BETTER IMMUNIZATION DATA
INITIATIVE

Product Vision for the Better Immunization Data (BID) Initiative

28 August 2014

PATH

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- Brian Taliesin, Senior Program Officer, Digital Health Solutions, PATH
- Henry Mwanyika, Country Director, BID Initiative Tanzania, PATH
- Derek Ritz, Principal, EcGroup
- Liz Peloso, Global Director, BID Initiative, PATH
- Kate Wilson, Director, Digital Health Solutions, PATH

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For more information about the Better Immunization Data Initiative, see our website at http://bidinitiative.org/, or contact BIDInitiative@path.org.

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Contents

Figures

Tables

Text Boxes

Abbreviations

3G	3rd generation
AIDC	Automated Identification and Data Capture
API	Application programming interfaces
BID	Better Immunization Data
CHW	Community health worker
cMYP	Comprehensive multi-year plan
CRDM	Collaborative Requirements Development Methodology *See http://jointlearningnetwork.org/content/what-crdm*
DHIS2	Open source Health Information Software. *See www.dhis2.org*
DIVO	District Immunization and Vaccination Officer
DOB	Date of birth
DTP1, DTP2, DTP3	Three dose regimen associated with diphtheria-tetanus-pertussis
DVDMT	District Vaccine Data Management Tool (Excel-based)
EA	Enterprise architecture
eHealth	Electronic health
EPI	Expanded Program on Immunizations
GAVI	Global Alliance for Vaccines and Immunizations *See www.gavialliance.org*
HCW	Health care worker
HepB	Hepatitis B vaccine
Hib	*Haemophilus influenzae* type B vaccine
HIS	Health information system
HIV/AIDS	Human immunodeficiency virus infection / acquired immunodeficiency syndrome
HL7	Health Level Seven International *See www.hl7.org*
HMIS	Health management information systems
HTTPS	Hypertext Transfer Protocol over Secure Socket Layer
ICD-10	International Statistical Classification of Diseases and Related Health Problems, 10th revision *See www.who.int/classifications/icd/en/*
ICT	Information and computer technology
ID	Identifier
IHE	Integrating the Healthcare Enterprise *See www.ihe.net*
iHRIS	Open source Human Resources Information Software *See www.ihris.org*
IIS	Immunization information system
IL	Interoperability layer
IMCI	Integrated Management of Childhood Illness *See www.who.int/maternal_child_adolescent/topics/child/imci/en/*
ISO/IEC	International Organization for Standardization/International Electrotechnical Commission *See www.iso.org and www.iec.ch*
IVD	Immunizations and Vaccines Department
LMIS	Logistics management information system
LOINC	Logical Observation Identifiers Names and Codes *See http://loinc.org/*
M&E	Monitoring and evaluation
MIS	Management information system
MoH	Ministry of Health
MSD	Medical Stores Department
NeSF	National eHealth standards framework
NGO	Nongovernmental organization
NID	National Immunization Days

NMFL	National Master Facility List
OAuth	Open standard for authorization
OpenEHR	Open source Electronic Health Record
OpenHIE	Open source Health Information Exchange *See www.ohie.org*
OpenLMIS/eLMIS	Open source Logistics Management Information System/electronic logistics management system *See www.openlmis.org*
OpenMRS	Open source Medical Records System. *See www.openmrs.org*
OPV	Oral polio vaccine
PCV2	Pneumococcal vaccine, second dose
PHII	Public Health Informatics Institute *See www.phii.org*
PMTCT	Prevention of mother-to-child transmission of HIV/AIDS
POD	Proof of delivery
RED	Reach Every District *See www.who.int/immunization_delivery/systems_policy/red/en/*
RFP	Request for proposal
RIVO	Regional Immunization and Vaccination Officer
RM-ODP	Reference Model for Open Distributed Processing *See www.rm-odp.net*
ROTA2	Rotavirus vaccine
SMS	Short message service
SMT	Stock Management Tool (Excel-based)
SNOMED	Systematized Nomenclature of Medicine *See http://www.ihtsdo.org/snomed-ct/*
SOA	Service-oriented architecture
UML	Unified Modeling Language
UNICEF	United Nations Children's Fund *See www.unicef.org*
VAR	Vaccine Arrival Reports
VEO	Village Executive Officer
VVM	Vaccine vial monitor
WHO	World Health Organization *See www.who.int*
XDS	Cross-enterprise document sharing

1. Overview

Overview of the problem

The global health community has made fundamental investments in the development, procurement, and introduction of new vaccines in lower-income countries. National governments have strengthened their immunization programs, yet systemic problems such as vaccine stockouts and identifying the unvaccinated continue to stall efforts to vaccinate all citizens. Even more disturbingly, questions linger about the accuracy of the routine immunization numbers—are the reported achievements even reliable Global stakeholders and national governments quietly acknowledge that routine immunization and vaccine introductions still face strong challenges related to data quality and have identified a few of the problems that matter most:

Chapter Summary

We are trying to improve information systems to increase vaccination coverage for under-reached populations. To do this, we need to:

- Identify who needs to be vaccinated.
- Know which individuals did not receive all of the recommended vaccinations.
- Improve ease and quality of data collection and visibility.

Accurate denominator	The source used to estimate number of clients for each clinic is provided centrally. However, in practice, the actual client numbers vary widely from the provided numbers.
Defaulter tracing	Ability to identify children that may not have received their full dosing regimen.
Unique identification of children	Individuals are associated with a particular health facility, so if they receive services from another clinic, their full immunization history may not be captured accurately.
Complexity of data collection forms	The complexity of data collection and reporting forms increases the burden on health workers and the chances of errors.
Data visibility	It is practically impossible to review data from clinics at the village or even district levels, especially stock status.

Unfortunately, information systems and a culture of evidence-based decision-making that would help solve these operational issues and provide actionable information to users do not yet exist.

While technology capabilities and internet/network connectivity are improving rapidly in Africa, effective, affordable information systems that automate national immunization data collection and support delivery of routine child health services (e.g., immunizations, nutrition screening and counseling) for health workers have not yet been built or deployed at scale. Fragmented information and computer technology (ICT) pilots are not interoperable with one another, nor linked into existing national-level information systems. In fact, it is common to

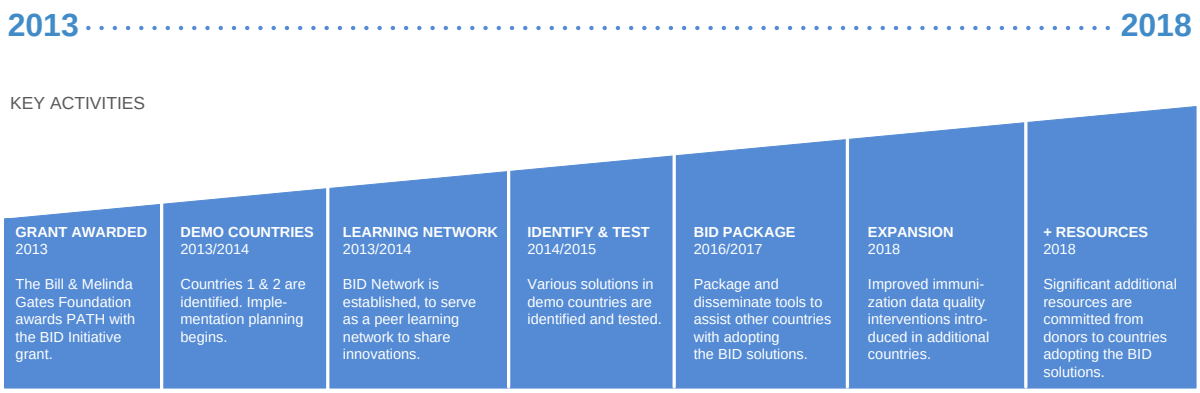
find that each health area and geographical area within a country will manage its own disparate data collection and infrastructure systems.

Vision and design of the Better Immunization Data (BID) Initiative

Led by PATH and funded by the Bill & Melinda Gates Foundation, the BID Initiative is grounded in the belief that better data, plus better decisions, will lead to better health outcomes. Its vision is to empower countries to enhance immunization and overall health service delivery through improved data collection, quality, and use. Reaching this vision requires investments in information system products, practices, people, and packaging.

The BID Initiative is unique. It is designed to partner with countries in Africa through the BID Learning Network (see http://bidinitiative.org/bid-learning-network/) to introduce information system products and immunization practices that can be tested in a few demo countries, packaged for dissemination, and then deployed at scale in many countries. BID also starts with the premise that we will build new information system products or practices only as a last resort. Instead, investments will be made to embrace and extend existing information system products and investments already made by donors and national governments in immunization best practices wherever possible. The BID Initiative is entering the identification and testing phase of the project shown in Figure 1-1.

Figure 1-1. BID Initiative key activities.



A key step in developing improved information system products is to understand the current state of the problem and the desired outcomes. While this seems simple, it is often not done, or not done appropriately.[1,2,3] Getting a comprehensive picture of the actual processes associated with immunizations; the issues and barriers experienced; and the data flow, all within the local context, is critical to designing an appropriate solution.

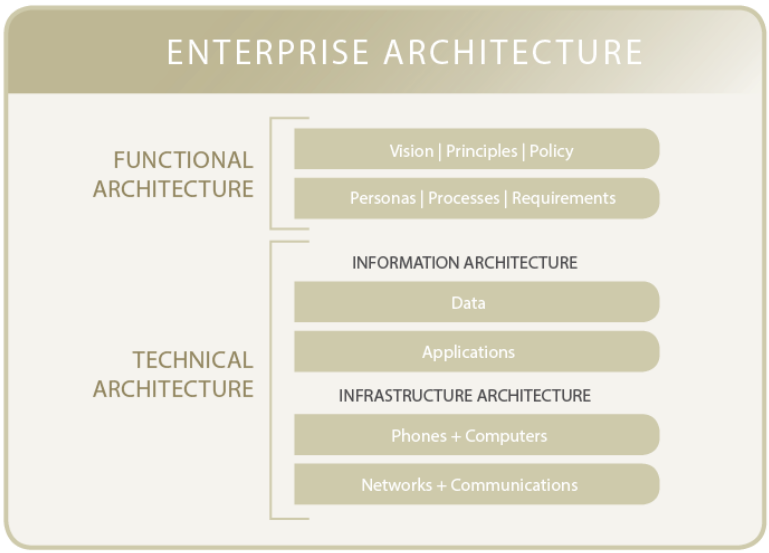
During the beginning phases of the project, the team worked with countries and partners to: prioritize which data collection problems should be focused on first, collect functional requirements for any desired information system solutions, assess existing information

systems deployed in the field and how they matched the requirements, and assess the financial ramifications of possible solutions.

Using an enterprise architecture approach

The use of enterprise architecture (EA) helps the BID Initiative and demo countries align investments in information systems with the missions, goals, and strategic objectives of the country.[4,5] Generally, there are layers or viewpoints that describe various aspects of EA such as those depicted in Figure 1-2, including the *Functional Architecture* describing the national vision, principles, and information policies; the *Information Architecture* containing the data and application standards to be followed; and the *Infrastructure Architecture* documenting the hardware to be used and the network and data exchange protocols to be followed.[6]

Figure 1-2. Enterprise architecture model.



As we drafted the design for the BID Initiative (consisting of both information system products and the tools and practices required for better use of the data), understanding and learning from previous projects and pilots was a critical step. One root cause of the fragmented ICT pilots mentioned before is focusing on the phones or the software application before considering the desired functionality of the system. As the infrastructure was never intended to be interoperable, nor linked into existing national-level information systems, it shouldn't be surprising that considerable challenges still exist.

Given this understanding, the BID Initiative has combined a "top down" approach with a "bottom up" view. We begin with the national strategies, incorporating the current context of the users (e.g., the functional architecture) before considering the facility applications (e.g., the technical architecture) that are in use and have gained traction and how they might tie together. The approach is described in more detail in the next chapter.

Chapter outlines

While we have not completed all layers of the EA with the demo countries, an initial package of documents is now available as a resource for both country electronic health (eHealth) managers and information systems developers when designing or evaluating solutions for

similar problems. The package is designed so readers can access specific sections of interest or read the entire package as a whole. The various chapters serve to document the approach for designing a scalable immunization information system for sub-Saharan Africa. Table 1-1-1 provides a short description of each chapter along with the question it intends to answer.

Table 1-1. Breakdown of chapters in BID's Product Vision.

Chapter	Description and the question the chapter addresses
1. Overview	What problem are we trying to solve? *This initial chapter describes the vision and the initial set of problems countries have identified with their current systems to manage routine immunizations and the vaccine supply.*
2. Enterprise Architecture Approach	Where do I start? *This chapter describes the architectural approach for the BID Initiative using various points of view to represent different audiences and perspectives. Interoperability, standards, and policies are discussed.*
3. User Personas	Who are we doing this for? *The user personas chapter describes the demographics, environment, and key challenges for the various country stakeholders that would be using aspects of the immunization information system. These personas are a method for enhancing engagement with stakeholders and build context for prototyping efforts.*
4. Business Process Matrix and Process Flow Diagrams	What are they doing today? *Through ongoing country consultation, a set of common processes was identified for an immunization system using the CRDM. The diagrams illustrate what the system looks like today, once the new processes have been implemented.*
5. Common Requirements	What must the information system products do? *As a second part of the CRDM, participants provided input into the functional requirements definition for the various information system prototypes. This helps ensure solutions will be able to meet the needs of the various stakeholders.*
6. Key User Scenarios	How could information system products improve data quality and use? *The user scenarios chapter uses a storytelling approach to describe how the users described in Chapter 3 were able to reach their respective goals through the use of the immunization information system.*
7. Landscape of Tools in Use	What systems and technology are available today? *A key principle of the BID Initiative is to promote strategic reuse of existing systems. This chapter lists the various information system products used by the various countries, along with models for how systems may fit within a national EA.*

[1] Shaw V. Health Information System Reform in South Africa: Developing an Essential Data Set. *Bulletin of the World Health Organization*. 2005;83(8):632–636.
[2] Kimaro H and Titlestad O. Challenges of User Participation in the Design of a Computer Base System: The Possibility of Participatory Customisation in Low Income Countries. *Journal of Health Informatics in Developing Countries*. 2008;2(1):1–9.
[3] Krickeberg K. Principles of Health Information Systems in Developing Countries. *Health Information Management Journal*. 2007;36(3):8–20.
[4] Spewak S and Hill SC. *Enterprise Architecture Planning: Developing a Blueprint for Data, Applications, and Technology*. Boston: QED Publishing Group, 1993.
[5] Ross J, Weill P. and Robertson D. *Enterprise Architecture as Strategy: Creating a Foundation for Business Execution*. Boston: Harvard Business School Press, 2006.
[6] World Health Organization, PATH. Planning an Information Systems Project: A Toolkit for Public Health Managers. Seattle: PATH; 2013. Available at: www.path.org/publications/detail.php?i=2343.

2. Enterprise architecture approach

Overview

This chapter is specifically intended to inform countries in the process of developing an eHealth infrastructure. It was developed under the auspices of the BID Initiative. Readers are not expected to be experts in ICT or in EA. However, a basic knowledge of eHealth and its role in supporting health care delivery workflows is assumed. The document is written in plain language with background information, illustrations of key points, and examples where it is thought they will be helpful.

Chapter Summary

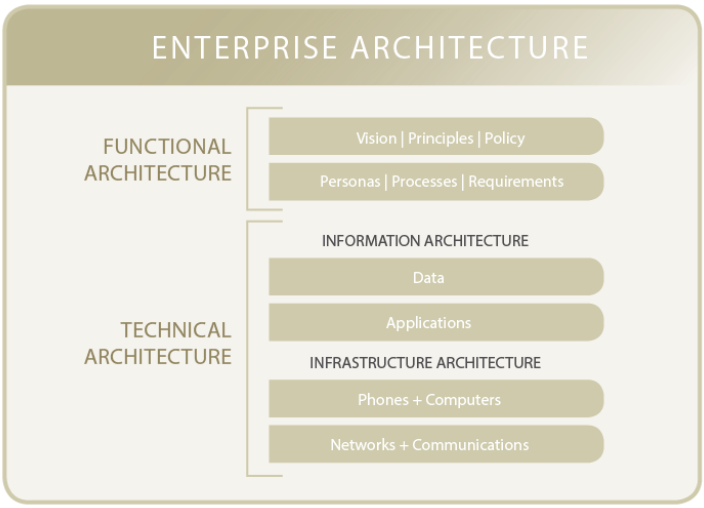
Defining the enterprise architecture approach is the starting point in developing a solution to the immunization system problem. To do this, we need to understand:

- Varied user needs and workflows, including data access and use.
- Interoperability, and other, standards.
- Sustainability and scaling challenges.

Briefly, an EA organizes how the business processes and ICT infrastructure are integrated and standardized to meet an organization's vision and requirements. The use of an EA helps countries leverage current information system investments as well as understand future investments that may be required. This chapter describes a health EA for the BID Initiative in terms of whole-system behaviors, not in terms of specific technologies that are part of the lower levels of the architecture. It is not intended to be a definitive description of any single country's health EA. Rather, it is held out as a starting point; a toolkit that may be adapted by countries, as necessary, to a specific country's needs and reflective of their unique context.

The BID EA is illustrated in Figure 2-1.

Figure 2-1. Enterprise architecture model.



Top-level principles

A number of core principles drove the architectural choices reflected in the BID design:

1. **Data collection is integrated into the workflow.** Workflow participants will capture high-quality data as an integral part of their workflow. This principle reflects the fact that for data quality and timeliness to improve, the use of data must be woven into the fabric of each workflow participant's business processes. All data will be captured electronically, as soon as possible and as close as possible to the step in the workflow where the data was generated. Paper-based systems will continue to play an ongoing role in the BID architecture. Yet even where paper-based workflows have been employed to capture and convey information, eventually it will be logged into a shared eHealth infrastructure as coded content.
2. **Data will be shared to support multiple workflows.** As an example of this principle, eHealth transactions regarding the immunization of a child imply supply chain transactions regarding the consumption of vaccines. In this case, we can leverage the eHealth transaction to forego extra data entry of the inventory transaction.
3. **Users have access to the data necessary to perform their duties.** One of BID's objectives is to improve data quality and use and, therefore, the workflow participants must have access to actionable, readily understandable data.
4. **Interoperability and openness.** The above principles should be realized via standards-based eHealth infrastructure. The preference will be to adopt existing eHealth standards wherever possible and to adapt them where necessary. There is no expectation that new standards need to be developed to support the BID Initiative.
5. **Sustainability.** Scale is the innovation. This principle means that simple, stable, readily adoptable solutions will be favored over technologically "sophisticated" ones that would be difficult to deploy on a national basis. Communications infrastructure will be leveraged and relied upon. This reflects a choice to favor solutions that have a small ICT footprint at the edge of the network and do the "heavy lifting" in centralized (hosted) data centers. Even where communications infrastructure is still nascent, the clear trend is for mobile-phone carriers to expand and enhance their network infrastructure. The network communications capacity is growing much more quickly than is the ICT professional services capacity, and this prefers a centralized ICT solution over a decentralized[a] one.

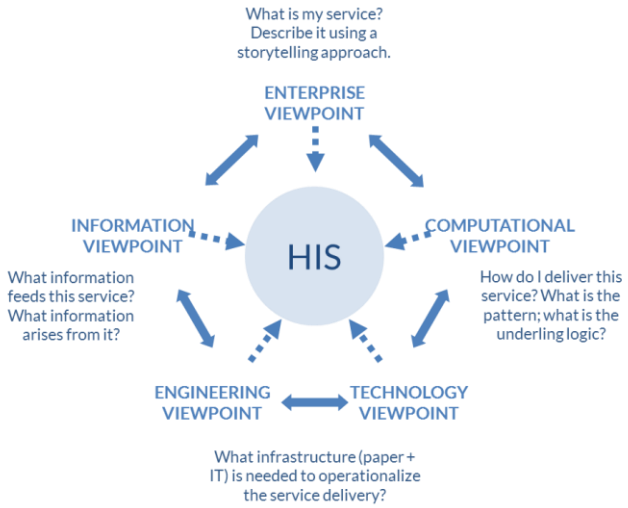
Using viewpoints to describe an enterprise architecture

Aspects of the BID EA were developed using a standards-based "storytelling" approach based on the ISO/IEC 10746 specification: *Reference Model for Open Distributed Processing (RM-ODP)*. The aspects of a country's immunization information system involve different stakeholders with different perspectives. The RM-ODP uses *viewpoints* to describe an EA in a comprehensive way that can be understood by the various stakeholders.

[a] As a concrete example, a data center-hosted, web browser-based electronic medical record system would be favored over a client-server application hosted at a facility on a dedicated server.

Figure 2-2 shows the five viewpoints of a health information system (HIS):

Figure 2-2. Viewpoints of a health information system.



Enterprise Viewpoint	The Enterprise Viewpoint describes care-delivery processes expressed through a set of characteristic user scenarios. Often, we document these processes using the Collaborative Requirements Development Methodology. *What is my service? Describe it using a storytelling approach.*
Information Viewpoint	The Information Viewpoint documents the Information Architecture that is needed to support the user stories, or is generated from them. *What information feeds this service? What information arises from it?*
Computational Viewpoint	The Computational Viewpoint describes how the workflow actors exchange information and the associated patterns of how the "conversation" is conducted with an electronic information system—extending the processes documented earlier. *How do I deliver this service? What is the pattern; what is the underlying logic?*
Engineering and Technology Viewpoints	The Engineering Viewpoint describes the Infrastructure Architecture (e.g., hosted web-based applications; interoperability standards). The Technology Viewpoint focuses on the choice of implementation technology (e.g., software applications, paper, computers, and other devices). *What infrastructure (paper and ICT) is needed to operationalize the service delivery?*

How does the "storytelling" approach work?

The EA viewpoints approach may be illustrated by working through a storytelling approach. The storytelling approach is a useful way to describe a process, the actors involved, and the context that eHealth infrastructure should account for. The example below uses a simplified

story based on a core immunization workflow. (Other system users will be introduced in Chapter 3: User Personas and their workflows will be discussed in Chapter 6: Key User Scenarios.)

- **Ruth** is the mother. Ruth has brought her new baby, **Esther**, to be immunized at the clinic.
- **Lucy** is the health worker at the clinic; she is a trained nurse with 16 years of experience.
- Lucy is using a tablet and barcode scanner to support her immunization workflow; the electronic **immunization registry** is also an actor in our story. The tablet's software application accesses a shared health infrastructure managed by the Ministry of Health (MoH).
- The information systems will play a role in the story, too. One of these is the **stock management tool (SMT)** used to manage the inventory of vaccines.

For this story, the setting is a busy primary care clinic in an urban center. The clinic has electricity and there is mobile phone coverage in the area, including "3G" (internet). The clinic's catchment area is near a border so there are often "new patients" who must have their health records established.

This story illustrates a vision for a future state. In this future state, babies born in urban facilities are assigned a unique identifier (ID) and a barcode label with this ID is affixed to the antenatal care card and to the baby's immunization card. There is also a national eHealth system that includes an immunization registry. One of the roles of the immunization registry is to help identify children using whatever personal IDs may be available to Lucy such as a phone number, a birth certificate number, or a mother's national identification card.

Note: ID cross referencing is at the very heart of being able to manage person-centric eHealth records. The Client Registry is sometimes also called an Enterprise Master Patient Index.

Step 1: Describe the story

The example immunization story is described in Figure 2-3 below. This represents the *Enterprise Viewpoint*.

Figure 2-3. Example immunization story.

- Ruth brings Esther to the clinic to be immunized. Lucy scans Esther's ID after she is weighed. This begins the immunization workflow for Esther.
- Lucy's tablet receives Esther's child health record. It indicates Esther is 11 wks old and needs her Penta2, OPV2, PCV2 and Rota2. Lucy confirms that this agrees with what is on Esther's immunization card.
- Lucy records clinical observations about Esther (her weight) and delivers the indicated immunizations. She talks with Ruth about what to watch for, and when Esther's next immunizations are due.
- Lucy updates Esther's immunization card and gives it back to Ruth. Lucy uses the tablet to update Esther's child shared health record.

Note: There may be confounding issues that make the story more complicated. Esther may not have an ID. Lucy's tablet might need recharging, or the eHealth infrastructure may be "down." What if there is an inventory stockout and not all of Esther's doses can be given? These are all possible issues, and will be handled as exceptions. Exceptions should be accommodated, but we design for what is supposed to happen.

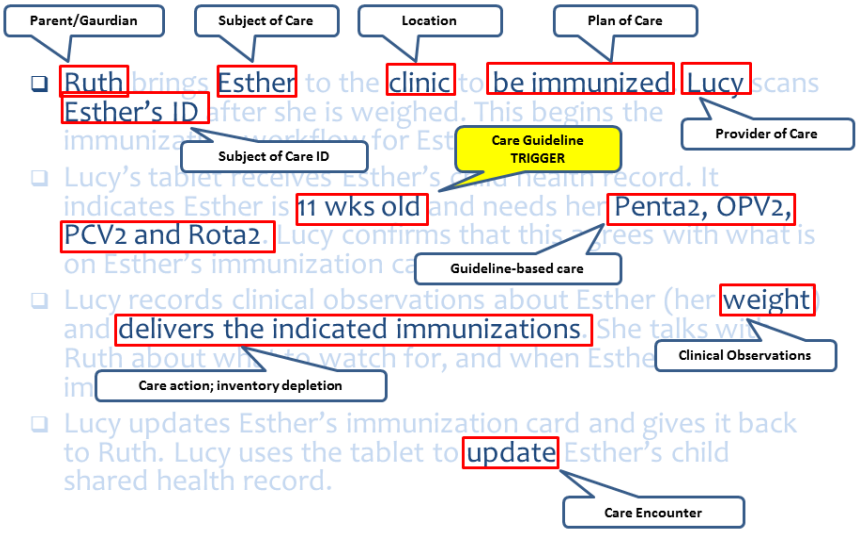
Step 2: Extract the data elements from the story

The next step in the approach is to analyze the story and extract from it the data elements that make up the *Information Viewpoint*.

Figure 2-4. Where story elements identify key content.

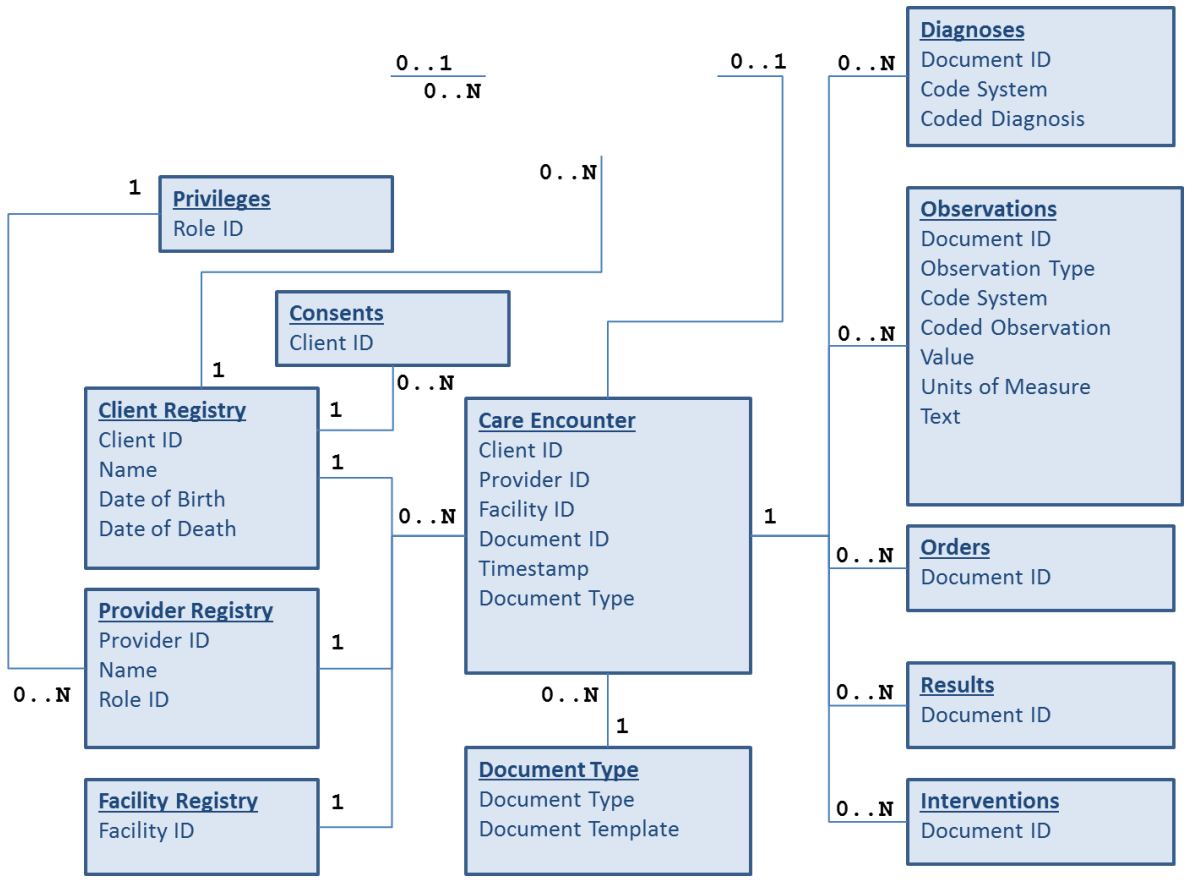
- Ruth brings Esther to the clinic to be immunized. Lucy scans Esther's ID after she is weighed. This begins the immunization workflow for Esther.
- Lucy's tablet receives Esther's child health record. It indicates Esther is 11 wks old and needs her Penta2, OPV2, PCV2 and Rota2. Lucy confirms that this agrees with what is on Esther's immunization card.
- Lucy records clinical observations about Esther (her weight) and delivers the indicated immunizations. She talks with Ruth about what to watch for, and when Esther's next immunizations are due.
- Lucy updates Esther's immunization card and gives it back to Ruth. Lucy uses the tablet to update Esther's child shared health record.

Figure 2-5. Story elements map to data elements.



Note: Esther's age (11 weeks old) is a key trigger for determining which immunizations she is due to receive.

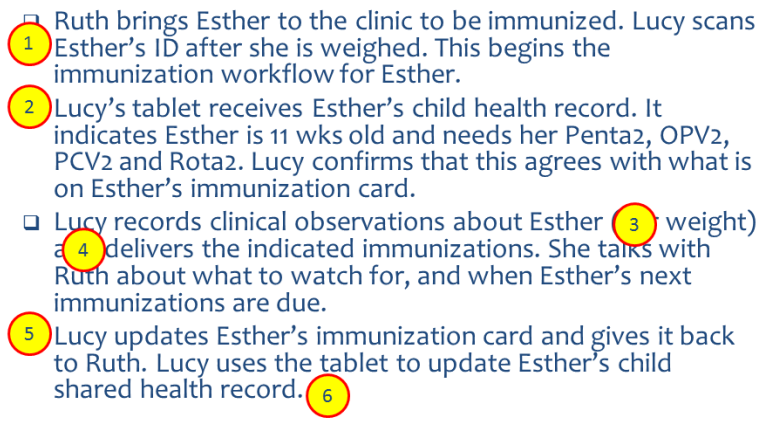
Figure 2-6. How data elements map to an informational model.[b]



Step 3: Derive the Computational Viewpoint

The next step in the "storytelling" EA approach is to derive from the story the communication patterns or *Computational Viewpoint*. These patterns describe how and when information is exchanged by the story's actors during the course of the workflow.

Figure 2-7. Key information exchanges within the system.



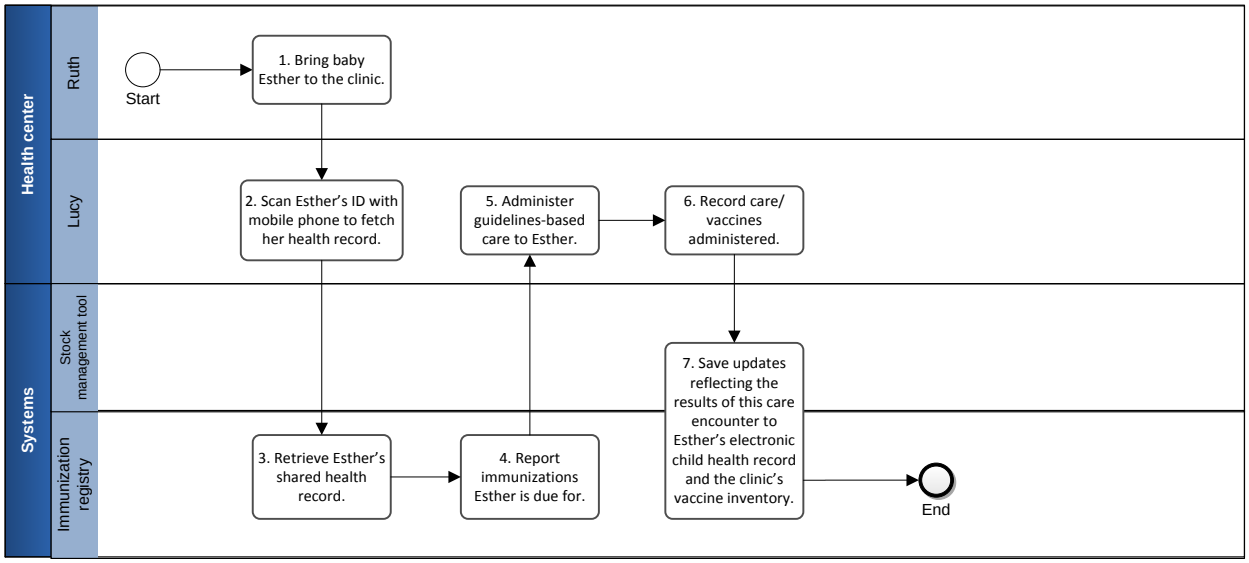
[b] This mocked-up "class diagram" is for illustration only. An actual information model would contain substantially more detail. For more information on class diagrams see http://en.wikipedia.org/wiki/Class_diagram.

As shown in Figure 2-7 above, there are six key interactions in the example story:

1. Lucy records Esther's ID.
2. Esther's child health record is retrieved showing Lucy what immunizations Esther should get.
3. Based on nationally set care guidelines, Lucy collects and captures clinical observations about Esther (e.g., her weight).
4. Based on the national Expanded Program on Immunization (EPI) protocol, Lucy gives Esther her doses of the required immunizations.
5. Lucy updates Esther's immunization card to record the vaccines administered.
6. Updates reflecting the results of this care encounter are simultaneously saved to Esther's electronic child health record and the clinic's vaccine inventory.

To better understand the information flow in this story, these six interactions may be graphically illustrated using a business process flow (Figure 2-8). A Unified Modeling Language (UML) sequence diagram of the process flow is shown in Appendix A (UML sequence diagram examples).

Figure 2-8. Business process flow depicting information exchanges for administering vaccines.



The business process diagram is a formal, standardized depiction of a workflow. These diagrams illustrate communications patterns between actors and are read from left to right.

The ability to readily identify Esther through a unique ID unlocks significant benefits. In any eHealth implementation, establishing an unambiguous ID for the patient is core functionality for managing the continuity of care. There are important points to note from Figure 2-8:

- With Esther's ID, we can fetch her child health record from the national eHealth infrastructure. This electronic record tells us where Esther is in her "health journey."
- At interactions three and four, we see how the eHealth record helps Lucy deliver effective, high-quality care to Esther. Based on Esther's health record, we know what immunizations she should get. We also know other important data about her (are there other health issues, for instance?). Using the tablet application, Lucy can see information about Esther and she also uses it to update the child's eHealth record to maintain continuity of care for Esther.

- The final two interactions (shown in the bottom right of the Figure 2-8) illustrate the principle of transaction reuse. Esther's care encounter is saved to her electronic health record indicating which immunizations she received to inform her health worker at her next care encounter. At the same time, a supply chain transaction records the inventory consumption associated with this event so that Lucy is able to effectively manage her vaccine stock levels.

Mapping to standards

Together, the story (Figure 2-3), the information model (Figure 2-5), and the communication patterns (Figure 2-8) may be used to map out the eHealth standards needed to support this workflow. The kinds of eHealth standards that need to be specified may be categorized as the 5 C's:

Care Guidelines Care guidelines are at the very heart of the story. These are typically evidenced-based protocols such as the World Health Organization's (WHO's) recommended immunization schedule, integrated management of childhood illness (IMCI), etc.[1]

Content eHealth content guidelines are at the heart of the information model. They can be thought of as the electronic equivalent of the "fields" on a paper form. Examples of content standards include the HL7 clinical document architecture templates such as the Immunization Content specification[2] published by Integrating the Healthcare Enterprise's (IHEs) Patient Care Coordination technical committee.

Coding Coding standards can be thought of as the standards that would apply to a specific field on a paper form. A form field intended to capture values for "SEX," for example, could follow the ISO 5218 specification: 0=unknown, 1=male, 2=female, 9=not applicable.

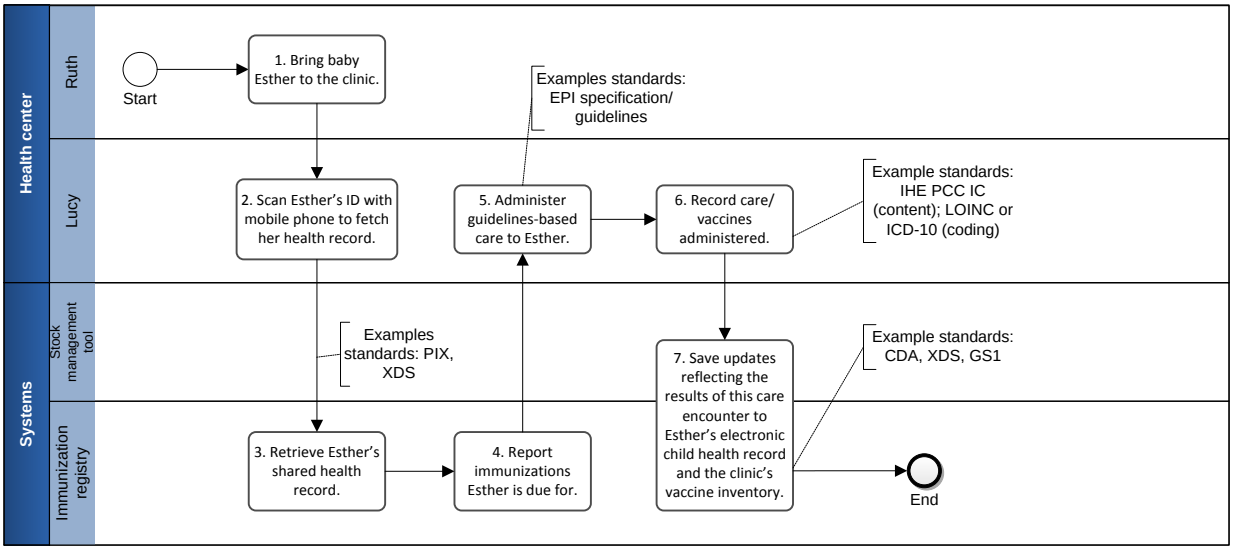
Communications As our sequence diagram illustrated, information is exchanged between the actors in our story. For interoperability, it is important that the protocols around this messaging adhere to precise standards such as IHE's cross-enterprise document-sharing (XDS) specification.[3]

Confidentiality, Privacy & Security Personal health information must be kept private. Standards include health care-specific profiles such as the IHE Basic Patient Privacy and Consents[4] specification and cross-industry standards for authentication, encryption, and secure communications such as OAuth (an open standard for authorization), public key infrastructure, and Transport Layer Security.

An example of some of the standards described above is shown in. The eHealth transactions may also be leveraged to generate supply chain transactions that are associated with captured care events (such as immunization). International supply chain organizations, such as GS1, have a complete suite of supply chain examples encompassing transportation, warehouse, and inventory transactions of all types.[5]

Figure 2-9 illustrates how the sequence diagram from Figure 2-8 may be used to map standards-based eHealth and supply chain transactions. For this example, the standards associated with IHE are being used.

Figure 2-9. Mapping interactions to standards.



Note: This EA design favours an internally interoperable "stack" of standards that has been internationally balloted. Such a strategy mitigates risk and ensures a network effect is realized from each conformant eHealth investment. Of 3 options that meet this criteria (HL7v3, OpenEHR, IHE), this design has been developed based on the technical frameworks of IHE.

- The IHE Patient Identity Exchange profile may be employed to resolve Esther's ID to an enterprise client ID, which can be used internally by the eHealth infrastructure to index electronic health records.
- We can retrieve Esther's child health record using her ID. This record can be exchanged using the IHE XDS profile.
- The process Lucy follows is based on care guidelines such as the WHO's EPI, IMCI, or official, national care guidelines and is supported by the user interface within the immunization registry application. These standards and official guidelines will dictate what clinical observations Lucy should capture and the immunization doses she will administer to Esther.
- Esther's guideline-based care event will be captured in a care encounter document. The content standards for this document may be driven by the IHE Patient Care Coordination committee's Immunization Content profile. Specific clinical readings that Lucy captured may be encoded in the resulting eHealth document using coding standards such as the Logical Observation Identifiers Names and Codes (LOINC) or WHO's International Classification of Diseases (ICD-10).
- The IHE Patient Care Coordination Immunization Content specification is a specialization of an HL7 clinical document architecture document. As before, information exchange with the national eHealth infrastructure may use the XDS communications profile.
- Along with Esther's care encounter document, a supply chain transaction may be automatically developed to reflect the vaccine inventory consumed during her immunization. The GS1 Inventory Activity message may be used to record the inventory depletion.

Although not shown in

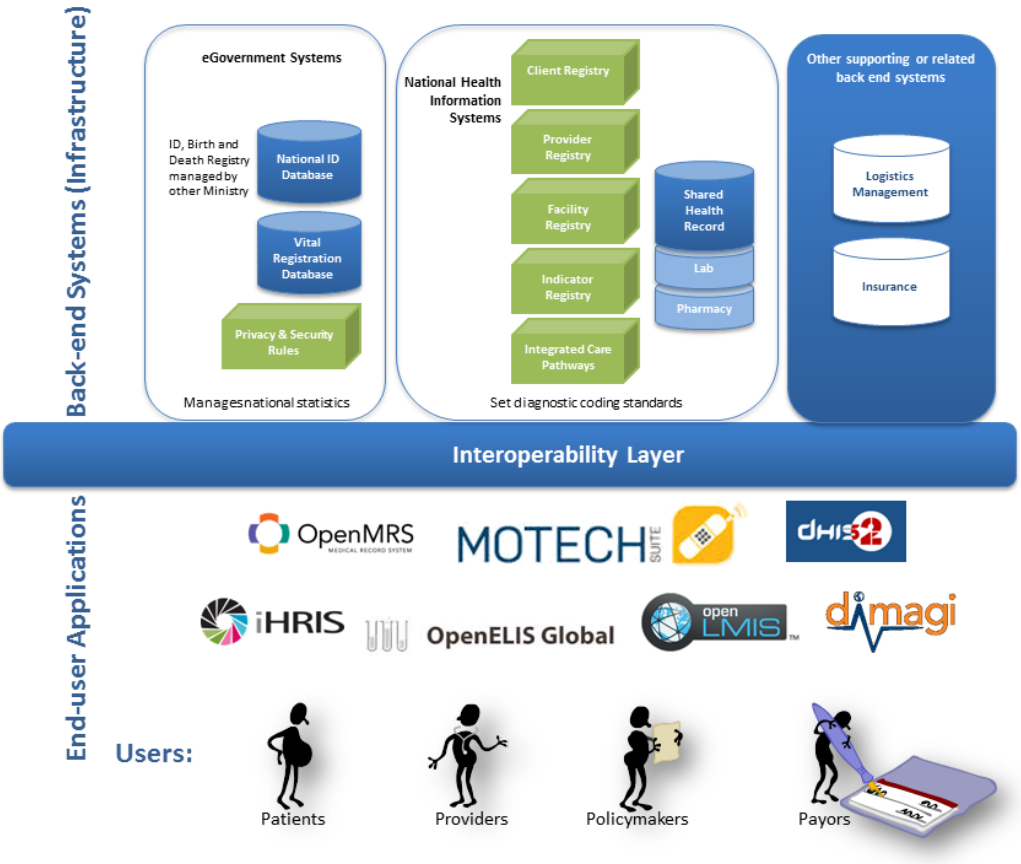
- Figure 2-9, security standards such as HTTPS, public key infrastructure, and others are part of the underlying eHealth infrastructure.

In the communication pattern shown in

Figure 2-9, all communications between the immunization registry application and the eHealth infrastructure will need to adhere to a standards-based pattern of communication which will be specified as part of a national eHealth standards framework (NeSF). An

example information structure, based on the Open Health Information Exchange (OpenHIE)[c] architecture, is shown in Figure 2-10. The scope of the NeSF would apply to the interactions between facility applications and an Interoperability Layer (IL) (shown in red).

Figure 2-10. A representative information structure (based on some commonly used applications).



Why focus on gathering person-centric data?

Referring back to our principles, there are a number of important aspects to this approach. To the fullest extent possible, **(1) person-centric data will be directly captured in a computable format** as part of the immunization workflow at the point of care delivery. The immunization registry is applied to support person-centric care delivery; this is in contrast to other Health Management Information Systems (HMIS) that are solely focused on summarized indicator collection.

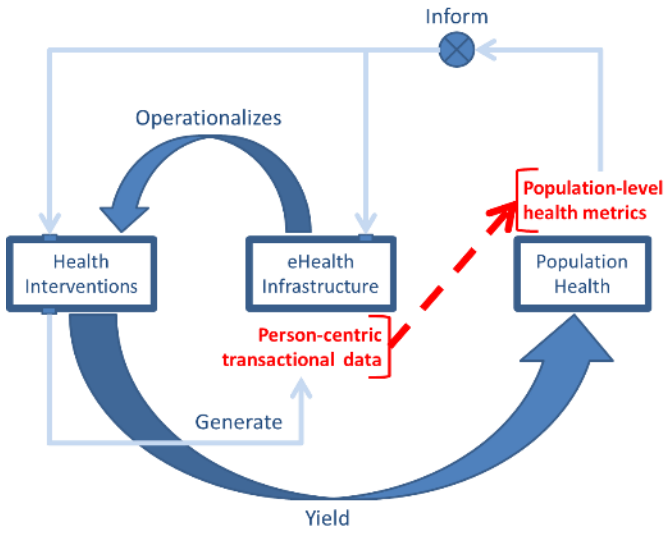
Leveraging eHealth infrastructure in this way will enable us to develop, **(2) share and leverage timelier and more accurate data**. Embedding the use of person-centric data within the fabric of the workflow is also a way to help operationalize EPI guidelines-based care. From a cold chain management standpoint, we have also automated calculation of the inventory consumption. This enables district-level to health-center replenishment based on a "better" signal: the actual observed demand.

[c] OpenHIE (www.ohie.org) is, in turn, based on the Infoway service-oriented architecture design (https://www.infoway-inforoute.ca/index.php/resources/technical-documents/architecture).

Furthermore, capturing computable data at the point of care delivery supports the development of metrics and indicators which may be aggregated and reported at the person, provider, health center, district, region, and national levels. Such data may be employed to drive feedback loops that can **(3) support continuous quality improvement** regarding person-centric care, provider and facility management, and planning and management at the district, regional, and national levels. The model for how this improves health is illustrated by

Figure 2-11.

Figure 2-11. An evaluative model for describing the health impact of eHealth.[6]



Note: *Health interventions yield population health. eHealth infrastructure operationalizes health interventions. Health interventions generate person-centric data, which can be aggregated to yield population-level indicators. Such indicators inform future changes to the eHealth infrastructure and the health interventions themselves.*

A strategy of selecting an **(4) internally interoperable "stack" of standards** (Text Box 2-1) mitigates risk and ensures a network effect is realized from each conformant eHealth investment. A standards-based system is more easily **(5) reusable** by other countries and **sustained** by the country's local eHealth teams, leveraging a shared eHealth infrastructure vs. separate systems for every program.

Importantly, this infrastructure is designed to be deployed at scale. This is a crucial distinction. Rather than merely considering the impact of disconnected pilot applications, this architectural model is designed for nationwide scale from the start.

Text Box 2-1. Interoperable stack.

Interoperable "stack": within the enterprise architecture model described earlier, there are different standards that allow the various systems to communicate and share data. Unfortunately, not all work well together, similar to plugging a US electrical cord in to a UK socket. Fortunately, there are three major suites or stacks of standards that countries can choose from: HL7v3, OpenEHR, and IHE.

[1] Page on WHO recommendations for routine immunization - summary tables. WHO website. Available at: www.who.int/immunization/policy/immunization_tables/en/.

[2] Integrating the Healthcare Enterprise (IHE). *IHE PCC Technical Framework Supplement – Immunization Content.* Oak Brook, IL: IHE; 2011. Available at: www.ihe.net/Technical_Framework/upload/IHE_PCC_Suppl_Immunization_Content_Rev2-2_TI_2011-09-09.pdf.

[3] Page on Cross-Enterprise Document Sharing. IHE website. Available at: http://wiki.ihe.net/index.php?title=Cross-Enterprise_Document_Sharing.

[4] Page on Basic Patient Privacy Consents. IHE website. Available at: http://wiki.ihe.net/index.php?title=Basic_Patient_Privacy_Consents.

[5] GS1. Logistics Interoperability Model: version 1. GS1; August 2007. www.gs1.org/sites/default/files/docs/sectors/transportlogistics/LIM_Foundation_Report.pdf

[6] Ritz D. Operationalizing guideline-based care. Presented at: AeHIN General Meeting.., September 23–-24, 2013; Manila, Philippines. Available at: www.aehin.org/Portals/0/Docs/2013%20Meetings/2013%20AeHIN%20GM/AeHINGM2013OperationalizingGBC_DerekRitz.pdf

3. User personas

Overview

A user-centered design approach is a key strategy of the Product Vision for the BID Initiative. Scalable, sustainable products are designed when development teams understand the viewpoint and experience of the users, like Ruth, Esther, and Lucy. In this section, we describe "who we are doing this for" and introduce the human actors spanning all levels of the immunization system and the challenges that they face which the BID Initiative will try and solve. These personas are intended to be representative archetypes of the key stakeholders who will participate in immunization-related workflows.

Chapter Summary

To effectively improve immunization coverage, we need to know the users at all levels of the immunization system–from parents and children to national-level policymakers.

What are their challenges, responsibilities, and level of connectivity? This knowledge will help us craft an impactful system that can be sustained and scaled.

Local

- Ruth is a new mother and lives in a small village.
- Esther is Ruth's first baby.
- Fatuma is a community health worker (CHW) in Ruth's village.

Clinic

- Lucy is a nurse at a busy urban clinic in a larger city near Ruth's village.
- Namsemba is a nurse working in the rural health clinic that Ruth frequents.

Regional

- Kwame is the Regional Immunization and Vaccination Officer (RIVO) in Abdu's region and communicates "district-level lessons" to his national-level colleagues to inform their strategies and tactics.

District

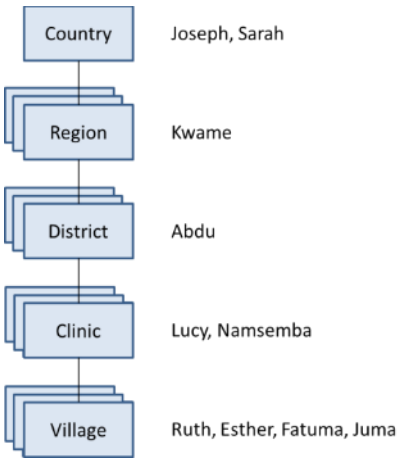
- Abdu is a District Immunization and Vaccination Officer (DIVO), providing vaccines and supportive supervision for Namsemba and Lucy's clinics.
- Juma is the Village Executive Officer (VEO) in Ruth's village and is responsible for recording vital statistics.

Country

- Sarah is the National Manager for the EPI and is responsible for overall strategy and advocacy campaigns.
- Joseph is the national logistics manager for EPI.

There is a natural hierarchy to the characters; sometimes in terms of reporting structure but more notably in terms of relative scope. This hierarchy is illustrated in Figure 3-1. For example, Joseph and Sarah operate at a national level so have all the regions of the country in their scope of management. Each region has a RIVO, which means Joseph and Sarah will be working with Kwame as well as his fellow RIVOs. In turn, each region has multiple districts, and Kwame will be working with Abdu and his fellow DIVOs.

Figure 3-1. Hierarchy of personas.



Personas

Ruth, Esther's mother

About Ruth and Esther

Photo: PATH/Debbie Kristensen

Ruth is 21 years old and Esther, her first baby, is 11 weeks old. She completed primary school and has basic literacy. Her husband attended secondary school for three years, but did not finish. They all live in a single-room house without electricity in a small village near Msindo. There is a public tap for drinking water a few hundred meters away.[1]

Esther was born at home. Although Esther's birth was not registered (and she does not have a birth certificate), the clinic assigned an ID to Esther when Ruth took her in for her first round of immunizations shortly after her birth. It takes Ruth just over an hour to walk to the Msindo clinic from her home.

Responsibilities

- Ruth and her husband work on her Uncle's farm, though Ruth takes time off as needed to take care of Esther.

Connectivity and eHealth

Ruth's husband has a mobile phone. He has received a short message service (SMS) message indicating that Ruth should go to the clinic so that Esther may receive her second round of immunizations.

Fatuma, community health worker

About Fatuma

Photo: PATH/Evelyn Hockstein

Fatuma is a CHW in Ruth's village and has held this role for eight months. She is 44 years old. Fatuma's four children are grown and have left the home. Two years ago, Fatuma's husband died of HIV/AIDS.

Fatuma has completed primary school and is functionally literate. She has no formal clinical certifications, but completed a CHW training program in her district. She doesn't receive formal compensation for her work, but the Village Health Council gave her a bicycle and a uniform. The villagers also make small contributions to her when she provides care.

Responsibilities

Fatuma provides a link between health service and the community. She spends one to two days per week on her duties which include: running sanitation campaigns, distributing medications and nutritional supplements, assisting nurses during outreach campaigns, monitoring growth in children, reminding HIV-positive patients to take medications, making referrals to health centers, distributing condoms, responding to emergencies, and reporting births.

Fatuma also visits homes and provides health education to expectant and new mothers about their pregnancy and newborns, nutrition, and sanitation. She visited with Ruth several times, providing health education information on antenatal, postnatal, and newborn care, as well as general hygiene, breastfeeding, and immunization.

Challenges

- Remembering when Esther is due for her next immunization.
- Going to the clinic when they have the necessary vaccines in stock.

Connectivity and eHealth

Fatuma has a mobile phone and uses it to report births to the VEO. She has received her first round of training to learn how to use the new eHealth application.

Juma, Village Executive Officer (VEO)

About Juma

Photo: PATH/Eric Becker

Juma is the VEO in Ruth's village and has held this elected role for seven years (and has three years left of his term). He is 52 years old. Juma completed secondary school but has no post-secondary education.

Responsibilities

Juma is responsible for maintaining the village register. He also works with the village committee to plan immunization outreach and other health-education activities, though he would like to see the village operate more strategically in regard to these efforts. Juma communicates frequently with the CHWs to identify children who are due for or who have missed immunizations and tries to use his influence to improve coverage

Challenges

- Village register is difficult to maintain.
- Not all births in the village are attended by a trained health worker.
- Villagers don't all understand the importance of formal health care and often use traditional methods.
- Health facility is far from the village so getting all children immunized on schedule is difficult.
- Lack of information on the types of health activities being implemented regionally, as well as their impact.
- Not trained in data analysis.
- Resource constraints (e.g., limited electricity, no computers, and transportation challenges).

Connectivity and eHealth

Juma has a phone with basic features which he uses for voice calls and SMS messaging.

Namsemba, health worker

About Namsemba

Photo: PATH/Gena Morgan

Namsemba is a nurse working in a health clinic in Msindo Village. She has 16 years' experience and is 38 years old. Namsemba has a diploma in nursing, and received Reach Every District (RED) training five years ago. She speaks English and Swahili.

Responsibilities

Namsemba's work varies from day to day, covering multiple programs from family planning, antenatal and postnatal care immunizations (both routine and outreach), and preventing mother-to-child transmission (PMTCT) of HIV/AIDS. She also provides scheduled outreach services to three different sites.

Namsemba uses paper-based service registers and tally sheets to record immunizations and paper ledgers to record stock movements. At the end of the month, she compiles the data and prepares a report for the DIVO.

Challenges

- Records, including child registers, are updated in bulk from handwritten notes, creating a heavy workload.
- Cumbersome to identify children who are due for or have missed immunizations.
- Copy of annual work plan in not on hand in the clinic.
- Frequent vaccine stockouts, resulting in unscheduled visits to the district store where stock is often unknown.
- Service register, ledger, and tally sheet stockouts.
- Reports are time-consuming to prepare, as data must be compiled from multiple ledgers.
- Difficulty in calculating accurate coverage rate based on outdated district estimates.

Connectivity and eHealth

Namsemba has a basic, personal mobile phone which is not connected to the internet and she has never used a computer. The health facility is not connected to the national electrical grid so the main source of power is solar.

Lucy, health worker

About Lucy

Lucy is a nurse working in a busy health center in Kubwamji, the largest city in the region. She has 12 years' experience and is 33 years old. Lucy has a diploma in nursing, and received RED training four years ago. She speaks English and Swahili.

Photo: PATH/Gena Morgan

Responsibilities

Although many services are offered in the clinic, Lucy's focus is on keeping up with the ever-increasing demand for immunizations. She facilitates education sessions, administers immunizations, and provides counseling when needed.

Lucy uses paper-based service registers and tally sheets to record immunizations and paper ledgers to record stock movements (despite the clinic's computer system). These are keyed

in later by clerical staff. At the end of the month, Lucy compiles the data and prepares a report for the DIVO.

Challenges

- Data accuracy isn't questioned (e.g., clinic currently shows a 400 percent coverage rate).
- Vaccine stock is adjusted on an ad-hoc basis as district vaccine store is next door to the clinic.
- Vaccine stock balances are often inaccurate as ledger entries are not always made.
- Difficulty in calculating accurate coverage rate based on outdated district estimates.
- Defaulter tracking is difficult, given the workload and the fact that mothers receive care from multiple clinics.
- Clinic's performance data is never reviewed or distributed.

Connectivity and eHealth

Lucy has a personal mobile phone which is not connected to the internet, though she does have some basic computer experience. She was trained on the clinic's vaccine stock-tracking system when it was implemented a couple of years ago (although she has rarely used the system since). The health facility is connected to the national electrical grid, and she has access to internet both through the clinic's wired network and "3G" (high-speed mobile network-based internet).

Abdu, District Immunization and Vaccination Officer (DIVO)

About Abdu

Abdu is the DIVO in Madiba district and supervises 32 health facilities. He has four years' experience and is 34 years old. Abdu received his advanced diploma in environmental science. He recently received RED training, as well as vaccine-management training as part of the deployment of the WHO SMT.

Photo: PATH/Eric Becker

Responsibilities

Abdu plans, manages, and monitors both existing and new immunization programs in his district, and coordinates these programs with other MoH programs.

He visits facilities in his district to ensure cold chain equipment is functioning properly and temperatures are monitored and within range, and resolves any issues that may exist. Abdu also reviews and discusses data management and reporting quality issues during his site visits and will also check stock balances and help determine stock-replenishment quantities.

Challenges

- Coordinating with other MoH programs is difficult without a way to easily view national activities.
- No time for monitoring and evaluation (M&E) or supportive supervision tasks.
- Lack of dependable transportation to deliver stock replenishments to clinics.
- Health facilities are scattered throughout the district and many are not reachable during the rainy season.
- Double entry of stock information in paper ledgers and electronic forms.
- Late and incomplete monthly reports from health facilities in his district.
- Complexity and size of electronic forms which don't align with monthly facility reports and are time-consuming to upload.

Connectivity and eHealth

Abdu has basic computer skills. His government-issued computer does not connect to the internet, so he typically uses his personal laptop for his work along with a personal modem to connect to the internet.

He uses the SMT (an Excel workbook) to manage stock movement and submit regional reports and the District Vaccine Data Management Tool (DVDMT—an Excel workbook) for logging the monthly immunization reports he receives from health facilities.

Kwame, Regional Immunization and Vaccination Officer (RIVO)

About Kwame

Kwame is the RIVO in Kileo region and supervises seven districts. He has 14 years' experience (two as RIVO and 12 as DIVO) and is 47 years old. Kwame has an environmental health degree and has also received vaccine-management training.

Photo: PATH/ Gena Morgan

Responsibilities

Kwame prepares an annual micro-plan at the end of each year based on the district micro-plans he receives. He also provides supportive supervision to districts in his region, and tries to visit each district at least twice per year. During his site visits, he checks that cold chain equipment is functioning properly and resolves any issues, and also discusses data management and reporting.

Kwame also acts as a transport officer for the regional office, reviewing requisition forms, selecting vaccines for shipment, updating stock ledgers, taking physical counts for monthly reports, and managing the emergency replenishment process.

Challenges

- National and regional funding don't meet estimated needs.
- Not able to provide additional supervision to poorer-performing districts due to lack of transportation funding and time.
- Tedious data-compilation processes for reporting and large file sizes are difficult to download.
- Lack of supplies of immunization registers.

Connectivity and eHealth

Kwame knows how to use a computer and uses a laptop to do his day-to-day job, connecting to the internet with a personal mobile modem. He uses the DVDMT to compile monthly immunization reports he receives from the districts.

Joseph, Logistics Officer

Joseph is the national Logistics Officer for the EPI and has held this role for two years. He is 36 years old and has a Bachelor's Degree in Pharmacy. He recently took an online course in statistics.

Photo: PATH/Eric Becker

Responsibilities

Joseph is responsible for: identifying, estimating, ordering, and receiving vaccines and immunization-related equipment in accordance with program plans and projections; overseeing cold chain equipment and transportation systems; providing technical support to provincial- and district-level managers; and report-writing and record-keeping of archived documents.

Challenges

- Supply chain data is regularly incomplete or erroneous.
- Lot number and expiry date are often "lost" as the vaccines move deeper into the supply chain.
- Stock management data is regularly incomplete or erroneous.
- Vaccine Arrival Reports (VARs) are not received from the central stores in a timely manner.
- Data management tools are not integrated with each other.
- Regular stockouts despite inventory being available.
- Physical counts aren't being made to update ledger values.
- Replenishment orders are often not created until the physical stock goes to zero.
- Gaps in knowledge and training of field staff.

Connectivity and eHealth

Joseph uses the WHO's Excel tools to track stock in the central stores and at the regional and district stock points.

Sarah, Expanded Program on Immunization (EPI) Manager

About Sarah

Sarah is the national manager for the EPI and has held this role for one year. She is 41 years old and has a Master's in Public Health.

Photo: PATH/ Eric Becker

Responsibilities

Sarah is responsible for: developing annual and multi-annual plans; immunization communication and mobilization; management of logistics, the cold chain, and vaccines; monitoring, supervision and evaluation of immunization services; and coordination of EPI activities at the national level that includes the development of policies, strategies, and human resource capacity-building.

Challenges

- Gap between the infrastructure available at the national office and what is available in the field.
- Data-entry errors in electronic files used for analysis and planning.
- No quick and easy access to accurate stock and coverage data for planning and reporting.
- No early warnings of potential stockouts or vaccine expirations.
- No easy way to share information to help with alignment.

Connectivity and eHealth

Much of the Information and Computer Technology (ICT) infrastructure at the district offices is old and slow, and there has been a pervasive underinvestment in ensuring ready network access and adequate capacity/airtime. Web-based communication and collaboration tools are not well-leveraged.

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[1] Tanzania National Bureau of Statistics and ICF Macro. 2010 Tanzania Demographic and Health Survey: Key Findings. Calverton, Maryland, USA: NBS and ICF Macro; 2011. http://www.measuredhs.com/pubs/pdf/SR183/SR183.pdf.

4. Business processes for immunization information systems

Overview

The purpose of this chapter is to illustrate the business processes and other important details that are part of a national immunization information system. By defining the processes and associated objectives, we can understand how the users would interact with a system and lay a strong foundation for improvements to a national immunization information system that effectively meets its users' needs.

These business process artifacts, coupled with user scenarios and use cases, are the foundation upon which health professionals and information system professionals can start discussing appropriate information system solutions that can scale and last after a specific project ends. The artifacts in this document have been compiled from multiple sources and are under various states of validation with EPI staff from more than a dozen countries.

Chapter Summary

In determining how to improve a system, we first need to understand what business processes and tasks are carried out today.

What are the objectives, outcomes, rules, triggers, inputs, and outputs that make up each of these processes?

This section briefly describes the 16 business processes and associated tasks related to the present-day operation of a national immunization information system from registering facilities to generating reports.

This document does not intend to be a definitive authority on the discipline of immunization and vaccine management or to provide guidance on how to organize and manage the immunization functions within a country. Rather, it is designed as both a road map and a tool. It serves as a road map for laying out the steps that MoH might take to develop an effective electronic Immunization Information System (IIS). It is also a tool that can be used to structure specific implementation projects, inform vendor requests for proposals (RFPs), self-assess existing IIS capabilities, and provide a methodology that is repeatable for other health system domains. This document describes business processes and requirements common to immunization systems in Africa that can be used as a starting point for adaptation and customization to a country-specific context.

Determining and documenting requirements using CRDM

The first step in developing a solution is to understand the current state of the problem and the desired outcomes. While this seems simple, it is often not done, or not done appropriately.[1,2,3] Getting a comprehensive picture of the actual processes associated with immunizations; the issues and barriers experienced; and the data flow, all within the local context, is critical to designing an appropriate solution. Good requirements-gathering helps avoid many costly revisions later[4] and identifies areas where interoperability with other information systems is critical.

PATH, in partnership with PHII, adapted and validated the CRDM for use in global health in 2009. This methodology, which was developed by PHII and used in the US health care system, has been widely used and tested both domestically and internationally. PATH has used and validated CRDM across different health domains including supply chain,[5,6] maternal health,[7] vaccines,[8] and health insurance[9,10] in countries including Ghana, India, Indonesia, Kenya, Malaysia, Mali, Nigeria, the Philippines, Rwanda, Senegal, Tanzania, Thailand, and Vietnam. The methodology emphasizes country ownership and produces a common set of requirements that can be used as a starting point by any country, saving both time and effort in analysis and design.

CRDM applies business process analysis and modeling in a richly collaborative manner with stakeholders, subject-matter experts, and users. A set of the basic steps for CRDM are shown below.

What are the steps in CRDM?

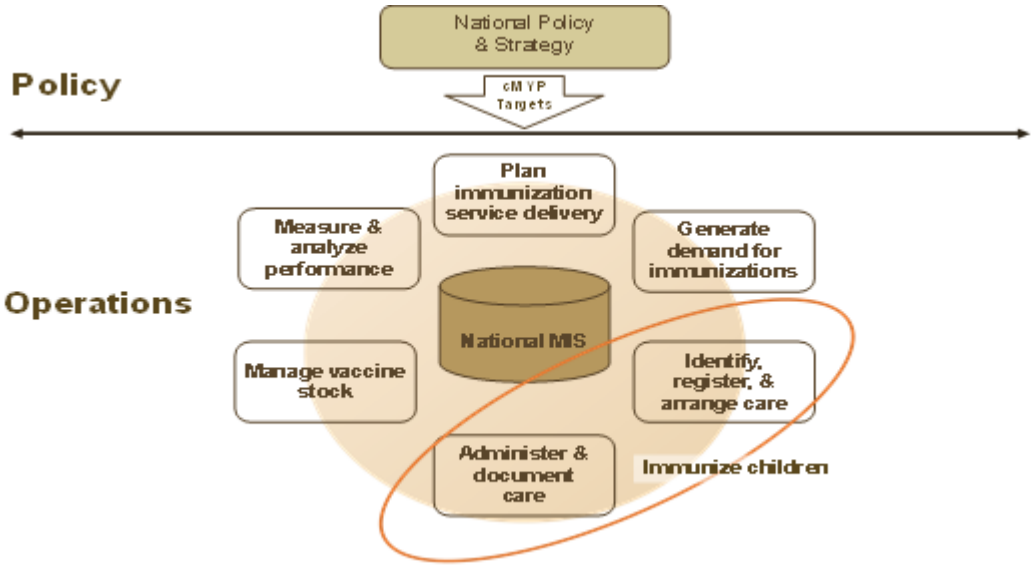
1. **Domain** – Set of functions and processes that defines the work of a specific area of the larger health system (i.e. supply chain).
2. **Process Framework** – Set of processes that defines the boundaries of a domain and the relationships between them and other systems and domains.
3. **Business Process** – Set of activities and tasks that logically group together to accomplish a goal or produce something of value for the benefit of the organization, stakeholder, or customer.
4. **Activity/Task Model** – Visual representation of a business process in terms of tasks, sets of tasks, and decision points in a logical workflow used to enhance communication and collaboration among users, stakeholders, and engineers.
5. **Requirement** – Statement that describes what an information system must do to support a task, activity, or decision. These are non-technology statements that usually begin with "the system must or shall…"

Business process framework for an immunization information system

In 2012, PATH documented an illustrative service delivery framework for immunizations as shown in Figure 4-1. Key to this framework is the relationship between policy and operations where the former drives the delivery of the latter. It also highlights, similar to

Figure 2-11, the continuous cycle that data and the Management Information System (MIS) infrastructure can provide to care delivery.

Figure 4-1. General immunization service delivery framework.



We identified 16 business processes across five key user scenarios as part of a comprehensive immunization information system. (As the identification of the child and the administration of the vaccine happen during the same care episode, they have been combined into one scenario—Immunize children.) Table 4-1 outlines the source of the different processes.

Table 4-1. Immunization business processes and sources.

#	Key User Scenario	Business Process	Source
1	Plan immunization service delivery	Register facilities	Adapted from work by PHII (2013)
2	Plan immunization service delivery	Plan service delivery	Ghana Immunization Information Systems project (2013)
3	Generate demand for immunizations	Generate reminders for upcoming and missed vaccinations	Adapted from work by PHII (2013)
4	Generate demand for immunizations	Immunization follow-up (also known as defaulter tracing)	BID Country Consultation Meeting (Nairobi, 2013)
5	Immunize children	Register client	BID Country Consultation Meeting (Nairobi, 2013)
6	Immunize children	Query patient record	Adapted from work by PHII (2013)
7	Immunize children	Update records	Adapted from work by PHII (2013)
8	Immunize children	Administer vaccine	BID Country Consultation Meeting (Nairobi, 2013)
9	Immunize children	Resolve duplicate patient records	Adapted from work by PHII (2013)
10	Immunize children	Resolve duplicate vaccine events	Adapted from work by PHII (2013)
11	Replenish inventory	Manage vaccine arrivals	Tanzania Stock Management Information Reviewed with country stakeholders (Dar es Salaam, 2013)

#	Key User Scenario	Business Process	Source
12	Replenish inventory	Distribute supplies to region/district	Reviewed with country stakeholders (Dar es Salaam, 2013)
13	Replenish inventory	Distribute to facility	Reviewed with country stakeholders (Dar es Salaam, 2013)
14	Replenish inventory	Manage inventory	Reviewed with country stakeholders (Dar es Salaam, 2013), and Country Consultation Meeting (Nairobi, 2013)
15	Replenish inventory	Maintain cold chain equipment	Reviewed with country stakeholders (Dar es Salaam, 2013)
16	Monitor and evaluate performance	Generate reports	Reviewed at BID Country Consultation Meeting (Nairobi, 2013)

Business processes of immunization information systems

This section briefly describes the 16 business processes and associated objectives relevant to the operation of a national immunization information system. Each process includes the following components:

Objective A concrete statement describing what the business process seeks to achieve. A well-worded objective will be SMART: Specific, Measurable, Attainable/Achievable, Realistic, and Timebound.

Measurable Outcomes The resulting transaction of a business process that indicates the goal(s) and objectives have been met.

Business Rules A set of criteria that defines or constrains some aspect of the business process. Business rules are intended to assert business structure or to control or influence the behavior. Examples in health care and public health include laws, standards, and guidelines.

Trigger An event, action, or state that indicates the first course of action in a business process. In some cases, a trigger is also an input.

Inputs Information received by the business process from external sources. Inputs are not generated within the process.

Outputs Information transferred out from a process. The information may have been the resulting transformation of an input, or it may have been information created within the business process.

These business process descriptions, detailed below, serve as the basis for elaboration of the tasks and the associated requirements in the sections that follow.

1. Register facilities

Objective

Enroll facilities (excluding private providers) into the IIS for vaccine reporting and reconcile the Immunization Information System Facility List with the National Master Facility List (NMFL).

Measurable Outcomes

- Number of facilities registered.
- Number of facilities that accurately match the NMFL.
- Number of facilities with accurately captured information.
- Number of facilities in IIS that are not in the NMFL.

Business Rules

National laws, regulations, and policies.

Trigger

- Change in national law.
- New business (facility).
- Merging of facilities.
- Change in any facility details (i.e., type, name, catchment area, etc.).
- New vaccine introduction.

Inputs

- Facility business purpose/type.
- Facility demographics such as:
    - Type of facility (i.e., outpost, clinic, hospital, etc.).
    - Data exchange.
    - Public or private facility.
    - District.
    - Geo-coordinates/location.
    - Size/catchment, communities/village name.
    - Cold chain capacity.
    - National facility identification.
    - Unique IIS identification.
    - Authorizing medical provider/main point of contact.

Outputs

- Facility code.
- Access the system.
- User identification/password.
- Facility record.
- List of communities linked with the facility.
- Facility contact information list.

2. Plan service delivery

Objective

Prepare for an immunization clinic, either at the facility or done on an outreach basis. The primary difference if done as outreach is that all equipment and vaccines must be properly packaged (cold box) for transport.

Measurable Outcomes

- Sufficient supplies are available to efficiently manage immunization clinic (e.g., no patient is turned away due to a stockout).
- Closed-vial waste is within thresholds.

Business Rules
- National and regional policies.
- WHO guidelines.

Trigger Immunization clinic planned for day.

Inputs
- Locally adjusted census data.
- Household surveys.
- Immunization registry forecasts.

Outputs
- Vaccines and supplies removed from inventory.
- Updated immunization register.

3. Generate reminders

Objectives
- Communicate to the patient or parent/guardian if a patient is due now, due on future date, or past due for an immunization.
- Generate notifications to the health care worker (HCW), patient, or parent/guardian if immunization is due now, due on future date, or past due.

Measurable Outcomes
- Number of notifications sent.
- Percentage of reminded patients.
- Number of patients who receive vaccine versus number of notifications/reminders.
- Number of patient status changes (e.g., moved or gone elsewhere).
- Number of providers or organizations generating reminder/recalls from the IIS.
- Percentage of increase of coverage for target populations.
- Number of patients who have not responded to X number of follow-up notification attempts.

Business Rules
- Provider protocol.
- National protocol.
- National policies and regulations.
- WHO immunization guidelines.

Trigger
- Occurrence of a public health event (e.g., outbreak).
- Recommended immunization time frames.
- Immunization program initiatives (i.e., improve low population coverage rates).
- Vaccine shortages.
- Vaccine recall.
- Revaccination (i.e., series).

Inputs
- Patient immunization history forecast/schedule.
- Public health event information.
- Patient demographics.
- Patient status (death, opt out, “moved or gone elsewhere”, etc.).
- Catchment.
- Vaccine shortage refill administering prioritization.
- Coverage rate.
- Patient contact information and preference.

Outputs
- Notification to candidates.
- Lists of immunization candidates.
- Reports.
- Status change.

4. Immunization follow-up

Objective Identify those children who were due to come for vaccination, missed their follow-up dates, and are now past due.

Measurable Outcomes
- Number of notifications sent.
- Percentage of children that receive an immunization.
- Number of child status changes to inactive.
- Number of providers or organizations conducting reminder/recalls.
- Percentage of increase of coverage for target populations.
- Number of clients who receive vaccine versus number of notifications.
- Number of clients who have not responded to follow-up notification attempts.

Business Rules
- Provider protocol.
- Local protocol.
- National and local policies and regulations.
- Immunization schedule.

Trigger
- Occurrence of a public health event (e.g., disease outbreak).
- Recommended immunization time frames.
- Immunization program initiatives.
- Low population coverage rates.

Inputs
- Patient immunization history and/or forecast.
- Public health event information.
- Population demographics (outreach, outside of catchment area).
- Patient status (death, opt out, moved, contraindicated).

Outputs
- Notification of mother/caregiver.
- List of children to be immunized.
- Reports on result of immunization follow-up.

5. Register client

Objective Start or contribute to the client's lifelong immunization record and allow providers and the client/mother to identify what vaccinations have been given.

Measurable Outcomes
- HCW/client receives communication about recommended vaccines for the client.
- Number of successful patient record searches.
- Percentage of up-to-date patient records in the IIS.

Business Rules
- National and local laws.
- Provider protocol.
- School/child care protocols.

Trigger
- Client clinical visit.
- Disease outbreak/ surveillance.
- Reminder/recall.
- Immunization programs or outreach.

Inputs
- Patient demographics (used to query, add, and/or update) including:
    - Name.
    - Gender.
    - Date of birth.
    - Parents' names.
    - Phone number.
    - Village name.
    - Patient immunization record (used to add or update).

Outputs
- Accurate patient vaccine record.
- Accurate patient forecast.
- User feedback on patient records (e.g., duplicate patient/vaccine records, incorrect date of birth, false merge, data quality).
- Patient record inactivated/sealed due to death.

6. Query patient record

Objective Correctly locate or identify a patient's immunization record.

Measurable Outcomes
- Patient receives communication about recommended vaccines.
- Number of successful patient record searches.
- Percentage of up-to-date patient records in the IIS.

Business Rules National and regional regulations concerning access of patient health information.

Trigger
- Inquiries made about vaccines for school attendance.
- Disease outbreak/surveillance.
- Reminder/recall.
- Public inquiries.
- Immunization programs or other partners' needs.

Inputs
- Patient demographics (used to query, add, and/or update) including:
  - Name.
  - Gender.
  - Date of birth.
  - Parents' names.
  - Phone number.
  - Village name.
  - Patient immunization record (used to add or update).
  - Patient immunization record (e.g., child health record, under-five card, etc.).

Outputs User feedback on patient records (e.g., duplicate patient/vaccine records, incorrect demographic data).

7. Update record

Objective Review and update a patient's record to provide a complete immunization history, which will be used to determine recommended vaccines and due dates, allowing providers to recommend and discuss immunizations with the patient.

Measurable Outcomes
- Mother or guardian receives communication about recommended vaccines for the patient.
- Number of successful patient record searches.
- Percentage of up-to-date patient records in the system.

Business Rules
- National and regional regulations concerning access of patient health information.
- National and regional policies concerning updates to patient records.

Trigger
- Patient visits a clinic.
- Patient death.

Inputs
- Patient demographics (used to query, add, and/or update) including:
  - Name.
  - Gender.
  - Date of birth.
  - Parents' names.
  - Phone number.
  - Village name.
  - Patient immunization record (used to add or update).
  - Patient immunization record (e.g., child health record, under-five card, etc.).

Outputs
- Accurate patient vaccine record.
- Accurate patient forecast.
- User feedback on patient records (e.g., duplicate patient/vaccine records, incorrect demographic data).
- Patient record inactivated due to death.

8. Administer vaccine

Objective Administer appropriate vaccine and record the relevant necessary data.

Measurable Outcomes
- Number of patients that receive age-appropriate vaccination.
- Number of shots due during clinic visit that are not given.
- Over-immunization is avoided.
- Vaccine inventory correlates with doses given and expected wastage rates.

Business Rules
- Provider standards of care.
- National and local rules and regulations.
- Recommendations for precautions and contraindications.

Trigger
- Client requests vaccination.
- Antenatal or postnatal care visit.

Inputs
- Client vaccine record.
- Precautions and contraindications.
- Vaccine stock status.
- Vaccine schedule.

Outputs
- Updated record of vaccination.
- Vaccine inventory decremented as appropriate.
- Patient immunization history is updated.
- Vaccine forecast for next visit.

9. Resolve duplicate patient records

Objective Identify duplicate patient records and consolidate them into one most accurate/suitable (best) record.

Measurable Outcomes
- Number of consolidated duplicate patient records.
- Number of records marked as “Not a Duplicate.”
- Number of possible duplicates pending manual review.
- Number of records automatically de-duplicated by IIS versus number of manual de-duplications.

Business Rules
- Evaluation criteria set by IIS program.
- National standards/regulations and rules (e.g., matching criteria points).

Trigger
- Periodic evaluations.
- Duplicate patient records are reported/identified.
- Patient record accessed/updated.
- System comparison against national identification system.

Inputs
- Patient demographics.
- Patient IIS records.
- User flag to mark as duplicate.

Outputs
- Consolidated patient record.
- Records deemed as “Not a Duplicate” are marked accordingly.
- Duplicate record report.
- Records are marked as “requiring additional information.”

10. Resolve duplicate vaccine events

Objective Identify duplicate immunization events within a patient record and update into one event.

Measurable Outcomes
- Duplicated vaccine events have been identified, updated into one event, and resolved in a timely manner.
- Number of duplicate vaccines identified.

Business Rules Vaccine de-duplication business rules.

Trigger
- Periodic evaluations.
- Suspected duplicate records are identified/reported.
- HL7 data is received.
- Patient record updates.
- Patient record queries.
- Data is received from another system.

Inputs
- Patient vaccine record.
- Data quality report (e.g., confidence ratings, completeness of data, specificity of data, etc.).

Outputs Updated patient vaccine record.

11. Manage vaccine arrivals

Objective Receive verified quantity and quality of goods into store and determine need for remedial action when necessary.

Measurable Outcomes
- Goods are accepted or rejected. Those goods that are accepted are placed into stock, and those that are rejected are stored for disposition.
- Records are updated with appropriate information.

Business Rules Vaccine arrival reporting process as defined by United Nations Children's Fund (UNICEF).

Trigger Advance notification of vaccine arrival.

Inputs
- Advance shipping notification.
- Airway bill, packing list, invoice, and release certificate.

Outputs
- VAR.
- Stock information entered into national warehouse system.

12. Distribute supplies to region/district

Objective Ensure timely ordering of the right commodities in the right quantity.

Measurable Outcomes
- Stock levels are routinely maintained within the minimum and maximum thresholds and stockout situations are reduced.
- Reduced closed-vial waste.

Business Rules National, WHO, and UNICEF guidelines.

Trigger
- Cyclical ordering process from subnational stores (e.g., quarterly, monthly).
- Emergency order.

Inputs Immunization needs are assessed based on historical usage reporting. These reports, along with current inventory levels, are used to create inventory forecasts.

Outputs
- Vaccine requisition, stock-on-hand reporting.
- Confirmation of order.
- Confirmation/rejection of order.

13. Distribute supplies to service delivery point

Objective Facility has sufficient supplies to meet service delivery needs.

Measurable Outcomes
- Number of vaccine stockouts.
- Percentage increase or decrease of expired inventory.
- Number of urgent (expedited) orders.
- Number or percentage increase or decrease of urgent orders.

Business Rules National and WHO guidelines.

Trigger
- Monthly distribution process.
- Low inventory.
- New vaccine recommendations.
- Public health event.

Inputs
- Usage reports (e.g., doses administered, expired, wasted).
- Inventory.
- Storage capacity.
- Distribution time frame.
- Temperature log.

Outputs
- Vaccine requisition, stock-on-hand reporting.
- Confirmation of order.
- Confirmation/rejection of order.

14. Manage inventory

Objective Maintain chain of custody and appropriate environmental conditions for stock and inventory.

Measurable Outcomes
- Waste/damage rate is reduced by one percent
- Stock records are accurate and detailed, and inventory measures such as stock turnover and under-stock situations are alerted appropriately.
- There is an adherence to environmental and security conditions and regulations.
- There is an ability to respond to requests in a timely manner.

Business Rules National and WHO guidelines.

Trigger
- Inventory/evaluation time frame.
- Vaccine shortage.
- Public health event or other alerts.

Inputs
- Vaccine inventory.
- Immunization forecasts.

Outputs
- Inventory report and updated inventory.
- Vaccine order.

15. Manage cold chain equipment

Objective Keep cold chain equipment in optimal working order.

Measurable Outcomes
- Reduced replacement costs due to improved maintenance of equipment.
- Reduced stockouts due to cold chain failure.
- Closed-vial waste due to cold chain failure.

Business Rules
- Temperature thresholds for cold chain equipment at level recommended by manufacturer.
- WHO and UNICEF guidelines.

Trigger
- Twice daily monitoring of cold chain temperatures.
- End-of-month reporting of temperatures and alarms.
- Temperature alarms repeatedly above threshold.

Inputs
- Temperature and/or alarms listed on refrigerator and freeze tags.
- Temperature listed on thermometer within or external to refrigerator.

Outputs Record of temperature and alarms on monthly reporting form.

16. Generate reports

Objective Provide the ability to access and analyze data to improve immunization program decision-making.

Measurable Outcomes
- Number of generated reports in response to requests from partners and other public health agencies in a timely manner.
- Number of identified data trends (i.e., data quality, program measures, etc.).

Business Rules
- Immunization program rules.
- User permissions.
- National and partner organization reporting requirements (e.g., WHO, Global Alliance for Vaccines and Immunizations [GAVI], etc.).

Trigger
- Request for data (e.g., IIS Annual Report).
- Progress report.
- Scheduled reports (e.g., monthly, quarterly, etc.).
- Site visit.
- Public health emergency (e.g., outbreaks).
- Partner reporting requests.

Inputs
- Parameters/criteria.
- Meta-data.

Outputs Reports (various formats: e.g., .csv, .xml, email, etc.).

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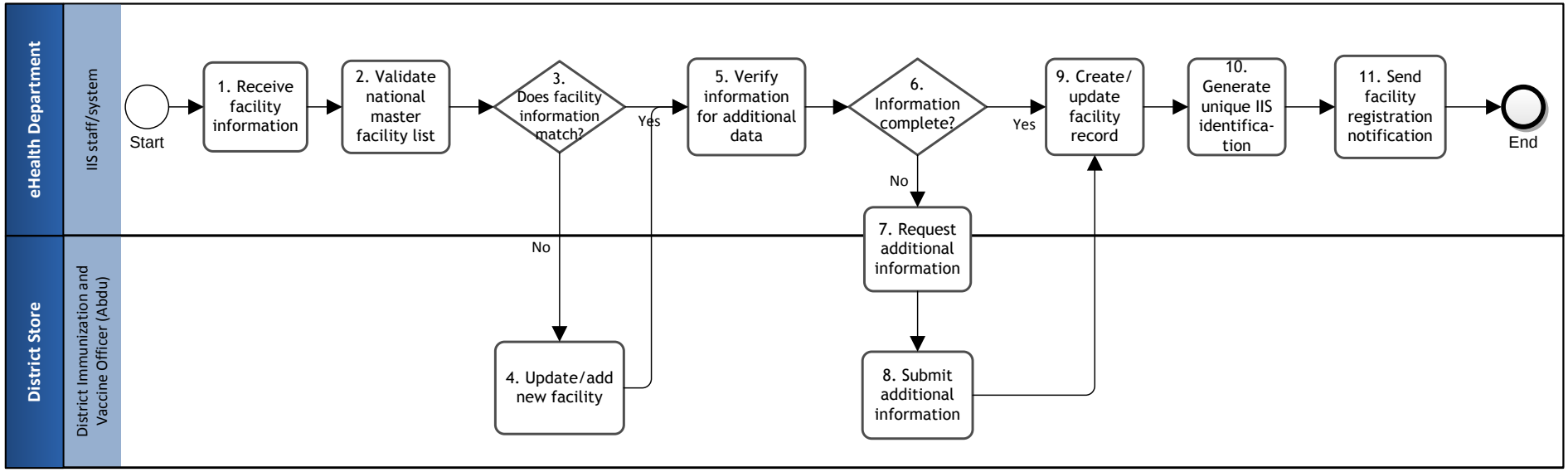
[1] Shaw V. Health information system reform in South Africa: developing an essential data set. *Bulletin of the World Health Organization*. 2005;83(8):632–636.
[2] Kimaro H and Titlestad O. Challenges of user participation in the design of a computer base system: the possibility of participatory customisation in low income countries. *Journal of Health Informatics in Developing Countries*. 2008;2(1):1–9.
[3] Krickeberg K. Principles of Health Information Systems in Developing Countries. *Health Information Management Journal*. 2007;36(3):8–20.
[4] Wiegers KE. *Software Requirements*. Redmond, WA: Microsoft Press, 2009.
[5] PATH. Strengthening Health Information Systems Through Collaborative Development of Common Requirements: Final Report to the Rockefeller Foundation. Seattle: PATH, 2011.

[6] PATH. Zambia Vision and Requirements for Computerized Logistics Management Information System: Produced with the Collaborative Requirements Development Methodology. Seattle: PATH, 2011.
[7] PATH and VillageReach. *Ethiopia mHealth Roadmap: Architecture and Design Appendix*. Seattle: PATH and VillageReach, 2012.
[8] PATH. Workshop Summary for the Electronic Logistics Management Information System (eLMIS). Seattle: PATH, 2011.
[9] PATH. Determining Health Insurance Information Systems Requirements in Developing Countries: Interim Report to the Rockefeller Foundation. Seattle: PATH, 2011.
[10] PATH. *Determining Common Requirements for National Health Insurance Information Systems*. Seattle: PATH, 2012. Available at: www.jointlearningnetwork.org/resources/documents/determining-common-requirements-national-health-insurance-information-systems.

Task Flow Diagrams

1. Register facilities

Figure 4-2. Step 1: Register facilities.



Process notes

Objective: Enroll facilities into the system for vaccine reporting and reconcile the IIS facility list with the NMFL.

1. Receive facility information

Can receive facility information from multiple sources (i.e., facility, NMFL, etc.).

Can receive information manually or automatically.

2. Validate NMFL

The facility information is validated against the NMFL to determine if there is a match (indicating this new registration is a duplicate).

3. Does facility information match?

IIS validates that the new facility exists in the NMFL to determine if it is a new facility or a match/update to an existing record.

If the facility exists in the NMFL, IIS will verify the information is complete. If the new facility does not exist in the NMFL, the IIS will add/update the facility in the IIS, or flag for correction/validation.

4. Update/add new facility

If all required information is complete, a new facility record is created in the IIS system.

5. Verify information for additional data

IIS system/staff reviews the facility information to determine if any updated information or additional information was provided to the IIS that was not available in the NMFL.

6. Information complete?

IIS system/staff reviews completeness of the information required to register the facility.

7. Request additional information

IIS system/staff requests necessary additional information needed to register the facility.

8. Submit additional information

The facility submits the requested information to the IIS system/staff.

9. Create/update facility record

If all required information is complete, a new facility record is created in the IIS system.

10. Generate unique IIS identification

IIS will generate a unique site identification number to assign to the facility.

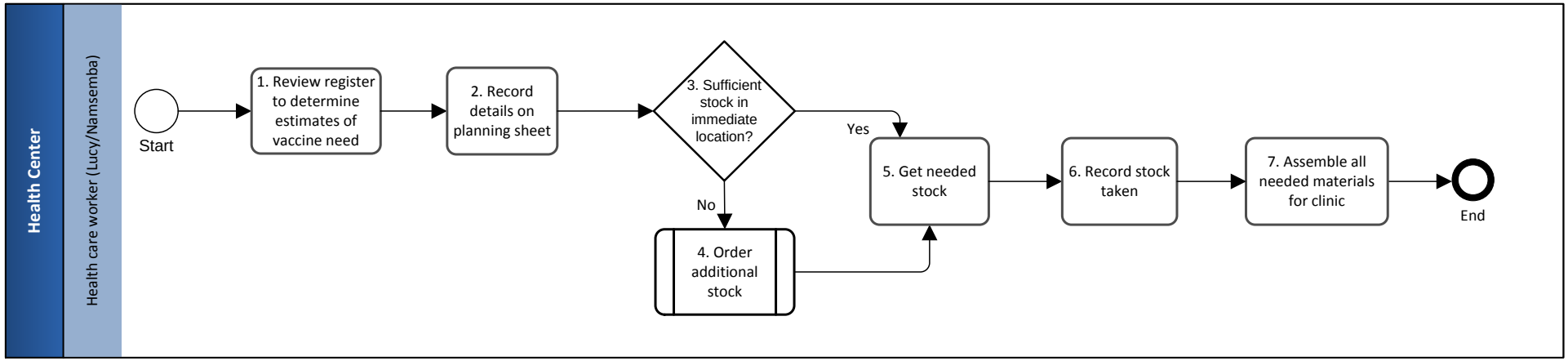
11. Send facility registration notification and IIS identification

IIS will send the facility a registration notification which could include their facility IIS identification number and other facility information.

The IIS notification can be customized to include messages to the facility (e.g., reference your IIS ID when placing vaccine orders, etc.).

2. Plan service delivery

Figure 4-3. Step 2: Plan service delivery.



Process notes

Objective: Prepare for an immunization clinic, either at the facility or done on an outreach basis. The primary difference if done as outreach is that all equipment and vaccines must be properly packaged (cold box) for transport.

1. Review register to determine estimates of vaccine need

The HCW will determine, based on reviewing records looking for vaccines due, previous experience and time since last clinic and other considerations, the relative number of vaccines they will need. This is done several days prior to the clinic.

2. Record details on planning sheet

The HCW records the details of the specific clinic—for outreach this will include such things as who is going, where, what supplies they need, and their transport. For static clinics, the major consideration is staffing and supplies.

Planning sheets are typically used just for outreach.

3. Sufficient stock in immediate location?

The HCW will go to the local stock supply (this may be in their own clinic cold storage, or in the district office cold storage) to determine if there is sufficient stock for the clinic. This is usually done the day before, or up to three days before the clinic.

4. Order additional stock

If there is insufficient stock at the local stock supply, additional stock is requested.

5. Get needed stock

On the morning of the clinic, the HCW retrieves the needed stock from the cold storage (either at their clinic or at an area office).

6. Record stock taken

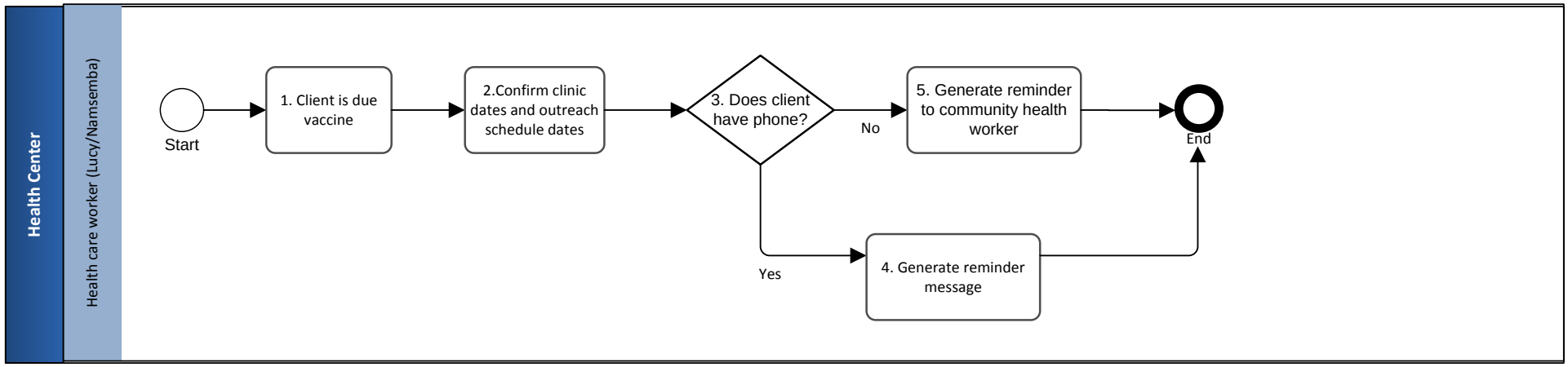
The stock taken is recorded in a log for these purposes. Any unused stock that is returned after the clinic is also recorded here, thus keeping an accurate inventory. Note: This step is often done AFTER the fact at the end of the day when reconciling the records.

7. Assemble all needed materials for clinic

The HCW assembles the vaccines, necessary registers, syringes, sharps container, etc., needed for clinic. If the clinic is remote, all items are packed up for transport. If local, they are organized in the clinic.

3. Generate reminders

Figure 4-4. Step 3: Generate reminders.



Process notes

Objective: Determine up to one week in advance who is due for vaccines and remind them.

1. Client is due vaccine

Based on existing records and set immunization schedule, it is determined the client is due for a vaccine sometime in the next week.

2. Confirm clinic dates and outreach schedule dates

Ensure the upcoming scheduled clinic or outreach dates are confirmed, and not cancelled due to weather, staff availability, holidays, transport issues, etc.

3. Does client have phone?

Consult record to identify if the client has a phone number with which they have indicated the clinic may contact them.

4. Generate reminder message

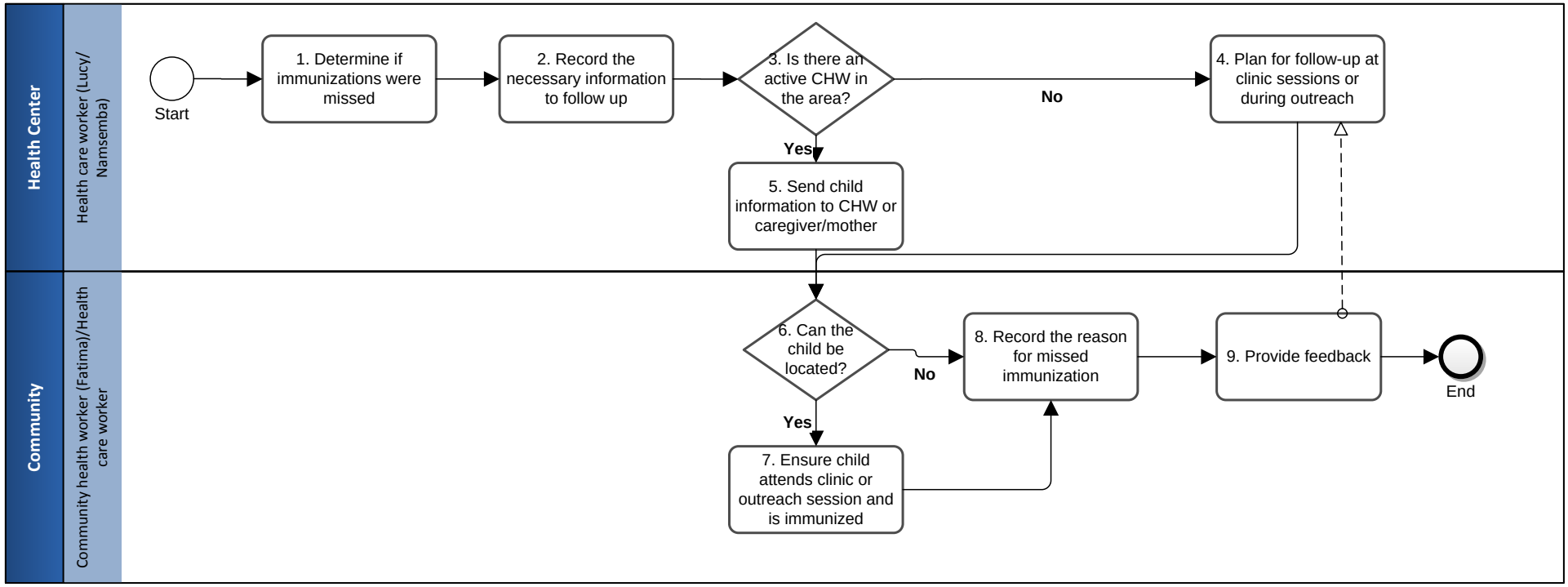
A specific SMS (or voice) reminder message can be sent to the phone number on record. The content of the message can include which child is due for immunization, and the clinic options (outreach or routine) including the location, date, and time window.

5. Generate reminder to CHW

A CHW is sent a list of all children in his/her area that are due for vaccinations, as well as the upcoming clinic opportunities and dates.

4. Immunization follow-up

Figure 4-5. Step 4: Immunization follow-up.



Process notes

Objective: Identify those who were due to come for vaccination, records indicate a missing vaccination, and now the patient is past due. There is a significant amount of variability in how this follow-up is done currently. This process flow assumes the child is registered and has begun an initial dose.

1. Determine if immunizations were missed

Currently, the HCW reviews the registration book to look for months (depending on how the register is organized) in which no information is recorded for the client. They then determine (based on the data that is entered) if the client is now overdue for an immunization and which one.

**This step could be automated by searching an electronic record based on specific rules (either an appointment given that was past or a record that shows more than a predetermined time has elapsed between immunizations).

2. Record the necessary information to follow up

Currently, the HCW will record the client's name, missed antigen, and any contact info necessary to follow up. This is often challenging, as information to trace is often lacking in the registers.

**An electronic record may also help to determine if the child is now receiving immunizations in another facility.

3. Is there an active CHW in that area?

This activity/decision varies widely by area. Some have good CHW coverage and rely on them as part of the team; others have the HCW do most of the follow up. If the client is in a village well-supported by a CHW for routine immunizations, the HCW will often contact them to follow up. If not, the HCW will follow up themselves.

4. Plan for follow-up at clinic sessions or during outreach

The HCW will add the defaulter information they have to their plan for outreach activities. When they are next in the client's village/neighborhood, they will go to the home and find them.

5. Send child information to CHW or caregiver/mother

Contact information, missed antigen, and any other relevant data are sent to the CHW either in a written report, during a meeting, or via phone. Individual reminders could also be sent to clients. Others within the community may also assist, such as religious leaders or village elders.

6. Can the child be located?

The CHW or HCW will attempt to find the child by going to their home, contacting relatives or neighbors, or any other means necessary. If they are reportedly in the area but not available at that time, the HCW or CHW will continue to try to reach them during subsequent days.

If the child is located, the CHW or HCW should also look for the Child Health Record and other indications of earlier vaccinations (e.g., scar).

7. Ensure child attends clinic or outreach session and is immunized

The CHW will go to the home and bring the client to clinic. HCWs seldom go to a child's home for routine vaccinations due to cost.

8. Record the reason for missed immunization

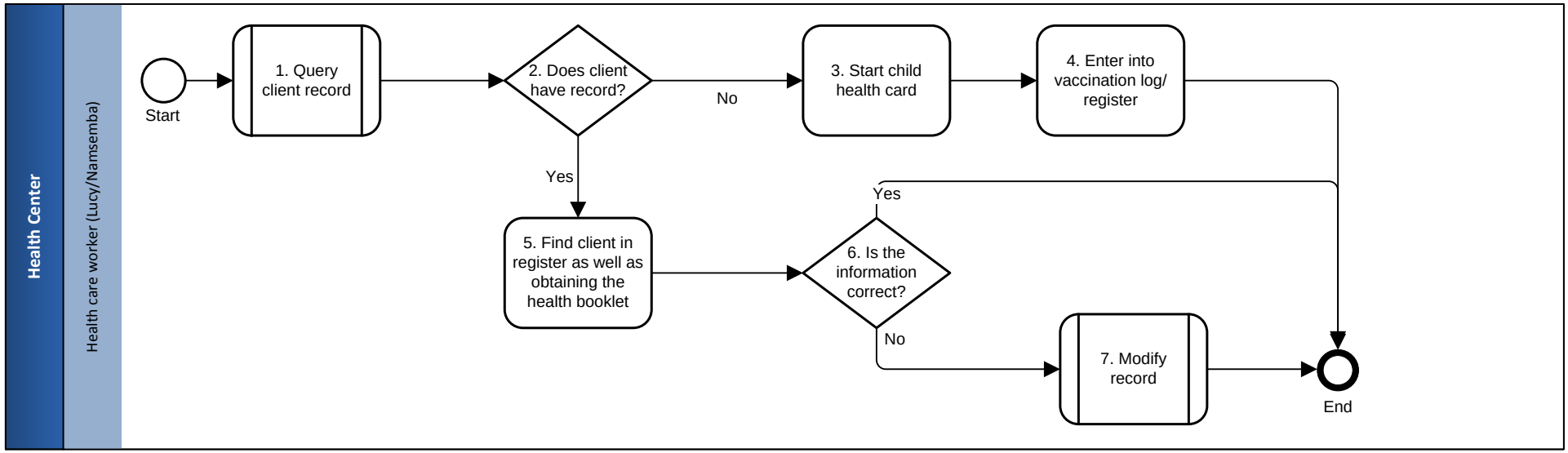
A reason should always be recorded for planning purposes (e.g., previous stockout, distance, etc.). If the patient is missing for some permanent reason (such as they have moved or died), that is recorded so that they are no longer considered defaulters for that area.

9. Provide feedback

To assist with clinic and outreach planning, the results of the follow-up are provided back to the HCW.

5. Register client

Figure 4-6. Step 5: Register client.



Process notes

Objective: Start or contribute to the client's lifelong immunization record. This will allow providers and the client/mother to identify what vaccinations have been given.

1. Query client record

The client is often initially registered at birth, since some vaccinations are given at birth or shortly after. It is still best practice to search for the record anyway to ensure it has not been entered. Some will be seen for the first time in a clinic or outreach activities. Those coming for follow-up will usually arrive at either a regular clinic or an outreach clinic.

2. Does client have record?

If they are seen first at birth (or for their first vaccines), they will not have a record. If the client presents under other circumstances, the HCW will ask the parent if the client has already been registered and for the child health booklet.

3. Start child health card

A record for recording the client's weight, immunizations, and other routine data monitoring is started. The clinician will record the client's name, date of birth, and other demographic data as well as the clinical information from the first visit. This record is then given to the parent to take home. It will need to be brought back to every visit.

4. Enter into vaccination log/register

A single-line entry is put into a vaccination/child health register for that client. The data from the visit is entered (immunization, weight, etc.). If the client is not from that area, there may be no entry in the registration log. Depending on the circumstances one may be entered (if the client will reside there for some time) or not (if they are there only for a short time).

5. Find client in register as well as obtaining the health booklet

The HCW needs to BOTH find the record in the register (either paper or electronic or both) as well as obtain the client's health booklet. If the health booklet is lost, a new one will be started and data from the register transcribed into it.

If the client is not from that area (this is more likely to happen in outreach), they may elect not to add them to their local register and record information only in the child health booklet.

6. Is the information correct?

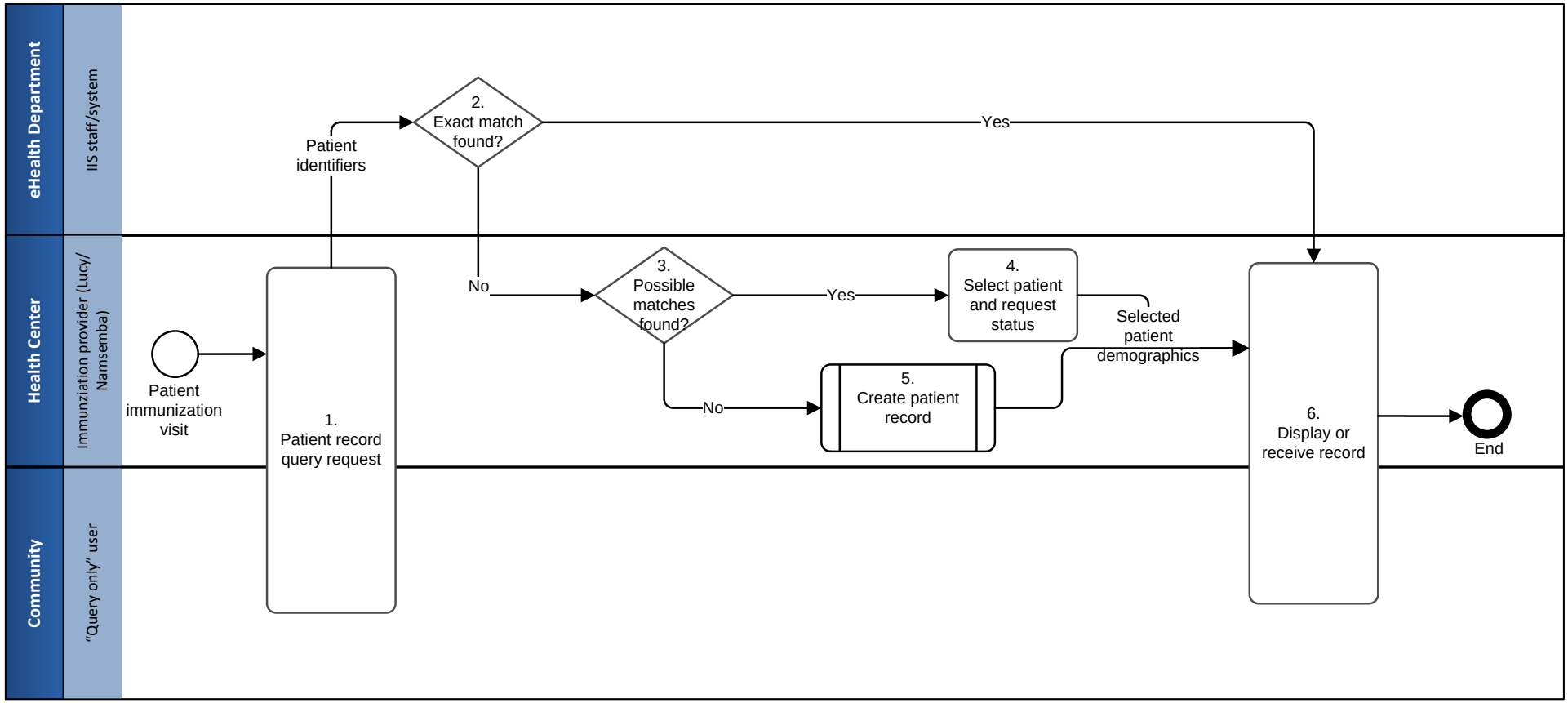
Validate the data in the record, name spelling, phone number, date of birth, etc.

7. Modify record

See subprocess. Correct data as needed.

6. Query patient record

Figure 4-7. Step 6: Query patient record.



Process notes

Objective: Correctly locate or identify a patient's immunization record as well as review and update a patient's record to provide a complete immunization history. This will be used to determine recommended vaccines and due dates, allowing providers to recommend and discuss immunizations with the patient.

1. Patient record query request

The provider or "Query Only" user queries the system with patient IDs (typically last name, gender, date of birth, and/or village).

Partial dates and near matches may be necessary.

A "Query Only" user may be a caregiver or other provider who needs to check the patient status only.

2. Exact match found?

The provider reviews matches returned by IIS to determine if the patient currently has a record in the system.

3. Possible matches found?

The IIS returns a list of possible matches based on patient IDs.

The provider reviews the list to determine if a patient record exists in the IIS that matches with their patient.

4. Select patient and request status

Some IIS systems will allow for the return of multiple matches.

If only exact matches are allowed, the user will supply more information, continue the search, or create a new record.

5. Create patient record

If a patient record was not found in the IIS, the provider creates a new record using required patient demographic IDs. See also "create new record process" for more detail.

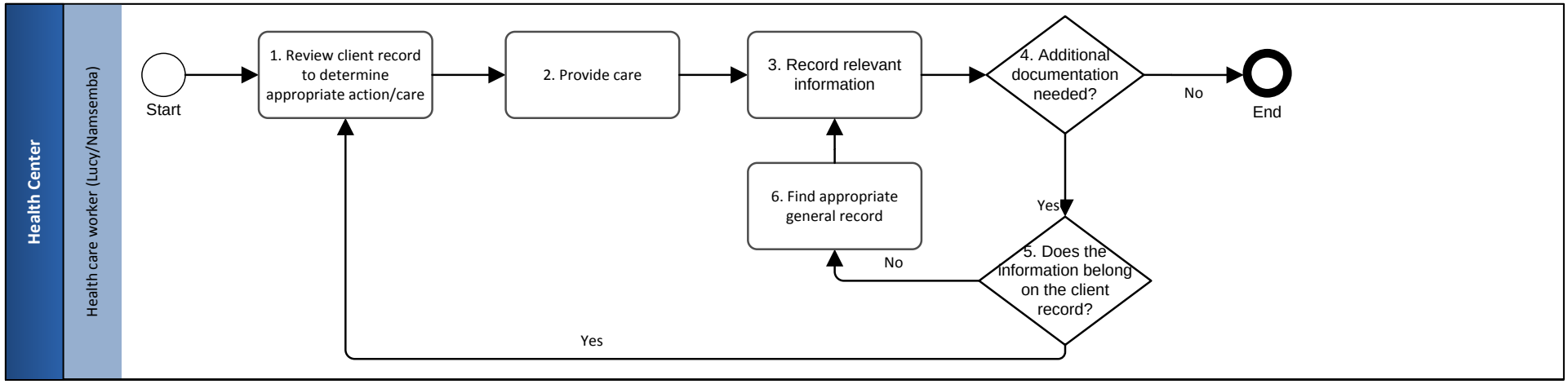
6. Display or receive record

The IIS matches the patient record, validates vaccines, identifies missed vaccinations, and returns a response with the patient's immunization history and recommended doses with due dates.

This information can be made available through the sending of the data to the user.

7. Update records

Figure 4-8. Step 7: Update records.



Process notes

Objective: Activities and considerations related to updating records.

1. Review client record to determine appropriate action/care

Prior to providing care (including giving a vaccine) the client's record should be consulted to determine what would be appropriate. This process starts with a query to find the correct patient.

2. Provide care

If the care is a vaccination, the vaccine is administered to the client according to guidelines.

3. Record relevant information

All relevant data and observations will be recorded according to standard protocols or guidelines.

4. Additional documentation needed?

Some care events may need additional information recorded to assist with aggregate reporting for billing, research purposes, or to document a non-routine event (such as an adverse reaction).

5. Does the information belong on the client record?

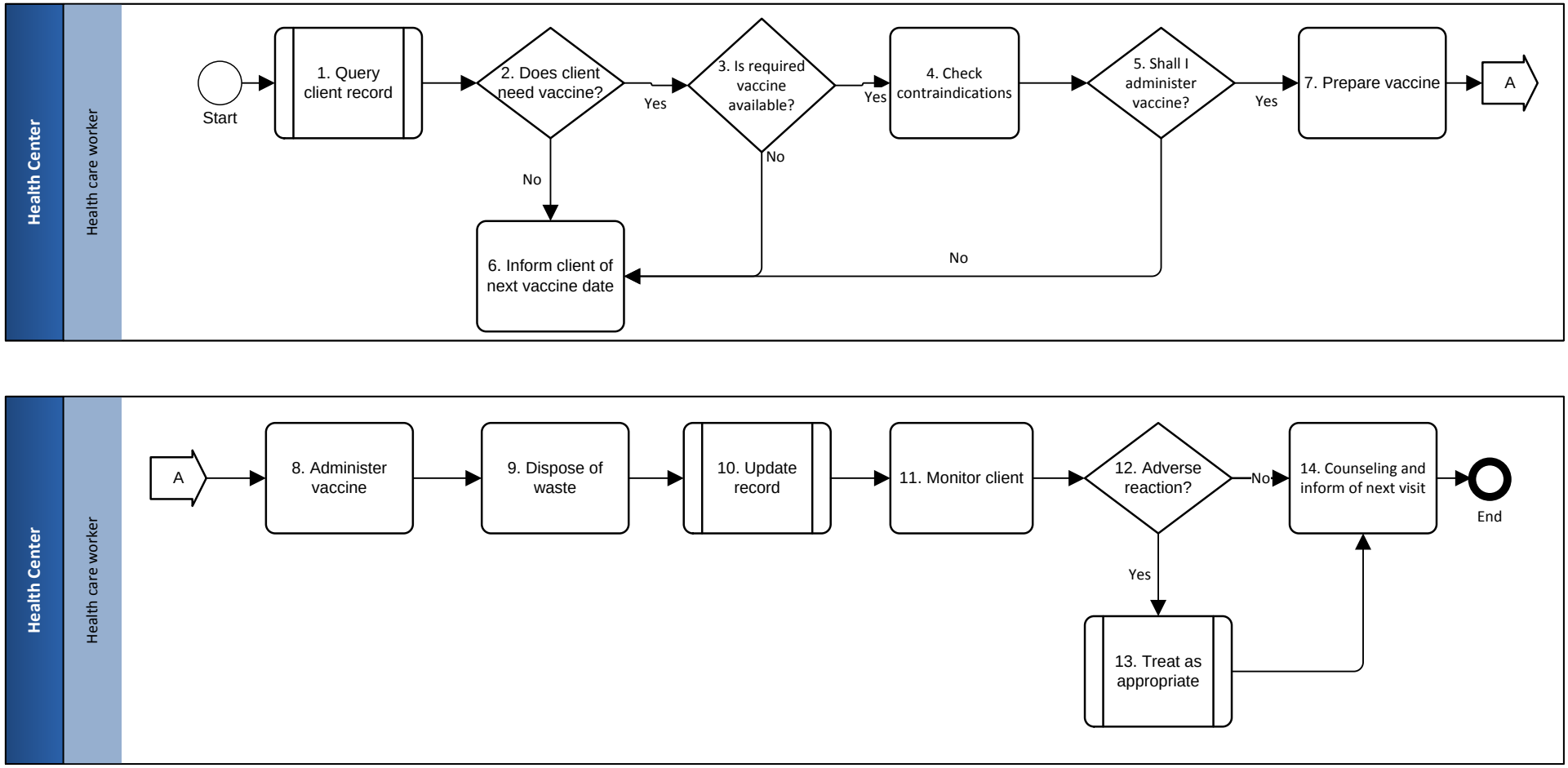
Not all information is relevant to the care of the client and needs to be documented on a client-centric record. Items related to stock use, billing, wastage, etc. may not be appropriate for a client record. It is important to note that most aggregate data can be extracted/abstracted from appropriately set-up client records.

6. Find appropriate general record

Appropriate general record, such as a stock tally, should be located. –.

8. Administer vaccine

Figure 4-9. Step 8: Administer vaccine.



Process notes

Objective: Determine what vaccines a client needs, administer those, and record the relevant necessary data.

1. Query client record

See subprocess. The system (or paper record) needs to be searched for the appropriate client record. The appropriate records are located and displayed.

2. Does client need vaccine?

After consulting the client record, the health worker determines if the patient is due a vaccine according to the vaccine protocol. This should be calculated and displayed by the system if electronic, or by protocol if on paper.

3. Is required vaccine available?

The health worker checks to see if the vaccine is available.

4. Check contraindications

The health worker examines the client and interviews them (or caregiver) to see if there are any contraindications to giving the vaccine.

5. Shall I administer vaccine?

The health worker checks to see if the vaccine can be administered to the client.

6. Inform client of next vaccine date

The HCW informs the client or caregiver when the next vaccine is due.

Other monitoring or interventions may still be done at this time (such as weight and general health education). If the vaccine is not available, the client is instructed when to return based on when it will be available.

7. Prepare vaccine

The vaccine is removed from the cold storage, validated, reconstituted if needed, and drawn up into the syringe.

8. Administer vaccine

The vaccine is administered to the client according to guidelines.

9. Dispose of waste

Properly dispose of the waste following administration; this includes sharps and empty vials.

10. Update record

The HCW updates the health facility's and client's records, indicating the antigen given and the date. See subprocess.

11. Monitor client

Client monitored for adverse reaction.

12. Adverse reaction?

Look primarily for immediate adverse reactions (anaphylaxis).

12. Treat as appropriate

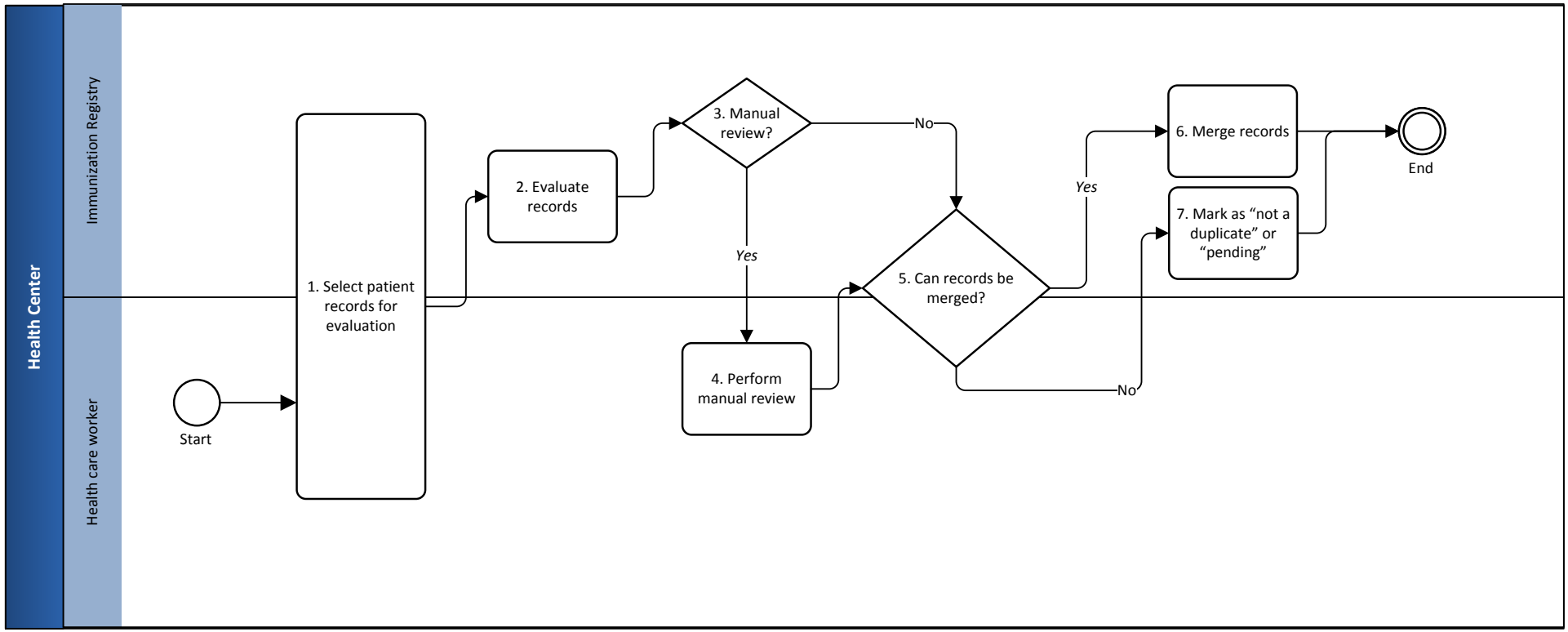
If the client exhibits an adverse reaction to the vaccine, the HCW treats them as appropriate.

13. Counseling and inform of next visit

Inform client when follow-up vaccine is required. This may also trigger a schedule process. Provide counseling regarding reactions and what to do.

9. Resolve duplication of patient records

Figure 4-10. Step 9: Resolve duplication of patient records.



Process notes

Objective: Identify duplicate patient records and consolidate them into one most accurate/suitable (best) record.

1. Select patient records for evaluation

Patient records are reviewed on a periodic basis (daily or weekly) to determine if they are unique patients. Potentially duplicated records are identified and grouped.

Some systems automatically initiate this process to ensure data integrity; however, individual users can select, or flag, the patient records to be evaluated.

2. Evaluate records

Potential patient record pairs are evaluated using demographic data including patient name, date of birth, national ID number, parent/guardian information, mother's maiden name, and address. As many fields as possible should be used for de-duplication purposes.

In addition to demographic data, immunization history can also be used to identify duplicate patient records.

3. Manual review?

Potential duplicate patient records are forwarded for resolution. If a merge cannot be automatically performed by the system, the records will be directed for manual review.

4. Perform manual review

Patient records are reviewed manually to determine if they are duplicates.

Manual review often occurs with name or date-of-birth typos or where there is too little demographic information to determine whether the records are duplicated.

5. Can records be merged?

User/system determines if the patient records can be merged into one record, if they are "not a duplicate", or if there is not enough information to make a decision.

For example: If a name or date of birth is slightly different, but other components match, a determination must be made whether the two records should be merged or marked as "separate."

6. Merge records

Patient records where predetermined criteria match are merged. Extra precaution should be taken for pediatric patient records because the inappropriate merging of pediatric records is more consequential than for adult records due to complex vaccination schedules and the risk of under-vaccination.

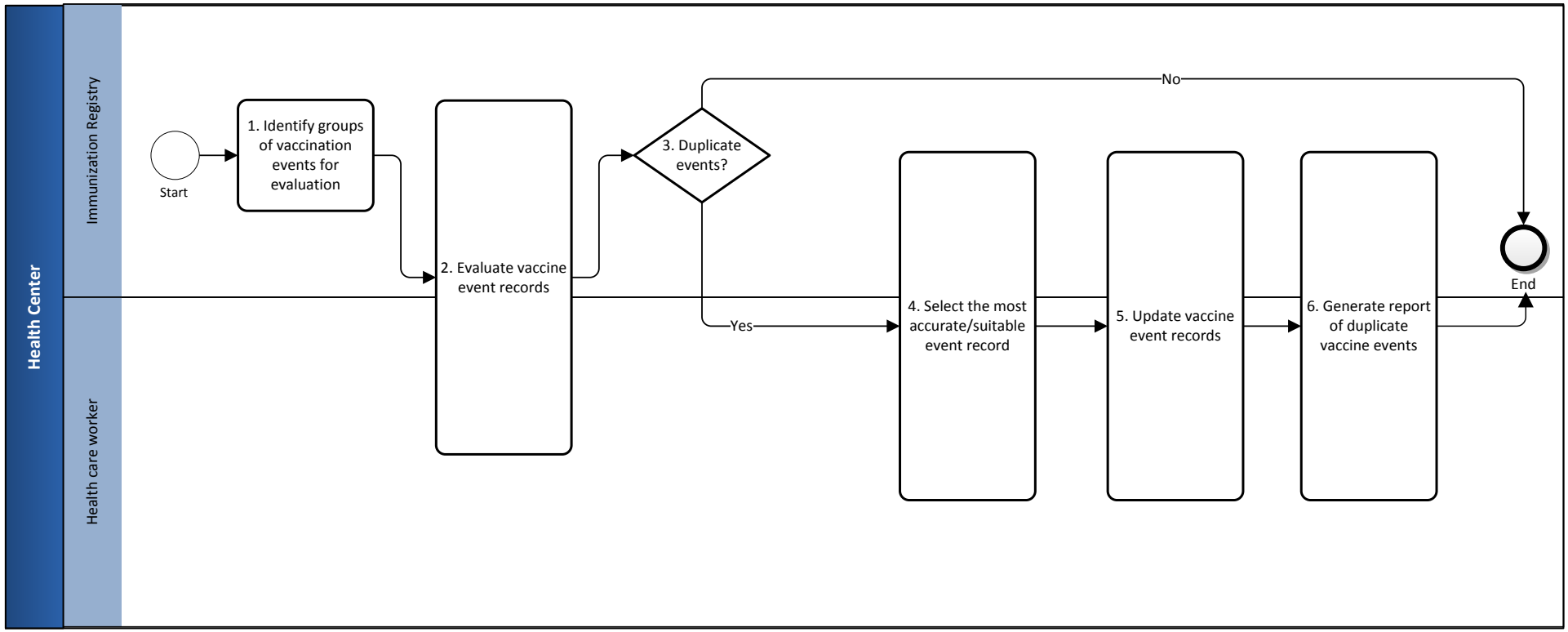
7. Mark as "not a duplicate" or pending

If it is determined that the records are for different individuals, the patient records are marked as "not a duplicate", and immunization histories are maintained separately in the system.

If user is still unsure if the record is a duplicate, it is marked as "pending" and revisited at a later time.

10. Resolve duplication of vaccine events

Figure 4-11. Step 9: Resolve duplication of vaccine events



Process notes

Objective: Identify duplicate immunization events within a patient record and update into one event.

1. Identify groups of vaccination events for evaluation

Vaccination events within a patient's record are reviewed to determine if they are unique events.

Potential duplicate events are identified and grouped within a patient's record.

2. Evaluate vaccine event records

Records are reviewed individually to determine if the recorded events are duplicates.

3. Duplicate events?

Event groups are evaluated using predefined criteria (e.g., encounter date, vaccine type and trade name, provider name, record source type, and vaccine lot number, etc.).

Categorized pairs (match/differ) are forwarded for resolution. If a classification cannot be made, they may be directed for manual review.

4. Select the most accurate/suitable event record

For events that match, the most accurate/suitable (best) event is selected based on level of confidence, completeness of data, and specificity of data. The event is used as the basis for an updated event.

This step can be performed manually or by the system.

5. Update vaccine event records

All available information is aggregated from the duplicate events into an updated event.

Both the updated event and the "best" event (reported "as-is") can be made available to view and utilize.

All reported events should be kept on file along with a documented audit trail so de-duplication decisions can be analyzed.

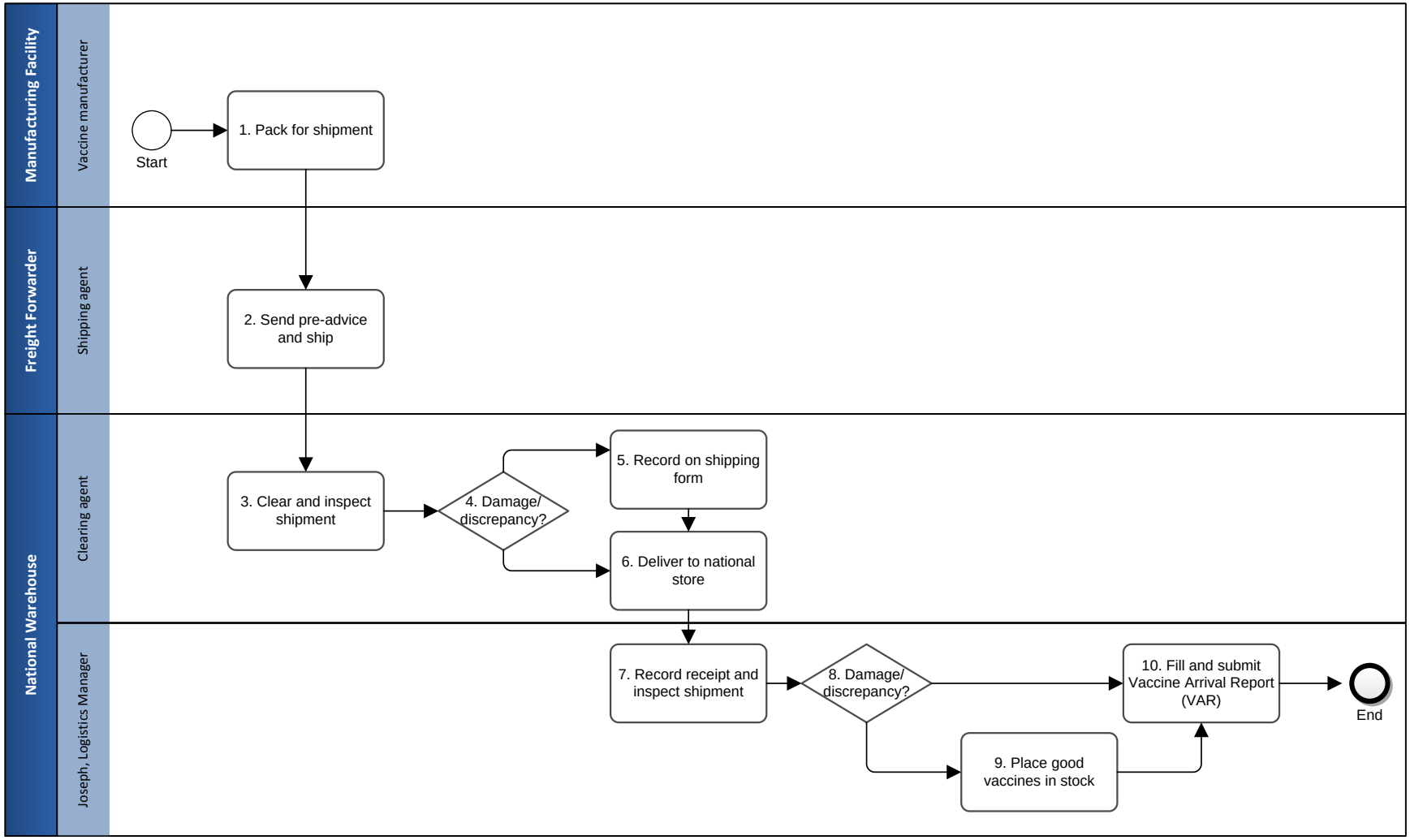
Viewing of retained events should be limited to administrative roles.

6. Generate report of duplicate vaccine events

The system generates a report of duplicate vaccine events. The report is printable and can be exported to several formats.

11. Manage vaccine arrivals

Figure 4-12. Step 10: Manage vaccine arrivals.



Process notes

Objective: Receive verified quantity and quality of goods into store.

1. Pack for shipment

The manufacturer processes the order and packs vaccines for shipment.

2. Send pre-advice and ship

- Label tertiary package with destination address, vaccine name, batch no., manufacturer date, expiry date, and quantity.
- Send pre-advice notice to UNICEF, national store (Medical Stores Department [MSD]) and immunization and vaccines department (IVD).
- The arrival report is sent by the shipping agent to the MoH, with UNICEF copied. UNICEF forwards it to MSD and IVD.
- Program managers or logisticians are notified of a shipment's pending arrival. This notification should happen prior to the physical arrival.
- The notification could be in several forms: telephone, fax, email, etc.

3. Clear and inspect shipment

Complete shipment form document at the airport. Inspect externally for damage. Transport it to MSD.

4. Damage/discrepancy?

Damaged items or discrepancies are noted on the receiving report.

5. Record on shipping form

Damaged items or discrepancies are noted on the shipping form.

6. Deliver to national store

Undamaged items are delivered to MSD.

7. Record receipt and inspect shipment

Thorough inspection is done at the national store. Vaccine vial monitor (VVM) tags are monitored and expiry date is noted. Physical counts of all items are done

8. Damage/discrepancy?

Damaged items or discrepancies are noted.

9. Place good vaccines in stock

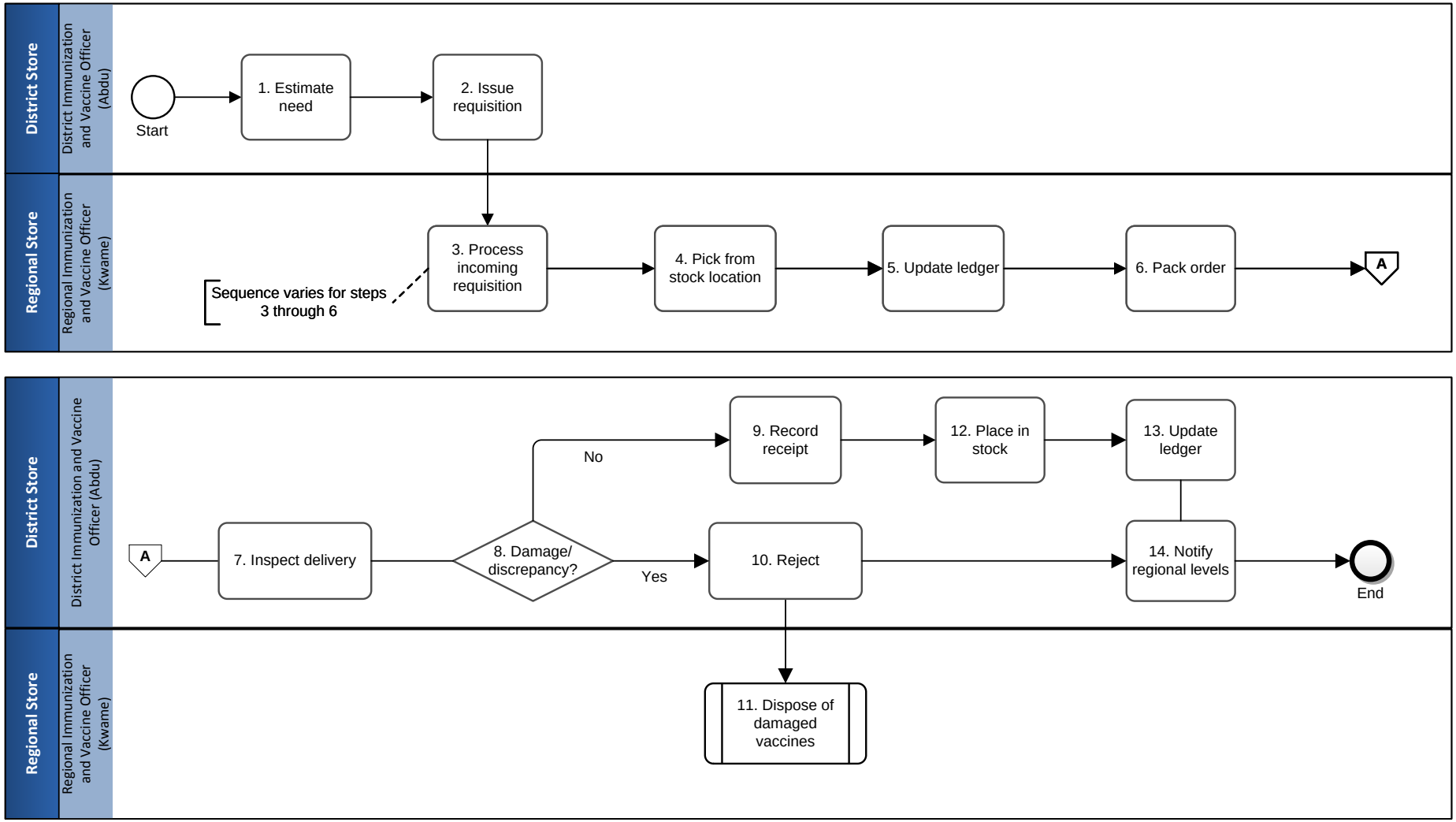
Stock is placed in allocated storage (multiple walk-in cold rooms). Tertiary boxes are unpacked to fit on shelves. Some of the packaging may be damaged, resulting in "loose" vials that need to be counted individually.

10. Fill and submit VAR

VAR is filled and submitted to UNICEF.

12. Distribute supplies to region/district

Figure 4-13. Step 11: Distribute supplies to region/district.



Process notes

Objective: Dispatch vaccines between stores or from a store to the health facility.

1. Estimate need

- Record current stock.
- Calculate required quantities based on guidelines and rules.
- SMT provides good model for estimation.

2. Issue requisition

- Create requisition based on estimated needs.
- Consider minimum and maximum safety levels.
- Paper requisition.

3. Process incoming requisition

- Requisitions are received from intermediate store and/or service delivery locations.
- Regional Immunization Officer specifies number of doses to be issued, depending on available stock.
- Calculate the number of doses required.

4. Pick from stock location

Stock is picked based on an inventory control method such as first in-first out or first expired-first out.

5. Update ledger

Update ledger with new quantity on hand after stock is picked for order.

6. Pack order

Order is packed with appropriate measures taken for cold storage if necessary.

7. Inspect delivery

- Perform physical inspection.
- Monitor VVM status.
- Check expiry date.
- District often picks up order, therefore inspection steps may change.

8. Record receipt

- Record the receipt of the batch or lot number to the tally sheet (Vaccine Control Card), ledger, and SMT.
- Ensure content of tally sheet and ledger is the same.

9. Reject shipment

Reject shipment if VVM status is above threshold.

10. Dispose of damaged vaccines

Dispose according to the policy.

11. Place in stock

After vaccines are checked and approved, they are formally released to stock and moved into storage in the appropriate area.

12. Update ledger

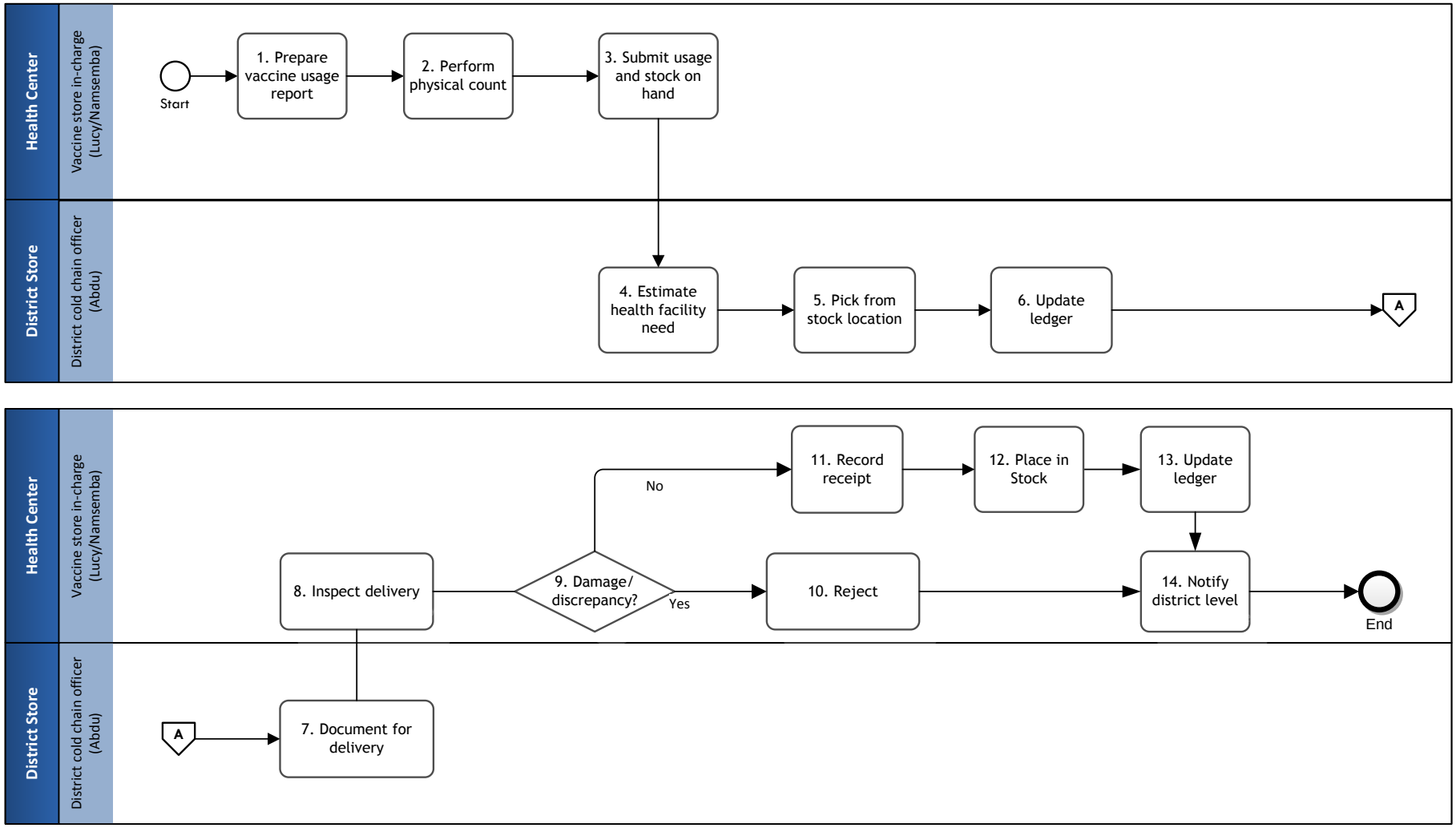
Update ledger with new quantity on hand after stock is picked for order.

13. Notify regional levels

Notify higher levels of the receipt of the goods.

13. Distribute supplies to health center

Figure 4-14. Step 13: Distribute supplies to health center.



Process notes

Objective: Dispatch vaccines between stores or from a store to the health facility.

1. Prepare vaccine usage report

Order request often different from monthly report.

2. Perform physical count

Record current stock.

3. Submit usage and stock on hand

- Calculate required quantities based on guidelines and rules.
- Requisition form varies from none to handwritten.

4. Estimate health facility need

- Based on calculations considering minimum and maximum safety levels.
- May be push or pull model, need may be estimated by DIVO or by health center staff.

5. Pick from stock location

Stock is picked based on first in-first out or first expired-first out inventory control methods.

6. Update ledger

Update ledger and SMT with new quantity on hand after stock is picked for order.

7. Document for delivery

The Issue Voucher at district is formalized and varies by location and in completeness.

8. Inspect delivery

- Perform physical inspection.
- Monitor VVM status.
- Check expiry date.

9. Record receipt

Double signatures on receipt.

10. Place in stock

After vaccines are checked and approved, they are formally released to stock and moved into storage in the appropriate area.

11. Update ledger

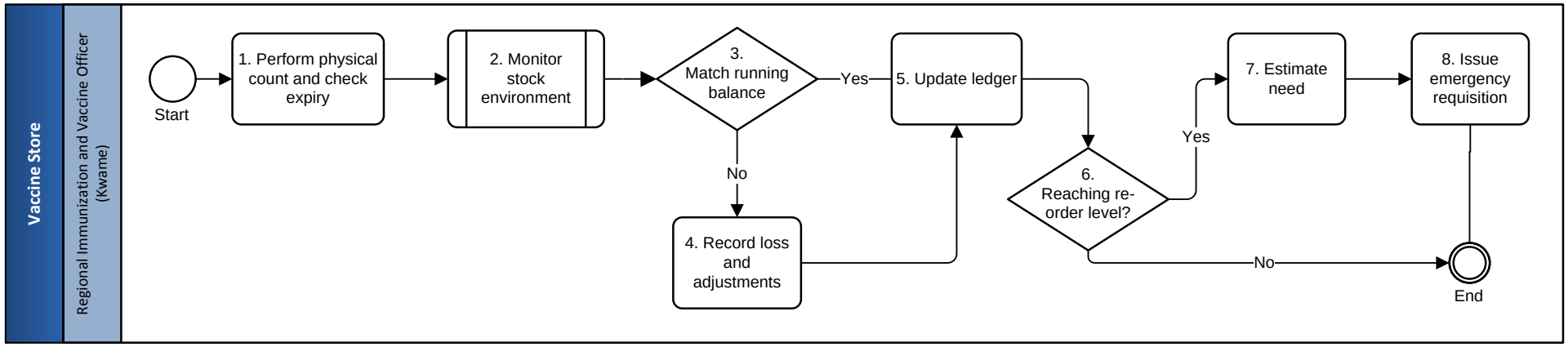
- Record receipt information on ledger.
- Best practices include adding lot, expiration date, and VVM status.

12. Notify district level

Reject shipment if VVM status is above threshold or if discrepancy in numbers.

14. Manage inventory

Figure 4-15. Step 14: Manage inventory.



Process notes

Objective: Manage vaccine inventory.

1. Perform physical count and check expiry

- Perform monthly at district and regional levels, every six months for MSD.
- Perform physical count.
- Perform physical check for damages.
- Check expiry dates.
- Also perform physical count of diluents.
- Health facility records daily, district/region records monthly, MSD records every six months.
- Record temperature.
- Recording diluents with vaccine on ledger is best practice.

2. Monitor stock environment

Action based on fridge tag alarms unclear.

3. Match running balance

Compare the number of unexpired and undamaged with running balance.

4. Record loss and adjustments

Record the discrepancy as loss, adjustments made, and the reason for the discrepancy.

Loss and adjustments not always captured on ledger.

5. Update ledger

- Update ledger and/or other systems with physical count quantity.
- Some bin cards in use.

6. Reaching re-order level?

Compare physical count quantity with allowed minimum balance.

7. Estimate need

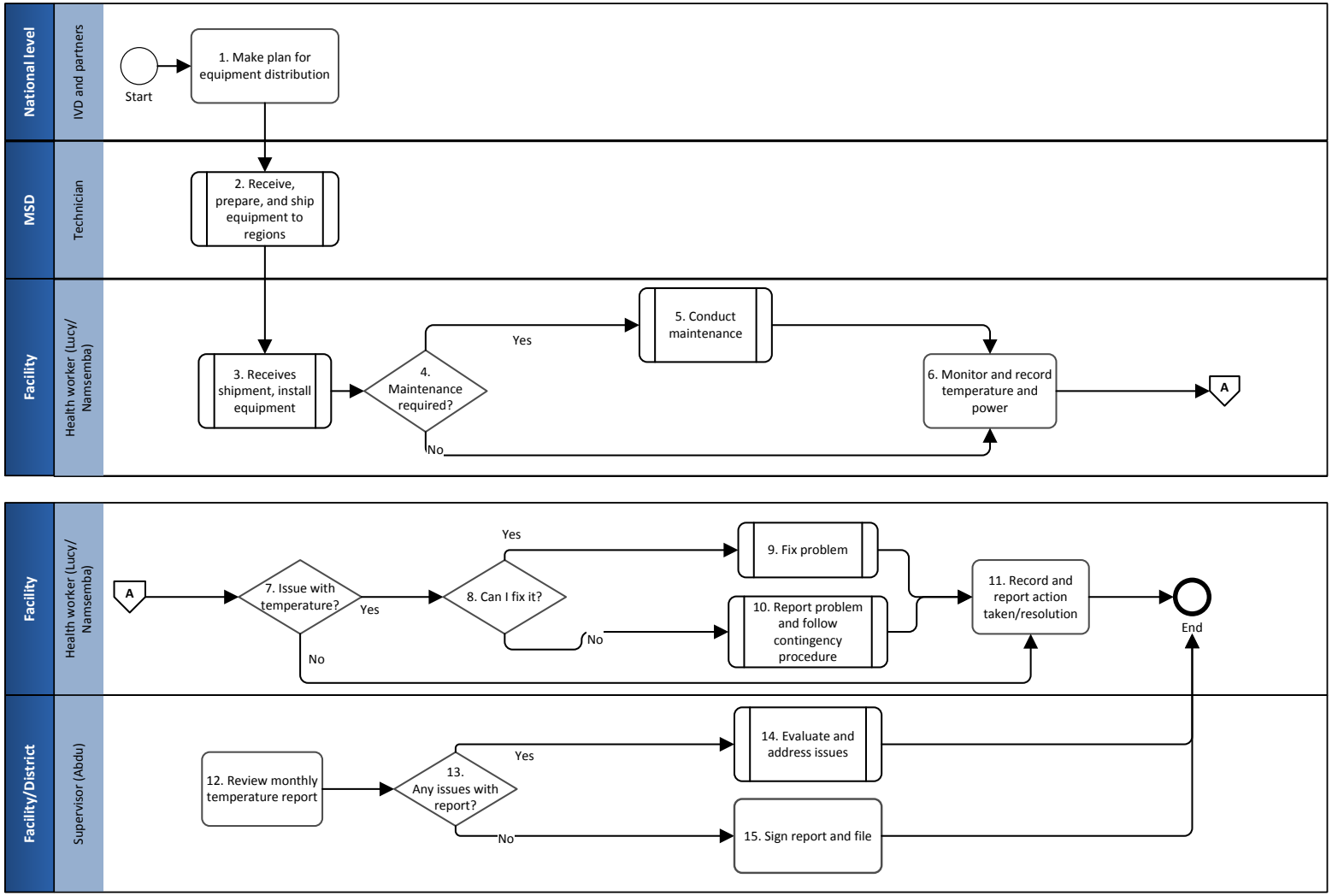
- Calculate required quantities based on guidelines and rules.
- Regional/national levels: requires counting diluents and syringes as well.

8. Issue emergency requisition

- Create requisition based on estimated needs.
- Consider minimum stock and safety levels.
- Requisition is often started via phone; although health center staff may travel directly to the district store and report the emergency at that time.

15. Manage cold chain inventory

Figure 4-16. Step 15: Manage cold chain inventory.



Process notes

Objective: Keep cold chain equipment in optimal working order.

1. **Make plan for equipment distribution**

- Contact stakeholders (varies between fridges and cold rooms).
- Review reports from districts and health facilities to estimate need.
- Forecast need.
- IVD allocates equipment order and distribution.

2. **Receive, prepare, and ship equipment to regions**

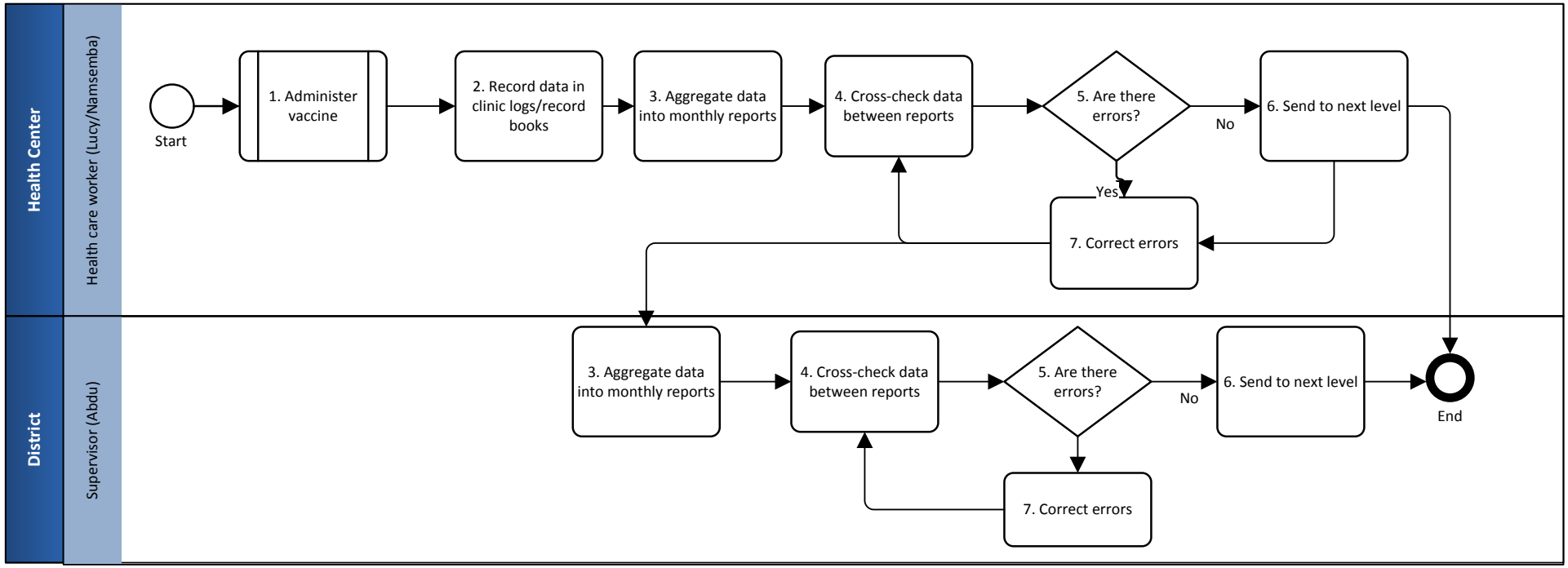
- Alert recipients in advance.
- Cold room supplies may be shipped directly to district, may go through other stops.
- Depending on the recipient, the shipment process may vary (number of stops).

3. **Monitor and record temperature and power**

- Monitor fridge tags and record temperature twice per day. The fridge tags record a month's worth of data, and then needs to be reset. Twice per day, user charts temperatures on a paper register and files it at the end of the month. Note on the chart if there were any temperature alarms on the fridge tag.
- The monthly report from the facility includes the number of alarms.
- Monitor and record interruptions in operation (power, cleaning, defrosting).

16. Generate reports

Figure 4-17. Step 16: Generate reports.



Process notes

This is a generic process for the completion of all common reports related to immunizations. These reports are currently done manually and are extremely time-consuming to complete.

1. Administer vaccine

See process for details.

2. Record data in clinic logs/record books

In addition to recording the immunization in the child health booklet, information regarding the antigens given, wastage, and usage are recorded in various logs. Some are patient-specific, some are simply tallies.

3. Aggregate data into monthly reports

At the end of each month, the individual tally sheets or books must be aggregated into a monthly report for that health center or district. The process for each is the same—only the source data is different.

4. Cross-check data between reports

The aggregate data is then validated or checked against other reports (e.g., the number of antigens given plus wastage should equal the amount of doses missing from the stock).

5. Are there errors?

Are there any errors or discrepancies in the reports? This includes missing data.

6. Send to next level

The report is then sent to the next administrative level for the process to be repeated and data to be further aggregated.

7. Correct errors

Errors in data (including missing and illegible data) must be corrected. This is often a very difficult process as accurate source data may not be available.

Note:

Although this describes the manual process, as long as appropriate data is collected at the source (during the vaccine-administering process, or while accounting for stock), most of these steps can be automated.

5. Common requirements for immunization information systems

Overview

The purpose of this chapter is to provide a common set of requirements associated with a national immunization information system. The requirements listed in this document have been compiled using the CRDM[a] from multiple sources with EPI staff from more than a dozen countries.

Chapter Summary

What must the information system do to support the defined business processes and tasks? This section summarizes the technical requirements that will ensure the system meets user needs, and therefore, the larger health need.

What are the steps in CRDM?

1. **Domain** – Set of functions and processes that defines the work of a specific area of the larger health system (i.e., supply chain).
2. **Process Framework** – Set of processes that defines the boundaries of a domain and the relationships between them and other systems and domains.
3. **Business Process** – Set of activities and tasks that logically group together to accomplish a goal or produce something of value for the benefit of the organization, stakeholder, or customer.
4. **Activity/Task Model** – Visual representation of a business process in terms of tasks, sets of tasks, and decision points in a logical workflow used to enhance communication and collaboration among users, stakeholders, and engineers.
5. **Requirement** – Statement that describes what an information system must do to support a task, activity, or decision. These are non-technology statements that usually begin with "the system must or shall…"

How to apply requirements at a practical level

This set of requirements provides a starting point for country- or project-specific requirements for an immunization information system. Open-source development projects and commercial off-the-shelf software suppliers may have existing technical specifications and documentation that allow for the evaluation and adaptation for local needs.

Here are three examples where the application of the requirements and CRDM can add value to countries, donors, technical agencies, and software developers:[1]

1. Preparing a request for proposal.

For project teams that have identified the need to implement an information system to support immunization information systems, the documentation provides both a framework that will allow the proper scoping of the project and a checklist that can be used when drafting terms of reference or an RFP. First, it will allow the team to define the functional

[a] For more information on the use of CRDM in ICTinformation technology projects in the US, please visit http://www.phiicrdm.org/methodology for an overview of the methodology and its uses.

scope and establish the essential requirements. The list of requirements provides a good head start in this prioritization process.

2. Evaluate alternative solutions.

Ideally, countries will be in a position where they have many alternatives and need to choose a system that best matches the complex and diverse organizational needs. This is often a tricky process in which different parts of the organization may prefer different solutions. Not every system will be equally strong across all requirements. The list of requirements may in this case be used to score different systems against a list of weighted and prioritized requirements based on country or team preferences, making the discussion more transparent and structured.

3. Conduct landscape analysis.

Even a seemingly narrow field like immunization information systems may actually cover many different kinds of systems. Some systems are in actuality more focused on patient care functions, while others could be characterized as supply chain systems. Nongovernmental organizations (NGOs), technical agencies, and donors can use these requirements to conduct further analysis of currently available systems (including commercial, publicly funded, and open source), and the requirements will provide an objective comparison to help with the mapping of system capabilities and the completeness of solutions evaluated.

As part of the BID Initiative, PATH will continue to work with countries and stakeholders to apply and refine the requirements, fostering the growth of solutions that are a good fit for a country's EA.

User and systems requirements supporting business processes

This section details functional user and system requirements for the business processes described in the previous sections.

User requirements

Functional user requirements are statements that describe what an information system needs to do to support the tasks or activities that make up the business process. These requirements answer the question, "What needs to happen to support the user to complete a work activity?" The requirements are organized in tables reflecting each business process and associated with the tasks they support. They serve as a reference during the development of an information system to ensure the final solution either built or procured meets users' needs.

Table 5-1. Business requirements for *Step 1. Register facilities*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
1.1	Receive Facility Information	IIS Staff/System	Have ability to receive facility information from multiple sources (e.g., automatically or manually in multiple formats).
1.2	Validate NMFL	IIS Staff/System	Have ability to interface with NMFL's database to validate if the facility is already registered in the NMFL (Note: If a facility is registered in the NMFL, then the facility information should be verified for accuracy and/or updated in the IIS).
1.3	Validate NMFL	IIS Staff/System	Have ability to flag any facilities that are registered in the IIS that are not in the NMFL.
1.4	Validate NMFL	IIS Staff/System	Have ability to validate NMFL with IIS master list.
1.5	Does Facility Information Match?	IIS Staff/System	Have ability to update IIS master facility registration information with information from the NMFL.
1.6	Update/Add New Facility	Facility Staff	Have ability to provide a temporary unique ID to facilities not listed in the NMFL.
1.7	Update/Add New Facility	Facility Staff	Have ability to add new facilities to IIS master registration list not listed in the NMFL.
1.8	Update/Add New Facility	Facility Staff	Have ability to link the NMFL ID with IIS ID as the same record (Note: Reference table used to show the translation of records [e.g., when records are merged, it maintains a reference of the old/expired/obsolete record ID numbers and references the new ID number]).
1.9	Update/Add New Facility	Facility Staff	Have ability to send notification of new facility to the NMFL manager.
1.10	Update/Add New Facility	Facility Staff	Have ability to update facility information not captured in the NMFL.
1.11	Update/Add New Facility	Facility Staff	Have ability to keep audit log of change history when any facility information is changed and saved (e.g., include date/time stamp).
1.12	Verify Information for Additional Data	IIS Staff/System	Have ability to prompt user to accept changes to IIS master registration list.
1.13	Verify Information for Additional Data	IIS Staff/System	Have ability to verify that all required fields are complete.
1.14	Verify Information for Additional Data	IIS Staff/System	Have ability to notify user of incomplete mandatory fields.
1.15	Validate NMFL	IIS Staff/System	Have ability to flag facility as temporary.
1.16	Update/Add New Facility	IIS Staff/System	Have ability to convert temporary facility to permanent facility.
1.17	Information Complete?	IIS Staff/System	Have ability to verify that all required facility information is complete.
1.18	Information Complete?	IIS Staff/System	Have ability to generate an exception report.
1.19	Information Complete?	IIS Staff/System	Have ability to generate report of missing information.
1.20	Information Complete?	IIS Staff/System	Have ability to generate email to facility.
1.21	Request Additional Information	IIS Staff/System	Have ability to support the process of receiving information.
1.22	Create/Update Facility Record	IIS Staff/System	Have ability to audit facility data changes with date/time stamp "last updated".

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
1.23	Create/Update Facility Record	IIS Staff/System	Have ability to collect total number of facility data changes and report to IIS staff.
1.24	Generate Unique IIS ID	IIS Staff/System	Have ability to generate a unique IIS ID.
1.25	Send Facility Registration Notification and IIS ID	IIS Staff/System	Have ability to send IIS registration notification w/IIS ID (e.g., SMS, mail, email, etc.).
1.26	Send Facility Registration Notification and IIS ID	IIS Staff/System	Have ability to insert/include instructions of how to use IIS ID (e.g., reporting requisition, etc.).
1.27	Receive Registration Information	Facility Staff	Allow user to send/acknowledge confirmation of receipt of the registration notification.

Table 5-2. Business requirements for 2. Plan service delivery.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
2.1	Review register to determine estimates of vaccine needed	Health Care Worker	Identify all children due (or overdue) for vaccination by the next clinic date.
2.2	Review register to determine estimates of vaccine needed	Health Care Worker	Sort the list by antigen.
2.3	Review register to determine estimates of vaccine needed	Health Care Worker	Provide range estimates for vaccine need based on historical data (high and low ranges).
2.4	Record details on planning sheet	Health Care Worker	Print list of necessary antigens and accessories (syringes, wipes, etc.) based on projected need.
2.5	Sufficient stock in immediate location?	Health Care Worker	Identify the stock at the local source.
2.6	Sufficient stock in immediate location?	Health Care Worker	Compare the list of needed antigens to the stock on hand and indicate if there is sufficient stock.
2.7	Sufficient stock in immediate location?	Health Care Worker	Show the actual numbers of each antigen in stock.
2.8	Order additional stock	Health Care Worker	Allow the user to generate a stock request based on the information provided.
2.9	Order additional stock	Health Care Worker	Allow the user to change the number of each antigen as needed (using the shortage as a guideline).
2.10	Order additional stock	Health Care Worker	Provide feedback for stock that is not available for ordering (back orders).
2.11	Order additional stock	Health Care Worker	Indicate that the order has been processed.
2.12	Order additional stock	Health Care Worker	Provide any relevant details for the order fulfillment (such as time of day to expect delivery or any special instructions).

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
2.13	Order additional stock	Health Care Worker	Provide means to include some mandatory user feedback, such as stock on hand and reason for order.
2.14	Get needed stock	Health Care Worker	Provide a printed list of (antigen) stock order to be fulfilled.
2.15	Record stock taken	Health Care Worker	Allow bar code reading of stock taken.
2.16	Record stock taken	Health Care Worker	Record stock removed from cold storage and taken to clinic.
2.17	Record stock taken	Health Care Worker	Maintain a tally of stock available at each location (cold fridge at center, out for clinic).
2.18	Assemble all needed materials for clinic	Health Care Worker	Provide a clinic materials checklist.

Table 5-3. Business requirements for *Step 3. Define criteria*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
3.1	Define Criteria	IIS Staff/System & Immunization Provider	Allow user to select reminder/recall parameters. May include but not limited to: age range, vaccine type(s)/schedules, lot number, geographic area, event triggers, etc.
3.2	Define Criteria	IIS Staff/System & Immunization Provider	Have ability to associate a patient with a clinic/site to generate a provider-based reminder/recall.
3.3	Define Criteria	IIS Staff/System & Immunization Provider	Have ability to validate data against the immunization schedule (Note: Can use the immunization schedule to best schedule reminders/recall for series vaccinations, etc.).
3.4	Select Notification Method	IIS Staff/System & Immunization Provider	Allow user to select one or more notification methods (e.g., telephone call, “robo call”, text message, letter, postcard, labels, email, CHW home visits, etc.).
3.5	Select Notification Method	IIS Staff/System & Immunization Provider	Have ability to maintain patient’s preferred contact method.
3.6	Generate List of Patients	IIS Staff/System & Immunization Provider	Have ability to produce a list of patients according to user-defined parameters.
3.7	Generate List of Patients	IIS Staff/System & Immunization Provider	Have ability to print the list of patients.
3.8	Generate List of Patients	IIS Staff/System & Immunization Provider	Have ability to log each time a user generates a list of patients.
3.9	Generate List of Patients	IIS Staff/System & Immunization Provider	Have the ability to display the date the reminder/recall notice was sent to a patient.
3.10	Generate List of Patients	IIS Staff/System & Immunization Provider	Have ability to display type of notification indicator per patient record (e.g., prevention or defaulter).
3.11	Generate List of Patients	IIS Staff/System & Immunization Provider	Have ability to track the number of reminder/recall attempts (i.e., per patient and total).

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
3.12	Generate List of Patients	IIS Staff/System & Immunization Provider	Prevent all records given an inactive or deceased status from being included in the list of patients for reminder/recall.
3.13	Send Notifications	IIS Staff/System & Immunization Provider	Have ability to generate electronic notifications.
3.14	Send Notifications	IIS Staff/System & Immunization Provider	Have ability to send electronic notifications.
3.15	Send Notifications	IIS Staff/System & Immunization Provider	Send reminder/recall notification to patient or designated health worker (e.g., via CHW).
3.16	Track Patient	Patient/Family	Have ability to assign CHW to a patient.
3.17	Track Patient	Patient/Family	Have ability to generate and send a list of defaulted/overdue patients to CHW.
3.18	Track Patient	Patient/Family	Allow CHW to send tracking updates to facility via SMS, email, etc.
3.19	Update Patient Information and/or Status	IIS Staff/System & Immunization Provider	Have ability to track notification attempts and log back to a patient's record.
3.20	Update Patient Information and/or Status	IIS Staff/System & Immunization Provider	Have ability to maintain an audit log of the changes and history.
3.21	Update Patient Information and/or Status	IIS Staff/System & Immunization Provider	Have ability to update patient record with tracking information in the IIS from the CHW.
3.22	Update Patient Information and/or Status	IIS Staff/System & Immunization Provider	Have ability to edit, update, and override patient information such as change of address (moved permanently or temporarily).
3.23	Active or Inactive?	IIS Staff/System	Have ability to allow a patient record to be inactive for a selected time frame (e.g., temporarily lost residence, crop harvest).
3.24	Client is due vaccine	System	Produce a report that identifies all children due a vaccination within the next month. The inputs to this report should be national vaccination schedule (rules based on each antigen), and the individual's vaccine record.
3.25	Confirm clinic dates and outreach schedule dates	System	Validate the clinic dates for all clinics in the next month (outreach and local).
3.26	Confirm clinic dates and outreach schedule dates	System	Provide a means to update the clinic calendar/schedule (e.g., with national holidays).
3.27	Does client have a phone?	System	Identify if the client due for a vaccination has a phone number on record.
3.28	Generate reminder message	System	Generate a pre-recorded reminder message for the client who is due a vaccination. The message can indicate the date and location of upcoming clinics (outreach and local).
3.29	Generate reminder to CHW	System	Determine the CHW responsible for the area in which the person due a vaccination resides.
3.30	Generate reminder to CHW	System	Send a list of all children (that the CHW has responsibility for) due vaccinations prior to the clinic.

Table 5-4. Business requirements for *Step 4. Immunization follow-up*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
4.1	Determine if immunizations were missed	Health Care Worker	Display a list of children who missed their immunization for each antigen.
4.2	Determine if immunizations were missed	System Admin	Allow the user or ministry to specify immunization schedule and thresholds for a child to qualify as requiring follow-up.
4.3	Determine if immunizations were missed	Health Care Worker	Allow the user to print a list of children requiring follow-up.
4.4	Determine if immunizations were missed	Health Care Worker	Allow the user to export a list for follow-up.
4.5	Record information to follow-up	Health Care Worker	Extract location and personal information.
4.6	Record information to follow-up	Health Care Worker	Categorize defaulter information by location and CHW.
4.7	Plan for follow-up at clinic sessions or during outreach	Health Care Worker	Display a list of planned outreach and clinic sessions.
4.8	Send child information to CHW or mother/caregiver	Health Care Worker	Send list of missing children by email or SMS.
4.9	Send child information to CHW or mother/caregiver	Health Care Worker	Send recall SMS to mother/caregiver.
4.10	Ensure child is immunized	Health Care Worker	Mark located children for future follow-up.
4.11	Record the reason	Health Care Worker	Allow the user to record reason: either permanent reason for not finding child or reason immunization was missed.

Table 5-5. Business requirements for *Step 5. Register client*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
5.1	Does the patient have a record?	Health Care Worker	Allow the user to search for the patient given some demographic information.
5.2	Does the patient have a record?	Health Care Worker	As a result of the search, return all potential matches.
5.3	Does the patient have a record?	Health Care Worker	Allow for searching and matching on partial information (such as partial birthdates).
5.4	Does the patient have a record?	Health Care Worker	Allow searching for children based on family relationships or demographics.
5.5	Does the patient have a record?	Health Care Worker	Allow a system administrator to configure search parameters: what fields are mandatory, when partial information is acceptable, etc.
5.6	Does the patient have a record?	Health Care Worker	Allow searching with wild cards.
5.7	Does the patient have a record?	Health Care Worker	Allow the user to find patient records using barcodes.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
5.8	Does the patient have a record?	Health Care Worker	Include results that look or sound similar to the search term (fuzzy logic).
5.9	Start Child Health Card	Health Care Worker	There will be a need for the patient to have their own paper record for some time. The child health book contains much more information than just immunizations and will require a much broader and more comprehensive solution to replace. In addition, it will serve as the paper back-up for patients and families as they rarely have online access to information.
5.10	Enter into vaccination log/register/ system	Health Care Worker	Allow the user to enter all necessary registration data.
5.11	Enter into vaccination log/register/ system	Health Care Worker	Allow family relations to be modeled by cross-referencing patient data. The mother and father field would thus refer to other records in the patient database.
5.12	Enter into vaccination log/register/ /system	Health Care Worker	Allow the user to select the place of birth from a list as defined by the system administrator.
5.13	Enter into vaccination log/register/ /system	Health Care Worker	Allow the user to select the health center of the patient from a list as defined by the system administrator.
5.14	Enter into vaccination log/register/ /system	Health Care Worker	Validate that a patient does not exist before adding a new record. (All added activities must be preceded by a search).
5.15	Enter into vaccination log/register/ /system	Health Care Worker	Enforce a minimal data set to allow for a new registration.
5.16	Enter into vaccination log/register/ /system	Health Care Worker	Uniquely identify every person.
5.17	Enter into vaccination log/register/ /system	Health Care Worker	Provide a mechanism to prevent unwanted duplication of records (e.g., the system warns if a child is registered with same name and DOB).
5.18	Enter into vaccination log/register/ /system	Health Care Worker	Provide a means to handle duplicates (such as merging records).
5.19	Enter into vaccination log/register/ /system	Health Care Worker	Allow for remote access and update of patient records (via mobile device).
5.20	Find patient in register as well as obtaining the child health booklet	Health Care Worker	Allow the system administrator to configure what information and what data will be returned to determine a match.
5.21	Find patient in register as well as obtaining the child health booklet	Health Care Worker	Allow users to modify or update appropriate patient data as needed.

Please note: Step 8 (Administer vaccine) contains a few of the requirements associated with Step 6 (Query patient record) within the context of a clinic setting. Additional requirements for the patient, community, and other contexts have yet to be documented.

Table 5-6. Business requirements for *Step 7. Update records*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
7.1	Review record to determine appropriate action/care	Health Care Worker	Allow user to be certain the record belongs to the subject of care (this means it contains enough information/demographics/photo/unique ID, etc.).
7.2	Review record to determine appropriate action/care	System	Provide a history of previous care.
7.3	Review record to determine appropriate action/care	System	Contain contact information.
7.4	Record relevant information	Health Care Worker	Update patient's vaccination record with all relevant information (date, dose, lot number, antigen).
7.5	Record relevant information	Health Care Worker	Allow the user to record additional vaccinations, even those that are not included in the national vaccination schedule.
7.6	Does the information belong on the client record?	Health Care Worker	Allow space to record any significant observations (such as reaction) that may be specific to that client.
7.7	Find appropriate general record/ledger	Health Care Worker	Allow for the recording of non-client-specific data, such as counts of antigens given.
7.8	Find appropriate general record/ledger	System	Allow for the reporting of aggregate data from the individual data to suit reporting needs.

Table 5-7. Business requirements for *Step 8. Administer vaccine*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
8.1	Query Client Record	Health Care Worker	Search if client is already in system (using at least two identifiers).
8.2	Query Client Record	Health Care Worker	Require a user to search if a patient is already in the system prior to starting a new medical record entry.
8.3	Query Client Record	System Admin	Allow a system administrator to configure or set if a search must happen in advance of allowing a new entry.
8.4	Query Client Record	Health Care Worker	Read client information from a bar code on a patient ID and retrieve patient information.
8.5	Does client need vaccine?	Health Care Worker	Allow the user to customize vaccine protocol.
8.6	Does client need vaccine?	Health Care Worker	Be able to determine vaccine required by looking at age of client, vaccines already given, and vaccine protocol.
8.7	Does client need vaccine?	Health Care Worker	Display vaccine(s) already given and vaccines due according to vaccine protocol.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
8.8	Is required vaccine available?	Health Care Worker	Display availability of vaccines stock.
8.9	Is required vaccine available?	Health Care Worker	Warn the user if required vaccine is not in stock.
8.10	Inform client of next vaccine date	Health Care Worker	Display due date of the next vaccine.
8.11	Update record	Health Care Worker	Allow the user to enter antigen information (e.g., batch number, expiry date, VVM status).
8.12	Update record	Health Care Worker	Update stock record.
8.13	Inform next visit	Health Care Worker	Display due date of the next vaccine.

Table 5-8. Business requirements for *Step 9. Resolve duplicate patient records*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
9.1	Select Patient Records for Evaluation	IIS Staff/System & User	Have ability to automatically identify new patient records as possible duplicates.
9.2	Select Patient Records for Evaluation	IIS Staff/System & User	Have ability to automatically identify existing patient records as duplicates.
9.3	Select Patient Records for Evaluation	IIS Staff/System & User	Have ability to prompt user of possible duplicate record prior to saving new record.
9.4	Select Patient Records for Evaluation	IIS Staff/System & User	Allow users to manually flag duplicate records.
9.5	Select Patient Records for Evaluation	IIS Staff/System & User	Have ability to schedule batching of duplicate record process.
9.6	Evaluate Records	IIS Staff/System	Support a rule-based algorithm to evaluate duplicate records.
9.7	Evaluate Records	IIS Staff/System	Have ability to generate a report of like IDs/confidence ratings (Note: Possible duplicates: name, address, quality data, reliable information, etc. Filter out missing/invalid value/data.).
9.8	Evaluate Records	IIS Staff/System	Allow rules to be easily editable by IIS staff.
9.9	Manual Review?	IIS Staff/System	Flag duplicate records that require manual review.
9.10	Manual Review?	IIS Staff/System	Have ability to combine two or more duplicate records according to business rules. (Note: Business rules should define which criteria to use to merge records [e.g., what information to keep from the duplicates]).
9.11	Manual Review?	IIS Staff/System	Allow user to manually flag records for manual review.
9.12	Perform Manual Review	User	Have ability to alert user of records pending for manual review.
9.13	Perform Manual Review	User	Allow user to view records simultaneously for decision to merge records.
9.14	Perform Manual Review	User	Allow user to navigate the system while reviewing possible duplicates.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
9.15	Perform Manual Review	User	Have ability to plan and organize projects/tasks/assignments (e.g., task management, assign statuses like “completed” or “high priority”, etc.).
9.16	Can Records Be Merged?	IIS Staff/System & User	Have ability to determine if records have appropriate criteria in order to merge (e.g., personal identifying data to watch).
9.17	Merge Record	IIS Staff/System	Allow user to select data elements to merge into a consolidated record (Note: Could access additional source of data to validate information [e.g., ask the person, look up in another database]).
9.18	Merge Record	IIS Staff/System	Support an audit trail when records are merged.
9.19	Merge Record	IIS Staff/System	Have ability to produce and access a cross-reference listing of pre- and post-merged records (i.e., a list that shows the old patient record information with the corresponding converted new patient record).
9.20	Merge Record	IIS Staff/System	Have ability to “undo merge”.
9.21	Merge Record	IIS Staff/System	Have ability to retain “pre-merged” records.
9.22	Mark as “Not Duplicate” or Pending	IIS Staff/System	Allow user to flag record as “not a duplicate” (Note: The system could believe records are duplicates, but they are not).
9.23	Mark as “Not Duplicate” or Pending	IIS Staff/System	Have ability to prevent matching for the same pair of records that have been flagged as “not a duplicate”.
9.24	Mark as “Not Duplicate” or Pending	IIS Staff/System	Allow user to manually flag a record as pending for manual review (e.g., not enough information).
9.25	Mark as “Not Duplicate” or Pending	IIS Staff/System	Have functionality to determine what pair of records is “not a duplicate of” (i.e., record 123 is a duplicate of record 456 and vice versa).
9.26	Mark as “Not Duplicate” or Pending	IIS Staff/System	Have ability to enter comments for records marked as “not duplicate”.

Table 5-9. Business requirements for *Step 10. Resolve duplicate vaccine events*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
10.1	Identify Groups of Vaccination Events for Evaluation	IIS System	Have ability to prompt the user that the new vaccine is a duplicate.
10.2	Identify Groups of Vaccination Events for Evaluation	IIS System	Have ability to generate a list of possible patient vaccine duplicates.
10.3	Identify Groups of Vaccination Events for Evaluation	IIS System	Have ability to manually initiate duplicate search process.
10.4	Identify Groups of Vaccination Events for Evaluation	IIS System	Have ability to automate duplicate search process.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
10.5	Identify Groups of Vaccination Events for Evaluation	IIS System	Allow users to manually flag duplicate events.
10.6	Identify Groups of Vaccination Events for Evaluation	IIS System	Have ability to display to the end user the vaccine type, manufacturer, administrator date, eligibility, and administrator who entered the dose for manual vaccine de-duplication review.
10.7	Evaluate Vaccine Event Records	IIS System & IIS Staff	Support a rules-based algorithm to evaluate duplicate events.
10.8	Evaluate Vaccine Event Records	IIS System & IIS Staff	Support probabilistic algorithm to determine and flag when duplicate events need manual review.
10.9	Evaluate Vaccine Event Records	IIS System & IIS Staff	Allow rules to be easily editable by IIS staff (add, remove, modify) when authorized.
10.10	Duplicate Events?	IIS System	Allow user to manually flag events for manual review.
10.11	Duplicate Events?	IIS System	Have ability to alert user of events pending for manual review.
10.12	Duplicate Events?	IIS System	Allow user to view events and event details simultaneously for decision to merge (i.e., two or more).
10.13	Duplicate Events?	IIS System	Allow user to navigate the system while reviewing possible duplicates (optional).
10.14	Select the Most Accurate/ Suitable Event Record	IIS System & IIS Staff	Have ability to automatically select the most accurate/suitable vaccination event to be used as the (primary or master) record.
10.15	Update Vaccine Event Records	IIS System & IIS Staff	Allow user to select data elements to merge into a consolidated event record.
10.16	Update Vaccine Event Records	IIS System & IIS Staff	Have ability to combine two or more duplicate event records according to business rules.
10.17	Update Vaccine Event Records	IIS System & IIS Staff	Support an audit trail when event records are merged.
10.18	Update Vaccine Event Records	IIS System & IIS Staff	Have ability to retain “pre-merged” event records.
10.19	Update Vaccine Event Records	IIS System & IIS Staff	Have ability to generate an audit list of vaccination events that are automatically merged.
10.20	Update Vaccine Event Records	IIS System & IIS Staff	Allow user to delete a duplicate vaccine event while still maintaining audit record.
10.21	Generate Report of Duplicates	IIS System & IIS Staff	Automatically schedule routine reports to run at a specific time.
10.22	Generate Report of Duplicates	IIS System & IIS Staff	Allow for the restriction of confidential personal identifiable information.

Table 5-10. Business requirements for *Step 11. Manage vaccine arrivals*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
11.1	Ship and send pre-shipment advice	Shipping Agent	Allow shipping agent to enter shipment details.
11.2	Ship and send pre-shipment advice	Shipping Agent	Send an email notification to the destination country.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
11.3	Ship and send pre-shipment advice	Shipping Agent	Allow manufacturer to enter shipment details (e.g., batch number, expiry date, Global Trade Identification Number, destination country).
11.4	Ship and send pre-shipment advice	Shipping Agent	Allow entry of required storage space for storage preparation.
11.5	Record Receipt and inspect shipment	IVD Logistician	Allow the user to scan using barcode Global Trade Identification Number on the tertiary package.
11.6	Record Receipt and inspect shipment	IVD Logistician	Allow the user to scan secondary package and prompt the user to verify the condition of the package.
11.7	Record Receipt and inspect shipment	IVD Logistician	Prompt the user to open secondary package for detailed inspection at random.
11.8	Record Receipt and inspect shipment	IVD Logistician	Retrieve and display shipment information from the centralized global vaccine shipment database.
11.9	Record Receipt and inspect shipment	IVD Logistician	Warn the user if the shipment is received at the wrong destination.
11.10	Place goods in stock	IVD Logistician	Export vaccine record for import to the national warehouse management system.
11.11	Fill and submit VAR	IVD Logistician	Display vaccine arrival information for verification.
11.12	Fill and submit VAR	IVD Logistician	Allow the user to verify the information display by pressing a button.
11.13	Fill and submit VAR	IVD Logistician	Update the centralized global vaccine shipment database.
11.14	Fill and submit VAR	IVD Logistician	Send VAR notification to interested parties.

Table 5-11. Business requirements for *Step 12. Distribute supplies to region/district*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
12.1	Estimate need	DIVO	Allow the user to enter population information of the district.
12.2	Estimate need	DIVO	Estimate stock need according to defined rules.
12.3	Estimate need	DIVO	Based on past consumption data.
12.4	Estimate need	DIVO	Based on minimum quantity threshold.
12.5	Estimate need	DIVO	Based on population.
12.6	Estimate need	DIVO	Enable flexible order point based on user-defined criteria.
12.7	Estimate need	DIVO	Display past consumption data.
12.8	Issue requisition	DIVO	Generate requisition based on need.
12.9	Issue requisition	DIVO	Display minimum quantity order increments.
12.10	Issue requisition	DIVO	Print the requisition.
12.11	Issue requisition	DIVO	Submit requisition.
12.12	Process incoming requisition	RIVO	Validate the requisition.
12.13	Process incoming requisition	RIVO	Have the ability to link equivalent items.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
12.14	Process incoming requisition	RIVO	Display requisition history.
12.15	Process incoming requisition	RIVO	Display current stock status of the requestor.
12.16	Process incoming requisition	RIVO	Display current stock status of the districts of the requestor region.
12.17	Process incoming requisition	RIVO	Have the ability to enter issued quantities.
12.18	Validate against the plan	RIVO	Display annual consumption plan by district.
12.19	Update ledger	DIVO	Record stock issues/update quantity on hand.
12.20	Update ledger	DIVO	Ability to use Automated Identification and Data Capture (AIDC) to collect and update ledger.
12.21	Inspect shipment	RIVO	Use AIDC to identify received stock.
12.22	Inspect shipment	RIVO	Display warning if the scanned diluents are different from received antigen.
12.23	Record Receipt	RIVO	Create receiving report.
12.24	Record Receipt	RIVO	Enter proof of delivery (POD).
12.25	Record Receipt	RIVO	Receive goods without a requisition reference.
12.26	Record Receipt	RIVO	Use AIDC to document receipt.
12.27	Place in stock	RIVO	Display storage requirements for items.
12.28	Place in stock	RIVO	Propose space/positions for each stock item.
12.29	Place in stock	RIVO	Have the ability to print batch and expiry date tag.
12.30	Place in stock	RIVO	Create/update bin card per item.
12.31	Place in stock	RIVO	Have the ability to enter VVM status.
12.32	Update ledger	RIVO	Update stock records with quantity received per lot, expiry date, VVM record, etc.
12.33	Notify regional level	RIVO	Send an email to IVD of the POD.

Table 5-12. Business requirements for *Step 13. Distribute supplies to service delivery point*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
13.1	Prepare vaccine usage report	Vaccine Store In Charge	Allow the user to enter usage report by antigen.
13.2	Prepare vaccine usage report	Vaccine Store In Charge	Allow the user to enter number of vials opened.
13.3	Prepare vaccine usage report	Vaccine Store In Charge	Calculate coverage rate.
13.4	Prepare vaccine usage report	Vaccine Store In Charge	Calculate wastage.
13.5	Perform physical count	Vaccine Store In Charge	Allow the user to enter current stock levels.
13.6	Perform physical count	Vaccine Store In Charge	Display a warning if number of diluents does not match the antigens.
13.7	Perform physical count	Vaccine Store In Charge	Allow the user to use AIDC to capture stock information.
13.8	Perform physical count	Vaccine Store In Charge	Prompt the user if the scanned diluents are different from antigen.
13.9	Submit usage and current stock levels	Vaccine Store In Charge	Print vaccine report and requisition form.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
13.10	Submit usage and current stock levels	Vaccine Store In Charge	Submit vaccine report to district.
13.11	Estimate facility need	DIVO	Allow the user to enter population information of the catchment area.
13.12	Estimate facility need	DIVO	Estimate stock need according to defined rules.
13.13	Estimate facility need	DIVO	Be based on past consumption data.
13.14	Estimate facility need	DIVO	Be based on minimum quantity threshold.
13.15	Estimate facility need	DIVO	Be based on catchment area.
13.16	Estimate facility need	DIVO	Enable flexible order point based on user-defined criteria.
13.17	Estimate facility need	DIVO	Display past consumption data.
13.18	Pick from stock location	DIVO	Use AIDC to identify stock to be picked.
13.19	Pick from stock location	DIVO	Warn if wrong batch is scanned.
13.20	Update ledger	DIVO	Record stock issues/update quantity on hand.
13.21	Document for Delivery	DIVO	Create issue voucher.
13.22	Document for Delivery	DIVO	Create barcode of packed stock.
13.23	Document for Delivery	DIVO	Print barcode of packed stock.
13.24	Inspect shipment	Vaccine Store In Charge	Use AIDC to identify received stock.
13.25	Inspect shipment	Vaccine Store In Charge	Display warning if the scanned diluents are different from received antigen.
13.26	Record Receipt	Vaccine Store In Charge	Create receiving report.
13.27	Record Receipt	Vaccine Store In Charge	Enter POD.
13.28	Record Receipt	Vaccine Store In Charge	Receive goods without a requisition/purchase order reference.
13.29	Record Receipt	Vaccine Store In Charge	Use AIDC to document receipt.
13.30	Place in stock	Vaccine Store In Charge	Display storage requirements for items.
13.31	Place in stock	Vaccine Store In Charge	Have the ability to print batch and expiry date tag.
13.32	Place in stock	Vaccine Store In Charge	Create/update bin card per item.
13.33	Place in stock	Vaccine Store In Charge	Have the ability to enter VVM status.
13.34	Update ledger	Vaccine Store In Charge	Update stock records with quantity received per lot, expiry date, VVM record, etc.
13.35	Notify higher level	Vaccine Store In Charge	Email POD to higher levels.

Table 5-13. Business requirements for *Step 14. Manage inventory*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
14.1	Perform physical count	Vaccine Store In Charge	Allow the user to enter current stock levels.
14.2	Perform physical count	Vaccine Store In Charge	Display a warning if number of diluents does not match the antigens.
14.3	Perform physical count	Vaccine Store In Charge	Allow the user to use AIDC to capture stock information.
14.4	Perform physical count	Vaccine Store In Charge	Prompt the user if the scanned diluents are different from antigen.
14.5	Monitor Stock Environment	Vaccine Store In Charge	Record temperature.
14.6	Monitor Stock Environment	Vaccine Store In Charge	Record VVM status.
14.7	Monitor Stock Environment	Vaccine Store In Charge	Have the ability to set threshold conditions antigen.
14.8	Monitor Stock Environment	Vaccine Store In Charge	Alert conditions outside threshold.
14.9	Monitor Stock Environment	Vaccine Store In Charge	Track lots and expiry dates.
14.10	Monitor Stock Environment	Vaccine Store In Charge	Have the ability to update stock record.
14.11	Monitor Stock Environment	Vaccine Store In Charge	Generate physical inventory count sheets.
14.12	Monitor Stock Environment	Vaccine Store In Charge	Display and transmit alerts and notifications for pending expiries.
14.13	Monitor Stock Environment	Vaccine Store In Charge	Display and transmit alerts and notifications for stockouts, overstock, understock.
14.14	Monitor Stock Environment	Vaccine Store In Charge	Record stock adjustments and prompt the user to enter reasons.
14.15	Estimate need	Vaccine Store In Charge	Estimate stock need according to defined rules.
14.16	Estimate need	Vaccine Store In Charge	Based on past consumption data.
14.17	Estimate need	Vaccine Store In Charge	Based on minimum quantity threshold.
14.18	Estimate need	Vaccine Store In Charge	Based on population.
14.19	Estimate need	Vaccine Store In Charge	Enable flexible order point based on user-defined criteria.
14.20	Estimate need	Vaccine Store In Charge	Display past consumption data.
14.21	Issue emergency requisition	Vaccine Store In Charge	Generate emergency requisition.
14.22	Issue emergency requisition	Vaccine Store In Charge	Submit emergency requisition.

Table 5-14. Business requirements for *Step 15. Maintain cold chain equipment*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
15.1	Make plans for equip. distribution	IVD & Partners	Allow estimation of storage capacity required at each level.
15.2	Make plans for equip. distribution	IVD & Partners	Allow import of equipment inventory information.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
15.3	Make plans for equip. distribution	IVD & Partners	Conduct comparison of storage space available as compared to what is required.
15.4	Make plans for equip. distribution	IVD & Partners	Define list of requirement of cold chain equipment, and place order and procure equipment pre-qualified by the WHO Performance Quality Safety team through UNICEF.
15.5	Make plans for equip. distribution	IVD	Allow entry of equipment received at MSD.
15.6	Make plans for equip. distribution	IVD	Define distribution list.
15.7	Receive, prepare and ship equipment to regions	RIVO	Allow entry of equipment received at regional level in cold chain inventory as floating stock.
15.8	Receive shipment, install equipment	DIVO	Allow entry of equipment received at district level in cold chain inventory as floating stock.
15.9	Receive shipment, install equipment	Health worker	Allow entry of equipment received at district level in cold chain inventory.
15.10	Receive shipment, install equipment	Health facility medical officer	Allow entry of equipment received at district level in cold chain inventory.
15.11	Maintenance required?	Health worker	Define based on temperature status, thickness of frost, routine maintenance plan, and other parameters if maintenance is required.
15.12	Conduct Maintenance	Health worker	Conduct routine maintenance or trouble-shooting based on health worker capability.
15.13	Conduct Maintenance	Health worker	Allow entry of maintenance status with remark.
15.14	Monitor and record temperature and power	Health worker	Monitor and record the temperature.
15.15	Issue with temperature	Health worker	Define, based on temperature status, if there is problem with equipment.
15.16	Fix problem	Health worker	Allow marking in the status of cold chain equipment, with action taken.
15.17	Report problem and follow contingency plan	Health worker	Allow marking in the status of cold chain equipment.
15.18	Any issue with Report	Supervisor	Mark issue in the temperature-recording document.
15.19	Evaluate and address issue	Supervisor	Mark action taken in the temperature-recording document.
15.20	Sign report and file.	Supervisor	Allow signing of the supervisor who conducted the status review.

Table 5-15. Business requirements for *Step 16. Generate reports*.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
16.1	Define Parameters	IIS Staff/System, Immunization Provider, & Other Partners	Allow user to select parameters (e.g., time, age, race/ethnicity, jurisdiction, vaccine grouping, vaccine dose count, specific program codes, other program codes, etc.).
16.2	Define Parameters	IIS Staff/System, Immunization Provider, & Other Partners	Allow user to select report output parameters (e.g., display options, summary vs. detail report, sort options, alphanumeric vs. date, etc.).
16.3	Define Parameters	IIS Staff/System, Immunization Provider, & Other Partners	Allow user to choose a report-generation time frame (i.e., run now or set the time for later).
16.4	Define Parameters	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to save parameters as “public” to allow other users to generate the same report using the same parameters.
16.5	Define Parameters	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to modify/delete saved “public” parameters.
16.6	Define Parameters	IIS Staff/System, Immunization Provider, & Other Partners	Have ability for system to determine if the report can be immediately generated or if it must be delayed based on size and generate a message “report processing” (i.e., based on types of criteria, size of data, etc.).
16.7	Define Parameters	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to prompt user to confirm the generation of a report at a later time if required.
16.8	Generate Report	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to save, display, or print report.
16.9	Generate Report	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to produce reports in multiple formats (i.e., text delimited file, etc.).
16.10	Generate Report	IIS Staff/System, Immunization Provider, & Other Partners	Allow user to delete a report and track on audit log.
16.11	Generate Report	IIS Staff/System, Immunization Provider, & Other Partners	Allow user to delete and/or modify data elements within a report (Note: Allows the user to modify report based on the audience).
16.12	Generate Report	IIS Staff/System, Immunization Provider, & Other Partners	Automatically schedule routine reports to run at a specific time.
16.13	Generate Report	IIS Staff/System, Immunization Provider, & Other Partners	Allow for the restriction of some predefined data such as duplicate records.
16.14	Generate Report	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to generate the report based on the parameters set.

ID	ACTIVITY	ENTITY / FUNCTIONAL ROLE	REQUIREMENT (The system must or should…)
16.15	Report Acceptable?	IIS Staff/System, Immunization Provider, & Other Partners	Allow user to return to and modify report criteria.
16.16	Analyze	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to verify that the report is in the correct format.
16.17	Analyze	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to send by email.
16.18	Analyze	IIS Staff/System, Immunization Provider, & Other Partners	Have ability to export data in selected file formats.
16.19	Analyze	IIS Staff/System, Immunization Provider, & Other Partners	Allow user to configure report displays.
16.20	Analyze	IIS Staff/System, Immunization Provider, & Other Partners	Be interoperable with a statistical analysis software.

System Requirements

This section also includes general system requirements (Table 5-16) which are not associated with a specific activity or business process but rather are associated with maintaining and operating it (e.g., security, privacy, performance). General system requirements differ from functional user requirements in another important aspect. These requirements most often are not visible to the end user, but are essential for the system to be able to perform and support the functionality a user does see and use. These requirements and categories were derived from *Planning an Information Systems Project: A Toolkit for Public Health Managers*.[2]

Table 5-16. General system requirements.

ID	Category	Performance Requirement
99.1.1	Performance	Make efficient use of data communication time.
99.1.2	Performance	Make efficient use of capabilities of lower-cost mobile devices.
99.1.3	Performance	Support data capacity considerations (including those for data transmission, storage, and processing) for all users over the expected lifetime of the system.
99.1.4	Performance	Use a database that can scale to support projected transaction volume.
99.1.5	Performance	Provide real-time response to transactions submitted by connected devices up to the configured national volume level.
99.2.1	Compatibility	Use open standards to promote interoperability.
99.2.2	Compatibility	Exchange actionable data between systems (need to enforce semantic interoperability).

ID	Category	Performance Requirement
99.2.3	Compatibility	Provide access from internet-enabled devices.
99.2.4	Compatibility	Support flexible models for data collection (e.g., including paper forms, web forms, SMS, barcode, etc.).
99.2.5	Compatibility	Comply with industry standards for data exchange.
99.2.6	Compatibility	Interface to open-source or third-party reporting tools.
99.2.7	Compatibility	Comply with industry standards for tracking and tracing of supplies.
99.3.1	Usability	Allow for flexible configurations based on the context of use, including the physical and social environment.
99.3.2	Usability	Transmit information in a language (script or voice) that is understood by the user population.
99.3.3	Usability	Emphasize ease of use and learnability to reduce training costs.
99.3.4	Usability	Be able to be learned by end users and supervisors to meet specified goals of system effectiveness and efficiency.
99.3.5	Usability	Enable easy data collection, organization, and dissemination.
99.3.6	Usability	Focus on the mobile-user experience with secondary use of a computer.
99.3.7	Usability	Allow users to find features in two clicks or fewer.
99.3.8	Usability	Enable pleasing and satisfying interaction for the user.
99.3.9	Usability	Provide a search interface to reduce data-entry burden and improve accuracy on mobile devices.
99.3.10	Usability	Support real-time data-entry validation and feedback to prevent data-entry errors from being recorded.
99.3.11	Usability	Support ability to calculate values on behalf of user (eliminating need to add, subtract, multiply, or divide).
99.4.1	Reliability	Enable a task to be canceled and rolled back to previous state.
99.4.2	Reliability	Enable users to work offline and then synchronize data when data connection is available.
99.4.3	Reliability	Allow a task to be interrupted and resumed.
99.4.4	Reliability	Enable earlier versions of a record to be recoverable.
99.4.5	Reliability	Enable backup of data so that information is recoverable in the event of a system or hardware failure.
99.4.6	Reliability	Accommodate loss of connectivity to hosted application (network may become unavailable while a user is in the process of submitting a form).
99.4.7	Reliability	Be able to reliably perform tasks within appropriate time with resistance to failures or deadlocks.
99.4.8	Reliability	Be deployed in an environment subject to power loss.
99.4.9	Reliability	Allow for client devices with low bandwidth or irregular connectivity.
99.5.1	Confidentiality, Privacy & Security	Prevent unauthorized access to patients' protected health information.
99.5.2	Confidentiality, Privacy & Security	Prevent updates to the database occurring only partially (atomicity), which can cause greater problems than rejecting an entire submission of a form.
99.5.3	Confidentiality, Privacy & Security	Trace and record changes to data taken by the system and by users (update/delete/add).

ID	Category	Performance Requirement
99.5.4	Confidentiality, Privacy & Security	Allow the administrator to establish access privileges and priorities.
99.5.5	Confidentiality, Privacy & Security	Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing, and auditing.
99.5.6	Confidentiality, Privacy & Security	Require each user to authenticate by role before gaining access to the system.
99.5.7	Confidentiality, Privacy & Security	Provide flexible password control to align to national policy and standard operating procedures.
99.5.8	Confidentiality, Privacy & Security	Protect system servers through the use of an internet firewall.
99.5.9	Confidentiality, Privacy & Security	Protect against viruses and malware.
99.5.10	Confidentiality, Privacy & Security	Allow for maintenance of security updates.
99.5.11	Confidentiality, Privacy & Security	Have a source code audit against security threats.
99.5.12	Confidentiality, Privacy & Security	Log transactions at the time of data entry.
99.5.13	Confidentiality, Privacy & Security	Maintain a transaction log history.
99.5.14	Confidentiality, Privacy & Security	Support privacy policies such as identifying who has access to the health data, and what data can be accessed.
99.6.1	Maintainability	Be built using technologies that enable local control, open competition, and transparency of the code.
99.6.2	Maintainability	Have adequate support resources to ensure scalability and sustainability.
99.6.3	Maintainability	Promote easier acquisition by supporting a range of devices and form factors.
99.6.4	Maintainability	Able to access the system at all levels/stores.
99.6.5	Maintainability	Enable local control of operations.
99.6.6	Maintainability	Be well-documented, including known issues.
99.6.7	Maintainability	Support repair or upgrade of a component in a running system.
99.6.8	Maintainability	Provide a unique version number for all future updates and releases.
99.6.9	Maintainability	Enable the system to detect incompatible versions of software running on different components.
99.6.10	Maintainability	Enable configuration to any national or subnational administrative structure or number of levels.
99.6.11	Maintainability	Have a support process that tracks and documents bugs from discovery to resolution.
99.6.12	Maintainability	Enable access to the central system from all levels of the health system.
99.6.13	Maintainability	Support changes to organizational alignment of facilities and personnel.

ID	Category	Performance Requirement
99.6.14	Maintainability	Include an administrable content management system.
99.7.1	Portability	Be able to provide continuity and access to data throughout changes in infrastructure (e.g., telecommunication, power) at the health-post level.
99.7.2	Portability	Support extensibility and/or the ability to accept new services or functionality.

[1] PATH. *Common Requirements for Logistics Management Information Systems*. Seattle: PATH; 2010. Available at: www.path.org/publications/detail.php?i=1865.
[2] World Health Organization, PATH. *Planning an Information Systems Project: A Toolkit for Public Health Managers.* Seattle: PATH; 2013. Available at: www.path.org/publications/detail.php?i=2343.

6. Key user scenarios

Overview

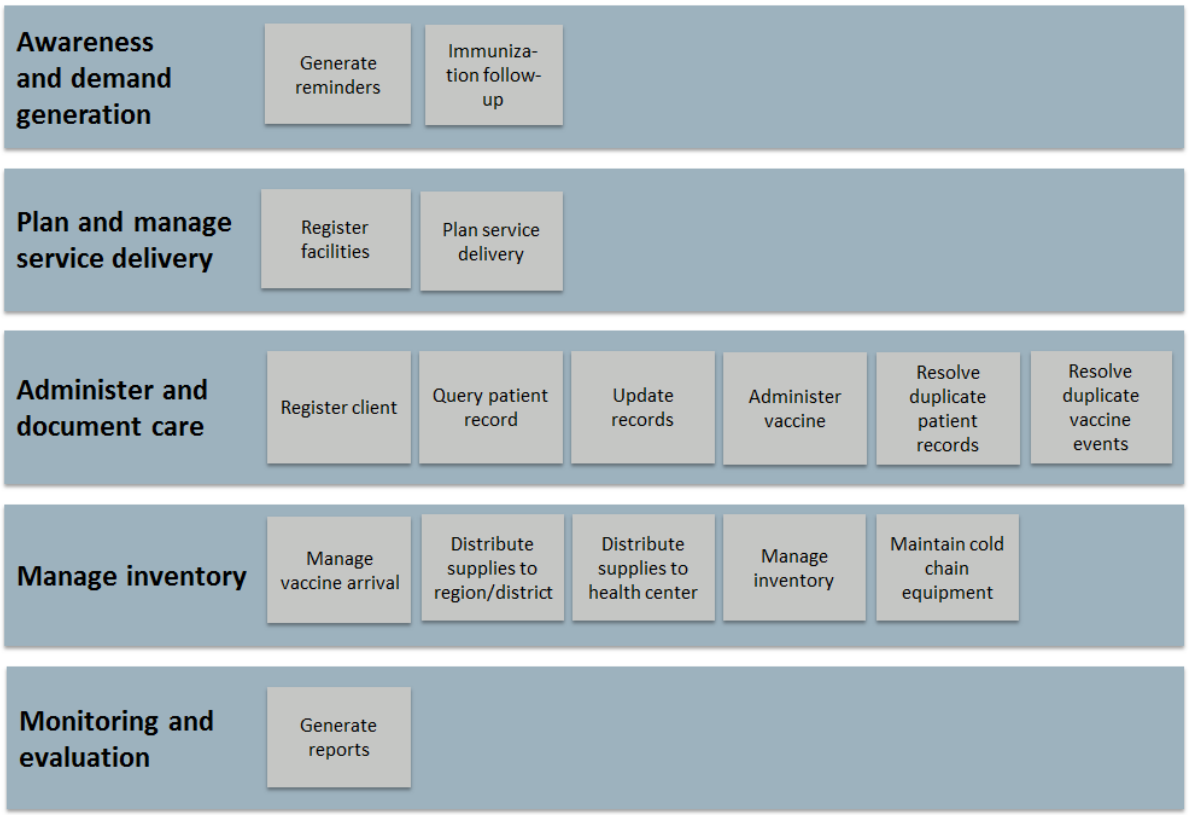
This chapter contains user scenarios that illustrate how immunization processes can be executed within a national eHealth infrastructure. It explores the dynamics of the immunization "system" and starts to answer to the question: "how will better data support better decisions?"

Chapter Summary

Once the immunization system is updated, given all that we learned in defining users, processes, tasks, and requirements, how will it be used? This section explores what the future will look like for our users focusing on how improved data will support better decision- making, resulting in improved immunization coverage.

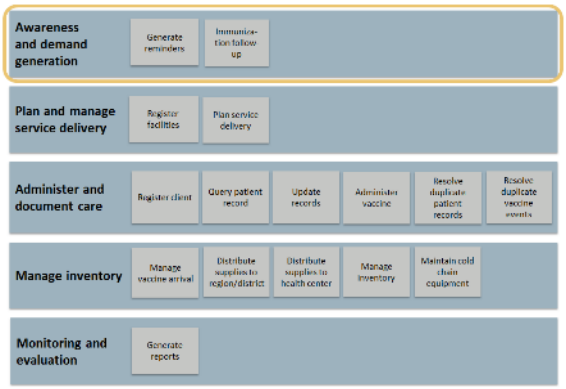
Each section focuses on one stage of the immunization system, illustrated in Figure 6-1, telling the day-to-day stories of the users we met in Chapter 3 (User personas) walking through the business processes outlined in Chapter 4. We talk about the workflows each of these users is responsible for in each stage of the system, and how they are better able to increase immunization coverage through the implementation of the BID EA. The scenarios in this chapter are shown using process diagrams. For a UML sequence diagram view, see Appendix E (Key user scenarios in UML format).

Figure 6-1. Immunization system core workflows.



A. Awareness and demand generation

Overview



Health care providers and community leaders are tasked with educating families in their communities about the importance of immunization and reminding them of the schedule of immunizations for babies and children. This can be accomplished via media campaigns (posters, radio advertisements, etc.), community education sessions, SMS messages, or personal face-to-face conversations. Together, these activities will build awareness of the importance and safety of vaccines and incentivize demand for immunizations, thereby increasing immunization coverage.

User workflows

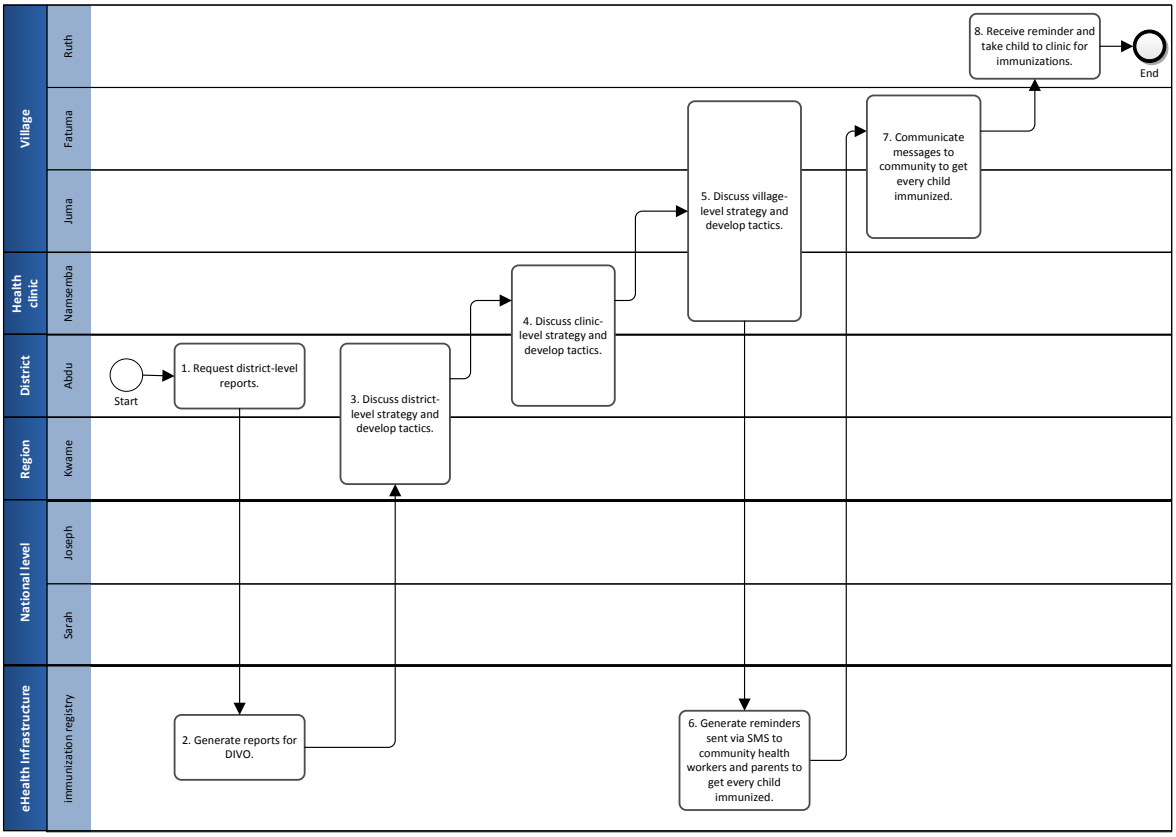
1. **Request district-level reports.** Abdu uses his computer to generate an immunization report from the eHealth database for his district showing summary information by catchment (i.e., clinic service area). The report lists the number of children who are due for immunizations in the near-term, broken down by type and by week, as well as information about women in the MoH's maternal care program. Abdu also generates a historical report showing trends in the catchment's immunization activities (including coverage) over the last number of months.
2. **Discuss district-level strategy and develop tactics.** Abdu and Kwame review these reports at their monthly meeting and use the data to create "action lists," planning how best to manage the immunization activities for the district over the planning horizon. They discuss what tactics are working well and strategize about new ideas that may improve results. Kwame also uses this district-level insight to inform his discussions with Joseph and Sarah about national-level strategy and tactics.
3. **Discuss clinic-level strategy and develop tactics.** Abdu uses his computer to generate two more immunization reports from the eHealth database specific to Namsemba's clinic and catchment area. One report lists each child who is coming up for immunization and highlights any that are past due; the other includes historical data. Abdu and Namsemba review these reports each month and use the data to create "action lists," planning how best to manage the immunization activities for Namsemba's clinic over the planning horizon. They discuss what tactics are working well and strategize about new ideas that may improve results.
4. **Discuss village-level strategy and develop tactics.** Fatuma and Namsemba meet with Juma monthly to review the current and historical reports Abdu has given them about the village's catchment areas. They plan for how best to manage the immunization activities in the village and to get important messages to the community about immunization and also discuss what has worked well and what hasn't. Namsemba discusses strategies and ideas with her CHW colleagues regarding how to improve coverage.
5. **Send immunization reminders to CHWs via SMS.** At the beginning of each week, Fatuma receives SMS messages from the electronic immunization registry for each child in the village that is due for immunization on her mobile phone. She also receives an alert message for any child that is past due for immunization, noting the child's name and

how many weeks past due they are. Fatuma uses these SMSs as her monthly "action list."

6. **Send immunization reminders to parents via SMS.** Ruth has access to her husband's mobile phone. The week before baby Esther is due for her next immunization, the electronic immunization registry sends an SMS reminder to this mobile phone.

These workflows are illustrated in Figure 6-2 below.

Figure 6-2. Immunization awareness and demand generation.



Health impact

The purpose of awareness and demand-generation activities is to ensure that families in the community receive messages regarding the importance of immunization so that immunization coverage is increased. There are four distinct ways that these messages are received by Ruth:

1. Sarah's national media campaign.
2. Community-level messages from Juma.
3. Specific SMS reminders to Ruth's mobile phone.
4. An in-person visit from Fatuma the week of Esther's scheduled immunization.

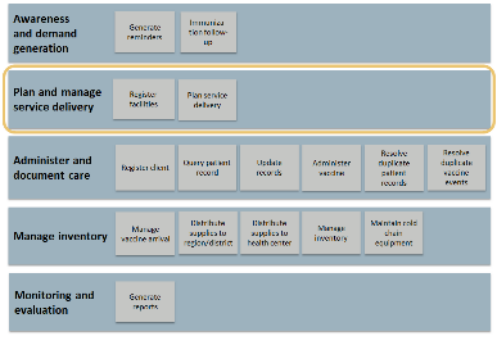
By multiplying this awareness across the village, district, region, and country, we expect to see an increase in demand and an improvement in immunization coverage.

Variations

These workflows can be adapted to work at the national or local levels, as well as in urban or rural settings. For example, SMS messages may be sent only to Fatuma and not to Ruth. Fatuma could get a list of children rather than an SMS for each child. There also is a very different degree of community engagement required in a large city versus a small village. Of the activities listed above, the ones applicable to mothers in Lucy's catchment area will be #1 and #3.

B. Plan and manage service delivery

Overview



Supported by the WHO publication of the Reach Every District (RED) approach in 2002, many of the planning functions for immunization service delivery are done at the district level. The district office is close enough to the clinic to be sensitive to what is happening there and yet the inclusion of several other facilities in the district helps average the individual variations and allows for more consistent planning. The same reports and engagement activities described in the district-level workflows of Figure 6-2 are used to manage district-level planning. A key to the successful execution of these district-level plans will be ensuring there is sufficient movement of vaccine stocks to the health centers. Refer to Appendix C (Linking supply and demand) for more information on how systems design impacts inventory management.

User workflows

These workflows are illustrated in

Figure 6-3.

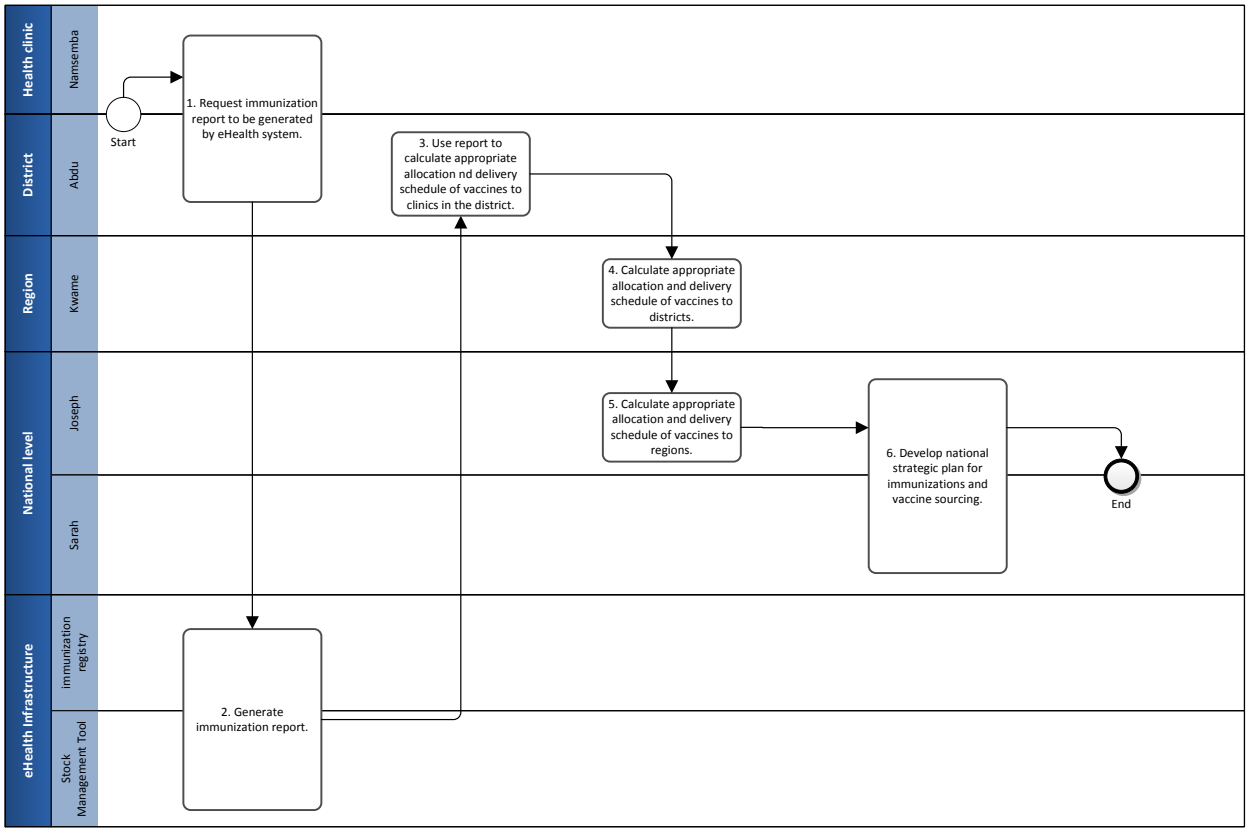
1. **Calculate and schedule deliveries to health centers:** Abdu and Namsemba use the report data discussed in Section A to calculate the appropriate allocation and delivery schedule of vaccine stock to Namsemba's clinic from the district store. Refer to Appendix B (Systems design and inventory management) for more information on how to make these calculations.
2. **Calculate and schedule deliveries to district stores:** Kwame calculates the appropriate allocation and delivery schedule of vaccine stock from the regional store to the district store based on Abdu's allocation and delivery schedule to each health center. Refer to Appendix B (Systems design and inventory management) for more information on how to make these calculations.
3. **Calculate and schedule deliveries to regional stores:** Joseph calculates the appropriate allocation and delivery schedule of vaccine stock from the national store to the regional store based on Kwame's district allocation and delivery schedule.

Develop national strategic plan: Sarah and Joseph review information on national demographic trends, improvements in coverage, and new vaccine-introduction initiatives to develop an annual immunization plan with an accompanying vaccine-sourcing plan. This

becomes a strategic document for the MoH, external funding agencies, and vaccine suppliers. NOTE: This workflow is supported by M&E and is not illustrated in

Figure 6-3.

Figure 6-3. Plan and manage service delivery.



Health impact

Planning and managing immunization service delivery effectively is necessarily tied to inventory management and allocations. If Abdu, Kwame, Joseph, and Namsemba make good calculations and schedule timely deliveries, Ruth and Esther will be able to receive the immunization services they require when they arrive at the clinic.

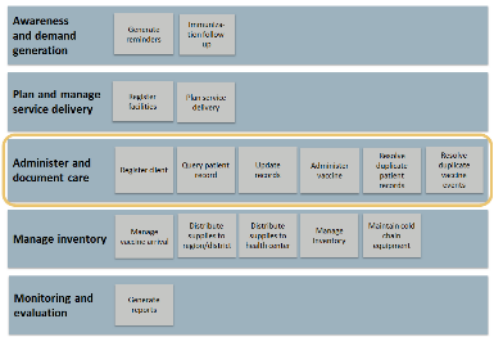
Variations

Significantly more inventory is required to support Lucy's busy urban clinic than is needed to support Namsemba's rural one. It is also easier to restock Lucy's clinic because it is in an urban center closer to the district stores. For these reasons, Lucy's urban clinic will likely be restocked more often.

C. Administer and document care

Overview

Administering and documenting care, that is immunizing children and keeping their health records current, is one of the most important stages of the immunization system. Updating the forms and processes used during this stage in order to improve data quality and ease of collection is a significant focus of the BID Initiative.

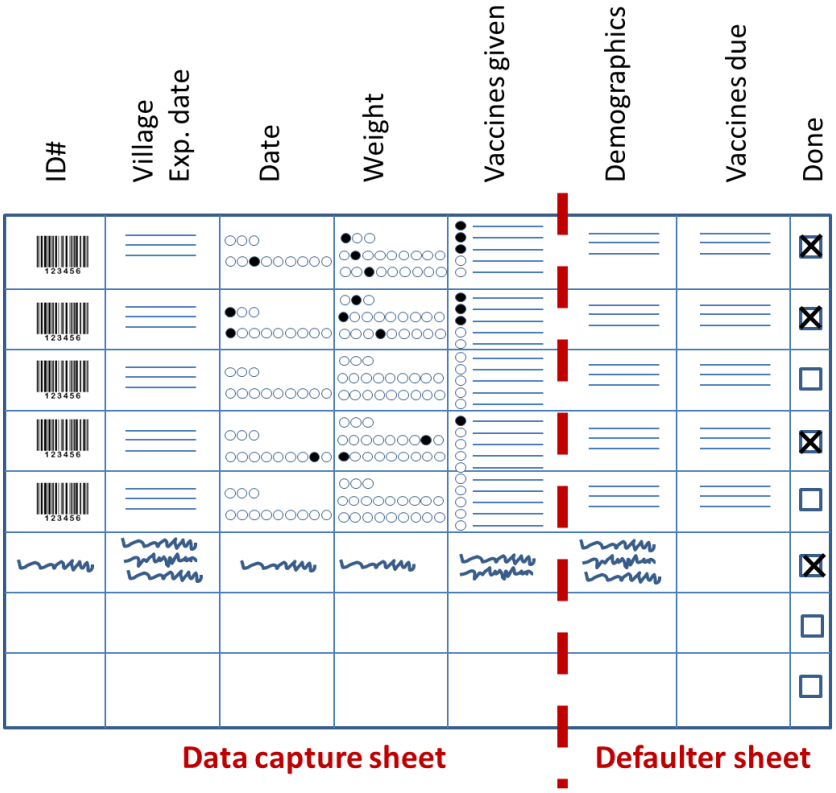


Moving from a backward audit log to a forward-looking action list is a **fundamental** change in how information is used to support the immunization system. The BID Initiative redesigned the paper system so that:

- It can be readily printed, on standard A4 paper stock, at the district level.
- It identifies which patients, grouped by village, are expected for their immunizations in the following two months.
- It makes it easy to record that patients received their scheduled vaccines using check boxes, as well as other key data (e.g., demographics, weight, dates, etc.).
- It provides a tear-off action list indicating which patients are defaulters.
- It provides a simple feedback loop; the form design lends itself to automated data capture at the district office using inexpensive, consumer-grade document scanner technology.
- It is tolerant of inevitable delays and challenges regarding the printing and distribution of refreshed action lists.

Figure 6-4 illustrates a mock-up of the new form, which will replace the immunization register.

Figure 6-4. Paper immunization registry example.

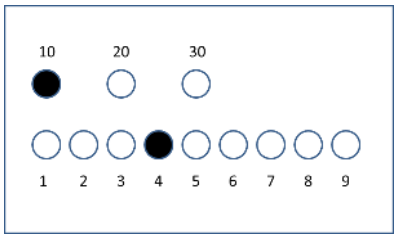


User workflows

1. **Capture birth data.** Juma collects basic information about births that do not occur in a clinic and sends it via SMS through the electronic immunization registry where it will be added to the national database. Once the birth data has been added it will be included in future reports, and will also trigger SMS messages when the child is due for vaccination as noted in Section A.

2. **Manually assign and add identification numbers.** Namsemba assigns an identification number to each baby who goes to the clinic who does not already have one. She also adds children's identification numbers manually to her action list if they are missing from the report. NOTE: These children's information will be the only data that is manually entered. Data entered for the children already listed on the reports will be machine-readable as in Figure 6-5.

Figure 6-5. Detail of machine-readable "data" column.



3. **Capture patient data.** Namsemba records the weight and date of immunization for each patient. This data is stored in the patient's electronic health record. For children who are not immunized, Namsemba records their weight on a simple tally sheet.
4. **Submit report to and create action list.** At the end of each month, Namsemba separates the data-capture forms, sending the left side to Abdu to be scanned or manually entered, and keeping the right side, which becomes her defaulter action list.
5. **Compile district-level reports.** Abdu scans or manually enters the data he receives from Namsemba and the other clinics in his district and submits them to the eHealth database every month. He will also generate new immunization forms for the following two months. As illustrated in Figure 6-7, these workflows are designed to provide a two-month forward-looking visibility.

Figure 6-6. Administer and document care.

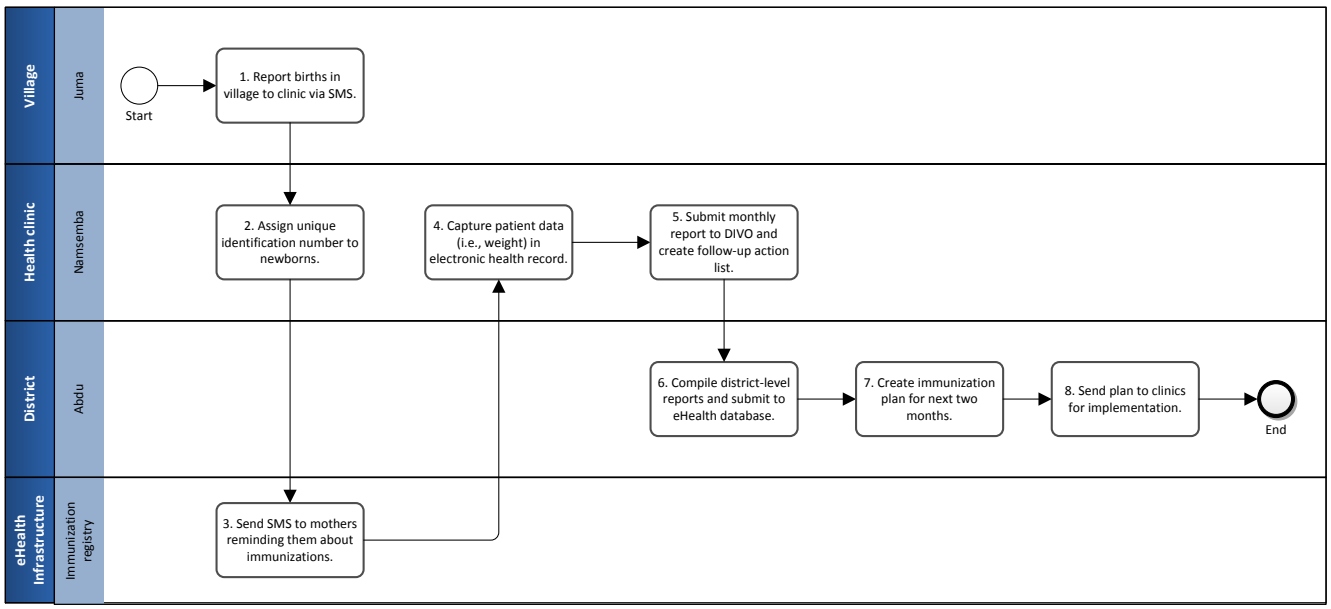
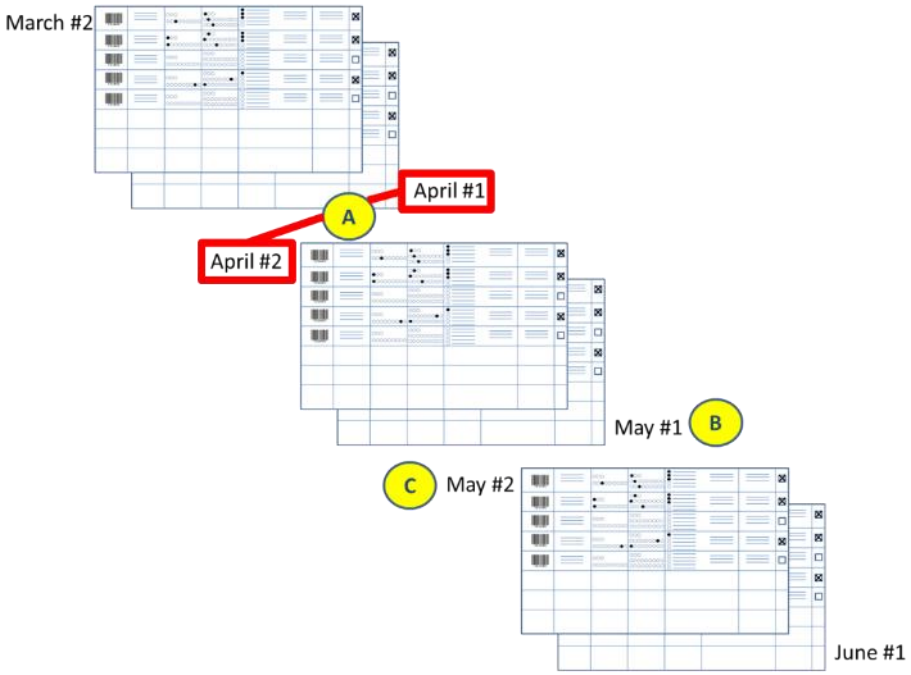


Figure 6-7. The pattern for worksheets.



Health impact

Improving the documentation of care administration in the rural clinic, and later using these data to guide decision-making, is the key to success of the overall BID program. The refinements discussed in this section will:

- Help address the "denominator problem (Text Box 6-1)," thereby yielding better data about the true number of children who need vaccinations in a given area and helping with national planning.
- Have the paper system become a forward-looking document actively supporting the immunizations that are supposed to be done in the coming two-month period and readily identifying defaulters.
- Minimize non-value-added data entry and tallying currently required from nurses and front-line caregivers. Instead, this data will be parsed from the data-capture sheet and readily summarized and aggregated by the eHealth system. The aggregated results regarding immunizations will be generated by summarizing these data. Similarly, data regarding vaccine inventory consumption will be developed based on the

Text Box 6-1. The denominator problem.

The denominator problem

Calculating the true number of children to be vaccinated in a given year can be difficult. This challenge is often referred to as the "denominator problem."

The denominator is the total number of children in an area used to calculate the coverage percentage required. For example, if my catchment of children under one year of age is 200 and I have fully immunized 100 of them, my fully immunized coverage rate is 50 percent. Since this number is often used for reporting, resource planning, and stock calculations, it can have a serious impact if it is wrong.

Another aspect of this problem is that it refers to percentages, not specific children. Finding the 20 percent of children who are not immunized in your area is very different than finding a list of 30 specific children who are not immunized.

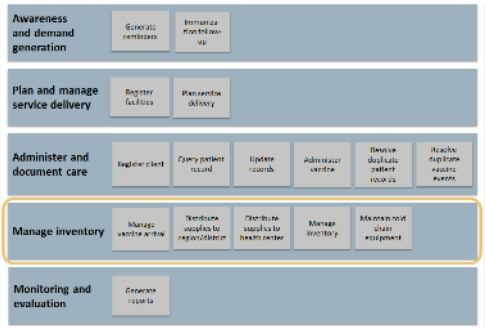
immunization “transactions”. Wastage will be calculated based on the physical counts logged at the time of inventory replenishment. As long as these wastage values are not outside of expected ranges, further analysis will not be required.

Variations

In a busy clinic such as Lucy’s, there will often be queuing and batching. One of the goals of the BID Initiative is to leverage useful technology and process redesign interventions to help improve the immunization workflow, where it is practical to do so. There are opportunities to manage the work in Lucy’s busy clinic in a way that helps increase throughput. Refer to Appendix D for more information on workflow design techniques.

Manage inventory

Overview



After immunizations are given, vaccine inventory must be managed to ensure there is no break in service. Replenishing clinic stock will be driven by the data collected in Section C and “tuned to the hum” of immunization transactions at each health center. Generally, vaccine stock will be “pulled” from the district based on actual usage rather than “pushed” based on forecasts. The exception, of course, is where an immunization outreach has been planned; for these, the anticipated outreach demand will need to be covered in addition to regular usage in the clinic. Over time, these processes will organically reduce the quantity of vaccine safety stock in the country.

User workflows

Managing clinic stock is preceded by care administration and documentation and informs district-level stock management. The following workflow describes stock management at the clinic level.

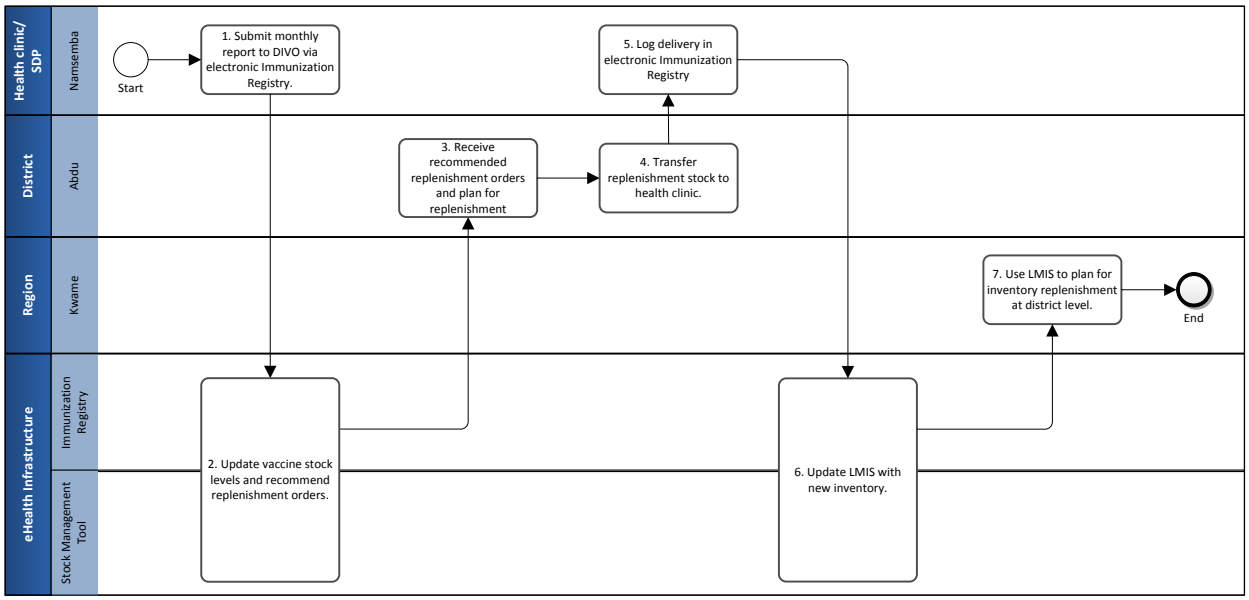
1. **Submit health center reports.** Namsemba provides her paper immunization registry forms and her vaccine stock on hand balances to Abdu. Lucy’s data is provided directly from the electronic immunization registry.
2. **Capture and report data.** Abdu receives Namsemba’s data and inputs the forms, which then updates the national electronic immunization registry and SMT. The immunization registry data and the SMT inventory levels are used to calculate the recommended health center replenishment orders sent back to Abdu.
3. **Review and manage vaccine stock delivery.** Abdu uses the immunization registry data to inform the health center replenishment plan recommended by the SMT.
4. **Transfer inventory to health center.** Abdu physically transfers inventory from his district stores to Namsemba’s clinic. The stock delivery is logged to the SMT, which then automatically updates the national database with the stock now on hand at Namsemba’s health center. The inventory movements from the district to the health centers are then used to develop the replenishment plan for Abdu’s district stores from the regional store.

NOTE: If Namsemba were to be reporting unacceptable wastage rates (based on the calculations), then some manner of exploratory (extra) inventory usage tracking would be

necessary to determine the root cause. There is a key premise: if the wastage rate is acceptable, information about the underlying cause of the waste is not needed. Such an assumption relies on the definition of "acceptable" to mean, "not requiring further explanation."

These workflows are illustrated in Figure 6-8 below.

Figure 6-8. Workflow for stock management at clinic level.



Health impact

Actual inventory consumption is automatically calculated as part of the care administration and documentation stage. Namsemba doesn't have to do it anymore, so has more time to care for patients. Health center replenishment is then based on these immunization transactions and the physical counts recorded at each month end (from which we calculate actual wastage).

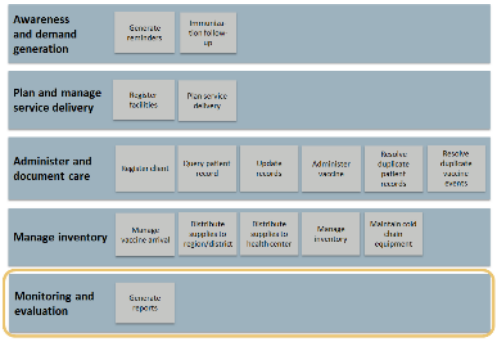
NOTE: To employ data-driven stock replenishment, we need to be able to accurately capture the immunization transaction information. If this cannot be done, then the "pull" system cannot be made to work effectively. *Everything* depends on the success of getting timely, good data from the workflows in Section C.

Variations

These workflows can also be generally applied to describe Lucy's replenishment. The difference is that the busy urban clinic has real-time access to the electronic immunization registry and to the SMT (for logging on-hand balances) so it would start at Step 3 in the stock management process in Figure 6-7. Also, for Lucy, her replenishments may happen on a shorter time cycle than Namsemba's (depending on the usage rates and on the available cold storage capacity at Lucy's urban clinic).

Monitor and evaluation

Overview



One of the core premises of the BID Initiative is that better data will support better decision-making. Therefore, at the heart of the M&E stage is having users collect computable, narrowly defined data during the management and execution of activities in the other four stages of the immunization system.

Continued learning of how the various scenarios work or fail in the country context will foster innovation. Based on this experimental "learning by doing" approach, we fully recognize that some interventions will prove unsuccessful, unscalable, or unsustainable. One of the underlying principles to this initiative is the recognition that it is not a single intervention—but rather a combination of interventions of both information system products and best practices coordinated throughout the varying levels of the health system—that are most likely going to demonstrate impact. This holistic approach is a key differentiator of the BID Initiative.

User workflows

In developing M&E workflows, it is useful to go from the "bottom up" to determine what indicators and management reports can be developed from the workflows described in Sections C and D, and then to add other indicators as needed. Referring to internationally recognized indicators, like those published by the WHO included in Text Box 6-2 below, can also be a good starting point.

Health impact

The data collected will be person-centric, allowing for disaggregation down to the child level. This will address the denominator problem and may prove to be the single greatest impact on M&E that will arise out of the BID Initiative. Additionally, data collection will be minimized to the narrow data set needed to support decision-making and management, reducing the overall burden of data collection at the point of care and directly connecting data to decision-making will help cultivate a culture of data literacy and use.

Variations

Specific M&E requirements will vary by country.

Text Box 6-2. WHO core immunization indicators.

WHO's 12 Core Immunization Indicators

The first 8 of these indicators can be readily developed from data that will be maintained in the eHealth system as envisioned by the BID initiative once this system is implemented at national scale.

Operations

Service Delivery

1. Proportion of districts with >= 80% DTP3 coverage among infants.
2. Proportion of districts with >= 90% measles coverage among infants.
3. Proportion of districts with a dropout rate (DTP1-DTP3) of less than 10%.
4. Proportion of districts in the country that have been supplied with adequate (equal or more) number of AD syringes for all routine immunizations during the year.

Logistics and cold chain

5. National level wastage rates of DTP and new vaccines. NOTE: wastage rate (%) = 100 * (1 – (# immunizations / stock usage expressed as # vaccine doses)).

Vaccine supply & quality

6. Proportion of districts in the country that had no interruption in vaccine supply chain during the year. NOTE: an interruption is defined as a stockout of any vaccine at any point in time during the year.

Surveillance and monitoring

7. Proportion of districts' disease surveillance reports received at the national level compared to the number of expected reports.
8. Proportion of districts' coverage reports received at the national level compared to the number of reports expected.

Advocacy and communication

9. Existence of an advocacy and communications strategic plan (annual) with identified focal point and annual budget.

Financial sustainability

10. Government financed recurrent program-specific immunization spending in the past year per million USD of total government spending.

Strengthening human and institutional resources

11. Proportion of districts that have had at least one supervisory visit of all health facilities in the last calendar year.

Management development

12. Proportion of districts with microplans that include immunization activities.

Source:
www.who.int/entity/immunization/monitoring_surveillance/routine/indicators/core_set_national_district.pdf?ua=1

7. Tools and standards in use

Overview

The BID Initiative product strategy surmises that what is needed by countries is to build on existing information system investments in tools and products, extending their functionality, geographic reach, or both rather than creating yet another tool from another organization. From our initial assessment and PATH's work in Digital Health Solutions more broadly, we know that existing data-collection system investments face barriers to scale in part because they were designed as standalone tools and were often implemented as pilots. The BID Initiative is structured to be able to support countries in their desire to bring these tools together and expand their functionality. PATH and the BID Initiative remain neutral on the information system or EA choices.

Chapter Summary

No one is starting from scratch and this section describes some of the many, many existing tools and systems currently in use in BID countries. Unfortunately, few of these tools and systems are integrated, which causes significant frustration as countries begin to seek reusable and sustainable products.

We also discuss the pros and cons of the two main emerging architectural patters that seek to address the integration gap:

- Open HIE – loosely coupled, service-oriented architecture
- DHIS2 – application specific interface and functionality

All countries currently use tools to collect and report data. These tools range from paper registers and tally sheets to fully automated data-collection systems using computers or mobile devices. In 2013, PATH completed a landscape analysis of data-collection tools that are deployed and used today for immunization reporting across 11 sub-Saharan African countries.[1,2] The BID Initiative will seek to leverage existing tools and data-collection systems where they exist. This may involve providing funding to stimulate new functionality for existing tools in use in Africa or elsewhere, or building interfaces to enable health workers or regional and national managers within the immunization programs to do their jobs more efficiently. The best-case scenario would be to modify a component or components of systems already in productive use in-country. While there is great need to be able to replicate the BID solution across countries, how this is done will be highly dependent on the country-specific context

Tools in use: Multi-country presence

During the BID Initiative Country Consultation Meeting in October 2013 in Nairobi, participants from 11 African countries were asked to identify health information systems and tools that they were currently using, or planned to use, to support immunization and vaccine activities (Table 7-1).

Several tools are being used across countries and workflows, though adoption varies and some countries are in early stages of deployment.

- The Excel-based tools deployed and supported by WHO—the District Vaccination Data Management Tool (DVDMT) and the SMT—are being used to support the routine collection of indicators, and many of the paper ledgers and monthly reports used by the facilities feed into these two tools.
- The Open Source Health Information Software (DHIS2) is also emerging as a useful tool and is being used to support multiple processes across multiple programs. Some countries are incorporating DHIS2 with other systems (such as Open Source Human Resources Information Software [iHRIS], LMIS) as part of a broader SOA.

A full list of the tools currently in use listed by country is included in Appendix F (Health information systems and tools in use), and those that were included in the landscape analysis but are not currently in use are included in Appendix G.

Table 7-1. Tools in use.

Tool name	Used for	Used by (✓) Planned (*)
DHIS2	✓ Planning ✓ Administer/document care. ✓ Measure and analyze performance. ✓ Identify/register/arrange care. ✓ Awareness and demand generation. ✓ Manage vaccine stock.	✓ Burkina Faso ✓ Cote D'Ivoire ✓ Ghana ✓ Liberia ✓ Nigeria ✓ Senegal ✓ South Africa (1.4) ✓ Tanzania ✓ Zambia
DVDMT(District Vaccination Data Management Tool)	✓ Planning. ✓ Administer/document care. ✓ Identify. ✓ Measure and analyze performance. ✓ Manage vaccine stock.	✓ Cote D'Ivoire ✓ Ghana ✓ Mozambique ✓ Nigeria ✓ Senegal ✓ Tanzania

Tool name	Used for	Used by (✓) Planned (*)
SMT	✓ Manage vaccine stock.	✓ Cote D'Ivoire ✓ Mozambique ✓ Nigeria ✓ Senegal ✓ Tanzania ✓ Zambia
cMYP (comprehensive multi-year plan)[a]	✓ Planning.	✓ Liberia ✓ Nigeria ✓ Senegal ✓ South Africa ✓ Tanzania
LMIS	✓ Measure and analyze performance. ✓ Manage vaccine stock.	* Ghana * Liberia ✓ Tanzania ✓ Zambia
iHRIS	✓ Planning.	✓ Ghana * Liberia * Tanzania ✓ Zambia

Functionality gaps

One of the most frequent complaints with these tools is the lack of integration with other systems and the inability to harmonize data elements and indicators. With a few exceptions, most of the tools identified are not part of an integrated national EA. The few examples of integrations are often between two individual tools and cannot be simultaneously used by other tools (e.g., an integration between Open Source Logistics Management Information System [OpenLMIS] with DHIS2).

Table 7-2 lists missing functionality as described by the country representatives:

Table 7-2. Missing functionality described by country representatives.

Functionality	Gaps
Planning	▪ Cross-checking data entries. ▪ Link/compatibility to other systems: especially burden of disease of districts, allocation of resources, DHIS2, EPI especially for child comprehensive care management and treatment, EYMP, and DVDMT. ▪ EPI cost analysis. ▪ Improved interoperability across cMYP planning and RED process.

[a] While the cMYP is not a data tool, participants identified the cMYP as an important planning tool.

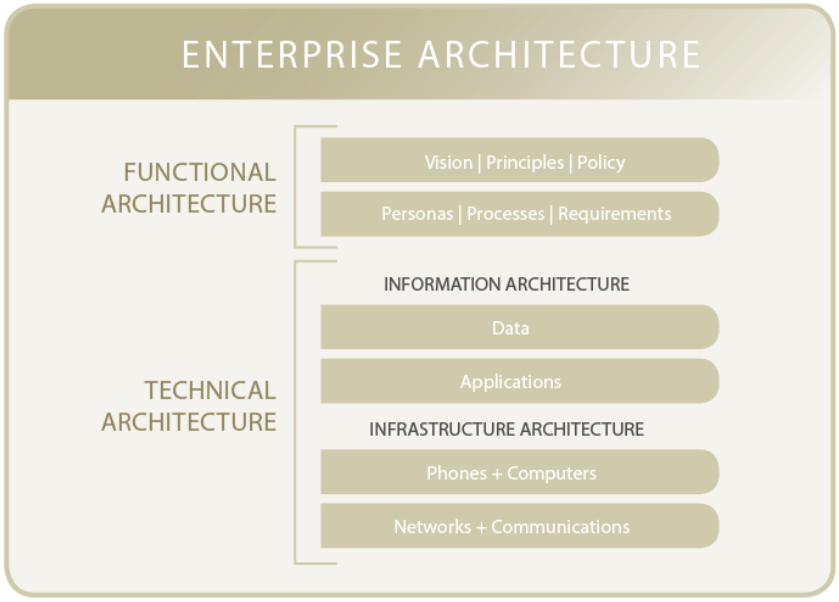
Functionality	Gaps
Administer and document care	▪ Lack of unique ID for patients and facilities. ▪ Compatibility of data across systems, especially DHIS2. ▪ Security/confidentiality of data; no backup functionality. ▪ Need to harmonize the different ledgers and registries.
Identify, register, and arrange care	▪ Lack of unique IDs. ▪ Messaging, defaulter tracing. ▪ Need to link the different registers. ▪ Need an immunization register. ▪ Link to DHIS2.
Measure and analyze performance	▪ Integration of DVDMT and SIG vision with DHIS2. ▪ Lack unique IDs. ▪ Link to all maternal and child health services, defaulters, and care registries. ▪ Interoperability of HMIS, KNBS, AfriAfya, and M-CHANJO. ▪ Need some level of offline capability. ▪ Single platform or interoperability across DHIS2, iHRIS, LMIS, and birth registry. ▪ Need a patient-based module, need a web-based system, need a stock-management module. ▪ Need immunization indicators.
Awareness and demand generation	▪ Lack messaging components. ▪ Need to develop an advocacy, communication and social mobilization strategy, and then identify the monitoring tools. ▪ Link with EPI. ▪ Should be linked with one single system vs. different messages coming from different programs.
Manage vaccine stock	▪ Lack GIS, stockouts notification, and ability to report stock levels to managers. ▪ Need a web-based system that will allow information to reach national level; currently stock is managed based only on amount of stock delivered to provinces vs. the estimated need. ▪ Monthly usage and wastage figures in electronic format will assist with better management. ▪ Systems currently are stand-alone and are not linked to each other; we want systems which will

Functionality	Gaps
	be web-based and can have all required data elements. ▪ They should link to ministry database (DHIS2). ▪ Would like capacity-building in SMT at all levels.

Technical architecture patterns

As mentioned previously, lack of an integrated national EA is a significant frustration for health officials. As countries begin to see reusability and sustainability in their tools, they are increasingly looking at the information architecture shown in Figure 7-1 for ways to share data across applications.

Figure 7-1. Enterprise architecture model.



Two architectural patterns are emerging:

1. A loosely coupled, SOA generally based on the **OpenHIE**[3] model, and
2. An application-specific option generally based on **DHIS2**[4] with underlying application programming interface (API) functionality.

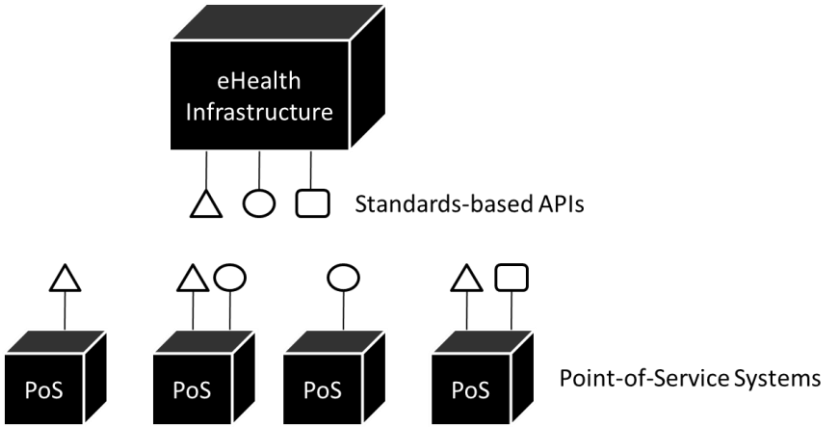
From the perspective of the user and the tools used at health facilities, both of these architectures can be made to look the same.

In order to leverage a shared eHealth Infrastructure—such as a national immunization database or the supply chain logistics information—tools and applications at the facility will need to be able to “speak” to the appropriate interface (API). For example, as illustrated in

Figure 7-2, the triangles from the PoS need to match with the API triangles and the squares with the squares.

BID favors standards-based APIs, in order to ensure that the systems implemented are reusable and supportable by the country’s local eHealth teams. The specifics of how these two architectural approaches could be implemented are explored in the following sections.

Figure 7-2. eHealth Infrastructure.

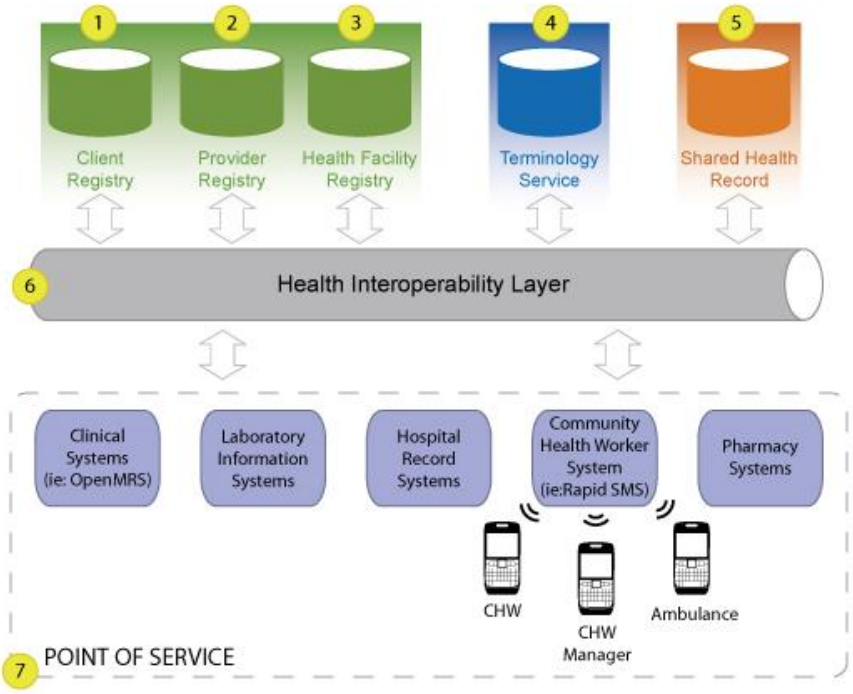


OpenHIE Architecture

The seven basic components of the OpenHIE architecture as applied to eHealth transactions and illustrated in Figure 7-3 are described below:

1. **Client Registry**, i.e., for whom—An Enterprise Master Patient Index, or Client Registry, manages the unique identity of citizens receiving health services with the country.
2. **Provider Registry**, i.e., by whom—A Provider Registry is the central authority for maintaining the unique identities of health providers within the country.
3. **Facility Registry**, i.e., where—A Health Facility Registry serves as a central authority to uniquely identify all places where health services are administered within the country.
4. **Terminology Service**, i.e., what health services are called—Terminology Service acts as a central authority to uniquely identify the clinical activities that occur within the care delivery process by maintaining a terminology set mapped to international standards such as ICD10, LOINC, SNOMED, and others.
5. **Shared Health Record**, i.e. compiled patient record—A Shared Health Record is a repository containing the normalized version of content created by the health system, after being validated against each of the previous registries. It is a collection of person-centric records for patients with information in the system.
6. **Interoperability Layer (IL)**, i.e., message flow—The Health IL receives all communications from facility applications within a health geography and processes them into the appropriate Registries and Records.
7. **H**ealth facility tools—facility applications, like Rapid SMS, are used by clinicians and CHWs to access and update Shared Health Records and to record health care transactions.

Figure 7-3. SOA/OpenHIE's model (from www.ohie.org).



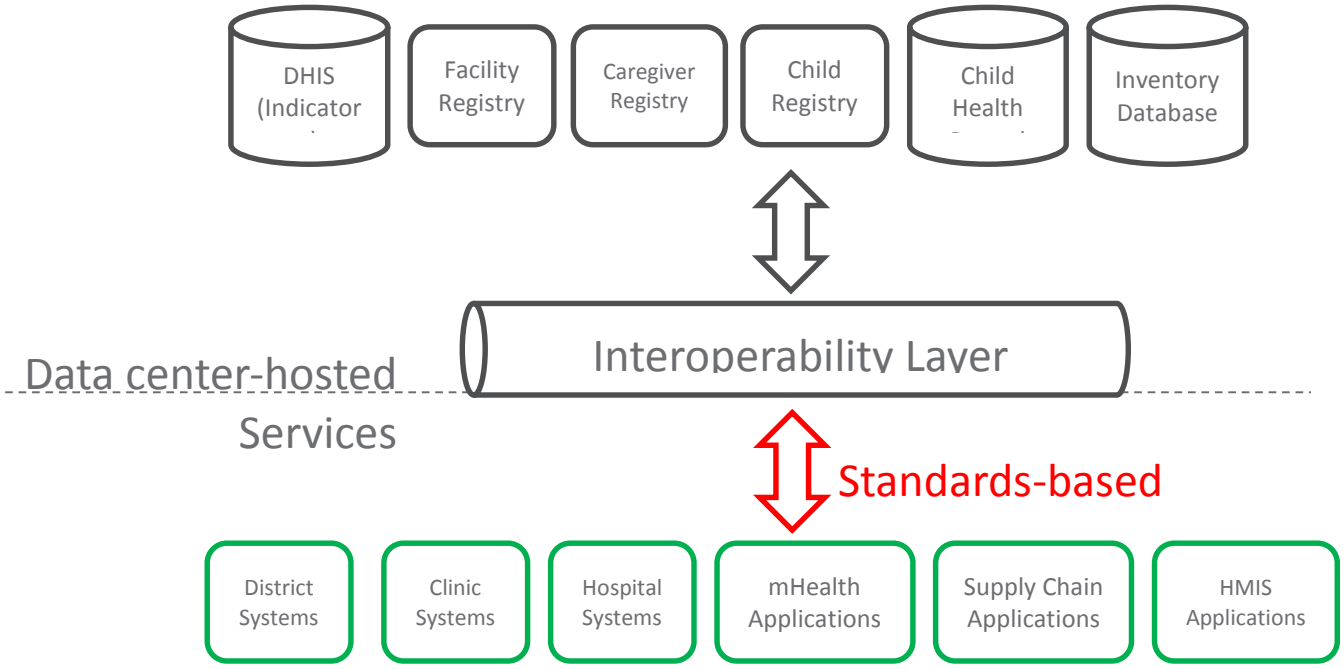
Using OpenHIE to support BID

Alongside the base OpenHIE design[b] the BID project will need to incorporate supply chain applications such as OpenLMIS/electronic Logistics Management System (eLMIS).[5] This application is currently being deployed in Tanzania, one of the BID demo countries, as a logistics and inventory management solution. Architecturally, OpenLMIS/eLMIS (or some other perpetual inventory "engine") will provide a shared inventory database above the IL, as well as an end-user facility application that can access the inventory database plus other eHealth infrastructure assets via IL-managed web service calls. These modifications are illustrated in Figure 7-4.

[b] Page on Architecture. OpenHIE website. Available at: http://ohie.org/architecture/. NOTE: as of the time of preparing this document, the OpenHIE architecture was undergoing changes to incorporate core health management information system (HMIS) functionality and native support of integrated care pathways, such as the EPI workflows essential to the BID initiative.

Figure 7-4. SOA for BID.[c,d]

DHIS2 architecture

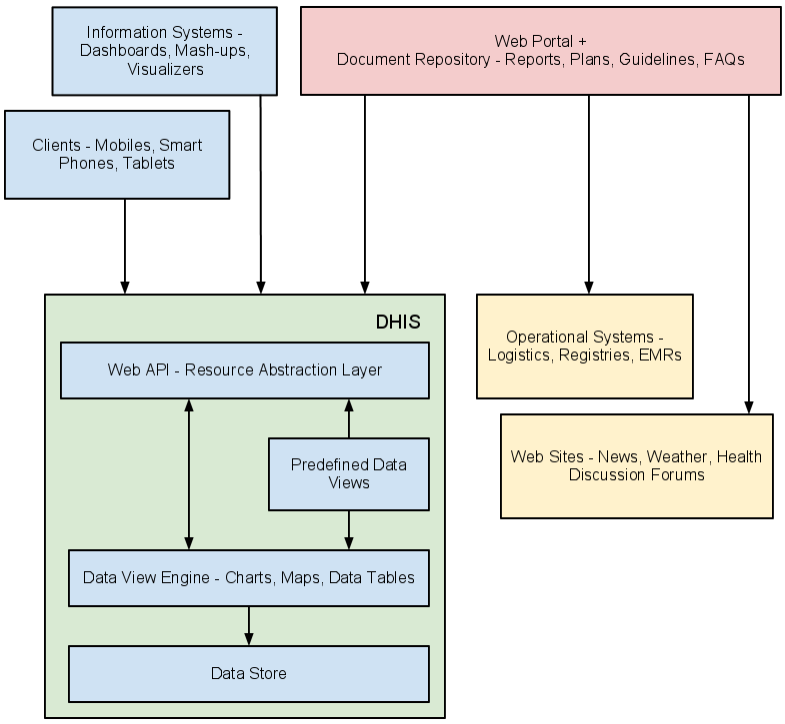


The DHIS2 architecture supports most emergent country-level requirements for routine eHealth data capture and can also serve as a management system for logistics, laboratory, and health care financing domains. It is designed ground-up with flexibility in mind. Data structures such as data elements, organization units, forms, and user roles can be freely defined, making it possible for the system to be adapted to a multitude of locale contexts and use-cases. It is important to note that though the core capabilities of DHIS2 map well to the health care requirements illustrated in Figure 7-4, the API is non-standard (i.e., specific to DHIS2 functionality).

As is the case with the OpenHIE architecture, inventory-specific functionality will need to be filled in via the functionality from eLMIS/OpenLMIS or some other inventory "engine". The DHIS "platform" model anticipates such application-level collaboration via a web portal interface (Figure 7-5).

[c] Workflow diagrams describing the OpenHIE message interactions can be found on their website. Available at: https://wiki.ohie.org/display/documents/OpenHIE+Architecture+Documentation
[d] A description of the OpenLMIS architecture, data model, and functionality can be found on their document repository website. Available at:: http://openlmis.hingx.org/discover

Figure 7-5. DHIS2 model (from www.dhis2.org).



DHIS2 can also be extended with additional software modules that can live side-by-side with the core modules, integrated into the DHIS2 portal and menu system. This is a powerful feature, as it makes it possible to extend the system with extra functionality when needed, typically for country-specific requirements.

The downside of the modular design is that it puts several constraints on the development process. Developers are limited to the DHIS2 technology in terms of programming language and software frameworks, in addition to the constraints put on the design of modules by the DHIS portal solution. Also, these modules must be included in the DHIS software when the software is built and deployed on the web server, not dynamically during run-time. However, DHIS has created a web API to address some of these issues.

Using DHIS2 to support BID

A potential configuration of DHIS2 for BID is shown in Figure 7-6. This would enable the DHIS platform to be leveraged, but with a façade that exposes its current API as a standards-based API. Such a configuration would enable facility applications to be reusable across either the SOA/OpenHIE or DHIS2 architectural platforms.

Figure 7-6. DHIS2 “Person” data model (from www.dhis2.org).

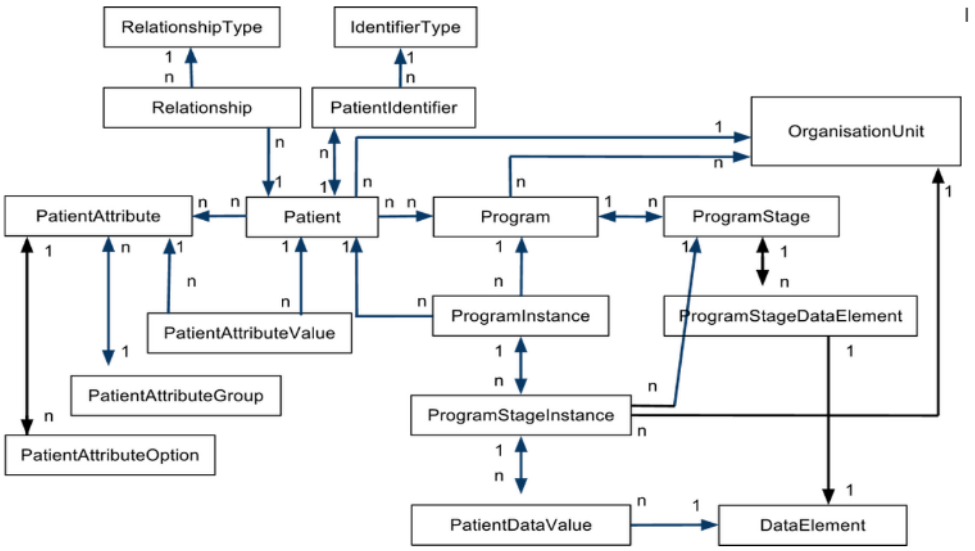
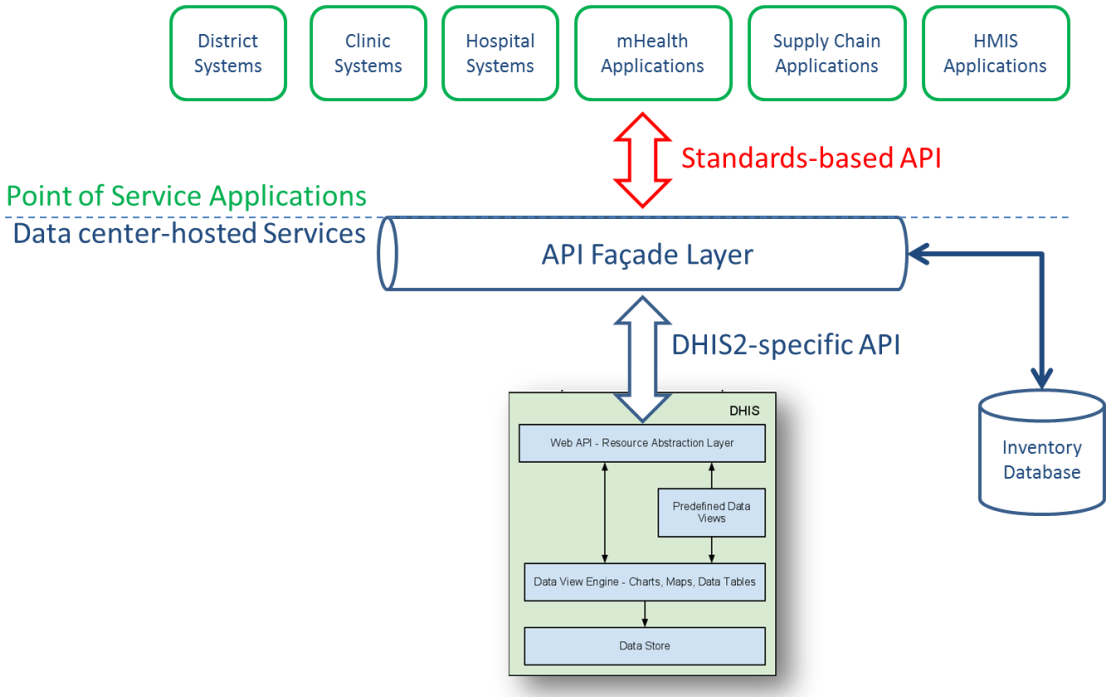


Figure 7-7. Using DHIS2 for BID.



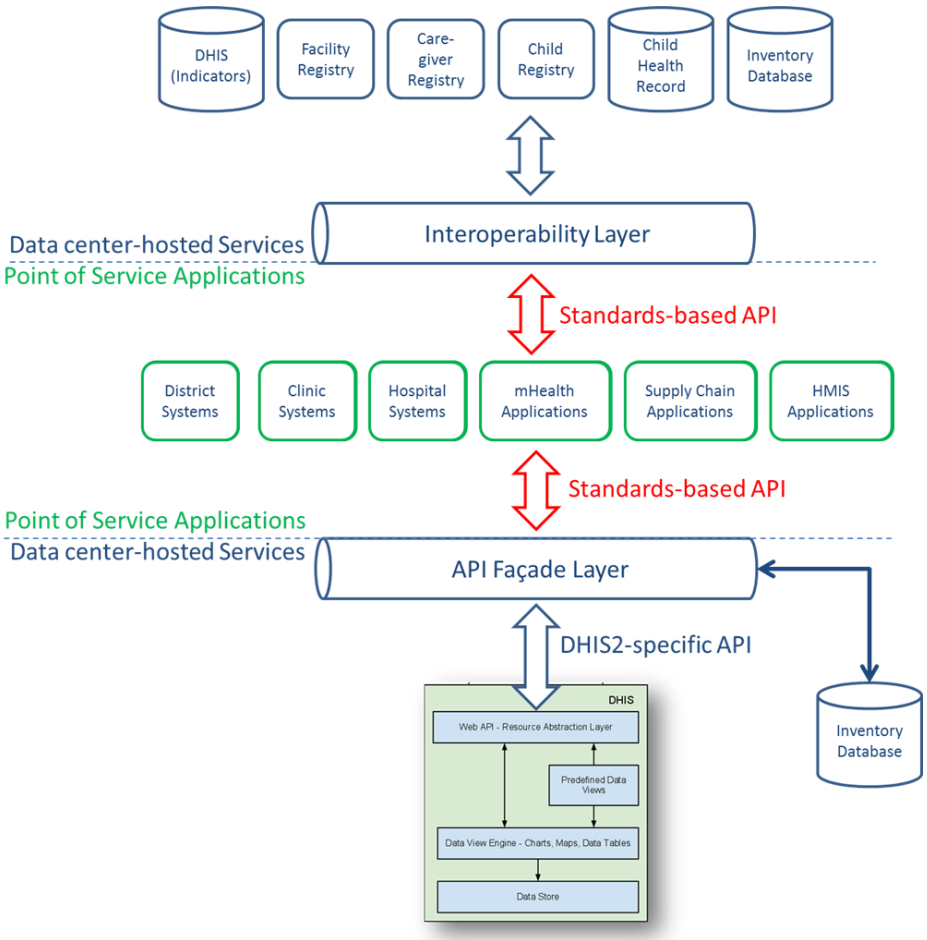
How do they compare?

Architecturally, an SOA/OpenHIE platform and a DHIS2-based platform are very different. The SOA option provides a set of loosely coupled service applications which may be independently changed out or evolved over time. The loose coupling of the systems affords scaling and redundancy opportunities and, potentially, risk-mitigation options as individual parts may be changed out without affecting the overall system “behaviors”.

DHIS2, on the face of it, is a monolithic option that represents the risks of “vendor lock-in”. However, it is actually made up of modules and so offers a “tightly” coupled way for the system to be extended, load balanced and, potentially, evolved. Applying an API IL, the risks of vendor lock-in are also somewhat mitigated, as standards-based services could operate in parallel with DHIS2 modules (for example, a national Enterprise Master Patient Index could be updated at the same time as DHIS2-based demographic information was being updated).

One of the goals of the BID initiative is to begin to develop reusable assets that may be leveraged by multiple countries. With an API façade, facility applications can work with either platform at the data center level. Either pattern for an EA helps the BID Initiative align investments in information systems with the missions, goals, and strategic objectives of the country.This is illustrated by Figure 7-8.

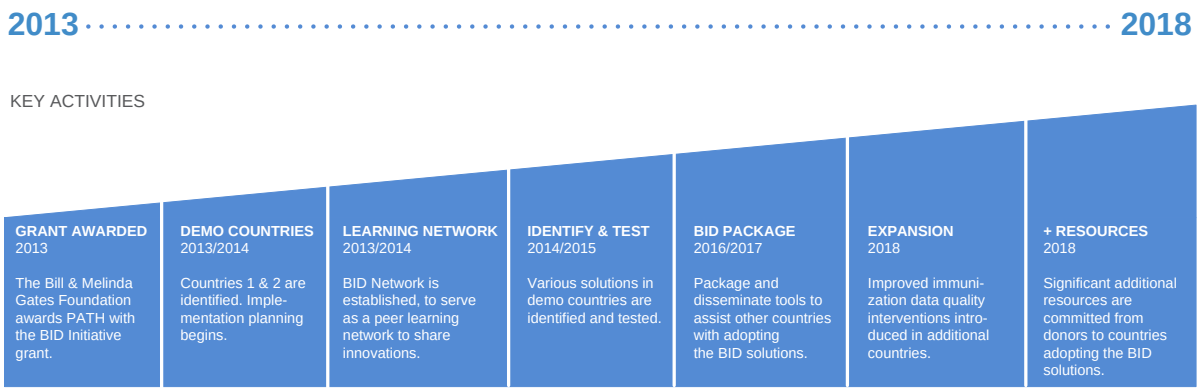
Figure 7-8. Reusing facility applications across multiple BID countries.



Next steps

The BID Initiative is entering the identification and testing phase of the project (see Figure 7-9).

Figure 7-9. BID Initiative key activities.



As part of this phase, there will be in-depth review of interventions in a selected number of sites. Based upon the challenges prioritized by the BID demo countries (accurate denominator, defaulter tracing, unique identification of children, complexity of data-collection forms, and data visibility), a series of facility applications will be tested and adjusted to be effective, efficient, and impactful. The learning from this phase will set the stage for the scaled roll-out across the demo country. These learnings will be used to: (a) document the iterations and learnings for each intervention to inform the selection of the information system products and practices to be initially deployed across an initial region; (b) help define the research questions that are part of the BID learning agenda; and (c) outline key portions of what should be included in the "packaging" of interventions and integration as part of the demo country's interoperable EA.

The *Product Vision for the Better Immunization Data Initiative* serves to document the approach taken for designing a scalable immunization information system for sub-Saharan Africa. As the phase progresses and the BID Package is developed, additional chapters and tools will be published so that countries can continue to enhance immunization and overall health service delivery through improved data collection, quality, and use.

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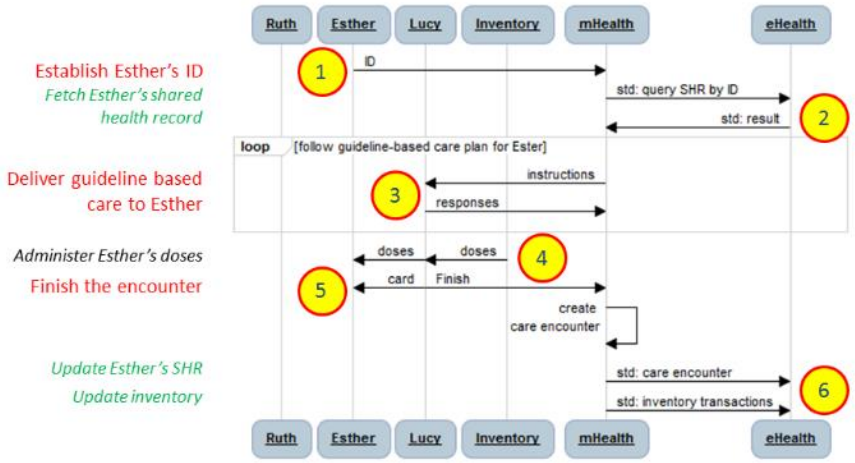
[1] PATH and WHO. Landscape Analysis of Health Information Systems Solutions, Technologies and Management Practices in Immunization. Ferney-Voltaire: PATH and WHO, 2008.
[2] Author's unpublished data on tools that exist, 2012.
[3] OpenHIE website. Available at: www.ohie.org.
[4] Page on Individual data records/Tracker. DHIS2 website. Available at: www.dhis2.org/individual-data-records.
[5] USAID DELIVER. eLMIS Functional Requirements. Dar es Salaam: USAID, 2012. Available at: www.deliver.jsi.com/dlvr_content/images/imgprocurement/Attachment7_eLMIS.doc.

8. Appendices

Appendix A. UML sequence diagram examples

This appendix provides background information for Chapter 2: Enterprise Architecture Approach and is also referenced in Chapter 6: Key user scenarios.

Figure 8-1. UML depiction of the communication patterns described in Figure 6-2. Immunization awareness and demand generation.

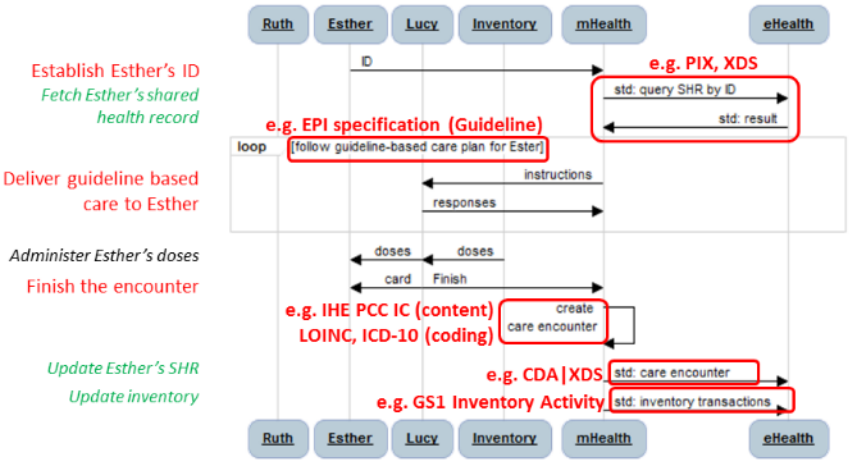


The sequence diagram was generated using a tool available online at: www.websequencediagrams.com. The "source code" for the diagram is shown below.

Figure 8-2. Source code for Figure 8-1.

```
participant Ruth
participant Esther
participant Lucy
participant Inventory
participant mHealth
participant eHealth

Esther -> mHealth: ID
mHealth -> eHealth: std: query SHR by ID
eHealth -> mHealth: std: result

loop follow guideline-based care plan for Esther
 mHealth -> Lucy: instructions
 Lucy -> mHealth: responses
end

parallel {
    Inventory -> Lucy: doses
    Lucy -> Esther: doses
}

parallel {
    Lucy -> mHealth: Finish
    Lucy -> Esther: card
}

mHealth -> mHealth: create \ncare encounter

mHealth -> eHealth: std: care encounter

mHealth -> eHealth: std: inventory transactions
```

Figure 8-3. UML mapping of interactions to standards.



Appendix B. Systems design and inventory management

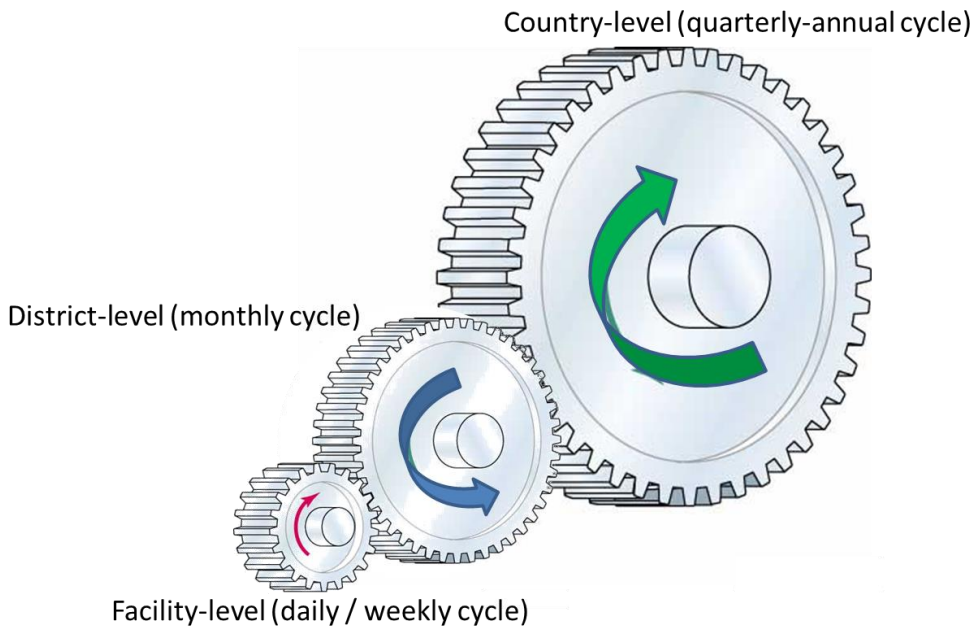
This appendix provides background information for Chapter 2: Enterprise Architecture Approach and is further referenced in Chapter 6: Key user scenarios and Chapter 7: Tools and standards in use.

National policymaking—using data gathered from information systems—guides immunization **planning** (i.e., if certain activities will take place, when they will occur, and how they will be managed at the different system levels).

Using the gear train in Figure 8-4, we have illustrated three different "paradigms" for data exchange and information systems design:

1. **Top down**: In "top down", the system design operationalizes a "command and control" posture. National policies and strategies are actualized through initiatives that are "pushed" down through successive levels of the organization from the national level, to the regions, to the districts, and down to the facility. This design uses the large green gear to drive the other two.
2. **Bottom up:** In "bottom up", the system is designed in a "pull" fashion to support the requirements at the facility. Each facilities on-the-ground immunization initiatives, and the inventory requirements that go with them, generate an aggregate demand at the district level. Likewise, the aggregated district requirements generate demand at the regional level, and the regional demands are aggregated at the national level. In this design, the small red gear would spin, causing the blue and green gears to spin based on the red gear's rate of rotation.
3. **Middle out**: A "middle out" design is a hybrid of the other two. Immunization planning, and the associated inventory planning, is done at the district level, and these plans are "pushed" to the SDPs for execution. These district-level plans, in aggregate, generate a "pull" on the regional and national levels. In this design, the blue gear would drive both the red gear and the green gear.

Figure 8-4.Three design paradigms.



We can easily apply this illustration to inventory management. We know that inventory consumption transactions are directly driven from the immunization service delivery and it is the actual consumption that drives replenishment. In such a design, immunization planning (and therefore, inventory planning) is done at the district level (spin the blue gear), but stock replenishment is driven by actual consumption at the facility (spin the red gear). In situations where the planning and replenishment cycles coincide (e.g., Namsemba's rural clinic is replenished only once per month), then there is no "pull" inventory replenishment unless a stockout situation is imminent—which should be rare.

Intuitively, we know that gears of different sizes will spin at different rates. This usefully illustrates the difference in the planning (and inventory replenishment) cycles at the facility level versus those at the district, regional, or national levels. We also know that safety stock requirements will correlate to the length of the replenishment cycle. On a weekly replenishment cycle, safety stock levels only need to cover the weekly consumption variability. On a monthly replenishment cycle, the safety stock requirements significantly increase. Of course, we also know that on longer planning cycles, the laws of averages plays in our favor. The monthly fluctuations, expressed as a percent of the average monthly consumption, are lower than the daily fluctuations expressed as a percentage of the average daily consumption.

There is anecdotal evidence that immunization planning at the district level is close enough to the SDPs for these plans to align well with the needs at the point of care and yet are far enough away to allow for more consistent and smoother planning. As a special note, when the data have been aggregated and "smoothed" for national-level reporting, individual issues at a facility could have hidden stockouts or dropouts at a local level.

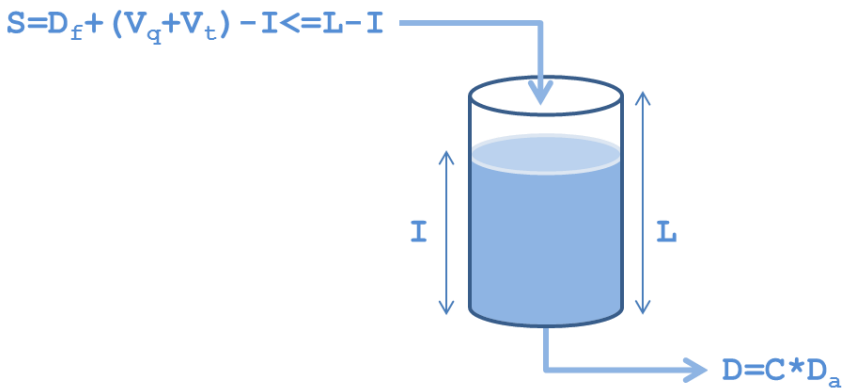
Appendix C. Linking supply and demand

This appendix provides background information for Chapter 7: Tools and standards in use.

Today, the immunization consumption data (demand) and the vaccine supplies are separated. However, as part of an eHealth architecture, the two systems can be linked as described below.

Figure 8-5 illustrates the basic relationships between supply and demand and how they impact inventory management.

Figure 8-5. The arithmetic of supply and demand.



- Replenishment supply of vaccines (S) equals demand forecasts (D_f) plus safety stock levels considering variability in quantity (Vq) and replenishment time (Vt), less existing inventory (I). This is limited by store capacity (L-I).
- Demand for vaccinations (D) equals the coverage area (%C) multiplied by the actual demand (D_a).

There are several ways that this coupling can be applied to our immunization processes:

- Supply is a “top up” replenishment, which may be zero if inventory covers the forecast demand plus total variability before the next replenishment cycle (i.e., time interval). Of course, if the inventory on hand is zero, then the re-supply quantity will equal the forecast demand quantity plus the safety stock quantity.
- Safety stock covers variability due to quantity and time. Variability due to quantity reflects demand forecast variability as compared to actual demand, shipment errors, shipment quality rejects, and spoilage within inventory. Variability due to time reflects uncertainty in the replenishment time frame (e.g., late shipments).
- The stockout incidence rate is a ***chosen*** value (*x*%). The safety stock level reflects a statistical expectation for variability of time and quantity. The chosen value answers the question “what values are needed for a statistical stockout to happen less than *x*% of the time?” Reducing the variability (e.g., fewer erroneous or late shipments; less inventory spoilage) allows either the safety stock levels to be reduced, or supports a reduction in the incidence of stockouts at the same safety stock levels.
- The sum of demand plus safety stock is bounded by the storage capacity limit. As this limit is approached, either the replenishment time interval must be reduced, the safety stock must be reduced, or new storage capacity must be added.
- The demand is sensitive to natural fluctuations in the number of babies being born during the replenishment time period and to changes in the coverage rate. The number of babies being born is a generally stable value into which we will have insight depending on the accuracy of maternal program data. The coverage rate is impacted by

improvements in communication programs that incentivize care-seeking behaviors (e.g., SMS messaging, local communications campaigns).

How does this impact health?

The key takeaway is that our "best" inventory supply option is to track observed demand, including demand that could not be filled, at the facility and use this information to ***pull*** replenishment inventory on a short-duration replenishment cycle (t). Such a strategy would minimize the capacity requirements at SDPs and minimize the safety stock required to support a stockout incidence, *x*, which we should set to the highest "service level" that can be accommodated by the capacity.

The *coupling* between the supply and the demand cycles is "best" done at the district level. Here is where demand-generation or demand-management initiatives can be planned for and appropriate inventory drawn into the regional inventory stores to support these plans. It is important to note that it is at the district level where management may be most effectively exercised to mitigate variability in quantity and replenishment time. Such district-level management affects safety stock requirements at the SDPs. Management exercised at the facility could never exert such impact on reducing this variability.

What is "better" about this? Person-centric data will be directly captured in a computable format, as part of the immunization workflow, at the point of care delivery. Leveraging eHealth infrastructure in this way will enable us to develop, share, and leverage timelier and more accurate data. By embedding the use of person-centric data within the fabric of the workflow, it is also a way to help operationalize EPI guideline-based care.

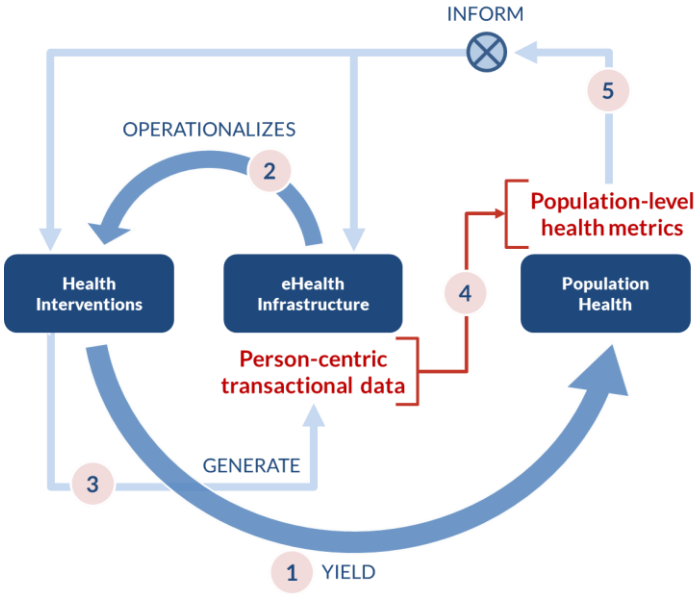
From a cold chain management standpoint, we have also metered the inventory consumption transaction. This enables district-level-to-facility replenishment based on a "better" signal: the actual observed demand. Lastly, capturing computable data at the point of care delivery supports the development of metrics and indicators which may be aggregated and reported at the person, provider, facility, district, regional, and national levels. Such data may be employed to drive feedback loops that can support continuous quality improvement regarding person-centric care, provider and facility management, and planning and management at the district, regional, and national levels. The model for how this links to population health is illustrated by Figure 8-5.

Such stock movement is triggered based on the diagram (and equations) shown in

Figure 8-6 below. An important exception to this "pull" inventory management is the case where access to a facility will be hampered or stopped altogether by weather (e.g., rainy season) or other events. In these instances, the equations still hold, but extra supply must be *pushed* to the facility because of the lengthened (or more highly variable) replenishment time.

Figure 8-6. An evaluative model for describing the health impact of eHealth[1]

[1] Ritz D. Operationalizing guideline-based care. Presented at: AeHIN General Meeting., September 23-24, 2013; Manila, Philippines. Available at: www.aehin.org/Portals/0/Docs/2013%20Meetings/2013%20AeHIN%20GM/AeHINGM2013OperationalizingGBC_DerekRitz.pdf



The supply cycle and the demand cycle are independent, but related. These are independent because, for the immunization event to occur, the cold chain had to previously deliver stock to the SDPs based on *anticipated* demand, but it is consumed based on *actual* demand.

Appendix D. Workflow design techniques

This appendix provides background information for Chapter 6: Key user scenarios.

Workflow design techniques can be used to improve the efficiency of care administration. We will discuss two techniques:

1. Segregate work into “fast track” and “slow track”.
2. Optimize the “bottleneck” work task.

1. Work segregation

Work segregation simply means that we will not want to slow down our routine or “fast track” babies behind cases where counseling or other support is needed.

Consider two mothers who bring their babies, Sarah and Rachel, to a clinic to be immunized. Before the immunizations happen, the babies are weighed, their immunization records located, and information added to their records. Sarah is at a healthy weight and is arriving at the right time to be immunized. Rachel is underweight and the mother will need to be counseled. Sarah is on the “fast track” and she can receive her immunizations and get in and out of the clinic quickly if she isn’t delayed waiting behind other cases where more support is needed. Rachel will need to spend more time at the clinic and should be diverted to another “track” so as not to interfere with the “fast track.”

From the point of view of the nurses at the clinic, even with work segregation, the same amount of time is spent doing the actual work. From the point of view of the mothers, however, work segregation markedly reduces the time many of them spend queuing at the clinic and makes getting their children immunizations more appealing.

2. Bottleneck work

A bottleneck occurs when the capacity of entire system is limited by a single resource. Think of trying to pour water from a bottle. The rate the water is poured is limited by the width of the bottle’s opening (i.e., the bottleneck). Widen the opening and the water can be poured more quickly; narrow the opening and the rate will slow. The rate for the overall process is limited by the bottleneck task.

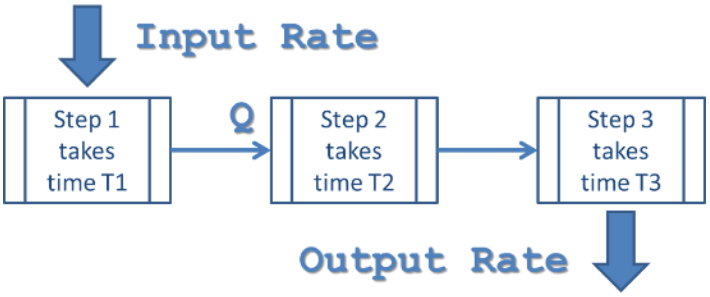
Figure 8-7 generically illustrates our simple, three-step immunization process:

1. Work before the vaccine administration (e.g., scan barcode identification, weigh baby, counseling, data capture, etc.).
2. Vaccine administration.
3. Work after the administration of the vaccine (e.g., waiting period, etc.).

Step 2, administering the vaccine, is our bottleneck because it takes the most time of the three steps. This means that if Lucy can immunize 20 children per hour, then the output rate from the final step (Step 3) will be 20 children per hour. If more children (input rate) are added to the system, a queue will result if no additional workers are added to provide vaccinations and the output rate will stay the same.

We can improve our immunization process by addressing the bottleneck task. For example, if Lucy has a helper, the input rate can be doubled and twice as many children can be immunized (2 * Step 2); if she has two helpers, three times as many children can receive care (3 * Step 2).

Figure 8-7. Bottleneck work process.



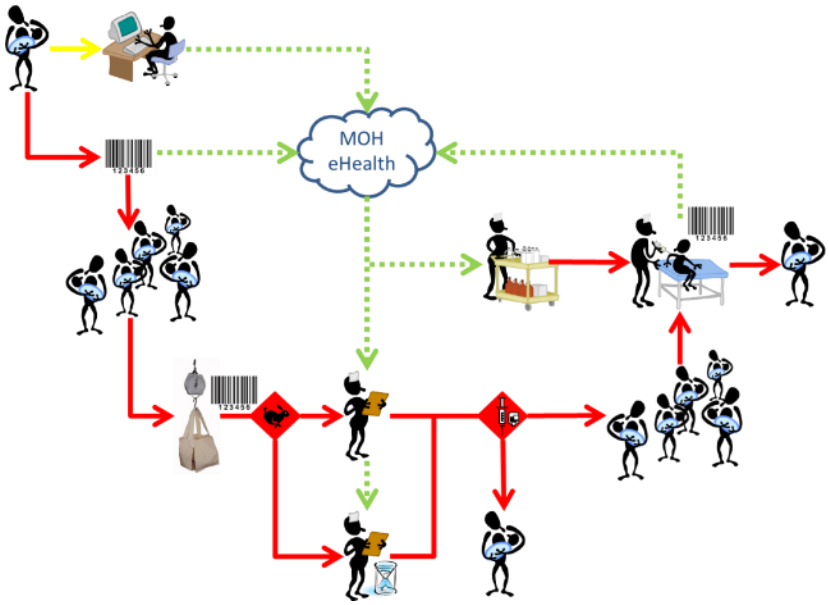
Of course, this all depends on the time needed to carry out Steps 1 and 3 remaining the same. For example, we want to introduce data capture to Step 1—especially for babies who do not have immunization cards or who do not have an assigned ID. This new work may take longer than the current paper-based task; however, as long as it doesn't take longer than Step 2, which is the current bottleneck, the input rate can remain the same. If Step 1 does become a bottleneck, then additional resources should be added to help with data capture.

Applying techniques to busy urban clinic

To leverage our techniques and make use of available technologies, a suggested workflow design is depicted in Figure 8-8. Note that all the information collected from the immunization activities is meant to support decision-making.

- The red arrows indicate physical flows of people and vaccines.
- The green dotted arrows indicate information flow.
- The yellow arrow at the top-left of the diagram indicates a one-time data-entry process.

Figure 8-8. Suggested immunization workflow (Lucy's busy urban clinic).



1. The mother brings her baby to be immunized. Upon arriving at the immunization clinic, the barcode on the baby's immunization card is scanned.

   a. If the mother does not have an immunization card or if she has a card without a barcode, a data-entry clerk at the clinic will enter the baby's demographic information into the MoH eHealth system manually and generate a barcoded identification card. After this one-time process, and for each subsequent visit, the mother will be able to just move through the workflow as described below.
2. Mother and baby join the queue waiting to be weighed.
3. Based on the barcode identification, the baby's child health record is retrieved from the MoH eHealth system and loaded onto the tablet computers used by the nurses.
4. When the baby is weighed, the barcode identification is again scanned, displaying the baby's health record on the nurse's tablet computer (or laptop, or even Smartphone) and indicates if the mother is to proceed along the "fast path" or the "slow path". Regardless of the path, the baby's weight is recorded on the immunization card and entered on the tablet computer, which saves it to the MoH eHealth system.
5. If the mother is on the fast path, she either joins the immunization queue or she is reminded of her baby's next visit and she is free to leave.
6. If the mother is on the slow path, she is counseled appropriately, and then she joins either the immunization queue or she is reminded of her baby's next visit and she is free to leave.
7. The appropriate vaccine inventory is moved to the immunization room based on information from the eHealth system based on the babies that are due to receive immunizations.
8. The nurse calls babies from the immunization queue into the immunization room in groups to receive their doses. The nurse groups babies who are receiving the same immunizations to improve throughput and reduce medication errors.
9. The immunizations given to each baby are recorded on the baby's immunization card and updated to the MoH eHealth system. The mother is reminded of the timing of the baby's next immunization visit.
10. After the baby is immunized, and the mother has waited to ensure there are no adverse effects, the mother and baby are free to leave.

Health impact

There are several positive effects from this updated workflow:

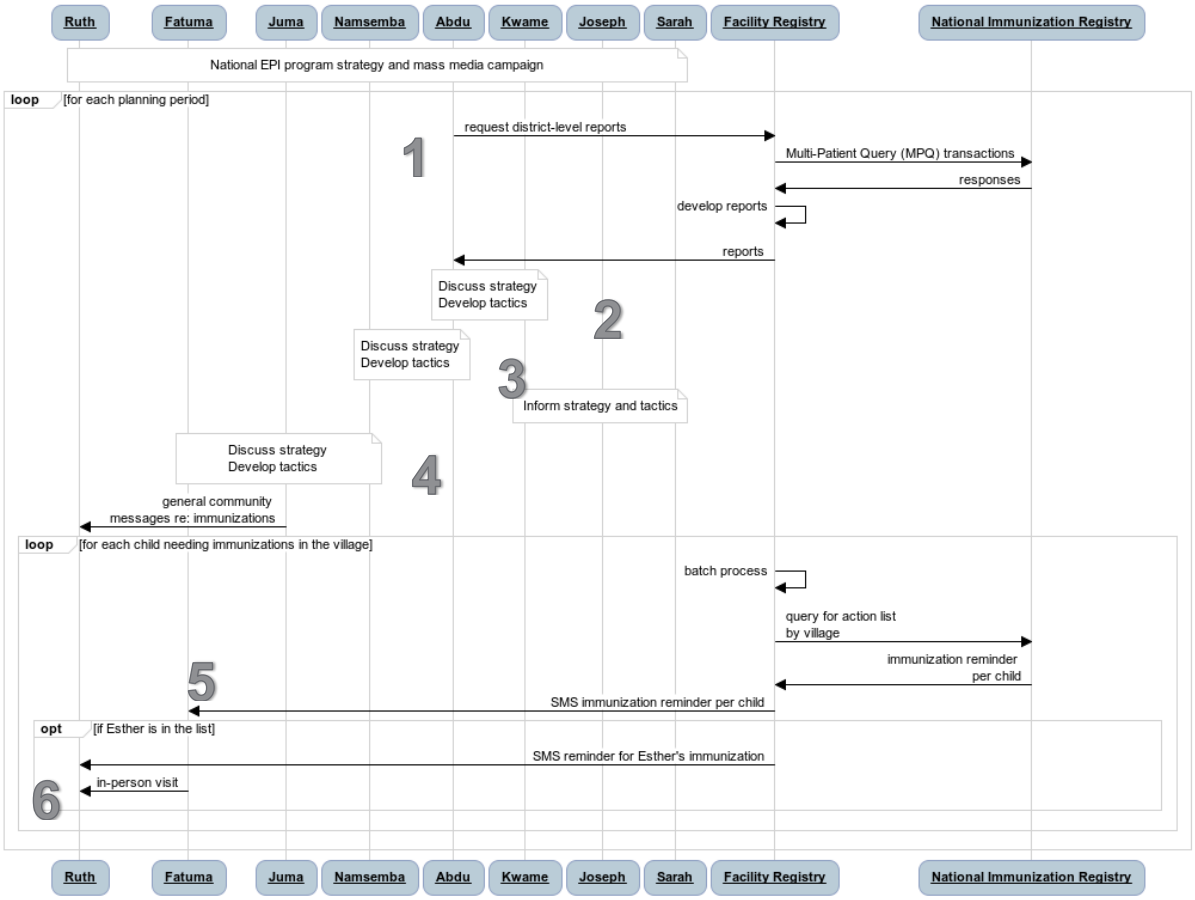
- The average duration for mothers whose babies do *not* require immunization will go down because we are segregating fast and slow workflows. Assuming there are no other issues that necessitate a counseling session (such as out-of-band weight off-scheduled visits), a well-baby visit will be very quick.
- We will be able to capture real-time information to the eHealth system about the babies that are coming for vaccination and provide real-time feedback to the nurse about the baby's immunization and overall health history. In a busy urban setting, this capability is especially important since mothers are more likely to receive care at multiple facilities over the course of the baby's immunization schedule.
- The workload on nurses to separately capture and collate data for aggregated reporting is reduced. This task will be done automatically by the electronic immunization registry.
- For mothers that scan their babies' card when they arrive but who do not, for whatever reason, complete the workflow, we will have a record of these "incomplete" events for follow-up.
- To support workflow analysis and improvement, we will also be able to compare time stamps between when a baby is scanned upon arrival and when they are scanned for weighing and when they are scanned for immunization. Scan patterns will allow us to do useful industrial engineering analyses that can help inform future system improvements.
- Lastly, although it is not a specific target for this first phase, the ability to be scanning inventory as well as child identifications will set us up for eventually achieving vial-to-child vaccine traceability.

Appendix E. Key user scenarios in UML format

This appendix provides background information for Chapter 6: Key user scenarios.

The process flow shown in the key user scenarios can also be displayed as UML sequence diagrams. Figures 8-9 to 8-11 below include additional details, such as showing multiple loops and optional steps between a local offline cache of patient data and a national immunization registry.

Figure 8-9. Immunization awareness and demand generation.[a]



[a] The sequence diagrams were generated using a tool www.websequencediagrams.com

Figure 8-10. Plan and manage service delivery

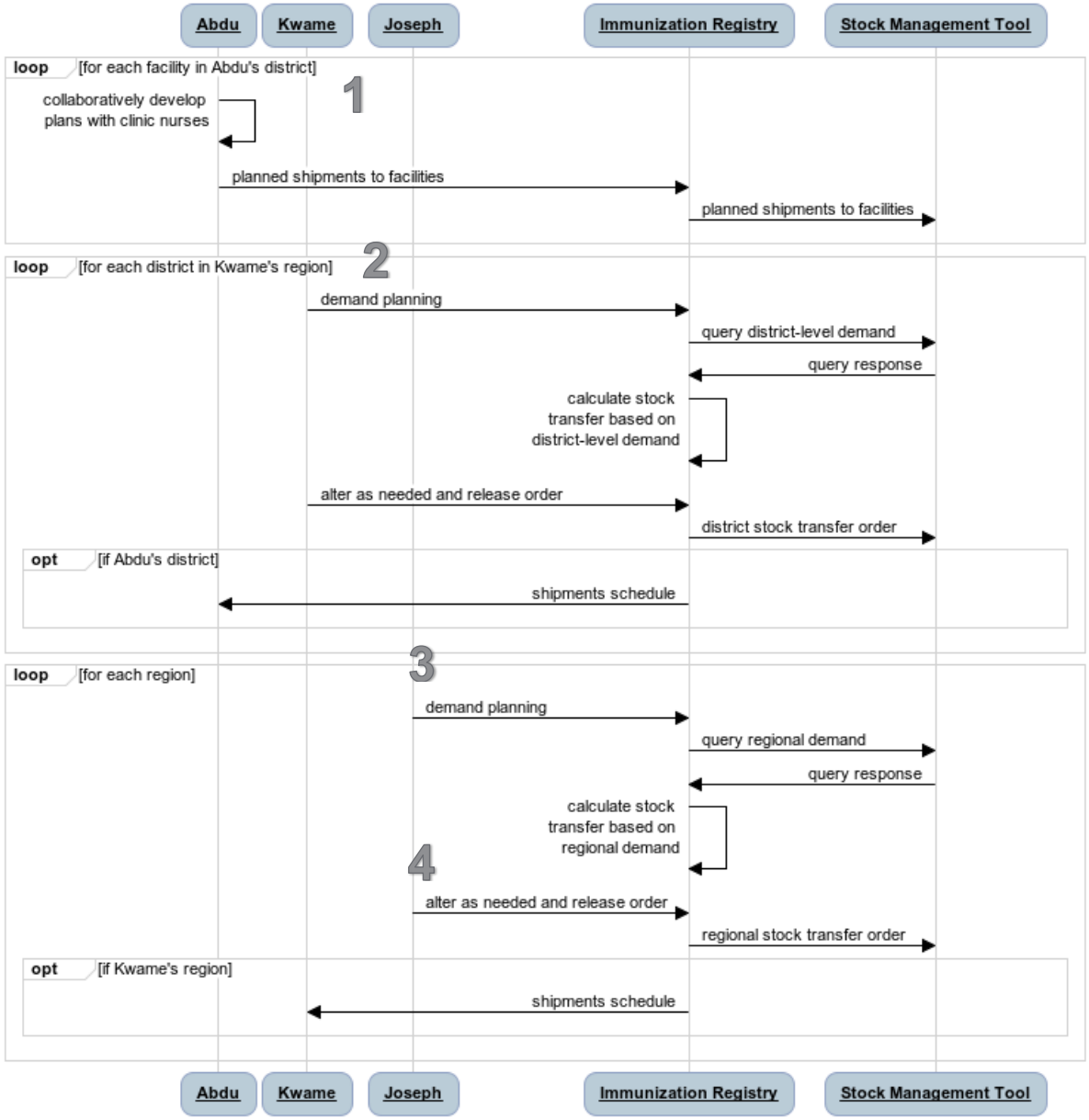
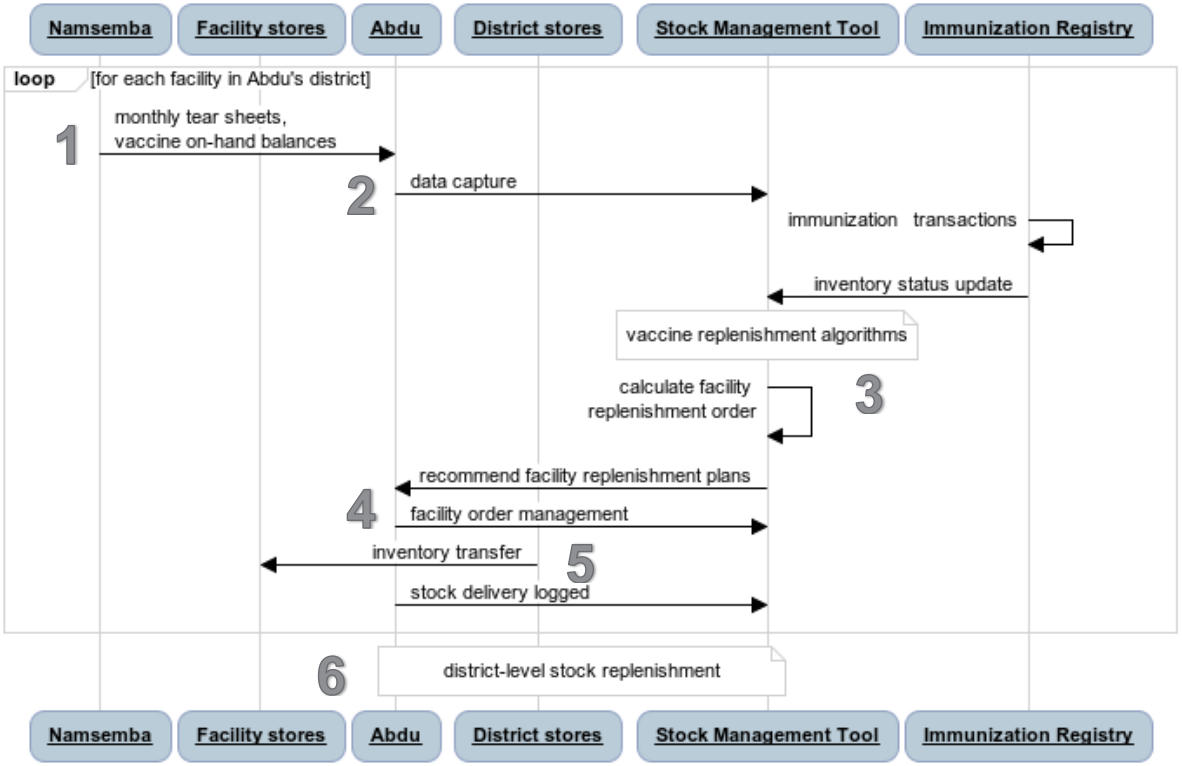


Figure 8-11. Manage stock



Appendix F. Health information systems and tools in use

This appendix provides background information for Chapter 7: Tools and standards in use.

The following systems and tools are currently being used, or planning to be used, to support immunization and vaccination activities in the specified countries. Tools that appear in multiple categories are in bold.

Burkina Faso

Planning	• DHIS2 • Documents de référence au niveau international • Plan d'action • Mécanisme de suivi et évaluation • Plan interpret de communication • Supports de communication
Awareness and demand generation	• Plan integral de communication • Supports de communication

Cote D'Ivoire

Planning	• DHIS (not necessarily for immunization)
Identify, register, and arrange care	• Fiche de pointage • Register de vaccination • Formulaire du rapport mensual PEX • Register du SIG • Rapports mensuels • Management Tool for electronic Patient Files (SIGDEP)
Measure and analyze performance	• **DVDMT** • SIG vision
Manage vaccine stock	• **SMT** • **DVDMT** • Fiche de stock

Ghana

Planning	• Dihpant • GIS • **Bottleneck analysis tool** • iHRIS • **DVDMT**
Administer and document care	• iHOST – hospital information system (patient and facility)
Identify, register, and arrange care	• GHS e-register • **MoTECH**
Measure and analyze performance	• DHIS2 • GHS e-register • **DVDMT** • **Bottleneck analysis tool**
Awareness and demand generation	• **MoTECH**

Manage vaccine stock	• Cold Chain Inventory (stockouts) • SMS for Life • **DVDMT** • Frontline SMS

Kenya

Administer and document care	• Electronic medical records
Measure and analyze performance	• HMIS • KNBS • AfriAfya • MCHANJO

Liberia

Planning	• cMYP • Microplans • Country operational plan • Red & REP strategy • Dashboards
Administer and document care	• Standardized facility-based ledger/registers for different services
Identify, register, and arrange care	• **BRIS (Birth Registration System)** • Standardized facility health registers
Measure and analyze performance	• DHIS2.1 • iHRIS • **LMIS** • **BRIS**
Manage vaccine stock	• **LMIS**

Mozambique

Planning	• Basic module-**HIS** • **DVDMT** • **SMT** • Resource records • Health service records
Administer and document care	• **HIS** • Resource records • Health service records
Identify, register, and arrange care	• SMSaude • Ante-natal register
Measure and analyze performance	• DHIS2 • **DVDMT**
Awareness and demand generation	• RED (strategy)
Manage vaccine stock	• **DVDMT** • **SMT**

Nigeria

Planning	• cMYP
Administer and document care	• DVDMT • DHIS2
Identify, register, and arrange care	• OpenMRS
Measure and analyze performance	• MADEX
Awareness and demand generation	• Mailafiya (giver of health) (awareness)
Manage vaccine stock	• SMT

Senegal

Planning	• cMYP • Epilog forces
Administer and document care	• **Registries**
Identify, register, and arrange care	• **Tacojo Registries**
Measure and analyze performance	• RIM • DHIS • DVDMT
Manage vaccine stock	• SMT

South Africa

Administer and document care	• Tier.net – HIV/AIDS system (patient-based) • ETR.net – TB system (patient-based) • cMYP
Identify, register, and arrange care	• Tick register (record services) • PHC register • ART register • TB register • Antenatal register
Measure and analyze performance	• DHIS1.4 • SRS
Awareness and demand generation	• RED (strategy)
Manage vaccine stock	• Paper-based at health facility • National estimates for financial use annually • Monthly ordering patterns

Tanzania

Planning	• PlanRep • List of certified nurses and midwives • **DHIS2** • cYMP • **DVDMT**

Administer and document care	• Care2x
Identify, register, and arrange care	• Master Facility List • mHealth Tanzania Public • Master facility list
Measure and analyze performance	• **DHIS2** • **DVDMT**
Awareness and demand generation	• SMSforLife
Manage vaccine stock	• **DVDMT** • SMT

Zambia

Planning	• **DHIS2** • **Smartcare**
Administer and document care	• **SmartCare** • **DHIS2** • HRIS • Integrated disease surveillance and response (IDSR)
Identify, register, and arrange care	• **DHIS2** • **Smartcare** • **Mwana** • National civil registration system
Measure and analyze performance	• Maternal civil registration • **DHIS2** • NHA • **FAMS** • Community-level HMIS
Awareness and demand generation	• **DHIS2** • National vital registration • AFC • National Health Accounts
Manage vaccine stock	• DLMIS (Drug and Logistics Management Information System) • **DHIS2** • **Smartcare** • **FAMS** • **Mwana** • SMT

Appendix G. Health information systems and tools not in use (or identified as part of an electronic Immunization Information System)

This appendix provides background information for Chapter 7: Tools and standards in use.

The following tools were identified during the landscape analysis; however, they have not yet been implemented by any of the surveyed countries.

- Aga Khan Health services
- Akvo-flow
- AMPATH's computer
- AMREF
- Childcount+
- CommCare
- CommTrack
- CTC2
- CyberTracker
- DevInfoAcquee
- doForms
- eIDSR
- EpiCollect
- EPICOR
- epiSurveyor
- eTBR
- GeoPoll
- Great Lakes University of Kisumu HIS
- Healthcare at my fingertips
- HealthMatch
- iForm builder
- ILSGateway
- Imogene
- IMSMA
- IQSMS
- JMBO
- Kenya polio campaign
- KoBo
- Mabenza Researcher
- Magpi
- Majella
- Mezzanine mobile health-enabling platform
- Millennium Villages Project
- Mobile Baby
- Mobile Data Studio
- Mosoriol Medical Record System
- ODK/form hub
- RapidSMS
- SMS Tech for Health
- Textit.in
- Training institution IS
- ZEPRS

Appendix H: Glossary

AfriAfya	NGO that explores how to use ICT for community health and development in rural and marginalized areas. *See www.afriafya.org*
BID Learning Network	Platform for participants in the BID Initiative to contribute ideas and share experiences, so as to develop solutions to common challenges. *See http://bidinitiative.org/bid-learning-network/*
Business process	A set of related work tasks or activities designed to produce a specific desired programmatic (business) result. The process can involve multiple parties internal or external to the organization and frequently cuts across organization boundaries.
Business rule	A set of statements that define or constrain some aspect of the business process. Business rules are intended to assert business structure or to control or influence the behavior of the health agency (business).
eHealth	The use of ICT to improve the efficiency and effectiveness of health systems.
Enterprise architecture	Defined by the National Institute of Health Enterprise Architecture as: "a comprehensive framework used to manage and align an organization's Information Technology (IT) assets, people, operations, and projects with its operational characteristics. In other words, the enterprise architecture defines how information and technology will support the business operations and provide benefit for the business." More information on enterprise architecture in low-income countries is available at: *Rational Systems Design for Health Information Systems in Low-Income Countries: An Enterprise Architecture Approach*. Mwanyika H, Lubinski D, Anderson R, Chester K, Makame M, Steele M, et al. Journal of Enterprise Architecture; 2011. http://homes.cs.washington.edu/~anderson/docs/2011/hm2011.pdf.
Functional architecture	In this context, the functional architecture includes the national vision, principles, and information policies, including those on privacy and data security. It can also include the repository of functional requirements for health applications.
Information systems	A study of complementary networks of people, processes, and the hardware and software products used to collect, create, distribute, and analyze data.
Input	Information received by the business process from external sources. Inputs are not generated within the process.
Interoperability	Defined by Heath Information Management Systems Society as: "Interoperability describes the extent to which systems and devices can exchange data, and interpret that shared data. For two systems to be interoperable, they must be able to exchange data and subsequently present that data such that it can be understood by a user."

ISO 5218	International coding standards for the representation of human sexes.
MOTECH	Open source software projected delivered by the Grameen Foundation that enables organizations to develop, manage, and monitor mHealth solutions. See www.motechsuite.org
Output	Information transferred out from a process. The information may have been the resulting transformation of an input, or it may have been information created within the business process.
Personas	Defined by IHE as: “a profile documents how standards will be used by each system's Actors to cooperate to address the problem.”
Rapid SMS	Open source framework for building mobile services for scale. *See www.rapidsms.org*
Scenario	A way to describe a process or processes, the personas involved, and the context that a system should account for using a storytelling approach.
Stack	A set or group of standards that are internally interoperable and work together.
Technical architecture	A combination of the data, network and data exchange protocols to be followed along with the application standards and hardware to be used.
Trigger	Event, action, or state that initiates the first course of action in a business process. A trigger may also be an input, but not necessarily so.

Appendix I. Additional Reading

- Shaw V. Health information system reform in South Africa: developing an essential data set. *Bulletin of the World Health Organization*. 2005;83(8):632–636.
- Kimaro H and Titlestad O. Challenges of user participation in the design of a computer base system: the possibility of participatory customisation in low income countries. *Journal of Health Informatics in Developing Countries*. 2008;2(1):1–9.
- Krickeberg K. Principles of Health Information Systems in Developing Countries. *Health Information Management Journal*. 2007;36(3):8–20.
- Wiegers KE. *Software Requirements*. Redmond, WA: Microsoft Press, 2009.
- PATH. Strengthening Health Information Systems Through Collaborative Development of Common Requirements: Final Report to the Rockefeller Foundation. Seattle: PATH, 2011.
- PATH. Zambia Vision and Requirements for Computerized Logistics Management Information System: Produced with the Collaborative Requirements Development Methodology. Seattle: PATH, 2011.
- PATH and VillageReach. *Ethiopia mHealth Roadmap: Architecture and Design Appendix*. Seattle: PATH and VillageReach, 2012.
- PATH. Workshop Summary for the Electronic Logistics Management Information System (eLMIS). Seattle: PATH, 2011.
- PATH. Determining Health Insurance Information Systems Requirements in Developing Countries: Interim Report to the Rockefeller Foundation. Seattle: PATH, 2011.
- PATH. *Determining Common Requirements for National Health Insurance Information Systems*. Seattle: PATH, 2012. Available at: www.jointlearningnetwork.org/resources/documents/determining-common-requirements-national-health-insurance-information-systems
- PATH. *Common Requirements for Logistics Management Information Systems*. Seattle: PATH; 2010. Available at: www.path.org/publications/detail.php?i=1865
- World Health Organization, PATH. *Planning an Information Systems Project: A Toolkit for Public Health Managers.* Seattle: PATH; 2013. Available at: www.path.org/publications/detail.php?i=2343.