Handbook

Digital Health Platform: Building a Digital Information Infrastructure (Infostructure) for Health

World Health Organization

ITU

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Handbook

Acknowledgements

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Foreword

Welcome to *Digital Health Platform Handbook*, a new toolkit designed to help countries create and implement a digital health platform (DHP) to serve as the underlying infrastructure for an interoperable and integrated national digital health system.

The COVID-19 global health emergency has dramatically underlined the importance of harnessing the full power of digital technologies to support public health programmes and outreach. Digital health platforms provide a vital central hub, linking together disparate and unconnected systems and applications, enabling faster, more efficient and more reliable information exchange, and promoting increased access to health data across a range of devices.

Strong digital health systems can be instrumental in supporting progress towards the Sustainable Development Goals (SDGs) and the implementation of the Digital Health Resolution adopted by WHO's World Health Assembly in 2018.

But while a DHP primarily advances SDG 3 focused on health, this 'platform concept' can also be effectively applied to ICT systems supporting other SDGs. Taking a 'whole of government approach' and thinking holistically and flexibly about digital systems design is increasingly essential, given the limited resources – financial or otherwise – available for public sector digital development in many countries. A 'platform concept' design approach also makes sense from a technical standpoint: re-using platform components improves system efficiency, increases return on investment, and provides a coherent and consistent environment that promotes seamless interoperability and allows software developers to focus efforts on ongoing improvements and innovations.

The publication of this new toolkit is particularly timely in the context of the adoption of WHO's *Global Strategy on Digital Health 2020-2024*. This strategy outlines the overarching vision, core principles and strategic objectives that should guide national digital health initiatives. This new *Digital Health Platform Handbook* complements that top-level vision, providing a detailed walkthrough of how to best design and implement appropriate technical solutions in the most cost-efficient and sustainable way.

The *Digital Health Platform Handbook* represents the culmination of efforts by various organizations and experts from across the health and ICT sectors. It also builds on and supplements other important digital health resources, including the *National eHealth Strategy Toolkit* and the WHO *Planning, Costing Guide for Digital Interventions for Health Programmes*. Taken together, these materials constitute a comprehensive approach for harnessing ICT applications and digital technologies to strengthen health systems and, ultimately, deliver improved health and well-being to all.

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Executive Summary

The Digital Health Platform Handbook [DHPH] aims to assist countries with the advancement of their national digital health system, specifically through the use of a digital health platform, or DHP. This digital platform provides the underlying foundation for the various digital health applications and systems used to support health and care services. It enables individual applications and systems to interoperate and work together in an integrated manner.

The DHPH is primarily designed for health sector planners and enterprise architects who are responsible for the design of a national digital health system, regardless of the country's level of digital development. Software developers and solutions providers should also read this handbook, to understand how their efforts can integrate with and benefit from the digital health platform. Moreover, since a DHP will improve how health applications and systems work together and accelerate innovation, countries at varying levels of digital health maturity will benefit from this handbook. Countries with relatively advanced digital health systems will learn how to better integrate and optimize their assets. Countries in earlier stages of digital maturity will learn how to lay down an initial foundation on which all future innovations will be built.

Working behind the scenes rather than directly with users, the DHP ties applications together through a standards-based, information infrastructure, called the 'infostructure', that consists of an integrated set of common and reusable components. DHP components are core technology services required by many (or even all) applications running in your digital health system, such as registries, identity authentication, or data repositories.

The concept of the DHP emerged from a recognition that most digital health progress thus far has arrived in the form of individual applications and information systems. While they do successfully accomplish specific tasks, these digital tools often operate independently from each other. They collect, manage, or process data within a siloed, 'vertical' environment, resulting in islands of isolated information that have yet to generate efficiency and improve health outcomes as hoped. Some of the problems generated by these siloed digital health applications and systems include:

- poor data management due to a lack of integrated applications and systems
- increased burden on health workers from system redundancies
- constraints to innovation because software developers spend time writing redundant code in individual applications that could be shared as common core technologies
- higher long-term project and legacy costs because resources are not pooled for core technology creation and integration, resulting in a need for re-engineering later on
- distraction from building a national infrastructure that connects multiple systems together
- absence of system-wide information and communication technology impacts due to the narrow focus of investments.

In examining these problems, a key lesson learned is the importance of taking a holistic view when developing a digital health system. A system-wide approach to application and architecture design that emphasizes the development of an integrated and interoperable whole is far better than a piecemeal approach that results in fragmented and isolated digital health tools.

The DHP's common infostructure serves as the foundation for a cohesive system. Its integration capabilities and use of core, reusable components tie together standalone applications and systems; in this manner, the DHP provides the 'horizontal' foundation for the 'vertical' applications.

This use of common components also streamlines your digital health system and makes your investments more cost effective. Instead of investing and re-investing in the development and deployment of application components that can be provided more efficiently by a DHP, your digital health budgets can focus on innovation and ongoing sustainability. Moreover, when scaling up existing and future applications within the underlying DHP infostructure, your return on investment will be greater.

Taking a holistic approach to digital health system building can also impact care delivery and health system operations. By focusing on interoperability amongst all of the digital health applications used by patients and facilities alike, information exchange can be improved across your system. A DHP facilitates this interoperability, enabling applications to exchange information even though they are not directly integrated. Importantly, this information exchange is standardized, so the data transmitted via the DHP are consistent and understandable. Better data access and quality improve operations throughout the health system. Having abundant and reliable data on hand can drive better decision-making in patient care, staff training and management, resource allocation, and policy-making. It can also help health planners leverage the latest technology trends such as big data, artificial intelligence, or the Internet of Things. As a result, your country's health goals can be achieved more efficiently, more effectively, and with reduced risk.

Building this cohesive digital health system requires multiple tasks and DHP development phases. It builds upon a country's national eHealth Strategy, or similar digital health roadmap, and employs a requirements gathering process to determine which applications and platform components are needed to realize national objectives. An important part of this process is identifying the technology components that are common to multiple applications in your system design; these generic, reusable components will form the basis of your DHP. You will also recognize which infostructure requirements can be satisfied by repurposing or modifying existing digital health assets, and which will demand the development or procurement of new components and applications. Decisions will need to be made about overall design principles, standards for ensuring interoperability, software type and licensing, and implementation paths. You will also need to formulate an operations plan for governing the DHP infostructure as well as activities to promote uptake and innovations that will be built on the new platform—essential steps for successful implementation and ongoing sustainability.

Ultimately, this process should produce a few key outputs for moving forward with DHP infostructure implementation:

- a set of engaged stakeholders for guiding DHP design and promoting its use;
- a high-level blueprint of the DHP infostructure, diagramming the platform's common components and how these will work with the applications;
- a national eHealth standards framework for defining the standards your national system will use to promote interoperability;
- a set of requests for proposals describing the DHP's various functional and technical requirements needed by system integrators and solutions providers to build or modify digital health applications and DHP components;
- an implementation roadmap for monitoring DHP infostructure rollout and defining the way forward;
- a governance framework detailing leadership and staffing responsibilities for overseeing, supporting, testing, and maintaining the DHP over time.

The DHPH helps you undertake this development process. It shows you how to outline your initial DHP infostructure architecture and requirements, leading you through the various design and implementation questions that you need to consider. At each step, relevant stakeholders are identified as well as resources for furthering the reader's knowledge. The DHPH also offers a variety of tools to assist with DHP design, including a mini-catalogue of common, core components, a breakdown of different types of standards and their uses, and templates for creating user stories and mapping components and standards to them. Finally, the DHPH illustrates the DHP development process with examples of countries that have already implemented a digital health platform or have laid the foundation for doing so. It is hoped that your country will soon join this growing group. The digital health community looks forward to learning about the cohesive infostructure and digital health system you build.

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Section 1 – Introduction

About the Digital Health Platform Handbook

Welcome to the Digital Health Platform Handbook! This resource, called the DHPH, serves as a handbook for implementing a Digital Health Platform [DHP], the underlying information infrastructure, or 'infostructure'[1], for digital health systems that support the delivery of a broad range of public health and care services. Interconnecting a country's health system and digital health system (so they are not fragmented or merely a collection of individual parts) will ensure greater systems performance and impact.

This guide focuses on the practical implementation of a platform to support the standards and interoperability component of a national eHealth Strategy. Building this platform will accelerate the development of the services and applications component of a comprehensive, national strategy for digital health.

A well-designed DHP will improve health systems by ensuring that existing digital health applications work together more effectively and by accelerating the development of new applications and tools. The promise of such digital health advancements is to significantly improve the availability and quality of information to inform decision-making—by health authorities, by service delivery organizations, and by individual clinicians and patients of health and care services. It is hoped that the use of a digital health platform will accelerate the growth in public health service delivery, ultimately leading to improved health outcomes.

DHPH role in building a strong digital health system

Designing and implementing a DHP is just one component of a digital health system (and a digital health system is just one part of the larger health system). The process to build and sustain a strong and functional system is made up of four phases:

1) strategic planning
2) requirements analysis and digital intervention identification
3) platform design
4) implementation, maintenance, and scale-up.[2]

Given the dynamic nature of health care and technology, this process is frequently non-linear and should be approached iteratively. As such, phases 2 and 3 are often carried out at the same time, with some steps repeated as more is learned about the digital health system's needs and

[1] The term digital health 'infostructure' refers to the development and adoption of modern information and communication technology [ICT] systems to help various health system stakeholders interact and make informed decisions about their own health, the health of others, and the health system. Included amongst these stakeholders are the general public, patients, and caregivers, as well as health workers, health managers, health policy-makers and health researchers. Adapted from: Government of Canada (2004). Canada's health infostructure. See: www.canada.ca/en/health-canada/services/health-care-system/ehealth/canada-health-infostructure.html (accessed 27 May 2020),

[2] https://digitalsquare.org/global-goods-guidebook

constraints. The specific steps taken throughout each phase, as well as the overall process, should be ordered according to a country's unique context. Implementers are expected to return to earlier steps as their national digital health system develops and evolves over time.

Table 1 lists several complementary and supporting resources designed to help successfully create and maintain an impactful digital health system.

Table 1: Building a digital health system: phases, activities, and resources

Phase	Activities	Resources (All websites accessed 27 May 2020)
Strategic Planning	Develop a national digital health strategy outlining overarching needs, desired activities, and outcomes.	*National eHealth Strategy Toolkit* (World Health Organization [WHO]/ International Telecommunication Union [ITU]) www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf *Digital Health: A Call for Government Leadership* (Broadband Commission/ITU/United Nations Educational, Scientific, and Cultural Organization [UNESCO]) www.broadbandcommission.org/Documents/publications/WorkingGroupHealthReport-2017.pdf
	Formulate a digital health investment plan to support the national strategy.	*Data Use Partnership Investment Road Map Process* (PATH) www.path.org/publications/detail.php?i=2734
Requirements Analysis and Digital Interventions Identification *(business architecture design)*	Conduct an inventory of existing or previously used software applications, systems, and solutions to better understand: the functional requirements needed in new or improved applications and systems where reuse and interoperability can be leveraged.	*Digital Health Atlas* (WHO) digitalhealthatlas.org/landing *Digital Health Platform Handbook* (this document)
	Select and adapt digital health interventions for improving health system business processes and addressing specific health system challenges.	*WHO Digital Implementation Investment Guide (DIIG): Integrating Digital Interventions into Health Programmes* (WHO/PATH) https://www.who.int/publications-detail/who-digital-implementation-investment-guide

Phase	Activities	Resources (All websites accessed 27 May 2020)
		mHealth for NCD "Be Healthy, Be Mobile" handbooks (WHO/ITU) https://www.itu.int/en/ITU-D/ICT-Applications/Pages/handbooks.aspx *Human Centered Design 4 Health* United Nations Children's Fund [UNICEF] https://www.hcd4health.org/resources
Digital Health Platform Design *(information architecture design)*	Design the digital health platform.	*Digital Health Platform Handbook* (this document)
	Define validated standards to use in digital systems.	See example of: *South African National Health Normative Standards Framework for Interoperability in eHealth* (Government of Republic of South Africa) www.gov.za/documents/national-health-act-national-health-normative-standards-framework-interoperability-ehealth
Implementation, Maintenance, and Scale Up	Implement digital health solutions and/or platform.	*Digital Health Platform Handbook* (this document) Sample resources for specific areas of digital health solutions implementation: *Mobile Solutions for Malaria Elimination Surveillance Systems: A Roadmap* (VitalWave) vitalwave.com/wp-content/uploads/2017/08/VITALWAVE-BMGF-Mobile-Tools-for-Malaria-Surveillance-Roadmap.pdf

Phase	Activities	Resources (All websites accessed 27 May 2020)
	Foster data-driven decision-making within the overall health system.	*Defining and Building a Data Use Culture* (PATH) www.path.org/resources/defining-and-building-a-data-use-culture/ *MEASURE Evaluation's data demand and use resources* www.measureevaluation.org/our-work/data-demand-and-use *Bridging Real-Time Data and Adaptive Management: Ten Lessons for Policy Makers and Practitioners* (USAID) www.usaid.gov/digital-development/rtd4am/policy-design-lessons
	Maintain, sustain, and scale digital health solutions and systems.	*MAPS Toolkit: mHealth Assessment and Planning for Scale* (WHO) www.who.int/reproductivehealth/topics/mhealth/maps-toolkit/en/ *Journey to Scale: Moving Together Past Digital Health Pilots* (PATH) www.path.org/resources/the-journey-to-scale-moving-together-past-digital-health-pilots/ *Beyond Scale: How to Make Your Digital Development Program Sustainable* (Digital Impact Alliance [DIAL]) www.digitalimpactalliance.org/research/beyond-scale-how-to-make-your-digital-development-program-sustainable/

Who should read the DHPH?

The intended readers of the DHPH are people with accountability for, who participate in, or who enable the healthcare system. Readers may include:

- health sector planners, particularly those with responsibility for digital health, who want to lead the implementation of a digital health platform;
- health sector enterprise architects responsible for the design of a digital health platform, who want to understand how to successfully develop a usable platform;

- ICT sector providers of digital health solutions and technology, such as software developers and solutions providers, who want to understand how their work fits into the digital health platform;
- health sector institutions that use digital health applications and systems, who want to understand how a digital health platform can better facilitate their work.

It is hoped that this handbook empowers planners, ICT architects, and solutions providers with the confidence to begin designing and implementing their own digital health platforms or applications and systems for a country's DHP. It is also meant to help software developers of digital health applications and systems effectively position the value proposition of their software in the context of a DHP.

Overall learning objectives of the Digital Health Platform Handbook

The DHPH aims to:

- define the digital health platform and how its individual components combine into an interoperable whole;
- explain why a digital health platform should be implemented and who will benefit;
- show the steps and key considerations involved in the design of a digital health platform;
- highlight ways to approach DHP implementation, as well as important factors that can help ensure sustainability and scale up in the future;
- explain how to develop a governance framework to effectively oversee and operationalize DHP implementation, in order to maximize its impact on digital health and health outcomes;
- share examples of countries' accomplishments in designing and implementing a digital health platform or interoperable components that can be leveraged for a national DHP in the future.

Note that the DHPH is not intended to be an exhaustive or comprehensive source of all information necessary to build a digital health system. It tries not to duplicate valuable resources and detail available elsewhere. Rather, it directs audiences to where those resources can be found, and provides an understanding of how those resources can be used to accelerate digital health.

Key terms and definitions

Digital health

Digital health is the application of information and communication technology in the health sector to help manage diseases and support wellness through data, images, and other forms of digital information.

Digital health system

A digital health system comprises all of the digital technology used to support the operations of the overall health system. Included in this system are software applications and systems, devices and hardware, technologies, and the underlying information infrastructure.

Digital health applications

This term describes the software, ICT systems, and digital tools used in the health sector, such as a laboratory information system or an interactive messaging application ('app'). Digital health applications can connect to and exchange data through the digital health platform.

Digital health platform [DHP]

The digital health platform is a common digital health information infrastructure ('infostructure') that digital health applications and systems are built upon in order to deliver digital health services for supporting healthcare delivery in a consistent and integrated manner. The infostructure is an integrated set of common and reusable components in the support of a diverse set of digital health applications and systems. It consists of software solutions and shared information resources to support integration, data definitions, and messaging standards for interoperability. By supporting interoperability, the underlying infostructure ties different components and external applications together into a streamlined and cohesive whole.

DHP component

A DHP component is an individual functionality internal to the digital health platform that allows external digital health applications and systems to provide and access information. Designed to be reusable, the DHP components are digital services or resources that the external applications link to and share on the platform, even though these applications and systems are not directly integrated with each other. Examples include patient and health facility registry services, terminology services, authentication services, and workflow support services.

Health system business process

A business process is a day-to-day activity (or set of activities) that an organization or entity in the health system carries out to achieve its function. For example, a laboratory's business processes include diagnostic orders management, specimen tracking, and diagnostic results communication.

Digital health intervention [DHI]

A digital health intervention is a discrete functionality of digital technology designed to improve health system processes in order to achieve health sector objectives. Designed for patients, healthcare providers, health system or resource managers, and data services, these interventions aim to improve specific health system business processes, helping strengthen the overall health system. For example, a laboratory may improve its business processes through digital health interventions that capture diagnostic results from digital devices, electronically transmit and track diagnostic orders, record results in a patient's electronic health record [EHR], and alert health workers and patients of the availability of the results.

Health journeys

In this handbook, health journeys are used as a form of user stories to identify and describe the functional requirements of the DHP. Health journeys illustrate the uses of the DHP by its beneficiaries (or things) who interact in the health sector: patients, health workers, administrators, and even health commodities. The health journey narrative details the specific tasks within the business process, using a specific health system actor's story and setting as the context.

Digital health moments

A digital health moment is the pain point in a health journey where gaps and inefficiencies in information flow or access occurs. Digital health interventions–ideally integrated within a DHP–are applied to these pain points, providing digital functionality that can make the business process more efficient, more useful, and higher quality. By applying DHIs to these moments, better health system performance can result.

Interoperability

Interoperability is the ability of systems, applications, and devices to communicate and share data with each other. This communication occurs 'in an unambiguous and predictable manner to exchange data accurately, effectively and consistently; and to understand and use the information that is exchanged[3]. A applications and systems, including those that are technically different and managed by different organizations. This interoperability allows digital health application users to manage and utilize information that supports health outcomes and health organization performance.

Enterprise architecture

Enterprise architecture frameworks or methodologies are blueprints of information systems, commonly used to help ICT implementers design increasingly complex systems to support the workflow and roles of people in a large enterprise such as a health system. When designing a DHP, enterprise architecture is used to describe how the DHP components will interact with each other, and specify how the DHP will interact with external applications and systems.

Open standards

Standards are a set of specifications and protocols used in product development that are usually established, approved, and published by an organization or body that is an authority in a particular field[4]. They 'ensure the reliability of the materials, products, methods, and/or services people use every day[5]. Product functionality, safety, compatibility, and interoperability can be improved by the application of validated standards. In ICT, common uses of standards include the definition of data exchange formats, communications protocols, programming languages, and hardware technologies.

Standards can be open or proprietary. ITU promotes the use of open standards, which it defines as:

- publicly available and intended for widespread adoption
- sufficiently detailed to permit the development and integration of various interoperable products and services
- developed, approved, and maintained via a collaborative and consensus-driven process.

[3] ITU (2016). Recommendation ITU-T H.810: Interoperability design guidelines for personal connected health systems. See: www.itu.int/rec/T-REC-H.810-201607-I/en/

[4] Note that some standards can be de facto, meaning the industry has adopted these protocols as accepted practice even if an official standards organization has not officially validated and published them.

[5] IEEE-SA (2011). What are standards? Why are they important? See: beyondstandards.ieee.org/general-news/what-are-standards-why-are-they-important/

Note on certain terminology used

In this handbook, the term 'country' is used to describe where the DHP will be implemented and the entity that is responsible for overseeing its design and implementation. While it is hoped that a DHP infostructure will be developed on a national level, we recognize that DHP development may initially occur at the regional, provincial/state, or local level. Infostructure development may also be driven by organizations in both the public and private health sectors, though we expect this work to follow national strategic goals and plans for digital health. Therefore, while reading this handbook, you should interpret the term 'country' in the manner appropriate to your context.

Also, the term 'patient' is used to describe a recipient of health services and care, even though the term 'client' is also widely used, and there are different meanings associated with each term. Since 'client' is used widely in computing as well as health care, we chose 'patient' for clarity's sake.

Overview of DHPH content

In Section 2 – Digital Health Platform Overview, we describe what a DHP is, why it is needed, and how it benefits people who use, work, and create technology solutions for the health sector.

In Section 3 – Overview of Digital Health Platform Development, we outline the DHP development process, highlighting how platform design derives from overall health system goals and requires consideration of the external applications that will connect to the DHP. It describes how national eHealth Strategies guide the process, summarizes the key questions and deliverables associated with each building phase, and points out how the subsequent sections of this handbook correspond with each phase. Finally, this section also provides important guidance on how to approach the DHP development process.

Section 4 – Context Analysis describes how to assess the context in which the DHP will be built and operate. It describes what is important to analyse and which tools and resources will help you gain a clear understanding of your country's digital health ecosystem. Included in this discussion is a description of how health business process mapping helps identify the digital health interventions needed to improve your health system. Results from this section will help you formulate the use cases, called 'health journeys', that will guide DHP design. Finally, this section also introduces stakeholder engagement, a key activity that will occur throughout all stages of DHP development, from its inception in the design phase through implementation and continued use by institutionalization.

In Section 5 – DHP Design, we explain the different steps involved in planning the DHP architecture, from design principles to the assignment of standards to the DHP components you will build or leverage from existing applications and systems. This section also explains how to use health journeys and digital health moments to select DHP components and the relevant standards to ensure interoperability.

Section 6 – DHP Implementation explains how to implement the platform design defined by the previous steps. We discuss implementation pathways and considerations, and issues concerning the development or acquisition of the software for the DHP components. This section also focuses on two tasks that are essential for implementation success and the ongoing sustainability of the digital health platform: policy and governance support and platform institutionalization within your country and its larger digital ecosystem.

Section 2 – Digital Health Platform Overview

Why is a DHP needed?

In the past decade, the public health sector has seen a tremendous increase in the use of digital health, the application of ICT to public health and care service delivery through data, images, and other forms of digital information. Digital health information systems can be found throughout a country's health infrastructure in the form of web-based services, mobile devices, or more conventional software applications and systems.

Digital health systems can help manage and improve the quality of care in a broad range of settings, from community clinics to long-term care facilities. These systems support essential public health functions, such as gathering surveillance data during disease outbreaks, serving as repositories for vital statistics and population health data, and tracking service delivery data to aid resource and health commodity planning. Digital health also helps health workers follow the best-practice guidelines and algorithms established for delivering high-quality care.

In addition to these service delivery functions, digital health can support essential operations in every health system, namely administering finances, managing and developing human resources, and procuring and maintaining commodities and equipment. Digital health systems can also support the management of payments and insurance, an important method for helping decrease administrative charges by providers and the risk of fraud FIGURE

For the individual user, mobile computing technologies, such as cell phones, tablets, and personal health devices [PHDs], have spawned the rapid growth of specific-purpose software applications ['apps'] that provide or track health information. With these apps, patients receive messages about health education and reminders of appointments and medication schedules, clinicians engage in telemedicine, and users monitor health indicators, such as blood pressure and exercise data. These health apps are moving the point of care out of the doctor's office and to the patients themselves.

With the adoption of these technologies offered by digital health systems, a tremendous volume of digitized information is produced. In principle, such data can be made available, searched, and analysed to support informed decision-making at all levels. Unfortunately, easy access to the data is constrained by the design of many existing systems, resulting in islands of isolated information that have yet to generate efficiency and improve health outcomes as hoped.

Current infrastructure challenges in implementing digital health

Siloed digital health systems have emerged because most digital health implementation projects occurred independently. Different information systems have been deployed within the same country or even within hospitals under the same umbrella organization. In many low-resource settings, philanthropic organizations have funded vertical programmes that

implemented one-off information systems to solve a single problem or to support a specific health area such as human immunodeficiency virus [HIV] prevention, care, and treatment. Many of these systems were not designed based on an underlying architecture that ties different components together into a streamlined and cohesive whole.

This missing architecture resulted in the lack of interoperability amongst information systems, as well as devices. Interoperability is the ability of systems, applications, and devices to communicate 'in an unambiguous and predictable manner to exchange data accurately, effectively, and consistently; and to understand and use the information that is exchanged'.[1] Instead of following this principle, many of the deployed applications and systems use proprietary software and do not apply validated standards. This poor practice prevents integration and stifles expansion to other systems and technologies. Even more recently, when open standards have been developed to solve this problem, these standards are not being adopted or consistently used.[2]

Because digital health implementation projects occurred independently of one another in many countries, they are not aware of other applications or systems that provide or need the same data. These software were also not designed to communicate and share information with one another.

Siloed applications and systems have generated the following problems:

- **Poor data management**: Access to the large amount and varieties of valuable digital information that has been captured is often limited to the application or system that directly captured it. Since such applications and systems do not refer to people, places, things, or concepts in a standardized manner, data sharing and consolidation is difficult to do. As a result, broader use of this information is hindered. To add to the problem, information must still be input manually into multiple applications in some countries. Lack of consistency in data entry and coding decreases data quality and creates opportunity for errors. Such problems can cause health workers and administrators to make poor decisions, compromising public health and patient safety.
- **Burden on health workers and administrators**: Requiring health workers and administrators to use multiple, unconnected digital health applications adds unnecessary burdens to their work. For example, a health worker may have to log in to multiple applications or systems with different access methods and user identities, even while doing work that is essentially interrelated. This duplicated effort creates confusion, increases errors in data entry, and takes the health worker away from providing quality services to patients.
- **Absence of system-wide ICT impacts**: The implementation of digital health initiatives do not often yield positive results because of funding requirements or the complexity of the problems being addressed. In some cases, ICT investments are mandated to address just one problem in an information system, even though multiple inefficiencies and gaps exist. If the problem is one part of a multifaceted issue or a multistep process, the system as a whole will not see the positive outcomes of the initial solution. Such practices result in lost opportunities for leveraging ICTs to improve system-wide workflows.
- **Wastage of digital health resources**: Public funds, including government resources and grants from philanthropic or aid organizations, are often used to pay for different digital health projects with overlapping, yet incompatible, functionalities. Multiple projects have repeatedly defined software requirements for the same set of functionality that is common across contexts instead of pooling resources and working with a shared core set

[1] ITU (2016). Recommendation ITU-T H.810: Interoperability design guidelines for personal connected health systems. https://www.itu.int/ITU-T/recommendations/rec.aspx?rec=14113&lang=en

[2] Global System for Mobile Communications Association (2016). Digital Healthcare Interoperability: Assessment of Existing Standards and How They Apply to Mobile Operator Services, in Order to Provide Global Recommendations to Increase Their Adoption. See: www.gsma.com/iot/wp-content/uploads/2016/10/Interoperability-report-web-version-final.pdf

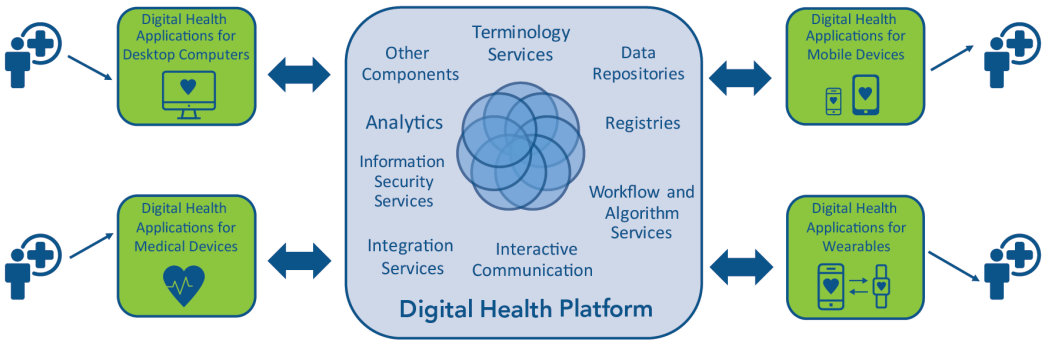
of technologies. These vertical projects often aim to save money by focusing on just one aspect of the information system. However, high legacy costs ensue when systems need to be integrated, requiring more monies to redesign and re-engineer the technologies. In addition to wasting public resources, these vertical projects often duplicate time and effort.

- **Constraints to innovation**: Private-sector and non-government software developers primarily wish to create digital health innovations. However, because of the siloed design of current infrastructure in many countries, developers often must devote time and resources to re-creating basic code and technologies that are common to multiple digital health applications. This work slows their efforts to truly innovate with their applications and systems—a problem that hinders progress in digital health.
- **Distraction from building national systems and infrastructure**: Focusing on the creation of standalone applications inhibits the development and deployment of national systems. This problem is made worse by the amount of resources and effort required to maintain many incompatible information systems. This problem undermines the government's ability to focus on the core functions of health service delivery.

What is a DHP?

A digital health platform is a common 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 messaging standards for interoperability (see Figure 1). The external digital health applications can be software programs, digital tools, or information systems such as EHRs, supply chain systems, insurance systems, and patient-engagement apps. By supporting interoperability, the underlying infostructure ties different components and external applications together into a streamlined and cohesive whole.

Figure 1: How a DHP interacts with external applications and users



The DHP allows one digital health application or system to work with other applications and systems, helping these software share health information and data about patients, health workers, health systems, and even commodities and equipment, such as medical devices and pharmaceuticals. As a result, other clinic departments, such as radiology or the laboratory, gain access to patient data that may have previously been available only at the admitting

desk. Moreover, relevant patient or health commodity information can be shared with health system entities outside the clinic and throughout the organization served by the DHP, including regulators, pharmacies, insurers and funders, suppliers, referral clinics, and health ministries.

Although facilitating the exchange of health information is a key purpose of a DHP, many DHPs also have broader goals. For example, a DHP can support, encourage, and enforce best-practice workflows across multiple external applications. So if WHO issues new guidelines for an antiretroviral regimen, workflow functionality built into the DHP can alert both the clinician and the pharmacist serving an HIV-positive patient. The alert pops up automatically once health workers input the specific treatment regimen into the different external applications that the clinician and pharmacist use.

How does the DHP work?

The DHP usually operates behind the scenes with the external digital health applications and systems that people use rather than directly with users. To understand this, a distinction is made between digital health software that are external to the DHP and DHP components**,** the software and digital tools inside the DHP. A user such as a lab technician or a clinician interacts with an external application or system, not with the internal DHP components. Instead, these components are used by the external digital health applications and systems. Therefore, the DHP remains hidden from the user (see Figure 1). In this way, the DHP functions like the backstage staff at a theatre performance; while the audience views the actors on stage, the actors rely on stage managers, prop masters, and others to make the performance run smoothly and spectacularly.

A DHP component provides individual functionality internal to the DHP, either a software service like authentication or a shared information resource like a health facility registry. These components are core technology services that are typically required by all digital health applications implemented throughout the organization or sector that the DHP serves. These components allow information to be created, accessed, stored, and shared by the external applications and systems. The following are examples of these core services:

- authentication services
- registry services
- terminology services and reference data
- workflow support services.

External digital health applications and systems link to and share these components on the DHP, without needing to integrate directly with one another.

The external digital health applications and systems interact with the DHP components through published standards-based interfaces, which can be application programming interfaces [APIs] and web services. External software interacting with the DHP through one of these interfaces knows that it must communicate in a predefined way or follow predefined steps to carry out a specific process through the DHP. The application or system will follow this interaction without necessarily knowing the technical details of how the DHP processes its communication with the application.

Is there only one type of DHP, or are there many variations?

The DHP can exist in many forms. Some platforms more tightly integrate services, tools, and systems into common workflows. Others, however, comprise a loose federation of external systems, linked via DHP components, such as only mediation and common base data standards.

Case studies throughout the handbook and in the Annex describe how countries have implemented systems similar to a DHP. These examples range from sophisticated, mature platforms to simple platforms that are only starting to emerge. For example, Canada implemented the Electronic Health Record Solution [EHRS] to enable health workers to exchange patient information across the country. This mature platform operates under the principle of storing data in a common place. Individual software applications at point-of-service [PoS] delivery put a copy of the information they capture about a patient in a set of repositories that are managed as part of the infostructure, without the applications having to interact or integrate with one other (see Appendix A: 'Canada case study' for more information).

In Liberia, the Ministry of Health [MoH] implemented mHero to connect its human resource information system [HRIS] with the Short Message Service [SMS] platform RapidPro so that messages could be exchanged directly with health workers during the Ebola outbreak in 2014. Although mHero is early in its development, the MoH is looking to expand it to interoperate with other systems and applications (see Appendix A: 'Liberia case study' for more information).

How does a DHP change over time?

Your DHP is expected to evolve and mature. Each DHP begins with the core set of components necessary to initially support the digital health applications or systems you wish to integrate via the DHP at first. These initial components may be very basic, but they will become more sophisticated as the digital health applications and systems that use the platform increase in number or complexity, or as the DHP supports more health services and programmes. To help you define a roadmap and overall benchmarks for DHP maturation, DHP maturity models are introduced in Section 6: 'DHP Implementation'.

How does the DHP connect with other digital platforms such as e-government?

The DHP usually does not exist in isolation within a country. Public sectors other than health care also use ICTs to support the delivery of social and economic services or e-government initiatives. These initiatives may be in the planning stages or already under way in many countries.

Estonia: Building off existing architecture to launch a new e-health platform

In 2005, the Estonian Ministry of Social Affairs launched a new e-health platform to create a unified national health information system [HIS]. This system linked public and private medical records, gave patients access to their records, and connected to other public information systems and registries. The project, funded by the European Union and the Estonian government, sought to increase efficiency in the health system, make time-critical information accessible for clinicians, and develop more patient-friendly healthcare services. Four e-health technologies were phased in: EHRs, digital images, digital registration, and digital prescriptions.

Estonia built on existing public information technology infrastructure and common registries in use to create an architecture for this new platform. The ministry built interoperability and security components to support key business processes involved in the four e-health technologies, including data entry, storage, registration, search, notification, and presentation. Estonia also leveraged its previous experience implementing many cross-institutional digital integrations, including e-banking, e-taxation, and e-school, among others. Estonia's use of unique identifiers to create digital identities for all residents benefited the project as well.

See Appendix A: 'Estonia case study' for the full case study.

To help integrate systems and institutionalize the DHP, the DHP can—and should—leverage some of the technologies provided by e-government initiatives. For example, e-government systems may provide core functionality that the DHP requires, such as unique identifiers for citizens that can be used to identify patients as well as individual health workers. Elements from other systems may be repurposed, such as enrolment mechanisms for registering citizens with e-government programs. DHP implementers may be able to take advantage of hardware and software vendors or telecommunication networks already in place for e-government initiatives.

What are the benefits of implementing a DHP?

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 e-health strategy.

How does the DHP benefit information technology administrators in health organizations and software developers who create external applications and systems for health workers and consumers?

The DHP simplifies information exchange within the health sector. The platform allows a user of an external application or system, such as a health consumer using an app on a mobile device, to access information gathered by other digital health software without requiring those tools to integrate directly with one another, or even to be aware of one another.

By providing a foundation of common components to digital health applications and systems, the DHP accelerates the development of new software as well as the rollout of improvements to existing software. Software developers produce more efficiently because their applications and systems only need to know how to connect to and interact with the DHP components as part of a workflow.

Developers can also make their external end-user applications and systems simpler, or 'light', because they do not need to build the common complex processes embedded in the DHP components, which are considered 'heavy'. This benefit frees developers to focus on creating easy-to-use and efficient apps for health consumers, health workers, and administrators. Developers can also ensure that their software gathers information that is consistent, understandable, and accessible to other healthcare programmes and services.

What benefits does the health sector gain from DHP implementation?

A DHP is expected to accelerate innovation in integrated and interoperable digital health solutions, enabling the health sector to achieve its health and care goals in a more predictable, efficient, and cost-effective manner—and with reduced risk.

To this end, a well-designed DHP supports the wider health sector in improving the following:

- overall quality and continuity of care
- adherence to clinical guidelines and best practices
- efficiency and affordability of services and health commodities, by reducing duplication of effort and ensuring effective use of time and resources
- health-financing models and processes
- regulation, oversight, and patient safety resulting from increased availability of performance data and reductions in errors
- health policy-making and resource allocation based on better quality data.

Canada: Developing the Electronic Health RecVord Solution [EHRS] Blueprint

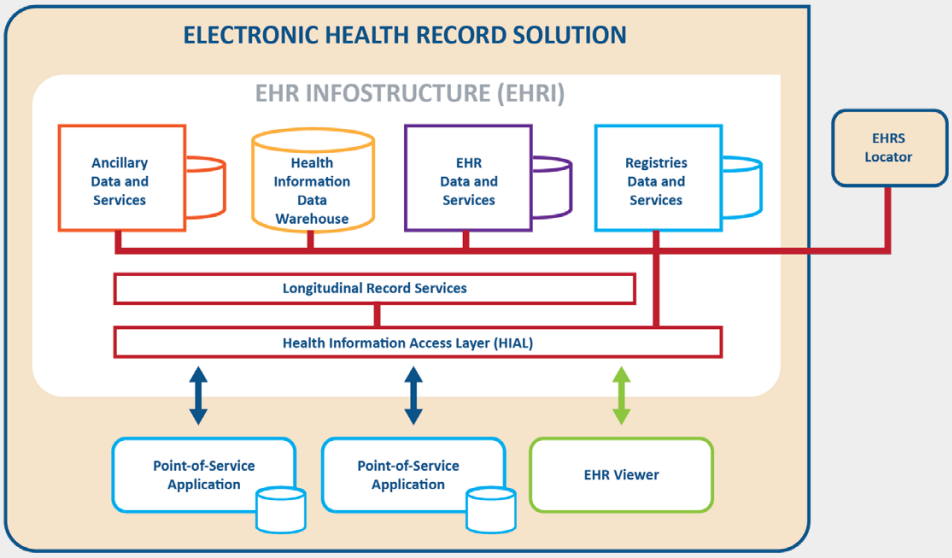
Canada Health Infoway conceptualized an architecture for implementing large-scale, national EHR solutions, resulting in an architecture called the EHRS Blueprint. The Blueprint is an early example of a DHP. The Blueprint offers an information system architecture, describing how each PoS application can connect to the shared infrastructure platform, or infostructure, through an interoperability layer called a Health Information Access Layer. Using agreed-upon standards facilitates these connections and interoperability.

The design approach taken is for each Canadian jurisdiction (province or territory) to implement an operational information infostructure. This infostructure allows a large number and variety of PoS software systems to either capture or access clinical and administrative information about citizens and the health services provided to them.

The architecture does not require individual software applications operating at the PoS delivery to interact or be integrated with one another. Instead, each software application saves a copy of the information it captures about a patient into a set of repositories that the infostructure manages—a key principle of the EHRS architecture.

The EHRS Blueprint has been used as a foundation for Infoway's programmatic approach to funding DHPs across the country. Adherence to the Blueprint concepts and approaches determines funding eligibility for e-health projects. Today, Blueprint-based information systems implemented by the health ministry support new digital health initiatives across the country.

See Appendix A: 'Canada case study' for the full case study and more information about the EHRS.



Source: Canada Health Infoway, Inc. (2006). Electronic Health Record Solution Blueprint: an interoperable EHR framework. See: www.infoway-inforoute.ca/en/component/edocman/391-ehrs-blueprint-v2-full/view-document?Itemid=0 (accessed 27 May 2020)

Section 3 – Overview of Digital Health Platform Development

Applying your eHealth Strategy and digital health interventions to DHP development

Since a digital health platform aims to provide the underlying information infrastructure for your country's entire digital health system, developing this platform needs to be done within the context of the larger whole.

A key reason for considering the overall health system context is to ensure that the platform and its external applications and systems match your country's health goals. An eHealth Strategy defines expected changes, called 'eHealth Outcomes', that will be achieved through digital health—either by improving information flows within the health system or by increasing electronic access to health services and information. These eHealth Outcomes help define which health system business processes require improvements that can be addressed through digital health.

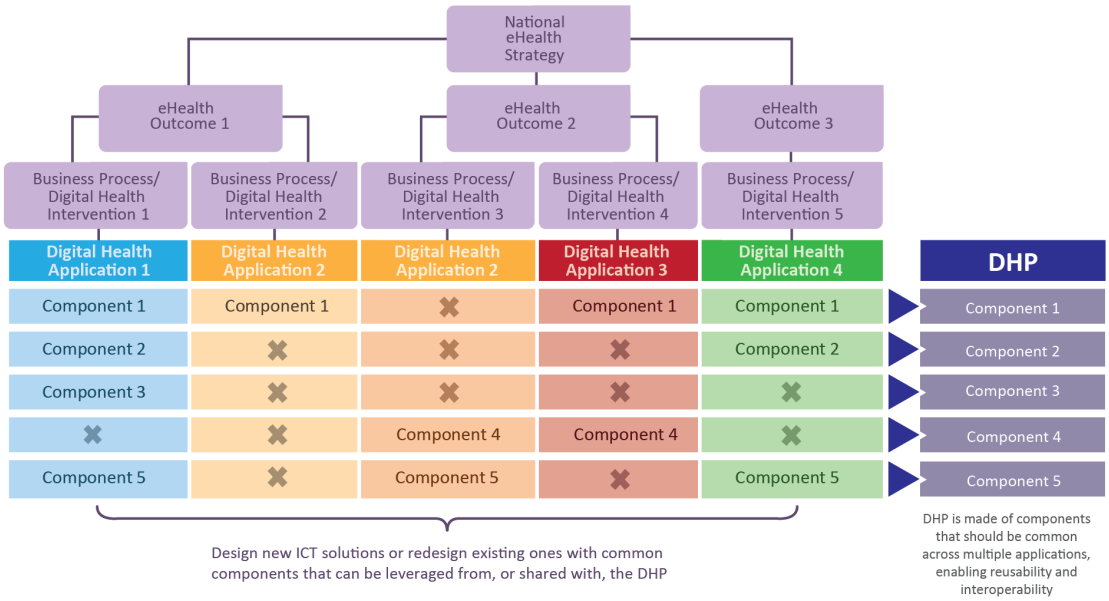
Improvements to a specific business process can be achieved by applying a digital health intervention(s) [DHIs], defined as a discrete functionality of digital technology designed to improve health system processes and address system challenges. See Section 4 – Context Analysis for more detailed information on health system business processes and DHIs. It describes how to identify and analyse the high-priority ones based on the outcomes defined in your eHealth Strategy.

As part of formulating an eHealth Strategy (or a similar national framework for digital health), your country may already have identified a need for a DHP or particular digital health applications and systems. In addition, your country may have discussed high-priority health system business processes and gaps which digital health interventions can address. You can leverage this earlier work, including the requisite stakeholder engagement that accompanied it, when planning your DHP.

Figure 2 shows how DHIs emerge from a country's eHealth Strategy, and how these interventions define the applications (and DHP components) needed in your health system. Sometimes, one application or system can provide the functionality for multiple interventions and even multiple eHealth Outcomes. For example, your health system may implement a telemedicine application to enable healthcare access to remote communities through Digital Health Intervention 2.4.1: Consultations between remote client and healthcare provider. This same application can also assist with other interventions that fit under a health system goal of improving workforce capacity in remote areas, such as Digital Health Intervention 2.4.4: Consultations for case management between healthcare providers or Digital Health Intervention 2.8.1: Provide training content to

healthcare provider(s).[1] In Figure 2, the dual purposes of one application is shown by Digital Health Application 2 being used for Interventions 2 and 3.

Figure 2: Process for identifying reusable DHP components from national eHealth Strategy outcomes



Your national eHealth Strategy may provide additional information that you can leverage for DHP development. Table 2 below highlights specific outputs from the *National eHealth Strategy Toolkit*[2] that may assist you when planning and rolling out your DHP. Even if you have not used this toolkit to develop your eHealth Strategy, adaptations of some of the documentation may exist among the stakeholders who led the eHealth Strategy development.

Table 2: *National eHealth Strategy Toolkit* chapters that are relevant for DHP development

National eHealth Strategy Toolkit Section	Relevance for DHP Development
Framework for National eHealth Vision (Part I, Chapter 2)	**Analysis of population health, health systems, and health strategy goals. Useful for DHP context analysis**
Governance Structure for eHealth Strategy Development (Part I, Chapters 4, 5)	**Lists of subject matter experts, prioritization for a governance continuum, stakeholder engagement activities, stakeholder roles, and a collaboration plan. An essential reference for DHP stakeholder analysis and engagement**

[1] The specific interventions (and numbering system) listed here are from the WHO's *Classification of Digital Health Interventions, version 1.0*. See Section 4: 'Broad health system overview' and www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/ (accessed 27 May 2020) for more information. Section 4: 'Health business process mapping' also provides additional examples of how specific DHIs emerge from a country's eHealth Strategy and guide digital health development.

[2] For more information, see: www.beyondstandards.ieee.org/general-news/what-are-standards-why-are-they-important/ (accessed 27 May 2020). This resource is recommended for the strategic planning phase of digital health system development (see Table 1).

National eHealth Strategy Toolkit Section	Relevance for DHP Development
Strategic Context (Part I, Chapter 6)	**Provides context on the health system, health strategy priorities, goals and challenges, and identification of development goals related to e-health. Useful for DHP context analysis**
eHealth Components and National eHealth Component Map (Part I, Chapters 9, 10)	**Outputs include requirements and documentation for environmental, organizational, and technical capacities of the eHealth Components, including architecture models. The national eHealth Component map is an excellent reference tool. Useful for DHP context analysis and DHP design**
Analysis of eHealth Barriers, Gaps, and Opportunities (Part I, Chapter 11)	**Provides an assessment of e-health opportunities, gaps, and barriers. Useful for identifying health journeys and how the DHP can improve digital health**
eHealth Vision Statement (Part I, Chapter 12)	**Review the eHealth Vision to understand how the DHP can support it**
Framework for an eHealth Action Plan (Part II)	**Several outputs could be adapted for DHP implementation:** • **sample governance structure (Part II, Chapter 3) for the DHP governance team** • **exercise of assigning outputs with action lines (Chapter 5) for DHP components** • **risk assessments and identification of dependencies between action items for DHP design and implementation steps** • **resource requirements (Part II, Chapter 7) for identifying resources needed by a DHP**

Importance of considering external application and system design when planning the DHP

Another reason to develop your DHP within the context of the larger whole is help you see how your DHP can leverage and optimize the technology used within your overall digital health system. Therefore, you need to consider the functionality, technological design, and composition of your external digital health applications and systems when you plan the characteristics of your DHP components.

There are two key reasons for considering the design of the applications and components at the same time: a) to understand how the external applications and DHP will interact, including any needed standards or interfaces that will enable interoperability; and b) to identify which components in the external applications and systems are generic, and therefore, reusable with other applications and systems. Instead of building these reusable technologies within each standalone external application or system, you can incorporate them into your DHP as components that are shared amongst all applications and systems connected to the platform. For example, a data repository can be housed on the DHP and shared with all external

applications and systems that need it. Designing your DHP and applications in this manner will reduce redundancy and improve efficiency within your digital health system.

Figure 2 above illustrates the process of leveraging reusable components for the DHP. In the bottom half of the figure, the components of each digital health application are mapped out, allowing you to visualize which components are common to multiple external applications and can be moved into your DHP (e.g. Components 1, 2, 4, and 5). A component that is not used in multiple applications is not generic, and therefore, not shareable via a DHP (e.g. Component 3, denoted by an 'X').

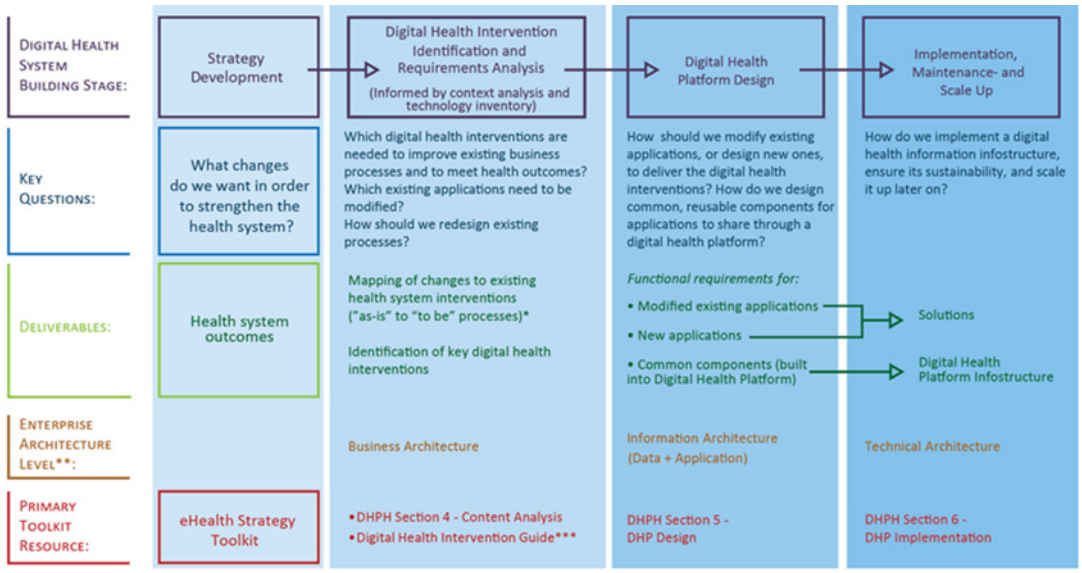
Summary of the DHP infostructure development process

Building a digital health platform information infrastructure resembles the remodelling of a house. Before construction begins, architects and users research desired changes and draw up plans. These plans reflect the users' ultimate needs and priorities as well as the constraints imposed by the existing setting, technologies, and structural architecture. Some priorities may require the modification of existing structures while others will require new construction. Implementation considers the logical progression for making the changes, ensures different systems are integrated, and involves ongoing maintenance.

During DHP infostructure development, your team first undertakes requirements gathering processes to identify the applications, components, and technologies needed within your platform. To do so, you analyse existing health system business processes to understand how specific digital health interventions can improve health system functioning, and ultimately, strategic health outcomes. Some of these DHIs will require modifications to existing digital health assets. Still other interventions will demand the development or procurement of new systems and applications. Whether new or modified, these applications and systems will be implemented as solutions that connect to the DHP infostructure. As noted, you will integrate the reusable components common to multiple applications into the DHP. Doing so lays the indispensible foundation of your infostructure—essential for ensuring interoperability between various external solutions and for enabling efficient and effective digital health system expansion in the future.

Figure 3 provides a handy visual summary of the overall DHP development process. Organized according to the digital health system building phases described in Table 1, this diagram illustrates the different stages of DHP development, from strategy development through eventual maintenance and scale-up. It shows the key questions that DHP planners and architects need to answer during each phase and the deliverables they will need to produce in response. To help systems architects place these deliverables within a familiar organizing framework, the corresponding enterprise architecture level is also indicated, Last, but not least, this figure also points you to the section in this handbook where the development phase is described in detail.

Figure 3: Visual summary of DHP development stages, key questions, and deliverables



* For definitions of "as-is" and "to-be" business processes, see DHPH Section 4 – Context Analysis.
**For definitions of the enterprise architecture levels, see DHPH Section 5 – DHP Design: 'Outline the Enterprise Architecture.'
***The Digital Health Intervention Guide is shorthand for *Planning, Implementation, and Financing Guide for Health Programmes* developed by WHO and PATH, 2018.

Specific DHP development tasks and recommended approach for completing them

Creating a digital health platform involves various tasks, from context analysis to ongoing institutionalization efforts once you have implemented the platform. In summary, these tasks are:

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

While many of the steps described in this toolkit are linear, it is expected that the design and implementation process will be iterative. You may go back and refine earlier steps if you gain new insight while doing a later step. The Implementation Approaches chapter in Section 6, for example, may be useful to read before you identify the first set of DHP components to design. Also, some steps may occur concurrently. For example, the formulation of governance structures and policies can occur while architects define the technical aspects of the platform.

Finally, we expect you to repeat the process described in this handbook as your platform matures. Initially, a simple DHP can be implemented delivering immediate value. Later, as additional needs are identified and as more digital health services and technologies emerge, the DHP can be extended over time.

During the DHP design and implementation process, change management best practices are essential to keep in mind. A DHP will change business processes across the health sector, affecting each user in different ways. Broad stakeholder involvement ensures that the DHP aligns with their interests, facilitates and/or expands upon their work, and is generally understood and supported. The final step of institutionalizing the DHP very much depends on effective change management and stakeholder engagement throughout the entire process.

Section 4 – Context Analysis

Introduction to context analysis

Your DHP will have a much greater impact on health if it is based on a thorough understanding of your existing digital health ecosystem. Therefore, prior to DHP design and implementation, it is a best practice to conduct analyses of the three factors that intersect during DHP development:

- the context where the DHP has impact:
  - your country's health system, including regional- and district-level institutions
  - systems operating within various health sector domains, such as supply chain management
- the people impacted by the DHP: health system stakeholders and actors
- the technology used to create or interact with the DHP:
  - existing digital health systems and applications being used in your country
  - ICT platforms, systems, and applications outside the health sector, but relevant to the DHP
  - ICT applications and systems that are currently being designed and developed, and whose generic, core components may be shared with a DHP for reuse by other applications

Understanding these factors will help you analyse and identify the use cases that will drive the design of your DHP: the health system business processes that digital health can optimize and standardize.

This section of the handbook highlights three important analyses to help you understand the context where your DHP will be implemented—a stakeholder analysis, a digital health technology inventory, and health business process mapping. In this section, we provide you with guidance, tools, and suggestions to help you with these important analyses.

To learn about your country's context for DHP development, you have two key ways to gather information: a) read documents through a literature review; and b) talk with people involved in the health system and digital health through stakeholder interviews. Table 3 outlines how to use each of these tools in producing your context analysis.

Table 3: Tools for conducting context analysis of your digital health ecosystem

Context Analysis Outputs	Context Analysis Tools	
	Literature review	Stakeholder interviews
Broad health system overview	Read literature that describes how the health system works in your context.	Ask questions to further your understanding of how the health system works.

Context Analysis Outputs	Context Analysis Tools	
	Literature review	Stakeholder interviews
Stakeholder mapping	Look for mentions of, and documentation of and by, different institutions and stakeholders	Note who the interviewee mentions as key actors in digital health. Ask your interviewee about other important stakeholders to interview, a network mapping approach for identifying other key informants and actors
Digital health technology inventory	Look for mentions of, and documentation of, different digital systems and applications used in the health sector	Ask your interviewee about the digital systems and applications they know of, support, or use in the health sector
Health business process mapping	Look for descriptions or diagrams showing how information, people, and goods move through the day-to-day processes of the health system Identify mentions of gaps or inefficiencies, including efforts made to correct these	Ask your interviewee about how business activities work and how information flows in the health system. Ask about his/her experiences with these activities, including the use of technology to assist them

Broad health system overview

Gaining a broad understanding of the health system is essential for DHP development, simply so you know what you are trying to improve and whom your digital health improvements will affect. You need to understand what types of information the health system uses and how information flows between institutions and people. Underlying this information flow are the key organizations, their governance structures, and their processes for serving patients.

For this overview, consider the following important questions:

- What is the governance structure of the health system? How does leadership and accountability work within it?
- How do patients access care and for what reasons? How successful is the system in reaching patients? How do the health system services match the population burden of disease? What are the health priorities for your health jurisdiction?
- How does financing of the health system work? What are the roles of health workers and facilities (public, private for-profit, and private non-profit)? What are the major health financing schemes (e.g. private insurance, government provision or subsidies, out of pocket, etc.)?
- How does the regulation and supply of health products (e.g. equipment, drugs, vaccines, devices) work?
- How do information and data—digital or otherwise—flow in the health sector?
- Who benefits from accessing this information, even if accessed anonymously?

As you examine your health system, be sure to recognize the various types of activities that are part of the day-to-day business of the health sector. Health service delivery involves much more than the interaction between a patient and clinician; resource management, record-keeping, communications, regulation, education, financial transactions, and data management are also essential. Specific activities within these categories, such as patient referrals or equipment regulation, can be called 'business processes'. This term is used throughout this handbook.

Figure 4 summarizes and categorizes many common health system business processes. It reflects some of the information captured in the *Classification of Digital Health Interventions version 1.0*, an initiative by WHO to compile and classify the many types of DHIs that can be used to improve business processes and address health system challenges.[1] Note that some of the business processes, or aspects of some of these, can be improved through digital health, while others require non-digital interventions. Each of these business processes can also be described in more specific terms to meet your needs and reflect the activities in your health system. For example, instead of simply describing all health education processes, you can focus on the day-to-day activities undertaken to engage patients with maternal health education for newborns.

Figure 4: Types of business processes in the health system

Facility based patient care services		Remote patient care services
• Patient health records • Clinical decision support • Patient care tracking • Scheduling (Patient, Provider) • Referrals within and outside the health center, including emergency response	• Laboratory and diagnostic management • Specimen tracking • Prescription management • Public health event response and location mapping	• Telemedicine (remote clinical services) • Personal health tracking(Devices) • Health Education • Patient engagement • On demand health information • Client feedback
Communications	**Health Sector Resource Management and Regulation**	
• Targeted and untargeted alerts and communications • Peer-to-Peer (Patient, Provider) • Patient to provider • Public health event notification • Patient-based reporting	• Health facility management (Regulation and Supervision) • Health worker management (Registration, Regulation, Capacity assessment, and performance management)	• Health worker education • Equipment and asset management and regulation • Commodity tracking and quality control • Location mapping
Individual Identity management and records	**Financial and Insurance management**	**Data management and processing**
• Civil registration and vital statistics (birth, death records) • Identity verification (patient provider, health manager) • Patient enrollment in health services	• Budget management • Health worker payment • Insurance membership • Insurance claims processing • Patients payments, subsidies and vouchers	• Data collection and management • Data storage and aggregation • Data coding and transformation • Data analysis • Data synthesis and visualizations

You or your colleagues have probably already performed a health system overview for other related planning work, such as developing an e-health strategy. Instead of starting over, look at what has already been completed. Supplement these resources with data gathered from any literature reviews and stakeholder interviews you conduct during the course of the context analysis.

[1] For more information, including a comprehensive listing of the different types of DHIs, see: www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/ (accessed 27 May 2020).

Learn more about health system overviews:

National eHealth Strategy Toolkit: https://www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf

Health System Assessment Approach: A How-To Manual: https://apps.who.int/medicinedocs/documents/s19838en/s19838en.pdfNote: All websites accessed on 27 May 2020.

Stakeholder analysis

Learning objectives:

- Explain why stakeholder analysis and engagement is essential for DHP development.
- Describe the process of stakeholder analysis.
- Offer suggestions of organizations or individuals who may be DHP stakeholders.
- Provide tools to use for stakeholder mapping and resources for more information.

Stakeholder analysis – key tasks

- List stakeholders.
- Research stakeholder's roles and backgrounds.
- Create stakeholder map.

Stakeholders will play an important role throughout DHP design and implementation. Because implementing a DHP can take time and require a variety of institutions to cooperate, stakeholder buy-in to the DHP's vision is essential for its long-term growth and sustainability. DHP stakeholders are defined as those people or organizations that have an interest in the DHP and how the platform will interact with various information systems. Stakeholders also have a vested interest in strengthening the health system. Some of your stakeholders will be closely involved as key leaders of the DHP, while others will be tangentially engaged in decision-making about the technology. For example, MoH ICT advisers may be engaged at nearly every step, from design-principle identification to software selection to DHP institutionalization. Associations of health workers and patients, on the other hand, may focus their inputs on the user experience with the digital tools connected by the DHP.

To engage stakeholders successfully, it is important to understand first who the stakeholders are, what their roles or interests are in a DHP, and how they potentially will be involved in its design and implementation. To do this, you will use a process called 'stakeholder analysis', the systematic collection and analysis of qualitative information to identify the key interests

to consider when developing or implementing a programme, product, policy, or initiative.[2] This process will provide valuable insight into stakeholder attitudes about the DHP, which will be essential for managing changes and preventing misunderstandings about platform development. Ultimately, the stakeholder analysis can help increase the success of your DHP.

List your stakeholders

Identifying your abstakeholders is an important first step in stakeholder analysis. DHP stakeholders can be organizations as well as individual actors in the digital health ecosystem. For example, your stakeholders may be those directly involved with health service delivery, such as health workers who use digital tools to manage data and communicate health information. Your stakeholders may also be solution vendors who specialize in developing software applications for health care. When listing potential stakeholders, think of those whom the DHP may affect, both now and in the future. These stakeholders may include health worker or ICT training institutions, mobile network operators, or patient advocacy groups.

POSSIBLE DHP STAKEHOLDERS
Public- and private-sector health facilities, laboratories, pharmacies, insurers, and suppliers of commodities and equipment
National and subnational health authorities and social service and emergency service institutions
ICT ministries and agencies, including those providing e-government infrastructure
ICT sector organizations (software, hardware, and network service providers, including mobile telecommunications)
National finance authorities
Regulatory authorities for health products and personnel, ICT, and insurance
National bureaus for vital statistics and citizen records
International ICT, health, and development aid organizations operating in-country
Local non-governmental and civil society health organizations
Donors
Organizations for patient advocacy, health professionals, health education, and support
Policy makers
Academic institutions, training institutions, research institutes, and think tanks

When compiling your stakeholder list, you may find literature reviews or other digital health mapping resources to be helpful. Refer to previous lists and analyses that may support DHP planning and design to save time and reduce duplication of effort. For example, if your country has a digital health or e-health strategy in place, look at the results of the stakeholder analysis undertaken to develop this plan. There is likely to be significant crossover between those involved in an overall digital health strategy and those interested in a DHP. The *National eHealth Strategy Toolkit* (Section 1, Chapter 5) includes a list of stakeholders inside and outside of the health sector that may be helpful to review. To complete an accurate list of your stakeholders,

[2] K. Schmeer (n.d.). Stakeholder Analysis Guidelines. See: www.who.int/workforcealliance/knowledge/toolkit/33.pdf

you may want to use a template to document contact details, as well each stakeholder's potential relationship to a DHP.

See the sidebar, 'Possible DHP Stakeholders', to help identify stakeholders to include on your list. Be as specific as possible when making your list, including names of organizations and individuals.

Gather information about your stakeholders

Once you have a thorough list of stakeholders, you may need to gather further information to define the role that each stakeholder will play in developing and implementing the DHP.

You may find it helpful to speak with people whom the DHP will affect, in addition to consulting literature reviews or other analyses. These conversations may identify which stakeholders are enthusiastic about the DHP and which are resistant, as well as help you learn more about stakeholder needs for a DHP. For your interviews, consider these questions:

- What is the person's specific role in the organization, and what is the organization's role in digital health?
- What are the business processes used in the person's everyday work, including how he or she exchanges data with patients, colleagues, and outside organizations?
- What is the person or organization's experience in using digital technologies?
- What does the stakeholder think are the current gaps, redundancies, and inefficiencies in the flow of information in the health system?
- What is the person or organization's perception of health system priorities and how ICTs should assist?
- What information systems (and from which organizations) should be integrated better to improve health?

In addition to interviews, you may learn helpful information about potential stakeholders by participating in working-group meetings, forums, or conferences.

Create stakeholder map

You will now use the information you collected to create a DHP stakeholder analysis map. A stakeholder map is a tool that describes each stakeholder based on your analysis of that person's level of interest and influence in DHP design, implementation, and ongoing sustainability. The map shows the role you expect each stakeholder to play in developing the platform.

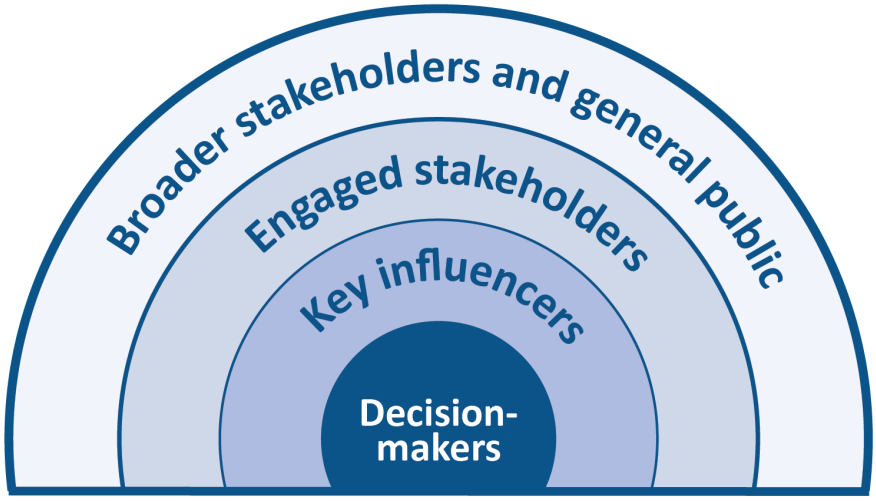
To identify stakeholder roles, it is helpful to categorize them according to their level of engagement in decision-making. The *National eHealth Strategy Toolkit* uses four categories for stakeholder roles, listed in decreasing order of engagement:

- decision-makers
- key influencers
- engaged stakeholders
- broader stakeholders and general public.[3]

[3] WHO and ITU (2012). *National eHealth Strategy Toolkit*, p. 23. See: www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf

Figure 5 shows how the level of engagement decreases as the stakeholder role moves farther away from the centre of the circle. See Section 1, Chapter 5 of the *National eHealth Strategy Toolkit* for further information on how these four stakeholder categories are defined. Adapt your categories to fit your context.

Figure 5: Stakeholder categories used in eHealth Strategy



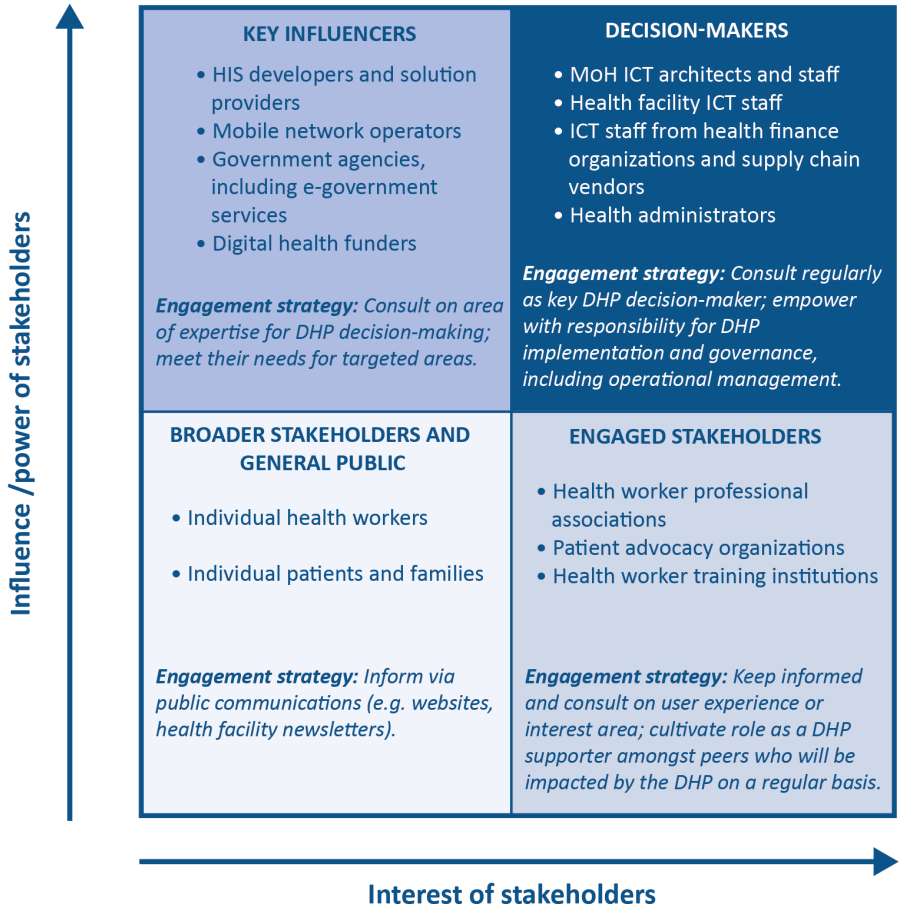
Source: WHO and ITU (2012). *National eHealth Strategy Toolkit*.

When categorizing your stakeholders and determining how to engage each group, you should gauge each stakeholder's level of *interest* in the DHP versus the level of *influence* on how the DHP will be designed and implemented. Stakeholders who have influence may be those who impact policy, resourcing, vision, or management of a DHP. Those who have interest may be impacted by the final DHP implementation but have less decision-making power over the design. A stakeholder mapping quadrant such as the Mendelow Matrix is a useful tool for showing the spectrum of interest and influence.[4]

Figure 6 is an example of a mapping quadrant using the four stakeholder categories. Potential DHP stakeholders are listed in the different quadrants as examples. Each stakeholder category also has sample engagement strategies.

[4] A.L. Mendelow (1981). Environmental scanning—the impact of the stakeholder concept. *ICIS 1981 Proceedings*. Paper 20. See: aisel.aisnet.org/icis1981/20

Figure 6: DHP stakeholder Mendelow Matrix showing interest and influence levels



Source: adapted from T. Morphy (n.d.). Stakeholder Analysis, Project Management, Templates, and Advice. See: *www.stakeholdermap.com/stakeholder-analysis.html* (accessed 27 May 2020)

Again, you should adapt this mapping quadrant to fit your country's specific needs for engaging stakeholders on DHP development.

Once you have identified and defined your categories of stakeholders, you can create a detailed stakeholder map that defines the role and engagement level of each stakeholder on your list. You should also specify the DHP development steps in which you envision the stakeholder will be involved. For example, some stakeholders may be more suited for designing the DHP architecture, while others may best be involved in operationalizing the DHP and managing it during implementation. Efficiency is important in planning the DHP, so you will need to balance stakeholder engagement throughout the process. Involving everyone at every step will not be necessary or productive.

Table 4 provides a template for this mapping. You may expand on this template, adding columns for 'influenced' or 'interested'. You could even qualify these levels to 'high influence', 'moderate influence', and so on. Regardless of how you tailor it, your stakeholder map is a resource for you to use throughout the design and implementation of your DHP.

Table 4: Stakeholder mapping template

Stakeholder Name	Institution	Contact Information	Relationship to DHP	Engagement Level	Steps of DHP to engage

Learn more about stakeholder analysis:

Stakeholder Analysis Guidelines (WHO) www.who.int/workforcealliance/knowledge/toolkit/33.pdf

National eHealth Strategy Toolkit (Part I, Chapter 5) www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf

Intergovernmental collaboration in global health informatics. In: *Global Health Informatics: How Information Technology Can Change Our Lives in a Globalized World. 1st ed.,* edited by H. Marin, E. Massad, M.A. Gutierrez, R.J. Rodrigues, D. Sigulem. London: Elsevier, 2017. See: www.elsevier.com/books/global-health-informatics/marin/978-0-12-804591-6.

The Mendelow Matrix Intergovernmental collaboration in global health informatics. In: *Global Health Informatics: How Information Technology Can Change Our Lives in a Globalized World. 1st ed.,* edited by H. Marin, E. Massad, M.A. Gutierrez, R.J. Rodrigues, D. Sigulem. London: Elsevier, 2017. See: www.elsevier.com/books/global-health-informatics/marin/978-0-12-804591-6.

Stakeholder Analysis, Project Management, Templates, and Advice: www.stakeholdermap.com/index.html

Back to Basics: How to Make Stakeholder Engagement Meaningful for Your Company (Chapter 2) : www.bsr.org/reports/BSR_Five-Step_Guide_to_Stakeholder_Engagement.pdf

Note: All websites accessed on 27 May 2020.

Digital health technology inventory

Learning objectives:

- Explain the benefits of conducting a digital health technology inventory for DHP planning.
- Outline some types of health system business processes that digital health can impact.
- Describe the technology inventory process, including what to look for and tools to use.

Technology inventory – key tasks

- Review eHealth Strategy or other documents about existing and upcoming digital health technologies.
- List existing digital health systems and applications.
- Inventory the attributes of each existing application and system.
- Identify the high priority applications and systems that are planned for development.
- Conduct an in-depth assessment of the applications and systems targeted for DHP development.

Before you design your DHP, it is important to know which digital health systems and applications are already in use. Examples of existing software may include health information systems, mobile applications used for health, online training systems for health workers, and supply chain systems for commodities. In addition to health-specific systems, your inventory should also include applications that intersect with health systems. Some examples include vital records, financial databases, and systems supporting social and emergency services.

To successfully plan the DHP, a best practice is to conduct a technology inventory in order to understand your current systems and applications. By doing so, you will understand the nature of existing DHP components, particularly in terms of interoperability, data exchange, and standards. Depending on your business needs, it may be most efficient to leverage these components when building your platform.

Tip: WHO's Digital Health Atlas [DHA] is an online tool for cataloguing the digital systems in your country and discovering systems in use around the world. This global inventory is a clearinghouse of software tools, implementation guidance, and user experiences implementing digital health projects around the globe. It can catalog information about digital health products and deployments, including maturity and scale, functionality, data capture, and interoperability. The DHA project registration form gathers useful data about each of your systems. You may want to use this tool for your inventory. Even if you do not, we recommend that you share your digital health projects via DHA, to contribute to the global community of practice. See digitalhealthatlas.org

Most countries will have some DHP components already in place, via existing platforms in the health sector, or standalone DHP components in individual systems. Existing platforms and initiatives that facilitate interoperability may also be planned or underway in your country, such as e-government initiatives. These efforts may provide certain core components required

by a DHP, particularly unique identifiers for citizens and enrolment mechanisms that can be repurposed for digital health. You may be able to further these existing components into a more mature platform.

APPLICATIONS CATEGORIES USED IN A HEALTH SYSTEM[5]
Census and population
Civil registration and vital statistics
Client applications
Client communication system
Clinical terminology and classifications
Community information system
Electronic health record and health information repositories
Electronic medical records
Emergency response system
Facility management information system
Geographic information system [GIS]
Health finance and insurance
Health management information system [HMIS]
Human resource information system [HRIS]
Identification registries
Knowledge management
Laboratory and diagnostic system [LIS]
Learning and training system
Logistics management information system [LMIS]
Pharmacy system
Public health and disease surveillance
Research information system
Data interchange interoperability and accessibility
Environmental monitoring systems

Some of the functionality listed in your systems may be in discrete software applications, while other functionality will be modules of broader systems or available under a cloud platform. For example, a human resources management system may include modules for health worker

[5] WHO (2018). Classification of digital health interventions v1.0. A shared language to describe the uses of digital technology for health, See https://www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/#:~:text=The%20classification%20of%20digital%20health,to%20support%20health%20system%20needs. (accessed 27 May 2020)

regulation, training, and management functionality. Moreover, these modules may be integrated with each other in either a tightly-coupled or a loosely-coupled manner. Functionality housed in tightly-coupled modules is very difficult or impossible to separate without re-programming the software. Loosely-coupled modules, on the other hand, enable relatively easy separation, since each module can operate quite independently while still interacting with each other.

If more than two systems or applications are already exchanging data in your context, then existing data standards are likely in place. Such standards may have evolved informally or be formally documented. In addition, your country may also have already adopted some international standards related to interoperability and information exchange, even if current digital health systems and applications do not use them yet. Wherever standardization has occurred, assess its potential for reuse across your health system.

Process for inventorying digital health technology

To understand the breadth of your existing digital health technology, start by making a list of the different types of digital systems and applications. WHO's Digital Health Atlas (see Tip, previous page) uses a list of common application and system types (see sidebar, 'Applications Categories used in a Health System'). Sources for this information may be stakeholder interviews or the review already conducted during eHealth Strategy development.

With this list in hand, record broad details about each system and application. You may want to use a template, such as the one below in Table 5. Two applications, Integrated Human Resource Information System [iHRIS] and District Health Information Software version 2 [DHIS 2], have been included as examples. Adapt this inventory template to fit your needs and the level of detail you require. Remember that your goal is to gain a broad understanding of your country's existing digital health systems and applications, and how they can be adapted and/or linked together over time in your DHP.

Identifying future systems and applications for development

In addition to examining your existing digital applications and systems, it is important to understand your country's plans for developing future ICT assets that will support and strengthen the health system. These plans could include modifications to existing software.

Look at your national eHealth Strategy to find this information. The stakeholders who collaborated on this document will have identified specific eHealth Outcomes, such as:

- implement a telemedicine system within clinics, including decision support for patient management and referrals
- develop a patient tracking and management system for mothers and children aged 0-5 years
- create a logistics support system for the supply of commodities
- leverage mobile communications infrastructure to communicate with patients (for appointment reminders, health worker-to-patient follow-up, health education, etc.)
- link pharmacy systems with electronic medical records
- establish and maintain a national patient registry
- link health financing systems with patient records in different venues (clinics, pharmacies, labs, referral hospitals, etc.).

Some of these eHealth Outcomes will require modifications to existing digital health assets, while other outcomes will demand the development or procurement of new systems and applications.

Within your digital technology inventory or in a separate document, briefly describe what will likely be needed in one or more digital health applications in order to accomplish each of the eHealth Outcomes. You could use some of the same categories used in Table 5, such as Purpose, Planned Scope, Connections and Interoperability with Other Digital Health Assets, Policy Framework or Environment, etc. The next chapter, 'Health Business Process Mapping', and the DHP Components chapter in Section 5 describe methods for identifying the specific components required by an application and/or the DHP.

Table 5: Inventory matrix of existing digital health systems and applications

Name of Digital System or Application	Purpose	Scale of Implementation / Geographic Scope	Summary of Software Used (architecture basics, type of license)	Level of Interoperability (with other system components)	Standards Used	Relevant Legal Policies Supporting or governing Implementation	Use of System or Application?	Contact	Challenges, Other Comments about System Implementation
iHRIS	Health workforce management	National with some districts implementing	HRIS is built on the LAMP architecture, which refers to a set of open source software programs commonly used together to run dynamic web-based applications: • Linux operating system • Apache web server • MySQL database management system • PHP scripting language.	Interoperable with RapidPro (mHero); common standards allow interoperability with DHIS 2	HL7 FHIR, CSV	Health worker data collection part of eHealth Strategy 2015-2020	MoH used for health worker retirement predictions; understand health worker distribution trends for recruitment; compare with payroll systems	John Doe, Head of HR at MoH	Timeline to expand to all districts delayed
DHIS 2	HIS for routine and event-specific patient data collection at district level health facilities	National, subnational to district and facility level; some rural areas reporting through DHIS 2 Tracker	Ubuntu Linex – open source (Note: WAR file requires you to install a Java servlet container (e.g. Tomcat or Jetty) and a relational database (PostgreSQL, MySQL and H2 are supported) is recommended for server setups and environments with high volumes of data and traffic.)	Not yet made interoperable with existing systems. Features a RESTful Web API allowing apps to be build using Javascript, CSS, and HTML5.	DHIS 2 is written according to the W3C standard for HTML and CSS. It runs on any standard compliant web browser (Chrome, Firefox, Opera, Safari and Internet Explorer 11).	National eHealth strategy; HMIS policies and procedures	National use for all HMIS data	Jane Doe, Head of HMIS at MoH; John Doe, Head of ICT at Ministry of Telecommunications	Poor network coverage limits timeliness of reporting; interoperability not yet tested with other systems

MySQL, PostgreSQL, and H2: open source database systems that use Structured Query Language; PHP: Hypertext pre-processor; WAR: Web application resource; RESTful: Representational state transfer web services; API: Application programming interface; CSS: Cascading Style Sheets; HTML5: Hypertext Markup Language version 5; HL7 FHIR: Fast Healthcare Interoperability Resources specification developed by Health Level-7 organization; CSV: Comma-separated values file; W3C: World Wide Web Consortium.

In-depth inventory of a particular digital health system or application

While Table 5 aims to provide a broad understanding of existing systems and applications, you may want a deeper understanding of the software that is the focus of DHP development. The questions below may be helpful when profiling a particular digital health system or application, such as an e-learning system for health workers or a financial application for health administrators. It is recommended that you document the answers to these questions.

- How does the digital health system or application uniquely identify users, locations, health facilities, and other organizational units?
- What data does the system or application exchange with other systems and applications?
- What is the profile of the users who implement these software? What kind of training do they need to maintain the systems and applications?
- What is the focus of the digital health application or system? Does it assist health services in general or a particular vertical health programme, such as HIV care? Is its focus wider than health?
- Who are the institutional owners, stakeholders, and funders that use, or encourage use of, the software?
- What funding is needed to implement and maintain the digital health system or application? Is that funding secure?
- What infrastructure is needed to support and scale the system (hardware, software, connectivity)? What barriers exist for scaling up?
- What are the application or system's business model, code licensing arrangements, and responsibilities for maintenance and support?
- What key constraints does the software face that a DHP could address?
- What DHP components may be useful to the digital health application or system?

Tip: Update your digital technology inventory on a regular basis to assist with ongoing planning and development of your DHP. You may consider establishing a publicly available digital inventory as part of a broader digital health knowledge management system.

Vietnam: Conducting a thorough landscape analysis and digital technology inventory

When Vietnam developed their national eHealth Strategy, government planners conducted a thorough mapping of the digital health environment including actors, systems, capacity, etc. This process included efforts to broadly understand the ICT and telecom environments and the structure of the national health system. As part of this analysis, government planners examined the ICT infrastructure, user access to information at multiple levels of the health system, and the level of existing interoperability amongst digital health systems and applications. The Vietnamese government even assessed the health informatics capacity of the workforce, learning about the scope and availability of training programs for ICT skills building in the health sector. In addition, these planners mapped out previous ICT and digital health challenges, as well as the approaches taken to address them. Such a thorough landscape analysis is beneficial for developing an eHealth Strategy as well as for conducting a context analysis when planning for DHP development.

Source: N.H. Luu, V.M. Hoang, N.G. Pham, V.H. Nguyen, T.T.T. Do & H.V. Hoang (2008). Public health, information technology and e-health development in Vietnam: a case from Vietnam. Conference paper presented at 'Making the eHealth Connection' meeting, Bellagio, Italy.

Health system business process mapping

Learning objectives:

- Explain the purpose of business process mapping in the context of DHP development.
- Describe how to use a national eHealth Strategy to identify the business processes that DHP-supported digital health interventions will aim to improve.
- Introduce Collaborative Requirements Development Methodology and its uses for a DHP.
- Describe the steps and tools used by Collaborative Requirements Development Methodology.
- Show different ways to document business processes.
- Explain how to use functional requirements to assess an existing application's fit with the DHP.

Business process mapping – key tasks

- Identify the health system business process you wish to improve.
- Conduct business process analysis.
- Do a business process redesign.
- Define functional requirements.
- Update your digital health technology inventory.

The next step in a context analysis is to understand the health system business processes that will benefit from the DHP. As noted earlier, a business process is a day-to-day activity (or set of activities) that an organization carries out to achieve its function, such as health worker performance management. Business process mapping is done to identify opportunities for improving the effectiveness and efficiency of a particular process. In the e-health context, business process mapping helps select specific digital health interventions that are needed, and thus, which processes a DHP should support and how. An end result of this mapping activity is a set of functional requirements for the high-priority digital health applications and their reusable components that can be built into a DHP (see Figure 2).

Identify the health system business processes you wish to improve

In order to scope your DHP in terms of how it will digitally support the health system, you need to first identify the business processes that ought to be considered for potential improvements. These are called 'high-priority business processes'.

When conducting your broad health system overview, you saw that a health system requires a large number of processes in order to function (see Figure 4). Therefore, it may seem overwhelming to choose which process(es) to focus on and prioritize. Remember that DHP development will be iterative and ongoing, so you will not need to fix or optimize every inefficient business process at once. Instead, start with just a few business processes that are high priority needs for your digital health system. Later on, when you wish to expand the functionality and scope of your DHP, you can return to this step to analyse more processes.

To identify your high-priority health system business processes, start with the desired eHealth Outcomes that you outlined in your eHealth Strategy to address a health system goal or need. Doing so will help you identify the processes that DHIs will improve or strengthen in order to achieve these outcomes. Figure 7 shows an example of how high-priority business processes

and digital health interventions derive from eHealth Outcomes. This figure corresponds to the top half of Figure 2 that you saw earlier in Section 3: 'Overview of DHP Development'.

Figure 7: Example of how high-priority health system business processes and digital health interventions are derived from an eHealth Strategy's outcomes[6]

To match evidence-based interventions with health system business process needs, see the *Implementation Investment Guide (DIIG): Integrating Digital Interventions into Health Programmes*. Developed by WHO and PATH, this toolkit helps digital health planners select, design, and implement digital interventions to achieve data, health systems strengthening, and health outcome goals. https://www.who.int/publications-detail/who-digital-implementation-investment-guide (accessed 27 May 2020)

Collaborative Requirements Development Methodology

Now that you have chosen which business processes are high priority for your current eHealth Outcomes, you can analyse and re-design these processes with DHIs that your DHP will support.

Collaborative Requirements Development Methodology [CRDM] is one approach for identifying and analysing how work (the business processes) gets done in an organization. Originally developed by the Public Health Informatics Institute [PHII] and applied to the global health sector by PATH, there are three key steps (see Figure 8):

1) **Business Process Analysis**: understand how a process (or set of processes) currently works

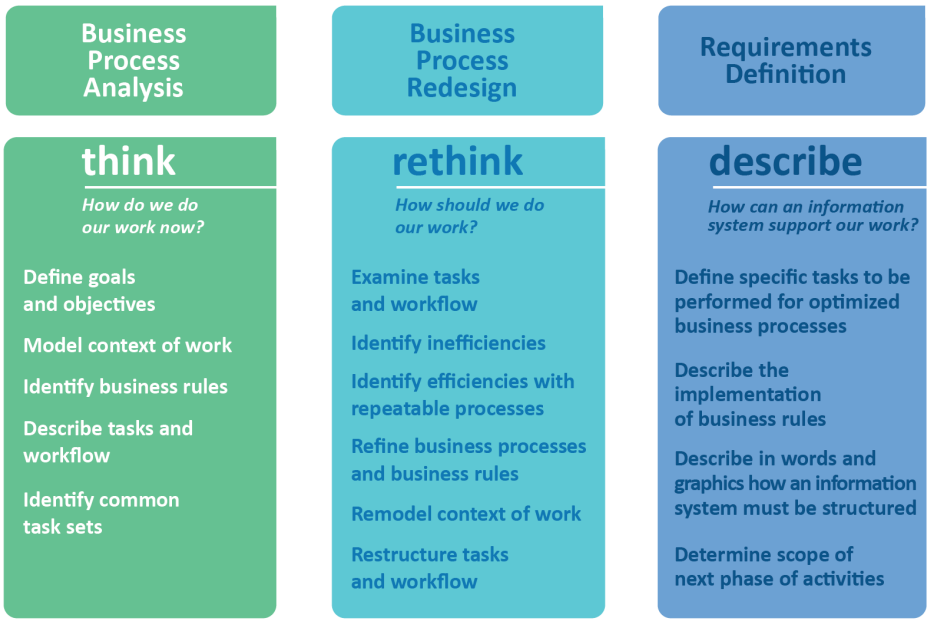
[6] The business processes and DHIs shown here are only examples of ones that can be used to meet the eHealth Outcomes listed; there are certainly many more that can help fulfill these outcomes. Also, the digital health intervention examples used here and later in this chapter are from the WHO's Classification of Digital Health Interventions version 1.0. See: www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/ (accessed 27 May 2020). Note that some DHIs listed here refer to all of the DHIs within a set of interventions (e.g. DHI 4.1 includes DHI 4.1.1: Non routine data collection and management, DHI 4.1.2: Data storage and aggregation, etc.).

2) **Business Process Redesign**: re-think the process(es) and how it can be improved
3) **Requirements Definition**: describe how a digital intervention (i.e. digital functionality of a system or technology) can support the process activities for the business process to work well

When implementing CRDM methodology, it is essential for you to collaborate with the digital health system stakeholders (or users) to develop a shared understanding of–and agreement on–what the system must do. Undertaking this collaboration during the design stage helps ensure the system actually meets user needs and improves efficiency. Applying this methodology can also be useful to gain buy-in from stakeholders.

CRDM can apply to any health-sector domain and the business processes within it. See Section 5: 'Identify DHP Components' for descriptions of the different health-sector domains such as insurance and financial management.

Figure 8: Collaborative Requirements Development Methodology Steps



Source: Public Health Informatics Institute (2008). See: *phii.org*

Conduct a business process analysis

The first step in CRDM is business process analysis, when you seek to understand how a high-priority business process (or set of processes) currently works. The goal is to thoroughly document the tasks, goals, and outcomes of the current process, or the 'as-is' state of the process that reflects the reality in the health system. Use the business process matrix template developed by PHII to describe existing digital health applications in terms of health business process objectives and characteristics (see Table 6). Each high-priority process should be mapped using this table, including those that have not been digitized yet. Table 6 focuses on a health worker training business process. It shows an example of how a training course for health workers providing HIV/AIDS treatment is analysed.

To gather information for the business process analysis, it is best to talk with actors in the health system. Key informant interviews with stakeholders as well as details from the digital health technology inventory will provide you with the information to complete a business process

matrix. If you have time, it is very useful to observe how the processes are carried out in practice. These first-hand observations enable you to validate what you have documented so far.

Learn more about CRDM

CRDM Overview (includes links to videos): www.phii.org/crdm

CRDM for Logistics Management Information Systems: www.path.org/publications/files/TS_lmis_crdm.pdf

CRDM for Maternal and Child Health Information Systems: www.path.org/publications/files/MCHN_mhis_crdm.pdf

CRDM at Asia eHealth Information Network [AeHIN] Workshop (Powerpoint presentation): aehin.org/Portals/0/Docs/Day%202%20Workshop%20Files/AeHIN-Day%202_Ses%205_Singletary%20PHII%20CRDM.pdf

Note: All websites accessed on 27 May 2020.

Table 6: Business process matrix template with HIV/AIDS refresher training example

	Objectives	Business Rules	Triggers	Task Set	Inputs	Outputs	Measurable Outcomes
Definition of Template Field	A concrete statement describing what the business process seeks to achieve. A well-worded objective will be SMART: Specific, Measurable, Attainable/ Achievable, Realistic, and Time bound.	A set of criteria that defines or constrains some aspect of the business process. Business rules are intended to assert business structure or to control or influence the behaviour. Examples in health care and public health include laws, standards, and guidelines.	An event, action, or state that indicates the first course of action in a business process. In some cases, a trigger is also an input.	The key set of activities that are carried out in a business process.	Information received by the business process from external sources. Inputs are not generated within the process.	Information transferred out from a process. The information may have been the resulting transformation of an input, or it may have been information created within the business process.	The resulting transaction of a business process that indicates the objectives have been met.
Example: Refresher Training for HIV/ AIDS Treatment	*To provide annual refresher training on the HIV/AIDS treatment protocol for health workers in in five districts to ensure correct implementation of procedures for PMTCT-STAT PEPFAR indicators*	*According to MoH guidelines, all health workers who prescribe HIV/AIDS treatment (i.e. nurses, technical officers, doctors, and pharmacists) should be required to take refresher course and pass with at least a 75% passing rate. Results will be shared with appropriate regulatory councils and the organization and/or agency running the training program.*	*SMS trigger to alert health worker know when the course must be completed. Once course is completed, results compiled by administrators and then sent to professional councils, facility managers, and the MoH.*	1) Existing HIV/AIDS Treatment course is updated and in-person refresher trainings are scheduled. 2) Administrator asks MoH to send a list of health workers who need to receive. information about course 3) Eligible health workers alerted to enrol in an upcoming refresher training (may require travel). 4) Reminders sent to those who have not yet passed course to complete it by end date. 5) Training managers share results with health facility managers, MoH and professional councils. 6) Health worker records updated with testing results at MoH.	• Revised course content • Health worker contact information (facility address or health worker email, if available) • Facility managers and agencies who will receive final reports	• Paper or email reminders to take refresher training • Health workers attending course • Health workers passing course • Reports to MoH, professional councils, administrators and facilities about health worker results	• Number of health workers contacted to take course • Number of health workers who complete online course • Number of health workers who pass online course • Number of reports shared with facilities about health worker performance

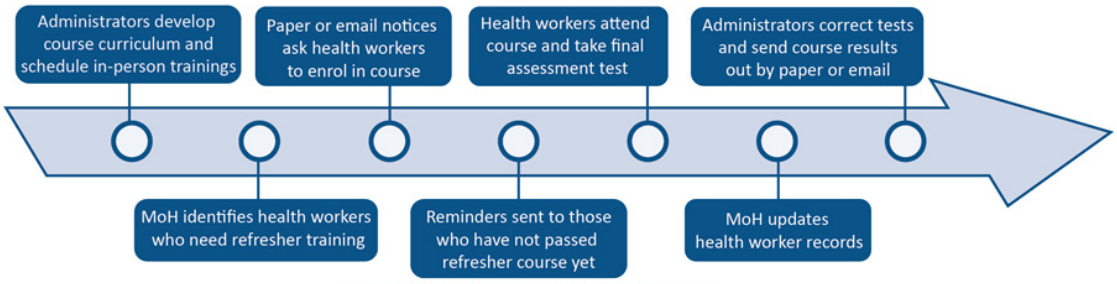
PMTCT-STAT PEPFAR indicators: Indicators used by President's Emergency Plan for AIDS Relief for measuring pregnant women with known HIV status at antenatal care.
Source: Top half of table (template categories) courtesy of Public Health Informatics Institute (2008). See: *phii.org*

Do a business process redesign

The second step of CRDM is business process redesign. The objective of this step is to identify how the process analysed in Step 1—the 'as-is' process—can be improved. Your output is a description of how you wish to redesign the workflow to make it more efficient, effective, or easier to use. Business process redesign creates your new vision—the 'to-be' process. Doing so will help you learn which DHIs may be needed. Once you identify the DHIs that you will use, you can determine which new applications or systems may be needed and also how existing ones may need to be technically or functionally modified for integration with the DHP. You may also discover that the approach needed to improve the process is not through a digital intervention.

To do this redesign, you can use various tools, including simply adding columns to the business process matrix table above; you can describe the changes to the business process in these columns. For a more visual display of your process, you may wish to use a context diagram to examine the 'who', the 'what', and the 'where' of current tasks. Figure 9 shows a context diagram that takes the major steps from the business process matrix (called 'Task Sets') and displays them in a flow chart that focuses simply on the actions. Other tools that can be used during this step are business process flow charts, unified modelling language [UML] sequence diagrams, or other frameworks that show visual representations of work processes.

Figure 9: Sample context diagram showing the existing 'as-is' business process for HIV/AIDS refresher training course



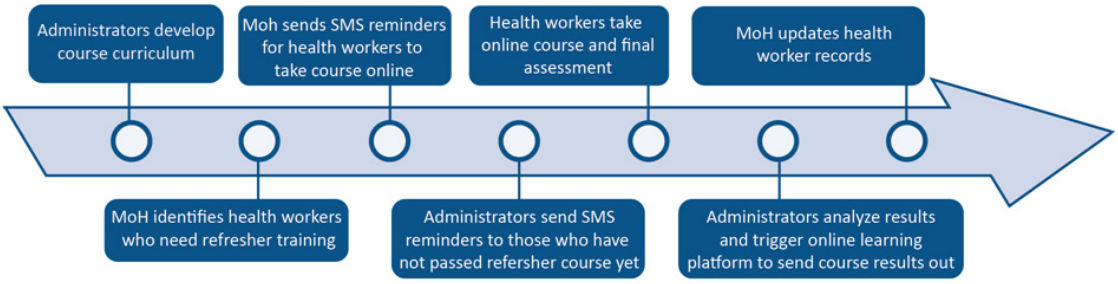
MoH = Ministry of Health; SMS = Short Message Service

With this visual, one can begin to picture where DHIs—and the systems and applications needed for carrying out these interventions—can be used at each stage of the process. To redesign and improve it, you can identify potential inefficiencies and knowledge or skills gaps. These challenges, sometimes called 'pain points', can be added to an 'as-is' flow diagram in order to help visualize where they occur in the process. See Table C.1 in Appendix C for a list of common pain points found in health system business processes.

> **Tip**: See Appendix C and Appendix D for more information and examples on identifying pain points and mapping business processes. Annex Figures D.1-D.3 illustrate how a business process is redesigned, using flow chart diagrams to show the transformation of the 'as-is' process into the 'to-be' process through the help of digital health interventions. Since business process mapping diagrams can provide the basis for a user story, the process used in the Annex examples is the one described in the pregnant mother health journey (see Figure 12), a user story that this handbook focuses on in later chapters.

Once you have identified pain points in the current 'as-is' process, you can redesign the process in order to reduce delays, eliminate redundancies, and improve the overall system flow. The improvements you envision in this redesign are 'to-be' processes. Later in this handbook, the 'to-be' processes that can be improved with the help of DHIs are called 'digital health moments'. Figure 10 shows the redesign of the HIV/AIDS refresher training business process. The red dots indicate where digital health interventions are envisioned to improve the functioning of the business process.

Figure 10: Sample context diagram showing the redesigned 'to-be' business process for HIV/AIDS refresher training course



MoH = Ministry of Health; SMS = Short Message Service

In the example above, there are a few DHIs that are incorporated into the redesign to improve the process:

- *Digital Health Intervention 2.8.1*[7]: Provide digital training content to healthcare providers—This intervention enables health workers to access an online course through their mobile phones after receiving an SMS message with a link to the course.
- Digital Health Intervention 2.8.2: Assess healthcare provider capacity and Digital Health Intervention 3.1.4: Record training credentials of healthcare providers—These interventions assess and record a health worker's training course performance, alerting health workers of their individual scores and how these will be shared with relevant actors in the health system. DHI 3.1.4 automatically disseminates health worker test results to facility managers, MoH human resource information systems, and professional councils.

[7] The digital health interventions (and the numbering system) are from the WHO's *Classification of Digital Health Interventions version 1.0*. See: www.who.int/reproductivehealth/publications/mhealth/classification-digital-health-interventions/en/ (accessed 27 May 2020). In addition, the *Implementation Investment Guide (DIIG): Integrating Digital Interventions into Health Programmes* (WHO/PATH) also provides in-depth practical guidance on selecting DHIs to improve health system functioning. See: https://www.who.int/publications-detail/who-digital-implementation-investment-guide (accessed 27 May 2020)

User stories

At the centre of business processes are people—the patients served by the health system as well as the health workers, policy-makers, regulators, managers, trainers, payors, etc. who support the health system. User stories capture the description of business processes—and the software or technology used to improve them—from end-user perspectives. In simple, easy-to-understand language, user stories describe how users interact with the business process workflow as well as any digital systems, including what users need these systems to do and why. These stories are also great ways to communicate with audiences who are less familiar with technology requirements.

You can use the data captured in the tables and flow diagrams described in this chapter to write a narrative of a user's experience in a health system business process. One form of a user story, called a health journey, is used later in this handbook to illustrate steps in DHP design and implementation. See Section 5: 'Identify DHP Components' for more information on health journeys, including two detailed examples as well as instructions on how to use these for designing your DHP.

Identify functional requirements for your DHP and high-priority, external digital health applications and systems

Once the high-priority business processes are well defined, particularly the 'to-be' processes in your redesign, the third step in CRDM is to identify functional requirements. Functional requirements are statements that describe how digital health systems and applications can be developed or enhanced to meet the needs described in the business process redesign. These requirements describe the functionality of a digital system, application, or technology, specifying what it needs to capture, perform, and display.

A clear set of functional requirements helps ICT architects understand how to design a digital system or application that best meets user needs. Application designers will use these requirements to design new software or enhance existing tools. The DHP architect should analyse these designs to identify any common and reusable components that can be incorporated into the DHP. (Note that an application or system will not always include components that can be shared through a DHP.)

The process for defining functional requirements specifically for a DHP involves a set of steps that are described in more detail in the next sections on DHP design and implementation. You will start with an initial set of requirements that will be refined and detailed more specifically as you proceed through the DHP infostructure planning process.

Learn more about functional requirements

Determining Common Requirements for National Health Insurance Information Systems: www.jointlearningnetwork.org/resources/determining-common-requirements-for-national-health-insurance-information-s

Electronic Health Record Requirements for Public Health Agencies: www.phii.org/ehrs-for-phas

Defining Functional Requirements for Immunization Information Systems: www.phii.org/resources/view/2091/defining-functional-requirements-immunization-information-systems

Graduate Tracking Requirements Project:_

iHRIS Toolkit: User Requirement Specifications: www.ihris.org/toolkit-new/plan/template-user-requirements-specifications/

Note: All websites accessed on 27 May 2020.

Update your digital health technology inventory

After defining your initial functional requirements, you may find that some of these requirements can be integrated into your DHP by modifying digital health applications that are already in use in your digital health system.

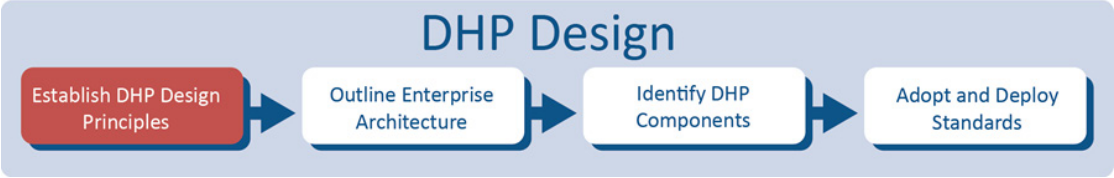
Update your digital technology inventory if existing applications or systems can be modified or if they should be retired when you eventually launch your DHP. You can classify each existing application according to its fit with the platform. Table 7 provides an example of some specific criteria to use when making these decisions.

Table 7: Sample criteria for assessing how existing applications and systems fit with the DHP

Classification Type	Description	Sample Criteria
Category A	Application or system retained as-is or with minor modifications	- Web service can be enabled with minimum effort - Business process re-engineered already - Meets target functional requirements - No replacement available from another commercial, off-the-shelf application
Category B	Application or system retained with major modifications	- Changes are needed to functionality, architecture, or standards - Functionalities require integration
Category C	Application or system not retained	- Low usage volume - Non-standard architecture - Can be replaced by common or cross-cutting applications with better functionalities, including commercial, off-the-shelf applications

Section 5 – Digital Health Platform Design

Establish DHP design principles



Learning objectives:

- Explain the importance of design principles for guiding DHP development.
- Describe how to define and establish DHP design principles.
- Outline resources and examples to help with principle definition.
- Provide guidance for stakeholder engagement in this process.

DHP design principles – key tasks

- Define key design principles.
- Validate the principles.
- Adhere to these principles throughout DHP design and implementation.

Principles are fundamental guidelines that underpin the design of platform architecture and the software applications that will connect to it. You need a consistent set of principles from the outset of planning the DHP to guide how DHP components are developed, how external applications interact with the DHP, and how technology infrastructure components support DHP outputs and growth. Develop these principles jointly with the DHP stakeholders. Use these principles to support coherent and consistent decision-making throughout DHP development. Doing so will help ensure the platform remains scalable, operationally manageable, and sustainable over time.

Various examples of principles for digital health architecture exist (see sidebar, 'Examples of principles for DHP'), such as those from the Open Group and the guiding principles for enterprise architecture. In addition, many organizations have aligned their implementations with the Principles for Digital Development. For example, the Open Health Information Exchange [OpenHIE] community advocates user-focused design, open standards, open data, and security through its work with countries on architectures for sharing health data on a large scale (see 'OpenHIE' sidebar in Section 6: 'Select software for your DHP'.

Define a set of design principles for your DHP

There is no one-size-fits-all approach to developing DHP design principles. Each country needs to define these principles according to its vision and goals for the platform, keeping in mind the context in which the DHP will operate. In particular, your country's ICT policy and regulatory environment is an important contextual area to keep in mind.

Consider adopting principles that include qualitative characteristics of DHP data, such as reliability, maintainability, and alignment. [1]Principles supporting interoperability and scalability are also important to include, because a key goal of a DHP is to enable disparate applications to communicate seamlessly on a platform that will grow over time.

Questions for Stakeholders:

- What is the vision of the DHP?
- What is important for implementation, maintenance, and future scale-up?
- Who needs to be made aware of these principles?
- How will the principles be shared?
- How can key stakeholders uphold these principles during implementation?

Stakeholder engagement is essential when defining a draft set of concrete principles for your platform. Bring stakeholders together to brainstorm the design principles that will best meet their vision of a DHP. Prior to this workshop, review any e-government policies that may affect principle definitions.

Stakeholders for DHP principles design

- Ministry of ICT adviser
- MOH digital coordinator
- Health facility ICT senior staff
- E-government coordinators
- Directors of health associations
- Chair of regional digital health network

What are the characteristics of a well-defined principle? Good principles are clear, complete, consistent, and stable. A standard format for defining principles is helpful, particularly when using the principles to explain and justify why specific design decisions are made. Table 8 provides a recommended format for defining principles from the Open Group.[2] You will want to highlight the rationale of why each principle is a guiding approach for your DHP. You and your stakeholders may decide to add other categories to the format to help with comprehension.

[1] R. Khayami (2011). Qualitative characteristics of enterprise architecture. Procedia Computer Science, 3, pp. 1277–1282. doi:10.1016/j.procs.2011.01.004

[2] R. Khayami (2011). Qualitative characteristics of enterprise architecture. Procedia Computer Science, 3, pp. 1277–1282. doi:10.1016/j.procs.2011.01.004

Table 8: Format for defining DHP design principles

Principle name	Short, specific and easy to remember
Principle statement	Succinct and unambiguous description of the fundamental rule
Rationale	Business benefits of adhering to the principle using business terminology
Implications	Requirements for business and information technology to apply principle, including costs, activities, etc.

Validate principles

Once you define your DHP principles, it is important to vet them amongst a broad range of stakeholders, which may include stakeholders other than the key players who have an interest in the DHP or who are influenced by the DHP – additional actors in e-government agencies or ICT regulatory authorities, for example. Validating the principles will help ensure adherence to them during the initial DHP design and throughout every implementation phase as the DHP matures. For this process, enlarge your stakeholder group beyond the key leaders to include input from external software application developers and end users of the DHP.

EXAMPLES OF PRINCIPLES FOR DHP
Privacy and security: Ensure that data is properly protected, prevent unauthorized access and changes, and maintain confidentiality to protect patient safety and privacy.
Data custodianship: Clearly define data ownership, data sharing consent procedures, and responsibilities for data provision and quality.
Data availability: Ensure that data is available to digital health applications and their end users whenever and wherever they wish (within the bounds of confidentiality) to guarantee patient safety and business continuity.
***Scalability*:** Be capable of continuing to perform as the DHP expands both vertically and horizontally over time in terms of data, external software, and users, with DHP processes being used efficiently across a range of applications and systems.
Policy adherence: Follow established national policies as well as specific governance policies defined for DHP development and implementation.

Consider these questions when validating principles:

- Do your principles reflect the goals of your DHP?
- Will the principles be clear to external application developers?
- How will you monitor adherence to the principles?
- What is the risk if principles are not followed?
- Are your principles adaptable as the DHP and its development context evolve?
- What resources are needed to ensure adherence to these principles?

After validation, publish design principles in a shared repository that all DHP implementers can access.

Adhere to principles throughout DHP implementation

You need to ensure that design principles are followed as you develop and implement the platform to uphold the integrity of the agreed-upon vision for the DHP. There may be significant risk if a principle is not met. For example, if one of your principles is for all applications to share data reliably, system interoperability may be reduced if external applications do not follow the data standards defined to achieve this.

Use the following strategies to move from principle to practice:

- Disseminate design principles amongst all new developers, vendors, and health facility administrators who are involved in DHP implementation or external application design.
- Review technical requirements documentation for each DHP component to ensure alignment with validated principles, since a decision that invalidates or undermines one principle may affect other aspects of the platform.
- Be flexible with the technical approaches to meet the principles, as more than one may exist.
- Monitor and evaluate component development and implementation against your principles.
- Continue to engage stakeholders on the importance of adhering to DHP principles.

Use of APIs: Foster interoperability amongst DHP components and between the DHP and external software solutions, enabling different applications and systems to communicate via the DHP.

Collaboration: Adopt a governance approach that includes multisector stakeholders in decision-making and management of DHP design and implementation.

Open standards: Use internationally accepted standards that promote interoperability for data, workflows, and technology.

Open source: When appropriate, use software code that is freely available and distributed for modification to avoid software vendor lock-in.

Data quality and integrity: Follow accepted data standards and create measures to uphold the integrity and reliability of data processed or stored by the DHP.

Usability: Create DHP components and external applications that will minimize the complexity for end users interacting with the information exchanged through the platform.

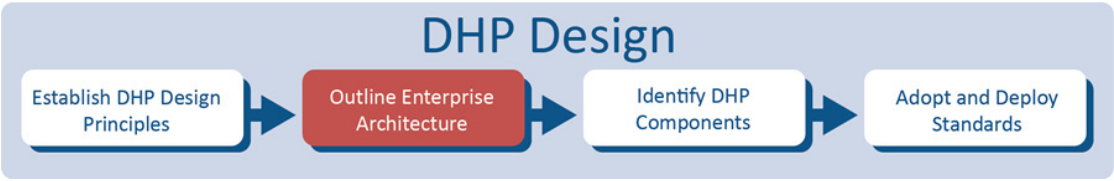
Learn more about platform architecture design principles

The Open Group Architecture Principles https://www.pubs.opengroup.org/architecture/togaf9-doc/arch/chap23.html

Principles for Digital Development https://www.digitalprinciples.org

Note: All websites accessed on 27 May 2020.

Outline the enterprise architecture



Learning objectives:

- Introduce the enterprise architecture tool and its various frameworks.
- Describe the role of four different views in an enterprise architecture and their implications for DHP design.
- Provide an overview of how to define the different architecture views.
- Outline practical considerations when defining an enterprise architecture for the DHP.

DHP enterprise architecture design – key tasks

- Review different types of enterprise architecture frameworks.
- Choose a framework appropriate for your context.
- Outline the different architecture views in broad terms.

Developing and implementing a DHP requires more than just a technology specification or the acquisition of systems, databases, and networks. A DHP needs to be planned and designed using architectural methods, showing how different components fit together and interact, similar to how the electrical and plumbing systems integrate into a building's structural design.

To help design the DHP, you will use an enterprise architecture. The public and private sectors have used this tool for years to outline and help manage complex systems. Like a blueprint of a building, an enterprise architecture is a comprehensive description of the various parts of the DHP, showing how they fit together, interact, and ultimately align with the goals and business processes of the health system. For this handbook, the organization developing the DHP – the 'enterprise' – is assumed to be the health sector of a country, although this entity can be more narrowly or widely defined.

Stakeholders for defining DHP enterprise architecture:

- Ministry of ICT adviser
- MoH digital coordinator
- HIS community advisers
- E-government coordinators
- ICT advisers from donors and non-governmental organizations

Different enterprise architecture frameworks

Multiple types of enterprise architectures are available, with more than 70 listed by the International Organization for Standardization [ISO]. Different architectures have different

strengths, and some enterprises use combinations of them. The most comprehensive, widely used, and accessible enterprise architectures include the Open Group Architecture Framework [TOGAF] and the Federal Enterprise Architecture framework. Other commonly used ones include the Zachman Framework, the Gartner methodologies, and the Reference Model of Open Distributed Processing.

Learn more about enterprise architecture frameworks

Survey of frameworks: www.iso-architecture.org/ieee-1471/afs/frameworks-table.html

L. Urbaczewski & S. Mrdalj (2006). A comparison of enterprise architecture frameworks. Issues in Information Systems, 7 (2), pp. 18–23. See: iacis.org/iis/2006/Urbaczewki_Mrdalj.pdf

Selecting an enterprise architecture framework – A.O. Odongo, S. Kang & I-Y. Ko (2010). A scheme for systematically selecting an enterprise architecture framework. 2010 IEEE/ACIS 9th International Conference on Computer and Information Science (ICIS), 18-20 August 2010. doi:10.1109/ICIS.2010.85

The Open Group Architecture Framework pubs.opengroup.org/architecture/togaf8-doc/arch/toc.html

Note: All websites accessed on 27 May 2020.

All enterprise architecture frameworks outline the business vision and processes, which are health service delivery and outcomes in the case of the DHP. They also describe how ICT supports the vision and processes through the following:

- software application functions
- software interaction
- data organization and standardization
- supporting hardware and ICT infrastructure.

Unlike many frameworks, TOGAF contains an architecture-development method, providing a step-by-step process for designing an enterprise architecture. TOGAF is also highly accessible, with many publicly available resources and training materials. However, you should review the elements of various architecture types to identify the most useful one for your context.

Different architecture views within the DHP

Just as there are different architectural plans for a building (e.g. structural, heating and cooling, plumbing), there are different architectural plans for a DHP, called 'views'. Each view represents the system from the perspective of different stakeholders involved in DHP design. Together these views comprise the overall enterprise architecture. This handbook uses the four different architecture views defined by TOGAF (see Table 9).

Table 9: TOGAF enterprise architecture views

Type of Architecture View	TOGAF Definition	Key Role within Overall Enterprise Architecture	Stakeholders Responsible for the Architecture	Implications for the DHP
Business architecture	Defines: • business strategy • governance • organization • key business processes	Models existing business processes, as well as the new or modified processes that digital technologies will support	Health planner involved in DHP implementation	Describes the health system business processes that identify the components and technologies needed in the DHP
Data Architecture (part of information architecture)	Part of overall information architecture Describes the structure of an organisation's: • logical and physical data assets • data management resources	Defines the nature and structure of the data gathered and stored Outlines how data is generated, collected, or used in a safe, reliable, and efficient manner at different points in the business processes	ICT architect responsible for DHP implementation Developers designing health information databases and applications that interact with these databases through the DHP	Describes how the DHP collects or uses different types of data at different moments of the health journeys Outlines the data standards that the DHP uses to ensure that external applications access and use data properly
Applications Architecture (part of information architecture)	Part of overall information architecture Provides a blueprint for: • individual software applications to be deployed • interactions between software • how software relates to the core business processes of the organization	Describes the manner in which software applications participate in the overall business processes	ICT architect responsible for DHP implementation Developers and vendors of external digital health applications	Describes: • software applications internal to the DHP • DHP components • external software applications used by end users • how DHP components interact with external applications, including APIs and standards needed for interoperability

Type of Architecture View	TOGAF Definition	Key Role within Overall Enterprise Architecture	Stakeholders Responsible for the Architecture	Implications for the DHP
Technology architecture	Describes the logical software and hardware components required to support the deployment of business, data, and application services, including: • information technology infrastructure • middleware • networks	Explains how hardware and software infrastructure enable the applications and data architectures within the information system, including: • hardware and network specifications needed for network communica tions	Health institution ICT managers	Describes the combinations of infrastructure technology and ICT standards required to implement the DHP components and their interactions with external applications, including the DHP integration services
	• communica tions • processing • standards	• expected processing load and its distribution across technology components		

Note that most enterprise architectures are based on a reference model that exists for their particular business sector. A reference model is an abstract framework that shows the relationship between concepts and entities within a particular environment. While a reference model provides a common language for discussing and developing the specifications and standards for information system parts in general, an enterprise architecture specifies concrete implementation and technology details for a particular information system.[3]In the healthcare sector, Estonia, Canada, Australia, and Great Britain among others have created reference architecture models.[4]The OpenHIE model is also a reference architecture model used in the health sector.

Process for outlining an enterprise architecture for the DHP

Once you review the different types of enterprise architecture frameworks and choose a model to follow, you can begin outlining each of the architecture views. The business architecture is the first view to define. You will have already identified in the context analysis which business processes in the health system you want to improve through digital health. These business processes, described by the health journeys and the digital health moments, are the business architecture. Once you identify the DHP components and match standards to them, you will

[3] Wikipedia (2017). Reference model. See: en.wikipedia.org/wiki/Reference_model and The Open Group (n.d.). TOGAF definitions. See: pubs.opengroup.org/architecture/togaf9-doc/arch/chap03.html

[4] Norwegian Directorate for eHealth (2015). *Study of 'One Citizen, One Health Record': International Experiences*, V6.1. See: ehelse.no/Documents/En%20innbygger%20-%20en%20journal/V6.1%20Internasjonale%20erfaringer_1.0.pdf

define the information architecture. At this stage, your goal is to outline a high-level overview of what each of these views will contain. Other chapters in this handbook describe how to design each of the architecture views in more detail.

Considerations when defining an enterprise architecture for the DHP

When outlining the enterprise architecture for the DHP in your country, it is essential to consider the scope of your DHP. This scope describes the extent of the platform architecture design based on available resources and an implementation timeline. Consider the following questions:

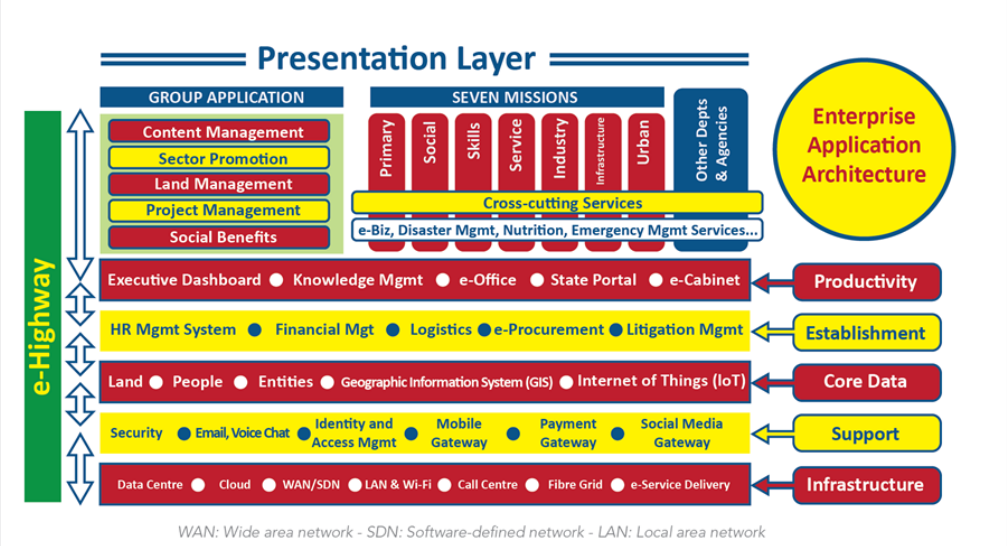
- What are your resource constraints (e.g. finances, human, time)? How will these resources increase or decrease over time? What changes are needed in these resources?
- How can you divide DHP development into stages? Can you create sections of your architecture first, followed by sections that require more advanced functionality or that meet lower priority busines needs in the health system?
- What is the vertical scope of your DHP architecture design?
- What is a feasible timeline for implementation, and what will be your major and intermediate milestones?

India: An enterprise architecture aligning with TOGAF

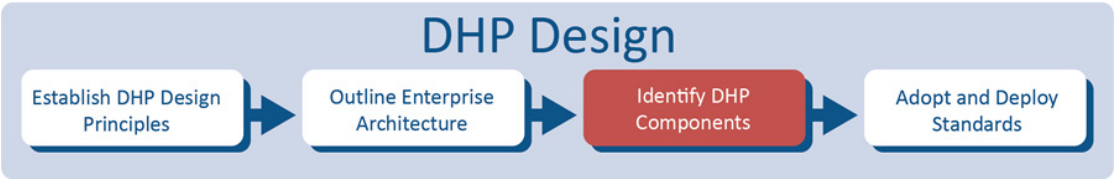
The state of Andhra Pradesh in India needed multiple government sectors to share data and engage with citizens through a common digital information system that each sector could leverage. The state government used the TOGAF methodology to design and plan its own enterprise architecture, called the 'Andhra Pradesh State Enterprise Architecture [APSEA]', which extends to all departments in the state. APSEA is guided by the principle of 'develop or procure once; use across the enterprise'.

APSEA includes detailed explanations and mapping of the four TOGAF enterprise architecture views: business, application, data, and technology. Within each of these views, APSEA outlined the process for stakeholder engagement and governance. The figure shows APSEA's application architecture view, which includes five core services: infrastructure, support, core data, establishment, and productivity. These services support 24 common applications and core data sets that all Andhra Pradesh state departments and agencies must use.

Source: State of Andhra Pradesh (n.d.). AP State Enterprise Architecture v 1.0.



Identify DHP components



Learning objectives:

- Describe the purpose and function of components commonly found in DHP designs.
- Discuss how these enabling components can be used across different health-sector domains.
- Show a sample architecture for a DHP.
- Explain how to identify enabling components for your DHP design through the use of digital health moments in health journeys.

DHP component identification – key tasks

- Write up your use case as a health journey.
- Identify the digital health moments in the journey.
- Review the various types of DHP components.
- Match the component to the functionality needed for each digital health.

You can now start designing the DHP's information architecture, made up of the applications and data architectures, as described in the previous chapter. To do so, you need to identify the platform's internal software, its DHP components.

DHP components versus external applications

Core DHP components are generic and common across a large number of use cases, as opposed to being specialized for one digital health application, such as supply chain management. In contrast to external applications, DHP components are reusable, shareable, interoperable, always scalable, and not standalone.

An external application does not need to offer the services a DHP component provides; rather, it can 'outsource' those services to the DHP component. Neither does the external application need to know the internal mechanics of how a component works. However, it does need to know how to connect to and interact with the DHP and how to use a DHP component as part of the work the application does. Table 10 summarizes these differences.

Stakeholders for DHP component design:

- E-government coordinators
- Ministry of ICT adviser
- MoH digital coordinator
- Non-governmental organization representatives
- MoH programme area representatives
- Registry, vital statistics, and other database managers
- Data analysts
- Representatives from-health sector domains

Table 10: Differences between DHP components and external applications that use the DHP

DHP Components	External Applications
Not standalone	Standalone; may have some shareable components
Reusable	Custom
Use-case independent	Use-case dependent
General purpose	Domain-specific or use-case specific
Always scalable	May be scalable

Some external applications, however, may offer internal components that can be exposed and shared with other applications through the DHP, such as data-storage functionality. Initially, this component can be 'domain specific', meaning it is designed for functionality within one health-sector domain. Sharing the component with the DHP makes it available to other external applications in the same domain or in other domains. These domain-specific components often require modifications to become useful across domains.

Health sector domains supported by the DHP
Service delivery and surveillance
Patient engagement
Insurance and financial management
Human resources management and capacity building
Commodities and supply chain management
Facility and equipment management and supervision

Types of DHP components

Within a platform architecture, two types of DHP components can be identified: functional and enabling.

Functional components are common, reusable services that support integration of a diverse set of digital health applications. They have specific functionality internal to the DHP that provides services to external digital health applications or to users. These platform-based software services enable external applications to access and share information through the platform, even though the external applications are not directly integrated with one another. The DHP may also provide a direct user interface for some features.

Enabling components are shared information resources that functional components leverage and operationalize when exchanging information across the health system. Enabling components provide a base upon which other applications, processes, or technologies are developed to make integration of systems viable at all levels. These components support data definitions and messaging standards for interoperability. They also provide the common information required to uniquely identify actors and resources, as well as data sets of numbers, text, and images that pertain to the various health-sector domains.

> The common ICT building blocks/components and digital investments framework developed by ITU and Digital Impact Alliance [DIAL] offers a visualization of a cross-sectoral enterprise architecture designed to help countries meet the Sustainable Development Goals.
>
> To view the common components and to understand how functional and enabling components fit into the overall architecture, see https://www.itu.int/pub/D-STR-DIGITAL.02-2019

Variation in component and overall platform design

Every DHP will differ due to the varying needs and operating contexts of the organizations participating in the platform. Differing health-sector resources, policy and regulatory environments, and digital health maturity determine the variation.

A DHP's design will change over time. You may initially prioritize core components to meet the needs of one business process and implement additional components later. Many components have a range of functionality, so you could implement a particular component in its most basic form, a more advanced form, or a form that lies somewhere in between. The order in which you must implement or deepen components is not predefined but depends on the needs and priorities, pain points, and feasibility in the context. However, some types and levels of components are prerequisites for others. Components can also be designed initially as specific to the health sector but later be modified for use by applications outside of health, such as those used in e-government services.

Remember that DHP components can provide any ICT capability that offers benefits when shared across external applications in a standard way. As long as you stick to the DHP design principles and any relevant regulatory guidelines, you can create whichever DHP components meet your needs best. In a way, components are limited only by the designer's imagination!

This chapter provides an overview of common types of functional and enabling components. It describes how the DHP and external applications can use these components for domain-specific functions. Note that it does not intend to be an exhaustive listing of DHP component types.

Common DHP components

Information mediation services

Purpose: To serve as a gateway between external digital health applications and all other DHP components, thereby ensuring interoperability

Component type: Functional

Domain-specific examples: not domain-specific, but this component:

- is used amongst different external applications in the same domain
- mediates information across different domains

Information mediation services, or 'integration services', provide a channel through which external applications connect to the other components in the DHP, such as registries, terminology services, and repositories.

This component primarily processes, translates, and logs information transactions, as well as communication errors, between internal DHP components and between the DHP and external applications. So the mediation component can either orchestrate the efficient passage of data from one external application to a DHP repository or transmit information amongst multiple external applications, bypassing the repositories altogether. Mediation components can also mediate interactions amongst external applications and the other DHP components (e.g. terminology services, workflow engines). As part of this process, information mediation services implement how standards are applied and operate, which is essential for an interoperable DHP.

Information mediation services can also act as a unified API for external applications across the platform, reducing the need for each DHP component to have its own API. Such functionality benefits DHP implementers as well as external application developers by reducing coding redundancy and speeding up the implementation process.

Why use the term integration services?

Various terms exist to describe the architectural module that provides integration; enterprise service bus [ESB], interoperability layer, and integration layer are all used with different nuances in definition.

In addition, the API tier enables application integration in a manner different from the ESB, allowing for the agile approach taken by developers of modern mobile and web-based apps. The API tier and ESB functionality can complement each other in enabling integration within the DHP's service-oriented architecture.

This handbook uses the term 'integration services' because it encompasses the ESB (and the functionality described by the interoperability and integration layers), as well as the API tier.

For these reasons, information mediation services could be considered the most important component that a DHP offers. The interoperability afforded by this component provides the means for all information transactions within the DHP to occur, operating like a giant telephone switchboard. This component does not stand alone, however; it needs to be developed in conjunction with other core components, such as registries, repositories, and so on.

Information mediation services also work closely with the information security components of the DHP, such as user authentication and device and external application authentication (see the 'Information security components' section later in this chapter).

Registries

Purpose: To enable unique and consistent identification of people, places, organizations across external digital health applications

Component type:

- *enabling:* registry data sets
- *functional:* services that process these data

Range of functionality:

- *basic*: simple lists
- *intermediate*: curation and change tracking of lists
- *advanced*: sophisticated matching algorithms

***Domain-specific examples*:**

- Use of facility, health worker, and patient registries to authenticate insurance eligibility and claims
- Use of facility registries for supply chain management
- Use of health worker registries for validating and tracking professional certification and ongoing trainings

The DHP needs a way to regularly and uniquely identify each person, place, or organization in the health system for external digital health applications to interact and share information accurately. Without common ways of identification, two (or more) different external applications cannot exchange data or participate in common business processes. For example, if Application A refers to a clinician as 'Dr Anika R. Singh' but Application B uses 'Dr Ani Singh', these two applications will not recognize that this record refers to the same person.

The DHP solves this problem through the use of registries. Registries manage master data about an individual unit. Master data is data such as identification numbers, names, locations, and other information useful for identification. Registries also provide algorithms and processes to match records. In this way, Dr Singh is properly recognized each time this data point appears in the digital system, whether her first name is listed as 'Anika', 'Ani', or 'A. R.' (her first and middle initials).

The individual units compiled in registries can refer to any person or place in the health system, from patients to health workers and from organizations that deliver health services to supply chain warehouses. In addition to providing unique identification, these registry services may

verify eligibility or certification, such as patient eligibility for subsidized care or the professional accreditation of a health worker. You can choose which registries to include in the DHP based on your user needs. Common registries include the following:

- **Facility registry**: manages unique identifiers for health service delivery locations, including hospitals, clinics, pharmacies, and standalone laboratories
- **Health worker registry** (or provider registry): manages unique identifiers for all types of health workers, including doctors, nurses, pharmacists, social workers, community health workers, and sometimes administrators
- **Patient registry**[5]: manages the unique identifiers of people receiving health services.

Note that these registries store only the minimum information needed for identification and regulation. Detailed information is housed in repositories, another DHP component (see the 'Shared repositories' section later in this chapter). For example, a patient registry may store any of the following information for a single patient: variations of names, different identification numbers, contact details, biometrics (photograph, fingerprints, etc.), and a list of health facilities that the patient visited.

To obtain these data, the registry uses existing official records (see Table 11), as well as its interactions with different external digital health applications, which submit data into the registries through the DHP. Therefore, your DHP architecture design may include linkages to e-government services or other digital systems housing official records that the registry needs to use. Registry service functionality may include using metadata for identification, resolution of duplicate records, and splitting or merging of identities when external applications use more than one identifier for the same person or entity.

Table 11: Sources of data for common registries used in the health sector

Official Institutions Collecting Data Useful for Registries	Source of Data	Patient Registry	Health Worker Registry	Health Facility Registry
National civil registration authorities	Vital statistics records; citizen identification programs	*	*	
Social service, emergency service, and e-government agencies	Geographic information system data for service provision points; patient lists for social and economic assistance programs	*		*
Health financers (government subsidy programs, insurance schemes)	Membership lists; accredited facility lists	*		*
Large-scale health worker employers (often national or subnational governments)	Health worker human resource and payroll records		*	

[5] A patient registry is also commonly known as a 'client registry'. The term 'patient registry' is used here to be consistent with the use of the term 'patient' throughout this handbook. See the note under 'Key terms' in Section 1.

Official Institutions Collecting Data Useful for Registries	Source of Data	Patient Registry	Health Worker Registry	Health Facility Registry
Health facility and health worker regulatory and certification authorities	Records of accredited hospitals and clinics, labs, and pharmacies; lists of registered and certified health workers		*	*

Registry functionality – that is, the ability to uniquely identify people and places – is an important prerequisite for many other DHP components, including repositories and workflows that cross two or more software applications. For example, patient and health worker registries ensure that health-record repositories or DHP telemedicine workflows refer to the correct patient and health worker. These two registries also ensure that health workers and patients receive targeted education content from either the e-learning repository or the patient health education repository. Similarly, accurate health facility identification is essential for supply chain workflows to deliver commodities and equipment between storage hubs and facilities. Shared financial workflows and repositories, as well as those for surveillance and supervision, also rely on facility registries, amongst others.

Learn more about registries:

WHO (2015). *Minimum Data Set for Health Workforce Registry – Human Resources for Health Information System*. See: *www.who.int/hrh/statistics/minimun_data_set/en/* (accessed 27 May 2020)

The pregnant mother health journey examples (see Table 13 in the 'Process for identifying DHP components' section later in this chapter) show how these registries are used (e.g. 'DHP-Patient-Registry service', and 'DHP-Identity-Authentication service').

Ethiopia's master facility registry enables robust data analysis and easy system integration

To reduce the number of separate and incompatible lists of health facilities in use throughout Ethiopia's health system, the MoH developed the master facility registry [MFR]. The MFR is a digital resource of centralized and standardized health facility data, including unique identifiers for each facility and information on the infrastructure, available equipment, health services, and human resources of each. This robust registry enables facility-based data analysis, a task that could not be easily accomplished with the disparate and non-uniform facility lists in use before. Through common APIs, the MFR also offers easy integration with other information systems or tools that will use or provide facility data (e.g. logistics management and information system, data visualization tools). Once integrated, these systems will automatically receive any changes that the MoH makes to the MFR, changes that will only need to be shared once because the MFR is designed as a centralized and authoritative source of data.

Source: Federal Democratic Republic of Ethiopia Ministry of Health (2016). Master Facility Registry. Paper from annual review meeting.

Shared repositories

Purpose: to store data, such as patient health data, for access by external digital health applications

***Component type*:**

- enabling: repository data sets
- *functional:* services that process these data

Range of functionality:

- *basic*: storage of one type of data
- *intermediate*: storage of a range of both structured and unstructured data
- *advanced*: summary health profile abstracted from other data

Domain-specific examples:

- medication repository
- diagnostic imaging repository
- e-learning content repository
- health education content repository
- budget and expenditure data repository

One of the most important DHP components, a shared repository provides a common place to store data that other DHP components and external applications can use.

For example, shared electronic health records (EHRs) allow different health facilities to exchange data about a patient, for purposes of follow-up, tracking, referrals, transfers, and telemedicine.

These repositories can serve a vital public health function, providing data for monitoring population health and disease surveillance, as well as planning and evaluating interventions. DHP repositories can also store other types of data tracked in the health system. For example, data related to financial transactions, supply chain management, and training of health workers can be pulled from multiple applications and organizations into common DHP repositories.

The DHP may also offer shared libraries of documents for users to access through a website portal provided by an external application or a portal supported on the DHP interface layer. These libraries may store documentation like health policies and regulations, information about the health system, common templates and forms used in specific health domains, and even technical documentation about the DHP itself.

A primary benefit of shared repositories is that they enable you to change external applications (by adding, modifying, or removing them) without losing your most valuable digital asset: the information itself. Shared repositories and their associated information mediation services also help ensure that information flows when it is needed, without the cost and complexity of accessing information across a number of external applications.

Data in repositories can be stored in different ways. Some repositories require structured, or coded, records, which facilitate relatively easy interpretation, processing, and analysis by machines. Other repositories store unstructured records, such as documents, diagnostic images, or free-text notes: the health worker's written or voice-recorded words, free of any codes. Many repositories manage a combination of both structured and unstructured records.

The level of detail housed in these repositories can vary, depending on your platform goals and how advanced your DHP is. In EHRs, you may start with storing just one type of data, such as diagnostic images taken by radiology technicians, or basic structured patient data, such as the minimum information needed for referrals or immunization history. As the DHP matures, you can gradually add different types of data, eventually leading to repositories that store every health data point associated with a patient. EHRs in their most advanced stages may synthesize the stored information into a summary health profile for an individual. When designing and implementing a shared repository, it is important to structure the data in a manner that is not specific to each external application that captures the information. Doing so allows maximum reuse of the data across a broad range of applications.

EHRs, EMRs, and PHRs: What's the Difference?

The various acronyms for describing health records can be confusing. Each is distinct and uses the DHP in different ways.

EMRs: Electronic medical records contain clinical data on a patient from one facility. EMRs are local records housed in an external application.

EHRs: Electronic health records are shared patient records that contain historical data about a patient that are compiled from all local EMRs. EHRs are housed in a DHP central repository, enabling access by multiple facilities across the health sector domains, including insurers and government agencies.

PHRs: Personal health records are health records that the patient himself controls and maintains in order to track his health. PHRs are external applications that can be linked with EHRs to enable sharing.

See the health journeys in Table 13 and 14, as well as Table D.1 in Appendix D, for examples of how these types of records are used in a DHP environment.

Through external applications or web interfaces, end users view, update, and upload data in DHP repositories. More advanced EHRs give patients direct access to their health records; patients may even input their own data from medical and mobile devices. In other cases, only health workers can authorize uploading patient data into EHRs. Some DHP implementations may give the systems and applications used by insurers or payers of subsidized care partial access to EHRs—to approve payment for services, for example. Repositories of insurance claims, subsidies, or out-of-pocket payments may also link to health-service records.

Privacy is a key concern in EHRs, and clear rules must be established for data sharing and access. See Section 5: 'Adopt and deploy standards' for more information on security standards and Section 6: 'Establish the governance framework' for information on policies that protect data privacy and patient confidentiality.

The examples of the health journeys (see Tables 13 and 14) show how a repository (called 'DHP-EHR-Repository' or 'DHP-EHR-Repository service') is used.

Terminology services

Purpose: to standardize the coding structure for data passing amongst external applications connected to the DHP

Component type:

- *enabling:* data dictionaries and other terminologies
- *functional:* services that process these data

Range of functionality:

- *basic*: simple coded lists
- *advanced*: sophisticated mapping and change management features

Domain-specific examples:

- standardize data for external applications sharing health records
- standardize coding used for payments and processing insurance claims
- standardize data coding of commodities managed through different supply chain applications

To exchange structured or coded data, different external applications need to code and classify the data in the same way. Without standardization, errors can occur in how machines and humans alike interpret information, and ultimately, in the decisions made by actors in the health system. For example, a clinician could write a prescription using the Latin abbreviation 'qd', meaning 'daily', a term that can be easily confused with 'qid', meaning 'four times a day'; this confusion could cause grave errors when dispensing and using medication.

The DHP helps solve this problem with terminology services. These components use codified reference lists to standardize the classification of data communicated amongst external applications. To create these reference lists, it is best to use common data standards, such as International Classification of Disease, 10th revision [ICD-10] codes, which are often established by international bodies. (See Section 5: 'Adopt and deploy standards' for information on the base data coding standards.) Terminology components can disseminate standards and facilitate managing changes in standards over time.

Many applications already in use when the DHP is implemented will have their own terminologies. You will need to map these coding systems to the DHP reference terminologies, a time-consuming and complex process, although likely a process you will have to complete only once. In addition, you can design the DHP terminology architecture as centralized services that are pushed out to external applications or as services that pull and translate local terminologies into the DHP.[6]

However terminology components are designed and implemented, a DHP that deploys well-planned terminology components ensures that external applications will speak the same language when exchanging data, even if each individual application originally captured

[6] Chapter 9 in B. Dixon, ed. (2016), Health Information Exchange: Navigating and Managing a Network of Health Information Systems, Elsevier Academic Press, provides more information on mapping and terminology architecture design.

that data with its own coding system. As a result, data exchanged through the DHP can be interpreted, aggregated, analysed, and compared with greater accuracy.

The chronic obstructive pulmonary disease [COPD] health journey (see Table 14) shows how a terminology service (called 'DHP-Terminology service') is used.

Ethiopia's National Health Data Dictionary underpins the exchange of quality health data

The Ethiopian MoH created a National Health Data Dictionary [NHDD] to serve as an authoritative reference resource for HIS that exchange data. A terminology services component manages the data exchange when information systems in Ethiopia's public health system input, share, or aggregate data or indicators. The component draws on the NHDD to harmonize these data according to national and international standards. For its terminology services component, the MoH uses Open Concept Lab [OCL], an open-source platform that can share updates to the NHDD amongst the various information systems that connect to it. In the future, the MoH will allow clinicians to connect with OCL through their mobile devices, enabling them to search and record diagnosis codes housed in the NHDD wherever they provide care.

The NHDD was initially populated with data definitions from Ethiopia's National Classification of Diseases, Health Management Information System Data Recording and Reporting Guidelines, and Community Health Information System Guidelines. It will be expanded with definitions from other key domains, such as supply chain, laboratory, and health insurance schemes. In addition to the national guidelines, the NHDD maps to the ICD-10, Systematized Nomenclature of Medicine – Clinical Terms [SNOMED-CT], and Columbia International eHealth Laboratory (CIEL) international data standards.

Source: Federal Democratic Republic of Ethiopia Ministry of Health (2016). National Health Data Dictionary. Paper from annual review meeting.

Workflows and algorithm services

Purpose: to optimize business processes by specifying rules to be followed or information to be exchanged

Component Type: Functional

Range of Functionality:

- *basic*: simple linear series of steps
- *advanced*: highly complex algorithms and workflows

Domain-Specific Examples:

- appointment reminders to patients
- clinical decision support algorithms
- workflows for processing financial subsidy/insurance claims
- collection of payments for services via mobile devices

You can build workflows and algorithms into your DHP to help automate the flow of digital health information and optimize decision-making by users. These components dictate the rules that end-user and external applications should follow in processing data. In some cases, these rules can actually be concrete directives for end users, such as national treatment guidelines or standard operating procedures for managing health commodities. In other cases, these rules are guidelines internal to the DHP for optimizing information flow. For example, software code in a DHP workflow can automate the dissemination and retrieval of the various data exchanged during diagnostic testing, pushing health worker directives and patient data to laboratories and billing departments, followed later by the distribution of results.

Thus, these components extend the functionality offered by repositories. Rather than simply storing information for external applications to access or add to, workflows and algorithms specify how information should be used to provide efficient and quality services. For example, while an EHR simply records that a doctor made a prescription, workflows and algorithms may help the doctor decide what to prescribe. Alternatively, these DHP components may tell external applications how to process and fulfil the prescription order in a standard, efficient way.

Workflow and algorithm components support cross-facility workflows and business processes that the DHP manages by allowing different external applications to exchange information. Therefore, different end-user applications used by facilities for scheduling, tracking inventory, or educating patients – applications that may have previously been siloed – may now be connected into the same digital health processes.

These workflow components can also digitize clinical guidelines and standard operating procedures available in narrative document form into algorithms for guiding health workers. When a particular health condition is diagnosed, health workers receive targeted care guidelines through external applications that access DHP workflow and algorithm components.

DHP workflow and algorithm components can greatly impact the quality of health service delivery and health systems. In addition to accelerating and automating business operations

and information flow, they can be mechanisms to encourage or enforce best practices, clinical guidelines, and policy.

Another benefit of workflow and algorithm components is their location within the DHP infrastructure itself. Because they are housed on the platform instead of within the external applications, these components allow external applications to operate merely as interfaces, since developers and solution providers no longer need to program workflow rules and processes into their software. Developers can then focus on optimizing other functionality in their external applications.

Note that data and workflow sequencing standards are essential for enabling more than one software application to participate in a given workflow that the DHP supports. See Section 5: 'Adopt and deploy standards' for information on defined workflows and interaction models commonly found in the health sector.

The health journey examples (see Tables 13 and 14 in the 'Process for identifying DHP components' section later in this chapter) show how some workflows are used (e.g. 'DHP-Workflows service', 'DHP-Order-Fulfilment service', 'DHP-Collaboration service', and 'DHP-Referrals service').

Payments services

The DHP payments services component powers the various financial transactions that occur in a health system, such as claims processing for health services and user payments for prescriptions, doctor visits, education class fees, and so on. In addition to tracking costs that patients incur, this component can be designed to track operating costs, from commodity and equipment purchases to health workforce budgets.

Purpose: To enable financial transactions to be validated, processed, tracked, and stored.

Component type: Functional

Range of functionality:

- *basic*: simple transaction formats and standards
- *advanced*: highly complex algorithms and workflows

Domain-specific examples:

- focused primarily on insurance and other payments to health workers in the financial-management domain
- health-related financial transactions do occur at non-health-sector entities that often define standards for electronic and mobile payments (e.g. e-government, financial, or banking institutions)

For many of these activities, specific workflows and algorithms designed for payment transactions will automate the flow of information between external applications and the DHP.

The functionality of the payments services component is not confined just to workflows, however. This component can provide connections to the various external services that process these transactions, namely electronic funds transfers [EFTs] from banks, credit card payments,

and online payments services like PayPal. This component can also work with mobile money services like M-Pesa. Because mobile devices use different operating systems and hardware for payments than desktop computers do, a payments services component that is mobile specific, called 'mobile payments', should be created. Since health system institutions do not have control over the APIs that banks and mobile network operators use, the DHP must provide functionality that allows interoperability across sectors.

As this aspect of payment services mediates interoperability with external applications that link to the DHP, this part of the component is housed within the external integration services in the DHP architecture.

The pregnant mother health journey (see Table 13) shows how a payments services component can be used in the DHP (called 'DHP-Payments service').

Interactive communication services

The interactive communication component provides mediation services to help digital health applications connect to mobile device services such as SMS, Unstructured Supplementary Service Data [USSD], interactive voice response [IVR], and voice. It can also provide a mediation layer for messaging functionality that is not unique to mobile devices, such as e-mail, chat (using WhatsApp Messenger, Google Talk, etc.), and social networks.

For example, external applications can work through the DHP to send alerts or information to mobile devices, such as reminders to take medication sent to patients, alerts about the status of commodity stock to facility operations managers, or health data tracked through a medical device used by the patient at home.

In the case of SMS, USSD, and IVR, channelling these transactions through a centralized service on a DHP can be cost effective for the external applications, as bulk-service negotiation with mobile network operators can reduce mobile service costs.

Purpose: to facilitate two-way communication between external digital health applications and communications services like SMS or e-mail

Component type: Functional

Range of functionality:

- *basic:* send simple or automated text messages or voice calls
- *intermediate:* use IVR with voice prompts to record data via number keys
- *advanced:* use Internet Protocol messaging tools (social networks)

Domain-specific examples:

- collect surveillance data in the field via USSD or SMS
- confirm eligibility for insurance or health subsidies
- transmit health education to patients or professional education updates to providers

This component will often work with workflow and algorithm services to process and automate alerts, responses, and data transmission. Data repositories store the content of messages mediated via the interactive communication component.

The pregnant mother health journey (see Table 13) shows interactive communication components as 'DHP-Messaging service'.

Geolocation services

The geolocation component empowers DHP-connected applications to identify and tag the actual geographic location of an object or device, such as a water source, building, mobile phone, or medical commodity. It uses multiple information signals to estimate the location of the object, generating a set of longitude and latitude coordinates just as a Global Positioning System [GPS] does. Then the component associates these coordinates with either a unique physical location, such as a street address, or a unique digital identifier, such as an Internet Protocol [IP] address, radio-frequency identification [RFID] tag, or device fingerprint.

Purpose: To tag an object with its geographic location

Component type: Functional

Range of functionality:

- basic: generating GPS coordinates for a person or object
- advanced: integrating location data with other data sets, including interactive maps that use decision-support tools

Domain-specific examples:

- track commodity shipments
- identify environmental hotspots to help control disease outbreaks
- locate affected populations and field staff during humanitarian crises
- facilitate contact tracing during surveillance
- identify faulty or expired equipment from remote location

Applications or DHP components using geolocation services can collect and share the spatial information with other DHP resources or applications, such as map repositories and data visualization tools. Geolocation services can also show under which administrative areas (e.g. provinces, districts) particular locations fall. These tools can display geodata on district, provincial, or national maps. They can also combine geodata with population, surveillance, or supply chain data sets to enable geospatial analyses. Such analyses could help identify sources of disease outbreaks, bottlenecks in the supply chain, or structures in the built environment that affect health and wellness.

Note that a country's data privacy policies may affect how much information geolocation services can gather.

Analytics

A DHP can have built-in analytical components, with tools that support the analysis of data for overall health-sector management, monitoring, systems improvement, performance management, and public health surveillance.

Analytics components can aggregate and analyse data housed within the DHP itself, such as in data repositories and registries. In cases where the DHP acts merely as a conduit and processor of data rather than as a storage unit, these components can apply analytical processing functions to log records of data that pass through the platform from external applications.

Purpose: To aggregate and transform data into formats suitable for analysis

Component type: Functional

Range of functionality:

- *basic*: simple analyses performed by users on a dashboard
- *advanced*: highly complex data mining for simulations and predictive modelling

Domain-specific examples:

- analysis of service delivery trends per facility
- predictive modeling of supply chain behavior
- aggregation and analysis of performance indicators

For analytics processing, warehouses are an essential component. DHP warehouses copy and aggregate data from other DHP data-storage components, such as registries, repositories, and record logs, into a database designed specifically for analytical purposes. These warehouses transform the data from multiple sources into formats suitable for analysis, helping optimize analytical queries and creating outputs more efficiently.

End users can view the DHP's analytic outputs using web interfaces and external data visualization applications. You could even allow users to view the analyses directly through the DHP's interface layer using the DHP's reporting component (see the 'Reporting services' section later in this chapter). Moreover, you could design your DHP to provide users with access to certain analytical tools while they view the data on the interface layer, empowering users to manipulate the data according to their needs. For example, health sector managers wanting to use population health data to set priorities for health interventions or policy-makers seeking hospital emergency care usage data for proposed legislation can interact directly with the data to produce tailored outputs. Health administrators can also use DHP analytics outputs to manage performance and improve quality.

On a different level, you can use these components to improve the DHP itself. You can apply DHP analytics components to internal DHP processes, such as workflows and transaction logs, to understand how well these components are working. You can then use this analysis to improve the DHP design by identifying new or modifying existing DHP components.

Common DHP components that provide information security services

User authentication and consent management

User authentication and consent management components in the DHP allow external applications to recognize a person's electronic signature or digital consent to common actions taken in the health system. For example, a patient may consent to a medical procedure, or a health worker may sign off on a prescription or referral. At the administrative level, a health worker may approve an insurance claim or a health administrator may acknowledge the delivery of health commodities through a digital signature.

This DHP component can also enable single sign-on [SSO] for users of multiple external applications that are linked through the DHP. Instead of requiring health workers or hospital administrators to enter a different username and password for each application, the platform can authenticate a user for multiple applications via the same sign-in credentials.

Purpose: To enable external digital health applications to recognize a person's digital consent; or, to authenticate the same user of multiple digital health applications

Component Type: Functional

Range of Functionality:

- *basic:* password-based verification and scanned signatures
- advanced: SSO, digital signatures, and biometrics

Domain-Specific Examples:

- patient authorizes consent for data sharing with digital signature
- health worker digital signature confirms diagnostic orders as basis for insurance or subsidy claim
- password verification used for health worker accessing e-learning modules
- patients access password-protected health data via mobile device

In all of these cases, the digital consent passes from the end-user application to the DHP consent component on the platform. At that point, the DHP verifies the user's identity as unique and then communicates that user's consent to the external application that seeks it, such as supply chain management or EHR software.

This DHP component may be less important when the DHP is in its infancy, when unique identification through registries is the initial goal for user authentication. However, the platform's ability to verify digital consent and the user's ability to sign off on data quality becomes essential as soon as sensitive health or financial information is exchanged or stored in shared repositories.

Enterprise mobility management

This DHP component serves the vital role of managing various devices (personal computers, laptops, tablets, smartphones, etc.) and the external applications on those devices. Enterprise mobility management [EMM] enables DHP administrators to control content and data on those devices as well.

A key function of EMM is enforcing security protocols, by authenticating and allowing a DHP connection only to those devices and applications that have been certified as conforming to DHP standards. So with EMM, DHP administrators can apply security controls and ICT security policies to protect device applications and content from unauthorized use. Device and external application authentication, remote wipe technology, and data encryption all EMM services.[7]

Purpose: to enable ICT administrators to centrally manage software and data on external devices, including enforcement of security protocols

Component type: Functional

Range of functionality:

- *basic:* remote device management, including policy compliance and secure containerization
- *intermediate:* Unified Endpoint Management [UEM], in which a single console manages all the computer-based devices within the system
- *advanced:* cognitive UEM, which uses artificial intelligence technology to identify vulnerabilities and optimize responses

Domain-specific examples: None. Functionality is uniform across all domains.

The EMM component also enables remote installation and updates of software. With this functionality, DHP administrators can push software to user devices, in contrast to the user-driven downloads that the applications store component offers (see the 'Applications store' section later in this chapter).

Because of its primary role in enforcing security protocols, the EMM component is housed under information security services in the DHP.

Common DHP components housed on the user interface layer

Data collection

The data collection component allows users, such as health insurance administrators, health workers, and patients themselves, to enter data directly into the DHP. Users input data via electronic forms made available on the interface layer. This layer then transmits the inputs into other DHP components, including registries and repositories for storage, processing, and use by other external applications.

[7] Wikipedia (2017). Enterprise mobility management. See: www.en.wikipedia.org/wiki/Enterprise_mobility_management

Purpose: to collect data inputs from various external sources and transmit them to other DHP components for storage and processing

Component type: functional

Range of functionality:

- *basic:* single record collection
- *advanced:* multirecord or tabular collection that allows comparisons

Domain-specific examples:

- user interface for tracking health worker training data
- user interface for patients to set up insurance-scheme profiles
- user interface for collecting routine disease surveillance data

To validate these data inputs before transmitting them into the DHP, the data collection component compares the information with defined parameter values and identifies errors and inconsistencies. Users may also need to authenticate their identities through DHP information security services before entering data.

At high levels of DHP maturity, external applications will collect most day-to-day data, and the DHP will operate behind the scenes. However, DHP designers may want to allow the DHP's own user interface to collect data directly, particularly at earlier stages in maturity.

Reporting services

The reporting component in the DHP allows users to view data that the DHP houses and processes. Users can directly look at reports or different data-visualization views via the interface layer, without needing access to an external application. Users could still employ external applications to see reports, but the DHP reporting component would not be used in those cases.

Purpose: To display the output of data collection and analysis

Component Type: Functional

Range of Functionality:

- *basic:* simple reports
- *advanced:* complex data-visualization views

Domain-Specific Examples:

- monthly reports of service delivery data
- commodity consumption and stock status reports
- usage reports of e-government services

Scheduling services

The scheduling services component provides an engine for setting up events or tasks. These tasks can be simple one-time events, such as a referral appointment at a specialist clinic. You may define and configure more complex events with this component as well. You can set up repeating events, from ongoing calendar appointments scheduled at regular intervals to automated data-aggregation, data-validation, or backup activities.

This component also allows the user to configure a trackable schedule, sometimes called a 'health schedule'. This type of complex event uses a predefined schedule based on milestones that trigger actions. When one milestone is met, another predefined event is set in motion. For example, health workers could receive alerts about the next phase of a professional education programme once they successfully complete a prerequisite. These milestones can include negative achievements, such as failure to remit payment for health services, which would trigger the dissemination of reminders and past-due notices. Milestones can be set at different intervals, so the first action triggered may occur two weeks after a reference point whereas the second action may occur just one week from the previous milestone.

The pregnant mother health journey (see Table 13) shows how this component is used (called 'DHP-Scheduling service').

Purpose: To create events or tasks based on a defined time period and/or intervals

Component type: functional

Range of functionality:

- *basic*: one-time events
- *advanced:* complex trackable schedules

Domain-specific examples:

- regularly scheduled maintenance checks on equipment
- variable, milestone-dependent schedules for patient physical rehabilitation
- performance management spot checks and ongoing reporting

Applications store

DHPs may have an app store where users can choose, download, and install external applications that are compatible with the DHP. Users can also download updates to these apps or set the apps to accept updates automatically.

For patient populations, apps would most likely be intended for patient self-care and self-management, enabling patients to interact with their own health records or their clinicians via personal computers or mobile devices. Apps could also support connections with other e-government services applications or portals, such as social services benefit programmes or insurance schemes.

For health workers, apps may focus on continuing education and professional training. Health workers could access individual and peer-to-peer learning courses offered by higher

education institutions or professional associations through the DHP applications store. If the DHP integrated with e-learning systems such as Moodle or Dudal, health workers could access content through their mobile devices via apps that this component makes available.

Purpose: To allow users to download DHP-compatible external applications onto their personal devices

Component type: Functional

Range of functionality:

- *basic:* simple searching and downloading of apps
- *intermediate:* automatic updates and advanced search algorithms
- *advanced:* group sharing of one app or content purchase

Domain-specific examples:

- e-learning apps for health workers
- nutritional education apps for patients
- e-government apps portal

Downloading apps through the applications store is user driven, unlike applications that DHP administrators manage through the EMM component, which are system driven.

Note that this component aims to supplement, but not supplant, the functionality of widely used app stores, such as Google Play, Microsoft Store, or Apple's App Store. This component does not create a full-service app store like these, but rather provides a means to access apps that are tailored for users of the health system.

Emerging DHP components

Current trends in ICTs and computing are spawning the development of new DHP components, as well as planting the seeds for future ones. The recent growth in m-health, electronic medical record-keeping, digital diagnostics, and PHDs has generated large volumes of data in the health sector. This pool of data will enlarge even further with the maturation of the nascent Internet of Things [IoT] technologies and networks. Such large data sets are called 'big data' because of their size and complexity. Harnessing the power of big data—through aggregation, complex analysis, and application of results to new technologies—will require, and generate, new DHP components.

Final frontier tricorder powered by AI engine

Star Trek – inspired 'tricorder' devices are finally being realized, as a result of advances in AI and IoT device technologies. Basil Leaf Technologies recently won the Qualcomm Tricorder XPRIZE for its consumer diagnostic device, called DxtER.

DxtER uses a set of IoT medical devices to gather diagnostic data such as vital signs, oxygen saturation, and blood cell counts from a patient. It also guides the user through a medical questionnaire and any follow-up tests based on responses and initial diagnostic results. Then, using analytic and machine learning components, DxtER compares these data with data sets of actual patient medical conditions and clinical emergency room diagnostic protocols.

With such tricorder devices, consumers can diagnose 13 common medical conditions in the comfort of their homes.

Sources: Qualcomm Tricorder XPRIZE (2017). Final Frontier Medical Devices. See: tricorder.xprize.org/teams/final-frontier-medical-devices/; S. Karlin (2017). More 'Star Trek' tech in real life: the Qualcomm Tricorder XPRIZE. Fast Company. See: www.fastcompany.com/40406304/more-star-trek-tech-in-real-life-the-qualcomm-tricorder-xprize/ (accessed 27 May 2020)

Many of these new components fall under the umbrella of artificial intelligence [AI] or data security. Tools are needed that can accurately aggregate and intelligently parse all of these diverse data arriving at such a rapid pace. Tools that can recognize the inaccuracies that accompany large, complex data sets are also essential; incorrect data can compromise the quality of care, not to mention the safety of patients and health workers. Components that protect data from malicious users must also be developed, since an increase in the scale of recorded sensitive information produces a concomitant rise in threats to data security.

Examples of emerging DHP components include:

- natural language processing [NLP]
- machine translation
- machine learning
- text-to-speech conversion
- image recognition
- blockchain security (see Appendix G: 'Data protection measures' for more information)
- semantic medical access
- wearable device access.

Interestingly, the benefits offered by the DHP itself necessitate the development of these emerging components. As the DHP infrastructure enables systems integration and data exchange, more and more data can be collected and shared. These aggregated and harmonized data sets then become the basis for improvements in AI technologies or big-data analytic tools. In turn, these improvements are incorporated into new DHP components that will enable further data processing and exchange. (See Appendix H: 'Internet of Things' for more information about the interrelationship amongst AI, big data, and IoT.)

World Food Program (WFP)'s efforts aided by chatbot

Food Bot, an open-source chatbot engine prototype built into the mobile data collection and reporting system used by the World Food Programme [WFP], enables remote, real-time collection of food-security data. Powered by an NLP engine and a set of components and APIs for routing messages and data, this chatbot operates within social-media and messaging applications that users access on their mobile devices.

Using this automated service, WFP can interact with and collect data from thousands in need of humanitarian aid, greatly increasing the scale and speed of its operations, as well as significantly reducing costs.

Food Bot's NLP engine does not currently use AI technology, but it is expected to be upgraded to machine-learning and machine-translation components once they emerge.

Sources: J. Bauer, L. Casarin & A. Clough (2017). Our experiment using Facebook chatbots to improve humanitarian assistance. ICTworks. See: www.ictworks.org/2017/08/07/our-experiment-using-facebook-chatbots-to-improve-humanitarian-assistance/; World Food Programme (2017). How many pizzas does it take to build a chatbot? mVAM Blog. See: mvam.org/2017/01/17/how-many-pizzas-does-it-take-to-build-a-chatbot/ (accessed May 2020)

Application of DHP components in health domains

You can leverage and tailor all of the generic enabling components in a DHP to meet the specific business-process needs of a health-sector domain. This section summarizes how six key health domains can use common enabling components to standardize and optimize the flow of data, leading to greater efficiency and improved performance. See Appendix B for additional details.

Service delivery and surveillance

The service delivery and surveillance domain often first comes to mind when thinking about the health sector. This domain comprises the day-to-day processes associated with diagnostic and treatment services, such as medical record-keeping, clinical decision support, and guideline-based care and referrals. Most of these processes and records may be paper based at first, with a DHP used simply to store reports of aggregated data. Over time, users may employ digital tools more and more to track individual patient care, automate scheduling, support clinical decisions, and aggregate data from various patient services (e.g. diagnostics, pharmacy) into shared records and standard reports. These digital tools may be increasingly linked together and standardized via the DHP—through the use of common registries and terminology, shared medical record repositories across multiple points of service, and standardized care workflows, amongst other enabling components.

Patient engagement

Patient engagement involves educating patients and empowering them to take charge of their own care, from prevention to treatment. Distributing health education content via websites and mobile devices has become widespread, supplementing traditional broadcast and print media. The emergence of digital health literacy gives patients a more personalized experience, as content and support can be tailored to each person. Digital tools may initially individualize

content based on a patient's general health profile (e.g. 55-year-old male smoker). These tools may evolve into more sophisticated targeting, providing content based on the patient's appointment and medical records data. A DHP can facilitate these personalized activities through health-education repositories, patient-engagement workflows, and patient registries. Other DHP-enabling components, such as interactive communications and app stores, can also improve efforts in this health domain.

Insurance and financial management

The financing structure of a health system can combine out-of-pocket payments, subsidies, grants based on fees or other criteria, reimbursement claims, and incentive payments. To better control finances, this health domain has increasingly digitized the management of costs and payments. A DHP can play a key role in improving financial and insurance management. For example, standard registries can help authenticate patient eligibility and claims, while analytics can track and forecast costs. The DHP payment services component can facilitate electronic and mobile payments, as well as standardize the workflows and terminology for claims, grants, or subsidies across the health sector.

Human resources management and capacity building

Health care workers – and their skills and capacity – are a central element of the health system. This health domain concerns itself with assuring that the health workforce is operating at capacity, in terms of numbers as well as professional skills. Therefore, collecting and tracking data on training, deployment, and shortages of health workers are critical for this domain. A DHP can help centralize these data, gathered from across the health sector by the disparate organizations that train, certify, regulate, employ, and pay health workers. Key DHP components for linking these data are registries, repositories, identity management, and workflows. A DHP can also accelerate and facilitate the use of digital tools for expanding the capacity of the health workforce. Centralized e-learning content, interactive communication tools, and workflows that enable telemedicine, remote mentorships, and continuing education are all possible with DHP enabling components.

Commodity and supply chain management

The supply of commodities, including drugs and other consumables, is essential to the health system. This domain is increasingly using digital systems to manage stocks, coordinate ordering and delivery, forecast needs, and solve bottlenecks. Regulation of commodities may also be managed digitally. A DHP can play a central role in linking the different parts of the supply chain system, which often crosses both the public and private sectors. Commodities can be monitored and dispensed efficiently and accurately with a DHP. The platform's common terminologies, data storage components, and supply chain workflows can automate the transfer of goods through the health system. DHP analytics and payment services components can improve commodity costing and inventory.

Facility and equipment management and supervision

Digital systems can facilitate management and supervision of health facilities as a whole, from infrastructure to quality of care. A health facility registry is an important starting point for uniquely identifying and mapping facilities. A DHP can also help optimize the various supervision and regulation practices in this domain. The DHP can help health administrators implement quality improvements in real time through common workflows, interactive communication, and

performance management analytics. It can also reduce the need for duplication in data collection through shared repositories of data on facility infrastructure, equipment, and performance.

Telemedicine initiatives and applications assist health service delivery and build human resource capacity while providing essential components for a DHP infostructure

Telemedicine initiatives are an important and growing part of digital health systems throughout the world. Telemedicine applications can leverage and contribute to DHP components on the back end, such as authentication services, workflows, interactive communications, and repositories for e-learning content, human resource training data, and patient information. The *Rede de Universidade de Telemedicina* (Telemedicine University Network) [RUTE] in Brazil and *Réseau en Afrique Francophone pour la Télémédecine* (Telemedicine Network in Francophone Africa) [RAFT] offer examples of how telemedicine applications have connected health workers from disparate and distant facilities for clinical consultations and ongoing mentoring.

RUTE connects over 100 public university and teaching hospitals in Brazil through telemedicine and telehealth units. These units support health workers' professional education and facilitate health care through video and web conferencing as well as the operation of nearly 60 special interest groups in various medical specialties and subspecialties. In addition to allowing remote consultations and sharing medical records, RUTE's high-capacity national network infrastructure enables and promotes the innovation of new applications and technologies in health education and remote data analysis. RUTE also promotes the integration of research institutions, streamlining data dissemination and furthering collaborations.

RAFT connects hundreds of health professionals worldwide through more than 60 sites located in sub-Saharan Africa, South America, and Asia. RAFT offers free video lectures to health professionals for continuing and postgraduate education, as well as a tool for facilitating online tele-expertise sessions, or peer-to-peer mentoring, amongst health workers regarding clinical cases. Available in French, English, Spanish, and Portuguese, RAFT's e-learning activities cover a wide range of medical topics, helping remote professionals improve knowledge and skills. Tele-expertise connects health workers in remote, infrastructure-limited settings with specialists from more developed regions, reducing problems with access to quality care. Health system professionals have also benefited from RAFT's tele-expertise functions outside of the clinical setting, using them to support the deployment of digital health systems.

To facilitate these telemedicine activities, RAFT developed the distance-learning application Dudal. RAFT's tele-expertise functionality is provided by Bogou, a web-based application that offers a secure environment for sharing patient data and conducting clinical mentoring. Bogou also supports Digital Imaging and Communications in Medicine [DICOM] images to help with remote diagnoses.

For more information about RUTE, see: rute.rnp.br. For more information about RAFT, see: raft.g2hp.net.

Sources: National Education and Research Network (2017). What is the Telemedicine University Network (RUTE)? See: rute.rnp.br/arute; National Education and Research Network (2014). RUTE surpasses 100 telemedicine units in full operation throughout Brazil. See: www.rnp.br/en/news/rute-surpasses-100-telemedicine-units-full-operation-throughout-brazil (accessed 27 May 2020); G. Bidiang, C. Perrin, R. Ruiz de Castañeda, Y. Kamga, A. Sawadogo, C. O. Bagayoko & A. Geissbuhler (2014). The RAFT telemedicine network: lessons learnt and perspectives from a decade of educational and clinical services in low- and middle-income countries. Frontiers in Public Health, 2(180). doi:10.3389/fpubh.2014.00180

Sample architecture for a DHP

A sample architecture for a complex DHP that uses many of the common core enabling components previously described is illustrated in Figure 11. Individual enabling components (*lavender*) are grouped by component type (*purple*), such as workflows, with some subcategories shown for certain components.

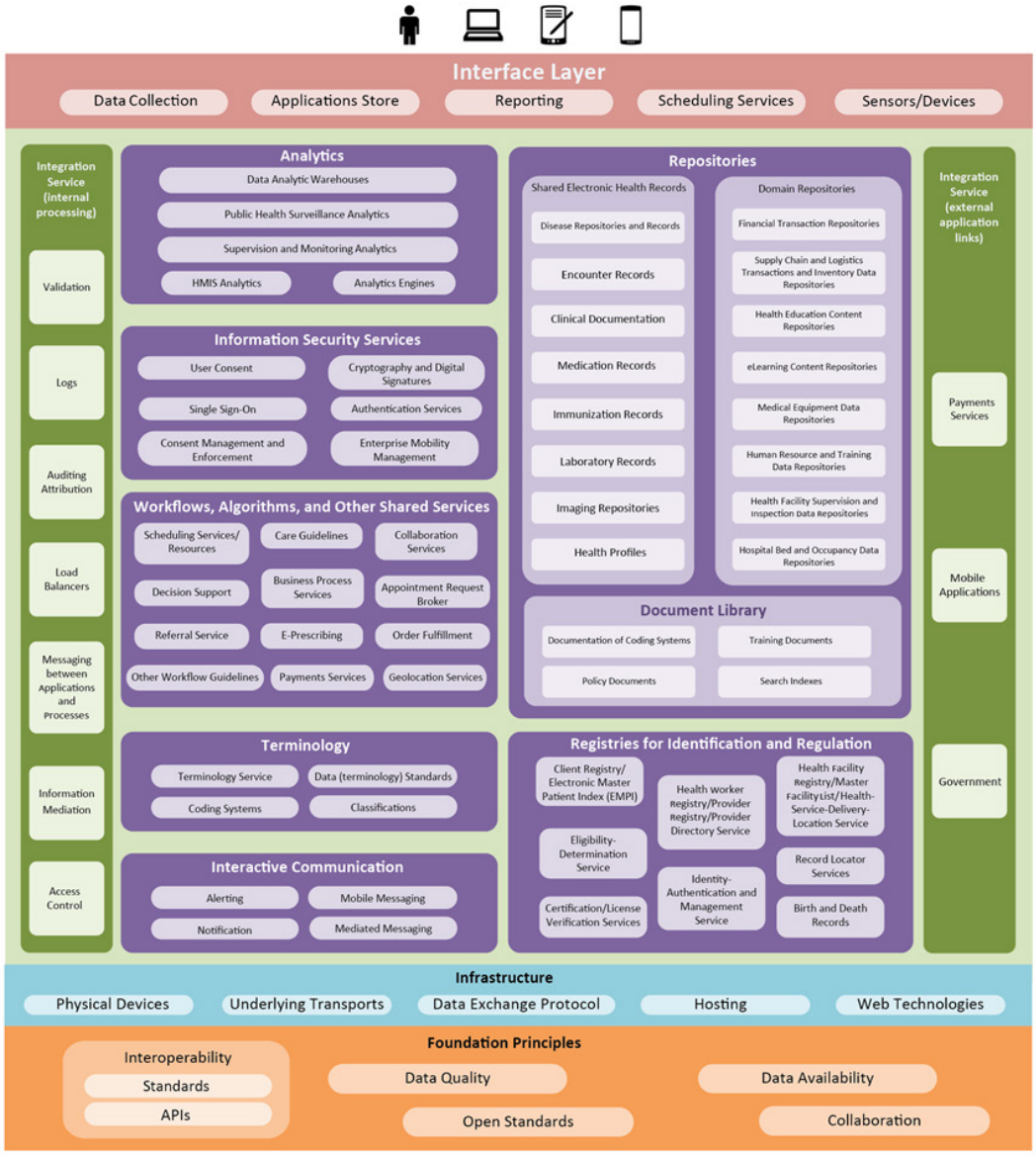
Data is exchanged within the DHP and amongst external systems through integration services, a 'skin' that wraps around the components (*light green*). The components within integration services (*dark green*) act as the switchboard that mediates this data exchange and the interaction amongst applications. This layer is divided in two and bookends the other DHP components to reflect its role as a mediator on internal processes as well as external connections. A mature DHP will provide links to multiple architectures, such as financial institutions and e-government services.

While integration services connect systems to the DHP, the interface layer connects people. The interface layer (*red*) offers users direct access to those DHP components that provide user interfaces as a key functionality. For example, a reporting interface allows users to access data stored in the DHP in different views, a task that a health planner or policy-maker may wish to do with population health data.

All DHPs are underpinned by foundational principles (*orange*) and must be supported by a technology infrastructure (*blue*).

Note that Figure 11 shows only a few types of components that could be included in your platform –by no means an exhaustive list. Moreover, it is designed to show a sample of the core components to help you visualize the different types and how the architecture fits together. So it is not meant to prescribe how your DHP should be designed. Instead, you can use this as a guide when creating your high-level blueprint of the DHP infostructure needed in your country.

Figure 11: Sample DHP architecture



Learn more about DHP components

Health Information Exchange: Navigating and Managing a Network of Health Information Systems, edited by B. Dixon, Elsevier Academic Press (2016)

SDG Digital Investment Framework, ITU (2018)

https://www.itu.int/pub/D-STR-DIGITAL.02-2019

Process for identifying DHP components

To identify components for your DHP design, start with the business architecture of your DHP enterprise architecture. You may have defined this architecture when doing business process analysis (see Section 4: 'Health business process mapping'), resulting in a table, flow chart, or user story that reflects the flow of information—and potential pain points—in a particular business process in the health system. Mapping specific DHP components to this business architecture defines your information architecture, comprising both the applications and data architectures. It describes your vision for how health system business processes will run with the help of an integrated and interoperable DHP. The output of this component-mapping process is a set of functional requirements for your DHP components. Use these when developing requirements documentation for your software development team or when writing Requests for Proposals [RFPs] for systems integrators or solutions vendors that you partner with. Section 6: 'Select software for your DHP' discusses requirements documentation further.

Write up your use case as a health journey and identify the digital health moments

This handbook uses a form of user stories called 'health journeys' to show users' experience in a health system business process. Health journeys illustrate the uses of the DHP by its beneficiaries (or things) who interact in the health sector: consumers, health workers, administrators, and even health commodities. The health journey identifies digital health needs, called 'digital health moments', which are pain points where digital health interventions—and therefore the DHP—can make the business process more efficient, more useful, and higher quality, resulting in better health-system performance.

When writing health journeys, include the following information:

- Identify the main actors in the journey, such as a patient and a health worker.
- Describe any background information about these users that is relevant to the business process.
- Write a separate paragraph for each business process step, showing how users experience it.
- Think about the inefficiencies and gaps in the process: the pain points.
- Describe how you want the system to operate so that it solves these pain points. For example, if tracking patients is a challenge, describe what the health workers and information system will do to follow patients accurately during their health system encounters. You may apply a digital health intervention to this problem, or you may decide that a non-digital intervention is best.

The interventions described will help identify DHP components and their functional requirements.

The pregnant mother health journey (see Figure 12) describes a potential journey in a community-based care setting of a developing country. The chronic obstructive pulmonary disease [COPD] health journey (see Figure 13) portrays a hypothetical journey in an integrated care setting of a developed country, with a significant patient self-management component. See Appendix D: 'Health journeys' for more details on both of these journeys.

Tip: Complement your health journey narrative with flow charts, context diagrams, and process matrices. These diagrams will help visualize the steps, pain points, and solutions for the business process. See Section 4: 'Health business process mapping' and Annex Tables C.1 and C.2, as well as Annex Figures D.1, D.2, and D.3, for examples. The diagrams in Appendix D illustrate the pregnant mother health journey (see Figure 12).

Figure 12: Pregnant mother health journey

Savita is a 25-year-old Indian woman who is pregnant with her first child. Since it is her first pregnancy, Savita does not know much about proper medical care, either antenatal care or care during her baby's birth. Asha, the Accredited Social Health Activist [ASHA] working in Savita's village, plays a critical role in facilitating maternal care as a community health worker. The following are the major events in Savita's health journey:

A. **Asha visits Savita and her family**

Asha learns that Savita is pregnant through her regular family visit as a community health worker. She advises Savita about the benefits of antenatal care [ANC}, as well as of delivering her baby at a health facility, not at home.

B. **Asha registers Savita in the Mother and Child Tracking System [MCTS]**

Asha records information about Savita into her personal cohort list and registers her in the MCTS, a digital health application designed to track the health of mothers and their children, as well as their interactions with the health system. Upon registration, the MCTS verifies Savita's identity with the externally-managed national citizen records system. An EHR is also set up for use in all encounters with a health worker. MCTS provides Savita with a bar-coded identification card to use each time she seeks care.

C. **Asha makes an appointment for Savita's first antenatal care visit with the clinician**

The same day, Asha arranges for Savita to visit the clinician attached to the primary health centre in her village. This will be Savita's first ANC visit. A few days before the appointment, reminder messages are sent via SMS to Asha's and Savita's mobile phones.

D. **Savita receives her first antenatal examination**

Clinic Registration scans Savita's ID card to confirm her identity and track that she showed for her appointment. At the start of the exam, the clinician pulls up Savita's EHR on his computer screen. The clinician updates the record with the exam findings and orders for lab tests, medications, and nutrition supplements.

E. **Savita receives lab tests**

Savita goes to the lab for the specified tests. The lab technician scans Savita's MCTS card to retrieve her health record and the lab orders. The lab technician obtains the test results and then updates the EHR. MCTS sends an alert to the clinician that the lab results are ready to view in the EHR.

F. **Savita visits the pharmacy**

Savita visits the pharmacy outside of the clinic to pick up her medications and nutrition supplements. The pharmacist scans the barcode on Savita's card to retrieve her health record and e-prescription. The pharmacist fills the prescription, assesses the guidance provided by the clinician for the medications and supplements, and reinforces these instructions with Savita.

G. **Savita receives the second and third antenatal care examinations**

For her second and third examinations, Savita visits a different clinic. Using Savita's MCTS card, the registration desk and the clinician pull up her records easily. The clinician updates the record and advises Savita on the importance of nutrition.

H. **Savita delivers her baby at a facility near her mother's home**

For her baby's delivery, Savita visits a different facility, one closer to her mother's home where it is customary for her to live during her pregnancy. Savita calls Asha to escort her to the maternity ward at the clinic when labour begins. She delivers a healthy baby girl.

I. **Savita and Asha are paid incentives for participation in the health intervention**

As Savita and Asha have followed all of the procedures for a safe and healthy delivery, Asha's supervisor authorizes payment of incentives to both of them for their participation in the MCTS health intervention.

Figure 13: Chronic obstructive pulmonary disease health journey

Cyril Lambert is a 60-year-old man who rarely visits the doctor. However, over the past two years, he has suffered from a persistent cough, with intermittent episodes of shortness of breath.

A. **Search for new family clinician**

Cyril's longstanding family clinician has recently retired. He finds a new clinician, Dr Martin, on a website and schedules an appointment via his mobile phone. Cyril also fills out the health history questionnaire [HHQ].

B. **New family clinician appointment**

At registration, the office assistant verifies Cyril's personal data and insurance eligibility and tells Cyril about the mobile app for booking appointments. Using assessment templates, the nurse and Dr Martin review the HHQ and enter exam findings into Cyril's EMR, which offers a possible diagnosis of COPD with asthma. Dr Martin electronically orders a chest X-ray, lab tests, and pulmonary function tests and requests alerts to his phone about the results. He prescribes an inhaler and counsels Cyril to stop smoking.

C. **Inhaler purchase at the pharmacy**

When filling the prescription, the pharmacist verifies that a substitute inhaler type is approved by insurance.

D. **X-ray and pulmonary function testing at local hospital**

The technicians electronically verify Cyril's identity, perform the tests, and enter the findings in Cyril's EMR.

E. **COPD diagnosis confirmation in follow-up appointment with Dr. Martin**

Dr Martin reviews the test results and confirms that Cyril has COPD. Dr Martin initiates a COPD care plan based on electronic clinical practice guidelines, sets care goals with Cyril, and describes optional navigation services for the COPD care activities. Dr Martin adjusts Cyril's inhaler medications and advises Cyril to monitor his COPD at home with an electronic peak flow meter. He instructs the pharmacist to provide education on this.

F. **Purchase of peak flow meter**

Cyril purchases an off-the-shelf electronic peak flow meter and fills the prescription for his revised inhaler medications. The pharmacist counsels Cyril on use of the device and inhaler medications and sends a video link to Cyril's PHR. The pharmacy system tells Cyril's EMR that education was given.

G. **COPD home monitoring**

Cyril decides to engage an online home monitoring service to monitor the peak flow results. Via his PHR, he finds a service online and loads the software on his computer. As part of the service registration, Cyril uploads his COPD care plan, enters health information, and authorizes the service to share data with his clinician network and the local emergency services department.

H. **Smoking-cessation programme at the public health department**

Cyril also enrols in an online smoking-cessation programme using his PHR and updates his care plan to indicate that this task assigned to him by Dr Martin is complete.

I. **Home monitoring service intervention**

When Cyril's peak flow results worsen, the home monitoring service contacts Cyril. Based on information provided by Cyril, the service recommends that he visit the local hospital's emergency department with his current medication. The home monitoring service sends Cyril's relevant health information to his EHR.

J. **Emergency department visit**

At the emergency department, the registrar and the triage nurse access Cyril's EHR from the national HIS, which notifies Dr Martin. The clinician conducts standardized assessments and orders medications and diagnostic tests. He recommends that Cyril see Dr Martin about adjusting his medications if his symptoms do not improve. The HIS sends an update and the discharge orders to Dr Martin.

Match DHP functionality and components to the health journey steps

From your health journey narrative, you can define the digital health moments and the specific DHP functionality needed for each of those moments. When using the CRDM approach discussed earlier in Section 4: 'Health business process mapping', you would make these the functional requirements for your DHP.

Use the template in Table 12 to describe digital health moments, DHP functionality, and DHP components.

Table 12: Template for identifying DHP functionality and components from health journeys

Journey Step	Digital Health Moment (where DHI is applied to business process)	DHP Functionality	DHP Components
A.1	**Moment name:** Each step in a specific moment is described here in non-technical language, including: • the health service provided • participant roles • setting for service • information gathered	Briefly describe the functionality needed to meet the needs of the digital health moment. Technical language can be used here.	Describe the interactions between the external applications and DHP components. DHP components are named explicitly, along with the nature of the interactions.

Tables 13 and 14 apply this template to the health-journey narratives shown on the previous pages (Figures 12 and 13). These examples depict only a subset of the digital health moments in the pregnant mother and COPD health journeys. Each of these digital health moments could be realized with different user interfaces or external applications and at varying levels of complexity.

Pregnant mother health journey—Savita

The example in Table 13 covers all of the major steps and digital health moments in Savita's health journey. See Annex Figure D.3 for a visual representation of this table.

Table 13: DHP functionality and components for pregnant mother health journey

Journey Step	Digital Health Moment (where DHI is applied)	DHP Functionality	DHP Components
A	*None: solution is not solved through digital systems.* **Linkage with community health worker**: Savita meets the community health worker, Asha, when she discovers she is pregnant. Asha provides basic information on safe childbirth to Savita and advises her on the health services to which she is entitled, including antenatal care.	N/A	N/A

Journey Step	Digital Health Moment (where DHI is applied)	DHP Functionality	DHP Components
B.1	**Enrolment in MCTS**: Savita, a new mother-to-be, is enrolled in MCTS. Asha records Savita's name and identification in her personal cohort list. Asha creates a new record for Savita in the MCTS software program.	Identification management for tracking person or place within system Data storage Workflow for tracking person's progress in care plan	MCTS uses the *DHP-Patient-Registry service* to create a new record for Savita with a unique MCTS identification. MCTS uses the *DHP-EHR-Repository service* to create an EHR for Savita. MCTS interacts with the *DHP-Workflows service* to create a complete individualized workflow for Asha to follow the progress of Savita's pregnancy in her local cohort list.
B.2	**Enrolment in MCTS**: Upon registration, MCTS verifies Savita's identity with the externally managed national citizen records system.	Authentication through link with government system	The *DHP-Patient-Registry service* uses the *DHP-Identity-Authentication service* to validate Savita's identity through the external national identity system and then map it to the MCTS record. To track Savita's encounters with MCTS, it generates a bar-coded identification card for Savita, with a copy for Asha.
B.3	**Enrolment in MCTS**: Asha creates a new record for Savita in the MCTS program.	Data storage	MCTS uses the *DHP-EHR-Repository service* to create an EHR for Savita.
C	Asha makes an appointment for Savita's first antenatal care visit with the clinician. The same day, Asha arranges for Savita to visit the clinician attached to the primary health centre in her village. This will be Savita's first ANC visit. A few days before the appointment, reminder messages are sent via SMS to Asha's and Savita's mobile phones.	Calendaring and scheduling functionality Workflow for routing reminders about appointments, including workflow to send SMS to mobile devices	When Asha sets Savita's appointment, MCTS uses the ***DHP-Scheduling service*** to put it on the electronic calendar. A few days prior to the forthcoming antenatal care visit, MCTS uses the ***DHP-Workflows service*** to remind Savita and Asha of the appointment. The reminder message is sent as an SMS using the ***DHP-Messaging service***.

Journey Step	Digital Health Moment (where DHI is applied)	DHP Functionality	DHP Components
D	First ANC visit: Savita visits the clinic for an antenatal care visit. Clinic Registration scans Savita's ID card to confirm her identity and track that she showed for her appointment. The clinician pulls up Savita's EHR on his computer screen. The clinician updates the record with the exam findings and orders for lab tests, medications, and nutrition supplements.	Identification management for tracking person or place within system Data storage Ability to create lab orders and e-prescriptions.	MCTS uses the ***DHP-Patient-Registry service*** to confirm Savita's identity from the bar code. MCTS uses the ***DHP-EHR-Repository service*** to retrieve Savita's EHR. The clinician updates the EHR and creates lab orders and e-prescriptions to her record.
E	Lab visit: Savita visits the lab and presents her MCTS card. The lab technician scans the barcode on Savita's card to retrieve her EHR and the lab orders. The lab technician draws the samples, performs the tests, and updates the EHR.	Identification management for tracking person or place within system Data storage Workflow for routing health worker orders, including to facilities external to DHP	MCTS uses the ***DHP-Patient-Registry service*** to confirm Savita's identity from the bar code. The laboratory information system [LIS] uses the ***DHP-EHR-Repository service*** to retrieve Savita's EHR for updating Savita's lab results. The LIS uses the ***DHP-Workflows service*** to inform the clinician about the results when Savita's EHR is updated.
F	Pharmacy visit: Savita goes to the pharmacy and presents her MCTS card. The pharmacist scans the barcode on Savita's card to retrieve her health record and e-prescription. The pharmacist fills the prescription, assesses the instructions Savita has already received from her clinician, and reinforces Savita's need to comply with the instructions for use.	Identification management for tracking person or place within system Data storage Workflow for retrieving e-prescriptions, determining needed commodities or substitutes, and updating EHR when complete	MCTS uses the ***DHP-Patient-Registry service*** to confirm Savita's identity from the bar code. The pharmacy system interacts with the ***DHP-e-Prescribing service*** to complete the following actions: retrieve the electronic prescription determine the nutritional supplements or the equivalent supplements to be provided dispense medications and supplements update the ***DHP-EHR-Repository*** after dispensing.

Journey Step	Digital Health Moment (where DHI is applied)	DHP Functionality	DHP Components
G	Savita receives the second and third antenatal care examinations. For her second and third examinations, Savita visits a different clinic. Using Savita's MCTS card, the registration desk and the clinician pull up her records easily. The clinician updates the record and advises Savita on the importance of nutrition.	Identification management for tracking person or place within system Data storage	MCTS uses the ***DHP-Patient-Registry service*** to confirm Savita's identity from the bar code. MCTS uses the ***DHP-EHR-Repository service*** to retrieve Savita's EHR. The clinician updates the EHR.
H	Savita delivers her baby at health facility. For her baby's delivery, Savita visits a different facility, one closer to her mother's home where it is customary for her to live during her pregnancy. Savita calls Asha to escort her to the maternity ward at the clinic when labour begins. She delivers a healthy baby girl.	Identification management for tracking person or place within system Data storage	MCTS uses the ***DHP-Patient-Registry service*** to confirm Savita's identity from the bar code. MCTS uses the ***DHP-EHR-Repository service*** to retrieve Savita's EHR. The clinician updates the EHR with notes about the delivery.
I	Savita and Asha are paid incentives. As Savita and Asha have followed all of the procedures for a safe and healthy delivery, Asha's supervisor authorizes payment of incentives to both of them for their participation in the MCTS health intervention.	Data storage Workflow for issuing payments to patient and ASHA registered in MCTS.	MCTS uses the ***DHP-EHR-Repository service*** to retrieve Savita's EHR. MCTS uses the ***DHP-Payments service*** to process intervention incentive payments for Savita and Asha.

COPD chronic disease health journey—Cyril

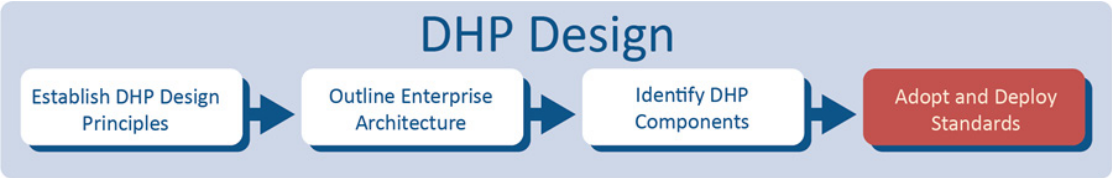
As Cyril's journey is quite long and has many digital health moments, this example just focuses on Step E, confirmation of the COPD diagnosis, a step involving some DHP components that differ from Savita's journey. Cyril's journey in Appendix D: 'Health journeys' shows how DHP functionality and components map to the digital health moments in the other steps.

Table 14: DHP functionality and components for one step in COPD chronic disease health journey

Journey Step	Digital Health Moment (where DHI is applied)	DHP Functionality	DHP Components
E.1	**Review test results**: Dr Martin accesses Cyril's information in his EMR and reviews the test results.	Data storage Workflow to pull order status and test results when done Workflow to send alert notifications	The EMR polls the *DHP-Order-Fulfilment service* to obtain the status of Dr Martin's orders. The *DHP-Order-Fulfilment service* sets flags to notify Dr Martin upon completion of the tests. The results for the lab and pulmonary function tests are retrieved from the *DHP-Order-Fulfilment service* to the EMR. The EMR accesses the *DHP-EHR-Repository* to show the test results to Dr Martin.
E.2	**Confirm diagnosis**: Dr Martin confirms the clinical diagnosis of COPD and asthma. Dr Martin enters COPD and asthma in Cyril's EMR problem list.	Data dictionary with diagnostic codes Data storage	The EMR obtains the diagnostic codes necessary for reimbursement and analytics from the *DHP-Terminology service* and places them in the EMR problem list. The EMR provides a copy of the problem list entries to the *DHP-EHR-Repository*.

Journey Step	Digital Health Moment (where DHI is applied)	DHP Functionality	DHP Components
E.3	**Initiate COPD care plan**: Dr Martin selects a COPD care plan based on clinical practice guidelines to set care goals with Cyril and explain optional navigation services that can help coordinate care activities. Cyril declines the services for now. Dr Martin adjusts Cyril's inhaler medications. Dr Martin customizes the order set, including enrolment in a COPD disease programme, peak flow monitoring service at home, and COPD education from the pharmacist regarding medications and devices. Dr Martin submits the care plan including the electronic orders, and prints confirmation of the orders for Cyril.	Clinical care plan templates and guidelines Workflow to populate templates and forms with data from other health institution or clinic department services Algorithm to disseminate templates and forms to appropriate health workers and health-related institutions as well as other appropriate external applications	The EMR retrieves a COPD care plan template from the *DHP-Reference-Information service*. The EMR retrieves Cyril's HHQ results from the *DHP-Referral service* and prepopulates the care plan with data from there as well as from the problem list in the EMR. The information in the completed COPD care plan template is copied to the *DHP-Collaboration service*, where the care plan can be shared with other health workers and Cyril's PHR software.
E.4	**Submit electronic orders**: The electronic prescription for new medications is submitted. The COPD programme enrolment order is submitted.	Data storage	The *DHP-e-Prescribing service* receives the prescription. The orders for the COPD programme enrolment, monitoring service, and education programme are submitted to the *DHP-Order-Fulfilment service*. The COPD programme Chronic Disease Management application polls the *DHP-Order-Fulfilment service* for new requests and, upon receiving the order, transmits a programme registration request and link to Cyril's PHR. A list of certified monitoring services is transmitted to Cyril's' PHR.

Adopt and Deploy Standards



Learning objectives:

- Explain what standards are and why they are essential for creating an interoperable DHP.
- Outline how international and national standards are the basis for DHP standards.
- Describe the different types of standards needed in the DHP.
- Explain how standards stacks are beneficial for creating interoperability in the DHP.
- Lay out the steps involved in adding standards to your DHP design.
- Provide practical guidance to consider when choosing and selecting standards.

Standards adoption key tasks

- Learn about different standards types and standards stacks.
- Identify interoperability points in DHP architecture.
- Develop standards strategy and framework.
- Publish standards and interface specifications.

Standards, when applied to information formats and processes shared amongst ICT systems, enable different digital applications and technologies to exchange information and participate in workflows. A DHP facilitates the use of common standards by its internal components and enforces the use of standards by external applications connecting to the platform. Thus, the DHP breaks down barriers between siloed applications and lays the groundwork for future digital health expansion.

Using common standards in your DHP is important for interoperability and scalability, as well as for the quality of DHP outputs. If each ICT product standardizes only for its own purposes or uses standards that are inconsistent with other products, information cannot be shared, combined, or compared. Therefore, standardization is recommended for anything that needs to be counted, compared, aggregated, or analysed, as well as for data used as a trigger or context for an automated process. Importantly, sharing health data in an unstandardized system increases the risk of harming the patient. Whenever there may be ambiguity or inaccuracy in the information exchanged, health conditions may be mistreated, population health trends or disease outbreaks may be overlooked, commodity supplies may be overestimated, or data privacy may be compromised. For this reason, it is essential to select appropriate standards from the outset.

Stakeholders for identifying DHP standards

- Ministry of ICT adviser
- HIS developers and vendors
- HIS community advisers
- E-government coordinators
- ICT advisers from donors and non-governmental organizations focused on software deployment

Sources of standards for the DHP

Health informatics standards used in the DHP ideally should be drawn from standards adopted at the international level. Using international standards has the advantage that detailed work in this area does not need to start from scratch. In addition, vendors of health software applications that operate in multiple countries, as well as their customers, benefit from using common international standards because less customization is required. This reduces the time, cost, and risks of acquiring and implementing new applications.

Even at the international level, a broad range of standards developing organizations and standards authorities exist, each defining and validating various standards to choose from. Some of these standards are complementary, some are duplicative, and some have issues in terms of their usability and extensibility. Therefore, you need to carefully assess any international standards as fit for purpose in the implementation and operation of your DHP.

In some cases, international standards suitable for your DHP's needs will not exist. You can use or adapt existing national standards instead, as many of these should have also been validated by their respective national bodies. The following descriptions note where key national standards are used, such as care guidelines. Note that there are not yet explicit international or national policies requiring the use of standards when creating digital health systems.

Tip: Remember to standardize the units of measure (e.g. grams, inches) used in data that the DHP handles. Overlooking these small details can have big consequences!

Types of standards

Consider a variety of standards in your DHP design, not just those concerning health informatics. Some non-health-specific international standards used in ICTs and some national standards that encompass multiple sectors pertain to a DHP. Brief descriptions of each type of standard to consider follow, with more attention given to health informatics standards.

National or international standards may also be formulated as 'open'.

ITU defines open standards as:

- publicly available and intended for widespread adoption
- sufficiently detailed to permit the development and integration of various interoperable products and services
- developed, approved, and maintained via a collaborative and consensus-driven process.

National multisectoral standards

A country may have established standards for referring to and identifying individual people, places, administrative areas, or government institutions. E-government agencies and telecommunications regulatory authorities may also have standards in place. Standards used to transmit financial data or code vital registration records are examples of national, multisectoral standards that will likely apply to your DHP. Note that national, multisectoral standards are not necessarily internationally recognized standards.

Information and communication technology standards

Participating external applications and systems need to adhere to a common set of standardized ICT protocols to support interoperability and maintain confidentiality during information exchange in the DHP. These standards may include networking, hardware, physical data storage, Internet, and telecommunications protocols that are well established and used broadly by many sectors (see sidebar, 'Common ICT standards'. Wireless communications with health devices may use standards such as Wi-Fi, Bluetooth, Bluetooth Smart, Zigbee, or near-field communication [NFC]. Some protocols are more suited for a closed network, while others are more suited to distributed networking environments and mobile telecommunications. Finally, Global Standard One [GS1] standards for product barcodes are important for tracking the movement of health commodities and equipment through the supply chain.

Using standard APIs helps create interoperability within the DHP ecosystem, enabling seamless interactions amongst the DHP components and between the DHP and external applications. Standard APIs established by DHP implementers should be made available to external application developers for their products. Ideally, APIs are designed and developed in an open manner, allowing potential users of each API to contribute to the design, development, and validation of the interface.

Common ICT Standards:
For connectivity: • TCP/IP • Bluetooth • USB
For interoperability: • XML data format standard • HTTP transfer protocol • ISO/IEEE 11073 data exchange protocol
For middleware: • Simple Object Access Protocol [SOAP] • Representational State Transfer [REST] API • See www.w3.org/standards/
For privacy and security: • HTTPS • Public key infrastructure [PKI] • OpenAuthorization [OAuth] • Device pairing
For service-oriented architecture, see: www.opengroup.org/standardsand www.omg.org/marketing/omg-standards.htm Note: All websites accessed 17 27 May 2020.

Health informatics base data standards

Health informatics base data standards provide a means for standardizing the data that the DHP and its external software applications exchange. Often established by international standards developing organizations and institutions, these health-specific standards focus on the structure and coding of data, essential for enabling semantic interoperability with the DHP. Various classification systems and reference terminologies are commonly used for these base data standards (see sidebar, 'Important international health informatics base data standards').

> **Tip:** When choosing a coding approach, consider using or adapting health insurance billing codes or pharmaceutical codes used in regulation and supply chain management.

A useful tool for standardizing health informatics data is a health data dictionary [HDD]. A HDD describes all of the information that a database collects and the standards that all of the data must follow to be shared properly, including how data appear on forms and how data is coded. DHP terminology components make the HDD available to external applications (see Section 5: 'Identify DHP components'). To help create an HDD for your DHP, use the openHDD tool from

the Joint Learning Network.[8] This web-based, open-source tool contains HDDs from several countries, which may be useful for customizing your own HDD.

The HDD and the DHP terminology component can facilitate communication amongst applications and systems that classify data in their own way. Many digital health applications have specialized ways for presenting data because of legacy systems and variations between countries and organizations. With the DHP terminology component, mapping between different standards schemes may be possible, provided it is safe to do so and no significant meaning is lost. Each application's standards are mapped to the DHP's HDD, facilitating accurate information exchange amongst the systems. For example, if Application A refers to 'multidrug-resistant tuberculosis [MDR-TB]' in one standard while Application B refers simply to 'TB', mapping to the standards defined in the HDD can prevent the clinical and public safety issues that can arise from misclassifying the disease.

Some classifications for health informatics base data standards can be more focused at the national level. For example, health data standards for classifications of drugs or commodities may be developed in conjunction with national drug regulatory authorities or bureaux of standards.

Important international health informatics base data standards

Classification Systems:

- ICD-10: International Classification of Diseases, Tenth Revision
- ICF: International Classification of Functioning, Disability, and Health
- ICHI: International Classification of Health Interventions

Reference terminologies:

- SNOMED CT: Systematized Nomenclature of Human Medicine Clinical Terms
- LOINC: Logical Observation Identifiers Names and Codes
- ISO/IEEE 11073: Set of standards for medical and personal health devices

See Appendix F for further details.

Health workflow standards

Health workflow standards support interoperability by standardizing the sequencing of health-related business processes that the DHP and external digital health applications support. Some examples of these processes are electronic scheduling, prescribing, and submitting orders. Many workflow standards are based on national and international healthcare guidelines, such as a country's maternal care guidelines, WHO's Expanded Programme on Immunization [EPI] guidelines, or international guidelines for COPD from the Global Initiative for Chronic Obstructive Lung Disease. Workflow standards can also derive from the specific workflow steps that you identified in the digital health moments and designed for the DHP components.

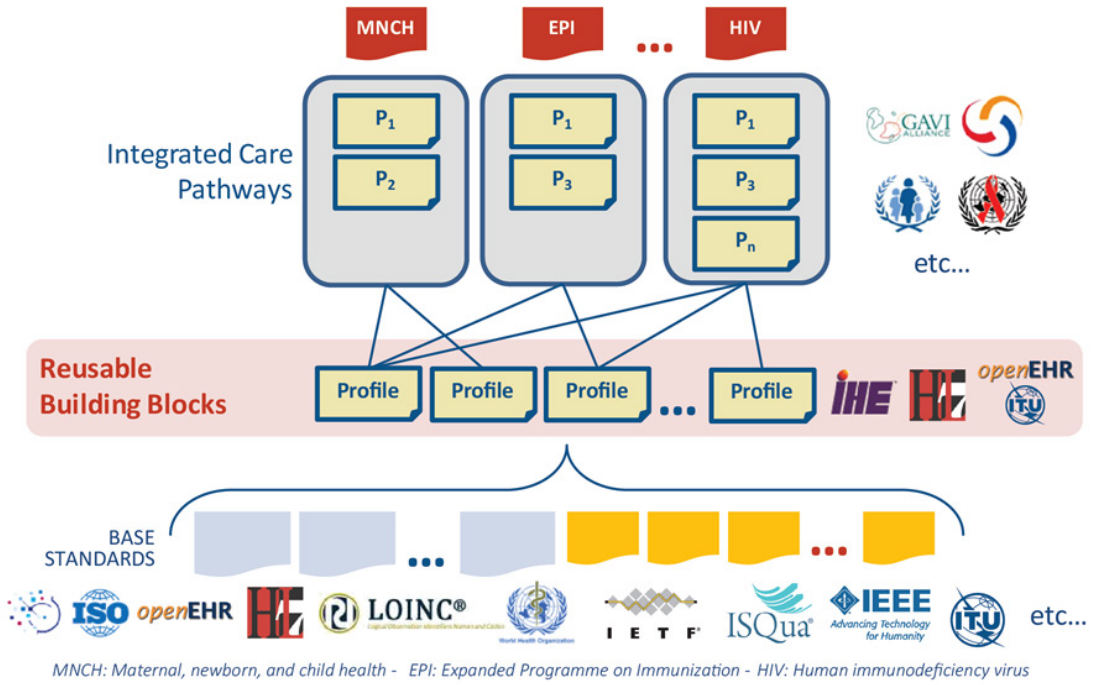
[8] openHDD is developed by PharmAccess Foundation, in partnership with PATH, for the Joint Learning Network [JLN]. See: www.jointlearningnetwork.org/technical-initiatives/information-technology/resources for various resources related to the openHDD tool and its usefulness in promoting interoperability. (Website accessed 27 May 2020)

There are two types of health workflow standards, those for high-level workflows and those for detailed workflows:

- **High-level workflows** define the standards for the workflows associated with overarching clinical pathways, sometimes called 'integrated care pathways', such as maternal, newborn, and child health [MNCH] care. High-level workflow standards provide High-level workflow standards provide guidelines for an entire health journey. For example, a high-level workflow standard may be to place all patients with COPD on a guideline-based COPD care plan, as Cyril is in the COPD health journey.
- **Detailed workflows**, or 'profiles', define how a set of standards is applied to specific processes found in a health journey: 'register or update the patient's demographic details', 'prescribe medications', and 'refer to the district hospital'. These profiles ensure that the digital health applications and the DHP execute these tasks in the same manner, following the same sequence of steps and pulling the required data each time. Some profiles, such as prescribing medications, are common across different countries. These profiles are designed to be interoperable and reusable, meaning they can be applied to multiple high-level workflows, as in the health journeys.

These workflow standards can work together with health informatics base data standards to help standardize the data and processes that a DHP manages. Figure 14 shows how various health informatics base standards (*bottom*) and health profiles/detailed workflows (*middle*) feed into integrated care pathways/high-level workflows (*top*). Since the profiles are reusable, the same detailed workflow standard set can be used by different high-level workflows: MNCH and EPI in this figure. Thus, if the DHP was designed to support both the pregnant mother and COPD health journeys, it could employ one reusable profile, such as the e-prescribing component that both journeys share, to standardize this process within both journeys.

Figure 14: Interaction amongst data standards, health profiles, and integrated care pathways.



Adapted from: D. Ritz, C. Althauser, K Wilson (2014). Connecting Health Information Systems for Better Health: Leveraging interoperability standards to link patient, provider, payor, and policymaker data. PATH and Joint Learning Network for Universal Health Coverage.

Standards stacks in health informatics

A collection of tools or standards that work together is commonly known as a 'stack' in ICT. In health informatics, a standards stack comprises both data standards and the reusable profiles/detailed workflows, shown in Figure 14 as the standards logos that apply to the bottom and middle levels. Health Level Seven [HL7] and openEHR are two different standards stacks used.

Standards stacks in e-health

Only the following standards stacks have been internationally balloted:

- **HL7 version 3:** www.hl7.org/implement/standards/product_brief.cfm?product_id=186
- **ISO 13606 (openEHR):** openEHR.org
- **Integrating the Healthcare Enterprise [IHE]:** wiki.ihe.net/index.php?title=Profiles
- **ITU-T H.810 (Continua Design Guidelines):** www.itu.int/en/ITU-T/studygroups/2013-2016/16/Pages/rm/ehealth.aspx

See Appendix F for more information.

The Clinical Information Modeling Initiative [CIMI] is leading ongoing efforts to integrate different stacks, particularly HL7 and openEHR.

See: https://www.opencimi.org

Note: All websites accessed 27 May 2020.

Using a standards stack can help you choose compatible base data, communication, and workflow standards. For example, if you choose the HL7 standards stack, you could apply the HL7 Clinical Document Architecture [CDA] to the structure of a clinical paper form to be submitted to a DHP repository and HL7 Version 3 to data exchange components in the DHP. Applying a standards stack to the DHP in this manner ensures that the standards are more readily compatible, an important benefit given the DHP goal of system-wide interoperability.

Most international health standards today do not describe the process (depicted in Figure 14) for combining various base data standards in a workflow to achieve a business purpose. For this reason, some organizations (e.g. HL7, openEHR, IHE, ITU-T, Continua) are working to create frameworks and interoperability profiles from existing standards (see sidebar, 'Standards stacks in e-health'). This approach offers the benefit of better industry consistency and commonality. Interoperability profiles are not currently available to address all use cases and digital health moments, however.

Learn more about standards:

World Health Organization (2014). *Joint Inter-Ministerial Policy Dialogue on eHealth Standardization and Second WHO Forum on eHealth Standardization and Interoperability. Geneva, 10-11 Feb 2014.* See: who.int/ehealth/events/final_forum_report.pdf?ua=1

World Health Organization (2013). *WHO Forum on Health Data Standardization and Interoperability. Geneva, 3-4 Dec 2012.* See: www.who.int/ehealth/WHO_Forum_on_HDSI_Report.pdf

Pan American Health Organization (2016). *eHealth in Latin America and the Caribbean: interoperability standards review.* See: iris.paho.org/xmlui/handle/123456789/28189

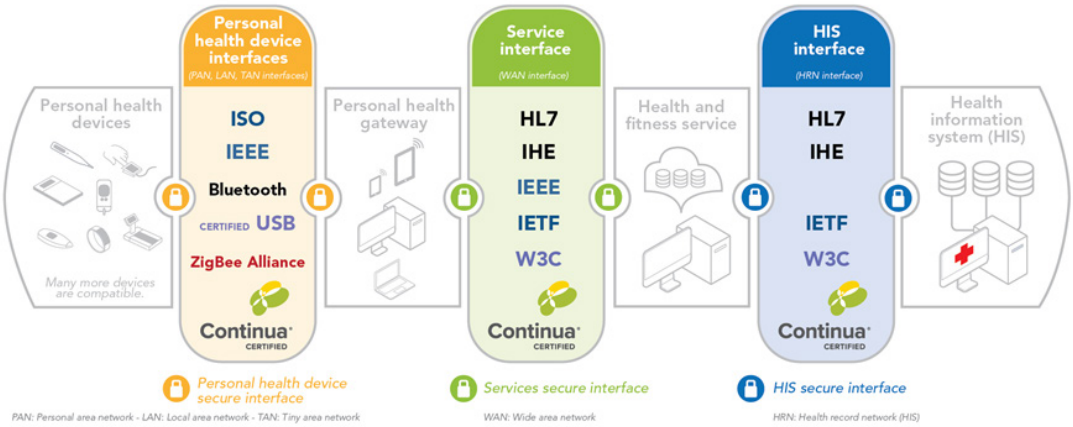
Note: All websites accessed on 27 May 2020.

Device standards

Some DHP architectures may seek to empower individual consumers with PHDs to help them actively and effectively manage their health and well-being. To create seamless interoperable connections between these PHDs and the DHP, device standards are required. Use the ISO/IEEE 11073 PHD standards stack, which covers each of the architecture layers through which medical data will pass, from the physical or wireless connection of the PHD itself to the external applications used in the HIS managed by the DHP. These standards cover the many aspects of communicating the semantics of medical data from device to manager, including the data exchange protocol, data representation, and terminology for communication.

Figure 15 shows how various standards from the ISO/IEEE 11073 PHD stack are used in a PHD reference architecture. The standards in this stack are based on the Continua Design Guidelines [CDG] from the Personal Connected Health Alliance [PCHA] and transposed by ITU in the ITU-T H.810 series of recommendations. Data is transmitted from the PHD to the PHD interface (*orange*) using an underlying ICT transport standard like Bluetooth, Bluetooth Smart, Zigbee, or NFC. Then, to enable interoperability at the service interface (*green*), IHE's PCD-01 transaction and the IT Infrastructure Technical Framework are applied. Farther down the path, the HL7 CDA R2 charge-coupled device [CCD]-based personal health monitoring record carries the data over the healthcare information service interface (*blue*) to the DHP. A description of each interface follows Figure 15.

Figure 15: The CDG end-to-end reference architecture.



Source: ITU-T H.810.

- **PHD interface:** interface between a PHD and a personal health gateway
- **Services interface:** interface between a personal health gateway and a health and fitness service
- **HIS interface:** interface between a health and fitness service and a health information system to the DHP.

The ISO/IEEE 11073 PHD series of standards optimizes interoperability by providing a different device specialization for each type of PHD, such as blood glucose monitors, thermometers, weighing scales, blood pressure monitors, pulse oximeters, and insulin pumps. They all share the same underlying data exchange protocol.

See Appendix F for more detailed information about the ISO/IEEE 11073 PHD standards. See Appendix I to learn more about the working group that defines and validates these standards.

Process for adding standards to the DHP design

Identify interoperability points and potential standards from digital health moments

The process of choosing or formulating standards begins with identifying where external digital health applications interact with the DHP and through the DHP with one another. The digital health moments in the health journeys are effective tools for identifying and validating these points of interoperability, or 'interoperability use cases'.

For example, if Application A is used at one digital health moment and Application B is used at another digital health moment in the same journey, then the interoperability use case is how these two applications interact. There are two components to this interaction:

- how each application will interact with the DHP
- which data the two applications will exchange with each other via the DHP.

Understanding this interaction will inform your selection of standards. Furthermore, when selecting standards, keep in mind that standards are applied across components and throughout a journey.

Take these steps to identify potential standards for your DHP:

1) Identify the external applications used in the health journey, such as EHRs or an application used for e-prescriptions at the pharmacy.
2) Describe how each of these applications will interact with the DHP.
3) List the types of data exchanged.
4) Research which standards will work best for these interactions, keeping in mind DHP design principles, any relevant ICT regulatory requirements, and which standards are already commonly used in your country. Collaborating with your stakeholders on a national standards framework will help define these. Information later in this chapter provides more information on this process.

The standards you choose should be added to the requirements documentation or the RFPs you prepare for those who will develop or modify systems within the DHP infostructure, individual DHP components, or applications that integrate with the DHP.

See Table 15 for an example of how standards can be identified for a DHP.

Table 15: Matching standards to digital health moments in the pregnant mother health journey

Digital Health Moment	External Applications Used	How Applications Interact with DHP	Types of Data Exchanged	Potential Standard to Use
First ANC visit: The clinician pulls up Savita's EHR on his computer screen. The clinician updates the record with the exam findings and orders for lab tests, medications, and nutrition supplements.	MCTS	MCTS sends clinician orders for lab tests to DHP EHR repository.	Lab test order Lab test results	LOINC
Lab visit: The lab technician scans the barcode on Savita's MCTS card to retrieve her EHR and the lab orders. The lab technician draws the samples, performs the tests, and updates the EHR.	MCTS, LIS	LIS updates Savita's EHR with lab results by sending the results to the DHP EHR repository.		

Develop a high-level standards strategy with stakeholders

Once you have identified interoperability use cases and potential standards through the health journeys, it is important to develop a national high-level strategy that will guide standards selection over time. Doing so helps ensure that standards are chosen in a consistent fashion as your country's DHP matures. For example, this strategy may outline a high-level objective of

adhering broadly to HL7, waiting until later to specify exactly which parts of HL7 to adopt. As part of this strategy, the SNOMED CT standard may be chosen for certain categories of clinical data, with each external application using different subsets of SNOMED CT as appropriate.

To formulate this strategy, engage stakeholders involved in DHP implementation and in the health-sector business processes that the DHP aims to improve. Stakeholders taking part in this exercise should include those who gather or generate information during the health journey's digital health moments, as well as those who may subsequently use that information for other purposes. Consider such stakeholders as health sector managers, health workers, representatives of health-sector financing organizations and commodity suppliers, and ICT managers. This group needs to agree on common definitions of health service processes and information concepts.

Learn more about standards selection:

Information on NESF development, country experiences with NESFs, and standards stacks: D. Ritz , C. Althauser , K Wilson (2014). Connecting Health Information Systems for Better Health: Leveraging interoperability standards to link patient, provider, payor, and policymaker data. PATH and Joint Learning Network for Universal Health Coverage. See: www.jointlearningnetwork.org/resources/connecting-health-information-systems-for-better-health

South Africa national e-health standards framework www.samed.org.za/Filemanager/userfiles/hnsf-complete-version.pdf

HingX risk assessment tool: www.hingx.org/Share/Details/1671

Note: All websites accessed on 27 May 2020.

A national e-health standards framework [NESF] can help institutionalize this strategy. An NESF is a tool that defines the standards for your DHP, referencing appropriate international and national standards, including those from outside the health sector. It provides clear documentation for how standards, or subsets of standards, will be applied in the DHP and, importantly, how these standards will apply to external applications that interact with the DHP. You could select a standards stack as the basis for the NESF if one is available and appropriate for your specific health journeys, as well as for the country's resource constraints. South Africa has created a detailed NESF for its digital health system development (see 'Learn more about standards selection' sidebar).

Publish standards and interface specifications once validated

Because interoperability is paramount in designing external digital health applications, it is essential to publish and disseminate the defined and validated standards. This enables developers of external software applications and solution vendors to successfully deliver the means for end users to interact with the DHP. You should openly publish API specifications as well, with a change management and versioning component for adding or updating APIs. This approach, combined with the provision of testing environments and a formal conformity-assessment process, can help ensure more rapid adoption and more reliable interfaces between

external applications and the DHP. See Section 6: 'Establish the governance framework' for more information.

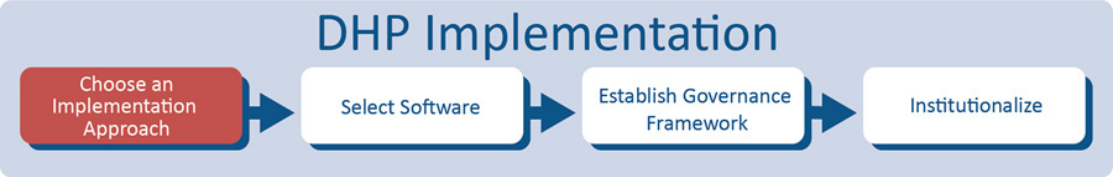
Additional guidance to consider for standards selection

In addition to the previous steps, consider the following when selecting standards for your DHP design:

- **Do a risk assessment to determine if a standards stack will work.** Since interoperable profiles in the DHP are essential, good planning will involve a risk assessment of the three standards stacks currently approved at the international level (HL7, openEHR, and IHE). HingX offers a risk assessment tool and toolkit for assistance with this task (see 'Learn more about standards selection' sidebar).
- **Choose standards that are not strangers.** Many countries will not have already defined national e-health standards and may not be able to select a standards stack. Therefore, it is important to select standards that are already commonly found in the health sector in your country. These standards will be most familiar to both developers and end users: health workers who need to add clinical codes to clinician orders and patient billing records, ICT staff who are setting up the technology for the DHP, and DHP implementers working with software developers on external applications for the DHP.
- **Choose standards that the clinical community will accept and support.** In addition to the international health standards established by recognized standards bodies, international health worker associations, such as those for nursing, rheumatology, and anaesthesiology, maintain their own professional standards. For this reason, it is essential to include the clinical community when developing the high-level strategy, an NESF, and the final selections for your DHP.
- **If using IHE, consider bringing use cases forward for validation as profiles.** As IHE is one of the international organizations seeking to create interoperability profiles for digital health, it may be invaluable to have IHE standardize the specific workflows in your DHP design. By doing so, you are not only designing standards for your own DHP but also contributing to international standards work. Note that the validation process is time intensive, taking about one year to define each profile. This may require considerable patience before all of the necessary specifications are produced and made available to software application vendors.

Section 6 – Digital Health Platform Implementation

Approaches to DHP implementation



Learning objectives:

- Describe different DHP implementation paths and considerations for each one.
- Provide practical guidance and tips for implementing a DHP.
- Explain how maturity models can be applied to DHP development and implementation planning.

Implementation approach – key tasks

- Review key guidance.
- Choose appropriate implementation path for your context.
- Determine how to best leverage e-government structures and investment.
- Apply maturity models to implementation planning.
- Create a strategic plan for DHP implementation.

Stakeholders for DHP implementation planning

- E-government coordinators
- Ministry of ICT adviser
- MoH Digital coordinator
- HIS architects and vendors
- ICT advisers from donors and non-governmental organizations

You are now at the stage to begin actually implementing the DHP. Up to this point, you have focused primarily on understanding the context in which the DHP operates and the architecture design of the platform. This section offers guidelines to help make implementation decisions and roll out the DHP.

Potential DHP implementation paths

There is no set way for implementing your DHP. Each country will take a different path because the contexts vary. There will be variation in the maturity of the digital ecosystem, the health system business process needs, and the types and scope of existing software. Resource availability – both monetary and human – also plays a role in implementation choices, requiring countries to set priorities and define realistic DHP implementation goals.

Even though contexts will vary, there are two overall approaches to DHP implementation:

- **ground-up approach:** design before you build
- **hub approach:** build while you design.

There also tends to be different end states for the DHP, as shown in Table 16.

Table 16: Types of end states for a DHP implementation

Centralized	• Most processes occur within the DHP itself, not in external applications. • External applications largely serve as front-end user interfaces for the DHP.
Decentralized	• Most processes occur within the external applications, including data storage. • The DHP largely provides integration services.
Hybrid	• The DHP provides many key enabling services, such as integration services, information security, some data storage, and some common registries, terminologies, and workflows. • External applications engage in data management, processing, and analysis, which are largely domain-specific activities through components that have not yet been shared with the DHP.

Ground-up approach

In the ground-up approach, you build your DHP from scratch. That is, you begin designing the DHP once you complete the context analysis and have a clear understanding of the health system business processes that you want to improve with digital tools: your health journeys. In many respects, you will follow the steps outlined earlier in this handbook, as this handbook is designed to introduce readers to each part of the process. So you will essentially build your DHP by doing the following:

1) Start with a design that aims to be interoperable and scalable. Therefore, identify specific APIs and standards needed for the DHP components you choose.
2) Before connecting any external applications, build the enabling components needed for your health journey, which will definitely include integration services and information security services. Depending on your vision for the DHP's end state, this building phase may include other enabling components, such as registries, repositories, terminologies, and key workflows.
3) Seed registries and repositories with data before connecting external user interfaces and applications.
4) Roll out your platform and connect the external applications.
5) Over time, expand your DHP according to new health journeys. Add new components and leverage or modify existing ones to meet the needs of the digital health moments within these journeys.

Tip: Refer to the digital health technology inventory that you did during the context-analysis phase. This inventory helps you understand which existing applications may be available to adapt for or link to your DHP. You will also know which application assets you can leverage to create these links.

Note that most countries usually will not follow a ground-up approach, as some or all of the health-sector domains typically will have information systems and applications already in place. For example, many countries already have digital systems for monitoring and reporting on an established set of population health and service delivery indicators, often using DHIS 2 or the equivalent. In this case, the hub approach to DHP implementation is likely the most practical approach to take.

Hub approach

In the hub approach, you will build your DHP from existing standalone business applications. Therefore, you will follow the DHP design process on systems and applications that have already been built to create an interoperable platform that exchanges data in a standardized way. You can also expand on these existing systems by building and linking to new external applications.

Since most existing standalone applications operate within a specific health-sector domain, you will link applications to create hubs of applications that relate to that domain. For example, you could connect health workforce management software with an e-learning application and health workforce certification tracking software to create a hub in the human resources management and capacity-building domain. To connect these software applications, you will expose a component in one application that can serve as a shared resource for the others, such as the health worker registry for the human resources domain hub. Open APIs and standards allow sharing of this component within the hub. Your result will be a network of external applications that share a common internal component, enabling standardized data exchange. Your hub is now a mini-DHP.

Tip: Well-designed, open software is best for exposing an application's component to share with another application. Such software will allow user interfaces to be decoupled from the core component, enabling you to reuse this core service in a DHP.

With the hub approach, build your DHP by doing the following:

1) Assess existing application assets for shareability.
2) Create a mini-DHP hub by choosing one standalone business application and connecting external applications to it through open APIs and standards.
3) Create more hubs specific to each domain in the same manner (e.g. create a supply chain hub in addition to your human resources domain hub). You will use a different health journey to create each hub.
4) Integrate individual facility systems with these hubs (e.g. a clinic system connects and interacts with a service delivery data hub, as well as a supply chain hub).
5) At the same time, begin seeding some DHP enabling components with common data or code. You could begin creating common registries by combining registry data from each

of the hubs or from existing databases housed in organizations that are not connected to the hubs. An existing health insurance membership database can serve as a basis for a patient registry, for example.

6) Slowly integrate the hubs by connecting common internal components that can be exposed and shared. Alternatively, identify common workflows that all hubs can share, thereby reducing duplicate code and computer processing. Your goal in this step is a single unified DHP, instead of multiple mini-DHPs.
7) Harmonize APIs into one combined API, and build the information mediation component to create the DHP integration services.
8) Keep expanding your DHP according to new health journeys. Add new components and leverage or modify existing ones to meet the needs of the digital health moments within these journeys.

Even though you start with existing applications in the hub approach, you are not starting with a DHP. A standalone business application only becomes part of a DHP when it shares components with other applications. So the steps described in this handbook for DHP design still apply. When you sit down with your digital health stakeholders to define your design principles and lay out the enterprise architecture for your DHP, you will identify DHP components and standards in relation to what has already been built.

When making decisions about where to start building your mini-DHP hubs, note that one health-sector domain is not intrinsically more important than another. It is also not necessary to establish interoperability in one domain before doing so in another domain. Determining which domain to prioritize for DHP development depends entirely on your context, which is why the activities described in Section 4: 'Context analysis' are so essential. The choice you make depends entirely on the problems that your health system stakeholders deem the most pressing and the most amenable to being addressed through a DHP.

New Zealand's hybrid approach to health ICT creates a successful decentralized system for data sharing

In 1992, the New Zealand government made the innovative decision to take a hybridized, public-private approach to enabling the exchange of digital health information in its health system. The government chose to focus primarily on the areas where its leadership role could have the most impact: a) developing national information technology infrastructure; b) establishing interoperability standards; and c) creating national policies and frameworks that encourage digital health within overall national healthcare strategies. As a result, the private sector took the lead in creating digital health solutions, and a robust, competitive marketplace for health ICT applications and technologies emerged.

This hybrid approach also helped foster a decentralized environment for sharing health data. Because private companies implemented multiple tools for managing medical records and supporting clinical decisions in local and regional health jurisdictions, health data – and the applications that collected and processed them – were housed in discrete systems around the country. The government's early adoption and promotion of the HL7 standard (amongst other internationally validated standards like SNOMED CT and LOINC) enabled private solution providers to exchange data easily amongst most of these different systems.

As a result, sharing of electronic health data is widespread throughout New Zealand, and primary care providers (used by 98 per cent of New Zealanders) report very high utilization of digital health tools. In 2010, a typical primary care provider shared patient data with an average of 58 other health-sector organizations, all via digital health systems. Moreover, a 2009 comparative survey of 11 Organisation for Economic Co-operation and Development [OECD] nations found that New Zealand primary care providers used EHRs, test results, prescriptions, and alerts at rates that were from 20 to 40 percentage points greater than the average.

Source: T. Bowden & E. Coiera (2013). Comparing New Zealand's 'Middle Out' Health Information Technology Strategy with Other OECD Nations. International Journal of Medical Informatics, 82(5), e87–e95.doi:10.1016/j.ijmedinf.2012.12.002.

Guidance on DHP implementation

Development of a DHP is not a once-off process but rather a continuous activity as the DHP matures with new components and as more external applications are connected. Even while the DHP matures, development continues on existing components as their requirements are adjusted over time and bugs are identified and solved. It is important to set priorities and organize development into phases to ensure that realistic implementation choices are made, considering resource constraints. This section gives some practical tips for developing your implementation plan.

Start with a small scope. Create an implementation timeline that breaks DHP development into phases. You will likely prioritize core DHP enabling components, such as registries and repositories, many of which are prerequisites for more advanced functionality. For example, in the pregnant mother health journey (see Table 17), setting up the DHP patient registry and a DHP identity authentication service (*highlighted in yellow*) that are linked to a national citizen record system is a higher priority than setting up the workflow service (*highlighted in blue*) for Asha to track her patient. Once enabling components are in place in your DHP, you will have the capacity to build an endless number of services that are based on them.

Table 17: Use of the health journey to prioritize DHP components during implementation planning (pregnant mother health journey used as example)

Digital Health Moment	DHP Functionality	DHP Components
Enrolment in MCTS: Savita, a new mother-to-be, is enrolled in the MCTS. Asha, the community health worker, records Savita's name and identification in her personal cohort list.	• Identification management for tracking a person or place within the system • Data storage • Workflow for tracking a person's progress in a care plan	• MCTS uses the ***DHP-Patient-Registry service*** to create a new record for Savita with a unique MCTS identification. • MCTS uses the DHP-Repository service to create an EHR for Savita. • MCTS also interacts with the ***DHP-Workflows service*** to create a complete individualized workflow for Asha to follow the progress of Savita's pregnancy in her local cohort list.
Enrolment in MCTS: Upon registration, MCTS verifies Savita's identity with the externally managed national citizen records system.	• Authentication through link with government system	• The DHP-Patient-Registry service uses the ***DHP-Identity-Authentication service*** to validate Savita's personal identity through the externally managed national identity management system. • To track Savita's encounters with MCTS, it generates a bar-coded identification card for Savita, with a copy for Asha.

Develop once, but reuse across the enterprise. For cost-effective and efficient DHP development, reuse the same solutions for a range of use cases and projects. Identify commonalities and components that different agencies and departments can use. Then, when possible, develop or procure these once. Alternatively, if you are using the hub implementation approach, leverage existing components without reinventing them, even if they need to be exposed and integrated into the DHP. This practice can lead to economies of scale and cross-financing, meaning that one health-sector institution or government agency can finance the development of a DHP component that will also benefit other organizations without the means to pay for its development.

Create a management plan. Alongside your implementation timeline, create a management plan with time-bound deliverables. A strong management plan clarifies the roles and responsibilities of everyone involved. It also establishes a sequential order for different implementation phases. Where applicable, link the management plan with your DHP operation business unit procedures (see Section 6: 'Establish the governance framework'). For example, identify which key policies, such as a data sharing agreement, need to be finalized before implementing data components of your DHP. Management plans should also outline which resources are needed for each task.

Standardize components in stages. While it is important to take a comprehensive view when selecting standards during the DHP architecture design phase, you do not need to apply your chosen standards all at once during implementation. You can work in stages, focusing first on the DHP functionality that is most needed according to your priority setting. Facility data is often standardized first, as they are useful for a variety of applications and workflows. Specific data-coding needs and a need to align DHP data with HMIS indicators can also be priorities for standardization. Updating existing standards or applying these standards to new DHP components may also be places to start standardization.

Stick to DHP design principles for solutions that appear to be one-off. Sometimes you may be asked to build DHP functionality that is not in your initial design, to respond to a pilot project, a funder's priorities, or an emergency health need such as a disease outbreak, for example. Due to time constraints, you may need to build a component that is limited in functionality and lacks the features that the team planned for and the health journey demanded. In those cases, make sure that the component adheres to the DHP design principle of interoperability, so that its functionality can be extended and more deeply integrated into the system later.

Tips for government investment in DHP implementation and uptake

- Develop a framework for government capacity building that focuses on how all branches and levels of government can share and use common DHP components. This framework can also detail how components and applications from other e-government platforms and services may be shared
- Incorporate DHP planning into government procurement practices so that e-government needs are consolidated across agencies. Reduce overall costs by creating common technology assets that are reusable and interoperable
- Distinguish between government investments in a shared common platform and investments in solutions by external innovators. This distinction will help guide the issuance of requests for proposals for systems integrators and solution providers for DHP development

mHero: How the Liberia Ministry of Health connected existing software to communicate with health workers during the 2014 Ebola outbreak

The MoH in Liberia wanted to connect with front-line health workers to communicate important information about testing, treatment, and protection during the 2014 Ebola outbreak. The MoH needed real-time feedback from health workers as well. IntraHealth International and UNICEF worked with the MoH to develop mHero, a two-way SMS system that connects data from existing software and HIS. Instead of creating new systems for this information exchange, mHero was deployed as a simplified type of DHP to use what was already in place. Harnessing the OpenHIE framework, mHero synchronized information from a health worker registry to connect digital health applications like RapidPro. After the outbreak, the MoH continued to embrace mHero as an important HIS and communication tool, using it to support many different kinds of workflows. mHero provided digital processes to support nutrition programs, send reminders to staff to complete DHIS 2 reporting, and learn more from health workers about mental health services that DHIS 2 indicators did not capture. Currently, the MoH is exploring ways the system can support Integrated Disease Surveillance and Response [IDSR] data collection and exchange.

See Appendix A: 'Liberia case study' for the full case study. Also, see www.mhero.org for further information.

Using maturity models to guide DHP development

Maturity models are frameworks used in ICTs and digital health to help guide implementation planning over the long term. Given that organizations, processes, technologies, and business functions continually evolve in the context of complex healthcare systems,[1] these models provide an overall roadmap for incrementally transforming a country's digital health system. In terms of a DHP, a maturity model helps you understand where your DHP development is now. It also shows where your DHP may be in the future: how its components and enablers can logically and gradually mature in complexity, functionality, and scale.

Maturity models show which technological, organizational, or environmental characteristics are needed at each maturity level. The expectation is that targeted business processes and, ultimately, the users' benefits will improve as the organization's digital health ecosystem matures along the model's pathway.

[1] J.V. Carvalho, A. Rocha & A. Abreu (2016). Maturity Models of Healthcare Information Systems and Technologies : A Literature Review. *Journal of Medical Systems,* 40(6), p. 131. doi: 10.1007/s10916-016-0486-5

Digital maturity:

- 'is demonstrated by how digital technologies are used as enablers to deliver a high-quality health service
- focuses on the advancement of the entire health service, not just the success of one technological system or a particular service's stakeholders
- encompasses not only the resources and ability to use a system, but also the level of interoperability with other systems and ultimately its impact on the public.'[1]

[1] K. Flott, R. Callahan, A. Darzi & E. Mayer (2016). A Patient-Centered Framework for Evaluating Digital Maturity of Health Services: A Systematic Review. Journal of Medical Internet Research, 18(4), e75. doi:10.2196/jmir.5047.

A wide variety of maturity models exist in digital health, though none is specifically designed for a DHP at this time. Most of the current models focus on a specific digital health technology or area, such as EHRs or telemedicine. Some models are domain agnostic, focusing instead on a generic function that a DHP or an external application can provide, such as analytics.

Consortia of organizations or international digital health working groups are currently developing maturity models that embrace principles and capacities germane to the broader concept of a DHP. For example, MEASURE Evaluation's forthcoming Health Information System Interoperability Maturity Model[2] offers a pathway for gradually developing interoperable HIS. Developed using a systems-thinking approach, this model focuses on key architectural issues, such as application linkages, standards, and data management, which may be highly relevant for many countries developing DHPs.

Some of these models recognize that progress along a maturity model is not limited to technology development. In addition to offering pathways associated with technical capacities of a digital health system, these models provide pathways for key enablers associated with DHP implementations. Examples of these enablers include governance, finance, the policy environment, and the capacity of the workforce to use or develop digital health tools. Countries must progressively evolve these enablers to realize the full benefits of a technology, including a DHP.

[2] This maturity model is offered as one part of a comprehensive package that includes a maturity model assessment tool and user guide. These tools can help countries identify gaps in their existing digital health systems and then develop a roadmap for addressing these needs based on the HIS Interoperability Maturity Model. MEASURE Evaluation is funded by USAID. See: www.measureevaluation.org/resources/tools/health-information-systems-interoperability-toolkit (accessed 27 May 2020) for more information.

Examples of maturity models
Interoperability maturity models: – MEASURE Health Information System Interoperability Maturity Model (see Appendix E) – National E-health Transition Authority of Australia Interoperability Maturity Model[3]
Health information systems maturity models: • PAHO/WHO Information Systems for Health Maturity Model (forthcoming)
EHR maturity models: – Canada Health Infoway (see Appendix E) – Healthcare Information and Management Systems Society [HIMSS] Maturity Model for EMRs13 • HIMSS Continuity of Care Maturity Model[13]
Information technology infrastructure maturity models: – National Health Service Infrastructure Maturity Model13
Telemedicine maturity models: – The Telemedicine Service Maturity Model[4] • Layered Telemedicine Implementation Model[14] • PACS (Picture Archiving and Communication System) Maturity Model[14]
Analytics maturity models: – Dell Healthcare Solutions 'Healthcare Analytics Adoption Model[14] – Analytical Maturity Model from Jason Burke[5]

Practical guidance for applying maturity models to your DHP

Select one or more maturity models that are appropriate for your context. As each development context is unique and DHP implementation will differ from country to country, there is not a specific prescribed model that you must follow. Some models are better suited for countries that have more mature digital systems. To help choose a model, review the goals that you defined for your DHP based on your analysis of digital health business processes – the processes that produced your health journeys. Looking at these specific use cases will define which maturity models may be useful in the near term. To determine which models may be useful in the long term, return to your context analysis. Your landscape analysis of the health system and your digital technology inventory may point to gaps in the health system that the health journeys you initially wrote do not address.

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[3] For further information on these maturity models and others, see: J.V. Carvalho, A. Rocha & A. Abreu (2016). Maturity Models of Healthcare Information Systems and Technologies: A Literature Review. *Journal of Medical Systems,* 40(6), p. 131. doi: 10.1007/s10916-016-0486-5.

[4] These articles discuss various telemedicine maturity models, assessment tools, and methodologies for developing a model. L. Van Dyk & C. Schutte (2013). The Telemedicine Service Maturity Model: A Framework for the Measurement and Improvement of Telemedicine Services. *Telemedicine*. InTech. doi:10.5772/56116 and L. Van Dyk, C. Schutte, & J Fortuin (2012). A Maturity Model for Telemedicine Implementation. *eTELEMED 2012 : The Fourth International Conference on eHealth, Telemedicine, and Social Medicine. doi.* Vol.10, p. 56116.

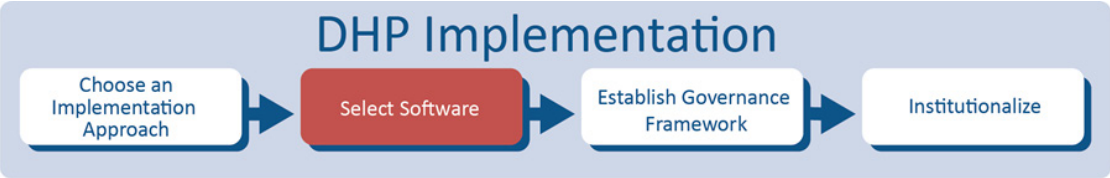
[5] For more information, see: J. Burke (2013). *Health Analytics: Gaining the Insights to Transform Health Care*. Hoboken, NJ: John Wiley & Sons

Take only what you need or what is relevant. You may find that certain aspects of one maturity model are useful while others are not. It is possible (even probable) that your country is at different levels in each category. For example, the Canada Health Infoway maturity model may provide guidance on platform governance and leadership that is appropriate for your context, even if the technology pathways do not yet apply to you.

Use maturity models to delineate broad strategies and milestones for your DHP implementation plan. Maturity models allow you to set benchmarks and provide a guide as to how you may move forward. As you implement your DHP, regularly return to the model you have chosen to evaluate accomplishments and plan new milestones. At the same time, review your digital health technology inventory to update it with the new systems and applications in the health sector—not just those connected to the DHP. Periodically comparing your inventory with your maturity model will help define overall strategies and goals. In addition to setting milestones, a maturity model can also be a useful educational tool, helping you explain to stakeholders the pathway for achieving the long-term benefits of a DHP.

Change or add maturity models as you expand your DHP further. You may find that you start building a roadmap for DHP development using one maturity model. Later, you may turn to another model once you start expanding into a specific domain (e.g. adding telemedicine services) or when your digital health system matures to the starting level of a maturity model that you wish to adopt.

Select software for your DHP



Learning objectives:

- Explain different ways to organize components in software for deployment.
- Describe key considerations when choosing software for the DHP components.
- Lay out the steps involved in choosing and customizing software for the DHP.
- Explain how cloud computing may benefit DHP implementation.
- Share best practices in software project management to assist with guiding developers.
- Show how the health journey can be used when choosing DHP software.
- At this point, you should have the blueprints in hand for your DHP architecture. Now it is time to act on these designs. You need to select and build or procure the software for the components, a key step for putting the DHP into practice.

Software selection – key tasks

- Determine how to organize components for deployment.
- Prepare technical documentation.
- Decide on the best approach for obtaining software.
- Establish licensing arrangements and development contracts.
- Match software to DHP components and standards.
- Provide guidance to developers.
- Create testing environments.
- Load data from existing sources.

Determine the optimal approach for organizing components for deployment

When choosing software for your DHP components, you need to consider how to organize those components during deployment.

There are three main approaches to organizing DHP components and software: single system (sometimes called 'centralized'), integrated, and interoperable. While advantages and risks are associated with each type, an interoperable approach is recommended since it is the most robust. An interoperable deployment allows a broad range of disparate software applications and information systems to exchange data accurately and reliably. OpenHIE is an example of an architecture that uses the interoperable approach (see 'OpenHIE' sidebar on next page). Table 18 explains the differences between the three types.

Stakeholders for DHP software selection:

- Ministry of ICT adviser
- HIS developers and vendors
- MoH digital coordinator
- E-government coordinators
- ICT advisers from donors and non-governmental organizations focused on software deployment

Table 18: Types of deployment approaches for organizing DHP components

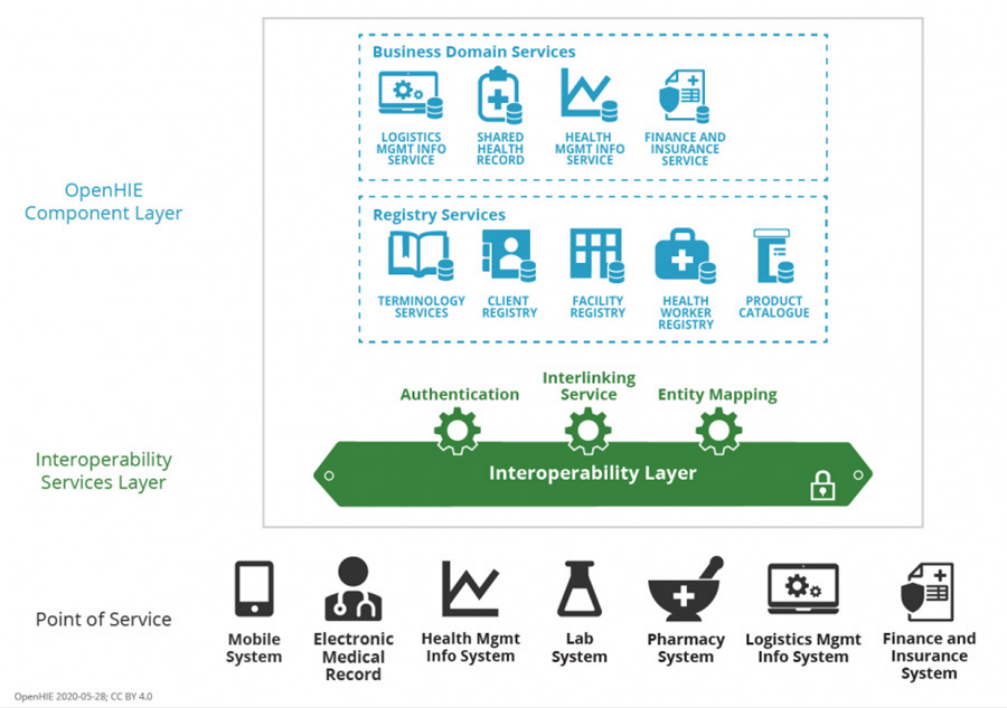
Deployment Approach	Definition	Advantages	Risks
Single System (Centralized)	All components are deployed in a single DHP software deployment.	• End-to-end health process support within one system • Low initial costs • Faster to deploy	• Single point of failure • Difficult to scale, leading to higher costs as the DHP matures • High degree of vendor lock-in
Two-Way Integration	Two discrete software systems are connected during deployment to form a DHP.	• Data shared between two systems • Supports some scalability	• Costly over the long run • Proprietary APIs and back-end database linkages impede change and encourage vendor lock-in • Reduced stability in data exchange interfaces
Interoperable	Deployment can involve myriad number and types of software providing different DHP components, since the robust design relies on agreed-upon and validated data, interface, and workflow standards.	• Standards based, so highly scalable and extensible with a variety of systems and technologies • Information exchange can cross sectors and organizations • If one piece of software fails to deliver a component, it can be switched for another with minimal disruption to the DHP overall	• Higher initial costs • Requires robust governance structures to implement data sharing effectively

The approach you use depends on your ICT infrastructure and capacity, as well as your budget. Bundling software can improve efficiencies and cost savings for governments. Keep in mind

that cost savings in the short term may not prove beneficial over the long run. In reality, DHP implementations will most likely use a combination of these approaches.

When deploying components, it is helpful to think of each component as a building block. By designing each one as an independent module that is coupled together with others loosely like building blocks, you will be able to change the software more easily to improve it. Changes can be made without disrupting the functionality and integrity of other components. Building your target architecture in this modular way does not diminish the need for integration within the DHP. Integration offered by the information mediation component and its unified API – the DHP's integration services –provides the glue to connect DHP components together. Such integration enables a building-block approach to happen.

OpenHIE community of practice promotes interoperability and builds open, reusable software components



Source: OpenHIE (© 2015). Architecture Framework. See: *ohie.org/#arch*

OpenHIE is a global community of practice that focuses on improving health through open and interoperable health information architectures. OpenHIE uses a collaborative approach to help countries develop large-scale architectures and provide peer-to-peer technical assistance. The OpenHIE community supports interoperability by creating a reusable architectural framework that introduces a service oriented approach, maximally leverages health information standards, enables flexible implementation by country partners, and supports interchangeability of individual components. OpenHIE reference technologies and open-source components are freely available. For more information about OpenHIE and to join the open communities, see: ohie.org

If you choose a design with discrete components, it may save some time to select software components that are known to work well together based on previous testing. For example, as noted in Section 5: 'Adopt and deploy standards', IHE has tested and certified that the various reference implementation software applications of OpenHIE work together in a common framework (see 'OpenHIE' sidebar). These positive results emerged despite a decentralized development process, in which a different organization created each application independently.

Prepare technical documentation for software requirements

During the design phase for the DHP, you listed the principles, components, and standards needed to deliver the functionality identified by the digital health moments in your health journey. In other words, this is the functionality of the digital health interventions you selected for addressing inefficiencies and gaps in your priority health system business processes.

In the implementation phase, you need to outline how software will work to support your DHP. You will detail exactly what you expect your components will do, how they will work, and with which other components and applications they are expected to interact. These details are functional requirements, a concept introduced in Section 4: 'Health business process mapping' and that you initially outlined during the design phase.

Software requirements documentation describes the functional requirements in a highly detailed manner. This technical specification will serve as the reference guide for the developers and project managers who will develop or procure the components for the DHP. It should also be used in the RFPs you issue to systems integrators and solutions vendors who will develop new or modify existing application solutions for integration with your DHP infostructure.

To create this documentation, write out the functional requirements for each component mapped to the digital health moments. When doing so, remember to consider the standards and technology infrastructure that you have chosen for the DHP, as these will influence the component specification and how these will function in the platform. You should also note any relevant ICT policies or regulations in your country that may impact the design of your DHP.

Several resources are available to assist with the process of gathering requirements, including templates, user stories, and examples of requirements documentation. See the resource list in Section 4: 'Health business process mapping'.

To ensure that the requirements for your DHP components drive software selection, not vendors, you must prepare requirements documentation before selecting software vendors or products.

Decide the best approach for obtaining software

When implementing DHP components, you have four options for obtaining the software:

1) **Use existing off-the-shelf software.** These programs or packages are ready to use and will not require any code development for customization.
2) **Use existing service-based software.** Like off-the-shelf software, these services can be used right away. Their lack of specific infrastructure requirements makes them even more convenient. However, to avoid security breaches, you must pay attention to the interconnections between the service and other system parts (e.g. other DHP components or external applications connecting to the DHP). See more about service-based software in the sidebar 'Using the cloud for your DHP'.

3) **Adapt an existing software product**. Adaptation allows you to customize the software code for the specific needs of your country's DHP. You could adapt software or solutions already in place in your health system, such as financial software or routine health data collection software. The licensing agreement must allow modifications before you can adapt existing software.
4) **Develop your DHP component from scratch.** Build entirely new software for your DHP functionality.

Determining which option to choose depends on how existing software meets your needs and what your resource constraints are. If existing software does not provide the exact functionality that the DHP needs and you have the time and money to create a customized solution, it is best to start from scratch or to adapt available tools, ideally using open-source software. However, if resource constraints are an issue, evaluate if existing software will be acceptable, even if not ideal. When making decisions, be sure your choice does not compromise the DHP principles that underpin your design.

Learn more about software selection

List of open-source health software en.wikipedia.org/wiki/List_of_open-source_health_software

(accessed 27 May 2020)

Various software programs are currently available that may provide many of the components that your DHP design requires. Many of these programs are designed for digital health and incorporate the recommended international standards for implementing an interoperable and scalable DHP. For open-source software for DHP components, consider the reference implementations developed under the OpenHIE framework.

Review and establish licensing arrangements and software development contracts

While reviewing software options, also consider the licensing arrangements and software development contracts. Table 19 lists types of licensing arrangements. When deciding between open-source and proprietary software, refer to your DHP design principles regarding stakeholder preferences. Also remember to consider any additional licensing costs resulting from prerequisites for operating systems or underlying software. Evaluate the viability of any available support communities when making decisions.

Table 19: Types of software-licensing arrangements

Open-source	• Code is available for customization without payment to original developers. • Some software will include a global community for support.
Free but not open-source	• The software product is free of charge, but code may not be modified or further developed.
Proprietary	• Usage requires payment, either a one-time fixed amount or based on usage or user numbers. • Hands-on support during customization and implementation is very likely provided.
Software as a Service	• Software is centrally hosted in the cloud, using a subscription model for payment. • Ability to customize some applications is limited.

The immediate cost considerations when entering into contracts with software vendors or developers are software development fees, licenses, and training. Issues related to being locked into a contract, either directly or indirectly, may incur high costs over the long term, however. Consider the following lock-in issues before entering into any agreements with vendors:

- If the vendor's or developer's service proves inadequate, will you be able to continue using and maintaining the software?
- Can you hold the vendor or developer accountable or change solution providers if needed?
- Will you be able to alter the code, if desired? To do so, is there sufficient documentation to transfer work to new developers?
- What is the availability of software developers who are familiar with the code and can provide maintenance services?
- Are these developers based locally? In other words, can they interact with users if needed?

Using the cloud for your DHP

To reduce costs and enable easy deployment and scaling of your DHP, you could host all, or even just a part, of your DHP on the cloud. Cloud computing uses an Internet-based, fee-for-service model to provide a wide range of services to its users, from computing infrastructure (e.g. servers, networks) to applications (e.g. middleware, end-user applications). So computing platforms and infrastructure can be hosted on the web, not just software. Like electric utility companies, cloud providers take responsibility for the set-up, maintenance, and operations of the hardware and software, charging users for usage only.

Benefits and drawbacks of cloud computing

Benefits to Health System	Drawbacks to Health System
Reduced capital, operating, and human resource costs; helpful for health systems with limited information technology infrastructure, budgets, and staff	External hardware and software ownership, so limited control over deployment, management, and customization
Easy to scale up and down; useful for health emergencies, seasonal shifts in service provision, and expansion of health facilities and vendors	External ownership of sensitive health data, elevating security and privacy concerns and potentially presenting legal problems
Shifts information technology staff from routine tasks to activities focused on DHP interoperability or components that will improve health system business processes	Data caps imposed by the cloud provider may limit data storage and, therefore, scalability
Offsite backup of data and applications	Requires a reliable and stable Internet connection

Digital health systems in low-resource settings can benefit from platforms that leverage the cloud. Interoperable components hosted remotely can be used to create rapidly deployable applications, including mobile apps. For example, data collection, decision support, and point-of-care diagnostic tools can be combined into an app for rapid diagnostic testing in the field. Since the platform hosts all of these tools and any data collected in the cloud, health workers simply use their mobile phones as an interface for interacting with the platform components.

Select the DHP software that matches your defined components, standards, and principles

Once you have a better sense of how you need the software to function and how you will obtain it, you should identify which applications will meet your DHP design. When doing so, refer to your overall design, making sure that the software choices reflect your chosen principles, components, and standards. It is important to identify which DHP components will require developers' time and skills and ensure that you have the infrastructure and capacity to support this development. In addition, keep in mind how certain digital health interventions fit with your overall DHP design and how these may be deployed within a connected digital system. See the *Implementation Investment Guide (DIIG): Integrating Digital Interventions into Health Programmes* (WHO/PATH), *https://www.who.int/publications-detail/who-digital-implementation-investment-guide (accessed 27 May 2020)* for further information.

Table 20 lists software that can be used for common DHP components. These suggestions have been designed to be interoperable. Note that the software listed are just examples; inclusion in the list does not indicate an official endorsement.

Table 20: Examples of software options to consider for common DHP components

DHP Component	Software Options
Patient registry	OpenEMPI, MEDIC Client Registry Reference Implementation
Health worker registry	OpenInfoMan, iHRIS*
Health facility registry	Resource Map, DHIS 2
Interoperability and integration	OpenHIM, MOTECH, MuleSoft, Mirth Connect**
Shared health record repository	OpenMRS,^ OpenSHR, OpenEMR, GNU Health
Shared health indicator repository	DHIS 2
Shared laboratory records	OpenELIS
Shared e-learning content repository	ORB
Supply chain workflows	OpenLMIS, Logistimo
Medical workflows	OpenSRP, Medic Mobile, CommCare
Data collection	Open Data Kit, KoBoToolbox, CommCare
Messaging	RapidPro, mHero
E-learning	Moodle
Data dictionary and terminology services	OCL
Scheduling and appointments	DHIS 2 Tracker, OpenSRP
Analytics	CommCare, DHIS 2, SMAP, Tableau
Geolocation	OpenMapKit, GeoODK, OpenStreetMap

* iHRIS offers additional features, as well.

** Mirth Connect's design is slightly different than other software like OpenHIM. See: marc.info/?l=openmrs-dev&m=135309467625798&w=2

^OpenMRS can act as an external application or as a shared health record repository internal to the DHP.

Learn more about cloud computing

Cloud computing en.wikipedia.org/wiki/Cloud_computing/

Choosing a cloud service provider azure.microsoft.com/en-us/overview/choosing-a-cloud-service-provider/

Note: All websites accessed on 27 May 2020.

Match suitable software programs with the requirements for each unique component, and identify which components call for new or adapted code. For each component in the health journey, it may be useful to list all of the external applications that interact with that component throughout the journey. The DHP component software should be able to interact with each of these external applications, while the external applications may often need to be adjusted to meet the set standards for interacting with the DHP component. Once you have identified the external applications, you can identify potential software options for a component, including whether you will use or modify existing software or develop new code. Table 21 identifies the components for the pregnant mother health journey and lists possible software and sourcing options for each component. Note that the software listed are just examples.

Table 21: Software options for some DHP components in the pregnant mother health journey

DHP Component	External Applications that Will Use DHP Component	Software Options
DHP-Patient-Registry service	MCTS	OpenEMPI, MEDIC Client Registry
DHP-Workflows service	MCTS	OpenSRP
DHP-Identity-Authentication service	MCTS	Aadhaar Identity Management System
DHP-EHR-Repository service	MCTS	OpenMRS
DHP-Messaging service	MCTS	RapidPro
DHP-e-Prescribing service	MCTS	

When choosing specific software applications, keep a long-term view in mind. Remember that new internal components and external applications will expand and change your DHP as you progress along your maturity model. Consider the following questions:

- Will other health journeys be developed in the future which may be able to leverage some of the same DHP components?
- If these new health journeys require alterations to the components, will the chosen software accommodate these changes?

As the likely answers to these questions are 'yes', make software choices that are 'agile', meaning they have the flexibility to accommodate other health journeys, or use cases.

For example, Figure 16 shows that both the pregnant mother and COPD health journeys desire functionality that tracks the progress of clinician orders (*highlighted in yellow)*. The COPD journey's workflow component is much more sophisticated, however. This workflow is more automated, with rules that tell the EHR to ask the DHP ('DHP-Order-Fulfilment service' component) to track each step and automatically populate the EHR with data. In the pregnant mother journey, the 'DHP-Workflows service' component simply sends clinician orders to the lab, returning an alert when results are ready.

If the pregnant mother journey is the first use case developed in the DHP, a foresighted implementer will choose workflow software for clinician orders that is flexible and can scale to accommodate the demands of more complex workflows in future health journeys.

Figure 16: Example of how similar DHP functionality in two different health journeys should be identified and taken into consideration when choosing or designing software

Pregnant mother journey

DHP Functionality	DHP Component
• Data storage • Workflow for routing health worker orders, including to facilities external to DHP	– **The laboratory information system uses the DHP-Workflows service to inform the clinician about the results when Savita's EHR is updated.** – MCTS uses the ***DHP-EHR-Repository service*** to retrieve Savita's EHR. The clinician reads the lab results.

COPD journey

DHP Functionality	DHP Component
• Data storage • Workflow to pull order status and test results when done • Workflow to send alert notifications	– **The EHR polls the DHP-Order-Fulfilment service to obtain the status of Dr Martin's orders. The DHP-Order-Fulfilment service has flags set to notify Dr Martin on the completion of the tests.** – **The results for the lab and pulmonary function tests are retrieved from the DHP-Order-Fulfilment service and populated in the EHR.** – The EHR accesses the ***DHP-EHR-Repository*** to show the test results to Dr Martin.

Provide guidance to developers who will adapt or create DHP functionality

To ensure that the DHP meets your design principles and delivers the functionality that your end users need, it is essential to provide proper guidance and requirements to developers. All developers involved in creating or adapting code for the DHP components, as well as those writing or modifying external digital health applications, need to understand the guidelines given in this section. It is important to return to and reiterate these guidelines regularly, particularly when embarking on a new phase of DHP development or when new developers or vendors join the work.

– **Stay focused on the requirements defined in the documentation**:

- Understand and adhere to the design principles validated by DHP stakeholders.
- Pay attention to the particular standards stacks or individual standards chosen for DHP design, including their development specifications.
- Modify code in accordance with updates to standards or the stacks in which they are bundled, since health informatics standards continue to evolve.
- Use standard APIs designed to maintain DHP interoperability.
- Note where DHP functionality covers workflow processes or interfaces that external application developers may be accustomed to including in their own code. DHP developers may learn from the experiences of external application developers or, in some cases, reuse or standardize their code into the DHP. As the DHP takes over support for these features, external application developers can leave them out.

- **Use systematic project management methods for software development.** This will help you track new features for components, as well as issues or bugs. Apply these methods throughout the process, from identifying features or bugs to testing with users.
- **Periodically talk with end users and test functionality to understand the needs** of the health workers, patients, and administrators who will use the software. Do the same with external application developers who will use the DHP.
- **Stay on schedule by taking a team-based development approach,** which shares the work tasks amongst a group of developers, not just one or two individuals.
- **Designate a team member as a business analyst.** This generalist role coordinates software implementation using an agile or Scrum methodology, popular project management approaches that build software in an incremental and flexible manner. These approaches respond in real time to changing client needs and lessons learned, not during the development cycle for the next version.

Create testing environments for your DHP software applications

Once you have chosen the software or worked with a team to create it, do not rush to roll out your DHP. Instead, it is a best practice to create a testing environment, called 'testing sandbox', where DHP implementers and software developers can see how the software operates in a simulated production environment that is isolated from live servers. In a testing sandbox, you will see how the internal software for a component or the external application will operate before it goes 'live' on the platform. You may uncover areas for revision, identify standards that should be implemented, or recognize enhancements that are needed before you load the software, or any data sources, into the DHP itself.

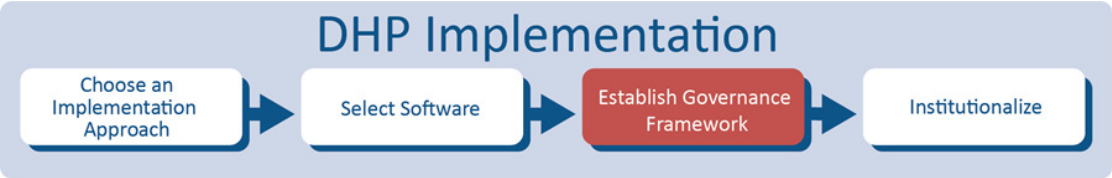
Sandboxes are great tools for testing interoperability between systems. You can see how DHP components support the data functions, structure, and coding within the DHP, as well as how different external applications access and use data through the DHP. To do this, you need to link 'dummy data', or fake data that match the structure and coding of actual data, to your DHP. Feed the dummy data into an external application or a DHP data storage component, such as a repository or registry, before beginning tests in the sandbox.

The staff or organizational business unit tasked with DHP conformity assessment will also use these sandboxes to assess whether external applications adhere to DHP specifications and standards. See Section 6: 'Establish the governance framework' for more details.

Load data from existing data sources

Once you see that the software for DHP components performs well in the testing environment, you can begin loading data sources into your DHP. You will need to populate some DHP components, such as registries, with 'seed' data to get them up and running. This process may involve importing data sources from existing databases or linking registries to data sources housed at other institutions, as outlined in Section 5: 'Identify DHP Components'.

Establish the governance framework



Learning objectives:

- Explain the importance of governance in DHP implementation and sustainability.
- Describe the various parts of a governance framework and how to develop them.
- Emphasize how DHP governance is situated within the e-health organization.
- Outline specific operational business units, policies, and procedures that may be included in a DHP governance framework.
- Illustrate how governance has furthered some countries' digital health systems.

DHP governance – key tasks

- Embed within e-health.
- Engage stakeholders.
- Develop a governance framework, including a governing body, policies, and operational units.
- Enforce the governance framework.

Simply put, governance may make or break your successful rollout of the DHP; this section will explain why.

A DHP requires governance structures for successful and sustained operation. It is important to put in place a framework that delineates management roles and responsibilities, as well as policies. In addition to providing much needed operational management, the governance framework plays an important role in maintaining the integrity of the DHP design, even while the platform grows in scale.

Delineating a governance framework can also elevate the visibility and viability of the DHP amongst key decision-makers who may not have committed to using the DHP for exchanging health system information. Decision-makers may feel more confident in participating in the platform once they see detailed documentation about DHP governance structures and policies, and understand how these will operationalize DHP implementation.

DHP governance framework stakeholders:

- E-government coordinators, specifically those overseeing e-health and data security
- Ministry of ICT adviser
- MoH digital coordinator
- Non-governmental organization representatives
- MoH monitoring and evaluation coordinators overseeing data management and quality

Developing effective, robust governance structures and processes takes time, just like creating and evolving DHP components and technologies. Some maturity models provide a roadmap for the progression your DHP organization can follow in terms of governance. See Section 6: 'Approaches to DHP implementation' for more information.

Embed DHP governance within e-health

A key place to start setting up governance mechanisms is within existing e-health leadership and governance. Per Section 9.1 of the *eHealth Strategy Toolkit*, these structures are charged with many of the tasks required to implement and govern the DHP, namely strategic architecture development and ongoing operations management of the national e-health environment. E-health governance also involves stakeholder engagement, policy and regulatory oversight, and monitoring and evaluation of digital health outcomes – additional DHP governance needs. Embedding DHP governance within national e-health structures will facilitate much-needed linkages with e-government institutions, as well.

If national e-health activities are not situated within the health ministry, it is important to make linkages with this institution. This will foster greater alignment of digital health goals with MoH goals, helping to expand the DHP's scope and usability, as well as to ensure sustainability. When Estonia implemented its national health records project, government, business, and non-governmental entities agreed on the governance of the project. The Estonian eHealth Foundation was established for ongoing standardization and central system maintenance (see Appendix A: 'Estonia case study').

Engage stakeholders in DHP governance

Stakeholder engagement is paramount for ensuring the success of your DHP, particularly in terms of governance. Without buy-in from stakeholders on how to operate and manage the DHP, it will be difficult to put the DHP design into practice and even harder to encourage uptake and usage over the long term. DHP governance can rely heavily on voluntary participation and consensus building, given that the DHP requires varied – and often disparate – health-related institutions to share data in a standardized manner. Therefore, engaging stakeholders early, often, and consistently is encouraged.

Questions for Stakeholders
• *What governance structure will align best with DHP goals?*
• *How should health system actors such as health workers, planners, or commodity suppliers be engaged in DHP governance?*
• *What policies and procedures are essential to establish first?*
• *Who should enforce the governance framework of the DHP?*
• *How will governance decisions be documented and monitored?*
• *How will the governance framework adapt over time?*

A useful way to engage stakeholders is to hold a meeting to clarify everyone's roles in DHP governance. At the meeting, you should ensure that everyone is aware of the DHP's purpose and principles. It may be useful to take stakeholders through a health journey to illustrate exactly how the DHP supports digital health moments—how the DHP supports the digital health interventions needed for improving your business process. Then discuss the governance needs for the DHP and how stakeholders will be involved. The sidebar, 'Questions for stakeholders', lists some sample questions for this discussion. Alignment on the different governance needs of the DHP is important both during initial rollout and in the future as the DHP continues to scale.

Develop a governance framework

To implement the DHP successfully, a governance framework is needed to guide overall administration and operation of the platform. This framework outlines the specific roles and responsibilities of a governing body, as well as its approach to management and decision-making. It describes policies and procedures required to roll out and operate the DHP effectively and to ensure that the DHP complies with the legal, regulatory, and technical requirements of an interoperable platform that exchanges sensitive, personal health information. To develop and carry out these policies and procedures, business units are needed. Therefore, the DHP governance framework should also outline the roles and responsibilities of each business unit within the DHP organization.

Because embedding DHP governance within the broader e-health organizational structure is essential, you may find that parts of this governance framework already exist and can be leveraged for DHP-specific operations.

DHP governing body

The DHP's governing body should be a dedicated management structure for the DHP that is housed within the larger national e-health organization. Its leader should be someone who has a clear understanding of the DHP's potential to improve health systems and a vision for how that can be achieved. This leader should be able to communicate the necessity and value of a DHP to public and private stakeholders, contributors, and consumers.

Depending on how the e-health organization is set up, you may wish to establish an advisory board, or even a board of directors, for DHP governance. In addition to ensuring that the DHP's mandate is met, this board will help promote DHP rollout and scale-up amongst key implementing partners, many of whom may already be DHP stakeholders. In some cases, this governing body may even establish a formal operational charter.

Learn more about governance

Health Information Exchange: Navigating and Managing a Network of Health Information Systems. Edited by B. Dixon, Elsevier Academic Press (2016).

The Open Group Architecture Governance

pubs.opengroup.org/architecture/togaf8-doc/arch/chap26.html blog.goodelearning .com/togaf/its-governance/Writing Good Governance Frameworks: A How-to Guide: www.claytonutz.com/knowledge/2012/april/writing-good-governance-frameworks-a -how-to-guide/

Note: All websites accessed on 27 May 2020.

DHP policies and procedures

The policies and procedures needed for effective DHP governance fall into two categories:

1) policies requiring more formal decision-making and consensual agreement by stakeholders, such as data use, data sharing, and conformity assessment
2) processes and protocols required for daily DHP operations, such as management of software development and deployment and ongoing technology maintenance.

The governance framework should detail the first, as these policies are important to codify within a document that stakeholders develop and share. Make sure to align the governance framework policies with the following:

- existing e-government and e-health policies and strategies
- existing national and institutional policies concerning data use and data privacy
- technical requirements demanded by the different components in your enterprise architecture (business, applications, data, and technology), including standards chosen for data and workflow processes.

Table 22 lists key policies and procedures needed to implement the DHP effectively and describes how DHP operational business units use them.

In any RFPs you prepare for systems integrators and solutions providers, you should include the parts of the governance framework concerning requirements for testing and compliance, training, and maintenance and technical support.

To read more about alignment with e-government, see the Korea case study (sidebar) in Section 6: 'Institutionalize the DHP'.

DHP operational business units

Ideally, the DHP management team within the e-health organization should define and set up business units to operationalize the platform. These units will undertake the day-to-day administrative tasks associated with implementing the DHP. Such work includes working with internal and external application developers to make sure that their software complies with DHP design principles and technical requirements. These units will also help define and enforce DHP policies and procedures. Table 22 describes these units and their responsibilities in more detail.

You may not have the resources or capacity to create individual teams for these units. Instead, think of these units as tasks for the staff who will manage and maintain the DHP.

Table 22: Roles and procedures of DHP operational business units

DHP Operational Business Unit and Role	Specific Policies and Procedures Needed for Operation
DHP components Plan and manage the purchasing, acquisition, development, and maintenance of software products that the DHP needs to operate. Liaise with DHP component developers and vendors.	• Management of the deployment of new or adapted components or the retirement of outdated components, with minimal disruption to existing operational components and external applications • Protocols for ongoing maintenance of platform and applications • System for tracking issues, or 'bugs', from identification to resolution
Standards setting and maintenance Identify fit-for-purpose standards and their integration into DHP component product acquisition or development projects.	• Identification and approval procedures for DHP standards • Guidelines for how standards will be maintained and how new standards will be incorporated over time • Criteria for how standards compliance is measured in internal DHP components, DHP interfaces, and external applications
Privacy and security Establish and enforce privacy and security requirements and protocols for personal health data in accordance with legislative or institutional policies, as well as best practices. Institute, monitor, and update data sharing agreements.	• Published privacy and security policies, including enforcement measures • Data sharing agreements that include: – standard protocols for handling personally identifiable health data – protocols for who has access to what data and how – protocols for dealing with breaches • Monitoring of the DHP and external applications for privacy breaches • Protocols for responding to privacy-related concerns or complaints received through the help desk. (See Appendix G: 'Data protection measures' for information on and examples of data sharing agreements.)
Interface development and maintenance Liaise with external software developers on DHP interface specifications.	• Communication of interface specifications and version changes to software application vendors • Maintenance of multiple testing environments for external application developers • Collaboration with the help desk for quality control and fixes to APIs

DHP Operational Business Unit and Role	Specific Policies and Procedures Needed for Operation
Data quality and master data management Manage the data policies and master data necessary for the DHP and connecting systems, ensuring that data is consistent, available, and understandable to users of DHP services. Liaise with providers of data, such as registry, e-government, and drug regulatory authorities.	• Policies delineating requirements for high-quality data and efficient data management, including protocols for ensuring that master lists are updated in the DHP • Provision of reference data to external applications through a DHP master data service • Protocols for managing identifiers, including problem resolution • Procedures for responding to data quality and management issues received through the help desk
Conformity assessment Ensure that external applications conform to DHP policies, specifications, and standards through published conformity assessment policy and assessment criteria. Manage testing sandboxes and certification schemes to verify conformance.	• Published criteria used for assessing adherence to DHP specifications and standards, including technical interoperability, standards compliance, appropriate interactions with master data in registries and repositories, and workflows; criteria regarding adherence to national policies on privacy and security of personal health data also included • Provision of testing environments for external application developers to demonstrate conformity to the criteria • Certification scheme and schedule to verify conformance with policies before applications are connected to the DHP • Procedures to remedy non-conformity
External software application onboarding Manage the enrolment and onboarding of new external applications. Liaise with help desk, technology administration, and interface teams.	• Procedures for bringing external applications on board, including: – additions and updates to master data required for the external application to function – configuration of hardware or telecommunication systems to allow new applications to connect to the DHP
Technology administration Operate and monitor the technologies needed for continuous operation of the DHP.	• Protocols for telecommunications, network infrastructure, and storage infrastructure • Processes and policies regarding outsourcing support, including service-level agreements

DHP Operational Business Unit and Role	Specific Policies and Procedures Needed for Operation
Help desk services Provide a visible point of contact to the DHP organization for users and developers. Field questions and complaints that are relevant to the DHP's interaction with external applications. Escalate recurring issues to the appropriate DHP business unit.	• Ticketing process that uniquely identifies each contact and service request, assigning resolution to an accountable person, unit, or organization; tickets ranked for urgency (timeliness) and severity (scope of problem's impact) • Protocols for responding to problems received through the help desk, including developing plans to fix faulty DHP components and any errors generated • Reporting requirements, potentially through a dashboard, to update status and resolution of help desk ticket items

Enforce the governance framework

To make sure that your governance framework is carried out according to plan, you need to install mechanisms for enforcement. Some potential mechanisms include the following:

- **Structure that holds DHP organization accountable**: Ultimately, overall e-health leadership and DHP management are responsible for ensuring that the governance framework is implemented as planned. For this reason, it is highly recommended to install a board of directors or to station the DHP organization within a government institution. In the absence of this formal structure, the DHP implementers should draft an agreed-upon set of performance goals for the DHP. DHP leadership, along with operational unit heads, will share responsibility for enforcement of these goals.
- **Performance indicators for each DHP operational business unit**: Have each team develop milestones regarding the development and implementation of procedures or systems that are required to fulfil the team's mission.
- **Periodic checks of adherence to policies and procedures**: DHP management, in conjunction with e-health leadership, must regularly monitor adherence to governance policies and operational procedures. Employ remediation measures and potential policy revisions where adherence is falling short.
- **Timeline for marking progress along a maturity model**: If applicable to your context, use a maturity model's governance pathway as a high-level guide to benchmark your progress in evolving governance structures and policies for the DHP. While a maturity model lacks the specifics that a governance framework provides, it can be a useful tool for measuring if operational systems and policies are moving forward.

Organizations in the Philippines use the Control Objectives for Information and Related Technologies version 5 [COBIT 5] framework for governance

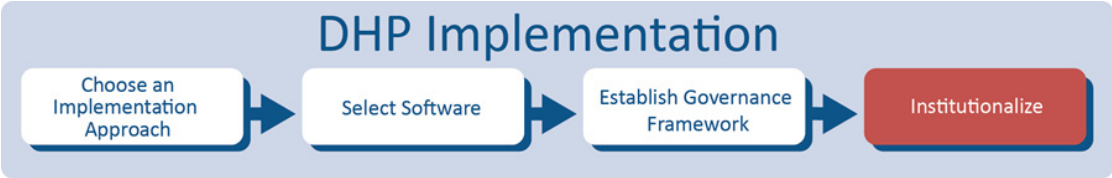
COBIT 5 is a framework for governing and managing information systems and other ICT technologies. It provides globally accepted principles, practices, analytical tools, and models to help organizations deploy ICT services and technology efficiently and effectively, ensure compliance with legal requirements, and minimize risk and security concerns.

Leaders at the University of the Philippines Manila found a pain point in the Data Privacy Act and its attendant penalties for breaches. This discovery highlighted the complexity of controlling sensitive personal health information, both paper and electronic, within the university system. To remedy this problem, an information technology council was created to advise the university chancellor; the council decided to adopt COBIT 5 to guide them forward. Subsequently, the university has designated a data protection officer at each college, and it has established a community of practice among each college's data office to help one another comply with the law. Throughout this process, COBIT 5 helped frame the activities of the information technology council.

The Philippines Department of Health [DoH] hired an external consultant to assist them with the COBIT 5 self-assessment programme, which is available for free (see www .isaca.org). The DoH undertook it with the assistance of a resource person certified in COBIT 5. The DoH will use the results of the self-assessment to invest in certain processes that are key to its internal ICT systems. Several other entities, including members of the Philippines National eHealth Governance Steering Committee and Technical Working Group, are also using COBIT 5.

Source: ISACA (2017). COBIT Framework. See: cobitonline.isaca.org

Institutionalize the DHP



Learning objectives:

- Explain the key factors and activities that facilitate DHP institutionalization.
- Outline the importance of change management processes.
- Describe how South Korea institutionalized its interoperable platform within the national infrastructure.

Institutionalization – key tasks

- Engage stakeholders.
- Raise awareness and build capacity.
- Develop a roadmap for DHP maturity.
- Encourage DHP usage with both 'sticks' and 'carrots'.
- Apply change management processes.

The path to institutionalization of a DHP does not begin after the DHP architecture is designed or the software is identified; rather, institutionalization begins from the very start of the steps outlined in this handbook. How well the DHP is institutionalized mainly depends on broad stakeholder engagement at all stages, from initial consultations to the establishment of DHP governance frameworks and policies.

Awareness raising and capacity building

As the DHP is deployed, a critical factor for its uptake and expansion by ICT and digital health decision-makers, as well as systems integrators and solutions vendors, is to educate this community about the DHP's value proposition—for health systems and for digital health innovations. Therefore, the DHP organizational unit and governing body need to devote time and resources towards ongoing educational efforts. They also need to create linkages amongst institutions that may benefit from connecting with the DHP. The DHP leadership should engage with health system managers, government staff, solutions vendor management, health worker professional associations, and policy-makers. Refer to the stakeholder analysis and mapping that you did when you started planning your DHP. To raise awareness about how your DHP supports – and improves – digital health, consider using national and international communities of practice, workshops, webinars, blogs, and wikis.

Stakeholders for DHP Institutionalization

- All stakeholders

Capacity building is another area of focus for institutionalization. Trainings are essential for ensuring that the DHP becomes a standard part of the digital health ICT infrastructure, particularly for the developers creating DHP components and external applications that link to the DHP. The following are examples of capacity-building activities:

- *for external application developers, systems integrators, and solutions providers:* trainings on how to best make use of DHP components in their applications and systems, adjust and optimize their applications and systems for information exchange through the DHP, and use the DHP as a basis for new digital health innovations
- *for DHP component developers and ICT staff:* peer learning in DHP architecture, specifically standards, interfaces, component design and implementation, ongoing platform maintenance, and governance, including compliance with relevant ICT policies and regulations in your country
- *for health*-sector *stakeholders:* sensitization on what the DHP does and trainings on the workflows of the digital health applications and systems they use.

Given that new stakeholders will continue to join the digital health field and that technology needs will change, these capacity-building activities should not be once-off events. Instead, offer trainings on a regular basis and provide additional training support through other means. The following are some suggested ways to build this capacity:

- dedicated website to DHP rollout that provides access to online trainings, DHP design and implementation experiences, standards guidelines, architecture designs, governance frameworks, and a community of practice for software developers
- hackathons for developers to understand how applications best connect to the DHP
- workshops amongst implementers to revisit governance frameworks, including any issues associated with DHP operations management, as the DHP evolves.

Development of a DHP roadmap with monitoring and evaluation indicators

To institutionalize and evolve the DHP successfully, you need a roadmap that considers all of the interdependent people, institutions, and processes required to meet the strategic goals and objectives of the health system and the DHP organization. The roadmap also provides a clear timeline that defines achievable progress milestones. Some maturity models for digital health may be helpful in defining goals. See Section 6: 'Approaches to DHP implementation' for more details.

The Journey to Scale: Moving Together Past Digital Health Pilots provides a framework for institutionalizing digital health programs. See: www.path.org/publications/detail.php?i=2498 (accessed 27 May 2020)

For any roadmap, it is important to have measures in place that show how you will monitor and evaluate success. Clearly define these indicators before you begin implementation, although you can alter them over time to accommodate changes in the environment or technology. Monitoring progress along these timelines will also help you identify barriers to achieving optimal success.

Ask the following questions periodically during DHP implementation:

- Is the DHP facilitating better data management?
- Has the burden on software developers, systems integrators, and solutions providers been eased, and is it easier for health workers and administrators to interact with multiple digital health applications?

- Do new stakeholders know about the DHP and its benefits?
- Is the health system seeing a benefit and impact from the DHP?
- Is the platform able to adapt to environmental changes, such as new health priorities, new technologies, or changes to policy or regulations?

If the answers are 'no', where are the deficiencies, and what measures can you take to improve the DHP and the user experience?

Factors encouraging uptake of the DHP

Encouraging external application developers, and the health workers and administrators who use their applications to connect to the DHP, may involve both 'stick' and 'carrot' approaches. 'Sticks', such as legal regulations or financial penalties, may be applied to those who fail to connect or comply. As noted earlier and as seen in the Korea case study (see sidebar, 'Institutionalization of South Korea's e-government framework' on the next page), on the next page), employing policy-making as a lever for more firmly embedding the DHP in formal institutions can be very important.

Depending on the context, much more effective motivators for using the DHP are the 'carrots': the benefits of the DHP that make people want to connect their information systems and applications to it. Continued uptake and ongoing success of the DHP will be much easier if you can demonstrate that the DHP offers the following benefits:

- ease of connecting to and using the DHP
- accelerator for improvements to existing external user applications and systems
- accelerator for the development of new external user applications and systems
- generator of tangible service quality and efficiency improvements.

In addition to these benefits, making it clear that the platform is regularly maintained will help DHP institutionalization. As standards, APIs, and technologies change, DHP operations staff need to update the platform components and infrastructure accordingly. Changes to clinical guidelines, regulatory directives, and national health or data policies will also require maintenance. See Section 6: 'Establish the governance framework' for more information.

Learn more about monitoring and evaluation, roadmaps, and change management in ICT:

Strategic Roadmaps

tfi.com/pubs/w/pdf/ti_sroadmaps.pdf

National eHealth Strategy Toolkit (Annex B provides links to e-health strategy roadmaps): www.itu.int/dms_pub/itu-d/opb/str/D-STR-E_HEALTH.05-2012-PDF-E.pdf

Monitoring and Evaluating Digital Health Interventions: A Practical Guide to Conducting Research and Assessment: www.who.int/reproductivehealth/publications/mhealth/digital-health-interventions/en/

TOGAF Architecture Change Management pubs.opengroup.org/architecture/togaf8-doc/arch/chap14.html

Note: All websites accessed on 27 May 2020.

Change management processes

The DHP is going to institute new processes for users and developers of applications and systems. Health workers may need to get used to the platform pushing care guidelines and suggested diagnoses to them. ICT staff may need to assist with systems in a wider network of facilities, as well as learn new APIs and workflows.

To adapt quickly and smoothly to these changes, change management processes are needed. The DHP organization needs to lead everyone through these changes, giving them time to challenge, question, and adapt to the new system. To assist with these changes, DHP leadership needs to anticipate and communicate any future changes that may require adaptation of the DHP and its components. Possible future changes could be new technologies, new or updated standards, and new or revised government policies or strategies. Leadership also needs to prepare DHP developers and implementers for new health priorities, and their accompanying health journeys, that will affect the DHP.

Institutionalization of South Korea's e-government framework

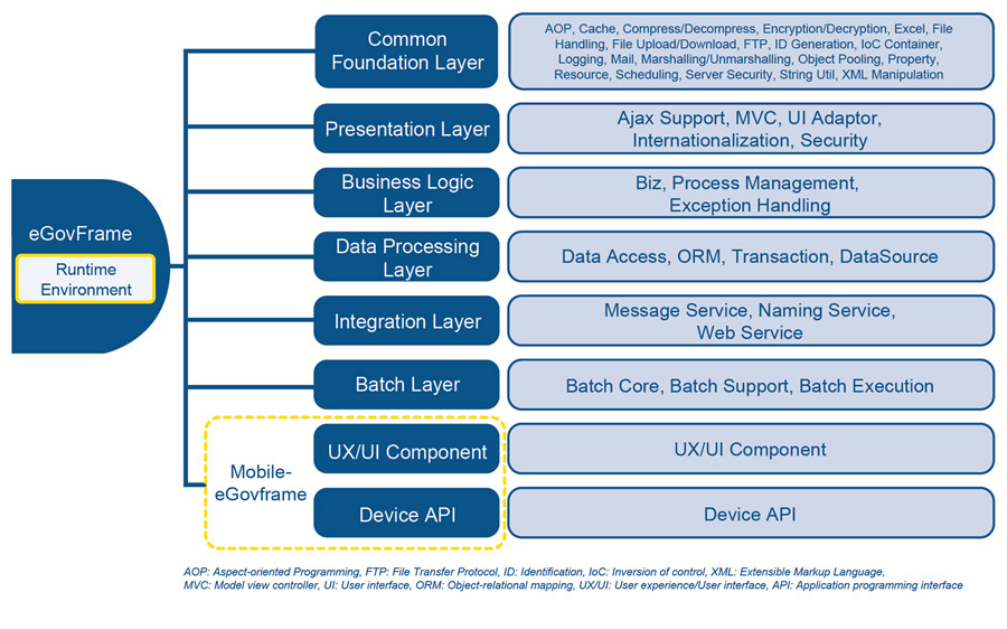
The Republic of Korea's strong leadership and commitment to developing robust digital infrastructure has made great progress in developing, implementing, and institutionalizing e-government. To help realize its mission, the government developed an e-Government Standard Framework, an infrastructure environment that aims to achieve interoperability and reusability of information systems. The standardization associated with these infrastructure-design goals helps move government institutions away from siloed systems.

All ministries and public agencies are recommended to use this standard framework, which enables module-based development of information system components. Developing components in this manner frees individual ministries of the task of building all of the components of an information system by themselves. Instead, the standard framework provides many of the key modules, similar to the DHP model.

Increased interoperability and reusability of information systems through the standard framework have reduced the costs of building new information systems.

In 2010, the government passed the Electronic Government Act, a law stipulating that the Ministry of Public Administration and Security formulate, share, and approve enterprise architectures.

As the backbone of the e-government system, this flexible, scaled framework serves as an example of a policy lever that can increase uptake of a platform similar to a DHP. It also embeds this platform into government institutions for years to come – an exemplary case of digital platform institutionalization.



Source: Republic of Korea (2010). Electronic Government Act. See: elaw.klri.re.kr/eng_mobile/viewer.do?hseq=25509&type=new&key (Accessed 17-27 May 2020).

Acronyms and Abbreviations Used

AeHIN: Asia eHealth Information Network

AI: Artificial intelligence

ANC: Antenatal care

AOP: Aspect-oriented Programming

API: Application programming interface

APSEA: Andhra Pradesh State Enterprise Architecture (India)

ASHA: Accredited social health activist (India)

CDA: Clinical Document Architecture

CDA R2: Clinical Document Architecture Release 2

CDG: Continua Design Guidelines

CIEL: Columbia International eHealth Laboratory

CIMI: Clinical Information Modeling Initiative

COBIT 5: Control Objectives for Information and Related Technologies version 5

COPD: Chronic obstructive pulmonary disease

CR: Client registry (OpenHIE)

CRDM: Collaborative Requirements Development Methodology

CSS: Cascading Style Sheets

CSV: Comma-separated values file

DHA: Digital Health Atlas

DHI: Digital health intervention

DHIS 2: District Health Information Software version 2

DHP: Digital health platform

DHPH: Digital Health Platform Handbook

DIAL: Digital Impact Alliance

DICOM: Digital Imaging and Communications in Medicine

DIG: Planning, Implementation, and Financing Guide for Digital Interventions for Health Programmes, or Digital Interventions Guide in shorthand

DoH: Department of Health (Philippines)

EHR: Electronic health record

EHRS: Electronic Health Record Solution (Canada)

EFT: Electronic funds transfers

EMM: Enterprise mobility management

EMR: Electronic medical record

EPI: Expanded Programme on Immunization

ESB: Enterprise service bus

FHIR: Fast Healthcare Interoperability Resources

FHIR-HL7: Fast Healthcare Interoperability Resources specification developed by Health Level-7 organization

FR: Facility registry (OpenHIE)

FTP: File Transfer Protocol

GIS: Geographic Information System

GPS: Global Positioning System

GS1: Global Standards One

H2: Open source database management system that uses Java Structured Query Language

HDD: Health data dictionary

HHQ: Health history questionnaire

HIAL: Health Information Access Layer

HIMSS: Healthcare Information and Management Systems Society

HIS: Health information system

HIV: Human immunodeficiency virus

HIV/AIDS: Human immunodeficiency virus/ acquired immune deficiency syndrome

HL7: Health Level Seven

HMIS: Health management information system

HRIS: Human resource information system

HRN: Health record network

HTML: Hypertext Markup Language

HTML5: Hypertext Markup Language version 5

HTTP: Hypertext Transfer Protocol

HTTPS: Hypertext Transfer Protocol Secure

HWR: Health worker registry (OpenHIE)

ICD-10: International Classification of Diseases, 10th revision

ICF: International Classification of Functioning, Disability, and Health

ICHI: International Classification of Health Interventions

ICT: Information and communication technology

IDSR: Integrated Disease Surveillance and Response

IEEE: Institute of Electrical and Electronics Engineers

IHE: Integrating the Healthcare Enterprise

iHRIS: Integrated Human Resource Information System

ILR: InterLinked Registry

IoC container: Inversion of control container

IoT: Internet of Things

IP: Internet Protocol

ISO: International Organization for Standardization

ISO/IEEE 11073: Set of standards for medical and personal health devices established by the International Organization for Standardization and the Institute of Electrical and Electronics Engineers working group

ITU: International Telecommunication Union

ITU-T: ITU Telecommunication Standardization Sector

IVR: Interactive voice response

JLN: Joint Learning Network

LAMP: Archetypal model of web service stacks, containing Linux operating system, Apache web server, MySQL relational database management system, and hypertext preprocessor (PHP) programming language

LAN: Local area network

LIS: Laboratory information system

LOINC: Logical Observation Identifiers Names and Codes

MCTS: Mother and Child Tracking System (India)

MDR-TB: Multidrug-resistant tuberculosis

MFR: Master facility registry

MNCH: Maternal, newborn, and child health

MoH: Ministry of Health

MVC: Model view controller

MySQL: Open source relational database management system that uses Structured Query Language

NESF: National e-health standards framework

NFC: Near-field communication

NHDD: National Health Data Dictionary

NLP: Natural language processing

OAuth: OpenAuthorization

OCL: Open Concept Lab

OECD: Organisation for Economic Co-operation and Development

OpenHIE: Open Health Information Exchange

ORM: Object-relational mapping

PACS: Picture Archiving and Communication System

PAHO: Pan-American Health Organization

PAN: Personal area network

PCD: Patient care device

PCD-01: Patient Care Device transaction for communicating PCD data

PCHA: Personal Connected Health Alliance

PHC: Primary health centre

PHD: Personal health device

PHII: Public Health Informatics Institute

PHR: Personal health record

PKI: Public key infrastructure

PMTCT-STAT PEPFAR indicators: Indicators used by President's Emergency Plan for AIDS Relief for measuring pregnant women with known HIV status at antenatal care

PoS: Point of service

PostgreSQL: Open source database system that uses Structured Query Language

RAFT: Telemedicine Network in Francophone Africa (*Réseau en Afrique pour la Télémedicine*)

RESTful: Representational state transfer

RFID: Radio-frequency identification tag

RFP: Request for Proposals

RUTE: Telemedicine University Network (*Rede de Universidade de Telemedicina*) (Brazil)

SDN: Software-defined network

SHR: Shared health record (OpenHIE)

SMS: Short Message Service

SNOMED-CT: Systematized Nomenclature of Medicine – Clinical Terms

SOAP: Simple Object Access Protocol

SSO: Single sign-on

TAN: Tiny area network

TCP/IP: Transmission Control Protocol/Internet Protocol

TOGAF: The Open Group Architecture Framework

TS: Terminology service (OpenHIE)

UEM: Unified Endpoint Management

UI: User interface

UML: Unified Modeling Language

UNESCO: United Nations Economic, Scientific, and Cultural Organization

UNICEF: United Nations Children's Fund

USB: Universal Serial Bus

USAID: United States Agency for International Development

USSD: Unstructured Supplementary Service Data

UX: User experience

W3C: World Wide Web Consortium

WAN: Wide area network

WAR: Web application resource

WFP: World Food Programme

WHO: World Health Organization

XML: Extensible Markup Language

Appendix A – Case Studies

Liberia case study

Country background and digital health context

Liberia's population of over 4.7 million inhabitants[1] is spread across 15 counties in this tiny West African nation bordered by Sierra Leone, Guinea, and Côte d'Ivoire. Since 2003, Liberia has been gradually rebuilding from nearly 14 years of devastating civil wars. As in many countries in West Africa, key health challenges in Liberia include maternal and child health mortalities and morbidities, malaria, and other infectious diseases. According to the 2013 Liberia Demographic Health Survey,[2] the maternal mortality ratio is 1 072 per 100 000 live births, and the under-five child mortality rate is 94 per 1 000 live births.

The West Africa Ebola outbreak in 2014-15[3] resulted in over 10 500 confirmed cases and more than 4 800 deaths in Liberia alone. Many of these deaths occurred amongst health workers who were providing testing, treatment, and care to other Ebola patients. Liberia experienced more health worker deaths than Guinea and Sierra Leone, two neighbouring countries also devastated by the Ebola epidemic.[4] There are concerns that Liberia could see sharp increases in maternal deaths as a result of this loss of health workers, reversing progress made in maternal care since the end of the last civil war.[5]

The Ebola outbreak highlighted major gaps in Liberia's health system—gaps that limited its ability to mobilize and respond to the epidemic quickly. In particular, disparate and weak health information systems [HIS] failed to provide accurate, timely, and accessible data about health services, workers, and facilities that are crucial in surveillance and rapid response.

Evolution of Liberia's national health information systems

Prior to the Ebola outbreak, the Liberia Ministry of Health [MoH] had begun improving its national digital health information systems. In 2008, District Health Information Software [DHIS] Version 1.4 was introduced to the country. By early 2011, the MoH had updated its health management information system [HMIS] to DHIS 2, scaling it to all 15 counties. During the Ebola crisis, health worker staff used DHIS 2 to support data entry about the epidemic.

With support from United States Agency for International Development [USAID] through the Rebuilding Basic Health Services project, the MoH introduced Integrated Human Resource Information System [iHRIS] in 2013. Developed by IntraHealth International, iHRIS is an

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1 Worldometers (2017). Liberia population. See: www.worldometers.info/world-population/liberia-population/

2 Liberia Institute of Statistics and Geo-Information Services (2014). *Liberia Demographic and Health Survey 2013*. See: www.dhsprogram.com/pubs/pdf/FR291/FR291.pdf

3 Centers for Disease Control and Prevention (2016). 2014 Ebola outbreak in West Africa—case counts. See: www.cdc.gov/vhf/ebola/outbreaks/2014-west-africa/case-counts.html

4 WHO (2015). *Health Worker Ebola Infections in Guinea, Liberia, and Sierra Leone*. Preliminary Report. See: www.who.int/hrh/documents/21may2015_web_final.pdf

5 World Bank (2015). *Disproportionate Deaths Among Health Care Workers from Ebola Could Lead to Sharp Rise in Maternal Mortality Last Seen 20 Years Ago—World Bank Report*. See: www.worldbank.org/en/news/press-release/2015/07/08/disproportionate-deaths-among-health-care-workers-from-ebola-could-lead-to-sharp-rise-in-maternal-mortality-last-seen-20-years-ago---world-bank-report

open-source system that enables health ministries, professional councils, and training institutions to track the numbers and types of health workers deployed, registered, licensed, and in training throughout the country. In Liberia, the ministry customized the iHRIS software to match the health system's workforce structure, using iHRIS's standardized reporting tools for rapid analysis, including the locations of health workers throughout all levels of the health system.

Before the Ebola outbreak, the government and its non-governmental organization partners had begun efforts to understand and test the interoperability of DHIS 2 and iHRIS, which would increase the amount of data available for informed decision-making.

Platform description and design approach

When the Ebola outbreak began to expand rapidly in August 2014, the MoH needed to better connect with front-line health workers who were testing and caring for Ebola victims. As many health workers had never been trained on Ebola, they did not know how to best treat patients and protect themselves from the disease. Given Ebola's rapid spread, the MoH needed to share important information with health workers quickly, as well as to understand the needs on the front lines of care.

Learn more about the mHero platform:

Overview of platform and tools for designing and using mHero mHero.org

Installation and configuration information wiki.ihris.org/wiki/MHero_Installation_and_Configuration/

Note: All websites accessed on 28 May 2020

In response, IntraHealth International, United Nations Children's Fund [UNICEF], and USAID jointly created mHero, a new platform that facilitated interoperability between iHRIS and RapidPro, an open-source Short Message Service [SMS] platform. This platform enabled real-time two-way communication between the MoH and its workers across the country. With mHero, ministry officials could design text messages, or workflows, in RapidPro and use iHRIS to select whom the messages should reach. MoH staff could target health workers by cadre, location, or facility, three of iHRIS's data fields. The data received from health workers' responses could then be updated in iHRIS. Using mHero in this manner, ministry officials could quickly learn which health facilities were open and where health workers were working—critical pieces of information given that some facilities shut down and some workers moved or abandoned their posts in the midst of the crisis. The MoH also used mHero to deliver important service-delivery directives and health education to the field.

Using mHero, the Liberia MoH sent over three-dozen workflows during the Ebola outbreak response and immediate recovery period. These vital communications reached more than

8 000 health workers from November 2014 to September 2016.[6] UNICEF supported all SMS costs through an agreement reached with Liberia's mobile-network operators.

When designing the mHero platform, IntraHealth, USAID, and UNICEF wished to leverage systems and technologies already in place, so health staff would not have to learn a new technology in the midst of a crisis. They also adhered to the Principles for Digital Development, specifically involvement of users in the design, and architecture built for scalability and sustainability.[7] By approaching the platform development in this manner, the three partners included the Liberian government as an active decision-maker in determining how the platform was used and the direction of its growth. As such, development of mHero was—and still remains to this day—truly country led.

Post-Ebola expansion of mHero

Since the end of the recent Ebola outbreak, the Liberia MoH has used mHero to support various use cases, including facility assessments, reminders of licensure expirations, and knowledge assessments for community health workers. mHero has also collected mental healthcare information that was not captured in DHIS 2. The MoH and its partners are currently augmenting mHero's scope to include disease-surveillance reporting (through DHIS 2 Tracker) and supply chain management—developments that will improve the ministry's rapid response to outbreaks and its ability to manage commodity and equipment stock levels effectively. One feature being added to mHero is expanding the alerting functionality. A system monitoring a disease through DHIS 2 could trigger alerts to be sent to health workers in a catchment area or facility via mHero if there is an outbreak. The reverse is also being developed: health workers could send messages through mHero that would trigger alerts, enabling proactive surveillance in the country.

On a policy level, mHero is now included in Liberia's five-year National Health Information System Strategic Plan 2016-2021, which is aligned with the National Health Plan and the Resilience Investment Plan. The MoH has also developed a step-by-step work plan, called mHero Roadmap, to help scale up mHero's implementation.

Development approach

Technical development and components mapping of mHero took place during a rapid hackathon at the UNICEF Innovation Hub in Kampala, Uganda, in early September 2014. During this five-day sprint, ten technical developers from IntraHealth, UNICEF, and ThoughtWorks developed a platform to allow RapidPro and iHRIS to communicate.

mHero's developers designed the platform for use with any human resource information system [HRIS] compliant with Care Services Discovery [CSD] standards for data transmission and any interoperable SMS tool. They chose Open Health Information Exchange [OpenHIE] (see Appendix I: 'OpenHIE') for mHero's development because OpenHIE's use of the CSD standards for exchanging health worker data had been tested and proven to work in low- and middle-income countries, unlike other standards. iHRIS is compliant with CSD, and the

[6] L. Fast & A. Waugaman (n.d.). Real-time information flows. In *Fighting Ebola with Information: Learning from the Use of Data, Information, and Technologies in the West Africa Ebola Outbreak Response*. See: www.digitaldevelopment.org/real-time-information-flows/

[7] A. P. BenDor (2016). mHero and the Principles for Digital Development: development done right. See: https://digitalprinciples.org/resource/mhero-and-the-principles-for-digital-development-development-done-right/

InterLinked Registry [ILR] was already being used to support OpenHIE workflows. Therefore, no new development or redevelopment was needed, allowing the team to pilot, deploy, and scale mHero rapidly during the Ebola crisis.

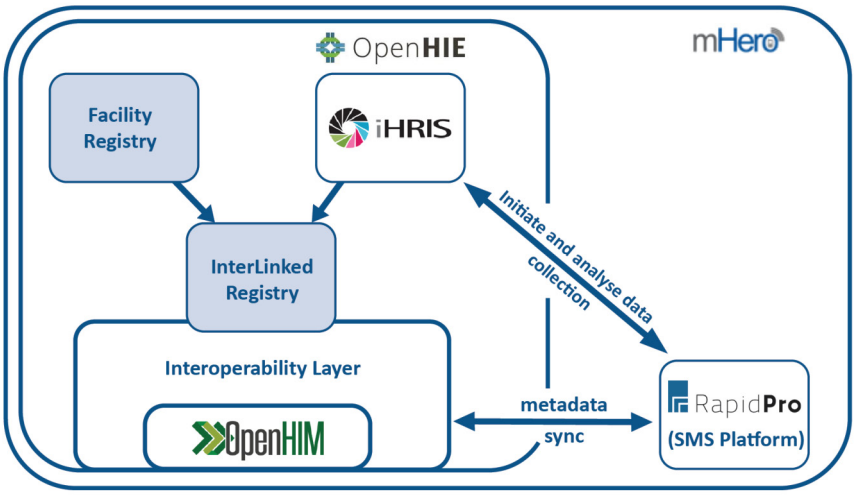
In designing mHero, developers also kept in mind the future growth of the platform to ensure that other systems could be interoperable with mHero. Their choice of OpenHIE paved the way for systems such as DHIS 2 to be added later. Once established and tested, this interoperability would allow updates from health workers via RapidPro's SMS to flow automatically to DHIS 2 as well as iHRIS.

Components

The mHero architecture is composed of several core components (see Figure A.1):

- human resources information system [HRIS], such as iHRIS
- SMS platform, such as RapidPro
- interoperability layer
- facility registry
- InterLinked Registry (combines facility data with health worker registries).

Figure A.1: mHero information flow



Source: *IntraHealth International (2017).*

In the mHero platform, the user interface for the health worker registry is built into iHRIS. mHero uses the facility registry that is also shared with DHIS 2.

mHero also leverages OpenHIE's architect°ural model of an information mediator or interoperability layer: Open Health Information Mediator [OpenHIM], in this case. OpenHIM is a middleware component that plays the roles of access control, audit log, and router, allowing external systems such as iHRIS and RapidPro to connect to a trusted agent (OpenHIM) and send data to secure endpoints. A well-instantiated middleware should have redundancies

and failovers to mitigate point-of-failure concerns; by its nature, this middleware provides implementers with a controlled interface for managing access to data in and out of the system.[8]

The ILR serves as the intermediary to facilitate data exchange between RapidPro (the SMS platform) and iHRIS. The ILR combines the functionality of the health worker registry with cached facility data from the facility registry. By doing so, the ILR allows iHRIS to be a canonical source of information on health workers. The development team chose OpenInfoMan as the reference software used for the ILR,[9] enabling the health worker registry to be incorporated into OpenHIM. OpenInfoMan is a reference implementation of CSD using XMLQuery [XQuery] and a representational state transfer [REST] API that uses XQuery [RESTXQ].

Standards

To ensure interoperability of the systems and software that mHero uses, developers designed the platform with internationally recognized standards for exchanging health information data:

- CSD
- mobile alert communication management [mACM]
- Fast Healthcare Interoperability Resources specification developed by Health Level Seven International [HL7 FHIR].

HL7 FHIR is a standard for sharing health worker and health facility data (see Section 5: 'Adopt and deploy standards' and Appendix F). While RapidPro does not support CSD or FHIR, it does include RESTful application programming interfaces [APIs] that are compatible and aligned with HL7 FHIR standards. Therefore, mHero's adoption of FHIR allowed easy management of additional and transformational load processes between the proprietary RapidPro API and HL7 FHIR standards. The developers of mHero built a facade on RapidPro to allow it to accept HL7 FHIR requests. Later, during the mHero implementation, a team led by Jembi Health Systems developed synchronization tools that were added to OpenHIM as a mediator. These tools automatically synchronized RapidPro contacts and iHRIS health worker data into the ILR.

An Integrating the Healthcare Enterprise [IHE] profile of the HL7 FHIR standard, mACM, allows plug and play with other systems for one-way alerting, such as one-way alerting to patients and providers. By adopting the mACM profile, mHero developers could provide a standards-based interface for any system that wanted to send an alert—not just RapidPro.

These data standards are important so that other HIS and SMS software can be used in mHero. They allow other HIS, such as DHIS 2, to connect and send alerts without having to work through APIs of specific SMS systems. Therefore, adoption and deployment of these standards has enabled the aforementioned expansion of mHero's alerting functionality. Future work is being explored to allow alerts coming from DHIS 2 Tracker.

Alignment with DHP and lessons learned

mHero is an example of a small-scale digital health platform [DHP]. Although the design is simple, the project team designed an enterprise architecture with components, standards, and technologies that enable interoperability and scalability.

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8 D. Settle (2016). *Spotlight: Behind mHero—a look at interoperability, architecture, standards, and the value of open source systems.* See: www.mhero.org/news/spotlight-behind-mhero-look-interoperability-architecture-standards-and-value-open-source

9 GitHub (2017). openhie/openinfoman-ilr. See: github.com/openhie/openinfoman-ilr/

mHero is also an example of a DHP built by linking existing external applications and systems. The project team started with iHRIS, which the Liberian MoH used, and connected it to an SMS platform to take advantage of the widespread use of mobile devices in Liberia. To make this connection between the two external applications, the team built an integration services layer, a core enabling component of a DHP. Since the Ebola crisis in 2014, the mHero team has expanded this 'mini-DHP' by adding DHIS 2 onto this platform, creating a hub in the service delivery and surveillance domain.

The development of mHero followed many of the steps in the project cycle described in the Digital Health Platform Handbook [DHPH] for designing and implementing a DHP:

- Create the enterprise architecture by mapping DHP components and standards to use-case needs.
- Establish governance mechanisms at the MoH, including procedures detailing how health units can access and use mHero.
- Include mHero in Liberia's national HIS strategy, demonstrating how the mHero platform is being institutionalized and could be scaled up in the future.

Most lessons learned from this first implementation of mHero are programmatic and operational in nature:

- Use MoH leadership to ensure success and sustainability.
- Raise awareness of the platform's functionality and ease of use amongst health workers.
- Ensure that the country has sufficient infrastructure and capacity for supporting the platform.[10]

Estonia case study

Country background and digital health context

Estonia, located in the Baltic region of northern Europe, is home to more than 1.3 million people. With a population density of 30 people per square kilometre, Estonia is the third most sparsely populated country in Europe.[11] Over 65 per cent of the population is urban.

Estonia's healthcare system is built on the principle of compulsory insurance, with access to private service providers available to all. The system is governed by the Health Services Organisation Act,[12] which details national requirements for the provision of health services, including managing, financing, and supervising health care. The Estonian Health Insurance Fund, an insurance scheme that covers approximately 95 per cent of the population, finances most healthcare services.[13] Other healthcare funders include rural municipality and city budgets, patients themselves, and additional sources derived as direct appropriation. Compulsory health insurance was established in Estonia in 1992.[14]

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10 USAID (2016). *mHealth Compendium Special Edition 2016: Reaching Scale*. See: www.africanstrategies4health.org/uploads/1/3/5/3/13538666/2016_mhealth_31may16_final.pdf

11 Enterprise Estonia (n.d.). Overview–Estonia. See: estonia.ee/overview/

12 Riigi Teataja (2013). Health Services Organisation Act. See: www.riigiteataja.ee/en/eli/ee/Riigikogu/act/531102013007/consolide/

13 Estonian Health Insurance Fund (n.d.) Estonian health care system. See: https://www.haigekassa.ee/en/people/health-care-services/estonian-health-care-system

14 Enterprise Estonia (n.d.). Estonia at a glance. See: estonia.eu/about-estonia/country/estonia-at-a-glance.html

National Health Information Exchange platform

In 2005, the Estonian Ministry of Social Affairs launched a new e-health concept by phasing in four projects: Electronic Health Records, Digital Images, Digital Registration, and Digital Prescriptions.

- The national electronic health records [EHRs] initiative enables digital health documents and data to flow amongst participants, including patients as well as service providers from multiple private and public institutions. This initiative gives patients access to health data online.
- The e-prescription initiative establishes a set of systems and standards that enable practitioners, insurers, patients, and pharmacists to participate in a common workflow for digital prescriptions.[15]
- The digital registration initiative aims to create a centrally-administered system for booking patient appointments and resources (e.g. health workers)[16]
- The diagnostic images archive allows health institutions to share diagnostic images with one another throughout the country.

All of these projects are part of Estonia's Health Information Exchange [HIE] platform, a unified national HIS linked with other public information systems and registers. The main goals of the platform are to:

- Increase the efficiency of the healthcare system, including making time-critical information more accessible.
- Reduce the level of bureaucracy in the work processes of providers.
- Develop higher quality and more patient-friendly healthcare services.
- Enable person-centric management of health information, and support a national transformation to personalized medicine.
- Open up and expand the market for health information technology software.

The core EHR initiative provides the basic integrated information technology system for all e-health solutions.[17] The national EHR project connected all health institutions with shared data sources and kicked off the ongoing standardization of digital health data artefacts.[18] Funding for developing the platform was a joint effort of Estonia and the European Union.

E-services

The government developed the HIE platform for users who had become accustomed to e-government services. Estonians had been using e-banking, e-taxation, e-school, and other e-services for years before the integrated digital health system was introduced. A governmental service bus called X-Road integrated many of the e-services, which enabled new, efficient digital processes to be implemented with less bureaucracy.[19]

Since 2002, all Estonian residents have had a personal digital identity. This digital identity operates through the use of unique identifiers (personal IDs), digital certification organizations (e.g. police, national certification centre), and physical security devices (e.g. smart card, mobile

[15] Estonian Health Insurance Fund (n.d.). Digital prescription. See: https://www.haigekassa.ee/en/people/digital-prescription

[16] Estonian eHealth Foundation (n.d.). Digital registration. See: www.e-tervis.ee/index.php/en/international-projects/finished-projects/digital-registration

[17] European Union Regional Policy (2007). Electronic health record. See: ec.europa.eu/regional_policy/en/projects/best-practices/estonia/1435/

[18] Estonian E-Health Foundation (n.d.). Health information system. See: www.e-tervis.ee/index.php/en/health-information-system/

[19] e-Estonia (n.d.). Building blocks of e-Estonia. See: https://e-estonia.com/solutions/

subscriber identity module [SIM] card). Residents use this digital identity when accessing government services or interacting with e-government platforms and portals for two purposes: identity authentication and digital signatures.

Platform description and design approach

The Estonian HIE platform encompasses the entire country, registering the health histories of nearly all residents from birth to death. Developing the platform within a mature standards-based ecosystem for national e-services has enabled its uptake and success. In addition, the platform has benefited from the clear governance structures created by the Estonian eHealth Foundation [EeHF][20], a public-private entity established by the Ministry of Social Affairs to initiate and maintain e-health activities. The EeHF is responsible for development and management of the HIE platform, central system and health registry maintenance, and ongoing standardization, including maintaining healthcare classifications and national care guidelines.

Learn more about the Estonia's Health Information Exchange platform:

Health and Welfare Information Systems Center Tehik.ee (in Estonian), formerly Estonian eHealth Foundation www.e-tervis.ee/index.php/en/ (in English)

Overview of X-Road www.ria.ee/en/x-road.html

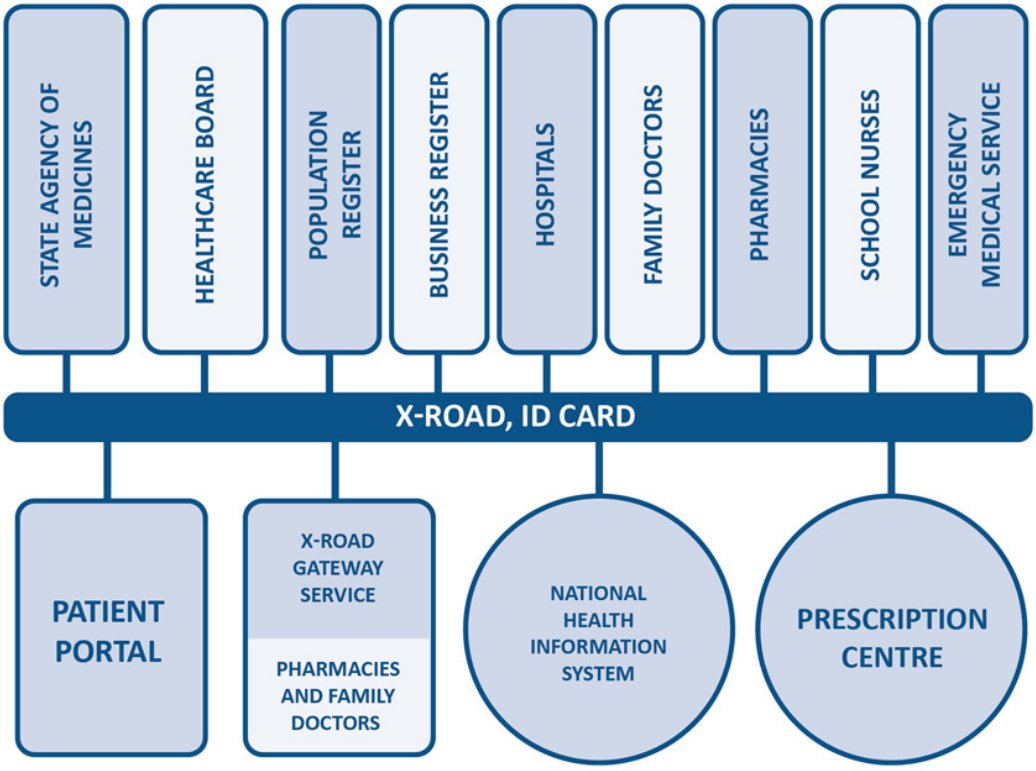
Overview of Estonia's digital ecosystem e-estonia.com

Note: All websites accessed on 28 May 2020.

Platform architects based the HIE platform on the standards-based public information technology infrastructure and on the common registries that existed at the time of national EHR development. The HIE platform incorporates many elements, including a national HIS, a prescription centre, a patient portal, and various registries (see Figure A.2).

[20] EeHF has been merged into the Health and Welfare Information Systems Center (TEHIK - Tervise ja Heaolu Informatsioonisüsteemide Keskus) of the Ministry of Social Affairs.

Figure A.2: Estonian HIE platform architecture



Healthcare Business Processes Supported by the HIE Platform

The Estonian HIE platform supports health care by enabling effective and efficient business processes through its digital health architecture and technology. Through an integrated and interoperable set of user-oriented applications, data storage systems, and internal technology components, the platform delivers solutions for two major types of processes: health service delivery and administrative processes. Examples of specific processes in each category are described in Table A.1.

Table A.1: Business processes supported by the Estonian HIE platform

Health Service Delivery Processes	Administrative Processes
Health records process: enables clinicians to share patient data with one another and with a person related to the patient.	*Consents process:* states a patient's request about health care or records, including restricting clinicians' or trustees' access to records.
Critical report process: enables ambulances and emergency care clinicians to receive a quick summary of a patient's health records.	*Demographics process:* gathers personal demographic data into shared records from sources such as a population registry, patient portal, or health provider.
Ambulance process: enables ambulance units to issue communications to a patient's subsequent care providers via shared health records.	*Usage audit process:* allows patient access to the health records access log.

Health Service Delivery Processes	Administrative Processes
Prescriptions process: connects clinician, pharmacist, insurer, and patient in one digital workflow.	*Assistance process:* assists a patient with access to digital health services.
Laboratory diagnostics process: requires all medical labs to report diagnostic results to shared health records, enabling patient-centric viewing of results.	*Professional digital licensing process:* registers an individual as a licensed health professional, enabling access to shared health records.
Imaging diagnostics process: regulates information sharing of diagnostic images and updates health records with radiology reports.	*Institution digital licensing process:* registers an institution into a special role of health institution, allowing network access to the health records system.
Epidemiology process: updates medical registries automatically from shared health records.	*Institution digital certification process:* allows digital authentication for institutions via cooperation with public authorities, such as a business registry or state information system authority.
Health certificates process: delivers specific health condition data to outside parties, such as a coach or authority.	*Personal digital certification process:* allows digital authentication for individuals (e.g. patients, health workers) through an identification card or mobile ID, via cooperation with the police, certification centre, and telecommunication services.
Referrals process: supports the transfer of patients from one provider to another.	*Reimbursement process:* connects the health service provider with the insurer, issuing claims through the platform.
Consultation process: allows patients to receive medical advice via digital health channels.	
Research process: allows scientific researchers to view certain data in shared health records, following approval from a special ethical committee.	

Functional elements

To operationalize the various digital health processes described in Table A.1, the Estonian HIE platform architecture includes components called 'functional elements'. Some of these functional elements were originally designed to support processes internal to a health institution, whereas others aimed to support digital health processes occurring across different institutions. Zones are used to group functional elements that support the same overarching purpose in the platform.

Interaction zones enable digital health participants to interact with the digital health processes:

- Application systems facilitate user interaction, process flow, and data management for a set of functions. Viewed as independent ecosystems, these external applications interact with other HIE systems.
- Portals enable user participation in the digital health processes by providing access to view and update data shared across institutions. Portals are built around a specific registry

or shared data system (e.g. patient portal) or as an access layer for a set of registries (e.g. citizen portal).

Standards zones enable interoperability between platform components:

- Schema specifications define data structures common to HIE, including communication messages amongst the systems.
- Reference data define classifications used to code the exchanged data values.
- Interaction specifications define the events of message exchange between the systems of HIE. An interaction specification links events of digital processes (the 'digital health moments') with the schema specifications, service provider systems, and service consumer systems. For example, institutions offering digital services over the X-Road in Estonia have to register and provide specification of the web services provided through Web Service Definition Language [WSDL][21].

Processing zones control the automated flow of interactions amongst other applications and systems. These zones are still largely virtual, with the process logic built into the local external applications. Some shared processes are planned for future development.

Data zones share some data services as part of the HIE. Besides acting as shared data sources, the data systems provide interaction, processing, and other functions:

- Registries maintain a set of unique entities defined by such properties as person names, facility names, license, medication, medical condition, document, and so on. Examples include the population registry, business registry, medical professionals' registry, and health document registry.
- Repositories store digital artefacts such as documents, images, and videos. A repository alone possesses little value; one or more registries are needed, and items stored in a repository can be linked to registry entries.
- Analytics provide alternate views on the registry and repository data and are often delivered in the form of linked tables, reports, or decisions.

Control zones support management of the entire HIE domain, such as surveillance, monitoring, and audit logs.

Standards

The HIE platform employs various standards to ensure systems interoperability. The Estonian eHealth Foundation designed, agreed upon, published, and maintained many of the integration standards for health information exchange on the platform.[22] Other international specifications (e.g. Digital Imaging and Communications in Medicine [DICOM]) are also used, and some vendor-specific specifications at the domain level are included (e.g. Estonian health insurance specification for claims[23]).

Connectivity standards used for HIE were based on the public information technology infrastructure (X-Road) provided by the Estonian Information System Authority.[24] The X-Road

[21] WSDL is an eXtensible Markup Language (XML) format for describing network services. These services are endpoints that operate on messages containing document-oriented or procedure-oriented information. See: w3.org/TR/wsdl (accessed 17 November 2017).

[22] Estonia Health and Wellness Center for Information Systems (2015). Standards 5.2. See: pub.e-tervis.ee/standards2/Standards/5.2/

[23] Estonian Health Insurance Fund (n.d.). TORU Reports: requirements for access to the Estonian Health Insurance Fund's health insurance database. See: https://www.haigekassa.ee/en/kontaktpunkt/healthcare-management-system-estonia/financing-health-care (in Estonian)

[24] Estonia Information System Authority (2017). Data exchange layer X-Road. See: www.ria.ee/en/x-road.html

is widely used in Estonia, but some connection transactions are not based on it. Specific, often point-to-point, connectivity agreements are also in place.

Finally, the HIE platform used classifications approved by the Estonian eHealth Foundation for data formats and structures.[25] To help ensure the consistent delivery of high-quality care, the HIE platform also used the process and care guidelines for healthcare service delivery established by the Health Board in the Estonian Ministry of Social Affairs and the Estonian Health Insurance Fund.

Security components and governance

As ensuring the privacy of patient data is deemed essential, the HIE platform protects its data through the following technical components and enforcement mechanisms:

- availability measures such as redundant infrastructures, distribution of X-Road endpoints and nodes, redundant network, redundant staff, and usability of interactive functions;
- integrity measures such as non-repudiation via digital stamps, non-repudiation via hash chains, non-repudiation via third-party logging, two-factor authentication, security audits, and technical documentation;
- confidentiality measures such as encrypted traffic, encrypted storage, and authorization;
- policy such as legislation and data protection guidelines;
- policy enforcement such as provider licensing procedures, data protection inspectorate audits, X-Road surveillance, query surveillance, personal access to audit logs, and digital certification procedure.

Technology architecture

The underlying technology architecture supporting Estonia's digital health system, including the HIE platform, is based on common state-of-the-art information and communication technologies [ICTs]:

- interactive technologies, including web clients, desktop software, mobile devices, and medical devices;
- integration technologies, including X-Road (secure web-service transport intermediary), DICOM transport protocols, and other transport protocols;
- network and Internet, including 3G, 4G, Wi-Fi, and asymmetric digital subscriber line [ADSL];
- hardware security module [HSM], including identification card, mobile ID, Universal Serial Bus [USB] token, and HSM server;
- data centres, including server computers, data storage systems, network equipment, and physical security measures.

Alignment with DHP and lessons learned

The Estonian HIE platform is a sample implementation of a highly complex DHP that benefits from its integration with Estonia's extensive infrastructure for e-government services. The HIE platform architecture and operational management structure incorporate many of the elements of DHP design and implementation that this handbook describes, including interoperability, reusability of components for multiple healthcare business processes, robust security measures, and adoption of strong governance systems to manage, maintain, and ultimately, sustain the platform.

[25] Estonia Health and Wellness Center for Information Systems (n.d.). Classifications. See: pub.e-tervis.ee/classifications/

Several lessons learned emerged from the project implementation.

Success factors:

- standardization of the digital artefacts
- strong regulatory environment
- reuse of existing infrastructure (e.g. identification card, X-Road, registries)
- attention paid to security and user authentication, resulting in zero registered privacy violations during the first six years of the system's existence.

Areas for improvement:

- Usability was not the top priority. The design of how patients and health workers access the digital system could be improved.
- Health information exchange placed higher demands on data security. Changing clinicians' habits in digital authentication took time and effort.
- Health workers were hesitant to share their digital notes with others and with patients. There is a need to raise awareness amongst the general population about the sharing of health data between healthcare providers and with the patient through a portal.

Challenges faced during implementation:

- Getting all stakeholders on board was challenging.
- Resources were planned only for the development of central systems. The lack of resources for integrating local systems created delays in adoption.
- Financing through the local health institution was an inhibitor of success. The development of local digital systems was budgeted from a different source, a process that took extra time.
- Data quality targets and measures could have been stronger, particularly given that uncertainties about data quality inhibit secondary use of collected data.

Canada case study

Country background and digital health context

Although Canada boasts one of the lowest average population densities in the world, at 3.5 persons per square kilometre, most of its population of 33 million is concentrated in urban areas. Over 80 per cent of the population lives in or near an urban centre, while only 19 per cent of the population lives in rural or remote locations.[26,27]

In Canada, the federal government sets and administers national principles for health services delivery through the Canada Health Act. However, all 13 provincial and territorial governments share responsibility for health services delivery. Each plans, finances, manages, and evaluates health services in its own jurisdiction. Within each jurisdiction, health authorities coordinate care delivery over a set geographical area, resulting in more than 100 separate health authorities throughout the country.

[26] Statistics Canada (2017). Population of Census Metropolitan Areas. See: www.statcan.gc.ca/tables-tableaux/sum-som/l01/cst01/demo05a-eng.htm

[27] Statistics Canada (2017). Census program. See: www12.statcan.gc.ca/census-recensement/index-eng.cfm

Learn more about Canada Health Infoway's platform:

Official Canada Health Infoway, Inc. website: www.infoway-inforoute.ca/en/

Information about the Canada Health Infoway national architecture:

Canada Health Infoway, Inc. (2006). *EHRS Blueprint: An Interoperable EHR Framework.* See:

www.infoway-inforoute.ca/en/component/edocman/resources/technical-documents/391-ehrs-blueprint-v2-full

Information on how Ontario province's eHealth architecture integrates with Infoway
http://www.ehealthblueprint.com/en/documentation/chapter/canada-health-infoway-chi-and-the-standards-collaborative

Note: All websites accessed on 28 May 2020.

In 1999, an Advisory Council on Health Infostructure recommended the establishment of a nationwide HIS that would significantly improve the quality, accessibility, and efficiency of Canadian health services. As a result, in September 2000 the federal government established Canada Health Infoway, an independent, not-for-profit corporation that was accountable to all 13 provincial and territorial governments as well as to federal authorities. Infoway's mission aimed to build on existing initiatives in order to accelerate developing and adopting HIS with compatible standards and communications technologies.[28]

Platform description and design approach

This case study highlights Infoway's development of a national information architecture for implementing large-scale EHR solutions called the 'Electronic Health Record Solution Infostructure'. The goals of this architecture are to create an EHR for each resident of Canada that would achieve the following:

- improve the quality, safety, accessibility, and timeliness of care for Canadians
- support more informed healthcare decision-making, research, and management
- improve the efficiency of the healthcare system and reduce costly duplication
- maximize return on information technology investments
- achieve standards-based solutions, allowing interoperability.

The design approach taken to achieve these goals is for each Canadian jurisdiction (province or territory) to implement an information infrastructure platform, or 'infostructure', that is connected nationally. These platforms would allow a variety of external software systems to either capture or access clinical and administrative information about patients and the health services provided to them. To connect to the platform for this data exchange, the external applications use a set of standardized interfaces provided by the platform.

A key principle for the architecture is that the platform manages the data captured by each point-of-service [PoS] software application in a set of common repositories, rather than individual

[28] Canada Health Infoway (2017). Digital health in Canada. See: www.infoway-inforoute.ca/en/

software applications having to interact or be integrated with one another. These common repositories store and share the following:

- diagnostic imaging and reports (via picture archiving and communication system [PACS] networks)
- lab results (via a laboratory information system [LIS])
- medication dispenses (via a drug information system [DIS])
- patient histories, allergies, encounters, problem lists, diagnoses, and care plans (via a shared health record repository).

Software applications can then use a service of the Health Information Access Layer [HIAL] to retrieve shared information as needed.

Figure A.3 provides a high-level outline of the structure of Infoway's platform.

Figure A.3: Overview of Canada Health Infoway electronic health record infostructure

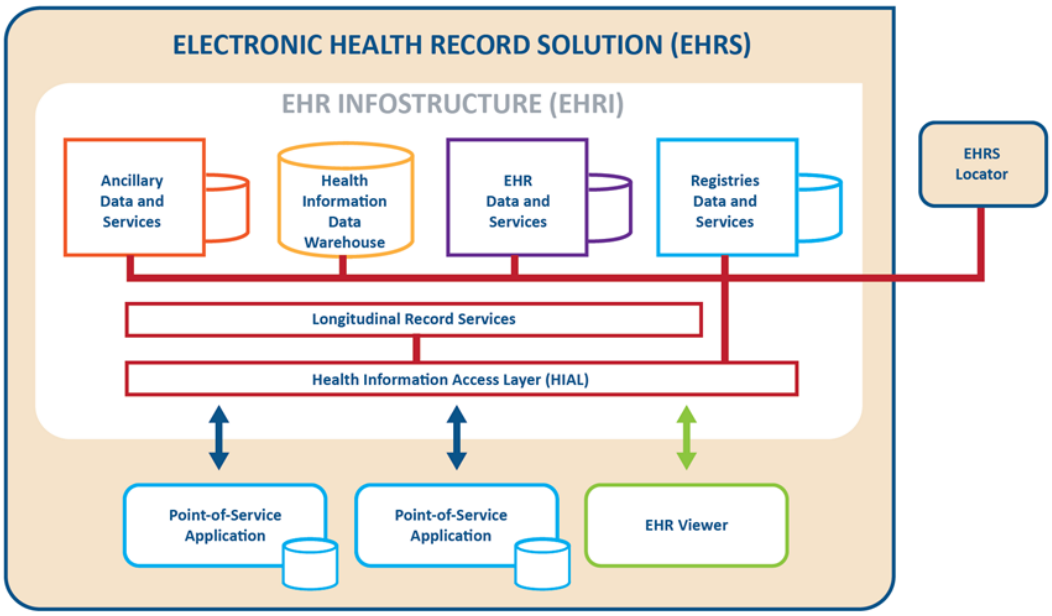
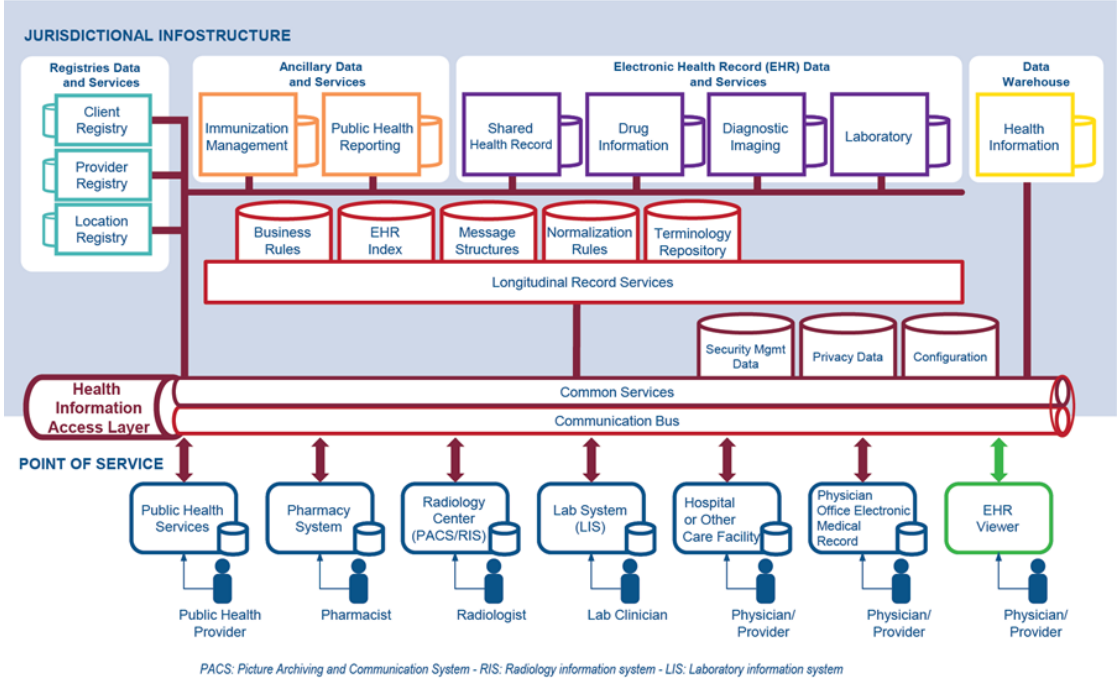


Figure A.4 shows the EHR Infostructure architecture in a more detailed manner, describing the specific components associated with each platform layer and the different PoS applications that interact with the platform.

Figure A.4: Detailed view of Canada electronic health record infrastructure



Using this infostructure approach, there is no single EHR application, but rather a comprehensive and scalable EHR solution. In this solution, a broad spectrum of purpose-specific software applications contributes to an EHR that can be maintained throughout a patient's lifetime. Doing so enables health workers to access valuable and potentially critical information for each person that would otherwise not be available locally.

Service-oriented architecture

The EHR Infostructure is highly scalable and extensible because it uses a service-oriented architecture [SOA] approach. A core principle of SOA is to hide the variability of underlying systems and databases. By providing external applications with access to data and functionality through standardized service requests and responses, the architecture does not expose the internals of the system, nor does it require the platform to be integrated with other systems in a tightly coupled way. Moreover, this architecture allows ICT planners to modify or replace platform components in a manner that limits the impact on the external software applications that use those services. In many cases, the service interface can remain unchanged. In addition, backwards compatibility can be provided when introducing new functionality or support for new data.

The EHR Infostructure platform allows for two forms of abstraction for the ICT planners, solutions providers, and developers who will adapt and create software for the platform. First, the EHR is not seen as a physical database; instead, it is seen as a set of services that provide and receive information. Second, the platform architecture does not need to be aware of the wide variety of external applications that may potentially connect to it; instead, the platform only sees a consistent set of standardized requests and responses to the services it provides. These services are displayed in Figures A.5 and A.6.

Figure A.5 shows the 'EHR Interoperability Profile', which describes how a PoS application interfaces with a single EHR service, such as 'Get Prescription' or 'List Service Delivery Locations'.

Figure A.5: EHR Interoperability Profile. Source: Canada Health Infoway

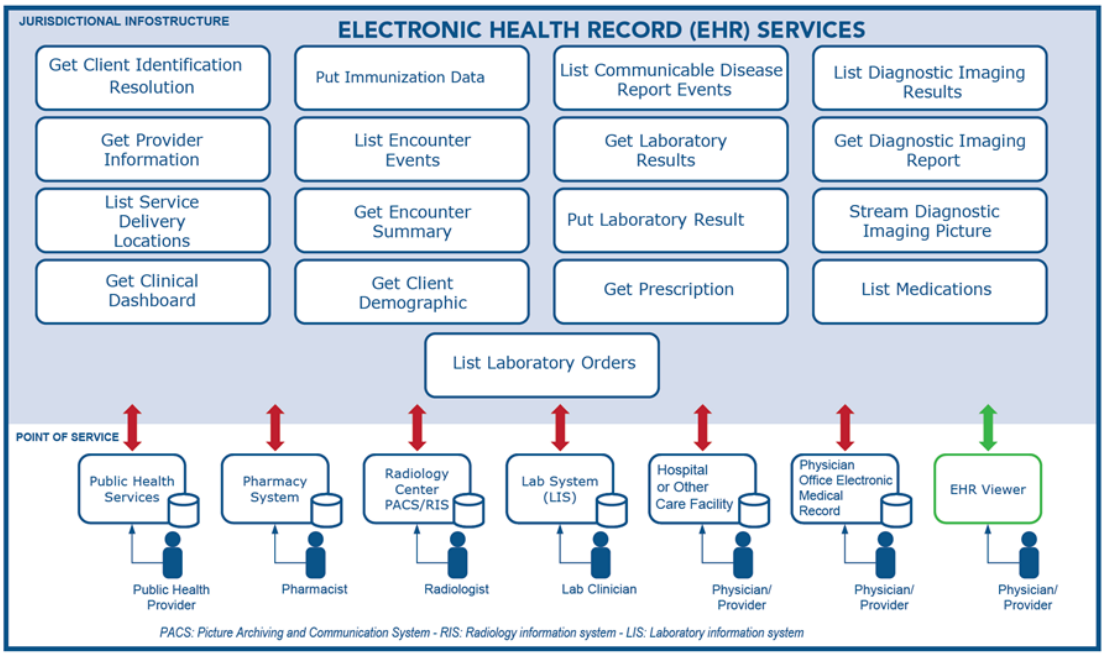
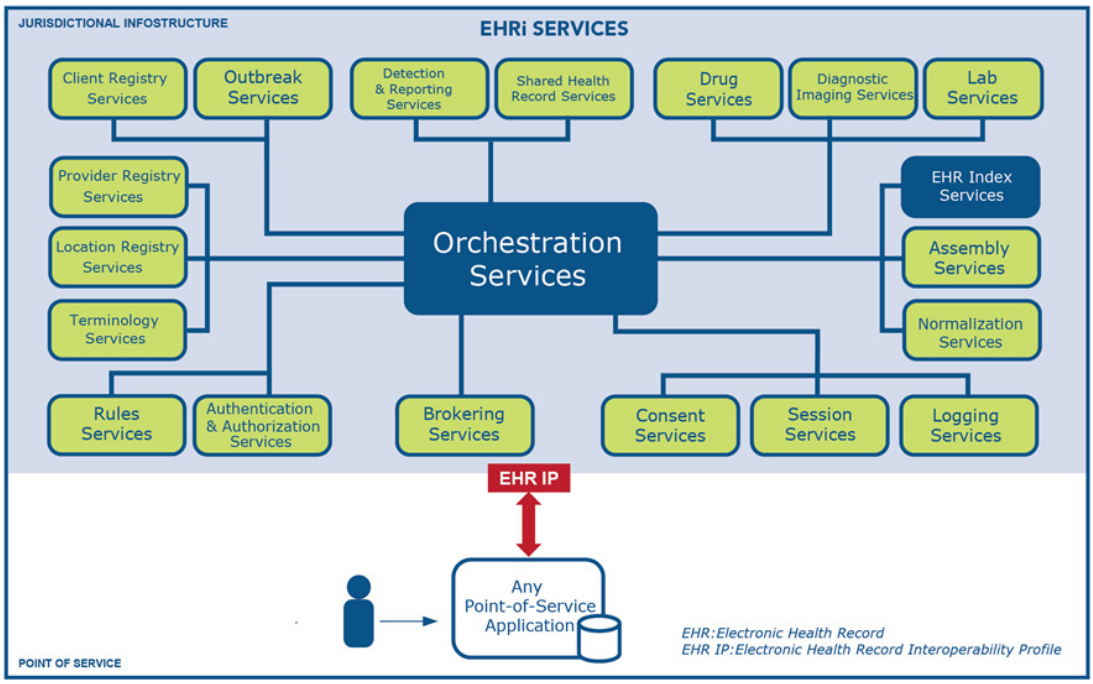


Figure A.6 is also an interoperability profile though this one shows the different activities and communications that occur amongst the EHR Infostructure services when responding to a single service request from a PoS application (shown in Figure A.5). As the focus is on the internal activities of the infostructure, the profile is appropriately named the 'Infostructure Interoperability Profile'.

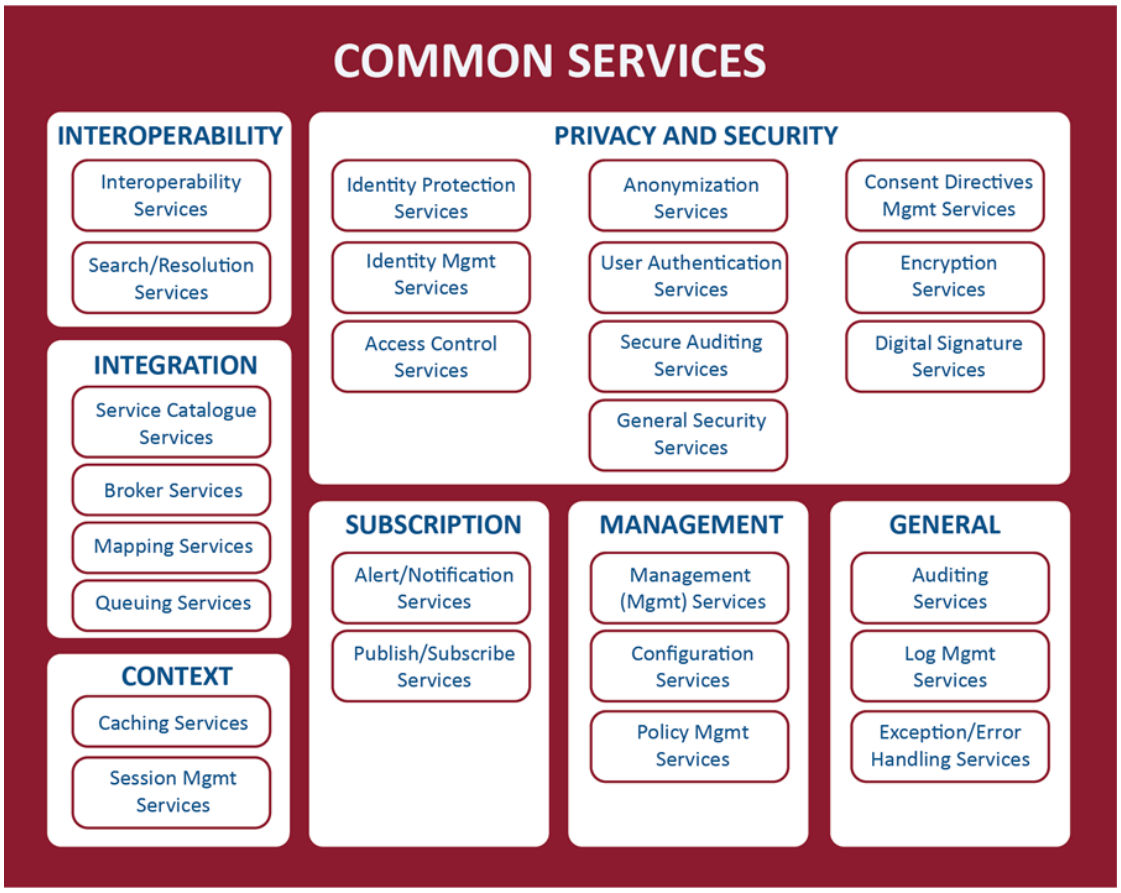
Figure A.6: Infostructure Interoperability Profile



In addition to providing a set of standardized interfaces for external applications to connect to the EHR platform, the platform design describes a set of common services. Included within

the Health Information Access Layer, these services are used in an orchestrated manner to provide interoperability, integration, privacy and security, auditing, subscription, and interface management components (see Figure A.7). Many of these common services mirror DHP components outlined in the DHPH main text.

Figure A.7: Common services included in Health Information Access Layer



Use of standardized interfaces and data formats

To enable data exchange between the PoS applications and the shared repositories, standardized and secure message-based interfaces are implemented in a manner that protects the privacy of personal health information. Common technology services and protocols that protect personal health data from inappropriate or inadvertent use were developed according to Infoway's EHR Infostructure privacy and security requirements.

Master data management practices are also implemented. Consistent identifiers for healthcare patients, providers, organizations, service delivery locations, and the services themselves are used. Such consistency in practice is essential because the EHR platform consolidates information from a broad variety of sources and care settings. It also leverages these data for various purposes. Therefore, a set of identity registries ensures the uniqueness and validity of identifiers that the participating systems use.

This approach requires that any information shared to the common repositories is standardized whenever it needs to be counted, compared, aggregated, or used by software systems to direct automated processes or workflows, as well as to support decision-making. The standardized identifiers or coding systems—also known as 'structured clinical terminologies'—are a form of

master data defined in the interface specifications used by the PoS software applications. These applications can either use the standardized data formats directly, or where it is safe and practical, they can map their local data into the formats required by the platform interfaces. Conversely, PoS applications can convert shared data stored on the platform through the interfaces back to the local format desired by the external application. In some cases, health jurisdictions that shared common repositories chose to accept a broad range of data types and content. Then they mapped that content to the common standards in use where the data were stored.

Alignment with DHP and lessons learned

Alignment with DHP design approach:

- The architecture is meant to ease data sharing via the EHR Infostructure, which has most of the core services and components required by a DHP.
- The PoS architecture, which is designed to hide the complexity of the underlying systems, enables multiple systems to interact without having to integrate tightly with one another.
- The EHR Infostructure platform also acts as a service mediator, sending and receiving information to applications and systems that require it.

Lessons learned:

- **Stakeholder engagement is important for successfully implementing a DHP.** Infoway has facilitated thought leadership with, and collaboration between, its stakeholders by sponsoring working groups for various subject domains and clinical disciplines. For example, Infoway working groups involve regular members from clinical reference groups (e.g. clinicians, nurses, and pharmacists), a heath information privacy group, and groups for diagnostic imaging, lab information systems, drug information systems, identity registries, infostructure, and architecture. Some of these groups use Infoway as a secretariat, having it serve a facilitation role for developing authoritative written work specific to the group's domain. These documents express a definitive, pan-Canadian understanding of the digital health needs and viable approaches to solving them. Infoway's involvement with stakeholders in this manner has been particularly helpful in accelerating progress and supporting leaders within their own jurisdictions.
- **Be clear about the investment priorities and process for DHP initiatives.** It was unclear how Infoway would serve as a strategic investor at the outset of the individual platform-development projects undertaken by health jurisdictions. There was no clear understanding of which types of projects Infoway would be prepared to invest in, how eligibility for funding would be determined, and how the funds would flow in an accountable, merit-based fashion. Methods and mechanisms took about two years to develop and implement. During this period, there was little to no progress in ICT development across the country, as stakeholders did not want to proceed in a way that might preclude them from receiving Infoway funding. As a result, many stakeholders in the healthcare community became very frustrated.

India case study

Country background and healthcare system overview

India comprises 29 states and seven union territories in a federal structure. Its population of 1.32 billion speaks 22 official languages, with hundreds of local dialects. While policy is designed at the federal level in consultation with state governments, the delivery of essential services, such as health care, is the responsibility of each state. Therefore, each state manages the healthcare services provided to its residents based on individual state healthcare budgets and priorities.

To provide a well-defined set of healthcare guidelines to the states, the Government of India's Ministry of Health and Family Welfare's National Health Mission [NHM] creates a national health plan, typically in five-year cycles. The NHM's vision is to ensure universal access to equitable, affordable, and quality healthcare services that are accountable and responsive to people's needs. At the same time, NHM aims to address India's wider social determinants of health. Within this framework, India's states create state-specific programmes and innovations. States also set their own outcome indicators based on local context and capacity. This flexibility and decentralization in health planning extends to the district level (the equivalent of counties), as well.

Digital health context

While national healthcare authorities have designed HIS for various programmes that can be replicated uniformly across states, each state implements its own HIS according to its needs. As India's states differ in capacities and priorities, there is a considerable lack of uniformity in HIS configuration and usage. Several standalone digital health applications developed at the national level are already running successfully in many states, including the Integrated Disease Surveillance Programme [IDSP], Tuberculosis Surveillance, and the Mother and Child Tracking System [MCTS]. However, integration across these systems remains a challenge, limiting the ability of the HIS to allow seamless data exchange and, ultimately, to facilitate comprehensive decision-making.

Learn more about MCTS and the Aadhaar Identity Management system:

Official website of India's National Health Mission: https://nhm.gov.in/

Official MCTS website: nrhm-mcts.nic.in/

Research on MCTS:

R. Gera, N. Muthusamy, A., Bahulekar, A. Sharma, P. Singh, A. Sekhar, & V. Singh (2015). An in-depth assessment of India's Mother and Child Tracking System (MCTS) in Rajasthan and Uttar Pradesh. *BMC Health Services Research*, 15(315). doi:10.1186/s12913-015-0920-2

A. Labrique, S. Pereira, P. Christian, N. Murthy, L. Bartlett & G. Mehl (2012). Pregnancy registration systems can enhance health systems, increase accountability and reduce mortality. *Reproductive Health Matters*, 20:39, pp. 113-117, doi: 10.1016/S0968-8080(12)39631

P. Nagarajan, J.P. Tripathy, & S. Goell (2016). Is Mother and Child Tracking System (MCTS) on the right track? An experience from a northern state of India. *Indian Journal of Public Health*, 60(1), p.34. doi: 10.4103/0019-557X.177298

Aadhaar Identity Management Official Site: uidai.gov.in/

Research on Aadhaar System:

R.K. Pati, V. Kumar & N. Jain (2015). Analysis of Aadhaar: a project management perspective. *IIM Kozhikode Society & Management Review*, 4(2), pp. 124-35. Doi: 10.1177/2277975215610687

All websites accessed on 28 May 2020

In addition to these health-specific digital applications, the government of India has successfully rolled out a nationwide digital identity management system with the primary objective of

providing a digital identity to all citizens. Created to reduce inefficiencies and identity fraud in distributing targeted subsidies, the Aadhaar system provides a unique 12-digit digital identity for each citizen. The Aadhaar system is more robust and sophisticated than the identity managemenft systems currently deployed in many countries. This unique identity management system captures a person's biometric data, including an iris scan and fingerprints, along with demographic details. It also contains features for maintaining data integrity, accurately identifying citizens, and preserving privacy.

To date, the government has enrolled over 98 per cent of the eligible population in the Aadhaar database. This proportion represents a very significant increase from those who had obtained other forms of government-issued identification in the past. Passports and tax identification numbers have largely favoured India's urban and wealthier populations, leaving poorer Indians without official proof of citizenship and thus without access to vital government services.

Integration between Mother and Child Tracking System and Aadhaar database

Integrating the Aadhaar database with India's HIS will help ensure that care reaches target populations as well as improve service delivery. Identity management is important for tracking and monitoring migrant patient populations, such as truck drivers, people who move frequently for socioeconomic or cultural reasons, or pregnant women who return to their maternal homes for deliveries. Patients who require continuity of care, such as tuberculosis patients or pregnant women, need to be able to access treatment services as they move around. In addition, proper identity management during service delivery helps ensure that the services and entitlements reach the targeted beneficiaries in a transparent manner, reducing identity fraud and duplication. Such transparent and continuous access can occur only if health workers use a robust nationwide identity management system for accessing patient health records.

This case study focuses on how a DHP would enable integration between the Aadhaar database and MCTS.

Overview of the existing Mother and Child Tracking System

MCTS aims to improve service delivery and outcomes in the maternal and child health programmes run by the various states of India. To help meet programme goals, MCTS offers name-based tracking of all pregnant women entitled to antenatal and postnatal care, along with a full set of immunizations for their children. This database creates work plans for each enrolled patient. Front-line community health workers, called accredited social health activists [ASHAs], use these work plans to encourage patients to attend an institution within the network of community clinics for scheduled visits as well as for the birth itself.

Developed in 2009 by the Ministry of Health and Family Welfare through the National Informatics Centre [NIC], MCTS is currently hosted and maintained at NIC's data centre, which hosts a majority of the state and federal governments' informatics services. Through various web-based menus, health workers can enter and access data, as well as generate reports and individual work plans for each patient. MCTS supports a single sign-on [SSO] login mechanism, with options for creating a new user account and installing a certificate to support the SSO login. An important feature of MCTS is its system-generated unique Family ID for families and Member ID for each family member.

Even though this digital system exists, ASHAs still largely rely on a paper system for initially recording patient and family data. ASHAs later submit these paper registers for data entry

into the MCTS. This process can affect the quality and timeliness of the services that the MCTS should deliver, as well as data quality and robustness.

Studies of MCTS implementations in different states have noted the system's benefits and its shortcomings. One study noted that the MCTS improved accountability, empowered the community, and resulted in better supervision of health workers.[29] Even so, the study observed multiple challenges that still exist, including incomplete beneficiary profiles, difficulties in registering beneficiaries by front-line health workers, the absence of clear processes and guidelines that govern data collection and management procedures, delays in data capture due to documentation workload on health workers, inadequate end-user training, and poor Internet connectivity.[30,31]

Benefits of Aadhaar's robust identity verification mechanisms

The Aadhaar database could potentially offer a number of benefits to MCTS if a DHP were to connect the two systems. To help correctly identify patients, Aadhaar currently offers the following features:

- **Biometric and demographic data collection**: At present, MCTS relies on a name-based tracking system to identify patients. However, an Indian name often has multiple spellings, likely due to the large numbers of languages and dialects spoken in the country. Aadhaar reduces the severity of this problem by collecting additional personal identity information, not just names.
- **No inherent structure used in the unique identity number for each citizen**: Most national identity numbers use an embedded structure in their sequencing, such as those used in China and the United States. These structured schemes may enable an identity thief or other interloper to make some inferences about the owner, such as place or date of birth. The Aadhaar number, however, has no structure, thereby helping preserve citizen privacy.

In addition, the lack of embedded structure in Aadhaar's numbers means that this identity scheme is well-equipped to handle large populations over a long period of time. Therefore, the Aadhaar database will be able to accommodate the expected growth in India's population for many years to come.

- **Extensive de-duplication mechanisms built in**: To avoid duplication of a citizen record, the Aadhaar database compares individual demographic and biometric data with a variety of parameters for data validation. This feature is particularly important for enforcing eligibility criteria for targeted beneficiaries.
- **Designed to only confirm identities, not to share demographic and biometric data:** The Aadhaar database uses an API that provides only a 'yes' or 'no' response to an external application when verifying whether a person is enrolled in Aadhaar. By not sharing any additional data stored with a person's record, the Aadhaar database further protects citizen identity and maintains data integrity.

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[29] P. Nagarajan, J.P. Tripathy, & S. Goell (2016). Is Mother and Child Tracking System (MCTS) on the right track? An experience from a northern state of India. *Indian Journal of Public Health*, 60(1), p.34. doi: 10.4103/0019-557X.177298

[30] R. Gera, N. Muthusamy, A., Bahulekar, A. Sharma, P. Singh, A. Sekhar, & V. Singh (2015). An in-depth assessment of India's Mother and Child Tracking System (MCTS) in Rajasthan and Uttar Pradesh. *BMC Health Services Research*, 15(315). doi:10.1186/s12913-015-0920-2

[31] P. Nagarajan, J.P. Tripathy, & S. Goell (2016). Is Mother and Child Tracking System (MCTS) on the right track? An experience from a northern state of India.

Alignment with DHP

While the Aadhaar identity management system was designed to be interoperable, MCTS was not. This legacy system is standalone (although future versions of MCTS and other Indian HIS may be built with openness, interoperability, and scalability in mind). Therefore, a DHP is needed to tie Aadhaar and MCTS together. A DHP would enable these two external applications to share information seamlessly with each other and other applications that connect to them; these two applications would also benefit from additional functionality provided by other DHP components that may be built.

To learn how MCTS could benefit from other DHP components, see Savita's health journey, which has served as a use case example in this handbook (see Figure 12 in the DHPH main text). Savita's journey emerged directly from a business-process redesign of MCTS. This journey shows how the national Aadhaar identity management system could potentially be integrated into MCTS via a DHP, along with many other DHP components, such as health record repositories and appointment scheduling. Such integration would greatly improve the existing system.

While DHP development and system integration for MCTS has yet to happen, a few key observations should be taken into account when designing a DHP, both its internal components and external applications:

- Any new system must be able to manage a very large number of patients at the start and scale seamlessly to handle even larger numbers. Given that the Indian health system managed 20.8 million live births and provided three antenatal care [ANC] check-ups to 22 million pregnant women from 2014-15, DHP technology needs to be robust, open, and certainly scalable.
- MCTS needs an appropriate mobile technology front end that seamlessly integrates with it. This solution would reduce ASHAs' use of paper registers to enrol patients in MCTS, helping to decrease data errors and improve the speed with which patients can receive quality care.
- The next generation of MCTS should leverage the registry services of the DHP. This DHP component will improve patient tracking and record-keeping by MCTS. As registry services are housed in a platform designed for integration and scaling up, this component's functionality could be extended seamlessly to programmes other than maternal care, such as supplemental nutrition and vaccinations.

Norway case study

Country background and digital health context

Norway has a sophisticated healthcare system that provides care services to over 6 million citizens, primarily through the 428 municipalities scattered throughout this rural, mountainous country. These local entities are responsible for providing primary healthcare and social care services. The Ministry of Health focuses on policy-making and funding, as well as on its direct role in specialist care, including ownership of hospitals. The MoH also issues directives to the boards of regional healthcare authorities.[32]

[32] A. K. Lindahl (n.d.). International health care system profiles: the Norwegian Health Care System. See: international.commonwealthfund.org/countries/norway/

Norwegian health authorities view digital health as a primary tool for empowering individual patients to manage their own health and thereby live longer lives. To realize this vision, the healthcare system has implemented several programmes, including the following:

- a national initiative to use new telecare services for primary health service delivery as well as for people with chronic diseases
- an m-health project aiming to reduce the development of non-communicable diseases (part of the World Health Organization [WHO]/International Telecommunication Union [ITU] Be He@lthy, Be Mobile programme)
- programmes to support e-prescribing, the national health portal (established in 2011), and Personal Connected Health.[33]

This case study describes the current state and plans for architecture testing and implementation of the national Personal Connected Health programme, which includes telehealth, telecare, and private initiatives, all supported by m-health solutions.

Learn more about Norway's Personal Connected Health programme:

Overview of programme

helse.no/Documents/E-helsekunnskap/Personal_Connected_Health_and_Care_Jon_H_Andersen.pdf

Personal Connected Health architecture

ehelse.no/Documents/Velferdsteknologi/2015-12%20Rapport%20anbefalinger%20arkitektur%20velferdsteknologi%20v1%20f.pdf (in Norwegian)

ITU-T H.810 series

See Appendix F

Continua Design Guidelines

www.pchalliance.org/continua-design-guidelines

Note: All websites accessed on 28 May 2020.

Platform description and design approach

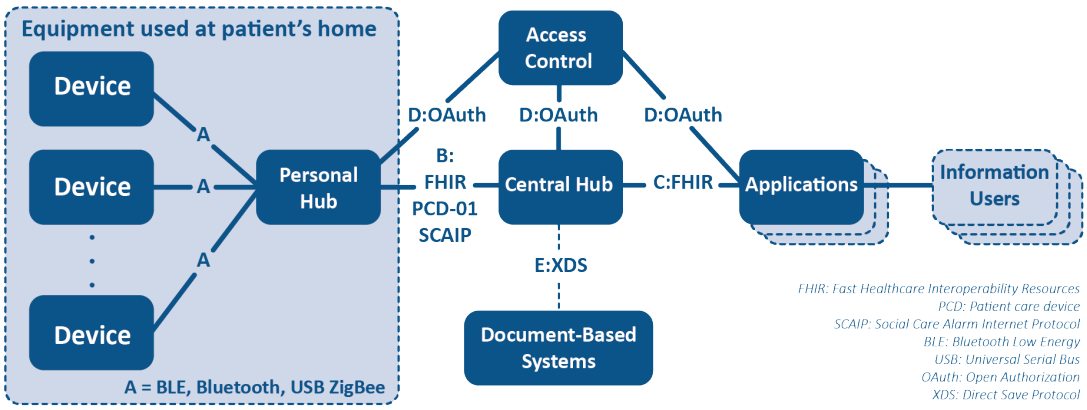
The architecture for the national Personal Connected Health programme in Norway is originally based on the ITU-T H.810 series of recommendations (also known as Continua Design Guidelines [CDG]). Recently, it has been updated to be in line with the latest developments in health standards. The directorate of e-health is a member of the Personal Connected Health Alliance [PCHA] (see Appendix I) and participates in efforts to update the ITU-T H.810 series recommendations with these new standards.

The architecture (see Figure A.8) is based on a storage node called a 'central hub', with HL7 FHIR-based interfaces to store and retrieve data (*B* and *C*). The architecture also includes document-based storage (*E*), but the main interfaces for submitting and retrieving data are based on FHIR. The FHIR interface provides interactive, web-friendly access to several third-party

[33] B. Astad & D. Gjolstad (2015). eHealth in Norway: future perspectives on integrated care and quality of services. See: grimstad.uia.no/ehelse/eHelseUKA2015/Presentations/Astad_Gj%C3%B8lstad_Grimstad.pdf

applications, creating the basis for an open ecosystem for the development of next-generation health services.

Figure A.8: Proposed reference architecture for public Personal Connected Health services in Norway



Source: Personal Connected Health Alliance (2017).

The central hub is meant to store raw data from sensors in personal health and medical devices, as well as from patients' responses on forms. This data storage can be realized in several ways:

- Each municipality can implement its own solution or rely on regional implementations.
- A central database with an FHIR interface and the proper access control mechanisms can be set up nationally through legislation that covers medical record systems or that covers personal health archive storage and distribution of data.

Currently, authorities in Norway are clarifying legal issues pertaining to the two national server alternatives. In the short term, it is likely that the implementation of a national server would be accompanied by solutions instituted by at least a few municipalities, with these solutions ideally designed to be closely integrated with the national architecture.

The FHIR implementation required to implement these functions in the central hub must support at minimum the following FHIR resources:

- observation
- questionnaire
- questionnaire response
- device
- patient
- bundle (for submitting transactions and getting search results).

The resources must support any extensions, and the system would preferably support resource profiles that can be enforced at different levels per server policy.

For future projects, it would be useful to include other resources, potentially the full FHIR specification. Vendors that support the full resource range would likely be preferred to allow for more flexibility and richer functionality. In the short term, extended functionality could also be handled by supporting the basic resource or using documents.

In addition, the implementation should support the following:

- REST-based interface to access the resources
- HL7 FHIR REST-based search API
- HL7 FHIR Draft Standard for Trial Use [DSTU]2 (and later, DSTU3)
- OpenAuthorization [OAuth]-based access mechanism, with a modular structure to allow implementation of different types of access rules, user roles, and mechanisms.

Refer to the proofs of concept at the end of this case study for a very basic example of an access rule implementation.

National Personal Connected Health programme stakeholders hope to rely on an off-the-shelf FHIR product from a vendor rather than developing one themselves. They believe the open source HL7 FHIR API for Java [HAPI-FHIR] could be the basis for such a product, but a commercial vendor would need to support it. Several possible vendors that already have implemented, or are implementing such product offerings, have been identified.

In addition, the work done in the United States on a set of open specifications to integrate Substitutable Medical Apps, Reusable Technology [SMART] with health ICT systems, called SMART on FHIR, has been an inspiration to the ongoing projects in Norway. Several proofs of concept and pilots using this standard have been set up to test the feasibility of these technical solutions. Programme stakeholders have recommended that the vendor reviews these specifications.

Alignment with DHP and lessons learned

The case study of the national Personal Connected Health programme in Norway highlights examples of a DHP implementation. As with the DHP, interoperability and standards play a key role in devices, software, and applications. The reference architecture replicates one that may be used in a DHP.

As part of Norway's effort to transition into digital health, the directorate of e-health and its partners have implemented various proofs of concept for the Personal Connected Health programme server and applications. Some information about the architecture, as well as salient implementation points, can be found in these proofs of concept.

- bitbucket.org/ehelse/ (repository containing several open-source projects, including server adaptations, apps, and clients)
- bitbucket.org/ehelse/hapi-fhir-ehelse/ (HAPI-FHIR-based instance with modifications for OAuth-based access control; also contains the original delivery from Capgemini in a different repository, but the link given here should be used as the basis for review)
- Another aspect to be highlighted from this case study is that Norway started this architecture from a standardized one (Continua architecture in the ITU-T H.810 series of standards). The architects then added the functionality needed for:
- their particular use case (health journey): the use of 'social alarms' within telecare services to allow elderly users to easily call emergency services
- the architecture: data observation upload using HL7 FHIR.

In terms of the latter, Norway decided to get involved in the formal process for defining and validating standards. It is actively contributing to define a new part of the Continua architecture, namely H.812.5, which will enrich the formal H.810 CDG. Doing so will increase the likelihood that products and services that implement the new specification will eventually be available to users in Norway, helping bring down implementation and operational costs.

Appendix B – How Health Sector Domains Use Common DHP Components

	Service Delivery and Surveillance	Patient Engagement	Insurance and Financial Management	Human Resources Manage-ment and Capacity Building	Commodities and Supply Chain Management	Facility and Equipment Management and Supervision
Overall Benefit of DHP to Domain	Standardize medical record-keeping, care delivery, referrals, and decision support. Aggregate service delivery data for analysis and quality improvement processes.	Empower patients to manage their own health through tailored health education, use of self-care prevention and treatment apps and devices, and access to personal health data through DHP.	Automate, standardize, and reduce errors in various financial-system processes, from insurance- and subsidy-scheme claims to cost tracking. Facilitate electronic payments across multiple health domains.	Link up data from disparate organizations that train, regulate, and employ health workers. Build capacity through e-learning and telemedicine.	Link up parts of supply chains, from central procurement to point of service.	Coordinate regulation processes into common workflows. Reduce duplicative efforts in data collection.
Common DHP Components						
Information Mediation	Provides integration services, which facilitate interaction within DHP and amongst external applications across all domains.					
Registries	Patient, health worker, and facility registries	Patient registry	Health worker, facility, and patient registries along with eligibility verification	Health worker registry, including license verification	Health facility registry	Health facility registry, including certification verification
Terminology Services	Use for medical data		Use for medical data		Use for commodities	
Shared Repositories	Shared records on patient histories, immunizations, diseases, reproductive histories, diagnostics, etc.; aggregated indicator data	Patient information repository; education content repository and library	Insurance transaction repository; subsidy repository; out-of-pocket payments data repository; budget and expenditure data repository	E-learning content repository and library; training data repository	Supply chain transaction and inventory data repository	Facility supervision data repository; facility infrastructure and equipment data repository
User Authentica tion and Consent	Use signing for consent for procedures, consent to share data, etc.	Use signing for consent to be traced.	Use signing to confirm the service was provided (as basis for insurance claim) or to confirm eligibility for subsidy.		Use signing to confirm receipts of supplies or other supply-chain activities.	
Workflows and Algorithms	Clinical decision support; e-prescriptions; diagnostics order fulfilment and results; appointments; referrals; provider-patient telemedicine; surveillance outbreak and response	Patient engagement and messaging; contact tracing	Payments services (mechanism to track costs, send information for processing claims, and enable mobile payments); insurance enrolment; claims and subsidy processing; financial transactions	E-learning assessment and certification; provider-provider telemedicine.	Supply chain and logistics workflows	Facility assessment and performance improvement workflows
Analytics	Service delivery and surveillance analytics (basic HMIS)	Patient engagement analytics	Financial and insurance analytics	Human resource analytics	Supply chain analytics	Facility performance and infrastructure analytics
Interactive	Use to allow surveillance data collection via USSD, SMS, or IVR (Note) and appointment reminders via SMS.	Use for patient engagement and messaging via USSD, SMS, or IVR.	Use to provide insurance or subsidy scheme eligibility confirmation via SMS, USSD, or IVR.	Use to provide professional updates or peer learning via SMS, USSD, or IVR.	Use to allow delivery receipt confirmation, emergency orders, or emergency stock status via SMS, USSD, or IVR.	
Common DHP Components Housed on User Interface Layer (Users directly access DHP via interfaces on these components.)						

	Service Delivery and Surveillance	Patient Engagement	Insurance and Financial Management	Human Resources Manage-ment and Capacity Building	Commodities and Supply Chain Management	Facility and Equipment Management and Supervision
Data Collection	User interface for collection of service delivery and surveillance data	User interface for collection of responses to patient education surveys	User interface for collection of financial and insurance data	User interface for collection of human resources and training data	User interface for collection of supply chain data	User interface for collection of facility status, facility supervision, and equipment status data
Reporting	Service delivery and surveillance reporting (basic HMIS)	Patient engagement reporting	Financial and insurance reporting	Human resource reporting	Supply chain reporting	Facility performance and infrastructure reporting
Applications Store	For downloading service delivery apps	For downloading patient engagement apps	For downloading insurance and financial apps	For downloading e-learning apps, peer learning apps, and provider-provider telemedicine apps	For downloading supply chain apps	For downloading supervision apps

Note – USSD is Unstructured Supplementary Service Data; IVR is interactive voice response; SMS is Short Messaging Service. All of these are mobile device services that transmit data and enable communications

Appendix C – Identifying Pain Points and Possible Solutions during Business Process Mapping

Understanding your health system's inefficiencies and challenges, which are often called 'pain points', is fundamental to the second step of the Collaborative Requirements Development Methodology [CRDM]. Table C.1 lists a number of commonly identified health system pain points, categorized by type.

Table C.1: Common pain points in the health system

Business Pain Points	Information Pain Points	Software Application Pain Points
Patients not accessing care Poor availability of medications and supplies Few trained health workers Lack of adherence to clinical guidelines Low access to health insurance Poor financing Poor resource allocation by management Supply chain bottlenecks	Duplication of data collection each time patient visits same or different facility Poor record-keeping Lack of tracking system for following up with patients Difficulties communicating prescriptions to pharmacies Difficulties verifying patient eligibility for payment Poor access to diagnostic test results Lack of best-practice information	Inability to exchange information amongst software applications Lack of unique identification system for people, places, and organizations Requiring multiple logins for the same user Inability of applications to use shared code for the same functionality Lack of extensibility Lack of usability

To identify pain points, look at your business process analysis—your 'as-is' process. Ask the following:

- What are the challenges that cause poor access to care, poor quality of care, and inefficiencies?
- Are there processes that better information and communication can improve?
- How could existing digital applications and systems be improved? What new systems and applications could be developed to improve those processes?
- Are there certain challenges that digital applications and systems cannot address?

To redesign your business process for a use case, identify solutions to the pain points[1], as in Table C.2.

[1] For more in-depth information on identifying solutions to pain points, see the *Implementation Investment Guide (DIIG): Integrating Digital Interventions into Health Programmes*, a toolkit developed by WHO/PATH, https://www.who.int/publications-detail/who-digital-implementation-investment-guide (accessed 27 May 2020)

Table C.2: Sample pain point solutions for maternal care business processes

Current Pain Points in Health System Business Processes for Maternal Care	Proposed Solutions to Pain Points in Maternal Care
Pregnant women are not using health system for ANC and safe delivery.	Process for connecting pregnant women with community health workers.
Facilities are unable to track patients accurately if they see multiple health workers or visit different facilities (e.g. clinics, laboratories, pharmacies, etc.).	Process for enrolling patients in a clinic registration system. System for tracking patient contact with different health workers and facilities.
Health workers cannot easily verify patient's identity.	Ability to compare patient personal data with national citizen records.
Health workers and support staff need to record a patient's data manually when the patient visits a separate facility, a time-consuming, redundant, and error-prone process.	System for disseminating the same health data for a patient amongst different facilities.
Some patients regularly miss appointments.	System to remind patients and outreach workers about upcoming appointments.

Appendix D – Health Journeys

Background on pregnant mother health journey

Savita's health journey is featured in the DHPH main text (see Figure 12) as a use case for illustrating the different DHP design and implementation steps. The journey describes an actual business process redesign of MCTS, a tracking database used in India for maternal and child health service delivery. This journey provides a vision for how DHP components can improve and expand MCTS functionality, improvements that would automate alerts and appointment reminders, allow data sharing amongst different health facilities, and even generate prescriptions and update health records with test results. The journey also indicates how MCTS could be integrated with the Indian government's national digital identification system for citizens, the Aadhaar identity management system, to provide authentication services. The India case study (see Appendix A) describes India's digital health environment and the MCTS-Aadhaar integration in more detail, providing further context for Savita's journey.

Background on Accredited Social Health Activists [ASHA]

Community health workers in India are known as ASHAs. The ASHA's primary responsibility is to identify new pregnancies in the local community and lead pregnant women through safe, institutional deliveries. Following these births, the ASHA continues to monitor the mother and infant until the child reaches five years. In addition, the ASHA serves as the first community contact for health-related issues, especially of women and children. She provides information on healthy behaviours and health determinants, such as nutrition, basic sanitation, and hygiene.

Learn more about India's ASHA programme:

India Ministry of Health and Family Welfare web page on ASHAs:

https://nhm.gov.in/index1.php?lang=1&level=1&sublinkid=150&lid=226 Studies of ASHA's Role in Improving Health:

F.N. Fathima, M. Raju, K.S., Varadharajan, A. Krishnamurthry, S.R. Ananthkumar & P.K. Mony (2015). Assessment of 'Accredited Social Health Activists'—a national community health volunteer scheme in Karnataka State, India. *Journal of Health, Population and Nutrition*, 33(1), pp. 137-145. See: www.ncbi.nlm.nih.gov/pmc/articles/PMC4438657/

S.S. Gopalan, S. Mohanty, & A. Das (2012). Assessing community health workers' performance motivation: a mixed-methods approach on India's Accredited Social Health Activists (ASHA) programme. *BMJ Open*, 2. doi:10.1136/bmjopen-2012-001557

L. Saprii, E. Richards, P. Kokho & S. Theobald (2015). Community health workers in rural India: analysing the opportunities and challenges Accredited Social Health Activists (ASHAs) face in realising their multiple roles. *Human Resources for Health*, 13(95). doi.org/10.1186/s12960-015-0094-3

K. Scott & S. Shanker (2010). Tying their hands? Institutional obstacles to the success of the ASHA community health worker programme in rural North India, *AIDS Care*, 22(supp2), pp. 1606-1612. doi: 10.1080/09540121.2010.507751

See Appendix A: 'India Case Study' for information on MCTS.

Note: All websites accessed on 17 November 2017 28 May 2020.

Typically aged 25 to 45 years, ASHAs are usually chosen by their communities through a rigorous selection process. ASHAs receive performance-based incentives for promoting certain health programmes, such as universal immunization, and for referring and escorting maternal and child health patients to the proper facilities. In the current system, ASHAs receive incentives for each institutional delivery that they facilitate. Some Indian states also offer a similar incentive to the mothers.

In Savita's health journey, an ASHA – named Asha – assists Savita in receiving maternal care.

Cultural norms for pregnant women in India

A pregnant Indian woman will normally return to her maternal home for the delivery and postnatal care of her baby. Thus, it is possible for a pregnant mother to start ANC in one community but migrate to another community for her baby's birth. This movement can often be problematic since the current MCTS does not have accurate tracking to facilitate continuity of care.

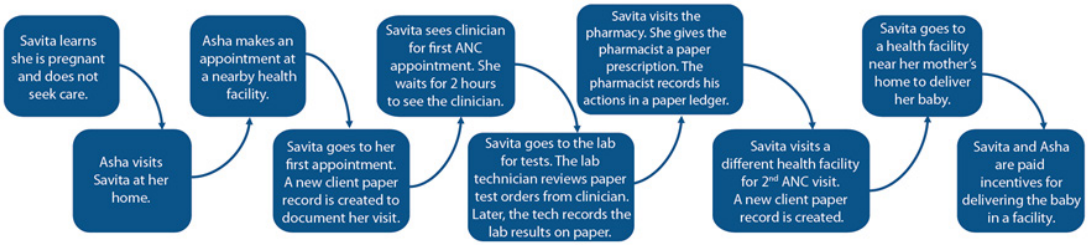
Diagrams for pregnant mother health journey

Current business process: 'As-is' flow chart

Figure D.1 is a flow chart diagram for the 'as-is' business process that Savita experiences in her local health system when she becomes pregnant. Like the context diagram example shown

in the DHPH main text, this flow chart is a method for displaying the output of the business process analysis step in CRDM (see Section 4: 'Health business process mapping' in the DHPH).

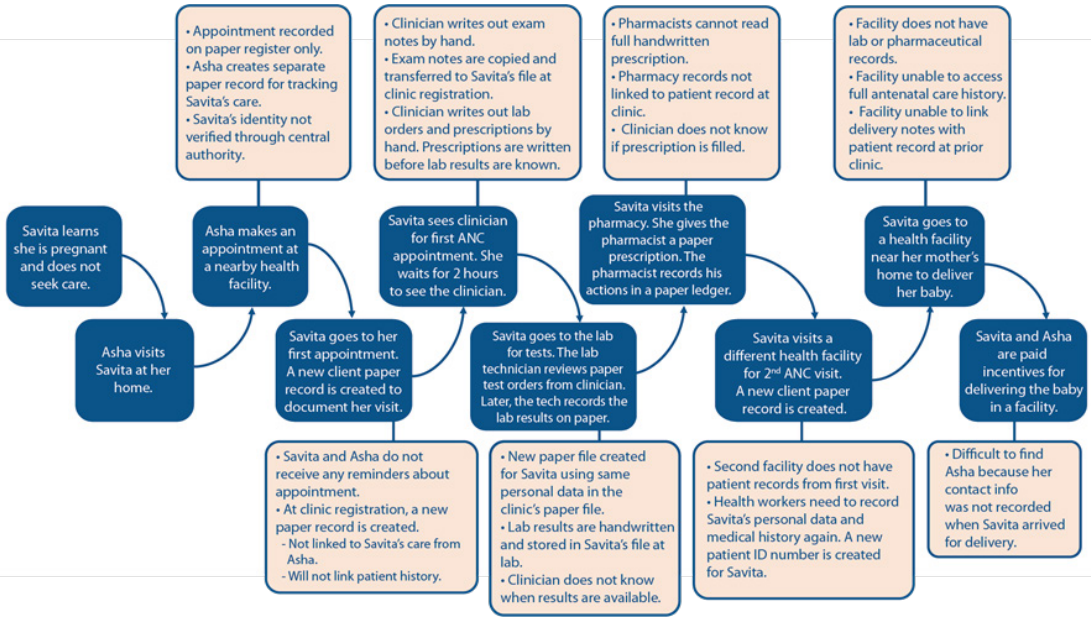
Figure D.1: Pregnant mother health journey "as-is" business process



Current business process with pain points: 'As-is' plus problems flow chart

Figure D.2 is an enhanced version of the 'as-is' flow chart depicted in Figure D.1, highlighting the specific pain points that cause inefficiencies in each step of the current business process for maternal care. The blue boxes correspond to the steps outlined in Figure D.1. The orange boxes describe the pain points. This diagram is an output of the business process redesign step in CRDM; by clearly identifying the pain points during health business process mapping, you can envision the digital health interventions [DHIs] that will improve the business process. Doing so will help you write your health journey narrative.

Figure D.2: Pregnant mother health journey "as-is" business process with pain points



Note that this diagram does not illustrate the downstream impact of these pain points on the quality of care delivered to the patient. It focuses instead on the inefficiencies in the information system that DHIs—and the DHP components that will support the systems and applications used to carry out these interventions—could help improve. Certainly, you could add additional graphic elements or a list of the possible downstream impacts of the pain points, such as the following:

- inaccurate diagnoses resulting from errors and omissions in record-keeping
- long wait times due to patient intake data gathered at each facility, sometimes on paper
- incorrect and incomplete prescriptions filled due to clinician's poor handwriting
- missed appointments or a break in continuity of care, including a non-facility-based delivery, because the facility does not have accurate patient records.

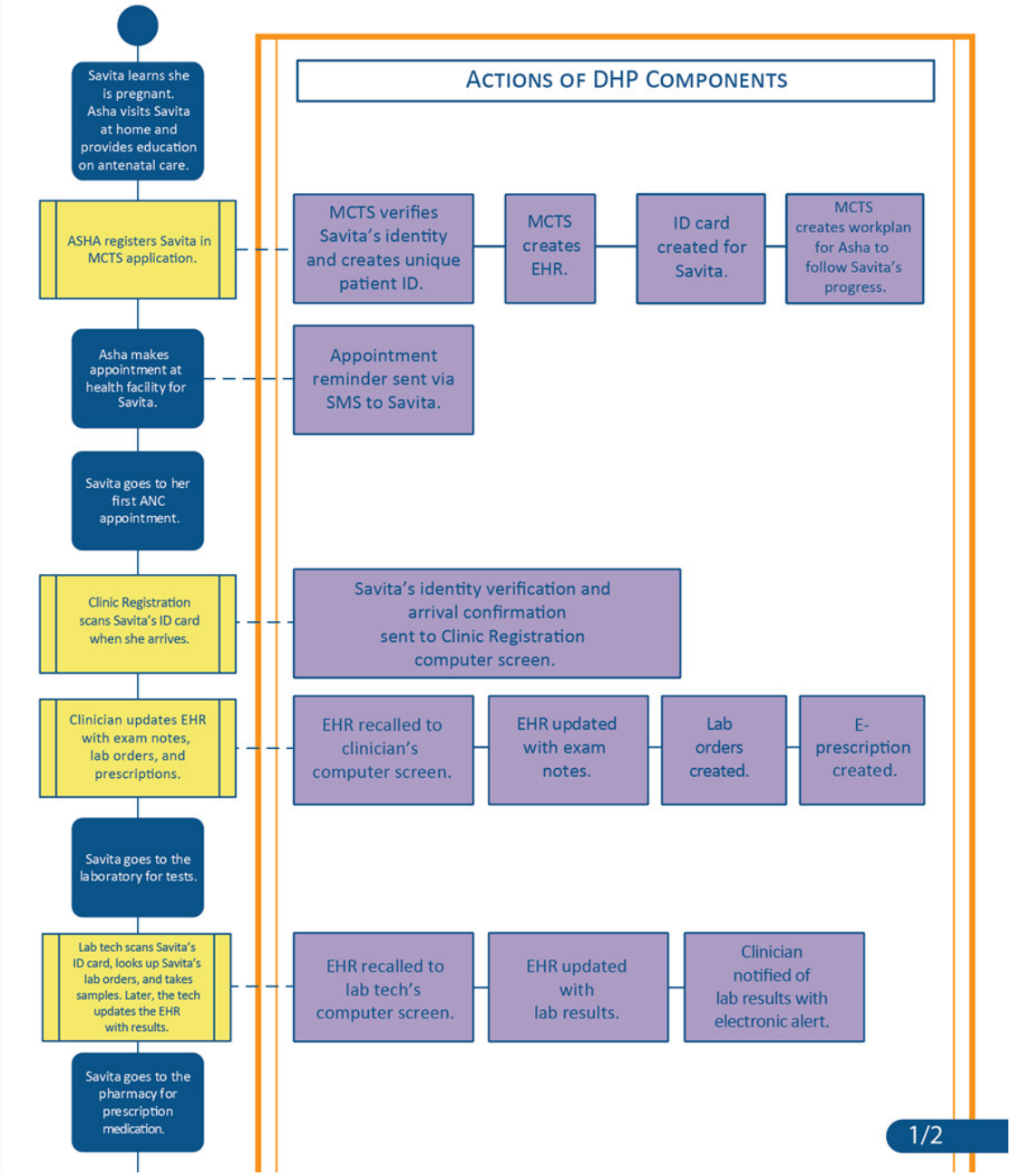
Redesigned business process: 'To-be' flow chart

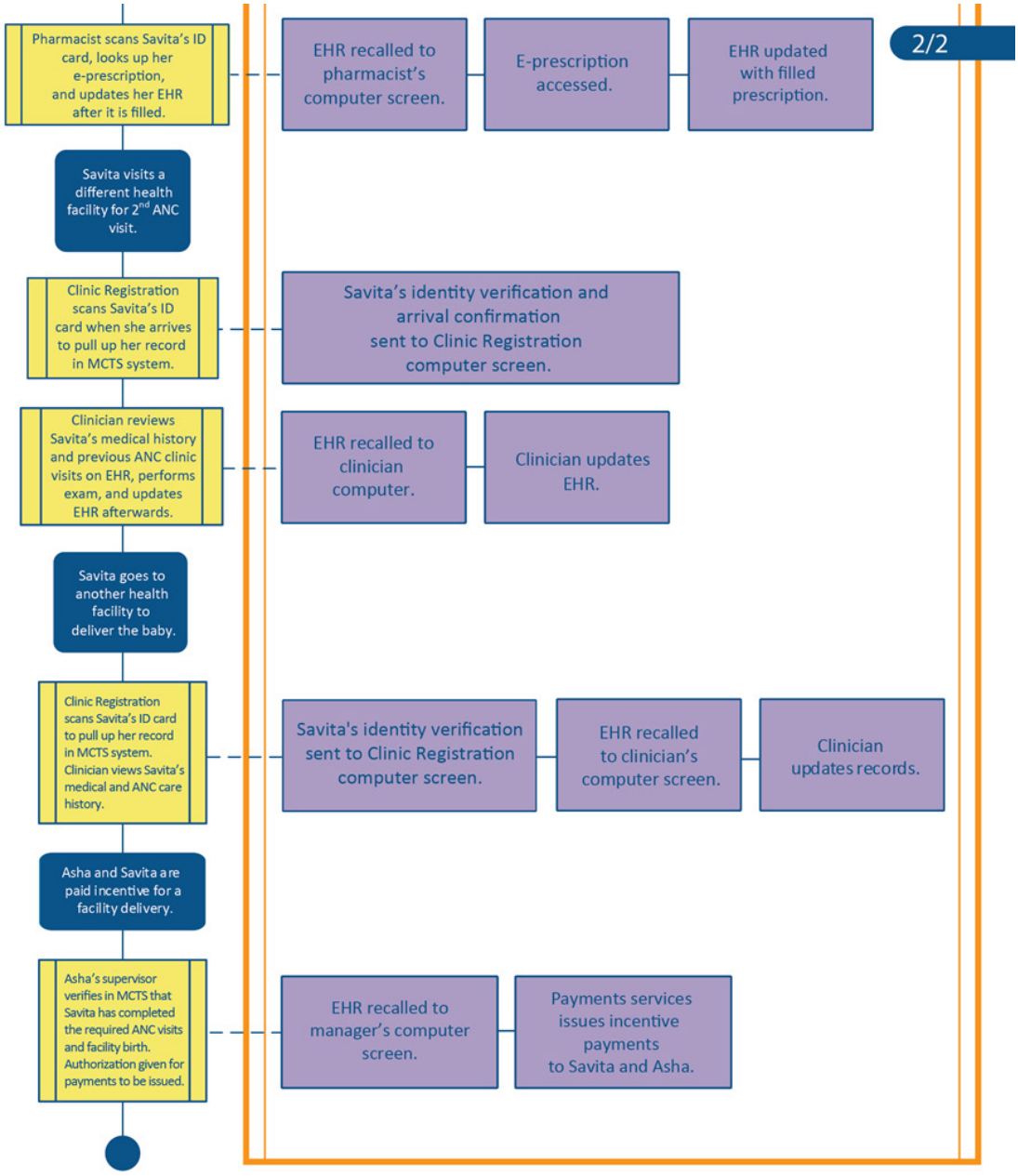
Figure D.3 reworks the 'as-is' business processes for maternal care with the DHIs identified during the business process redesign stage of CRDM. It shows how maternal care service delivery could operate if DHIs are applied to the pain points. Therefore, Figure D.3 is a flow chart diagram of the 'to-be' business processes for maternal care.

> The teal boxes show each of the tasks that Savita or her ASHA do during the maternal care business process. These tasks are 'analogue' tasks, meaning that they occur whether or not a digital HIS is in place. Many of them correspond to the blue boxes in Figures D.1 and D.2 above. For some of these tasks, a digital health intervention can be applied though it is not mandatory. For example, when an appointment is scheduled for Savita at the health facility, an SMS reminder may be sent to Savita, if the digital tools are in place. The tasks described in the light green boxes, however, are indeed 'digital' tasks. These steps show when Savita, her ASHA, or both must interact with technology, such as when Savita is registered into the MCTS database. The places where DHIs are applied are the health journey's digital health moments, shown by the purple box (or set of boxes) attached to a task. These purple boxes describe (in very basic terms) the functional requirements of the digital health applications and DHP components used to enable the digital health moments.

You will notice that Figure D.3 corresponds directly with the pregnant mother health journey written in story form (see Figure 12 in the DHPH main text). It also corresponds with Table 13 in the DHPH, which outlines the DHP functionality and components needed to meet the digital health moments in Savita's journey. Thus, the diagrams used during business process mapping can help you outline and organize your health journey narratives—your user stories—when you sit down to write them.

Figure D.3: Pregnant mother journey redesigned "to-be" business process





DHP solutions for chronic obstructive pulmonary disease health journey: comprehensive version

In the DHPH main text, the COPD health journey narrative is described in full (see Figure 13), but the table showing how DHP components map to this journey (see Table 14) only focuses on one part. Table D.1 provides a much more robust description of how a DHP would help meet the digital health moments in Cyril's health journey. However, this table still only covers journey steps A to E since Cyril's health journey is quite long and comprehensive. Also note that the digital health moments that repeat are not included in Table D.1; they are only mentioned once. These moments would reoccur multiple times throughout Cyril's interactions with the health system, such as when setting appointments, registering upon arrival at facilities, and so on.

Table D.1: COPD health journey, Steps A-E

Cyril Lambert is 60 years old. Up to this point in his life, Cyril has rarely gone to the doctor, but over the past two years, he has been suffering from a persistent cough, with intermittent episodes of shortness of breath.

A. The family clinician that he has seen in the past has recently retired. Cyril decides to see a new clinician who is accepting patients, Dr Martin, and requests an appointment.

Step	Digital Health Moment (where DHI is applied)	DHP Components
A.1	**Find new family clinician:** Cyril consults a medical association website for clinicians accepting new patients and determines that Dr Martin's practice is just a few minutes away by public transit.	Website uses an interface to the ***DHP Provider-Directory-Service*** to retrieve the list of family physicians who have designated that they are accepting patients. Once the provider is selected, the website pulls the clinician's practice address by accessing the ***DHP Health-Service-Delivery-Location service.***
A.2	**Request new appointment:** Cyril clicks on a link in the SMS message to go to the website to request an appointment with Dr Martin.	The website links to the ***DHP Appointment-Request-Broker*** and presents an interactive appointment request form. The request form asks for a public identifier from Cyril as well as sufficient demographic information to ensure that Cyril is uniquely identified. The request is placed in a queue for Dr Martin.
A.3	**Respond to appointment request:** Dr Martin's office administrator reviews the request and notes that Cyril is not currently a patient. The administrator responds to Cyril with three proposed appointment dates.	The electronic medical record [EMR] application polls the ***DHP Appointment-Request-Broker*** for new requests. The EMR application passes the public identifier to the ***DHP-Patient-Registry service*** to verify Cyril's identity. If there is any ambiguity, a list of candidate matches is sent back to the office administrator's application for selection of the correct patient. Upon verification of Cyril, the ***DHP-Patient-Registry service*** copies the current demographics for Cyril to the EMR application in order to initialize him as a new patient. The ***DHP-Patient-Registry*** also returns Cyril's preferred communication mode, in this case his SMS address for his mobile phone. The EMR application pushes the SMS-formatted content directly to the telecommunication network.

Step	Digital Health Moment (where DHI is applied)	DHP Components
A.4	**Select preferred appointment:** Cyril receives the scheduled appointment notification via SMS. He responds with the number of the appointment date he prefers.	The ***DHP-Appointment-Request-Broker*** receives Cyril's SMS response and confirms the preferred appointment time with a message to Dr Martin's EMR application. The EHR application sends an SMS confirmation message to Cyril, along with a link to the ***DHP-Referral service*** for Cyril to complete his Health History Questionnaire [HHQ].
A.5	**Confirm appointment:** Cyril receives the appointment confirmation via SMS. Cyril clicks on the link to a secure mobile website to complete the HHQ prior to his appointment.	The ***DHP-Referral service*** collects the information from the HHQ mobile web interface and places it in a queue for retrieval by Dr Martin's EMR. The ***DHP-Referral service*** retains a copy for subsequent use by Cyril for other referrals.

B. At the appointment, Dr Martin carefully reviews the information in Cyril's HHQ about his present illness, including his past medical, family, and social history. He discovers that Cyril has a history of smoking 45 to 50 packs of cigarettes per year. Upon completion of the examination, Dr Martin's presumptive diagnosis is chronic obstructive pulmonary disease [COPD] with asthma. Dr Martin electronically orders a chest X-ray and refers Cyril for pulmonary function tests. He prescribes inhalation therapy and counsels Cyril to stop smoking. Dr Martin records the findings of this visit as a chart note in Cyril's EHR.

Step	Digital Health Moment (where DHI is applied)	DHP Components
B.1	**Register patient:** The medical office assistant confirms Cyril's identity and registers his arrival in the EMR at Dr Martin's clinic. The assistant confirms that Cyril's information and his emergency contact's information are still current. The medical office assistant determines if Cyril has a private medication insurance plan and validates his account information. The assistant advises Cyril that a mobile electronic booking application is available for him to book subsequent appointments and sends him an e-mail with a link to where he can download the app, along with instructions on enrolling in the DHP e-booking service.	If Cyril's contact or address information change, it is updated in the EMR application, with a message submitted to the ***DHP-Patient-Registry service*** to update it. The EMR application accesses the ***DHP-e-Prescribing service*** that communicates with Cyril's insurance company to verify his account information and determine his eligibility for medications reimbursement. The ***DHP-Appointment-Request broker*** has a secure two-stage onboarding process that ensures the end-user identity created by Cyril is unique and that his user identity is correctly associated with the public identifier used to identify Cyril as a healthcare patient.

Step	Digital Health Moment (where DHI is applied)	DHP Components
B.2	**Complete nursing assessment:** The clinic nurse: accesses the EMR application and opens Cyril's HHQ record reviews the Patient Assessment Template data with Cyril, performs an assessment (e.g. height, weight, blood pressure, medication history), and enters these data into the template prior to Cyril being seen by Dr Martin submits the assessment.	A request is sent to the ***DHP-Referral-service*** that returns the HHQ to the EHR. The Patient Assessment template is a standardized assessment form established by the family clinician professional association. The template form is accessed from the ***DHP-Reference-Information service.*** The observations recorded in the form are persisted in the EMR and pushed to the ***DHP-EHR-Repository service***.
B.3	**Update integrated health assessment:** Dr Martin validates Cyril's health information, including medications. Dr Martin performs a physical examination of Cyril and updates the data in the Patient Assessment Template.	The EHR accesses the ***DHP-EHR-Repository service*** to return a recent history of Cyril's filled medications and lab results. New observations recorded in the form are persisted in the EMR and pushed to the ***DHP-EHR-Repository service.***
B.4	**Decision support:** Once Dr Martin submits the symptoms (smoking history, persistent cough, and sputum) into Cyril's record, the Clinical Decision Support System reviews these along with previous diagnostic test result. The system issues a COPD Screening alert message.	The ***DHP-Decision-Support service*** monitors inputs of data from and to the ***DHP-EHR-Repository service***. Business rules in the service recognize possible indicators of COPD and pass a message to Dr Martin's EMR, offering reference information to assist the clinician in confirming a possible COPD diagnosis.
B.5	**Confirm probable diagnosis:** Dr Martin reviews the data from the decision support service and enters 'possible COPD' and 'asthma' in Cyril's problem-diagnosis list.	The ***DHP-Decision-Support service*** offers a standardized order set for confirmation of COPD and asthma. It also provides the list of recommended orders to the EMR.

Step	Digital Health Moment (where DHI is applied)	DHP Components
B.6	**Enter orders:** Dr Martin customizes the electronic order set for Cyril's orders and interventions as needed, which include an inhaler medication, lab test, pulmonary function test, and chest X-ray. **Submit electronic orders:** Dr Martin submits the electronic orders in the EMR application, and they are sent to the DHP for fulfilment. Because Dr Martin is particularly concerned about Cyril's present health status, he requests notifications to be sent to his smartphone once the tests are completed.	The EMR submits the orders to the ***DHP-Order-Fulfilment service.*** The ***DHP-Order-Fulfilment service*** places each order in a separate queue by type: the lab order in a queue for retrieval by Dr Martin's most frequently used diagnostic lab; the Pulmonary Function Test order for retrieval by the asthma evaluation centres ambulatory EMR; the imaging requisition for retrieval by the X-ray department of the hospital where Dr Martin has clinician privileges. The ***DHP-Order-Fulfilment service*** sets flags to notify Dr Martin on the completion of the tests. On retrieval of the orders, each of these systems initiates appointment requests to Cyril's personal health record [PHR] application using the ***DHP-Appointment-Brokering service***. Upon confirmation of appointment times from Cyril's PHR, the ***DHP-Appointment-Brokering service*** updates the order requests' status to 'booked'.
B.7	**Prescribe inhaler:** Dr Martin uses his EHR to select an inhaler for Cyril's use. Dr Martin reviews the dosage and usage instructions from his EMR and counsels Cyril on the use of the product. Cyril receives a printed version of the prescription to take to the pharmacy of his choice. The prescription is electronically submitted.	The ***DHP-e-Prescribing service*** provides to the EMR a list of products that Cyril's medication insurance will reimburse, including monograph information. The ***DHP-e-Prescribing service*** provides automatically checks the inhaler product prescription for any drug interactions, using the known list of filled medications provided by the ***DHP-EHR-Repository service.*** No conflicts are indicated. The ***DHP-e-Prescribing service*** places the electronic prescription in a queue for retrieval by a pharmacy system.
B.8	**Confirm test appointment:** Upon returning home, Cyril is notified about the pending appointment requests in his PHR. Cyril reviews the requested appointments and confirms times that he is available.	Upon retrieval of the orders, each of these systems initiates appointment requests to Cyril's PHR application using the ***DHP-Appointment-Brokering service.*** Upon confirmation of appointment times from Cyril's PHR, the ***DHP-Appointment-Brokering service*** updates the order requests' status to 'booked'.

Step	Digital Health Moment (where DHI is applied)	DHP Components
B.9	**Complete lab test:** Cyril attends the appointment. The lab technician verifies Cyril's identity and retrieves the order request from the laboratory information system [LIS]. Samples are taken. Once the lab results are determined, Dr Martin is notified.	The LIS retrieves the test order from the ***DHP-Order-Fulfilment service***. When the lab test is complete and results are available, the LIS updates the status of the appointment to 'completed' in the ***DHP-Appointment-Brokering service*** and the ***DHP-Order-Fulfilment service***, along with the test results. The ***DHP-Order-Fulfilment service*** pushes a notification to Dr Martin's smartphone.

C. The same day, Cyril goes to the pharmacy and purchases his inhaler.

Step	Digital Health Moment (where DHI is applied)	DHP Components
C.1	**Visit new pharmacy:** Cyril presents his identity at the pharmacy, and the pharmacist verifies that Cyril's information is in the pharmacy system. The pharmacist obtains Cyril's private insurance account information.	The pharmacy system interacts with the ***DHP-Patient-Registry service*** to validate Cyril's public identifier with his demographic information. The pharmacy system interacts with the ***DHP-e-Prescribing service*** to verify Cyril's insurance eligibility for medication reimbursement.
C.2	**Fill prescription:** The pharmacist scans the barcode on Cyril's printed prescription; the pharmacy system retrieves the electronic prescription. The pharmacist does not have the prescribed inhaler in inventory but does have an approved substitute available. The pharmacist fills the prescription, assesses the instructions that Cyril has already received from his clinician, and reinforces Cyril's need to comply with the instructions for use.	The pharmacy system interacts with the ***DHP-e-Prescribing service***: retrieves the electronic prescription determines what the insurance provider will accept as a substitute medication. The pharmacy system uses the ***DHP-e-Prescribing service*** to update the electronic prescription. It indicates that an approved substitute has been used and that the prescription has been filled and dispensed. The pharmacy system then submits the dispensed mediation to the ***DHP-EHR-Repository service*** to update Cyril's medication history.

D. Cyril goes to the local hospital and gets his chest X-ray and pulmonary function tests done. The chest X-ray and pulmonary function test findings are consistent with COPD and asthma.

Step	Digital Health Moment (where DHI is applied)	DHP Components
D.1	**Chest X-ray findings:** The hospital X-ray department verifies Cyril's identity in the radiology information system [RIS]. The X-ray technician performs the X-ray and verifies for the radiologist that the resulting digital image is readable.	The RIS interacts with the ***DHP-Patient-Registry service*** to verify Cyril's identity. The RIS retrieves the diagnostic imaging order from the ***DHP-Order-Fulfilment service.*** When the digital image is verified, the RIS updates the status of the appointment to 'completed' in the ***DHP-Appointment-Brokering service***.
D.2	**Radiology report:** The radiologist retrieves the image, finds evidence consistent with the presence of COPD and asthma, and provides this information in the radiology report, along with a reference image from the X-ray scan.	When the radiologist records the finding, the RIS updates the status of the diagnostic imaging order to 'completed' in the ***DHP-Order-Fulfilment service.*** The ***DHP-Order-Fulfilment service*** pushes a notification to Dr Martin's smartphone. The RIS submits a copy of the radiologist's report, along with a reference image, to the ***DHP-EHR-Repository service.***
D.3	**Pulmonary function tests:** The hospital pulmonary function ambulatory clinic verifies Cyril's identity in the Ambulatory-EMR [A-EMR] application. The technician performs the pulmonary function tests on Cyril.	The A-EMR interacts with the ***DHP-Patient-Registry service*** to verify Cyril's identity. The A-EMR retrieves the test order from the ***DHP-Order-Fulfilment service.*** When the tests are completed, the A-EMR updates the status of the appointment to 'completed' in the ***DHP-Appointment-Brokering service.***
D.4	**Pulmonary test findings:** The specialist reviews the test results and finds evidence consistent with the presence of COPD and asthma. The specialist documents the findings in the A-EMR application.	When the specialist records the findings, the A-EMR updates the status of the test order to 'completed' in the ***DHP-Order-Fulfilment service.*** The A-EMR submits a copy of the findings to the ***DHP-EHR-Repository service***.

E. Cyril has a follow-up appointment with Dr Martin, who confirms that Cyril has COPD and enters COPD into Cyril's problem list. Dr Martin initiates a COPD care plan based on clinical practice guidelines, sets care goals with Cyril, and offers him navigation services to assist with coordinating the activities associated with this new diagnosis. Dr Martin adjusts Cyril's inhaler medications based on the standardized guidelines and advises Cyril to obtain an interoperable electronic peak flow meter for monitoring his COPD at home. As part of the care plan, a referral is made to the community pharmacist for education on the use of the electronic peak flow meter and the revised medications.

Step	Digital Health Moment (where DHI is applied)	DHP Components
E.1	**Review test results:** Dr Martin accesses Cyril's information in his EMR and reviews the test results.	The EMR polls the ***DHP-Order-Fulfilment service*** to obtain the status of Dr Martin's orders. Orders that have been fulfilled are flagged for review. The results of the lab and pulmonary function tests are retrieved from the ***DHP-Order-Fulfilment service*** to the EMR.
E.2	**Confirm diagnosis:** Dr Martin confirms the clinical diagnosis of COPD and asthma. Dr Martin enters COPD and asthma in Cyril's EMR problem list.	The EMR obtains the diagnostic codes necessary for reimbursement and analytics from the ***DHP-Terminology service*** and places them in the EHR problem list. The EMR provides a copy of the problem list entries to the ***DHP-EHR-Repository service***.
E.3	**Initiate COPD care plan:** Dr Martin selects a COPD care plan to set care goals with Cyril. He explains that navigation services are available to assist with coordinating Cyril's care, but Cyril declines the services for now. Dr Martin customizes the order set, including enrolment in a COPD disease program, peak flow monitoring service, and education regarding COPD medications and devices. Dr Martin submits the care plan, including the electronic orders. He prints confirmation of the orders for Cyril.	The EMR retrieves a COPD Care Plan Template from the ***DHP-Reference-Information service.*** The EMR retrieves Cyril's HHQ results from the ***DHP-Referral service*** and prepopulates the care plan with data from the results, as well as from the problem lists in the EMR. The information in the completed COPD care plan template is copied to the ***DHP-Collaboration service***. Doing so allows the care plan to be shared with other healthcare service providers and Cyril's PHR application.
E.4	**Submit electronic orders:** The electronic prescription for new medications is submitted. The COPD program enrolment order is submitted.	The ***DHP-e-Prescribing service*** receives the prescription (see earlier e-prescribing actions). The orders for the COPD program enrolment, monitoring service, and education program are submitted to the ***DHP-Order-Fulfilment service***. The COPD program chronic disease management application polls the ***DHP-Order-Fulfilment service*** for new requests. Upon receiving the order, it transmits a program registration request and link to Cyril's PHR. A list of certified monitoring services is transmitted to Cyril's PHR.

Appendix E – Maturity Models

Canada Health Infoway maturity model[1]

Maturity Level (in descending order)	Typical Clinical Data Sharing Processes	Typical Technology, Infrastructure, and Applications	Key Milestones
5) Optimize	PoS solutions provide decision support and protocol guidance within a facility based on DHP data and protocols. DHP provides process management and/or advanced analytics to optimize clinical and administrative performance across the system.	Cross-organizational shared engines for business and clinical rules Business and clinical process management Advanced analytics platforms	Advanced care coordination Clinical and/or administrative decision support supported by analytics
4) Collaborate	Care coordination and linked workflows across non-affiliated organizations Expansion of data sets and of system-wide distribution of notifications Initial provision by the DHP of analytics to support care decisions and care coordination	Enhanced PoS systems, clinical and business analytics platforms, and business process management platforms	Care coordination services, including cross-organization Mature EHR and hospital integration to DHP Quality of service and stakeholder services Increased maturity and scope of collaboration use cases Sharing of more messages, documents, and complex data
3) Interoperate	Access to and distribution of relevant subsets of the clinical records Initial system-wide distribution of notifications, including results, admissions, discharge summaries, and consult notes	Some specialty systems for select chronic diseases supported Expanded disease registries Secure identification and distribution systems Viewers that aggregate data from a repository or multiple systems	Quality of service and stakeholder management services Increased maturity and scope of collaboration use cases Sharing of more messages and documents and more complex data sets

[1] For more in-depth information about this model, including a description of maturity levels, other domains and their maturity level characteristics and milestones, and information on how Canada Health Infoway, Inc. applied it to their digital health system planning, see Canada Health Infoway, Inc. (2015). *Health Information Network (HIN) Maturity Model: A Discussion Paper*. See: www.infoway-inforoute.ca/en/component/edocman/resources/reports/2834-health-information-network-hin-maturity-model (accessed 1 March 2018).

Maturity Level (in descending order)	Typical Clinical Data Sharing Processes	Typical Technology, Infrastructure, and Applications	Key Milestones
2) Anticipate	Access to a broader range of third-party systems More comprehensive data gathered at PoS Data shared with one or more clinical systems as appropriate Shared data repositories	External systems such as HIS, EHRs, and pharmacy systems are connected to the DHP. Standardized master data and registries are expanded to incorporate additional sources, consumers, and clinical information domains.	Data sharing between PoS systems Clinical data accessed from repositories (e.g. patient summary, digital imaging, immunization, etc.), either centralized or federated sources
1) Initiate	Basic encounter information gathered Simple encounter history provided Information sharing for: identity verification patient and clinic addresses wellness counselling, care planning, and test results (possibly).	User and application authentication, key master data, logging, and DHP service interfaces and orchestration focused on a specific health programme area, with just a few software applications to be supported	External end-user applications can authenticate themselves and their users. Basic health and information processes, such as patient enrolment in care processes, capture of demographics and current status, and historic and future events, are calendared. Basic notifications to health providers may be in place.

MEASURE interoperability maturity model

This maturity model is offered as one part of a comprehensive package that includes a maturity model assessment tool and user guide. See: www.measureevaluation.org/resources/tools/health-information-systems-interoperability-toolkit for more information.[2]

[2] MEASURE Evaluation website accessed 1 March 2018.

Health Information Systems Interoperability Maturity Toolkit

MEASURE Evaluation
December 2017
Version 0.5

HEALTH INFORMATION SYSTEMS INTEROPERABILITY MATURITY MODEL						
Domain	**Subdomain**	**Level 1: Nascent** **The country lacks HIS capacity or does not follow processes systematically. HIS activities happen by chance or represent isolated, ad hoc efforts.**	**Level 2: Emerging** **The country has defined HIS processes and structures, but they are not systematically documented. No formal or ongoing monitoring or measurement protocol exists.**	**Level 3: Established** **The country has documented HIS processes and structures. The structures are functional. Metrics for performance monitoring, quality improvement, and evaluation are systematically used.**	**Level 4: Institutionalized** **Government and stakeholders use the national HIS systems and follow standard practices.**	**Level 5: Optimized** **The government and stakeholders routinely review interoperability activities and modify them to adapt to changing conditions.**
Leadership and governance	**Governance structure for HIS**	Evolving governing body for health information systems (HIS) is constituted on a case-by-case basis OR no governing body exists.	An HIS governing body is formally constituted and has a scope of work that includes the people responsible for data governance oversight. The governing body oversees interoperability directly or through a separate technical working group (TWG).	The HIS governing body conducts regular meetings with stakeholder participation.	The HIS governing body is government-led, consults with other ministries, and monitors implementation of HIS interoperability using a work plan. It mobilizes resources—financial, human resources (HR), and political—to accomplish its goals.	The HIS governing body is legally protected from interference or organizational changes. The HIS governing body and its TWGs are nationally recognized as the lead for HIS interoperability. The governing body works in liaison with other similar working groups regionally and/or around the world.
	Interoperability guidance documents[1]	HIS interoperability guidance documents are absent, and HIS interoperability is implemented on a case-by-case basis.	The governing body for HIS interoperability has drafted the necessary HIS interoperability guidance documents.	Interoperability guidance documents developed, tested, and adopted, and include reference terminologies and technical standards for data exchange.	The interoperability guidance documents are government-owned. They are consistently used and referenced in efforts to guide implementation of HIS interoperability.	Processes are in place to regularly monitor the implementation of the interoperability guidance documents. The interoperability guidance documents are regularly reviewed and updated based on lessons learned from implementation. These documents reflect international best practices.

[1] The approved documents (policies, strategies, and frameworks) that guide HIS and digital health/eHealth work in a country

Domain	Subdomain	Level 1: Nascent	Level 2: Emerging	Level 3: Established	Level 4: Institutionalized	Level 5: Optimized
Leadership and governance	**Compliance with data exchange standards**	No structure, processes, and procedures (e.g., working groups, steering committees, or units) are in place to guide or enforce compliance with data exchange, messaging, and data security standards. No criteria for certification and compliance exist. No regulatory framework for compliance exists.	Structures (working groups, steering committees, or units) are in place to guide or enforce compliance.	The HIS has developed or adopted and implemented a regulatory framework for compliance.	The government enforces the regulatory framework for compliance. The subsystems in the national HIS are required to meet compliance and certification criteria.	Compliance with standards for data exchange, messaging, and security is regularly reviewed. The regulatory framework is reviewed and updated to reflect best practices for data exchange, messaging, and systems security.
	Data ethics	The country has no healthcare-specific data laws, regulatory frameworks, or ethics provisions to guide data security, privacy, and confidentiality.	The country has drafted laws, policies, or a regulatory framework for data security and privacy that address issues related to health data.	The country has an approved health data regulatory framework.	The health data security and privacy laws have been implemented, and there are guidelines on how to operationalize the laws in the HIS. HIS users have been sensitized on the data security and privacy laws. The government and stakeholders consistently enforce the data security and privacy laws.	The country has a recognized mechanism (e.g., committee or working group) for reviewing data ethics issues in the national HIS, and for updating policies, procedures, and laws, as needed. This mechanism reflects industry best practices.
	HIS interoperability monitoring and evaluation	No tracking, or ad hoc tracking, is done of HIS interoperability activities related to plans, resources, and budgets for the national HIS.	The methods and tools to report on HIS interoperability implementation are defined and documented.	HIS interoperability activities are regularly monitored and reviewed accordingly. Regular reports on HIS interoperability performance are generated and disseminated to stakeholders.	Mechanisms to track and measure performance of HIS interoperability work are government-approved and government-led.	Results from monitoring of HIS interoperability are used for planning. Decisions about future activities take this analysis into consideration.
	Business continuity	No government-approved business continuity plan (BCP) is in place at the national or subnational levels of the HIS.	The HIS has developed a BCP that outlines the processes needed to ensure continuity of critical business processes.	The BCP has been audited. Audit results show that at least 50% of the BCP has been implemented.	The BCP has been audited. Audit results show that at least 75% of the BCP has been implemented.	The BCP has been audited. Audit results show that all or most of the BCP has been implemented.

Domain	Subdomain	Level 1: Nascent	Level 2: Emerging	Level 3: Established	Level 4: Institutionalized	Level 5: Optimized
Leadership and governance	**Financial management**	No clear plan exists for financial management of HIS, including interoperability activities.	High-level financial management structures, including budgets, are developed for the national HIS, including interoperability in the country based on HIS work plans.	Detailed financial management structures, including budgets for HIS interoperability at the national and subnational levels, are developed based on the HIS work plan. HIS expenditures are monitored against HIS budgets.	The HIS budget is part of the Ministry of Health's budgeting process. Financial audit processes are in place and are carried out regularly to promote accountability in HIS spending.	An established, long-term HIS financial management system is owned, reviewed, tracked, and updated by the government, and is supported by stakeholders.
	Financial resource mobilization	There is no documented plan for financial resources for HIS strengthening, including HIS interoperability.	Financial resources for HIS strengthening, including HIS interoperability, are mostly donor driven.	A costed work plan at national and subnational levels is in place that covers both the information and communications technology (ICT) infrastructure (network, hardware, and software), and personnel for HIS needed for HIS strengthening, including HIS interoperability. At a minimum, this work plan identifies the activities, timeframe, costs, and sources of funding for HIS interoperability.	Government and implementing partners have sufficient funding to implement the costed work plan. The government owns the costed work plan.	A government-owned, costed, long-term work plan (five years or more) is in place to support ICT and human resources for HIS strengthening, including HIS interoperability. A mechanism is in place to regularly review and update the work plan.
Human resources	**Human resources policy**	There is no human resources (HR) policy that recognizes HIS-related cadres. Distribution of HIS human resources is ad hoc.	A national needs assessment has been completed showing the number of staff and types of skills needed to support HIS, including digital HIS and interoperability. HIS-related cadre roles and responsibilities are mapped to the government's workforce and schemes of work.	An HR policy and/or strategic plan exists that identifies the HIS, digital HIS, and interoperability skills and functions needed to support the national HIS and its digital HIS and interoperability.	Implementation plans are in place for growing a cadre of staff at national and subnational levels for digital HIS and interoperability.	A long-term plan is in place to grow and sustain staff with the skills needed to sustain HIS and digital HIS and interoperability. Performance management systems are in place to monitor growth and sustainability of the HIS workforce.

Domain	Subdomain	Level 1: Nascent	Level 2: Emerging	Level 3: Established	Level 4: Institutionalized	Level 5: Optimized
Human resources	**Human resources capacity (skills and numbers)**	The country has no dedicated cadre of staff for maintaining the digital HIS and interoperability. Responsibility for the HIS is added to existing positions.	The country depends on technical assistance from external stakeholders to support the national and subnational digital HIS and interoperability.	The country has a growing staff with skills in governance and leadership, data collection, data management, data sources, health information technology (IT), and managing information products. The staff are sufficient in numbers and skills at the national level, but inadequate at subnational levels.	The country has staff in sufficient numbers with relevant skills to support the digital HIS and interoperability at national and subnational levels.	The country has a sufficient and sustainable number of staff with an appropriate mix of skill sets to support the digital HIS and interoperability at national and subnational levels, and the interoperability of key systems. A human resources for health strategic plan is in place to continuously upgrade staff skills to reflect international best practices in digital HIS and interoperability, preferably with locally generated funds.
	Human resource capacity development	The country has no national training programs to build human resource capacity on digital HIS, including interoperability.	A nationally recognized pre-service training curriculum exists that outlines needed competencies for human resources for digital HIS and the interoperability of the HIS.	A plan exists for in-service training of HIS staff to build skills around digital HIS and interoperability based on a nationally or internationally recognized HIS curriculum.	The country has the capacity to train enough staff to support digital HIS and interoperability, through in-country pre-service and in-service training institutions or partnerships with other training institutions. Government and stakeholders provide sustainable resources for health ministry staff to receive training on HIS, including digital HIS and interoperability.	Opportunities and incentives are in place for continuing education in digital HIS and interoperability for HIS-related cadre staff, to keep them up-to-date as the HIS field evolves.

Domain	Subdomain	Level 1: Nascent	Level 2: Emerging	Level 3: Established	Level 4: Institutionalized	Level 5: Optimized
Technology	**National HIS enterprise architecture**	A national HIS enterprise architecture document defining technology requirements and data exchange formats for interoperability does not exist OR there is a draft document, but it has not been validated or shared with the country's HIS community.	A validated national HIS enterprise architecture exists that defines technology requirements and exchange formats for interoperability. It is validated, but not widely shared or systematically applied by the HIS community. Point to point data exchange between some HIS applications exists, but there is no systematic implementation of the agreed-upon architecture.	Foundational tools and rules for HIS interoperability exist. They include a health information management system for routine and surveillance data, and core authoritative registries (Facility Registry, Metadata Dictionary, Master Patient index, and Health Worker registry). The Interoperability Service Layer (ISL) for the HIS is operational and provides core functions, such as data authentication, translation, and interpretation.	The government owns, enforces, and leads implementation of the national HIS enterprise architecture, including the ISL and core authoritative registries (Facility Registry, Metadata Dictionary, Master Patient index, and Health Worker registry).	The national HIS enterprise architecture and its ISL are fully implemented using industry standards. The ISL provides core data exchange functions and is periodically reviewed and updated to meet the changing country data needs. There is continuous learning, innovation, and quality control in the work on HIS interoperability.
	Technical standards[2]	No defined technical standards exist for use in the country's HIS data exchange. Applications are hosted by the providers without any control from the government or Ministry of Health.	An HIS ICT infrastructure assessment has been conducted and the needs for a coherent HIS ICT infrastructure architecture have been documented. The country has adopted or developed technical standards for health data exchange, messaging, and security.	An interoperability lab exists for new partners to test technical standards or for onboarding new HIS subsystems, and a certification mechanism exists for new HIS subsystems to be integrated in the national HIS.	Technical standards for national data exchange have been published and disseminated in the country under the government's leadership. The ISL is orchestrating data exchange between existing HIS applications hosted by the integrated ICT infrastructure supporting the national HIS.	A routine review of standards and requirements compliance is conducted to ensure continuous integration of the various subsystems.

[2] Including standards for data exchange, transmission, messaging, security, privacy, and hardware

Domain	Subdomain	Level 1: Nascent	Level 2: Emerging	Level 3: Established	Level 4: Institutionalized	Level 5: Optimized
Technology	**Data management**[3]	No national document for data management procedures exists for the national HIS.	Electronic data management procedures for the HIS are clearly developed and documented in a nationally recognized document.	A roadmap is in place to migrate data collection and reporting from a paper system to an electronic system, complete with necessary data security safeguards. A documented mechanism is in place for maintaining data quality throughout the data supply chain.	National electronic data management processes are published and disseminated for the HIS. A standard operating procedure and/or data use plan is in place to facilitate data use by the country and its stakeholders. A data warehouse, integrating data from all HIS subsystems and allowing for data triangulation and quality control, is fully functional and in use.	Data access and use are constantly monitored, and data management systems are updated accordingly. Electronic data transmission is the default method to move data among information systems. Dashboards displaying information from multiple sources are available to decision makers.
	HIS subsystems	The country's HIS mainly consists of stand-alone program-specific subsystems working in silos, and addressing only the basic information needs (routine HIS, surveillance system, and human resources). Program-specific parallel systems exist.	HIS data exchange is mainly facilitated by a single subsystem directly linked to other subsystems to enable basic data exchange.	Guidelines for compliance with technical standards for HIS subsystem interoperability with the national HIS have been disseminated. An increasing number of HIS subsystems are web-based and integrated with the ISL following the national standards requirements.	The government requires all HIS subsystems to comply with the country's interoperability plan, including use of technical standards.	Most HIS subsystems are exchanging data electronically, according to industry standards/best practices.
	Operations and maintenance (for computer technology)	Operations and maintenance services for electronic systems are ad hoc or non-existent.	Maintenance for network and hardware is a mix of reactive and evolving preventive procedures.	The country is receiving technical support to build a strong in-country capacity for computer technology maintenance. Standard operating procedures exist that detail protocols for routine network and hardware maintenance.	The country has the capacity for strong in-country technical maintenance. Computer operations and maintenance services are part of the HIS plan or the country's strategic plan for health. A disaster recovery plan for digital HIS is in place, and it meets best practices.	The operations and maintenance services plan is continuously reviewed and adapted to evolving HIS interoperability requirements, and follows industry-based standards. Regular simulations are undertaken to increase the ability of technology staff to respond to a disaster.

[3] Procedures on how data are captured, stored, analyzed, transmitted, and packaged for use across the data supply chain

Domain	Subdomain	Level 1: Nascent	Level 2: Emerging	Level 3: Established	Level 4: Institutionalized	Level 5: Optimized
Technology	**Communication network: local area network (LAN) and wide area network (WAN)**	The country has no reliable network connection to support a national HIS.	An ICT infrastructure assessment has been conducted to determine LAN and WAN requirements for the country's HIS. The country is using mainly unreliable wireless (2G, 3G or 4G) modems to connect to the HIS services.	A national implementation plan to meet the LAN and WAN requirements in the country exists. A national network maintenance plan exists to ensure high uptime, including procedures to recover from network failure. The country has started to implement a technical solution to ensure permanent connectivity to the HIS services.	All national offices and at least 50% of the subnational offices of the Ministry of Health and health service providers have a strong and reliable network connection to the various HIS network services. An HIS-dedicated ICT and network support team is in place.	All or almost (>75%) all the Ministry of Health's national and subnational offices and health service providers have a reliable and robust network connection. A team dedicated to support connectivity exists and has adequate financial, human, and technology resources. Industry-based standards are followed.
	Hardware	The country has limited/ inadequate hardware (servers, user computers, printers, and supportive accessories) to support a national HIS.	An ICT infrastructure assessment has been done to identify the hardware required at national and subnational levels. Less than 50% of the Ministry of Health's national and subnational offices have the required hardware (computers, printers, connecting devices, etc.).	50% or more of the Ministry of Health's national and subnational offices have the required hardware, including back-up hardware.	Seventy-five percent (75%) of the Ministry of Health's national and subnational offices have the required hardware. There is a back-up and recovery plan for the national HIS.	The hardware meets national and/or international specifications, and a long-term plan (five years or more) is in place that details how to keep hardware up-to-date.

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Appendix F – Description of Common Standards Used

Units of measure

Units of measure, while standardized, may be derived from two or more measurement schemes, such as metric and imperial systems. Other units are derived from scientific and medical systems. Some reference terminologies include units of measure as part of their representation of a clinical concept.

While units generally can be converted mathematically from one system to another, references to units of measure are often embedded in the text. Describing the units of measure in this manner can create problems when data are consolidated from a variety of systems. Not only do readers need to understand the standard being used, but they also need to convert or compare actively while they read. Relying on readers to apply the conversion presents serious safety issues when the basic unit used in observations is not the same from one observation to another.

For this reason, each implementation of a DHP should support a single set of units of measure to be used consistently across source systems. If this is not possible, then the DHP should ensure that all values are converted to one consistent set of measures when transferring data with units of measure across different systems.

Unified Code for Units of Measure

An example of a standardized set of units of measure is the Unified Code for Units of Measure [UCUM] maintained by the Regenstrief Institute.[1] This code system aims to include all units of measure currently used in international science, engineering, and business. The purpose is to facilitate unambiguous communication of quantities—and their respective units—in a digital environment. A typical application of UCUM is electronic data interchange protocols, though UCUM could also be used in other types of machine communication.

Formats of health base data standards

Health informatics base data standards use two types of coding systems to allow accurate and consistent data exchange between the DHP and its external applications: classifications and reference terminologies. These systems are defined, maintained, and validated by international standards developing organizations. You do not choose between one or the other; instead, you will often employ both since the two types—and the various systems within each type—serve different functions.

Classifications

A classifications system arranges terms into classes or groups based on common characteristics, such as physiological system or type of disease. These categories are usually hierarchical, placing subsets underneath broader headings. Thus, a classification requires rules to be followed when applying codes, as the data are limited to the defined categories. Classifications can also be assigned to unstructured data by trained health information management staff

[1] G. Shadow & C. J. McDonald (2014). *The Unified Code for Units of Measure*. Regenstrief Institute and the UCUM Organization. See: www.unitsofmeasure.org/ucum.html

after the data have been captured on paper or by voice recording, or when consolidating information such as in a discharge report.

ICD-10: International Classification of Diseases, Tenth Revision

The International Classification of Diseases [ICD] is a set of alphanumeric codes that serve as the international standard for reporting diseases and health conditions.[2] Maintained and validated by WHO, ICD serves as the basis for the identification of global health trends and statistics used in clinical diagnosis as well as in research. In population health statistics, ICD is used to monitor the incidence and prevalence of diseases, including counting deaths, disease cases, and injuries and tracking symptoms, reasons for clinical encounters, factors that influence health status, and external causes of disease. ICD is used to monitor adherence to safety and quality guidelines, as well as reimbursements and trends in resource allocation.

ICD defines the diseases, injuries, and health conditions in a hierarchy. This classification allows data users to do the following:

- easily store, access, and analyse health data for evidence-based decision-making
- exchange and compare health data amongst hospitals and clinics, regions, and countries
- conduct data comparisons across different time periods.

First established as the International List of Causes of Death in 1893, ICD has been revised over time to reflect changes and advances in medical science. The 43rd World Health Assembly endorsed ICD-10 in May 1990.

ICF: International Classification of Functioning, Disability, and Health

The International Classification of Functioning, Disability, and Health, known more commonly as ICF, is the WHO framework for measuring health and disability at both the individual and population levels.[3] Unlike ICD, which focuses on the diagnosis and health condition, ICF is a classification of health function, from body functions to an individual's activities, including one's ability to participate in these activities. As the functioning and disability of an individual occurs in a context, ICF also includes a list of environmental factors.

In the 54th World Health Assembly on 22 May 2001, all 191 WHO Member States officially endorsed ICF as the international standard to describe and measure health and disability (resolution WHA 54.21).

ICHI: International Classification of Health Interventions

The International Classification of Health Interventions [ICHI] is a classification of the interventions employed to assess, improve, maintain, or promote health.[4] WHO is developing ICHI to provide a common reporting tool and to enable comparisons between health interventions.

This classification covers a broad range of health interventions, including prevention, public health, acute care, primary care, rehabilitation, and assistance with functioning. ICHI codes classify the actions taken for a target population or individual and the methodology used

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2 WHO (2016). *International Classification of Diseases (ICD)*. See: www.who.int/classifications/icd/en/

3 WHO (2017). *International Classification of Functioning, Disability, and Health (ICF)*. See: www.who.int/classifications/icf/en/

4 WHO (2016). *International Classification of Health Interventions (ICHI)*. See: www.who.int/classifications/ichi/en/

in implementation. Extension codes allow users to describe additional detail about the intervention.

WHO released the latest draft in 2015, although active review and development of content continues. Once finalized, ICHI will be freely available for adoption by WHO Member States. Reference terminologies

A reference terminology defines terms used in health data according to the relationships between the concepts, so it is an ontology, in which the terms are organized by meaning rather than alphabetically. These meanings, and the relationships between them, enable a computer to interpret and process these terms in a formal and reproducible manner. Unlike classifications, reference terminologies are more comprehensive and less restrictive to specific predefined categories.

SNOMED CT: Systematized Nomenclature of Human Medicine Clinical Terms

The Systematized Nomenclature of Human Medicine Clinical Terms [SNOMED CT] is an international terminology of health terms designed for EHRs and other digital health information.[5] It is a clinically validated and semantically rich vocabulary that standardizes the data input into EHRs and other external software applications, such as medical histories and patient problem lists.

This reference terminology structures the listings of health terms, called 'concepts', according to their definitions and relationships with other concepts. Unlike classifications like ICD, the SNOMED CT terminology interprets the actual phrases used by health workers into standardized terms. While large and comprehensive in scope, the SNOMED CT terminology can also be categorized into specialty reference sets. SNOMED CT terms can be mapped to classifications like ICD-10, helping enable semantic interoperability.

The SNOMED International[6]maintains and validates SNOMED CT and distributes it to national public health systems for a fee.

LOINC: Logical Observation Identifiers Names and Codes

The Logical Observation Identifiers Names and Codes [LOINC] terminology is used to identify laboratory and clinical test results.[7] Maintained by the Regenstrief Institute, LOINC has the main goal of facilitating the exchange and pooling of results for clinical care, outcomes management, and research.

The LOINC database provides a set of universal names and identification codes for identifying laboratory and clinical test results in the context of report messages that use other existing health information standards. These other standards include HL7, American Society for Testing and Materials [ASTM] E1238, and European Committee for Standardization Technical Committee 251 [CEN/TC 251]. Fields in the report messages transmit the identity of the source laboratory and special details about the test sample.

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5 SNOMED International (2017). What is SNOMED CT? See: www.ihtsdo.org/snomed-ct/what-is-snomed-ct/

6 SNOMED International is the trading name of the International Health Terminologies Standards Development Organization (IHTSDO), the entity's legal name. See: ihtsdo.freshdesk.com/support/solutions/articles/4000095393-why-did-you-change-your-name-from-ihtsdo-to-snomed-international- (accessed 17 November 2017)

7 Regenstrief Institute (2017). FAQ: LOINC basics. See: loinc.org/faq/basics/#what-is-loinc/

11073: Medical device communication nomenclatures

The 11073 nomenclatures, defined in the standards set by the International Organization for Standardization/Institute of Electrical and Electronics Engineers' working group [ISO/IEEE 11073], are primarily intended to be used in interdevice protocol data units as values of fields. These field values are typically object-oriented attributes, which specify particular alternatives amongst a related semantic set. Each nomenclature term consists of a systematic name that explains the term, a unique code value, and a reference identifier. The reference identifier has the form MDC_XXX_YYY (with MDC referring to 'medical device communication').

Using a consistent nomenclature enhances interoperability since all implementations maintain the same semantic meaning for the numeric codes. Using nomenclature codes also assists with international implementations by reducing the use of strings.

Health workflow standards

Health Level Seven International [HL7] standards

Health Level Seven International and its members provide a framework (and related standards) for the exchange of digital health data. To enable seamless communication of data, these standards define the format of health information: the language, structure, and data types required for different and disparate systems to share, retrieve, and process these data.

As the industry has evolved, Health Level Seven International has produced several versions of standards:

- HL7 Version 2: initially, this version used delimited text strings, but it has evolved to use XML
- HL7 Version 3: a more comprehensive, yet more complex, standard based on a single Reference Information Model
- HL7 Clinical Document Architecture: a companion standard to HL7 version 3, which uses XML to share information via an electronic document format
- HL7 FHIR: a REST-based specification that uses predefined representations of health concepts, which are less complex and well suited for mobile and web use.

ISO 13606

The ISO 13606 series of standards specifies how data on a single patient are communicated between EHR systems or between the EHR and a data repository. ISO 13606 defines how the systems architecture can communicate EHR data in a reliable manner, which keeps the original clinical meaning of the information intact, as well as preserves data confidentiality.

ISO/TC 215 (CEN 215) standards

ISO/TC 215 health informatics standards encompass a wide range of health domains, including healthcare delivery, clinical research, public health, and prevention and wellness. At present, more than 150 standards have been published, with many more under development. ISO/TC 215 standards enable consistent exchange of data within many common parts of a digital health system, such as medical devices, health records, telehealth systems, security and authentication components, terminologies, and messaging and communication standards. See www.iso.org/committee/54960/x/catalogue/ for a list of published standards.

Once the ISO adopts and validates the standards from this committee, the European Committee for Standardization Technical Committee 215 [CEN/TC 215] adopts and publishes the ISO/TC 215 standards.

Personal health device standards

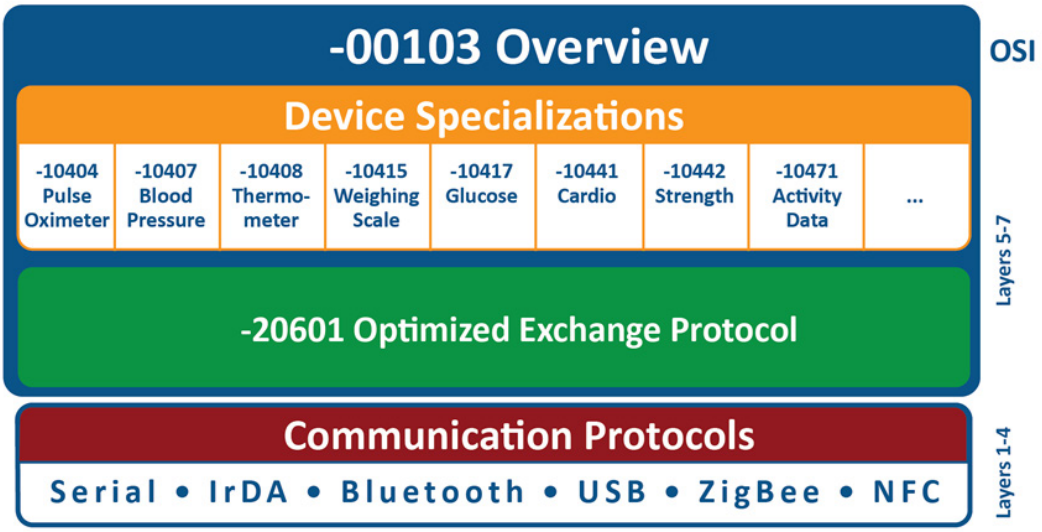
ISO/IEEE 11073 Personal Health Devices series

The ISO/IEEE 11073 personal health devices [PHDs] series of standards enables interoperability between PHDs, such as glucose monitors, weighing scales, and physical activity trackers, and external software applications that process the data collected by the PHDs. These applications could be used by an individual's personal computer, tablet, mobile phone, set-top box, or an HIS.

These standards cover the many aspects of communicating the semantics of medical data from device to manager, including data exchange protocol, data representation, and terminology for communication. The standards can share very specific data, including measurement modalities, user changes to device settings, and device specifications such as serial number, configuration, and network location.

The ISO/IEEE 11073 PHD series of standards can be layered together as a stack over various types of underlying transports. Doing so provides device interoperability optimized for the specific devices being interfaced (see Figure F.1).

Figure F.1: ISO/IEEE 11073 PHD standards stack



IrDA: Infrared Data Association - USB: Universal Service Bus - NFC: Near-field communication - OSI: Open Systems Interconnection model

Many manufacturers and stakeholders worldwide, including the United States Food and Drug Administration and CEN, have recognized or adopted the ISO/IEEE 11073 PHD series of standards.[8]

[8] Government Publishing Office (2013). Notices. *Federal Register*, 78(151). See: www.gpo.gov/fdsys/pkg/FR-2013-08-06/pdf/2013-19020.pdf

ITU-T H.810 series

The Continua Design Guidelines [CDG] define a framework of underlying standards and criteria that are required to ensure the interoperability of devices and data used for personal connected health. They also contain design guidelines that further clarify the underlying standards or specifications by reducing options or adding missing features to improve interoperability.

These guidelines focus on the following interfaces:

- PHD interface: the interface between a PHD and a personal health gateway
- Services interface: the interface between a personal health gateway and a health and fitness service
- HIS interface: the interface between a health and fitness service and an HIS.

The CDG comprises a series of specifications, which taken as a whole represent a yearly release. This series contains the ITU-T H.810-H.819 interoperability design guidelines for personal health systems and the ITU-T H.820-H.859 interoperability compliance testing of personal health systems (for health record network [HRN] interface, personal area network [PAN], local area network [LAN], and wide area network [WAN]). The full list of standards amongst H.800-H.899 e-health multimedia services and applications can be found on Study Group 16's e-health website: itu.int/go/trm/eh/.

For additional information about ITU-T standards efforts related to e-health applications, see the report *E-health Standards and Interoperability* (www.itu.int/dms_pub/itu-t/oth/23/01/T23010000170001PDFE.pdf).

Appendix G – Data Protection Measures

Health information systems and software gather a lot of data, most of it personal, sensitive data about an individual's identity and health. Preserving the security and integrity of these data while ensuring patient privacy is paramount in the field of health care. Since the DHP promotes data sharing between digital health applications, including sensitive data, DHP design and implementation need to particularly emphasize both privacy and security. Moreover, with new laws coming into effect, such as the General Data Protection Regulation [GDPR] in Europe and the recent regulatory changes in Canada, China, Japan, Switzerland, and the USA-EU privacy shield[1], the DHP needs to embrace key concepts that reflect the major paradigm shift occurring in privacy and security policy.

Essential privacy and security principles

Privacy and security are key tenets in the Principles for Digital Development. It is essential that digital systems employ measures to mitigate risks during data sharing. These systems must also protect end users' personally identifiable information in an equitable, transparent, responsible, and fair manner.

Learn more about data privacy and security:

D. Manset (2017). Big data and privacy: fundamentals of digital trust toward a digital skin. In L. Menvielle, (ed.), *Connected Health: New Challenges for the 21st Century,* Palgrave McMillan. In Press.

J. Bresnick (2016). Is blockchain the answer to healthcare's big data problems? *Health IT Analytics.* See: healthitanalytics.com/news/is-blockchain-the-answer-to-healthcares-big-data-problems

J. Bresnick (n.d.). Exploring the use of blockchain for EHRs, healthcare big data. *Health IT Analytics.* See: healthitanalytics.com/features/exploring-the-use-of-blockchain-for-ehrs-healthcare-big-data

Note: All websites accessed on 28 May 2020.

[1] For Canada's Personal Information Protection and Electronic Documents Act, updated in 2015, see: www.priv.gc.ca/en/privacy-topics/privacy-laws-in-canada/the-personal-information-protection-and-electronic-documents-act-pipeda/. For China's Cybersecurity Law, effective on 1 June 2017, see: https://www.newamerica.org/cybersecurity-initiative/digichina/blog/translation-cybersecurity-law-peoples-republic-china/ (in Chinese). For Japan's Act on the Protection of Personal Information and related updates to guidelines, effective 30 May 2017, see: www.ppc.go.jp/files/pdf/Act_on_the_Protection_of_Personal_Information.pdf or www2.deloitte.com/jp/en/pages/legal/articles/dt-legal-japan-regulatory-update-17may2017.html. For Switzerland's updates to the Data Protection Act (DPA) and the Ordinance to the DPA, likely effective in late 2018, see: www.admin.ch/opc/en/classified-compilation/19930159/index.html. For the USA-EU Privacy Shield Framework, effective 12 July 2016, see: www.privacyshield.gov/welcome. (All sources listed here accessed 17 November 2017.)

In general, digital health systems and applications should respect and uphold the following principles:

- **Privacy by design and by default:** The design of all information systems and applications should include all of the needed security features for upholding and preserving privacy over time. These systems and applications must also ensure that these security features by default collect, retain, and share the minimum amount of personal data needed to achieve a specific purpose.
- **Informational self-determination:** All individuals should be given the right to access, modify, erase, or be forgotten from information systems and applications that collected, processed, or stored their personal information.
- **Clear consent:** All users of a system or application must provide voluntary and clear consent before their personal data are collected. These individuals should be able to revoke consent at any point in time.
- **Transparency:** Patients, health workers, and any other end users of a system or application need to receive clear information about how their data will be collected, used, and stored. Moreover, information systems and applications should offer reliable traceability on data flows.
- **Purpose limitation:** The purpose of data collection and processing should be clearly defined to minimize the risk of data misuse, particularly in the application of data sets to purposes other than originally stated.
- **Pseudonymization:** Whenever applicable, personally identifiable information should be made pseudonymous or anonymous to guarantee the highest possible level of identity protection.

Overview of privacy laws and regulations

National privacy laws and regulations are essential for establishing clear legal guidelines, strengthening individuals' trust and confidence in the digital environment, and holding organizations accountable for data they collect, process, store, and use. The European Union, in particular, has emphasized the fundamental importance of protecting personal privacy, with its policies setting the standard for this area of law. The Privacy and Electronic Communications Directive 2002/58/EC[2] and the Data Protection Directive 95/46/EC[3] (currently being updated by the GDPR[4]) serve as the primary laws that govern data protection and security practices. Notably, the Data Protection Directive defines health data as a special category of data to which a higher level of protection applies. In the United States, the Health Insurance Portability and Accountability Act [HIPAA][5] defines how organizations must protect health data.

In many countries, including in lower middle-income countries, e-government laws concerning privacy and security and specific policies related to health data are in place. These policies have often been modelled after the aforementioned regulations in the European Union and United States. Be sure to learn the legal and regulatory framework in place for securing data when designing the privacy and security architecture, as well as the operational and governance processes, for your DHP.

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[2] European Parliament (n.d.). 32002L0058 - Directive 2002/58/EC. *EUR-Lex*. See: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX%3A32002L0058%3Aen%3AHTML

[3] European Parliament (n.d.). 31995L0046 - Directive 95/46/EC. *EUR-Lex*. See: eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX%3A31995L0046%3Aen%3AHTML

[4] European Parliament (2016). Regulation (EU) 2016/679 of the European Parliament of the Council. *Official Journal of the European Union*. See: ec.europa.eu/justice/data-protection/reform/files/regulation_oj_en.pdf

[5] National Institutes of Health (n.d.). HIPAA privacy rule. See: privacyruleandresearch.nih.gov/pr_08.asp

Data sharing agreements

A data sharing agreement [DSA] is a contract agreed upon by the parties engaged in data exchange to clarify privacy rules and practices, as well as communication protocols, and to ensure that all parties follow these guidelines. DSAs outline who has access to which data, how these data can be shared, and when they can be shared, amongst other data exchange protocols. In addition to playing an important role in enforcing privacy policies, DSAs build institutional trust and support transparency and accountability.

Table G.1: Information input into data sharing agreements

Required Information to Include	Helpful Information to Include
Agreement purpose Statements about: – data ownership – access and restrictions to access – data verification and validation. Dates defining the terms of the agreement Signatures of the parties representing institutions engaged in data sharing (e.g. MoH and software vendor)	Statements about: – data sharing frequency – data quality – data use. Information about: – auditing – warranties – data stewardship – constraints.

Table G.2 provides additional resources about DSAs, as well as links to examples.

Table G.2: Data sharing agreement resources

Resource	Description
Data Use and Reciprocal Support Agreement [DURSA] www.healthit.gov/sites/default/files/draft_nhin_trial_implementations_production_dursa-3.pdf	Sample DURSA developed by Nationwide Health Information Network Cooperative DURSA Workgroup, held 23 January 2009
Sequoia Project DURSA www.sequoiaproject.org	Additional materials about DURSA by the Sequoia Project, including webinars and descriptions of DURSA components
OpenHIE Data Sharing Agreement Template docs.google.com/document/d/1tc63jB4AAtPknU9sjPTXt38VTpfEp8AIuEaYYtAAUCw/edit	Template of a framework that can be adapted for data sharing through OpenHIE
The Indiana Network for Patient Care: A Case Study of a Successful Healthcare Data Sharing Agreement www.americanbar.org/content/dam/aba/publishing/aba_health_esource/Sears.authcheckdam.pdf	Case study of a DSA, including annex of actual agreement

Resource	Description
Data Governance and Data Sharing Agreements for Community-Wide Health Information Exchange: Lessons from the Beacon Communities egems.academyhealth.org/articles/abstract/10.13063/2327-9214.1057/	Lessons learned about data governance and data sharing, based on the experiences of six federally funded communities participating in the Beacon Community Cooperative Agreement Program; this paper offers guidance for navigating data governance issues and developing DSAs to facilitate community-wide health information exchange

Note: All resources in table accessed 28 May 2020.

Privacy-preserving techniques

In addition to the data protection activities occurring in the policy and operational environment of the DHP, there are technologies that can further protect data and uphold personal privacy. Some of these technologies, such as consent management and digital signatures, are common DHP components described in the DHPH main text (see Section 5: 'Identify DHP components'). Other technologies are still emerging but hold promise for helping organizations face the complex and evolving privacy issues associated with big data, the Internet of Things, and greater ease in data sharing. Note that many unknowns still exist, however, as the health sector offers few examples of these security technologies thus far.

This overview describes some techniques for preserving privacy that may be useful to consider for your DHP. Note that all of them may be used in conjunction with one another.

Blockchain security

Blockchain security revolutionizes data security by creating digital trust within a potentially untrustworthy network. Simply stated, the blockchain is the technology behind Bitcoin.[6] This cryptographic protocol enables a distributed, public, and trustable ledger where digital object transactions are signed with the issuer's and recipient's identities. These transactions are then verified by a community of peers and stored as incremental 'blocks' in a shared database. Each of these blocks represents a stakeholder's communication in the data value chain.

Blockchain security thus relies on a checks-and-balances system to secure data within the data value chain. In such a system, data and copies of these data are distributed to the linked nodes that collectively monitor, validate, and store any changes to the original data. Thus, any changes need to be approved by a majority of the group. Additionally, changes occurring within all of the blocks are timestamped and electronically signed, thus creating a permanent, reliable, and safe record. The latest iteration of the data serves as the reference point for the next cycle of changes and validation. In this manner, the collective 'watch' serves as a check on unauthorized accesses or alterations to the data, making security a built-in feature of the system.

Blockchain security design can accommodate the various application and device types used in digital health to trace and document all data flows and transactions occurring on the network. Using REST APIs, the blockchain can integrate with either web-based or mobile applications. The blockchain also works with the various mobile communications, medical devices, and sensors that collect data within your HIS. A DHP can thus play a valuable role in providing

[6] S. Nakamoto (2008). Bitcoin: a peer-to-peer electronic cash system. See: bitcoin.org/bitcoin.pdf

this integration, serving as a hub for communications traceability between the blocks (i.e. stakeholders in the data value chain).

In health care, blockchain security could prove invaluable for increasing user trust in patient data exchanges and, ultimately, the quality of services delivered. Just one record is watched over and approved by a patient's trusted 'inner circle', which can include the healthcare team and the patient's loved ones. With one authoritative record, health workers can trust the patient history, possibly leading to better clinical decision-making. One record transaction secured by a blockchain can also help insurers and health subsidy providers reduce billing fraud by preventing data misuse. Fraud prevention is one of the main drivers of the various blockchain-prototyping efforts currently occurring in the health sector. Creating interoperable healthcare information systems with a blockchain is seen as a primary means for achieving complete, transparent, immutable, and trustable traceability across the data value chain.

Note that existing privacy policies and regulations, such as the European Union's GDPR, may affect how data are shared using a blockchain, especially with the 'right to be forgotten'.

Table G.3: Benefits and limitations of blockchain security for healthcare data

Benefits	Limitations
Reduced data errors and data misuse, due to increased provenance and data transactions traceability	Data storage limits for permissions, data type, and size.
Validation by multiple users, not just one, creates greater trust in data transactions.	Collective validation slows transactions.
Empowers patients in governing access and changes to their records, due to immutable traceability	Requires integration between each node's system and even greater integration if data are moved off chain to accommodate storage limits.
Data transaction of records amongst multiple facilities or users (e.g. health workers, patients, administrators) are secure.	Potentially difficult integration with legacy proprietary systems.

Dynamic consent

Dynamic consent gives patients or other digital health users greater control over data protection. With this technique, users have continuous and easy access to any consent agreements regarding their data. Users can view and update consent agreements at any time through a web or mobile interface. Dynamic consent, then, does not require users to track down or keep copies of consent forms that they have already signed, and it accommodates changes in personal privacy preferences though a simple click on a web page.

Anonymization/Pseudonymization

Data security is not limited to consent-based techniques. Some technologies rely on anonymization/pseudonymization techniques, using cryptography to hide the identity of a user's data. Making patient data anonymous is particularly important when mining data in medical research or when identifying population health trends. In these scenarios, analyses run on encrypted, aggregated data sets must not reveal individual identities or even provide clues to help malicious users decipher identities. Differential privacy, homomorphic encryption, and secure multiparty computing are applicable approaches for keeping personal data pseudonymous.

Appendix H – Internet of Things

One aspect of digital health that holds tremendous promise for transforming health care is the Internet of things [IoT], which refers to the networking of physical devices and other objects in our everyday environment through embedded technology, allowing these devices to collect and exchange data. IoT devices can range from wearable health monitors or fitness trackers to embedded sensors in furniture, buildings, and household objects, such as scales, appliances, and medication dispensers. Many of the sensors in these devices work in conjunction with a smartphone app, allowing the user control over the device as well as the ability to view the data. IoT hardware is also being built into many smartphones, transforming them into IoT wearables and obviating the need for a separate sensor in some cases. In addition to tying into smartphone apps that are physically present with the user, IoT networks can connect to remote computer systems via ICT infrastructure. These systems can monitor and control the IoT network from a distance, as well as process and store the data collected.

> The ITU-T Study Group 20: 'Internet of things and smart cities and communities' is responsible for studies relating to IoT and its applications. In addition, Study Group 20 focuses on smart cities and communities [SC&C], including studies relating to big-data aspects of IoT and SC&C, as well as e-services and smart services for SC&C.[1]
>
> [1] ITU (2017). ITU-T Study Group 20: Internet of things (IoT) and smart cities and communities (SC&C). See: www.itu.int/en/ITU-T/studygroups/2017-2020/20/Pages/mandate.aspx

With this embedded connectivity, users can have access to IoT data in real time, whenever they want and from any location. Users may also benefit from automated processes, such as device activation and deactivation, ongoing data collection at set intervals, and workflows that send alerts or messages pertaining to the device's purpose. For example, a glucose sensor may automatically activate to take a measurement, transmit the reading to a patient's health record, and send back an analysis of the glucose level, including health education messages about the benefits of diet and exercise. At the same time, these IoT data may trigger alerts to the patient's clinician, so she can track the patient's condition.

Analysts predict that IoT-related technology will flourish in health care more than in any other sector. Nearly 40 per cent of IoT-related technology will be used for health purposes by 2020.[1] IoT will also increase in other sectors that may yield downstream effects on health. For example, IoT networks of the future will help governments implement and benefit from smart cities. This urban-planning concept envisions the development of cities that optimize resource allocation and service delivery based on data collected from IoT networks embedded throughout the municipality. Smart cities may yield changes in the built environment and the lifestyles of urban dwellers that improve health.

Interrelationship of Internet of things, big data, and artificial intelligence

The enormous amount of data gathered by IoT is another key value proposition of this technology: these data sets will drive innovation in technology and in health system models

[1] D. Dimitrov (2016). Medical Internet of things and big data in healthcare. *Healthcare Informatics Research*, 22(3), pp. 156–163. doi:10.4258/hir.2016.22.3.156

for serving patients. Called 'big data' because of their size, variation, and complexity, large data sets (of non-IoT data) have recently helped generate great improvements in artificial intelligence [AI] technologies. To build an AI engine that relies on pattern recognition to learn, developers need diverse and voluminous data for their AI to practice with and learn from. In a way, aggregated data can be seen as the nutrients that fuel the hungry brain of an AI tool as it matures and grows. Thus, big data has contributed to recent developments in AI technologies, such as machine learning, natural language processing, and machine translation. In turn, big data has leveraged these technologies to help analyse the information. Given the large volumes of data that IoT technologies are expected to generate as the Internet of things flourishes, AI innovations are likely to expand even further.

Learn more about the Internet of things:

S. M. R. Islam, D. Kwak, M. H. Kabir, M. Hossain & K. S. Kwak (2015). The Internet of things for health care: a comprehensive survey. *IEEE Access,* 3, pp. 678–708. doi:10.1109/ACCESS.2015.2437951

D. Dimitrov (2016). Medical Internet of things and big data in healthcare. *Healthcare Informatics Research,* 22(3), pp. 156–163. doi:10.4258/hir.2016.22.3.156

M.N.K. Boulos & N.M. Al-Shorbaji (2014). On the Internet of things, smart cities and the WHO Healthy Cities. *International journal of health geographics*, 13(1), p.10. doi: 10.1186/1476-072X-13-10

These AI tools, and certain big data analytics that do not rely on AI, will likely have a significant impact on how the health sector carries out its business. Big data analytics are the analytical tools and methods used to derive value from all of the information collected. Many types of big data are difficult to process and use because they are unstructured. Image files and content in textual form—such as those housed in the millions of SMS, chat, and e-mail messages shared daily or even in a health worker's notes on a patient—are examples of unstructured data commonly exchanged in the health sector. However, when connected to computer systems that use big data analytics, predictive analytics and modelling of individual—as well as group—behaviours can be realized. Such information will fundamentally alter the ways that governments, organizations, and businesses serve their citizens and customers. Analysis of large data sets in real time will help optimize resource allocation and processes, identify upcoming trends and problems, and personalize the services provided.

Uses of the Internet of things in health care

Home-based patient monitoring

Standard health service delivery around the world relies on the health worker's discharge orders, and often a series of follow-up visits, for managing patient recovery once patients leave the facility setting. The emergence of IoT devices presents an opportunity to alter and improve upon this standard practice. IoT devices will allow health workers to tailor post-operative and post-facility care plans through better education, more accurate monitoring, and timely reminders delivered to patients in their own homes. Home-based patient monitoring via IoT devices and applications also helps many patients live safely at home who would otherwise

not be able to do so—an increasingly important service for elderly and disabled populations. Examples of these patient-monitoring systems include intelligent boxes and packaging to detect medication adherence, telerehabilitation systems for monitoring and providing guidance on remote physical therapy, and sensors measuring various vital signs, such as glucose level, blood pressure, body temperature, and blood oxygen saturation. Given the promise of IoT devices, some hospitals in the United Kingdom are developing plans to pair future patients with the forms of healthcare technology most appropriate for their conditions; IoT devices, then, will give new meaning to the term 'digital prescription'.

Information gathered through home-based patient monitoring empowers healthcare teams, as well as the patients and caregivers themselves, with more accurate insights into patient behaviour and physical status. Consequently, health workers can better tailor their recommendations and health education messages for the achievement of recovery and wellness goals. At the same time, patients themselves can watch the data outputs generated by the IoT technology, encouraging greater engagement of patients in their recovery progress. At the health system level, IoT-enabled remote monitoring of patients can free up demand for hospital and outpatient facility beds and appointment time slots, as well as allow greater flexibility in health workforce scheduling.

Remote diagnosis

IoT can also realize diagnosis of patients outside of facilities or even without a health worker physically present. A combination of IoT devices and telemedicine applications can enable health workers to interpret symptoms and provide basic care and education from a distance. Unlike phone-consultation services currently used to provide care remotely, IoT data capture actual clinical measurements and images, not just self-reporting of symptoms by the patient. As a result, diagnoses by health workers can be more robust and accurate.

In addition, IoT devices can provide early detection of and rapid response to medical emergencies. For example, some wearable IoT devices have been designed to detect falls, with sensors transmitting real-time data that trigger communications with health workers, emergency service providers, and family members and caretakers. Such technology can avert death and disability, as well as instil greater confidence and autonomy amongst users and their caregivers.

Population-based modelling

Beyond direct service delivery, IoT data can be used at the population level to model how certain health determinants affect patient populations. Adoption of IoT devices can help medical researchers gather behavioural and lifestyle data, as well as a set of clinical measures that are continually taken over hours, days, or weeks, rather than the incidence data typically captured during a clinic visit. These data can provide researchers and clinicians with insights into population health risk factors that clinic visits and population surveys do not easily detect. Once a robust and diverse set of data is collected, researchers can undertake population-based modelling of a health determinant's impact on a particular patient population. They can also create more informed and nuanced clinical guidelines and policy.

IoT devices may assist with identifying risk factors and modelling impacts in chronic disease research, for example. Environmental and lifestyle factors are well known to be important determinants of the onset and progression of chronic disease, but observational data based on a person's daily activities are elusive. Data gathered by the IoT network may help close the

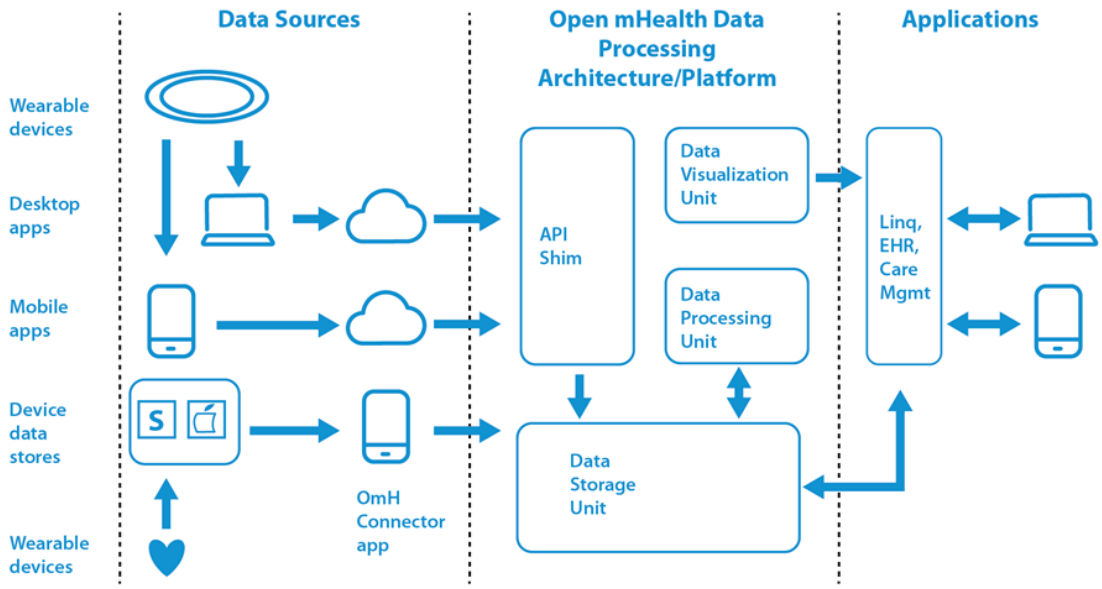
information gap. A number of companies are piloting IoT products that may help clinicians predict the onset of chronic disease in the future.

Role of DHPs

A DHP can provide the robust infrastructure to enable IoT technologies, allowing IoT data to be exchanged with other applications so that the device outputs become useful and meaningful. The DHP's integration services and APIs provide the switchboard through which each IoT device sends its data, regardless of whether the device was built for a specific proprietary system. Given that many device designs to date have not emphasized interoperability,[2] this DHP functionality offers a huge benefit to developers of IoT solutions. As long as the IoT device is configured for a DHP API, it should not need to be entirely re-engineered in order to communicate with applications outside of its proprietary design. Figure H.1 shows a DHP architecture designed for m-health and IoT.

Connecting an IoT device to the platform allows it to reap the benefits from other DHP components. DHP functional components will link IoT data to DHP enabling components—information resources such as registries, repositories, and digital maps—helping tie device data to a specific patient and location. Terminology services and data dictionaries will transform data organized in different formats into one common structure. Such transformation will enable aggregation, paving the way for analytics components, including big data analytics tools, to make sense of the IoT outputs. More importantly, these analytics will make the data useful to patients, health workers, and health planners. Other DHP components, such as the workflows, messaging, and repositories powering telemedicine applications, will also make IoT data useful to patients and health workers. For these reasons, building a DHP as the underlying infrastructure for an IoT network is indispensable for delivering the quality of care and efficiency improvements promised by IoT.

Figure H.1: DHP architecture using m-health and IoT technologies



API: Application programming interface - OmH: Open mHealth - EHR: Electronic health record - mgmt: management

[2] D. Dimitrov (2016). Medical Internet of things and big data in healthcare.

Business model and system architecture

Widespread adoption of IoT m-health solutions requires substantial upgrades in the design and overall thinking of business models and reference architectures for data, applications, and technology. Health-sector business models will need to switch from a mainframe health paradigm (i.e. centralized, hospital centric, expert driven, reactive, and costly) to a new personal health paradigm (i.e. distributed, home and consumer centric, data rich, preventive, and efficiency driven). IoT architectures will need to put in place intelligent business processes made up of problem-solving components that will produce real-time, qualitative answers based on data.

Given the sensitivity of healthcare issues, business models also must provide a high degree of transparency to engender trust amongst users. While the ubiquitous data collection afforded by IoT devices and networks offers convenience and patient empowerment, it can also feel intrusive to some users. To ease these concerns, the locus of control over data usage needs to rest with the user. Opt-in permissions and dynamic consent techniques (see Appendix G) should be adopted. In addition, open communication and socialization mechanisms between patients and health workers should be established. Doing so will help create a trusted community where people can share information about how personal data are used and protected as well as how to interpret diagnostic or health status data collected by the IoT device.

When creating an efficient reference business architecture that values socialization, innovation, and knowledge sharing, it is worth considering a distributed licensing model. Core technology could be licensed to a number of partners, allowing them to differentiate and innovate independently. This licensing model would help create an IoT ecosystem that drives competition, innovation, and differentiation.

Core principles

For this vision to become a reality, several core principles must be in place.

Interoperability

One of the most commonly cited barriers to the growth of IoT is the complexity of the technology supply chain. Any one IoT application may rely on multiple equipment vendors, communication service providers, system integrators, and online platforms. Multiple competing standards further complicate the landscape for IoT users. To simplify these IoT solutions and increase their usability, interoperability must be embraced.

As standards are an important means of guaranteeing interoperability at the device and network layer, industry convergence around an accepted set of standards is important. ISO/IEEE 11073 standards have been developed and validated for communication amongst medical, healthcare, and wellness devices and external computer systems. These standards provide a framework for automatic, detailed data capture of patient-related and vital signs information as well as device operational data (see Section 5: 'Adopt and deploy standards' and Appendix F for more information).

Procurers should seek out IoT solution providers who incorporate internationally recognized and validated standards, as well as open APIs, in their designs. In addition to enabling seamless data exchange within an IoT network, these open architectures will support expansion. As a result, m-health vendors will benefit from economies of scale, improving affordability and penetration in less developed markets.

Energy efficiency

IoT devices are very small by necessity, so they can be easily embedded in physical objects and mechanisms. The bandwidth and memory required to transmit IoT data are often fairly minimal, because those data consist of relatively simple information. For example, reporting changes in temperature or transmitting basic instructions, such as opening a valve, requires very little bandwidth and memory.

While their data demands may be low, IoT devices do need to boast a long lifespan for these networks to be successful in health care. If devices need to be changed or upgraded regularly, many of the benefits of a fully automated IoT network can be lost. Remote users may need to travel to a medical centre more frequently, and resources, both capital and human, will need to be spent on these upgrades. Some users may choose not to upgrade to avoid the hassle or extra cost. Other users may choose not to use an IoT healthcare network at all.

Therefore, improving energy efficiency within these devices is essential. Advances in semiconductor technology, particularly the advent of system-on-a-chip [SoC] architecture, helps ensure longevity of power sources. This innovative technology takes many discrete computer system components (e.g. central processing unit [CPU], random access memory [RAM], memory, network hardware) and packages them on a single chip, reducing the power consumption of each component. SoC also allocates more space in the IoT device to the battery, allowing larger batteries and therefore lengthening the time span between charges. This increased power efficiency is delivered with no impact on processing power. These types of innovations in energy efficiency will need to continue for ongoing IoT uptake over the long term.

Security

If patients and health workers are to embrace IoT applications, implementing end-to-end security measures across the IoT network will be necessary. Generating large amounts of ubiquitous personal health data via a continuously connected global IoT network raises legitimate concerns about privacy and security. Such concerns are particularly merited because many standard data security measures cannot yet be deployed to protect data travelling through IoT.

Interestingly, many of the biggest security challenges lie in the very things that make IoT technology viable: the devices' small, energy-efficient design, their ubiquitous mobility within a network, and their variation. Equipped with low-speed processors, minimal memory, and limited battery power, IoT devices do not yet have the capacity to execute the complicated computations that traditional data security techniques demand. The wide variation in the different types of devices and sensors used in IoT further complicates the development of IoT security protocols. Computational measures for the simplest devices, such as a radio-frequency identification tag, may need to be vastly different from those used in smartphones. Finally, unique security challenges arise in IoT because the devices move around, connecting and disconnecting from different networks throughout the course of a user's day. This dynamism poses serious challenges for developers, as security configurations differ from network to network and because a device may use multiple network protocols at once.[3]

For procurers of IoT solutions, there are a number of ways to guarantee that a new product or service meets the necessary security conditions. The most obvious of these is certification

[3] S. M. R. Islam, D. Kwak, M. H. Kabir, M. Hossain & K. S. Kwak (2015). The Internet of things for health care: a comprehensive survey. *IEEE Access,* 3, pp. 678–708. doi:10.1109/ACCESS.2015.2437951

against standards (preferably international ones). ISO is pioneering work for IoT, but regional standards bodies such as the National Institute for Standards and Technology and the European Telecommunications Standards Institute are also working on IoT standards. The main advantage of standards, as opposed to legislation, is that they are market driven, responsive to technological change, and developed in an open and collaborative setting with multiple stakeholders.

In addition to cybersecurity standards for IoT, voluntary coregulatory and self-regulatory initiatives can add a lot of value. Work currently under way at the Alliance for Internet of Things Innovation in Europe is a good example of this. Stakeholders from the industry and user community are coming together, without the threat of binding legislation, to identify gaps in the research agenda, share best practices, and develop recommendations for standards-setting bodies and policy-makers.

Appendix I – Organizational Resources for DHP Implementers[1]

Several organizations focused on digital health can serve as resources while you design and implement your DHP. These resources can be roughly divided into two types—standards developing organizations [SDOs] and communities of practice—although some of these are hybrids that offer knowledge sharing as well as forums for standards development.

Digital health standards developing organizations

Multiple SDOs are working closely with one another to build and maintain a coordinated standard infrastructure for this industry. This section introduces some of the dominant SDOs working in digital health.

International Telecommunication Union

www.itu.int/en/ITU-T/e-Health/Pages/default.aspx

The International Telecommunication Union [ITU] is the United Nations specialized agency for information and communication technologies [ICTs]. ITU works to ensure that networks and technologies seamlessly connect and that underserved communities worldwide have access to these ICT systems. Since 2003, digital health standardization has been on the agenda of the ITU Telecommunication Standardization Sector [ITU-T]. ITU's work on digital health standardization was bolstered by the World Telecommunication Standardization Assembly adoption of Resolution 78 (Dubai, 2012; Rev. Hammamet, 2016), 'Information and communication technology applications and standards for improved access to e-health.' During study period 2013-16, ITU worked on Question 28 under Study Group 16 concerning the standardization of multimedia systems that support e-health applications. Under this Question, ITU, in collaboration with the Personal Connected Health Alliance, adopted the CDG for personal health devices, as found in the ITU-T H.810 series. Question 28 continues maintenance of the series and undertakes related work in e-health standardization. For more information on the CDG and the H.810 series, see: itu.int/pub/T-TUT-EHT/

Participation in standards development is open to all members of the Union. Interested parties can apply for ITU membership via its website (see: itu.int/en/membership/Pages/sm-form.aspx).

International Organization for Standardization

www.iso.org/home.html

ISO/TC 215: www.iso.org/committee/54960.html

ISO is an international non-governmental organization whose members develop international standards for products, services, and systems in nearly every industry. With a membership of more than 160 countries, ISO convenes industry experts and applies a consensus-based process to develop standards for different sectors.

[1] All of the websites provided in this appendix were accessed on 17 November 2017.

ISO establishes digital health standards through its Technical Committee 215 for health informatics. ISO/TC 215 has a wide scope; its health informatics standards address healthcare delivery, clinical research, public health, and prevention and wellness. Currently, it contains two advisory groups and the following working groups:

- Working Group 1: Architecture, frameworks, and models
- Working Group 2: Systems and device interoperability
- Working Group 3: Semantic content
- Working Group 4: Security, safety, and privacy
- Working Group 6: Pharmaceutical and medicines business
- Joint Working Group 1: Traditional Chinese medicine (informatics)
- Joint Working Group 7: Application of risk management to information technology networks incorporating medical devices
- Task Force 1: Quantities and units to be used in e-health
- Task Force 2: Traditional medicines.

According to the Partner Standards Development Organization Agreement between ISO and IEEE Standards Association [IEEE-SA],[2] ISO adopts and publishes all of the ISO/IEEE 11073 standards via a fast-track process. Once ISO adopts these standards, CEN also adopts and publishes them.

The membership of ISO is country based, rather than individual or entity based. Obtain further details about enrolment from the secretariat of ISO/TC 215.

World Health Organization

www.who.int/classifications/en/

The World Health Organization established the WHO Family of International Classifications [WHO-FIC] to improve health by ensuring that health information can be consistently gathered, interpreted, and shared around the globe. These classifications, such as the ICD-10 codes and the ICF framework, help provide a common language for describing a person's health status as well as a health system. Applying these reference classifications to health data increases the reliability of statistical systems at different levels of the health system. Such improvements can lead to better health care and, ultimately, better health for individuals and communities.

To accomplish its work in developing and disseminating these classifications, WHO created the WHO-FIC Network, a group of collaborating centres located in various countries. Users who experience significant problems using the WHO-FIC classifications should liaise with the centre in their region. For a list of collaborating centres, see: www.who.int/classifications/network/collaborating/en/

Health Level Seven International

www.hl7.org

Health Level Seven International and its members provide a framework (and related standards) for the exchange of digital health data. These standards support the accurate and consistent sharing of information needed for delivering health services, from direct patient care to

[2] IEEE-SA (n.d.). Global engagement: International Organization for Standardization (ISO). See: standards.ieee.org/develop/intl/iso.html

management and evaluation of services. The HL7 FHIR specification is one example of the important standards that HL7 International produces. The organization's membership currently includes more than 1 600 members representing over 50 countries and a variety of health-sector stakeholders, from providers to payers and from government entities to vendors. HL7 aims to enable interoperability for seamless and secure sharing of global health information.

openEHR

www.openehr.org

The virtual community openEHR develops specifications and approaches for digitizing health data from paper records into electronic ones. Its overall aim is to ensure that all forms of electronic data are interoperable. Operating within a service-oriented software architecture, openEHR uses multilevel, single-source modelling, an approach that assigns a separate layer to each model built by a domain expert. The openEHR Foundation publishes the specifications used for the model.

openEHR builds interoperability into its components and systems using open data, models, and APIs. The openEHR archetype specification is now an ISO standard (ISO 13606-2), and countries have applied this standard and openEHR's reference model components to define their national standards for e-health information.

Integrating the Healthcare Enterprise

www.ihe.net

IHE provides tools, specifications, and services, as well as a testing environment for conformity assessment, to promote interoperability amongst systems and devices in health care. To improve how public- and private-sector entities share health data, the IHE initiative produces and shares 'integration profiles', specifications that describe use cases for managing clinical information and how existing standards can address these cases. IHE engages clinical and technical experts to develop these profiles and then holds regular events for testing vendors' solutions that use these profiles.

The IHE initiative is organized into various domains, each focused on a specific healthcare area, such as pharmacy, patient-care coordination, or surgery. The IHE Product Registry shares results of the profiles that have been tested in Europe, North America, and Asia, as well as additional information for ICT professionals.

Regenstrief Institute

www.regenstrief.org

The Regenstrief Institute Center for Biomedical Informatics seeks to improve health care using digital health solutions, including clinical applications, digital decision-support tools, and analytics. To promote and enable semantic interoperability, the Regenstrief Institute collaborates with standards developers around the globe to develop clinical data standards, notably UCUM and LOINC (see Appendix F), and leads the Health Standards Collaborative, a forum for the development community of information technology healthcare standards in the United States.

IEEE 11073 Personal Health Device Working Group

standards.ieee.org/develop/wg/PHD.html

The IEEE 11073 PHD Working Group, established under IEEE-SA, develops standards that define interoperability between PHDs (e.g. blood pressure or blood glucose monitors) and computing engines (e.g. set-top boxes, cell phones, personal computers).

The operation of IEEE 11073 PHD Working Group is governed by the IEEE-SA Operations Manual and Standards Board Bylaws. Membership in the working group is free and open to any individual. To join, contact the IEEE liaison at the working group's webpage.

IEEE and ISO also have a cooperation agreement; see the 'International Organization for Standardization' section previously in this appendix.

Communities of practice

Various forums, communities of practice, and working groups are available to support DHP design and implementation efforts. These groups foster knowledge sharing, help build technical skills, and advocate for the adoption of digital health best practices such as standards-based architecture, interoperable design, and strong governance. The following are some examples of well-established communities with which you can engage to help build your DHP.

OpenHIE

ohie.org

Open Health Information Exchange [OpenHIE] i is a community of practice that facilitates open collaboration and support to countries implementing large-scale HIS architectures. Guided by the principles of transparency, openness, technology sharing, and knowledge exchange, OpenHIE works to build sustainable architectures that improve health outcomes amongst the underserved. It offers an architectural framework, reference technologies, and peer support that countries can use to improve their own HIS.

The OpenHIE architecture emphasizes flexibility and interoperability through its component-based design, use of open standards and interfaces, and specifications for an interoperability layer. This layer is a middleware component that manages information exchange between OpenHIE's core components and external applications. Both open-source and proprietary applications can leverage the OpenHIE architecture or play the role of OpenHIE components, as long as they conform to the open standards.

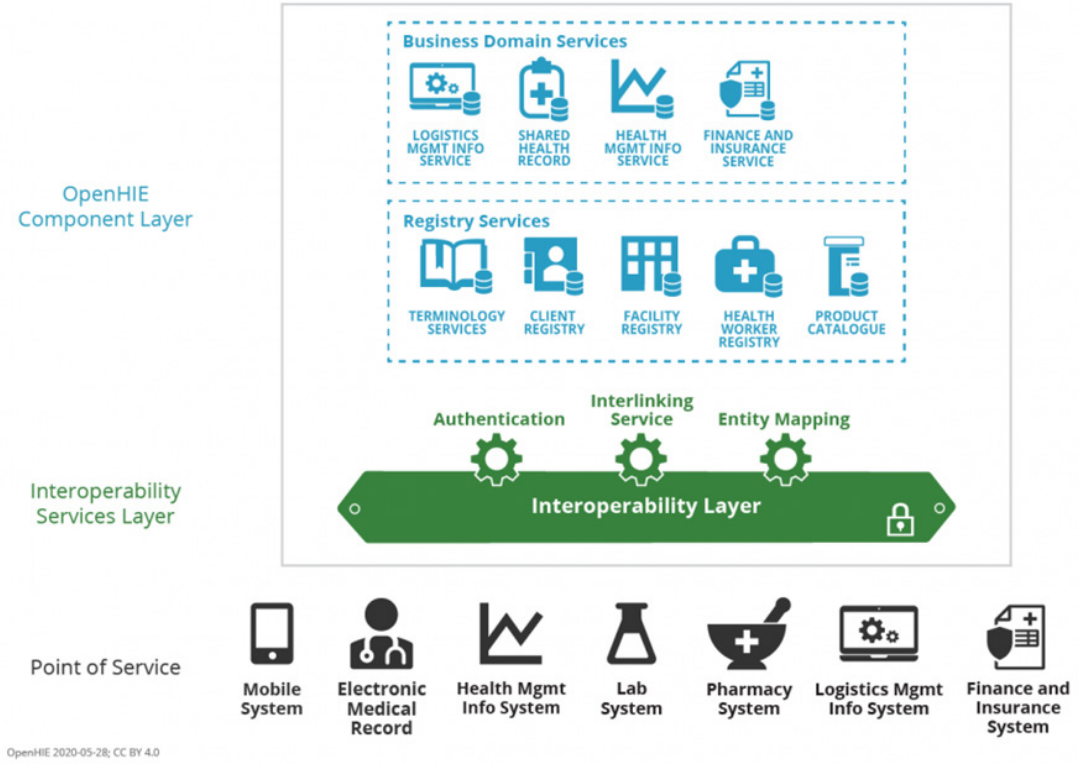
The OpenHIE architecture includes six core components for health data management (shown in the component layer of the architecture diagram in Figure I.1):

- terminology services [TS] mapped to international standards such as ICD-10, LOINC, SNOMED CT, and others
- client registry [CR][3]
- shared health record [SHR]
- HMIS for aggregated healthcare data
- health facility registry [FR]

[3] 'Client registry' is the same as the term 'patient registry' which the DHPH uses.

- health worker registry [HWR].

Figure I.1: OpenHIE architecture. Source: OpenHIE (n.d.). See: ohie.org



These components are loosely coupled yet integrated, making it easy to share information as well as add or change services when needed, such as when technologies or clinical guidelines change. This flexible design enables ICT implementers to tailor the architecture to a country's specific needs. OpenHIE offers reference implementation software for each of these components, but it is possible to use OpenHIE architecture without using this software as the components.

The interoperability layer mediates communications between external PoS applications and the OpenHIE core components, using open standards to transform the communications and data being exchanged into understandable formats. It then routes the information to the appropriate infrastructure service. In this manner, disparate systems that do not share the same design are able to exchange information with one another—the essence of interoperability. This interoperability layer also serves as a single access point for all external applications, a design that streamlines the information-transaction process and simplifies security, since an external system just needs to be authenticated once.

Several community groups openly collaborate and share information about their OpenHIE implementations. All communities are open to anyone who wishes to learn more about OpenHIE components or who is in the process of implementing this architecture. Community members from around the world connect, collaborate on tools, and share experiences, best practices, and technologies in an interactive wiki and frequent virtual meetings. These OpenHIE communities include the following groups:

- **Client Registry Community**: focuses on accurate, reliable, and stable identification and deduplication of individuals; see: wiki.ohie.org/display/SUB/Client+Registry+Community/

- **Health Management Information System Community**: supports the development of standard practices for interoperability between HMIS; see: wiki.ohie.org/display/SUB/Health+Management+Information+System+Community/
- **Facility Registry Community**: supports the creation of a facility registry that meets local requirements and industry standards; see: wiki.ohie.org/display/SUB/Facility+Registry+Community/
- **Health Worker Registry Community**: focuses on open-source standards and applications for health worker registries, as well as methodologies for how health worker registries could integrate the health system; see: wiki.ohie.org/display/SUB/Health+Worker+Registry+Community/
- **Interoperability Layer Community**: focuses on the middleware layer that creates interoperability within the OpenHIE network; see: wiki.ohie.org/display/SUB/Interoperability+Layer+Community/
- **OpenHIE Implementers Network**: discusses problems and experiences implementing OpenHIE components; see: wiki.ohie.org/display/SUB/OpenHIE+Implementers/
- **Shared Health Records Community**: emphasizes knowledge sharing about storage and use of patients' electronic health data; see: wiki.ohie.org/display/SUB/Shared+Health+Record+Community/
- **Terminology Service Community:** focuses on strategies, best practices, and tactics for developing and deploying terminology services that support consistent reporting and aggregation of clinical data; see: wiki.ohie.org/display/SUB/Terminology+Service+Community/

Healthcare Information and Management Systems Society

www.himss.org

The Healthcare Information and Management Systems Society [HIMSS] is a global non-profit organization that aims to improve health systems and outcomes through information technology. HIMMS includes more than 50 000 individuals, 250 non-governmental organizations, and 600 corporate members who collaborate in applying ICT systems and digital tools to improve the quality, safety, and cost-effectiveness of healthcare systems, as well as access to this care. HIMSS helps members define best practices and share resources, tools, and knowledge with one another. HIMSS supports 11 professional communities offering peer-to-peer networking and support:

- Clinical and Business Intelligence Community
- Connected Health Community
- Emerging Professionals Community
- Federal Health Community
- Healthcare Cybersecurity Community
- HIMSS Executive Institute
- HIT User Experience Community
- Innovation Community
- Interoperability and Health Information Exchange Community
- Nursing Informatics Community
- Clinician Community.

Personal Connected Health Alliance

www.pchalliance.org

The Personal Connected Health Alliance [PCHA] is a non-profit organization dedicated to making personal connected health a reality. Made up of technology, medical device, and healthcare industry service providers, PCHA publishes and maintains the CDG, a set of interfaces that allow health data to flow amongst sensors, gateways, and end services in PHDs.[4] The CDG ensure reliable interoperability of PHDs by defining the underlying standards and providing implementation guidelines that add missing features to or narrow the options provided by these standards. The CDG leverages the ISO/IEEE 11073-PHD standards to enable accurate and seamless data transmission.

PCHA employs a testing and certification process to ensure that personal connected health devices are compliant with the CDG. Devices featuring the Continua logo indicate that the device has met CDG conformance requirements, as well as basic interoperability requirements with other CDG-compliant devices. Information regarding the Continua Certified program and PCHA membership can be obtained from PCHA's website.

Asia eHealth Information Network

www.aehin.org

The Asia eHealth Information Network [AeHIN] promotes better use of ICTs within health systems across south and southeast Asia. Through peer-to-peer sharing and learning networks, AeHIN seeks to improve HIS, vital records, and overall digital information flow. It actively promotes best practices and principles that are essential for successful digital health systems and applications. These tenets include interoperability, use of standards within and across countries, strong and sustainable governance, e-health capacity, and monitoring and evaluation.

Twice a month, AeHIN supports the Regional AeHIN Hour, an online learning and sharing call (see: aehin.hingx.org/ITG.TeamFusion.Custom.AeHIN/Home/AehinHour/). AeHIN members learn how e-health, HIS, and civil registration and vital statistics implementations can be improved in the region. Furthermore, members benefit from the AeHIN HingX website (see: aehin.hingx.org), which features reusable tools, guidelines, and personal experiences categorized by health domain. Members can learn about such topics as standards and data exchange. Policy briefs and country case studies are also available.

Global Digital Health Network

https://www.globaldigitalhealthnetwork.org/ The Global Digital Health Network is a global community of practice for digital health that primarily aims to serve low-resource settings and underserved populations. Comprised of more than 2 800 individuals from 104 countries, the network provides a forum for members to collaborate and share knowledge about digital health implementations, including the development and deployment of HIS as well as innovative technologies to improve health services and outcomes. Capacity building, knowledge management, advocacy, and best-practice promotion are some of the network's key activities. It meets monthly and holds an annual forum to facilitate knowledge exchange and networking. The Global Digital Health Network was formerly called the mHealth Working Group.

[4] Personal Connected Health Alliance (n.d.). Continua Design Guidelines. See: www.pchalliance.org/continua-design-guidelines

List of acronyms and abbreviations

A-EMR	Ambulatory electronic medical record
ADSL	Asymmetric digital subscriber line
AeHIN	Asia eHealth Information Network
AI	Artificial intelligence
ANC	Antenatal care
API	Application programming interface
ASHA	Accredited social health activist (India)
ASTM E1238	American Society for Testing and Materials health information standards
BLE	Bluetooth Low Energy
CDG	Continua Design Guidelines
CEN/TC 251	European Committee for Standards Technical Committee health informatics standards
COPD	Chronic obstructive pulmonary disease
CPU	Central processing unit
CR	Client registry (OpenHIE)
CRDM	Collaborative Requirements Development Methodology
CSD	Care Services Discovery standards
DHI	Digital health intervention
DHIS	District Health Information Software (numbers that follow indicate version)
DHP	Digital health platform
DHPH	Digital Health Platform Handbook
DICOM	Digital Imaging and Communications in Medicine
DIG	Planning, Implementation, and Financing Guide for Digital Interventions for Health Programmes, or Digital Interventions Guide in shorthand
DIS	Drug information system
DSA	Data sharing agreement
DSTU	Draft Standard for Trial Use (numbers that follow indicate version)
DURSA	Data Use and Reciprocal Support Agreement
EeHF	Estonian eHealth Foundation
EHR	Electronic health record
EHRS	Electronic Health Record Solution (Canada)

EMR	Electronic medical record
FHIR	Fast Healthcare Interoperability Resources
FR	Facility registry (OpenHIE)
GDPR	General Data Protection Regulation (European Union)
HAPI-FHIR	HL7 application programming interface for FHIR, using Java
HHQ	Health history questionnaire
HIAL	Health Information Access Layer
HIE	Health Information Exchange (Estonia)
HIMSS	Healthcare Information and Management Systems Society
HIPAA	Health Insurance Portability and Accountability Act
HIS	Health information system
HL7	Health Level Seven
HL7 FHIR	Fast Healthcare Interoperability Resources specification developed by Health Level-7 organization
HMIS	Health management information system
HRIS	Human resource information system
HRN	Health record network
HSM	Hardware security module
HWR	Health worker registry (OpenHIE)
ICD	International Classification of Diseases
ICD-10	International Classification of Diseases, 10th revision
ICF	International Classification of Functioning, Disability, and Health
ICHI	International Classification of Health Interventions
ICT	Information and communication technology
IDSP	Integrated Disease Surveillance Programme (India)
IEEE	Institute of Electrical and Electronics Engineers
IEEE-SA	Institute of Electrical and Electronics Engineers Standards Association
IHE	Integrating the Healthcare Enterprise
iHRIS	Integrated Human Resource Information System
IHTSDO	International Health Terminologies Standards Development Organisation
ILR	InterLinked Registry

IoT	Internet of Things
IrDA	Infrared Data Association
ISO	International Organization for Standardization
ISO/IEEE 11073	Set of standards for medical and personal health devices established by the International Organization for Standardization and the Institute of Electrical and Electronics Engineers working group
ITU	International Telecommunication Union
ITU-T	ITU Telecommunication Standardization Sector
IVR	Interactive voice response
LAN	Local area network
LIS	Laboratory information system
LOINC	Logical Observation Identifiers Names and Codes
mACM	Mobile Alert Communication Management
MCTS	Mother and Child Tracking System (India)
MoH	Ministry of Health
NHM	National Health Mission (part of Government of India's Ministry of Health and Family Welfare)
NIC	National Informatics Centre (India)
OAuth	OpenAuthorization
OpenHIE	Open Health Information Exchange
OpenHIM	Open Health Information Mediator
OSI	Open Systems Interconnection model
PACS	Picture archiving and communication system
PAN	Personal area network
PCHA	Personal Connected Health Alliance
PHD	Personal health device
PHR	Personal health record
PHS	Public Health Service (Canada)
PoS	Point of service
RAM	Random access memory
RESTXQ	Representational state transfer-based application programming interface that uses XQuery

RESTful	Representational state transfer
RIS	Radiology information system
SC&C	Smart cities and communities
SCAIP	Social Care Alarm Internet Protocol
SDO	Standards development organizations
SIM	Subscriber identity module
SHR	Shared health record (OpenHIE)
SMART on FHIR	Set of open specifications to integrate Substitutable Medical Apps, Reusable Technology with health ICT systems
SMS	Short Message Service
SNOMED-CT	Systematized Nomenclature of Medicine – Clinical Terms
SOA	Service-oriented architecture
SoC	System-on-a-chip architecture
SSO	Single sign-on
TS	Terminology service (OpenHIE)
UCUM	Unified Code for Units of Measure
UNICEF	United Nations Children's Fund
USB	Universal Serial Bus
USAID	United States Agency for International Development
USSD	Unstructured Supplementary Service Data
WAN	Wide area network
WHO	World Health Organization
WHO-FIC	WHO Family of International Classification
WSDL	Web Service Definition Language
XDS	Direct Save Protocol
XML	Extensible Markup Language
XQuery	XML Query, a query programming language used with XML- or similarly-structured data
X-Road	Secure web-service transport intermediary (Estonia)

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