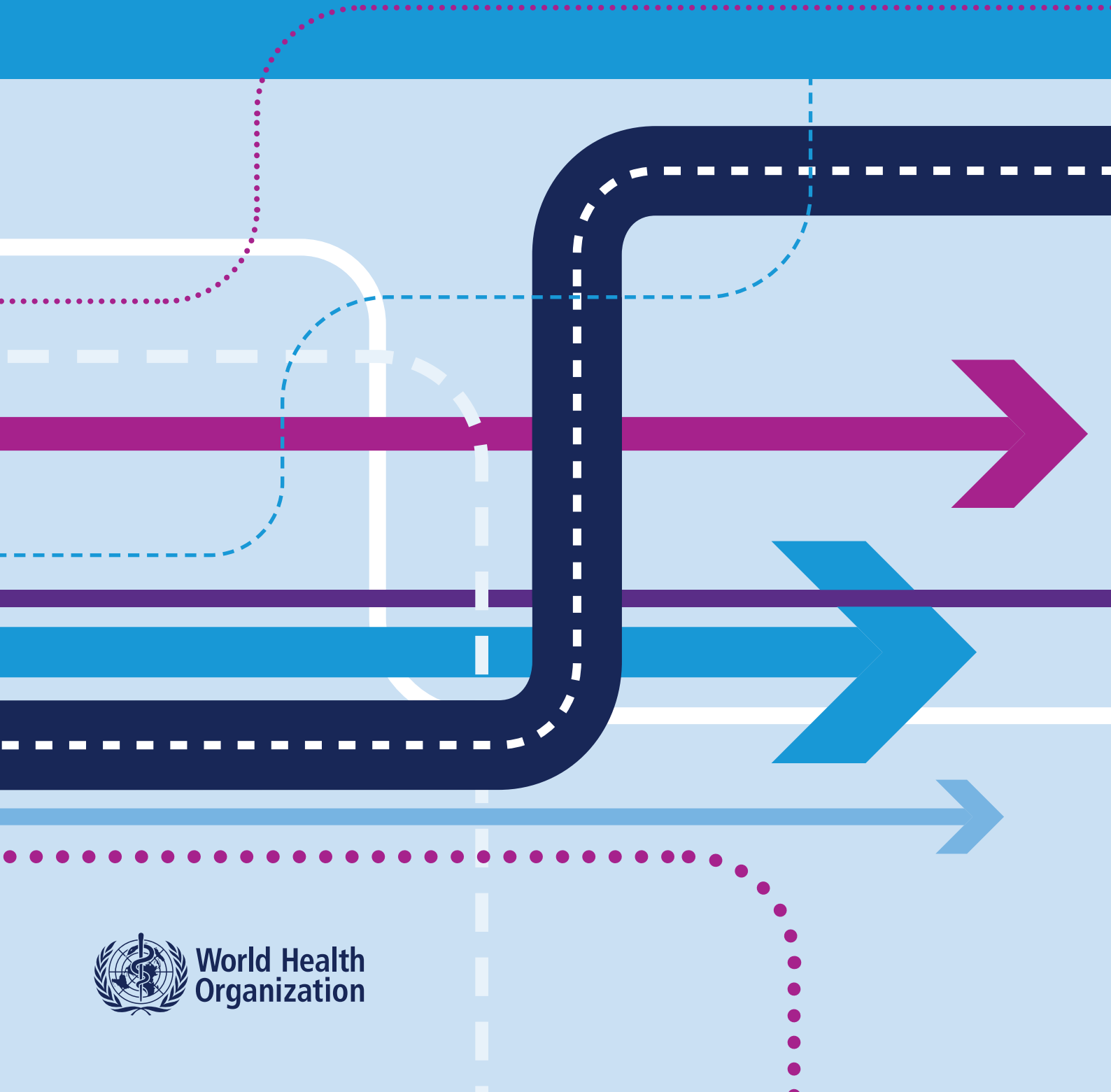
Digital transformation handbook for health supply chain architecture



World Health Organization

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Digital transformation handbook for health supply chain architecture

(SMART Guidelines collection)

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Contents

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Abbreviations and acronyms

DH&I WG	Digital Health and Interoperability Working Group
DHSC	digital health supply chain
DIIG	*Digital Implementation Investment Guide*
eRIS	Electronic Regulatory Information System
ERP	enterprise resource planning
FTE	full-time equivalent
GFPVAN	Global Family Planning Visibility and Analytics Network
GHSC-PSM	Global Health Supply Chain Program–Procurement and Supply Management
HSCIS	health supply chain information system
HTSS	Health Technical Support Services
ICT	information and communications technology
IT	information technology
ITU	International Telecommunication Union
KPI	key performance indicator
MOH	ministry of health
NPC	National Product Catalog
NSCA	National Supply Chain Assessment
OpenHIE	Open Health Information Exchange
QA	quality assurance
RFP	request for proposal
RFQ	request for quotation
SCISMM	Supply Chain Information System Maturity Model
SCSA	Supply Chain Systems Architecture
SMART	Standards-based, Machine-readable, Adaptive, Requirements-based and Testable
TOGAF	The Open Group Architecture Framework
TSS	Target Software Standards
TWG	technical working group
USAID	United States Agency for International Development
WHO	World Health Organization
WMS	warehouse management system

Glossary

deployment	Making a software system available for use beyond testing purposes.
digital health	The systematic application of information and communications technologies, computer science and data to support informed decision-making by individuals, the health workforce and health systems, to strengthen resilience to disease and improve health and wellness *(1, 2)*.
digital health supply chain intervention	An intervention that involves the use of digital technologies to improve the management and operation of health supply chains. It aims to enhance the efficiency and effectiveness of health supply chain processes such as planning, procurement, distribution and warehouse management.
digital transformation	In the health context, using digital technologies to fundamentally change and improve how health services are delivered and accessed across all health programme areas *(3, 4, 5)*. The process involves using innovation, analytics and feedback mechanisms to achieve systems-level changes.
digitalization	In the health context, the process of digitally automating and simplifying processes to streamline individual health programmes and reduce manual efforts for greater efficiency. Digitalization is the second step in digital transformation *(3, 6)*.
digitization	The process of converting and organizing data from manual paper records into a digital format for easier entry, storage and retrieval. Digitization is the initial step in digital transformation *(3, 7)*.
end users	People who will be using the digital systems.
enterprise architecture	A blueprint of business processes, data, systems and technologies that helps planners, software developers and managers design increasingly complex systems to support the workflow and roles of people in a large enterprise such as a health system *(1)*.
features	The characteristics of a system that include look and feel as well as what the system can do (e.g., “order processing” can be a feature of an order management solution).
functional requirements	A description of what the digital system needs to do to support the tasks that make up the business process and address the identified challenges.
functions	Business processes within a system that help the system perform (e.g., “receiving inventory” and “picking inventory” are functions of the “warehousing” feature of a warehouse management system).
health supply chain information system	A paper-based or software tool that supports the management and/or operations of the health supply chain. Such software tools (e.g., for order management or warehouse management) are also commonly referred to as electronic logistics management information systems.
interoperability	The ability of different applications to access, exchange, integrate and use data in a coordinated and consistent manner, through the use of shared application interfaces, value sets, concepts and standards within and across organizational, regional and national boundaries. In the health context, this provides timely, safe and seamless portability of information to help ensure good health outcomes *(1)*.
nonfunctional requirements	A description of how the digital system needs to operate and perform in order to support the tasks that make up the business process.
open-source software	Software with source code that is published and made freely available to the public so anyone can inspect, modify and enhance the code within set guidelines *(8)*. While the source code is open to everyone, the implementation of the software is not necessarily without costs. Open-source software must have a license approved by the Open Source Initiative *(9)*.

open standards	Standards that are documented and made freely available to the public. Open standards are developed, approved and maintained via a collaborative and consensus-driven process. Open standards facilitate interoperability and data exchange and are intended for widespread adoption *(10)*.
order management	The planning, directing, monitoring and controlling of the processes related to customer or requisition orders. Order management includes order promising; order entry; order pick, pack and ship; billing; and reconciliation of the customer account *(11)*.
order management system	A paper-based or software tool that supports the processes for fulfilling requisition orders (e.g., a software tool that supports entry and processing of requisition orders from health facilities to regional or central warehouses to replenish inventory).
organogram	A visual representation of an organization's structure that shows the hierarchy of various roles and reporting relationships.
registry	A governed, authoritative and centralized information system that captures, stores and maintains the unique attributes and identifiers of health facilities, health service users, health products and/or the health workforce using a predefined canonical minimum data set.
SMART Guidelines	The WHO guidelines for developing **S**tandards-based, **M**achine-readable, **A**daptive, **R**equirements-based and **T**estable components for implementing digital health capabilities. The components include interoperability standards, code libraries, algorithms, and technical and operational specifications. The SMART Guidelines provide a five-step pathway to advance the adoption of best clinical and data practices, even if a country is not yet fully digital *(12, 13)*.
stakeholder	In the context of digital health transformation, anyone who is affected by or interested in the consequences of the efforts, including the planning team, end users, beneficiaries and funders.
systems architecture	A technical framework based on a conceptual model that defines how the system should be structured and how its elements should be connected.
total cost of ownership	The resources required to support a digital health intervention throughout its life cycle.
traceability	The ability to trace something. In some cases, it is interpreted as the ability to verify the history, location or application of an item by means of documented identification *(14)*.
use case	An example scenario of how the end user will use a system.
warehouse management system	A computer application that manages and optimizes workflows and the storage of goods within a warehouse. It often interfaces with automated data capture and enterprise resource planning systems *(11)*.

Introduction

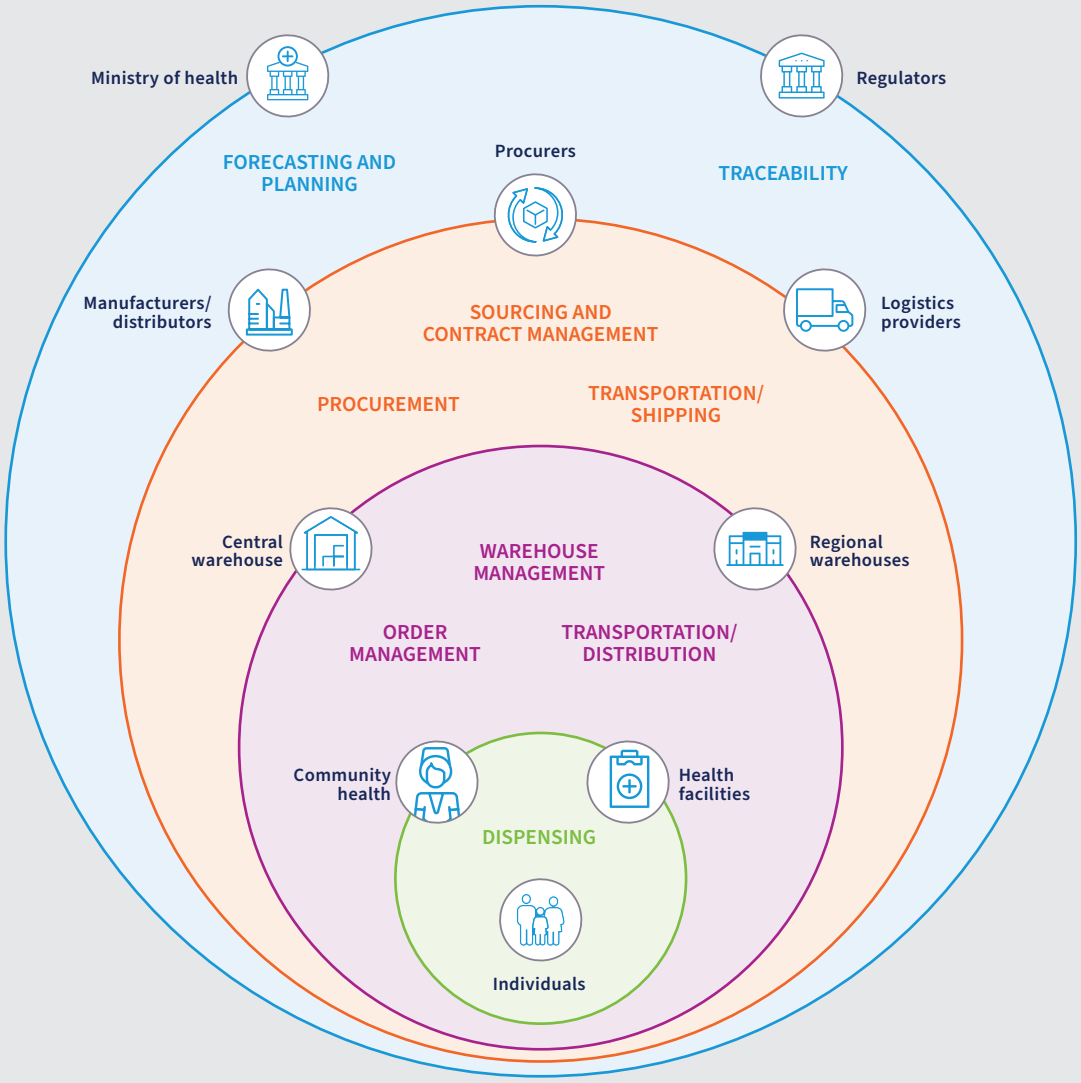
Health supply chain processes, which ensure that medicines and other health products are available for delivery to individuals, are integral to the public health care system. Supply chain processes such as forecasting and planning, sourcing, procurement, order management, warehouse management and dispensing must operate in harmony to facilitate the flow of health products from manufacturers to the individuals who need them.

Because supply chain processes overlap with health processes that take place at the community and facility level, well designed digital health supply chain (DHSC) architectures and information management approaches that encompass the needs of all stakeholders are essential.

Supply chain processes that are enhanced by digital tools, technologies and automation offer numerous advantages not only to organizations, operational staff and health care workers but, most importantly, to the individuals who are at the centre of these processes (Fig. 1).

Fig. 1

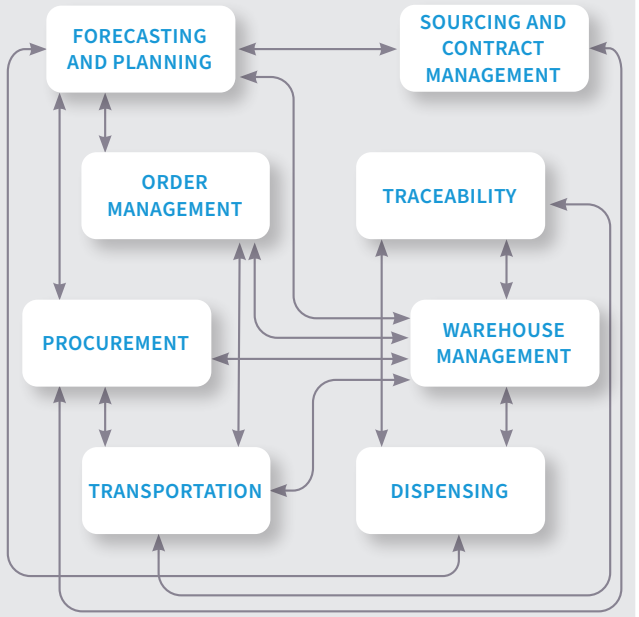
Fig 1. Public health supply chain partners and processes



Vital information such as order details, shipping details and inventory data must be exchanged among partners in the supply chain to enable seamless movement of health products. Fig. 2 depicts the flow of information across supply chain processes to support the streamlined delivery of health products. As supply chains become increasingly complex, involving diverse global and local partners overseeing distinct processes, comprehensive digital transformation becomes essential.

Fig. 2

Fig 2. Information flow across supply chain processes



Supply chain processes that rely on manual data entry and siloed systems pose numerous challenges that hinder efficiency and effectiveness.

- → Manual processes for inventory management, ordering and distribution are prone to errors, leading to stockouts and/or overstocking of essential medical supplies. Stockouts, in turn, affect individuals' access to health services.
- → Lack of real-time visibility into inventory levels and demand patterns makes it difficult to anticipate and respond promptly to changing health care needs, particularly during emergencies or outbreaks.
- → Manual recordkeeping increases administrative burdens and can result in delays in tracking product recalls or expiration dates, risking patient safety.
- → Collaboration among stakeholders such as health care providers, purchasers, manufacturers and distributors is limited, hindering coordination and exacerbating supply chain inefficiencies.

Overall, the absence of a holistic digital ecosystem to manage the health supply chain undermines resilience, agility and the ability to deliver critical health care services to communities.

Digital health and the DHSC

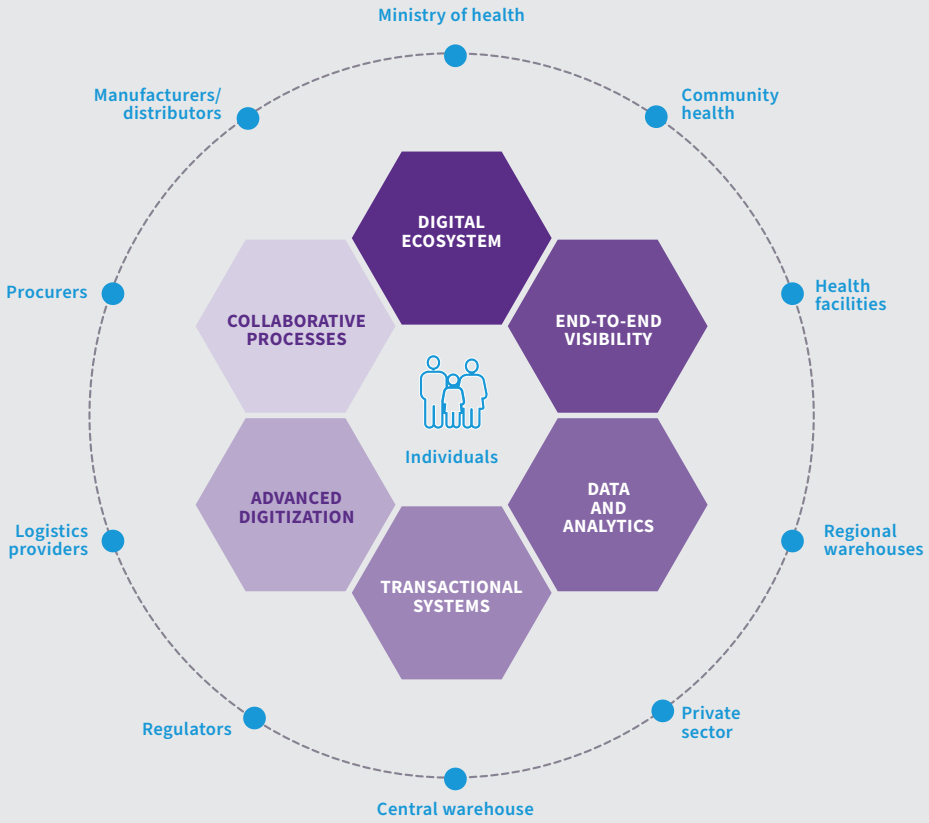
Within WHO's *Global Strategy on Digital Health 2020–2025 (15)*, *digital health* refers to "the field of knowledge and practice associated with the development and use of digital technologies to improve health." *Digital health supply chain* refers to the knowledge and practice of adopting digital technologies to improve health supply chains and enable the delivery of quality-assured health products to individuals when and where they need them (Fig. 3).[1]

Digital technologies improve supply chain efficiency by automating otherwise manual tasks in areas such as planning, procurement, order processing and management, warehouse management, inventory allocation and route optimization. This automation reduces errors, streamlines processes and frees up staff time for more strategic tasks. It empowers individuals and health care organizations by providing timely data and the ability to swiftly adapt to evolving changes in the supply chain. It facilitates collaborative processes and interoperability across systems – including supply chain, health management and regulatory processes. It also provides real-time visibility into inventory levels, shipment statuses and actual consumption, enabling improved decision-making and responsiveness to changes in demand or supply.

[1] DHSC interventions for health management and support personnel are described in WHO's corresponding document *Classification of Digital Interventions, Services and Applications in Health* at https://www.who.int/publications/i/item/9789240081949, specifically "3.2: Supply chain management."

Fig. 3

Fig 3. Digital health supply chain



What this handbook covers

Several low- and middle-income countries have undertaken initiatives to digitalize their health supply chain, but until now, no comprehensive and holistic approach has been available to guide them in implementing this transformation. This handbook offers that guidance to countries and helps them formulate a strategy and plan a multistep, holistic implementation of scalable and sustainable components of a DHSC architecture, including approaches they can adapt to their specific context. It does not delve into the intricacies of supply chain processes or the specific functional specifications of various health supply chain information systems (HSCISs), but it points to some helpful resources on those topics.

This handbook assumes that the country has conducted supply chain process and maturity assessments and has adopted an appropriate supply chain design. Improvements to supply chain performance or design are prerequisites to proceeding with the steps delineated in this handbook.

This handbook can be a useful resource in the following scenarios:

- when defining and implementing a digital transformation strategy and architecture for the health supply chain that aligns with the national health supply chain strategy and other relevant strategies;
- when seeking to upgrade or make interoperable existing DHSC solutions in a holistic manner;
- when seeking to enhance health supply chain data availability to support timely monitoring of supply chain exceptions such as inventory shortages and product expiries or diversions;
- when seeking to coordinate health supply chain digital transformation initiatives that are duplicative and burdensome to operational staff and health care workers (for example, when different implementation teams or organizations deploy supply chain systems such as logistics management information systems and facility inventory management systems that have overlapping functions, requiring staff to enter the same data in multiple systems); and
- when paper-based systems are being replaced with enhanced technology, including subnational systems that were not included in a previous digital system implementation.

How to use this handbook

This handbook provides a stepwise approach to digitalizing the health supply chain, as depicted in Fig. 4.

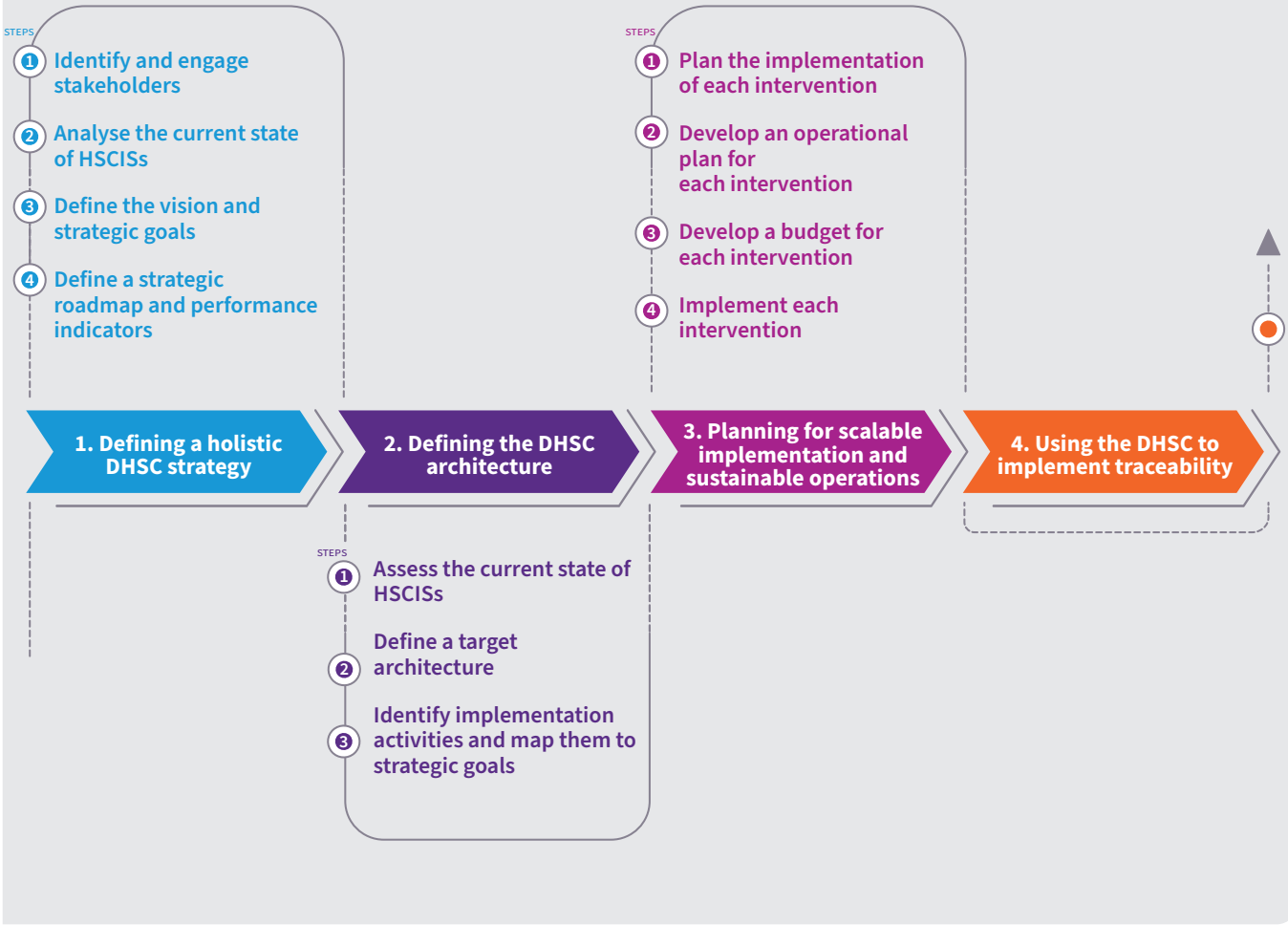
- **Chapter 1** provides guidance on defining a holistic vision, strategic goals and objectives for a DHSC that aligns with the country's strategic priorities for information technology (IT) and digital health.
- **Chapter 2** outlines approaches to defining the DHSC architecture, which will serve as the blueprint for the various supply chain system interventions.
- **Chapter 3** offers guidance on implementing the DHSC in a sustainable and scalable manner, taking into account human resource and financial factors.
- **Chapter 4** explores how the DHSC can support pharmaceutical traceability to enhance patient safety.
- **Chapter 5** presents examples from countries at various stages of implementing a DHSC, to illustrate some of the concepts presented in the preceding chapters.

BEFORE USING THIS HANDBOOK

Familiarity with resources such as the *Digital Implementation Investment Guide* (DIIG) *(1)*, the Supply Chain Information System Maturity Model (SCISMM) *(16)*, the OpenHIE framework *(17)* and The Open Group Architecture Framework (TOGAF®) *(18)* is highly recommended before using this handbook.

Fig. 4

Fig 4. The stepwise approach used in this handbook



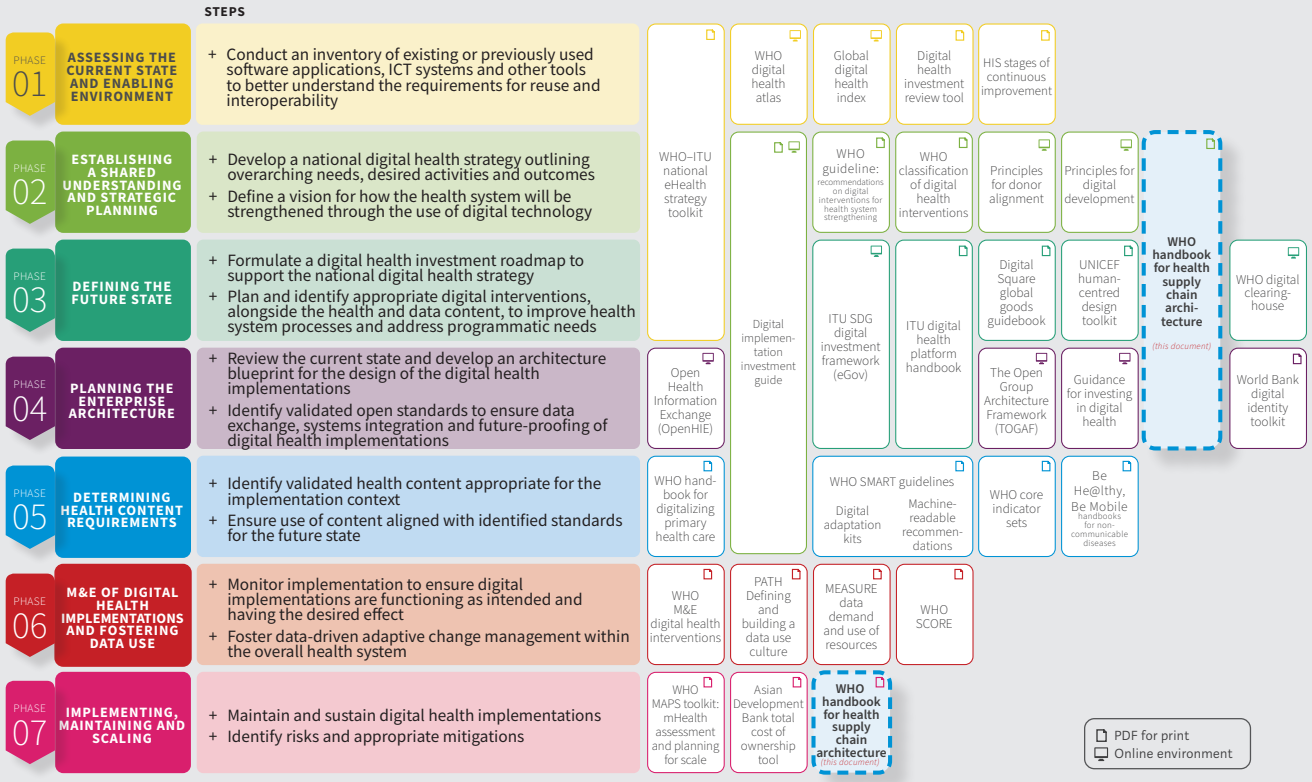
Alignment with the DIIG

This handbook uses the framework and approaches set forth in the DIIG, which helps governments and technical partners plan a digital health implementation that focuses on one or more health programmes to support national health system goals. This handbook complements the DIIG by providing guidance on implementing a DHSC to ensure timely availability of quality-assured health products.

Fig. 5 outlines the phases and steps involved in implementing a digital health enterprise and shows how this handbook complements other resources.

Fig. 5

Fig 5. DIIG process for planning and implementing a digital health enterprise



ICT = information and communications technology
ITU = International Telecommunication Union
M&E = monitoring and evaluation
SMART = Standards-based, Machine-readable, Adaptive, Requirements-based and Testable

Source: adapted from the 2020 *WHO Digital Implementation Investment Guide (1).*

Alignment with WHO's SMART Guidelines

This handbook aligns with WHO's SMART Guidelines initiative by offering guidance on DHSC implementations that synchronize with digital health initiatives. The SMART Guidelines call for **S**tandards-based, **M**achine-readable, **A**daptive, **R**equirements-based and **T**estable components that help systematize digital health capabilities and accelerate the consistent delivery of lifesaving interventions.

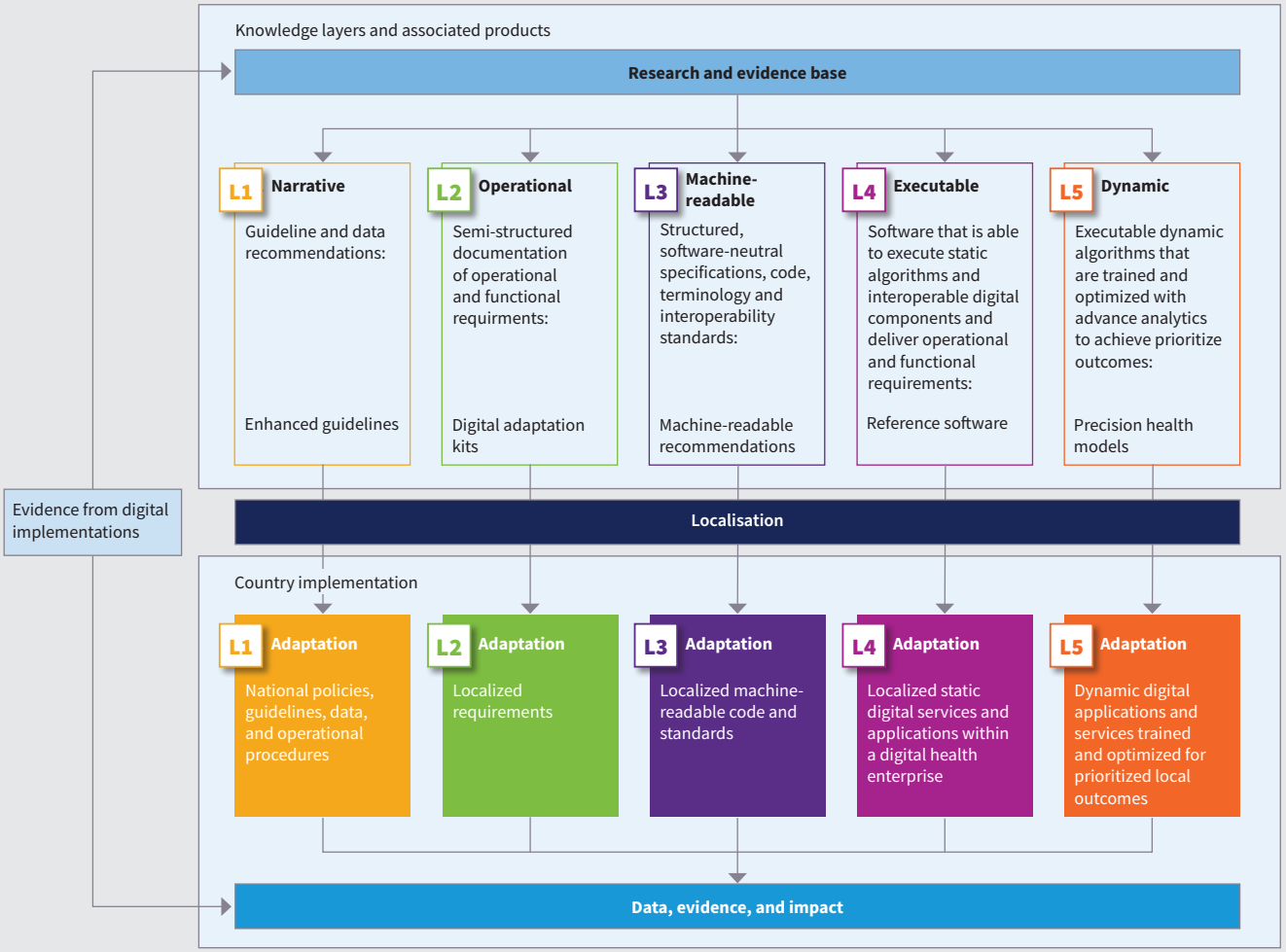
The SMART Guidelines offer a step-by-step pathway that builds five progressive knowledge layers and associated products, to advance the adoption of best clinical and data practices:

- → L1 Narrative: enhanced guidelines and data recommendations
- → L2 Operational: digital adaptation kits
- → L3 Machine-readable: machine-readable recommendations
- → L4 Executable: reference applications and services
- → L5 Dynamic: precision health models.

These steps help developers translate recommendations into specifications and standards, help technologists integrate recommendations into updatable digital systems and help countries localize, make interoperable, institutionalize and update digital systems consistent with evidence-based recommendations *(13)*. Each layer can be adapted and localized within the country context (Fig. 6).

Fig. 6

Fig 6. WHO SMART Guidelines approach

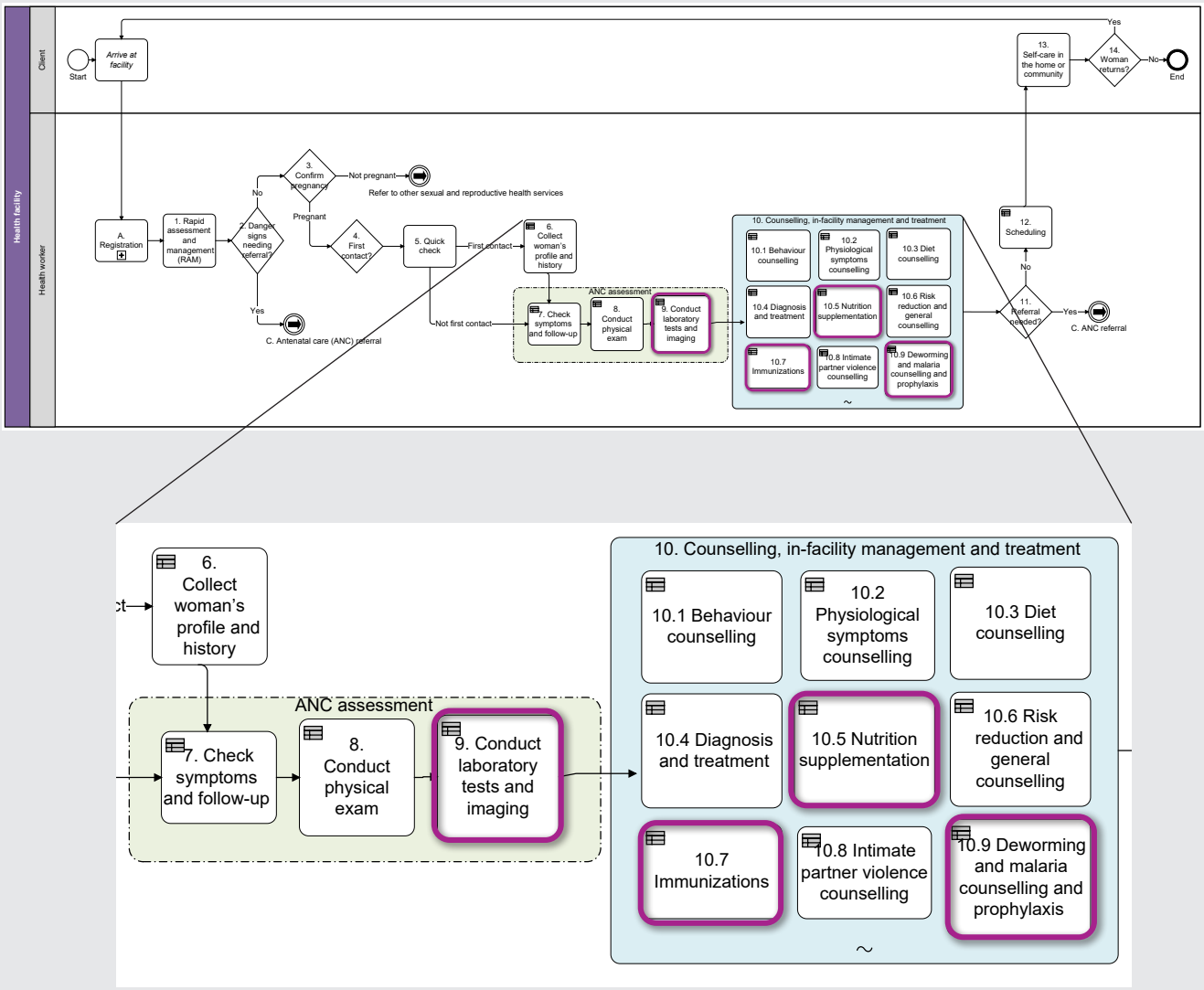


Source: adapted from *WHO SMART Guidelines (12)*.

This handbook aligns with the L1 Narrative layer by providing guidelines for digital transformation of health supply chains. The SMART Guidelines focus primarily on digital capabilities for health care, but they acknowledge the importance of digital transformation of the health supply chain. In particular, they define recommended public health and clinical business processes that use structured, task-based workflows. Many of the clinical health information needs within these tasks intersect with the information managed within the supply chain (Fig. 7).

Fig. 7

Fig 7. Sample workflow for an antenatal care business, with connections to the supply chain highlighted



Source: adapted from the 2021 WHO *Digital Adaptation Kit for Antenatal Care (20)*.

How this handbook was developed

This handbook reflects experiences shared by and feedback from a variety of experts compiled through the following:

- A series of in-country and virtual consultations and feedback sessions with stakeholders who have supported DHSC implementations in countries including Ethiopia, Malawi and Rwanda. These consultations and sessions gathered insights on the role of leadership and governance in the successful digital transformation of the health supply chain, approaches adopted in developing holistic DHSC strategies and architectures and lessons learned from ongoing transformation efforts.

- → Meetings of a DHSC small working group created under the Digital Health and Interoperability Working Group (DH&I WG) *(2)*, a volunteer community of practice dedicated to strengthening country health systems and outcomes through the appropriate and responsible use of digital information technologies. DH&I WG has more than 250 members representing governments, donors, multilateral organizations, academia, the private sector and nongovernmental organizations. The small working group met monthly to review the handbook and provide input as individual experts on its structure and content.

Desk reviews of documents relevant to country health supply chain digitalization also contributed context for this handbook. These documents included digital health strategy, DHSC strategy and architecture documents from countries such as Australia, Malawi and Rwanda; guidance documents on supply chain software standards; and information system resources such as SCISMM *(16)* and the Target Software Standards (TSS) *(19)*. The desk reviews aimed to identify resources that offered insights into defining architectural approaches for the public health and supply chain sectors. The documents were selected based on their relevance, credibility, and potential to contribute valuable perspectives on best practices and innovative strategies. The outcomes of the desk reviews were evaluated by the DHSC small working group to ensure alignment with the public health sector and the context of low- and middle-income countries and to assess the applicability of the identified approaches.

Insights and templates were also drawn from practical experiences in different countries, including Ethiopia, Rwanda and Malawi. Examples from these three countries are included in this handbook because they have implemented a comprehensive architectural approach to health supply chain digitalization, including the development of a strategic framework.

The steps outlined in this handbook are informed by the Principles for Digital Development (Annex 1). Some methodologies and templates have been adapted from prominent sources such as the DIIG, the *National eHealth Strategy Toolkit (19)* from WHO and the International Telecommunication Union (ITU), SCISMM and the OpenHIE framework *(17)*.

Who this handbook is for

This handbook is for countries, organizations and teams that want to plan and implement digital transformation of the public health supply chain. The first four chapters provide guidance on the different phases and areas of digital transformation, as summarized in Table 1.

Table 1. Summary of chapters 1–4

	Illustrative target organizations	Illustrative target user teams and roles	Purpose of the chapter
Chapter 1. **Defining a holistic DHSC strategy**	» Ministry of health (MOH) » Central warehouse	» Senior management/leaders » Chief digital officers » Supply chain leaders	To help define a vision and strategic goals to guide DHSC implementation
Chapter 2. **Defining the DHSC architecture**	» MOH » Central warehouse	» Chief digital officers » Technical/system/enterprise architects	To help define a DHSC architecture that can guide and help coordinate all digital transformation activities
Chapter 3. **Planning for scalable implementation and sustainable operations**	» MOH » Central warehouse » Donors and funding partners » Implementing partners	» Chief digital officers » Project sponsors » Project managers » Technical/system/enterprise architects and team » Supply chain/operational leaders and team	To provide guidance on factors such as governance, human resource capacity and infrastructure in developing a viable implementation plan for each DHSC intervention
Chapter 4. **Using the DHSC to implement traceability**	» MOH » Central warehouse » Donors and funding partners » Regulatory authority » Implementing partners	» Chief digital officers » Technical/system/enterprise architects and team » Supply chain/operational leaders and team » Regulatory/market surveillance and control/vigilance teams	To help implement medical product traceability and verification features using DHSC components

Chapter 1

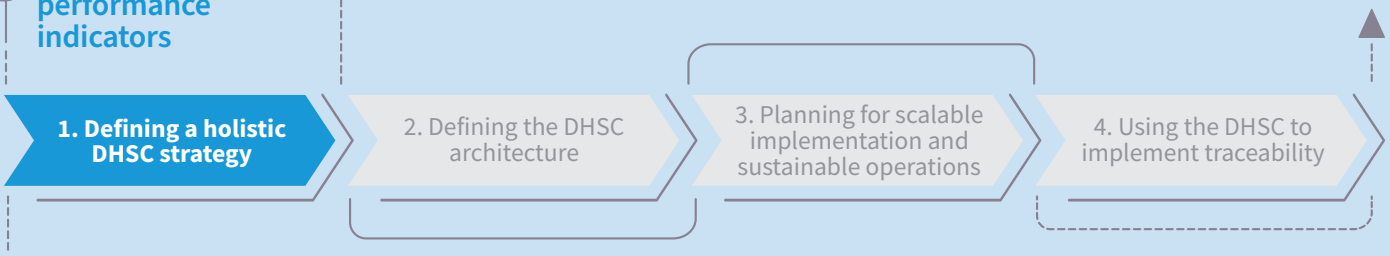
Defining a holistic DHSC strategy

Step 1 Identify and engage stakeholders

Step 2 Analyse the current state of HSCISs

Step 3 Define the vision and strategic goals and objectives

Step 4 Define a strategic roadmap and performance indicators



Guiding principles

The following principles, informed by the Principles for Digital Development (Annex 1), can guide the development of the DHSC vision and strategic goals.

- → Align with a relevant national priority (such as patient safety, universal health care, or access to medicines and health products).
- → Take a user-centred approach.
- → Strive for an ecosystem of interoperability and collaboration.
- → Continuously engage all stakeholders.
- → Use, reuse and enhance existing resources, assets and capabilities.
- → Aim for scalability and sustainability.

Outputs

The steps outlined in this chapter will result in the following outputs:

- **DHSC vision;**
- **DHSC strategic goals;**
- **DHSC strategic objectives; and**
- **DHSC strategic roadmap.**

Defining a holistic DHSC strategy

Implementation of tools and technologies to digitally transform the health supply chain cannot happen in isolation. The DHSC strategy should align closely with the country's IT strategy, health strategy, medicines and health product strategies, supply chain strategy and digital health strategy. National priorities should be the driving force behind DHSC implementation initiatives.

Why is a strategy necessary?

A holistic DHSC strategy is essential to achieving comprehensive digital transformation of the health supply chain. It can offer a clear vision and direction and ensure alignment across all national digital transformation initiatives (Fig. 8) *(21)*. Such initiatives may include the following:

- → national health strategy, which establishes a vision and priorities to address the most pressing health care challenges and improve health care for the population;
- → national medicines and health product policies, which aim to increase access to and use of high-quality, affordable medicines and health products;
- → national health supply chain strategy, which supplements the health strategy to specifically address the supply chain management of products that support the country's health care system;
- → national digital or IT strategy, which defines the vision for the country's IT adoption and offers guidance for progress in IT infrastructure and software deployments and standards;
- → national digital health (eHealth) strategy, which complements the health strategy by establishing a vision to digitize health data and digitalize health care processes, aiming to empower health workers through digital tools and technologies, improve data availability and promote interoperability;
- → national DHSC strategy, which complements both the health supply chain strategy and the digital health strategy establishing the vision and priorities to digitalize the supply chain aspects of the health care system and complementing the digital health and health supply chain strategies, or becoming an integral component of either strategy; and
- → other overlapping strategies such as a national pharmaceutical traceability strategy, which could rely on the DHSC strategy for digital infrastructure and data to enable tracking and tracing of commodities.

A strategy sets out measurable objectives and timelines for achieving them. A well defined DHSC strategy that thoroughly accounts for future growth requirements can ensure scalable and sustainable digital transformation of the health supply chain. Clear and quantifiable strategic objectives are instrumental in identifying and allocating the necessary resources, as well as monitoring progress towards the established vision.

Fig. 8

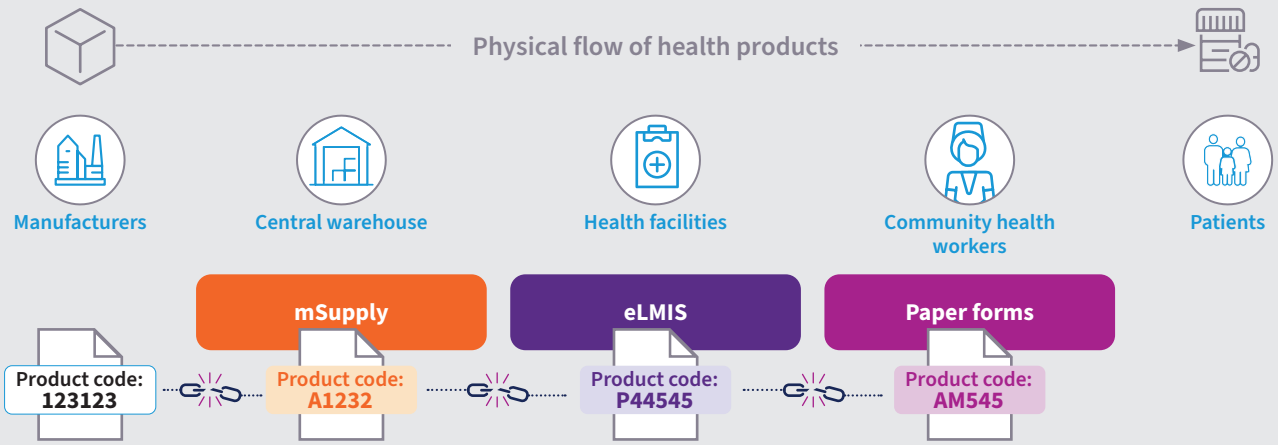
Fig 8. Alignment of national strategies

The risks of forgoing a guiding DHSC vision and strategy are significant and include the following:

- → fragmented or disconnected implementation of digital tools and technologies for the supply chain, resulting in noninteroperable processes and systems;
  - » Example: The central warehouse's warehouse management system (WMS) is implemented without considering the electronic logistics management information system used by downstream facilities. This affects the ability of downstream facilities to send stock replenishment requests or orders to the central warehouse electronically, which ultimately affects process and product traceability.
- → lack of interoperable supply chain systems, resulting in time-consuming manual collection of data for supply chain analysis, forecasting and supply planning;
  - » Example: The central warehouse's WMS uses formats for data elements (such as orders and inventory) that differ from those used by the downstream facilities' electronic logistics management information system. This means manual effort will be needed to collect and combine data for analysis.
- → inconsistent application of product nomenclature;
  - » Example: Different systems across different supply chain levels do not follow national or global standards to identify, represent and process health products or aggregate and analyse data, making it difficult to identify potential stockouts or products that are about to expire (Fig. 9).
- → fragmented systems that affect the visibility of the supply chain and the ability to address exceptions such as stockouts, product expiries and product recalls in a timely manner;
- → future effort and cost if systems need to be redesigned, modified or repurposed to align with health and other systems;
- → nonscalable supply chain systems, which require additional cost to enhance or replace to provide needed processes, functionalities and data;
- → digital investments that do not provide tangible benefits to organizations or, more importantly, to individuals; and
- → multiple overlapping technology implementations that result in burdensome duplicate processes for supply chain staff and health workers and redundant maintenance costs.

Fig. 9

Fig 9. Inconsistent use of standardized product nomenclature across the supply chain



The following sections describe five steps to developing a DHSC vision, strategic goals and measurable objectives, including key activities and outputs, potential risks and mitigation strategies, and best practices.

- → Step 1. Identify and engage all relevant stakeholders.
- → Step 2. Analyse the current state of HSCISs.
- → Step 3. Define the DHSC vision and strategic goals.
- → Step 4. Define a strategic roadmap and performance indicators.

Step 1 Identify and engage all relevant stakeholders

Identifying and engaging all relevant stakeholders involves recognizing everyone who has an interest or role in the DHSC implementation and actively involving them in the process. This ensures that diverse perspectives are considered, fosters collaboration and gains support for successful DHSC outcomes.

INPUTS

- National health strategy and priorities (e.g., patient safety, universal health access, availability of medicines and health products)
- Organograms of organizations such as the MOH, regulatory authority and central warehouse (to engage necessary teams and staff)

TASKS

1. Identify focal points from all stakeholder organizations (including the MOH, regulatory authority, IT authority, central and regional warehouses, health facilities, implementation partners and funders) whose input will be vital in defining the vision and strategic goals.
2. Identify relevant managerial and technical staff from stakeholder organizations who can provide inputs.
3. Define a stakeholder matrix to clearly establish roles and responsibilities.
4. Establish a technical working group (TWG) and a steering committee to help facilitate analysis and development of the vision, strategic goals and architecture. The TWG should support the overall governance and planning of DHSC implementation activities, and the steering committee should provide leadership and oversight for all implementation activities.

OUTPUTS

- DHSC stakeholder matrix
- DHSC steering committee terms of reference
- DHSC TWG terms of reference

BEST PRACTICES

- Secure upfront buy-in and support from key senior leaders within the MOH who will champion the cause. This will ensure continuity of ownership over digital transformation initiatives. Key donors could support the process of onboarding champions.
- If a TWG already exists for digital health, create a task force for DHSC within that TWG rather than creating a new TWG. This task force can focus on digital and supply chain aspects of public health.

Potential risks	Mitigation strategies
Lack of engagement and participation from identified stakeholders	» Under the leadership of the MOH, establish a steering committee and a TWG and schedule regular meetings. » Identify and enlist a DHSC sponsor (such as a senior MOH leader). » Use the steering committee structure shown in Annex 2.
Unclear approval and decision-making process	Have the TWG establish a governance process to review and approve DHSC initiatives.
Relevant stakeholders and/or decision-makers excluded from the TWG or steering committee	Determine appropriate participation in the TWG or steering committee not only by using organograms but also including all relevant public health and health supply chain partners (e.g., donor organizations, implementing partners and MOH health programme teams) in the initial meetings. Also, develop an agreed-upon list of stakeholders to be excluded from the initial meetings.

Step 2 Analyse the current state of HSCISs

Analysing the current state to identify digital transformation priorities involves evaluating existing processes, capabilities, supply chain challenges and identified priorities to pinpoint areas where DHSC can have the most significant impact. This step helps prioritize investments and initiatives that will drive efficiency, enhance service delivery, and support long-term strategic goals.

INPUTS

- National health strategy and priorities (e.g., patient safety, universal health care, availability of medicines and health products)
- National health supply chain assessments
- Identified improvements based on supply chain assessments
- Details on the national supply chain and digital health and health product traceability systems, if available
- Supply chain improvements and any associated digital achievements

TASKS

1. Identify health supply chain challenges and problems and digitalization needs that align with digital health, the national supply chain strategy/vision and the medicines and health product traceability strategy needs and priorities. Include challenges from the perspective of end users such as supply chain leaders, operational staff, health care workers and pharmacists who support dispensing and patients.
2. Prioritize challenges, problems and needs that should be addressed within a defined time frame (e.g., one year, three years or five years).

OUTPUTS

- Health supply chain digital transformation priorities

RESOURCES

National Supply Chain Assessment (NSCA) Toolkit (22)

Template for prioritizing DHSC challenges (Annex 3)

Illustrative template that maps today's challenges to future outcomes (Annex 4)

BEST PRACTICE

- To ensure a comprehensive assessment of the current health supply chain, consider all factors that affect the health supply chain, such as stakeholders, human resource capacity, infrastructure, political priorities, technology maturity and maturity of processes (including regulatory and insurance).

Potential risks	Mitigation strategies
Misalignment of technical and political priorities	» Establish connections between political and technical priorities by identifying the mutual benefits of pursuing technical priorities. » Promote engagement and dialogue between technical experts and political leaders and communicate critical health supply chain challenges and their effects on the country. » Have technical experts and leaders convey the advantages of digital transformation to senior political leaders in advocacy sessions, emphasizing the alignment of technical priorities with their political goals.
Lack of relevant inputs (e.g., *NSCA Toolkit*, national supply chain strategy or national digital health strategy) to inform data-driven decisions, leading to arbitrary priority setting	» Conduct detailed assessments of the health supply chain and its systems using tools such as the *NSCA Toolkit (22)* and SCISMM *(16)*. » Use outputs from such assessments as key inputs for the DHSC initiative.

Step 3 Define the DHSC vision and strategic goals and objectives

The DHSC vision provides a guiding beacon by summarizing the ideal future state of health supply chain digitalization and how to achieve it. Strategic goals guide the country's actions and decisions to achieve the vision. They translate to strategic objectives that are specific, measurable, achievable, relevant and time-bound. The goals should link to the DHSC implementation activities.

INPUTS

- National supply chain strategy
- National health strategy
- National digital health strategy
- National medicines and health product policies
- National IT strategy
- Health supply chain digital transformation priorities

TASKS

1. Identify solutions that will address the identified challenges. Include the end-user perspectives by considering factors such as feasibility and ease of use.
2. Define realistic strategic goals that will help achieve the identified solutions within a reasonable timeframe. Each strategic goal may have its own timeline, depending on its priority.
3. Define strategic objectives for each goal. These will inform the DHSC architecture and link to implementation activities. (See Fig. 10 for examples of strategic objectives.)
4. Define an overarching DHSC vision that aligns with existing national strategies and provides a sustainable path to comprehensively addressing the identified strategic priorities within a reasonable timeframe. (Consider a timeline for the strategy, perhaps five years, based on the breadth and depth of implementation efforts.)

OUTPUTS

- DHSC transformation vision
- DHSC strategic goals
- DHSC strategic objectives

BEST PRACTICES

- Identify and engage key stakeholders, including management and technical personnel, who can help define the DHSC vision and goals.
- Conduct a visioning workshop to engage stakeholders and better manage their involvement. Apply the "Design with people" principle in the workshop, using methodologies such as human-centred design (as described at https://www.hcd4health.org/resources).

Potential risks	Mitigation strategies
Dependence on senior leaders for key decisions could delay the process of approving and endorsing the strategy.	» Keep the stakeholder matrix updated and implement appropriate delegation plans for decision-making if primary decision-makers are not available. » Identify the alternate focal points or decision-makers.

Step 4 Define a strategic roadmap and performance indicators

A strategic roadmap for DHSC sets out timelines and milestones for achieving goals related to digitalizing the health supply chain. It serves as a guiding framework for the country, helping it stay focused on strategic objectives, allocate resources efficiently and track progress effectively.

INPUTS

- DHSC strategic goals
- DHSC strategic objectives
- Timelines of other initiatives and priorities (e.g., digital strategy, IT strategy, supply chain strategy)

TASKS

1. Define a strategic roadmap that outlines the high-level timeline for achieving the strategic goals and objectives.
2. Define performance indicators for all strategic objectives, to measure progress and effectiveness.

OUTPUTS

- DHSC strategic roadmap
- Performance indicators

BEST PRACTICE

- Capture baseline performance for comparison with improvements after implementation and to help assess return on investment, value and impact.

Potential risks	Mitigation strategies
No dedicated staff to develop and monitor performance indicators	» Use existing operational staff to define indicators using existing resources such as the NSCA key performance indicators (KPIs) *(22)*. » Incorporate the identified KPIs into ongoing operational processes and workflows (where feasible) to minimize manual data collection and analysis.
Funding gaps to advance strategic goals	» Adopt a phased approach to achieving the goals. Define phases that are manageable from a funding and capacity perspective. » Engage and collaborate with partners and donors to identify funding opportunities. » Temporarily reduce the scope of specific lower-priority initiatives until additional funds are available.
Available funding does not align with the established timeline	» Develop the roadmap iteratively in close collaboration with funding partners to incorporate their feedback and ensure alignment.

Progress check

The steps outlined in this chapter will result in the following outputs (Fig. 10):

- DHSC vision
- DHSC strategic goals
- DHSC strategic objectives
- DHSC strategic roadmap.

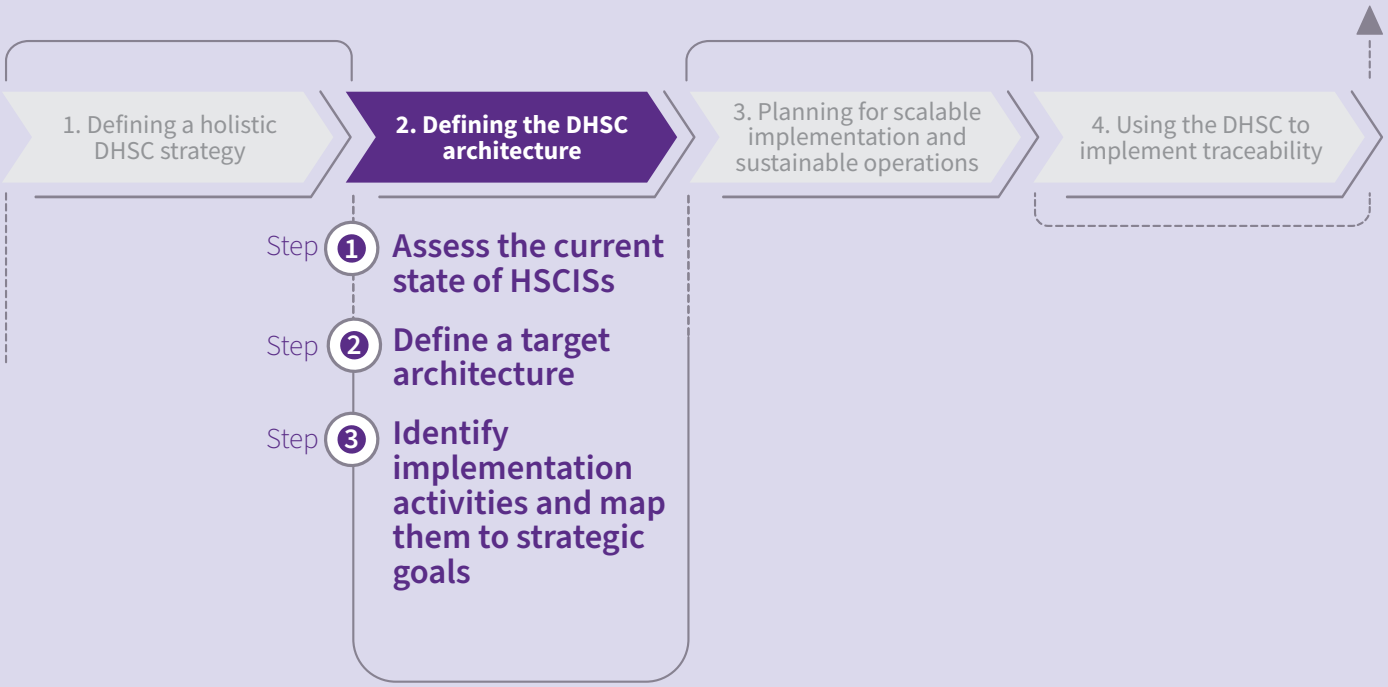
Fig. 10

Fig 10. Example of outputs from this chapter

Vision	Consistent and timely access to quality medicines and medical products for the population, through seamless supply chain enabled by technologies that provide efficient tools for providers					
Strategic goals	1. Implement system-driven processes to provide timely access to quality data		2. Achieve interoperability of systems to enable effortless exchange of data		3. Enable traceability of all health products to ensure patient safety	
Strategic objectives	Automate 80% of central warehouse operations	Automate receiving and dispensing in 75% of health facilities	Standardize product, facility, and other master data	Deploy interop layer and integrate central and regional HSCISs	Deploy a data warehouse to aggregate supply chain data	Enable national-level batch traceability
Strategic roadmap	Year 1: Digitalization of central warehouse	Year 2: Digitalization of health facilities	Year 2: Data standardization	Year 3: System integrations	Year 3: Data aggregation	Year 4: Batch traceability

Chapter 2

Defining the DHSC architecture



Guiding principles

The following principles, informed by the Principles for Digital Development (Annex 1), can guide the development of the DHSC architecture.

- → Engage key stakeholders throughout the process to gain buy-in, understand diverse perspectives and ensure that activities meet the needs of all parts of the health supply chain.
- → Align with other architectures such as the country's digital health architecture and IT architecture.
- → Define an architecture with system components aimed at improving the end-user experience, ensuring operational efficiency, and delivering high-quality services to individuals.
- → Strive for an ecosystem of cross-functional collaboration and interoperability.
- → Use, reuse and enhance existing resources, assets and capabilities.
- → Ensure that the architecture can scale to accommodate future adaptations and adjustments in response to evolving needs and emerging technology trends.
- → Incorporate inclusive architecture and technology approaches that consider infrastructure challenges such as unreliable network connectivity in remote supply chain locations.
- → Adopt open standards and open-source tools wherever feasible.

Outputs

The steps outlined in this chapter will result in the following outputs:

- **current state of HSCISs;**
- **future-state DHSC architecture;**
- **list of DHSC implementation activities mapped to strategic goals; and**
- **high-level roadmap of DHSC implementations.**

Defining the DHSC architecture

The application architecture, which is a component of the broader enterprise architecture, serves as a blueprint for the core systems and applications that are the building blocks of a DHSC. The architecture should comprehensively support all the supply chain functions, their data requirements and the need for interoperability between not only various supply chain functions but also between the entire ecosystem and other digital health systems (including health financing and insurance systems and regulatory systems). The DHSC architecture should align with the priorities of the country's information and communications technology (ICT) architecture and the digital health architecture.

Is a DHSC architecture necessary?

The health supply chain comprises several business processes that ensure the availability of health products to individuals. Forecasting and supply planning processes ensure adequate supply to meet demand. Procurement and distribution processes ensure that medicines and health products are sourced and delivered to the right locations and are available to individuals when needed. Warehouse management processes support receiving, storage and management of inventory.

Health supply chains should be able to quickly respond to exceptions such as stockouts and quality issues like product recalls. More importantly, they should support patient safety by ensuring that the products dispensed to and consumed by individuals are quality assured and are not falsified. Processes and supporting systems need to operate together by exchanging data to ensure efficient and effective delivery of health products to individuals.

At the national level, the DHSC architecture will define the required functional and technical capabilities in supply chain systems to support forecasting and supply planning, procurement, order management, warehouse management and all other supply chain functions. At the subnational level, the architectural components will provide capabilities for requisitioning, inventory management, dispensing and other last-mile supply chain functions. These system capabilities will facilitate system-driven transactions, reducing manual data entry and delivering high-quality, real-time data. The DHSC architecture thus provides a holistic blueprint of all required systems and capabilities across all supply chain levels.

The DHSC architecture outlines how the systems will interoperate and exchange data. It provides the necessary foundation, standards and digital components for the country to achieve the following (Fig. 11):

- → timely visibility of the end-to-end health supply chain, enabling supply chain leaders to make informed decisions to deliver health products to individuals when and where they need them; and
- → the ability to track, trace and verify health products, enabling supply chain leaders to ensure that quality-assured products are delivered to individuals and to mitigate quality issues swiftly.

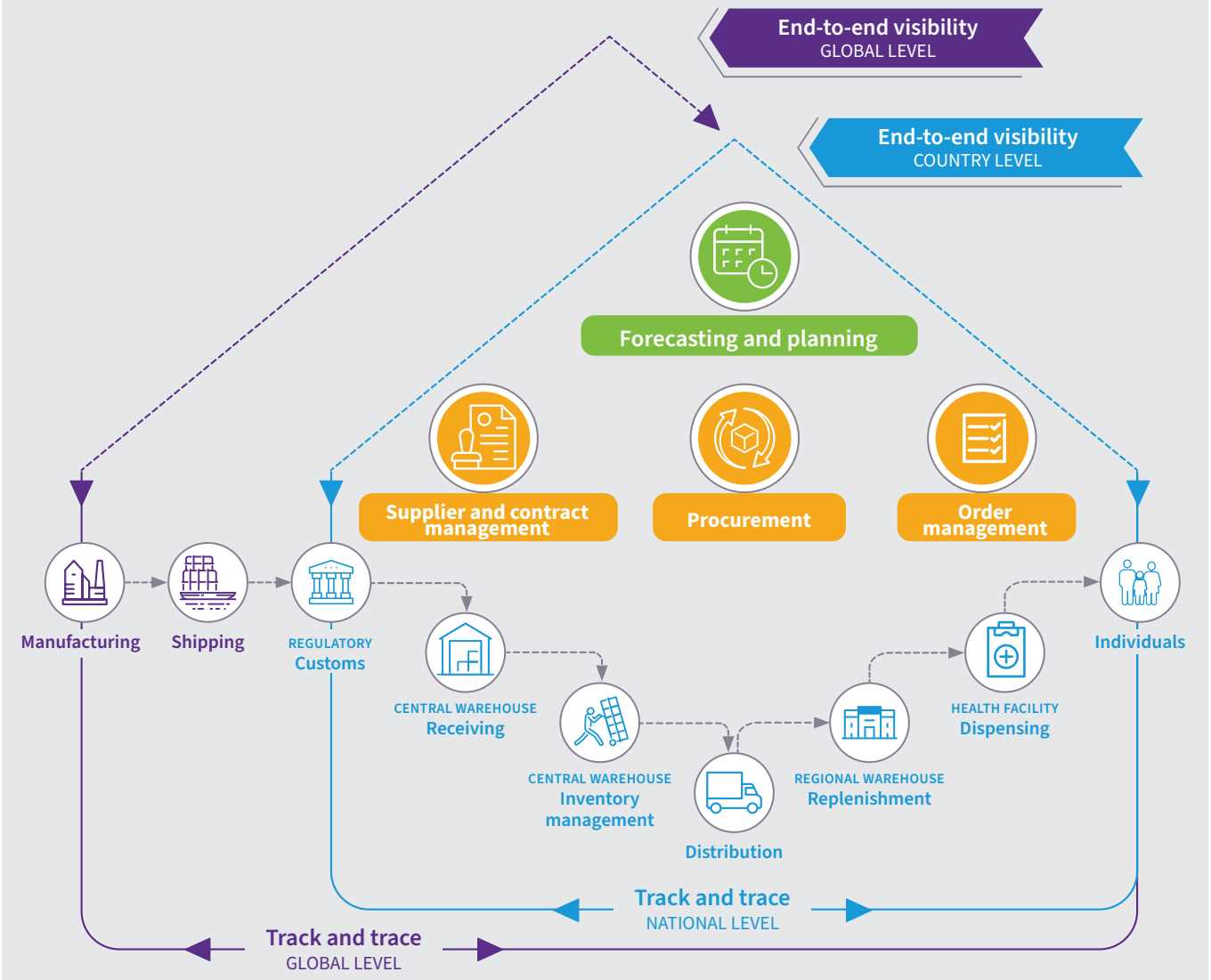
What are the risks of forgoing a DHSC architecture?

The lack of an overarching DHSC architecture leads to risks such as those listed below:

- → siloed and duplicative systems that lack the ability to adapt and scale, requiring more effort and money to maintain and sustain;
- → lack of compliance with global and open standards, resulting in a lack of interoperability among processes, systems and data, which in turn, affects the timely availability of aggregated data for visibility, analysis, exception management, reporting and decision-making;
- → laborious manual processes for aggregating, reconciling and triangulating data for accurate forecasting and planning, potentially resulting in an insufficient supply of products;
- → limited ability to track and trace commodities and verify the authenticity of products;
- → risk of having numerous software applications geared towards specific functions, without a comprehensive solutions perspective, which can result in isolated data that are difficult for other applications to access and thus less accessible for effective decision-making, service enhancement and achieving positive health outcomes; and
- → inability to achieve the desired level of digital transformation and systems maturity.

Fig. 11

Fig 11. Health supply chain end-to-end visibility and traceability



The following sections detail the steps to defining an overarching DHSC architecture. They also illustrate various architectural approaches that countries can adopt based on their health supply chain context and design.

→ Step 1. Assess the current state of HSCISs.

→ Step 2. Define a DHSC target architecture.

→ Step 3. Identify implementation activities and map them to strategic goals.

Step 1 Assess the current state of HSCISs

Assessing the current state of HSCISs involves a thorough evaluation of their capabilities, utilization, technical challenges and overall system maturity. This step helps identify strengths, gaps, inefficiencies and areas for improvement in existing systems that can be duly considered while defining the architecture.

INPUTS

- NSCA outcomes (if available)
- SCISMM assessment outcomes (if available)
- DHSC strategic goals and objectives
- National digital health strategy
- Landscape analysis of existing hardware, current state of infrastructure (electricity, internet, etc.), existing software technologies and current state of master data (e.g., product and facility data) management

TASKS

1. Gather the list and details of existing HSCISs and map them to appropriate services (such as supply chain functions, master data management and analytics).
2. Conduct SCISMM assessment (if not already done).
3. Analyse SCISMM assessment outputs to identify HSCIS gaps that need to be addressed to achieve the DHSC strategic goals.

OUTPUTS

- List of existing HSCISs
- SCISMM assessment report (if conducted as part of this step)
- HSCIS gaps that need to be addressed to achieve the DHSC strategic goals

RESOURCES

Template for listing HSCISs (Annex 5)

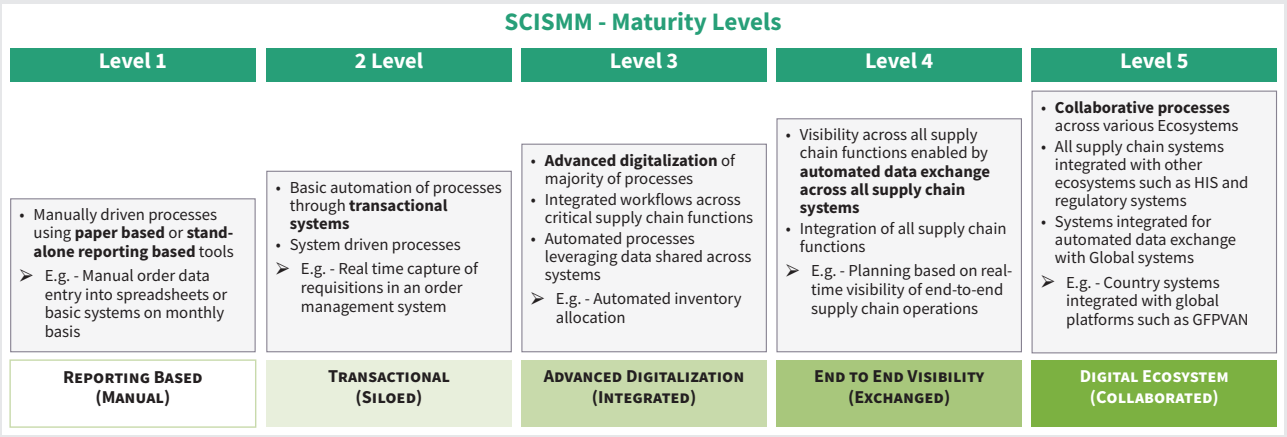
SCISMM *(16)*

Potential risks	Mitigation strategies
No partner or funding to conduct SCISMM assessments	Identify needed assessment activities during the annual work planning process in order to budget for, identify and request funding from partners.
Master data are not identified as an essential building block in the current state assessment	Conduct holistic assessments of the current HSCISs using SCISMM *(16)* to identify gaps in tools and governance and highlight impacts on interoperability, data quality, supply chain visibility and the ability to track and trace.
Some HSCISs are assigned too much priority for inclusion in the architecture while user adoption and efficacy are low	Plan and perform assessments such as SCISMM *(16)* on an annual basis to analyse utilization gaps and identify ways to mitigate gaps through continuous user training and making utilization of systems the only way to perform processes.

The appropriate DHSC architecture will depend on the current maturity and state of the supply chain information systems that support various supply chain functions. Tools such as SCISMM *(16)* can help with assessing the current maturity level and the level to advance to, depending on the country's priorities and readiness. SCISMM provides a continuum of maturity for systems that support health supply chain functions (Fig. 12), including the level of automation and digitalization of processes that are supported by HSCISs.

Fig. 12

Fig 12. SCISMM maturity levels for HSCISs



Source: reproduced by permission of the publisher from Digital Square; found via its web page on SCISMM *(16)*.

Step 2 Define a target DHSC architecture

This step involves defining a target DHSC architecture to ensure that all of the HSCISs are optimally structured and aligned with strategic goals.

INPUTS

- Assessment of the supply chain to identify opportunities for digital transformation
- List of existing HSCISs
- SCISMM assessment report
- HSCIS gaps that need to be addressed to achieve the DHSC strategic goals

TASKS

1. Draw the current-state architecture of the HSCISs by mapping existing systems against the DHSC architecture framework.
2. Identify gaps and necessary digital interventions based on the current state.
3. Define a future state of the DHSC architecture that considers core supply chain functions and foundational components while using existing digital assets where appropriate.

OUTPUTS

- Current-state architecture of health supply chain systems
- Future state of the DHSC architecture

RESOURCES

DHSC architecture framework (described later in this section)

SCISMM *(16)*

TSS v2 *(20)*

Country examples (Chapter 5)

BEST PRACTICE

- While upstream health supply chain levels such as the central warehouse use advanced systems to manage inventory and distribution, it is important to have sufficient system coverage at the lowest supply chain level to capture actual consumption. Health supply chains typically rely on inventory distribution data from warehouses or data on inventory issues from pharmacies to determine consumption. However, actual consumption should include what is dispensed to individuals, product expiries, wastages and inventory shrinkage. Systems, especially at the last mile of the supply chain, should have the ability to track and capture batch details and serial numbers, where available, as part of product expiries, wastages, inventory shrinkage and dispensation.

Potential risks	Mitigation strategies
Design of the DHSC architecture not aligning with best practices	» Consult resources such as this handbook, SCISMM *(16)* and TSS v2 *(20)*, along with principles such as the Principles for Digital Development (Annex 1), TOGAF *(18)* and the OpenHIE *(17)* framework, to help ensure alignment with best practices. » Engage with the practitioner community through groups such as the DHSC small working group to seek feedback on design.
Risk of choosing technology solutions prematurely, without considering innovation trends and potential future changes, resulting in those solutions quickly becoming outdated or challenging to adapt	In addition to following the outlined DHSC architecture framework, consider scalability and sustainability when selecting digital solutions for the health supply chain. A key mandate of the TWG should be oversight in this area.

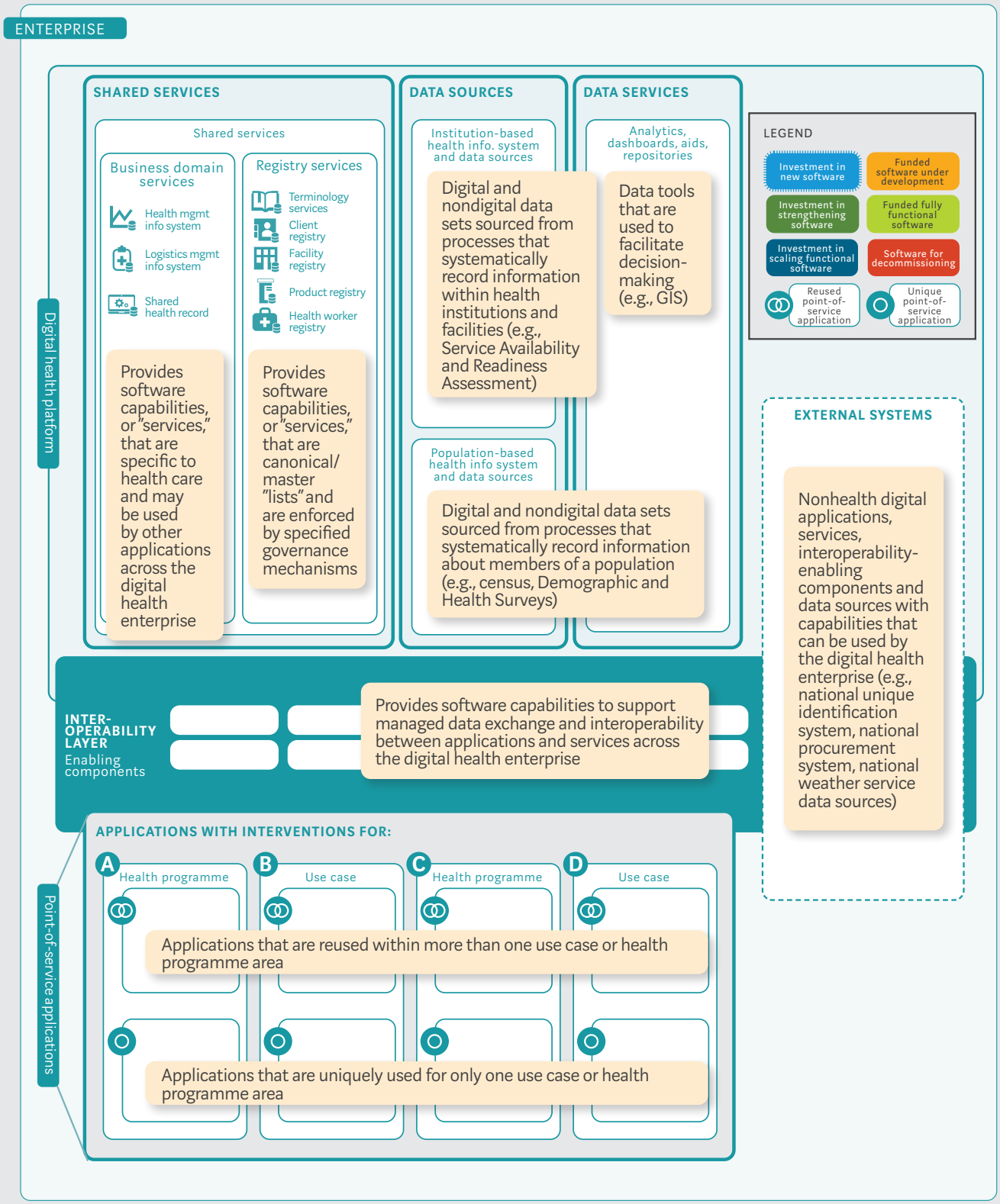
DHSC architecture framework

The DIIG outlines the components of a digital health enterprise architecture (Fig. 13). DHSC architectural components relate to the business domain services within this architecture.

Fig. 14 shows a DHSC architecture framework with components that support services such as foundational services, supply chain functional services, analytics, interoperability and traceability. This framework is based on the guiding principles of TOGAF and the OpenHIE framework.

Fig. 13

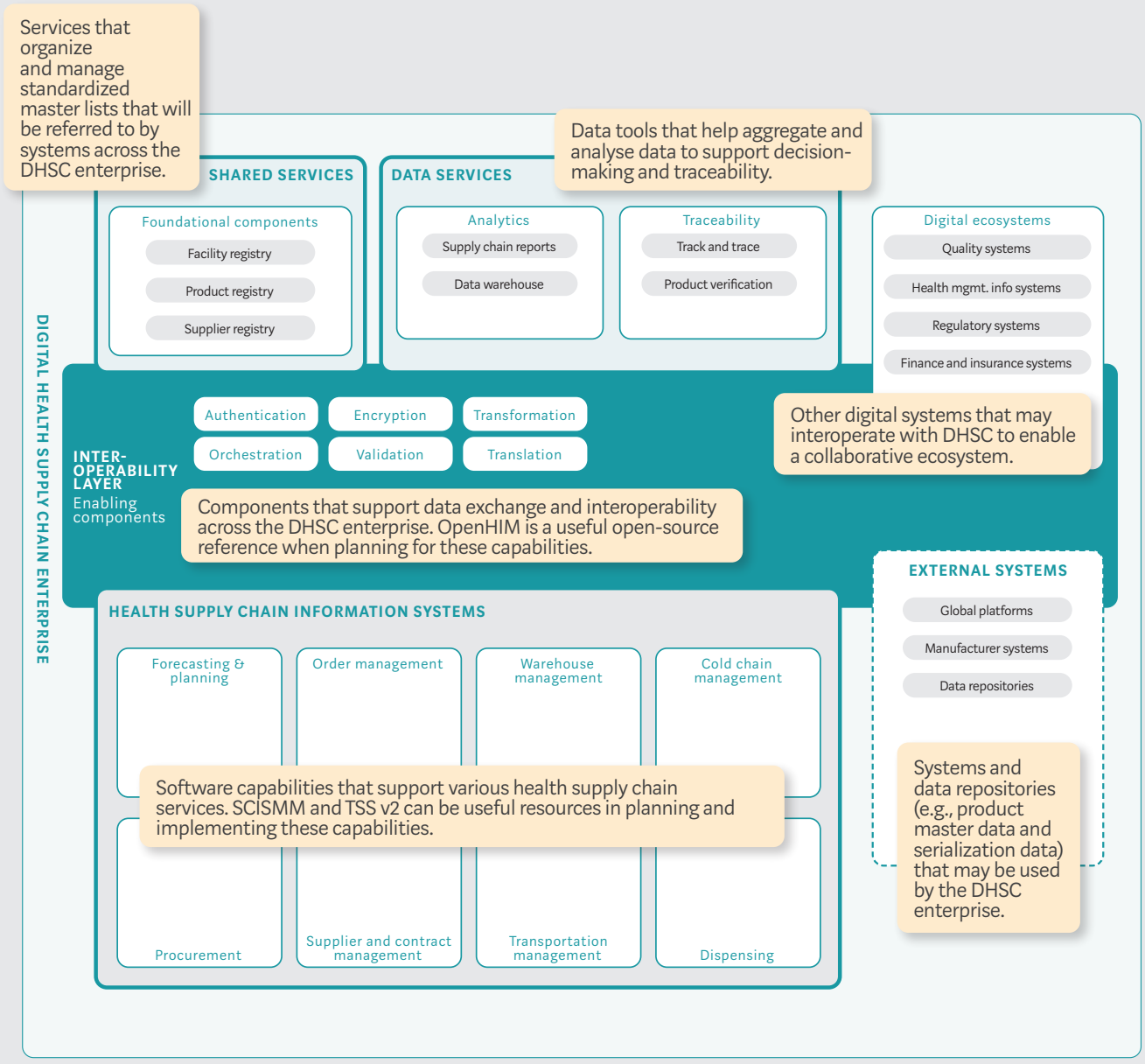
Fig 13. DIIG digital health enterprise architecture framework



Source: adapted from the 2020 *WHO Digital Implementation Investment Guide (1)*.

Fig. 14

Fig 14. DHSC architecture framework



The key components are as follows.

- **Foundational components.** These components provide system capabilities for organizing and managing master data such as product, facility and supplier data. They complement other registries, such as the client registry and terminology services, in the digital health enterprise architecture. These components are foundational in that they enable interoperability of transactional data across health supply chain information systems and processes. They ensure a uniform and standardized referencing of products, facilities and suppliers across processes, including those for planning, order management and warehouse management.
- **Interoperability layer.** This component facilitates the exchange of data across various systems as well as across levels of the health system. Interoperability of DSHC systems and DHSC with other digital ecosystems is essential to ensure seamless data exchange that facilitates efficient supply chain operations and supports patient safety by enabling commodity traceability. The use of an interoperability layer eliminates the need for point-to-point integrations of systems, which over time are not sustainable and are expensive to maintain. With the interoperability layer, systems that share data with other systems need to publish data only once. The interoperability layer can transform the data as needed and route them to multiple consuming systems. Any future integrations can be accomplished by integrating with the interoperability layer without disrupting existing systems and their integrations.
- **HSCISs.** These systems support the various supply chain processes. Note that one system or digital platform might support one or more supply chain processes. For example, an enterprise resource planning (ERP) system could support procurement, order management and warehouse management processes.

  Resources such as SCISMM, TSS v2 and the IHE white paper on the supply of products for health care *(23)* provide details on the functional and nonfunctional requirements of various HSCISs as well as foundational and data management capabilities such as product master data management and interoperability. These resources specify what capabilities should be supported by each of the components within the "health supply chain information systems" layer.
- **Data services.** These include components that support data aggregation and analysis. Digital infrastructure such as the data warehouse and reporting and analytics tools would be part of the analytical components of these services. These components also include traceability services that use the aggregated supply chain data to enable health product tracking, tracing and verification. (See Chapter 4 for more details on how the DHSC can enable traceability capabilities.)
- **External systems.** These include systems that are outside the public health ecosystem but may integrate with it to exchange data, including manufacturers' systems, global platforms developed by funders or procurement agencies, and global or regional data repositories that aggregate master or transactional data.
- **Digital ecosystems.** These are other digital ecosystems that benefit from health supply chain data. Examples include the following:
  - regulatory systems that combine supply chain data from the dispensing system with health information and individuals' data to conduct post-market surveillance and pharmacovigilance;
  - regulatory systems that use supply chain data such as data on inventory or products dispensed from various facilities to perform product recalls in the event of quality issues;
  - finance and insurance systems that combine data from the dispensing system with individuals' information to verify and process insurance claims; and
  - laboratory or quality monitoring systems that integrate with HSCISs to trigger alerts on quality issues or trigger swift product quarantines or recalls.

Illustrative architectural approaches and governance options

Countries often have a mixture of needs and capabilities that should be reflected in their DHSC architecture. They can adopt an architecture framework using an approach that aligns with their supply chain design and level of digital maturity. This section provides examples of architectures that are based on digital maturity and examples based on supply chain design (with different governance options).

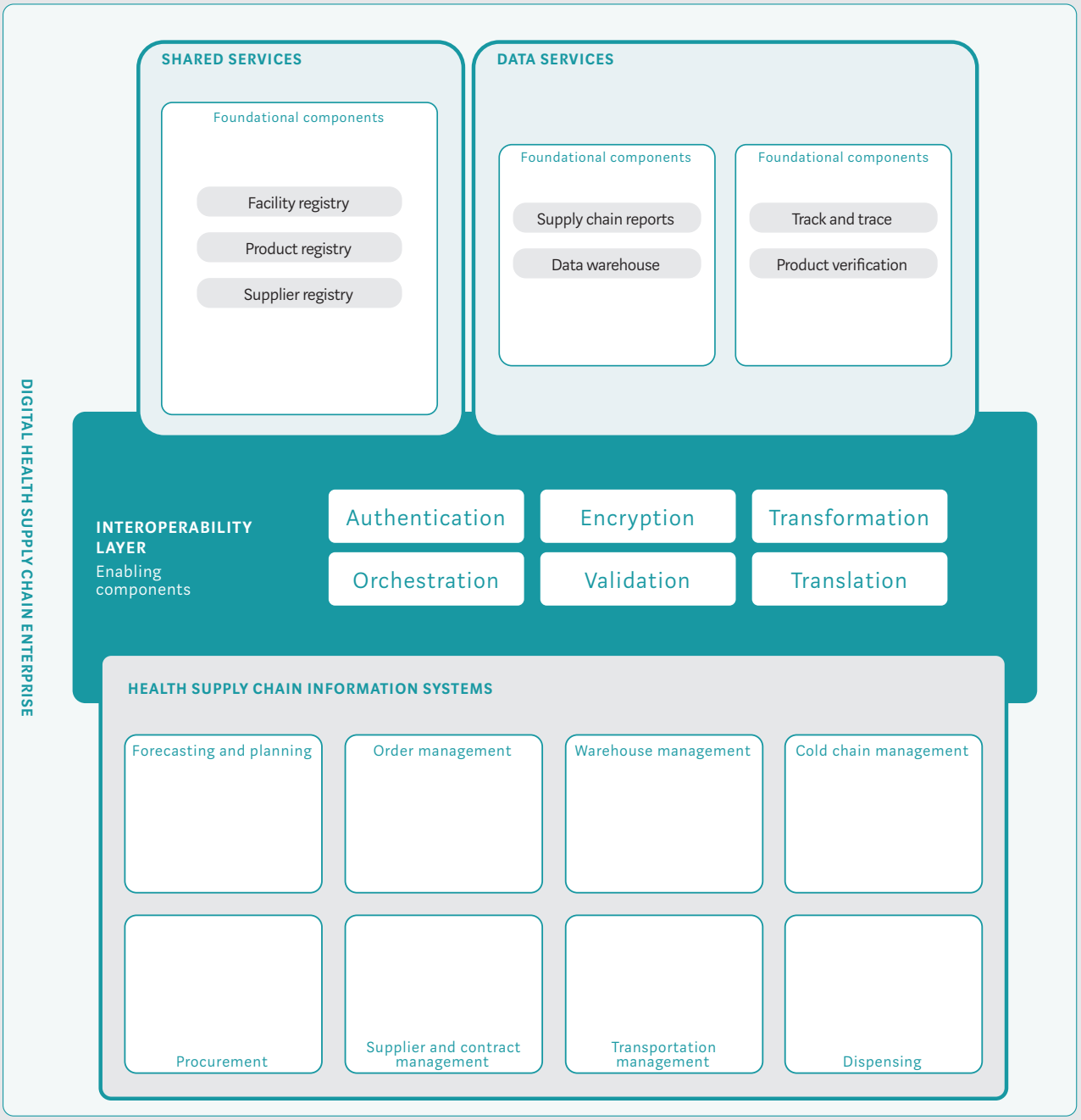
In practice, however, both factors will help determine the appropriate architecture framework.

The examples based on digital maturity use the SCISMM maturity levels. Levels 1 and 2 involve manual data entry and siloed systems, so this section focuses on the higher maturity levels.

→ **Maturity-based architecture: moving from SCISMM Level 3 to Level 4.** This architectural approach helps countries advance their supply chain systems from advanced digitalization and point-to-point integration (Level 3) to end-to-end integration and visibility by digitalizing key health supply chain processes and implementing standards-based information exchange using intermediaries like an interoperability layer (Level 4) (Fig. 15).

Fig. 15

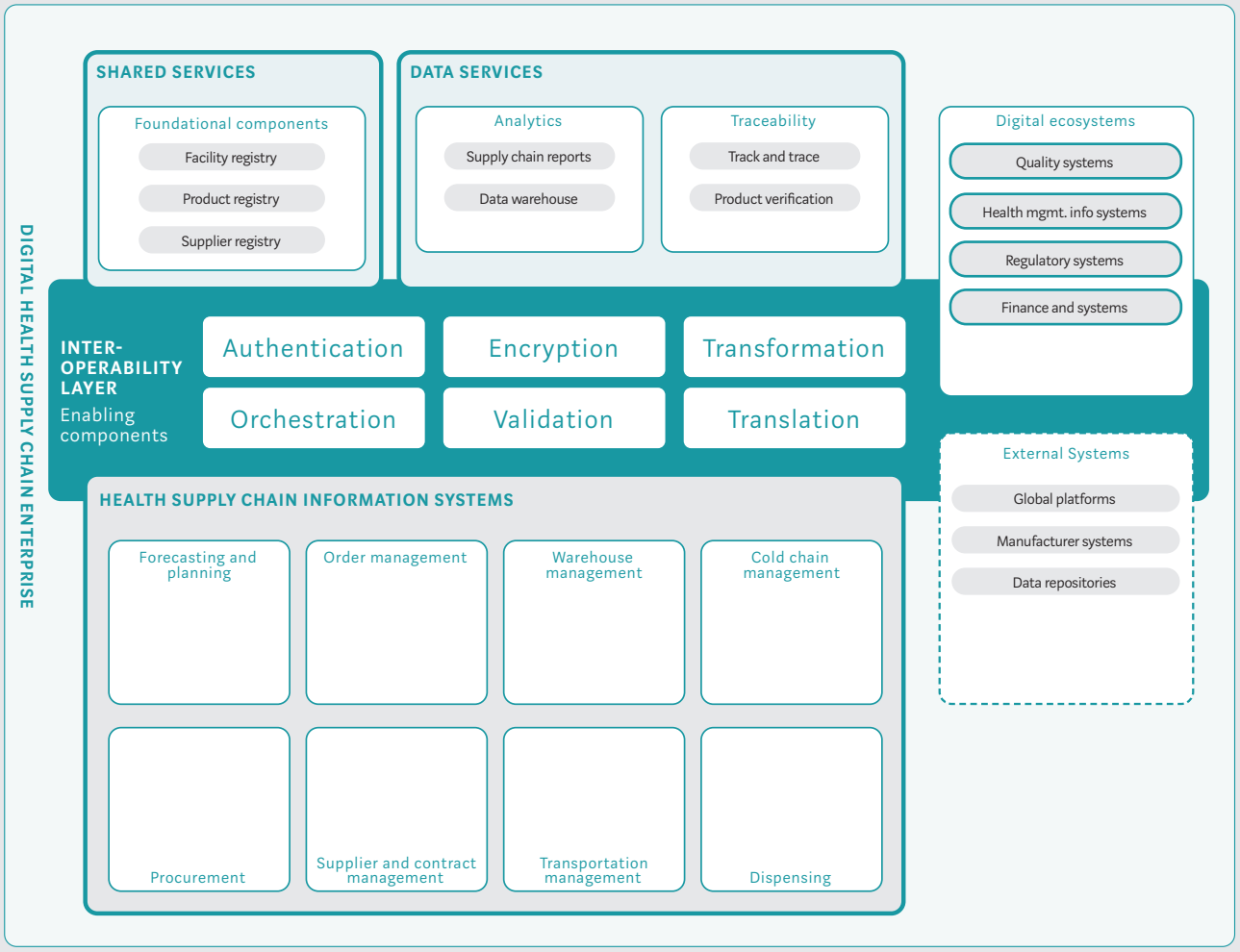
Fig 15. Maturity-based architecture: moving from SCISMM Level 3 to Level 4



→ **Maturity-based architecture: moving from SCISMM Level 4 to Level 5.** Countries planning to advance their DHSC from an exchanged architecture to a collaborative ecosystem can adopt this architectural approach (Fig. 16). A critical step is defining and prioritizing the use cases that are expected to be supported within the health system and supply chain. With this approach, DHSC systems interoperate not only with each other but also with other digital ecosystems such as health information systems, finance and insurance systems and regulatory systems, enabling maturation to Level 5. This approach also promotes integration with external systems such as manufacturer systems and global platforms of donors (such as the Global Family Planning Visibility and Analytics Network, or GFPVAN).

Fig. 16

Fig 16. Maturity-based architecture: moving from SCISMM Level 4 to Level 5

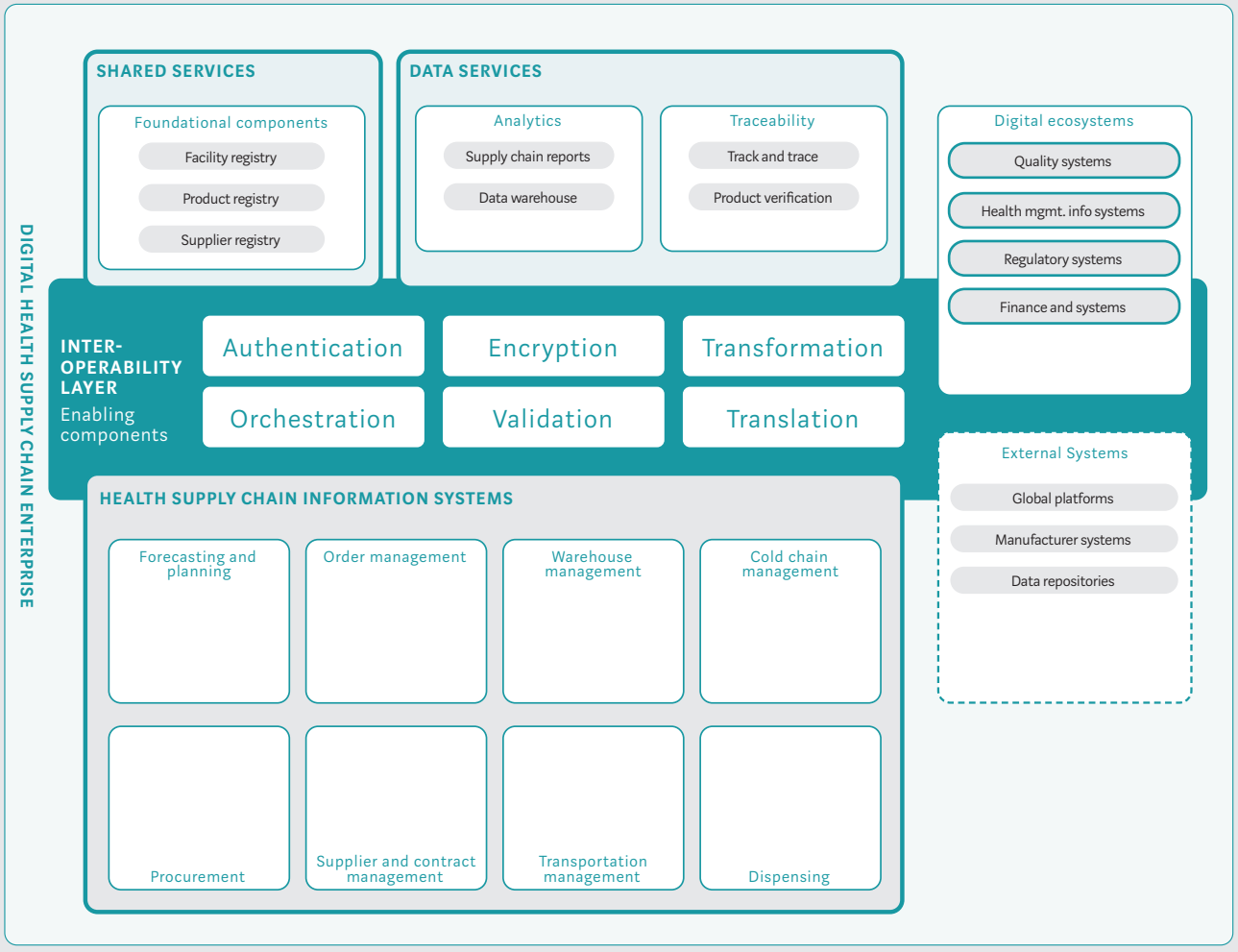


The following governance options for an architecture that is based on supply chain design assume SCISMM Level 5 maturity.

→ **Architecture based on supply chain design: centralized management.** Countries that manage their health supply chain centrally can adopt this approach, which resembles the general framework depicted earlier in Fig. 14. All health supply chain services, including those used by district and service delivery point facilities, are centrally managed using this approach (Fig. 17). This approach is suitable if central warehouses manage when and how much inventory to push to downstream facilities.

Fig. 17

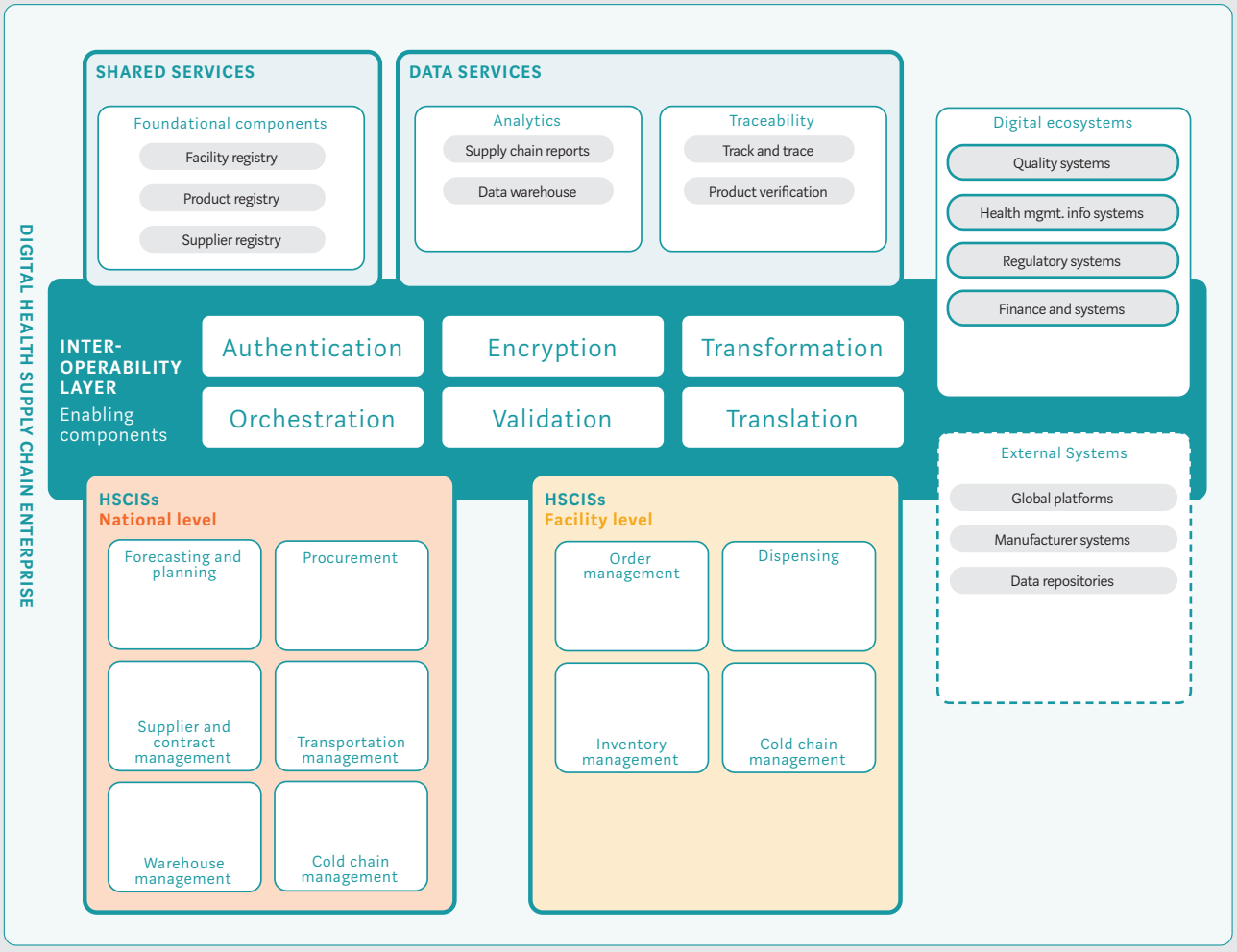
Fig 17. Architecture based on supply chain design: centralized management



→ **Architecture based on supply chain design: decentralized management (option A).** Countries with health supply chain management divided between the central level and the facility level can adopt this architecture (Fig. 18). Health supply chain functions such as forecasting and planning, procurement and supplier and contract management are managed at the central level. Downstream facilities are managed by an organization different from the one that manages central warehouses. That means the health supply chain services used by facilities are managed separately from those used at the central level. This approach caters to supply chain design where downstream facilities order pharmaceutical products from central levels through a pull mechanism for replenishment.

Fig. 18

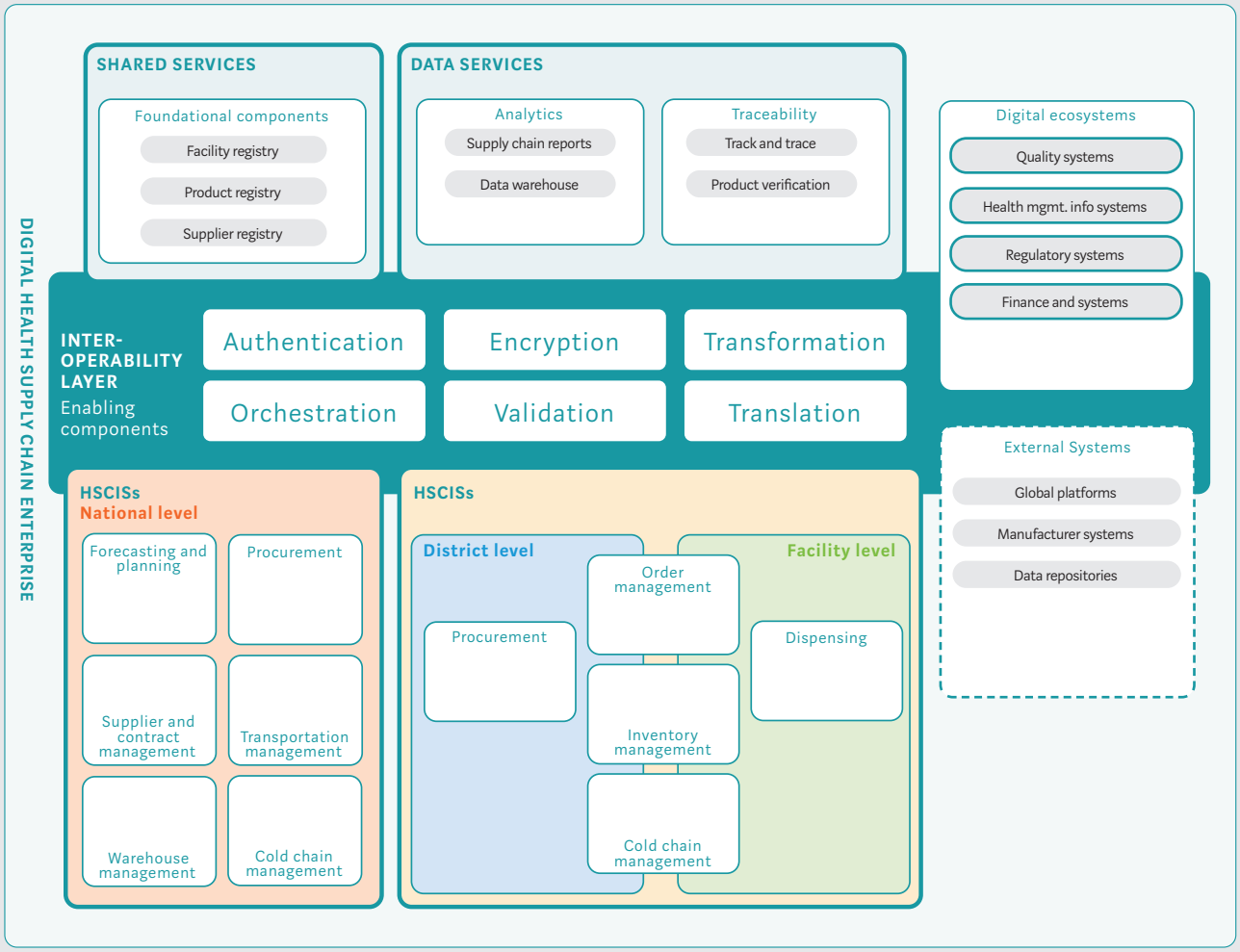
Fig 18. Architecture based on supply chain design: decentralized management (option A)



→ **Architecture based on supply chain design: decentralized management (option B).** This is a variation of the previous approach (Fig. 19). It allows district-level supply chain organizations to procure from sources other than central warehouses and therefore maintain a procurement system separate from the one used at the national level.

Fig. 19

Fig 19. Architecture based on supply chain design: decentralized management (option B)



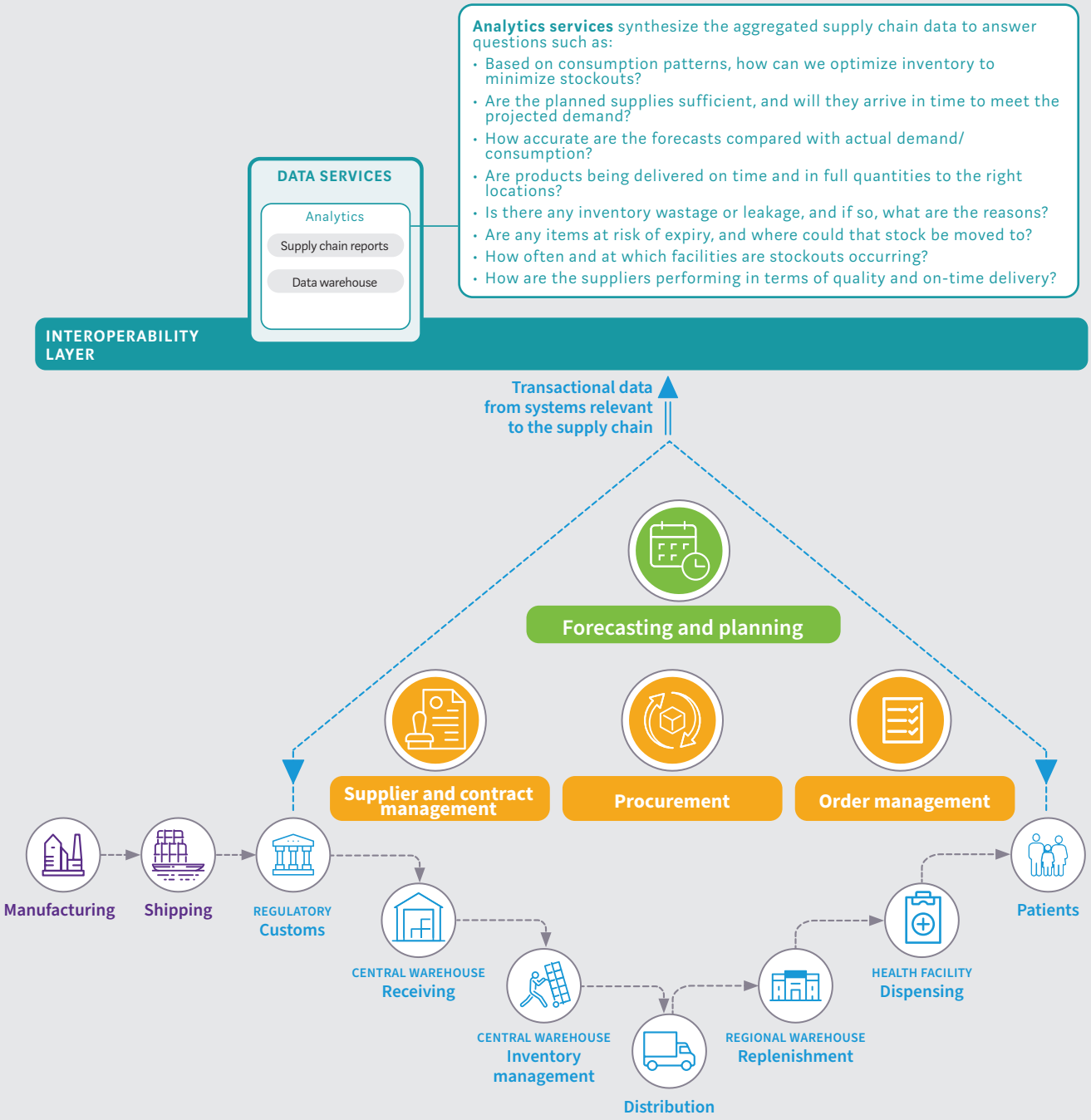
In addition to the architectural approaches detailed above, SCISMM, TSS v2 and the IHE white paper *(23)* can provide guidance on the health supply chain functions that information systems should support to minimize manual tasks and improve data quality and availability. These resources can help countries choose the level of advancement for their HSCISs depending on their readiness.

As noted earlier, one benefit that the DHSC architecture should deliver is timely visibility of the end-to-end health supply chain so leaders can make informed decisions to deliver health products to individuals when and where they need them.

Fig. 20 depicts how DHSC systems can support various supply chain processes. The real-time data from these systems help enable comprehensive supply chain management (including, for example, end-to-end visibility), thus helping supply chain leaders make effective supply decisions; take corrective actions to address exceptions such as stockouts, product recalls and expiries; and ensure availability of medicines when and where they are needed.

Fig. 20

Fig 20. Benefits of cross-enterprise analytics services



Step 3 Identify implementation activities and map them to strategic goals

This step focuses on translating the identified DHSC architectural interventions into implementation activities. The activities will be mapped out on a timeline to prepare a roadmap for overall implementation.

INPUTS

- Current state of HSCISs
- Future-state DHSC architecture
- DHSC strategic goals

TASKS

1. Prioritize DHSC interventions based on strategic goals.
2. Define the implementation activities for the prioritized DHSC interventions.
3. Develop a high-level roadmap of the implementation activities.

OUTPUTS

- List of DHSC implementation activities mapped to strategic goals
- High-level roadmap of DHSC implementations

Potential risks	Mitigation strategies
Activities are not aligned with DHSC strategic goals	Identify and plan implementation activities after the vision, strategy and architecture have been developed and approved. Review any ongoing activities and adjust them to ensure alignment with DHSC goals and priorities.

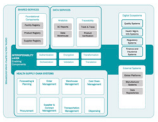
Progress check

The steps outlined in this chapter will result in the following outputs (Fig. 21):

- **current state of HSCISs**
- **future-state DHSC architecture**
- **list of DHSC implementation activities mapped to strategic goals**
- **high-level roadmap of DHSC implementations.**

Fig. 21

Fig 21. Example of outputs from this chapter

Vision	Consistent and timely access to quality medicines and medical products for the population, through seamless supply chain enabled by technologies that provide efficient tools for providers					
Strategic goals	1. Implement system-driven processes to provide timely access to quality data		2. Achieve interoperability of systems to enable effortless exchange of data		3. Enable traceability of all health products to ensure patient safety	
Strategic objectives	Automate 80% of central warehouse operations	Automate receiving and dispensing in 75% of health facilities	Standardize product, facility, and other master data	Deploy interop layer and integrate central and regional HSCISs	Deploy a data warehouse to aggregate supply chain data	Enable national-level batch traceability
Strategic roadmap	Year 1 Digitalization of central warehouse	Year 2 Digitalization of health facilities	Year 2 Data standardization	Year 3 System integrations	Year 3 Data aggregation	Year 4 Batch traceability
DSHC architecture	**Year 1 and 2 Target architecture** 			**Year 3 and 4 Target architecture maturity to next level** 		
Implementation roadmap	**Enhance WMS** **Integrate WMS and National Product Catalog (NPC)**	**Implement barcode-scanning capabilities**	**Develop and implement the interop mediator**	**Integrate HSCISs through the mediator**	**Design data models and implement data warehouse**	**Aggregate data from all HSCISs and enable analytics**
DHSC outcomes	**WMS deployed and rolled out across 40% of supply chain facilities** **WMS-NPC integration: 100%** **Barcode-scanning feature: 60%**		**Interop mediator deployed and 30% of integrations completed**		**Implementation pending**	

Chapter 3

Planning for scalable implementation and sustainable operations

Guiding principles

The following principles, informed by the Principles for Digital Development (Annex 1), can guide the implementation of the DHSC interventions.

- → Plan for sustainability from the start.
- → Engage local resources to build capacity.
- → Promote collaboration across implementation partners to align and complement efforts.
- → Develop plans grounded in the local context to set realistic expectations and milestones.

Outputs

The steps outlined in this chapter will result in the following outputs:

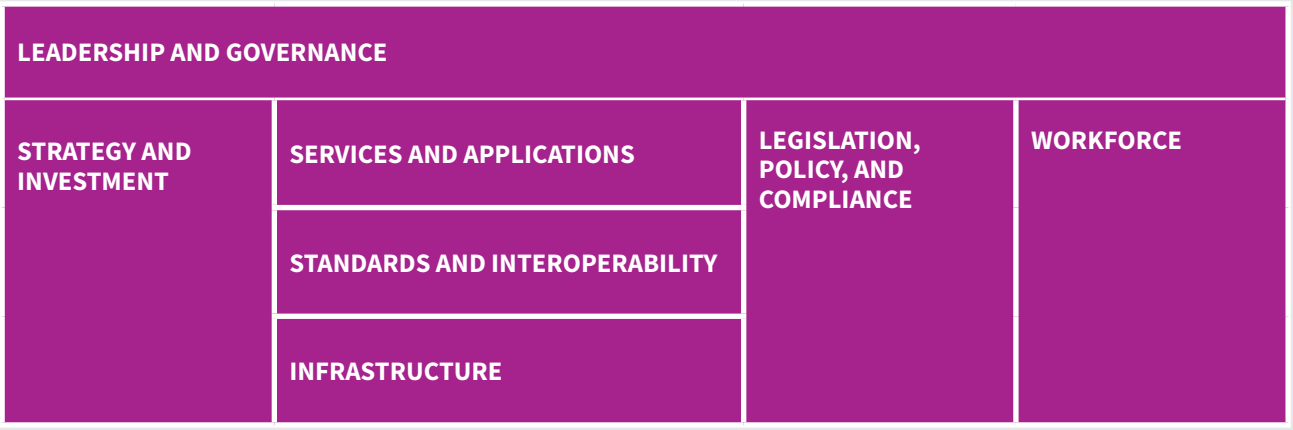
- **detailed project management plans for each implementation activity;**
- **stakeholder matrix to manage operations;**
- **operations sustainability plan;**
- **implementation and operations performance monitoring and evaluation framework;**
- **DHSC implementation materials such as requirements, specifications, test scripts and job aids; and**
- **developed DHSC applications.**

Planning for scalable implementation and sustainable operations

The previous chapters helped define the vision, strategic goals and architecture for the DHSC. This chapter outlines key considerations for realizing the DHSC vision, strategic goals and objectives. They are derived from the seven foundational building blocks of digital health as outlined in the WHO-ITU *National eHealth Strategy Toolkit* (Fig. 22).

Fig. 22

Fig 22. Building blocks of digital health and DHSC implementation



Source: adapted from the 2012 WHO-ITU *National eHealth Strategy Toolkit (19)*.

Table 2 provides illustrative considerations for each building block to help ensure successful DHSC implementation.

WHAT IS GOVERNANCE?

In the context of the health supply chain, *governance* is the process of establishing and implementing policies, procedures and mechanisms to ensure that the supply chain processes and the systems to manage those processes are managed effectively, ethically and in alignment with established objectives and stakeholders' interests. It involves decision-making, defining roles and responsibilities, setting goals and objectives, and monitoring performance to ensure accountability and compliance with regulations and standards.

Table 2. Illustrative implementation considerations for the DHSC

	Factor	Illustrative considerations	
		What is the current state?	**What is needed?**
Enabling environment	**Leadership and governance**	» Can any national priorities be cited that align with DHSC goals to secure support from senior leadership? » Does a dedicated department oversee health ICT, digital health and the health supply chain? » Does the country have a national digital governance framework, such as TWGs?	» DHSC that is strongly connected to a national priority to guarantee senior leadership support and momentum » Digital department that has a mandate to advance DHSC implementations » Governance of DHSC implementations by either a dedicated TWG or a subcommittee within the digital health working group, if one exists
	Strategy and investment	» Is the DHSC strategy endorsed and agreed upon by all stakeholders? » What investments in DHSC are currently ongoing? What additional investments are planned?	» Consensus among senior leadership and all stakeholders regarding the DHSC vision and strategic roadmap, to ensure alignment of all stakeholder investments with the DHSC architecture » DHSC investment roadmap to help identify funding needs and potential funding sources
	Legislation, policy and compliance	» Does any existing legislation support data sharing, data standardization and traceability of pharmaceutical products? » Are policies in place regarding data storage, usage, retention and security? » Do mechanisms exist to ensure compliance with legislation and policies?	» Legislation that provides guidelines to manufacturers and other supply chain partners on product data standardization, labelling, data sharing and pharmaceutical traceability » Guidelines for manufacturers and supply chain partners to achieve compliance in phases » Procedures to monitor and promote compliance with legislation and policies
	Workforce	» Are there individuals in supply chain operational and technical roles who have the necessary skill sets? » Are knowledge management mechanisms in place, such as ongoing training and information-sharing programmes? » Is a strategy in place for incremental capacity development and talent retention?	» List of roles across areas such as management, technology and operations with job descriptions and necessary skill sets » Knowledge management procedures that include targeted training programmes, visual job aids, advocacy material and video tutorials » Capacity-building strategy that includes technical cooperation with the private sector and fostering its development to acquire the required skill sets
	Standards and interoperability	» Are standardized reusable components in use, such as facility registries, product registries and supplier registries? » Is an interoperability framework in use to guide how systems integrate and exchange data? » Is an interoperability mediator in place to support data orchestration, translation and integrations? » Are standardized protocols in use for data exchange between systems? » Have global and open standards been adopted for data management and exchange?	» List of essential reusable components that are needed as part of the DHSC implementation and that are part of the DHSC architecture » Interoperability framework that includes guidelines for data exchange, standardization and adoption of open standards as well as a plan for an interoperability mediator, if one is not in place » Harmonized master data registries » Adoption of global and open standards (e.g., the Health Level Seven International Fast Healthcare Interoperability Resources) to promote interoperability among systems, processes and data
ICT environment	**Services and applications**	» What supply chain applications in use can be enhanced and reused? » Are processes in place to maintain and update software applications? Is a framework in place to engage the private sector in software application maintenance and upgrades?	» DHSC strategy and architecture to indicate existing reusable applications along with new applications, including the necessary changes required for existing applications » Procedures governing application maintenance, including the organization responsible for hardware and software maintenance, criteria for upgrades or replacements and a framework for involving the private sector in maintenance and improvements
	Infrastructure	» What are the electricity conditions across all supply chain facilities and at data centres where servers will be located? » How is the network connectivity and bandwidth across supply chain facilities such as central warehouses, district pharmacies and service delivery points? » Do potential users of DHSC applications have the necessary devices? If not, what additional devices (e.g., computers, tablets or smartphones) are needed?	» Budgeted plan to establish the required infrastructure for electricity and network connectivity at the designated sites and facilities » Budgeted plan to acquire the required devices for supply chain users » Infrastructure requirements included within government budgets, highlighting potential funding requirements

Sources: adapted from the 2012 WHO-ITU *National eHealth Strategy Toolkit (19)* and the 2015 WHO *MAPS Toolkit (24)*.

Detailed plans are also needed for each DHSC initiative or intervention. As outlined in the upcoming steps, each intervention should include a project implementation plan, an operational plan and a budget that considers the total cost of ownership.

Step 1 Plan the implementation of each DHSC intervention

This step focuses on developing a comprehensive plan, which is essential for guiding various DHSC implementation activities.

INPUTS

- Prioritized DHSC interventions
- List of DHSC implementation activities

TASKS

1. Develop a project charter.
2. Develop a project management plan.
3. Establish a project governance and reporting mechanism through the steering committee and/or TWG.
4. Define the project performance monitoring and analysis framework.

OUTPUTS

- Project charter
- Project management plan
- Steering committee and TWG terms of reference
- Project performance monitoring and analysis framework

RESOURCES

Risk register template (Annex 6)

The project charter should include details about the following:

- scope
- stakeholders
- timeline
- budget
- risks
- deliverables
- quality criteria
- governance mechanism.

The project management plan should include the following:

- detailed project implementation plan with activities, timelines and milestones for each phase (such as design, development, testing and deployment);
- stakeholder matrix with responsibilities and accountabilities (such as a RACI matrix – responsible, accountable, consulted, informed);
- resource details, including people, hardware and software;
- budget details for phases;
- communication plan, including frequency of project management and technical meetings, issue management and escalation process;
- risk register with mitigations;
- change control process;
- change management plan (including training and rollout plan); and
- quality management and closure plan.

The project performance monitoring and analysis framework should include the following:

- project baseline (such as initial schedule, budget and indicators related to the supply chain process that is being digitalized); and
- reporting schedule, mechanism and template that includes various aspects such as schedule, quality, budget and risks.

Step 2 Develop an operational plan for each DHSC intervention

The operational plan should determine the necessary resources and the effort needed to effectively maintain and run the DHSC systems.

INPUTS

- List of DHSC implementation activities
- DHSC stakeholder matrix

TASKS

1. Update the stakeholder matrix, if required, to establish the system owner/custodian and system users.
2. Identify required operational resources (such as maintenance personnel, hardware, network infrastructure and backup power).
3. Develop an operations and sustainability plan.
4. Develop an operational performance monitoring and evaluation framework.

OUTPUTS

- Updated DHSC stakeholder matrix that includes operations management
- Operations and sustainability plan
- Operational performance monitoring and evaluation framework

The operations and sustainability plan should include the following:

- details of stakeholders who will own and maintain the DHSC system/application;
- required resources (such as maintenance personnel, hardware, network infrastructure and backup power);
- recurring knowledge management needs (including training, job aid updates, recruitments and job rotations);
- recurring costs for the required resources, system subscriptions, knowledge management, monitoring and evaluation, and efforts to maintain and operate the application;
- plan for data backups and system redundancy to mitigate the impact of system failures;
- change management and governance process for new requirements arising from evolving needs; and
- financial strategy to cover all recurring operational costs.

The operational performance monitoring and analysis framework should include the following:

- baseline KPIs related to the supply chain process being digitalized; and
- reporting schedule, mechanism and template that includes various aspects such as operational costs, risks, KPIs, and any constraints and issues.

Step 3 Develop a budget for each DHSC intervention

This step helps prepare the budget based on costs to implement as well as costs to scale and operate DHSC systems.

INPUTS

- Project management plan for the implementation
- Operations and sustainability plan
- Historical budgets and costs, if available

TASKS

1. Identify all cost drivers. (See Table 3.)
2. Determine all implementation costs.
3. Determine all operational costs for the life of the DHSC intervention, which could typically be five to 10 years.
4. Develop a budget matrix for the life of the DHSC intervention.
5. Identify funding sources and potential funding needs.

OUTPUTS

- Total cost of ownership
- Budget matrix
- Funding needs

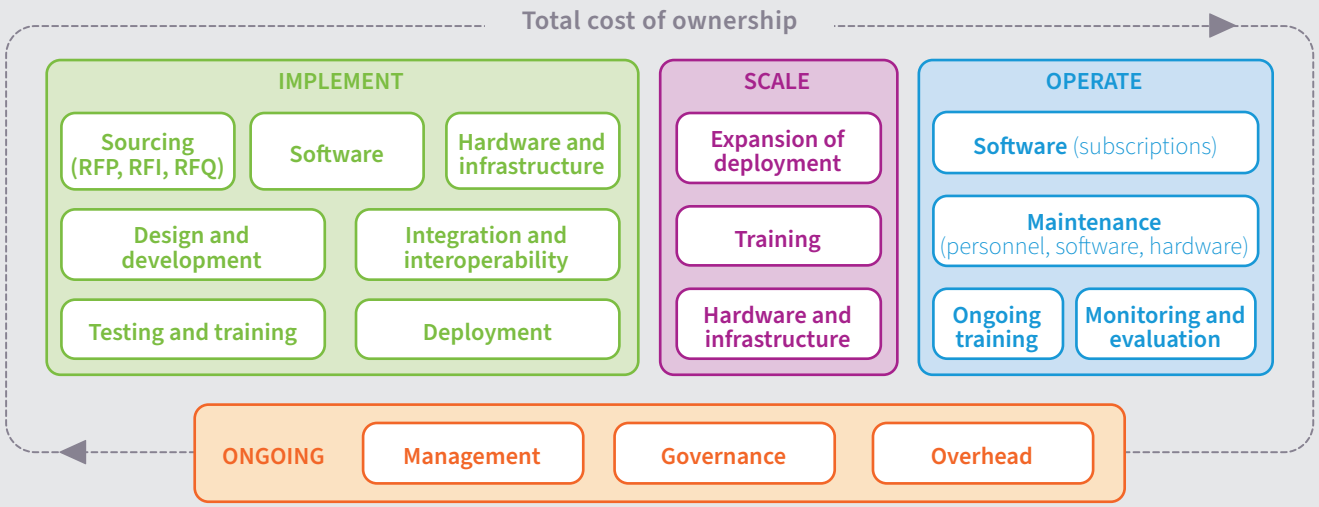
RESOURCES

Budget matrix template (from the DIIG)

Fig. 23 illustrates the costs to consider as part of the total cost of ownership. Table 3 lists illustrative cost drivers of DHSC implementation.

Fig. 23

Fig 23. Cost components to determine the total cost of ownership



RFP = request for proposal
RFI = request for information
RFQ = request for quotation

Source: adapted from the 2020 WHO *Digital Implementation Investment Guide (1)*.

Table 3. Illustrative cost drivers of DHSC implementation

	Cost categories	Cost drivers
Ongoing costs	**Management**	» Complexity of intervention » Full-time equivalents (FTEs) needed » Turnover » Staff capacity
	Governance	» Number of stakeholders needed for coordination » Time needed for approvals » Amount of travel and meetings required for buy-in, coordination and approvals
	Overhead	» Logistical costs such as per diems, meeting rooms and stationery » Administrative costs
Upfront implementation costs	**Sourcing**	» Complexity of required features and functionality » Local capacity and whether international sources need to be explored » Procedural requirements around governmental approvals and competitive evaluations
	Software	» Licensing model and associated cost » Scale of implementation (number of end users, number of devices, etc.)
	Hardware and infrastructure	» Devices, servers and other infrastructure needed » Sophistication of devices needed (depending on system availability needs, data retention policies, etc.) » Reliability of electricity in country and alternatives needed » Infrastructure to support reliable internet connectivity
	Design and development	» Customizations and localizations (e.g., language translations) needed » Local capacity with required skill sets » Technical trainings needed
	Integration and interoperability	» Maturity of interoperability standards » Use of standards or lack thereof » Existing data-sharing policies » Licensing fees associated with standard use » Availability of interoperability mediator and related requirements
	Testing and training	» Amount of travel and meetings required » Number of end users, testing users and trainers » Scale and frequency of training » Existing capacity gaps
	Deployment	» Number of end users » Number of facilities
Upfront scaling costs	**Expansion of deployment**	» Number of end users » Number of facilities
	Training	» Amount of travel and meetings required » Number of end users, testing users and trainers » Scale and frequency of training
	Hardware and infrastructure	» Devices, servers and other infrastructure needed » Sophistication of devices needed depending on system availability needs, data retention policies, etc. » Reliability of electricity in country and alternatives needed » Infrastructure to support reliable internet connectivity
Operations costs	**Software**	» Annual or per user subscription/licence fees
	Maintenance	» Amount of bug fixes needed » Anticipated updates released per year » Amount of travel needed for onsite maintenance support » Number of end users and devices managed » Utility costs related to hardware
	Ongoing training	» On-the-job training vs. formal training mechanism » Turnover
	Monitoring and evaluation	» Complexity and scope of intervention » FTEs needed to support monitoring and evaluation activities » Amount of data needed to be collected manually vs. data available electronically through automated processes » Size and complexity of data collected; number of systems that data are collected from » Amount of information needed to disseminate

Source: adapted from Digital Impact Alliance's Principles for Digital Development (https://digitalprinciples.org).

Step 4 Implement each DHSC intervention

This step encompasses several tasks needed to implement the identified DHSC interventions, including vendor selection, system design, development, validation and training.

INPUTS

- Prioritized DHSC interventions
- List of DHSC implementation activities

TASKS

1. Define functional and nonfunctional requirements for the DHSC intervention being implemented.
2. Identify the implementation partner/vendor through appropriate sourcing mechanisms, such as requests for proposal (RFPs) and requests for quotation (RFQs).
3. Develop the intervention's solution design and integration specifications to meet functional and nonfunctional requirements.
4. Develop and/or configure the intervention.
5. Integrate the intervention with other interventions through an appropriate interoperability platform, if available.
6. Validate the intervention through system, integration and user acceptance testing.
7. Train the users.
8. Roll out the intervention.

OUTPUTS

- DHSC intervention functional and nonfunctional requirements
- Sourcing documents such as RFPs and RFQs
- Contracts for software and implementation
- Solution design and integration specifications
- DHSC application components
- System, integration and user acceptance test scripts
- User training materials
- DHSC application issues log

RESOURCES

SCISMM *(16)*

TSS v2 *(19)*

Potential risks	Mitigation strategies
» Underestimating the costs and/or overlooking hidden costs	» Use the guidance provided in this section to estimate all cost elements, including operational costs, to help budget for and identify funding sources to ensure successful implementation and continuous operations.
» Human resource capacity constraints » Not having people with the appropriate skill sets » Lack of awareness of the required skill sets	» Identify the necessary roles and skill sets early on. Use multiple strategies to add capacity, such as outsourcing, recruiting and engaging part-time consultants. Budget for additional staffing needs and identify funding sources to bridge capacity gaps. Plan for a phased rollout of systems to align with the availability of funding and staffing capacity. » Use a resource matrix, such as the one in Annex 7, to plan out necessary roles and responsibilities across phases of implementation and operations.
» Poor adoption and use of systems if training does not contain appropriate content for the level of skill sets	» Perform a skills assessment for each user before completing the training plan. » Complete a training needs assessment before conducting training. » Target and adapt training to meet the needs of the training audience.
» Lack of reliable infrastructure (such as electricity, internet connectivity and computers) as HSCISs are rolled out to downstream facilities	» Determine needs across all supply chain facilities and develop a detailed budget that includes operational costs. » Adopt a phased approach to roll out systems across supply chain facilities. » Align funding and other financial resources with the planned rollout phases.
» Inconsistent use of supply chain processes across supply levels and facilities, leading to poor data quality, interoperability, aggregation and data availability	» Conduct a supply chain system and process maturity assessment (using tools such as SCISMM) to identify process gaps and inconsistencies. » Address gaps during the system design phase and ensure consistent training of staff at all supply chain levels for uniform adoption and use of the system.

Potential risks	Mitigation strategies
» Saturation of existing digital tools and HSCISs due to lack of acceptance of emerging technology and enhancements	» Conduct regular assessments using tools such as SCISMM to identify any new or potential gaps and improvement opportunities. » Plan to enhance or upgrade existing tools in a phased manner to meet changing supply chain needs.
» Budget dependence on political factors such as election timelines and outcomes	» Budget for DHSC initiatives at the start of a government's term. » If initiatives require time beyond political events that might affect the budget, consider options for scaling back or phasing, depending on the context.
» Budget rigidity that creates an obstacle to accommodating unforeseen but necessary changes (due to factors related to technological advances, regulatory changes, staffing, etc.)	» Ensure that budgets account for potential changes and include a buffer. » If the buffer is exceeded, seek additional funding sources before scaling back the initiative.

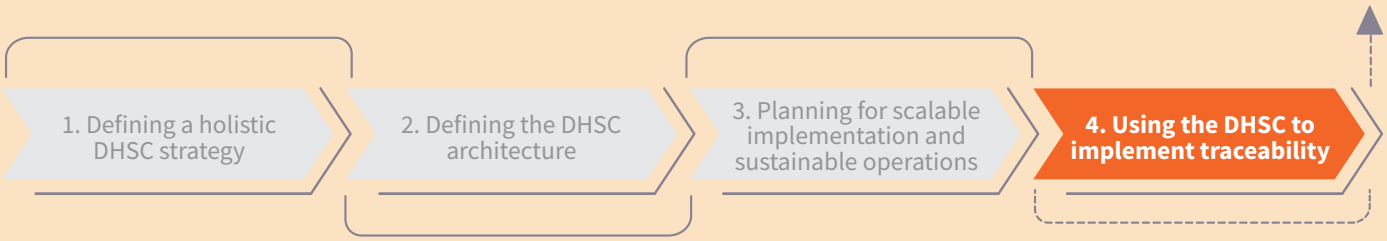
Progress check

The steps outlined in this chapter will result in the following outputs:

- **detailed project management plans for each implementation activity**
- **stakeholder matrix to manage operations**
- **operations sustainability plan**
- **implementation and operations performance monitoring and evaluation framework**
- **DHSC implementation materials such as requirements, specifications, test scripts and job aids**
- **developed DHSC applications.**

Chapter 4

Using the DHSC to implement traceability



Using the DHSC to implement traceability

One key benefit of the DHSC architecture is the ability to track, trace and verify health products. Traceability of health products is important to mitigate the risk of falsified medicines and ensure patient safety and quality health care. This chapter explores the use of the DHSC architecture framework to implement and institutionalize traceability, which requires efforts across multiple areas such as regulatory, human resources and processes such as procurement and customs. The chapter focuses mainly on deploying technologies that use the DHSC architecture framework to support traceability.

What is traceability?

The global standards organization GS1 describes traceability as the ability "to see the movement of health products across the supply chain" *(25)*. Traceability means being able to trace the path of health care products from the manufacturer to individuals, identifying ownership changes at different points along the supply chain. Traceability also aids in the whereabouts of products at any given moment, including their intended route towards the point of dispensing.

Why is traceability important?

Tracing and tracking enhance the efficiency and integrity of the health supply chain. By providing global visibility into every change of product ownership along the supply chain, traceability helps identify falsified health products and prevents their dispensation to individuals (among other benefits, which include efficiencies in inventory management and prevention of medicine shortages), ultimately helping to ensure patient safety. Traceability thus plays an important role in ensuring quality health care for individuals.

Traceability also supports the ability to manage product recalls in the event of confirmed or potential quality issues. Visibility into product movements and whereabouts helps health care personnel swiftly locate the products from a batch and initiate a recall.

Most existing traceability systems for health products are based on regulatory requirements. To ensure the effective implementation of these requirements, global harmonization and alignment with the global framework *(14)* of health product identification, marking and data sharing are critical. In this context, it is important to note that traceability systems are developed gradually and aim to maximize the capabilities and potential of existing digital systems used in a country or region. The common denominator to ensure interoperability across national traceability systems is the use of global standards for traceability.

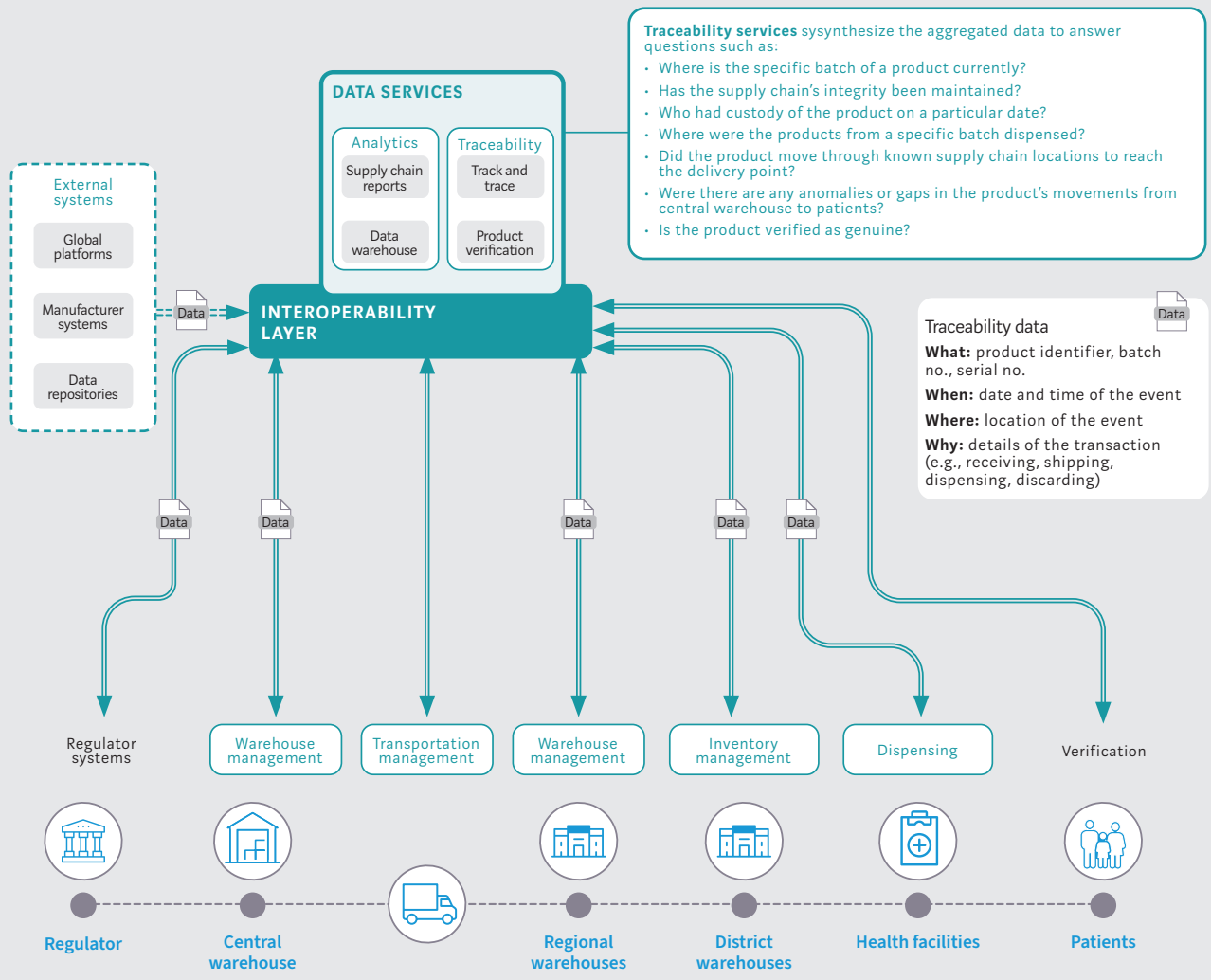
Traceability models

The three main models for implementing traceability are the centralized, semi-centralized and distributed models. They differ mostly in how they store the data and share them with the relevant health authority and across actors in the supply chain. The centralized model involves a single database or repository for storing all traceability data. In a semi-centralized model, the traceability data are spread across multiple databases or repositories. In the distributed model, traceability data are maintained separately by each supply chain partner.

This handbook does not recommend a particular model because the best choice depends on the context and various other factors. But it uses the centralized model – the most widely implemented model – to illustrate a traceability use case within a DHSC architecture (Fig. 24). Details on the traceability models are available in WHO's *Policy Paper on Traceability of Medical Products (14)* and the International Coalition of Medicines Regulatory Authorities (ICMRA) guidance on traceability *(26)*.

Fig. 24

Fig 24. Achieving track and trace capabilities through DHSC architecture components



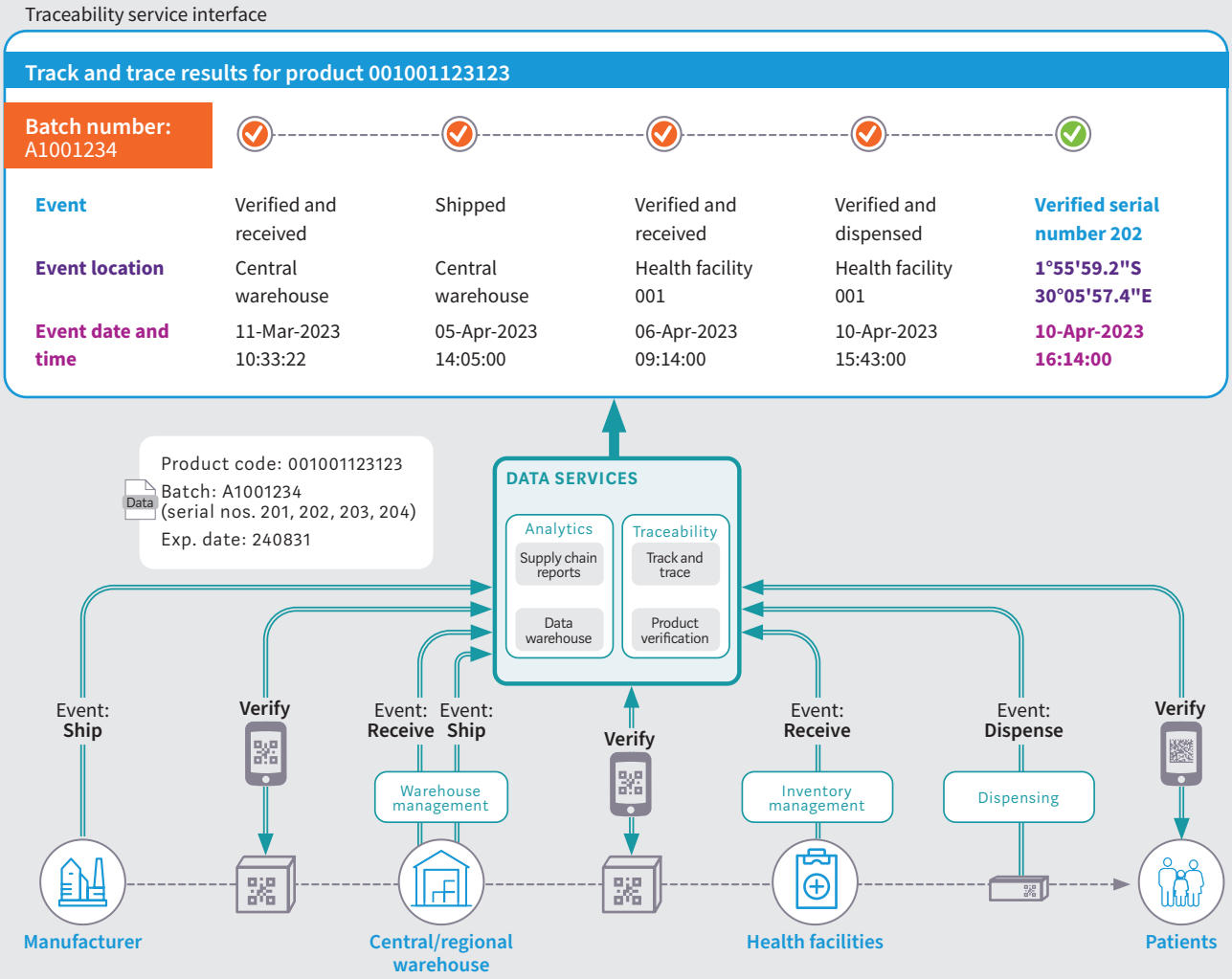
For a centralized traceability model, the following technology components are essential. Note that many of the components required for enabling tracking, tracing and verification can use existing supply chain systems and architectural elements:

- → foundational components – namely, globally unique identification of facility and product based on global standards and captured in a data carrier such as a barcode, as well as supplier master registries to provide master data that help combine data from disparate systems and derive traceability by providing the foundational layer for interoperability;
- → database or repository – to aggregate and organize master data, transactional data and supply chain events data from various systems;
- → interoperability layer – to facilitate data exchange and orchestration to and from various disparate systems to enable data sharing and data querying;
- → HSCISs – to share data related to supply chain transactions and events; and
- → traceability and analytical components – to synthesize the aggregated data and generate results for track, trace and verification queries. The analytical capabilities of existing reporting or business intelligence tools can be used for this. These components also include tools such as web-based and mobile applications that individuals can use to track, trace or verify health products.

Fig. 25 depicts how supply chain transactional data and event data can be aggregated from existing HSCISs in the data repository to provide verification and track and trace services.

Fig. 25

Fig 25. Illustrative example of a traceability service interface



The following are some factors to consider.

- → While the institutionalization of traceability could be a drawn-out, intensive process, the use of existing technology assets where feasible can help minimize the costs of system development and implementation.
- → Designing the exchange of traceability data requires a technical understanding of applicable standards as well as a structured methodology. Traceability processes should be designed according to a structured architecture that is independent of the technology used to capture and share data. This independence is crucial to the flexibility and scalability of the system – that is, the ecosystem and the technology may evolve while the design of the traceability data content stays the same.
- → One of the most important and challenging areas related to the implementation of traceability, or any DHSC process, is the quality of the master data. In a traceability model, sharing data across all stakeholders of the supply chain creates an information flow that precedes the physical flow of the product. This creates a data chain-of-custody effect that requires each stakeholder in the process to share responsibility for maintaining data integrity and quality. It is important that the required data be limited to the master data needed for the traceability system and that it be defined in consultation with the stakeholders.
- → While the tracking and tracing of a product is predominantly conducted in country, traceability in fact commences before the product reaches that country. For example, manufacturers identify and mark the product using global standards and store traceability data in their databases, and those data are transferred to the recipient country to support local processes.

Chapter 5

Country examples

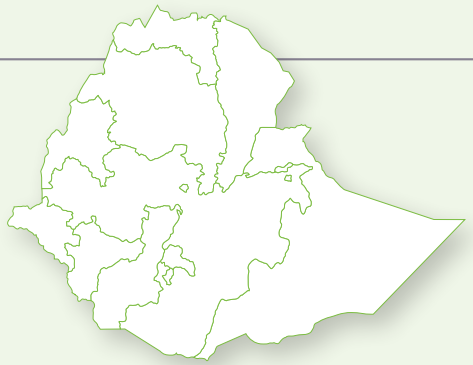
Ethiopia

Malawi

Rwanda

Ethiopia's DHSC initiative

About Ethiopia



Public health supply chain structure (2023)

Central warehouse	1	Functional hospitals	383
Branch warehouses	19	Functional health centres	3826
		Functional health posts	17 569

Status

The Government of Ethiopia issued its Information Revolution Roadmap in April 2016, which recognized digital health projects as major transformational tools. Under MOH leadership, it subsequently issued an eHealth Architecture (January 2018), strategy (2020) and blueprint (August 2021). The eHealth Architecture created a foundational framework for health information systems to interact and for proper management of systems and coordination of stakeholders. Digitization of the supply chain is part of the eHealth Architecture and aligns with the Digital Ethiopia 2025 initiative, which encourages all government sectors to proactively explore and embrace appropriate technologies.

Process

The supply chain systems were developed with support from development partners. Initial workshops were conducted to consider various assessment results and observed gaps and envision Ethiopia's future HSCISs. TWGs were established under the leadership of top management to provide system analysis and process optimization. A change management team was established to manage changes during implementation.

Current state

As of March 2024, national and facility-level supply chain systems were in use in Ethiopia. (See Fig. 26.) These systems are integrated and share information, and the product directory system accounts for differences between national-level and facility-level systems. In addition, the supply chain system and Electronic Regulatory Information System (eRIS) are integrated with eCustom and eTrade systems.

Future state

An ERP system that is underway will unify various systems, from downstream supply chain systems to other upstream systems. (See Fig. 27.) A centralized master data management tool will ensure a single source of information and comprehensive traceability. New technologies will enable end-to-end visibility across the pharmaceuticals supply chain.

Insights

- The MOH's leadership of the effort, engagement of all key stakeholders in drafting the architecture, and the incorporation of every partner's priorities and inputs will help to sustainably enhance implementation.
- The health supply chain initiative aligns with the priorities of the national digitization agenda.
- National TWGs and the steering committee will help ensure governance and alignment of DHSC initiatives.
- Engagement of all key stakeholders from the beginning will ensure a collaborative and aligned effort with optimal use of resources.
- Alignment of various national strategies and digital architectures will ensure optimal use of resources and interoperable digital ecosystems.
- The roadmap, strategy, blueprint and architecture will ensure that all health system digitalization efforts align with a sustainable and scalable shared vision.

Fig. 26

Fig. 26. Current-state supply chain systems in Ethiopia

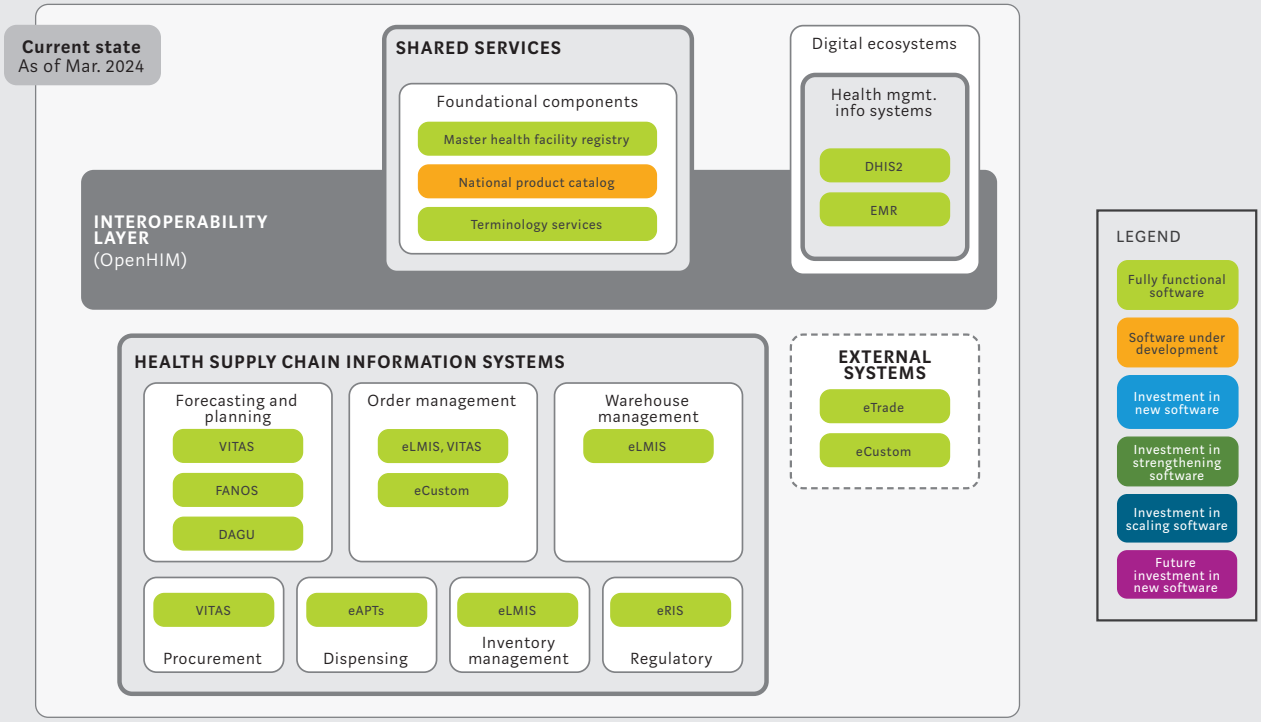
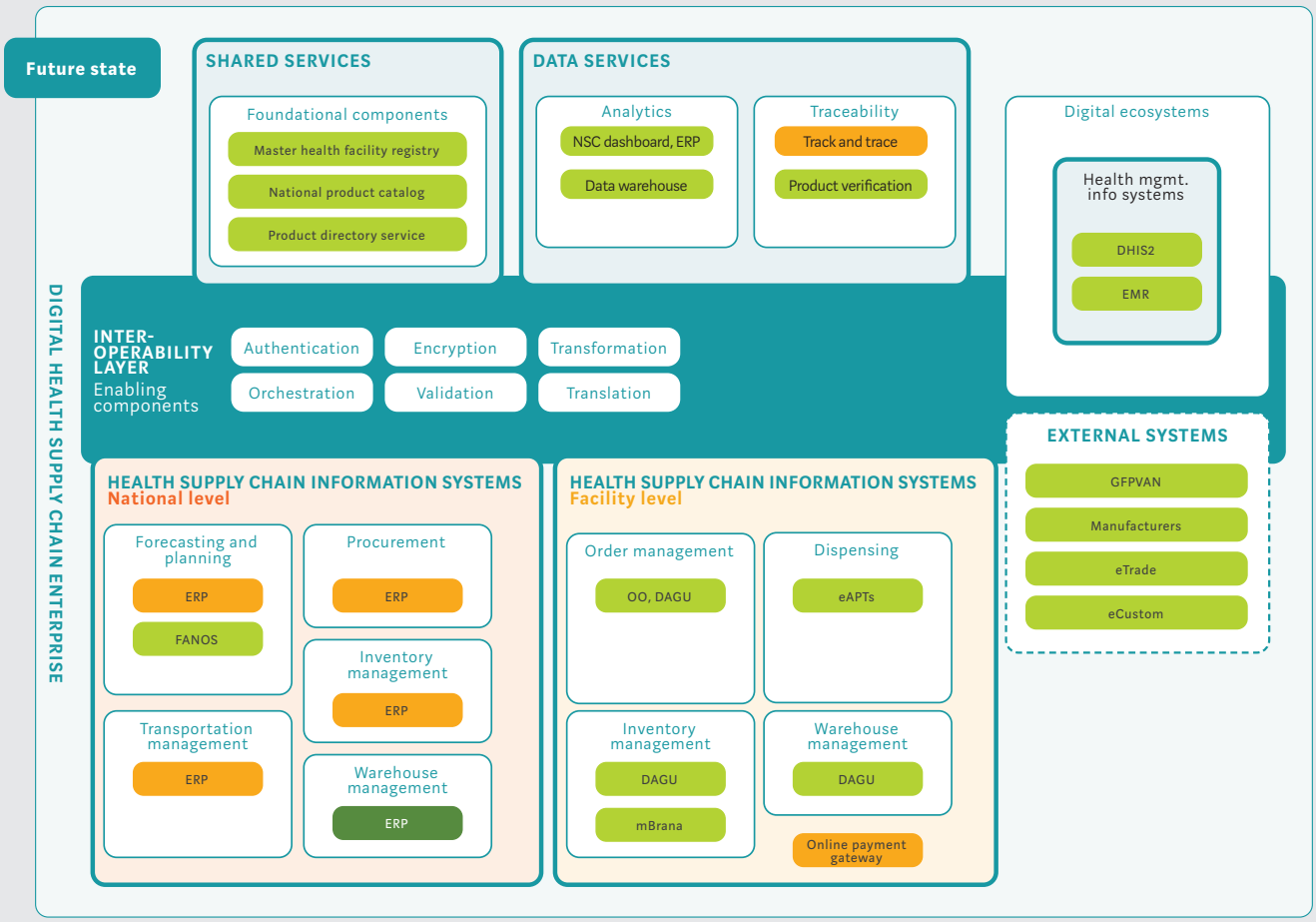


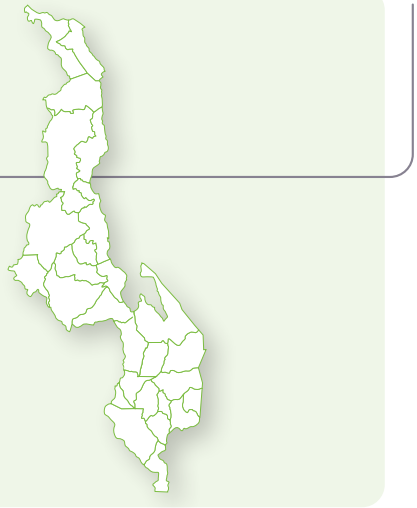
Fig. 27

Fig. 27. Future-state supply chain systems in Ethiopia



Malawi's DHSC initiative

About Malawi



Public health supply chain structure

Central warehouse	1	Health facilities	720
Regional warehouses	3		

Status

The country's Supply Chain Systems Architecture (SCSA) was collaboratively developed in 2021 under the leadership of the Health Technical Support Services (HTSS) division of the MOH. It was approved by the deputy minister of health in September 2022.

Process

The SCSA was developed with support from the USAID GHSC-PSM and was informed by a SCISMM assessment and an October 2021 workshop that was held to help shape the vision, strategy and architecture for Malawi's HSCISs. The workshop included stakeholders such as the MOH, the Central Medical Stores Trust, the Digital Health Division, the Pharmacy and Medicines Regulatory Authority and partners such as USAID, the United Nations (UN) Development Programme, the United States Centers for Disease Control and Prevention, and the UN World Food Programme. The SCSA was updated based on feedback from subsequent reviews, and a second workshop in September 2022 at which the final version was approved.

Current state

As of December 2023, various HSCISs lacked clarity about their functions, sometimes resulting in overlaps, as depicted in Fig. 28.

Future state

The SCSA provides a comprehensive framework that defines supply chain systems and how they will function together using shared services such as the National Product Catalog (NPC). It accounts for differences between national-level and facility-level systems and aligns with the country's Master Supply Chain Transformation Plan, as depicted in Fig. 29. Fig. 30 shows the visualization of the future-state architecture from the SCSA itself.

Insights

- Syncing DHSC priorities with Malawi's national agenda, as directed by its top leaders, has created momentum and ensured cohesion among all stakeholders.
- Having HTSS and the MOH lead the effort ensured collaboration and engagement among all stakeholders. This will help sustainably advance SCSA implementations.
- A steering committee initiated after the SCSA launch is helping to provide governance and ensure alignment of all DHSC initiatives.
- Engaging all stakeholders from the beginning (including government organizations, supply chain partners donors and implementing partners) will help ensure a collaborative and aligned effort with optimal use of resources.
- An overarching strategy and architecture such as SCSA ensures that the efforts of all donors and partners align and serve a common national vision.
- Holistic assessments such as SCISMM provide insights into gaps in and opportunities for health supply chain digitalization.

Fig. 28

Fig. 28. Current-state supply chain systems in Malawi

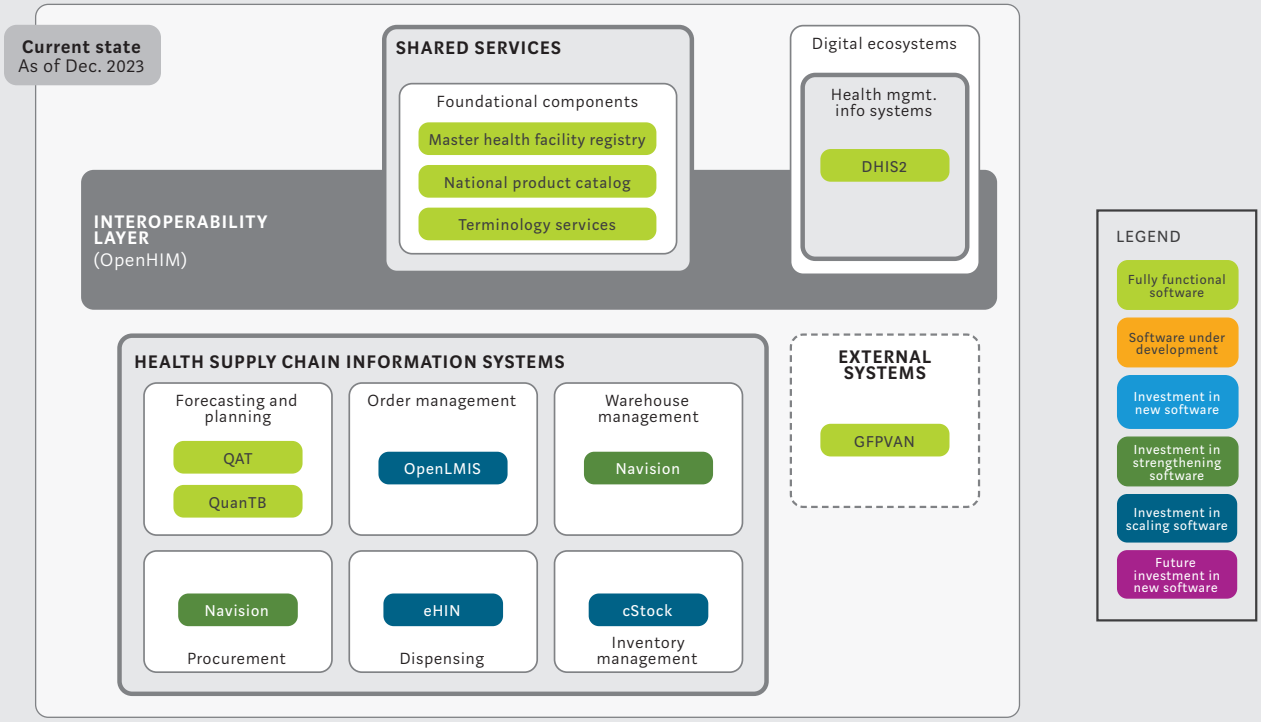


Fig. 29

Fig. 29. Future-state supply chain systems in Malawi

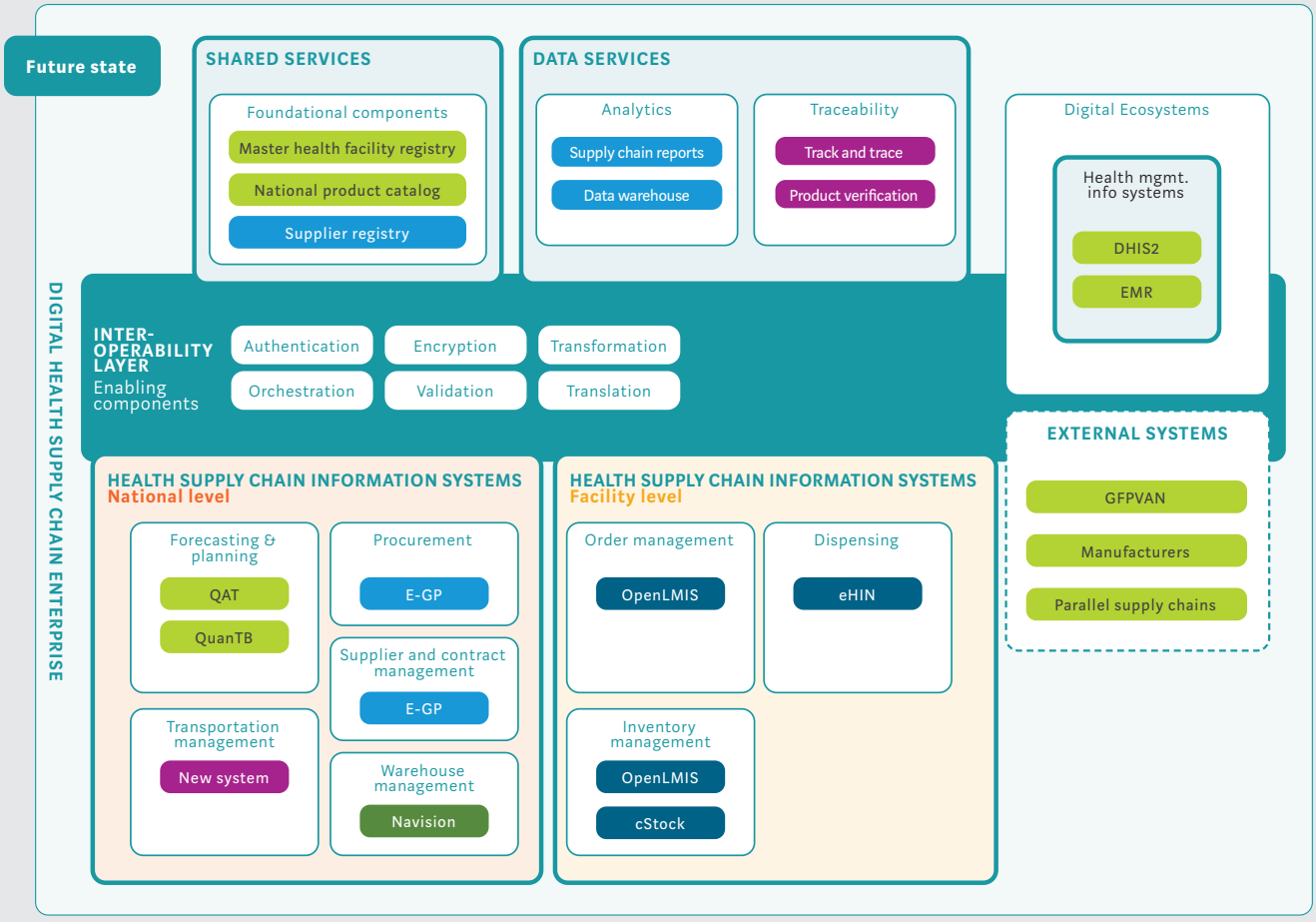
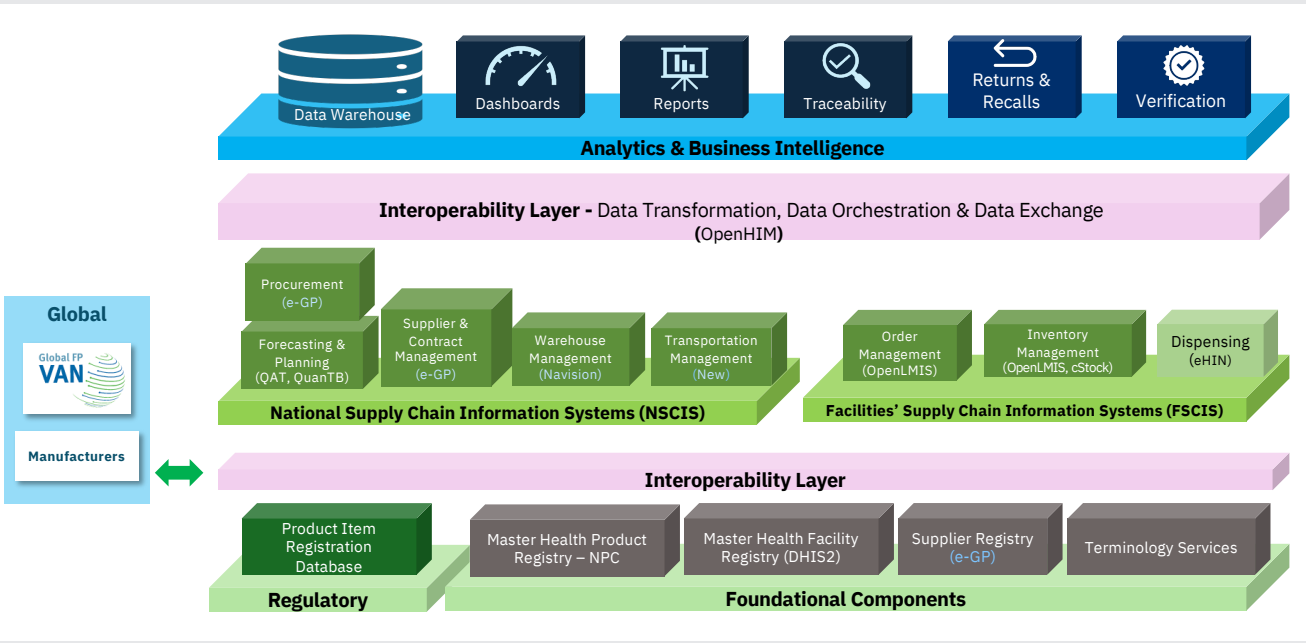


Fig. 30

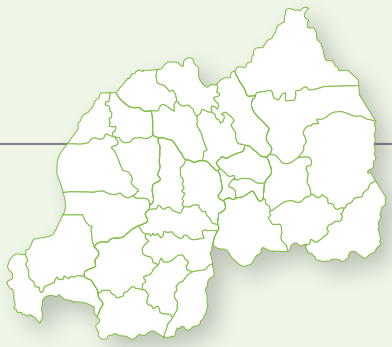
Fig. 30. Visualization of future-state architecture from Malawi's SCSA



Source: adapted from *Malawi Supply Chain Systems Architecture for Commodity Tracking and Tracing* (2022). Malawi Ministry of Health and Population.

Rwanda's DHSC initiative

About Rwanda



Public health supply chain structure

Central warehouse	1	Public and referral hospitals	47
Branch warehouses	30	Health centres	546

Status

Rwanda's Digital Supply Chain (DSC) Strategy and Architecture was collaboratively drafted in 2022 under the leadership of the MOH's Chief Digital Office. It is currently being aligned with and incorporated into the country's overall digital health strategy.

Process

The DSC Strategy and Architecture was developed with support from USAID through its GHSC-PSM project and was informed by the results of a SCISMM assessment. A collaborative workshop with all key stakeholders was conducted in February 2022 to help shape the vision, strategy and architecture for the country's HSCISs. Participants included the MOH, Rwanda Medical Supply, Rwanda Food and Drugs Authority, Rwanda Biomedical Centre, Rwanda Social Security Board, Rwanda Information Society Authority and partners including USAID and the private sector.

Current state

As of February 2022, the SCISMM assessment emphasized the need for standardizing product master data management and adopting a comprehensive integrated approach for implementing HSCISs. (See Fig. 31.)

Future state

The DSC Strategy and Architecture provides a comprehensive framework that outlines the HSCISs and how they will function together using shared services such as the NPC. It will help enable end-to-end visibility and pharmaceutical traceability. (See Fig. 32.)

Insights

- MOH leadership of the effort and engagement of all key stakeholders ensured a comprehensive architecture that incorporated every partner's priorities and inputs.
- A TWG helps provide governance and ensures that all health supply chain digitalization initiatives align with the DSC Strategy and Architecture.
- Recognition of the need to align various national strategies and architectures (such as those for digital health and for the DHSC) will help ensure that efforts lead to optimal use of resources and that digital ecosystems are interoperable.
- The overarching strategy and architecture ensures that all DHSC implementations (such as the ongoing ERP implementation) are aligned towards a sustainable and scalable shared vision.
- Holistic assessments such as SCISMM provide insights into gaps and opportunities in the health supply chain and help prioritize digitalization investments.

Fig. 31

Fig. 31. Current-state supply chain systems in Rwanda

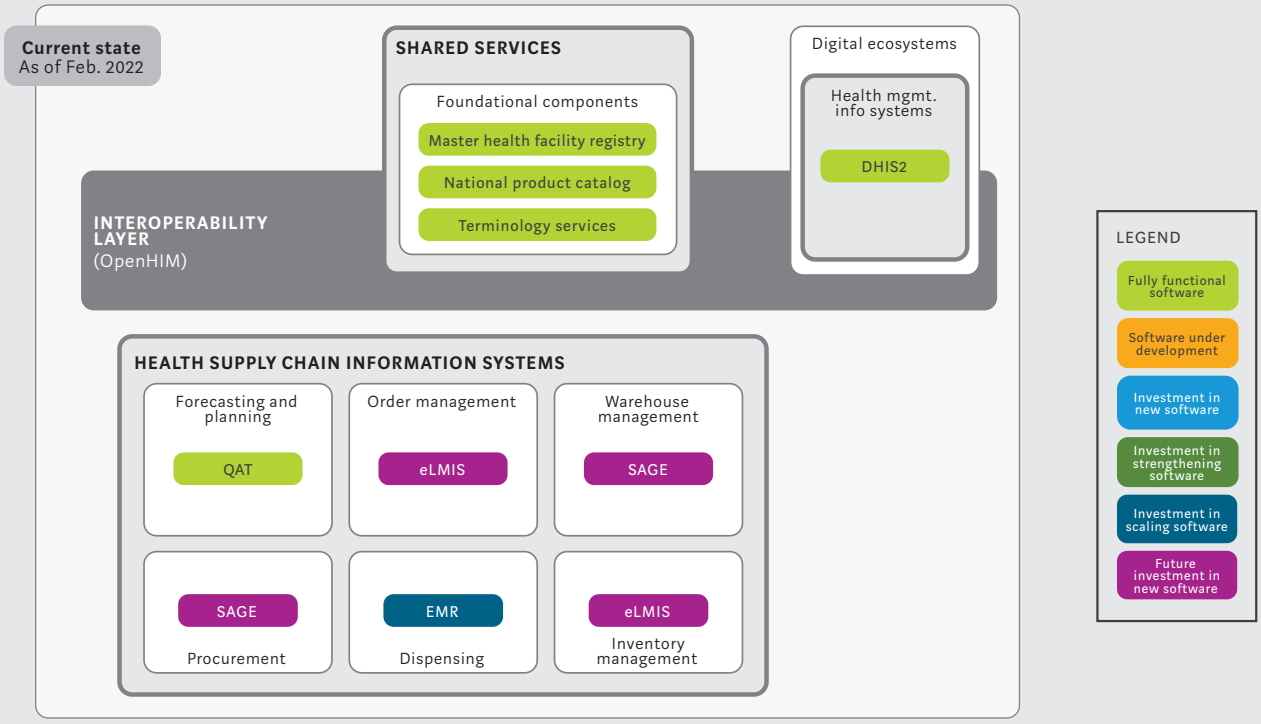
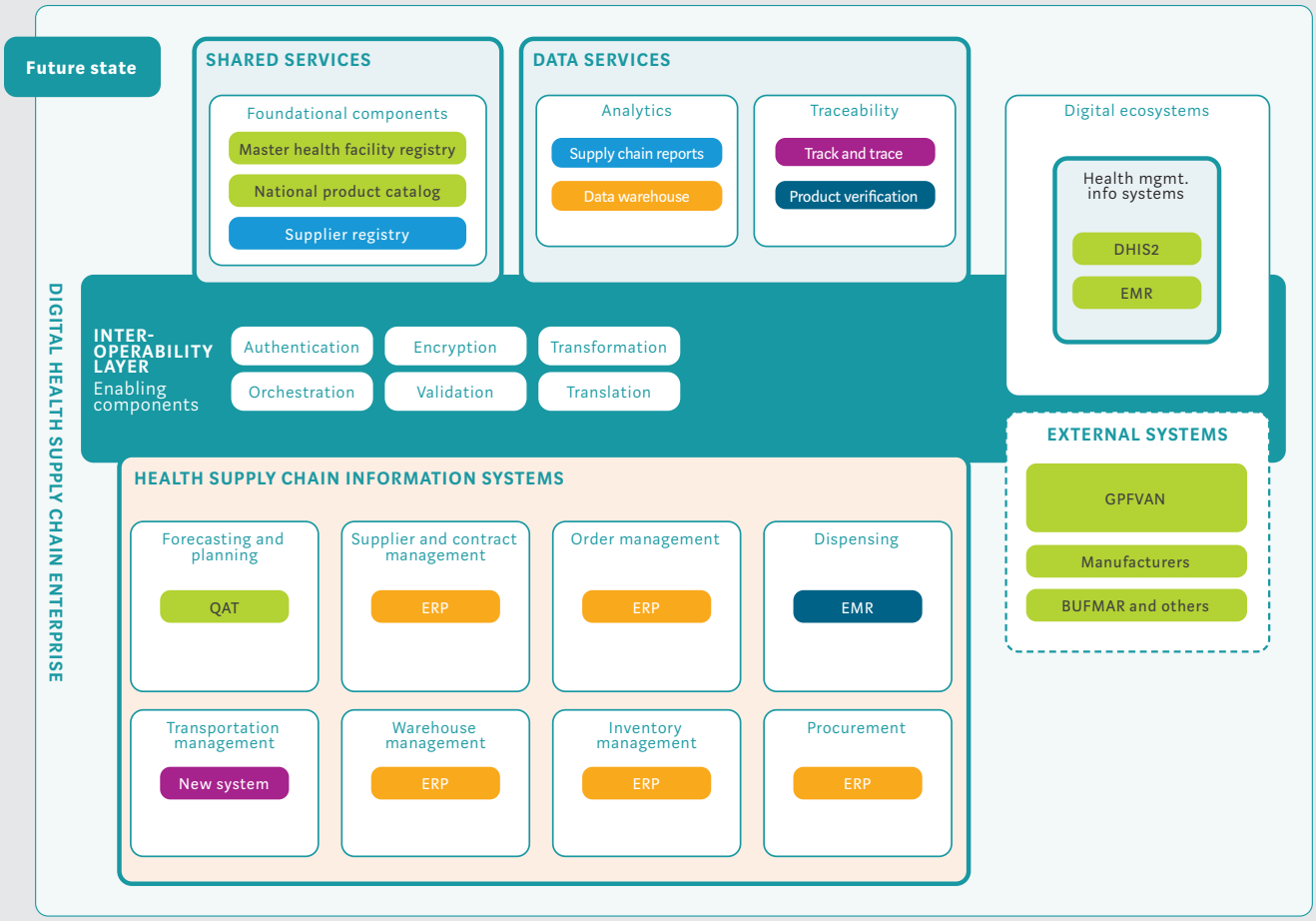


Fig. 32

Fig. 32. Future-state supply chain systems in Rwanda



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2 All linked references were accessed on 15 October 2024.

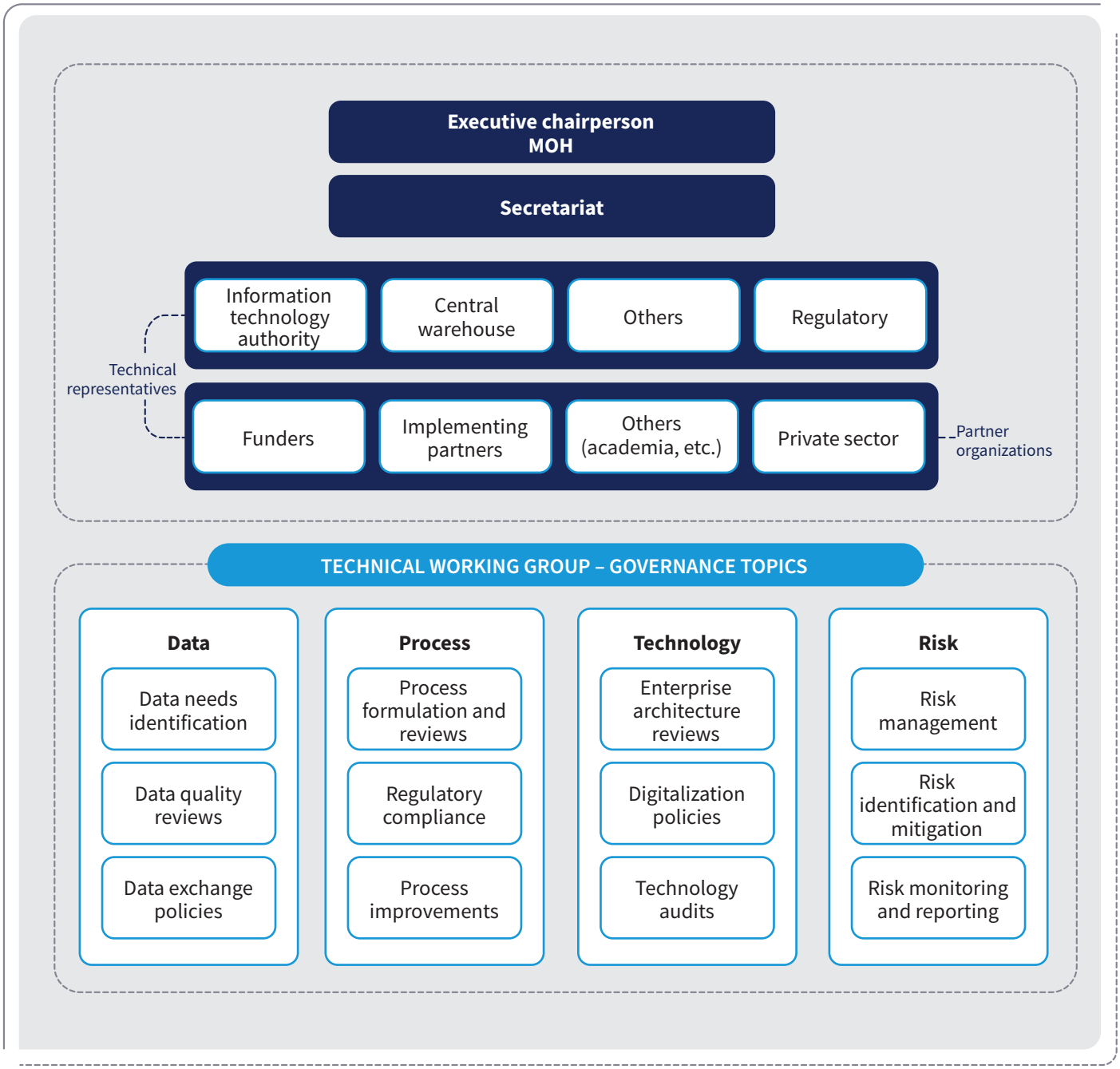
Annex 1. Principles for digital development

 **Understand the existing ecosystem**	Trust starts with a thorough understanding of the dynamic cultural, social and economic context in which you are operating.
 **Share, reuse, and improve**	Build on what works, improve what works, and share so that others can do the same.
 **Design with people**	Good design starts and ends with people that will manage, use, and ideally benefit from a given digital initiative.
 **Design for inclusion**	Consider the full range of human diversity to maximize impact and mitigate harm.
 **Build for sustainability**	Build for the long-term by intentionally addressing financial, operational, and ecological sustainability.
 **Establish people-first data practices**	People-first data practices prioritize transparency, consent, and redressal while allowing people and communities to retain control of and derive value from their own data.
 **Create open and transparent practices**	Effective digital initiatives establish confidence and good governance through measures that promote open innovation and collaboration.
 **Anticipate and mitigate harms**	Harm is always possible when it comes to technology. To avoid negative outcomes, plan for the worst while working to create the best outcomes.
 **Use evidence to improve outcomes**	Evidence drives impact: continually gather, analyse, and use feedback.

Source: adapted from Digital Impact Alliance's Principles for Digital Development (https://digitalprinciples.org).

Annex 2. Steering committee example structure

The following diagram illustrates an example organizational structure of a DHSC steering committee.



Annex 3. Template for prioritizing DHSC challenges to address

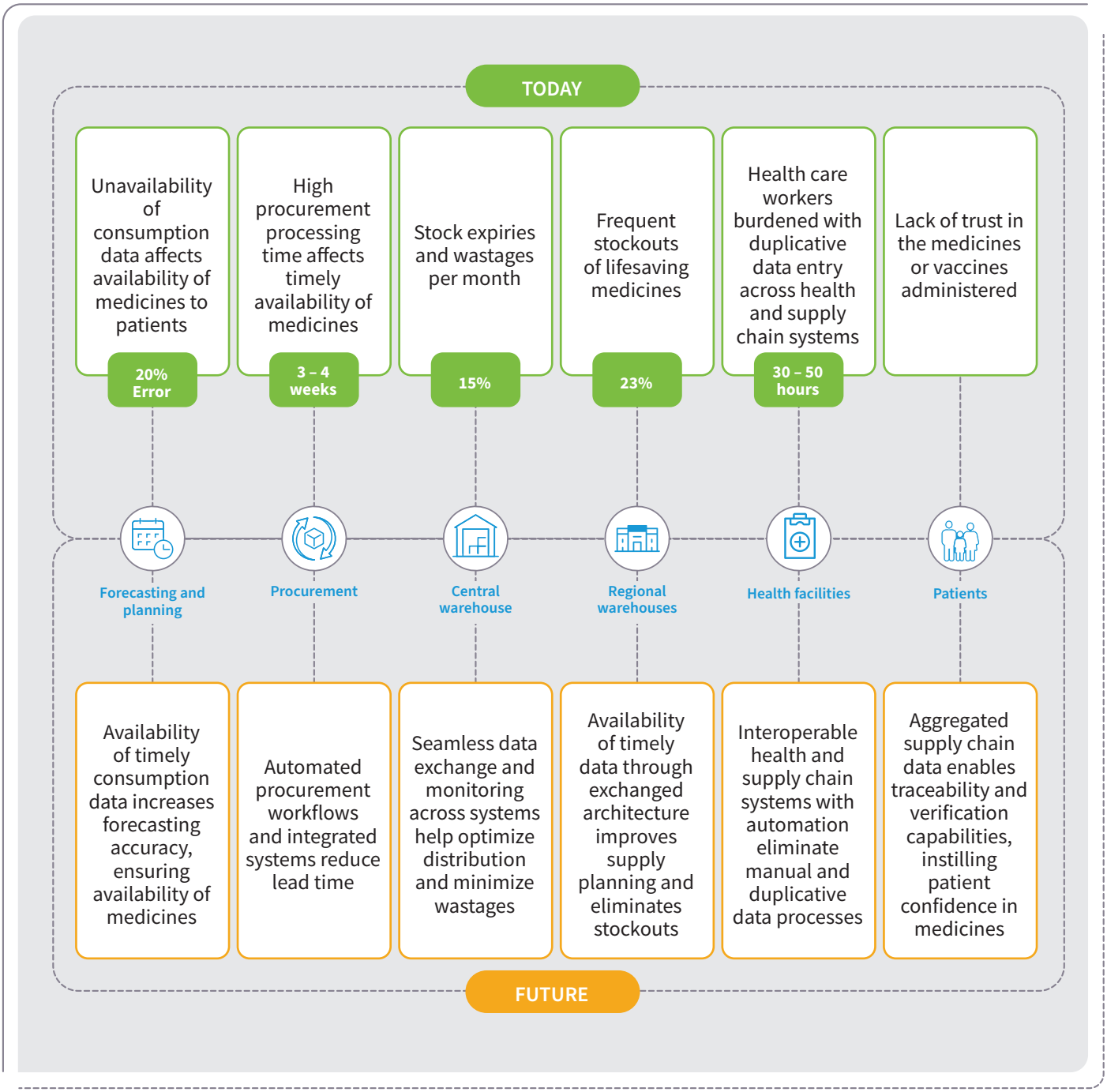
The following table offers some considerations for ranking supply chain challenges and bottlenecks. It can be useful in guiding discussion and reaching consensus among stakeholders. The table describes three hypothetical examples of bottlenecks, which receive scores of Low (1), Medium (2) or High (3) based on responses to three questions. Adding the scores yields the prioritized ranking.

Bottleneck	1. How much impact does this bottleneck have on the process? (1–3)	2. What is the likelihood of overcoming this bottleneck? (1–3)	3. Is this important to a wide range of stakeholders? (1–3)	Score	Prioritized ranking
Example: Unavailability of timely consumption data results in inaccurate forecasts and frequent stockouts.	Low (1)	High (3)	Yes (3)	1+3+3=7	HIGHEST
Example: Aggregating data from paper forms is burdensome and rarely done correctly.	Medium (2)	Medium (2)	Some (2)	2+2+2=6	MEDIUM
Example: Inability to track and trace health products using serial numbers.	Low (1)	Low (1)	Some (2)	1+1+2=4	LOW

Source: adapted from the 2020 WHO *Digital Implementation Investment Guide (1)*.

Annex 4. Illustrative template that maps today's challenges to future outcomes

This type of template can be used to map the transition from current critical challenges faced by supply chain partners and their processes to the future vision of a DHSC.



Annex 5. Template for listing health supply chain information systems

The following table is a template for assessing the current landscape of HSCISs and identifying systems and gaps.

	MOH	Regulatory authority	Central warehouse	Branch warehouse	Service delivery point	Community health worker	Individuals
Forecasting and planning	**Planning system**						
Procurement management							
Supplier and contract management							
Order management			**OpenLMIS**	**OpenLMIS**	**OpenLMIS**		
Warehouse management			**ERP**			**RapidSMS**	
Transportation management							
Dispensing					**OpenClinic**		
Analytics	**Health analytics platform**						
Track and trace							**NPC mobile app**
Cold chain management							
Foundational components	**NPC**						
Regulatory		**Registration system** **NPC mobile app**					

In progress

Deployed

Annex 6. Risk register template

The following table is a template for ranking risks and identifying mitigation steps.

#	Risk title	Description	Priority	Impact	Prob-ability	Status	Mitigation steps	Owner	Raised	Reviewed	Closed
001	Inadequate training	IF system training is not delivered with appropriate content for the audience, THEN the adoption and use of the system may fail.	Low	Major	Medium	Mitigate	» Perform a skills assessment for each user before completing the training plan. » Complete a training needs assessment before conducting training. » Target and adapt training to meet the needs of the training audience.		2018-01-28	2019-08-16	

Annex 7. Resource matrix for DHSC implementation

The table below illustrates the technical roles needed for DHSC implementation. The following resources on human resource planning for health supply chain digital transformation can also be helpful:

- People that Deliver (PtD): Building human resources for supply chain management theory of change *(1)*
- People that Deliver: Supply chain management professionalisation framework *(2)* and
- People that Deliver: PtD outsourcing toolkit *(3)*.

Role category	Role	Phase(s) in which it is required		Position type	Skill sets	Responsibilities
		Deployment	Operation			
Leadership	**Chief technology officer / chief information officer / chief digital officer**	✓	✓	Permanent	» Leadership skills: ability to manage multiple IT teams and provide guidance on digital initiatives » Strategy skills: ability to perform strategic planning for IT initiatives and provide oversight to ensure that strategic objectives are met » Technology skills: knowledge of the latest technologies and trends, understanding of enterprise architecture and data management » Interpersonal skills: communication and presentation skills, relationship and team development skills	» Liaise with senior technical leadership across different organizations to facilitate IT work planning and budgeting » Facilitate approvals of workplans, budgets and funding requests » Develop and implement IT policies and standards » Manage multiple IT teams, including implementation teams, infrastructure personnel and IT manager » Oversee key IT initiatives and ensure successful deployments in line with strategic objectives » Lead vendor management
Leadership Technical	**IT manager**	✓	✓	Permanent	» Leadership skills: ability to manage technical teams » Strategy skills: ability to support strategic planning for IT initiatives » Technology skills: knowledge of existing technologies used in country and latest trends, understanding of data management and application support needs » Interpersonal skills: communication and presentation skills, relationship and team development skills	» Liaise with senior leadership to facilitate IT work planning and budgeting » Implement IT policies and standards » Manage IT personnel » Oversee day-to-day operations of IT tools » Identify IT improvement opportunities » Liaise with IT vendors when required to facilitate troubleshooting or enhancements
Leadership	**Project manager**	✓		Contracted/ temporary	» Understanding of business requirements and high-level IT architectures/solutions » Project management skills such as planning, budgeting, risk management, team management and time management » Experience in various project management methodologies such as agile, waterfall and software development lifecycle » Ability to coordinate with and manage multiple stakeholders » Interpersonal skills such as communication, presentation and team development	» Set project objectives and charter » Develop project plan to manage resources and timeline within the allotted budget » Provide regular status updates to team and senior leadership » Identify and assess risks and develop mitigation strategies » Coordinate efforts of all team members to meet project objectives » Monitor and manage project performance and progress

Role category	Role	Phase(s) in which it is required: Deployment	Phase(s) in which it is required: Operation	Position type	Skill sets	Responsibilities
Leadership Technical	**Solution architect**	✓		Contracted/ temporary	» Knowledge of various technology options and trends, such as cloud services, software as a service and open source » Experience in software design and architecture » Knowledge of IT infrastructure » Technical leadership skills such as providing technical guidance and vision » Ability to understand business requirements and map them to technology solutions » Understanding of best practices in software development, architecture and IT deployments » Analytical and problem-solving skills	» Gather business requirements to define scope and develop technology solutions and architecture to satisfy requirements » Prepare technology specifications to implement, using best-practices » Analyse existing systems and identify improvements and integration requirements » Guide technical team members in implementing technology solutions » Coordinate with various technical teams such as integration specialists, infrastructure specialists and quality assurance (QA) personnel to guide them in various aspects of IT implementation » Coordinate with senior leadership to communicate about technology options, cost impact and budget needs
Technical	**Business analyst**	✓		Contracted/ temporary	» Analytical and problem-solving skills » Writing and communication skills » Ability to understand and gather business requirements » Knowledge of supply chain processes » Interpersonal skills such as coordination across various teams and stakeholders	» Gather and analyse business requirements and map business processes » Collaborate with technical teams to translate business needs into technical requirements » Develop use cases or user stories to convey business needs to technical teams » Coordinate with QA team to ensure that test cases for validating technical solutions are developed according to business needs » Collaborate with multiple technical and business teams » Collaborate with QA and training teams to prepare test cases and training material
Technical	**Developer/ programmer**	✓		Contracted/ temporary	» Knowledge of and experience with programming languages such as Java, Python and C++ » Knowledge of and experience with technology options such as relational databases, web frameworks and object-oriented development » Ability to understand business requirements and develop programs to meet those requirements » Interpersonal skills such as ability to coordinate various technical and process teams » Analytical and problem-solving skills » Experience in developing software solutions using open-source tools	» Design and develop software programs that meet business requirements » Deploy the developed software across multiple environments, such as test, staging and production » Troubleshoot and fix bugs in software programs » Collaborate with QA and training teams to prepare test cases and training material

Role category	Role	Phase(s) in which it is required		Position type	Skill sets	Responsibilities
		Deployment	Operation			
Technical	**Integration specialist**	✓		Contracted/ temporary	» Knowledge of and experience with ETL (Extract, Transform and Load) tools » Knowledge of and experience with SQL » Knowledge of and experience with service-oriented architecture » Knowledge of and experience with various data transfer protocols, schemas and formats » Knowledge of available data transformation and interoperability tools and experience with at least two tools	» Design integration solutions to use interoperability features across multiple systems » Develop integration standards and protocols » Coordinate with implementation team members such as architects and programmers to develop application integrations » Maintain the developed integrations and troubleshoot issues
Technical	**Database administrator**	✓	✓	Permanent	» Knowledge of various database tools » Data modelling » Database management, including performance monitoring, optimizing and tuning » Database backup and recovery » Data security	» Advise on relevant database tools to use » Support database activities such as data modelling, performance monitoring, data cleansing and tuning » Monitor databases to ensure timely backup and recovery when required » Ensure security of databases and administer relevant access to appropriate users » Coordinate with teams deploying various IT tools to support database activities
Technical	**Infrastructure specialist**	✓	✓	Permanent	» Proficiency with network protocols such as TCP/IP, DNS, DHCP and VPN » Knowledge of firewalls, intrusion detection/prevention systems and VPNs for secure data transmission » Proficiency with Linux, Unix and Windows Server environments for installation, configuration and maintenance » Experience with virtualization platforms such as VMware, Hyper-V and KVM » Familiarity with scripting (e.g., PowerShell, Bash) to automate system tasks » Experience with cloud infrastructure services » Ability to design, implement and manage cloud-based solutions » Experience with SAN, NAS and other storage solutions » Understanding of best practices in securing systems and networks, including patch management, malware protection and secure access controls » Familiarity with regulations such as those ensuring that infrastructure complies with legal and regulatory requirements	» Identify, analyse and solve complex hardware and software issues across the infrastructure » Manage network configurations, routers, switches, firewalls and load balancers and perform troubleshooting » Define backup strategies and disaster recovery plans and ensure business continuity » Optimize systems and networks for high availability and efficiency

Role category	Role	Phase(s) in which it is required		Position type	Skill sets	Responsibilities
		Deployment	Operation			
Leadership Technical	**QA/test manager**	✓		Contracted/ temporary	» Knowledge of software implementation methodologies, including agile and waterfall » Knowledge of and experience with automated testing tools » Experience with testing large-scale IT tools, managing test teams and troubleshooting test scenarios and technical issues » Experience with testing phases such as system testing, performance testing, user acceptance testing and integration testing » Experience with test case development, test results reporting and stakeholder management » Experience with and knowledge of defect tracking tools such as JIRA	» Manage testing teams to perform test scenarios such as system testing and user acceptance testing » Develop and guide the team in developing test cases and scripts based on business requirements » Develop test management plans that include resource plan, risk management, timeline and scope » Coordinate across multiple teams such as development team and infrastructure team to manage testing of IT tools at different intervals of the implementation » Monitor testing progress and provide status reports to senior leadership
Technical	**Test analyst**	✓		Contracted/ temporary	» Knowledge of software implementation methodologies, including agile and waterfall » Knowledge of and experience with various automated testing tools » Experience with testing large-scale IT tools and troubleshooting test scenarios and technical issues » Experience with testing phases such as system testing, performance testing, user acceptance testing and integration testing » Experience with test case development and test scripting » Experience with and knowledge of defect tracking tools such as JIRA	» Develop test cases and scripts based on business requirements » Conduct testing across different phases such as system testing, performance testing and user acceptance testing, and capture test results » Coordinate across teams such as the development team and infrastructure team to manage testing of IT tools at different intervals of the implementation
Technical	**System administrator**		✓	Permanent	» Experience with the system, network and database administration of IT tools » Knowledge of, experience with and certifications in various operating systems » Experience with system administrative tools such as virtualization and VMware » Experience with networking (WAN/ LAN), hardware and scripting tools (e.g., Python and Perl) » Experience with and knowledge of IT helpdesk activities such as data security and user management » Troubleshooting skills	» Support installation of IT tools/ software and hardware (e.g., servers) » Monitor performance of systems and ensure uptime » Manage various servers, networks and other technology tools to maintain operations of IT applications » Monitor for technical issues and troubleshoot » Ensure data security by adding/ modifying/deleting user accounts and providing users with appropriate access to data » Apply version updates, hot fixes and any other software/ hardware revisions required for all the applicable tools

Role category	Role	Phase(s) in which it is required		Position type	Skill sets	Responsibilities
		Deployment	Operation			
Technical	**Support engineer**		✓	Permanent or contracted/ temporary	» Knowledge of and experience with supply chain software » Knowledge of networking and hardware setup » Experience with software support activities such as troubleshooting, coordinating with users and vendors, and applying fixes » Proficiency in remote setup or virtual tools to troubleshoot technical issues » Knowledge of defect tracking tools such as JIRA	» Provide day-to-day support to users of software tools to troubleshoot any issues » Monitor performance of software tools and ensure uptime » Provide regular maintenance of software tools and applying version updates, hot fixes, etc. » Capture technical issues and resolutions for status reporting
Technical	**Superuser/ trainer**	✓	✓	Permanent	» Knowledge of supply chain processes and features of relevant software tools » Experience using two or more supply chain software tools » Experience training end users	» Train end users on various functionalities and features in supply chain software tools » Help users with system administrative activities that can be managed by end users (e.g., password change). » Perform simple and basic configuration of systems, where applicable, to enhance or add features to software tools

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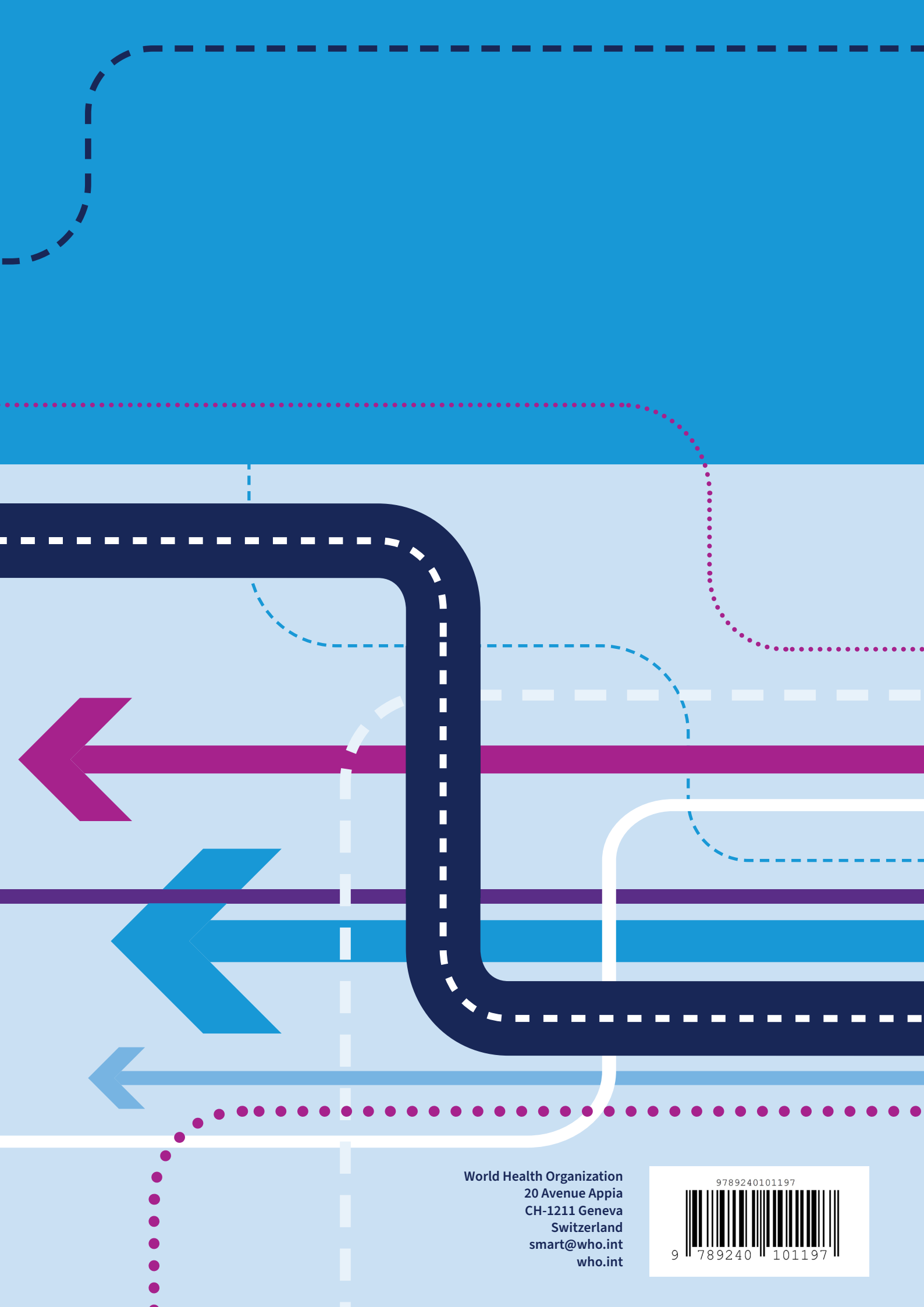

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