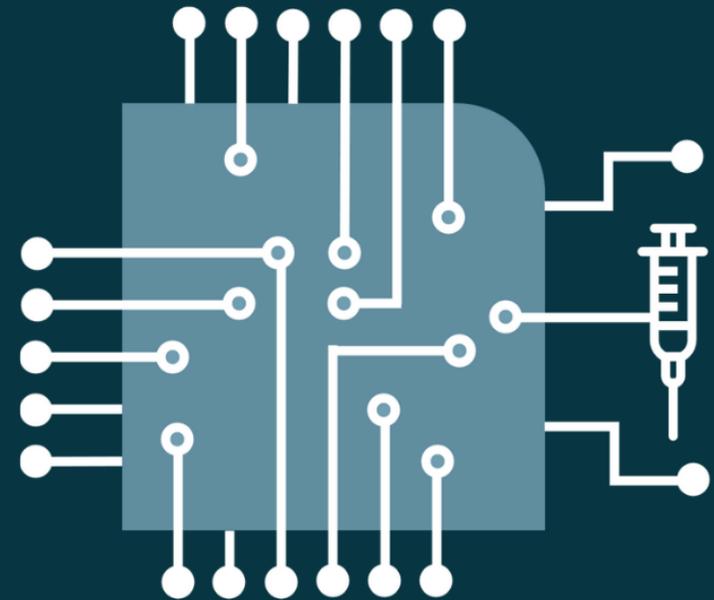


Electronic Immunization Registries

in Low- and Middle-Income Countries



May 2021



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List of Acronyms

AEFI | Adverse event following immunization

API | Application programming interface

CDC | United States Centers for Disease Control and Prevention

COVID-19 | Coronavirus disease 2019

CRVS | Civil registration and vital statistics

DHIS2 | District Health Information Software 2

EIR | Electronic immunization registry

eLMIS | Electronic logistics management information system

HMIS | Health management information systems

ID | Identifier

LMIC | Low- and middle-income country

LMIS | Logistics management information systems

OpenSRP | Open Smart Register Platform

PAHO | Pan American Health Organization

SMART | Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable

TechNet-21 | The Technical Network for Strengthening Immunization Services

UNICEF | United Nations Children's Fund

USAID | United States Agency for International Development

WHO | World Health Organization

Foreword



Skye Gilbert

**Executive Director,
Digital Square at PATH**

Electronic immunization registries (EIRs) can play an important role in supporting global efforts towards vaccine equity. Many people benefit from EIRs, whether they are individuals who may receive EIR-generated reminders about upcoming vaccines, or health system managers, who are equipped with high-quality, timely data to support equitable immunization programs. As more countries strengthen or institute EIRs, we hope this report provides additional guidance to country governments and their partners.

This report adds to a growing foundation of resources that support the thoughtful development of EIRs around the world. In particular, the report aims to complement [the Landscape Analysis published by VillageReach in 2020](#) and EIR guidance documents from the [Pan American Health Organization](#) and the [European Centre for Disease Prevention and Control](#). It builds on the work of the [BID Initiative](#) and the [IDEAL project](#) to capture and share lessons, best practices, and resources that support the implementation of high-quality, sustainable EIRs.

This report also aligns closely with the USAID priorities as set out in [Accelerating the Journey to Self-Reliance Through Strategic](#)

[Investments in Digital Technologies: A Vision for Action in Digital Health](#). The Vision identifies four strategic priorities for USAID investments:

1. Country-level capacity in digital health.
2. National digital health strategies.
3. National digital health architectures.
4. Global goods (digital health tools that are adaptable to different contexts).

In summary, this report links to important guiding documents, and provides pragmatic, experience-based insights that can support country stakeholders looking to strengthen their understanding of electronic immunization registries, including how they may align to national digital health strategies or architecture. This report also highlights common systems and global goods that are in use across low- and middle-income country contexts. We hope you find it useful and informative.

Executive Summary

Routine vaccination is one of the most cost-effective and successful public health interventions. Despite significant gains in the last decade, global vaccination coverage has stalled at 86 percent;¹ this has been further disrupted by the COVID-19 pandemic. A major obstacle to closing the vaccination gap is a lack of timely, high-quality data to enable planning, quality assurance, and service delivery. Without accurate information such as current coverage rates, vaccine stock levels, and community demographics, health care providers struggle to identify individuals who have not received vaccinations. Health care providers also often have poor visibility into vaccine supply chains.

Electronic immunization registries (EIRs) are replacing the paper-based system of manual record keeping that has characterized most countries' vaccination services until recently. EIRs are confidential, population-based, computerized information systems that record data on vaccine doses delivered. EIRs are designed to capture individualized data (i.e., the vaccine record for each individual) on doses administered by multiple health care providers. EIRs track critical information needed to ensure that every child is registered for vaccination from birth and receives all recommended vaccines. In aggregate, these data can be used to inform vaccination program monitoring, planning, or forecasting.

With increasing digitalization of health systems in low- and middle-income country (LMIC) contexts, there is increasing interest from governments, implementing partners, and investors to introduce and scale EIRs.

This report reviews previous experience with EIRs in LMIC contexts with the aim to:

- 1. Identify where EIRs have been implemented in LMICs and what common systems have been used.**
- 2. Summarize how and why EIRs can add value for vaccination programs.**
- 3. Provide recommendations on the functional and nonfunctional requirements for EIR system design.**

Findings and recommendations are based on review and synthesis of documents on registry design, implementation, or outcomes in LMIC contexts.

Use of EIRs in LMICs

Historically, most LMICs have used paper-based reporting and submitted aggregate reports (not individualized data) from the facility level to higher levels of the health system. EIRs can help to solve several common health system challenges—including poor data quality, lack of unique IDs, inaccurate population denominators, poor stock management, and poor planning and coordination—that negatively affect vaccination coverage and equity.

The decision to introduce an EIR should be based on an assessment of the local context and enabling environment, including whether an EIR is the appropriate tool given the identified vaccination or health systems challenges, and whether there is

sufficient readiness to implement an EIR. The EIR implementation strategy should address the key building blocks of human capacity, standards and interoperability, governance and policy, process and information sources, investments and funding, and infrastructure. A national digital health strategy and roadmap should guide the implementation to ensure the EIR is interoperable with existing systems and contributes to the national digital health enterprise architecture.

Many countries in Latin America and Asia, and an increasing number of countries in Africa, are planning, piloting, or implementing EIRs. More than 50 LMICs have implemented an EIR at some scale, including pilot implementations. These include countries across the spectrum of digital health maturity. A variety of systems have been implemented across LMICs, with some countries piloting or using multiple systems. These systems all capture individualized data in an electronic database but vary in how the data are digitized. Common systems implemented across LMICs include the DHIS2 Tracker, Open Smart Register Platform (OpenSRP), OpenMRS, and Shifo's Smart Paper Technology Solution.

Added value

An emerging body of evidence based on country experiences in implementing EIRs indicates that EIRs can lead to improvements in vaccination service delivery. This report uses the list of health systems challenges from the World Health Organization's (WHO's) *Classification of Digital Health Interventions*² to explain how EIRs can help address each challenge.

EIRs have the potential to add value to vaccination programs in the following ways:

Information: EIRs can improve the quality and reliability of vaccination data, as well as data accessibility and use at all levels of the health system.

Availability: EIRs can improve the sufficient supply of vaccine stock, reduce health worker time on data and reporting to put toward patient care, and inform allocation of human resources.

Quality: EIRs can improve continuity of care and adherence to vaccination guidelines, track vaccine quality issues, better target supportive supervision, and motivate and empower health workers.

Acceptability: EIRs can affect the acceptability of vaccination services negatively or positively, depending on whether the community is appropriately sensitized to the EIR.

Utilization: EIRs can increase the uptake of vaccination services by improving adherence to vaccine schedules, improving access, and reducing loss to follow-up.

Efficiency: EIRs can save health worker time on manual, paper-based record keeping and can be used for more efficient clinical workflows, data flows, and operational planning.

Cost: There are upfront and ongoing costs associated with developing and implementing an EIR, but EIRs can also result in cost savings primarily by saving health worker time.

Accountability: EIRs can improve the health sector's understanding of its client population, provide transparency in vaccine stock transactions, and increase the accountability of health workers by tracking their service delivery.

Collectively, these improvements in vaccination service delivery should contribute to improved vaccination coverage and equity, and ultimately improved health outcomes. Pre-post studies in Bangladesh, China, Pakistan, and Vietnam have demonstrated increases in child vaccination coverage among intervention groups using an EIR compared to control groups after at least one year of EIR implementation.³

EIR Design

Identifying requirements is the first step in the development process for any software, including an EIR. Requirements are statements that describe the functionality of an information system. They can be categorized as functional requirements that describe *what* the system should do or nonfunctional requirements that describe *how* the system should work.

This report provides an overview of common requirements for EIRs and lessons from how they have been operationalized in LMIC contexts. Building on previous reviews of EIR requirements, we identify six categories of functional requirements and six nonfunctional requirements.

Each requirement includes operational lessons learned that should be taken into consideration when designing or implementing an EIR. Key themes from the lessons include:

- Ensure the EIR is acceptable and useful for health workers and aligned to their clinic workflows. This can be achieved with a user-centered design process.
- Start with the critical requirements for a minimum viable product and take an agile development approach to iterate and add new requirements over time based on user feedback.

- Design the EIR to be interoperable with existing systems (e.g., birth registries, facility registries, national identifiers, logistics management information systems).
- Adapt the EIR for the local context and engage the community involved to understand the health data that are entered into the registry and to address any fears or misconceptions surrounding the digital systems.
- Design the system to be flexible to adapt, change, and scale over time.

Functional Requirements
<ul style="list-style-type: none"> • Registration and search • Patient records • Vaccination monitoring and follow-up • Health facility registration and management • Stock management • Data and reporting
Nonfunctional Requirements
<ul style="list-style-type: none"> • Data exchange and interoperability • Offline capability • Alignment with international standards • Data privacy and security • Scalability and capacity • Usability

Conclusion

Building on the findings in this report, we recommend the following steps for decision-makers considering implementing an EIR:

- First, identify the vaccination program or health system challenges that you are trying to solve and whether an EIR may be the appropriate tool to address them.
- If an EIR is determined to be a potential solution, use the EIR Readiness Assessment Tool to understand whether the appropriate enabling environment is in place to support an EIR.
- If there is sufficient readiness, identify EIR system requirements considering the operational lessons learned in this report.
- Consider whether an existing system or global good can be adapted for your context.
- Design and implement the EIR in line with the national digital health strategy and roadmap.

As new countries introduce EIRs, stakeholders should continue to share lessons learned on what works—and, importantly, what does not—so that others can learn and iterate on their own systems. And as EIRs are scaled, we should continue to build the evidence base for how they are adding value for vaccination programs.

Introduction

This report builds on lessons from previous experience with electronic immunization registries (EIRs) and other primary health care registries in low- and middle-income country (LMIC) contexts to provide recommendations on system design. In addition, the report summarizes how registries can affect service delivery and outcomes.

Specifically, the three objectives of this report are to:

1. Identify where EIRs have been implemented in LMICs and what common systems have been used.
2. Summarize how and why EIRs can add value for vaccination programs.
3. Provide recommendations on the functional and nonfunctional requirements for EIR system design.

The information provided in this report is intended to complement the existing resources available on EIRs (see Box 1) by providing evidence rooted in experiences from LMIC contexts. In doing so, the report provides recommendations to stakeholders on whether to introduce an EIR and how to design requirements for such systems.

This report should not be viewed as a definitive authority on EIR system requirements or design but rather as considerations for stakeholders involved in the development and implementation of EIRs. The primary audiences for this report are decision-makers and technical staff, such as government officials, United States Agency for International Development (USAID) Mission staff, and implementing partners. Other global, government, or private-sector stakeholders may also benefit from the findings in this report.

Structure of the report

The first section of this report provides an overview of EIR implementations in LMIC contexts. This section defines what an EIR is, identifies common health system challenges they are designed to address, provides an overview of which LMICs have implemented EIRs, and highlights common systems that are in use.

The second section of the report summarizes the potential added value of EIRs for vaccination programs, including experiences from LMIC contexts. This section also examines how EIRs can add value in the context of the COVID-19 pandemic.

The third section of the report focuses on considerations for EIR design, including functional and nonfunctional requirements. This section provides specific examples of how these requirements have been operationalized, including lessons learned based on implementation experience.

The report concludes with recommendations for stakeholders considering, planning for, or currently implementing EIRs.

Summary of methods

The findings in this report are based on a nonsystematic review of literature on EIR implementations in LMIC contexts. The research team developed a framework focused on key questions, identified and reviewed documents, synthesized findings, and developed recommendations.

Research questions were identified in collaboration with USAID and the United States Centers for Disease Control and Prevention (CDC) and correspond to the three objectives of this report. The research team developed a qualitative coding and analysis framework in alignment with the research questions.

Due to the nature of the research questions and the early phase of registry implementation in many contexts, inclusion criteria for literature were flexible in terms of the types and quality of the evidence included. The research team employed a search strategy for documents published in peer-reviewed journals as well as unpublished, or gray, literature such as evaluation reports, program reports, or policy documents.

Landscaping began with a review of recent EIR landscapes, including those conducted by VillageReach,⁴ HealthEnabled,⁵ and PATH and the Pan American Health Organization (PAHO).⁶ For published literature, the research team searched databases with a focus on identifying new literature that may not have been captured by existing reviews. For unpublished literature, the research team focused on websites of targeted international organizations, nongovernmental organizations, and system developers. Some documents were received directly from vaccination stakeholders; others were identified using the “snowballing” technique based on references of included documents. Each identified document was catalogued in an Excel spreadsheet and its relevance assessed based on whether it contained information that answered the research questions.

Documents were included if they met all the following criteria:

- The document included information about registry design, implementation, or outcomes.
- The registry was implemented in an LMIC.

- The registry focused on vaccination or other primary care services (e.g., family planning or antenatal care).
- The document was available in English.
- The document was published between 2000 and 2021.

Documents were analyzed using a qualitative coding tree that mapped each of the constructs in the research framework. Results were synthesized to generate findings and lessons learned for the report.

Limitations of the research approach include:

- Some EIR implementations were not well documented, there was limited documentation on the detailed system requirements, or documentation was not available in English. Given this, it is possible that the landscape of progress in implementing EIRs by country may be incomplete—particularly for more recent EIR introductions that are not yet documented.
- Second, in many of the source documents, the EIR’s added value was described qualitatively, either conceptually or through anecdotes, and not rigorously measured. This review summarized (and where possible triangulated) the limited information on how EIRs can potentially add value but did not attempt to assess the certainty of the evidence.
- Finally, the lessons learned from existing EIR implementations may not be generalizable to all settings and should be considered with the local context in mind.

Additional details on the research methods can be found in [Appendix A](#).

Box 1: Complementary resources on EIRs

EIR guidance documents:

- Pan American Health Organization. *Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation*. Washington, DC: PAHO; 2017.
- European Centre for Disease Prevention and Control (ECDC). *Designing and Implementing an Immunisation Information System*. Stockholm: ECDC; 2018.
- Pancholi J, Birdie R, Guerette J, Chritz S, Sampath V, Crawford J. *Landscape Analysis of Electronic Immunization Registries: Lessons Learned from a Landscape Analysis of EIR Implementations in Low and Middle Income Countries*. Seattle, WA: VillageReach; 2020.

Planning and assessment tools:

- EIR Country Readiness Assessment Tool

Relevant communities and networks:

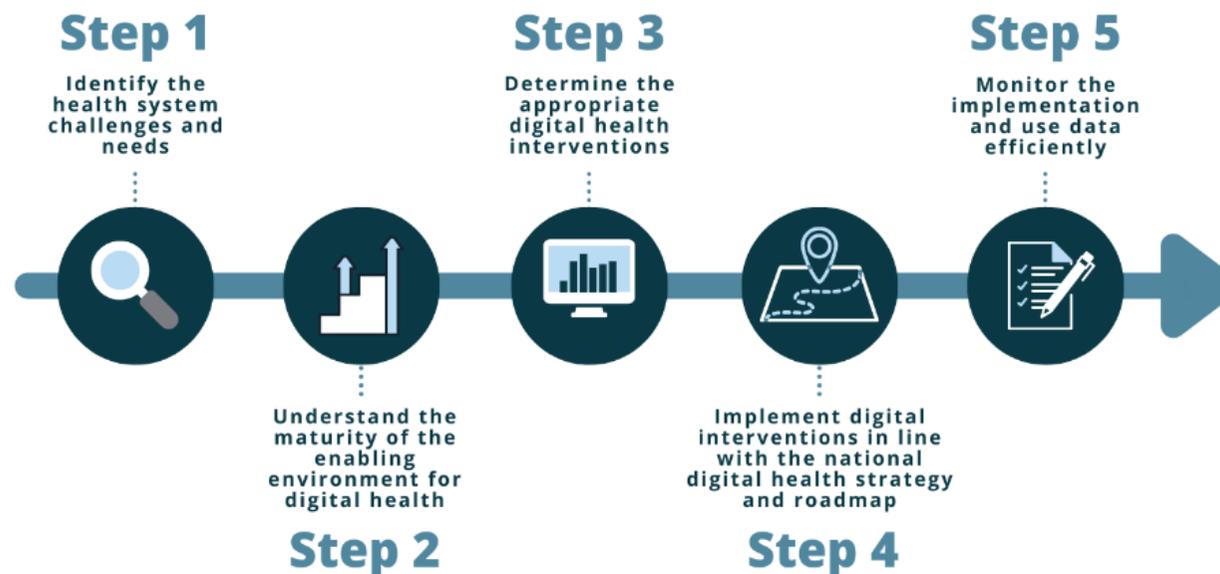
- American Immunization Registry Association: Repository of resources focused on immunization information systems, primarily in the United States.
- BID Initiative: Resources, blog posts, and documented lessons learned from implementing a suite of solutions, including EIRs, in Tanzania and Zambia.
- Boost community: An online platform that supports a global community of immunization professionals to connect, learn, and lead.
- The Technical Network for Strengthening Immunization Services (TechNet-21): A website that includes online resources for learning about and discussing the latest developments in immunization, supporting a network of immunization professionals from around the world.

Overview of EIRs in LMICs

Routine vaccination is one of the most cost-effective and successful public health interventions. Despite significant gains in the last decade, global vaccination coverage has stalled at 86 percent;¹ this has been further disrupted by the global pandemic of COVID-19. A major obstacle to closing the vaccination gap is a lack of timely, high-quality data to enable planning, quality assurance, and service delivery. Without accurate information such as current coverage rates, vaccine stock levels, and community demographics, health care providers struggle to identify individuals who have not received vaccinations. Health care providers also often have poor visibility into vaccine supply chains.

EIRs are replacing the paper-based system of manual record keeping (also referred to as the legacy system) that has characterized most countries' vaccination services until recently. In recent years, a growing number of countries have embraced EIRs to improve data quality and program performance. By providing timely, accurate, and complete data, as well as reducing workloads associated with paper-based records, EIRs allow health workers to do their jobs more effectively and efficiently. EIRs also track the critical information needed to ensure that every child is registered for vaccination from birth and receives all recommended vaccines.

Figure 1. Strategic health systems digitalization



The decision to introduce an EIR should be based on an assessment of the local context and enabling environment, including whether an EIR is the appropriate tool given the identified vaccination or health systems challenges, and whether there is sufficient readiness to implement an EIR (Figure 1, Steps 1 to 3). This report discusses common challenges that EIRs are designed to address ([pages 12-15](#)), and the CDC's EIR Readiness Assessment Tool provides a framework for understanding where countries are on the spectrum of digital readiness. The EIR Readiness Assessment Tool considers key building blocks, adapted from the World Health Organization (WHO)/International Telecommunication Union eHealth building blocks,⁷ that are necessary to support an EIR. These building blocks are as follows:

- **Human capacity**—including health care workers' digital literacy, technical support to maintain digital systems, mechanisms for capacity development and information sharing, routine supportive supervision, and existence of a digital health unit within the government.
- **Standards and interoperability**—including the existence of a master facility list, unique identification system, data standards and interoperability policies, and a national digital health architecture or health information exchange.
- **Governance and policy**—including leadership and political will to support digital health, existing digital health strategy and governance structure, and clear responsibilities and accountability for digital health implementations.
- **Process and information sources**—including existence of tools and processes for data capture (e.g., home-based records, vaccination registers); review, reporting, and feedback; data use (e.g., defaulter tracking); and quality improvement (e.g., data improvement plans).

- **Investments and funding**—including integration of digital health in national planning/budgeting cycles and strategies for long-term funding, including for operations and maintenance.
- **Infrastructure**—including health facility electricity and Internet connectivity, availability of hardware (computers, mobile devices), and capacity for ongoing system maintenance and technical support.

Country governments are encouraged to develop a national digital health strategy and investment roadmap to ensure the EIR is integrated with existing systems and contributes to the national digital health enterprise architecture (Figure 1, Step 4). The WHO *Digital Implementation Investment Guide* provides direction on how to design, cost, and implement digital health interventions as part of a digital health enterprise.⁸ Understanding the national digital health ecosystem is important to identify other systems the EIR should be interoperable with, such as existing logistics management information systems (LMIS), health management information systems (HMIS), facility registries, or civil registration and vital statistics (CRVS) systems.

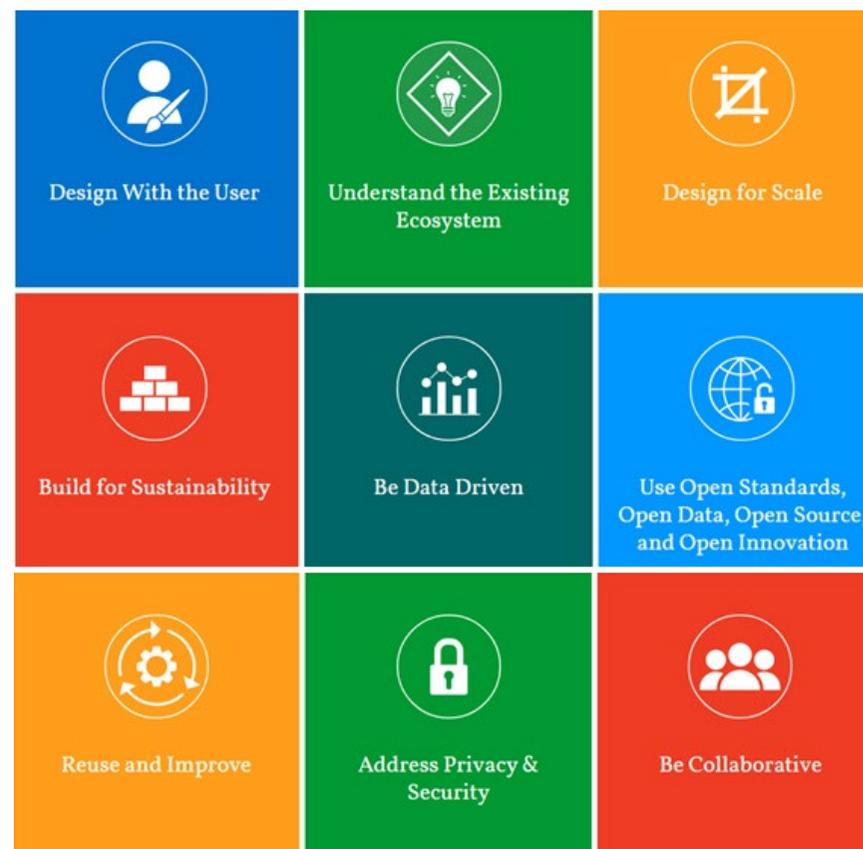
Once stakeholders have determined that an EIR is the appropriate tool given the health systems challenges they are solving and the country readiness for EIR implementation, the software development process can begin. Several different systems and complementary mobile applications have been developed and piloted in LMIC contexts to capture individualized vaccination data and support vaccination service delivery. There are also considerations unique to low-resource contexts that need to be factored into EIR design decisions, such as unreliable or inconsistent Internet connectivity in health facilities, limited birth registration coverage, or inequities in mobile phone ownership.

This report reviews experience with EIRs in LMIC contexts to highlight common systems in use and lessons learned from their design.

The successful implementation and scale-up of EIRs (Figure 1, Steps 4 to 5) requires a well-planned and well-executed rollout that accounts for all phases of technology introduction and the wide range of stakeholders involved in their use. A change management strategy, for example, ensures that the digital platforms are adopted and integrated within existing systems and workflows, helping to further a culture of data use. Implementation plans must also strive to socialize the new digital systems with users at every tier of the health system to build local champions of the registries. Though they are not direct users of the EIRs, the community must also be engaged to help them better understand the health data that are entered into the registries and to address any fears or misconceptions surrounding the digital systems. Finally, there should be a plan to monitor and evaluate use of the EIRs and how vaccine indicators are changing over time. These and other implementation considerations are critical to the long-term success of the EIRs; however, such considerations are beyond the scope of this report.

Finally, all phases of EIR planning, design, implementation, and scale should be guided by the Principles for Digital Development to integrate best practices from the digital health community (see Figure 2). The USAID *Digital Investment Tool* can be used to support stakeholders on integrating best practices, based on the Principles, into digital system development and implementation.

Figure 2: The Principles for Digital Development provide best practices to implementing digital solutions.



Source: [The Principles for Digital Development website](#)

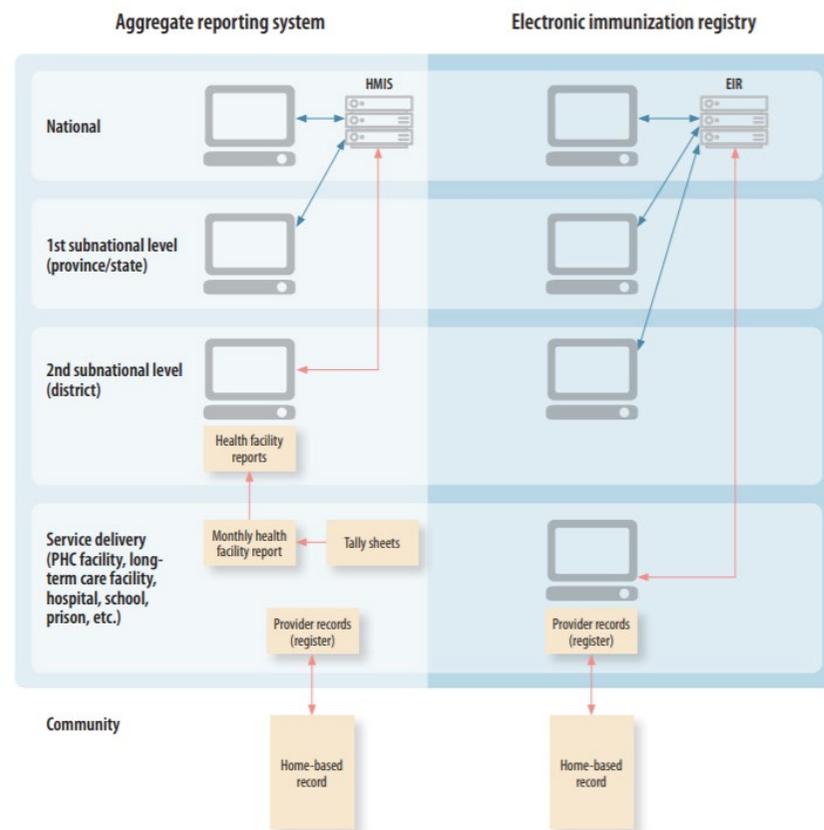
EIR definition

EIRs are confidential, population-based, computerized information systems that record data on vaccine doses delivered. EIRs are designed to capture individualized data (i.e., the vaccine record for each individual) on doses administered by multiple health care providers. The information captured in EIRs can be used by providers at the point of service to determine an individual's vaccine schedule and eligibility to ensure each individual receives the right vaccine dose at the right time. EIR data can also be aggregated to inform vaccination program monitoring, planning, or forecasting.^{9,10}

EIRs are often one component of a broader vaccination information system that may include separate databases for information related to supply chain, surveillance of vaccine-preventable diseases, or monitoring of adverse events following immunization (AEFIs).^{10,10} EIRs may also be used in conjunction with mobile applications that support aspects of vaccination data collection, monitoring, or service delivery. It is important to consider interoperability with these other health information systems or digital tools from the initial EIR conceptualization and design phase.

Historically, most LMICs have used aggregate reporting systems for vaccination, where health facilities tally and report the total number of vaccine doses administered by key dimensions like antigen and patient age and sex. These are often recorded with paper-based tools at the health facility or other points of service and entered into a digital database at the district level or above. In contrast, EIRs capture digitized information on individual vaccination records. Both aggregate reporting systems and EIRs generally maintain a home-based record, often referred to as an “immunization or vaccination card,” which is an individual vaccine record that is stored in the household. Figure 3 shows a side-by-side comparison of these systems.¹¹

Figure 3. Comparison of an aggregate reporting system and an electronic immunization registry.



Source: *Guidance on Developing a National Deployment and Vaccination Plan for COVID-19 Vaccines*. Geneva: World Health Organization; 2020 (WHO/2019-nCoV/NDVP/2020.1). Licence: CC BY-NC-SA 3.0 IGO.

Abbreviations: EIR, electronic immunization registry; HMIS, health management information systems; PHC, primary health care.

Common challenges EIRs are designed to address

EIRs should be designed to address the challenges or barriers faced by health systems that impede vaccination coverage and equity. Using the WHO classification of digital interventions and health systems challenges,² Table 1 lists common challenges that EIRs are designed to address.^a Table 1 also lists which system requirements help to address each challenge; these requirements are explained in detail later in this report in the section on “Considerations for EIR design.” Many EIRs will only address a subset of these challenges, depending on the EIR design. For example, not all EIRs include a stock management component to address challenges related to availability of stock commodities. Or, as noted earlier, EIRs can be interoperable with other tools or systems that collectively work to address these health system challenges.

^a Note that “[The added value of EIRs](#)” section of this report also uses the WHO classification of health system challenges as an organizing framework. In this way, one can identify how the potential added value of EIRs directly addresses the challenges identified here.

Table 1. Common challenges EIRs are designed to address.

Information		
WHO health system challenge	Vaccination challenge	Related requirement
1.1 Lack of population denominator	Countries with aggregate reporting systems may not have an accurate count of individuals in the catchment area. Denominators are often inaccurate, infrequently adjusted, and inconsistent between levels of the health system. ¹² They are further complicated by migration, nomadic populations, or urbanization. ¹³	<ul style="list-style-type: none"> • Registration at birth • Unique ID
1.2 Delayed reporting of events	Most paper-based reporting systems have challenges with timely data. Facilities generally submit monthly reports to the district so there is a time lag in reporting vaccination events.	<ul style="list-style-type: none"> • Vaccine event data • Reporting
1.3 Lack of quality/ reliable data	Paper-based systems with manual data entry and manual calculations lead to data recording that is incomplete and error prone. Facility health workers may not be motivated to improve the data quality if they do not use the data themselves.	<ul style="list-style-type: none"> • Vaccine event data • Clinical decision support
1.5 Lack of access to information or data	A shortage of paper-based reporting forms can result in improvised tracking or no tracking at all. It is challenging to share paper reports with all levels of the health system and specific information can be siloed. Individual-level data are not accessible to higher levels of the health system.	<ul style="list-style-type: none"> • Reporting • Data aggregation at different geographic or administrative levels
1.6 Insufficient utilization of data and information	There is not a strong data use culture at all levels of the health system. Health care workers do not consider data as something useful to their daily work. ¹⁴	<ul style="list-style-type: none"> • Reporting • Vaccination monitoring and follow-up • Usability
1.7 Lack of unique identifier	Without a unique ID, it is challenging to find client records and know what vaccination is needed.	<ul style="list-style-type: none"> • Unique ID

Availability		
WHO health system challenge	Vaccination challenge	Related requirement
2.1 Insufficient supply of commodities	Stock management of vaccines and other supplies is often a challenge for health systems.	<ul style="list-style-type: none"> • Stock management

Quality		
WHO health system challenge	Vaccination challenge	Related requirement
3.1 Poor patient experience	Errors can occur in vaccine administration, leading to poor patient experience and lower confidence in the vaccination program.	<ul style="list-style-type: none"> • Clinical decision support
3.2 Insufficient health worker competence	Paper tools are not user friendly or health workers are not properly trained, leading to data and reporting challenges.	<ul style="list-style-type: none"> • Clinical decision support • Usability
3.4 Low health worker motivation	Health workers are overburdened and do not have time to spend on vaccination data systems, ¹⁵ nor are they motivated to use the vaccination data.	<ul style="list-style-type: none"> • Reporting
3.6 Inadequate supportive supervision	Often it can be difficult and time consuming to properly supervise health care workers' vaccination activities.	<ul style="list-style-type: none"> • Reporting • Data aggregation at different geographic or administrative levels
3.7 Poor adherence to guidelines	Vaccination care guidelines are not available reliably at point of care in a user-friendly format. ¹⁶	<ul style="list-style-type: none"> • Clinical decision support

Utilization		
WHO health system challenge	Vaccination challenge	Related requirement
5.4 Loss to follow-up	A big vaccination challenge is locating children who do not complete their vaccination schedule.	<ul style="list-style-type: none"> • Undervaccinated individuals • Reminder and recall messages

Efficiency		
WHO health system challenge	Vaccination challenge	Related requirement
6.1 Inadequate workflow management	Health workers are unable to predict daily vaccination appointments, which leads to stock wastage and an inability to plan. ¹⁷	<ul style="list-style-type: none"> • Reporting • Clinical decision support • Stock management

6.3 Poor planning and coordination	Health workers are unable to plan out the vaccination schedules of patients, leading to a lack of scheduling follow-ups. ³	<ul style="list-style-type: none"> • Clinical decision support • Reminder and recall messages
6.4 Delayed provision of care	Vaccinations can be delayed due to lack of vaccine supply ¹⁸ or difficulty knowing who is missing a vaccination.	<ul style="list-style-type: none"> • Clinical decision support • Stock management

Cost

WHO health system challenge	Vaccination challenge	Related requirement
7.1 High cost of manual processes	Paper-based vaccination registries are time consuming for health workers who are already overburdened, need to complete complex forms, and produce reports by hand.	<ul style="list-style-type: none"> • Reporting • Clinical decision support
7.2 Lack of effective resource allocation	It is challenging to effectively plan outreach services and distribution of vaccine stock and supplies. ¹⁴	<ul style="list-style-type: none"> • Reporting • Data aggregation at different geographic or administrative levels • Stock management

Accountability

WHO health system challenge	Vaccination challenge	Related requirement
8.1 Insufficient patient engagement	Caregivers and patients are not being informed when they need to come in for a vaccination, leading to lower coverage. ³	<ul style="list-style-type: none"> • Clinical decision support • Reminder and recall messages
8.5 Poor accountability between the levels of the health sector	There is variability in vaccination systems and in required reporting, which leads to incomplete and incompatible data. ¹⁹	<ul style="list-style-type: none"> • Interoperability • Standards • Reporting • Data aggregation at different geographic or administrative levels

Country progress in implementing EIRs

Many countries in Latin America and Asia, and an increasing number of countries in Africa, are planning, piloting, or implementing EIRs. This includes countries across the spectrum of digital health maturity.

Digital Square developed a standardized 5-point scale for digital health maturity using data from the Global Digital Health Index, supplemented with World Economic Forum Networked Readiness Index indicators.²⁰ Each country is categorized 1 to 5, with 1 being the lowest and 5 being the highest level of maturity. Countries at lower digital maturity levels generally lack or have yet to implement digital policies, have 2G infrastructure and variable electricity, and have a workforce with limited digital literacy skills. In contrast, countries at the higher digital maturity levels have digital policies that are enforced and have 3G infrastructure, reliable electricity, and a digitally literate workforce.

More than 50 LMICs have implemented an EIR at some scale, including pilot implementations (Figure 3). The majority of LMICs are categorized as digital health maturity levels 2 and 3. Most LMICs that have implemented an EIR are also in levels 2 and 3. Mozambique and Haiti are the only LMICs in the lowest level of digital health maturity that have piloted an EIR.^b All countries categorized as digital health maturity level 5 are high-income countries, with the exception of Malaysia, where an EIR has not been introduced.

Appendix B provides details on EIR implementation status by country.

^b Haiti used ODK as an EIR that captured individual-level electronic data for an oral cholera vaccine campaign in 2011 but has not continued its use for routine vaccination services.

Maturity Level 1

Total countries: 10
Total LMICs: 10

EIR implementations in LMICs

Haiti | Mozambique

Maturity Level 2

Total countries: 49
Total LMICs: 48

EIR implementations in LMICs

Afghanistan | Belize | Cote d'Ivoire | The Gambia
Guatemala | Guinea-Bissau | Honduras | India
Malawi | Micronesia | Nepal | Nicaragua | Pakistan
Senegal | Sierra Leone | Tanzania | Uganda
Venezuela | Vietnam | Zambia | Zimbabwe

Maturity Level 3

Total countries: 98
Total LMICs: 69

EIR implementations in LMICs

Albania | American Samoa | Argentina | Benin
Bolivia | Brazil | China | Colombia | Costa Rica
Dominican Republic | Ecuador | El Salvador
Ethiopia | Ghana | Grenada | Indonesia | Iran
Kenya | Mali | Marshall Islands | Mexico | Mongolia
Nigeria | Paraguay | Peru | Rwanda | Sri Lanka

Maturity Level 4

Total countries: 35
Total LMICs: 5

EIR implementations in LMICs

Bangladesh | Thailand

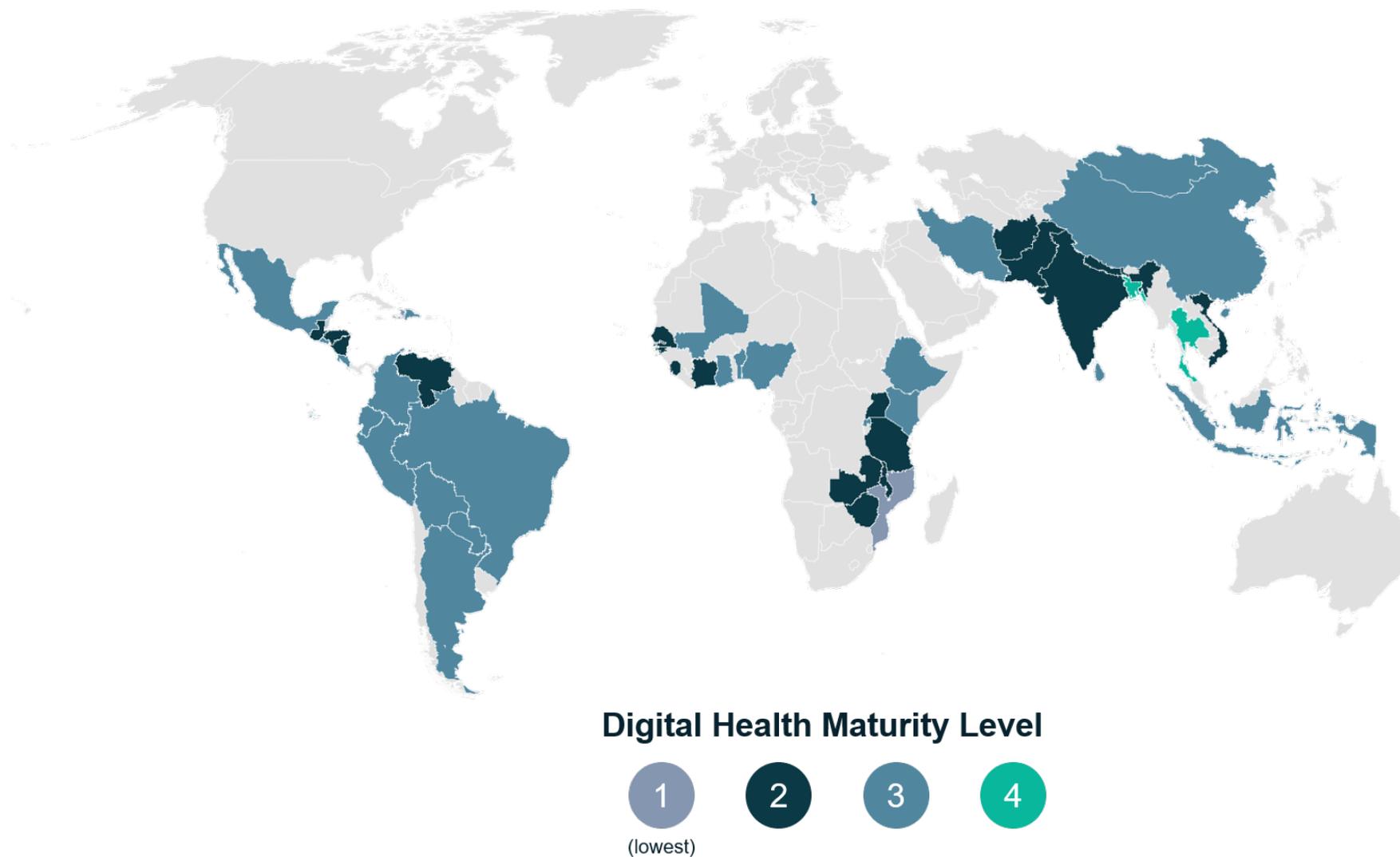
Maturity Level 5

Total countries: 25
Total LMICs: 1

EIR implementations in LMICs

None

Figure 4. Map of LMICs that have piloted or implemented an EIR, by digital health maturity level.



EIR implementation status is based on a desk review conducted from late 2020 to early 2021. These results have not been validated by countries and therefore may not capture the most up-to-date information on EIR implementation status. In addition, with the introduction of COVID-19 vaccines, some countries are introducing new EIRs to track COVID-19 vaccine deployment, many of which have not been comprehensively captured here.

Common systems in use

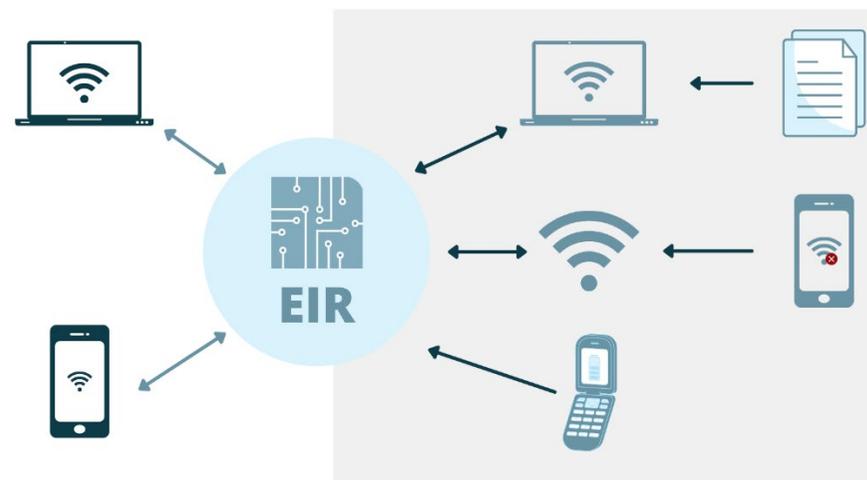
Across LMICs, a variety of systems have been implemented. Some countries have multiple systems because they have conducted multiple pilots with different systems, they use unique systems in different subnational areas, or they use a suite of complementary systems (e.g., an EIR paired with a mobile app). Appendix B provides a detailed table of the systems implemented, by country.

To meet our definition of an EIR, each tool or system must capture individualized data in an electronic database. However, systems vary in how the data are digitized (Figure 5). In some contexts, data are entered directly into the EIR at the point of care, usually by a health worker or data clerk. This data entry could use a mobile phone, tablet, or computer in online or offline mode. (Offline mode usually means the data are stored locally until they can be synced to the database; offline capability is further discussed in the [nonfunctional requirements section](#).) In other contexts, data are collected on paper at the point of care and later entered into the EIR. Data entry from paper can be a manual or automated process (e.g., scanning forms) and can take place at the health facility or at a higher level of the health system.

Current systems in use across LMICs also differ in their software model and licensing. Software models can include custom-developed software, commercial off-the-shelf software, free packaged software, open source software, or software as a service. The WHO *Digital Implementation Investment Guide* summarizes the benefits and risks of each model.⁸ Many countries in Latin America were among the earliest EIR implementers and developed custom-built software from scratch; more recently, open source software options have become available. Open source means the source code and software product are freely available, although there are still costs associated with their implementation. Open source tools

tend to benefit from contributions from many developers, a peer-review process, and facilitated information sharing.¹⁵ Open source software is also adaptable, enabling countries to customize and design tools that meet their needs.

Figure 5. EIR data entry approaches.



DHIS2 Tracker, OpenMRS, Open Smart Register Platform (OpenSRP), and Shifo's Smart Paper Technology Solution are systems that have been implemented as EIR platforms in two or more LMICs. Each system is summarized in Table 2. DHIS2 Tracker, OpenMRS, and OpenSRP are open source systems and are included in the Digital Square *Global Goods Guidebook*.²¹ Smart Paper Technology was developed by Shifo, a nonprofit organization, and is available for a service fee per registered patient per year (which may be subsidized for high-priority countries).

Table 2. Common EIR systems in use across LMICs.

DHIS2 Tracker

The DHIS2 Tracker is an extension of the DHIS2 platform and supports management, collection, and analysis of transactional or disaggregated data. The Tracker shares the same design concepts as the overall DHIS2—a combination of a generic data model and flexible metadata configuration through the user interface that allows for rapid customization to meet a wide range of use cases.

The EIR tracker metadata package enables individual-level tracking and includes automated program indicators of aggregated data. It incorporates the WHO-recommended vaccination schedule and can be adjusted to match country schedules. There are complementary packages for AEFI tracking, vaccine-preventable diseases, and birth notification. A package is in development to support mass vaccination campaigns.

A DHIS2 toolkit for COVID-19 vaccine delivery is also available to support countries in operationalizing WHO guidance.

Website: <https://dhis2.org/tracker/>

Immunization toolkit: <https://dhis2.org/immunization/>

COVID-19 vaccine delivery toolkit: <https://dhis2.org/covid-vaccine-delivery/>

OpenMRS

OpenMRS is a software platform and a reference application that enables design of a customized medical records system. It is a common platform upon which health informatics and eHealth efforts in low-income countries can be built. The system is based on a conceptual database structure that is not dependent on the actual types of medical information to be collected or on particular data collection forms, so it can be customized for different uses.

OpenMRS is based on the principle that information should be stored in a way that makes it easy to summarize and analyze (i.e., minimal use of free text and maximum use of coded information). At its core is a concept dictionary that stores all diagnoses, tests, procedures, drugs, and other general questions and potential answers.

Website: <https://openmrs.org>

Atlas—map of places where OpenMRS is used:
<https://atlas.openmrs.org>

Talk—the OpenMRS discussion forum:
<https://talk.openmrs.org>

Wiki—information on the OpenMRS software and community: <https://wiki.openmrs.org>

Demo: <https://openmrs.org/demo/>

OpenSRP

OpenSRP is an open source mobile health platform to empower frontline health workers and simultaneously provide program managers and policymakers with current data for decision-making and policymaking.

Website: <https://smartregister.org/>

EIR case study in Kenya, Pakistan, and Zambia:

<https://bidinitiative.org/blog/case-study-celebrates-lessons-and-catalytic-potential-of-rapid-iterative-software-development-across-three-countries/>

Shifo Smart Paper Technology

Shifo Smart Paper Technology Solution is an HMIS and LMIS solution to improve routine data collection, reporting, and use. It was designed from the ground up as a sustainable, affordable solution that works everywhere, regardless of infrastructure limitations such as electricity, network, or security.

Health workers record data on Smart Paper Forms, which are modeled after and replace existing paper forms (e.g., register books, tally sheets, stock books, and summary reports). Smart Paper Forms are scanned at subnational (district/provincial level) points where health workers used to deliver the monthly reports. When scanned, Smart Paper Technology digitizes and quality assures handwritten data. In some cases, manual quality assurance of data is required and the system flags those cases. Finally, the Solution generates all required HMIS and LMIS reports, integrates data to DHIS2, and triggers data for action interventions from community to national levels.

Website: <https://shifo.org/en/solution/>

This report primarily focuses on the design of the EIR system itself; however, there are many implementation considerations about how to roll out an EIR that are critical for scale and sustainability. LMIC experiences with EIRs have resulted in valuable recommendations related to implementation, such as:

- **Country ownership:** Engage key government, partner, and other stakeholders from the beginning and throughout all EIR development and implementation phases to support country ownership and sustainability.^{4,22}
- **User-centered design:** Engage end users to provide input throughout system development.²² EIRs must be useful to end users in their day-to-day work to be accepted and used.²³
- **Rollout strategy:** Consider who conducts the rollout of the EIR, how training will be provided to health workers, whether a phased approach will be used, and how to sensitize the community to any changes in service delivery or data collection.²⁴
- **Effective data use:** Pair the EIR tool with data use interventions that address any gaps in current data use for decision-making. Data use interventions may include teaching health workers data analysis skills, introducing job aids for data use, or creating peer support networks to facilitate information sharing.²²
- **Parallel systems:** Develop a clear roadmap for how and when the legacy system can be phased out, as well as the steps to fully transition to use of only the digital system. In the interim, it can be burdensome for health care workers to

use parallel systems, which can reduce motivation and data quality.²⁵

- **Cost:** Understand and plan for the upfront and long-term costs associated with an EIR. EIRs require ongoing human and financial resources. (Section II includes more detail on costs to consider.)
- **Monitoring and evaluation:** Systematically monitor and evaluate the EIR rollout to track EIR use, capture lessons learned, and address any issues as they emerge. PAHO adapted the WHO data quality self-assessment tool to add an EIR module to evaluate the quality of the EIR data itself, user satisfaction with the tool, and availability of hardware, infrastructure, and human resources to support its use.²⁶

The following section discusses the value that EIRs add to vaccination programs and the wider health system, but an EIR's full potential value can only be achieved if it is designed well and implemented effectively.

The added value of EIRs

An emerging body of evidence indicates that EIRs can lead to improvements in cost savings, vaccine stock levels, and data quality, among other areas. There are also many indirect impacts, such as reductions in manual record keeping and labor, and vaccine wastage with better demand forecasting of vaccines.

To further understand the added value of EIRs, the research team developed a conceptual framework to guide the analysis of the literature reviewed (Figure 6). This framework includes service delivery characteristics that map directly to health system challenges found in the WHO *Classification of Digital Health Interventions*.² Digital health interventions are designed to address one or more challenges. In turn, these challenges articulate how service delivery changes because of a digital health intervention. In theory, improving vaccination service delivery will lead to improved vaccination coverage and equity, and ultimately to improved health outcomes.

This section explains how EIRs could affect each aspect of service delivery and highlights relevant available evidence from LMIC implementations. While emerging evidence indicates that EIRs can lead to improvements in areas such as cost savings, vaccine stock levels, and data quality, there are outstanding questions on the effectiveness and impact of EIRs.

It is also important to note that any service delivery outputs or outcomes will be influenced by the registry design and its implementation. For example, countries that implement EIRs that do not include stock management functionality may not expect to see reduced vaccine stockouts. Other studies have highlighted

important enablers and barriers to scaling EIRs in LMICs.^{27,28} For example, if health workers are expected to continue data entry in the legacy systems in parallel to the EIR, they may not expect to see time-saving efficiencies. To fully achieve the potential of EIRs, the human capacity, standards and interoperability, governance and policy, information sources, investment and funding, and infrastructure to support them must be in place.

Figure 6. Conceptual framework for how electronic immunization registries can affect vaccination service delivery and outcomes.



Information

Information refers to the quality and reliability of vaccination data, as well as the data's accessibility and use. This service delivery area includes population denominators and unique identifiers (IDs), timely reporting of events, communication channels, access to information, and utilization of information.

Potential added value: Data Quality

- More granular information is available when moving from aggregate reporting to individual-level electronic data.
- Generating unique identifiers (or using existing identifiers) for every child can facilitate individual-level monitoring and follow-up and provide more accurate population denominators and coverage calculations.
- EIRs that capture electronic data at the point of service can provide more timely reporting of vaccine events.
- Built-in data validation and automated calculations can limit data entry errors or manual calculation errors to improve data accuracy.
- Required data fields can improve data completeness.

EXPERIENCES FROM COUNTRIES

Data Quality

- The mixed-methods nonexperimental evaluations of the MyChild Solution in Afghanistan, The Gambia, and Uganda showed improved data quality (completeness, timeliness, and consistency) as all children who received vaccines were registered.⁶
- *Completeness*: Studies have found high data completeness in EIRs in terms of the percentage of children captured in the registry. EIR completeness was 90% in Mongolia²⁹ and 99% in Brazil.³⁰
- *Accuracy*: Studies have found high levels of accuracy, which usually is measured by comparing paper-based records and EIR records. EIR accuracy was 93% in Mongolia, which indicates that “the electronic registry can be used to reliably estimate vaccination coverage provided that the denominator data are accurate.”²⁹ The BID Initiative also reported improvements in data accuracy resulting from data validation components integrated into the EIR.¹⁴ In Vietnam, “health workers perceived the data in [the EIR] to be more accurate than the data in paper registries.”⁶ In Jiangsu Province, China, using the legacy system paper records made it impossible to calculate precise AEFI incidence rates; but by using the EIR, they can be calculated automatically and compared across areas or populations.³¹
- *Timeliness*: The introduction of an electronic health record system in one hospital in Tororo District, Uganda, led to improved timeliness and availability of reports from the hospital to the district (although the study could not establish improved data accuracy).³² Another study of 11 health centers in rural Tanzania found the introduction of handheld computers to collect routine information in outpatient departments, laboratories, and vaccination clinics resulted in an improvement in the timeliness of data entry. The proportion of records entered on the same day as attendance at the health center improved from 67% to 85%.³³

Potential added value: Data accessibility and use

- Data that are standardized and digitized are easier to access and use. This allows for more flexible analysis, easier linkages with other data sources, and improved efficiency of data flows.
- Data uploaded into an EIR database provides users at all levels of the health system immediate access. (See below.)
- Individualized electronic data enable new types of analyses, as these data can be aggregated at different levels or for subpopulations (e.g., monitoring vaccine coverage by birth cohort).^{28,34}

Individual	<ul style="list-style-type: none"> • Record of their vaccination history • Information can be used to print new vaccination cards
Health Provider	<ul style="list-style-type: none"> • Decision-making for client care (the right child receives the right dose of a vaccine at the right time based on their vaccine schedule and medical history) • Target individuals due for vaccination and identify defaulters • Reduce missed opportunities for vaccination at clinical encounters • Reduce revaccination due to unverifiability of previous immunizations • Track vaccinations for transient or nomadic populations, such as some indigenous communities and seasonal migrant workers • Estimate vaccine stock needs to reduce wastage and stockouts
Health Manager	<ul style="list-style-type: none"> • Resource allocation and operational planning for the implementation of vaccination programs • Response to outbreaks • Understand true denominator and forecast vaccine needs for stock management • Monitor program implementation • Create and adjust vaccination strategies • Identify areas of low coverage
National	<ul style="list-style-type: none"> • Inform and refine in-country immunization policies and guide annual operational plans and budgets

EXPERIENCES FROM COUNTRIES

Data accessibility and use

- A global synthesis of successful improvements of vaccination data use found that “there is moderate-certainty evidence that EIRs may improve data use at the district level when used consistently and mixed evidence of their effect on data use at the health-facility level.”⁶
- The BID Initiative reported that as health workers had improved access to data, they saw more value in the data and how the data could be applied to their daily work.¹⁴ Related monitoring and evaluation data from the BID Initiative in Tanzania showed a more than twofold increase in the ability of nurses and in-charges to identify low-coverage areas and individual defaulters.
- In the city of Rajshahi, Bangladesh, the Electronic Birth Registration Information System, a digitized birth and childhood vaccination registry, has made data sharing between government departments and other partners “easy with little probability of error, duplication and inconsistency due to electronic storage of data.”¹⁷

Availability

Availability refers to the sufficient supply of commodities, services, equipment, and qualified health workers, which are necessary to provide vaccination services.

Potential added value

- EIRs can improve the availability of vaccine stock through better allocation and forecasting based on the schedules of individual children.
- EIRs can forecast service delivery needs based on individual vaccine schedules to allocate human resources.
- EIRs can save health worker time by eliminating duplicative data entry for reporting and automating calculations. This time saved can be put toward service delivery and thereby increase the availability of skilled health workers. (Discussed further under the section on “efficiency.”)

EXPERIENCES FROM COUNTRIES

Availability

- In Tanzania, an evaluation of the integrated EIR-LMIS system that includes stock notifications showed the odds of a facility vaccine stockout reduced over time after introduction of the new system.³⁵
- In Albania, the integrated EIR-LMIS system automatically calculates the number of vaccine doses required for the following month, which informs nurses how much stock to order and helps ensure vaccines are available without requiring large quantities of buffer stock. Although not directly attributable to the EIR, district stockouts of measles-mumps-rubella vaccine reduced from 67 days in 2009 to 0 days in 2012 after introduction of the EIR.³⁶

Quality

Quality refers to the patient's care experience and the quality of care received, which can be influenced by health worker competence and motivation, the quality of health commodities, continuity of care, supportive supervision, and adherence to guidelines.

Potential added value

- Access to each individual's complete vaccine records (regardless of where the vaccines were delivered) can improve continuity of care.
- Embedded clinical decision support can improve adherence to vaccination guidelines (e.g., alerting a health worker which vaccine are due or if a child is outside the recommended age range).
- Stock management can track vaccines by lot, as well as identify quality issues and who may have been affected by a lot with quality issues.
- Supportive supervision can be better targeted to underperforming facilities.
- EIRs can save health worker time, which can allow more quality time with patients and contribute to a better patient experience. (Discussed further under the section on "efficiency.")
- EIRs can motivate health workers to improve their quality of care by empowering them with actionable data.

EXPERIENCES FROM COUNTRIES

Quality

- In Mongolia, the EIR supports adherence to vaccination guidelines. A 2016 study showed that of nearly 20,000 doses of PCV13 recorded in the EIR, only 87 (0.004%) were invalid. The most common reason was that the recorded vaccine data were prior to the date the vaccine became available.²⁹
- In Albania, an assessment of the EIR pilot found that the most valuable changes were to the way people work and collaborate. Notably, vaccinators felt empowered to improve the quality of their work and were motivated by the EIR. It helped them make sense of the data so instead of focusing on "a rather abstract coverage indicator," they could focus on actual children and concrete tasks.³⁷ Similarly, vaccinators using the Teeko (now renamed Hayat) app in Sindh Province, Pakistan, reported increased pride and motivation as a result of tracking their performance and reaching targets or receiving recognition from supervisors.³⁸

Acceptability

Acceptability refers to whether individuals and communities find the care provided to be acceptable.^c This is influenced by whether service delivery aligns with local norms and individual beliefs and practices.

Potential added value

- EIRs have the potential to negatively affect acceptability of vaccination services if the community mistrusts or does not understand the purpose of the EIR. Conversely, EIRs are appropriate when socialized with communities. Their use can build trust between the health system and community and lead to increased acceptability of vaccinations services.

^c Note that this section is not intended to capture whether the registry itself is acceptable to health workers, managers, or communities—although that is an important aspect of its design and implementation.

EXPERIENCES FROM COUNTRIES

Acceptability

- Some caregivers in Tanzania were resistant to the use of unique IDs in the form of barcodes to track their children; as a result, they feared bringing their children to receive vaccination services. Other studies have also highlighted the importance of sensitizing the community to the EIR (e.g., in Zambia).³⁹
- The Teeko mobile app (now renamed Hayat) used by vaccinators in Afghanistan and Pakistan includes a 60-second video that vaccinators can play during a vaccine event to educate caregivers on routine vaccination, thereby improving awareness and acceptability.³⁸

Utilization

Utilization refers to the uptake of services, including the demand, geographic accessibility, adherence to schedule, and loss to follow-up.

Potential added value

- EIRs can be used to identify communities that are undervaccinated to target outreach services and thereby improve geographic accessibility.
- Individual vaccine records, clinical decision support, and reminder/recall messages can improve adherence to the vaccine schedule and decrease loss to follow-up.
- Health workers can use EIR data for defaulter tracing, which can decrease loss to follow-up.
- Improved quality of care can increase demand and utilization of vaccination services.
- EIRs can be used to send health promotion or education messages to patients, which can increase demand and utilization of services.

EXPERIENCES FROM COUNTRIES

Utilization

- EIRs have been shown to improve the timely utilization of vaccination services. In Vietnam, the EIR pilot implementation in Ben Tre Province improved timeliness of vaccination registration for newborns from an average of 33.4 days after birth to 8.5 days after birth once the EIR was introduced.⁴⁰ A pre-post evaluation of all children born in Ben Tre Province (n = 67,000) from 2013 to 2015 showed that on-time vaccination of oral poliovirus vaccine, Quinvaxem, and measles 1 increased after the EIR introduction.⁴¹

Efficiency

Efficiency includes aspects of workflow management, referrals, planning and coordination, timely provision of care, and access to transportation, which all influence the efficiency of service delivery. PAHO defines vaccination program efficiency as “achievement of the goals of the vaccination program, in terms of coverage, completeness of schedules, timeliness of vaccination, and equity in access to the program by the entire target population, focusing efforts to achieve the same or better results in terms of quantity and quality with the least possible investment of financial resources, human resources, and time.”³⁴

Potential added value

- EIRs can save health worker time that was previously consumed by manual, paper-based record keeping by automating indicator calculations, reporting, and generation of lists of children for follow-up. Some EIRs automate reminder/recall messages as well.
- EIRs reduce revaccination that can result from the inability to verify previous vaccinations.
- EIRs using mobile devices can enable a more efficient workflow by integrating data entry and clinical care.
- EIRs can be used to measure the number of vaccines delivered by vaccinator, facility, or outreach visit to assess productivity, improve resource allocation, or target supportive supervision.
- EIRs can inform more efficient operational planning. For example, EIRs can help identify and target areas of low

coverage or detect or address vaccine-preventable disease outbreaks early.

- EIRs, when linked to other health information systems, can create further efficiencies. EIRs can be linked to civil registries for more complete registration, to disease surveillance databases to detect vaccine-preventable disease outbreaks and assess vaccine effectiveness and safety, or to LMIS for improved stock management and forecasting.

EXPERIENCES FROM COUNTRIES

Efficiency

- In Tanzania, facility health workers using the EIR saved more than 70 hours or eight full working days each year as a result of automated reporting. It also took an estimated 41% less time to register and vaccinate each child using the EIR compared to the legacy paper-based system.¹⁴
- In Vietnam, the EIR shortened the time required for recording and reporting vaccinations compared to the legacy system. Commune health workers could generate reports in 2 minutes compared to 20 minutes with the paper-based system. With the legacy system it previously took two days to search vaccine records, prepare the list of upcoming vaccinations due, and send paper-based reminders; this could be done in 15 minutes with the EIR.⁴⁰
- The BID Initiative reported workflow efficiencies from using tablets: “The legacy systems had reinforced a static clinic environment, where health workers had to remain at a table to enter data into large registries and paper forms. The tablets allowed a dynamic and more efficient clinic workflow where the health workers could move with the patient while still entering data.”¹⁴ As noted earlier, the integrated EIR-LMIS system in Albania automatically calculates required vaccine doses for the following month. Anecdotal evidence points to more efficient stock management and less overstocking as a result.³⁶

Cost

Cost refers to the use of resources within the health system, including the cost of manual processes, lack of effective resource allocation, client-side expenses, or lack of coordinated payer mechanisms. In this context, there are costs associated with the introduction and maintenance of an EIR, as well as potential cost savings from improvements in processes or resource allocation. Costs categories related to the initial development, implementation, and ongoing maintenance of an EIR are summarized in Table 3.

Potential added value

- There are upfront costs associated with the initial development and implementation of an EIR and ongoing costs for its maintenance.^d (See Table 3.)
- EIRs save health worker time by automating calculations, reporting, and reminder/recall messages, and reducing duplicative processes.
- Better stock forecasting may reduce cost by better assessing the amount of buffer stock needed.
- EIRs may result in modest cost savings for printing (by eliminating paper-based tools), transportation (by eliminating in-person submission of paper-based monthly reports and reducing emergency vaccine restock trips), and other cost categories.

^d The *WHO Digital Implementation Investment Guide (DIIG)* provides a systematic process to guide development of a costed implementation plan for a digital health intervention. The PAHO guidance document *Electronic Immunization Registry: Practical Considerations for*

EXPERIENCES FROM COUNTRIES

Cost

- Two costing studies by the BID Initiative in Tanzania and Zambia analyzed the incremental costs of implementing an EIR between 2013 and 2018. Total costs to develop, deploy, and maintain EIRs were US\$4.2 million in Tanzania and \$3.6 million in Zambia. The annualized cost was <\$10 per child under 1 year of age.⁴² The micro-costing study compared the service delivery and logistical costs of EIRs in health facilities that used the digital system against a sample without EIRs. The study determined that the time savings generated by the digital tools led to significant cost savings. Because EIRs automate what used to be a paper-based system, health workers spend less time delivering and reporting on vaccination services. The average annual reduction in resource costs for Tanzania was estimated at \$10,236 per health facility; cost savings for resources were estimated at \$6,542 per district.⁴³

Planning, Development, Implementation, and Evaluation provides cost considerations specific to EIRs.

Table 3. Cost categories associated with an EIR.

Cost Category	Examples of associated costs
Administrative support	<ul style="list-style-type: none"> • Wages of administrative personnel who provide support • for related processes • Office supplies • Travel and meetings
Development	<ul style="list-style-type: none"> • Developer costs • System customization costs, in the event that a readymade system is being adapted for the country • Costs of pilot deployment and subsequent modifications to the system
Scale-up	<ul style="list-style-type: none"> • Cost of technical support at the national level • Travel and meetings • Training
Hardware	<ul style="list-style-type: none"> • Computers, tablets, or mobile phones • Central processing units (CPUs) • Printers • Surge protectors
Software	<ul style="list-style-type: none"> • System software licensing (per user, per environment, free, etc.) • Licensing of other necessary software products
Network infrastructure	<ul style="list-style-type: none"> • Internet connectivity costs
Security	<ul style="list-style-type: none"> • System security costs (antivirus, firewall, etc.) • Backup costs
Physical infrastructure	<ul style="list-style-type: none"> • Proper space for hardware and data entry
Training	<ul style="list-style-type: none"> • Costs of travel and meetings for personnel in charge of training and participants • Hours devoted to staff training
Data servers	<ul style="list-style-type: none"> • Servers for data storage and protection
Management and technical support	<ul style="list-style-type: none"> • Help desk/call center • Wages of personnel assigned to answer user queries • Time devoted to the formulation of registry guidelines
Maintenance	<ul style="list-style-type: none"> • Cost of preventive maintenance • Cost of corrective maintenance • Cost of evolutionary maintenance • Cost of adaptive maintenance • Renewal of software licenses • Replacement of obsolete or lost equipment
Human resources at the local level	<ul style="list-style-type: none"> • Wages of data entry clerks (if a new position is created or overtime is required) • Wages of personnel in charge of the system
Communications	<ul style="list-style-type: none"> • Strategy for communication and dissemination of EIR use
Monitoring and evaluation	<ul style="list-style-type: none"> • Wages of HR professionals (with different profiles) • Data quality assessments • Field inspections • Periodic data quality evaluations at all levels

Source: Pan American Health Organization (PAHO). *Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation*. Washington, DC: PAHO; 2017.

Accountability

Accountability occurs within levels of the health sector as well as between the health sector and individuals or communities.

Accountability includes patient engagement and awareness of service entitlement, mechanisms for community feedback, transparency in commodity transactions, accountability between levels of the health sector, and adequate understanding of beneficiary populations.

Potential added value

- EIRs can improve health sector accountability for patient care by generating individual vaccine schedules, defaulter lists, and notifications for overdue vaccines.
- EIRs enable new analyses (e.g., cohort tracking) using more timely, reliable data, which can improve the health sector's understanding of its client populations and thus increase accountability.
- EIRs can provide transparency in vaccine stock transactions to identify potential theft or leakage.
- EIRs can increase the accountability of health workers by tracking their service delivery, performance, and productivity. This may include monitoring their use of the EIR and data entry errors.

EXPERIENCES FROM COUNTRIES

Accountability

- Multiple studies mention the use of EIRs for evidence-based performance management. For example, in rural Pakistan, the Teeko mobile app includes GPS tracking of vaccinator outreach visits, which increased vaccinator accountability as district supervisors could track their location and movement.³⁸ The Teeko app also required the vaccinator to upload a photo of the vaccination or updated home-based record as proof of vaccination.³⁸ The Zindagi Mehfooz EIR, which operates at scale in the Sindh Province of Pakistan is also used to monitor vaccinator outreach activities using real-time EIR data.⁴⁴

Vaccination outcomes

Collectively, these improvements in vaccination service delivery should contribute to improved vaccination coverage and equity, and ultimately improved health outcomes. There are limited outcome studies of EIRs in LMICs, but those that do exist show an improvement in vaccination coverage. Pre-post studies in Bangladesh, China, Pakistan, and Vietnam have demonstrated increases in child vaccination coverage among intervention groups using EIRs compared to control groups after at least one year of EIR implementation. These differences were statistically significant in Bangladesh and Vietnam only. Notably, each EIR also included SMS reminders and, in Pakistan, decision support systems.³

EIRs and COVID-19

The critical role of vaccination services has become even clearer during the COVID-19 pandemic. But these services have been jeopardized by a disruption to essential health services widely reported by countries around the globe, particularly during periods of lockdown. In an analysis of essential health services across six countries, disruptions tended to be most significant for vaccination and other preventative services. For example, Pakistan saw declines of 25 to 49 percent in routine vaccinations.⁴⁵ These declines can be attributed to many factors, including the public's concerns about exposure to COVID-19 in health facilities, difficulties accessing care, a disruption to vaccine supply chains, and the redeployment of health workers to other urgent COVID-19-related efforts.⁴⁶

To mitigate the impact of the pandemic, countries and policymakers have advocated for temporary policy changes to ensure the continuation of vaccination services. For example, WHO issued guidance in March 2020, recommending the suspension of mass vaccination campaigns but also recommending the use of physical distancing and infection control measures to continue provision of vaccination services as a core health service.⁴⁷ WHO argued that the deaths prevented by sustaining routine vaccination outweigh the unlikely risk of COVID-19 deaths associated with vaccination clinic visits, particularly for young children.

Nearly a year into the COVID-19 pandemic, more than 90 percent of countries reported experiencing continued disruption to essential health services. One-third of countries reported disruptions to vaccination services.⁴⁸ At the same time, new vaccines against

COVID-19 have been developed and are being deployed as part of the pandemic response. EIRs can be used to capture data about COVID-19 vaccine delivery, and the data that EIRs capture on routine vaccination can help with understanding and curbing the devastating impacts of global pandemics.

How EIRs can support vaccination service delivery during the COVID-19 pandemic

EIRs ensure the right patients receive the right vaccinations at the right time by enabling patient identification, recording vaccine histories, and tracking patients who have dropped out or missed a recent vaccine. This role has only become more important in the context of the COVID-19 pandemic.

Supporting COVID-19 vaccine introduction

As many countries are beginning to deploy COVID-19 vaccines, it is essential to capture data to monitor and evaluate the vaccine introduction. This includes transactional stock data on the vaccines and related supplies, as well as patient-level or aggregate data on administered doses and AEFIs. WHO provides detailed guidance on COVID-19 vaccination monitoring as part of their [COVID-19 vaccine introduction toolkit](#).

Countries that are already using digital tools may be able to expand the scope of those tools to capture data on COVID-19 testing, cases, or vaccination. Where EIRs are already in use for routine vaccinations, they can be leveraged to capture individual-level data

on COVID-19 vaccination as well. In this way, EIRs can be used to identify which individuals have received vaccines, send reminders for follow-up vaccinations, and monitor AEFIs. The EIR data can be used to monitor the vaccine rollout in real time and identify and address any vaccine uptake, equity, stock, or safety issues that emerge. Individualized information captured in EIRs can also be used to populate vaccine certificates that can support continuity of care or cross-border travel, among other use cases.

However, even where EIRs are already in use, they will need to be adapted to align with the COVID-19 vaccination strategy and target population. New requirements, data elements, indicators, and reports will need to be added to the EIR functionality. For example, EIRs used for childhood routine vaccinations will need to be expanded to capture adult populations. New vaccination sites (e.g., pharmacies, hospitals, long-term care centers) would need to be added to the system and new EIR users at these sites may require training or hardware. Given the urgency of COVID-19 vaccine introduction, WHO has suggested that countries that do not have existing EIRs will likely need to rely on their existing reporting systems.⁴⁹

Monitoring the effects on routine vaccination

For non-COVID-19 vaccines, EIRs can help stakeholders understand changes in vaccination service delivery. EIRs can provide aggregate reports of population-level vaccination rates, helping to identify gaps in coverage and monitor how routine vaccination is affected by adverse events or external shocks to a country's health system. In Pakistan, the Zindagi Mehfooz EIR was scaled in 2017 to achieve more equitable vaccination coverage. Then in 2020, this registry served as a critical system for determining where vaccination services had suffered most by tracking individual children and their vaccination status, and

generating lists of defaulters.⁴⁴ These records helped to determine what regions of the country were hardest hit by disruptions to vaccination services and implicate other services that also may have suffered, such as maternal and child health care.

Planning for supplemental immunization activities or catch-up campaigns

More than a year into the pandemic, the United Nations Children's Fund (UNICEF) estimates that 60 mass vaccination campaigns across 50 countries are postponed as of April 2021.⁵⁰ In Kenya, COVID-19 disruptions to routine vaccination services and supplementary immunization activities heightened the risk of measles outbreaks. Using measles serological data provided, researchers were able to estimate the impact of reduced measles vaccination coverage and suspended supplementary immunization activities due to COVID-19. Results from several different coverage scenarios indicated a significant probability of a large measles outbreak.⁵¹ These findings and other country reports indicate that supplementary immunization activities and catch-up campaigns will be critical tools for many national health systems hit hard by COVID-19.

Coupled with other information, such as geospatial data, EIRs can help generate meaningful insights and encourage data-driven decisions when countries are finally able to plan for catch-up campaigns. As countries begin to reinstate essential health services, EIRs can quantify the number of missed vaccines and determine which areas have been undervaccinated. These individual-level data will enable decision-makers to target vaccination services and allocate funding to those areas most in need.

Communicating health messages

Many EIRs include contact information and messaging features for patients' caregivers, allowing for direct communication to caregivers. These messaging features have historically been used to notify caregivers about upcoming vaccination sessions or overdue vaccines. As the global community develops a greater understanding of COVID-19—including its transmission patterns, full range of symptoms, and treatment options—health workers have the ability to share health promotion messages with patients. This might include information about safely accessing health facilities, upcoming vaccination sessions, and preventative measures. Critically, most existing COVID-19 vaccines require two doses. Research suggests that multidose vaccines may have lower adherence or completion rates, with drop-off after the initial dose. EIR messaging features could be critical for ensuring higher rates of completion for the COVID-19 vaccine series.

EIRs can also facilitate the exchange of information among health providers and provide platforms for peer support. The need to stay connected has become even more critical under COVID-19. Messaging features offer a connection between health facilities triaging supplies and patient services under a strained health system.

Supporting safe vaccination practices

EIRs can also help prevent overcrowding in clinics by scheduling specific clinic times for vaccinations and notifying caregivers. This ensures the more equitable distribution of health services. Children not receiving vaccines are redirected to their community health posts, which are often closer and more accessible, to avoid congestion at clinics. By analyzing EIR data, health officials can identify health trends, prioritize, and coordinate upcoming vaccination clinics so as not to further overburden facilities. In

Tanzania, for example, the country's EIR was adapted to include features that scheduled individual children for vaccinations at specific dates and times. This feature allowed facilities to comply with guidance on social distancing. Furthermore, messaging features and data visualizations helped to project patient volumes and better plan for upcoming vaccination clinics. By scheduling patients' clinic visits, facilities ensured smaller groups and limited wait times to reduce the risk of COVID-19 transmission.

Considerations for EIR design

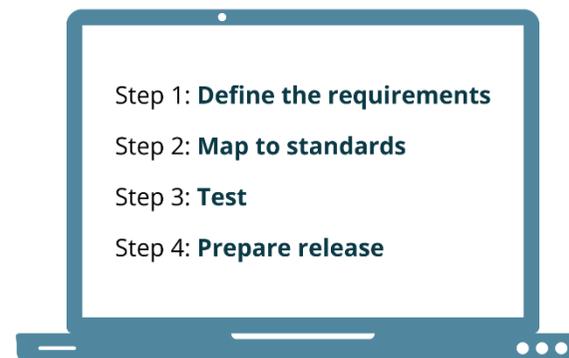
This section provides an overview of common requirements for EIRs and lessons from how they have been operationalized in various contexts. Requirements are statements that describe the functionality of an information system. They answer the question, “What must the information system do?” System requirements include functional and nonfunctional requirements:

- **Functional requirements** describe *what* the system should do. Functional requirements are the specific behaviors and functions that a system must provide to support business processes and workflows.
- **Nonfunctional requirements** describe *how* the system should work. Nonfunctional requirements define the quality attributes of the system or the environmental conditions under which the system will remain effective.

Identifying these requirements is the first step in the software development process, followed by mapping the requirements to standards, testing the software solution, and preparing releases or iterations of the system for use (Figure 7).⁵² The Collaborative Requirements Development Methodology approach can be used to define system requirements (Box 3).

It is important to clearly and comprehensively document requirements to inform the EIR development. A single system can have hundreds of detailed requirements.⁵³ This report does not aim to document the level of detail required by a software developer but identifies and explains categories of recommendations for consideration.

Figure 7. The software development process.



Source: BID Initiative. *BID Initiative Briefs: Recommendations and Lessons Learned. Software Development Cycle*. Seattle, WA: PATH; 2017. https://bidinitiative.org/wp-content/uploads/VAD_BID_LessonsLearned_SoftwareCycle_v1_rev03.pdf.

The list of requirements provided in this report was informed by a 2020 landscape review conducted by VillageReach that identified 11 critical and 6 optional EIR requirements,⁴ a 2014 meta-review of PAHO region EIR implementations,⁵⁴ the BID Initiative experience in designing EIRs for Tanzania and Zambia,^{53,55} and other country and regional EIR guidance documents.^{34,56,57}

WHO is in the process of developing SMART (Standards-based, Machine-readable, Adaptive, Requirements-based, and Testable) Guidelines for vaccination that will include recommended requirements and associated documentation to support a standardized approach to digital tools for vaccination.⁵⁸

Box 2: How should you use these requirements?

These requirements, and lessons learned from operationalizing them, may be useful when:

- Drafting a request for proposals or service-level agreement for an electronic immunization registry (EIR).
- Working with a developer to design a new EIR or new EIR modules.
- Revising or adding functionality to an existing EIR.
- Implementing an EIR.

Box 3: Collaborative Requirements Development Methodology

Overview: The Public Health Informatics Institute and PATH developed a Collaborative Requirements Development Methodology that provides tools and a process to document workflows and define requirements to support those workflows. The process begins with understanding current workflows, then redesigning or improving upon current workflows, and finally describing how an information system can support the workflows. To learn more, visit: <https://www.phii.org/crdm>.

Think

How do we do our work now?

Rethink

How should we do our work?

Describe

How can an information system support our work?

Application to electronic immunization registries:

The BID Initiative applied the Collaborative Requirements Development Methodology to collect and document the requirements for electronic immunization registries in Tanzania and Zambia. The detailed workflows and resulting requirements are documented in the *BID Product Vision*.⁵⁵

Functional requirements

Functional requirements describe *what* the system should do and how end users interact with the system. Functional requirements for EIRs have been categorized by the following functions:

- Registration and search.
- Patient records.
- Vaccination monitoring and follow-up.
- Health facility registration and management.
- Stock management.
- Data and reporting.

Registration and search

Registration and search requirements include the ability to register a child, assign a unique ID, and search for and manage clients in the EIR.

Enrollment at birth^e

Enrollment at birth refers to registering a child in the EIR as close to birth as possible. This ensures that every child born is registered in the EIR and their vaccination progress can be tracked. Proper registration also ensures an accurate denominator, based on the registered birth cohort, for tracking vaccination coverage in different areas.

^e This requirement assumes the EIR is intended to capture data on childhood vaccinations. For EIRs designed to capture data on vaccinations of other populations (e.g., school-age

In practice, the research team observed three main avenues for registering a child in an EIR:

- Registration by a health worker in a maternity clinic immediately after birth.
- Registration by a health worker in an vaccination clinic after birth.
- Registration by a community leader or caregiver after birth.

In some countries, the EIR is accessible to maternity clinic staff to support enrollment as close to birth as possible. In Albania, maternity nurses enter the child's information, such as identification and contact information of the caretaker.³⁶ After enrollment, a schedule of future vaccination appointments is created for reference. Similarly, in Uruguay, trained personnel attend nearly 99.5 percent of deliveries and administer the Bacille Calmette-Guerin vaccination before discharge as part of the country's maternal and child health program. If the child is unable to get the vaccination due to medical reasons, they are still enrolled in the system at birth to be tracked.^{59,60} While registration by maternity clinic staff may ensure more timely and complete data capture for births, use of an EIR requires planning for additional hardware and training for maternity clinic staff. There are also limitations to this approach if many births happen outside of facilities.

When child registration does not happen in the maternity clinic, a common practice is to register a child on their first vaccination clinic visit. Registration could also happen during an outreach visit or other vaccination service delivery (discussed further in the [“Nonroutine data collection and management”](#) section below).

children, pregnant women, adults), an enrollment and registration requirement would still apply.

A third observed approach, particularly relevant for home births, is allowing community leaders or caregivers to register a child after birth. For example, in the case of home births, the BID Initiative trained village representatives or community health workers to send an SMS with details about the child so they can be registered.⁶¹ However, this approach was ultimately abandoned because village leaders did not see this as their responsibility and it was not cost-effective.²⁸ In another example, a mobile health app, mTika, was introduced in Bangladesh to register births, track each child's vaccination status, and send SMS reminders for upcoming

vaccinations. Mothers who were registered in mTika while pregnant were taught how to send an SMS birth notification to register their child after birth. This notification autogenerated a unique ID for the child as well as a vaccination schedule to follow. Once the caregiver and child were captured in the system, they would receive future reminders for vaccination appointments. However, if the mother did not complete a birth notification through mTika, the child would then be registered at a vaccination site.⁶²

Box 4: Linkage to birth registration systems

Civil registration and vital statistics (CRVS) systems capture vital events in an individual's life, such as birth, death, and cause of death. Electronic immunization registries (EIRs) and CRVS birth registration systems can be linked to ensure that all children registered at birth are captured in the EIR and to check that all children receiving vaccines have been registered in the CRVS system. Linking these systems is most effective if there is a well-functioning CRVS system in a country. However, according to the WHO *SCORE for Health Data Technical Package: Global Report on Health Data Systems and Capacity, 2020*, only 4 percent of low-income, 34 percent of lower-middle-income, and 65 percent of upper-middle-income countries have complete registration of births.^a

The EIR and birth registration systems can be directly linked through interoperable software or there can be a more manual process to compare data across the systems. In Costa Rica, the EIR and birth registration system are designed to be interoperable in real time. When a patient's national ID number is entered, the EIR automatically connects to the national registry and fills in details, such as the person's name, date of birth, calculated age, and sex.^a In Bogotá, Colombia, the records in the EIR and birth registry are compared on a monthly basis to identify any discrepancies; children who are captured in only one database are then added to the other for more complete population coverage.^a In Araraquara, Brazil, there is a routine search through the civil registry to confirm children registered are also captured in the EIR.^a

Vaccination can also be a means to promote and improve birth registration. In Nicaragua, health workers who administer vaccines at birth direct caregivers to visit hospital-based birth registration booths before discharge. For nonfacility births, vaccinators and civil registry officials jointly visit homes during annual vaccination weeks to vaccinate and register children. Preliminary results showed these approaches were successful at increasing birth registration.⁷²

OpenCRVS is a Digital Square-supported global good that has been deployed in Bangladesh. Further details on OpenCRVS are available in the *Digital Square Global Goods Guidebook*.

LESSONS LEARNED FROM IMPLEMENTATION

Enrollment at birth

- *The EIR should support registration in the maternity ward with minimum information.* This was a requirement highlighted by the BID Initiative because children may be discharged from a maternity ward with incomplete information—for example, without an assigned name. Registration should still be possible despite the limited information.⁵³
- *It is a best practice to register children as close to birth as possible.* This ensures that every child born is registered in the EIR and their vaccination progress can be tracked. Proper registration also ensures an accurate denominator, based on the registered birth cohort, for tracking vaccination coverage in different areas.
- *Linking an EIR to other birth registration systems may improve data quality and achieve better registration coverage.* Chile and Costa Rica, two countries with high birth registration timeliness and coverage as recorded in their civil registries, are considering linking their EIRs to the civil registration database.²³ In Zambia, the EIR is linked to a UNICEF mobile vaccine application (mVacc) that collects birth notifications.²⁵ These approaches require close collaboration with partners to develop technical integration between systems.
- *If EIR registration is low, consider implementing registration incentives.* For example, linking vaccination to eligibility for school entry or other social programs could incentivize registration.⁶⁰ Financial incentives could also be used by linking funding to registration.⁶³
- *SMS birth notifications may be used to register home births.* The BID Initiative has suggested using this approach selectively for targeted areas with a high percentage of home births, as it can be costly to train and follow up with community leaders.⁶¹ Even with training, there were issues with the quality of data provided via SMS and the cost of sending the SMS was a financial barrier.²⁵

Client management and unique identifiers

Client management is the ability to access and search a child's records within an EIR, consolidate duplicate records, and warn if a child already exists in the system. This allows for easy and quick retrieval and updating of data.

An efficient way to facilitate client management is through the use of unique IDs. Unique IDs are given to children for identification when they are registered into the system. By assigning each child a unique ID, health workers can search and manage records with ease. Having a unique ID provides another way to search for the child's records if they do not have their health card. Additionally, with an ID, a child's records can be accessed by any facility the child visits, helping to ensure the right child receives the right vaccine at the right time.

A unique ID solves issues that arise from children going to multiple facilities. Not only are health workers able to verify and pull up the same records, they are also able to update the central database, which provides a more complete registry and reduces missing or conflicting data. Using a unique ID can eliminate fraudulent and duplicate identities in the system, preventing gaps in coverage. Assigning a unique ID is also helpful for dealing with the challenge of inconsistent common IDs, like unknown birth dates or flexible spelling of names.³³ Additionally, unique IDs are useful for tracking nomadic or mobile populations, so their comprehensive vaccine record is tracked even if they receive care in different facilities.

In practice, there are several ways that unique IDs can be generated. Table 4 presents various types of unique IDs and examples of how they have been implemented in LMIC contexts.

To support client management, an EIR can be designed to search for a client based on partial information or based on family

relationships or demographics. The EIR can automatically identify individual records as duplicates or possible duplicates and flag them for manual review.⁵³ Identification of duplicates can happen as a real-time alert when a child is being registered or as a generated report of suspected duplicate entries on a less frequent basis.⁴ The Zambia EIR was not initially designed to automatically identify new child records as possible duplicates, but based on experience, the implementation team suggested this functionality for inclusion in a minimum viable product (the most basic set of functionality in a software required for use).⁵³ By flagging and eliminating duplicate records, EIRs are able to provide more accurate data for decision-making.

LESSONS LEARNED FROM IMPLEMENTATION

Client management and unique identifiers

- *The home-based record should include the unique ID.* This allows for rapid and accurate identification of the child's record when they present their home-based record at the point of service. The BID Initiative recommends including a human-readable unique ID in the EIR that can be written on the home-based record in the case of stockouts of barcode/QR code stickers.²⁵
- *Plan for community sensitization on unique IDs to build knowledge and trust.* For example, in Tanzania, some mothers were initially confused by or did not trust the barcode stickers included on their child's vaccination card, sometimes removing them. Some mothers even thought that the barcodes were a way to track and kidnap children, so they feared attending vaccination services as a result. After health workers communicated the purpose and benefits of barcodes, community perceptions and acceptance of the barcodes improved. It was important for this messaging to come from health workers who were trusted by the community.^{3,4,64} The need for sensitization will be context dependent; for example, in Zambia, there were not the same concerns about QR codes.²⁷
- *In contexts with multiple potential IDs, consider designing the EIR to capture any relevant ID.* Costa Rica's EIR includes a drop-down list of options for the ID; for example, a national ID number can be entered if the patient is a resident or a passport number can be entered if the patient is a foreigner.⁷¹
- *Consider a sustainable supply of materials and equipment to support the choice of unique ID.* In Tanzania and Zambia, it was challenging to find a local vendor that could print barcodes and QR codes in bulk, which was an important sustainability consideration. In addition, it was learned that tablets used for the EIR had to have a 5-megapixel camera to adequately read the barcodes.²⁵
- *Design client search requirements based on health worker workflows and feedback.* In Kenya, developing user-centered software based on "field-tested workflows of clinical information" allowed for problems to be solved as they arose.¹⁵ In Haiti, health workers faced challenges with scanning certain barcodes. The challenges were addressed by adding parameters to the input form so only five-digit numeric entries would be accepted by the software.
- *An EIR should automatically identify if new child records are possible duplicates and the management of duplicate records should be planned for.* Automatic identification of possible duplicates can help prevent duplicate records; but even with this functionality in place, duplicates may occur if the information is slightly different between records or is not synced across the system.
- *All individuals who receive vaccines should be registered into the EIR regardless of age, citizenship, or other factors.*¹⁰ This supports monitoring and planning for all individuals eligible for vaccination.

Table 4. Types and examples of unique IDs.

Type	Methods	Description	Examples
Machine generated	Barcode/QR code	When a child is registered into the system, an autogenerated barcode/QR code links the child to a specific and unique ID. This ID allows different facilities to access the child’s records, increasing safety and reducing errors. Often, the barcode/QR code is adhered to the child’s health card.	<ul style="list-style-type: none"> • Tanzania: A 2D barcode sticker adheres to the child’s health card and is linked to a randomly generated ten-digit number.²⁵ • Zambia: A QR code sticker adheres to the child’s health card and is linked to a randomly generated seven-digit number.²⁵ • Haiti: Vaccine cards with unique numeric barcodes were distributed at vaccine posts or during a door-to-door household census prior to a vaccine campaign.⁶⁵ • Albania: Barcodes are added to existing health or vaccination cards.³⁶ • Pakistan: QR code stickers are provided for identification.⁶⁶ • Vietnam: Unique identification numbers and barcodes are assigned after EIR registration.⁴⁰
	SIM cards	Cellphone-based EIRs may use SIM cards to uniquely identify caregivers.	
	Near-field communication (NFC) chip cards	NFC is a short-range wireless technology that enables two devices to communicate with each other and share small amounts of data. If a machine-generated unique ID is linked to an NFC chip-enabled card, a health worker could read it with another NFC-enabled device.	<ul style="list-style-type: none"> • Uganda and Kenya: BroadReach has pilot tested the use of NFC cards with an vaccination application for populations near the Uganda-Kenya border. The card can be viewed and updated by health workers in both countries using a mobile system.⁶⁷
Human generated	Combination of variables	Combination of different variables—for example, one’s name, parental names, numbers, date of birth, or place of birth—to generate a unique ID.	<ul style="list-style-type: none"> • Namibia: The birth notification system (not specific to vaccination) generates a unique ID based on the date and time of registration down to the millisecond.⁶⁸

	Existing national ID	If unique IDs already exist for another civil registration or social services program, these can be used. For example, in some countries, national IDs or birth registration numbers are given at birth and are often linked to a civil registration and vital statistics system.	<ul style="list-style-type: none"> • Latin America: Many countries use national ID numbers provided by the civil registry office.⁴ • Costa Rica: When a patient's national ID number is entered, the EIR automatically connects to the national registry and fills in details, such as the person's name, date of birth, calculated age, and sex.⁷¹
Biometric	Fingerprints, irises, facial images, etc.	<p>Health records can be linked to an individual's fingerprint or other biometric marker that uniquely identifies them. Upon arrival at a facility, the fingerprint is scanned to pull up records.</p> <p>UNICEF has developed guidelines and considerations on using biometric technologies for children: https://data.unicef.org/resources/biometrics/.</p>	<ul style="list-style-type: none"> • SimPrints Technology Ltd.; Gavi, the Vaccine Alliance; and NEC Corporation are collaborating to develop and test fingerprint biometrics for children under the age of 5 years as a unique ID for vaccination. Initial pilots are happening in Tanzania and Bangladesh.^{68,69} • India: The Aadhaar program captures fingerprints and iris scans to link an individual to their unique 12-digit ID for government services—and the Aadhaar number is being used as a unique ID for COVID-19 vaccinations. • South Africa: Drafted a policy proposing to use biometrics (iris) for infant ID management.⁶⁸

Adapted, and expanded with implementation examples, from: Pancholi J, Birdie R, Guerette J, Chritz S, Sampath V, Crawford J. *Landscape Analysis of Electronic Immunization Registries: Lessons Learned from a Landscape Analysis of EIR Implementations in Low and Middle Income Countries*. Seattle, WA: VillageReach; 2020.

Patient records

Patient record requirements refer to the data captured for each patient record, which should include demographic data, vaccine event data, caregiver information, and potentially data on other health areas beyond vaccination.

Individual demographic data

EIRs should capture demographic data about each individual in the system. In addition to their unique ID, individual demographic data may include:

- First name.
- Family (last) name.
- Sex.
- Date of birth.
- Caregiver and/or mother's name, contact information, and unique ID.
- Place of residence (e.g., home address, community, or village).
- Status (active versus inactive or deceased).
- Other sociodemographic information (e.g., ethnicity).

The BID Initiative suggests that first name should be an optional field since a child may be discharged from the maternity ward without a first name.⁵³

Overall, individual demographic data are important for identification and monitoring of individual vaccination status. These data also enable a health worker to look up the individual even in the absence of their unique ID (e.g., if they have misplaced or forgotten to bring their home-based record, the health worker can use demographic

information to find their EIR records). The date of birth is important to calculate an individual's vaccine schedule. Name and contact information for the caregiver and/or mother are important for targeted follow-up as discussed under "caregiver information and reminders" below. Information on sex and place of residence are important for vaccination programs to calculate aggregate vaccine coverage by sex or location and identify any disparities in coverage. Status is important to know which individuals to exclude from these aggregate reports or reminders.

Other sociodemographic information could be captured in EIRs to support additional equity analyses and understand potential risk factors for undervaccination. For example, the WHO guidance on COVID-19 vaccine delivery recommends that countries consider capturing equity dimension, such as vaccination "by socioeconomic, ethnic, linguistic, religious, or any socially disadvantaged populations."¹¹ Similarly, PAHO recommends considering capturing variables, such as ethnicity, nationality, or occupation in an EIR.³⁴ The EIR landscape published by VillageReach also identified other potential social determinants of health to capture related to the family's socioeconomic status, such as "caregiver education level, heating source and indicators of overcrowded living," but noted that "collecting this data can be off-putting to families".⁴

LESSONS LEARNED FROM IMPLEMENTATION

Individual demographic data

- *An EIR minimum viable product should capture family name, mother's name, caregiver's name, unique ID, gender, date of birth, and contact information as required fields in a patient record.* The BID Initiative recommends an agile approach to EIR development that prioritizes these critical requirements first, with the option to add new requirements based on user feedback in subsequent iterations.⁷⁰ These data elements may be adapted to the local context; for example, the Teeko app (now renamed Hayat) implemented in Afghanistan and Pakistan captured the child's father's name rather than the mother or caregiver's name.³⁸
- *Consider what demographic variables are most relevant to capture in the EIR to support equity analyses for the given context.* Capturing additional sociodemographic variables can enable new analyses and equity insights, but the added value of these variables must be balanced with the time required to collect them and the potential sensitivity of the information.⁴

Vaccine event data

In addition to individual demographic data, each patient's record should include information on the vaccine event itself, which may include:

- Date of vaccination.
- Antigen.
- Dose.
- Place of vaccination.
- Vaccinator (who administered the vaccine).
- Administration strategy (e.g., clinic, outreach, campaign, school based, etc.).
- Details on the vaccine itself (e.g., manufacturer, serial lot number, lot expiration date, commercial formulation such as hexavalent or pentavalent).
- Any reason for not administering a vaccine (e.g., contraindications, patient refusal, stockout, etc.).
- AEFIs.

This information is important to record the vaccine history of each individual to assess whether they received the right vaccine at the right time. Details on the place of vaccination, vaccinator, and strategy can be used to assess various programmatic approaches for planning and for tracing any errors. Details on the vaccine itself are used to trace vaccine stock and are particularly important to identify anyone who may have received a vaccine from a lot with quality issues. Vaccine event data are often captured by the vaccinator or a data collector at the point of service delivery.

LESSONS LEARNED FROM IMPLEMENTATION

Vaccine event data

- *Data entry should happen as close to the vaccine event as possible.* This is important for the timeliness and quality of vaccine data.^{4,34} For example, in Uruguay, data entry has been embedded into the vaccination workflow; this has contributed to a “very strong culture of recording immunizations on the forms immediately upon vaccination,” which in turn contributes to high data quality.⁵⁹ However, timely data entry can be challenging for health workers, particularly if they are expected to complete electronic data entry in parallel to paper-based recording.³⁹
- *An EIR should be flexible and adaptable to capture data on vaccines outside of the national Expanded Programme on Immunization schedule and to add new vaccines when necessary.* “EIRs need to be flexible enough to accommodate new vaccines, new schedules, and special situations.”²³ Special situations can include alternative vaccine schedules due to care delivered in the private sector, foreign travelers, or migration into the country. For example, when children move to Albania, they may have received vaccines from their home country that are not part of the Albanian vaccine schedule; there is no way to enter these vaccinations into the EIR so the child’s record is incomplete.³⁶
- *EIRs can automatically record the dose number but should allow manual editing.* “The EIR can be programmed to calculate the number of the dose administered. For instance, if a user known to the vaccination services has already received two doses of pentavalent vaccine, the next administered dose of the same vaccine will be the third. This information means the system can automatically record the next vaccine dose as the third dose. It is important to ensure that doses are properly assigned or, at least, that the system allows manual editing.”¹⁰

Nonroutine vaccine event data

Nonroutine data collection and management focuses on the ability of EIRs to be flexible and to capture vaccination data in routine as well as nonroutine settings, such as at outreach events, health fairs, and vaccination campaigns. An EIR should have the ability to record vaccinations delivered in these settings and indicate the administration strategy (e.g., outreach event).⁵³

This requirement has been operationalized in various ways. In Panama and Honduras, the electronic tool itself is only used within health facilities; outreach activities are captured through paper-based recording for later data entry into the EIR. In Panama, the EIR “allows inclusion of different vaccination strategies (health facility, vaccination campaigns, outreach modalities: school vaccination program, health workers, vaccination in businesses, farms, etc.),” whereas in Honduras, vaccination campaigns are registered as outreach activities.²⁶ In other settings, it may be feasible for an outreach worker to carry a mobile phone or tablet for direct data entry into the EIR during outreach service delivery.

LESSONS LEARNED FROM IMPLEMENTATION

Nonroutine vaccine event data

- *Workflows in outreach settings can be very different from clinic settings so it is important to consider the feasibility of using the EIR for outreach.* When outreach services or campaigns are vaccinating many individuals that are not yet registered in the EIR, this poses a challenge. While it is important to capture individualized data in the system, the process of registering individuals takes time and can slow down vaccine delivery. The benefits of having complete registration must be weighed against the public health need to vaccinate as many people as feasible. In Tanzania, health workers have occasionally created “dummy IDs” to record all the vaccines delivered during a campaign to a single ID. In this case, it was not feasible to register all individuals, but the EIR was still used to track the total vaccines administered. In Haiti, a cholera vaccine campaign took a different approach by first registering all eligible individuals via wireless tablets in a house-to-house census. Individuals were provided a vaccine card with a unique barcode that they later presented at a health post to receive their vaccine.⁶⁵
- *Using the EIR during outreach visits may require procuring additional hardware.* If outreach events or campaigns happen in parallel to fixed site vaccinations, then each site will require the appropriate hardware to use the EIR.
- *Forgoing data collection during nonroutine vaccine events can lead to data challenges later.* In Zambia, health workers stated that “it is very difficult and frustrating to back-enter immunization data after outreach,” which could explain why the data were “significantly more likely to be missing or contain errors.”³⁹

Linkages to other health areas

While capturing vaccine event data is central to an EIR, EIRs can also be designed to capture data on other health areas, including current health status, disease and health history, and delivery of nonvaccination services. For example, the EIRs in Tanzania and Zambia capture data on services typically delivered alongside vaccinations, such as measurement of the child's weight, vitamin A administration, and the use of bednets.¹⁴ In the legacy system, these indicators are normally tracked on the paper-based child health register alongside vaccination information. In Tanzania, the EIR also includes data on the mother's tetanus vaccination history to indicate the tetanus protection of the child.⁵²

Having this additional information digitized has proven useful in Tanzania. One health worker shared his experience that with paper-based reporting, it was challenging to keep track of underweight children for follow-up. However, using the EIR reports, he was able to follow up with caregivers of underweight children and, if necessary, refer them to the district nutritional department. His facility has successfully reduced the number of underweight children in the villages targeted for outreach.⁷¹

Vaccination can serve as a first use case for a country to implement an individualized electronic registry, which can later be expanded to capture data on other health areas.

LESSONS LEARNED FROM IMPLEMENTATION

Linkages to other health areas

- *Consider what nonvaccination data elements should be captured in the EIR based on existing workflows and the added value of digitizing the data elements.* In countries where other child health indicators (e.g., weight, vitamin A) are routinely captured alongside vaccination data, it may be feasible to integrate them into the EIR data capture. However, the BID Initiative has cautioned against potential scope creep—where an iterative EIR development process may continue to generate new requests for nonvaccination data capture.⁵²
- *If additional data elements are captured in the EIR, ensure they are consistent across the implementation area.* In Mexico, the open code EIR was modified based on user feedback, but this resulted in different versions of the system across regions. This led to data inconsistency, potential data manipulation, and eventually the need for a new EIR in 2013.⁶³ User feedback must be integrated in a uniform way across the system.

Vaccination monitoring and follow-up

This group of requirements specifies how the EIR supports monitoring individual vaccination schedules. Clinical decision support is embedded in the EIR to calculate the vaccination schedule for each individual and identify individuals who are due or overdue for vaccines. Further, EIRs can produce lists or reports of undervaccinated individuals for follow-up.

Clinical decision support

Clinical decision support is automated, data-driven decision support for health workers built into the EIR. Many different types of clinical decision support can be embedded in EIRs. Common ones include creating a vaccination schedule for each patient, scheduling vaccination appointments, generating lists of patients due at a health center for vaccination, automating reminders of missed vaccinations, and providing guidance for health workers on their vaccination activities.

Clinical decision support is important because it leads to improved quality and efficiency of care. If an EIR automatically creates a vaccination schedule based on a child's birth date and vaccine history, health workers no longer have to create one by hand, which saves time and improves accuracy.⁷² During vaccination appointments, the EIR can use the vaccination schedule and up-to-date vaccine history to prompt health workers on what vaccines are required for that individual at that time. This helps prevent errors in vaccine administration.⁷³ When health workers are planning for future vaccination activities, they do not need to review the data for each individual; instead, they can automatically receive reports on individuals expected for vaccinations in a specific time period.³⁶ Additionally, caregivers can receive reminders of vaccination status,

either proactively for upcoming vaccination due dates or retroactively if a child is behind on their vaccination schedule.⁷²

When designing clinical decision support with an EIR, it is helpful to think about how the decision support is generated and how the health worker interacts with it. For example, the format of the system could be built on evidence-based health care protocols or process algorithms that use if/then rules to guide the health worker, or it could be some form of machine learning.⁷⁴

The clinical decision support can be embedded within the EIR itself or can be produced by the EIR as a separate tool. The tool could be an alert to the health worker to complete a certain task or to prevent them from making an error in vaccine administration. For example, in Brazil, the EIR will alert health workers if they try to schedule a vaccination ahead of the recommended schedule.³⁰ The tool could also be presented as an interactive checklist or guide for the health worker to follow when administering a vaccine.¹⁶ Data in the EIR can also be used to produce tools that the health worker would encounter separately from the EIR. This commonly occurs as printed reports, as in Iran where health workers receive a printed table of all vaccines and dates the vaccination should occur.⁷⁵

Another design consideration for a clinical decision support tool is whether the tool is mandatory or optional. An alert could be ignored unless there is a specific action needed to turn it off. A printed report is only helpful if it is integrated into the health workers' activities. Whether a clinical decision support tool is mandatory or not depends on the specifics of the implementation, but it is important to consider when the EIR is being designed.

Overall, clinical decision support tools can add value for health workers and to vaccination programs, but they require thoughtful design to ensure they can be integrated into clinical workflows and support appropriate clinical decision-making.

LESSONS LEARNED FROM IMPLEMENTATION

Clinical decision support

- *Design clinical decision support tools to support health workers' activities and workflows.* The tool should add value for health workers and integrate seamlessly into their existing tasks.
- *Be aware of how health workers are using the tools.* If the tool does not work, larger issues can arise if the issue is not addressed. In one case, available drop-down menu options were not appropriate, so instead, health workers entered information manually. This led to thousands of duplicate data categories.³³ These issues can be identified and corrected through user-centered design processes, user feedback loops, and pilot testing.
- *Mobile devices (phones, tablets) can enable health workers to use the EIR during vaccination service delivery.* Whereas desktop and laptop computers can tie health workers to their desk, mobile devices can be integrated more easily into workflows to make use of clinical decision support at the point of care.⁵³
- *The EIR should be flexible to change the recommended vaccine schedule as necessary.* Clinical decision support is often based on the recommended vaccine schedule, which may need to be adjusted if new vaccines are added to the schedule or there is a change to the guidance on vaccine timing or dosing for existing vaccines. For example, many African countries added inactivated polio vaccine to the routine schedule in the last decade.

Identification of undervaccinated individuals

One important feature of an EIR is to identify undervaccinated individuals or those who miss one or more vaccine doses. As noted above, embedded clinical decision support can be used to calculate the appropriate vaccination schedule and identify overdue vaccines. This enables follow-up of undervaccinated individuals to support the completion of their vaccine schedule.

EIRs identify undervaccinated individuals in multiple ways. First, an individual's record can highlight any missed or overdue vaccinations. This alerts the health worker to provide any "catch-up" doses during a care visit. Second, EIRs can autogenerate lists of individuals who have missed vaccinations. This information can be used to directly follow up with individuals or caregivers. Third, EIRs can aggregate data on missed vaccinations by geography to identify low-coverage areas. This information can be used to plan for timely, targeted outreach or other action to improve coverage and prevent vaccine-preventable disease outbreaks in hotspots or other undervaccinated areas.

What does this look like in practice? In Tanzania, a defaulter report is generated every two weeks that includes the child's name, mother's name and phone number, village, and details about which vaccine was missed. Health workers first verify whether any children on the defaulter list were vaccinated without their information being updated in the system. Then, they attempt follow-up using the mother's phone number. If they are unable to reach the mother or caregiver, the health worker shares the information with village and community leaders to help locate the child or find out if they have moved away.⁷⁶

Box 5: Zero-dose children.

"Zero-dose" children are an important subset of undervaccinated children who have not received any vaccines. According to 2019 World Health Organization/UNICEF vaccine coverage estimates, there are 14 million children worldwide who have not received an initial dose of vaccines. These children live disproportionately in Africa and particularly in conflict-affected countries.^a Gavi, the Vaccine Alliance, has suggested that reaching zero-dose children should be the highest priority for vaccination programs.^a However, unless an EIR is linked to a comprehensive birth registration system or has high birth registration rates, zero-dose children are unlikely to be captured in the EIR. This poses a challenge to vaccine coverage and equity in the absence of other interventions to identify and register zero-dose children. One promising practice in Pakistan triangulated data from the Zindagi Mehfooz EIR system with polio zero-dose registries to identify and enroll zero-dose children for routine vaccination.⁵⁶

LESSONS LEARNED FROM IMPLEMENTATION

Identification of undervaccinated individuals

- *Information on undervaccinated individuals should be presented in a user-friendly way to ease interpretation and prompt action at a glance.* For example, in Pakistan, the app was designed to use traffic light colors to indicate defaulter status.³⁸
- *Plan a regular cadence to generate and distribute coverage reports and defaulter lists.* Distributing these reports periodically (e.g., biweekly or monthly) can enable timely action to improve vaccine coverage.
- *Create a plan and accountability for taking action to address defaulters.* For instance, during a cholera vaccine campaign in rural Haiti, teams went door to door, looking for children based off the generated list of undervaccinated children.⁶⁵ In other countries, health workers can efficiently and conveniently make phone calls or send text messages directly from the EIR.
- *Include the caregiver's name, phone number, and address in defaulter reports.* This enables health workers to make phone calls or send text message reminders. If the phone number is missing, the address can be used for follow-up home visits.
- *Time and resources are required to follow-up with undervaccinated individuals.* Making phone calls or manually sending text message reminders to caregivers can be time consuming and may require mobile data. Additional outreach visits to undervaccinated areas also require health worker time and resources.

Reminder and recall messages

As noted above, the EIR should capture contact information for the individual, as well as the mother and/or caregiver in the case of child vaccinations. This contact information, combined with the individual's vaccination schedule and status, can be used to generate reminder or recall messages. Reminders are sent in advance of a scheduled vaccine and recall messages are sent to alert that a vaccine is overdue. Client communications could also be used to improve client knowledge about behaviors or vaccination services.

Follow-up reminders can improve vaccine adherence. There is strong evidence, primarily from high-income countries, that reminder and recall systems are effective at increasing vaccination rates. There is limited evidence from LMIC contexts, but a few studies do show acceptability of these systems and positive results of reminders or recalls on vaccination.⁷⁷

Reminder and recall systems may be embedded in the EIR or another interoperable solution. For example, Zambia's EIR is linked to a separate mobile app, mVacc, which is supported by UNICEF.⁷⁸ Client messages can be manual or automated, and can use various mechanisms such as phone calls, text messages, emails, or postcards.⁷⁹ The messages may be tailored or untailored for the specific client. The timing and content should be determined by the health system.⁷⁴

LESSONS LEARNED FROM IMPLEMENTATION

Reminder and recall messages

- *Consider dimensions of accessibility (such as local mobile phone access and literacy rates) to determine whether SMS messages are appropriate.* Women are often the primary caregiver, but in LMICs, they are 21 percent less likely to own a mobile phone than men.⁸⁰ Where mobile phone access is limited, alternative client communication methods should be considered.¹⁶ If local literacy rates are low, voice-based and dialect-specific reminders may be more effective than SMS-based reminders.⁷³ Or, in the case of the mTika mobile app in Bangladesh, illiterate mothers were taught to recognize symbols used in SMS messages.⁶²
- *Leverage the messaging system for sharing information beyond vaccination reminders and recall.* These systems can also share educational information about vaccination and other health practices. In an epidemic, client communications can be used to rapidly disseminate health messages.⁸¹
- *Caregiver phone numbers can change frequently.* An out-of-date phone number makes communication difficult or impossible, and it can be a time-intensive process to get the updated number.³
- *Consider frequency of client messages.* While reminder and recall messages have the potential to improve vaccination uptake, sending SMS messages too frequently can weaken their effectiveness.⁸⁰

Health facility registration and management

Health facility management is the ability to have a complete, comprehensive list of health facilities within the EIR. This includes the ability to register new facilities, edit existing facility information, and remove or otherwise indicate inactive facilities. An EIR user should be able to search across the health facility list.

Health facility registration is important to understand where vaccinations are delivered and to plan for vaccine service delivery. EIRs should have data on all the health facilities in the implementation's jurisdiction. Capturing data from private- and public-sector facilities will maximize the utility of the information to measure population coverage. At minimum, the name and location of the facility are needed, but other information—like type of facility, infrastructure, or referral hierarchies—could be collected as well.

LESSONS LEARNED FROM IMPLEMENTATION

Health facility registration and management

- *If the country has an existing facility registry, introducing an EIR can be an opportunity to validate it.* When an EIR is being designed and implemented, it is important to first see if there is already a facility registry for the geographic area. If there is a registry in place, the EIR should be designed to be interoperable with the software that already exists. It can also be designed to validate the existing registry. This was the intent in the BID Initiative product vision, where the EIR was designed to validate facility information against the national master facility list.⁸²
- *If the country does not have an existing facility registry, the EIR introduction can be an opportunity to build one for use beyond vaccination.* In some settings, an EIR may be one of the first digital tools implemented at the health facility level across the health sector. If there is no existing health facility registry, the EIR implementation therefore acts as the impetus to create one.

Stock management

Stock management is necessary to manage inventories of commodities, like vaccines, that are used in public health programs. Stock management helps to ensure adequate supplies and prevent stockouts by facilitating forecasting and planning for appropriate levels of stock; this in turn may allow for more exact stock management, which can reduce the need for excess buffer stock. As mentioned in relation to vaccine event data, stock information is also important to trace vaccine lots in case of quality or safety concerns.

Some EIRs directly capture information about vaccine stock, whereas others are designed to be interoperable with existing electronic logistics management information systems (eLMIS). EIRs may include the ability to monitor and track vaccines to the point of administration. Having stock data alongside service delivery data is important to understand consumption patterns and can automate updating the stock balance. For example, the Albanian EIR-eLMIS system automatically deducts a dose from the stock balance when a vaccine event is recorded; then, at the end of the month, nurses perform physical stock counts to make any adjustments to the stock balance.³⁶ The system should be flexible to allow for stock adjustments to account for unused doses, expired or broken bottles, and other events.³⁴

The EIR may also include reports, visualizations, or clinical decision support related to stock. The BID Initiative EIRs in Tanzania and Zambia provide automated notifications to health workers when vaccine stocks are low, and health workers have the ability to order additional inventory through the EIR.⁴ In

Pakistan, the EIR includes visualizations of stock by commodity so health workers are aware of current stock levels.³⁸

While not all EIRs include stock management, stock management is a recommended requirement for a minimum viable product.⁷¹

LESSONS LEARNED FROM IMPLEMENTATION

Stock management

- *If the EIR automatically updates the stock balance based on vaccines administered, there should be a clear process in place for health workers to make any necessary stock adjustments.* Adjustments are necessary to account for any vaccines that are lost, discarded, damaged, or destroyed. In Albania, nurses did a physical stock count to make adjustments at the end of each month. This frequency could be adapted to the local context.
- *Frontline health workers may require additional training or support on stock management.* While facility health workers are used to registering patients and recording vaccine events, they may not have used paper-based stock management tools under the legacy system. This was the case in Albania, where vaccinators did not previously record stock and reported some difficulty in using the EIR-eLMIS stock module compared to other modules.³⁶
- *If there are multiple stock management tools, they should be interoperable and harmonized.* It was initially a challenge in Tanzania when a new vaccine information management system was introduced in addition to the EIR. Facility health workers prioritized the new system and did not use the EIR stock management component consistently.⁶

Data and reporting

Data and reporting refer to the ability of the system to analyze the data to generate reports. This generally requires aggregating data at different geographic or administrative levels to meet reporting requirements and could include specific types of reports, such as for AEFIs.

Reporting

An important requirement of EIRs is the ability to generate simplified reports on vaccine administration. In terms of content, there are many different types of reports possible (Box 6). Determining which reports are included in an EIR depends on the intended users, level of the health system, and the specific implementation. This could include standard reports or ad hoc, customizable reports. It may also include the ability to export, download, or print reports.

The ability to create reports is important because it makes the data captured by the EIR accessible to those who can use it. Reports and data visualizations or dashboards can condense large amounts of data into digestible information to inform action.

When deciding how to design the reporting capabilities of an EIR, there are several considerations.

First, who is the audience for the report and what information do they need? Reports are important for all levels of the health system. Facility staff can use reports on geographic vaccine coverage to identify locations for outreach services. District staff can use reports of vaccination coverage by health facility to provide supervision to underperforming facilities. National and regional staff can use reports of vaccination coverage to allocate resources appropriately. Some systems also generate reports for patients or caregivers. For

example, the EIR in Bogotá, Colombia, allows caregivers online access to download a hard copy of their individual vaccination card.³⁴ Identifying the audience can help determine their information needs and the data required for decision-making. Then, more specific decisions about the appropriate indicators, their calculation, and time frame can follow.

Box 6: Common reports included in EIRs.

- Vaccination coverage reports (e.g., by sex, age, geographic area, vaccine, dose, vaccination delivery strategy, population group, etc.).
- Future vaccination schedule reports.
- Defaulter (delayed cases) reports.
- Vaccine stock reports.
- AEFI reports.
- Data quality reports (e.g., duplicate records).
- Vaccine-preventable diseases reports.

Second, how should the information be presented? Data can be presented as a dashboard, table, list, graph, or map. It is important to consider what method is the most appropriate for the type of data and how to best present information to support interpretation and action for the intended audience. For example, a report intended to show vaccination coverage by geography may be helpful to present as a map. A report on missed vaccinations may be helpful to present as a list of individuals with their missing doses indicated alongside their contact information to support follow-up.

Third, how should the reports be deployed to facilitate their use?

Health workers who are expected to produce reports will need to be trained on how to create them. The time and resources needed for training will depend on the number of reports the staff are being asked to create and the complexity of the software. Health workers who are expected to use the reports will need to be trained on how to interpret the reports.

LESSONS LEARNED FROM IMPLEMENTATION

Reporting

- *Data in the reports should be as close to real time as possible for the most accurate results.* This is dependent on Internet connectivity; however, as found in Zambia, even monthly syncing led to an improvement in reporting.⁸³
- *Consider which reports can be automated.* Automation is also considered in the section on [clinical decision support](#) above. Reports that are not automated should be simple and quick to create, and target staff should be trained on how to create them.
- *The software should be flexible to adjust to changes in reporting needs over time.* Reporting needs change over time. If the software is unable to adapt, then the EIR's usefulness will decrease. In Uruguay, the original EIR software was limited to a specific set of reports. Only when the country's EIR transitioned to a new software could reports be produced on vaccine timeliness and departmental-level vaccination coverage.⁵⁹
- *Include the option to export the reports and/or underlying data.* In Iran, it was helpful for reports to be printable for easy sharing with parents and schools.⁸⁴ Similarly, in Costa Rica, EIR users have the ability to export reports in Excel or PDF.⁷¹ Exporting to Excel enables users to customize their own analyses outside of the EIR.
- *Strengthen health care workers' capacity for data use.* As a primary audience for the EIR, it is important that health care workers have the capacity to analyze and use EIR data to inform decisions and take action.⁸⁵

Data aggregation at different geographic or administrative levels

EIRs should have the ability to aggregate data at different geographic or administrative levels to meet reporting requirements. Data users should be able to look at vaccine coverage by geographic level as well as by vaccine, dose, age, provider, or facility.⁴ This EIR functionality is important to enable identification of areas of lower vaccination coverage to inform future vaccination activities.

LESSONS LEARNED FROM IMPLEMENTATION

Data aggregation at different geographic or administrative levels

- *Aggregating data at different levels is dependent on the availability and accuracy of administrative or geospatial data on each level.* For example, to aggregate data by facility, a complete facility registry is needed; to aggregate up to the district level requires a complete crosswalk of facilities to their corresponding district; and so on up to the national level. Similarly, geographic aggregation requires relevant geospatial data.
- *Reports should be created for and accessible to stakeholders at all levels of the health system.* Box 3 describes the importance of EIR information to inform decisions at each level of the health system. In Zambia, EIR reports were only accessible at the facility and district levels, which inhibited the national monitoring and evaluation staff from monitoring vaccination in real time.²⁸

Adverse event reporting

Adverse event reporting is a specific type of report that focuses on AEFIs. This report can be integrated into the EIR or can be captured in a separate system that is interoperable with the EIR. Data elements captured include the AEFI itself as well as information like notification, investigation, management, and final classification of the AEFI;⁸⁶ date of the onset of symptoms;⁸⁶ and clinical manifestations and hospitalizations. WHO considers adverse event reporting an EIR best practice.⁴

By integrating with an EIR, AEFI data can be used in conjunction with stock management and vaccine event data for greater impact. Capturing AEFIs in the EIR can help improve the quality and timeliness of AEFI data, so actions taken in response to these data can be more evidence based and responsive. In Brazil, estimates for AEFI incidence had a more precise numerator and denominator when the adverse event reporting was linked to an EIR. And, since the EIR had information on the child's previous vaccinations, there were more data available to figure out the cause of an AEFI.⁸⁶

If the EIR captures information about the administered vaccine, then the AEFI can be traced to a specific vaccine lot. In this situation, an individual child can receive a vaccine, then later, if they have an adverse reaction, the specific vaccine lot can be traced and investigated. Other children who received vaccines from the same lot can be directly followed up to see if they had a reaction. This ability is vital for vaccine safety and can have significant impact on the overall success of a vaccination program.⁷² In addition to identifying quality issues with vaccine lots, adverse event reporting is important for correcting programmatic errors, investigating other vaccine-related events, and gathering information on factors related to public vaccine acceptability.

Nonfunctional requirements

Nonfunctional requirements describe *how* the system works or its quality attributes. Nonfunctional requirements discussed in this report include:

- Data exchange and interoperability.
- Offline capability.
- Alignment with international standards.
- Data privacy and security.
- Scalability and capacity.
- Usability.

Data exchange and interoperability

Interoperability is the capability of two or more systems to communicate and exchange data through specified data standards and communication protocols. Interoperable solutions improve efficiencies in data collection, increase data quality, and enable more powerful analysis of data across systems. Interoperable digital tools enable vaccination data to be exchanged across regional, national, and international levels and across other digital health information systems. EIRs are often interoperable with other information systems like facility registries, health worker registries, HMIS, LMIS, CRVS systems, electronic health records, or insurance systems. Interoperability should also be considered between EIRs if multiple distinct systems are used across a country. Understanding the existing ecosystem from the outset—by engaging with a diverse set of stakeholders (e.g., vaccination program staff, technical government staff, and ministry of health officials) as well as landscaping strategies, policies, and systems—can identify interoperability needs to that should be factored in the design.

Box 7: Additional resources for interoperability best practices.

- The World Health Organization led the development of the [*Digital Implementation Investment Guide*](#), which provides guidance for countries on integrating digital interventions into health programs, including a section on interoperability.
- The [OpenHIE Community of Practice](#) is building open standards for health information systems. Its work includes [architecture and standards](#) for health information exchange.
- MEASURE Evaluation developed the [Health Information Systems Interoperability Maturity Toolkit](#) to assess the components of health information system interoperability using a defined maturity model.
- Digital Square developed an [interoperability brief](#) that provides a definition of interoperability and includes a case study of how it has been applied to maternal, neonatal, and child health services—including vaccination—in Tanzania.
- The [Principles for Digital Development](#) provide guidance and best practices for digital development projects.

This requirement can be implemented as individual-level data sharing (e.g., between an EIR and a birth registration system) or as aggregate data sharing (e.g., between an EIR and a national HMIS). In Zambia, the EIR is built on the OpenSRP platform and is designed to be interoperable with District Health Information Software 2 (DHIS2), OpenMRS, RapidPro, and other tools.¹⁵ In Albania, health workers use a mobile phone application that is able to exchange information with the EIR.³⁶ In Vietnam, Viettel developed an application programming interface (API) to enable the EIR to connect with private facilities' independent systems.⁸⁷

EIRs can be developed as a module of a current digital health information system or as an independent system. If the EIR is a module of a larger system, then the software will be interoperable with the larger system from the onset. However, if vaccination functionality is being added to a system that already exists, that system may not have been designed to meet specific needs of vaccination use cases. If the module does not meet the needs of the vaccination staff, then work burden of the staff could increase as they try to use an incomplete system or need to use additional parallel systems.⁸⁸ Albania initially planned to build an EIR on an existing platform but ultimately developed a new system because the existing health information system did not have the ability to access national vaccination records.³⁶ By deciding to create the EIR separately, Albania had to intentionally plan for interoperability with the existing platform. In contrast, in Latin America, early EIRs were developed independently of other health systems and just for vaccination program use, which meant that they were not interoperable.²³

A common interoperability challenge is capturing vaccination services delivered at private facilities. Often, private facilities use their own data collection systems, and it can be difficult to ensure that the data are captured in the EIR. Pakistan has an EIR that is

in use across the Sindh Province, but children who are vaccinated at private facilities are not registered in the EIR.⁸¹ It is important to design ways to collect these data so the EIR has complete data on the population. As mentioned above, one way to do this is to use an API to connect the systems.

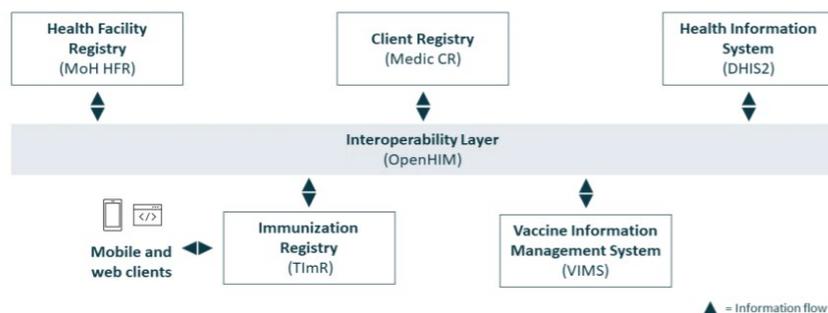
Interoperability allows for better tracking of cross-country or cross-territory migration. When an individual moves districts or countries, an interoperable EIR can easily transfer their vaccination records to the new registry. When it is unclear that a client has moved to a new facility or territory, records may be duplicated, which decreases the accuracy of population denominators.^{87,89}

Interoperability also allows for synergies with other information systems, including:

- Linking to CRVS systems for more complete birth registration and estimates of target populations.
- Linking to a vaccine-preventable diseases surveillance system to monitor vaccine impact.
- Linking to electronic health records to access additional personal health data.
- Linking to a stock management system to reduce vaccine waste.
- Linking to client and facility registries to improve data quality.

Finally, interoperability strengthens the health care system by increasing the value of the connected systems as opposed to individual tools. Parallel data capture can be eliminated or prevented from being created in the first place.²⁸ Interoperable EIRs can connect all vaccination data for more complete vaccination histories, efficient data analyses, and useful results.

Figure 7. Tanzania's EIR was designed for interoperability with other systems at the national level.



Source: PATH. *Digital Data Briefs: Interoperability Brief*. Seattle, WA: PATH: 2020. <https://digitalsquare.org/resourcesrepository/interoperabilitybrief>.

Abbreviations: CR, client registry; DHIS2, District Health Information Software 2; EIR, electronic immunization registry; HFR, health facility registry; MoH, ministry of health, TImR, Tanzania Immunization Registry; VIMS, vaccine information management system.

LESSONS LEARNED FROM IMPLEMENTATION

Data exchange and interoperability

- *During the EIR planning phase, align on language and terminology so stakeholders have a shared understanding of terms like “interoperability.”* This term may be conceptualized or understood differently by individuals in the health sector versus the information technology sector, which can lead to confusion. “Clear definitions of terms to ensure a common understanding of the technical language used is critical to developing and implementing an EIR.”⁸⁸
- *Regularly update systems architecture diagrams to support strategic decisions on interoperability and streamlining.* Understanding the wider national health information system and logistics systems architecture can help streamline data flows for improved efficiency and quality of care. This is particularly important in complex health information systems, like in Tanzania, where it was recommended by an external evaluation of the BID Initiative.⁹⁰

Offline capability

An EIR should be able to work in an environment subject to loss of power or Internet connectivity. This may include entering and storing data when there is no or limited Internet connectivity and then syncing that data to the online registry at a later date. This requirement is particularly important in LMICs where there may be limited or unreliable access to electricity and/or Internet connectivity.^{4,26,91} A recent survey of 730 health centers in Cambodia, Ethiopia, Kenya, Myanmar, Nepal, and Niger showed that 25 percent still had no access to electricity, and another 25 percent were regularly affected by outages and other reliability issues.⁹² It is important to design the EIR to work within these constraints.

There are multiple ways offline functionality can be implemented. Health workers can use a mobile phone or tablet to collect vaccination data even when there is no connectivity. The device stores the data locally until an Internet connection is available. In some cases, the health worker can access the stored data in the EIR to view or update before the data are synced.⁴ Another implementation method is combining a paper-based system with the EIR. In Albanian health facilities without Internet connection, health workers use paper forms to collect vaccination data. Every month, they report to a central health facility, which has access to the EIR and Internet connectivity, and at that point the information is entered into the EIR. In this case, there is not an offline version of the EIR software. Instead, the offline functionality is built into the operationalization of the EIR.³⁶ Shifo's Smart Paper Technology Solution is also designed in this way: health workers at the point of service enter data in Smart Paper Forms that are then scanned at the district or provincial level.⁹³

LESSONS LEARNED FROM IMPLEMENTATION

Offline capability

- *Consider multiple data input options that allow for limited, intermittent, or no Internet connectivity.* In Albania, health workers are able to input data from paper records into the online system at the facilities, at home, or at an Internet café.³⁶ In Brazil, health centers were able to send data directly to the State Secretary of Health to input into the system.⁹⁴
- *If using mobile devices, consider how they are charged.* If power is often unavailable, then using solar energy instead can allow for more consistent power.³³
- *Working offline should be part of health workers' normal routine.* If the EIR has offline capability, then the health workers should know what working online versus offline means for their work.
- *Consider how data are synced between devices.* Synchronization issues between two devices used in the same facility or with the central database⁵³ can lead to health workers become discouraged.²⁸ Working offline should not increase these problems.
- *Slow or intermittent Internet connectivity causes unique challenges that differ from no Internet connectivity.* It can be challenging to enter data quickly when the connection is slow or erratic.⁶ One EIR user noted that "when the system is blocked this creates problems as we miss information, and we have to reboot the system [...] and we get bored because of our work we are obliged to process things quickly."³⁶ When data uploads are slow, it can lead to user perceptions that the data entered are being lost.⁹⁰ EIRs should allow for data synchronization even when the Internet connection is intermittent and slow.

Alignment with international standards

According to the International Organization for Standardization, an international standard is “a document containing practical information and best practice. It often describes an agreed way of doing something or a solution to a global problem.”⁹⁵ It is important that an EIR is aligned to international standards because standards establish a common understanding across each level of the health system¹⁴ and ensure the EIR meets the needs of the vaccination program.⁸⁸ There are many types of international standards, including:^{34,53}

- Care guidelines, like recommended vaccination schedules.
- Content guidelines, or which data fields to collect.
- Coding standards, or how the data are formatted when stored.
- Interoperability standards, or how information is exchanged between information systems.
- Privacy standards to protect personal health information.
- Security standards for authentication, encryption, secure communication, etc.
- Common terminology standards, or how symptoms, diagnoses, and treatments are described.
- Messaging standards, or how messages are sent and received.
- Software accreditation standards.

An EIR should align with all the above international standards. In addition to international standards, the EIR should also align with national policies, standards, and national digital health architectures.

LESSONS LEARNED FROM IMPLEMENTATION

Alignment with international standards

- *Meaningfully engaging relevant stakeholders throughout the EIR system development process can help ensure alignment to standards.* This was the experience of the BID Initiative, where involvement of government departments for information and communication technology and monitoring and evaluation helped ensure alignment with national policies and strategies.¹⁴

Data privacy and security

The Principles for Digital Development highlight the need to address privacy and security, including consideration of how data are collected, used, stored, and shared.⁹⁶ Because EIRs store individual medical data, the data privacy and security requirements are essential to the protection of confidential patient-level data and their ethical usage. An EIR's privacy and security policies should align with national or international standards. If there are no country guidelines for privacy and security, they should be formulated and implemented. Safeguarding patient data is more important than ever because EIRs and electronic medical records are more prone to breaches than legacy paper-based systems.

There are many ways to ensure the privacy and security of patient data:⁹⁷

- **Confidentiality:** Anonymize data exports; provide password-protected access for authorized users with automatic logout after inactivity; and provide ability for allowed users to view confidential data.
- **Authentication:** Adhere to complex password requirements; provide mechanisms to securely change or reset passwords; and lock out users after a specified number of wrong password attempts.
- **Audit trail and logs:** Log system logins/logouts and activities performed by users; log all data and system errors; and log exchange of data with other systems.
- **User management:** Provide role-based access to the system; allow users to change their own passwords; and allow administrators to request a password reset.

To ensure that information is secured in an EIR, developers can follow the “privacy by design” strategy.⁹⁸ This strategy puts privacy at the forefront, building a system that proactively incorporates

security measures such that there are no gaps. Not only should privacy protection apply to internal threats, which include negligence by health workers, privacy protection should also consider external threats from hackers. Taking these things into consideration will ensure that patient data are only disclosed to the intended person. It is also important to ensure the safety of patient data because neglecting privacy and security issues can compromise public trust.⁹⁸

LESSONS LEARNED FROM IMPLEMENTATION

Data privacy and security

- *Be transparent about how the EIR aligns with international standards and national legislation on data protection and data privacy (especially those relating to health care data and records).⁹⁰*
- *Any system using Internet connectivity for managing health data is subject to security and privacy challenges. Strategies to maintain anonymity and preserve confidentiality can be difficult to implement. Moreover, relying on proprietary resources may be problematic if the underlying algorithms cannot be examined or shared.⁷²*
- *Design EIRs to protect data from unauthorized use and disclosure for varying levels of user access.⁸⁵*

Scalability and system capacity

Scalability and capacity requirements consider how systems scale nationwide, accommodate concurrent users, and are deployable across multiple devices and web architecture. EIRs need to be flexible to accommodate an increasing number of enrolled children, new vaccines that may be added to the recommended schedule, new age groups, new facilities, and other changes to the vaccination program within a country.

One way that scalability can be implemented is through the configuration of the EIR at different levels. For instance, in Albania, not only can national-level EIR administrators change vaccination schedules, they can also add new vaccines to the system. The addition of the vaccine in the vaccination schedules will be automatically updated in the EIR without changing the software. In addition, immediate supervisors have the ability to reconfigure the EIR, such as adding new nurses and health centers to the EIR system.³⁶

In Vietnam, the volume of data captured in the National Immunization Information System was identified as a barrier to scale-up. Despite conducting a sizing and infrastructure assessment to inform the server capacity and connectivity bandwidth, the number of clients, data transactions, and system users were not adequately anticipated for national scale. Nearly 20 million clients were captured in the National Immunization Information System, and this number will continue to increase as the population grows. The large amount of data housed within the National Immunization Information System meant that the system ran slower than anticipated. To address this challenge, both technological fixes (such as updating servers) and operational fixes (such as creating standard operating procedures for system downtime) were used.²⁷

LESSONS LEARNED FROM IMPLEMENTATION

Scalability and system capacity

- *Be aware of data storage capacity and consider future methods for increasing capacity.* Before implementing or scaling an EIR, it is important to know how much data can be stored before the systems slows down. Population-prediction analyses and stress tests are useful tools for quality control.^{36,87} Solutions to increase capacity include archiving data after a certain number of years⁹⁰ or acquiring more servers.^{28,87}
- *Ensure data are backed up or retrievable.* There should be a “a fallback solution (e.g., live replica)” and a “back-up and restore solution (e.g., restore the back-up of yesterday).”⁹⁰ Ideally, the backup approach should be part of the system design or a formalized process. In Honduras, there is no formal protocol to back up the EIR data, but a backup process is conducted weekly by the Health Statistics Unit.²⁶
- *Ensure the software design includes plans for data backup and retrieval.* The plan should include “master data management, data back-up, retrieval and storage, and data protection scenarios.” Additionally, it may be beneficial to do an independent technical evaluation of the EIR design and plan to scale.⁹⁰

Usability

In line with the Principles for Digital Development principle to “design with the user,” the EIR needs to meet usability requirements. The EIR should be user friendly for people with low computer literacy and be easy to learn and intuitive. The EIR can include alerts—for example, when the user navigates away from a form without saving—or informative tool tips or error messages. This may include clinical decision support messages or alerts, as discussed under functional requirements. Real-time data entry validation, predefined drop-down menus, and intuitive navigation between pages can all support usability. The EIR can be designed to support multiple languages and adjust the display to fit screens of various sizes for ease of use.⁹⁷

LESSONS LEARNED FROM IMPLEMENTATION

Usability

- *Software processes should be user friendly and intuitive for health workers.* It is easier to implement a new software if it is based on existing processes.³⁶ For example, digital vaccine cards could be color-coded to resemble the paper registries used previously. In Zambia, usability was achieved by designing the EIR to resemble the paper forms that health workers were familiar with.⁹⁹

Conclusion

EIRs have the potential to add value for vaccination programs, health systems, and beneficiaries if they are designed and implemented well and appropriate to the context. Reviewing previous experiences with EIRs can help to identify what has worked or has not—and, by doing so, build on the strengths and address the weaknesses of previous implementations.

Building on the findings in this report, we recommend the following steps for decision-makers considering implementing an EIR for the first time. Many of these recommendations can also be used to improve or expand existing EIR implementations:

- **First, identify the vaccination program or health system challenges you are trying to solve and whether an EIR may be the appropriate tool.** Reviewing the common challenges that EIRs are designed to address, as well as the potential added value of EIRs captured in this report, can help to inform this discussion.
- **If an EIR is determined to be a potential solution, use the EIR Readiness Assessment Tool to understand whether the appropriate enabling environment is in place to support an EIR.** The EIR Readiness Assessment Tool considers key building blocks, adapted from the WHO/International Telecommunication Union eHealth building blocks,⁷ that are necessary to support an EIR. These include:
 - Human capacity.
 - Standards and interoperability.

- Governance and policy.
- Process and information sources.
- Investments and funding.
- Infrastructure.

- **If there is sufficient readiness, identify EIR system requirements considering the operational lessons learned in this report.** Identifying clear requirements with input from all key stakeholders is the first step in the software development process. This report outlines functional and nonfunctional requirements for consideration, as well as lessons learned from operationalizing them.

Crosscutting themes include:

- Ensure the EIR is acceptable and useful for health workers and aligned to their clinic workflows. This can be achieved with a user-centered design process.
- Start with the critical requirements for a minimum viable product and take an agile development approach to iterate and add new requirements over time based on user feedback.
- Design the EIR to be interoperable with existing systems (e.g., birth registries, facility registries, national IDs, LMIS).
-

Adapt the EIR for the local context and engage the community to understand the health data that are entered into the registry and to address any fears or misconceptions surrounding the digital systems.

- Design the system to be flexible to adapt, change, and scale over time.

Similarly, system requirements can be used to expand the functionality of an EIR—creating new workflows and system efficiencies, or otherwise strengthening the software.

- **Consider whether an existing system or global good can be adapted for your context.** DHIS2 Tracker, OpenSRP, OpenMRS, and Shifo’s Smart Paper Technology Solution have been used as EIRs in multiple LMIC contexts. The Digital Square *Global Goods Guidebook* identifies other emergent and established global goods that are adaptable to different contexts. Otherwise, digital tools that are already used in a specific context may have the ability to add an EIR module; particularly, given the COVID-19 pandemic, many digital tools have been adapted to include vaccination data.¹⁰⁰
- **Design and implement the EIR in line with the national digital health strategy and roadmap.** Country governments are encouraged to develop a national digital health strategy and investment roadmap to ensure the EIR is integrated with existing systems and contributes to the national digital health enterprise architecture. This supports sustainability and scale of the EIR.

As new countries introduce EIRs, stakeholders should continue to share lessons learned on what works—and, importantly, what does not—so that others can learn and iterate on their own systems. And as EIRs are scaled, the evidence base will continue to grow, providing new information on how EIRs add value for vaccination programs.

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Appendix A: Additional details on research methods

This landscape was based on a nonsystematic review of literature on electronic immunization registry (EIR) implementations in low- and middle-income country settings. The research team developed a research framework focused on key questions, identified and reviewed documents, synthesized findings, and developed recommendations.

Research questions were identified in collaboration with stakeholders from the United States Agency for International Development and Centers for Disease Control and Prevention. The research questions that guided this work were as follows:

1. What electronic immunization registries and other primary health care registries have been implemented and where?
2. Among electronic registries that have been implemented, how have the functional and technical requirements been designed and operationalized?^f
 - a. What are the requirements?
 - b. What challenges were the registries designed to solve? Are there common categories of challenges across implementation contexts?
 - c. How have the requirements been operationalized?
 - d. What has/has not worked in practice (in implementing the requirements)?

3. What are the ways that electronic immunization and other primary health care registries add value for health systems and/or health outcomes?
 - a. What evidence is there on whether, how, and why the registries are contributing to improvements in vaccination program performance, coverage, and equity? For which populations and in what contexts?

Documents were reviewed and analyzed using ATLAS.ti (version 9). Table A1 lists the coding tree that was used. After coding and during analysis, the functional requirements codes were further grouped and categorized

^f The original research question referred to functional and technical requirements. The final report uses the term “nonfunctional” requirements in place of “technical” requirements, as we found this terminology more commonly used.

Table A1. Qualitative coding tree.

Themes	Subthemes	Definition
Health System Challenges		Existing challenges in the system that electronic immunization registries are designed to address. For example: lack of unique identifier, inaccurate or uncertain population denominators, incomplete or untimely data, siloed public and private sectors, unreliable or inconsistent Internet connectivity, difficulty identifying and following up with defaulters, poor data visibility at the facility level, incomplete data collection tools, overburdened health care providers.
Operationalization	Challenges	Any challenges mentioned that are related to the use or implementation of electronic immunization registries. For example: acceptability of barcodes as a unique ID.
	Best practices	Best practices or things that worked well in implementation.
Functional Requirements	Enrollment at birth	Information on all children born in the system's catchment area. Should be entered within a set period of time, such as 48 hours. Possible linkage to civil registration and vital statistics system.
	Unique and unequivocal ID	A unique ID number or system for identifying each child. Examples:
	Vaccine event data	Data on vaccination provider, vaccine dose, date of vaccination, patient age, patient sex, patient contact information, target group, and geographical area.
	Client management	Ability to search for, identify, and consolidate duplicate records.

Functional Requirements	Clinical decision support	Calculate follow-up vaccination schedule, follow-up reminders.
	Identification of undervaccinated children/missed vaccination	Ability to access information on children who are undervaccinated or, when possible, unvaccinated.
	Stock management	Manages inventories of commodities, such as vaccines, used in public health programs. Includes ordering, storing, tracking, and controlling inventory.
	Health facility management/mapping	Digital approaches that enable administrative functions related to management of facilities.
	Mechanisms for aggregating data at different geographic levels	Allows data users ability to easily aggregate data at different geographic levels in order to meet reporting requirements.
	Nonroutine data collection and management	Ability to access data on outreach and campaign events, including microplanning, potential future use of decision support, data from an electronic immunization registry on the timing and locations of vaccination sessions might allow vaccinators to better time clinic hours, and mobile and outreach strategies.
	Reporting	Ability to generate simplified reports on vaccine administration.
	Adverse event reporting	Ability to collect information on unexpected negative reactions to a vaccination, as well as document the death of a child who will no longer be followed in the system.

Functional Requirements	Caregiver information and reminders	Caregiver (and child) contact information, including locations. Reminders for caregivers that it is time to return for their child's next vaccination dose via text, or email or voice. May or may not include automated individual follow-up of vaccination schedules.
	Linkages to other health areas	Current health status, disease, health history, delivery of nonvaccination services.
	Social determinants of health	Information on a family's socioeconomic situation, such as caregiver education level, heating source, and indicators of overcrowded living.
Technical Requirements	Data exchange and interoperability	Capability of two or more systems to communicate and exchange data through specified data formats and communication protocols.
	Offline capability	Ability to work in offline mode until system can be synced online.
	Alignment with international standards	Alignment with World Health Organization vaccination schedules or other care guidelines, with content guidelines (e.g., HL7 data standards), or with coding standards.
	Data privacy and security	Mechanisms in place to ensure data security and patient protection.
	Scalability and capacity	How the system is designed to scale nationwide or to accommodate concurrent users.
	Licensing	Whether software is open source or proprietary.
Added Value	Information	Population denominator, high-quality data, access to data, use of data, unique ID.
	Availability	Availability of commodities, services, equipment, health workers.

Added Value	Quality	Quality of care provided, including patient experience, health worker motivation + competence.
	Acceptability	Alignment with local norms and individual beliefs/practices.
	Utilization	Demand for services, geographic access, adherence, reduced loss to follow-up.
	Efficiency	Workflow management/referrals, planning and coordination, timely provision of care.
	Cost	Reduced manual processes, effective resource allocation, client-side expenses, coordinated payer mechanism.
	Accountability	Patient engagement, awareness of services, community feedback mechanisms, etc.
Outcomes	Coverage and equity	Improved vaccination coverage and equity.
	Health outcomes	Improved health outcomes in vaccine-preventable disease incidence, morbidity, and mortality.

Appendix B: EIRs implemented, by country

Country	Summary
<p>Afghanistan</p>	<p>MyChild Solution, which is built on Shifo's Smart Paper Technology, is being implemented on a subnational scale within the Mihterlam District of Laghman Province. It was designed to replace a paper-based system, with the addition of a digital component that allows paper forms to be scanned and uploaded to an electronic medical record for each child. ^{101,102}</p> <p>Hayat (formerly Teeko+ in pilot phase) is a bespoke software that has been implemented subnationally in Afghanistan. It is a mobile Android application and web portal to track vaccinations and other maternal, newborn, and child health services. Hayat is in progress to add stock management capabilities as well. ^{103,102}</p>
<p>Albania</p>	<p>The national Immunization Information System, a database and web-based software application developed by the MOH and Project Optimize, is being implemented nationally in Albania. The Immunization Information System is able to record vaccination events, create vaccination schedules, and manage stock. ³⁶</p>
<p>American Samoa</p>	<p>The national Immunization Information System, which is based on the proprietary software WebIZ™ developed by Envision, is implemented on a national scale. In addition to American Samoa, all United States–affiliated Pacific Islands use this EIR. ^{89,104}</p>
<p>Argentina</p>	<p>NOMIVAC is the Federal Register of Nominal Vaccination in Argentina. It is implemented nationally and already being used for registering COVID-19 vaccinations. ^{105,101}</p>

Bangladesh	<p>mTika, an implementation of the open source software OpenSRP, was piloted in the Kaliganj Subdistrict under the Gazipur District of Bangladesh. mTika registers mother and children, tracks vaccinations, creates vaccination schedules, and allows health workers to send SMS reminders to caregivers and patients. ^{15,106}</p> <p>The Electronic Birth Registration Information System, which is built on the software Bangla, is used by the Department of Public Health in Rajshahi City, Bangladesh. The Electronic Birth Registration Information System registers births as well as tracks vaccination data.¹⁷</p> <p>DHIS2 Tracker is a module of the DHIS2 open source software. DHIS2 Tracker was first implemented in 2019 with a pilot in three districts.¹⁰¹</p>
Belize	A vaccination module was added to the national Belize Health Information System around 2014. ²³
Benin	The VaxTrac organization was funded to create an EIR for Benin. The tablet-based system created was initially piloted in 39 health facilities in 2012, then expanded to 100 facilities. ^{107,108,109}
Bermuda	In 2019, a national nominal EIR was implemented in Bermuda. In December 2020, it was announced that an EIR from PAHO would be used to support COVID-19 vaccination rollout. ^{101,110,111}
Bolivia	Bolivia is currently piloting an EIR. ¹⁰¹
Brazil	<p>The Information System of the National Immunization Program (Sistema de Informação do Programa Nacional de Imunização) is currently being implemented on a national level in Brazil. It is a database of vaccine information, as well as the information system on AEFI.^{86,94,112}</p> <p>The first EIR implemented in Brazil was in the municipality of Araraquara in the state of Sao Paulo in 1987. In 2011, the EIR was refreshed and renamed the Juarez System.^{86,113,112}</p>
Burkina Faso	Burkina Faso uses DHIS2 Tracker to collect other health data. It is interested in implementing an EIR but has had challenges with funding. ¹¹⁴

China	In 2006, Jiangsu Province implemented an EIR that collects vaccination data from vaccination clinics and uploads these data to provincial servers. It was planned to connect this EIR to maternal, newborn, and child health systems and health information management systems. ³¹
	The EIR Smartphone Application (EPI app) is implemented in two townships in Xuanhan County, Dazhou City, Sichuan Province. Village doctors use the app to track vaccination records, locate undervaccinated children, and receive information about vaccination. ³
	The Zhejiang Provincial Immunization Information System is implemented subnationally and links to all vaccination clinics in the province. In addition to the client application software in clinics, the software also is available at the Zhejiang provincial Center for Disease Control and Prevention. ¹¹⁵
Colombia	Nominal Vaccination Information System (SINV in Spanish) is implemented subnationally in the area of Bogotá. SINV supports real-time data entry, locates undervaccinated children, and provides caregivers online access to vaccination records. ^{34,101}
	PAIWEB is used nationally in Colombia to register vaccinations under the Programa Ampliado de Inmunización. PAIWEB is being expanded for to the COVID-19 vaccine rollout with the addition of a cold chain registry. ^{101,116}
Costa Rica	SINOVAC was designed by the Costa Rican government from 2009–2010 to register all vaccination data in the country. SINOVAC is implemented nationally ²³
Cote d'Ivoire	Cote d'Ivoire is currently piloting an EIR in three health facilities with Orange. ¹¹⁷
Dominican Republic	In 2014, the Dominican Republic was in the process of developing an EIR. ²³
Ecuador	Ecuador has implemented an EIR. ¹⁰¹
El Salvador	El Salvador includes vaccinations given at birth in the national electronic birth records. ²³
Ethiopia	Medic Mobile software is used as a platform for mobile data collection. Community health workers enter data directly to support antenatal care and vaccination activities. ¹¹⁸

The Gambia	The MyChild Solution, which is built on Shifo's Smart Paper Technology, has been implemented in two regions since March 2020. This software was piloted in 2017 along with two other EIR tools. MyChild Solution was prioritized by the MOH due to its interoperability with DHIS2. ¹¹⁹
Ghana	DHIS2 Tracker, an open source software that is a module of DHIS2, is used in Ghana to support vaccination efforts. It has been fully or partially deployed in seven different regions. ^{120,121}
Grenada	Grenada has implemented an EIR. ¹⁰¹
Guatemala	SIGSA Web had a vaccination registry module into which paper records were uploaded. Due to challenges with entering paper-based data and new government leadership in 2011, the project lost support. ⁶
Guinea-Bissau	The Guinea-Bissau Twin Registry-NI was implemented by the Bandim Health Project in 2009. Vaccination data are collected in the registry, along with other types of data. ¹²²
Haiti	Electronic mHealth System is built on the open source software ODK. It was piloted in 2011 by the MOH, GHESKIO, and Partners In Health for an oral cholera vaccination campaign in Port-au-Prince and two rural communities in the Artibonite Valley. ⁶⁵
Honduras	SINOVA is a bespoke system used at the national level. Phased implementation of SINOVA started in 2009. Health facilities submit paper forms, and data entry into SINOVA occurs at the regional level. ²⁶
India	The Mother and Child Tracking System is a bespoke system implemented nationally in India across all regions. It monitors service delivery, including vaccinations, and can act as a two-way communication system. ¹²³
Indonesia	The Technologies for Health Registries, Information, and Vital Events (THRIVE) project built a tool, using the OpenSRP, open source software, that is implemented subnationally in five districts of Indonesia. ^{15,101,124}

Iran	Iranian Immunization Registry is a bespoke web-based system that was implemented in 2016 in Shiraz City, with plans to make it into a national vaccination registry. ^{75,84}
Kenya	<p>The Kenya Immunization Platform (KIP) was developed by the MOH and built on the OpenSRP open source software. It is implemented in Siaya County. Health care workers use a tablet to register children and record vaccination events. It is able to follow up on children across health facilities and record services other than vaccination. ¹⁵</p> <p>The Kilifi Vaccine Monitoring System is the electronic registry within the Kilifi Health and Demographic Surveillance System. As of 2016, it was being implemented in 36 different vaccine clinics. ¹²⁵</p> <p>Regional Action through Data implemented an electronic health information system to support vaccination continuity of care for children who live along the Uganda-Kenya border. ¹²⁶</p> <p>The AMPATH program provides vaccinations for children. Vaccinations that occur at AMPATH clinics are entered from paper forms into the AMPATH Medical Record System, which is an implementation of OpenMRS, an open source software. ¹²⁷</p>
Kyrgyz Republic	Kyrgyz Republic is currently in discussions about implementing an EIR using DHIS2. ¹¹⁷
Laos	DHIS2 is being piloted on a small scale in Laos. ¹¹⁷
Malawi	Emmunize is currently being piloted in Malawi. ¹⁰¹
Mali	An EIR, built on the DHIS2 open source software, is being implemented in two Bamako municipalities. There are plans for a big scale-up in the future. ^{117,128}
Marshall Islands	The national Immunization Information System, which is based on the proprietary software WebIZ developed by Envision, is implemented on a national scale. In addition to Marshall Islands, all United States-affiliated Pacific Islands use this EIR. ^{89,104}
Mauritania	An EIR pilot is being planned, with support from Mastercard. ¹¹⁷

Mauritania	OpenSRP is being used as an EIR in Mauritania. ²¹
Mexico	<p>Sistema Integral de Vacunación was developed in 2018 to link health records with a mobile application into which vaccinators can input vaccination data.^{101,129}</p> <p>PROVAC was Mexico's EIR since 1991, but it was terminated in 2013 due to coverage discrepancies.⁶³</p>
Micronesia, Federated States	The national Immunization Information System, which is based on the proprietary software WebIZ developed by Envision, is implemented on a national scale. In addition to Micronesia, all United States-affiliated Pacific Islands use this EIR. ^{89,104}
Mongolia	In 2017, the MOH developed an EIR to record vaccinations for the introduction of the PCV13 vaccine. The implementation began in two districts with plans to expand nationally if successful. ²⁹
Mozambique	mVacciNation, software developed by Mezzanine, was first piloted in Mozambique in 2014. It uses mobile phone technology to support health workers and caregivers. ¹³⁰
Nepal	VaxTrac was implemented in two districts of Nepal by the Vial to Child Project in 2014. This was the second country implementation of this software, with the first being in Benin. ¹⁰⁹
Nicaragua	Nicaragua uses mVac, an open source mobile application for vaccination. ²³
Nigeria	Nigeria is planning on using DHIS2 Tracker as an EIR in all 28,000 health facilities. DHIS2 Tracker is a module of the open source software DHIS2. DHIS2 has already been adopted at the national level. ^{131,132}

Pakistan	<p>The Zindagi Mehfooz (Safe Life) Digital Immunization Registry is built on the open source software OpenSRP. It was piloted in 2016 in Korangi Town in Sindh Province before being selected for further scale-up. Since 2020, the whole province has been using Zindagi Mehfooz; there also is a pilot in Gilgit Baltistan.^{66,101,117,133}</p> <p>EPI MIS is a web-based system that manages different aspects of Pakistan’s EPI program, such as human resources, vaccination coverage, microplanning, and cold chain equipment, among others. This is implemented in six of the eight regions of Pakistan.¹¹⁸</p> <p>Child Electronic Registration and Vaccination, built on the open source software OpenSRP, is linked to the EPI MIS. It is being piloted in two districts of Khyber Pakhtunkhwa and one district of the Islamabad Capital Territory.¹¹⁸</p> <p>Hayat (formerly Teeko+ in pilot phase) is a bespoke software that was piloted in the Tando Muhammad Khan District of Sindh Province.^{38,118}</p> <p>e-Vaccs is an app to track vaccinator movements through GPS. When implemented in Punjab Province in 2014, there was an increase in vaccinator attendance and in geographic coverage.^{38,134}</p> <p>A new EIR is being piloted in Pakistan.¹¹⁷</p>
Paraguay	Paraguay is currently implementing a national EIR called PAI Infovac. ^{23,101}
Peru	Padrón Nominal is a children population registry created in 2012 that collects vaccination data. Padrón Nominal was intended to register children on a national scale; however, as of 2018, it had not been fully implemented. ⁶³
Rwanda	DHIS2 Tracker, a module of the DHIS2 open source software, was deployed at the health facility level in Rwanda in 2018. It is being used currently for COVID-19 vaccine delivery. The MOH is planning to develop a custom EMR system to use in the future. ¹³⁵
Senegal	Senegal is using DHIS2 Tracker, a module of the DHIS2 open source software, as an EIR. ¹⁰¹

Sierra Leone	VacTrac was piloted in 2016 in the Western Area District. VacTrac was developed with funding from the Bill & Melinda Gates Foundation and was initially piloted in Benin and Nepal before being used in Sierra Leone. VacTrac is able to use biometrics to identify individual vaccination records. ^{107,118}
Solomon Islands	The Solomon Islands are currently in discussions about implementing DHIS2 Tracker as an EIR. ¹¹⁷
Sri Lanka	DHIS2 Tracker was deployed in Sri Lanka for COVID-19 vaccine delivery in January 2021. It can track vaccinations and AEFI, as well as manage vaccine stock. ¹³⁶
Tanzania	The Tanzania Immunization Registry (formerly the Tanzania Immunization Information System) is built on SanteSuite, an open source software (formerly OpenIZ). After successful rollout in four regions, the government planned to scale nationally by 2019. The Tanzania Immunization Registry is integrated with the vaccine information management system. ^{35,53} mVaccination, a software developed by Mezzanine that allows health workers to capture vaccination data and track vaccine stock. It is implemented on a subnational level in Tanzania. ¹³⁷
Thailand	The StatelessVac project is being implemented in the Chiang-Rai Province on the border of Thailand, Myanmar, and Laos. The tool developed for this project uses mobile health functionalities for case registration and management to increase vaccination coverage of the stateless populations who reside in the area. ¹³⁸
Tunisia	OpenSRP is being used as an EIR in Tunisia. ²¹
Uganda	MyChild Solution, which is built on Shifo's Smart Paper Technology, was one of many EIR tools piloted in Uganda. The MOH assessed all interventions piloted and decided to scale up the MyChild Solution in 30 districts, with funding from Gavi, the Vaccine Alliance. ^{101,135}
Venezuela, RB	Venezuela is piloting a platform to track yellow fever vaccinations. ²³
Vietnam	The National Immunization Information System developed from ImmReg, which was piloted in Ben Tre Province in 2012. Over the next five years, the system absorbed another pilot system called VacTrax, which was scaled up to the national level as the National Immunization Information System. ^{87,139}

Zambia	<p>The Zambia Electronic Immunization Registry, built on the open source software OpenSRP, was first deployed in Southern Province in 2017. It was then expanded in pilots in six facilities in Livingstone and then deployed in 299 facilities in Southern Province. There are plans to expand into Western Province by 2021. ^{15,53}</p> <p>The SmartCare™ electronic health record system is used by over 900 health facilities in Zambia. It has a vaccination module, but it is used by less than 10 percent of health facilities. ³⁹</p>
Zimbabwe	<p>Zimbabwe is currently piloting a custom-made EHR in two districts. ¹¹⁷</p>

Abbreviations: AEFI, adverse event following immunization; AMPATH, Academic Model Providing Access to Healthcare; DHIS2, District Health Information Software 2; EIR, electronic immunization registry; EPI, Expanded Programme on Immunization; MIS, Management Information System; MOH, Ministry of Health; OpenSRP, Open Smart Register Platform; PAHO, Pan American Health Organization; PCV13, 13-valent pneumococcal conjugate vaccine; SINOVAC, Sistema Nominal de Vacunación

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