aiming for context-specific, optimized health outcomes. This layer involves creating anonymized, normalized datasets for analysis and algorithm development, with considerations for ethical and data ownership issues¹⁰⁵. The progressive logic of the SMART Guideline components is shown in Figure 24.



There is significant emphasis on applying the SMART guidelines, particularly as numerous LMICs plan to enhance their digital systems after the COVID-19 pandemic, also considering the abundant availability of Digital Public Goods (DPGs).

These guidelines are relatively recent, and notably, the second operational layer, the Digital Adaptation Kit (DAK), is attracting considerable interest. All five countries involved in the DIPC project are exploring the potential adoption of the yet-to-be-published DAK for immunization. However, the process of adopting DAKs is inherently country-specific and is still in the early phases of accumulating experience and insights.

At the time this review was conceived, DAKs were in the process of being adopted in at least 10 countries (informal communication with WHO, 23-06-02). Zambia, Zimbabwe, Malawi, Nigeria, and Kenya, where WHO is offering technical assistance and support, are implementing the DAK for antenatal care. Malawi, Zambia, and Zimbabwe are also adopting it for family planning. Additionally, plans for DAK adoption are progressing in Indonesia, Morocco, and Pakistan. Ethiopia, Ghana, Rwanda, Iraq, and Cameroon have also begun their journey of DAK adoption. In these countries, the WHO is not only providing technical assistance but is also facilitating implementation research studies. These studies aim to validate the adaptation and integration of DAKs into existing health systems and to evaluate service delivery and data outcomes before and after the introduction of the respective DAK.

Recently, the Clinical Decision Support Community of Practice at the Geneva Digital Health Hub has begun implementing SMART guidelines pursuing the goal to standardize the digitalization of the Integrated Management of Childhood Illness, thereby facilitating a more rapid and effective adoption of evidence-based practices (Beynon et al., 2023).

Unfortunately, Evidence generated by the adoption of the SMART guidelines are still scarce. Most of the studies are still underway and findings have not yet been released. However, learnings from Zambia and Rwanda regarding ANC DAK implementation offer some helpful guidance for DIPC implementers ¹⁵⁵.

Figure 24. WHO SMART guidelines - Progressive layers across components (Source: PMID: 33610488)

1. **Digital Eco-system:** Findings showed that Rwanda and Zambia have well-established digital health ecosystems with increasing demand and adoption into digital health services. However, both countries face challenges with fragmented digital health landscapes and inadequate standards and legislation, leading to barriers in data sharing and interoperability.

This observation from the Rwandan and Zambian context may also become apparent in DIPC project countries. Whilst digital health strategies have been produced across the five DIPC countries, the stage of their implementation may hamper efforts. As such, this aspect ought to be considered and implementers should therefore be aware. Digital landscape assessments that were validated by MoH staff formed the basis of the customization process of the ANC DAKs and led to a number of follow-up stages, including consultations and interviews with stakeholders in the digital eco-system, government stakeholders in digital health policy among others.

2. **Localization of the DAKs:** The research from Zambia and Rwanda identified some customization requirements for the WHO ANC module through the use of the DAKs. Over 80% of the generic DAK content was adopted, with some modifications and additions made to align the module with national requirements and service delivery packages. As such, the results show that using the DAKs provided a systematic and structured approach to customizing the generic WHO digital ANC module to the specific contexts of Rwanda and Zambia. The format and process of the DAKs appeared to have offered a starting point for incorporating WHO guidelines into digital systems while allowing flexibility for country-specific adaptations.
3. **Integration with Existing Systems:** The landscape assessment was critical in the process of DAK customizations as it helped to determine how the ANC digital module would be integrated in accordance with the WHO **Implementation Investment Guide (DIIG)** recommendations on digital interventions for health system strengthening, (WHO, 2020b), which states the aim to „support a cohesive approach to implementation, in which different digital interventions can operate together, rather than as duplicative and isolated implementations”. Integrating the customized ANC digital module with existing digital health systems required careful consideration and mapping of integration points. Aligning new digital tools with existing digital governance systems ensured local ownership and coherence of digital health initiatives.
4. **Context-Specific Enhancements:** The adaptation process allowed for context-specific enhancements and modifications to the ANC module. Each country team added, removed, and modified elements from the DAK to align with national requirements and service delivery packages, ensuring relevance and usability.
5. **Collaboration and Stakeholder Engagement:** Strong leadership, governance, and coordination were essential for successful implementations. In Rwanda and Zambia, collaboration and constant engagement between the maternal health program and ICT leads were critical to coordinate requirements for adapting the digital module in both countries. This is an important lesson to take away for the DIPC countries, as an active and collaborative engagement with country partners, immunization program managers and other stakeholders and technical experts will be paramount according to these findings.
6. **Data Infrastructure and Skills Gap:** Adequate data infrastructure and skills were crucial for optimal usage of the digital tool. Assessing IT infrastructure and skills gaps prior to deployment helped ensure the effective implementation of the digital module.

This finding relates to DIPCs efforts to improve data quality and use as well as the work package and country activities specific to capacity strengthening. Muliokela and colleagues¹⁵⁵ recommend a mapping exercise of data infrastructure systems against business requirements and reporting needs to develop an understanding of the data infrastructure requirements, in our case relevant to immunization.

7. **Consideration of National Guidelines:** The process of customization was guided by national protocols and guidelines, and decisions on modifications and inclusions were based on the country-specific ANC package. Adherence to national guidelines and standards was essential for the successful

integration of the digital module. This observation can be directly translated to the DIPC context, as national immunization guidelines, clinical standards and health policies must guide any efforts to adopt the DAK in the DIPC countries.

8. **Capacity Strengthening:** Capacitating Ministries of Health from the outset was important to ensure ownership and sustainability of the adaptation processes for SMART guidelines, including the use of DAKs, in future initiatives.

These inferred lessons highlight the importance of collaboration and coordination between stakeholders, and the need for alignment with existing digital health governance and infrastructure. These insights can be valuable for the work ahead within the DIPC initiative in its country projects. Whilst the DAK for Immunization have not yet been formally published, a number of considerations outlined above can already be addressed as part of any preparatory processes.

No data are yet available on the subsequent effects of DAK adoption with regards to service delivery and data use outcomes and such effects can only be assessed later on in the process. Publications around the processes used and early learnings across the different countries are however forthcoming (informal communication with WHO, 23-06-16) for Zambia, Zimbabwe, Malawi, Ethiopia and Ghana and once published will be of great value to the DIPC initiative and its implementers.

The ultimate goal of SMART guidelines is to ensure the systematic and transparent adoption of WHO recommendations into digital systems at the country level. By providing interoperable standards and software-neutral content, the SMART guidelines support global access to effective digital solutions in LMICs and thus are a potential further stepping stone towards achieving UHC and the SDGs.

4. Xcertia mHealth App Guidelines

Source: <https://www.himss.org/sites/hde/files/media/file/2020/04/17/xcertia-guidelines-2019-final.pdf>

Xcertia is a joint mHealth app collaborative effort, non-profit organization, pioneered by the American Medical Association (AMA), American Heart Association (AHA), DHX Group and Healthcare Information and Management Systems Society (HIMSS). The collaboration builds on each organization's ongoing efforts to foster safe, effective, and reputable mHealth solutions. In 2019, Xcertia released its updated guidelines for mobile health applications (mHealth apps), addressing five key areas of design and development: privacy, security, operability, usability and content. Even though these guidelines are especially suited for the mHealth sector, topics such privacy and security are generally relevant for any software developer and this resource can be applied beyond mHealth.

Annex 5. Integration & Interoperability

1. Digital Health Platform Handbook: Building a Digital Information Infrastructure (Infostructure) for Health¹⁰⁸

Source: <https://iris.who.int/handle/10665/337449?&locale-attribute=zh>

This guideline, written for planners and enterprise architects in the health sector, is useful for countries that are at an earlier stage of digital maturity. This handbook helps countries to build robust national health platforms focusing on system integration in support of the SDGs both within and beyond the health domain.

Thus, this handbook highlights the development of a digital health platform (DHP) to serve as the foundational infrastructure for an interoperable and integrated national digital health system. A DHP serves as a unified information infrastructure (infostructure) for building various digital health applications, facilitating consistent and efficient healthcare delivery.

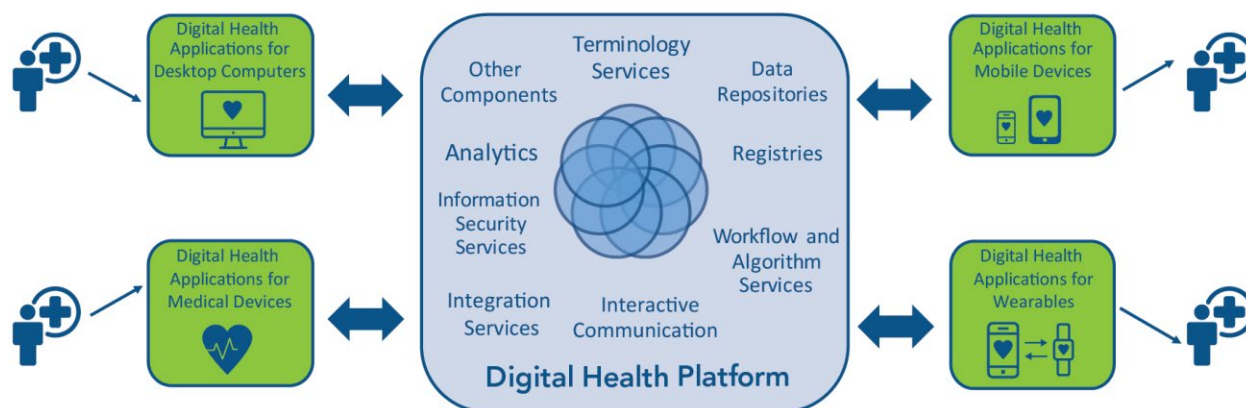
Infostructures include a range of integrated, reusable components like software and shared resources, enhancing interoperability through consistent data definitions and messaging standards. It supports a variety of applications, from software programs to information systems like EHR, supply chain systems, insurance systems, and patient-engagement apps. The core strength of this platform lies in its ability to unify these diverse elements into a cohesive and streamlined system, ensuring seamless integration and communication across different digital health tools (Figure 25). Implementing a DHP is a key way to facilitate standards and interoperability. A DHP also enhances and accelerates the development of digital health services and applications as part of a wider national eHealth strategy that should have been planned in advance together with a digital ecosystem analysis.

In details, this handbook describes various tasks, from context analysis to ongoing institutionalization efforts to implement a DHP. In summary, these tasks are:

1. Conduct a context analysis
 - a. Assess your country's health system, actors, and digital health assets already in place, classified based on their fit with the DHP
 - b. Identify and redesign priority health system business processes that you wish to improve with digital health interventions
2. Design your DHP architecture
 - a. Establish DHP design principles
 - b. Outline the enterprise architecture
 - c. Identify which components the DHP should provide to match health system needs and their functional requirements
 - d. Adopt and deploy standards for the DHP to enable interoperability
3. Implement your DHP
 - a. Choose an implementation approach
 - b. Select software for the platform
 - c. Establish a governance framework to define DHP operational support and governance
 - d. Institutionalize the DHP

Illustrative case studies from Liberia, Estonia, Canada, India and Norway are included. The model proposed by Estonian for example, demonstrates key interactions between DHP and e-government systems. Estonia developed a unified digital platform connecting public and private sectors via secure, interoperable architectures. This platform enhanced cross-sector digital integration in areas like e-taxation, e-banking, and e-school, using unique national electronic identifiers¹⁷⁹. In Liberia, the Ministry of Health put in place

mHero during the 2014 Ebola outbreak. mHero linked the existing systems- human resources information systems with SMS via a DHP for efficient information exchange among health workers, leveraging OpenHIE for integrated disease surveillance and response. Similarly to mHero, Uganda’s FamilyConnect, and Mozambique’s Sistema Electronico de Logistica de Vacinas represent digital platforms integrated with e-government and robust trust frameworks¹⁹.



DHPs have the potential to enhance interoperability through a standards-based Health Information Exchange and an information architecture (infostructure). The infostructure includes integrated, reusable components essential for efficiently operating digital health systems, such as registries, data repositories, and identity authentication. It is a vital part of the complex national health systems.

DHP could work as a horizontal base digital solution that connects vertical siloed information systems including functional and non-functional requirements that are housed within individual digital health applications. All data passes through the DHP hub, whether they are stored on the DHP alone or divided among multiple external repositories and applications (WHO, 2017).

2. Health Information Systems Interoperability Maturity Toolkit (MEASURE Evaluation, 2017)

Source: <https://www.measureevaluation.org/tools/health-information-systems-interoperability-toolkit.html>

The aim of this Toolkit is to assist Ministries of Health, their implementing partners, and other stakeholders in evaluating the digital Health Information System’s landscape. It does this by identifying their current capacity, processes, and structures across key domains for HIS interoperability, as well as determining the necessary maturity levels needed to achieve HIS interoperability. The MEASURE Evaluation project, funded by USAID, published this HIS toolkit in 2017 and update it in 2019 with lessons learnt in Ghana and Uganda.

The toolkit addresses three broad domains that are critical to HIS interoperability: technology, the broad area of leadership and governance of the HIS, and human resources. Each domain is then structured into several more specific subdomain.

The evaluation of domains and subdomains utilizes a 5-point scale:

- **Level 1 (Nascent):** Absence or inconsistency in HIS capacities, with activities being sporadic or ad hoc.
- **Level 2 (Emerging):** HIS structures are defined but not systematically documented, lacking formal monitoring or measurement.
- **Level 3 (Established):** HIS structures are documented and functional, with systematic use of performance metrics and quality improvement measures.

Figure 25. Digital Health Platform as conceptualized by Digital Health Platform Handbook: Building a Digital Information Infrastructure (infostructure) for Health

- **Level 4 (Institutionalized):** National HIS system is used by government and stakeholders, adhering to standard practices.
- **Level 5 (Optimized):** Regular review and adaptation of interoperability activities by government and stakeholders to respond to changing conditions.

Results are summarized in a sample radar graphs for domains and subdomains. The assessment process is designed to be self-administered. By interpreting the assessment's findings, countries can chart a course to fortify their HIS interoperability, paving the way for more robust and resilient systems.

3. Digital implementation investment guide (DIIG): integrating digital interventions into health programmes (WHO, 2020b)

Source: <https://www.who.int/publications/i/item/9789240056572>

The Digital implementation investment guide: integrating digital interventions into health systems, (also known as the DIIG), has been published by WHO in collaboration with partners UNICEF, UNFPA and PATH in 2022.

The DIIG provides a road map to facilitate the integration of DHIs into health programs following the 9 Principles for Digital Development³ to help stakeholders effectively and appropriately apply digital technologies in their health programs. This practical guide serves as a companion to the **WHO guideline: recommendations on digital interventions for health system strengthening⁸** and elaborates the process of identifying ideal DHIs for specific contexts based on previous experiences and offers a systematic approach to the project cycle to increase the chances of successful integration.

DIIG provides users with step-by-step guidance through planning, costing and implementing digital health interventions, drawing guidance from the WHO guideline—recommended digital health interventions, providing direction to ensure investments are needs-based and contribute effective and interoperable systems aligned with national digital architecture, country readiness, health system and policy goals.

The DIIG guides the implementation through 9 steps:

- Step 1 Identifying target health programmes and establishing a shared understanding
- Step 2 Assessing the current state and country readiness
- Step 3 Designing digital health interventions for scale and impact
- Step 4 Defining capabilities and functionalities of digital health interventions
- Step 5 Linking digital health interventions to the national enterprise architecture
- Step 6 Monitoring & evaluation of digital health implementations
- Step 7 Costing for implementation, maintenance and scale

Moreover, the DIIG presents a 'process matrix worksheet' designed to evaluate the processes, objectives, outcomes, and potential bottlenecks for each step. For instance, when examining the efficiency of various COVID-19-related health initiatives, one should itemize the requisite processes, delineate the associated tasks, and specify the anticipated outcomes for each. Subsequently, the framework facilitates the alignment of pertinent digital health interventions to address the recognized bottlenecks. The DIIG approach is holistic and yields an instructive case study, particularly with respect to COVID-19 vaccine distribution. Additionally, this guide elucidates the architectural framework of OpenHIE, establishing DIIG as a principal resource for Digital Health Interventions (DHIs) backed by the Global Fund (as stated by Mark Landry, Senior Specialist for Country Digital Health Information Systems at the HELINA conference in Cape Town in 2023).

Annex 6. Scaling up

1. The MAPS Toolkit¹⁴

Source: <https://apps.who.int/iris/handle/10665/185238>

The **mHealth Assessment and Planning for Scale (MAPS)** toolkit is a self-assessment tool that guides project teams whilst they are scaling up their innovations. MAPS Toolkit guides implementers through an iterative cyclical process of thorough assessment, careful planning and targeted improvements. The MAPS Toolkit helps to evaluate the progress of scaling up DHIs through a detailed set of self-assessment questions areas across six axes (Groundwork, Partnerships, Financial health, Technology & architecture, Operations, and M&E, Figure 26).

These six axes contain a set of structured questionnaires for both team members and teams as a whole with a resulting scorecard that will help projects gain a better understanding of where that project needs to go towards scale and sustainability. The toolkit also serves as a decision tool, helping implementers devise strategies to overcome barriers to scale. The activities contained within the toolkit are meant to be iterative and completed multiple times throughout the life-course of the project post-pilot. This toolkit also offers planning and guidance features to address and overcome the challenges inherent in scaling up. This tool is designed for use by project managers, specifically teams with a DH product that has already been deployed, and who are aiming to scale the product and increase impact.



2. Understanding scale of digital tools: a framework and triangulation tool to measure scale of digital deployments in the context of the COVID-19 pandemic

Source: <https://static1.squarespace.com/static/59bc3457ccc5c5890fe7cacd/t/6079b1e1f-cf6d26d8daf480f/1618588133318/Understanding+scale+of+digital+health+tools.pdf>

This triangulation tool, utilized by Digital Square, offers the digital health community a method for assessing scale. This tool is grounded in two of the nine Principles⁸²: “Design for scale” and “Reuse and improve”. It underscores that leveraging, adapting, and deploying digital tools that are already widespread within a country can offer the ICT into national health systems. In practice, the tool evaluates the scope of an intervention across three integrated dimensions: the number of end-users, the extent of tool usage, and the degree of institutionalization (Figure 27). This tool should help to overcome several complexities like: the dynamic and context-specific nature of the “end user,” affected by various factors that influence both the quantity and type of users. The term “end user” might refer to individual users or healthcare facilities; the ever-evolving ecosystem within a country and the fluctuating landscape of available tools across nations;

Figure 26. Conceptual model of the MAPS Toolkit to measure digital health project maturity across six axes

the changing capacity of a country, influenced by variations in digital literacy, infrastructure availability, and financial resources over time.

SAMPLE SURVEY QUESTIONS	NOT AT SCALE (0)	SCALING (1)	AT SCALE (2)
Number of end users			
Tool used nationally or subnationally	Subnational		National
Percentage of regions the tool is deployed in	<50%	50%–90%	>90%–100%
Estimated users (as a % of total users)	<25%	26%–65%	>65%
Subtotal number of users <i>Take the average sum of the three questions to get dimension score.</i>			
Breadth of tool use			
Number of health focus areas addressed by this tool	≤5	6–9	≥10
Number of Map and Match use cases addressed by this tool	1	2–3	4
Number of data registries working with the tool	0		1
Using popular standards (e.g., Aggregate Data Exchange, Fast Healthcare Interoperable Resource Health Level 7)	0		1
Subtotal breadth of users <i>Take the average sum of the four questions to get dimension score.</i>			
Institutionalization of tool			
Has the government contributed funding for implementation of the tool?	No	Partial	Fully
Has any long-term implementation partner or donor contributed to implementation and sustainability of the tool?	No	Partial	Fully
Is this tool in the national digital health strategy? (y/n)	No		Yes
Subtotal Institutionalization <i>Take the average sum of the three questions to get dimension score.</i>			
Overall scale	0–0.49	0.5–1.49	1.5–2.0
<i>Take the average sum of three dimension scores to get overall scale score.</i>			

3. PATH’s “The journey to scale – moving together past digital health pilots”

Source: [The Journey to Scale: Moving Together Past Digital Health Pilots \(path.org\)](https://path.org)

This PATH report is concerned with moving beyond pilot projects to achieve scalable DHIs. The document highlights the need for systematic approaches to scaling digital health solutions, to ensure they become an integral part of healthcare delivery systems and is primarily intended for global health practitioners, policymakers, donors, and technology developers who are involved in implementing digital health programs. It aims to provide these stakeholders with a clear understanding of the pathways and levers necessary for achieving large-scale, sustainable digital health interventions.

The guidance supports the scaling of digital health by advocating for a deliberate, coordinated approach that aligns on a shared goal of institutionalization. It emphasizes the need for robust investment strategies, effective program management, supportive policies, and the development of human capacity. The report identifies key factors that enable successful scale-up, including the importance of a strong case for action, effective leadership, viable economic models, and interoperability standards.

Figure 27. Integrated dimensions of “Understanding scale of digital tools: a framework and triangulation tool to measure scale of digital deployments in the context of the COVID-19 pandemic”

By focusing on these elements, the guidance helps ensure that digital health interventions can transition from small-scale pilots to widespread, routine use within health systems. This approach not only enhances the impact of digital health solutions on health outcomes but also promotes sustainability and long-term integration into national health strategies.

The report also draws on lessons from other sectors and successful case studies to provide practical examples and recommendations. This comprehensive approach aims to create a cohesive framework that can guide stakeholders in scaling digital health interventions effectively, thereby improving healthcare access and quality for populations in low- and middle-income countries.

Annex 7. Monitoring & Evaluation

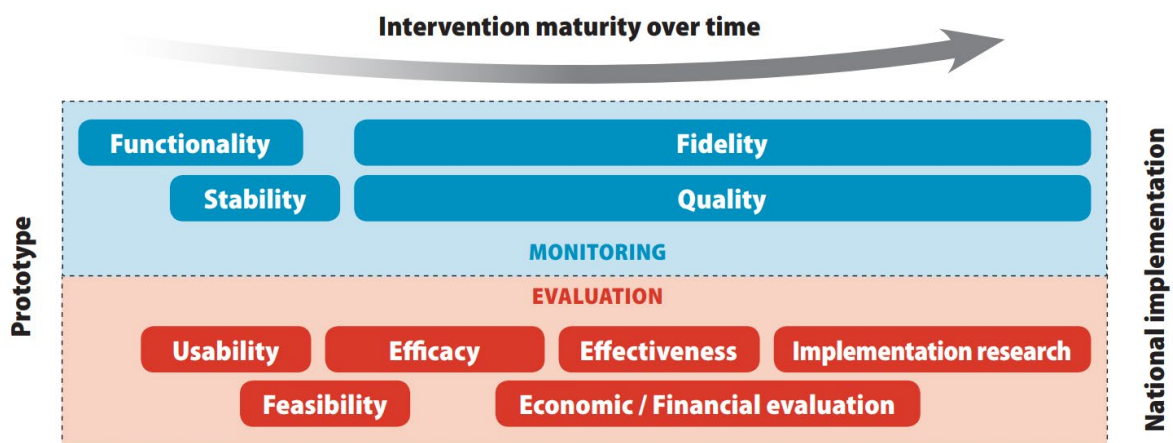
1. Monitoring and Evaluating Digital Health Interventions ²⁹

Source: <https://apps.who.int/iris/handle/10665/252183>

This guide offers comprehensive insights into improving the effectiveness and value of M&E initiatives in the sphere of DH. Specifically, it introduces approaches and methods (Figure 28) deemed beneficial for:

- (i) Monitoring the deployment of interventions, with an emphasis on the quality and fidelity of input components, and
- (ii) Evaluating project outputs and impacts on multiple fronts, ranging from user satisfaction and process enhancements to health outcomes and cost-effectiveness.

The guide facilitates the development of value propositions, the selection of pertinent indicators, and decision-making on suitable evaluation designs for digital health initiatives. Furthermore, it provides techniques for evaluating the accuracy and accessibility of data produced by the intervention and gives directives for effective result reporting. Designed with specific digital health projects in mind, this guide establishes a framework for both overseeing the project’s progress and gauging its impact. With its reader-friendly layout, it can be viewed as an indispensable resource during both the planning and evaluation phases of a digital intervention.



2. Monitoring the implementation of digital health (WHO)

Source: [Monitoring the implementation of digital health: an overview of selected national and international methodologies](#)

This document, which is a study concentrates on monitoring implementation efforts of digital health initiatives. It is based on consolidated information from the WHO, the European Commission, the Nordic eHealth Research Network, OECD, and the Statistical Conference of the Americas.

Specifically, the resource reviews national digital health monitoring activities in eight countries, and includes a valuable discussion the ongoing issue around internationally agreed measures for digital health indicators. The study acknowledges progress in monitoring digital health but emphasizes the need to strengthen evidence for shaping healthcare system transformation. It highlights challenges in measuring governance, health data reuse, and system-wide interoperability, suggesting ongoing efforts are required to adapt metrics to the evolving landscape of digital health.

Figure 28. Methods and objectives of monitoring and evaluation activities across the lifespan of a digital health programme







3. The Evidence DEFINED framework ¹¹³

Source: <https://www.nature.com/articles/s41746-023-00836-5#Fig1>

There is a need for objective, transparent, and standards-based evaluation of DHPs that can bring clarity to the digital health marketplace. Designed for real-world use, the Evidence DEFINED helps to streamline DHI assessment.

This resource is an evaluative protocol for digital health that consists of four distinct steps (Figure 15), as detailed in its Quick Start Guide:

1. Initial screening against fundamental requirements, such as data privacy standards compliance.
2. Adoption of a recognized evidence assessment methodology initially devised for non-digital interventions (e.g., GRADE18).
3. Application of the ‘Evidence DEFINED’ supplementary checklist.
4. Utilization of evidence-to-recommendation guidelines to proffer recommendations on appropriate DHI adoption levels.

The Evidence DEFINED Framework					
A Rigorous, Rapid Approach to Assess Clinical Value for Digital Health Interventions (DHIs)					
Evidence DEFINED	Goals				
Evidence in D igital health for E ffectiveness of I nterventions with E valuative D epth	1. Facilitate rapid & rigorous DHI evidence assessment in organizations. 2. Guide DH solutions providers who wish to drive product adoption.				
Target Audience					
Designed to support digital health evidence assessment within stakeholder organizations including:					
 Payers	 Pharmacy Benefit Managers	 Health Systems	 Pharmaceutical Companies	 Trade Organizations	 Professional Medical Societies
The Evidence DEFINED Framework is comprised of the following steps:					
Step 1	Screening	Each organization defines and screens for absolute requirements (e.g., compliance with data privacy standards, appropriate reading levels, absence of clinical red flags, etc.). This avoids investing effort in DHIs that are not candidates for adoption.			
Step 2	Apply an established method designed for non-digital products	Apply an established evidence assessment framework that was developed for non-digital interventions (e.g., GRADE). Many stakeholder organizations already use such frameworks routinely for evidence assessment in non-digital domains.			
Step 3	Apply the Evidence DEFINED supplemental checklist	Apply the Evidence DEFINED supplemental checklist (Supplementary Table 2) to address considerations unique to DHIs or requiring greater vigilance in digital health.			
Step 4	Make actionable recommendations	Apply evidence-to-recommendation guidelines (Table 2) to generate a defensible recommendation regarding levels of adoption that may be appropriate for the relevant DHI.			
In Scope		Out of Scope			
<ul style="list-style-type: none"> • Generating defensible recommendations regarding adoption levels that may be appropriate for a digital health intervention • Assessing clinical evidence for digital health interventions through a rapid, rigorous, consistent process 		<ul style="list-style-type: none"> • Decisions for individual patients, caregivers, or clinicians • Products that serve diagnostic functions exclusively • Evaluation in critical domains other than clinical evidence (e.g., patient experience, product design, data security, etc.) 			

The framework deals with the extent to which the adoption of digital health interventions (DHIs) is supported by clinical evidence (Figure 29) and while evidence remains a pivotal domain of assessment, other crucial areas include patient experience, cost, health equity, and more.

Figure 29. The DEFINED framework

4. Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth ¹¹⁴

Source: <https://www.jmir.org/2011/4/e126/>

In digital health, the consolidated standards of Reporting Trials of Electronic and Mobile Health Applications and Online Telehealth (CONSORT-EHEALTH) serves as an extension of the CONSORT statement. It offers guidance on reporting trials for web-based (eHealth) and mobile health (mHealth) interventions. This standard comprises 17 subitems, with four specifically addressing the vital issues of intervention attrition (non-use) and user engagement, dosage, and adherence. These aspects are often overlooked, even though they play a critical role in determining an intervention's future impact. The checklist has potential applications beyond just web-based and mobile interventions, even in scenarios where internet connectivity is not a constraint. However, adapting it to such contexts necessitates further research. CONSORT-EHEALTH is designed for reporting trials and provides a basis for improving transparency and consistency in the presentation of research on eHealth interventions.

5. Framework for the Economic Evaluation of Digital Health Interventions

Source: [A Framework for the Economic Evaluation of Digital Health Interventions | Policy Research Working Papers \(worldbank.org\)](#)

The document aims to provide a structured approach to assessing the economic value of digital health interventions (DHIs). Its primary objective is to establish a consistent method for evaluating DHIs' costs and benefits, enhancing decision-making in resource-constrained health systems. The target audience includes policymakers, investors, product developers, and researchers who need to determine the economic feasibility and impact of DHIs.

The framework follows a step-by-step approach, consisting of:

1. **Determining Context:** Identifying the health system and digital environment in which the DHI will be implemented.
2. **Intervention Type:** Specifying the nature of the digital health intervention.
3. **Level of Complexity:** Assessing the complexity of the intervention, its causal pathways, and outcomes.
4. **Analytical Principles:** Applying economic evaluation principles such as defining the comparator, timeframe, costs, benefits, and accounting for predictive analytics and uncertainty.
5. **Value Proposition:** Representing the value proposition through disaggregation (using an impact inventory) and aggregation as needed by decision-makers.

The document also identifies several gaps in the current literature, such as a lack of comprehensive economic evaluations of DHIs, particularly in LMICs, and the need for methodological improvements to address the unique aspects of digital health interventions. It highlights the importance of incorporating broader social impacts and ensuring methodological transparency to improve the usefulness of economic evaluations in guiding investments and policy decisions.

6. mHealth Evidence Reporting and Assessment ¹¹⁶

Source: <https://www.bmj.com/content/352/bmj.i1174>

The mHealth Evidence Reporting and Assessment (mERA) checklist, crafted by the WHO's mHealth Technical Evidence Review Group (mTERG), is designed to enhance the comprehensive reporting of mHealth interventions. This checklist delineates a core set of details to accurately describe the mHealth intervention's content, its implementation context, and its specific technical features, ensuring that others can replicate the intervention. In its concluding remarks, mTERG underscored the checklist's purpose: not just aiding authors in documenting mHealth research but also serving as a resource for reviewers, policymakers, and journal editors to respectively synthesize quality evidence and critically assess mHealth study reports for transparency and completeness. mERA is tailored to mHealth interventions and provides a framework for assessing and reporting the evidence generated by these studies.

7. iCHECK-DH ⁷³

Source: <https://www.jmir.org/2023/1/e46694/>

A team of international experts, under the guidance of the Geneva Digital Health Hub, devised the Guidelines and Checklist for the **Reporting on Digital Health Implementations** (iCHECK-DH). This was done to enhance the comprehensive documentation of digital health implementations. The result was a 20-item checklist concerning, as example, claims, methods, sustainability, interoperability, budget planning, with detailed explanations and examples that should standardize the quality of reporting and, indirectly, improve implementation standards and best practices. To validate its practicality and efficacy, the checklist was piloted on various real-world digital health projects, and refinements were made in response to feedback. The foundational objective behind iCHECK-DH's development was to pinpoint the essential information required to define a digital health implementation thoroughly. This aids in recognizing critical success and failure factors and facilitates its replication in diverse contexts

Annex 8. Sustainability & Financing

1. The Principles of Donor Alignment for Digital Health 86

Source: <https://digitalinvestmentprinciples.org/>

This document outlines 10 principles for donors to align their investments with countries' digital health strategies with the goals to:

- Pursue an integrated approach to strengthening health systems
- Enhance and extend the delivery of quality health services
- Improve data, and the capacity to use it, for improved health outcomes.

These Principles acknowledge the ongoing fragmentation, duplication, and lack of interoperability prevalent in the digital health systems of many LMICs. They also emphasize that substantial progress is needed to enhance health outcomes, economic and gender equity, and to achieve the SDGs. This progress requires improved coordination between donors who finance digital systems and the governments of the countries where these systems are implemented. Therefore, it is both essential and urgent for donors to align their investments with the digital health strategies of these countries to enable them to: 1) Collaborate, 2) Prioritize national plans, 3) Quantify costs, 4) Track & measure, 5) Strengthen donor skills. Donors are also requested to invest in: 6) National strategies, 7) Maturity continuum, 8) Country capacity, 9) Global goods, 10) Sharing and peer-learning.

These Principles are today endorsed by the most important donors for DH (Bill & Melinda Gates Foundation, World Bank, BMZ, GAVI, European Union, UNICEF, USAID, CDC, UNFPA, ...).

USAID is actualizing these principles through the initiation of a new Digital Health Vision for Action for the Agency. This initiative concentrates on the practical application of these principles within its planning, procurement processes, and programmatic activities^{180,181}. On the basis of these principle, USAID furthermore developed the USAID Digital Health Vision.

2. Digital Health Investment Review Tool to guide the investment in DH ¹¹⁸

Source: <https://mcsprogram.org/resource/digital-health-investment-review-tool/>

This tool provides support for strategic investments in DH and it starts with a key premise that “a country’s eHealth strategy should be based upon national health priorities, available and potential resources and the current eHealth environment”. Due to this, and to ensure relevance to the broader goals of health systems development, the first step offered is to establish a country’s “national context for eHealth.” This is done through a simple self-assessment process where a country determines its own national context based on a perception of the “established ICT environment” and the “enabling environment for eHealth”¹⁷⁵.

The tool aims to:

- Structure requests for proposals (or other donor procurement mechanisms) in a more organized and precise manner,
- Influence the wording and specifications in grants and contracts, and

- Provide informed guidance and facilitate decision-making by procurement officers who are evaluating digital health proposals.

The toolkit develops a clear “process framework” for 12 eHealth components (Policy Landscape, HIS Ecosystem, Key Stakeholders, System Users, Relevant Groups, Scale, Cost of Ownership, M&E Plan, Open vs. Proprietary, Privacy & Security, Resume & Improve and Change Management) that proposes development of a clear and continuous management process, timely stakeholder engagement, creation of an initial draft vision, and a subsequent iteration to extend consultation and refine strategic recommendations. Each component comes with a self-assessment worksheet.

Depending on the developmental stage of the proposed system (ranked as: Level 1: None or Nascent; Level 2: Emerging; Level 3: Established; Level 4: Institutionalized; Level 5: Optimized), varying degrees of emphasis might be assigned to different questions. For instance, a digital health innovation in its early stages might not prioritize the Total Cost of Ownership for a small-scale field trial as much as a system that is being proposed for implementation at a national scale. Each stage has reference to guidelines or framework.

3. WHO's Digital Implementation Investment Guide: Integrating Digital Interventions into Health Programmes

Source: <https://www.who.int/publications/i/item/9789240010567>

The WHO's **Digital Implementation Investment** Guide provides a detailed approach for planning, costing, and financing digital health interventions, with an emphasis on financing and costing. The guide outlines different phases of implementation, each with associated costs that need to be considered for effective budgeting. As such, the guide details investment planning guidance for the “development phase”, “integration & interoperability”, “scale up” as well as “sustained operations”, and introduces concepts, such as a “Budget Matrix”.

Overall, the guide offers a thorough and systematic approach to budgeting for digital health interventions, accentuating the need to consider both upfront and ongoing costs, while also focusing on scalability and long-term sustainability.

This guide can be complemented by **PATH's The Journey to Scale: Moving Together Past Digital Health Pilots**¹¹¹ which specifically addresses the challenges of institutionalizing a product or service within the health system.

4. Sustainable Development Goals Digital investment framework (eGoV)¹¹⁹

Source: <https://www.itu.int/pub/D-STR-DIGITAL.02-2019>

The **SDG Digital Investment Framework** guides governments and partners in adopting a comprehensive approach to invest in digital infrastructure and enhancing SDG programing across sectors. This framework is structured into four layers:

The SDG Digital Investment Framework is organized into four interrelated layers designed to support governments in taking a whole-of-government approach to digital investments for achieving the Sustainable Development Goals (SDGs). Here's a summary of these layers:

1. **SDG Targets:** These represent the 17 goals and 169 targets set by the United Nations to achieve sustainable development. They provide high-level, measurable objectives for governments to align their digital investments and development goals.
2. **Use Cases:** Detailed descriptions of the steps or user journeys required to achieve specific business objectives that contribute to one or more SDG Targets. They are user-centric, sector-specific, and highlight the actors involved. Use Cases define the necessary business processes and can be improved through digital technology.
3. **WorkFlows:** Generic business processes that are applicable across multiple sectors and support the delivery of Use Cases. These processes include client case management, client communication, procurement, and content management. They are common across various SDG-related programs. They help streamline and integrate operations, allowing for efficient and scalable implementation of digital solutions.
4. **ICT Building Blocks:** Reusable software components that provide essential functionality to support generic WorkFlows. These components are designed for scalability, interoperability, and compliance with relevant standards. They can be open-source, commercial off-the-shelf (COTS), or freely available.

This framework helps governments map their development goals to specific digital solutions, ensuring efficient and coordinated use of resources. It promotes the reuse of digital infrastructure across sectors, maximizing return on investment and supporting sustainable digital transformation. Drawing from enterprise architecture planning, the framework connects SDG targets with ICT building blocks, aligning tech investments with business strategies. This framework serves as both a simplified guide and a reference, enabling governments to efficiently map out their digital strategy to kickstart their digital investment and planning endeavor.

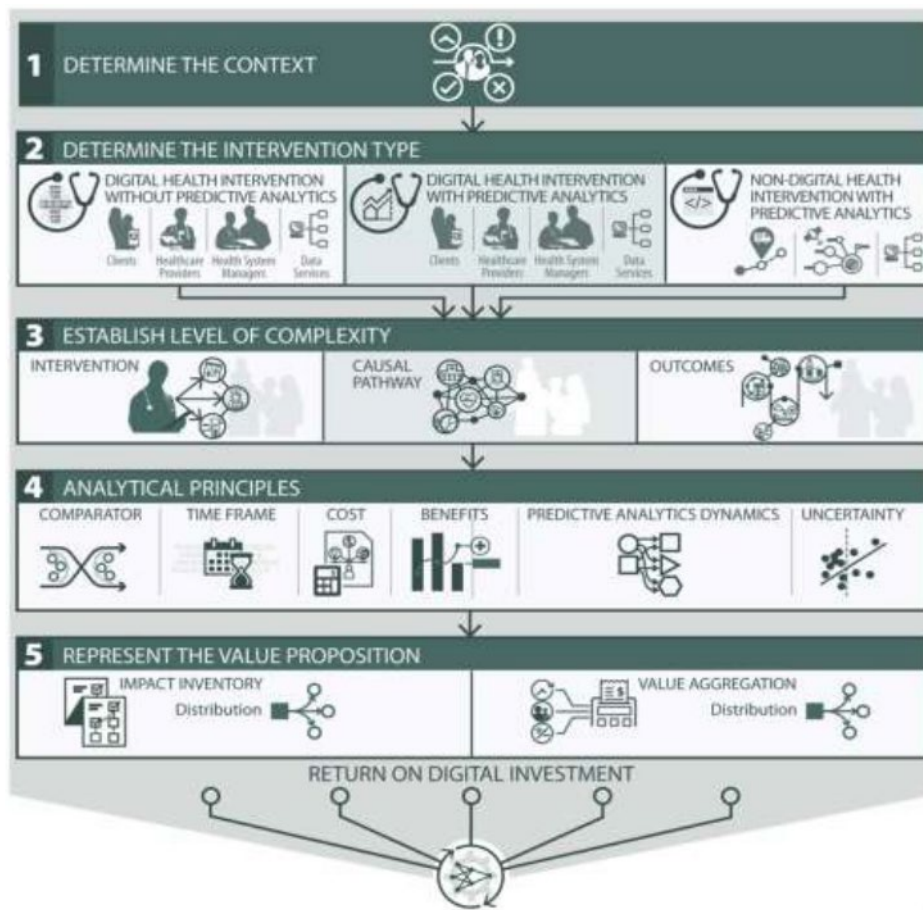
This framework also provides examples, summarizes the use cases, workflows, and ICT building blocks that have so far been cataloged; and presents a step-by-step process for applying the framework to an organization's architecture and investment planning.

5. A Framework for the Economic Evaluation of Digital Health Interventions

Source: <https://openknowledge.worldbank.org/handle/10986/39713>

The World Bank commissioned a specialized economic evaluation framework (Wilkinson, Wang, Friedman, & Görgens, 2023). This framework is designed for countries facing decisions on which DHIs to scale up within constrained health budgets. It aids in defining the value of DHIs and using economic evaluation for well-informed choices. Using a 'gap map' of evidence from economic evaluation of DHIs, this resource highlights the scarcity of economic data.

The framework comprises 5 steps: (1) determine the context, (2) determine the intervention type, (3) establish level of complexity, (4) analytical principles, and (5) presenting the value proposition (Figure 30).



The stages are described in detail as part of the resource. Its implementation promotes methodological transparency, enhancing the overall utility of economic evaluations of digital health interventions. Moreover, the framework is firmly based on and embedded within existing guidelines, including **WHO’s Classification of digital interventions, services and applications in health vers. 2.0⁴** and refers to the project maturity cycle of the WHO’s Guide to Monitoring and Evaluating DHIs (both described earlier).

6. Total Cost of Ownership Tool Digital Health Sustainability Calculator

Source: <https://digitalsquare.org/market-analytics>

To ensure digital health sustainability, it’s crucial to recognize the impact of market forces on the digital health landscape. This includes how market dynamics influence the introduction, adoption, and scaling of digital health tools, their associated costs, and the financial strategies for digitally transforming health systems. To navigate these complexities, Digital Square introduced two tools aimed at fostering a more sustainable digital health ecosystem.

The Total Cost of Ownership Tool is a user-friendly Excel-based tool that aids health managers in crafting realistic budgets for digital health initiatives. It shines a light on often-missed hidden costs, key cost drivers, and variances, with a special focus on operational expenses that are frequently underestimated during the budgeting phase.

the **Digital Health Sustainability Calculator** offers insights into the financial requirements for maintaining sustainable digital health services within a country. Utilizing data from costed country roadmaps, this

Figure 30. Digital Health Intervention Economic Evaluation Framework (Source: World Bank, 2023)

tool provides preliminary inputs to help stakeholders comprehend the full financial scope of sustaining digital health efforts.

7. Closing the digital divide: More and better funding for the digital transformation of health

Source: <https://transformhealthcoalition.org/investing-in-digital-health/>

Developed by Transform Health, this framework champions the need for enhanced and more cohesive financial backing, both domestically and internationally, to foster the equitable, inclusive, and sustainable digital evolution of health systems in LMICs.

It presents six strategic recommendations targeted at national governments, international donors, and the private sector.

1. More investment from domestic and international sources
2. Better coordinated and aligned investments
3. A costed digital health strategy and investment road map
4. A robust regulatory framework and policy environment
5. Mechanisms for meaningful multi-stakeholder engagement
6. Improved digital connectivity

Annex 9. Gender, Equity & Inclusion

1. Roundtable on Digital Inclusion

Source: https://www.un.org/techenvoy/sites/www.un.org.techenvoy/files/general/Definition_Digital-Inclusion.pdf

Digital inclusion is considered a social determinant of health ¹²⁵. **“Roundtable on Digital Inclusion”** is a “living document” in which the UN defined digital inclusion as *“equitable, meaningful, and safe access to use, lead, and design of digital technologies, services, and associated opportunities for everyone, everywhere”*. Whilst the text is not specific to the health domain, it should be considered as a fundamental resource to guide the integration of “gender inclusion and equity” into digital programing.

This document provides a concise overview of definitions and key thematic areas in digital inclusion. It underscores the necessity of adopting an intersectional approach to address systemic challenges like racism, unconscious bias, gender discrimination, LGBTQ+ discrimination, and other biases against marginalized groups and provides an overview of digital inclusion considerations related to data disaggregation, the availability of an enabling infrastructure and connectivity, as well as factors pertaining to access, affordability and participation.

To exemplify, with regards to the topic of data disaggregation, the resource highlights the collection of data through digital applications on criteria such as ability, migration or displacement status, age, location, indigenous identity, education, and income as particularly important to monitor and evaluate any digital intervention. To date, these data are by and large missing, but they are needed to capture the multifaceted nature and extent of ongoing exclusion and will provide the evidence required to identify precise policy interventions to remedy the status quo.

Another factor that is considered in the documents is the importance of affordable connectivity, given that mere access to the Internet is often inadequate and pattered by determinants such as those listed above. Digital access must be meaningful and cater to the practical online requirements of individuals. Such access encompasses digital equipment, frequency and depth of use, necessary skills, cultural considerations, and the availability of content in native languages. For example, English’s predominance online inherently privileges its speakers, thereby amplifying their engagement in digital activities and economies.

2. Bridging the Digital Gender Divide. Include, upskill, innovate (OECD)

Source: <bridging-the-digital-gender-divide.pdf> (oecd.org)

The objective of this OECD report is to enhance the evidence base and provide policy recommendations to support the equitable participation of women in the digital economy. It aims to address the various barriers that contribute to the digital gender divide and to promote gender equality in digital access, skills, and opportunities.

The primary audience includes policymakers, government officials, international organizations, and stakeholders involved in gender and digital inclusion. The report is intended to guide these entities in formulating and implementing effective policies to bridge the digital gender gap.

The report adopts a multifaceted approach that integrates data analysis, policy evaluation, and case studies. It examines the root causes of the digital gender divide, such as access, affordability, education, skills, and socio-cultural norms. It also explores the impact of digital transformation on gender equality and identifies key areas where policy interventions can make a significant difference. The report also outlines a number of current gaps and challenges that need to be addressed going forward:

1. **Access and Affordability:** Women are less likely to own smartphones or have access to the Internet, especially in developing regions, due to cost barriers.
2. **Education and Skills:** There is a significant gap in women's enrolment in STEM fields and their acquisition of digital skills, which hampers their ability to compete in the digital economy.
3. **Socio-Cultural Norms:** Gender biases and societal expectations limit women's participation in the digital world and their career advancement in tech industries.
4. **Employment and Entrepreneurship:** Women are underrepresented in ICT jobs, leadership positions, and innovative entrepreneurship. They also face challenges in accessing venture capital and other funding.
5. **Safety and Security:** Online harassment and cyber violence disproportionately affect women, discouraging their use of digital technologies.

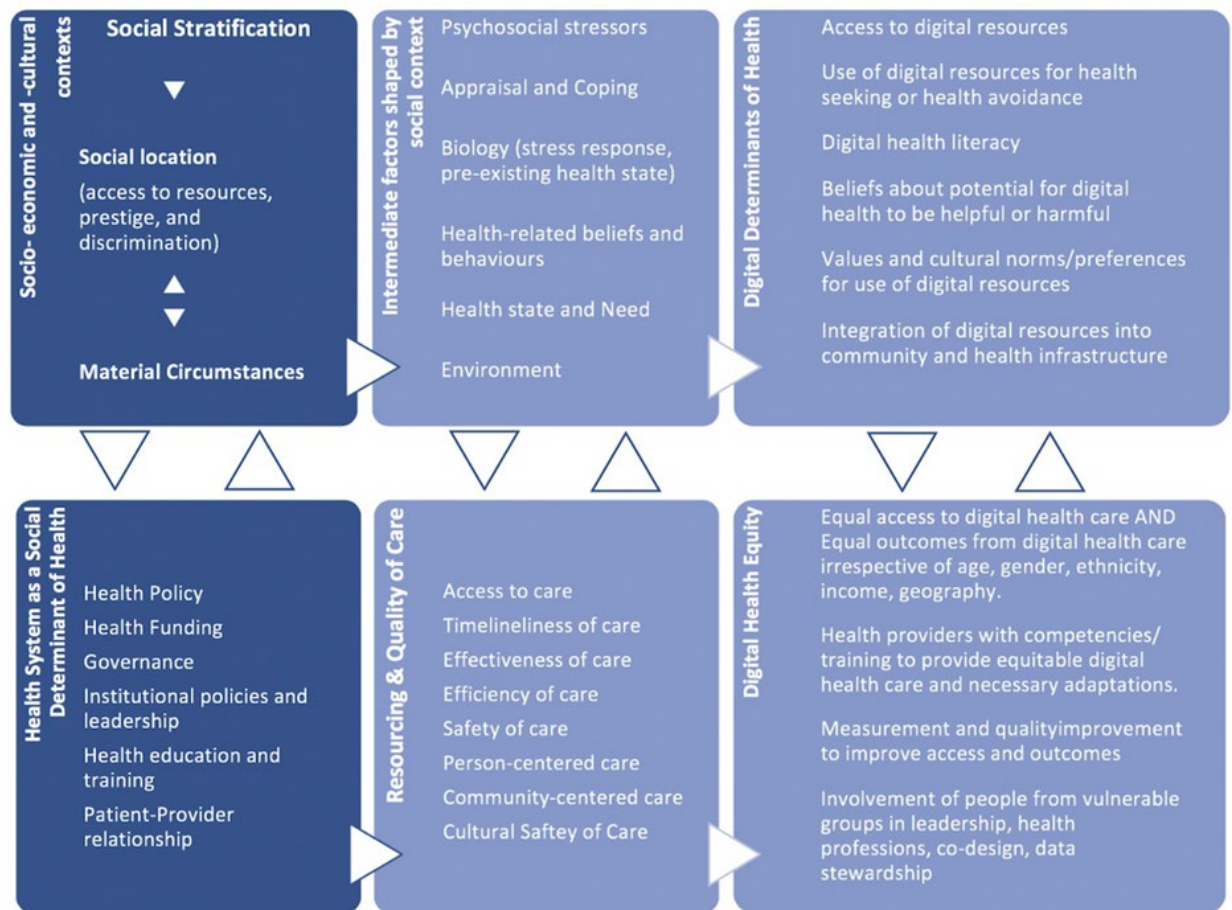
The report highlights the need for coordinated policy actions to address these gaps, including raising awareness, enhancing digital literacy, improving access and affordability of digital tools, and fostering an inclusive digital culture. It highlights the importance of evidence-based policymaking and the collection of gender-disaggregated data to monitor progress and adjust strategies accordingly.

3. Digital Health Equity Framework (DHEF)

Source: [Untitled \(jmir.org\)](#)

Digital Health Equity Framework (DHEF)¹³⁰ integrates health equity factors with digital determinants of health to address the comprehensive nature of health disparities. The DHEF acknowledges social stratification and intersectional factors like race, age, income, and geography, which influence health outcomes.

This framework goes beyond the health system's role as a social determinant of health by postulating that health equity encompasses digital health equity, thus involves going beyond individual factors to consider the entire health system. Digital determinants of health, such as access to resources and digital health literacy, interact with intermediate factors like psychosocial stressors, preexisting health conditions, and health-related beliefs and behaviors. The DHEF emphasizes the role of the health system as a determinant of health and advocates for equitable resourcing and quality of digital health care to reduce disparities. Taking an ecological perspective, the framework recognizes the influence of social, cultural, and economic contexts on individuals' use of technology and their overall health.







Further research is needed to quantify the assertions of the framework alongside investigations to assess the ways in which digital determinants of health may affect digital health equity (Crawford & Serhal, 2020). However, in the meantime, for those working in DH planning, programming and implementation, this framework highlights the many intersections that if not addressed adequately, can have the unintended consequences of compounding or furthering health inequities.

4. National Institute on Minority Health and Health Disparities Research Framework Expanded for Digital Health Equity (Richardson et al 2022)

Source: [A framework for digital health equity | npj Digital Medicine \(nature.com\)](#) ¹⁸²

This framework highlights the importance of addressing digital determinants of health (DDoH) such as access to technology, digital literacy, and community infrastructure, along with social determinants of health (SDoH) and thus holds relevance for those working to digitize health solutions that form part of the health and also broader public systems. The authors emphasize the need for interventions targeting community and societal-level determinants to effectively address health inequities (Figure 32). They also discuss the potential for intervention-generated inequalities in digital health and advocate for incorporating multi-level approaches and considering DDoHs in digital health interventions development and implementation to promote equity and impact.

Figure 31. Digital Health Equity Framework (Crawford & Serhal, 2020)

		Levels of Influence*			
		Individual	Interpersonal	Community	Societal
Domains of Influence (Over the Lifecourse)	Biological	Biological Vulnerability and Mechanisms	Caregiver–Child Interaction Family Microbiome	Community Illness Exposure Herd Immunity	Sanitation Immunization Pathogen Exposure
	Behavioral	Health Behaviors Coping Strategies	Family Functioning School/Work Functioning	Community Functioning	Policies and Laws
	Physical/Built Environment	Personal Environment	Household Environment School/Work Environment	Community Environment Community Resources	Societal Structure
	Digital Environment	Digital Literacy, Digital Self-Efficacy, Technology Access, Attitudes Towards Use	Implicit Tech Bias, Interdependence (e.g. shared devices), Patient-Tech-Clinician Relationship	Community Infrastructure, Healthcare Infrastructure, Community Tech Norms, Community Partners	Tech Policy, Data Standards, Design Standards, Social Norms & Ideologies, Algorithmic Bias
	Sociocultural Environment	Sociodemographics Limited English Cultural Identity Response to Discrimination	Social Networks Family/Peer Norms Interpersonal Discrimination	Community Norms Local Structural Discrimination	Social Norms Societal Structural Discrimination
	Health Care System	Insurance Coverage Health Literacy Treatment Preferences	Patient–Clinician Relationship Medical Decision-Making	Availability of Services Safety Net Services	Quality of Care Health Care Policies
Health Outcomes		 Individual Health	 Family/ Organizational Health	 Community Health	 Population Health

5. Why Gender Matters for Digital Health

Source: <https://health.bmz.de/studies/why-gender-matters-for-digital-health/>

Why Gender Matters for Digital Health is a technical brief published by GIZ ¹³¹, which contains recommendation specific to gender-sensitive programing in DH, i.e., it provides evidence-based guidance on how to address gender inequalities while developing digital health solutions. The paper describes how DH solutions can be used as tools to empower marginalized groups if designed in a manner that “recognizes and identifies existing gender specific differences, problems and inequalities and integrates them into strategies and measures.” Moreover, in describing some of the challenges and risks, including the digital gender divide, risks of violence and algorithmic biases, attention is drawn to areas that DH planners and implementers should be aware of.

The paper evaluates the gender-specific advantages and challenges associated with Digital Health Interventions (DHIs). It concludes with seven key recommendations aimed at enhancing gender sensitivity in digital health initiatives.:

1. Design with the (gendered) user
2. Understand the existing (gendered) ecosystem
3. Be (gender-disaggregated) data driven
4. Address (gendered) privacy and security needs
5. Use open standards, open source, open innovation
6. Include a gender objective and budget
7. Plan for gender and diversity in human resources

These recommendations are derived with reference to the **Principles for Digital Development** ⁸⁴.

6. Youth-centred digital health interventions

Source: <https://www.who.int/publications/i/item/9789240011717>

Released in 2021 by WHO's Department of Sexual and Reproductive Health and Research, this framework guides the planning, development, and implementation of digital solutions to promote better health among young people. It is intended for DHI designers, developers, implementers, researchers, and funders, and usable as a start-to-finish primer for newcomers in digital health as well a resource with specific insights for those already engaged in the field.

The guide is based on an underlying theoretical framework which was developed for the purpose of and is described in detail within this guide (Framework for youth-centred digital health interventions). It covers three phases of DH programing: planning, developing, and implementing. The first part covers topics including the conduct of landscape analyses, needs assessments, and human-centered design that respects cultural diversity and addresses the marketing of digital solutions and their evaluation.

The second part of the guide includes real-life implementation examples of digital initiatives designed specifically for young people and their perspectives on various aspects of DH programing, advice on good practice and pitfalls, as well case studies from leaders in the field.

Readers may find particularly useful that each section refers to additional tools and resources to inform the respective program stage. The document also provides key lesson's learned by funders to guide future investments and scale up of youth-centered digital health interventions.

7. UNICEF's GenderTech Toolkit: Building digital solutions for, with, and by girls

Source: [Innovation and Technology for Gender Equality | UNICEF East Asia and Pacific](#)

The UNICEF EAPRO Gender and Innovation team is developing a toolkit on best practices to support digital innovators, designers, and implementers who seek to address the particular considerations for girls as users of digital solutions. The aim is to ensure equal benefits for girls and young women in the digital sphere and to thereby bridge the gender digital divide. It is not DH specific, but can be applied in the context of DH. The toolkit comprises four distinct tools:

1. **How to build digital solutions for girls' digital realities:** This tool assists innovators in creating digital products that cater to the needs of both young women and girls, as well as male users. It offers eight best practices and includes practical steps, advice, and examples to guide teams in designing for female user journeys, considering their digital realities.
2. **How to co-create digital solutions with girls:** Recognizing the importance of co-creation, this guide emphasizes putting end users at the forefront of the design process. It particularly addresses the need for intentional efforts to include girls in co-creation activities, providing eight tips and best practices for teams to co-create digital solutions that meet both boys' and girls' needs.
3. **How to include girls in digital product user testing:** Targeted efforts are needed to include female users in design and product testing, an aspect that is often neglected in the process. This learning brief comprising 11 best practices, and guides teams to consider limitations related to e.g., movement, cultural practices, consent, and venue selection that may present challenges or render it difficult for female users to participate in activities for product design and user testing.

- 4. How to conduct consultations with girls:** Remote consultations for digital product development has become more commonly used since the COVID-19 pandemic given the need to shift to remote approaches. This guide supports teams in conducting remote consultations with girls on digital platforms when face-to-face contact is not feasible. It offers practical tips to address differences between in-person and online sessions, as well as challenges impacting girls' digital use and participation. While tailored for the needs of adolescent girls, some tips may benefit other groups engaged in remote consultations.

8. WHO-ITU Global standard for accessibility of telehealth services

Source: [9789240050464-eng.pdf \(who.int\)](#)

The “WHO-ITU Global Standard for Accessibility of Telehealth Services” was written to facilitate equitable access to telehealth services, particularly for individuals with disabilities. This guidance outlines technical requirements that telehealth platforms must meet to be accessible to persons with various impairments, thereby promoting inclusivity and addressing the digital divide.

The guidance is intended for governments, telehealth platform developers, healthcare providers, and civil society groups advocating for accessible health services. Governments can use it to create regulations ensuring that telehealth services are inclusive, while developers and healthcare providers can adopt these standards voluntarily to enhance the accessibility and usability of their platforms.

This guidance supports the integration of AI into digital health solutions by specifying accessibility features that must be incorporated into telehealth platforms, such as compatibility with assistive devices, real-time captioning, and text-to-speech functionalities. By addressing these requirements, telehealth platforms can leverage AI to provide more effective and user-friendly services, ensuring that all patients, regardless of their abilities, can benefit from digital health innovations.

9. WHO's Ethics and governance of artificial intelligence for health

Source: [9789240029200-eng.pdf \(who.int\)](#)

The WHO's “Ethics and Governance of Artificial Intelligence for Health” guidance document addresses the ethical, legal, and social challenges associated with integrating AI into health systems. This guidance has been designed to help ensure AI technologies enhance healthcare delivery while protecting human rights and promoting equity. Targeted primarily at ministries of health, this guidance is also relevant for technology developers, healthcare providers, regulatory agencies, and other stakeholders involved in AI for health.

The guidance emphasizes the need for collective action among all stakeholders to integrate ethical norms throughout the design, development, and deployment of AI technologies. It provides a structured approach to managing the ethical implications of AI, so that transparency, accountability, and inclusiveness can be ensured. By adopting these principles, stakeholders can mitigate risks such as exacerbating existing biases, compromising patient autonomy, and creating disparities in healthcare access.

Moreover, the document outlines practical advice for AI developers, ministries of health, and healthcare providers, aiming to foster responsible AI use that aligns with human rights and ethical standards. It supports the integration of AI into digital health solutions by promoting the development of interoperable and transparent AI systems that can be effectively regulated and monitored. This approach not only enhances the efficiency and effectiveness of healthcare delivery but also builds public trust in AI technologies.

Overall, the WHO guidance serves as a foundational framework to navigate the complexities of AI in health, ensuring that its implementation contributes to improved health outcomes globally while safeguarding ethical principles and human rights.

10. WHO's Ethics and governance of artificial intelligence for health – Guidance on large multi-modal models

Source: [Ethics and governance of artificial intelligence for health. Guidance on large multi-modal models \(who.int\)](#)

The “Guidance on Ethics and Governance of AI for Health: Large Multi-Modal Models” issued by WHO is essential for several reasons. Firstly, it addresses the integration of large multi-modal models (LMMs) into digital health solutions, which are advanced AI systems capable of handling diverse data types such as text, images, and biosensor data. This guidance is vital because it builds on the previous 2021 document “Ethics and Governance of Artificial Intelligence for Health,” expanding the scope to include the complex challenges and opportunities presented by LMMs.

The primary audience for this guidance includes governments, technology developers, healthcare providers, and policymakers. It is designed to assist these stakeholders in navigating the ethical, legal, and technical complexities of deploying AI in healthcare settings. By providing a framework for the responsible development and use of LMMs, the guidance helps ensure that these technologies are used in ways that promote human well-being, safety, and public interest while safeguarding autonomy, inclusiveness, and equity.

The importance of this guidance lies in its comprehensive approach to governance, emphasizing the need for transparency, accountability, and sustainability in AI applications. It outlines specific measures that can be taken at various stages of AI implementation—from development and provision to deployment—thereby supporting stakeholders in mitigating risks such as bias, misinformation, and privacy concerns. Additionally, it encourages the adoption of international standards and collaborative efforts to ensure that AI technologies contribute positively to global health outcomes.

By extending the principles and recommendations from the 2021 document, this guidance specifically addresses the unique challenges posed by LMMs, such as their potential for rapid, widespread adoption and the novel risks they introduce. It also highlights the need for robust international governance frameworks to manage these risks effectively and promote the equitable use of AI in health.

In summary, this guidance is a key resource for the ethical and effective integration of LMMs into digital health solutions, ensuring that advancements in AI contribute to improved health outcomes while upholding fundamental ethical principles and human rights.

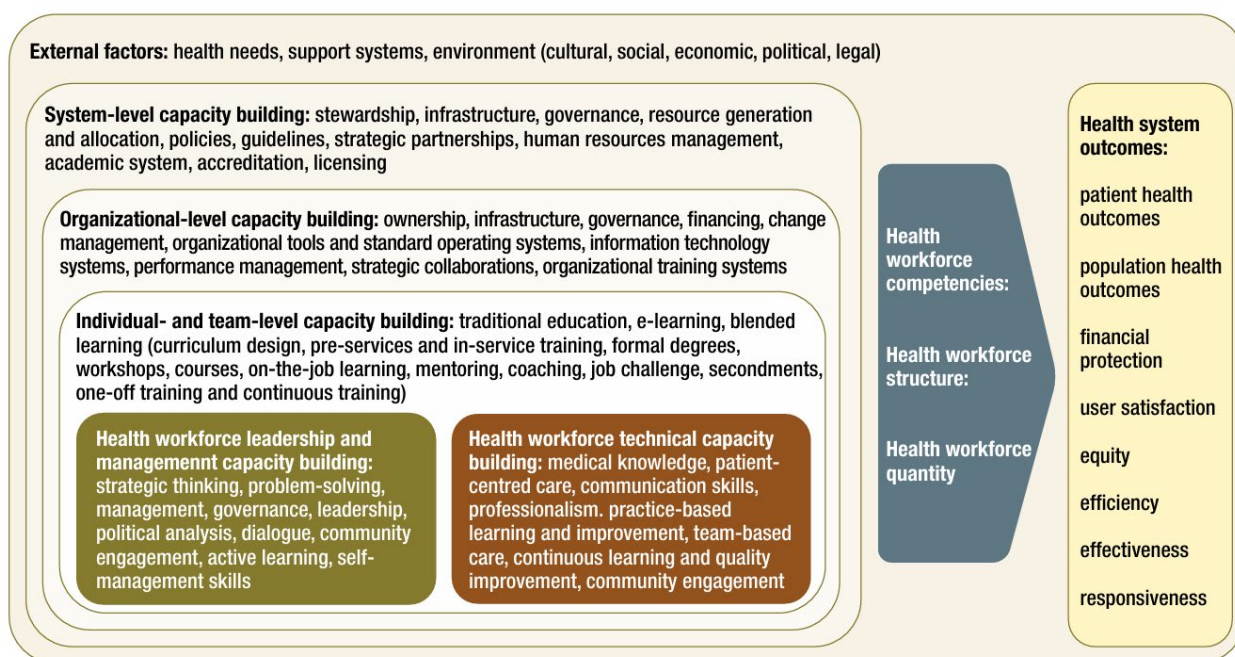
Annex 10. Capacity Strengthening

1. Digital education for building health workforce capacity

Source: <https://www.who.int/publications/i/item/9789240000476>

This guide addresses some fundamental questions about the use of digital modalities to deliver training for the HWs, including a presentation of the existing evidence, and the postulation of a framework for building health workforce capacity, based on external factors, system-level factors, institutional factors and individual factors required to embed ICT as foundations for transforming the health education system (Figure 33).

The guideline underscores the urgent need to address challenges in the global health workforce through digital education or e-learning, offering a framework for policy directives. Key thematic areas that are covered include increasing student enrollment, improving learning outcomes, reaching health workers in remote areas, strengthening educator competency, and enabling lifelong learning.



The document also highlights that the effectiveness of digital education to enhance competencies and satisfaction of health care workers is largely dependent on implementation methods. According to the guideline, factors influencing effectiveness include learning objectives, modalities (e.g., mobile phones, online education), delivery modes, instructional methods, assessment tools, learning pedagogies, study populations, and specific health topics.

The digital divide poses a significant implementation barrier, both within and between countries, limiting equal access to digital education. The report emphasizes the need for further research, rigorous evaluations, audits, investments, and collaborations to optimize digital education approaches.

A framework for building health workforce capacity through digital education identifies four levels of factors: external, system-level, institutional, and individual. External factors include the population's digital and health literacy, receptiveness to innovations, and governmental support. System-level factors involve long-term plans, policy incorporation, technical infrastructure, funding, and multisectoral collaboration. Institutional factors encompass organizational ownership, infrastructure, governance, financing, and individual beliefs within educational institutions. Individual factors relate to the attitudes and behaviors of administrators, teachers, students, and support staff.

Figure 33. Conceptual framework for the use of e-learning for building health workforce capacity in improving health system outcomes (Source: WHO, 2020 - adapted from Tudor et al. 2018)

Addressing these factors is essential for maximizing the potential of digital education and reducing the digital divide. The report combines scientific evidence, practical suggestions, and guidance to help stakeholders formulate effective approaches using digital tools for health workforce education and capacity building.

2. Empowering the health workforce – Strategies to make the most of the digital revolution¹³⁸

Source: <https://www.oecd.org/els/health-systems/Empowering-Health-Workforce-Digital-Revolution.pdf>

This strategy document, published by the OECD focuses on challenges regarding the process of digital transformation in the European region. Moreover, the resource elaborates on evidence regarding HWs barriers and enablers to engaging in the digital transformation and measures to better enable the HWF.

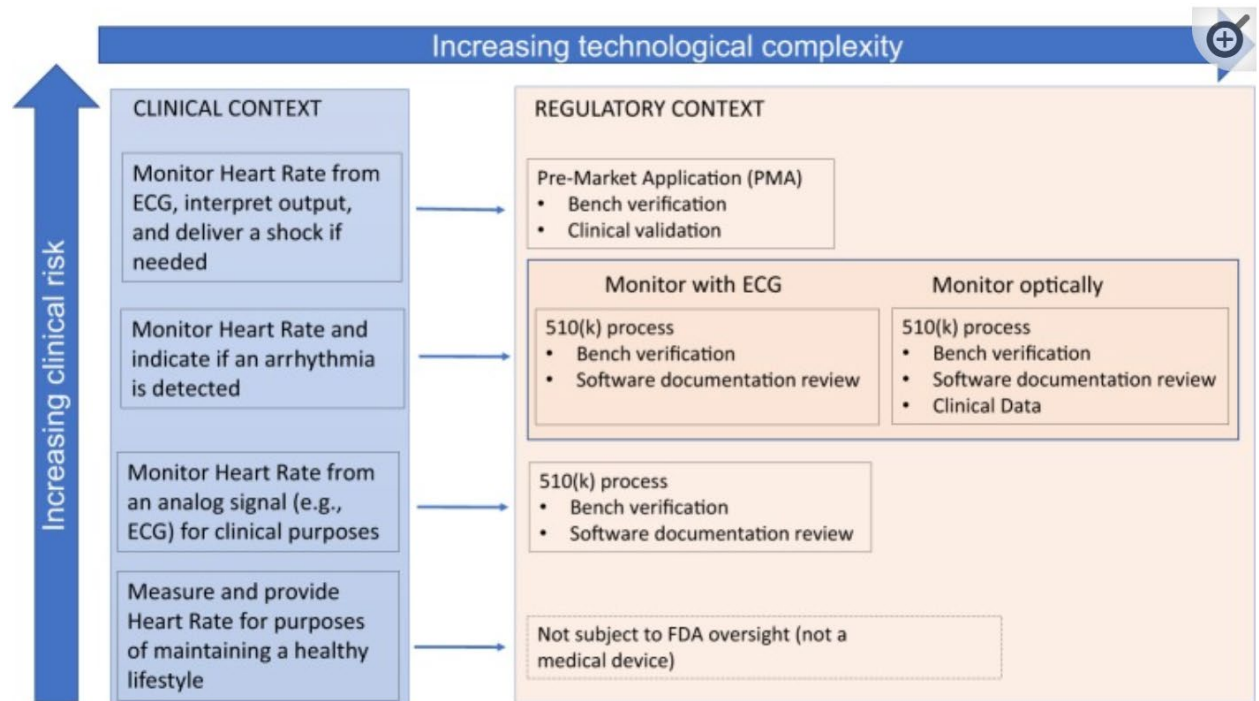
Whilst this document concerns the European region only, some of the learnings may still be applicable to contexts in LMICs to some extent. If anything, the lack of evidence from LMICs should inspire investigations on the topic which to directly inform and benefit the ongoing efforts of DH planners and implementers in the global south.

The resource documents that HWs in the European region employ digital tools in their day-to-day work, but they question their value, and even perceive them as hindrances. Opportunities for gaining further digital competencies were lacking and concerns were raised around existing systems from pre-digital times lacking alignment with the new technologies. Concerns about poor usability of tools and transparency, data privacy, and workflow disruption prevailed and placed undue burden on the HWs. On a positive note, HWs acknowledged the benefits of digital technologies but question their overall value. It was also noted that barriers, including social norms, gender inequality, and limited access to digital devices persist.

Even though these are the experiences of European HW, who find themselves in very different health care and infrastructural environments compared to their professional counterparts in LMICs, there are still some parallels that can be drawn for DH planners and implementers. This also applies to the recommendations from the report, which focus on merging digital skills into health education, improving user-friendliness, and fostering inclusivity in workforce planning. These measures aim to overcome barriers, empowering health workers and enhancing their role in the ongoing digital transformation.

Annex 11. Technical Standards for Developers

Four of the most commonly used standard references are: Evidence Standards Framework for Digital Health Technologies ⁴¹, ISO 82304-2 ¹⁸³, the Digital Health Applications (DiGA) ¹⁸⁴ and Food and Drug Administration’s process.



1. Evidence Standards Framework for Digital Health Technologies (ESF)

The National Institute for Health and Care Excellence (NICE) created the Evidence Standards Framework for Digital Health Technologies (ESF), in collaboration with NHS England, Public Health England and MedCity. Although ample research has been undertaken globally into what evidence should look like, this tiered approach is the most established methodology to date. The framework, which was recently updated, groups products into tiers based on their functionality, each of which outlines what developers must establish for their digital health technology.

2. ISO 82304-2

The ISO 82304-2 developed as a new European standard, was launched in 2021. The standard has been designed for self-certification by developers, enabling innovators to easily identify if they meet the standard. It has also been designed to inform assessment processes being developed with different accrediting bodies. For assurance, the guidance asks organizations to demonstrate different types of evidence, and indicates, based on some intended usages, that an observational study or a RCT is required.

Figure 34. Digital Health: A Path to Validation (Source: Simon C. Mathews, Michael J. McShea, Casey L. Hanley, Alan Ravitz, Alain B. Labrique & Adam B. Cohen)

3. The Digital Health Applications (DiGA) process

Created in Germany in 2020, the DiGA requires healthcare tools to meet specified criteria to be recognised under the Digital Healthcare Act as medical products. The certification requests data on evidence, with the requirement for a quantitative comparative study with the methodology adequate for the product. The DiGA also considers the maturity of digital health technologies in their product development cycle. Innovators can apply for the DiGA without an RCT and get temporary registration for a year, but they have to complete an RCT within this year. This gives lower maturity technologies time to gather evidence.

4. Food and Drug Administration (FDA)

In the United States of America, the FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of human and veterinary drugs, biological products, and medical devices. In 2020, FDA established the Digital Health Center of Excellence (DICE) with the objective of empowering stakeholders to promote health care through responsible and high-quality digital health innovations. The FDA's goal is to offer innovative regulatory approaches that ensure efficient oversight with minimal burden, all while upholding the FDA's standards for product safety and effectiveness. A list of guidance documents can be found online⁶⁹, offering clear insights into the FDA's regulations pertaining to digital health products.

Annex 12. Digitizing Immunization Programs

1. Guidance on the use of digital solution to support COVID-19 national deployment and vaccination plans

Source: <https://www.digitalhealthcoe.org/knowledgebase/guidance-on-the-use-of-digital-solutions-to-support-the-covid-19-national-deployment-and-vaccination-plans>

Introducing any new vaccine, especially to new target populations and using new delivery strategies, is challenging, especially in emergencies like during the COVID-19 pandemic. Thus, in 2021, the Digital Centre for Excellence¹¹ (DICE) initiative published this guidance on using digital solutions to support COVID-19 national deployment and vaccination plans (NDVPs). This guide, prepared by the COVAX working group, focuses on assessing the national context to identify facilitators and barriers for applying the most suitable and sustainable DH solutions. It also helps prioritize activities such as regulatory preparedness, coordination and planning, delivery strategies, supply chain management, human resource management, and monitoring.

Specifically, this guideline and included framework identify and target 12 pillars:

1. Regulatory preparedness
2. Planning and coordination
3. Costing and funding
4. Identification of the target populations
5. Vaccination delivery strategies
6. Preparation of supply chain and management of health care waste
7. Human resource management and training
8. Vaccine acceptance and uptake
9. Vaccine safety monitoring, management of adverse events following immunization and injection safety
10. Immunization monitoring systems
11. COVID-19 surveillance
12. Evaluation of COVID-19 vaccine introduction

For each pillar, DICE defines the activities to be prioritized, identifies potential bottlenecks, and suggests relevant digital interventions. By recommending DHIs, the guide provides an overview of the most promising evidence-based digital innovations and procedures that can be deployed at different stages of vaccine planning, distribution, and scaling up in LMICs, using the NDVP framework.

DICE recommends that the proposed actions in this guideline complement broader guidance and strategically reference the WHO Digital Implementation Investment Guide (DIIG) and UNICEF's digital health guidance for the COVID-19 response.

2. Primer on Digital Solutions for COVID-19 Vaccination Service Delivery

Source: https://www.usaid.gov/sites/default/files/2023-02/COVID-19_Primer_FINAL_CLEARED%20%28002%29.pdf

The COVID-19 Primer provides examples to planners, funders, and implementers looking to utilize digital health tools for pandemic and post-pandemic response.

¹¹A multi-agency initiative co-led by UNICEF and the World Health Organization, DICE provides coordinated technical assistance to national governments and partners on digital health interventions that address health priorities in the context of the COVID-19 pandemic, as well as post-pandemic health system needs.

This primer highlights a framework adapted from the World Bank for digital health use in vaccine delivery systems and suggests how the global health community and policymakers can utilize digital health tools and data to support vaccination efforts. Case studies in the annex show how countries adapted digital tools for COVID-19 immunization across ten identified use cases. The primer also demonstrates how data from one use case can be valuable for others and emphasizes the importance of strategic planning and interoperability for sustainable health systems.

The Primer highlights the importance to plan and implement digital health systems in keeping the following six considerations for digital health implementations:

1. Understand the enabling environment for digital health systems
2. Follow established processes and guidance when implementing digital health systems
3. Adapt and scale
4. Conduct thorough requirements gathering
5. Consider global goods and digital public goods
6. Leverage data exchange

By doing this, it identifies nine areas:

1. Microplanning
2. Supply chain
3. Cold chain
4. Records (including immunization registries)
5. Decision support
6. Vaccine certificates
7. Monitoring
8. Risk communication and engagement
9. Training and human resources for health

For each area, the primer presents the topic's value, necessary requirements, users and suggested digital tools. Additionally, it features a detailed case study for each area.

3. Guidance on developing a national deployment and vaccination plan for COVID-19 vaccines

Source: <https://www.who.int/publications/i/item/WHO-2019-nCoV-Vaccine-deployment-2021.1-eng>

This guidance is designed to guide national governments in developing and updating their National Deployment and Vaccination Plan for COVID-19 vaccines. It does **not** address ICT implementation but should be used as a supplement to **Guidance on the use of digital solution to support COVID-19 national deployment and vaccination plans**.

This guidance document provides a framework to help countries:

- Develop and update their National Deployment and Vaccination Plan for introducing COVID-19 vaccines.
- Design strategies for the deployment, implementation, and monitoring of COVID-19 vaccines.
- Ensure that the plan and related funding align with other national COVID-19 recovery and response plans.
- Fully integrate implementation into national governance mechanisms.

4. Digital Health Information Interventions for Immunization Demand Generation: A guide for selecting appropriate tools and technologies

Source: <https://www.gavi.org/programmes-impact/our-impact/digital-health-information-dhi>

GAVI, in collaboration with UNICEF, the WHO, the Vaccination Demand Hub, and HealthEnabled, provides recommendations for country immunization programs to identify appropriate digital health interventions that can enhance vaccine confidence and immunization demand.

The guide Digital Health Information Interventions for Immunization Demand Generation: A Guide for Selecting Appropriate Tools and Technologies presents a stepwise approach and considerations for selecting and planning digital technologies to improve immunization demand. It draws on evidence and early experiences from Gavi-supported countries. The guide examines digital solutions for immunization demand categorized as follows:

- **Supported with strong evidence:** Caregiver mobile phone reminders, conditional cash transfers, and social and behavior change mobile messages.
- **Promising:** Health worker eLearning and remote training, health worker job aids, alerts, and reminders.
- **Emerging/new:** Call centers, hotlines, automated information menus, social media engagement, service experience feedback, supportive supervision, coaching, peer support, and adverse events following immunization (AEFI) reporting, monitoring, and support.
- **Less likely to show success:** Vaccination-themed video games, unique project-specific apps, centrally-curated push messages, text-based SMS, and digital as a stand-alone intervention.

The guide illustrates how digital tools can support immunization uptake and demand, offering a roadmap for digital demand intervention planning and selection, along with key considerations for design, development, and implementation. It explores steps in the journey and relevant digital solutions.

Some suggested approaches for decision-makers and programs considering digital technologies to improve immunization demand include:

- Plan for scale.
- Engage the government from the beginning.
- Co-create with the intended audience.
- Work with local creative content developers.
- Negotiate with mobile network operators.
- Consider the source of data on digital access.
- Develop a marketing promotion strategy.
- Take advantage of opportunities for repeat exposure.
- Provide a link to physical services.

5. Digital Square's Electronic Immunization Registries (EIRs)

Source: https://media.path.org/documents/HSID_BID_LessonsLearned_EIR_br.pdf

This brief summarizes the approaches and interventions implemented in partnership with the governments of Tanzania and Zambia to improve immunization data quality and usage. Both countries adopted an Electronic Immunization Registry (EIR) as the primary tool among a suite of interventions to address

data-related challenges. Key stakeholders in both countries adapted common requirements to their specific contexts, embracing the core principles of open technology and interoperability.

Key recommendations based on lessons learned for developing EIR platforms include:

1. Establish clear system requirements and expectations with all key stakeholders at the beginning of the process.
2. Allow sufficient time for software development and testing.
3. Ensure a user-centered design methodology to provide timely testing and input throughout system development.
4. Build sustainability plans from the start by involving the Ministry of Health in all processes and engaging local technology partners as needed.
5. Pair the EIR tool with data use interventions to enhance understanding of the value of data at all government levels.
6. Use SMS birth notifications selectively and where appropriate.
7. Remain flexible throughout the process, adjusting strategies as new lessons are learned.
8. Collaborate with the government and partners to understand the current landscape

Concerning EIRs, also Digital Square has developed insightful briefs available here: <https://digitalsquare.org/resourcesrepository/eirlandscape>

Their report, **“Electronic Immunization Registries in Low- and Middle-Income Countries”** built on lessons from previous EIR experiences in LMIC contexts provides system design recommendations. It also summarizes how registries can impact service delivery and outcomes. The three objectives of this report are to:

- Identify where EIRs have been implemented in LMICs.
- Summarize how and why EIRs can add value to vaccination programs.
- Provide recommendations on the functional and nonfunctional requirements for EIR system design.

The report offers stakeholders guidance on whether to introduce an EIR and how to design system requirements.

Additional briefs from Digital Square include:

- **“How EIRs Can Support Immunization Delivery During COVID and Beyond”**: This brief explores the benefits of electronic immunization registries in the context of the COVID-19 pandemic.
- **“Considerations for EIR Design”**: This brief examines functional and non-functional requirements, as well as lessons learned related to EIR design.
- **“EIR Recommendations for Country Stakeholders”**: This brief provides recommended steps for decision-makers considering the implementation of a new EIR. These recommendations can also be applied when scaling or improving an existing EIR.

6. Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation

Source: <https://iris.paho.org/handle/10665.2/34865>

In 2020, PAHO published a comprehensive guide to help EPI managers plan, develop, implement, and evaluate EIRs. This guide draws extensively on experiences from the Region of the Americas.

The main objectives of this document are:

- **Knowledge Generation:** To provide immunization program managers at the national and subnational levels with knowledge related to information systems and immunization registries.
- **Support for Teams and Experts:** To offer teams, EPI managers, and health information systems experts relevant background and experiences for developing, implementing, maintaining, monitoring, and evaluating EIR systems, aiding in their implementation planning.
- **Recommendations:** To provide technical, functional, and operational recommendations for discussing and analyzing the standard requirements needed for developing and implementing EIRs in the Region of the Americas and other regions.
- **Documentation and Sharing:** To serve as a platform for documenting and sharing lessons learned and successful experiences in EIR implementation.

The document is structured into three major sections:

1. **Background:** An overview of EIR-related information.
2. **EIR Planning and Design:** Guidance on the planning and design processes.
3. **EIR Development and Implementation:** Insights into the relevant processes and their structure.

This guide also covers topics not extensively discussed in other guidelines, such as cost estimation, data quality monitoring and evaluation, and ethical obligations. It also proposes criteria for selecting the appropriate digital solution.

Additionally, each chapter is supported by a literature review of EIR requirements and summarize the experiences of countries in the Region of the Americas and other regions that have developed or are implementing EIRs.

7. Digital Square's Digital Applications and Tools Across an Epidemic Curve

Source: <https://digitalsquare.org/resourcesrepository/datec>

This strategic guide developed by Digital Square and GIZ provides a framework for selecting the best digital tools for various stages of an outbreak. It emphasizes integrating existing digital technologies into epidemic responses. Adapting existing tools to different phases of a response can be the most strategic use of digital interventions, provided they are paired with a systematic approach to adapt, utilize, and scale data from deployments.

The framework identifies 13 critical use cases and provides a visual mapping of these tools across different epidemic phases. It offers practical guidance on adapting existing digital tools for rapid deployment and effective management during health crises, aiming to improve response efficiency and data-driven decision-making.

The guide also focuses on:

- Digital tools to support a well-functioning health system
- Rebuilding and strengthening health systems
- Interoperability
- Routine surveillance
- Utilization of outbreak control tools
- Investor coordination

8. Considerations for integrating COVID-19 vaccination into immunization programmes and primary health care for 2022 and beyond

Source: <https://www.who.int/publications/i/item/9789240064454>

This guide does not focus on digital solutions but provides a comprehensive strategy for incorporating COVID-19 vaccination into existing health systems, particularly primary health care. It is designed for public health planners and immunization program managers, outlining principles, benefits, risks, and operational steps for integration, drawing on experiences from various countries. Furthermore, this guide emphasizes a strategic, evidence-based approach to managing the pandemic while maintaining essential health services.

Specifically, the guide:

- Provides principles for integrating COVID-19 vaccination into immunization programs.
- Offers an overview of the benefits and risks of integrating COVID-19 vaccination.
- Summarizes country experiences with integration and identifies approaches for integrated service delivery.
- Proposes key steps to guide countries on operationalizing the integration of COVID-19 vaccination at national and subnational levels: assessing readiness, developing a plan, and identifying short-term capacities and investment needs.
- Prioritizes a research agenda to generate further evidence on best practices for integrating COVID-19 vaccination

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