IMMUNIZATION SYSTEM AND USER REQUIREMENTS DOCUMENTATION (SURD)

MALAWI LOCALIZATION

MALAWI

MINISTRY OF HEALTH AND POPULATION

Abbreviations

AIDC	Automated Identification and Data Capture
API	application programming interfaces
AEFI	adverse event following immunization
BCG	Bacille Calmette-Guerin
CHW	community health worker
CHN	Community Health Nurse
CHV	Community Health Volunteer
CRDM	Collaborative Requirements Development Methodology *See http://jointlearningnetwork.org/content/what-crdm*
DHIS	District Health Information Software
DTDS	Digital Tracking and Decision Support
DOB	date of birth
DTP1, DTP2, DTP3	three-dose regimen associated with diphtheria-tetanus-pertussis
EPI	Expanded Programme on Immunization
GIS	Geographic Information System
GIZ	Deutsche Gesellschaft für Internationale Zusammenarbeit
HPV	Human papillomavirus
HSA	Health Surveillance Assistant
HepB	hepatitis B vaccine
Hib	*Haemophilus influenzae* type B vaccine
ID	identifier
IIS	immunization information system
MUAC	mid-upper arm circumference
MOH	Ministry of Health
NMFL	National Master Facility List
NNT	Number Needed to Treat
OPV	Oral poliovirus vaccines
PCV	Polycythemia Vera
Penta	Five vaccines given together
Rota	Rotavirus
SHSA	Senior Health Surveillance Assistant
SOP	Standard Operating Procedures
SURD	System and User Requirements Document
UID	Unique Identifier
VDPV	vaccine-derived polioviruses
WPV	Wild poliovirus.

Contents

Introduction

In Malawi, health services are provided by public, private for-profit, and private not-for-profit sectors. The following governmental departments provide public services: the Ministry of Health (MOH); district, town, and city councils; Ministry of Defense; and Ministry of Internal Affairs and Public Security (Police and Prisons).

Malawi's health system is organized at four levels, namely community, primary, secondary, and tertiary. The different levels are linked to each other through an established referral system.

(1) At the community level, services are delivered through village clinics and outreach clinics by Health Surveillance Assistants (HSA).

(2) At the primary level, services are delivered through health centers and health posts.

(3) The secondary level mainly provides backup services to those provided at the primary level, including surgical services, mostly obstetric emergencies, and general medical and pediatric inpatient care for common acute conditions. District hospitals and Christian Health Association of Malawi hospitals provide secondary health care services, although some have specialist functions.

(4) At present, tertiary-level hospitals provide services similar to those at the secondary level, along with a range of specialist surgical interventions. Central hospitals fall under this level.

In Malawi, implementation of digital health started in 1999 with the introduction of the District Health Information Software (DHIS). To date, there are many digital health systems supporting different programs across all the levels of health services. However, these systems are not integrated, and some of the sections in the health facility do not have digital health systems. This is not in line with the 2020–2025 MOH Digital Health Strategy vision, which is "To attain a sustainable and harmonized country-led digital health system that covers all areas of service provision and enables efficient delivery of health services to beneficiaries at all levels of the health system." Recognizing the gaps that exist in the Malawi digital landscape, the MOH, through the Digital Health Division, is working on the implementation of the Hospital-Wide System to realize the vision of the Digital Health Strategy, with immunization being one of the core modules.

Objectives

This immunization SURD aims to provide a common language across various audiences—program managers, software developers, and implementers of digital systems—to ensure a common understanding of the appropriate health information content within the immunization health program area in Malawi, as a mechanism to catalyze the effective use of these digital systems. The key objectives of this immunization SURD are:

- To ensure adherence to public health and data use guidelines and facilitate consistency of the health content that is used to inform the development of a person-centered digital tracking and decision-support (DTDS) system.

- To enable health program leads and digital health teams (including software developers) to have a joint understanding of the health content within the digital system through a transparent mechanism to review the validity and accuracy of the health content.

- To provide a starting point of the core data elements and decision-support logic that should be included within DTDS systems for immunization.

Information detailed in this immunization SURD reflects Malawi-specific workflow processes and data, as derived from the GIZ-funded Collaborative Requirements Development Methodology (CRDM) validation workshop held in Salima, Malawi, in July 2023, facilitated by Digital Square. In addition, this immunization SURD describes linkages to related services for immunization, such as facility registry, stock management, and considerations for scheduling follow-up and generating reminders.

Immunization SURD scope

The scope of the immunization SURD components defined in this guideline are limited to the below key processes that were identified as the health content requirements for a Malawi-specific immunization DTDS system.

- Generate reminders.
- Immunization follow-up.
- Plan service delivery.
- Register client.
- Query client record.
- Anthropometric measurements.
- Administer vaccine.
- De-duplication of client records.

- De-duplication of vaccine events.
- Manage vaccine arrivals.
- Distribute supplies to region/district.
- Distribute supplies to facility.
- Manage inventory.
- Generate reports.

Immunization SURD components

This Immunization SURD is composed of seven interlinked components:

(1) User personas

User personas are detailed representations of the different types of users or stakeholders who interact with a software system, application, or product. These personas provide insights into the specific roles, responsibilities, needs, and goals of various users within the context of the system. Creating system user personas helps developers and designers design user-centred solutions that cater to the diverse needs of different user groups.

(2) User scenarios

User scenarios are detailed descriptions of interactions between users and a product, service, or system. They provide a narrative of how a user might engage with the offering to accomplish a specific task, achieve a goal, or address a particular need. User scenarios help designers, developers, and stakeholders understand user behaviour, needs, and expectations, enabling them to create more user-centred and effective solutions.

(3) Business processes and workflows

Business processes and workflows are systematic sequences of activities, tasks, and steps designed to achieve specific organizational goals, produce desired outcomes, and deliver value to customers, stakeholders, or end-users. These processes provide a structured approach to managing and executing tasks, ensuring efficiency, consistency, and alignment with business objectives. Workflows often encompass the flow of information, resources, and tasks through different stages, departments, or roles within an organization.

(4) Data elements

Data elements are individual pieces of information that are collected, stored, and processed within a system or database. These elements can be as simple as a single value or as complex as a combination of values that provide meaningful information. In the context of software development, databases, information systems, and data elements are fundamental building blocks that allow users and applications to manage, retrieve, and manipulate data.

(5) Decision support logic (immunization schedule)

Decision support logic refers to the set of rules, criteria, algorithms, and processes used within a software system or application to assist users or automated processes in making informed and effective decisions. This logic is designed to analyze available data, information, and contextual factors to provide recommendations, insights, or outcomes that guide decision-making.

(6) Indicators and reporting requirements

Indicators are specific and measurable variables that provide evidence of progress or achievement toward a particular goal, objective, or outcome. They are often used to track trends, patterns, or changes over time. Indicators serve as signals or pointers that reflect the state of a system or process.

(7) *Functional and non-functional requirements*

Functional and non-functional requirements are essential components of a software or system specification that define what the system should do (functional) and how it should perform (non-functional). These requirements provide a comprehensive understanding of the system's capabilities, features, and characteristics, guiding the design, development, testing, and evaluation processes.

High-level immunization SURD workflow
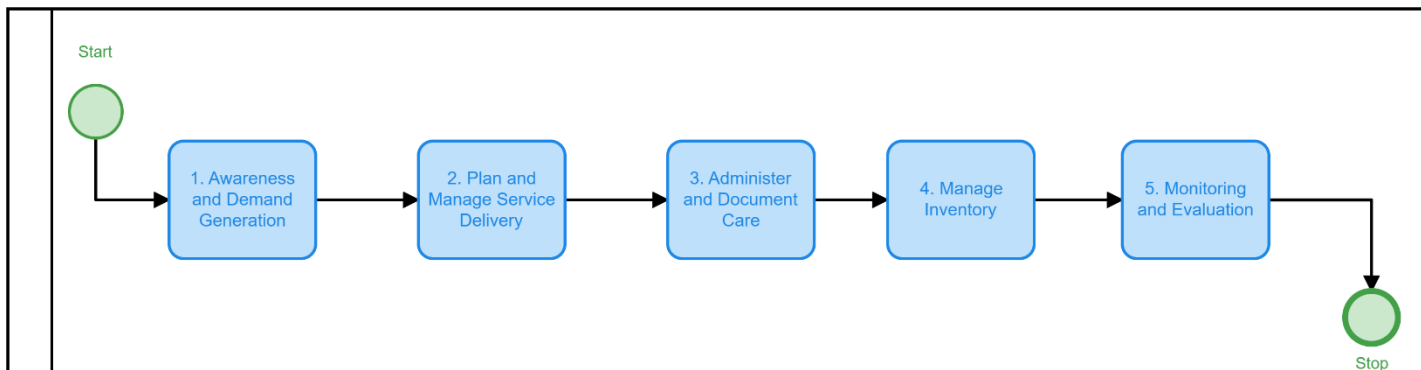
User personas

Occupational title	Description	Different names
Caregiver	A family member or other person who is looking after a child or elderly or disabled person.	Parent, mother, father
Community Health Volunteer	These are chosen by the community and are responsible for assisting the HSAs with taking the weight and height of the child and capturing mid upper arm circumference (MUAC) details.	Volunteer assistant, volunteer health worker
Health Surveillance Assistants (HSA)	Facilitate education sessions, administer immunizations, provide counseling when needed, record stock movements, and compile/generate reports.	Disease Control and Surveillance Assistants
Senior Health Surveillance Assistants	Supervise and coordinate delivery of services in the designated under-5 clinic stations and consolidate service delivery reports. Responsible for providing health talk to the mothers, taking vitals (height and weight), immunizations, provision of vitamins as necessary, documents service.	Senior HSA
Expanded Programme of Immunization (EPI) Manager	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.	Program Manager, EPI Coordinator, EPI Focal Person
Client	A person who intends to receive vaccination services from the targeted health worker personas.	Vaccinated person, patient, infant, baby
Clerical staff	Assist in scheduling appointments, answering phones, greeting patients, keeping and documenting medical records, handle medical billing.	Registration clerk
Immunization Supply Chain Officer	Responsible for managing and optimizing the entire supply chain process related to vaccines and immunization programs. This role involves coordinating the procurement, storage, distribution, and inventory management of vaccines and related supplies to ensure that they are available, accessible, and effectively delivered to health care facilities and communities.	National Supply Chain Officer
Cold chain technician	Responsible for the proper management, maintenance, and monitoring of the cold chain system used in the storage and transportation of vaccines.	Cold chain assistant

User persona annexes

Provider persona: Michael, Community Health Volunteer (CHV)	
Demographics	**Age**: 20 years old **Experience**: 1 year
Responsibilities	• Help in data collection. • Help during under-5 clinic (e.g., weight taking). • Help tracking missed children during vaccination campaigns. • Help in disseminating health education messages to the communities.
Context descriptions	Saukira Health Centre, nestled amidst the lush landscapes of Malawi countryside, serves as a vital lifeline for the local community. With its modest yet resilient infrastructure, the facility offers essential health care services to a population often hindered by geographical and economic challenges. A single-story building, adorned with vibrant murals depicting health awareness, houses consultation rooms, a basic laboratory, and a small pharmacy. Dedicated health care professionals, including two nurses and a resident Clinical Officer, work tirelessly to provide preventive care, treat common ailments, and conduct maternal and child health programs. The facility's reach extends beyond its walls, as mobile clinics venture into remote areas to ensure equitable access to medical care. Despite limited resources, Saukira Health Centre stands as a beacon of health and hope, addressing the unique health care needs of the rural African community it serves.
Challenges	• CHVs often work in resource-constrained environments, lacking proper medical supplies, transportation, and equipment to effectively carry out their duties. • Inadequate training and skills development can hinder CHVs from providing accurate and up-to-date health information and services to their communities. • Many CHVs have other responsibilities, such as household chores or income-generating activities, which can limit the time they can dedicate to their volunteer work. • Some communities may be resistant to accepting advice or services from CHVs due to cultural beliefs, scepticism, or mistrust.
Opportunities	• Digital tools provide CHVs with updated health information and training, improving their ability to offer accurate care. • CHVs can use digital platforms to collect data, aiding authorities in making informed decisions and targeting resources effectively. • Digital interventions empower CHVs to deliver health education and promote healthier behaviours, benefiting community well-being. • Digital platforms streamline referrals by CHVs, ensuring timely specialized care for patients needing higher-level treatment.

	Provider persona: Lucy, District Environmental Health Officer (DEHO)
	Demographics — **Age**: 37 years old **Experience**: 13 years Has access to a personal phone and a government-issued computer

Responsibilities	- Provide strategic guidance and mentorship for Environmental Health and Preventive Services. - Manage initiatives to ensure proper sanitation and waste disposal within the district. - Track disease trends and potential environmental risks, taking preventive measures to safeguard public health. - Organize campaigns to control disease-carrying vectors such as mosquitoes, reducing the risk of vector-borne illnesses. - Conduct educational programs to raise awareness about environmental health issues and promote community engagement in maintaining a healthy environment.
Context descriptions	Zomba District Hospital, situated in the heart of Malawi, stands as a vital health care hub serving the local community. Amidst vibrant landscapes, the hospital's modest yet resilient infrastructure houses essential medical departments, including maternity, pediatrics, surgery, and outpatient services. With a team of dedicated doctors, nurses, and support staff, the hospital addresses a wide spectrum of health care needs, from basic medical care to emergency interventions. Though faced with resource constraints and occasional shortages, the staff's unwavering commitment ensures the delivery of vital healthcare services. The hospital's influence extends beyond its walls, as it partners with community health workers and outreach programs to enhance preventive care and health education. Zomba District Hospital remains a cornerstone of health and healing, embodying the resilience and compassion of Malawi's health care system.
Challenges	- Facing resource constraints in executing effective sanitation and disease prevention programs. - Promoting proper sanitation and waste management is challenging due to cultural barriers and low community engagement. - Inadequate resources and difficult access hinder efforts to control diseases like malaria and cholera transmitted by vectors. - Addressing emerging health risks from environmental degradation and climate change demands adaptive strategies and resourceful planning.
Opportunities	- Digital tools enable officers to gather and analyse environmental health data in real time, facilitating more informed decision-making and targeted interventions. - Geographic information systems (GIS) integrated into digital platforms can help officers map and analyse environmental hazards, disease hotspots, and resource distribution, aiding in more precise planning and resource allocation. - Digital platforms can be used to disseminate health education materials and interactive content, engaging communities and fostering awareness about proper sanitation, waste management, and disease prevention. - Digital interventions allow for remote training of staff and community health workers, enhancing their skills in environmental health management and empowering them to play a more active role.

	• Digital tools can facilitate the creation of early warning systems for disease outbreaks and environmental emergencies, enabling timely responses and reducing the impact on public health.

	Provider persona: Sharon, Health Surveillance Assistant (HSA)	
	Demographics	**Age**: 35 years old **Experience**: 11 years Has access to a personal phone
Responsibilities		• Ensure availability of accurate, complete, and updated information required for effective immunization and vaccination events. • Undertake field visits for monitoring and supervision of vaccination activities to improve immunization coverage. • Conduct disease surveillance at health posts and at the community level for vaccine-preventable diseases. • Draft monthly, quarterly, and final reports to other levels, i.e., regional and national. • Participate in routine vaccination data verification. • Provide education to the community on vaccine-preventable diseases. • Conduct training for health care workers on immunization activities. • Conduct methods of tracing defaulters and zero doses of vaccines in the community.
Context descriptions		Zomba District Hospital, situated in the heart of Malawi, stands as a vital health care hub serving the local community. Amidst vibrant landscapes, the hospital's modest yet resilient infrastructure houses essential medical departments, including maternity, pediatrics, surgery, and outpatient services. With a team of dedicated doctors, nurses, and support staff, the hospital addresses a wide spectrum of health care needs, from basic medical care to emergency interventions. Though faced with resource constraints and occasional shortages, the staff's unwavering commitment ensures the delivery of vital healthcare services. The hospital's influence extends beyond its walls, as it partners with community health workers and outreach programs to enhance preventive care and health education. Zomba District Hospital remains a cornerstone of health and healing, embodying the resilience and compassion of Malawi's health care system.
Challenges		• Lack of transport. • No budget for airtime and data. • Scarcity/destruction of data tools (registers, updated ledger books) at facility level. • Lack of a PC to use for work.

| Opportunities | • Digital tools enable officers to gather and analyse immunization data in real time, facilitating more informed decision-making and targeted interventions. |
| | • Digital platforms can be used to disseminate health education materials and interactive content, engaging communities and fostering awareness about immunization and disease prevention. |

User scenarios

[User scenarios are detailed descriptions of interactions between users and a product, service, or system. They provide a narrative of how a user might engage with the offering to accomplish a specific task, achieve a goal, or address a particular need. User scenarios help designers, developers, and stakeholders understand user behavior, needs, and expectations, enabling them to create more user-centered and effective solutions.]

Key personas	**District Environmental Health Officer:** *Lucy* **Community Health Volunteer:** *Michael*
	As Lucy, the District Environmental Health Officer in Zomba, I want to utilize a digital health platform to track immunization coverage rates across different communities in real time, enabling me to identify under-immunized areas and devise targeted vaccination campaigns to ensure all children receive essential vaccines. Additionally, I need a digital tool that allows me to send automated SMS reminders to parents and caregivers in Zomba District about upcoming immunization sessions, increasing attendance rates and contributing to improved vaccine coverage. Finally, I want a comprehensive digital dashboard that compiles immunization data from various health centers within Zomba District, providing me with a clear overview of vaccination trends and helping me make data-driven decisions to enhance immunization programs. As Michael, a Community Health Volunteer serving within the catchment area of Saukira Health Centre in Zomba District, I need a mobile app that provides me with the latest immunization schedules and helps me keep track of the vaccination status of children in my community, ensuring that no child misses out on life-saving vaccines. Additionally, I would like access to a digital platform that offers interactive educational materials on the importance of immunization, making it easier for me to communicate with parents and address their concerns, ultimately increasing acceptance of vaccines within the community.
Processes	Manage service delivery: - Collect community demographic data. - Draw community map. - Conduct situation analysis. - Conduct stakeholder analysis. - Conduct session planning. - Logistics and supply forecasting. - Annual workplan development.

Business processes and workflows
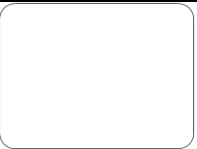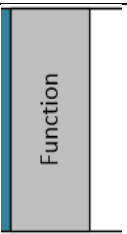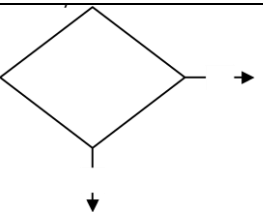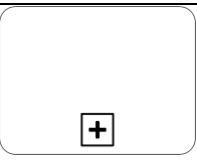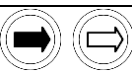
Overview of business process matrix

A set of processes and tasks that logically group together to accomplish a goal or produce something of value for the benefit of the organization, stakeholder, or customer. Together these processes define the boundaries of the system domain.

Title	Definition
Process name	Set of tasks that accomplish a specific goal.
Persona	Individuals interacting to complete the process.
Objectives	A concrete statement describing what the process seeks to achieve.
Task set	The general set of activities performed within the process.

Task flow diagrams notation

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. CRDM utilizes a simplified subset of symbols from the Business Process Model and Notation 2.0 specification as described below.

Symbol	Description		Symbol	Description
Group	A group, department, organization, or unit that contains multiple functional lanes (functional groups). Often the physical location where the tasks take place. Also referred to as a "pool."			Numbered item with a short description of an action performed by the function or persona.
Function	A persona or function that performs or is accountable for designated tasks in the process. Sometimes referred to as a "lane."			Numbered item that requires a choice to be made in the process, typically, an approval or a decision point.
	A process mapping shape used to define the "start" of the process.			Numbered item used to refer to another process.
	A process mapping shape used to define the "end" of the process.			Multi-page connector that links to another page when a process is too large to fit on a single page.

Symbol	Description		Symbol	Description
→	Sequence flow showing the logical direction of information and tasks.		[dotted line with bracket]	A text description to add clarity or context to any point of the process. (Although the narrative process note provides a more robust option.)

Core workflow 1: Awareness and demand generator

Overview of awareness and demand generator processes

No.	Process name	Personas	Objectives	Task set
	Title	Individuals interacting to complete the process.	A concrete statement describing what the process seeks to achieve.	The general set of activities performed within the process.
A	Generate reminders	● HSA ● CHN ● Volunteer ● Client	To communicate to the client or parent/guardian if a client is due now, due on a future date, or past due date for immunization.	*Starting point: HSA checks if client is due for immunization.* ● Checklist of clients due for immunization. ● Confirm clinic/outreach dates. ● Send reminder message to client. ● Send reminder message to CHW. ● Receive message reminder (client/CHW).
B	Immunization follow-up	● HSA ● CHN ● Volunteer	To identify children who are due to come for vaccination, missed their follow-up dates, and are now past due.	*Starting point: HSA checks registry and determines if immunizations were missed.* ● Review planned immunization list and determine if some were missed. ● Determine if CHW is available in the area. ● Follow up with CHW to ensure child is vaccinated. ● Record vaccination event. ● Plan for follow-up at clinic/outreach session for missed vaccinations.

Process flows: A. Generate reminders
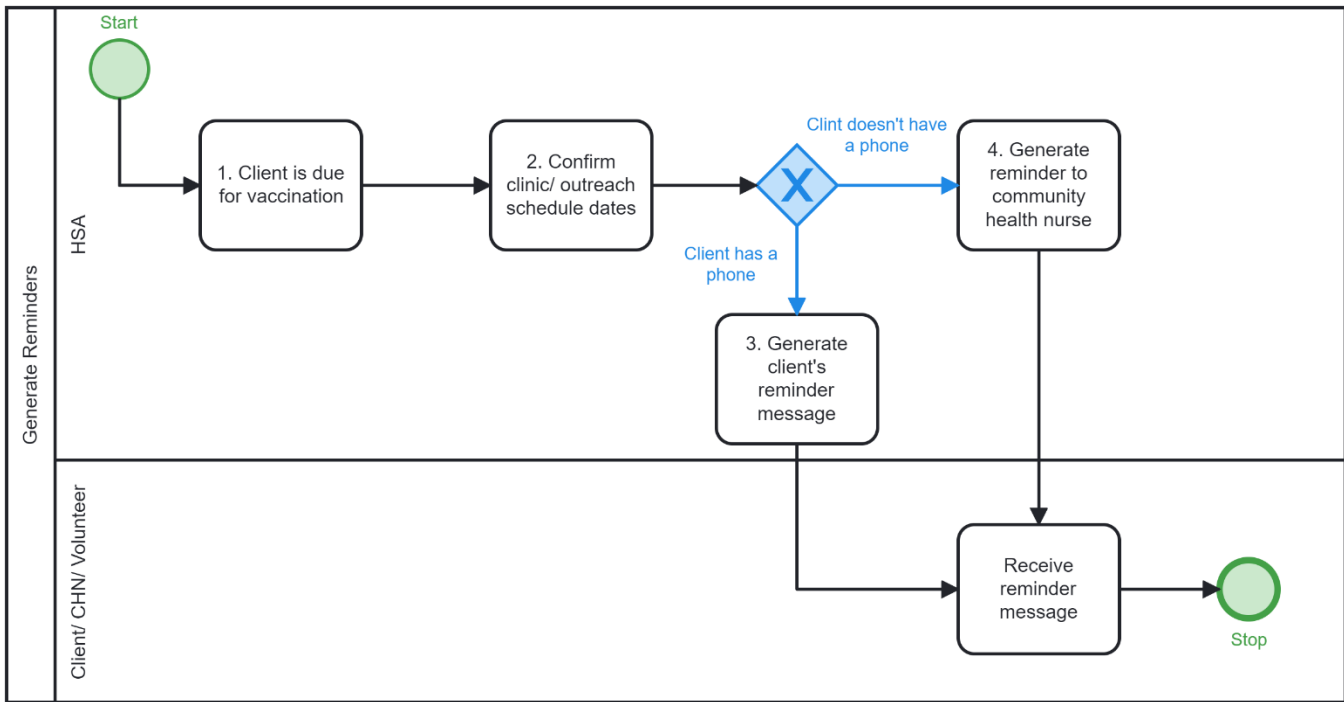
Data elements

	Data element label	Description and definition
A1	Client ID	Unique, system-generated patient ID.
A2	Client name	Client's first and last name.
A3	Vaccination	Client's required vaccination according to schedule.
A4	**Vaccination status**	**Current status of required vaccine.**
	Vaccine due	Vaccination is due.
	Vaccine overdue	Vaccination is overdue.
A5	Client contact number	Client's or guardian's contact number, if available.
A6	Facility name	The name of the facility.
A7	Facility location	Physical address where the facility is located.
A8	Outreach start date	Start date of vaccination outreach.
A9	Outreach end date	End date of vaccination outreach.
A10	Reminder message to CHW (template)	
A11	CHW name	CHW's first and last name.
A12	CHW operation location	CHW's operation location.

Process flows: B. Immunization follow-up
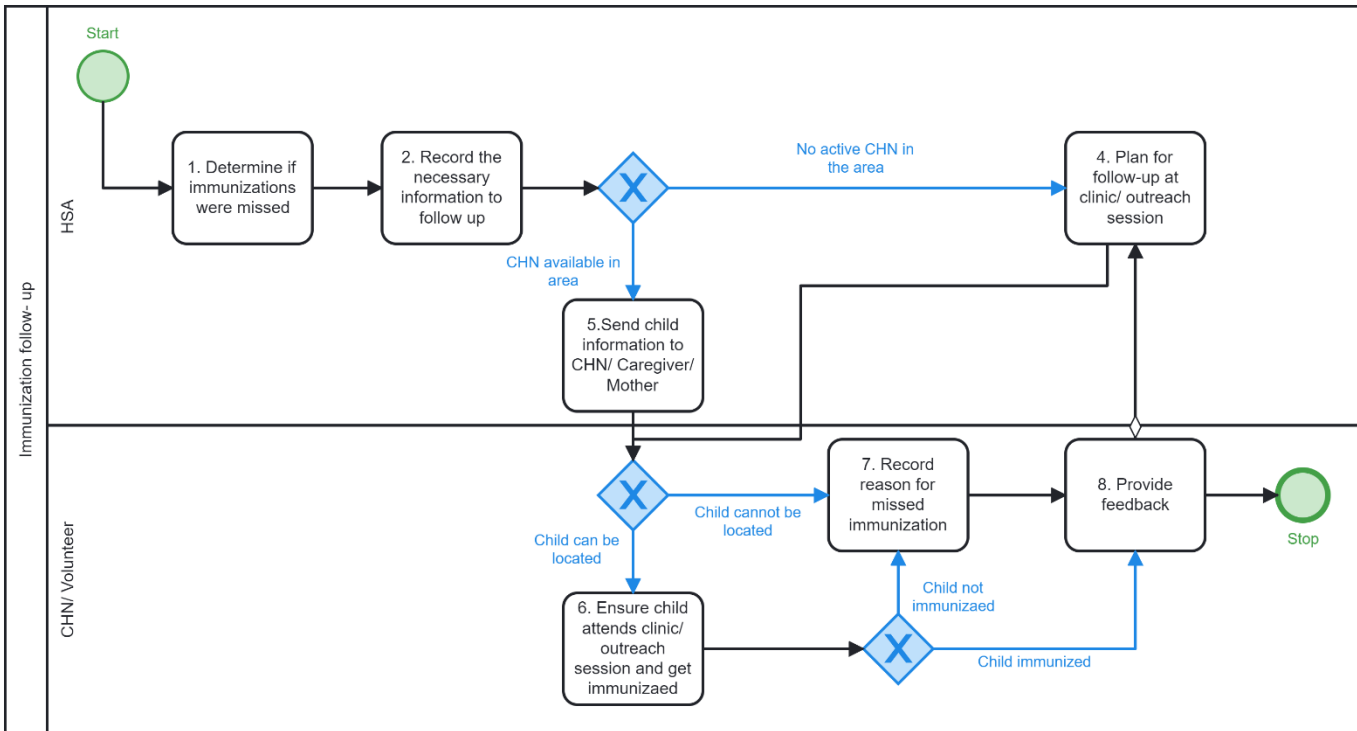
Data elements

Note: Data elements with an asterisk* represent elements that have been pulled from another process.

	Data element label	Description and definition
	Search immunization event record for missed immunizations	
B1	Client ID*	Unique, system-generated patient ID.
B2	Client name*	Client's first and last name.
B3	Vaccination*	Client's required vaccination according to schedule.
B4	**Vaccine status – overdue***	**Current status of required vaccine.**
B5	Client contact number*	Client's or guardian's contact number, if available.
B6	Facility name*	The name of the facility.
B7	Facility location*	Physical address where the facility is located.
B8	Outreach start date*	Start date of vaccination outreach.
B9	Outreach end date*	End date of vaccination outreach.

Core workflow 2: Plan and manage service delivery

Overview of key plan and manage service delivery processes

No.	Process name	Personas	Objectives	Task set
	Title	Individuals interacting to complete the process	A concrete statement describing what the process seeks to achieve	The general set of activities performed within the process
C	Plan service delivery	• HSA	To prepare for an immunization clinic, either at the facility or done on an outreach basis.	*Starting point: HSA wants to prepare for an immunization clinic or outreach.* • Collect community demographic data. • Conduct situational analysis. • Conduct stakeholder analysis. • Session planning. • Logistics and supply forecasting. • Develop annual workplan.

Process flows: C. Plan service delivery
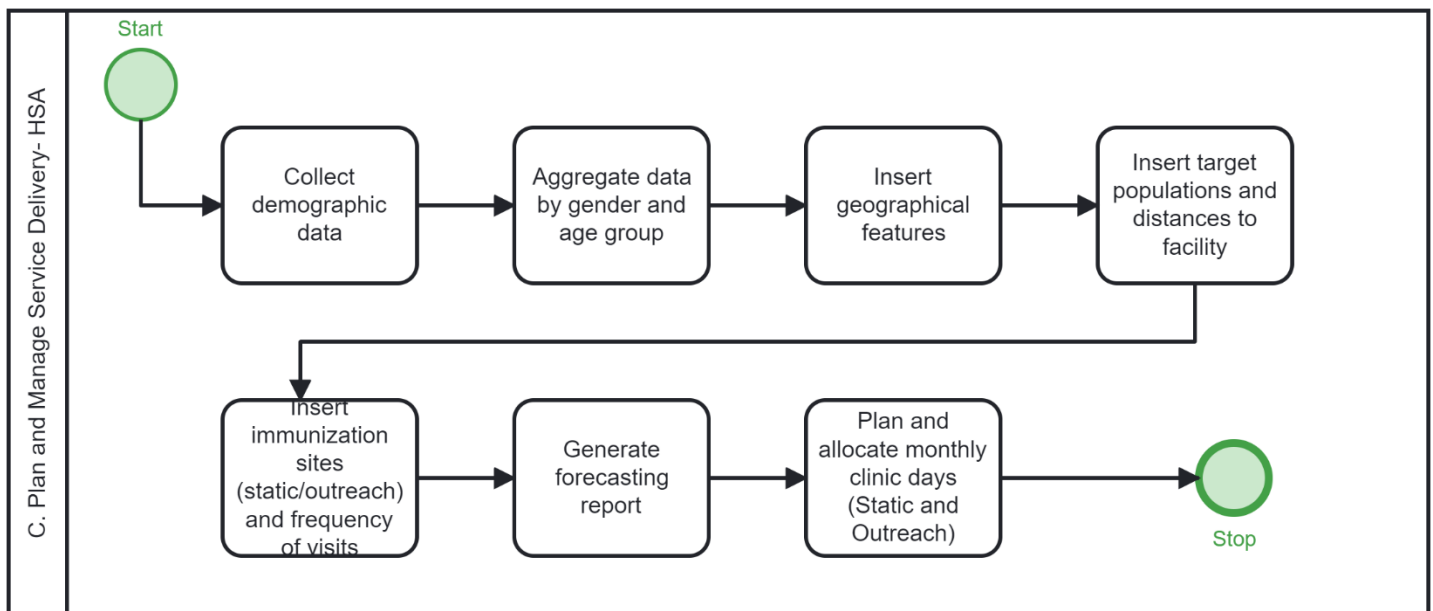
Data elements

	Data element label	Description and definition
C1	Facility ID	The unique identifier for the facility.
C2	Facility name	The name of the facility.
C3	Facility address	The address of the facility.
C4	**Facility type**	**The type of facility.**

	Data element label	**Description and definition**
	Level 1 – Community facility	These are run by certified medical clinical officers.
	Level 2 – Health dispensaries/posts	These facilities are run by clinical officers.
	Level 3 – Health centers	These are small health facilities with minimal services; they offer first line of support to clients and patients. They are run by clinical officers and nurses.
	Level 4 – Community and rural hospitals	These are small hospitals with minimal facilities, yet some offer services like the big hospitals. They are run by at least one doctor, clinical officers, and nurses.
	Level 5 – District hospitals	These are hospitals that offer holistic services and are run by a director who is a medic and at best a doctor by profession.
	Level 6 – Central/referral hospitals	These are referral hospitals. They are run by directors who are medics by profession and have over 100 beds capacity for their inpatients. They also do research and offer specialized treatments to patients.
	Mobile	This is a mobile (i.e., temporary) immunization clinic.
C5	**Facility ownership**	**Type of organization that owns the facility.**
	Government-owned	The facility is government-owned.
	Not-for-profit	The facility is not-for-profit-owned.
	For-profit	The facility is for-profit owned.
C6	Facility location (physical address)	Physical address where the facility is located.
C7	Facility contact information	Contact information for the facility.
C8	Record date	Date when facility was recorded on the register.
C9	Operational status	Operational status of the facility.
C10	Administrative level/areas	Administrative level of the facility.
C11	Geographic coordinates (GPS)	Global positioning system coordinates.
C12	Vaccine units in stock	Number of vaccine units in stock.
C13	Vaccine units required	Number of vaccine units required.
C14	Vaccine units shortfall	Number of vaccine units shortfall.
C15	Next clinic date	The date that the next immunization clinic is scheduled.
C16	Number of clients due	Number of clients due at the next immunization clinic.
C17	Number of clients overdue	Number of clients overdue at the next immunization clinic.
C18	Vaccine product name	The name of the vaccine.
C19	Vaccine product description	The description of the vaccine.
C20	Product ID	The vaccine product code.
C21	Vaccines doses ordered	Number of vaccine doses ordered.

	Data element label	Description and definition
C2 2	Stock request date	Date new vaccine stock ordered.
C2 3	Stock request number	Unique identifier for the stock request (order).
C2 4	Stock requestor ID	The UID (provider ID) of the person requesting stock, if available.
C2 5	Stock requestor first name	The first name of the person requesting stock, if UID not available.
C2 6	Stock requestor last name	The first name of the person requesting stock, if UID not available.
C2 7	Number of vaccine doses dispensed	Number of vaccine doses dispensed/removed from fridge at facility to prepare for clinic.

Core workflow 3: Administer and document care

Overview of key administer and document care processes

No.	Process name	Personas	Objectives	Task set
	Title	Individuals interacting to complete the process	A concrete statement describing what the process seeks to achieve	The general set of activities performed within the process
D	Register client	● HSA	To start and contribute to the client's lifelong vaccine record.	*Starting point: HSA wants to register client information into the health record.* • Query the client record. • Create client record. • Update a client health profile.
E	Query client record	● HSA	To correctly locate or identify a client's immunization record as well as review and update a client's record to provide a client's complete immunization history.	*Starting point: Client immunization visit.* • Search for the client. • Determine if there is an exact match, or partial matches. • Use additional search criteria to establish an exact match. • Create a new registration.
F	Anthropometric measurements	● HSA ● Volunteer	To take client's measurements and record in the growth chart.	*Starting point: Client has completed registration process.* • Record client's weight. • Record client's height. • Record client's MUAC. • Determine if child is severely malnourished or has high fever.
G	Administer vaccine	● HSA	To determine what vaccines a client needs, administer those, and record the relevant necessary data both in the system as well as on the appropriate health profile.	*Starting point: Client requires vaccination.* • Query the client record. • Determine vaccine is available and safe to give. • Prepare and administer the vaccine. Record appropriate data. • Monitor for adverse events, and counsel and refer for treatment and record event as appropriate. • Schedule next visit. • Generate the digital certificate if needed.

No.	Process name	Personas	Objectives	Task set
H	De-duplication of client records	• HSA	To identify duplicate client records and consolidate them into one most accurate/suitable (best) record.	*Starting point: Identify duplicate client records and flag for evaluation.* • Flag duplicate records for evaluation. • Produce a list of the duplicate records and review them. • Determine if they can be merged into a single record. • Merge as appropriate or mark as not duplicate.
I	De-duplication of vaccine events	• HSA	To identify duplicate vaccination events within a client record and update into one event.	*Starting point: Identify duplicate vaccine events and flag for evaluation.* • Identify potential duplicate events. Determine duplicate events. • Update record appropriately. • Generate report to show the resolution.

Process flows: D. Register client
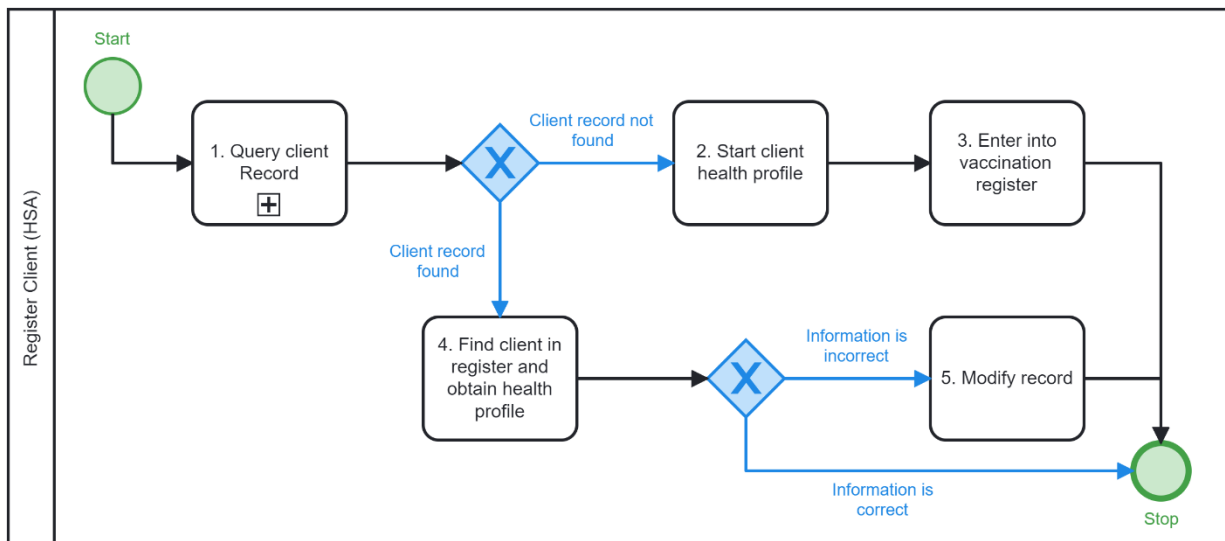
Data elements

	Data element label	Description and definition
D1	Client ID	Unique, system-generated patient ID.
D2	Facility code	Code of the facility.
D3	Catchment area	Area whereby the facility is located.

	Data element label	Description and definition
D4	Client's birth registration number	Client's birth registration ID.
D5	Client first name	Client's first or given name.
D6	Client family name	Client's last or family name.
D7	Client birthdate	Client's date of birth, capturing day, month, and year of birth.
D8	Age	Estimated age in years/months of the client, captured if client birthdate is unknown.
D9	**Gender**	**Client's biological sex at birth, either male or female.**
	Male	Client identifies as male.
	Female	Client identifies as female.
D10	Contact number	Number where client may be reached.
D11	Client physical address	Client's address, including village name, landmark, and region.
D12	Next of kin (guardians)	Client's next of kin details, including name, address, relationship, religion, occupation, source of income, marital status, TA, and contact number.

Process flows: E. Query client record
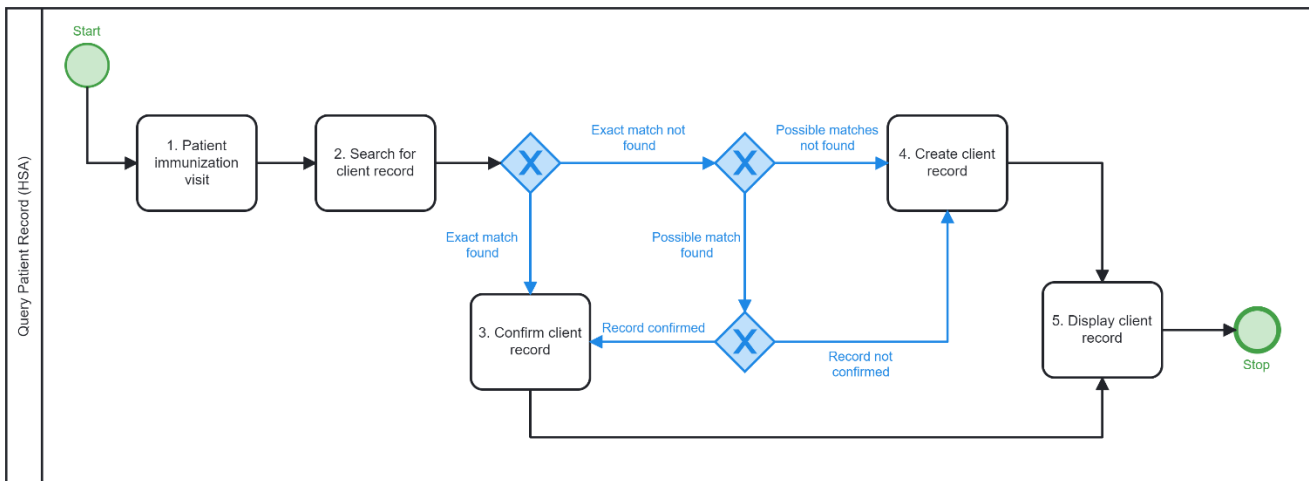
Process flows: F. Anthropometric measurements
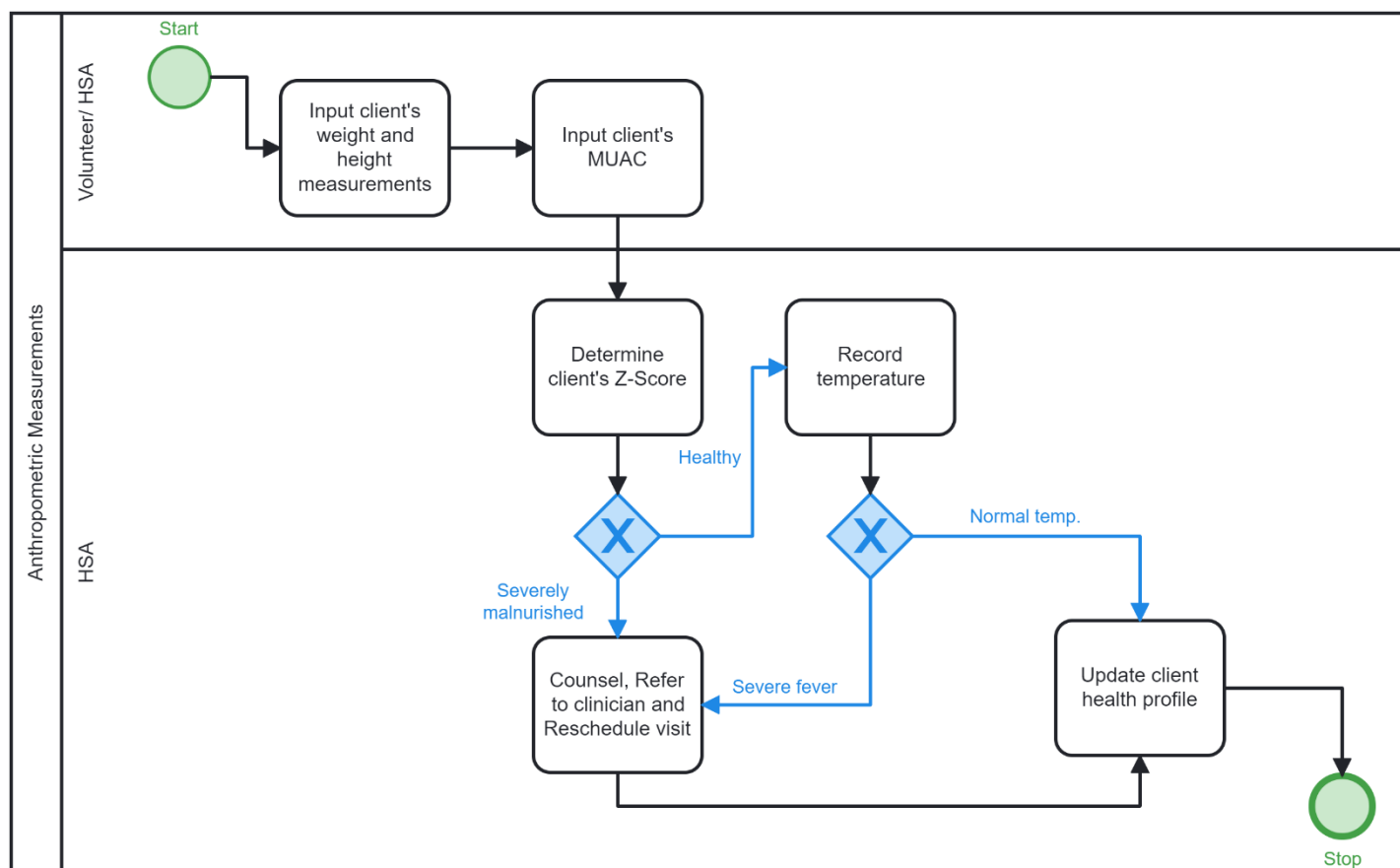
Data elements

Note: Data elements with an asterisk* represent elements that have been pulled from another process.

	Data element label	Description and definition
E1	Client ID*	Unique, system-generated patient ID.
E2	Client first name*	Client's first or given name.
E3	Client family name*	Client's last or family name.
E4	Client birthdate*	Client's date of birth, capturing day, month, and year of birth.
E5	Age*	Estimated age in years/months of the client, captured if client birthdate is unknown.
E6	**Gender***	**Client's biological sex at birth, either male or female.**
	Weight	Client's weight.
	Height	Client's height.
E7	MUAC	Client's upper arm circumference measurements.
E8	Z-score (severely malnourished/healthy)	Client's Z-score indicators.
E9	Temperature (severe fever/ normal)	Temperature of client.

E10	Referral details	Details of referral if necessary.

Process flows: F. Administer vaccine
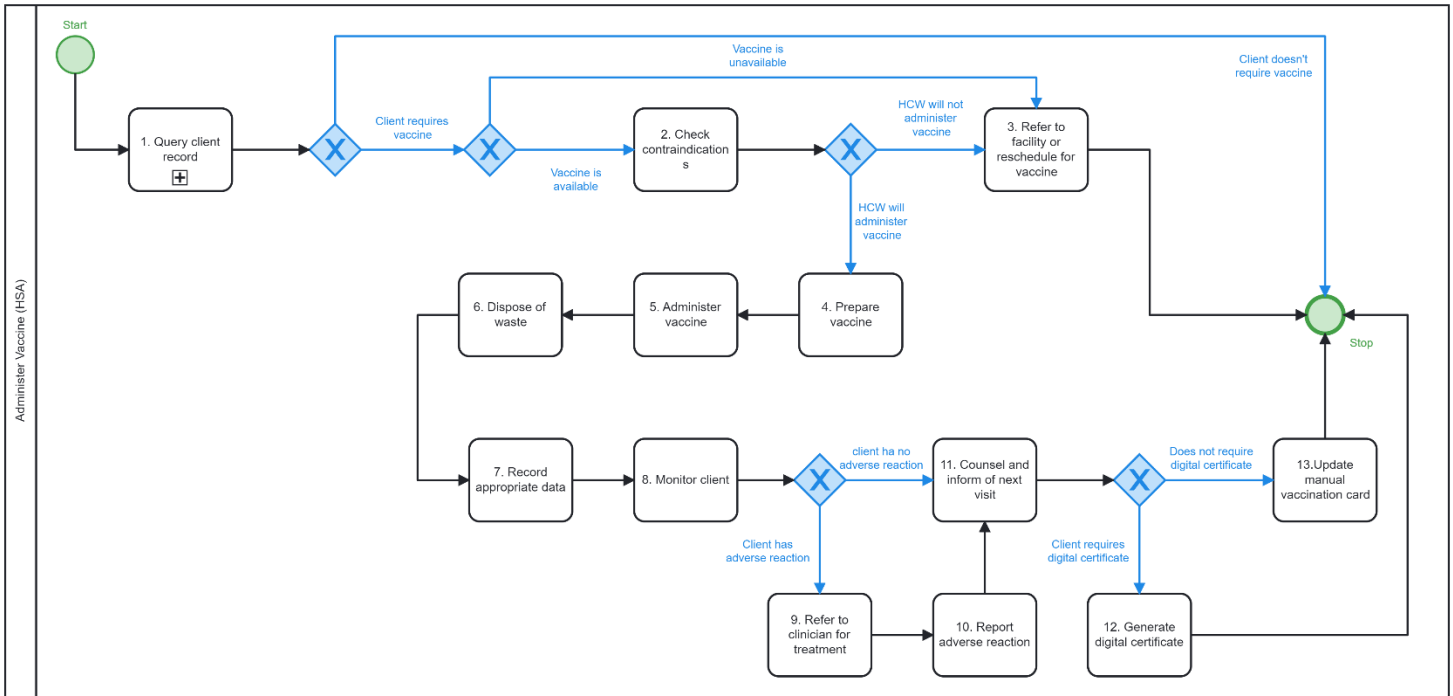
Data elements

Note: Data elements with an asterisk* represent elements that have been pulled from another process.

	Data element label	Description and definition
F1	Client details (search)*	Search any client registration details.
F2	Display client record*	Display client record.
F3	**Vaccine schedule**	**Display client's current vaccine card.**
	Vaccine type	The type of vaccine.
	Vaccine dose	Vaccine dose i.e., first, second, third, first booster, etc.
	Vaccination status	Vaccine due/missed/requested (non-routine).
	Vaccine available (Y/N)	Is vaccine available at the moment?
F4	Allergies	Has the client had any severe, life-threatening allergies to vaccines or anything else?
F5	Health status (fever or severely malnourished)	Is the client currently very sick and/or have a very high temperature (>39°C).
F6	Administer vaccine (Y/N)	Does the HCW recommend the vaccine be administered?
F7	**Reason for non-administration of vaccine**	**Reason for non-administration of vaccine.**
	Stockout	Reason for non-administration of vaccine is vaccine stockout.
	Postpone	Reason for non-administration of vaccine is vaccination has been postponed.

	Data element label	Description and definition
	Contraindication	Reason for non-administration of vaccine is vaccine contraindication.
	Guardian refusal (religious beliefs, adverse event following immunization [AEFI])	Reason for non-administration of vaccine is guardian refusal.
	Other (specify)	Reason for non-administration of vaccine other (specify).
F8	Client first name*	Client's first or given name.
F9	Client family name*	Client's last or family name.
F10	Client ID*	Unique, system-generated patient ID.
F11	Vaccine type*	The type of vaccine.
F12	Vaccine dose*	Vaccine dose i.e., first, second, third, first booster, etc.
F13	Vaccination status*	Vaccine administered/due/missed/requested (non-routine).
F14	Follow-up date	The scheduled date for immunization follow-up.
F15	Additional notes	Any additional notes.
F16	Vaccine type*	The type of vaccine.
F17	Vaccine product code	The vaccine product code.
F18	Vaccine dose*	Vaccine dose i.e., first, second, third, first booster, etc.
F19	Date of administration	Date that the vaccine was administered to the client.
F20	**Mode of administration**	**Route in which vaccine was administered.**
	Oral route (PO)	Oral vaccine is administered through drops to the mouth.
	Subcutaneous route (sub cut)	Subcutaneous injections are administered into the fatty tissue found below the dermis and above muscle tissue.
	Intramuscular route (IM)	Intramuscular injections are administered into the muscle through the skin and subcutaneous tissue.
F21	Vaccine batch number	The batch number of the vaccine for traceability purposes.
F22	Vaccine manufacturer (drop-down)	The manufacturer of the vaccine for traceability purposes.
F23	Place of administration*	The place where the vaccine was administered to the client.
F24	Vaccinator (provider ID)*	The UID of the person performing the vaccination, if available.
F25	Strategy	E.g., campaign, routine, school-based.
F26	Client ID*	Unique identifier generated for new clients or returned from a query to client registry.
F27	Client consent	Indicates if the client (or caregiver if client <18 years old) has given consent.
F28	Facility ID*	The unique identifier for the facility.
F29	Next visit date	Next date client is due for vaccination (immunization appointment).
F30	Client has an adverse reaction (Y/N)	Client has experienced an adverse reaction to the vaccine.
F31	**Type of adverse reaction experienced**	**Adverse reaction experienced by client.**
	Dizziness	Client has experienced an adverse reaction of dizziness.
	Screaming	Client has experienced an adverse reaction of screaming.
	Fainting	Client has experienced an adverse reaction of fainting.
	Anaphylactic shock	Client has experienced an adverse reaction of anaphylactic shock.

	Data element label	Description and definition
	Other (specify)	Specify any other adverse reaction experienced.
F32	**Identity**	
	Date AEFI reported first received at health facility	Date when the facility-level stage is created for the AEFI case.
	Country where this AEFI reported	The name of the country where the data are first entered.
	Location (address)	The geographic location of the case (address).
	Worldwide unique number	Unique number used for communicating the details of the case at the international level.
F33	**Patient identifier**	
	Patient identifier	The name of the patient or initials as decided by the country.
	Date of birth	Date of birth of patient.
	Sex	Male or female.
	Medical history	Medical history of patient.
F34	**Vaccine**	
	Primary suspect vaccine name (generic)	The vaccine that is suspected to have caused the AEFI.
	Other vaccines given just prior to AEFI	Other vaccines given just prior to AEFI.
	Vaccine batch number	Batch number of all vaccines mentioned above.
	Vaccine dose number for this particular vaccine	The dose number for the vaccine.
	Diluent batch/lot number	The batch/lot number (if applicable).
F35	**Event**	
	Date and time of vaccination	Date and time of vaccination.
	Date and time of AEFI onset	Date and time of AEFI onset.
	Adverse events	The case diagnosis + signs and symptoms.
	Outcome of AEFI	Recovered/resolved; recovering/resolving; not recovered/not resolved; recovered/resolved with sequelae; fatal; unknown.
	Serious	If the event resulted in death, threatened the patient's life, caused disability, hospitalization, or congenital anomaly.
F36	**Reporter**	
	Name of the first reporter of AEFI	Name of first reporter of AEFI.
	Institution/location	The address of the reporter.
	Position/department	Reporter's designation.
	Email ID	Reporter's email ID.
	Reporter's phone number	Telephone/contact number.
	Date of report	Date when the report was submitted by the reporter.
	Additional comments	Any additional comments.
F37	Next visit date	Client's next visit day.
F38	Additional comments	Any additional comments.
F39	Name*	The full name of the tested person.

	Data element label	Description and definition
F40	Date of birth*	The tested person's date of birth (DOB), if known. If unknown, use assigned DOB for administrative purposes.
F41	Unique identifier*	Unique identifier (ID) for the tested person, according to the policies applicable to each country. There can be more than one unique identifier used to link records (e.g., national ID, health ID, medical record ID).
F42	Vaccine type*	The type of vaccine.
F43	Vaccine product code*	The vaccine product code.
F44	Vaccine dose*	Vaccine dose, i.e., first, second, third, first booster, etc.
F45	Date of administration*	Date that the vaccine was administered to the client.
F46	Mode of administration*	Route by which vaccine was administered.
F47	Vaccine batch number*	The batch number of the vaccine for traceability purposes.
F48	Vaccine manufacturer*	The manufacturer of the vaccine for traceability purposes.
F49	Place of administration*	The place where the vaccine was administered to the client.
F50	Certificate number, date, issuing authority	Certificate details.

Process flows: G. De-duplication of client records
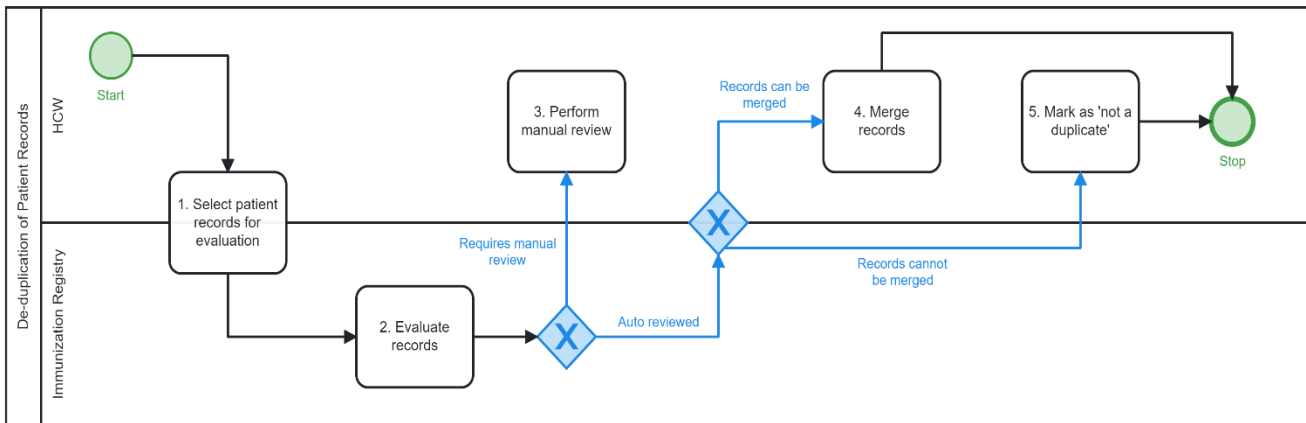
Process flows: H. De-duplication of vaccine events
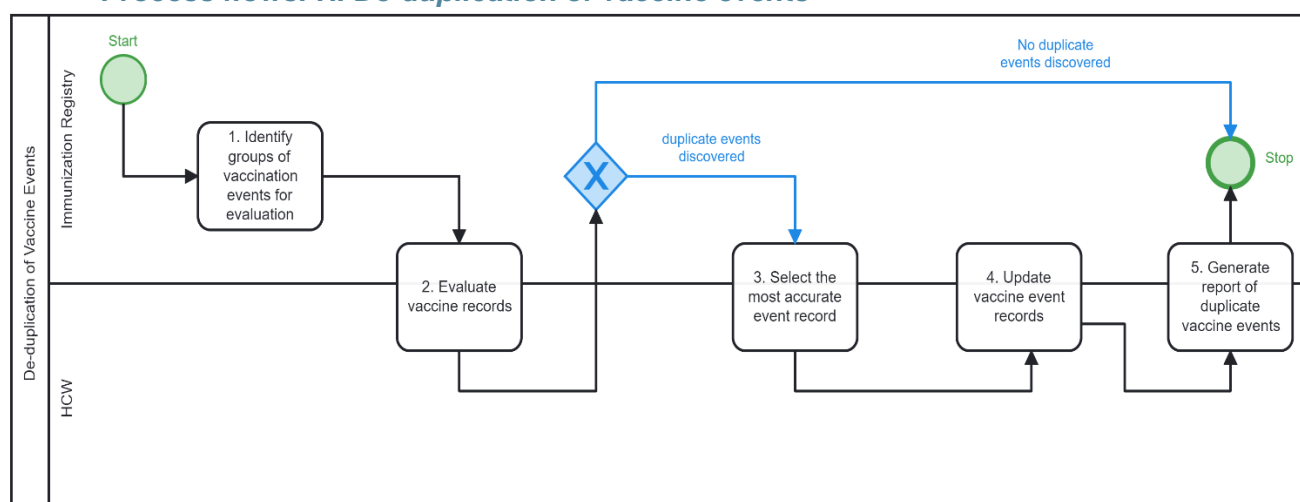
Core workflow 4: Manage inventory

Overview of key manage inventory processes matrix

No.	Process name	Personas	Objectives	Task set
	Title	Individuals interacting to complete the process.	A concrete statement describing what the process seeks to achieve.	The general set of activities performed within the process.
I	Manage vaccine arrivals	● CCT ● CCA ● National supply chain officer (NSCO)	To manage the arrival of vaccines to the national warehouse.	*Starting point: National warehouse receives the shipment.* ● Receive, inspect, and clear the shipment and update shipping form. ● Report any damaged shipment. ● Fill and submit vaccine arrival report.
J	Distribute supplies to region/district	● ISCO ● CCT ● EPI Coordinator	To issue a requisition to the regional store for vaccine stock.	*Starting point: The EPI coordinator estimates the vaccine stock need for the district.* ● Issue a requisition for vaccine stock to the regional store. ● Inspect stock delivery and record receipt. ● Update stock ledger. ● Notify requisition and receipt of stock to regional levels.

No.	Process name	Personas	Objectives	Task set
K	Distribute supplies to health center	● EPI Coord ● EPI focal person ● CCT ● SHSA	To submit usage on hand to the district store and receive vaccine stock.	*Starting point: The health center SHSA and EPI coordinator prepare vaccine usage report.* ● Prepare and submit vaccine usage report. ● Record receipt of stock. ● Update health center stock ledger. ● Notify district on rejected stock.
L	Manage inventory	● EPI focal person ● HAS/SHSA	To receive and request stock in the vaccine store.	*Starting point: The EPI focal person receives vaccines at the regional store.* ● Update ledger with received stock. ● Record loss and adjustments. ● Issue emergency requisition.

Process flows: I. Manage vaccine arrivals
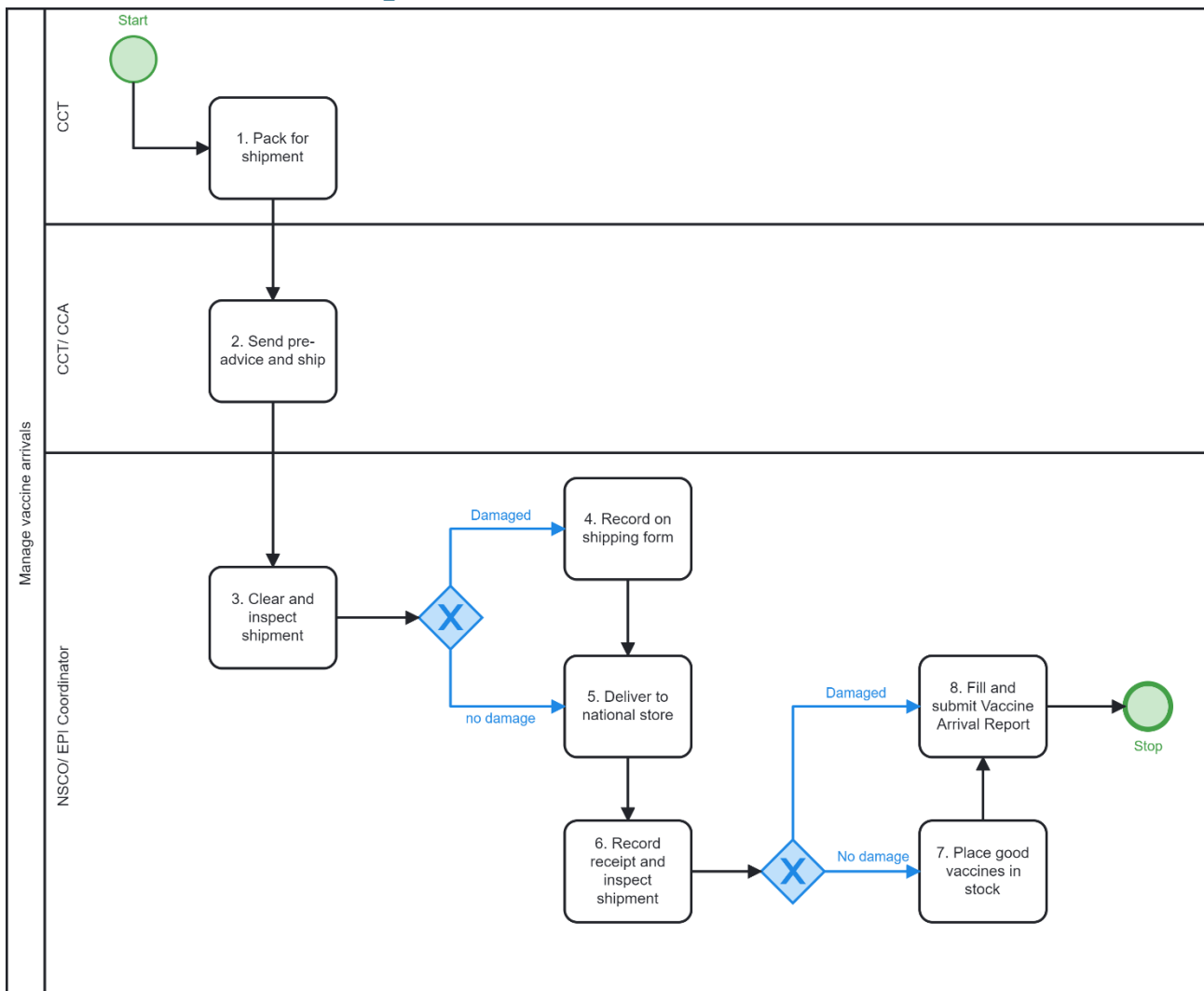
Process flows: J. Distribute supplies to region/district
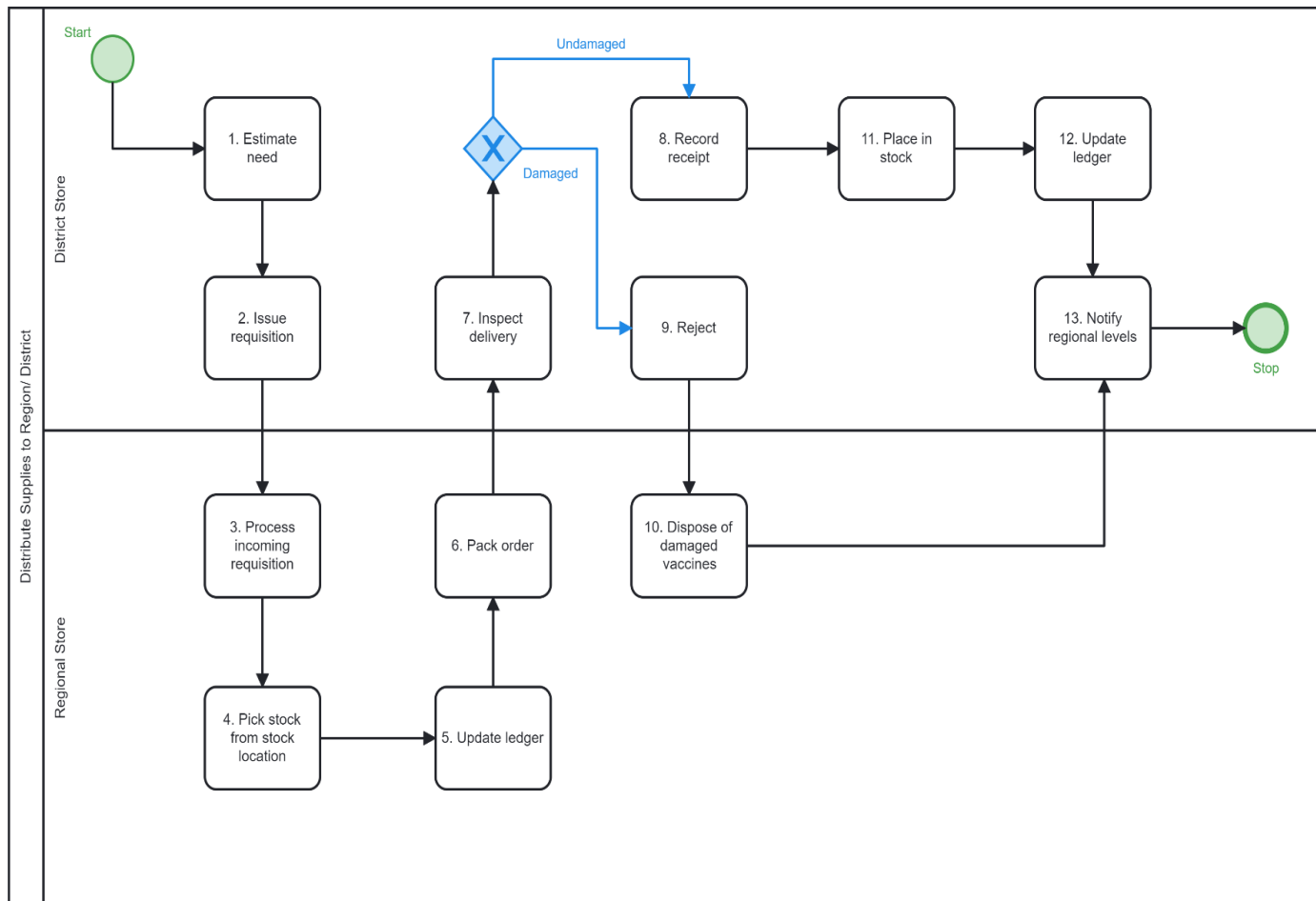
Process flows: K. Distribute supplies to health center
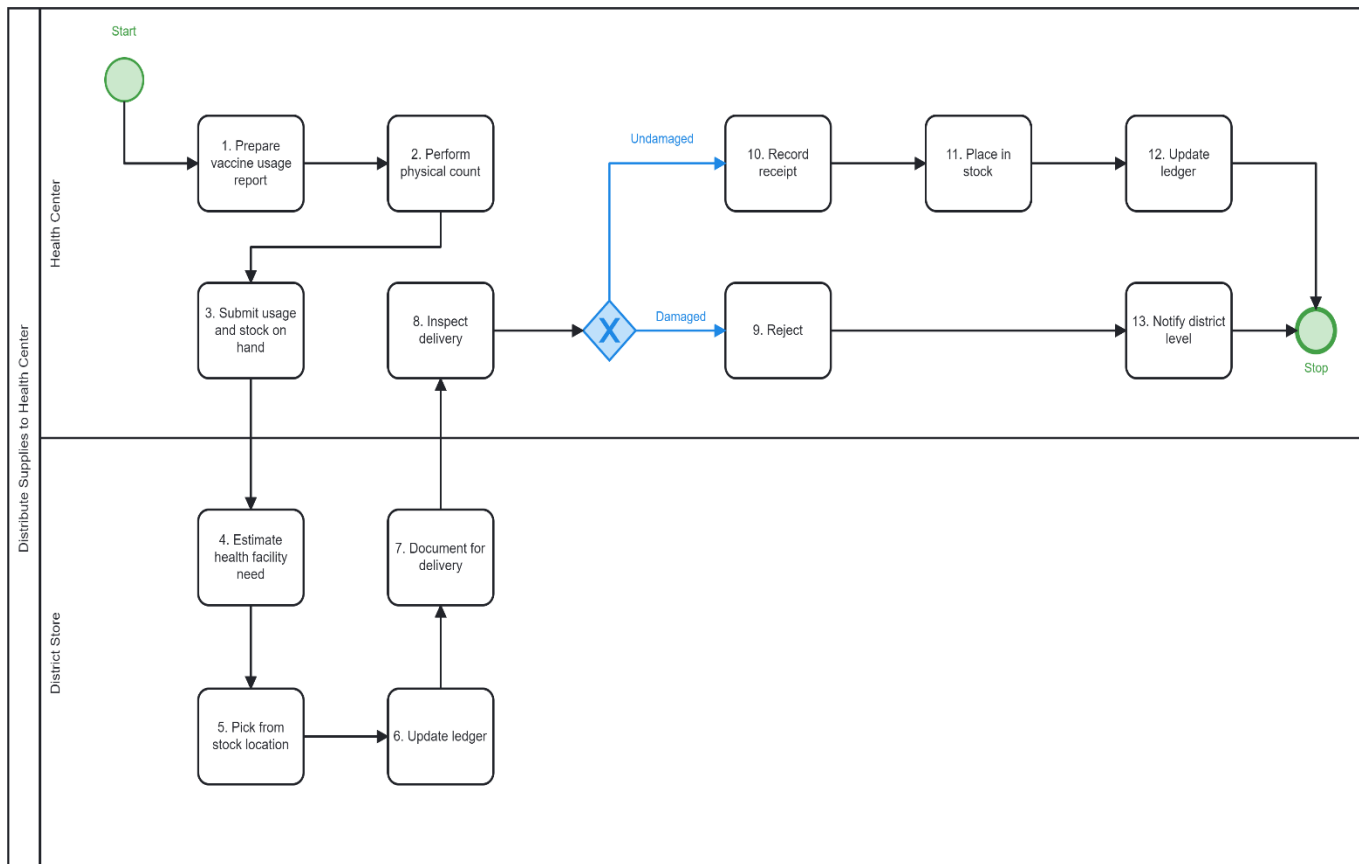
Process flows: L. Manage inventory
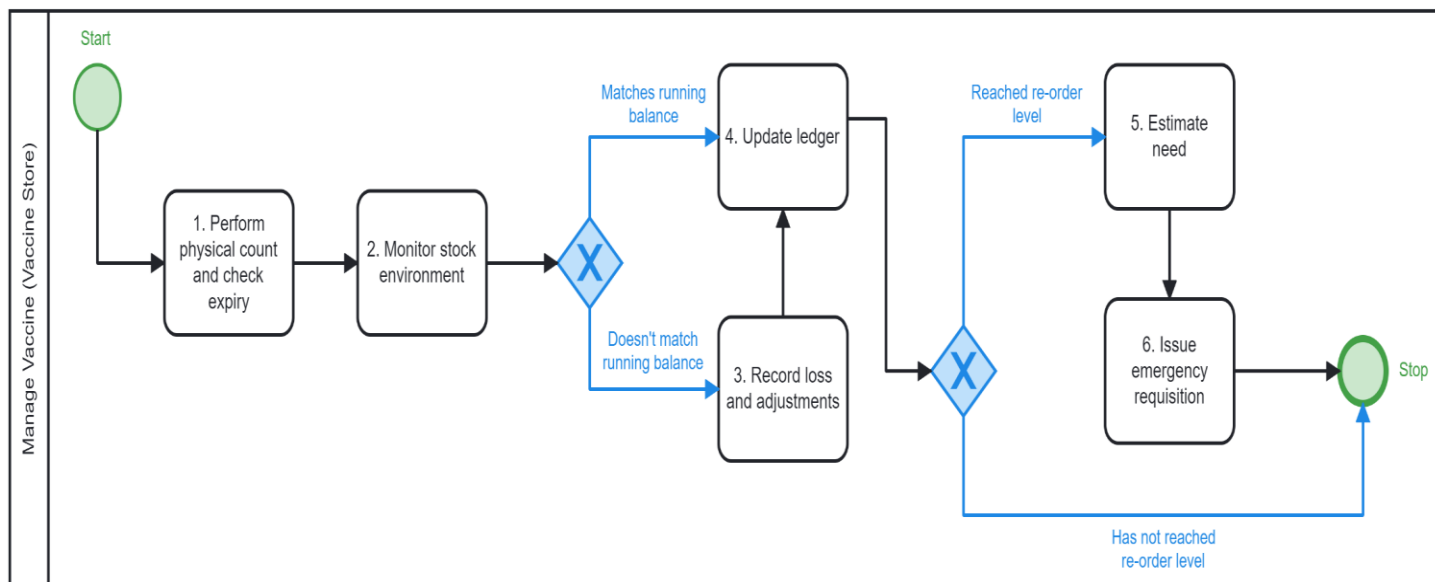
Data elements

	Data element label	Description and definition
L1	Date	Current date/date of report.
L2	Stock at beginning	Amount of stock at beginning of period.
L3	No. doses received	Total number of doses received during period.
L4	VVM (Stage: 1, 2, 3, 4)	VVM (Stage: 1, 2, 3, 4) of received vials.
L5	No. doses issued	Number of doses issued during period.
L6	VVM (Stage: 1, 2, 3, 4)	VVM (Stage: 1, 2, 3, 4) of issued vials.
L7	Place (sent to/received from)	Place (sent to/received from).
L8	Batch lot number	Batch lot number of vials received or sent.
L9	Name of manufacturer	Name of manufacturer.
L10	Expiry date	Expiry date of each batch.
L11	No. doses discarded	Number of doses discarded.
L12	Reason for discard	Reason for discard.
L13	Balance in stock (doses)	Balance in stock (doses) at end of period.
L14	Issued by	Issued by.

Core workflow 5: Monitoring and evaluation

Overview of key monitoring and evaluation processes

N o.	Process name	Process ID	Personas	Objectives	Task set
	Title	ID used to reference this process throughout the immunization SURD	Individuals interacting to complete the process	A concrete statement describing what the process seeks to achieve	The general set of activities performed within the process
M	Generate Reports	IMZ.K	• HSA	The objective is to provide the ability to access and analyze data to improve immunization program decision-making. This process outlines the general process to generate a variety of reports that are routinely needed by IIS, providers, and other partners.	*Starting point: Time for periodic (usually monthly) reporting.* • Check data quality. • Correct fixable errors. • Generate and review aggregate reports. • Provide feedback on any changes required.

Process flows: M. Generate reports
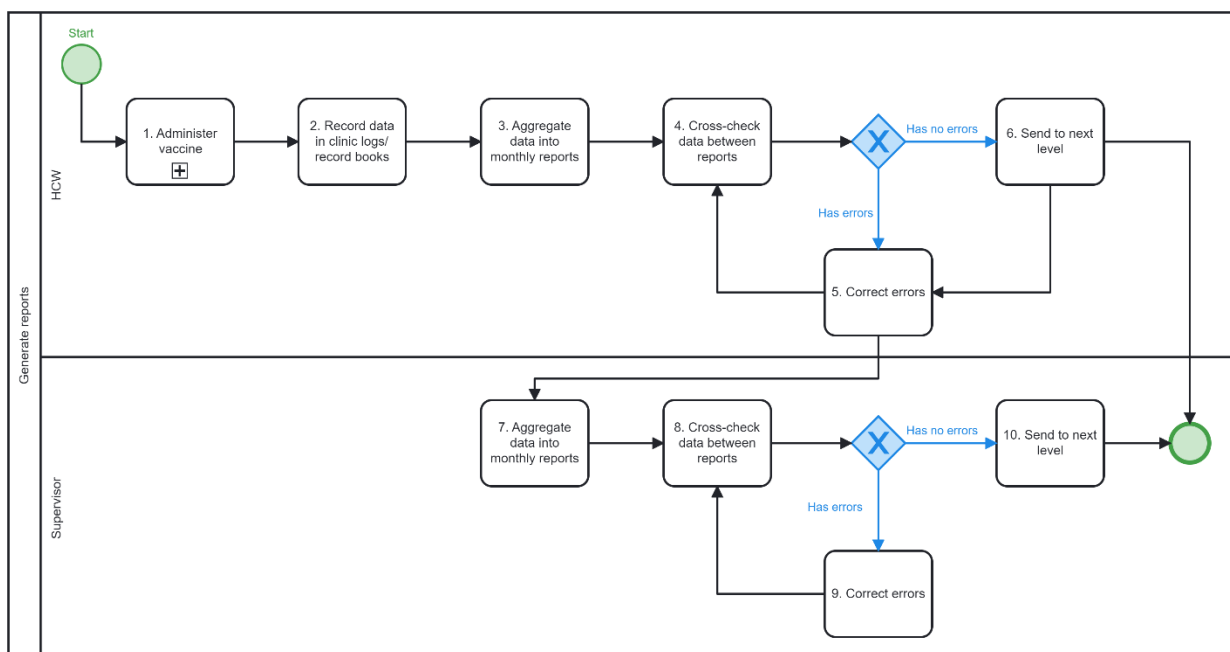
Data elements

	Data element label	Description and definition
M1	Unique identification	Unique identifier generated for new clients, or a universal ID, if used in the country.
M2	Report identification	A unique identifier for the instance of the report that has been generated.
M3	Report status	The status of the report (for example, initial, complete, etc.).
M4	Report type	The type of report which has been generated (i.e., is the report a list of individuals, a summary, etc.).
M5	Report indicator code	The indicator or measure definition which is being reported on (for example: dropout rate, defaulters, etc.).
M6	Coverage rate	Report generated indicates the coverage rate of vaccinations versus target population.
M7	Dropout rate	Report generated indicates the aggregate dropout rate based on antigen.
M8	Immunization sessions conducted	Report generated indicates the immunization session conducted.
M9	Availability of vaccine and injection supplies	Report generated contains summary data related to availability of vaccine and injection supplies.
M10	Wastage of vaccine and injection supplies	Report generated contains summary data related to wastage of injection supplies.
M11	Adverse events following immunization	Report generated contains summary data related to adverse events following immunization.
M12	Report subject area	Location (facility or place) for which the data in the report are being represented.
M13	Report generation date	The date on which the report was generated.
M14	Reporting period	The period for which data in the report have been included (for example: from 2021-01-01 until 2021-02-01).
M15	Improvement indicator	Indicates to the receiver how to interpret the data (i.e., what constitutes an improvement or deterioration).
M16	Increase is improvement	Indicates that when the measure scores increase, the data can be interpreted as an improvement (used for coverage indicator).
M17	Decrease is improvement	Indicates that when measure scores decrease, the data can be interpreted as an improvement (used for dropout, wastage, AEFI indicators).
M18	Report generator/author	Indicates the organization or location which is generating or producing the report.
M19	Report measures	Grouping of information related to the values of a measure for each population group in the report.
M20	Measure identifier/meaning	Codifies the meaning of the group/measure. For example, if the report indicator is "Coverage," each antigen/vaccine would have a measure (i.e., BCG coverage or BCG target).
M21	Measure population	Information related to the population of the reported measure/score in this group. For example, if the indicator being reported is "BCG coverage," it would represent the population for that grouping.
M22	Measure numerator	The count of individual objects (persons, doses, etc.) that was used as the numerator to calculate the measure score.

	Data element label	Description and definition
M23	Measure denominator	The count of individual objects (persons, doses, etc.) that was used as the denominator to calculate the measure score.
M24	Measured score	The calculated score of the measure/indicator that is being reported on.
M25	Disaggregation	The stratification values within the group – each will track the disaggregation of each indicator (column I of annex C).
M26	Disaggregation group meaning	Indicates the overall strata or disaggregation which is being represented in the report (for example: by gender, by region, by age group, etc.).
M27	Disaggregation measures	An individual grouping of population and measures for the specified stratification. For example, if the stratifier is "by gender," then there would be a "male" or "female" stratum.
M28	Disaggregation measure identifier/meaning	The type or value this stratum represents (male, female, region 1, dose 3, etc.).
M29	Disaggregation measure population	A description of the population which makes up this stratifier.
M30	Disaggregation numerator	The count of individual objects (persons, doses, etc.) which were used as the numerator for the disaggregation score.
M31	Disaggregation denominator	The count of individual objects (persons, doses, etc.) which were used as the denominator for disaggregation score.
M32	Disaggregated score	The computed score for this disaggregation. For example:
		Report indicator: Coverage.
		Measure: BCG vaccination coverage.
		Population numerator: All BCG doses given for period.
		Population denominator: Population of surviving infants.
		Disaggregation grouping: By gender.
		Disaggregation measure meaning: Male.
		Disaggregation population numerator: # of males given BCG.
		Disaggregation population denominator: # of surviving infant males.
		Disaggregation score: # of males given BCG / # of surviving infant males.

Reports

ID	Name of report
1	Number of children vaccinated with malaria vaccine.
2	Number of children vaccinated with MR 1, MR 2, and PENTA 3 in MV implementation districts.
3	Malaria vaccine coverages – cumulative.
4	Penta and measles-rubella 1 coverage, number of unvaccinated children and dropout rate by district.
5	Doses of OPV administered and coverage by district.
6	Doses of BCG and measles-rubella 2 administered and coverage by district.
7	Doses of PCV administered and coverage by district.
8	Doses of rotavirus vaccine administered and coverage by district.

ID	Name of report
9	Doses of Td administered and coverage by district.
10	Number of children protected at birth and fully immunized, by district.
11	Number of outreach clinics performed and canceled by district.
12	Number of children vaccinated with malaria vaccine by district.
13	Doses of HPV 1 and HPV 2 administered and coverage by district.
14	Doses of vitamin A administered and coverage by district.
15	Doses of dewormer administered and coverage by district.

Decision support logic: Vaccine schedule

Visit	Age	Antigen
1	At birth	BCG, OPV0
2	6 weeks	OPV1, Pentavalent 1, PCV1, Rota 1
3	10 weeks	OPV2, Pentavalent 2, PCV2, Rota 2
4	14 weeks	OPV3, Pentavalent 3, PCV3, IPV
5	5 months	MV1
6	6 months	MV2, vitamin A (vitamin A continues twice per year until the child is 5 years)
7	7 months	MV3
8	9 months	MR1, TCV (9 months–under 15 years)
9	15 months	MR2
10	22 months	MV4
11	9 years	HPV1, HPV2 (2nd dose after 6 months) for girls up to 14 years
12	12 years above	Pfizer
13	15 years	Td (2nd after 4 weeks, 3rd after 6 months, 4th after 5 years) for pregnant women and women of childbearing age up to 45 years
14	18 years above	AstraZeneca, Janssen (Johnson & Johnson)

Indicators

EPI INDICATORS					
1. Routine Immunization	**Name of Indicator**	**Definition**	**Calculation of indicator**		**Multiplying factor**
	Completeness of reports	Absolute number of reports received		Number of monthly reports received	Number
		Number of reports received at given period out of the expected reports to receive at that given period	Numerator	Number of reports received	100
			Denominator	Total reports expected to receive	
	Timeliness of reports	Absolute number of reports received on timely in reporting period		Number of reports received on time	
		Proportion of reports received from the expected reports to receive	Numerator	Number of reports received on time	100
			Denominator	Number of reports expected to receive	
	Planned static immunization sessions	Absolute number of static immunization sessions planned per month		Number of static sessions planned	Number
	Static immunization sessions conducted	Absolute number of static immunization sessions conducted per month		Number of static immunization sessions conducted	Number
	Planned outreach immunization sessions	Absolute number of planned outreach sessions per month		Number of planned outreach sessions	Number
	Outreach immunization sessions canceled	Absolute number of outreach immunization sessions canceled		Number of outreach immunizations sessions canceled	Number
	Outreach immunization sessions canceled	Percentage of outreach immunization sessions canceled	Numerator	Number of outreach sessions canceled	100
			Denominator	Total number of planned outreach sessions	
	Protected at birth	Total infants protected at birth against neonatal tetanus		Number of infants protected at birth against neonatal tetanus	Number
	BCG vaccinations	Total BCG vaccinations given per month		Number of BCG vaccinations administered	Number
	OPV 0 vaccinations	Total OPV 0 vaccinations given per month		Number of OPV 0 doses administered	Number
	OPV 1 doses administered	Total OPV 1 doses given per month		Number of OPV 1 vaccinations administered	Number
	OPV 2 doses administered	Total OPV 2 doses given per month		Number of OPV 2 vaccinations administered	Number

	OPV 3 doses administered	Total OPV 3 doses given per month		Number of OPV 3 vaccinations administered	Number
	IPV vaccinations given	Total IPV vaccinations given per month		Number of IPV vaccinations administered	Number
	DTP-HepB-Hib 1 vaccinations given	Total DTP-HepB-Hib 1 vaccinations given per month		Number of DTP-HepB-Hib 1 vaccinations administered	Number
	DTP-HepB-Hib 2 vaccinations given	Total DTP-HepB-Hib 2 vaccinations given per month		Number of DTP-HepB-Hib 2 vaccinations administered	Number
	DTP-HepB-Hib 3 vaccinations given	Total DTP-HepB-Hib 3 vaccinations given per month		Number of DTP-HepB-Hib 3 vaccinations administered	Number
	PCV 13_1 vaccinations given	Total PCV 13_1 vaccinations given per month		Number of PCV 13_1 vaccinations administered	Number
	PCV 13_2 vaccinations given	Total PCV 13_2 vaccinations given per month		Number of PCV 13_2 vaccinations administered	Number
	PCV 13_3 vaccinations given	Total PCV 13_3 vaccinations given per month		Number of PCV 13_3 vaccinations administered	Number
	Rota 1 doses administered	Total Rota 1 vaccinations given per month		Number of Rota 1 vaccinations administered	Number
	Rota 2 doses administered	Total Rota 2 vaccinations given per month		Number of Rota 2 vaccinations administered	Number
	Measles 1 vaccinations given	Total measles-rubella 1 vaccinations given per month		Number of measles 1 vaccinations administered	Number
	Measles 2 vaccinations given	Total measles-rubella 2 vaccinations given per month		Number of measles 2 vaccinations administered	Number
	Children under 1 fully immunized	Total children under 1 fully immunized per month		Number of under-1 children fully immunized	Number
	Td 1 vaccinations given to pregnant women	Total Td 1 vaccinations given to pregnant women per month		Number of Td 1 vaccinations administered to pregnant women	Number
	Td 2 vaccinations given to pregnant women	Total Td 2 vaccinations given to pregnant women per month		Number of Td 2 vaccinations administered to pregnant women	Number
	Td 3 vaccinations given to pregnant women	Total Td 3 vaccinations given to pregnant women per month		Number of Td 3 vaccinations administered to pregnant women	Number

	Td 4 vaccinations given to pregnant women	Total Td 4 vaccinations given to pregnant women per month		Number of Td 4 vaccinations administered to pregnant women	Number
	Td 5 vaccinations given to pregnant women per month	Total Td 5 vaccinations given to pregnant women per month		Number of Td 5 vaccinations administered to pregnant women	Number
	Td 1 vaccinations given to women of childbearing age	Total Td 1 vaccinations given to women of childbearing age per month		Number of Td 1 vaccinations administered to women of childbearing age	Number
	Td 2 vaccinations given to women of childbearing age	Total Td 2 vaccinations given to women of childbearing age per month		Number of Td 2 vaccinations administered to women of childbearing age	Number
	Td 3 vaccinations given to women of childbearing age	Total Td 3 vaccinations given to women of childbearing age per month		Number of Td 3 vaccinations administered to women of childbearing age	Number
	Td 4 vaccinations given to women of childbearing age	Total Td 4 vaccinations given to women of childbearing age per month		Number of Td 4 vaccinations administered to women of childbearing age	Number
	Td 5 vaccinations given to women of childbearing age	Total Td 5 vaccinations given to women of childbearing age per month		Number of Td 5 vaccinations administered to women of childbearing age	Number
	HPV 1 vaccinations given	Total HPV 1 vaccinations given per month		Number of HPV 1 vaccinations administered	Number
	HPV 2 vaccinations given	Total HPV 2 vaccinations given per month		Number of HPV 2 vaccinations administered	Number
	Vitamin A supplementation	Total vitamin A supplemented to children 6–11 months, per month		Number of children 6–11 months supplemented with vitamin A	Number
	Vitamin A supplementation	Total vitamin A supplemented to children 12–59 months per month		Number of children 12–59 months supplemented with vitamin A	Number
	Vitamin A supplementation	Total vitamin A supplemented to postnatal mothers per month		Number of postnatal mothers supplemented with vitamin A	Number
		Total number of children 12–23 months dewormed per months		Number of children 12–23 months dewormed per month	Number

		Total number of children 24–59 months dewormed per month		Number of children 24–59 months dewormed per month	Number
BCG vaccination coverage per month	Percentage of under-1 children immunized by BCG	Numerator	Number of under-1 children immunized by BCG	100
			Denominator	Projected under-1 livebirths population	
BCG cumulative coverage	Percentage of cumulative under-1 children immunized by BCG			Cumulative coverage of BCG	
OPV 1 vaccination coverage per month	Percentage of under-1 children immunized by OPV 1	Numerator	Number of under-1 children immunized by OPV 1	100
			Denominator	Projected under-1 surviving infants population	
OPV 1 cumulative coverage	Percentage of cumulative under-1 children immunized by OPV 1			Cumulative coverage of OPV 1	
OPV 3 vaccination coverage per month	Percentage of under-1 children immunized by OPV 3	Numerator	Number of under-1 children immunized by OPV 3	100
			Denominator	Projected under-1 surviving infants population	
OPV 3 cumulative coverage	Percentage of cumulative under-1 children immunized by OPV 3			Cumulative coverage of OPV 3	
IPV vaccination coverage per month	Percentage of under-1 children immunized by IPV	Numerator	Number of under-1 children immunized by IPV	100
			Denominator	Projected under-1 surviving infants population	
IPV cumulative coverage	Percentage of cumulative under-1 children immunized by IPV			Cumulative coverage of IPV	
DTP-HepB-Hib 1 vaccination coverage per month	Percentage of under-1 children immunized by DTP-HepB-Hib 1	Numerator	Number of under-1 children immunized by DTP-HepB-Hib 1	100
			Denominator	Projected under-1 surviving infants population	
DTP-HepB-Hib 1 cumulative coverage	Percentage of cumulative under-1 children immunized by DTP-HepB-Hib	Cumulative coverage of DTP-HepB-Hib 1			
DTP-HepB-Hib 3 vaccination coverage per month	Percentage of under-1 children immunized by DTP-HepB-Hib 3	Numerator	Number of under-1 children immunized by DTP-HepB-Hib 3	100
			Denominator	Projected under-1 surviving infants population	
DTP-HepB-Hib 3 cumulative coverage	Percentage of cumulative under-1 children immunized by DTP-HepB-Hib 3			Cumulative coverage of DTP-HepB-Hib 3	

	PCV 1 vaccination coverage per month	Percentage of under-1 children immunized by PCV 1	Numerator	Number of under-1 children immunized by PCV 1	100
			Denominator	Projected under-1 surviving infants population	
	PCV 1 cumulative coverage	Percentage of cumulative under-1 children immunized by PCV 1		Cumulative coverage of PCV 1	
	PCV 3 vaccination coverage per month	Percentage of under-1 children immunized by PCV 3	Numerator	Number of under-1 children immunized by PCV 3	100
			Denominator	Projected under-1 surviving infants population	
	PCV 3 cumulative coverage	Percentage of cumulative under-1 children immunized by PCV 3		Cumulative coverage of PCV 3	
	Rota 1 vaccination coverage per month	Percentage of under-1 children immunized by Rota 1	Numerator	Number of under-1 children immunized by Rota 1	100
			Denominator	Projected under-1 surviving infants population	
	Rota 1 cumulative coverage	Percentage of cumulative under-1 children immunized by Rota 1		Cumulative coverage of Rota 1	
	Rota 2 vaccination coverage per month	Percentage of under-1 children immunized by Rota 2	Numerator	Number of under-1 children immunized by Rota 2	100
			Denominator	Projected under-1 surviving infants population	
	Rota 2 cumulative coverage	Percentage of cumulative under-1 children immunized by Rota 2		Cumulative coverage of Rota 1	
	Measles-rubella 1 vaccination coverage per month	Percentage of under-1 children immunized by measles-rubella 1	Numerator	Number of under-1 children immunized by measles-rubella 1	100
			Denominator	Projected under-1 surviving infants population	
	Measles-rubella 1 cumulative coverage	Percentage of cumulative under-1 children immunized by measles-rubella 1		Cumulative coverage of measles-rubella 1	
	Measles-rubella 2 vaccination coverage per month	Percentage of under-1 children immunized by measles-rubella 2	Numerator	Number of under-1 children immunized by measles-rubella 2	100
			Denominator	Projected under-1 surviving infants population	
	Measles-rubella 2 cumulative coverage	Percentage of cumulative under-1 children immunized by measles-rubella 1		Cumulative coverage of measles-rubella 2	

	Children under 1 fully immunized coverage per month	Percentage fully immunized under-1 children	Numerator	Number of fully immunized under-1 children	100
			Denominator	Projected under-1 surviving infants population	
	Cumulative under-1 children fully immunized	Percentage of cumulative under-1 children fully immunized		Cumulative coverage of fully immunized	
	Td 2+ for pregnant women vaccination coverage per month	Percentage of pregnant women immunized by Td2+	Numerator	Number of pregnant women immunized by Td2+	100
			Denominator	Projected population of pregnant women	
	Td2+ for pregnant women cumulative coverage	Percentage of pregnant women cumulatively immunized by Td2+		Cumulative coverage of Td2+	
	Td2+ for women of childbearing age vaccination coverage per month	Percentage of women of childbearing age immunized by Td2+	Numerator	Number of women of childbearing age immunized by Td2+	100
			Denominator	Projected population of women of childbearing age	
	Td2+ for women of childbearing age cumulative coverage	Percentage of women of childbearing age cumulatively immunized by Td 2+		Cumulative coverage of Td2+ for women of childbearing age	
	HPV 1 vaccination coverage per month	Percentage of adolescent girls immunized by HPV 1	Numerator	Number of adolescent girls immunized with HPV 1	100
			Denominator	Projected population of adolescent girls of 9–13 years	
	HPV 1 cumulative coverage	Percentage of adolescent girls cumulatively immunized by HPV 1		Cumulative coverage of HPV 1 in adolescent girls	
	HPV 2 vaccination coverage per month	Percentage of adolescent girls immunized by HPV 2	Numerator	Number of adolescent girls immunized with HPV 2	100
			Denominator	Projected population of adolescent girls of 9–13 years	
	HPV 2 cumulative coverage	Percentage of adolescent girls cumulatively immunized by HPV 2		Cumulative coverage of HPV 2 in adolescent girls	
	Dropout of OPV	Dropout rate for OPV	Numerator	Doses administered for OPV 1 – OPV 3	100
			Denominator	Doses administered for OPV 1	
	Dropout of DTP-HepB-Hib	Dropout rate for DTP-HepB-Hib	Numerator	Doses administered for DTP-HepB-Hib 1 – DTP- HepB-Hib 3	100

			Denominator	Doses administered for DTP-HepB-Hib 1	
	Dropout of PCV	Dropout rate for PCV	Numerator	Doses administered for PCV 1 – PCV 3	100
			Denominator	Doses administered for PCV 1	
	Dropout of Rota	Dropout rate for Rota	Numerator	Doses administered for Rota 1 – Rota 2	100
			Denominator	Doses administered for Rota 1	
	Dropout of measles-rubella	Dropout rate for measles-rubella	Numerator	Doses administered for DTP-HepB-Hib 1 – measles-rubella 1	100
			Denominator	Doses administered for DTP-HepB-Hib 1	
	Overall dropout	Overall dropout rate	Numerator	Doses administered for BCG – measles-rubella 1	100
			Denominator	Doses administered for BCG	
	Districts/health facilities with DTP-HepB-Hib 3 coverage of <50%	Total districts/health facilities with DTP-HepB-Hib 3 coverage of <50%		Number of districts/health facilities with DTP-HepB-Hib 3 coverage of <50%	Number
	Districts/health facilities with DTP-HepB-Hib 3 coverage of 50% – 79%	Total districts/health facilities with DTP-HepB-Hib 3 coverage of 50% – 79%		Number of districts/health facilities with DTP-HepB-Hib 3 coverage of 50% – 79%	Number
	Districts/health facilities with DTP-HepB-Hib 3 coverage of 80% – 89%	Total districts/health facilities with DTP-HepB-Hib 3 coverage of 80% – 89%		Number of districts/health facilities with DTP-HepB-Hib 3 coverage of 80% – 89%	Number
	Districts/health facilities with DTP-HepB-Hib 3 coverage of 90% – 95%	Total districts/health facilities with DTP-HepB-Hib 3 coverage of 90% – 95%		Number of districts/health facilities with DTP-HepB-Hib 3 coverage of 90% – 95%	Number
	Districts/health facilities with DTP-HepB-Hib 3 coverage of 96% – 100%	Total districts/health facilities with DTP-HepB-Hib 3 coverage of 96% – 100%		Number of districts/health facilities with DTP-HepB-Hib 3 coverage of 96% – 100%	Number
	Districts/health facilities with DTP-HepB-Hib 3 coverage of >100%	Total districts/health facilities with DTP-HepB-Hib 3 coverage of >100%		Number of districts/health facilities with DTP-HepB-Hib 3 coverage of >100%	Number
Vaccines and injection materials					
	Doses opened for use	Total doses of BCG vaccine opened for use		Number of BCG doses opened for use	Number
		Total doses of OPV vaccine opened for use		Number of OPV doses opened for use	Number
		Total doses of IPV vaccine opened for use		Number of IPV doses opened for use	Number

		Total doses of DTP-HepB-Hib vaccine opened for use		Number of DTP-HepB-Hib doses opened for use	Number
		Total doses of PCV 13 vaccine opened for use		Number of PCV 13 doses opened for use	Number
		Total doses of Rota vaccine opened for use		Number of Rota doses opened for use	Number
		Total doses of measles vaccine opened for use		Number of measles doses opened for use	Number
		Total doses of Td vaccine opened for use		Number of Td doses opened for use	Number
	Unopened vials wasted in stock	Total doses of unopened BCG vials wasted		Number of doses in unopened BCG vials wasted	Number
		Total doses of unopened OPV vials wasted		Number of doses in unopened OPV vials wasted	Number
		Total doses of unopened IPV vials wasted		Number of doses in unopened IPV vials wasted	Number
		Total doses of unopened DTP-HepB-Hib vials wasted		Number of doses in unopened DTP-HepB-Hib vials wasted	Number
		Total doses of unopened PCV 13 vials wasted		Number of doses in unopened PCV 13 vials wasted	Number
		Total doses of unopened Rota vials wasted		Number of doses in unopened Rota vials wasted	Number
		Total doses of unopened measles vials wasted		Number of doses in unopened measles vials wasted	Number
		Total doses of unopened Td vials wasted		Number of doses in unopened Td vials wasted	Number
	Vaccine wastage	Vaccine wastage rate for BCG	Numerator	Total doses of BCG used and wasted – total doses of BCG administered	100
			Denominator	Total doses of BCG used and wasted	
		Vaccine wastage rate for OPV	Numerator	Total doses of BCG used and wasted – total doses of OPV administered	100
			Denominator	Total doses of OPV used and wasted	
		Vaccine wastage rate for IPV	Numerator	Total doses of IPV used and wasted – total doses of IPV administered	100
			Denominator	Total doses of IPV used and wasted	
		Vaccine wastage rate for DTP-HepB-Hib	Numerator	Total doses of DTP-HepB-Hib used and wasted – total doses of BCG administered	100

			Denominator	Total doses of DTP-HepB-Hib used and wasted	
		Vaccine wastage rate for PCV 13	Numerator	Total doses of PCV 13 used and wasted – total doses of PCV 13 administered	100
			Denominator	Total doses of PCV 13 used and wasted	
		Vaccine wastage rate for Rota	Numerator	Total doses of Rota used and wasted – total doses of Rota administered	100
			Denominator	Total doses of Rota used and wasted	
		Vaccine wastage rate for Measles	Numerator	Total doses of measles used and wasted – total doses of measles 1 and measles 2 administered	100
			Denominator	Total doses of measles used and wasted	
		Vaccine wastage rate for Td	Numerator	Total doses of Td used and wasted – total doses of Td administered	100
			Denominator	Total doses of Td used and wasted	
	Vaccine stock-out	Number of health facilities with stock-out of BCG per month		Number of health facilities with stock-out of BCG	Number
		Number of health facilities with stock-out of OPV per month		Number of health facilities with stock-out of OPV	Number
		Number of health facilities with stock-out of IPV per month		Number of health facilities with stock-out of IPV	Number
		Number of health facilities with stock-out of DTP-HepB-Hib per month		Number of health facilities with stock-out of DTP-HepB-Hib	Number
		Number of health facilities with stock-out of PCV 13 per month		Number of health facilities with stock-out of PCV 13	Number
		Number of health facilities with stock-out of Rota per month		Number of health facilities with stock-out of Rota	Number
		Number of health facilities with stock-out of measles per month		Number of health facilities with stock-out of measles	Number
	Injection material stock-out	Number of health facilities with stock-out of 0.05 ml syringes per month		Number of health facilities with stock-out of 0.05 ml syringes	Number
		Number of health facilities with stock-out of 0.5 ml syringes per month		Number of health facilities with stock-out of 0.5 ml syringes	Number

		Number of health facilities with stock-out of 2 ml RUPF syringes per month		Number of health facilities with stock-out of 2 ml RUPF syringes	Number
		Number of health facilities with stock-out of 5 ml RUPF syringes per month		Number of health facilities with stock-out of 5 ml RUPF syringes	Number
		Number of health facilities with stock-out of 5-liter safety boxes per month		Number of health facilities with stock-out of 5-liter safety boxes	Number
Adverse Events Following Immunization					
	Cases of minor adverse events following immunization	Number of bacterial abscess cases reported per month		Number of bacterial abscess cases reported	Number
		Number of severe local reaction cases reported per month		Number of severe local reaction cases reported	Number
		Number of lymphadenitis cases reported per month		Number of lymphadenitis cases reported	Number
		Number of sepsis cases due to immunization reported per month		Number of sepsis cases due to immunization reported	Number
	Cases of serious adverse events following immunization	Number of cases with high fever of >38ºC reported per month		Number of cases with high fever of >38ºC reported	Number
		Number of deaths with 30 days of immunization reported per month		Number of deaths with 30 days of immunization reported	Number
		Number of encephalopathy cases reported per month		Number of encephalopathy cases reported	Number
		Number of seizure cases reported per month		Number of seizure cases reported	Number
		Number of paralysis cases reported per month		Number of paralysis cases reported	Number
		Number of significant disability cases reported per month		Number of significant disability cases reported	Number
		Number of birth defect cases reported per month		Number of birth defect cases reported	Number
		Number of toxic shock syndrome cases reported per month		Number of toxic shock syndrome cases reported	Number
Disease surveillance					
	Suspected measles cases detected	Number of suspected measles cases reported per month		Number of suspected measles cases reported	Number

Investigation of suspected measles cases	Number of reported suspected measles cases investigated per month		Number of suspected measles cases investigated	Number
Suspected measles cases with blood specimens collected within 30 days of rash onset	Percentage of suspected measles cases with blood specimen collected with 30 days of rash onset	Numerator	Number of suspected measles cases with blood specimens collected within 30 days of rash onset	100
		Denominator	Total number of suspected measles cases reported	
Districts that reported at least 1 suspected case of measles with a blood specimen per year	Percentage of districts that reported at least 1 suspected case of measles with a blood specimen per year	Numerator	Number of districts that reported suspected measles cases	100
		Denominator	Total number of districts	
Annualized non-measles febrile rash illness	Annualized non-measles febrile rash illness rate	Numerator	Number of suspected measles cases reported – confirmed cases + Epi Link cases	Time period in months or year
		Denominator	Total population	
AFP cases reported	Number of AFP cases reported per month		Number of AFP cases reported	
Non-AFP detection rate	Non-AFP detection rate	Numerator	Total number of AFP reported – WPV, VDPV & compatibles	100,000
		Denominator	Total under-15 population	
AFP stool adequacy	AFP stool adequacy rate	Numerator	Number of 2 stool samples collected within 14 days and in good condition	100
		Denominator	Total AFP detected	
Neonatal tetanus (NNT) cases reported	Total number of suspected NNT cases reported		Number of suspected NNT cases reported	Number
NNT investigation	Total number of suspected NNT cases investigated		Number of suspected NNT investigated	Number
NNT incidence rate	Incidence rate of confirmed NNT cases per 1000 livebirths by district	Numerator	Total number of confirmed NNT cases	1000
		Denominator	Total livebirths in district	
Districts with NNT incidence rate of >1 per 1000 livebirths	Percentage of districts with NNT incidence rate of >1 per 1000 livebirths	Numerator	Number of districts with NNT incidence rate of >1 per 1000 livebirths	100
		Denominator	Total number of districts	

Functional requirements

ID	ACTIVITY	REQUIREMENT (The system must or should…)
Awareness and demand generation		
FXNREQ.01	Define criteria	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.
FXNREQ.02	Define criteria	Have ability to associate a client with a clinic/site to generate a provider-based reminder/recall.
FXNREQ.03	Define criteria	Have ability to validate data against the immunization schedule (Note: Can use the immunization schedule to best schedule reminders/recall for series vaccinations, etc.).
FXNREQ.04	Select notification method	Allow user to select one or more notification methods (e.g., telephone call, "robo call," text message, letter, postcard, labels, email, HSA home visits, etc.).
FXNREQ.05	Select notification method	Have ability to maintain client's preferred contact method.
FXNREQ.06	Generate list of clients	Have ability to produce a list of clients according to user-defined parameters.
FXNREQ.07	Generate list of clients	Have ability to print the list of clients.
FXNREQ.08	Generate list of clients	Have ability to log each time a user generates a list of clients.
FXNREQ.09	Generate list of clients	Have the ability to display the date the reminder/recall notice was sent to a client.
FXNREQ.10	Generate list of clients	Have ability to display type of notification indicator per client record (e.g., prevention or defaulter).
FXNREQ.11	Generate list of clients	Have ability to track the number of reminder/recall attempts (i.e., per client and total).
FXNREQ.12	Generate list of clients	Prevent all records given an inactive or deceased status from being included in the list of clients for reminder/recall.
FXNREQ.13	Send notifications	Have ability to generate electronic notifications.
FXNREQ.14	Send notifications	Have ability to send electronic notifications.
FXNREQ.15	Send notifications	Send reminder/recall notification to client or designated health worker (e.g., via HSA).
FXNREQ.16	Track client	Have ability to assign HSA to a client.
FXNREQ.17	Track client	Have ability to generate and send a list of defaulted/overdue clients to HSA.
FXNREQ.18	Track client	Allow HSA to send tracking updates to facility via SMS, email, etc.
FXNREQ.19	Update client information and/or status	Have ability to track notification attempts and log back to a client's record.

FXNREQ.20	Update client information and/or status	Have ability to maintain an audit log of the changes and history.
FXNREQ.21	Update client information and/or status	Have ability to update client record with tracking information in the IIS from the HSA.
FXNREQ.22	Update client information and/or status	Have ability to edit, update, and override client information such as change of address (moved permanently or temporarily).
FXNREQ.23	Active or inactive?	Have ability to allow a client record to be inactive for a selected time frame (e.g., temporarily lost residence, crop harvest).
FXNREQ.24	Client is due vaccine	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.
FXNREQ.25	Confirm clinic dates and outreach schedule dates	Validate the clinic dates for all clinics in the next month (outreach and local).
FXNREQ.26	Confirm clinic dates and outreach schedule dates	Provide a means to update the clinic calendar/schedule (e.g., with national holidays).
FXNREQ.27	Does client have a phone?	Identify if the client due for a vaccination has a phone number on record.
FXNREQ.28	Generate reminder message	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).
FXNREQ.29	Generate reminder to HSA	Determine the HSA responsible for the area in which the person due a vaccination resides.
FXNREQ.30	Generate reminder to HSA	Send a list of all children (that the HSA has responsibility for) due vaccinations prior to the clinic.
FXNREQ.31	Determine if immunizations were missed	Display a list of children who missed their immunization for each antigen.
FXNREQ.32	Determine if immunizations were missed	Allow the user or ministry to specify immunization schedule and thresholds for a child to qualify as requiring follow-up.
FXNREQ.33	Determine if immunizations were missed	Allow the user to print a list of children requiring follow-up.
FXNREQ.34	Determine if immunizations were missed	Allow the user to export a list for follow-up.
FXNREQ.35	Record information to follow-up	Extract location and personal information.
FXNREQ.36	Record information to follow-up	Categorize default information by location and HSA.
FXNREQ.37	Plan for follow-up at clinic sessions or during outreach	Display a list of planned outreach and clinic sessions.
FXNREQ.38	Send child information to HSA or mother/caregiver	Send list of missing children by email or SMS.

FXNREQ.39	Send child information to HSA or mother/caregiver	Send recall SMS to mother/caregiver.
FXNREQ.40	Ensure child is immunized	Mark located children for future follow-up.
FXNREQ.41	Record the reason	Allow the user to record reason: either permanent reason for not finding child or reason immunization was missed.
Plan and manage service delivery		
FXNREQ.42	Receive facility information	Have ability to receive facility information from multiple sources (e.g., automatically or manually in multiple formats).
FXNREQ.43	Validate NMFL	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).
FXNREQ.44	Validate NMFL	Have ability to flag any facilities that are registered in the IIS that are not in the NMFL.
FXNREQ.45	Validate NMFL	Have ability to validate NMFL with IIS master list.
FXNREQ.46	Does facility information match?	Have ability to update IIS master facility registration information with information from the NMFL.
FXNREQ.47	Update/add new facility	Have ability to provide a temporary unique ID to facilities not listed in the NMFL.
FXNREQ.48	Update/add new facility	Have ability to add new facilities to IIS master registration list not listed in the NMFL.
FXNREQ.49	Update/add new facility	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]).
FXNREQ.50	Update/add new facility	Have ability to send notification of new facility to the NMFL manager.
FXNREQ.51	Update/add new facility	Have ability to update facility information not captured in the NMFL.
FXNREQ.52	Update/add new facility	Have ability to keep audit log of change history when any facility information is changed and saved (e.g., include date/time stamp).
FXNREQ.53	Verify information for additional data	Have ability to prompt user to accept changes to IIS master registration list.
FXNREQ.54	Verify information for additional data	Have ability to verify that all required fields are complete.
FXNREQ.55	Verify information for additional data	Have ability to notify user of incomplete mandatory fields.
FXNREQ.56	Validate NMFL	Have ability to flag facility as temporary.
FXNREQ.57	Update/add new facility	Have ability to convert temporary facility to permanent facility.
FXNREQ.58	Information complete?	Have ability to verify that all required facility information is complete.
FXNREQ.59	Information complete?	Have ability to generate an exception report.
FXNREQ.60	Information complete?	Have ability to generate report of missing information.

FXNREQ.61	Information complete?	Have ability to generate email to facility.
FXNREQ.62	Request additional information	Have ability to support the process of receiving information.
FXNREQ.63	Create/update facility record	Have ability to audit facility data changes with date/time stamp "last updated".
FXNREQ.64	Create/update facility record	Have ability to collect total number of facility data changes and report to HSA.
FXNREQ.65	Generate unique IIS ID	Have ability to generate a unique IIS ID.
FXNREQ.66	Send facility registration notification and IIS ID	Have ability to send IIS registration notification w/IIS ID (e.g., SMS, mail, email, etc.).
FXNREQ.67	Send facility registration notification and IIS ID	Have ability to insert/include instructions of how to use IIS ID (e.g., reporting requisition, etc.).
FXNREQ.68	Receive registration information	Allow user to send/acknowledge confirmation of receipt of the registration notification.
Plan service delivery		
FXNREQ.69	Review register to determine estimates of vaccine needed	Identify all children due (or overdue) for vaccination by the next clinic date.
FXNREQ.70	Review register to determine estimates of vaccine needed	Sort the list by antigen.
FXNREQ.71	Review register to determine estimates of vaccine needed	Provide range estimates for vaccine need based on historical data (high and low ranges).
FXNREQ.72	Record details on planning sheet	Print list of necessary antigens and accessories (syringes, wipes, etc.) based on projected need.
FXNREQ.73	Sufficient stock in immediate location?	Identify the stock at the local source.
FXNREQ.74	Sufficient stock in immediate location?	Compare the list of needed antigens to the stock on hand and indicate if there is sufficient stock.
FXNREQ.75	Sufficient stock in immediate location?	Show the actual numbers of each antigen in stock.
FXNREQ.76	Order additional stock	Allow the user to generate a stock request based on the information provided.
FXNREQ.77	Order additional stock	Allow the user to change the number of each antigen as needed (using the shortage as a guideline).
FXNREQ.78	Order additional stock	Provide feedback for stock that is not available for ordering (back orders).

FXNREQ.79	Order additional stock	Indicate that the order has been processed.
FXNREQ.80	Order additional stock	Provide any relevant details for the order fulfillment (such as time of day to expect delivery or any special instructions).
FXNREQ.81	Order additional stock	Provide means to include some mandatory user feedback, such as stock on hand and reason for order.
FXNREQ.82	Get needed stock	Provide a printed list of (antigen) stock order to be fulfilled.
FXNREQ.83	Record stock taken	Allow bar code reading of stock taken.
FXNREQ.84	Record stock taken	Record stock removed from cold storage and taken to clinic.
FXNREQ.85	Record stock taken	Maintain a tally of stock available at each location (cold fridge at center, out for clinic).
FXNREQ.86	Assemble all needed materials for clinic	Provide a clinic materials checklist.
Administer and document care		
FXNREQ.87	Does the client have a record?	Allow the user to search for the client given some demographic information.
FXNREQ.88	Does the client have a record?	As a result of the search, return all potential matches.
FXNREQ.89	Does the client have a record?	Allow for searching and matching on partial information (such as partial birthdates).
FXNREQ.90	Does the client have a record?	Allow searching for children based on family relationships or demographics.
FXNREQ.91	Does the client have a record?	Allow a system administrator to configure search parameters: what fields are mandatory, when partial information is acceptable, etc.
FXNREQ.92	Does the client have a record?	Allow searching with wild cards.
FXNREQ.93	Does the client have a record?	Allow the user to find client records using barcodes.
FXNREQ.94	Does the client have a record?	Include results that look or sound similar to the search term (fuzzy logic).
FXNREQ.95	Start Child Health Card	There will be a need for the client 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 backup for clients and families, as they rarely have online access to information.
FXNREQ.96	Enter into vaccination log/register/system	Allow the user to enter all necessary registration data.
FXNREQ.97	Enter into vaccination log/register/system	Allow family relations to be modeled by cross-referencing client data. The mother and father field would thus refer to other records in the client database.
FXNREQ.98	Enter into vaccination log/register/system	Allow the user to select the place of birth from a list as defined by the system administrator.
FXNREQ.99	Enter into vaccination log/register/system	Allow the user to select the health center of the client from a list as defined by the system administrator.
FXNREQ.100	Enter into vaccination log/register/system	Validate that a client does not exist before adding a new record. (All added activities must be preceded by a search).

FXNREQ.10 1	Enter into vaccination log/register/system	Enforce a minimal dataset to allow for a new registration.
FXNREQ.10 2	Enter into vaccination log/register/system	Uniquely identify every person.
FXNREQ.10 3	Enter into vaccination log/register/system	Provide a mechanism to prevent unwanted duplication of records (e.g., the system warns if a child is registered with same name and DOB).
FXNREQ.10 4	Enter into vaccination log/register/system	Provide a means to handle duplicates (such as merging records).
FXNREQ.10 5	Enter into vaccination log/register/system	Allow for remote access and update of client records (via mobile device).
FXNREQ.10 6	Find client in register as well as obtaining the child health booklet	Allow the system administrator to configure what information and what data will be returned to determine a match.
FXNREQ.10 7	Find client in register as well as obtaining the child health booklet	Allow users to modify or update appropriate client data as needed.
Query client record		
FXNREQ.10 8	Review record to determine appropriate action/care	Allow user to be certain the record belongs to the subject of care (this means it contains enough information/demographics/photo/unique ID, etc.).
FXNREQ.10 9	Review record to determine appropriate action/care	Provide a history of previous care.
FXNREQ.11 0	Review record to determine appropriate action/care	Contain contact information.
FXNREQ.11 1	Record relevant information	Update client's vaccination record with all relevant information (date, dose, lot number, antigen).
FXNREQ.11 2	Record relevant information	Allow the user to record additional vaccinations, even those that are not included in the national vaccination schedule.
FXNREQ.11 3	Does the information belong on the client record?	Allow space to record any significant observations (such as reaction) that may be specific to that client.
FXNREQ.11 4	Find appropriate general record/ledger	Allow for the recording of non-client-specific data, such as counts of antigens given.
FXNREQ.11 5	Find appropriate general record/ledger	Allow for the reporting of aggregate data from the individual data to suit reporting needs.
Administer vaccine		
FXNREQ.11 6	Query client record	Search if client is already in system (using at least two identifiers).
FXNREQ.11 7	Query client record	Require a user to search if a client is already in the system prior to starting a new medical record entry.
FXNREQ.11 8	Query client record	Allow a system administrator to configure or set if a search must happen in advance of allowing a new entry.
FXNREQ.11 9	Query client record	Read client information from a bar code on a client ID and retrieve client information.
FXNREQ.12 0	Does client need vaccine?	Allow the user to customize vaccine protocol.

FXNREQ.12 1	Does client need vaccine?	Be able to determine vaccine required by looking at age of client, vaccines already given, and vaccine protocol.
FXNREQ.12 2	Does client need vaccine?	Display vaccine(s) already given and vaccines due according to vaccine protocol.
FXNREQ.12 3	Is required vaccine available?	Display availability of vaccines stock.
FXNREQ.12 4	Is required vaccine available?	Warn the user if required vaccine is not in stock.
FXNREQ.12 5	Inform client of next vaccine date	Display due date of the next vaccine.
FXNREQ.12 6	Update record	Allow the user to enter antigen information (e.g., batch number, expiry date, VVM status).
FXNREQ.12 7	Update record	Update stock record.
FXNREQ.12 8	Inform next visit	Display due date of the next vaccine.
De-duplication of client records		
FXNREQ.12 9	Select client records for evaluation	Have ability to automatically identify new client records as possible duplicates.
FXNREQ.13 0	Select client records for evaluation	Have ability to automatically identify existing client records as duplicates.
FXNREQ.13 1	Select client records for evaluation	Have ability to prompt user of possible duplicate record prior to saving new record.
FXNREQ.13 2	Select client records for evaluation	Allow users to manually flag duplicate records.
FXNREQ.13 3	Select client records for evaluation	Have ability to schedule batching of duplicate record process.
FXNREQ.13 4	Evaluate records	Support a rule-based algorithm to evaluate duplicate records.
FXNREQ.13 5	Evaluate records	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.).
FXNREQ.13 6	Evaluate records	Allow rules to be easily editable by HSA.
FXNREQ.13 7	Manual review?	Flag duplicate records that require manual review.
FXNREQ.13 8	Manual review?	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]).
FXNREQ.13 9	Manual review?	Allow user to manually flag records for manual review.
FXNREQ.14 0	Perform manual review	Have ability to alert user of records pending for manual review.
FXNREQ.14 1	Perform manual review	Allow user to view records simultaneously for decision to merge records.
FXNREQ.14 2	Perform manual review	Allow user to navigate the system while reviewing possible duplicates.
FXNREQ.14 3	Perform manual review	Have ability to plan and organize projects/tasks/assignments (e.g., task management, assign statuses like "completed," "high priority," etc.).

FXNREQ.14 4	Can records be merged?	Have ability to determine if records have appropriate criteria to merge (e.g., personal identifying data to watch).
FXNREQ.14 5	Merge record	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]).
FXNREQ.14 6	Merge record	Support an audit trail when records are merged.
FXNREQ.14 7	Merge record	Have ability to produce and access a cross-reference listing of pre- and post-merged records (i.e., a list that shows the old Client record information with the corresponding converted new Client record).
FXNREQ.14 8	Merge record	Have ability to "undo merge."
FXNREQ.14 9	Merge record	Have ability to retain "pre-merged" records.
FXNREQ.15 0	Mark as "not duplicate" or pending	Allow user to flag record as "not a duplicate" (Note: The system could believe records are duplicates, but they are not).
FXNREQ.15 1	Mark as "not duplicate" or pending	Have ability to prevent matching for the same pair of records that have been flagged as "not a duplicate."
FXNREQ.15 2	Mark as "not duplicate" or pending	Allow user to manually flag a record as pending for manual review (e.g., not enough information).
FXNREQ.15 3	Mark as "not duplicate" or pending	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).
FXNREQ.15 4	Mark as "not duplicate" or pending	Have ability to enter comments for records marked as "not duplicate."
De-duplication of vaccine records		
FXNREQ.15 5	Identify groups of vaccination events for evaluation	Have ability to prompt the user that the new vaccine is a duplicate.
FXNREQ.15 6	Identify groups of vaccination events for evaluation	Have ability to generate a list of possible client vaccine duplicates.
FXNREQ.15 7	Identify groups of vaccination events for evaluation	Have ability to manually initiate duplicate search process.
FXNREQ.15 8	Identify groups of vaccination events for evaluation	Have ability to automate duplicate search process.
FXNREQ.15 9	Identify groups of vaccination events for evaluation	Allow users to manually flag duplicate events.
FXNREQ.16 0	Identify groups of vaccination events for evaluation	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.
FXNREQ.16 1	Evaluate vaccine event records	Support a rules-based algorithm to evaluate duplicate events.
FXNREQ.16 2	Evaluate vaccine event records	Support probabilistic algorithm to determine and flag when duplicate events need manual review.
FXNREQ.16 3	Evaluate vaccine event records	Allow rules to be easily editable by HSA (add, remove, modify) when authorized.

FXNREQ.16 4	Duplicate events?	Allow user to manually flag events for manual review.
FXNREQ.16 5	Duplicate events?	Have ability to alert user of events pending for manual review.
FXNREQ.16 6	Duplicate events?	Allow user to view events and event details simultaneously for decision to merge (i.e., two or more).
FXNREQ.16 7	Duplicate events?	Allow user to navigate the system while reviewing possible duplicates (optional).
FXNREQ.16 8	Select the most accurate/suitable event record	Have ability to automatically select the most accurate/suitable vaccination event to be used as the (primary or master) record.
FXNREQ.16 9	Update vaccine event records	Allow user to select data elements to merge into a consolidated event record.
FXNREQ.17 0	update vaccine event records	Have ability to combine two or more duplicate event records according to business rules.
FXNREQ.17 1	Update vaccine event records	Support an audit trail when event records are merged.
FXNREQ.17 2	Update vaccine event records	Have ability to retain "pre-merged" event records.
FXNREQ.17 3	Update vaccine event records	Have ability to generate an audit list of vaccination events that are automatically merged.
FXNREQ.17 4	Update vaccine event records	Allow user to delete a duplicate vaccine event while still maintaining audit record.
FXNREQ.17 5	Generate report of duplicates	Automatically schedule routine reports to run at a specific time.
FXNREQ.17 6	Generate report of duplicates	Allow for the restriction of confidential personal identifiable information.
Generate reports		
FXNREQ.17 7	Define parameters	Allow user to select parameters (e.g., time, age, race/ethnicity, jurisdiction, vaccine grouping, vaccine dose count, specific program codes, other program codes, etc.).
FXNREQ.17 8	Define parameters	Allow user to select report output parameters (e.g., display options, summary vs. detail report, sort options, alphanumeric vs. date, etc.).
FXNREQ.17 9	Define parameters	Allow user to choose a report-generation time frame (i.e., run now or set the time for later).
FXNREQ.18 0	Define parameters	Have ability to save parameters as "public" to allow other users to generate the same report using the same parameters.
FXNREQ.18 1	Define parameters	Have ability to modify/delete saved "public" parameters.
FXNREQ.18 2	Define parameters	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.).
FXNREQ.18 3	Define parameters	Have ability to prompt user to confirm the generation of a report at a later time if required.
FXNREQ.18 4	Generate report	Have ability to save, display, or print report.
FXNREQ.18 5	Generate report	Have ability to produce reports in multiple formats (i.e., text delimited file, etc.).
FXNREQ.18 6	Generate report	Allow user to delete a report and track on audit log.

FXNREQ.18 7	Generate report	Allow user to delete and/or modify data elements within a report (Note: allows the user to modify report based on the audience).
FXNREQ.18 8	Generate report	Automatically schedule routine reports to run at a specific time.
FXNREQ.18 9	Generate report	Allow for the restriction of some predefined data such as duplicate records.
FXNREQ.19 0	Generate report	Have ability to generate the report based on the parameters set.
FXNREQ.19 1	Report acceptable?	Allow user to return to and modify report criteria.
FXNREQ.19 2	Analyze	Have ability to verify that the report is in the correct format.
FXNREQ.19 3	Analyze	Have ability to send by email.
FXNREQ.19 4	Analyze	Have ability to export data in selected file formats.
FXNREQ.19 5	Analyze	Allow user to configure report displays.
FXNREQ.19 6	Analyze	Be interoperable with a statistical analysis software.

Non-functional requirements

Requirement ID	Category	Non-functional requirement
NFXNREQ.001	Security – confidentiality	Provide password-protected access for authorized users
NFXNREQ.002	Security – confidentiality	Provide a means to ensure confidentiality and privacy of personal health information
NFXNREQ.003	Security – confidentiality	Provide ability for allowed users to view confidential data
NFXNREQ.004	Security – confidentiality	Anonymize data that is exported from the system
NFXNREQ.005	Security – confidentiality	Prevent remembering username and password
NFXNREQ.006	Security – confidentiality	Automatically log out the user after specified time of inactivity
NFXNREQ.007	Security – confidentiality	Provide encrypted communication between components
NFXNREQ.008	Security – authentication	Notify the user to change their password the first time they log in
NFXNREQ.009	Security – authentication	Adhere to complex password requirements
NFXNREQ.010	Security – authentication	Provide a mechanism to securely change a user's password
NFXNREQ.011	Security – authentication	Notify the user of password change to their account
NFXNREQ.012	Security – authentication	Reset a user's password in a secure manner
NFXNREQ.013	Security – authentication	Lock a user out after a specified number of wrong password attempts
NFXNREQ.014	Security – authentication	Notify a user if their account is locked due to wrong password attempts
NFXNREQ.015	Security – authentication	Provide role-based access to the system
NFXNREQ.016	Security – audit trail and logs	Log system logins and logouts
NFXNREQ.017	Security – audit trail and logs	Record all authentication violations
NFXNREQ.018	Security – audit trail and logs	Log all activities performed by the user, including date-and-time stamp
NFXNREQ.019	Security – audit trail and logs	Log access to views of individual client records
NFXNREQ.020	Security – audit trail and logs	Log access to data summaries, reports, analysis, and visualization features
NFXNREQ.021	Security – audit trail and logs	Log exchange of data with other systems
NFXNREQ.022	Security – audit trail and logs	Generate analysis of the usage of different system features and reports
NFXNREQ.023	Security – audit trail and logs	Log all data and system errors
NFXNREQ.024	Security – user management	Allow user with permission to create a new user and temporary password

NFXNREQ.025	Security – user management	Provide role-based access
NFXNREQ.026	Security – user management	Allow roles to be associated with specific geographical areas and/or health care facilities
NFXNREQ.027	Security – user management	Allow cascading user management and assignment of roles
NFXNREQ.028	Security – user management	Allow user to change their own password
NFXNREQ.029	Security – user management	Allow admin user to request password reset
NFXNREQ.030	Security – user management	Notify the user to regularly change their password
NFXNREQ.031	Security – user management	Allow each user to be assigned to one or more roles
NFXNREQ.032	Security – user management	Support definitions of unlimited roles and assigned levels of access, viewing, entry, editing, and auditing
NFXNREQ.033	System requirements – general	Provide a unique version number for each revision
NFXNREQ.034	System requirements – general	Enable earlier versions of a record to be recoverable
NFXNREQ.035	System requirements – general	Enable deployment in an environment subject to power loss
NFXNREQ.036	System requirements – general	Work in an environment that is subject to loss of connectivity
NFXNREQ.037	System requirements – general	Generate IDs that are unique across different installations or sites
NFXNREQ.038	System requirements – general	Report version number when saving data to the database
NFXNREQ.039	System requirements – general	Be designed to be flexible enough to accommodate necessary changes in the future
NFXNREQ.040	System requirements – general	Allow for offline and online functionality
NFXNREQ.041	System requirements – general	Show the number of records that are not yet synchronized
NFXNREQ.042	System requirements – general	Have ability to easily back up information
NFXNREQ.043	System requirements – general	Warn user if no valid backup for more than a predefined number of days
NFXNREQ.044	System requirements – general	Must have the ability to store images and other unstructured data
NFXNREQ.045	System requirements – scalability	Scalable to accommodate new demands
NFXNREQ.046	System requirements – scalability	Be able to accommodate at least [*x* number of] health care facilities
NFXNREQ.047	System requirements – scalability	Be able to accommodate at least [*x* number of] concurrent users
NFXNREQ.048	System requirements – usability	Be user-friendly for people with low computer literacy
NFXNREQ.049	System requirements – usability	Provide informative error messages and tooltips
NFXNREQ.050	System requirements – usability	Alert the user when navigating away from a form without saving

NFXNREQ.051	System requirements – usability	Support real-time data-entry validation and feedback to prevent data-entry errors from being recorded
NFXNREQ.052	System requirements – usability	Simplify data recording through predefined drop-down menu or searchable lists, radio buttons, check boxes
NFXNREQ.053	System requirements – usability	Support multiple languages
NFXNREQ.054	System requirements – usability	Use industry standard user interface practices and apply them consistently throughout the system
NFXNREQ.055	System requirements – usability	Easy to learn and intuitive to enable user to navigate between pages
NFXNREQ.056	System requirements – usability	Provide guidance to users to better support clinical guidelines and best clinical practices
NFXNREQ.057	System requirements – usability	Be reliable and robust (minimize the number of system crashes)
NFXNREQ.058	System requirements – usability	Adjust display to fit small screens (e.g., mobile phones)
NFXNREQ.059	System requirements – configuration	Configure the system centrally
NFXNREQ.060	System requirements – configuration	Configure business rules in line with guidelines and standard operating procedures (SOPs)
NFXNREQ.061	System requirements – configuration	Configure error messages
NFXNREQ.062	System requirements – configuration	Configure workflows and business rules to accommodate differences between facilities
NFXNREQ.063	System requirements – interoperability	Communicate with external systems through mediators
NFXNREQ.064	System requirements – interoperability	Provide access to data through application programming interfaces (APIs)
NFXNREQ.065	System requirements – interoperability	Link with insurance systems to verify eligibility and submit claims
NFXNREQ.066	System requirements – interoperability	Exchange data with other approved systems
NFXNREQ.067	System requirements – interoperability	Accept data from multiple input methods, including paper, geocoding (GPS)
NFXNREQ.068	System requirements – interoperability	Communicate with external systems through mediators
NFXNREQ.069	System requirements – hardware and connectivity	Allow for data exchange and efficient synchronization across multiple facilities and points of service when internet is available, even when it is intermittent and slow