SMART GUIDELINES COLLECTION

Digital adaptation kit for immunizations

Operational requirements for implementing WHO recommendations in digital systems

World Health Organization

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(SMART Guidelines collection)

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Contents

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Abbreviations

AEFI	adverse event following immunization
BCG	bacille Calmette–Guérin (vaccine)
bOPV	bivalent oral polio vaccine
DAK	digital adaptation kit
DTP vaccine	diphtheria–tetanus–pertussis vaccine
EIR	electronic immunization registry
EPI	Expanded Programme on Immunization
HAV	hepatitis A virus
Hib	*Haemophilus influenzae* type b
HMIS	health management information system
HPV	human papillomavirus
ICD	International Classification of Diseases
ICD-11	International Classification of Diseases 11th Revision
ID	identification
IIS	immunization information system
IPV	inactivated polio vaccine
JE	Japanese encephalitis
MCV	measles-containing vaccine
NMFL	National Master Facility List
OPV	oral polio vaccine
PCPOSS	person-centred point-of-service system
PIRI	periodic intensification of routine immunization
polio	poliomyelitis
SIA	supplementary immunization activity
SMART	standards-based, machine-readable, adaptive, requirements-based and testable
SNOMED	Systematized Nomenclature of Medicine
TBE	tick-borne encephalitis
TCV	typhoid conjugate vaccine
ViPS	Vi polysaccharide
WC-rBS	whole cell-recombinant B subunit
WHO	World Health Organization

Glossary

Note: Terms in definitions that are also defined in this glossary are shown in italics.

Business process	A set of related activities or *tasks* performed together to achieve the objectives of the health programme area, such as registration, counselling and referrals *(1,2)*.
Clinic	The setting where health workers are administering services that include vaccinations. This may be in clinics for children aged under 5 years that include monitoring and some other health promotion activities, or it may be in stand-alone vaccination clinics set up for specific vaccinations, such as COVID-19 or seasonal influenza.
Campaign	A time-limited event aimed at vaccinating a main target population against one or more specific diseases. Campaigns may be *supplementary immunization activities (SIAs),* "catch-up campaigns", or *periodic intensification of routine immunization (PIRI*) activities, or through innovative local strategies that ensure individuals receive routine immunizations for which they are overdue and eligible. This may also include the activities around new vaccine introductions.
Data dictionary	A centralized repository of information about the *data elements* that contains their definition, relationships, origin, usage and type of data. For this digital adaptation kit, the data dictionary is provided as a spreadsheet.
Data element	A unit of data that has specific and precise meaning.
Decision-support logic	A set of decision rules for standard and exceptional cases that is separate from the *business process*. This will help to reduce the complexity of the *business process* depiction without losing the detail necessary for coding the rules required for system functionality.
Decision support (for health workers)	Digitized job aids that combine an individual's health information with the health worker's knowledge and clinical protocols to assist health workers in making diagnosis and treatment decisions *(3,4).*
Decision-support table	Semi-structured way to depict each discrete decision that will need to be embedded in the system. Depending on the complexity of the clinical guidelines, there will likely be multiple decision-support tables.
Defaulter	A person who has missed the scheduled dose of a vaccine.
Digital health	The systematic application of information and communications technologies, computer science and data to support informed decision-making by individuals, the health workforce and health systems to strengthen resilience to disease and improve health and wellness *(1,5)*.
Digital tracking	The use of a digitized record to capture and store clients' health information to enable follow-up of their health status and services received. This may include digital forms of paper-based registers and case management logs within specific target populations, as well as electronic medical records linked to uniquely identified individuals *(3,4)*.
Electronic immunization registry (EIR)	Computerized individualized immunization registries that facilitate monitoring and tracking of individual immunization schedules and contain individuals' immunization histories, supporting health workers to determine whether an individual is up to date on their immunization schedule and whether that individual has been vaccinated in a timely manner.
Functional requirement	Capabilities the system must have to meet the end users' needs and achieve *tasks* within the *business process*.
Health information system (HIS)	A system that integrates data collection, processing, reporting and use of the information necessary for improving health service effectiveness and efficiency through better management at all levels of health services *(6)*.
Health management information system (HMIS)	An information system specifically designed to assist in the management and planning of health programmes, as opposed to delivery of care *(6)*.
Home-based record	A health document used to record the history of health services received by an individual. It is kept in the household, in either paper or electronic format, by the individual or their caregiver and is intended to be integrated into the health information system and complement records maintained by health-care facilities *(7)*.
Immunization information system (IIS)	Population-based, computerized databases that record immunization doses administered by multiple health workers and that can be used in the design and maintenance of effective immunization strategies.

Interoperability	The ability of different applications to access, exchange, integrate and use data in a coordinated manner through the use of shared application interfaces and standards, within and across organizational, regional and national boundaries, to provide timely and seamless portability of information and optimize health outcomes.
Non-functional requirement	General attributes and features of the digital system to ensure usability and overcome technical and physical constraints. Examples of non-functional requirements include ability to work offline, multiple language settings and password protection.
Periodic intensification of routine immunization (PIRI)	An umbrella term to describe a spectrum of time-limited, intermittent activities used to administer routine vaccinations – including catch-up doses – to under-vaccinated populations and/or raise awareness of the benefits of vaccination. Examples include Child Health Days, National Vaccination Weeks, intensified social mobilization efforts, etc. PIRI activities are intended to augment routine immunization services by providing a catch-up opportunity for those who are the usual target for routine services but have been missed or were not reached during the year. A key distinction between PIRI and *supplementary immunization activities (SIAs)* is that PIRI doses are recorded on the home-based record/immunization card as routine immunization doses and included in the administrative routine immunization coverage data. By contrast, SIA doses are considered "supplemental" and not included in the administrative routine immunization coverage.
Person-centred point-of-service system (PCPOSS)	Person-centred point of service system (PCPOSS) are digital systems that facilitate the provision and delivery of health services to individuals (i.e. persons, clients, patients, health service users) at the point of service or point of care. This includes software capabilities and embedded health interoperability standards that enable health workers to access, record and update individuals' health information. This also includes software capabilities and embedded health interoperability standards that enable screening, managing, treating and/or communicating with individuals. PCPOSS encompass various services and application types including community-based information systems, decision support systems, electronic medical (or health) record systems and personal health records *(4)*.
Persona	A generic aggregate description of a person involved in or benefitting from a health programme.
Reminder	A notification sent to remind a client that they have a vaccine due. The same mechanism may be used to alert clients that they have missed a scheduled vaccine.
Standard	In a software, a standard is a specification used in digital application development that has been established, approved and published by an authoritative organization. These rules allow information to be shared and processed in a uniform, consistent manner independent of a particular application.
Supplementary immunization activity (SIA)	Vaccination campaigns that aim to quickly deliver vaccination of one (or multiple) antigens to a large target population with the objective of closing immunity gaps in the population. Achieving high population level immunity and speed are the priority, and typically there is no screening of vaccination history/status. The supplementary doses given are tallied but not included in the routine administrative national coverage data. SIA doses may be recorded in campaign cards. Note that these campaigns are out of scope for this document.
Task	A specific action in a *business process*.
Terminologies	For clinical care, terminologies are structured vocabularies covering health-related concepts – such as diseases, diagnoses, laboratory tests and treatments – to enable the storage, analysis and exchange of data in a consistent and standard way *(8).*
Vaccination location	Designated location where vaccinations are administered to individuals. These sites may be established and operated by health-care organizations, government agencies or other entities involved in public health efforts. Vaccination locations can vary in size and set-up depending on the scale of the vaccination campaign and available resources. A health-care facility may have multiple vaccination locations under it. Some vaccination locations may be established temporarily during an outbreak or pandemic as part of a facility, while others may be permanent facilities.
Vaccination record	A health document used to record the history of vaccinations received by an individual. Vaccination record may be in a digital or paper format. Depending on the context, vaccination record may also be referred to as a home-based record, vaccination card, child health booklet and integrated maternal and child health book.
Workflow	A visual representation of the progression of activities (tasks, events, decision points) in a logical flow illustrating the interactions within the *business process (2)*.

GLOSSARY REFERENCES[1]

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1 All references were accessed on 10 July 2024.

Overview of the SMART guidelines digital adaptation kits

Background

As digital technologies are increasingly being leveraged to enable and support health service delivery and accountability, health ministries and partners have recognized the value of digital health as articulated within the World Health Assembly resolution *(1)* and the WHO *Global strategy on digital health 2020–2025 (2)*. Similarly, funding agencies have advocated for the rational use of digital tools as part of efforts to expand coverage and quality of services, as well as promote data use and monitoring efforts *(3,4,5)*.

However, guidelines are often only available in a narrative format that requires a resource-intensive process to be elaborated into the specifications needed for operationalizing into digital systems. This translation of guidelines for digital systems often results in subjective interpretation for implementers and software vendors, which can lead to inconsistencies or inability to verify the content within these systems, potentially leading to adverse health outcomes and other unintended effects *(6,7,8,9)*. Despite the abundance of digital tools developed and deployed for health, there is often limited transparency in the data model, logic model and the evidence-based clinical or public health recommendations contained in these digital tools, as system documentation may be unavailable or proprietary, requiring governments to start from scratch and expend additional resources each time they intend to update and deploy such a system *(10)*. This lack of health content documentation undermines the credibility of such systems, leading to dependency on one vendor and haphazard deployments that are unscalable, impeding the opportunity for interoperability that would otherwise enable continuity of care *(9,11,12)*.

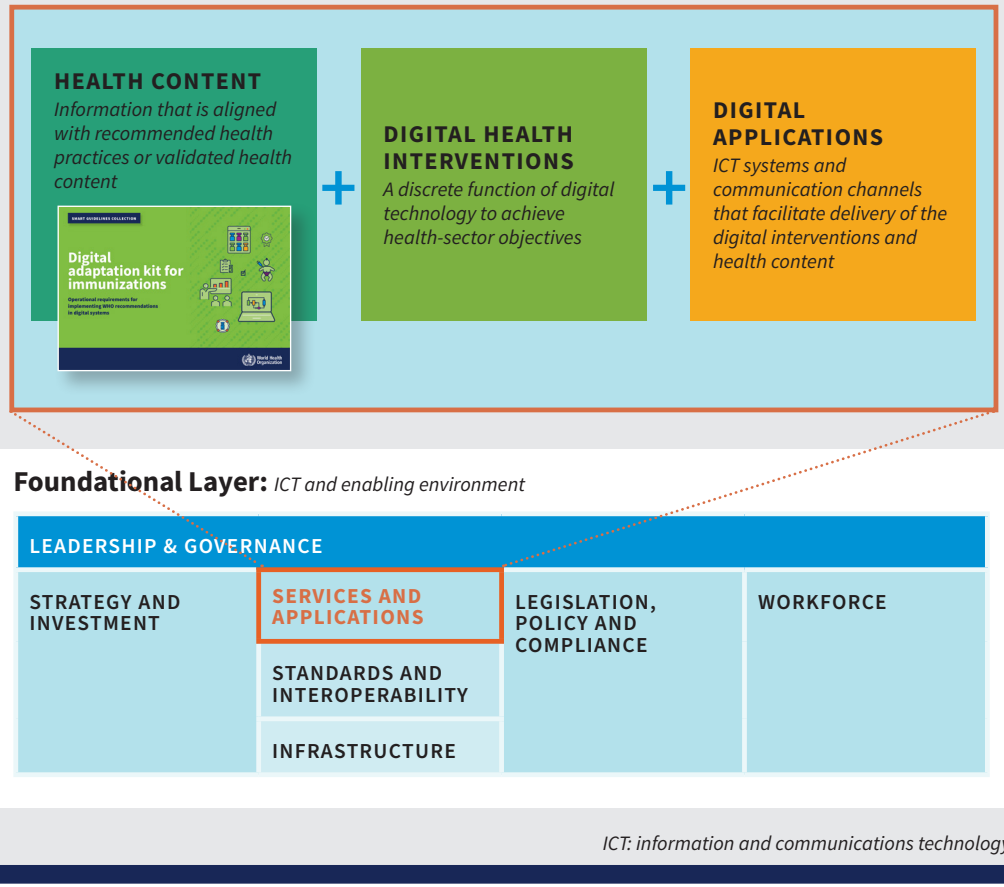
WHO standards-based, machine-readable, adaptive, requirements-based and testable (SMART) guidelines provide essential ingredients to facilitate digital health transformation of health programmes in a way that is consistent with recommended clinical, public health, data practices and interoperability standards. To ensure countries can effectively benefit from digital health investments, "digital adaptation kits" (DAKs), which are the second knowledge layer of the SMART guidelines approach, are designed to facilitate the accurate reflection of WHO clinical, public health and data use guidelines within the digital systems that countries are adopting. DAKs are operational, software-neutral, standardized documentation that distil clinical, public health and data use guidance into a format that can be transparently incorporated into digital systems *(12)*. Although digital implementations comprise multiple factors – including the (i) health domain data and content, (ii) digital intervention or functionality, and (iii) digital application or communication channel for delivering the digital intervention – DAKs focus primarily on ensuring the validity of the health content (see **Fig. 1**) *(13,14)*. Accordingly, DAKs provide the generic content requirements that should be housed within digital systems, independently of a specific software application and with the intention that countries can customize them to local needs.

For this DAK, the requirements are based on systems that provide the functionalities of person-centred point-of-service systems (PCPOSS) (see **Box 1**) and include components such as personas, workflows, core data elements, decision-support algorithms, scheduling logic and reporting indicators. Operational outputs, such as spreadsheets of the data dictionary and the detailed decision-support algorithms, are included as part of the DAK as practical resources that implementers can use as starting points when developing digital systems. Furthermore, data components within the DAK are mapped to standards-based terminology, such as the International Classification of Diseases (ICD), to facilitate interoperability.

The DAKs follow a modular approach in detailing the data and content requirements for a specific health programme area – such as antenatal care, family planning, sexually transmitted infections. **This DAK focuses on providing the content requirements for PCPOSS used in primary health care settings by health workers for provision of immunization services.** In the context of immunization programmes, electronic immunization registries (EIRs), immunization information systems (IIS), and immunization modules within a electronic medical record system can all serve as the PCPOSS. In certain contexts, the terms EIR and IIS are used interchangeably. IIS are population-based, computerized databases that record immunization doses administered by multiple health-care providers and that can be used in the design and maintenance of effective immunization strategies *(15)*. IIS are designed to provide relevant information related to the distinct management areas of the Expanded Programme on Immunization (EPI). Whereas EIRs, a part of IIS, are computerized individualized immunization registries that facilitate monitoring and tracking of individual immunization schedules and contain individuals' immunization histories, supporting health workers to determine whether an individual is up to date on their immunization schedule and whether that individual has been vaccinated in a timely manner *(15)*. Apart from EIR, IIS include capabilities for supply chain management, logistics management and adverse event reporting, but these functionalities are out of scope of this DAK. **As the focus of this DAK is on person-centred care and longitudinal tracking of a person's health status and services, this DAK focuses on requirements for a PCPOSS for immunizations, which includes EIRs.**

Fig. 1

Digital adaptation kits representing health content within broader needs for digital health implementations



ICT: information and communications technology.

Source: Adapted from *(14)*.

Box 1

What is a person-centred point-of-service system?

A person-centred point-of-service system (PCPOSS), digital in nature, facilitates the provision and delivery of health services to individuals (i.e. persons, clients, patients, health service users) at the point of care. A PCPOSS includes software capabilities that enable health-care providers to access, record and update individuals' health information as well as interactively communicate with them. The term PCPOSS encompasses various services and application types including:

- **Community-based information systems:** Systems that "facilitate data collection and use at the community level. These applications are utilized by community-based workers who provide health promotion and disease prevention activities" *(16)*.
- **Decision support systems:** Digital "tools that combine medical information databases and algorithms with patient specific data. They are intended to provide health-care professionals and/or users with recommendations for diagnosis, prognosis, monitoring and treatment of individual patients" *(16)*.
- **Electronic health record systems:** "Secure, online system that holds information about people's health and clinical care and is managed by health workers" *(16)*.
- **Personal health records:** A "record of an individual's health information in a structured digital format for a set of defined use cases over which the person has agency" *(16)*.

End users of PCPOSS can include all health worker occupational groups operating at all care levels, including those operating outside of formal health-care facilities (e.g. community health workers and health volunteers).

Based on the principle of "collect once, use many times" *(17)*, this DAK outlines the requirements of a PCPOSS that facilitates the use of more reliable source data for aggregate indicators at management levels by providing access to primary data collected directly at the point of care, allowing a shift away from the need for aggregate indicators to be reported separately and for investments in paper-based or digital indicator reporting systems. Data collected for the purposes of service delivery can also be used to calculate aggregate indicators required for reporting and accountability, including monitoring provider, stock and system performance. Factors affecting overall health system performance can thus be highlighted more promptly and accurately while reducing the clerical burden on health workers.

Digital health interventions incorporated into this digital adaptation kit

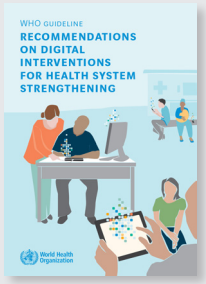
In the context of this DAK, the PCPOSS focuses on the following digital health interventions *(16)*, based on the WHO recommendation related to person-centred point-of-service systems (see **Box 2**).

- Enrol person(s) for health services/clinical care plan
- Longitudinal tracking of person's health status and services
- Manage person-centred structured clinical records
- Manage person-centred unstructured clinical records (e.g. notes, images, documents)
- Provide prompts and alerts according to protocols
- Provide checklists according to protocols
- Screen persons by risk or other health status
- Transmit targeted alerts and reminders to person(s)
- Identify persons in need of services
- Communication and performance feedback to health workers
- Routine health indicator data collection and management
- Data storage and aggregation
- Data synthesis and visualizations.

Box 2

WHO recommendation related to person-centred point-of-service systems

WHO has provided the following context-specific recommendation for the use of an integrated system that provides both digital tracking of client's health status and services and decision support *(14)*.



Effective coverage **Accountability coverage**	Digital tracking of clients' health status and services (digital tracking) combined with decision support	**RECOMMENDATION 8:** WHO recommends digital tracking of clients' health status and services, combined with decision support under these conditions: ▸ in settings where the health system can support the implementation of these intervention components in an integrated manner; and ▸ for tasks that are already defined as within the scope of practice for the health worker. *(Recommended only in specific contexts or conditions)*

Digital adaptation kits within the strategic vision of SMART guidelines

The operational and standardized documentation reflected within the DAKs represents one of the steps within a broader vision of SMART guidelines. SMART guidelines aim to maximize health impact through improved fidelity and uptake of recommendations within standards-based digital systems via a systematic process for transforming guideline development, delivery and application *(18,19)*. Within this vision, DAKs serve as a prerequisite for developing computable, or machine-readable, guidelines, as well as executable reference software and advanced analytics for precision health. **Fig. 2** provides an overview of the different layers of the SMART guidelines continuum and where DAKs fit within this strategy *(18,19,20)*. The DAKs are intended to be adapted by countries to inform the creation of a localized requirements document, which can be then used to inform country implementation of a PCPOSS.

Objectives

This DAK for immunization builds on existing resources that have been created to support the development and implementation of EIRs *(15,21)* to provide a common language across various audiences: health programme managers, software developers and implementers of digital systems to ensure a common understanding of the appropriate health information content, as a mechanism to catalyse the effective use of an EIR. The key objectives of the DAK are:

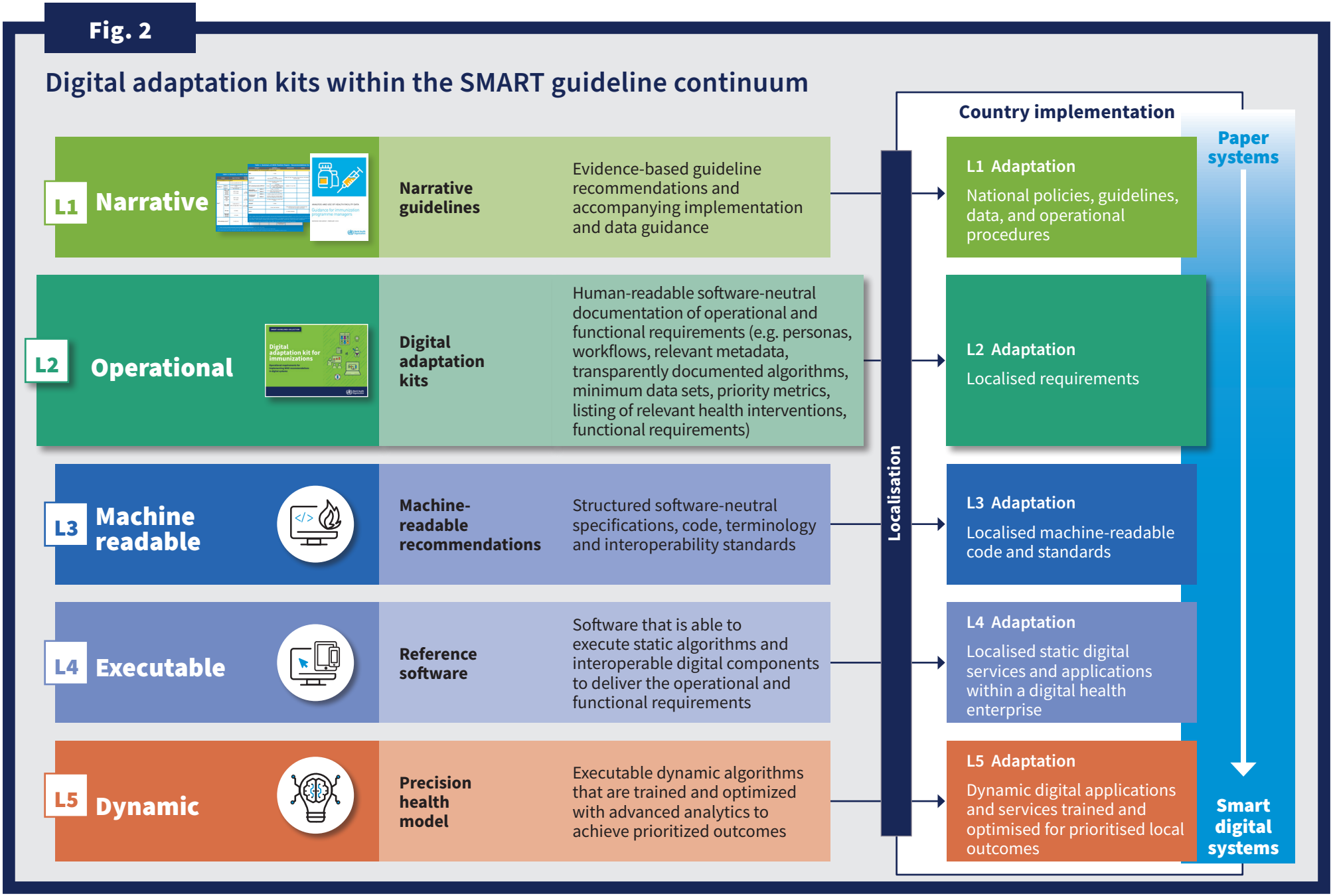
- to ensure adherence to WHO clinical, public health and data use guidelines, and facilitate consistency of the health content that is used to inform the development of a PCPOSS;
- to enable both health programme leads and digital health teams (including software developers) to have a joint understanding of the health content expected to be within the digital system(s), with a transparent mechanism to review the validity and accuracy of the health content; and
- to provide a starting point of the core data elements and decision-support logic that should be included within PCPOSS for immunizations.

Information detailed in this DAK reflects generic workflow processes, data and decision-support algorithms, as derived from WHO recommendations for routine immunization and other related WHO documents described below. The outputs of the DAKs are intentionally generic and will need to be contextualized to local policies and requirements.

DAKs have also been developed for antenatal care, family planning, HIV, tuberculosis and child health in humanitarian emergencies. This approach is being expanded to additional health domains, such as postnatal care and birth defects surveillance. All these DAKs work towards a comprehensive approach for standardized software requirements for primary health care settings.

Fig. 2

Digital adaptation kits within the SMART guideline continuum



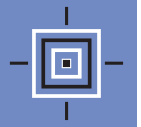
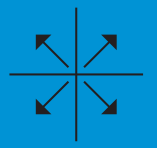
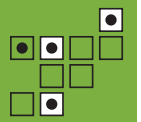
Source: Adapted from *(18)*.

Components of a digital adaptation kit

The WHO SMART guidelines DAK comprises eight interlinked components: (1) health interventions and recommendations; (2) generic personas; (3) user scenarios; (4) generic business processes and workflows; (5) core data elements; (6) decision-support logic; (7) indicators and performance metrics; and (8) functional and non-functional requirements. **Table 1** provides an overview of each of the contributing components of the DAK, which this document elaborates. All information within the DAK represents a generic starting point, which can then be adapted according to the specific context.

Table 1. Components of the digital adaptation kit

Component	Description	Purpose	Output/artifacts	Adaptation needed
1. Health interventions and recommendations	Overview of the health interventions and WHO recommendations included within this digital adaptation kit (DAK). DAKs are meant to be a repackaging and integration of WHO guidelines and guidance documents in a particular health domain. The list of health interventions is drawn from the universal health coverage menu of interventions compiled by WHO *(22)*.	**Setting the stage** – To understand how this DAK would be applied to person-centred point-of-service systems (PCPOSS) in the context of specific health programmes and interventions.	» **List of related health interventions** based on WHO universal health coverage essential interventions; and » **List of related WHO recommendations** based on guidelines and guidance documents.	» Contextualization to reflect current or planned national policies.
2. Generic personas	Depiction of the end users, supervisors and related stakeholders who would be interacting with the digital system or involved in the care pathway.	**Contextualization** – To understand the wants, needs and constraints of the end users.	» **Description, competencies and essential interventions** performed by targeted personas.	» Greater specification and details on the end users based on real people (e.g. health workers) in a given context; and » High-level information to describe the provider of the health service (e.g. the general background, roles and responsibilities, motivations, challenges and environmental factors).
3. User scenarios	Narratives that describe how the different personas may interact with each other. The user scenarios are only illustrative and are intended to give an idea of a typical workflow.	**Contextualization** – To understand how the system would be used and how it would fit into existing workflows.	» Example **narrative** of how the targeted personas may interact with each other during a workflow.	» Greater specification and details on the real needs of end users in a given context.
4. Generic business processes and workflows	A business process is a set of related activities or tasks performed together to achieve the objectives of the health programme area, such as registration, counselling and referrals *(1,23)*. Workflows are a visual representation of the progression of activities (tasks, decision points, interactions) that are performed within the business process *(1,23)*.	**Contextualization and system design** – To understand how the digital system would fit into existing workflows and how best to design the system for that purpose.	» Overview **matrix** presenting the **key processes** for immunization; and » **Workflows** for identified business processes with annotations.	» Customization of the workflows that can include additional forks, alternative pathways or entirely new workflows.

Component	Description	Purpose	Output/artifacts	Adaptation needed
5. Core data elements 	Data elements are required throughout the different points of the workflow. These data elements are mapped to the codes of the International Classification of Diseases 11th Revision (ICD-11) and other established concept mapping standards to ensure the data dictionary is compatible with other digital systems.	**System design and interoperability** – To know which data elements need to be logged and how they map to other standard terminologies (e.g. ICD and Systematized Nomenclature of Medicine [SNOMED]) for interoperability with other standards-based systems.	» List of data elements. » Link to **data dictionary** with detailed data specifications in spreadsheet format (available *here*).	» Translation of "data labels" into the local language and additional data elements created depending on the context.
6. Decision-support logic 	Decision-support logic and algorithms to support appropriate service delivery in accordance with WHO clinical, public health and data use guidelines.	**System design and adherence to recommended clinical practice** – To know what underlying logic needs to be coded into the system.	» List of decisions that need to be made throughout the encounter. » **Link to decision-support logic and contraindications tables** in a spreadsheet format with inputs, outputs and triggers for each decision logic (available *here*). » **Scheduling logic** for services (available *here*).	» Change of specific thresholds or triggers in a logic (IF/THEN) statement; and » Additional decision-support logic formulas depending on the context.
7. Indicators and performance metrics 	Core set of indicators that need to be aggregated for decision-making, performance metrics and subnational and national reporting. These indicators and metrics are based on data that can feasibly be captured from a routine digital system, rather than survey-based tools.	**System design and adherence to recommended health monitoring practices** – To know what calculations and secondary data use are needed for the system, based on the principle of "collect once, use many" *(17)*.	» **Indicators table** with numerator and denominator of data elements for calculation, along with appropriate disaggregation (available *here*).	» Changing calculation formulas of indicators; » Adding indicators; and » Changing the definition of the primary data elements used to calculate the indicator based on data available.
8. Functional and non-functional requirements 	A high-level list of core functions and capabilities that the system must have to meet the end users' needs and achieve tasks within the business process.	**System design** – To know what the system should be able to do.	» **Table of functional and non-functional requirements** with the intended end user of each requirement, as well as why that user needs that functionality in the system (available *here*).	» Adding or reducing functions and system capabilities based on budget and end user needs and preferences.

Throughout the DAK, there are identification (ID) numbers to simplify tracking and referencing of each of the components. Note that the DAK represents an overview across the different components, while the comprehensive and complete outputs of each component (e.g. data dictionary and decision-support tables) are included in appended spreadsheets. **Box 3** provides an overview of the notation guidance.

Box 3

ID notation guidance

Component 1: Health interventions and recommendations
No notations used.

Component 2: Generic personas
No notations used.

Component 3: User scenarios
No notations used.

Component 4: Business processes and workflows

» Each workflow will have a "Process name" and a corresponding letter. Each workflow will also have a "**Process ID**" that is structured: "**Abbreviated health domain**" (e.g. immunization [IMMZ]) "**Corresponding letter for the process**" (e.g. A), **i.e. IMMZ.A**

» Each activity in the workflow will be numbered with an "**Activity ID**" that is structured: "**Process ID**" from above "**Activity number**", **i.e. IMMZ.B7**

Component 5: Core data elements (data dictionary)

» Each data element will have a running number and a "**Data element (DE) ID**" that is structured: "**Activity ID**" (e.g. IMMZ.B7)."DE"."Sequential number of the data element" (**i.e. IMMZ.B7.DE.1, IMMZ.B7.DE.2**)

Component 6: Decision-support logic

» Each decision-support logic table will have a running number and a "**Decision-support table (DT) ID**" that is structured: "**Activity ID**" (e.g. IMMZ.D2)."DT"."Antigen name" (**i.e. IMMZ.D2.DT.Measles, IMMZ.D2.DT.Cholera**)

Component 7: Indicators and performance metrics

» Each indicator will have an "**Indicator (IND) ID**" that is structured: "**Abbreviated health domain**" (e.g. IMMZ)."IND"."Sequential number of the indicator"(**i.e. IMMZ.IND.1, IMMZ.IND.2**)

Component 8: High-level functional and non-functional requirements

» Each functional requirement will have a "**Functional requirement (FXNREQ) ID**" that is structured: "**Abbreviated health domain**" (e.g. IMMZ)."FXNREQ"."Sequential number of the functional requirement" (**i.e. IMMZ.FXNREQ.1, IMMZ.FXNREQ.1**)

» Each non-functional requirement will have a "**Non-functional requirement (NFNREQ) ID**" that is structured: "**Abbreviated health domain**" (e.g. IMMZ)."NFXNREQ"."Sequential number of non-functional requirement" (**i.e. IMMZ.NFXNREQ.1, IMMZ.NFXNREQ.2**)

How this digital adaptation kit was developed

A mapping of existing WHO guidelines, guidance and tools relevant for the development of a DAK for immunizations was carried out first. Key resources that were identified included all WHO immunization-related clinical guidelines and relevant immunization guidance documents (see **section 1.2** for additional details on the guidelines and guidance used to develop this DAK).

A desk review of the above resources was conducted, where the recommendations from clinical guidelines were extracted and synthesized to form the components of the DAK for immunizations. This process also guided the development of the workflows for key immunization programmatic and data processes, decision-support logic algorithms and a data dictionary. The indicators and performance metrics included in the DAK for immunizations were informed by vaccination coverage information available on WHO Immunization Data Portal *(24)*. The data elements required to calculate the indicators and to build the algorithms in the decision-support logic were based on the relevant clinical guidelines and guidance documents. The data elements were mapped onto standardized terminologies and classifications by a medical terminologist to facilitate the adoption of interoperability standards into digital systems.

All components of this DAK for immunizations were refined through a series of in-depth technical consultations with external experts and stakeholders and relevant teams from the Department of Immunization, Vaccines and Biologicals, which were responsible for developing the WHO guidelines and guidance used to guide the development of this DAK; DAKs are derivative guidance documents that support the implementation of WHO guidelines and guidance in digital systems. These teams also reviewed and validated the sections of the DAK for immunizations relevant to their area of expertise to ensure that each component reflects the narrative in WHO guidelines and guidance.

Other published DAKs, and the teams responsible for their development, were consulted as needed to ensure alignment across the SMART guidelines programme.

Individual, external contributors involved in the development and review of this DAK declared any potential conflicts of interest prior to providing their contributions. These declarations were reviewed and found none of the contributors to have conflicting interests that would influence the content of this publication.

How to use this digital adaptation kit

Target audience

The primary target audience for this DAK are health programme managers within the health ministries, who will be working with their digital or health information systems counterparts in determining the health content and programme requirements for a PCPOSS or EIR for immunizations. The health programme manager is responsible for overseeing and monitoring the implementation of the clinical practices and policies for the health programme area, in this case immunizations.

The DAK also equips individuals responsible for translating health-system processes and guidance documents for use within digital systems with the necessary components to kick-start the process of developing PCPOSS in a standards-compliant manner. These individuals are also known as business analysts who interface between health content experts and software development teams. Specifically, the DAK contains key outputs, such as the data dictionary and decision-support algorithms, to ensure the validity and consistency of the health content with the PCPOSS.

Use of this DAK requires collaboration between health programme managers responsible for immunization and counterparts in digital health or health management information systems. Although each DAK focuses on a particular health programme area (in this case immunizations), the DAKs are envisioned to be used in a modular format and link to other health programme areas within primary health care settings to support integration across services.

Scenarios for using the digital adaptation kit

The SMART guidelines, and the DAK in particular, may be used across various scenarios, some of which are listed below.

Scenario 1 **Incorporating WHO guideline content into existing digital systems**	Countries that already have digital systems in place, such as electronic medical records, EIRs and decision support tools, may use the information within the DAK to crosscheck if the underlying content and data for specific health programme areas are aligned with the latest WHO recommendations. Users of the DAK can identify and extract specific decision support algorithms that would need to be incorporated into their existing digital systems. By reviewing this systematic documentation, health programme managers and implementers can more readily identify differences in workflows, data inputs and decision-support logic to examine the rationale for deviations and understanding local adaptation of global guidelines.
Scenario 2 **Transitioning from paper to digital**	Some countries may currently have paper-based systems that they would like to digitalize. The process of optimizing paper-based client-level systems into digital records with decision support may be overwhelming. Users in this scenario may review the DAK as a starting point for streamlining the necessary data elements and decision support that should be in the optimized client-level digital system. Users may then refer to the paper-based tools to determine if there are missing fields or content that should also be included within the digital system. Additionally, users should review the WHO *Digital transformation handbook for primary health care (25)*, which provides stepwise guidance on how to map data on paper-based forms into a digital system, including ways of accounting for redundant or orphaned data elements that may not add value to the health system or the health worker.

Scenario 3 **Linking aggregate health management information systems (HMIS) to PCPOSS used at point of care**	In some instances, countries may already have implemented a digital system for aggregate reporting and HMIS but have not yet implemented digital systems that function at the service-delivery level. The DAK can guide the development of a PCPOSS that includes an electronic medical (or health) record system, a community-based information system, decision-support system and personal health records that operates at the point of service, or point of care, and ensures that there are linkages from the data collected at the service-delivery levels (e.g. community or facility level) to the aggregate levels. As such, a component of the DAK provides aggregate indicators derived from individual level data to provide the linkage between different levels (e.g. service delivery at the community or facility level and aggregate reporting at the district and national levels). Complementary guidance dedicated specifically to aggregate-level data such as *Analysis and use of health facility data: guidance for immunization programme managers (26)* can also be consulted for supporting the use of routine data at the facility management and district levels.
Scenario 4 **Leveraging data standards to promote interoperability and integrated systems**	This DAK includes data elements mapped to International Classification of Diseases 11th Revision (ICD-11) codes, and other terminology and classification standards, to support the design of interoperable systems. The data dictionary provides the necessary codes for different data elements, thus reducing the time needed for implementers to incorporate these global standards into the design of their digital systems.
Scenario 5 **Linking point-of-service systems used at the point of care by health workers to personal health records systems held by individuals**	A critical part of service delivery in any health domain relies on engaging with clients. Digital interventions aimed at clients themselves – such as on-demand information services, targeted client communication (e.g. transmitting health information and reminders), reporting of health-system feedback by clients on the quality of care, accessing their own medical records/home-based records, and self-monitoring of their health and diagnostic data *(16)* – are all emerging approaches for complementing the services provided by health workers. Specifically for immunizations, clients will need to have access to their immunizations' history for purposes of continuity of care and/or providing proof of vaccination for purposes not related to health care (e.g. coverage monitoring surveys, access to education and for domestic or international travel).

Linkages to the broader digital health ecosystem

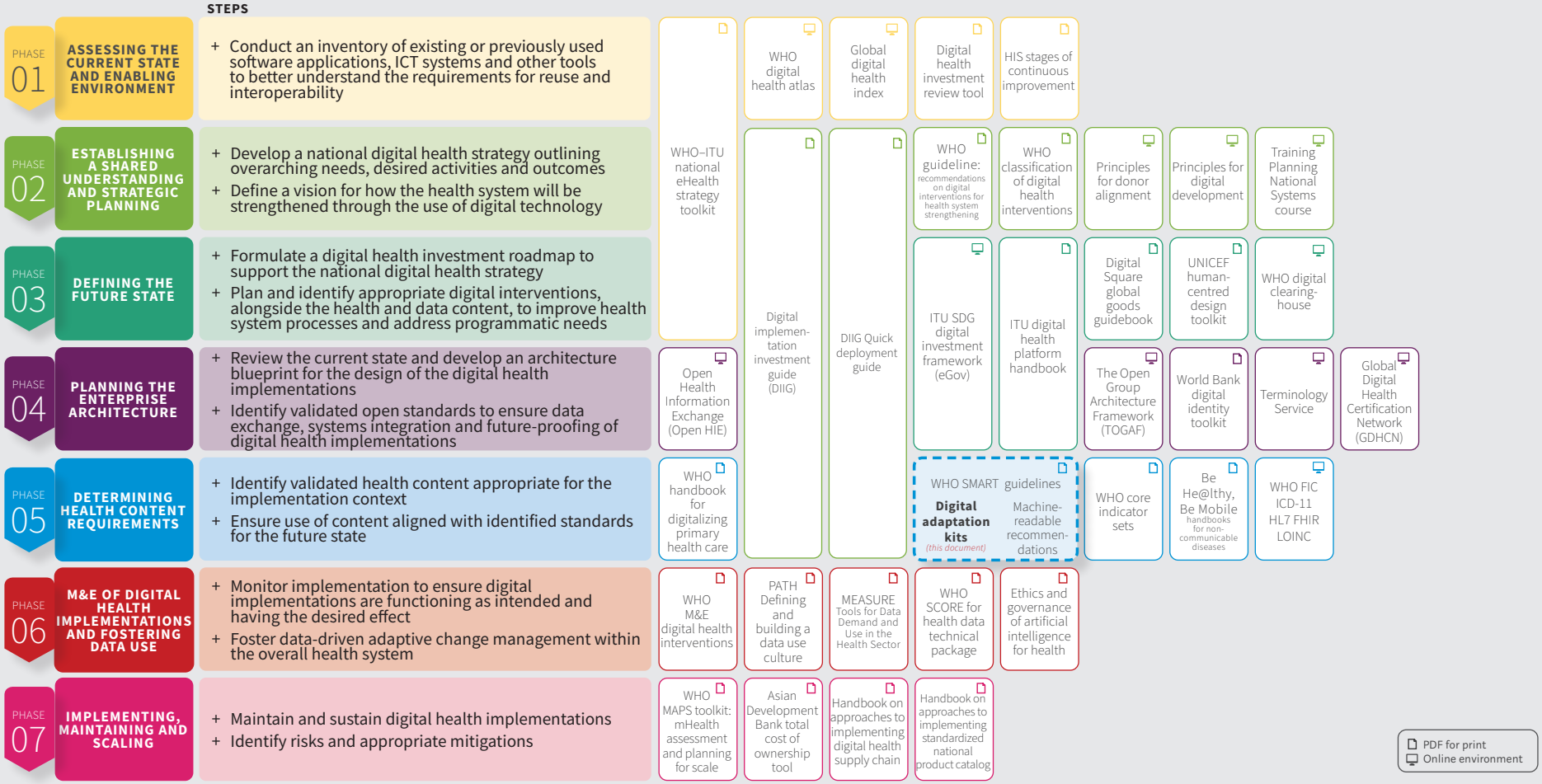
SMART guidelines and DAKs represent one piece of the resources in the broader digital health ecosystem and should be used once there is a strategic vision by health ministries on how to use digitized immunization data in the context of PCPOSS to support immunization programme goals. For example, this DAK builds on the Product Vision for the Better Immunization Data (BID) Initiative *(21)*, but immunization programme managers should also refer to guidance on *Electronic immunization registry: practical considerations for planning, development, implementation and evaluation (15)*, which is intended to provide a background, foundation, planning, design, development and implementation considerations for EPI programme managers. However, in contexts where an overarching vision for digital health may not exist, users should first consult the *National eHealth strategy toolkit (27)* co-authored by WHO and the International Telecommunication Union, the *WHO guideline: recommendations on digital interventions for health system strengthening (14)* and the *WHO digital investments and implementation guide (13)* to establish a better understanding of how to select and apply appropriate digital health interventions.

Fig. 3 situates DAKs within the broader set of resources for planning and implementing digital health systems.

The DAK for immunizations, in particular, should be used to inform the overall individual-level data and functionality needs of the immunization programme. This is not restricted for use in an EIR, as the content requirements outlined in this DAK can also be used to inform the design of an immunization module within an electronic medical record (EMR) system, for example. The data and functional requirements outlined in this DAK can be supported by multiple services and applications, including for example, civil registration and vital statistics systems and logistics management information systems.

Fig. 3

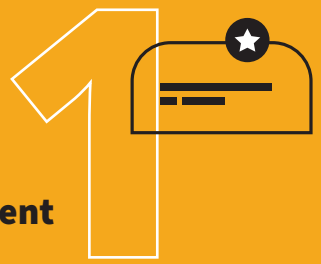
Planning and implementing a digital health enterprise: phases, steps and resources



HIS: health information system; ICT: information and communications technology; ITU: International Telecommunication Union; M&E: monitoring and evaluation; SDG, Sustainable Development Goal.

Source: Adapted from WHO *(1)*.

Digital adaptation kit content for immunizations



Component 1

Health interventions and recommended interventions

1.1 List of interventions referenced in this DAK based on WHO universal health coverage list of essential interventions

Interventions referenced in this DAK are based on WHO universal health coverage list of essential interventions.

» General vaccine administration practices for all age groups, including children, are:

- counselling on the vaccine(s) to be administered
- document and report on immunizations administered
- document vaccinations received on a personal immunization record, including the home-based record
- observe for any adverse event following immunization (AEFI)
- targeted history and physical examination for vaccination
- defaulter tracing
- follow-up visit(s).

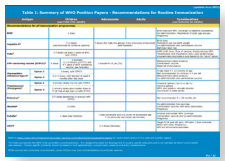
» Vaccination, based on individual characteristics, include:

- bacille Calmette–Guérin (BCG)
- cholera
- dengue
- diphtheria–tetanus–pertussis (DTP)
- *Haemophilus influenzae* type b (Hib)
- hepatitis A
- hepatitis B
- human papillomavirus (HPV)
- Japanese encephalitis (JE)
- malaria
- measles
- meningococcal
- mumps
- pneumococcal
- poliomyelitis (polio)
- rabies
- rotavirus
- rubella
- seasonal influenza
- tick-borne encephalitis (TBE)
- typhoid
- varicella
- yellow fever.

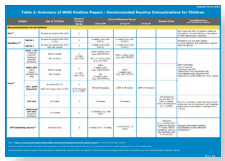
Note: The decision-support logic related to COVID-19 vaccinations is not included in this DAK owing to the currently evolving science regarding COVID-19 immunizations and boosters at the time of publication. However, the relevant data from the *Digital documentation of COVID-19 certificates: vaccination status: technical specifications and operational guidance (28)* were incorporated into this document.

1.2 WHO guidelines, recommendations and guidance

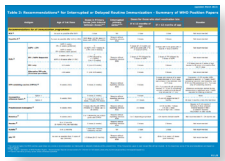
These interventions draw from the following WHO guidelines and guidance.



Summarizes recommended routine immunizations for all age groups (updated in 2024), including cited WHO vaccine position papers (29)



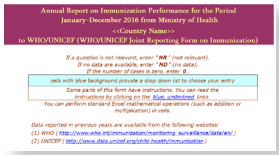
Detailed information of routine immunizations for children (updated in 2024) , including cited WHO vaccine position papers (29)



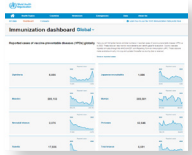
Recommendations for interrupted and delayed vaccination (updated in 2024), including cited WHO vaccine position papers (29)

Summarizes WHO recommendations for the vaccination of health workers (updated in 2024), including cited WHO vaccine position papers (29)

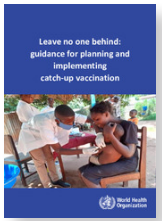
Analysis and use of health facility data: guidance for immunization programme managers (26)



Sample of the WHO/UNICEF joint report form on immunization (30)



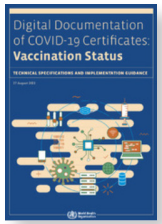
The WHO Immunization Data Portal: providing access to important immunization data and insights (24)



Leave no one behind: guidance for planning and implementing catch-up vaccination (31)

Electronic immunization registry: practical considerations for planning, development, implementation and evaluation (15)

Monitoring metrics related to the global COVID-19 vaccination strategy in a changing world (32)



Digital documentation of COVID-19 certificates: vaccination status: technical specifications and implementation guidance (28)

Generic personas

A persona is a depiction of a relevant stakeholder or "end user" of the system. Although the specific roles and demographic profile of the personas will vary depending on the setting, these generic personas are based on the WHO core competencies and credentials of different health worker personas. This is a starting point, generalized based on multiple contexts, and further contextualization using human-centred design methodologies will be required to truly understand the needs, motivations and challenges of the personas addressed.

2.1 Targeted generic personas

The targeted personas for this DAK for immunizations are health workers operating in care settings that are able to provide the required essential interventions for immunization delivery. The key competences of health workers, community health workers and EPI managers are defined by WHO in Tables 2–4.

Table 2. Descriptions of key generic personas

Name	Description	Other names/examples	ISCO code
Health worker	Health workers facilitate education sessions, administer immunizations, provide counselling when needed, record vaccinations administered, record stock movements and compile, generate, and submit reports.	Nurse, registered nurse, practical nurse	3221 Nursing associate professional
Community health worker	Community health workers provide health education, referral and follow-up, case management and basic preventive health care and home visiting services to specific communities. They provide support and assistance to clients by reminding them to get their vaccinations, responding to emergencies and reporting births.	Community health volunteer, village health worker, volunteer assistant, volunteer health worker, treatment supporter, health promoter	3253 Worker, community: health
EPI Manager	Expanded Programme on Immunization (EPI) managers develop annual and multi-annual plans, immunization communication and mobilization, management of cold chain and vaccine logistics, monitoring, supervision and evaluation of immunization services, and coordination of EPI activities at the national and subnational levels *(20)*.	Programme manager	1342 Manager, health service

ISCO: International Standard for Classification of Occupations.

Table 3. Descriptions of related personas

Name	Description	Other names/examples	ISCO code
Caregiver	Mother, father, guardian, carer of the child, infant, elderly or disabled person.	Parent, guardian	N/A
Client	In the context of this document, a client is a person who intends to receive immunization services from the targeted health worker personas. A client who is 15 years of age or younger is considered a child.	Vaccinated person	N/A
Child	A client who is 15 years of age or younger and who intends to receive immunization services from the targeted health worker personas.	Infant, baby, client	N/A
System administrator	A systems administrator, or a dedicated electronic immunization registry (EIR) staff, supervises the operation and storage of electronic health records and makes sure the server functions properly to allow clients and staff to communicate with each other, coordinate their actions and take care of essential tasks.	IT manager, technical support, EIR staff	2522 Administrator, IT systems
Clerical staff	A clerical staff assists in scheduling appointments, answers phone calls, greets clients, keeps/documents medical records and handles medical billing.	Registration clerk	3252 Clerk, information: health

ISCO: International Standard for Classification of Occupations; IT: information technology; N/A: not applicable.

Table 4. Descriptions of settings

Setting Title	Description	Other names/examples	ISCO code
Vaccination location	Designated location where vaccinations are administered to individuals. These sites may be established and operated by health-care organizations, government agencies or other entities involved in public health efforts. Vaccination locations can vary in size and set-up depending on the scale of the vaccination campaign and available resources. A health-care facility may have multiple vaccination locations under it. Some vaccination locations may be established temporarily during an outbreak or pandemic as part of a facility, while others may be permanent facilities. In some circumstances, outreach vaccination sites are established to provide services to hard to reach remote populations by moving immunization services closer to them.	Vaccination site, health-care facility, health centre, village, post, school, college, community hall	N/A

ISCO: International Standard for Classification of Occupations; N/A: not applicable.

2.2 Additional considerations for contextualizing personas

This section provides an overview of the generic roles of the targeted personas. It will be important to contextualize these personas to local settings. The descriptions of the generic personas given above can be supplemented by reflecting on the following additional considerations:

- **Background and demographics** (e.g. gender, age, whether from the community, familiarity with digital devices, possession of a mobile phone/smartphone, etc.).
- **Local environment** and any relevant contextual information about their surroundings (e.g. work site characteristics; rural or urban; availability of electricity, water or internet; distance from nearest referral facility, etc.).
- **Expected roles and responsibilities:** What are the **expected** roles and responsibilities based on country context? How does this differ from the roles and responsibilities defined by WHO?
- **Actual roles and responsibilities:** What are their **actual** roles and responsibilities, if there is any difference from what is expected?
- **Context:** What is the availability of internet connectivity? How are these personnel compensated? What is the distance to the nearest referral facility? What other personas/health workers do they interact with?
- **Challenges:** What are the day-to-day challenges the end user might face?
- **Motivations:** What does success look like to them? Are there performance targets they are expected to achieve?

Component 3: User scenarios

User scenarios are a narrative description of how the end user would interact with the digital system. The user scenario is provided to help the reader better understand how the system will be used and how it would fit into existing workflows. The user scenario provides context in a story-telling format. Furthermore, within the user scenario, it should be possible to derive the key components that are further elaborated in the rest of this DAK. This includes the core data elements, decision-support logic and core functionality of a digital system that would be needed. Although there is no clear template for a user scenario, it should:

» include personas involved based on the generic personas component;
» have narrative description of who and how a digital system would be used;
» provide details on what kinds of data are collected and decisions are made;
» reflect the workflows that will be further elaborated on in **Component 4: Generic business processes and workflows**.

3.1 How to interpret user scenarios

User scenarios are helpful tools to better understand the context in which a digital tool would operate and gain insights into which key data elements are needed to be recorded and accounted for in the database. Additionally, the context in which the digital tool would operate, illuminated by the user scenarios, provides insight into some functional and non-functional system requirements. For example, highlighted in yellow are key data elements that need to be recorded and/or calculated. Highlighted in blue are decision-support logic that can be automated in the system. Highlighted in green are key functional and non-functional requirements that should be included in the system.

For example, the interpretation of the user scenario for routine vaccination clinic, defaulter tracing and catch-up campaign are shown in **Tables 5–7**.

Table 5. Interpretation of the routine vaccination clinic user scenario

Data element to be collected	Decision-support logic to be embedded	Functional and non-functional requirements
» Unique identifier » Name » Date of birth » Vaccine type » Date and time of vaccination	» Determine which vaccines are due at this time (taking into account last vaccine date and national vaccine schedule) » Determine which vaccines are due for the next visit (taking into account last vaccine date and national vaccine schedule)	» Ability to generate SMS messages based on trigger events » Indicate consent to receive reminders

Table 6. Interpretation of the defaulter tracing user scenario

Data element to be collected	Decision-support logic to be embedded	Functional and non-functional requirements
» Name » Sex » Date of birth » Caregiver's full name » Contact phone number » Administrative area » Vaccine type » Date and time of vaccination	» Determine list of vaccines due for each child (taking into account last vaccine date and national vaccine schedule) » Determine if vaccines are past due (by more than a set number of days) for each child	» Register children who have been vaccinated or those to be vaccinated » Generate a list of children who are due (or overdue) for a vaccine within a specific timeframe and catchment area » Send a list of children who are overdue for follow-up to another health worker » Ability to automatically send SMS messages reminders

Table 7. Interpretation of the catch-up campaign user scenario

Data element to be collected	Decision-support logic to be embedded	Functional and non-functional requirements
» Number of children vaccinated (through monthly reports)	» Determine which vaccines are past due at this time (taking into account date of birth, last vaccine date and national vaccine schedule) » Determine if overall coverage is below target	» Ability to generate monthly and ad hoc reports » Ability to sort and filter reports by vaccination location, and other attributes as needed

3.2 User scenario for a routine vaccination clinic

Key personas	Caregiver (mother): Ruth Child: Esther Health worker: Lucy

Ruth is 21 years old and Esther, her first baby, is 10 weeks old. Ruth completed primary school and has basic literacy. Her husband attended secondary school for three years, but he did not finish. They all live in a two-room house with intermittent electricity in a village near Msindo.

Esther was born at home. Although Esther's birth was not registered (and she does not have a birth certificate), the clinic (also known as the vaccination location that also provides vaccination services) assigned an ID to Esther when Ruth took her in for her first round of immunizations shortly after her birth. It takes Ruth just over an hour to walk to the Msindo clinic from her home. Ruth enjoys going to the clinic as it is a chance to talk to other new mothers, and she gets helpful information from the nurse about keeping her baby healthy.

The Msindo clinic is open five days a week in the morning. There are three nurses who work at the clinic, one of them being Lucy who has 12 years of experience and a diploma in nursing. Lucy is responsible for ensuring the delivery of scheduled vaccines to children as part of the "Under-5 Programme". She screens and monitors children who are at risk and may require intervention to prevent future health issues. Lucy also provides preventative care (such as vaccines and other supplements) and teaches mothers about various health topics related to their child(ren).

Ruth and Esther arrive at the clinic just after 09:00, and there are already five other mothers waiting in line with their babies. When it is Ruth's turn, she goes to the table where Lucy is sitting and hands her Esther's paper vaccination card (or home-based record), which she received during Esther's first clinic visit. The card contains Esther's name, date of birth and a record of each vaccine given, as well as her weight at that visit. Lucy uses the ID on the top of the card to look up Esther's record on her tablet. She finds the record and can see in the system that Esther is due for four vaccines at this time. Lucy weighs Esther using the scale set up beside the desk, and she records her weight on both the paper card and in the electronic immunization registry (EIR) on her tablet for growth monitoring. She tells Ruth that Esther is gaining weight well, and they briefly discuss some questions Ruth has about breastfeeding.

Lucy takes the appropriate vaccines out of the small cooler box beside her table. She filled the cooler box earlier that morning based on what she would typically need based on an average clinic day. She has access to more vaccines, but they are in the refrigerator in the storage room. She prepares each vaccine, making sure that it is not expired and that the small symbol on the vial indicates it is safe to give. Lucy administers each vaccine (starting with the ones given by mouth, then the injections) to Esther. While Ruth comforts Esther, Lucy records the vaccines given in the EIR on the tablet, as well as on Esther's paper immunization card, also sometimes referred to as a home-based record or personal immunization record. She tells Ruth when to bring Esther back for her next vaccines, and she also writes this on Esther's paper immunization card. Lucy also advises Ruth on what to do if Esther develops a fever or other symptom(s) following vaccination. Since the clinic operates every weekday morning, Ruth understands that while she should try to come on the date given, it is not an actual appointment and just a guideline to come within a day or two of that date. Lucy also informs her that they have a new system that can send SMS reminder when Esther is due for a vaccine to her phone if she would like. Ruth agrees that she would like this reminder, and Lucy confirms her phone number in the system and checks the box that indicates she would like to receive these notifications.

Corresponding business processes (see **Component 4**)	This scenario refers to the following business processes: C. Client registration D. Administer vaccine E. Client reminder

3.3 User scenario for defaulter tracing

Key personas	Health worker: Lucy Community health worker: Aminata

At the Msindo clinic, Lucy is responsible for ensuring the delivery of scheduled vaccines to children as part of the "Under-5 Programme". Lucy has an estimate for the number of children that need to be vaccinated in the clinic. This estimated number is based on the population her clinic serves, as it is the only clinic in the area. Lucy works closely with Aminata, a community health worker, to find and encourage caregivers to bring their children to the clinic for vaccination. Aminata lives in the village and is the wife of the school's headmaster. She is well respected in the community and has been a community health worker for the past 10 years. Although she is not paid for this work, she is happy to know she is helping her community raise healthy children. She is responsible for both children and pregnant women, and she regularly councils them to ensure they attend appointments and get the care they need in a timely manner. Aminata has completed secondary school, and her training for this role has been both on the job, as well as some workshops that are held a few times a year.

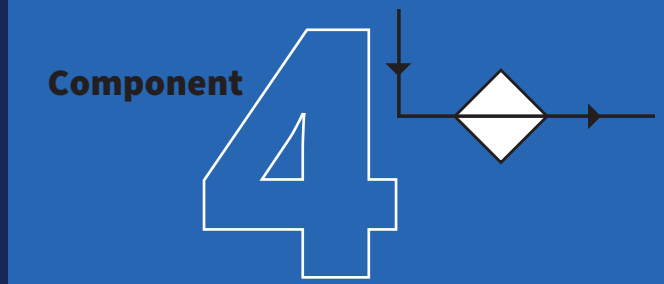
At the clinic, Lucy registers each child who has come for their first vaccines in the electronic immunization registry (EIR), which has been implemented to replace the cumbersome paper ledger book. The child's name, sex, date of birth, caregivers' name and some other identifying information are entered into the EIR, and the EIR notes which vaccine(s) are needed. Lucy enters the date each vaccine is given into the EIR and no longer needs to add the same information into a large paper ledger book.

Now with an EIR in place, Lucy no longer takes several hours each week reviewing her paper ledger and calculating overdue status to determine which children need follow-up. Lucy can see on her tablet the list of children who are overdue or late for their vaccines based on the vaccine schedules determined by national policies and their relevant contact information she may need for follow-up (e.g. caregivers' name and contact info). This list is also sent to Aminata via an SMS message once a week so that she can help with follow-up. At the clinic, the staff started using the EIR to automatically send an SMS message to the caregiver to remind them when their child is due to come for the next vaccine. Lucy is hopeful that this will help to reduce the number of children who are brought in late for their vaccines.

Corresponding business processes (see **Component 4**)	This scenario refers to the following business processes: B. Plan service delivery C. Client registration E. Client reminder F. Defaulter tracing I. Report generation

3.4 User scenario for periodic intensification of routine immunization campaign (catch-up campaign)

Key personas	District EPI manager: John
John has been the district Expanded Programme on Immunization (EPI) manager for the past six years. John is responsible for developing annual and multi-annual plans, immunization communication and mobilization, management of cold chain and vaccine logistics, monitoring, supervision and evaluation of immunization services, and coordinating EPI activities at the national and subnational levels. He closely monitors the monthly reports that each vaccination location sends that includes the number of children vaccinated as a proportion of the vaccination location's catchment area and looks for potential issues that may require his attention. Some examples include inaccurate report data, situations where the overall vaccine coverage in a vaccination location may be lower than their targets, or if a vaccination location had vaccine stock-outs. John is also responsible for keeping track of the target population of children in his district and a map of where that population is located. Vaccination locations in John's district, like the rest of the region, continue to have significant challenges owing to displacement caused by natural disasters including reduced hours when administering routine vaccines or been closed altogether. Many caregivers refrained from bringing their children for routine vaccinations, even when the vaccination locations were open, owing to difficulties obtaining transportation to the vaccination location. As a result, John has noticed that the coverage rates for most vaccines is much lower than before. Following improvements to infrastructure and as people begin to return to their homes after the recovery efforts, most clinics have returned to operating normally. However, there are still many children who are overdue for their vaccines. During a workshop last month, John and his fellow district EPI manager colleagues were informed that they should plan for local catch-up campaigns as part of a coordinated national plan to address low vaccination coverage. John and his team have conducted these catch-up campaigns previously, typically one or two times a year during national "Child Health Week" events or "Immunization Days". Since this campaign will be larger owing to the number of overdue vaccines, the national EPI programme is working with other partners to offer additional support. John is responsible for reviewing the plan created by the national government for the campaign in his region, examining the budget and overseeing the campaign's implementation. John works closely with stakeholders (coordination) and the community (communication) to implement the districts' immunization plans.	
Corresponding business processes (see **Component 4**)	This scenario refers to the following business processes: B. Plan service delivery I. Report generation



Generic business processes and workflows

A business process is a set of related activities or tasks performed together to achieve the objectives of the health programme, such as registration, counselling or referrals *(13,23)*. Workflows are a visual representation of the progression of activities (tasks, events, interactions) that are performed within the business process *(23)*. The workflow provides a "story" for the business process being diagrammed and is used to aid communication and collaboration among users, stakeholders and engineers.

This DAK focuses on key business processes that are part of routine immunization programmes and mass immunization campaigns (see **Table 8**). The significant difference between routine immunizations and mass immunization campaigns is in the planning phase (see process **B. Plan service delivery**). The remaining business processes, most importantly process **D. Administer vaccine** (which drives most of the decision logic of whether to vaccinate or not), are the same regardless of whether they are part of the routine immunization programme or a mass immunization campaign. The workflows of the identified processes use standard notation for business process mapping. **Table 9** provides an overview of this notation. For each process type, the corresponding business processes, data elements and decision support needs are detailed in the subsequent sections of this document.

Table 8. Overview of business processes

#	Process	Process ID	Personas	Objectives	Task set
	Title	ID used to reference this process throughout the DAK	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
A	Vaccination location registration	IMMZ.A	System administrator	All vaccination locations (including private sector facilities, government centres and/or other entities involved in public health efforts) able to administer vaccines must be registered and uniquely identified to enable appropriate tracking of vaccine coverage and stock. In the case of a health-care facility with multiple vaccination locations, only the facility will be registered.	Starting point: System administrator registers new vaccination location or update information about existing vaccination location. » Validate against the National Master Facility List (NMFL) » Notify NMFL team of changes/updates » Request and submit additional information » Create and update vaccination location record » Generate unique identifier for vaccination location » Send vaccination location registration notification

#	Process	Process ID	Personas	Objectives	Task set
	Title	ID used to reference this process throughout the DAK	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
B	Plan service delivery	IMMZ.B	Health worker	In preparation for a vaccination session, ensure sufficient supply and organize workload	Starting point: Health worker reviews historical vaccination records to determine vaccine need estimates. » Record details on planning sheet » Order additional stock » Record stock received » Assemble all needed materials for immunization session
C	Client registration	IMMZ.C	Client, health worker	Create, retrieve and/or update the clients' vaccine record by including personal data in the EIR to support future vaccine administration	Starting point: Client arrives at the vaccination location and the health worker locates the client's vaccination history. » Search for client's record via EIR » Review and update client's record » Create a new client record as required
D	Administer vaccine	IMMZ.D	Health worker	To determine which vaccines a client needs, administer those and record the relevant necessary data both in the EIR as well as in the appropriate paper records, such as the home-based record or paper immunization card.	Starting point: When the client has been registered and will receive vaccines, if needed. » Capture client history, including vaccinations history, to check for contraindications » Determine required vaccinations, if any » Inform client when to return for vaccine » Prepare and administer vaccine » Dispose of waste » Record appropriate data » Monitor client » Generate digital or paper vaccination certificate
E	Client reminder	IMMZ.E	Health worker	To remind clients it is time to return for a vaccine	Starting point: Client records are evaluated to determine if they meet the defined criteria » Select notification method » Generate list of clients » Send notifications
F	Defaulter tracing	IMMZ.F	Health worker, community health worker	To identify those who are overdue for a vaccine and reach out to them to schedule their vaccination	Starting point: Health worker needs to determine if any vaccines were missed according to the national schedule » Plan for follow-up directly or during outreach » Send client information to community health worker » Ensure client attends clinic or outreach session and is vaccinated » Provide feedback » Update record to document reason/lost to follow-up

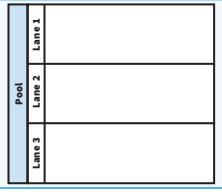
#	Process	Process ID	Personas	Objectives	Task set
	Title	ID used to reference this process throughout the DAK	Individuals interacting to conduct the process	What the process seeks to achieve	The general set of activities performed within the process
G	Resolve duplicate client records	IMMZ.G	Health worker, system administrator	To identify duplicate client records and consolidate them into one most accurate/ suitable record	Starting point: Flag potentially duplicate client records for evaluation » Produce a list of potential duplicate records » Perform manual review » Merge and deduplicate records as needed
H	Resolve duplicate vaccination events	IMMZ.H	Health worker, system administrator	To identify duplicate vaccination events within a client record and update into one event	Starting point: Identify groups of potential duplicate vaccination events for evaluation » Evaluate vaccination event records » Update vaccination event records as needed » Generate report of duplicate vaccination events
I	Report generation	IMMZ.I	Health worker	To provide the ability to access and analyse data and to improve immunization programme decision-making	Starting point: Define parameters for reporting » Generate report » High-level review » Analyse

ID: identification; IMMZ: immunization.

4.1 Overview of key business processes

This section illustrates the workflows of the identified processes using standardized notations for business process mapping. **Table 9** first provides an overview of this notations, and **Fig. 4** provides a workflow diagram of all the key processes involved in immunization service delivery. Some of these individual business processes are further detailed in **Fig. 5–13**.

Table 9. Business process symbols used in workflows

Symbol	Symbol name	Description
	**Pool**	A **pool** consists of multiple "swim lanes" that depict all the individuals or types of users that are involved in carrying out the business process or workflow. Diagrams should be clear, neat and easy for all viewers to understand the relationship across the different swim lanes. For example, a pool would depict the business process of conducting an outreach activity, which involves multiple stakeholders represented by different lanes in that pool.

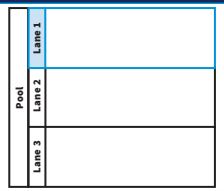
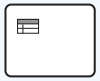
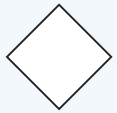
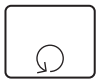
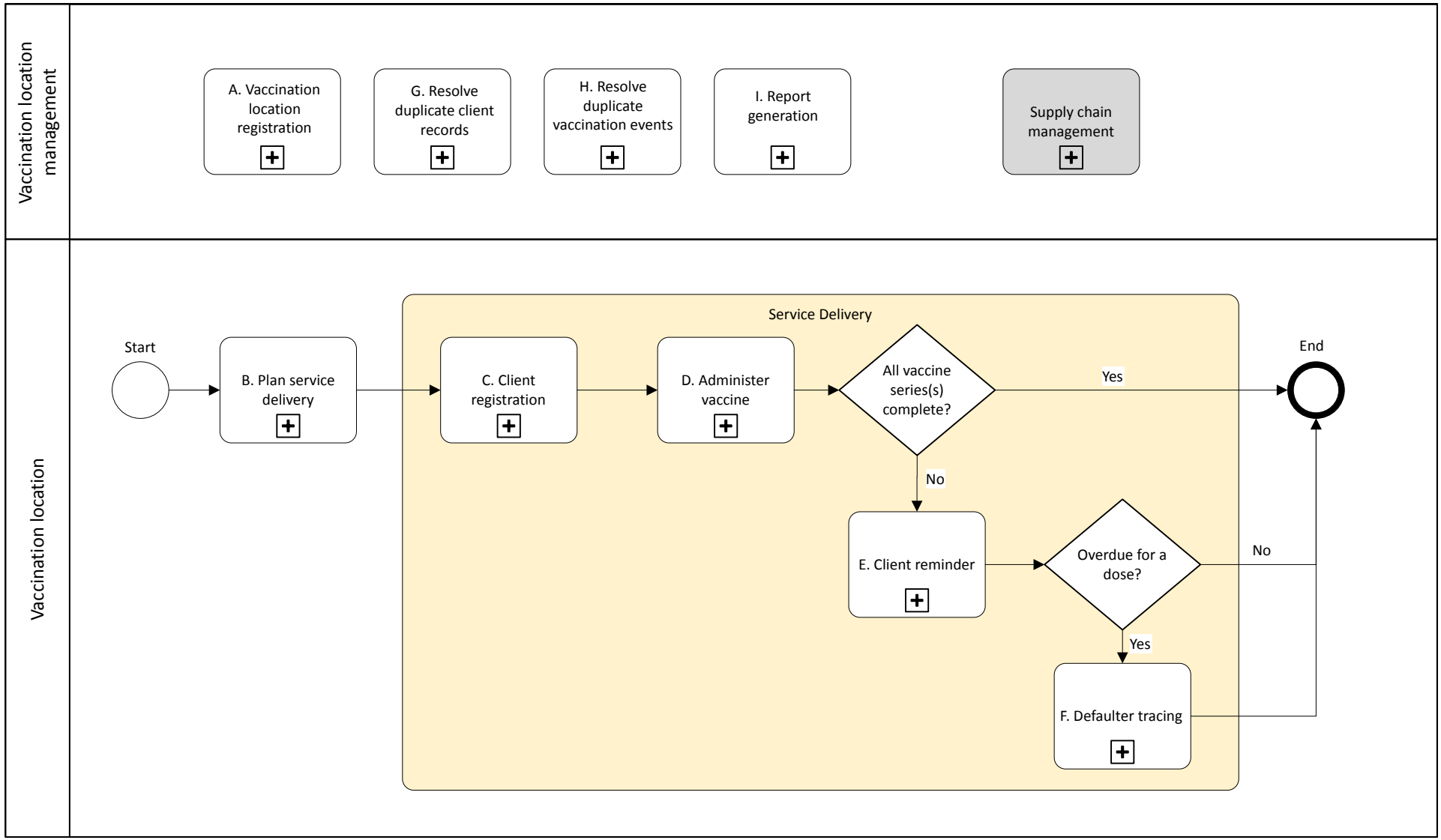
Symbol	Symbol name	Description
	**Swim lane**	Each individual or type of user is assigned to a **swim lane**, a designated area for noting the activities performed or expected by that specific actor. For example, a family planning health worker may have one swim lane; the supervisor would be in another swim lane; the clients would be classified in another swim lane. If the activities can be performed by either actor, then those activities can be depicted overlapping the two relevant swim lanes.
	**Start event or trigger event**	The workflow diagram should contain both a **start** and an **end event,** defining the beginning and completion of the task, respectively.
	**End event**	There can be multiple **end events** depicted across multiple swim lanes in a business process diagram. However, for diagram clarity, there should only be one end event per swim lane.
	**Activity, process, step or task**	Each activity should start with a verb, (e.g. “Register client”, “Calculate risk”). Between the start and end of a task, there should be a series of activities noting the successive actions performed by the actor in that swim lane. There can also be subprocesses within each activity.
	**Activity with subprocess**	This denotes an activity that **has a much longer subprocess** to be detailed in another diagram. If the diagram starts to become too complex and unhelpful, the subprocess symbol should be used to reference this subprocess depicted in another diagram (an activity with subprocess in a grey box is not covered in this DAK).
	**Activity with business rule**	This denotes a decision-making activity that requires the business rule, or decision-support logic, to be detailed in a “decision-support table”. This means that the logic described in the decision-support table will come into play during this activity as outlined in the business process. This is usually reserved for complex decisions.
	Sequence flow	This denotes the flow direction from one process to the next. The end event should not have any output arrows. All symbols (except start event) may have an unlimited number of input arrows. All symbols (except end event and gateway) should have one and only one output arrow, leading to a new symbol, looping back to a previously used symbol or to the end event symbol. Connecting arrows should not intersect (cross) each other.
	**Gateway**	This symbol is used to depict a fork, or decision point, in the workflow, which may be a simple binary (e.g. yes/no) filter with two corresponding output arrows or a different set of outputs. There should only be two different outputs that originate from the decision point. If more than two outputs or sequence flow arrows are needed, you most likely are trying to depict “decision-support logic” or a “business rule”. This should be depicted as an “Activity with business rule” (above) instead.
	**Throw – Link**	The “**Throw – Link**” serves as the start an off-page connector. It is the end of the process when there is no more room for the workflow page. It is the end of a process on the current page or the end of a subprocess that is part of a larger process. There will need to be a “Catch – Link” that follows the “Throw – Link”.
	**Catch – Link**	The “**Catch – Link**” serves as the end an off-page connector. It is the start of the new process on a different page from the “Throw – Link” or the start of a subprocess that is part of a larger process. There needs to be a “Throw – Link” that is aligned to the “Catch – Link”.
	**Loop activity**	This “**Loop Activity”** symbolizes an activity or task that is repeated until it no longer needs to be repeated. For example, vaccine administration can happen as many times as the number of vaccines that need to be given.

Fig. 4. Overview of key immunization processes



Note: The grey box is not covered in this DAK.

4.2 Workflows

Workflows represent the progression of activities performed within the business process. They help users and stakeholders to understand the relationship between activities, data elements and decision-support needs. The following workflows depict processes that have been generalized across different contexts and may not reflect the variability and nuances across different settings. The simplicity of the workflow may not adequately illustrate the nonlinear steps that may occur.

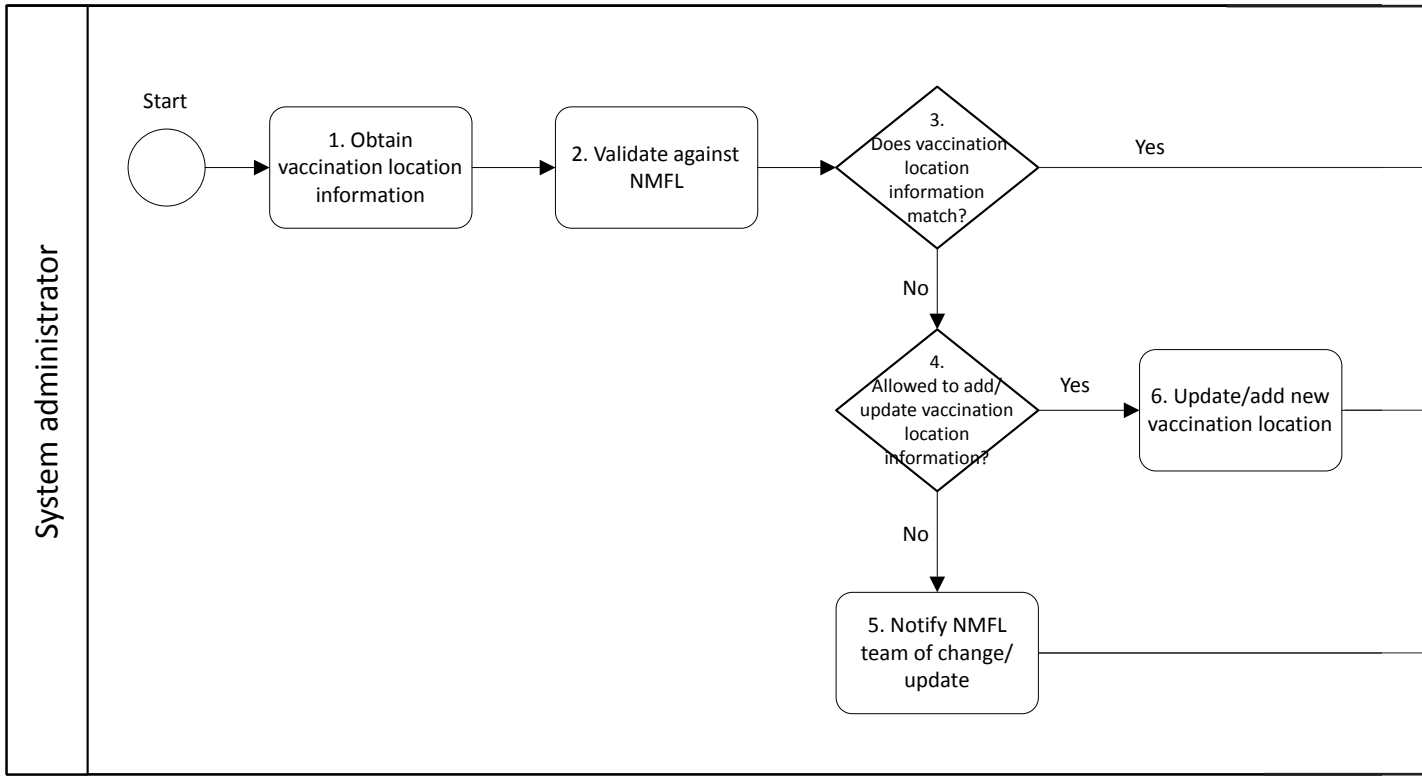
A. Business process for vaccination location registration

Objective: To register and uniquely identify vaccination locations in order to administer vaccines and enable appropriate tracking of vaccine coverage and stock (see **Fig. 5**). There are situations where the locations providing vaccines may not be a permanent physical facility but rather some kind of public health authority (as is the case with some temporary or pop-up clinics). These may be included as per local policy or needs. Additionally, there may be cases where a health-care facility has multiple vaccination locations across the region, district, or catchment area. In this case, only the facility will be registered.

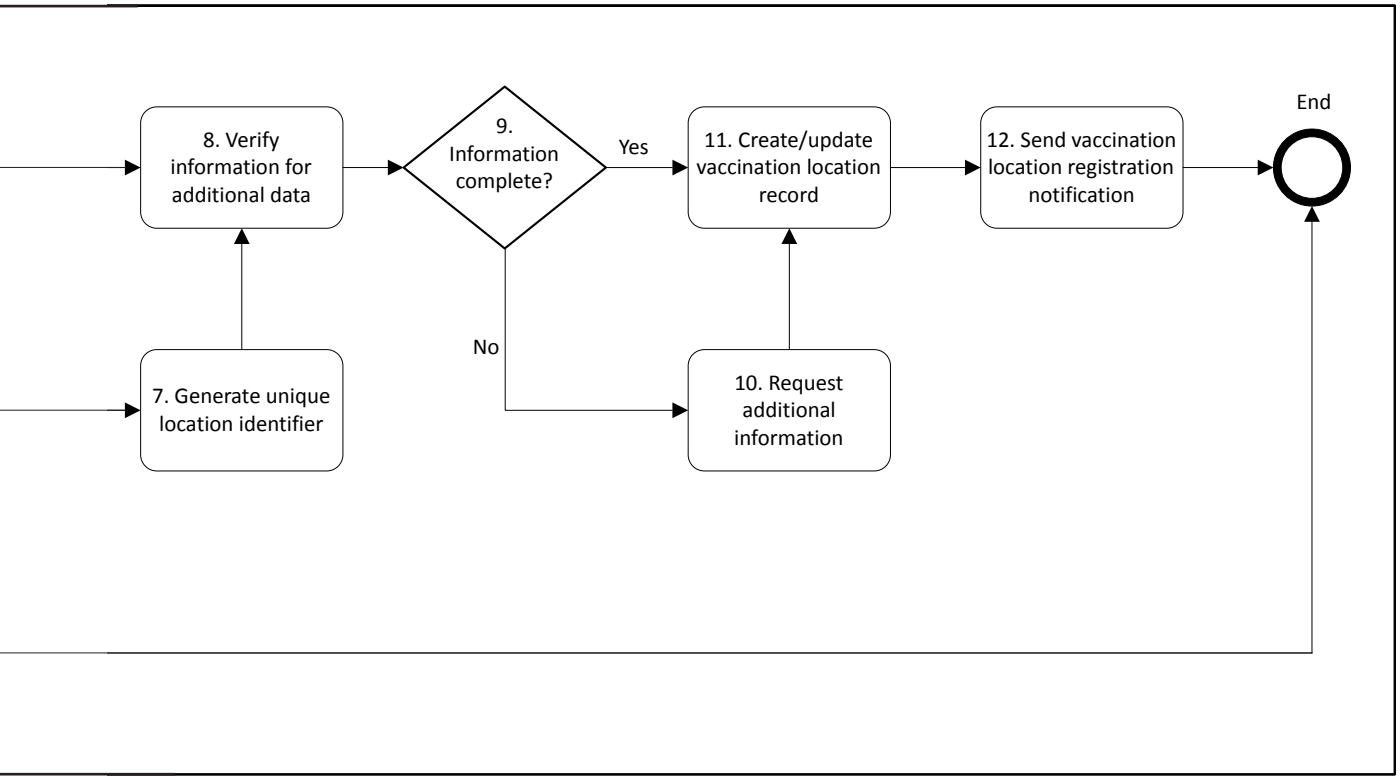
Many countries have a National Master Facility List (NMFL), also called a facility registry. The process for updating and maintaining vaccination locations is not a part of this workflow.

Each step in the workflow is completed by either the responsible person (manually) for the system or automated, depending on system implementation. In some situations, automation is ideal for certain data, including vaccination location notification coming directly from the NMFL. In other scenarios, manual data entry (e.g. changes to fridge capacity) may require system administrator to enter data from a paper form.

Fig. 5. Workflow A: vaccination location registration business process



EIR: electronic immunization registry; NMFL: National Master Facility List.


8. Verify information for additional data
9. Information complete?
Yes
11. Create/update vaccination location record
12. Send vaccination location registration notification
End
No
7. Generate unique location identifier
10. Request additional information

A. VACCINATION LOCATION REGISTRATION BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Obtain vaccination location information**
   - » Vaccination location information may be obtained from multiple sources (e.g. from a vaccination location list, an NMFL, a service within the national HMIS, etc.) and is ideally standardized across the country/region. Information can be received manually or automatically. In the case of temporary clinics, satellite or remote clinics, the vaccination location may be an organizing entity such as a public health unit. It is important to note that there will be two separate lists, one for the EIR and a separate NMFL. Not all facilities provide immunization services, and in some cases (such as temporary clinics), they may not be included in the NMFL. This will be dictated by local policy.

2. **Validate against the NMFL**
   - » The vaccination location information is validated against the NMFL to determine if there is a match (indicating this new registration is a duplicate). This step may be automated.

3. **Does vaccination location information match?**
   - » The system validates whether the new vaccination location exists in the NMFL to determine if it is a new vaccination location or a match/update to an existing record.
   - » If the vaccination location exists in the NMFL, system administrator will verify that the information is complete. If the new vaccination location does not exist in the NMFL, the system administrator will add/update the vaccination location in the PCPOSS or flag for correction/validation. This step, or portions of this step, may be automated.

4. **Allowed to add/update vaccination location information?**
   - » In some circumstances, all vaccination location data are owned and updated solely by the NMFL and then shared with other systems. It will also depend on the type of information. For example, the name of the vaccination location may be “owned” by the NMFL, but other data, such as the type of fridge, may be managed by the PCPOSS.

5. **Notify NMFL team of change/update**
   - » The NMFL team will make appropriate changes.

6. **Update/add new vaccination location**
   - » If all required information is complete, a new vaccination location record is created in the PCPOSS.
   - » There may be cases where a health-care facility has multiple vaccination locations across the region. In this case, only the facility will be registered.

7. **Generate unique location identifier**
   - » PCPOSS will generate a unique ID number to assign to the vaccination location or entity that is permitted to deliver vaccines. This only applies to new facilities.

8. **Verify information for additional data**
   - » System administrator reviews the vaccination location information to determine if any updated information or additional information was provided to the PCPOSS that was not available in the NMFL. This step may be automated.

9. **Information complete?**
   - » System administrator reviews completeness of the information required to register the vaccination location. This step may be automated.

10. **Request additional information**
    - » System administrator requests necessary additional information needed to register the vaccination location. This may be requested from the vaccination location directly or the most appropriate source (e.g. a district information officer, a cold chain officer, NMFL staff, etc.) depending on the data needed.

11. **Create/update vaccination location record**
    - » If all required information is complete, a new vaccination location record is created in the PCPOSS.

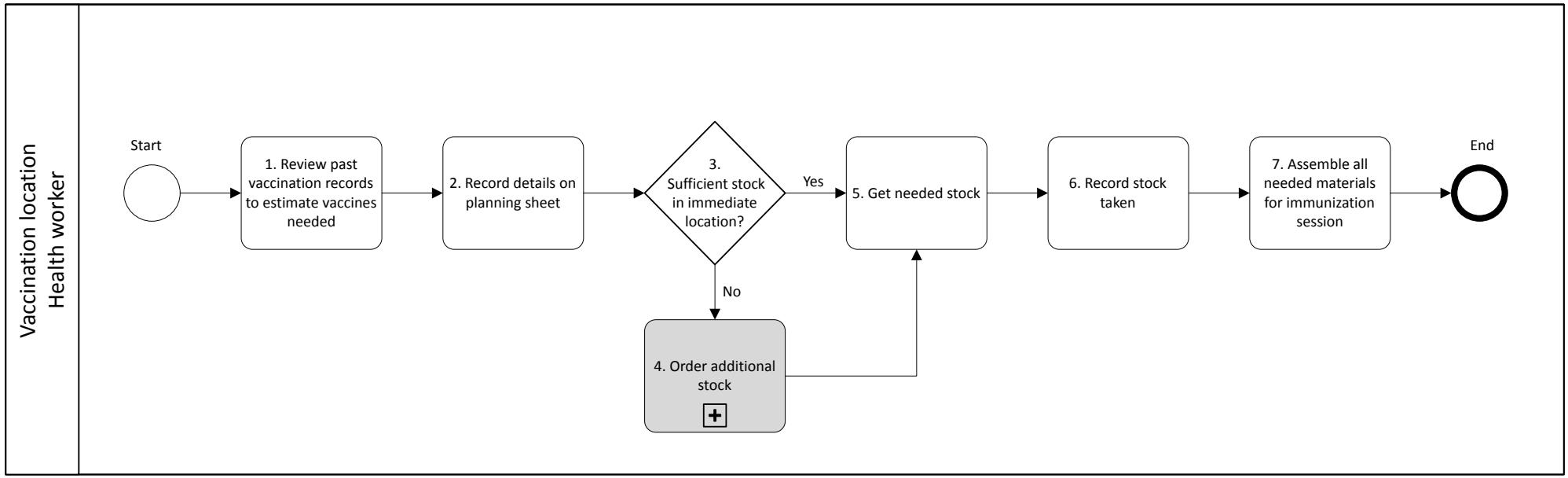
12. **Send vaccination location registration notification**
    - » The system will send the vaccination location a registration notification, which could include their vaccination location ID number and other vaccination location information.
    - » The notification to the EIR can be customized to include messages to the vaccination location (e.g. “Please reference the ID when placing vaccine orders”, etc.). This step may be automated.

B. Business process for plan service delivery

Objective: To prepare for an immunization session, either at the vaccination location or done on an outreach basis (see **Fig. 6**). The primary difference if done as outreach is that all equipment and vaccines must be properly packaged (cold box) for transport.

Note: There are opportunities to integrate an EIR with stock management systems to provide the health worker with automated views and stock alerts.

Fig. 6. Workflow B: plan service delivery business process



***Note*:** The Activity with subprocess in the grey box (4. Order additional stock) is not covered in this DAK.

B. PLAN SERVICE DELIVERY BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Review past vaccination records to estimate vaccines needed**
   - » The distribution of vaccines is commonly based on the total target population, past consumption trends or maintaining stock levels within preset minimum and maximum levels. The health worker will determine, based on reviewing records looking for vaccines due, adjusting for wastage, considering the anticipated first context, drawing on previous experience, evaluating the time since last immunization session and taking other relevant considerations into account, the relative number of vaccines needed. This is typically done several days prior to the immunization session.
   - » Under some circumstances, the vaccination records may be obtained from a paper immunization register, EIR and/or a list of eligible clients who have been entered or registered through a screening and scheduling system, which may be outside of the EIR. There are potential opportunities to obtain these data electronically (although that is out of scope for this workflow, it should be considered).

2. **Record details on planning sheet**
   - » The health worker records the details of the specific immunization session – for outreach, this will include information such as who is going, where, what supplies they need and their transport. For static immunization sessions, the major consideration is staffing and supplies.
   - » Planning sheets are typically used just for outreach and temporary immunization sessions.

3. **Sufficient stock in immediate location?**
   - » The health worker will go to the local stock supply (this may be in their own vaccination location cold storage or in the district office cold storage) to determine if there is sufficient stock for the upcoming sessions. For outreach clinics or vaccination locations without cold storage, this is usually done the day before or up to three days before the sessions. Most vaccination locations with proper cold storage have a routine stock management process that aims to ensure sufficient stock is always available and can organize daily vaccination services. This should, in fact, be the standard in many countries where every day is vaccination day.
   - » If there is a link to a stock management system, or if the PCPOSS has stock management functionality, then this information may be available through the PCPOSS.

4. **Order additional stock**
   - » If there is insufficient stock at the local stock supply, additional stock is requested by the health worker. This may be done through an external logistics management system either directly or in an automated way. Not all vaccination locations have the ability to do last-minute stock replenishments.

5. **Get needed stock**
   - » On the morning of the immunization session, the health worker retrieves the needed stock from the cold storage (either at their vaccination location or at an area office).

6. **Record stock taken**
   - » The stock taken is recorded in a log for record keeping purposes. Any unused stock that is returned after the immunization session is also recorded here, thus keeping an accurate inventory.
   - » Note: This step is often done at the end of the day when reconciling the records.
   - » Note: This may also be recorded in the stock management system to manage the local stock.

7. **Assemble all needed materials for immunization session**
   - » The health worker assembles the vaccines, necessary registers, syringes, sharps container, etc., needed for the immunization session. This will also often include a list of clients due for vaccines that may be automatically generated (see **E. Client reminder process**) or even manually on paper. If the immunization session is remote, all items are packed up for transport. If local, they are organized in the vaccination location.

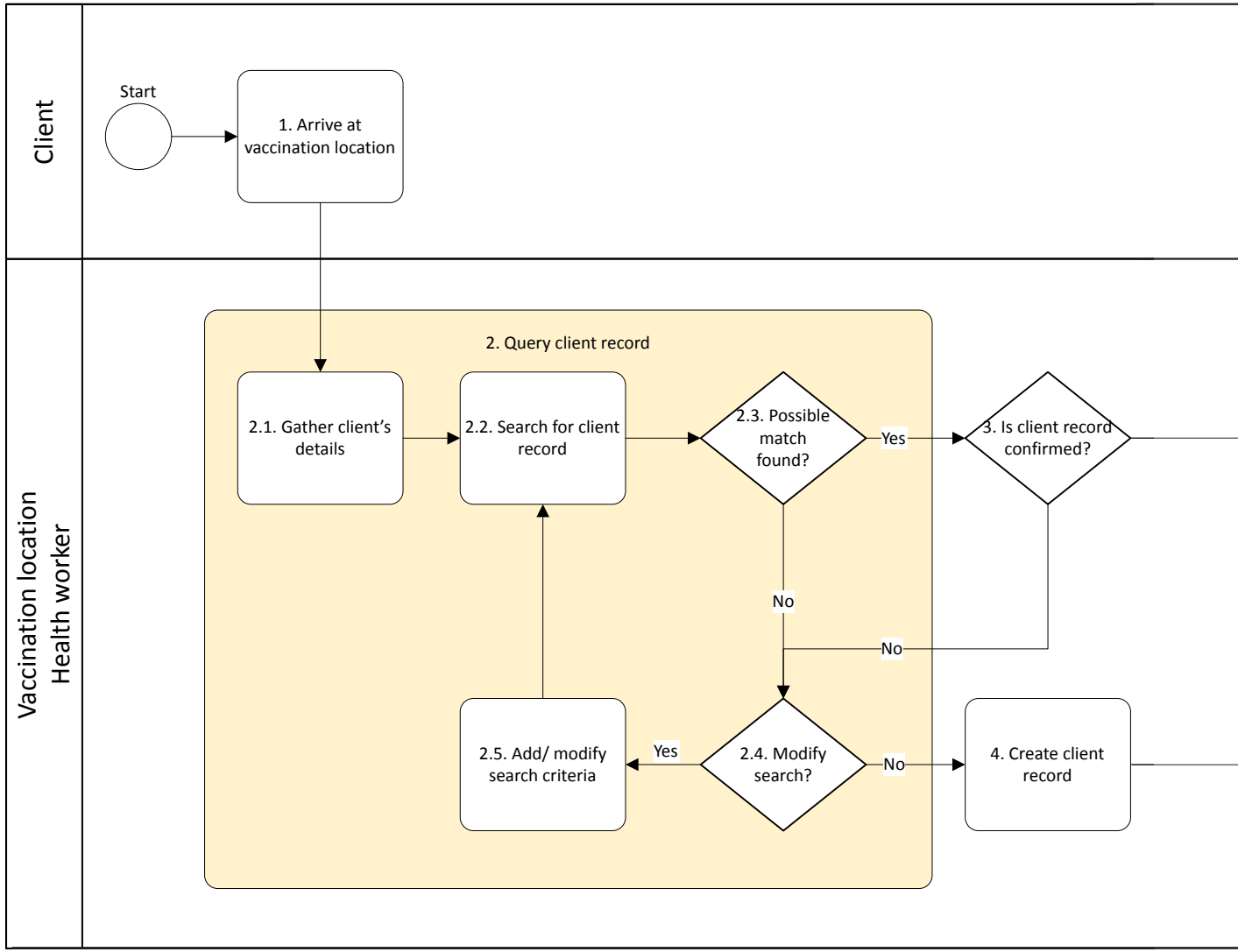
C. Business process for client registration

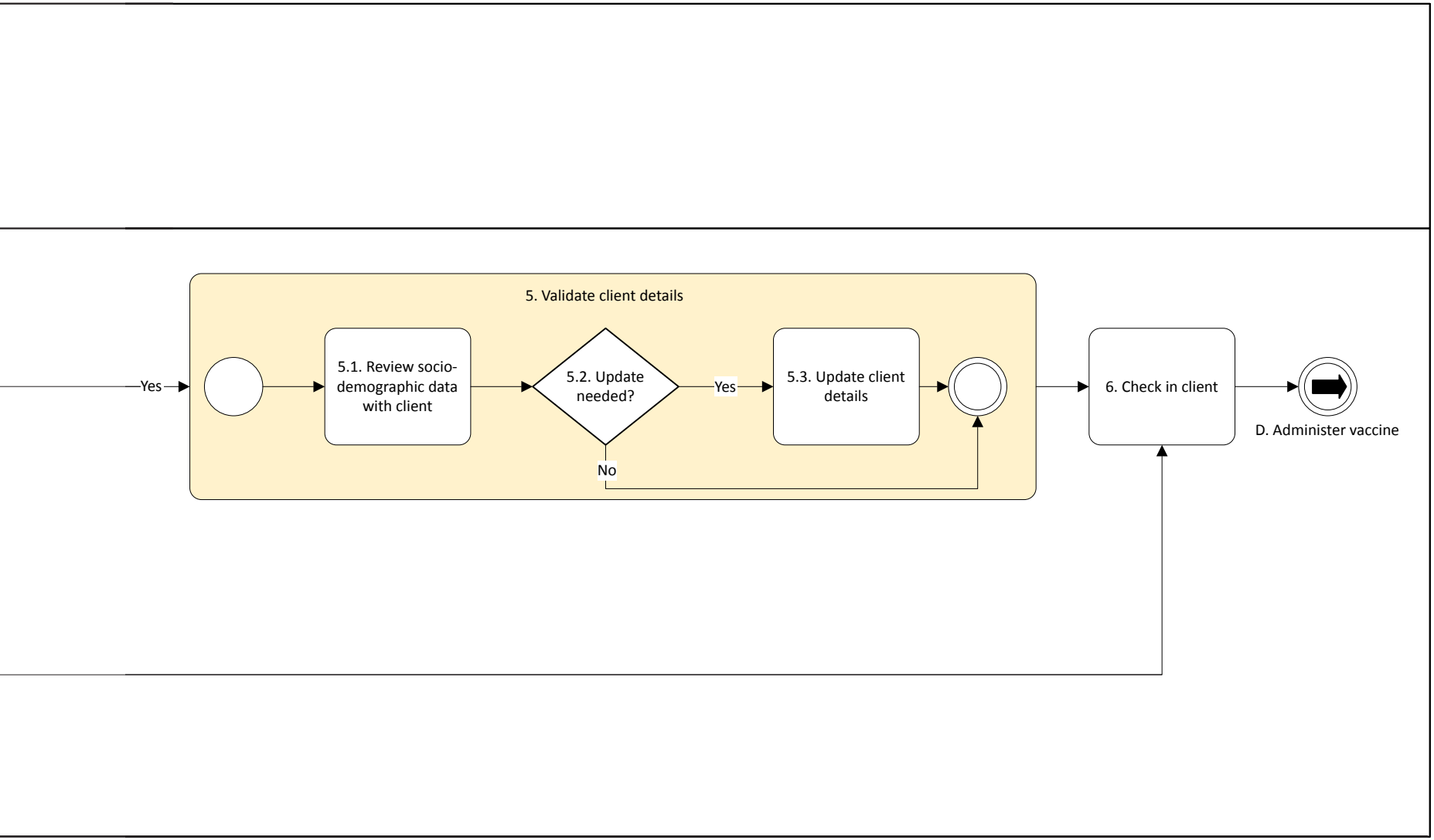
Objective: To correctly locate, identify, update or create a client's immunization record to provide a complete immunization history. This record will be used to determine vaccination history, recommended vaccines and due dates, allowing the health worker to recommend and discuss immunizations with the client. It may also be used to recreate a client's record in case the original paper record is lost (see **Fig. 7**).

Adult clients requiring a new vaccine (such as COVID-19 vaccines) will typically not be in the system as it may not have been available when they received their childhood vaccines. How this is handled will vary widely. It may be possible to import records from another system (such as a universal health insurance system), from a list from another source (such as an external scheduling or registration system), or they may all be required to be entered manually. This will depend on local capacity and policy.

The process of obtaining or updating a paper and/or digital home-based record is out of scope of this workflow. If starting with a paper record, there are some vaccination records (home-based record) that may require additional security/validation features in the paper record for validation. For more information, please refer to *Digital documentation of COVID-19 certificates: vaccination status (28)*.

Fig. 7. Workflow C: client registration business process




5. Validate client details
Yes
5.1. Review socio-demographic data with client
5.2. Update needed?
Yes
No
5.3. Update client details
6. Check in client
D. Administer vaccine

C. CLIENT REGISTRATION BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Arrive at vaccination location**
   - » Client arrives at the vaccination location.
   - » Client could already be registered at the vaccination location for another service.

2. **Query client record**
   - » The client is often initially registered at birth since some vaccinations are given at birth or shortly after. It is still best practice to search for the record anyway to ensure it has not been entered and to avoid duplicate records. Some will be seen for the first time in a clinic or outreach activities. Those coming for follow-up will usually arrive at either a regular clinic or an outreach clinic.
   - » New vaccines that target older age groups may require the client to register in an external scheduling or related system. These records may be automatically imported into the system or may need to be manually imported or entered.
   - – **2.1 Gather client's details**
     - Ask the clients whether they have previously been issued a unique identifier.
     - Do the clients have an ID card/number/barcode?
     - Ask the clients whether they are returning or new clients.
     - For returning clients, details will be retrieved from the registry of clients at the vaccination location.
     - Determine if the client is new to the vaccination location.
   - – **2.2 Search for client record**
     - This search process can be done through a variety of means depending on what mechanisms are available in country. For example, clients can be searched for by using their name, unique identifier, a QR code or even biometrics. This process can be carried out either online or offline.
     - The health worker should enter as much data as possible to obtain a good match. Partial dates and near matches may be necessary. The existence of unique client identifiers will facilitate this process.
     - It is possible that records may need to be imported or linked from an external system such as a birth registry or a scheduling system.
   - – **2.3 Possible matches found?**
     - The EIR returns a list of possible matches based on client identifiers.
     - The health worker reviews the list to determine if a client record exists among the options of possible matches.
   - – **2.4 Modify search?**
     - Does the search need to be modified due to a typo or mistake?
     - Is there any possible additional demographic or other information available that can be used to search the client record?
   - – **2.5 Add/modify search criteria**
     - Modify the search criteria or add any possible additional demographic or other information to improve the search.

3. **Is the client record confirmed?**
   - » Is there sufficient information to confirm one of the potential records belongs to the client?

4. **Create client record**
   - » The client's relevant demographic and other data are entered into the PCPOSS, and they are issued a unique ID. This may be a 1D or 2D barcoded sticker to affix to their paper record, or simply a unique number that can also be recorded on the paper record to facilitate finding the record quickly and accurately in the future. This ID may be generated by the system or by an external authority and associated with the record at this point.
   - » A paper-based or digital home-based record may also be created.

» When a vaccination location-based paper register exists, a single-line entry is put into a vaccination/child health register for that client. The data from the visit are entered (immunization, weight, etc.). If the client is not from that area, there may be no entry in the vaccination location-based paper register. Depending on the circumstances one may be entered, if the client will reside there for some time, or not, if they are there only for a short time. If there is a vaccination location-based register or record kept for non-routine vaccines, this should also be updated.

» If the client has received vaccines previously, the vaccination history should also be added, especially for young children who have not completed their series of primary childhood vaccinations. For adult clients being entered for the first time, local policy will determine if previous vaccinations are back entered. Often the details of historical vaccines are not even known in this case.

5. Validate client details

» Review and update client record

– **5.1 Review sociodemographic data with client**

• Review client's non-clinical information (name, address, contact information, etc.).

– **5.2 Update needed?**

• Has the client moved? Has the client changed contact information? Has any other sociodemographic information changed?

– **5.3 Update client details**

• Ask the client to provide updated information if address or other details have changed since the last contact.

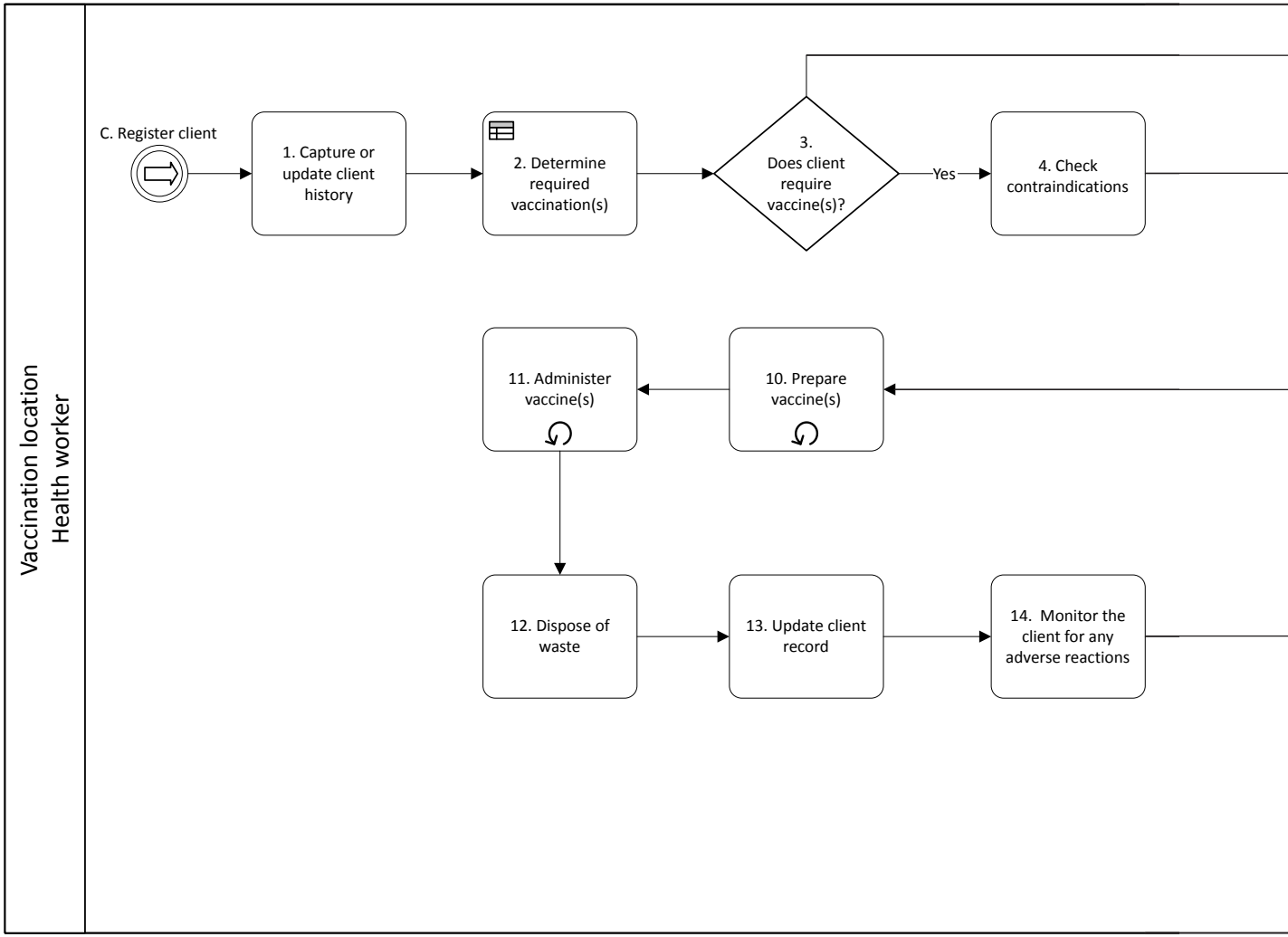
6. Check-in client

» Add client to the relevant queue for vaccine administration. (See **D. Administer vaccine process**).

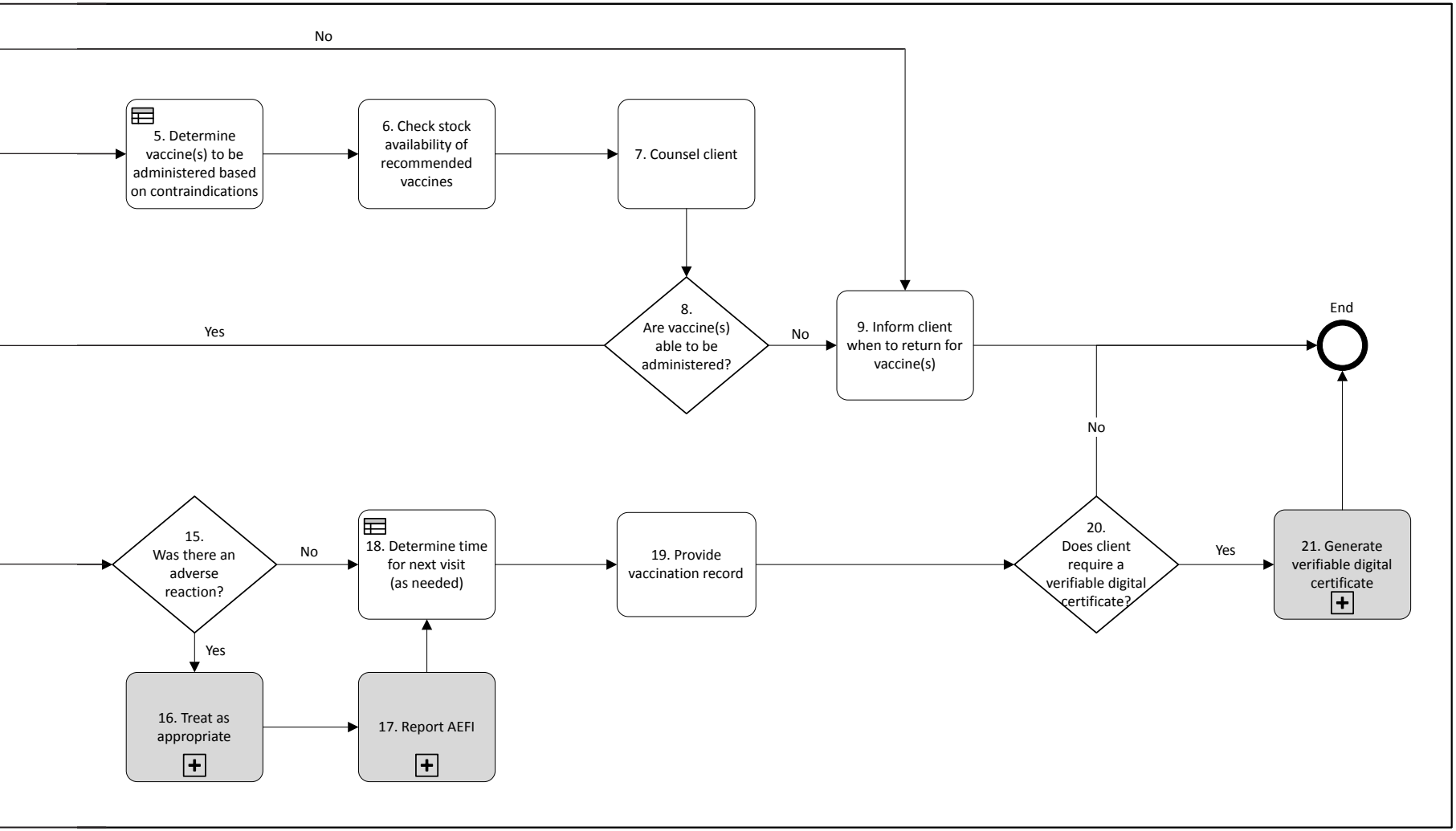
D. Business process for administer vaccine

Objective: To determine what vaccines a client needs, administer those and record the relevant necessary data both in EIR as well as on the appropriate paper records (see **Fig. 8**). Clients will enter this vaccination process in a variety of ways and through different activities and/or campaigns. They may be coming for one in a series of routine childhood vaccines, they may be a health worker requiring a vaccine for work, they may be an adult seeking a vaccine for COVID-19 or an annual flu vaccine, or a student getting a vaccine for HPV at a school vaccination clinic. Campaigns may be supplementary immunization activities (SIAs), periodic intensification of routine immunization (PIRI) activities or innovative local strategies that ensure individuals have the opportunity to receive routine immunizations for which they are overdue and eligible. The following workflow and business process apply to PIRI activities, including intensification activities and catch-up campaigns. PIRI activities are used to administer routine vaccinations based on eligibility and vaccination history, whereas SIAs vary widely and aim to quickly deliver vaccination to a large target population without screening of vaccination history or determining eligibility (everyone in the age range will be eligible regardless of vaccine status, since the dose is supplemental to any series). Hence, SIAs are out of scope of this document.

Fig. 8. Workflow D: administer vaccine business process



AEFI: adverse events following immunization.
Note: The activities with subprocesses in grey boxes are not covered in this DAK (16. Treat as appropriate, 17. Report AEFI and 21. Generate verifiable digital certificate).


No
5. Determine vaccine(s) to be administered based on contraindications
6. Check stock availability of recommended vaccines
7. Counsel client
8. Are vaccine(s) able to be administered?
Yes
No
9. Inform client when to return for vaccine(s)
End
No
15. Was there an adverse reaction?
No
18. Determine time for next visit (as needed)
19. Provide vaccination record
20. Does client require a verifiable digital certificate?
Yes
21. Generate verifiable digital certificate
Yes
16. Treat as appropriate
17. Report AEFI

D. ADMINISTER VACCINE BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Capture or update client history**
   - » Discuss history with client and review available records. The health worker records information on current and past medical history, previous immunizations received, immunization status and other background information.

2. **Determine required vaccinations, if any**
   - » After consulting the client record, the health worker determines if the client is due for a vaccine according to the national immunization schedule. This should be calculated and displayed by the system. The list of vaccinations displayed by the system may not be the list of vaccinations that the client receives.
   - » Decision-support tables for the following antigens are provided to determine whether a client is due for vaccination(s):
     - BCG
     - hepatitis B
     - polio
     - DTP
     - Hib
     - pneumococcal
     - rotavirus
     - measles
     - rubella
     - HPV
     - JE
     - yellow fever
     - TBE
     - typhoid
     - cholera
     - meningococcal
     - hepatitis A
     - rabies
     - dengue
     - malaria
     - mumps
     - seasonal influenza
     - varicella.

3. **Does client require vaccine(s)?**
   - » Based on the immunization schedule, the health worker decides if a vaccination is recommended or not.

4. **Check contraindications**
   - » The health worker examines the clients and interviews them (or caregivers) to see if there are any contraindications to the vaccine(s) due.

5. **Determine vaccine(s) to be administered based on contraindications**
   - » The digital system evaluates the information on contraindications and flags to the health worker if further evaluation is needed or if vaccination is contraindicated for specific antigens.
   - » The health worker determines the vaccine(s) to be administered based on the potential contraindications. For example, if the child is currently unwell, has a fever or is vomiting the health worker may choose to delay the administration of one or more of the vaccines.
   - » Contraindications tables for the following antigens are provided to determine whether vaccination(s) can be administered based on contraindications:
     - BCG
     - hepatitis B
     - polio
     - DTP
     - Hib
     - pneumococcal
     - rotavirus
     - measles
     - rubella
     - HPV
     - JE
     - yellow fever
     - TBE
     - typhoid
     - cholera
     - meningococcal
     - hepatitis A
     - rabies
     - dengue
     - malaria
     - mumps
     - seasonal influenza
     - varicella.

6. **Check stock availability of recommended vaccine(s)**
   - » The health worker checks to see if the recommended vaccines are available. This includes ensuring that vaccines are not expired and that the vaccine vial monitors show they have been kept at the recommended temperatures. The health worker should use the vaccines with the closest expiry dates to prevent them from being wasted.

7. **Counsel client**
   - » The health worker provides counselling on the benefits of the immunization, the potential adverse reactions and what to do in those instances.
   - » If, after thorough counselling, the client or the caretaker (depending on whether the client is a child) agrees to receive the vaccination, the vaccines may be administered. The business process and workflow will need to be updated accordingly if the Member State has other processes for obtaining consent depending on local laws and regulations.
   - » Counselling not only facilitates the provision of the required vaccine(s) but also plays a role in addressing vaccine hesitancy and promoting acceptance.
   - » After counselling, the health worker documents the vaccine(s) to be administered in the client's record.

8. **Are vaccine(s) able to be administered?**
   - » Based on stock availability, counselling for the recommended vaccine(s) and/or potential contraindications, the health worker decides whether the vaccine(s) can be administered.

9. **Inform client when to return for vaccination**
   - » If the client or caregiver is not within the appropriate window for the vaccination, the health worker informs them when the next vaccination is due.
   - » If the vaccine is not available, the vaccination activity is marked as incomplete in the client's record and the client is instructed when to return based on when it will be available.
   - » If the client does not agree to receive the vaccination, the vaccination activity is marked as incomplete in the client's record.
   - » Other monitoring or interventions may still be done at this time (such as weight and general health education).

10. **Prepare vaccine(s)**
    - » The vaccine is removed from the cold storage, validated, reconstituted if needed, and drawn up into the syringe (if injectable) in preparation for administration. If multiple vaccines are needed, this task can be done multiple times according to the number of vaccines needed. A vaccine being validated refers to (i) ensuring the vaccine is correct, (ii) ensuring the vaccine is not expired, and (iii) and ensuring the vaccine vial monitor is not indicating that it should not be given.

11. **Administer vaccine**
    - » The vaccine is administered to the client according to guidelines. If multiple vaccines are needed, this task can be done multiple times according to the number of vaccines needed.

12. **Dispose of waste**
    - » Properly dispose of the waste following administration. This includes disposing needles, sharps and empty vials into proper containers.

13. **Update client record**
    - » The health worker updates the client's record in the PCPOSS (updates to the paper immunization registers might also be needed depending on the stage of PCPOSS implementation) and client's home-based record, if needed, completing all relevant and required information (vaccine given, date, lot number, etc). Additionally, this activity is marked as complete in the client's record.

14. **Monitor client for any adverse reactions**
    - » Client is monitored for adverse reactions immediately after the vaccine has been administered.

15. **Was there an adverse reaction?**
    - » Look primarily for immediate adverse reactions (anaphylaxis).

16. **Treat as appropriate**
    - » If the client exhibits an immediate adverse reaction to the vaccine, the health worker treats them as appropriate.

17. **Report AEFI**
    - » Report any AEFI per national policies and reporting mechanisms.
    - » This should include the documentation of the adverse event and the completion of the AEFI reporting form as required by national and international policies.
    - » A more detailed guidance on AEFI was previously developed *(33)*.
    - » Late-onset or delayed reactions after receipt of the vaccination may also occur. Such reactions may not be reported or recorded in a client's record. Hence, these types of delayed reactions are out of scope of this business process.

18. **Determine time for next visit (as needed)**
    - » Inform client when a follow-up vaccination is required. This should be calculated and displayed by the system. This may include a specific scheduling process that is outside of the EIR.
    - » Scheduling-logic tables for the following antigens are provided to determine the time for a next visit according to the schedule include:
        - BCG
        - hepatitis B
        - polio
        - DTP
        - Hib
        - pneumococcal
        - rotavirus
        - measles
        - rubella
        - HPV
        - JE
        - yellow fever
        - TBE
        - typhoid
        - cholera
        - meningococcal
        - hepatitis A
        - rabies
        - dengue
        - malaria
        - mumps
        - seasonal influenza
        - varicella.

19. **Provide vaccination record to client**
    - » Provide a record of the vaccination event(s) to the client, regardless of whether it is home-based record or record in a digital or paper format.
    - » It is important to ensure the client has access to their immunization history so that:
        - health workers can use it as a reference to offer a subsequent dose and/or appropriate health services;
        - clients know which vaccine(s) they received;
        - clients know when their next dose, and of which vaccine, is due; and
        - health workers treating and investigating a delayed AEFI are able to appropriately conduct the investigation and causality assessment as per existing guidance on AEFI and vaccine safety.

20. **Does the client require a verifiable digital vaccination certificate?**
    - » For some vaccines, the client may require an official verifiable digital vaccination certificate as proof of vaccination for purposes not related to health care (e.g. establishing the vaccination status of individuals in coverage monitoring surveys, for work, for university education and/or for international travel).
    - » A vaccination record and verifiable digital certificate may be the same depending on the context and scenario of use.

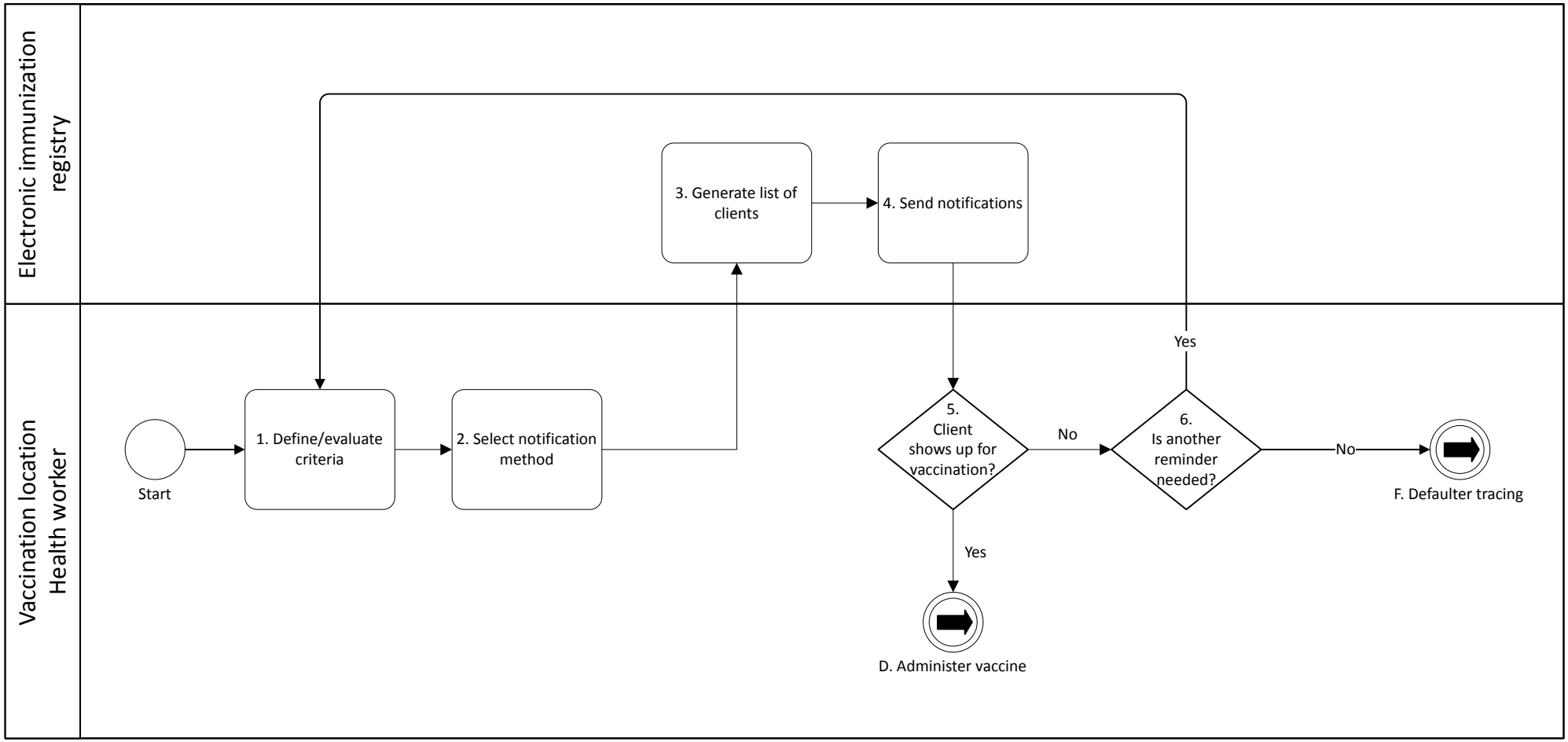
21. **Generate verifiable digital certificate**
    - » Generation of the certificate will depend on if the system is online or offline, and specific details and processes may vary by country.
    - » *A detailed guidance on digital vaccination certificates for COVID-19* was previously developed *(28)*.

E. Business process for client reminder

Objective: To send vaccine reminders and recalls to a client or caregiver notifying that the client is due, due on a future date, or past due for a vaccine (see **Fig. 9**). This is typically done electronically and automatically.

For clients already electronically registered, the same process may also be used to notify them of a new vaccine that is available for which they are eligible. This could include relevant disease specific vaccines (such as those for COVID-19 or seasonal influenza). This would be more of a notification than a reminder.

Fig. 9. Workflow E: client reminder business process



E. CLIENT REMINDER BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Define/evaluate criteria**
   - » The health worker can set filter criteria in the PCPOSS to identify clients who are due or overdue for vaccinations. Such filters could include age range, health worker, vaccine type, vaccine lot number or geographic area.
   - » Filters can also be used to identify clients that are overdue for a vaccine as a result of a shortage, those recommended to receive a new vaccine or series of vaccinations, clients residing in a specified geographic area (catchment boundaries) or populations with a high-risk status. Client records are then evaluated to determine if they meet the defined criteria.
   - » It is important to note that only clients who are already registered in the system can be evaluated by the system. Many clients who received their vaccines prior to a system being available would likely not be registered.

2. **Select notification method**
   - » Notification method can be selected for the whole list of candidates or separately for individual clients in the list. Communication methods could include through community health workers, home visits, letters, SMS or calls. Note: Some PCPOSS only have a single notification method, eliminating the need for this step. This could also be pre-determined based on the client or caregiver's preferences during registration or vaccine administration.

3. **Generate list of clients**
   - » A target list of potential clients is created based on the filter criteria. If resources are limited, client lists can be further filtered and prioritized using additional criteria. This step is often automated.

4. **Send notifications**
   - » Notifications are distributed to designated recipients. This step can often be automated depending on the selected notification method. However, in some circumstances, it may be done manually by the health worker (more likely for missed appointments or those to be followed up by a community health worker) or through call centres.
   - » Note: If the client has moved or is deceased, the client's record in EIR will be updated, and a reminder will not be sent.

5. **Client shows up for vaccination?**
   - » Did the client arrive to receive the vaccine?

6. **Is another reminder needed?**
   - » If the client did not go to the vaccination location for the vaccination, an additional reminder or reminders may be needed. The vaccination location or system administrator will have determined how to handle invalid contact information (such as phone number) and a limit to the number of additional reminders to be sent.

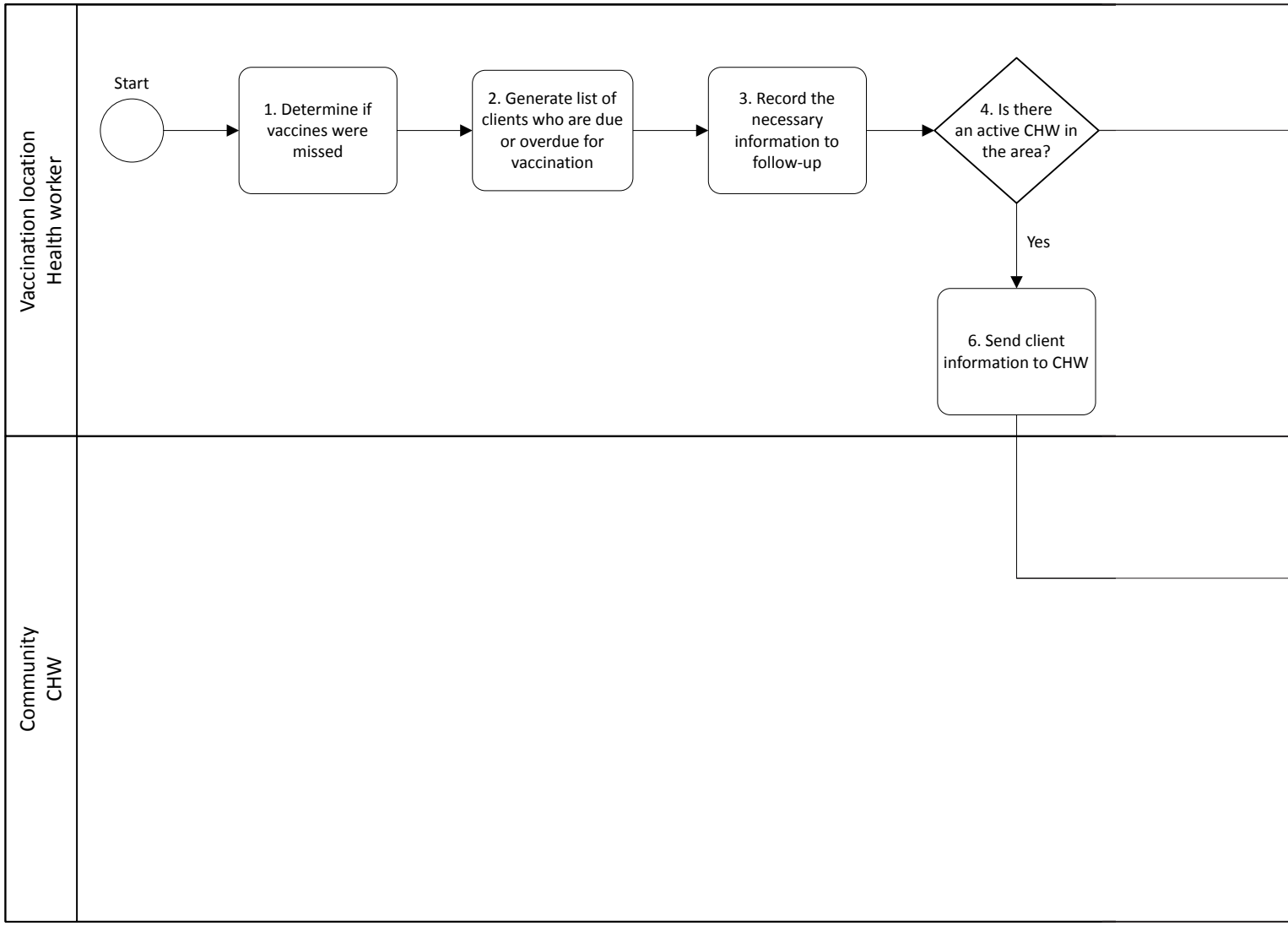
7. **Administer vaccine**
   - » If the client shows up for a vaccination, proceed to administer the vaccine (see **D. Administer vaccine process** for more details).

8. **Defaulter tracing**
   - » If the client does not show up after the appropriate number of reminders, and after a certain time frame, additional measures may need to be taken to find the client. The details of this process may vary widely (see **F. Defaulter tracing process** for more details).

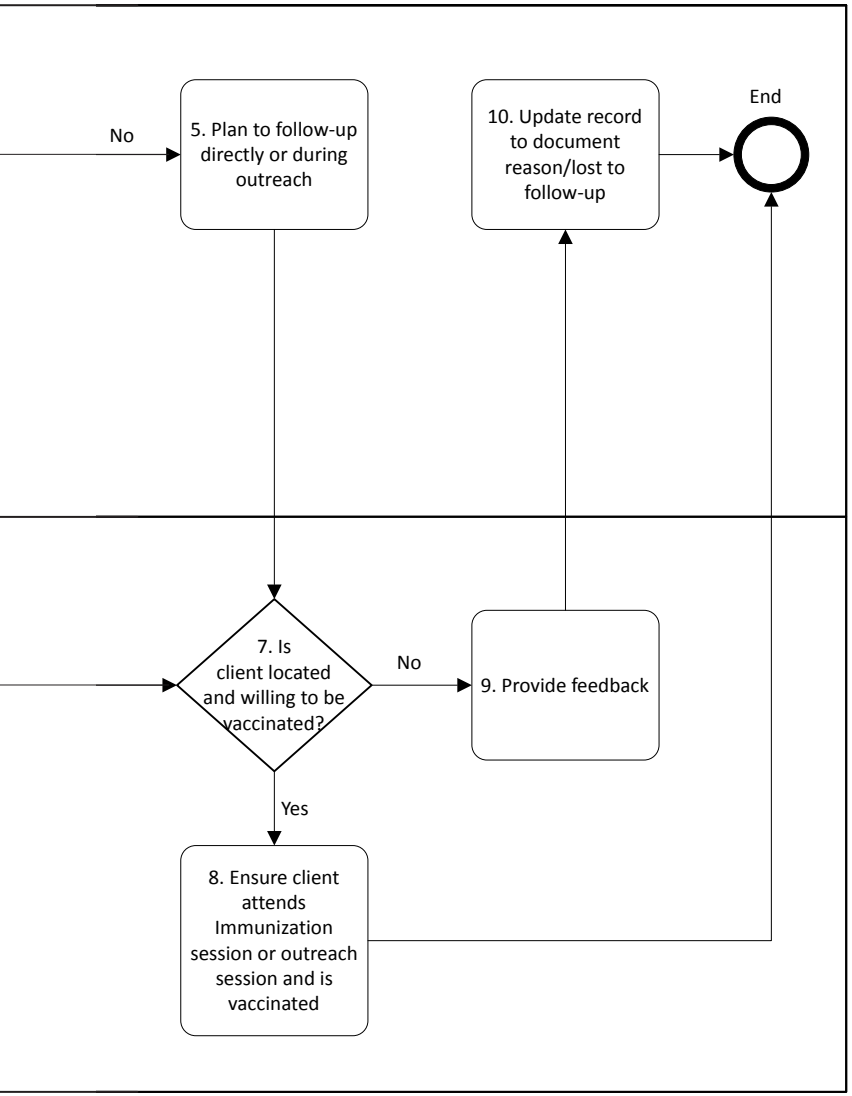
F. Business process for defaulter tracing

Objective: To identify those who are overdue for a follow-up dose and/or vaccination as part of their immunization schedule and to encourage them to come in for vaccination (see **Fig. 10**). There is a significant amount of variability in how this follow-up is done currently. This process flow assumes the client is electronically registered and has started an initial dose. This also assumes that there are no automated reminders sent by the PCPOSS and that follow-up is done by the health worker, or that electronic reminders have already been sent, but the client has not arrived for their vaccine (see **E. Client reminder business process** for automated reminders). This process may also be done as a part of a "catch-up campaign" where coverage in an area has fallen below certain thresholds and a large number of clients are overdue for vaccinations. These campaigns may include broader advertising and the addition of extra outreach sessions or pop-up clinics.

Fig. 10. Workflow F: defaulter tracing business process



CHW: community health worker.


No
5. Plan to follow-up directly or during outreach
10. Update record to document reason/lost to follow-up
End
7. Is client located and willing to be vaccinated?
No
9. Provide feedback
Yes
8. Ensure client attends Immunization session or outreach session and is vaccinated

F. DEFAULTER TRACING BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Determine if vaccines were missed**
   - » In a paper-based system, the health worker reviews the registration book to look for months (depending on how the register is organized) in which no information is recorded for the client. They then determine (based on the data that are entered) if the client is now overdue for a vaccine and which one.
   - » With a PCPOSS, this process could be automated by searching the PCPOSS records based on specific rules (either a missed scheduled appointment or a record that shows more than a predetermined time has elapsed between immunizations), producing a list of "defaulters" or those having missed doses. If a PCPOSS is used and connected to a network, it can be determined whether the clients are receiving vaccines in another vaccination location so they would not be considered defaulters for follow-up.

2. **Generate list of clients who are due or overdue for vaccination**
   - » After determining if vaccines were missed, the health worker or PCPOSS generates a list of clients who are either due or overdue for a vaccine.

3. **Record the necessary information to follow up**
   - » In a paper-based system, the health worker will record the client's name, missed antigen(s) and any contact information necessary to follow up. This is often challenging, as information to trace is often lacking in the registers.
   - » With a PCPOSS in place, this list may be generated automatically. Occasionally, owing to a variety of factors (e.g. poor weather for an extended time, a health system crisis such as an epidemic or pandemic, or extended staffing challenges) some areas will have a significant number of defaulters requiring more intensive resources to follow up.

4. **Is there an active community health worker in that area?**
   - » This varies widely by area. Some areas have good community health worker coverage and rely on them as part of the team; in others, health workers do most of the follow-up. If the client is in a village well-supported by a community health worker for routine immunizations, the health worker will often contact them to follow up. If not, the health worker will follow up themselves.

5. **Plan to follow-up directly or during outreach**
   - » The health worker will add the defaulter information they have to their plan for outreach activities, or if needed and appropriate, for campaign planning. When they are next in the client's village/neighbourhood, they will go to their home to find them. If they are not doing outreach in the area, they may try to contact the caregiver to remind them to come to clinic.

6. **Send client information to the community health worker**
   - » Contact information, missed antigen and any other relevant data are sent to the community health worker either in a written report, during a meeting or via phone.

7. **Is client located and willing to be vaccinated?**
   - » The community health worker or health worker will attempt to find the client by going to their home, contacting relatives or neighbours, or any other means necessary. If they are reportedly in the area but not available at that time, the health worker or community health worker will continue to try to reach them during subsequent days. If the client is located, the community health worker or health worker should find out if they are willing to continue with their vaccination schedule.

8. **Ensure client attends clinic or outreach session and is vaccinated**
   - » The community health worker may go to the client's home and bring them to the clinic. Health workers seldom go to a client's home for routine vaccinations due to cost. The health worker or community health worker may call or message the caregiver rather than go to their home, if feasible.

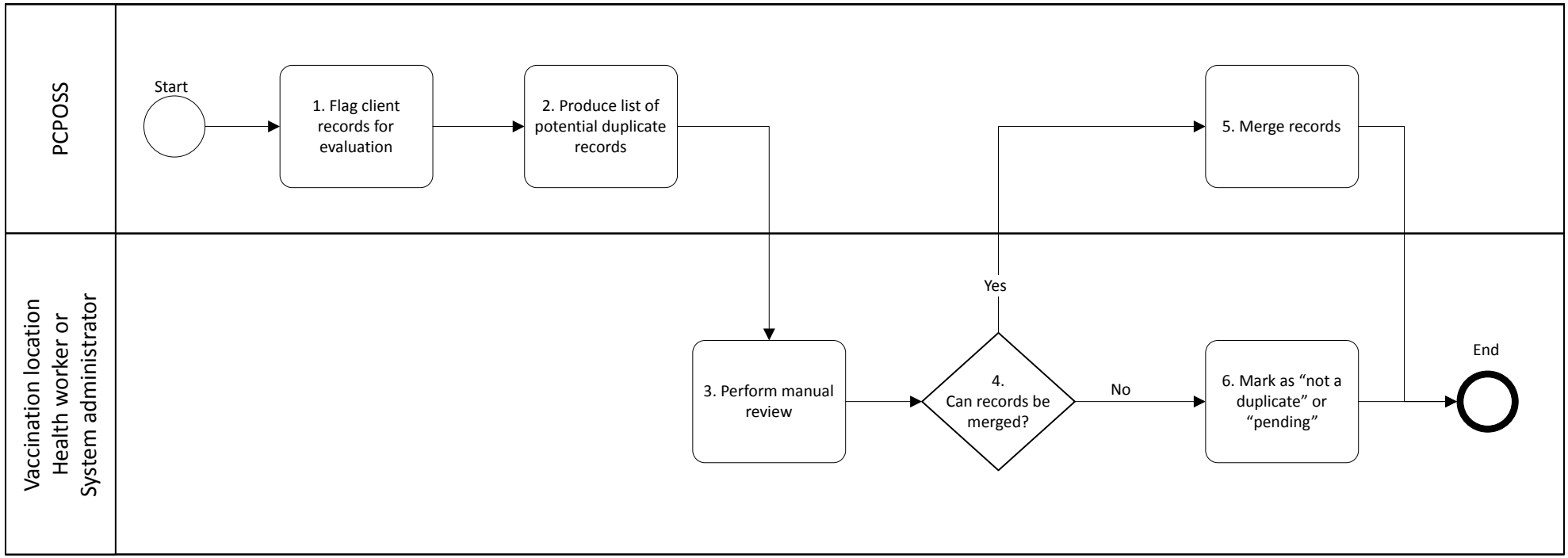
9. **Provide feedback**
   - » To assist with clinic and outreach planning, the results of the follow-up are provided back to the health worker. This will include the reason the client is not returning, if known.

10. **Update record to document reason for incomplete immunization series or lost to follow up**
    - » The client's record should be updated to indicate if the client is missing for some permanent reason (such as they have moved or died), so that they are no longer considered defaulters for that area. It can also indicate if the situation is temporary, in which case the client will remain active. This would also include if the client refused to continue with the vaccines for any reason (hesitancy, illness, etc.) or has permanent contraindications. This information may be used to determine if appropriate future interventions are needed.
    - » The reason for a missed or late dose may also be entered in the client's record.

G. Business process for resolve duplicate client records

Objective: To identify duplicate client records and consolidate them into one most accurate/suitable (best) record (see **Fig. 11**). This may be a fairly complex process and is typically not done by health workers; however, they will need to identify potential duplicates if they come across them.

Fig. 11. Workflow G: resolve duplicate client records business process



G. RESOLVE DUPLICATE CLIENT RECORDS BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Flag client records for evaluation**
   - » Client records are reviewed on a periodic basis (daily or weekly) to determine if they are unique clients. Duplicate records are often discovered during the defaulter tracing process. Potentially duplicated records are identified, grouped and marked as "pending" by default.
   - » Some systems automatically initiate this process to ensure data integrity. However, individual users can also select, or flag, the client records to be evaluated.
   - » Duplicate records may be the result of data entry errors, lack of ID at birth, changes in name, changes in date of birth, client having moved to another area, etc.

2. **Produce list of potential duplicate records**
   - » Potential client record pairs are evaluated using demographic data including client name, date of birth, national ID number, parent/guardian information, mother's maiden name and address. As many fields as possible should be used for de-duplication purposes. In addition to demographic data, immunization history can also be used to identify duplicate client records.

3. **Perform manual review**
   - » Potential duplicate client records are presented for resolution. Even potential duplicate client records with a high degree of certainty should still be presented for manual review to determine if they are duplicates. This review may be done during district-level review or planning meetings, or potentially by a specialized system administrator with input from the appropriate resources.

4. **Can records be merged?**
   - » Either system administrator or a health worker determines if the client records can be merged into one record, if they are "not a duplicate" or if there is not enough information to make a decision. For example, if a name or date of birth is slightly different, but other components match, a determination must be made whether the two records should be merged or marked as "not a duplicate".

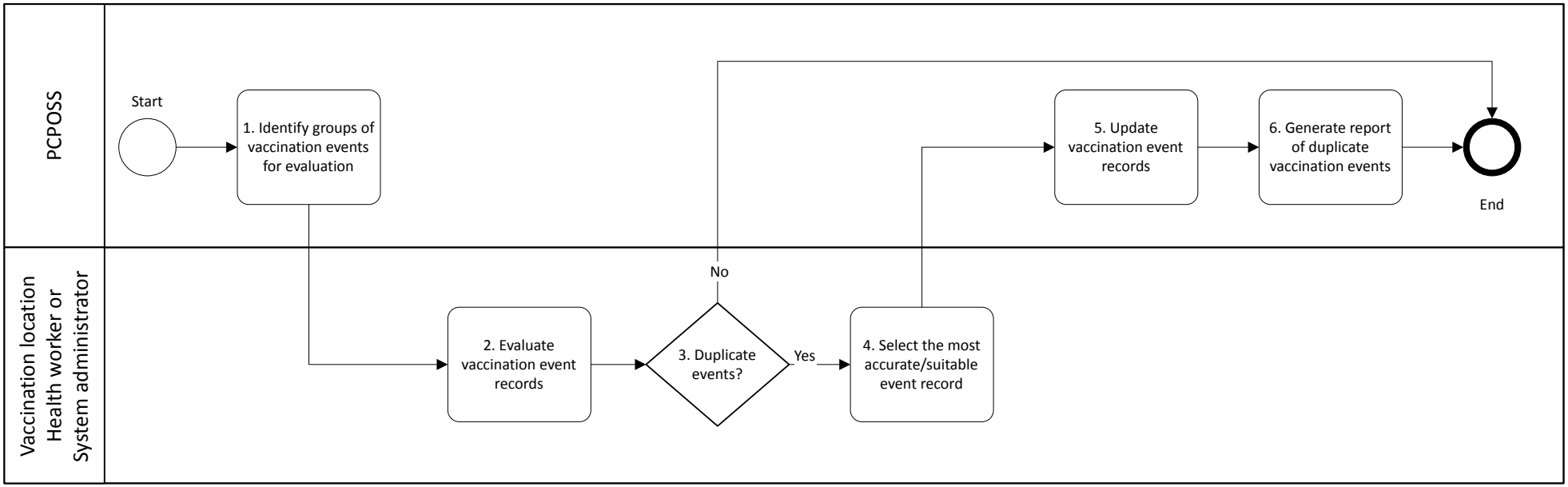
5. **Merge records**
   - » Client records confirmed to be duplicates are merged. Extra precaution should be taken for paediatric client records because the inappropriate merging of paediatric records is more consequential than for adult records due to complex vaccination schedules and the risk of under-vaccination.

6. **Mark as "not a duplicate" or pending**
   - » If it is determined that the records are for different individuals, the records are marked as "not a duplicate", and immunization histories are maintained separately in the system.
   - » If the health worker or system administrator is still unsure if the record is a duplicate, it is left as "pending", escalated for further review and revisited at a later time.

H. Business process for resolve duplicate vaccination events

Objective: To identify duplicate vaccination events within a client record and update into one event (see **Fig. 12**). Although it is typically the function of a PCPOSS to alert the user of potential duplicate events, the amount of automation in the resolving of the duplicates will vary. In some systems, it can be done in a more automated way, while in other circumstances it is preferable to have the health worker, or a trained system administrator, review and make decisions. Ideally, duplicate events are flagged, and an alert is sent at the time they are entered so they may be dealt with immediately by the health worker and are not saved in a PCPOSS. This process assumes duplicate records have been saved to the system.

Fig. 12. Workflow H: resolve duplicate vaccination events business process



H. RESOLVE DUPLICATE VACCINATION EVENTS BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Identify groups of vaccination events for evaluation**
   - » Events (or groups of events) are evaluated using predefined criteria (e.g. encounter date, vaccine type and trade name, provider name, record source type, vaccine lot number, etc.).
   - » Potential duplicate events are identified and grouped within a client's record.

2. **Evaluate vaccination event records**
   - » Records are reviewed individually to determine if the recorded events are duplicates.
   - » Vaccination events within a client's record are reviewed individually to determine if the recorded events are duplicates or are unique events.
   - » The potential duplicates are marked or classified as potential duplicate and are flagged for resolution.

3. **Duplicate events?**
   - » A classification is made to determine if the events are duplicates.

4. **Select the most accurate/suitable event record**
   - » For events that match, the most accurate/suitable event is selected based on level of confidence, completeness of data and specificity of data. This step can be performed manually or by the PCPOSS.

5. **Update vaccination event records**
   - » All available information is aggregated from the duplicate events into an updated event.
   - » The updated event will be made available to view and utilize in the client record. All reported events should be kept on file along with a documented audit trail so de-duplication decisions can be analysed.

6. **Generate report of duplicate vaccination events**
   - » PCPOSS generates a report of duplicate vaccine events, and potentially the resolution, if appropriate. The report is printable and can be exported to several formats.

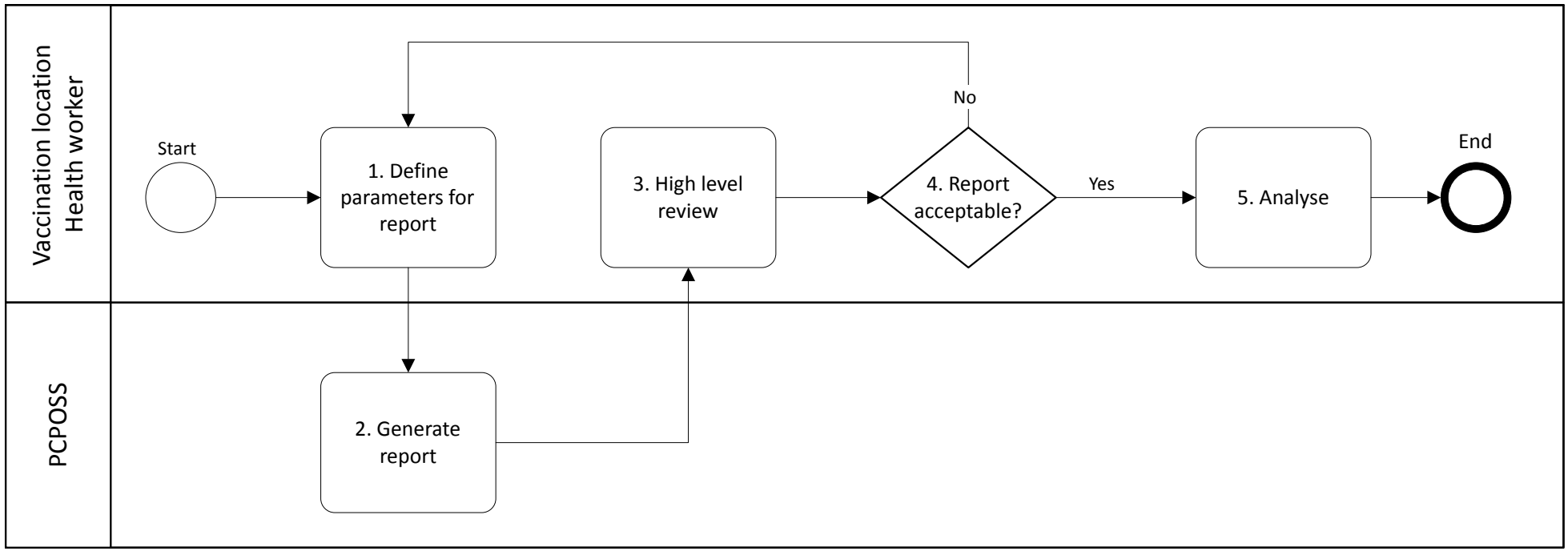
I. Business process for report generation

Objective: To provide the ability to access and analyse data to improve immunization programme decision-making (see **Fig. 13**). This business process outlines the general process to generate a variety of reports that are routinely needed by the system administrator, health workers and other partners.

Reports will be defined and set up initially in the system and are expected to be revised and updated as necessary. Reports can be individually generated, automatically generated and/or even sent to other reporting systems. They may include dashboards, which are predefined summaries that are frequently automatically updated. They will also include aggregate reports that are typically required to be sent from vaccination location to district.

Examples of reports include reports on coverage, reminder/recall, client list, vaccine uptake, vaccination by health worker and/or vaccination location, comparison between district of residence and district of vaccination, list of refusals, stock consumption, wastage or any other ad hoc required information. Additional data quality dimensions and indicators can be measured or assessed against defined standards to determine quality of data *(34)*.

Fig. 13. Workflow I: report generation business process



I. REPORT GENERATION BUSINESS PROCESS NOTES AND ANNOTATIONS

1. **Define parameters**
   - » The overall report format and data are defined and implemented according to the immunization programme needs. These needs are usually predetermined by monitoring and evaluation requirements, such as national reporting requirements, donor requirements.
   - » Specific parameters or attributes for reporting can include reporting by age groups, vaccine series, a specific vaccine grouping or any other attributes or parameters needed based on the information available. These may be preselected or selected when the report is generated.

2. **Generate report**
   - » A report is generated by the EIR based on the parameters selected by the health worker. Other personas may also include EPI managers, system administrator and other partners.
   - » This may be done automatically on a specific schedule, or it may be generated as needed.
   - » For dashboards, they are typically refreshed when accessed or viewed. Reports may be printed, online viewable only and/or sent electronically to another reporting system.
   - » In the case of multiple vaccination locations under the same facility, reporting will be done at the facility level.

3. **High-level review**
   - » Health workers, EPI managers or other personas, with appropriate role-based access, review the report to validate the information.

4. **Report acceptable?**
   - » Health workers or other personas determine whether the report meets their needs and is correct. If the data are incorrect, the parameters may need to be adjusted. The report definition may also need to be modified as data needs change.

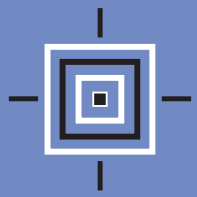
5. **Analyse**
   - » Health workers or other personas analyse the data. The data are then leveraged to increase coverage rates, evaluate providers, reallocate vaccines, etc.

4.3 Additional considerations for adapting workflows

As a reminder, these workflows are meant to be generic and high-level. They will require a level of customization and adaptation as they are being translated into a digital system for a specific context. These workflows are 80% complete, whereby the other 20% will need to be done through a series of human-centred design methods and mechanisms to complete the workflows for an implementation. For example, there might be additional workflows that need to be drawn out, or there might be additional activities that is expected of a health worker in the vaccination location to conduct. Some workflows are not included owing to the high level of contextualization required, including billing, stock management, configuration (of vaccination location level specifics) and follow-up (which can be automated). Alternatively, there might be some activities and tasks a health worker would not be expected to do. Although these workflows can be considered as a starting point, it is helpful to conduct further validation through interviews with the targeted personas or shadowing their work to obtain a better sense of the differences that would need to be reflected in the digital system.

Component 5

Core data elements



This section outlines the minimum set of data corresponding to different points of the workflow within the identified business processes. This data set can be used on any software system and lists the data elements relevant for service delivery and executing decision-support logic, as well as for populating indicators and performance metrics. Although this section provides a high-level overview of the data elements, a more complete data dictionary in spreadsheet form detailing the input options, validation checks and concept dictionary codes is available *here*.

Inclusion of a data element in the table does not by itself indicate that data collection is required. Additionally, some data elements are dependent on other data elements (e.g. test results are only entered when a test has been performed). This will require review and adaptation.

5.1 Simplified list of core data elements template

Table 10 provides a simplified list of core data elements and is merely a snapshot of the comprehensive *data dictionary*. As with the workflows, this data dictionary is 80% generic with the expectation that the other 20% will be supplemented and modified through country adaptation.

Table 10. Workflow core data elements for identified business processes

Activity ID. Activity name	Data element ID	Data element name	Description and definition
Business process IMMZ.C: Client registration			
IMMZ.C1.Arrive at vaccination location	N/A – No data are recorded during this activity		
IMMZ.C2.Query client record	N/A – No data are recorded during this activity		
IMMZ.C3.Is client record confirmed?	N/A – No data are recorded during this activity		

Activity ID. Activity name	Data element ID	Data element name	Description and definition
IMMZ.C4.Create client record OR IMMZ.C5.3.Update client details	IMMZ.C.DE.1	Unique identifier	Unique identifier for the client, according to the policies applicable to each country. There can be more than one unique identifier used to link records (e.g. national identification [ID], health ID, immunization information system ID, medical record ID)
	IMMZ.C.DE.2	Name	The full name of the client
	IMMZ.C.DE.3	First name	Client's first name or given name
	IMMZ.C.DE.4	Family name	Client's family name or last name
	IMMZ.C.DE.5–DE.9	Sex	Documentation of a specific instance of sex information for the client
	IMMZ.C.DE.10	Date of birth	Client's date of birth (DOB) if known; if unknown, use assigned DOB for administrative purposes
	IMMZ.C.DE.13	Age	The client's calculated age (presented as number of years, months, weeks, days) based on the DOB and the visit date
	IMMZ.C.DE.14–DE.17	Caregivers (multiple)	Details of the client's caregiver (person) who could be next of kin (e.g. partner, husband, mother, sibling, etc.)
	IMMZ.C.DE.18	Contact phone number	Client's phone number; can be a landline or a mobile phone number
	IMMZ.C.DE.19	Address	Client's home address or address that the client is consenting to disclose
IMMZ.C6.Check in client	N/A – No data are recorded during this activity		
Business process IMMZ.D: Administer vaccine			
IMMZ.D1.Capture or update client history	IMMZ.D1.DE.109	Birth dose	Indicates if the client received a dose within 24 hours of birth. Whether a birth dose is counted as part of the primary series will depend on the antigen
	IMMZ.D1.DE.103–DE.107	Type of dose	The type of dose in a series that the client received
	IMMZ.D1.DE.8	Completed the primary vaccination series	Indicates if the client has completed the primary vaccination series of a product/antigen. If the client has not yet completed their primary series, it means they may be expected to receive more doses to complete their vaccination regimen for the respective product/antigen
IMMZ.D1.Capture or update client history OR IMMZ.D13.Update client record	IMMZ.D.DE.19	Vaccine type	Vaccine type/category that was administered or was to be administered. Any vaccine code available in the IMMZ.Z vaccine library list of codes applies in this data element
	IMMZ.D.DE.20	Date and time of vaccination	Represents the visit/encounter date, which is the date and time when each vaccine was administered to the client
	IMMZ.D.DE.124	Dose number	Vaccine dose number including dose number within series
IMMZ.D2.Determine required vaccinations	IMMZ.D.DE.156–DE.160	Immunization recommendation status	The current status or recommendation for a specific immunization for an client
IMMZ.D3.Does client require vaccine(s)?	N/A – No data are recorded during this activity		
IMMZ.D4.Check contraindications	N/A – No data are recorded during this activity		
IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	IMMZ.D.DE.161–DE.199	Potential contraindications	Specific situations or medical conditions in which it is advised or recommended to avoid or delay administering a particular vaccine
IMMZ.D6.Check stock availability of recommended vaccines	N/A – No data are recorded during this activity		

Activity ID. Activity name	Data element ID	Data element name	Description and definition
IMMZ.D7.Counsel client	IMMZ.D.DE.86–DE.91	Client education and counselling on immunization	Providing information, guidance and support to client or caretakers (such as parents or legal guardians) regarding immunization practices
IMMZ.D8.Are vaccine(s) able to be administered?	N/A – No data are recorded during this activity		
IMMZ.D9.Inform client when to return for vaccine(s)	N/A – No data are recorded during this activity		
IMMZ.D10.Prepare vaccine(s)	N/A – No data are recorded during this activity		
IMMZ.D11.Administer vaccine(s)	N/A – No data are recorded during this activity		
IMMZ.D12.Dispose of waste	N/A – No data are recorded during this activity		
IMMZ.D13.Update client record	IMMZ.D.DE.1–DE.4	Immunization event status	The current status of the individual immunization event
	IMMZ.D.DE.5–DE.17	Reason vaccine was not administered	The reason this immunization event was not performed
	IMMZ.D.DE.18	Vaccine brand	The brand or trade name used to refer to the vaccine received
	IMMZ.D.DE.21	Country of vaccination	The service delivery country where the vaccine administration occurred
	IMMZ.D.DE.22	Administrative area	The service delivery location (location name, city, municipality, town or village) where the vaccine administration occurred
IMMZ.D14.Monitor the client for any adverse reactions	N/A – No data are recorded during this activity		
IMMZ.D15.Was there an adverse reaction?	N/A – No data are recorded during this activity		
IMMZ.D16.Treat as appropriate	N/A – No data are recorded during this activity		
IMMZ.D17.Report AEFI	IMMZ.D.DE.95–DE.105	Reaction manifestation	The manifestation of the reaction (e.g. infected abscess, swelling, rash, hives, diarrhoea, etc.) which was observed after administering the vaccine
	IMMZ.D.DE.107–DE.113, IMMZ.D.DE.174	Type of reaction	If the event resulted in a reaction, what is the type of reaction
	IMMZ.D.DE.115–DE.124	Reaction outcome	The outcome of the reaction (e.g. death, recovered, recovering)
IMMZ.D18.Determine time for next visit	IMMZ.D.DE.185	Date/time of follow-up appointment	Date the client is to return for next vaccination
	IMMZ.D.DE.186	Recommended follow-up date	Date when follow-up is recommended based on vaccination schedule
IMMZ.D19.Provide vaccination record	N/A – No data are recorded during this activity		
IMMZ.D20.Does client require a verifiable digital certificate	IMMZ.D.DE.150	Digital certificate needed	Indicates if a digital certificate is required

Activity ID. Activity name	Data element ID	Data element name	Description and definition
IMMZ.D21.Generate verifiable digital certificate	IMMZ.D.DE.151	Certificate issuer	The authority or authorized organization that issued the vaccination certificate
	IMMZ.D.DE.152	Health Certificate Identifier (HCID)	Unique identifier used to associate the immunization event represented in a paper vaccination card to its digital representation(s)
	IMMZ.D.DE.153	Certificate valid from	Date in which the certificate for an immunization event became valid. No health or clinical inferences should be made from this date
	IMMZ.D.DE.154	Certificate valid until	Last date in which the certificate for an immunization event is valid. No health or clinical inferences should be made from this date
	IMMZ.D.DE.155	Certificate schema version	Version of the core data set and HL7 Fast Health Interoperability Resources (FHIR) implementation guide that the certificate is using

DE: data element; ID: identification; IMMZ: immunization; N/A: not applicable.

5.2 List of calculated data elements

The DAK for immunizations does not have any calculated data elements at this time. Age is not listed as a calculated data element in this DAK as it will be an implementation level real-time calculation based on the date of birth and visit date.

5.3 Additional considerations for adapting the data dictionary

Some settings may require the inclusion of additional data elements into the full data set or changes to response options based on contextual differences. Additionally, the transition from paper-based forms to digital systems may require some reflection on whether data elements currently on the paper forms should be incorporated into the digital system. Furthermore, the following assumptions are made about country's responsibilities as foundational aspects of implementing this DAK:

» It will be up to the country to determine the mechanism for unique ID of the client. It may be based on a national unique ID, biometrics or a system-generated unique ID.
» It will be up to the country to determine the list of vaccine products available.

The **Annex** provides additional guidance for adding data elements to or amending existing data elements in the data dictionary.

Component 6

Decision-support logic

The decision-support logic component of the DAK provides the decision logic and algorithms, as well as the scheduling of services, in accordance with WHO guidelines. In this DAK, the decision logic and algorithms deconstruct the recommendations within the immunization guidelines and guidance into a format that clearly labels the inputs and outputs that would be operationalized in a digital decision-support system.

6.1 Decision-support logic overview

Table 11 provides an overview of the decision-support tables and scheduling-logic tables for the **IMMZ.D2 Determine required vaccinations** business processes in a PCPOSS. Decision-support tables and scheduling-logic tables based on WHO evidence-based recommendations are not relevant to other business processes in a PCPOSS in the context and scope of this DAK. The structure of the decision-support tables is based on an adaptation of the Decision Model and Notation, an industry standard for modelling and executing decision logic *(35)*. These decision-support tables and scheduling-logic tables detail the business rules, data inputs and outputs to support PCPOSS business processes.

Immunization schedules vary by vaccine product, epidemiological situation, and national policies. The decision-support logic and scheduling logic in the DAK were curated based on the WHO recommended immunizations schedules and related position papers *(29)*. Because of this, there are decision-support table "options" and scheduling-logic "options" based on the various immunization strategies outlined in the recommendations that countries can choose and adapt as relevant.

Table 11. Overview of decision-support tables and scheduling-logic tables for vaccine delivery

Decision-support table (DT), contraindications table and scheduling-logic table (S) identification (ID)	Table description
IMMZ.D2.DT.BCG	Recommended vaccinations for bacille Calmette-Guérin (BCG) as per WHO recommendations
IMMZ.D5.DT.BCG contraindications	Performing a contraindication check for BCG vaccines as per WHO recommendations
IMMZ.D18.S.BCG schedule	Recommended vaccination schedule for BCG as per WHO recommendations
IMMZ.D2.DT.Hepatitis B.Birth dose	Recommended administration of the birth dose for hepatitis B as per WHO recommendations
IMMZ.D2.DT.Hepatitis B.3 doses	Recommended vaccinations for hepatitis B following the 3-dose schedule as per WHO recommendations
IMMZ.D2.DT.Hepatitis B.4 doses	Recommended vaccinations for hepatitis B following the 4-dose schedule as per WHO recommendations

Decision-support table (DT), contraindications table and scheduling-logic table (S) identification (ID)	Table description
IMMZ.D2.DT.Hepatitis B.Delayed start	Recommended vaccinations for hepatitis B following the delayed start schedule as per WHO recommendations
IMMZ.D5.DT.Hepatitis B contraindications	Performing a contraindication check for hepatitis B vaccines as per WHO recommendations
IMMZ.D18.S.Hepatitis B.Birth dose schedule	Recommended birth dose vaccination schedule for hepatitis B as per WHO recommendations
IMMZ.D18.S.Hepatitis B.3-dose schedule	Recommended 3-dose vaccination schedule for hepatitis B as per WHO recommendations
IMMZ.D18.S.Hepatitis B.4-dose schedule	Recommended 4-dose vaccination schedule for hepatitis B as per WHO recommendations
IMMZ.D18.S.Hepatitis B.Delayed start schedule	Recommended delayed start vaccination schedule for hepatitis B as per WHO recommendations
IMMZ.D2.DT.Polio.Birth dose	Recommended administration of the birth dose for poliomyelitis (polio) as per WHO recommendations
IMMZ.D2.DT.Polio.bOPV plus IPV	Recommended vaccinations for polio following the bivalent oral polio vaccine (bOPV) plus inactivated polio vaccine (IPV) schedule as per WHO recommendations
IMMZ.D2.DT.Polio.Sequential IPV–bOPV	Recommended vaccinations for polio following the sequential IPV–bOPV schedule as per WHO recommendations
IMMZ.D2.DT.Polio.IPV-only	Recommended vaccinations for polio following the IPV-only schedule as per WHO recommendations
IMMZ.D5.DT.Polio contraindications	Performing a contraindication check for poliovirus-containing vaccines as per WHO recommendations
IMMZ.D18.S.Polio.Birth dose schedule	Recommended birth dose vaccination schedule for polio as per WHO recommendations
IMMZ.D18.S.Polio.bOPV plus IPV schedule	Recommended bOPV plus IPV vaccination schedule for polio as per WHO recommendations
IMMZ.D18.S.Polio.Sequential IPV–bOPV schedule	Recommended sequential IPV–bOPV vaccination schedule for polio as per WHO recommendations
IMMZ.D18.S.Polio.IPV-only schedule	Recommended IPV-only vaccination schedule for polio as per WHO recommendations
IMMZ.D2.DT.DTP.On-time start	Recommended vaccinations for diphtheria–tetanus–pertussis (DTP) following the on-time start schedule as per WHO recommendations
IMMZ.D2.DT.DTP.Delayed or interrupted series	Recommended vaccinations for DTP following the delayed start or interrupted series schedule as per WHO recommendations
IMMZ.D2.DT.DTP.Pregnancy	Determine whether DTP vaccinations are needed for pregnant women as per WHO recommendations
IMMZ.D2.DT.DTP.Pregnancy starting with 3 doses	Recommended vaccinations for diphtheria and tetanus following the schedule outlined for pregnant women who have received three childhood DTP doses as per WHO recommendations
IMMZ.D2.DT.DTP.Pregnancy starting with 4 doses	Recommended vaccinations for diphtheria and tetanus following the schedule outlined for pregnant women who have received four childhood DTP doses as per WHO recommendations
IMMZ.D5.DT.DTP contraindications	Performing a contraindication check for DTP vaccines as per WHO recommendations
IMMZ.D18.S.DTP.On-time start schedule	Recommended on-time start (at ≤12 months of age) vaccination schedule for DTP as per WHO recommendations
IMMZ.D18.S.DTP.Delayed or interrupted schedule	Recommended delayed or interrupted series vaccination schedule for DTP as per WHO recommendations
IMMZ.D18.S.DTP.Pregnancy starting with 3 doses schedule	Recommended vaccination schedule for pregnant women who received 3 childhood DTP doses as per WHO recommendations
IMMZ.D18.S.DTP.Pregnancy starting with 4 doses schedule	Recommended vaccination schedule for pregnant women who received 4 childhood DTP doses as per WHO recommendations
IMMZ.D2.DT.Hib.3 doses	Recommended vaccinations for *Haemophilus influenzae* type b (Hib) following the 3 primary doses without a booster schedule as per WHO recommendations
IMMZ.D2.DT.Hib.3 doses with booster dose	Recommended vaccinations for Hib following the 3 primary doses with a booster schedule as per WHO recommendations
IMMZ.D2.DT.Hib.2 doses with booster dose	Recommended vaccinations for Hib following the 2 primary doses with a booster schedule as per WHO recommendations

Decision-support table (DT), contraindications table and scheduling-logic table (S) identification (ID)	Table description
IMMZ.D5.DT.Hib contraindications	Performing a contraindication check for Hib vaccines as per WHO recommendations
IMMZ.D18.S.Hib.3 doses schedule	Recommended 3 primary doses without a booster vaccination schedule for Hib as per WHO recommendations
IMMZ.D18.S.Hib.3 doses with booster dose schedule	Recommended 3 primary doses with a booster vaccination schedule for Hib as per WHO recommendations
IMMZ.D18.S.Hib.2 doses with booster dose schedule	Recommended 2 primary doses with a booster vaccination schedule for Hib as per WHO recommendations
IMMZ.D2.DT.Pneumococcal.2 doses with booster dose	Recommended vaccinations for pneumococcal following the 2 primary doses with a booster schedule as per WHO recommendations
IMMZ.D2.DT.Pneumococcal.3 doses	Recommended vaccinations for pneumococcal following the 3 primary doses schedule as per WHO recommendations
IMMZ.D5.DT.Pneumococcal contraindications	Performing a contraindication check for pneumococcal vaccines as per WHO recommendations
IMMZ.D18.S.Pneumococcal.2 doses with booster dose schedule	Recommended 2 primary doses with a booster vaccination schedule for pneumococcal as per WHO recommendations
IMMZ.D18.S.Pneumococcal.3 doses schedule	Recommended 3 primary doses vaccination schedule for pneumococcal as per WHO recommendations
IMMZ.D2.DT.Rotavirus	Recommended vaccinations for rotavirus as per WHO recommendations
IMMZ.D5.DT.Rotavirus contraindications	Performing a contraindication check for rotavirus vaccines as per WHO recommendations
IMMZ.D18.S.Rotavirus schedule	Recommended vaccination schedule for rotavirus as per WHO recommendations
IMMZ.D2.DT.Measles.Ongoing transmission	Recommended vaccinations for measles following the ongoing transmission schedule as per WHO recommendations
IMMZ.D2.DT.Measles.Low transmission	Recommended vaccinations for measles following the low levels of measles transmission schedule as per WHO recommendations
IMMZ.D2.DT.Measles.MCV dose 0	Recommended administration of dose 0 for measles as per WHO recommendations
IMMZ.D2.DT.Measles.Supplementary dose	Recommended administration of supplementary dose for measles as per WHO recommendations
IMMZ.D5.DT.Measles contraindications	Performing a contraindication check for measles-containing vaccines (MCV) as per WHO recommendations
IMMZ.D18.S.Measles.Ongoing transmission schedule	Recommended ongoing transmission vaccination schedule for measles as per WHO recommendations
IMMZ.D18.S.Measles.Low transmission schedule	Recommended low levels of measles transmission vaccination schedule for measles as per WHO recommendations
IMMZ.D18.S.Measles.MCV dose 0 schedule	Recommended measles dose 0 vaccination schedule for measles as per WHO recommendations
IMMZ.D18.S.Measles.Supplementary dose schedule	Recommended measles supplementary dose vaccination schedule for measles as per WHO recommendations
IMMZ.D2.DT.Rubella.High incidence	Recommended vaccinations for rubella following the high incidence of measles schedule as per WHO recommendations
IMMZ.D2.DT.Rubella.Low incidence	Recommended vaccinations for rubella following the low incidence of measles schedule as per WHO recommendations
IMMZ.D5.DT.Rubella contraindications	Performing a contraindication check for rubella vaccines as per WHO recommendations
IMMZ.D18.S.Rubella.High incidence schedule	Recommended vaccination schedule for rubella for countries with high incidence of measles as per WHO recommendations
IMMZ.D18.S.Rubella.Low incidence schedule	Recommended vaccination schedule for rubella for countries with low incidence of measles as per WHO recommendations
IMMZ.D2.DT.HPV.2 doses	Recommended vaccinations for human papillomavirus (HPV) following the 2-dose schedule as per WHO recommendations
IMMZ.D2.DT.HPV.Single dose	Recommended vaccinations for HPV following the single-dose schedule as per WHO recommendations
IMMZ.D5.DT.HPV contraindications	Performing a contraindication check for HPV vaccines as per WHO recommendations

Decision-support table (DT), contraindications table and scheduling-logic table (S) identification (ID)	Table description
IMMZ.D18.S.HPV.2-dose schedule	Recommended 2-dose vaccination schedule for HPV as per WHO recommendations
IMMZ.D18.S.HPV.Single-dose schedule	Recommended single-dose vaccination schedule for HPV as per WHO recommendations
IMMZ.D2.DT.JE.Inactivated Vero cell-derived vaccine	Recommended vaccinations for Japanese encephalitis (JE) following the inactivated Vero cell-derived vaccine schedule as per WHO recommendations
IMMZ.D2.DT.JE.Live attenuated vaccine	Recommended vaccinations for JE following the live attenuated vaccine schedule as per WHO recommendations
IMMZ.D2.DT.JE.Live recombinant vaccine	Recommended vaccinations for JE following the live recombinant vaccine schedule as per WHO recommendations
IMMZ.D5.DT.JE contraindications	Performing a contraindication check for JE vaccines as per WHO recommendations
IMMZ.D18.S.JE.Inactivated Vero cell-derived vaccine schedule	Recommended inactivated Vero cell-derived vaccination schedule for JE as per WHO recommendations
IMMZ.D18.S.JE.Live attenuated vaccine schedule	Recommended live attenuated vaccination schedule for JE as per WHO recommendations
IMMZ.D18.S.JE.Live recombinant vaccine schedule	Recommended live recombinant vaccination schedule for JE as per WHO recommendations
IMMZ.D2.DT.Yellow fever	Recommended vaccinations for yellow fever as per WHO recommendations
IMMZ.D5.DT.Yellow fever contraindications	Performing a contraindication check for yellow fever vaccines as per WHO recommendations
IMMZ.D18.S.Yellow fever schedule	Recommended vaccination schedule for yellow fever as per WHO recommendations
IMMZ.D2.DT.TBE.FSME-Immun	Recommended vaccinations for tick-borne encephalitis (TBE) following the FSME-Immun schedule as per WHO recommendations
IMMZ.D2.DT.TBE.Encepur	Recommended vaccinations for TBE following the Encepur schedule as per WHO recommendations
IMMZ.D2.DT.TBE.TBE-Moscow	Recommended vaccinations for TBE following the TBE-Moscow schedule as per WHO recommendations
IMMZ.D2.DT.TBE.EnceVir	Recommended vaccinations for TBE following the EnceVir schedule as per WHO recommendations
IMMZ.D5.DT.TBE contraindications	Performing a contraindication check for TBE vaccines as per WHO recommendations
IMMZ.D18.S.TBE.FSME-Immun schedule	Recommended FSME-Immun vaccination schedule for TBE as per WHO recommendations
IMMZ.D18.S.TBE.Encepur schedule	Recommended Encepur vaccination schedule for TBE as per WHO recommendations
IMMZ.D18.S.TBE.TBE-Moscow schedule	Recommended TBE-Moscow vaccination schedule for TBE as per WHO recommendations
IMMZ.D18.S.TBE.EnceVir	Recommended EnceVir vaccination schedule for TBE as per WHO recommendations
IMMZ.D2.DT.Typhoid.TCV	Recommended vaccinations for typhoid following the typhoid conjugate vaccine (TCV) schedule as per WHO recommendations
IMMZ.D2.DT.Typhoid.ViPS	Recommended vaccinations for typhoid following the unconjugated Vi polysaccharide (ViPS) schedule as per WHO recommendations
IMMZ.D2.DT.Typhoid.Ty21a	Recommended vaccinations for typhoid following the live attenuated Ty21a vaccine schedule as per WHO recommendations
IMMZ.D5.DT.Typhoid contraindications	Performing a contraindication check for typhoid vaccines as per WHO recommendations
IMMZ.D18.S.Typhoid.TCV schedule	Recommended TCV vaccination schedule for typhoid as per WHO recommendations
IMMZ.D18.S.Typhoid.ViPS schedule	Recommended unconjugated ViPS vaccination schedule for typhoid as per WHO recommendations
IMMZ.D18.S.Typhoid.Ty21a schedule	Recommended live attenuated Ty21a vaccination schedule for typhoid as per WHO recommendations
IMMZ.D2.DT.Cholera.WC vaccines	Recommended vaccinations for cholera following the whole-cell (WC) vaccines schedule as per WHO recommendations

Decision-support table (DT), contraindications table and scheduling-logic table (S) identification (ID)	Table description
IMMZ.D2.DT.Cholera.WC-rBS vaccine 3 doses	Recommended vaccinations for cholera following the WC-recombinant B subunit (WC-rBS) vaccine 3 doses schedule as per WHO recommendations
IMMZ.D2.DT.Cholera.WC-rBS vaccine 2 doses	Recommended vaccinations for cholera following the WC-rBS vaccine 2 doses schedule as per WHO recommendations
IMMZ.D18.S.Cholera.WC vaccines schedule	Recommended WC vaccination schedule for cholera as per WHO recommendations
IMMZ.D18.S.Cholera.WC-rBS vaccine 3 dose schedule	Recommended WC-rBS vaccine 3 doses vaccination schedule for cholera as per WHO recommendations
IMMZ.D18.S.Cholera.WC-rBS vaccine booster dose for children aged 2–5 years schedule	Recommended WC-rBS vaccine booster dose for children aged 2–5 years vaccination schedule for cholera as per WHO recommendations
IMMZ.D18.S.Cholera.WC-rBS vaccine 2 dose schedule	Recommended WC-rBS vaccine 2 dose vaccination schedule for cholera as per WHO recommendations
IMMZ.D18.S.Cholera.WC-rBS vaccine booster dose for children aged more than 6 years schedule	Recommended WC-rBS vaccine booster dose for children aged more than 6 years vaccination schedule for cholera as per WHO recommendations
IMMZ.D2.DT.Meningococcal.MenA conjugate vaccine 1 dose	Recommended vaccinations for meningococcal following the MenA conjugate vaccine 1-dose schedule as per WHO recommendations
IMMZ.D2.DT.Meningococcal.MenA conjugate vaccine 2 doses	Recommended vaccinations for meningococcal following the MenA conjugate vaccine 2-dose schedule as per WHO recommendations
IMMZ.D2.DT.Meningococcal.Monovalent MenC conjugate vaccine	Recommended vaccinations for meningococcal following the monovalent MenC conjugate vaccine schedule as per WHO recommendations
IMMZ.D2.DT.Meningococcal.Quadrivalent conjugate vaccines 1 dose	Recommended vaccinations for meningococcal following the quadrivalent conjugate vaccines 1-dose schedule as per WHO recommendations
IMMZ.D2.DT.Meningococcal.Quadrivalent conjugate vaccines 2 doses	Recommended vaccinations for meningococcal following the quadrivalent conjugate vaccines 2-dose schedule as per WHO recommendations
IMMZ.D2.DT.Meningococcal.Polysaccharide vaccines	Recommended vaccinations for meningococcal following the polysaccharide vaccines schedule as per WHO recommendations
IMMZ.D5.DT.Meningococcal contraindications	Performing a contraindication check for meningococcal vaccines as per WHO recommendations
IMMZ.D18.S.Meningococcal.MenA conjugate vaccine 1-dose schedule	Recommended MenA conjugate vaccine 1-dose vaccination schedule for meningococcal as per WHO recommendations
IMMZ.D18.S.Meningococcal.MenA conjugate vaccine 2-dose schedule	Recommended MenA conjugate vaccine 2-dose vaccination schedule for meningococcal as per WHO recommendations
IMMZ.D18.S.Meningococcal.Monovalent MenC conjugate vaccine schedule	Recommended monovalent MenC conjugate vaccination schedule for meningococcal as per WHO recommendations
IMMZ.D18.S.Meningococcal.Quadrivalent conjugate vaccines 1-dose schedule	Recommended quadrivalent conjugate vaccines 1-dose vaccination schedule for meningococcal as per WHO recommendations
IMMZ.D18.S.Meningococcal.Quadrivalent conjugate vaccines 2-dose schedule	Recommended quadrivalent conjugate vaccines 2-dose vaccination schedule for meningococcal as per WHO recommendations
IMMZ.D18.S.Meningococcal.Polysaccharide vaccines schedule	Recommended polysaccharide vaccination schedule for meningococcal as per WHO recommendations
IMMZ.D2.DT.Hepatitis A.Inactivated HAV 2 doses	Recommended vaccinations for hepatitis A following the inactivated hepatitis A virus (HAV) 2-dose schedule as per WHO recommendations
IMMZ.D2.DT.Hepatitis A.Inactivated HAV 1 dose	Recommended vaccinations for hepatitis A following the inactivated HAV 1-dose schedule as per WHO recommendations

Decision-support table (DT), contraindications table and scheduling-logic table (S) identification (ID)	Table description
IMMZ.D2.DT.Hepatitis A.Live attenuated HAV 1 dose	Recommended vaccinations for hepatitis A following the live attenuated HAV 1-dose schedule as per WHO recommendations
IMMZ.D5.DT.Hepatitis A contraindications	Performing a contraindication check for hepatitis A vaccines as per WHO recommendations
IMMZ.D18.S.Hepatitis A.Inactivated HAV 2-dose schedule	Recommended inactivated HAV 2-dose vaccination schedule for hepatitis A as per WHO recommendations
IMMZ.D18.S.Hepatitis A.Inactivated HAV 1-dose schedule	Recommended inactivated HAV 1-dose vaccination schedule for hepatitis A as per WHO recommendations
IMMZ.D18.S.Hepatitis A.Live attenuated HAV 1-dose schedule	Recommended live attenuated HAV 1-dose vaccination schedule for hepatitis A as per WHO recommendations
IMMZ.D2.DT.Rabies	Recommended vaccinations for rabies as per WHO recommendations
IMMZ.D5.DT.Rabies contraindications	Performing a contraindication check for rabies vaccines as per WHO recommendations
IMMZ.D18.S.Rabies schedule	Recommended vaccination schedule for rabies as per WHO recommendations
IMMZ.D2.DT.Dengue.3 doses with pre-vaccination screening	Recommended vaccinations for dengue following the 3-dose schedule with pre-vaccination screening as per WHO recommendations
IMMZ.D2.DT.Dengue.3 doses without pre-vaccination screening	Recommended vaccinations for dengue following the 3-dose schedule without pre-vaccination screening as per WHO recommendations
IMMZ.D5.DT.Dengue contraindications	Performing a contraindication check for dengue vaccines as per WHO recommendations
IMMZ.D18.S.Dengue schedule	Recommended vaccination schedule for dengue as per WHO recommendations
IMMZ.D2.DT.Malaria	Recommended vaccinations for malaria as per WHO recommendations
IMMZ.D5.DT.Malaria contraindications	Performing a contraindication check for malaria vaccines as per WHO recommendations
IMMZ.D18.S.Malaria schedule	Recommended vaccination schedule for malaria as per WHO recommendations
IMMZ.D2.DT.Mumps	Recommended vaccinations for mumps as per WHO recommendations
IMMZ.D5.DT.Mumps contraindications	Performing a contraindication check for mumps vaccines as per WHO recommendations
IMMZ.D18.S.Mumps schedule	Recommended vaccination schedule for mumps as per WHO recommendations
IMMZ.D2.DT.Seasonal influenza	Recommended vaccinations for seasonal influenza as per WHO recommendations
IMMZ.D5.DT.Seasonal influenza contraindications	Performing a contraindication check for seasonal influenza vaccines as per WHO recommendations
IMMZ.D18.S.Seasonal influenza schedule	Recommended vaccination schedule for seasonal influenza as per WHO recommendations
IMMZ.D2.DT.Varicella.1 dose	Recommended vaccinations for varicella following the 1-dose schedule as per WHO recommendations
IMMZ.D2.DT.Varicella.2 doses	Recommended vaccinations for varicella following the 2-dose schedule as per WHO recommendations
IMMZ.D5.DT.Varicella contraindications	Performing a contraindication check for varicella vaccines as per WHO recommendations
IMMZ.D18.S.Varicella.1-dose schedule	Recommended 1-dose vaccination schedule for varicella as per WHO recommendations
IMMZ.D18.S.Varicella.2-dose schedule	Recommended 2-dose vaccination schedule for varicella as per WHO recommendations

IMMZ: immunization.
Source: WHO *(29)*.

6.2 Decision-support tables

Each of the decision logics listed in the overview table (see **Table 11**) is elaborated in the decision-support implementation tool found here. These decision-support tables comprise the components described in **Table 12**.

It is important to note that the decision-support logic here is translated directly from the WHO guidelines and guidance documents and has been reviewed by the panel of experts who have created those guidelines documents. We do not anticipate the decision-support logic to change much as the logic was created and reviewed by clinical experts. However, some level of adaptation may be needed depending on changes to the workflow and/or changes to the data dictionary.

Any changes to the decision-support logic should be considered carefully, as an embedded decision-support system can greatly affect the quality of care at the point of care. As helpful as decision-support logic can be to the health worker, incorrect decision-support logic can also be detrimental. Thus, any new decision-support logic should be carefully reviewed and agreed upon by in-country clinical experts and tested with a standard set of cases to ensure consistency.

Table 12. Components of the decision-support tables

Decision ID	**The name of the "decision" describing which algorithm or logic is represented (e.g. whether a client needs to be vaccinated for mumps). The Decision ID should correspond to the number in the overview table on "overview" tab**				
Business rule	**The description of the decision that needs to be made based on IF/THEN statements with the appropriate data element name for the variables. The rule should demonstrate the relationship between the input variables and the expected outputs and actions within the decision-support logic (e.g. IF client has not been vaccinated against mumps THEN give mumps vaccine)**				
Trigger	**The event that would indicate when this decision-support logic should appear within the workflow, such as the activity that would trigger this decision to be made**				
Inputs		**Output**	**Guidance displayed to health worker**	**Annotations**	**Reference(s)**
These are the variables or conditions that need to be considered to determine the consequent actions or outputs.	If there are multiple input entries on the same row (such as here), these different inputs are considered as "**AND**" – conditions that need to be in place at the same time.	The decision support that the system must recommend as action to be taken given the criteria are met. The software will refer to the contents here to make relevant automated decision support. Action will trigger the system to perform a decision-support outcome.	Pop-up alert messages for the health worker; it should include the written content that will appear in the pop-up messages notifying the health worker of the appropriate next steps.	This column should be used for any other notes, annotations or communication messages within the team. This should include any additional information that does not fit into the other columns. Note that this message WILL NOT appear as a pop-up message. While noting down the annotations, please note the correct audience for the annotation (who is this message for?).	A reference to this decision rule
Inputs placed on different rows are considered as "OR" conditions that can be considered independently of the inputs on other rows.					

Table 13 is an example of a decision-support table for determining if a client is due for measles vaccination in countries with ongoing transmission in which the risk of measles mortality remains high. **Table 14** is an example of a contraindications table for measles, illustrating potential contraindications for measles vaccination.

Table 13. Example decision-support table for measles vaccination in countries with ongoing transmission in which the risk of measles mortality remains high

Decision ID	**IMMZ.D2.DT.Measles.Ongoing transmission**					
Business rule	**Determine if the client is due for a measles vaccination according to the national immunization schedule**					
Trigger	**IMMZ.D2 Determine required vaccination(s) if any**					
Inputs			**Output**	**Guidance displayed to health worker**	**Annotations**	**Reference(s)**
Countries with ongoing transmission in which the risk of measles mortality remains high (countries that provide first dose of measles-containing vaccine (MCV) at 9 months and second dose of MCV at 15 months)						
Number of MCV primary series doses administered Count of vaccines administered (where "Vaccine type" = "Measles-containing vaccines" and "Type of dose" = "Primary series")	**Client's age** Today's date − "Date of birth"	**Time passed since a live vaccine was administered** Today's date − latest "Date and time of vaccination" (where "Live vaccine" = TRUE)				
–	**Client's age is less than 9 months** Today's date − "Date of birth" < 9 months	–	**Client is not due for first dose of measles-containing vaccine (MCV1)** "Immunization recommendation status" = "Not due"	Should not vaccinate client as client's age is less than 9 months. Check for any vaccines due and inform the caregiver of when to come back for MCV1.	In countries with ongoing transmission in which the risk of measles mortality remains high, MCV1 should be given at 9 months of age. As a general rule, live vaccines should be given either simultaneously or at intervals of 4 weeks. An exception to this rule is oral polio vaccine (OPV), which can be given at any time before or after measles vaccination without interference in the response to either vaccine.	WHO recommendations for routine immunization – summary tables (March 2023) *(28)*
No measles primary series doses were administered Count of vaccines administered (where "Vaccine type" = "Measles-containing vaccines" and "Type of dose" = "Primary series") = 0	**Client's age is more than or equal to 9 months** Today's date − "Date of birth" ≥ 9 months	**No live vaccine was administered in the last 4 weeks** Today's date − latest "Date and time of vaccination" (where "Live vaccine" = TRUE) ≥ 4 weeks	**Client is due for MCV1** "Immunization recommendation status" = "Due"	Should vaccinate client with MCV1 as no measles doses were administered, client is within appropriate age range and no live vaccine administered in the past 4 weeks. Check for contraindications.		
		Live vaccine was administered in the last 4 weeks Today's date − latest "Date and time of vaccination" (where "Live vaccine" = TRUE) < 4 weeks	**Client is not due for MCV1** "Immunization recommendation status" = "Not due"	Should not vaccinate client with MCV1 as live vaccine was administered in the past 4 weeks. Check for any vaccines due and inform the caregiver of when to come back for MCV1.		

Inputs			Output	Guidance displayed to health worker	Annotations	Reference(s)
MCV1 was administered Count of vaccines administered (where "Vaccine type" = "Measles-containing vaccines" and "Type of dose" = "Primary series") = 1	**Client's age is less than 15 months** Today's date − "Date of birth" < 15 months	–	**Client is not due for second dose of measles-containing vaccine (MCV2)"Immunization** recommendation status" = "Not due"	Should not vaccinate client with MCV2 as client's age is less than 15 months. Check for any vaccines due and inform the caregiver of when to come back for MCV2.	In countries with ongoing transmission in which the risk of measles mortality remains high, MCV2 should be given at 15–18 months. The minimum interval between MCV1 and MCV2 is 4 weeks. As a general rule, live vaccines should be given either simultaneously or at intervals of 4 weeks. An exception to this rule is OPV, which can be given at any time before or after measles vaccination without interference in the response to either vaccine.	
	Client's age is more than or equal to 15 months Today's date − "Date of birth" ≥ 15 months	**No live vaccine was administered in the last 4 weeks** Today's date − latest "Date and time of vaccination" (where "Live vaccine" = TRUE) ≥ 4 weeks	**Client is due for MCV2** "Immunization recommendation status" = "Due"	Should vaccinate client with MCV2 as client is within appropriate age range and no live vaccine administered in the past 4 weeks. Check for contraindications.		
		Live vaccine was administered in the last 4 weeks Today's date − latest "Date and time of vaccination" (where "Live vaccine" = TRUE) < 4 weeks	**Client is not due for MCV2** "Immunization recommendation status" = "Not due"	Should not vaccinate client with MCV2 as live vaccine was administered in the past 4 weeks. Check for any vaccines due and inform the caregiver of when to come back for MCV2.		
MCV2 was administered Count of vaccines administered (where "Vaccine type" = "Measles-containing vaccines" and "Type of dose" = "Primary series") = 2	–	–	**Measles primary series is complete** "Completed the primary vaccination series" = TRUE (where "Vaccine type" = "Measles-containing vaccines")	Measles primary series is complete. Two measles primary series doses were administered. Check if a measles supplementary dose is appropriate for the client.	An additional dose of MCV should be administered to children infected with HIV receiving highly active antiretroviral therapy (HAART) following immune reconstitution. If CD4+ T lymphocyte counts are monitored, an additional dose of MCV should be administered when immune reconstitution has been achieved (e.g. when the CD4+ T lymphocyte count reaches 20–25%). Where CD4+ T lymphocyte monitoring is not available, children should receive an additional dose of MCV 6–12 months after initiation of HAART.	

Table 14. Example contraindications table for measles vaccination

Decision ID	IMMZ.D5.DT.Measles contraindications			
Business rule	**Check for contraindications before administering the vaccine(s) due**			
Trigger	**IMMZ.D5 Determine vaccine(s) to be administered based on contraindications**			
Potential contraindications	**Output**	**Guidance displayed to health worker**	**Annotations**	**Reference(s)**
The client is pregnant "Potential contraindications" = "Currently pregnant"	**Measles vaccination contraindicated** "Immunization recommendation status" = "Contraindicated"	Do not vaccinate client with measles as measles vaccination is contraindicated for pregnant client.	–	WHO recommendations for routine immunization – summary tables (March 2023) *(28)*
The client has history of anaphylactic reactions "Potential contraindications" = "History of anaphylactic reactions"	**Measles vaccination could be contraindicated. Clinical judgement required. Create a clinical note.** "Immunization recommendation status" = "Further evaluation needed"	Do not vaccinate client with measles if client has history of anaphylactic reaction to any component of the vaccine (e.g. neomycin or gelatin).	–	
The client has history of severe allergic reactions "Potential contraindications" = "Severe allergic reactions"	**Clinical judgement required. Create a clinical note.** "Immunization recommendation status" = "Further evaluation needed"	Do not vaccinate client with measles if client has history of severe allergic reactions to any component of the vaccine (e.g. neomycin or gelatin).	–	
The client is severely immunosuppressed "Potential contraindications" = "Severely immunosuppressed"	**Measles vaccination contraindicated** "Immunization recommendation status" = "Contraindicated"	Do not vaccinate client with measles as measles vaccination is contraindicated for severely immunosuppressed client.	–	
The client has a symptomatic HIV infection "Potential contraindications" = "Symptomatic HIV infection"	**Clinical judgement required. Create a clinical note.** "Immunization recommendation status" = "Further evaluation needed"	Client has symptomatic HIV infection. Measles vaccination may be considered if the client is not severely immunosuppressed according to conventional definitions, consider risks of vaccination and make a clinical judgement.	–	

Note: While vaccines are universally recommended, some clients may have contraindications to particular vaccines. Additional contraindications may be included in *Measles vaccines: WHO position paper – April 2017 (36).*

All the decision-support tables for this DAK are available *here*.

6.3 Scheduling-logic overview

In addition to specific decision-support logic that needs to be detailed, there is also scheduling logic to facilitate the digital tracking of clients and ensure that appropriate services are provided in a timely manner according to clinical protocols. For example, it will be important for the health worker to know when the client's next polio vaccination is due based on the recommended vaccination schedule for polio as per WHO recommendations. In the case of immunization, decision-support logic is derived from scheduling logic. **Table 11** provides an overview of the different scheduling-logic tables included in this DAK. The details within each scheduling logic are elaborated here. **Table 15** provides an example scheduling-logic table for measles vaccination.

Table 15. Example scheduling-logic table for measles vaccination schedule in countries with ongoing transmission in which the risk of measles mortality remains high

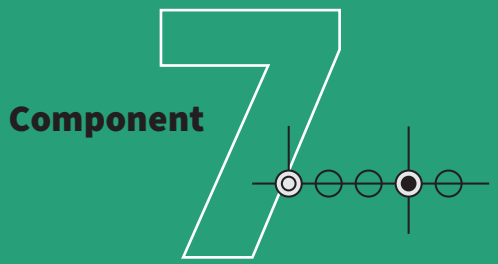
Schedule ID	**IMMZ.D18.S.Measles.Ongoing transmission schedule**									
IMMZ.D Administer vaccine										
Service name	**Service description**	**Trigger event**	**Trigger date**	**Create condition**	**Due date**	**Overdue**	**Expiration**	**Completion**	**Comments**	**Reference(s)**
The name of the service for which the schedule is relevant	Description of the service (to provide clarity)	What event signals the start of the service schedule?	What is the date of the signalling event that will be used to determine a service's due date?	Are there any conditions that specify when a service should be given?	How is the due date of the service calculated?	When does the service become overdue?	When does the service expire?	How does the health worker complete the service?		
Schedule for countries with ongoing transmission in which the risk of measles mortality remains high										
MCV dose 1 (MCV1)	Provision of MCV1 from the primary series	**Child's birth**	"Date of birth"	The client is due for MCV1 if the client is at least 9 months of age.	"Date of birth" + 9 months	To be determined by Member States; however, there is no recommended overdue date and individuals are always eligible to be vaccinated.	To be determined by Member States; however, there is no recommended expiration date and individuals are always eligible to be vaccinated.	**MCV1 was administered** Count of vaccines administered (where "Vaccine type" = "Measles-containing vaccines" and "Type of dose" = "Primary series") = 1	–	WHO recommendations for routine immunization – summary tables (March 2023) *(28)*

MCV2	Provision of the MCV2 from the primary series	**MCV1 was administered** Count of vaccines administered (where "Vaccine type" = "Measles-containing vaccines" and "Type of dose" = "Primary series") = 1	"Date of birth"	The client is due for MCV2 if the client is at least 15 months of age.	"Date of birth" + 15 months	To be determined by Member States; however, there is no recommended overdue date and individuals are always eligible to be vaccinated.	To be determined by Member States; however, there is no recommended expiration date and individuals are always eligible to be vaccinated.	**MCV2 was administered. The primary series has been completed.** "Completed the primary vaccination series" = TRUE (where "Vaccine type" = "Measles-containing vaccines")	–	

The complete sets of the decision-support tables and scheduling-logic tables for this DAK are available here. Note: Scheduling logic for each antigen is located to the right of the decision-logic tables.

6.4 Additional considerations for adapting the decision-support logic

The decision-support logic elaborated here should be adapted to country policies, which may vary according to country's vaccination schedule and uses. It will be up to the country to determine the vaccination dose schedule per national policies. Additionally, some antigens, including rubella and mumps, are currently given in combinations with other antigens. As these antigens do not have stand-alone vaccines available, the recommended combination vaccination and their schedules may vary and will be determined by the country.



Indicators and performance metrics

This section details indicators and performance metrics that would be aggregated from core data elements identified in **Component 5**. The indicator ID list in **Table 16** is a snapshot set of indicators that can be aggregated for decision-making, performance metrics, and subnational and national reporting based on data collected from individual-level, routine health systems *(32)*. These indicators may be aggregated automatically from the digital tracking tool to populate a digital HMIS. The full list of indicators is available here.

Note that immunization coverage here is estimated by comparing the number of vaccinations for each vaccine and dose administered during the reporting period (year/month) to the estimated number of people in the target group for the same period (year/month). This method is advisable whenever there is no certainty that close to 100% of the target population are registered in the EIR. However, sometimes EIRs are also used to calculate 'cohort coverage'. In that method, the denominator includes all people from a certain birth cohort (i.e. selected based on their date of birth), and the corresponding numerator includes all people from that cohort who were vaccinated with the vaccine and dose under consideration. The difference with the described method is that the selection of both numerator (doses) and denominator (number in target group) considers the date of births of the individuals rather than the date of vaccination for the vaccine and dose for which coverage is calculated.

For national or programmatic level tracking, it may be recommended for countries to monitor immunization coverage for individual doses and/or for additional vaccines that are currently not monitored globally (i.e. malaria, cholera and TBE). For such, an indicator template is provided here.

Table 16. Indicators and performance metrics

Indicator ID	Indicator name	Definition	Numerator description	Denominator description	Disaggregation	References
IMMZ.IND.12	Immunization coverage for measles and rubella-containing vaccine, 1st dose	The percentage in the target population who have received a 1st dose of measles and rubella-containing vaccine during the reporting period	Number of measles and rubella-containing vaccine doses (1st dose) administered through routine services during the reporting period	Number in target group	Administrative area Sex Age in years Age group (depending on schedule)	WHO Immunization facility analysis guide *(26)* WHO Handbook on immunization data *(37)*
IMMZ.IND.13	Immunization coverage for measles and rubella-containing vaccine, 2nd dose	The percentage in the target population who have received the 2nd dose of measles and rubella-containing vaccine during the reporting period	Number of measles and rubella-containing vaccine doses (2nd dose) administered through routine services during the reporting period	Number in target group	Administrative area Sex Age in years Age group (depending on schedule)	WHO Immunization facility analysis guide *(26)* WHO Hanbook on immunization data *(37)*
IMMZ.IND.37	Drop-out rate from the 1st dose of measles and rubella-containing vaccine to the 2nd dose	The percentage in the target population who received a 1st dose of measles and rubella-containing vaccine in the primary series but have not received the 2nd dose of measles and rubella-containing vaccine in the primary series (i.e. are past due for measles and rubella-containing vaccine 2nd dose) during the reporting period	Number of clients who received a 1st dose of measles and rubella-containing vaccine during the reporting period who should have received the 2nd dose of measles and rubella-containing vaccine during the reporting period but did not receive it	Number of clients in the target population who received dose 1 of measles and rubella-containing vaccine during the reporting period	Administrative area Sex Age in years Age group (depending on schedule)	WHO Immunization facility analysis guide *(26)*
IMMZ.IND.42	Availability of vaccine stock and supplies	The proportion of vaccination locations that had availability of vaccine stock or injection supplies during (or for) the reporting period or sub-period	The number of vaccination locations with stock available (i.e. no stock-outs) during (or for) the reporting period or sub-period	Total number of vaccination locations	Administrative area Vaccine type/supply type	WHO Immunization facility analysis guide *(26)*

Component 8

High-level functional and non-functional requirements

This section provides an overview of illustrative functional and non-functional requirements that may be considered to kick-start the process of designing or adapting the EIR and/or other PCPOSS. Functional requirements describe the capabilities the system must have to meet the end users' needs and achieve tasks within the business process. Non-functional requirements provide the general attributes and features of the digital system to ensure usability and overcome technical and physical constraints. Examples of non-functional requirements include the ability to work offline, multiple language settings and password protection.

Table 17 highlights some key functional requirements for executing the business processes listed in **Component 4**. **Table 18** provides some non-functional requirements as general characteristics of the overall system. The complete set of functional and non-functional requirements can be accessed here. These are not exhaustive lists, and they should be modified according to context and user persona needs.

8.1 Functional requirements

Table 17. Functional requirements

Requirement ID	Activity ID and description	As a...	I want...	So that...
Business process C: client registration				
IMMZ.FXNREQ.035	IMMZ.C2.Query client record	Health worker	To search for a client using at least two identifying information	I improve my chances of finding a match and distinguishing between similar records
IMMZ.FXNREQ.036	IMMZ.C2.Query client record	Health worker	To search for the client record given some demographic information	I can find the client record if I do not have the unique ID
IMMZ.FXNREQ.037	IMMZ.C2.Query client record	Health worker	The system to return all potential matches based upon search criteria	I can find the best match
IMMZ.FXNREQ.038	IMMZ.C2.Query client record	Health worker	The search to match on partial information (such as partial birthdates)	I have a better chance of finding a match
IMMZ.FXNREQ.039	IMMZ.C2.Query client record	Health worker	The system to allow search parameters configuration: mandatory fields, when partial information is acceptable, etc.	A search can be optimized without compromising confidentiality
IMMZ.FXNREQ.040	IMMZ.C2.Query client record	Health worker	To search with wild cards (using a symbol to replace one or more characters)	I can find something without knowing the exact spelling

Requirement ID	Activity ID and description	As a...	I want...	So that...
IMMZ.FXNREQ.041	IMMZ.C2.Query client record	Health worker	To find client records using barcodes that contain the client ID	I can quickly pull up the correct record
IMMZ.FXNREQ.042	IMMZ.C2.Query client record	Health worker	The ability for searches to include results that look or sound similar to the search term (phonetic search)	I can find something that may be spelt incorrectly
IMMZ.FXNREQ.043	IMMZ.C2.Query client record	Health worker	The system to identify any records that may have been imported from another system	I can verify the quality of imported data
IMMZ.FXNREQ.044	IMMZ.C2.Query client record	Health worker	The system to prompt a search for the client (check if it is already in the system) prior to starting a new record	Duplicates are prevented
IMMZ.FXNREQ.045	IMMZ.C2.Query client record	Health worker	The system to retrieve and display, as a search result, a specific set of data (demographic information/photo/unique ID, etc.)	I can select the correct record
IMMZ.FXNREQ.046	IMMZ.C2.Query client record	Health worker	The system to display the most probable matches at the top of the list	I can review them first
IMMZ.FXNREQ.047	IMMZ.C2.Query client record	Health worker	To be able to extend the search to external systems (such as a birth registry or a scheduling system)	Duplicates of client record are prevented
IMMZ.FXNREQ.048	IMMZ.C2.Query client record	Health worker	To enter additional search criteria if there are multiple possible matches	My list of matches is shorter and easier to review
IMMZ.FXNREQ.049	IMMZ.C4.Create client record	Health worker	The system to enforce a minimal required data set for new registrations	Sufficient data is entered to be able to identify the client
IMMZ.FXNREQ.050	IMMZ.C4.Create client record OR IMMZ.C5.Validate client details	Health worker	To select the place of birth from a standardized list of locations	Entry errors are prevented
IMMZ.FXNREQ.051	IMMZ.C4.Create client record OR IMMZ.C5.Validate client details	Health worker	To select the vaccination location of the client from a list of locations	Entry errors are prevented
IMMZ.FXNREQ.052	IMMZ.C4.Create client record	Health worker	The system to uniquely identify every client using a system generated unique identifier or an existing identifier (e.g. health care, national ID, health unique ID)	The client can be definitively identified using that number
IMMZ.FXNREQ.053	IMMZ.C4.Create client record	Health worker	The system to generate a unique identifier	The client can be uniquely identified for vaccination activities across systems using the same ID
IMMZ.FXNREQ.054	IMMZ.C4.Create client record	Health worker	Validate a unique identifier when system is offline	Entry errors are prevented
IMMZ.FXNREQ.055	IMMZ.C4.Create client record OR IMMZ.C5.Validate client details	Health worker	The ability to generate a barcode label to affix to the paper record	The record can easily be uniquely identified by scanning the ID
IMMZ.FXNREQ.056	IMMZ.C4.Create client record OR IMMZ.C5.Validate client details	Health worker	The ability to associate a unique ID generated by another authority (local or global) to the record	The record can be more easily shared or identified with other appropriate systems
IMMZ.FXNREQ.057	IMMZ.C5.Validate client details	Health worker	The system to display the information of the selected record	I can validate and update (if needed) client information

Requirement ID	Activity ID and description	As a...	I want...	So that...
IMMZ.FXNREQ.058	IMMZ.C5.Validate client details	Health worker	To be able to modify appropriate client data as needed	The record contains up to date information
IMMZ.FXNREQ.059	IMMZ.C5.Validate client details	Health worker	The system to track that I have changed an existing record	Accountability for data modification is ensured
IMMZ.FXNREQ.060	IMMZ.C5.Validate client details	Health worker	The system to identify changes made to the record for my confirmation before saving	I can have the opportunity to double check the data to prevent entry errors
Business process D: administer vaccine				
IMMZ.FXNREQ.061	IMMZ.D1.Capture or update client history	Health worker	The system to provide a history of previous care (including previous vaccination records)	I have access and review client's history
IMMZ.FXNREQ.062	IMMZ.D1.Capture or update client history	Health worker	To add client's health history (including previous vaccination records)	I can appropriately determine which vaccinations are required
IMMZ.FXNREQ.063	IMMZ.D2.Determine required vaccination(s)	Health worker	The system to display vaccines due according to predefined vaccine protocol	I can assess which vaccines need to be administered
IMMZ.FXNREQ.064	IMMZ.D2.Determine required vaccination(s)	Health worker	The system to determine vaccines due for a given client by considering relevant information, such as the age of the client, vaccine products, vaccines already given and predefined vaccine protocol	It helps me with selecting the appropriate vaccines for the client
IMMZ.FXNREQ.065	IMMZ.D2.Determine required vaccination(s)	Health worker	The system to ensure I have the most up-to-date vaccine protocols	It will recommend the correct schedule
IMMZ.FXNREQ.066	IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	Health worker	To be alerted of any relevant potential contraindications for the vaccine (e.g. based on age, previous allergic reactions, etc.)	I can withhold the vaccine, if contraindicated
IMMZ.FXNREQ.067	IMMZ.D5.Determine vaccine(s) to be administered based on contraindications	Health worker	To be able to quickly access information regarding any contraindications by antigen	I can access all information on contraindications in one place
IMMZ.FXNREQ.068	IMMZ.D6.Check stock availability of recommended vaccines	Health worker	The system to display stock availability of recommended vaccines	I can check if the vaccines are available
IMMZ.FXNREQ.069	IMMZ.D6.Check stock availability of recommended vaccines	Health worker	The system to warn if required vaccine is not in stock	I can alert the client if the vaccine is not available
IMMZ.FXNREQ.070	IMMZ.D6.Check stock availability of recommended vaccines	Health worker	The system to display the expiry date of stock to ensure expired vaccines are not administered	I give safe and effective doses only
IMMZ.FXNREQ.071	IMMZ.D12.Dispose of waste	Health worker	To update stock record	I know which stock adjustments have not been done automatically (such as in instances if something is wasted)
IMMZ.FXNREQ.072	IMMZ.D13.Update client record	Health worker	To document why a vaccine was not given	The client has a complete record
IMMZ.FXNREQ.073	IMMZ.D13.Update client record	Health worker	To update clients' vaccination record with all relevant information (i.e. date, dose, batch number, lot number, vaccine type, vaccine vial monitor status)	The client has a complete record, and doses can be traced
IMMZ.FXNREQ.074	IMMZ.D13.Update client record	Health worker	The system to associate the context data for each entry (e.g. the vaccination location where the dose was given, the health worker administering it)	The client has a complete record and I can investigate if any issues arise

Requirement ID	Activity ID and description	As a...	I want...	So that...
IMMZ.FXNREQ.075	IMMZ.D13.Update client record	Health worker	To record additional vaccinations, even those that are not included in the national vaccination schedule	The client has a complete record
IMMZ.FXNREQ.076	IMMZ.D13.Update client record	Health worker	The system to log updates of client information	Users are accountable for the data they modify
IMMZ.FXNREQ.077	IMMZ.D13.Update client record	Health worker	The system to request confirmation if data is modified	Accidental or erroneous changes will not be saved
IMMZ.FXNREQ.078	IMMZ.D14.Monitor the client for any adverse reactions	Health worker	To record any significant observations (such as reaction) that may be specific to that client	I can treat as appropriate
IMMZ.FXNREQ.080	IMMZ.D18.Determine time for next visit (as needed)	Health worker	The system to display due date of the next vaccine	I can inform the client when to return for their next vaccination
IMMZ.FXNREQ.081	IMMZ.D19.Provide vaccination record	Health worker	To be prompted for any data required to produce a digital vaccine certificate	The record will have all relevant data to produce a certificate
IMMZ.FXNREQ.082	IMMZ.D20.Does client require a verifiable digital certificate?	Health worker	To be prompted to ask client if they want a digital vaccination certificate where appropriate	The digital vaccination certificate can be generated
IMMZ.FXNREQ.083	IMMZ.D21.Generate verifiable digital certificate	Health worker	The system to apply an authorised digital signature when necessary and appropriate	The identity of the issuing authority can be validated

FXNREQ: functional requirement; IMMZ: immunization.

The full set of functional requirements defined for this DAK is available *here*.

8.2 Non-functional requirements

Table 18. Non-functional requirements

Requirement ID	Category	Non-functional requirement
IMMZ.NFXNREQ.001	Performance	Make efficient use of data communication time
IMMZ.NFXNREQ.002	Performance	Make efficient use of capabilities of lower-cost mobile devices
IMMZ.NFXNREQ.003	Performance	Support data capacity considerations (including those for data transmission, storage and processing) for all users over the expected lifetime of the system
IMMZ.NFXNREQ.004	Performance	Use a database that can scale to support projected transaction volume
IMMZ.NFXNREQ.005	Performance	Provide real-time response to transactions submitted by connected devices up to the configured national volume level
IMMZ.NFXNREQ.006	Performance	Provide real-time messages such as “report processing” or “in progress” for transactions that affect the system performance
IMMZ.NFXNREQ.007	Compatibility	Use open standards to promote interoperability
IMMZ.NFXNREQ.008	Compatibility	Exchange actionable data between systems (need to enforce semantic interoperability)
IMMZ.NFXNREQ.009	Compatibility	Provide access from internet-enabled devices
IMMZ.NFXNREQ.010	Compatibility	Support flexible models for data collection (e.g. including paper forms, web forms, SMS, barcode, etc.)

Requirement ID	Category	Non-functional requirement
IMMZ.NFXNREQ.011	Compatibility	Comply with industry standards for data exchange
IMMZ.NFXNREQ.012	Compatibility	Operate with open-source or third-party reporting tools
IMMZ.NFXNREQ.013	Compatibility	Comply with industry standards for tracking and tracing of supplies
IMMZ.NFXNREQ.014	Compatibility	Enable streamlined data collection, organization and dissemination
IMMZ.NFXNREQ.015	Interoperability	Provide access to data through application programming interfaces
IMMZ.NFXNREQ.016	Interoperability	Link with insurance systems to verify eligibility and submit claims
IMMZ.NFXNREQ.017	Interoperability	Allow for data exchange and efficient synchronization across multiple facilities and points of service when the internet is available, even when it is intermittent and slow
IMMZ.NFXNREQ.018	Configuration	Configure the system centrally
IMMZ.NFXNREQ.019	Configuration	Configure business rules in line with guidelines and standard operating procedures
IMMZ.NFXNREQ.020	Configuration	Configure error messages
IMMZ.NFXNREQ.021	Configuration	Enable configuration to any national or subnational administrative structure or number of levels
IMMZ.NFXNREQ.022	Usability	Allow for flexible configurations based on the context of use, including the physical, regulatory and social environment
IMMZ.NFXNREQ.023	Usability	Transmit information in a language (script or voice) that is understood by the user population
IMMZ.NFXNREQ.024	Usability	Emphasize ease of use and learnability to reduce training costs
IMMZ.NFXNREQ.025	Usability	Be able to be learned easily by end users and supervisors to meet specified goals of system effectiveness and efficiency.
IMMZ.NFXNREQ.026	Usability	Enable easy data collection, organization (predefined drop-down menus or searchable lists, radio buttons, check boxes) and dissemination
IMMZ.NFXNREQ.027	Usability	Focus on the mobile-user experience with secondary use of a computer
IMMZ.NFXNREQ.028	Usability	Allow users to find features in two clicks or fewer
IMMZ.NFXNREQ.029	Usability	Provide a search interface to reduce data-entry burden and improve accuracy on mobile devices
IMMZ.NFXNREQ.030	Usability	Support real-time data-entry validation and feedback to prevent data-entry errors from being recorded
IMMZ.NFXNREQ.031	Usability	Support ability to calculate values on behalf of user (eliminating need to add, subtract, multiply or divide)
IMMZ.NFXNREQ.032	Usability	Provide an appropriate localized experience with both language and cultural translations
IMMZ.NFXNREQ.033	Usability	Support ability to recalculate the immunization scheduled or provide clinical decision support in the event that the client does not receive vaccines on time or has contraindications to their administration
IMMZ.NFXNREQ.034	Usability	Be user-friendly for people with low computer literacy
IMMZ.NFXNREQ.035	Usability	Provide informative error messages and tooltips
IMMZ.NFXNREQ.036	Usability	Alert the user when navigating away from a form without saving
IMMZ.NFXNREQ.037	Usability	Use industry-standard user interface practices and apply them consistently throughout the system
IMMZ.NFXNREQ.038	Usability	Provide guidance to users to better support clinical guidelines and best clinical practices
IMMZ.NFXNREQ.039	Usability	Be reliable and robust (minimize the number of system crashes)

Requirement ID	Category	Non-functional requirement
IMMZ.NFXNREQ.040	Usability	Adjust display to fit small screens (e.g. mobile phones)
IMMZ.NFXNREQ.041	Reliability	Enable a task to be cancelled and rolled back to previous state
IMMZ.NFXNREQ.042	Reliability	Enable users to work offline and then synchronize data when data connection is available
IMMZ.NFXNREQ.043	Reliability	Allow a task to be interrupted and resumed
IMMZ.NFXNREQ.044	Reliability	Enable earlier versions of a record to be recoverable
IMMZ.NFXNREQ.045	Reliability	Enable backup of data so that information is recoverable in the event of a system or hardware failure
IMMZ.NFXNREQ.046	Reliability	Accommodate loss of connectivity to hosted application (network may become unavailable while a user is in the process of submitting a form)
IMMZ.NFXNREQ.047	Reliability	Be able to reliably perform tasks within appropriate time with resistance to failures or deadlocks
IMMZ.NFXNREQ.048	Reliability	Be deployed in an environment subject to power loss
IMMZ.NFXNREQ.049	Reliability	Allow for client devices with low bandwidth or irregular connectivity

ID: identification; IMMZ: immunization; NFXNREQ: non-functional requirement.

The full set of non-functional requirements defined for this DAK is available *here*.

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Annex. Guidance for adding data elements to or amending existing data elements in the data dictionary

When adapting the data dictionary, data elements may need to be modified or added as a result of the structure of existing paper registers or local reporting requirements. If starting from paper-based registers and forms, additional guidance can be found in the *Digital transformation handbook for primary health care (1)*, and below is an overview of the data mapping to provide a template for standardizing the data dictionary. When amending the wording of data elements, it is important to ensure that the standard terminology codes still reflect the data element as originally intended.

What to note	Description
Activity ID	The identification (ID) number of the task in the workflow in which the data element is collected. This will denote the point in time at which this data element is collected.
Form ID	If an existing paper register or forms have an existing ID number, it should be noted as the form ID. Indicate the form ID in which the data element appears. This is important for ensuring that the design of the digital system has taken into account all the required paper forms and data elements on those paper forms.
Form data element label	List the label of the data element as written on the original form (or translated as closely as possible). This will be key in keeping track of which data elements from the original paper forms are duplicated. It is important to note that duplicate data fields could have been included purposely in multiple forms (e.g. name, date of birth, village) to identify an individual client.
Data element label	The label of the data element written in a way end users can easily understand (e.g. "education level", "weight", "height", "reasons for coming into facility"). The data element label in this column will be used in the digital form as the digital register should not simply replace the paper registers, but it should also streamline processes and link duplicated data elements.
Description and definition	The description and definition of the data element, including any units that define the field (e.g. weight in kilograms). Provide a clear explanation of what this data field is requesting. This definition will be key for streamlining to resolve duplicate data elements and how required calculations are documented. Although the data element labels could vary across paper forms, it is important to clearly note the definition of this specific data element as data elements with the same definition can be reconciled for one time data entry. Alternatively, it could also be discovered that data elements with the same data element labels are used to mean different things. This would require a change in the data element labels so that data entry is done accurately.
Multiple choice	If the data element is indicative of a multiple-choice question (e.g. symptoms), then indicate the type of multiple-choice question here. The types would be: » Select one (i.e. only one input can be chosen) » Select all that apply (i.e. more than one input option can be chosen) Each individual answer option should be listed in the input options column and be classified with one of the data types listed below.

Data type	The data types *(2)* are: » Boolean (i.e. true/false, yes/no) » String (i.e. a sequence of Unicode characters – e.g. name) » Date (e.g. date of birth) – used when only the date is recorded » Time (e.g. time of delivery) – used when only the time is recorded » DateTime (e.g. appointment) – used when the date and time are recorded » ID (e.g. unique identifier assigned to the health service user) » Quantity – a number that is associated with a unit of measure outlined in the standard for Unified Code for Units of Measure; quantities include any number that is associated with a unit, such as "number of past pregnancies", where "past pregnancies" is the unit of measure *(3)* (if the data type is a quantity, there should be an associated subtype listed in the quantity subtype column) » Signature (e.g. supervisor's approval) – an electronic representation of a signature that is either cryptographic or a graphical image that represents a signature or a signature process » Attachment (e.g. image) – additional data content defined in other formats » Coding (e.g. symptoms, reason for coming to the facility, danger signs) – multiple-choice data elements for which the input options are codes » Codes (e.g. pregnant, HIV positive, combined pill) – data elements that are input options to multiple-choice data elements, which are none of the above data types.
Input options	Input options are used for multiple-choice fields only. Write the list of responses from which the health worker may select. Each of these options should be labelled with a Data type as indicated above. For other fields, leave this column blank.
Calculation	If a calculation is needed to define the data element, write the formula here. Leave this column blank if no calculation is needed. Write the formula using standard mathematical symbols and the data element label included in the formula (e.g. for the body mass index calculation, "weight in kilograms/(height in meters)2").
Quantity subtype	Quantity data types can include any number that is associated with a unit of measure. However, there are many subtypes of Quantity that should be listed here: » Integer quantity – a whole number (e.g. number of past pregnancies, pulse, systolic blood pressure, diastolic blood pressure) » Decimal quantity – rational numbers that have a decimal representation (e.g. exact weight in kilograms, exact height in centimetres, location coordinates, percentages, temperature) » Duration – duration of time associated with time units (e.g. number of minutes, number of hours, number of days).
Required	Note whether this field is: » Required (R) » Optional (O) » Conditional on answers from other data fields (C).
Reason for requiring data	If this field is required (R), state the reason here: » Accountability for national-level reporting » Service delivery or clinical decision-making » Client ID. The digital system should not only replace paper registers, but also streamline processes; thus, it is important to understand why a certain data field is actually required and seek opportunities to optimize data flows. Given the high volume of data collection required of health service providers, it might be better to remove a data entry field if it serves no real purpose for the clinician, public health reporting or any other identified purpose.

Explain conditionality	If this field is conditional on answers from other data fields (C), denote what the conditionality is here. Conditionality helps to define the rules that govern the presence or absence of a data element based on certain criteria. This is common for data elements that are a part of follow-up questions. For example, if the input of one data element field is true, then some additional data inputs may be required.
Linkages to decision support tables	List the decision support tables here if this data element contributes to decision logic. If it does not contribute to decision logic, and it is not needed for service delivery, consider removing it as a data field when designing the digital system. This would reduce the burden of data collection for health workers.
Linkages to aggregate indicator	List the indicators here if this data element contributes to an aggregate indicator. If the data element does not contribute to calculation of an aggregate indicator, leave this column blank. If the data element does not contribute to an aggregate indicator and is not needed for service delivery, consider removing it as a data field when designing the digital system. This would reduce the burden of data collection for health workers.
Annotations	If there is an issue or inconsistency in how a data field is defined, make a note of the issue here. Irregularities and inconsistencies will need to be resolved at a later stage through a process of team discussion and triangulation. This column should also be used for any other notes, annotations or communication messages within the team.
Mapping to standardized classifications and terminologies *(3)*	A column should be added to each classification or terminology code system (e.g. International Classification of Diseases 11th Revision [ICD-11], Systematized Nomenclature of Medicine [SNOMED], Logical Observation Identifiers Names and Codes [LOINC]) that the digital system is planned to use and interoperate with. The code used for each data element should be logged in these columns. This is a highly resource-intensive, but necessary, task. Any existing standardized code systems that can be used, should be used for the purposes of interoperability so data can be exchanged with any other critical health information systems (e.g. laboratory systems, supply chain systems). This part can also be done through a terminology service.
Mapping comments and considerations	Any comments and considerations related to the mapping of data elements to standardized classification and terminology code systems should be noted here.
Mapping Relationship *(4)*	For each classification and terminology code system that a data element that can be mapped to, this column should be used to identify the relationship between the original intent of the data element (i.e. "source concept") with the classification or terminology mapping available in the existing code systems (i.e. "target concept"). The field should indicate: » Related to – The concepts are related to each other, but the exact relationship is not known » Equivalent – The definitions of the concepts mean the same thing. » Source is narrower than target – The source concept is narrower in meaning than the target concept » Source is broader than target – The source concept is broader in meaning than the target concept.

ANNEX REFERENCES[3]

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