ELECTRONIC IMMUNIZATION REGISTRY:

Practical Considerations for Planning, Development, Implementation, and Evaluation

Pan American Health Organization

World Health Organization
REGIONAL OFFICE FOR THE Americas

Original version in Spanish:
Registro nominal de vacunación electrónico: consideraciones prácticas para su planificación, desarrollo, implementación y evaluación.
ISBN: 978-92-75-31953-6

Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation.
ISBN: 978-92-75-11953-2

Suggested citation. Pan American Health Organization. Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation. Washington, D.C.: PAHO; 2017.

Cataloguing-in-Publication (CIP) data. CIP data are available at http://iris.paho.org.

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Acknowledgements

The document "Electronic Immunization Registry: Practical Considerations for Planning, Development, Implementation and Evaluation" was written jointly by Marcela Contreras, Gabriela Félix, and Martha Velandia with support from experts in countries of the Region of the Americas and other regions of the world, under the general coordination of Cuauhtémoc Ruiz Matus of the Comprehensive Family Immunization Unit of the Department of Family, Health Promotion and Life Course in the Pan American Health Organization (PAHO). Other PAHO technical staff members who collaborated in the development of the document were Gabriela Fernández, Gladys Ghisays, David Novillo, Claudia Ortiz, Carla Sáenz, Samia Samad, and Octavia Silva.

We would like to express our gratitude to the professionals from other institutions that contributed to the revision of this document: Rebecca Coyle and Carmela Gupta of the American Immunization Registry Association (AIRA); Laurie Werner of the BID Initiative/PATH; Tarik Derrough of the European Center for Disease Prevention and Control (ECDC); Kristie Clarke, Daniel Elhman, David Lyalin, and Daniel Martin of the United States Centers for Disease Control and Prevention (CDC); Tove Ryman of the Bill & Melinda Gates Foundation; William Avilés and Heather Zornetzer, independent consultants; Antonia Teixeira from the Brazilian Ministry of Health; Carolina Danovaro and Jan Grevendonk of the World Health Organization (WHO); Daniel Otzoy of the Central American Network of Health Informatics; and Patricia Arce from the Secretary of Health of Bogotá.

Lastly, we would like to express our gratitude to the Bill & Melinda Gates Foundation for its technical and financial support in the development of this document and activities to improve the quality and use of data in the Region of the Americas. Similarly, we would like to extend our thanks to all the national immunization programs in the Region, whose experiences and contributions allowed this important work to be carried out.

Acronyms

AIRA	American Immunization Registry Association
BCG	Bacillus Calmette-Guérin (vaccine against serious forms of tuberculosis)
CDC	U.S. Centers for Disease Control and Prevention
CPU	central processing unit
CRDM	Collaborative Requirements Development Methodology
DPT	diphtheria/pertussis/tetanus vaccine (also abbreviated DTP)
DQA	data quality audit
DQS	data quality self-assessment
EHR	electronic health record
EIR	electronic immunization registry
EMR	electronic medical record
EPI	Expanded Program on Immunization
ESAVI	events supposedly attributable to vaccination or immunization (also known as adverse events following immunization or AEFI)
EU	European Union
GIS	geographic information systems
GVAP	Global Vaccine Action Plan
HIS	health information systems
HPV	human papillomavirus
ICT	information and communication technology
IIS	immunization information systems
ISP	institutional service provider
LIS	laboratory information systems
MOH	Ministry of Health
NGO	nongovernmental organization
PACS	picture archiving and communication systems
PAHO	Pan American Health Organization
PATH	Program for Appropriate Technology in Health
PHII	Public Health Informatics Institute
RENIEC	National Registry of Identification and Marital Status (Spanish acronym)
RIAP	Regional Immunization Action Plan
RIS	radiology information systems
RUAF	Single Registry of Affiliates (Spanish acronym)
TAG	Technical Advisory Group
TCO	total cost of ownership
UID	unique identifier
VPD	vaccine-preventable diseases
WHO	World Health Organization

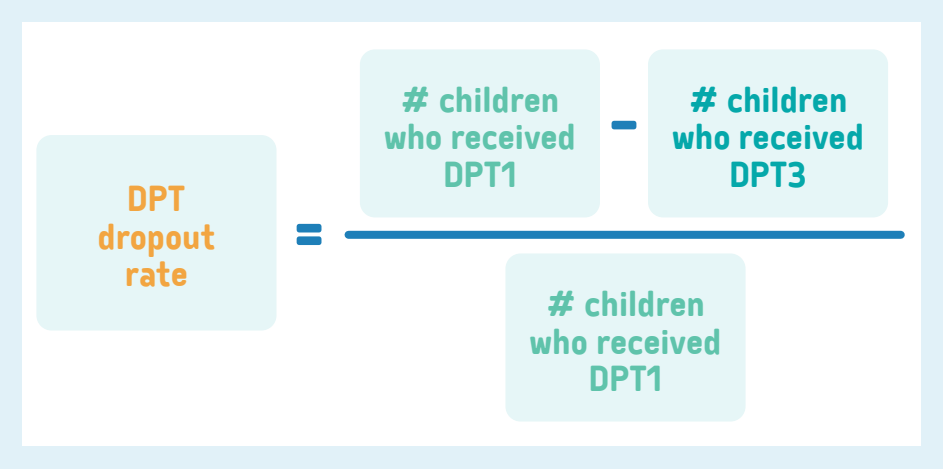
Glossary

Business rules
Rules that describe a condition and specify an action to be taken on the basis of said condition.

Continuing education in information and communication technologies
Courses or programs for health professionals (not necessarily formally accredited) that support learning and development processes and facilitate acquisition of information and communication technology skills applicable to the field of health. This includes current methods for the exchange of scientific knowledge, such as electronic publications, open access, digital literacy, and the use of social networks.

Defaulters
Individuals who do not access health services in time to receive vaccination.

Dropout rate
Refers to the percentage of vaccination recipients (e.g., children) who begin their schedules but do not complete them. For example, the DPT dropout rate is calculated by dividing the number of children 12-23 months who received DPT1 minus the number of children 12-23 months who received DPT3 by the number of children 12-23 months who received DPT1.



eLearning
Consists of the application of information and communication technologies to learning. It can be used to improve the quality of education, increase access to education, and create new and innovative forms of education that can reach a greater number of people. Includes distance learning or training activities.

Electronic immunization registry (EIR)
Confidential, population-based information system that contains data on vaccine doses administered. This type of system allows monitoring of vaccination coverage by service provider, vaccine, dose, age, target group, and geographical area, and yields results that facilitate individualized monitoring of immunization recipients. EIRs support immunization programs by providing timely and precise information. According to PAHO, individualized registries are those registries which identify the vaccination data of each individual, thus providing access to individual vaccine history and facilitating active capture, in addition to supporting monthly planning of those who should be vaccinated and following up defaulters or dropouts [1, 2].

Electronic medical record
An electronic record of information on the health of each patient. Also known as "electronic clinical history."

Extramural activities
Vaccine administration that takes place outside a health facility, as part of a campaign or routine immunization program.

Immunization program efficiency

Refers to 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.

Individualized vaccination registry

An individual registry ordered by origin of data on each vaccinated person. Upon administering each vaccine, the unique ID of the individual is recorded, as well as his or her name and other general data, such as contact information for reminders, the date of administration of each vaccine, and other data on the vaccination (facility, vaccinator, etc.). Allows determination of whether a person is up to date on immunization schedule for his or her age and even to determine if he or she has been vaccinated in a timely and correct fashion. Individualized registries can be paper-based or electronic.

Interoperability

Communication between different technologies and software applications for the exchange and use of data in an effective, precise, and robust manner. Intra- and extraorganizational interoperability allow for more agile information flows and processes.

Intersectoral

Government sectors other than the health sector (e.g., education, finance, social development, etc.).

mHealth

Short for "mobile health," this term refers to the practice of medicine and public health with the support of mobile devices as ancillary tools to improve diagnostic processes, using mobile phones, patient monitoring devices, and other wireless devices.

Non-individualized immunization registry

Any immunization registry based on immunization events and not on individuals that pools data on vaccinated individuals by ranges of variables, such as age group, sex, place of residence, and/or health facility in which the vaccine was administered, but does not disclose the name of each vaccinated individual and does not allow individualized monitoring of vaccination status. For example: doses applied by vaccination schedule and by type of vaccine to a vaccine recipient. Its main objective is to allow the number of people vaccinated to be counted and thus allow calculation of immunization coverage by dividing this number by the target population for that vaccine and dose.

Offline electronic immunization registry

An EIR that operates offline (disconnected from the Internet) and, as a result, is not available for real-time immediate use, can be operated independently, and can be synchronized by use of removable storage media. Database transfers at all levels should follow a standardized flow for data consolidation.

Online electronic immunization registry

An EIR system that operates online (connected to the Internet) and is available for real-time immediate use. Requires adequate infrastructure (connectivity) to be able to operate; however, it can be adapted to operate via synchronization in limited-connectivity environments.

Paper-based individualized registry

In the majority of countries, each vaccination center keeps an individualized paper-based record that tends to include the name and date of birth of the user, information on the mother or caregiver in the case of children, address and/or telephone number, day, month, and year of visit, vaccines administered, and the number of corresponding doses. When ordered by user, this registry allows monitoring of individual vaccination schedules; this facilitates monthly planning of vaccinations and monitoring of those who are behind on their doses.

Principles
Recommendations for practice.

Programmatic errors
Preventable error caused by inappropriate handling, prescription, or application. For example: vaccinating someone who has a contraindication, poor vaccine administration technique, administration of vaccines not indicated at the proper age, duplicate administration of the same vaccine, duplicate registration of a single immunization event, incorrect route of administration, and use of expired vaccines, among others.

Standardization
Corresponds to the application of standards, i.e., regulations, guidelines, or definitions of technical specifications, to make feasible the integrated management of health systems at all levels. It is a requirement for successful interoperability. Its adoption has the potential to contribute to the exchange of information and data between information systems within and outside organizations.

Telehealth (including telemedicine)
Health services delivery by means of information and communication technologies, especially where distance is a barrier to accessing health care.

Total cost of ownership
The total cost of ownership (TCO) is calculated through a comprehensive evaluation of all costs associated with information systems and ICTs. The TCO takes into account all organizational expenses pertaining to hardware and software procurement, management and technical support, communications, training, system upkeep, updates, operating costs, networking, security, licensing costs, and the opportunity costs of system downtime, among others.

Use case
Description of the steps and/or the activities that should be conducted in order to carry out a given process. In the context of eHealth, it is a sequence of interactions that will take place between a system and its actors in response to an event initiated by a main actor in the system itself. Use case diagrams are used to specify the communications and patterns of a system through its interaction with users and/or other systems.

User
Health provider or other person who uses an information system, whether the EIR or another.

Vaccine recipient
Individual who accesses the health services and benefits from an immunization program.

Variables
Fields in the immunization record.

Introduction

Electronic immunization registries (EIRs) are tools that facilitate the monitoring of individual immunization schedules and the storage of individual immunization histories, and, consequently, help enhance the performance of the Expanded Program on Immunization (EPI), in terms of both coverage and efficiency.

Evidence suggests that EIRs are cost-effective tools that help increase coverage, improve the timeliness of vaccination, reduce revaccination due to unverifiability of previous immunizations, and provide reliable data for decision-making, e.g., where to search for unvaccinated individuals in order to ensure the right to equitable immunization. EIRs also enable monitoring of the immunization process with a view to optimizing ancillary activities. For example, EIRs provide accurate and timely information, thus facilitating planning of resources and activities. Furthermore, from a process standpoint, knowing the productivity of each vaccinator could help improve workload distribution. These tools also allow detection of problems in implementation of existing regulations (e.g., administration of vaccines to nontarget populations) and assist in directing training and supervision activities. Finally, it has been proven that EIRs offer useful, reliable information for conducting vaccine effectiveness and safety studies, among other research.

Progress toward the development and implementation of EIRs responds to progress both in immunization programs and in information and communication technologies (ICTs) and connectivity, as well as to the information requirements of the EPI. Immunization schedules have become a great deal more complex with the introduction of new, more expensive vaccines that benefit not only the pediatric population, but the general population throughout the life cycle. This has led to an increase in program budgets, which, in turn, created a need for increasingly precise, complete, and systematic accountability. In a context of relatively high vaccination coverage, it has become more difficult to detect who lacks complete compulsory vaccine coverage, thus hindering strategies for identification and immunization of these individuals. Finally, ICTs, geographic information systems (GIS), and connectivity are increasingly omnipresent and attainable, which has allowed the development of user-friendly information systems and databases to handle large volumes of information simultaneously and rapidly while ensuring data security and confidentiality.

Developing an EIR, implementing it at the country level, and, above all, ensuring its sustainability are not easy, fast, or inexpensive processes. However, the experience generated by multiple EIR development projects, and the success of some of these programs, can be used as sources of best practices and provide many lessons learned. This document on EIRs compiles these experiences and provides an overview of the EIR planning, design, and implementation stages to make the road easier for countries that are considering embarking on this journey or have already done so. The document introduces important concepts, examples, country experiences, case studies, tools (such as checklists and data quality assessment forms, among others), and practical considerations and questions to facilitate decision-making at each stage of EIR development and implementation.

ABOUT THIS DOCUMENT

This document is designed to support EPI managers and their teams in the implementation of EIR-related information systems, using the various experiences compiled at the global level – and, especially, in the Region of the Americas – as a foundation. Within this context, the main objectives of this document are as follows:

» To generate knowledge related to information systems and immunization registries for immunization program managers at the national and subnational levels;

» To provide teams, EPI managers, and experts in health information systems with relevant background and experiences for development, implementation, maintenance, monitoring, and evaluation of EIR systems, so as to support planning of their implementation;

» To provide technical, functional, and operational recommendations that can serve as a basis for discussion and analysis of the standard requirements needed for development and implementation of EIRs in countries of the Region of the Americas and other regions;

» To serve as a platform for documentation and sharing of lessons learned and successful experiences in EIR implementation.

This document is structured into three major sections: background; EIR planning and design; and EIR development and implementation, taking into account the relevant processes and their structure (Figure 1).

The content of the chapters is supported by a literature review of aspects related to EIR requirements, and summarizes the experiences of the countries of the Region of the Americas and other regions that already have EIRs in place or are at the development and implementation stage. Many of the experiences presented herein have been shared during the three editions of the "Regional Meeting to Share Lessons Learned in the Development and Implementation of Electronic Individualized Vaccination Registries," held in 2011 in Bogotá (Colombia), in 2013 in Brasilia (Brazil), and in 2016 in San José (Costa Rica), in addition to ad hoc meetings held by the Pan American Health Organization/World Health Organization (PAHO/WHO) and Member States.

TARGET AUDIENCE

This document is geared toward decision-makers in Ministries of Health, immunization programs and their managers, and national information and statistics units or departments within PAHO Member States, in order to provide support and guidance for the adoption and implementation of electronic immunization registries.

FIGURE 1.
General model of module structure

GENERAL CONSIDERATIONS

PAHO/WHO recommends the use of EIR systems given the potential benefits that these information systems can provide to the countries of the Region. However, it is important to note that under no circumstances does PAHO intend to force countries to implement this type of information system; rather, it recommends that their use be considered taking the current context into account, although actual implementation will depend on each country's national priorities and realities.

The tables, variables, and methods presented in this document are general considerations, and do not necessarily constitute exhaustive recommendations on the part of PAHO; each country can define their utility and feasibility.

The ordering of modules in this document allows the reader to decide what chapters to focus on. There is no need to read chapters in the order they are presented.

ACKNOWLEDGMENTS

The Improving Data Quality for Immunizations (IDQi) project team is grateful for the financial contributions of the Bill and Melinda Gates Foundation that made this work possible. Furthermore, we are deeply thankful for the technical and content contributions provided by the countries of the Region of the Americas, by our colleagues at WHO Headquarters, and by the Members of the IDQi Project Technical Advisory Group.

1

Background on health information systems

Decision-makers at all levels of the health system require relevant, reliable, and timely information to support the decision-making process. Information systems play a key role in producing the information that will guide the strategic, managerial, and operational decisions of any health program. Furthermore, they provide essential data for monitoring and accountability, both to higher hierarchical levels and to the beneficiary population in general. In this context, the Expanded Program on Immunization (EPI) uses multiple information systems, including Electronic Immunization Registries (EIRs). This chapter will provide background and context on health information systems, their concepts and building blocks, past experiences, and how EIRs fit into this conceptual framework.

By the end of this chapter, you will be able to define:

- What is eHealth.
- What is a health information system.
- The phases of development and implementation of such a system.
- The reasons for failure of an electronic information system.

1.1 WHAT IS eHEALTH AND WHAT ARE HEALTH INFORMATION SYSTEMS?

A health information system is a set of interrelated components that collect, process, store, and distribute information on health to support decision-making and control processes, as well as to support data analysis, communication, and coordination within the system itself [3-4].

Health information systems provide the foundations for decision-making and have four key functions: data generation, compilation, analysis and synthesis, and communication and use. HISs compile data from the health sector and other related sectors, analyze them, assure their quality, relevance, and timeliness, and convert them into information for health-related decision-making [5]. HISs should operate within the framework of each country's eHealth strategy, so as to ensure their governance and sustainability.

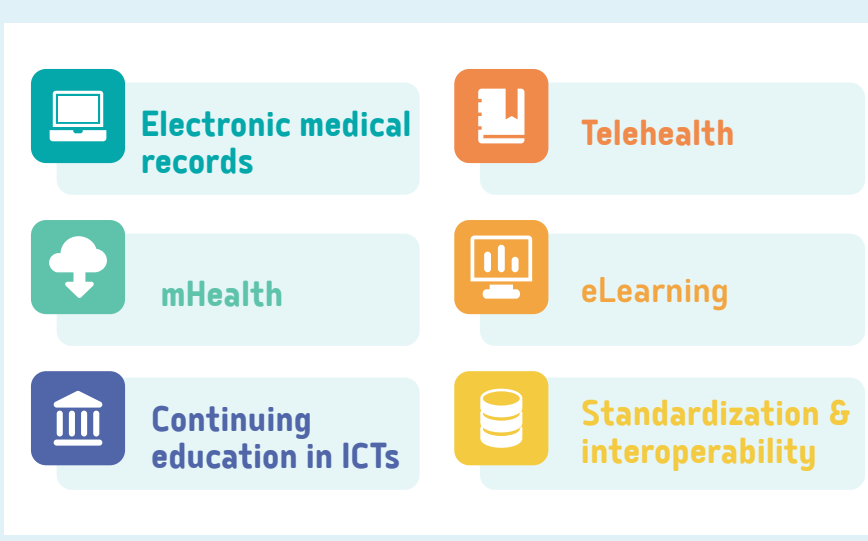
1.1.1

DEFINITION OF EHEALTH

According to the World Health Organization (WHO), eHealth consists of "the cost-effective and secure use of ICTs in support of health and health-related fields, including healthcare services, health surveillance, health literature, and health education, knowledge and research" [5]. In 2011, PAHO published the "Strategy and Plan of Action on eHealth (2012-2017)" [3], which defined six key eHealth components for the Region (Figure 2):

- Electronic medical records;
- Telehealth;
- mHealth;
- eLearning;
- Continuing education in information and communication technologies;
- Standardization and interoperability.

FIGURE 2.
eHealth components for the Region of the Americas



ICT, information and communications technology

1.1.2

HEALTH INFORMATION SYSTEMS

In 1973, WHO defined health information systems as "a mechanism for the collection, processing, analysis, and transmission of information required for organizing and operating health services." An HIS is a set of interrelated components that collect, process, store, and distribute data to support decision-making and control processes, as well as to support data analysis, communication, and coordination within the system itself [6]. At present, and given the massive progress toward widespread use of ICTs, the mistaken concept has arisen that an information system only includes software. This definition disregards several critical elements concerning the system's users, generation of data, the transformation of data into information, and the translation of this information into knowledge for decision-making. It is essential to note that the elements of an information system include people, data, work processes or methods, and material resources (usually computing and communication resources).

1.1.3

BENEFITS OF AN ELECTRONIC HEALTH INFORMATION SYSTEM

The basic objective of health information systems is to contribute to the improvement of health outcomes by providing pertinent, high-quality data in a timely fashion. Improvements in health information systems arise from the changing information needs of programs, sectors, users, and the population. The main benefits include:

- Helping reduce errors in data entry and in calculation of health indicators.
- Improving the efficiency of processes and information and work flows.
- Helping identify problems and opportunities to improve the use of resources and inputs.
- Reducing the administrative burden, facilitating timely access to information, and automating the generation of key reports.
- Facilitating communication of results to the population, community, and beneficiaries.
- Allowing automatic aggregation and disaggregation of data and indicators by geographical levels.

KEY CONSIDERATIONS

- Coordination with other health entities and sectors is essential in order to identify opportunities for synergistic work and data sharing.
- Communication between different health facilities and information-sharing ability across different programs within these facilities are prerequisites for the availability of complete, timely information to support decision-making. An ever-greater number of health information systems are being implemented, including picture archiving and communication systems (PACS), radiology information systems (RIS), laboratory information systems (LIS), and electronic medical records (EMR), which, in turn, are connected to hospital information systems and admission, discharge, and transfer (ADT) systems.
- Interconnectivity across these various levels requires the use of computer standards, such as DICOM and HL7. Thus, the use of these standards should not be optional when health systems are being developed; failure to adopt them would make it impossible to connect different systems and share relevant information so that the health facility operates in the best possible way.

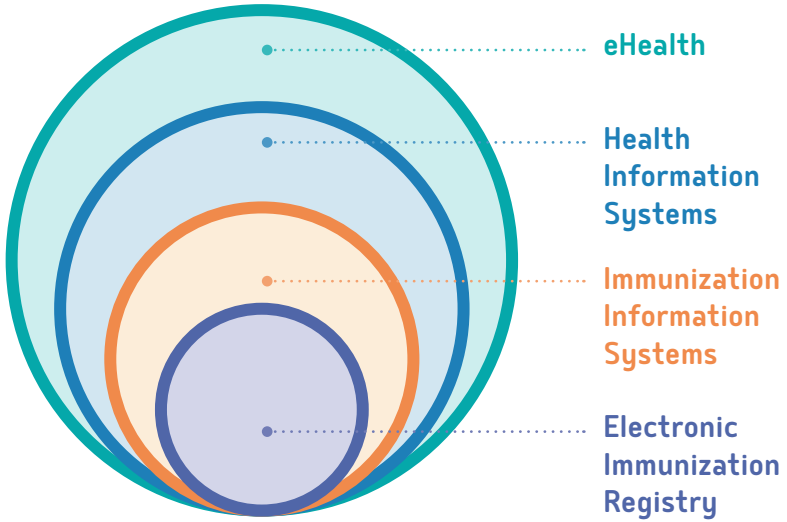
1.1.4

IMMUNIZATION INFORMATION SYSTEMS

Information systems play a key role in producing the information that will guide the strategic, managerial, and operational decisions of the EPI within each country. The ultimate goal is to have information that fulfills three criteria: quality, coverage, and credibility. This allows the EPI to make decisions aimed at reducing the morbidity and mortality associated with vaccine-preventable diseases (VPDs) and to improve the performance of program management. These systems also produce essential data for monitoring and accountability, both from an administrative standpoint (to higher hierarchical levels) and to the beneficiary population in general. Strategic and policy decisions of the EPI that are guided by data include targeting of vaccination strategies and tactics to reach vulnerable and under-immunized populations; communication, education, and social mobilization activities; and the adjustment of vaccination schedules, among others. Managerial decisions concern ensuring the availability of vaccine and supply stocks at all levels, with a guaranteed cold chain, and vaccinators trained to provide safe, high-quality immunization services that can cover the entire population. Finally, the day-to-day operational decisions include estimating the approximate number of people to be vaccinated every week or month and the amount of vaccines and supplies needed both for vaccination within the facility and for extramural activities, among others.

Just as immunization information systems are designed to provide relevant information related to the distinct management areas of the EPI, an electronic immunization registry (EIR) – which is part of the immunization information system – provides information on immunization regarding the program's target populations. Figure 3 illustrates the interrelationships among these information systems.

FIGURE 3.
Interrelationships among health information systems and immunization information systems



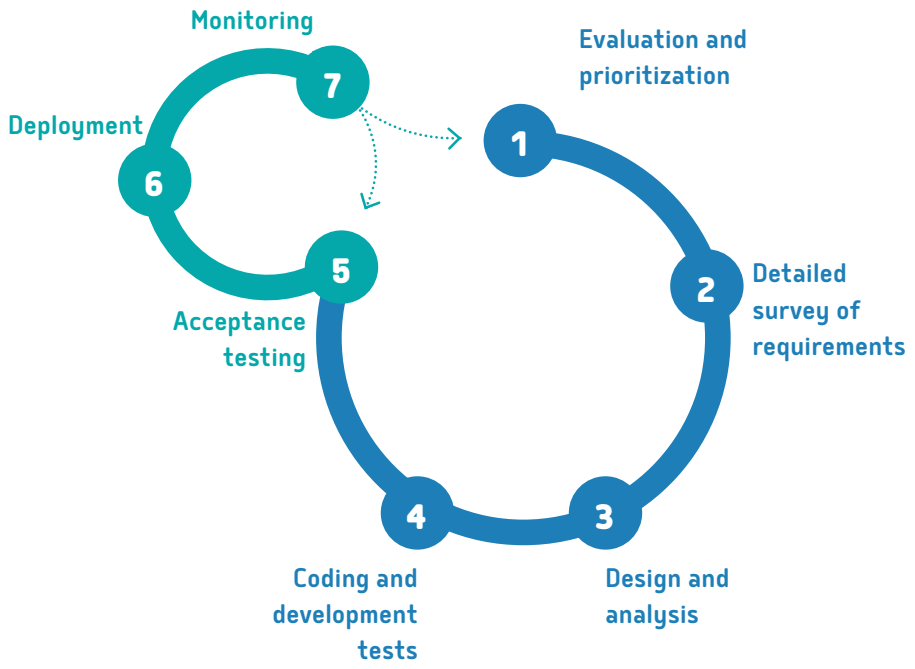
1.2 HOW TO DEVELOP AND IMPLEMENT A HEALTH INFORMATION SYSTEM

The process of development and implementation of a health information system includes several phases or stages (Figure 4). This model is based on an information system cycle also known as the software cycle, which refers to the stages of conception, design, development, evolution, and implementation of an information system from an iterative standpoint (known as the agile method for software development) [7]. In this methodology, great importance is given to the monitoring step before creating a new iteration – the phase in which what needs to be modified and/or adapted is determined.

At each of these stages, it is important to conduct an evaluation of the purpose of the system, the key or most relevant activities to ensure appropriate monitoring, the actors involved, and the role of each participant. A detailed roadmap should be prepared, defining the checkpoints (or control points) and exit points of each stage and clearly specifying the exit criteria necessary to advance to the next stage. A description of each stage is provided below:

1. **Evaluation and prioritization:** initial research is conducted and the needs of the information system are identified in order to define its scope.
2. **Detailed survey of requirements:** surveys, interviews, and observational activities are conducted to define and document the functional requirements of the information system: what its intended function is and how it will be designed.
3. **Design and analysis:** this stage involves deciding how to represent the requirements of the information system so they can be interpreted by a technical development team. Use cases are defined, as are users at all levels, system requirements, and the manner in which the system will compile, store, and present its data (and, ultimately, its indicators). Finally, non-functional requirements (connectivity, usability, number of users, etc.) are employed to decide which technology platform will be used to construct the system.
4. **Coding and development tests:** during this stage, the system software itself is developed and operational tests are carried out in a production environment.
5. **Acceptance testing with users and key stakeholders:** at this stage, operational tests are carried out by the end users of the system. This stage can be used to strengthen and improve the system on the basis of user feedback.
6. **Deployment:** the information system is implemented in a server and made available to users. After the initial deployment, user training can be planned and escalated according to resources, priorities, and needs.
7. **Monitoring:** the quality and quantity of information entered in the system are evaluated and results are reported and documented in order to produce corresponding actions. According to the results of continuous monitoring, necessary changes can be prioritized and adjustments made to the software.

FIGURE 4.
Iterative cycle of electronic information system design and implementation



KEY CONSIDERATIONS

- At all stages of development, clear and detailed documentation – both related to the process in general and to specific technical aspects – plays a key role. It is essential that a complete project manual be compiled and maintained once the HIS is in operation.

- Each stage is defined on the basis of the following questions:
  - » What is the purpose of this stage?
  - » What are its key activities?
  - » Who should be involved and what is the role of each player?
  - » What are the checkpoints along the way?
  - » What are the exit points or outcomes of each stage?
  - » What are the exit criteria to move on to the next stage of the cycle?

- It is important to have human resources and a sustainable budget throughout the information system cycle.

1.3 REASONS FOR FAILURE OF AN ELECTRONIC HEALTH INFORMATION SYSTEM

Many electronic health information systems are rolled out as pilot projects in a given geographical area or with a small functional scope, but never achieve full scale at the country level. There are multiple potential reasons for the failure of implementation of an information system, including:

» Inadequate survey of requirements.

» System design not aligned with needs or context.

» System architecture that does not fit the established scope.

» Lack of documentation of project stages.

» Lack of commitment and/or knowledge of the authorities or decision-makers with regard to the project.

» Interests of stakeholders and cooperation agencies.

» Underestimated, ill-defined, or unrealistic budget.

» Failure to maintain the system during project planning and development.

» Dependence on a third party for system updates and incremental maintenance.

» Lack of training or training appropriate for the type of user (during the implementation stage, the maintenance stage, or both).

» Inadequate system transition process and lack of acceptance of the new system.

» Lack of clear strategies, aligned with country policies and regulations, for data confidentiality and security.

» Inadequate monitoring of the information system.

» Inadequate logistical conditions (lack of reliable electrical supply, lack of backup equipment, etc.).

» Lack of end-user participation in the development process and lack of adaptation of the system to users' goals, needs, and workflow.

» Inability of the information system to keep up with changes in the involved organizations, the needs of the market, or government actions.

Annex 1, "*Lessons learned from health information systems that have failed,*" provides a detailed overview of past system failures and proposes actions that can be implemented to face the challenges that can lead to such failure.

KEY CONSIDERATIONS

- Account for and manage the risk of failure during implementation of a health information system.
- Create strategic and operational plans (see Section 3.1) in accordance to the capacities and strengths of the country and considering the different realities within the same country.
- Consider every stage of the information system cycle (see Section 1.2) and provide for systematic monitoring and quality evaluations between stages.
- Ensure the continuity of software development and its maintenance not only in terms of processes, but also in terms of human resources.

COUNTRY CASE STUDY

LIMITED DESIGN

In the context of a technical knowledge transfer program sponsored by the European Union (EU), an EU country helped a middle-income country implement its immunization registry system. When the program ended, the receiving country's officials discovered they had no way to modify reports or functionality, or even access the database directly. They abandoned the system.

What went wrong?

It is likely that not enough time was spent planning and designing the project. It was simply assumed that what worked in one country would work in another. Many factors, not only functionality, affect the feasibility and usefulness of a system in a specific country. Among these factors, it is likely that a clear definition of the needs or requirements for the system within the context of the receiving country was not established and that neither the system's flexibility requirements nor who would be in charge of maintenance were specified.

NOT PLANNING TO SCALE

In a low-income country, a consortium of donors and technical partners implemented a text message (SMS)-based system to track the biologics used in a public health program. While it was scaled up nationally for some biologics, it was not easy to extend its use to a large number of other products, because, if there are many biologics, sending a different text message for every transaction will be too cumbersome and costly.

What went wrong?

The system design was not aligned with the wider eHealth and mHealth vision; instead, it was focused on demonstration of a technology. Failing to think through what would happen in the long term meant that the Ministry of Health of the country in question might not be able/willing to adopt or maintain the system.

LACK OF COMMITMENT TO THE PROJECT FROM THE AUTHORITIES

The EPI of a country decided to implement an EIR, and thus proceeded to set up a work team and begin the system planning process. A strategic and operational plan, supported by international organizations and with active involvement of staff from several related departments, was developed. The document was then delivered to the authorities for their approval and adoption. However, approval was never given and the team did no further work on the project.

What went wrong?

Even though planning was carried out adequately, this was not formalized by the authorities. As a result, the formed work team was not able to continue with the activities identified and did not advance with the system. The formalization of the system's plan by the authorities and the work team responsible for the management of the project is important. To this end, the authorities should be involved from the start and mechanisms should be sought to protect development and implementation of the EIR when a change of administration occurs.

Cases drawn from World Health Organization/Program for Appropriate Technology in Health (PATH). Planning an information systems project: a toolkit for public health managers. Seattle: PATH; 2013.

2

Background on individualized immunization registries

Electronic immunization registries (EIRs) are tools that facilitate monitoring of individualized vaccination schedules and, as a result, help improve the performance of the Expanded Program on Immunization (EPI), in terms of both coverage and efficiency. This chapter describes what an EIR is and how it compares to current non-individualized registries, the advantages of using EIRs, the characteristics that define an "ideal" EIR, the stages of development of a system with these characteristics, and the best time for its implementation.

By the end of this chapter, you will be able to define:

- What is a nominal immunization registry.
- How vaccination systems that use aggregate data compare to paper-based and electronic nominal immunization registries.
- The advantages of using an EIR.
- The defining characteristics of an ideal EIR.
- The best time to develop an EIR.

The EPI requires at least four types of information systems for decision-making[1] (Figure 5):

» A registry of vaccinated individuals (i.e., an individualized immunization registry)

» Supply chain

» Epidemiological surveillance of vaccine-preventable diseases (VPDs)

» Monitoring of events supposedly attributable to vaccination or immunization (ESAVI)

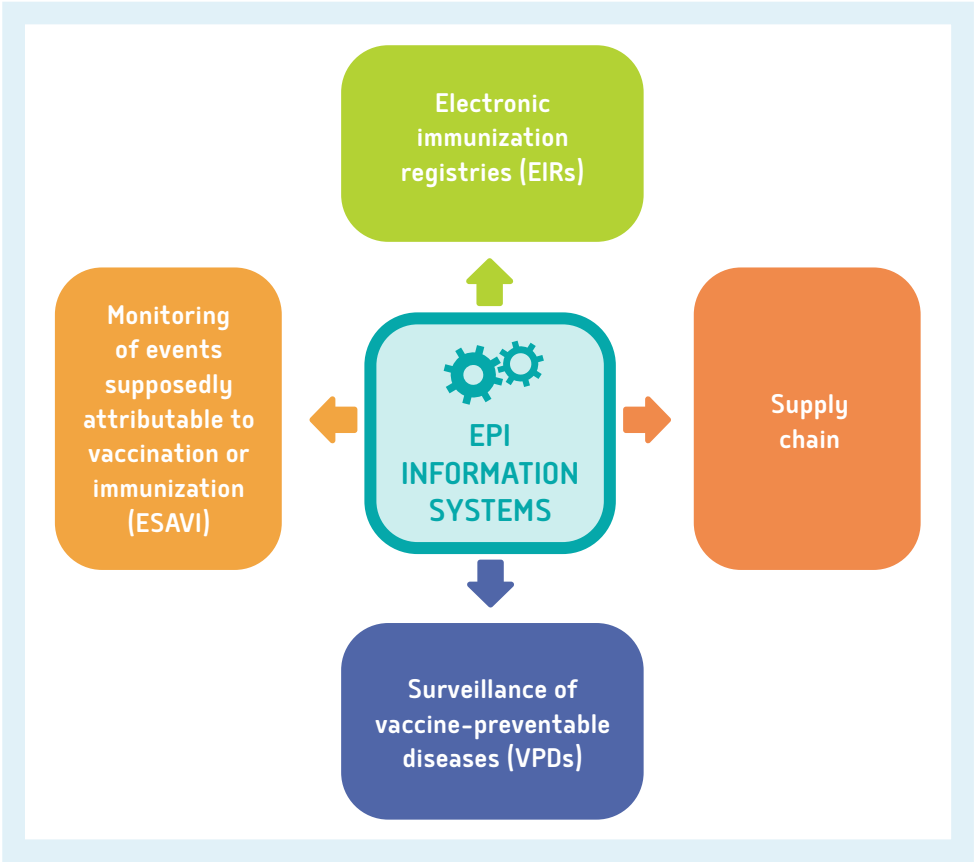
This document refers only to individualized immunization registry information systems.

[1] This list only includes information that is obtained on a routine basis, not from special studies or surveys. Furthermore, it does not include information on financial and human resources, as these data are usually part of the overall health system.

2.1 WHAT IS AN ELECTRONIC IMMUNIZATION REGISTRY?

The Pan American Health Organization defines individualized immunization registries as those that identify vaccination data for each person and allow access to each individual's vaccine history, thus facilitating active search, in addition to supporting monthly planning of who needs to be vaccinated and monitoring of defaulters or dropouts. Electronic immunization registries (EIRs) are computerized individualized immunization registries that are part of the immunization information system. Depending on their connectivity, EIRs can be defined as online EIRs, offline EIRs, or a combination of both.

FIGURE 5.
Immunization information systems



The U.S. Centers for Disease Control and Prevention (CDC) define immunization information systems (IISs) as confidential, population-based, computerized databases that record immunization doses administered by multiple health care providers and that can be used in the design and maintenance of effective immunization strategies [8-13].

EIRs require a database with two types of information:

» Demographic data: identification of the vaccine recipient (unique or individualized identifying information, place of residence of each person, contact data, etc.).

» Vaccination-event data: information on the vaccination event itself (date administered, doses applied, place of administration, and who administered it, among others).

These data are then processed and aggregated immunization data are generated by dose applied, age, sex, or other variables of interest, as well as data on the vaccine history of each individual.

The core functions of an EIR are as follows:

» Facilitate the individualized and timely monitoring of immunization schedules.

» Provide outputs (reports, tables, figures) that facilitate monitoring of vaccination coverage, disaggregated by vaccine, dose, geographical area, age, and provider or facility.

» Facilitate the active search of unvaccinated individuals/defaulters/dropouts.

» Support and facilitate the identification of biologics, syringes, and other immunization supplies requirements at all levels of the health system, especially at the operational level.

COUNTRY CASE STUDY

URUGUAY

The EIR system of Uruguay was established in 1987 to provide a computerized registry of all children born in the country and allow monitoring of their vaccination history. The system is based on the use of a single vaccination registration form. Vaccination centers, both public and private, complete one such form for each immunized child and according to the doses and biologicals administered. These paper forms are submitted at the departmental level to the offices of the Honorary Commission for the Tuberculosis Campaign and Prevalent Diseases (CHLA-PE), which enter the data into the system. Every 15 days, each region of Uruguay sends an electronic update to the national level. They also submit paper forms or slips of children born in other departments to the respective departments where their data were entered. There is a consolidated database at the national level.

Uruguay is now developing a more modern EIR system that takes into account the information requirements of all levels.

Source: Ministry of Health, Uruguay

2.2 COMPARISON OF IMMUNIZATION SYSTEMS USING NON-INDIVIDUALIZED DATA, PAPER-BASED INDIVIDUALIZED IMMUNIZATION REGISTRIES, AND EIRs

Historically, non-individualized immunization information systems and paper-based individualized immunization registries have been the main sources of information on EPI performance indicators. However, the increasing complexity and growing budget of the program, in addition to the information requirements of vaccine recipients, have led to an increase in information needs, which are limited by the use of these systems. In view of the foregoing, EIRs can be a useful tool to meet the information requirements of the vaccinated population, for monitoring of performance indicators, and to support management, accountability, and provide evidence for decision-making in the program.

Non-individualized immunization information systems only allow monitoring of the number of doses administered by age group, type of doses, and geographical location, and are influenced by population mobility and errors in population estimates. The difference is that EIRs allow the following actions:

AT THE INDIVIDUAL LEVEL:

1. Timely monitoring of each person to identify:
    a. Compliance with vaccination schedules.
    b. Recipients who are behind on their schedules.
    c. People who have not been vaccinated since their entry into the system. This means that the individuals in the target population are known, facilitating the adaptation of immunization strategies to possible causes of non-vaccination.
    d. The simultaneity and timeliness of vaccination.
    e. Potential program errors in individual vaccination. This allows reduction and avoidance of dose recording errors, which sometimes lead to negative dropout rates, as well as of paradoxical over-recording of late doses as compared to first doses of a vaccine, and facilitates timely access to vaccination.

2. Automate sending of immunization reminders.
3. Support decision-making in the event that the person has not followed the national immunization schedule or has contraindications.
4. Replace the vaccination card by providing an easy-to-obtain individual vaccination history.

FOR PROGRAM MANAGEMENT AND DECISION-MAKING:

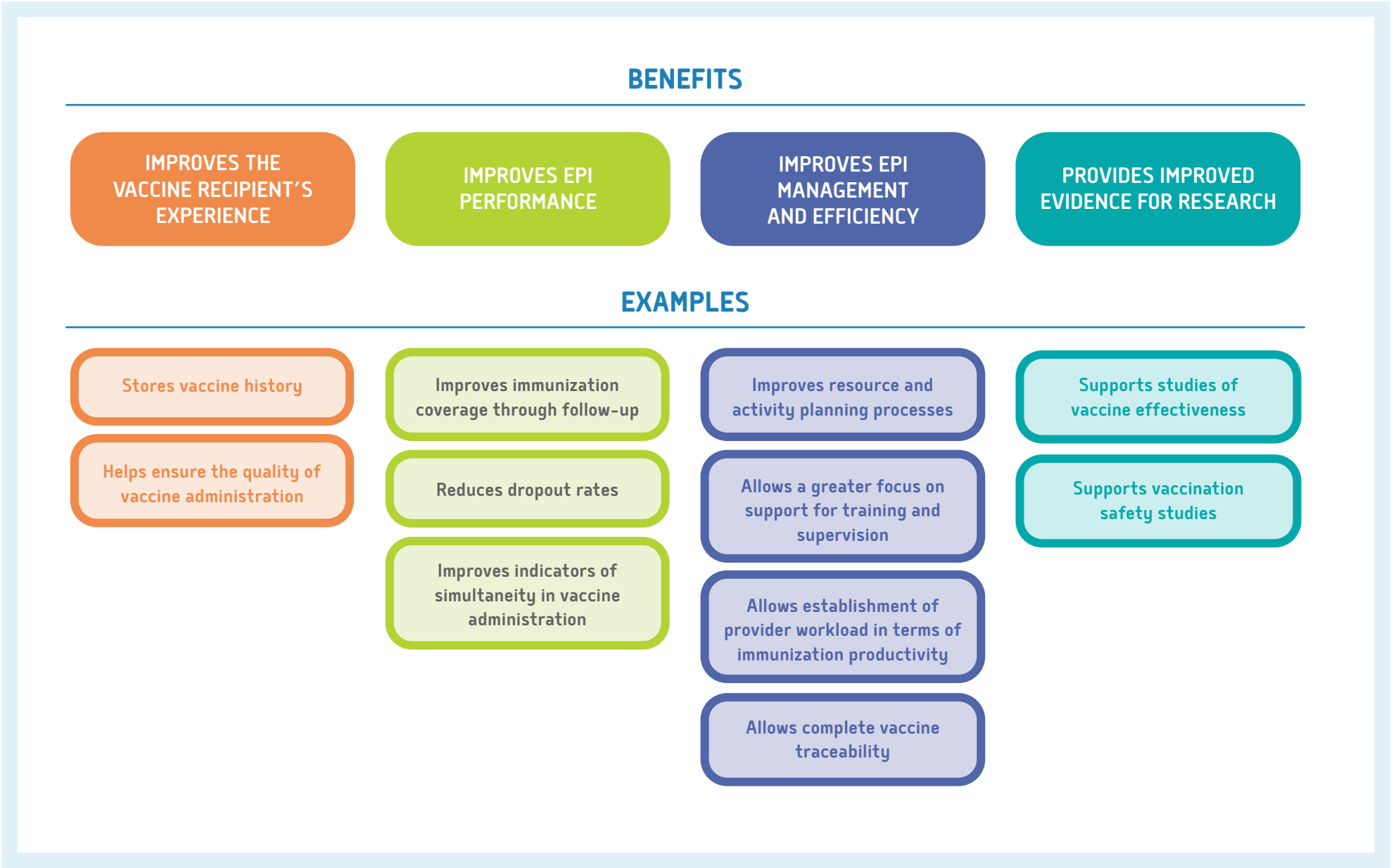
1. Monitor vaccine refusals (if the EIR includes refusal data).
2. Monitor coverage by cohort: the denominator used can be dynamic and not an annual fixed goal, as is the case with non-individualized immunization information systems.
3. Provide timely knowledge of immunization status for the country and/or a specific geographical area.
4. Calculate the productivity and workload of health facilities and vaccinators at a given time, if the necessary variables are available.
5. Facilitate the traceability of program vaccines, if the EIR includes lot number data.
6. Improve planning of resources, since the system provides more detailed information on vaccination activities.
7. Detect program errors, e.g., immunization of non-target populations.
8. Detect pockets of unvaccinated individuals.
9. Provide reliable vaccine data at the individual level in case of outbreaks and for special studies, among others.
10. Facilitate and optimize data visualization and analysis at all levels of responsibility in the health system.

2.3 ADVANTAGES OF USING EIRs IN THE EXPANDED PROGRAM ON IMMUNIZATION

As mentioned above, vaccination schedules have become more complex with the introduction of new target groups and new and more expensive vaccines, as well as with the exponential increase of program budgets. For these reasons, program management and accountability requires more disaggregated, accurate, complete, and timely information. On the other hand, various studies conducted over the last 15 years indicate that investment in information technology in health not only makes it possible to incorporate innovative aspects into program management, but also brings important benefits to public health and socioeconomic aspects in the countries in which these technologies are implemented. Additionally, these studies point out the need to formulate standards, coordinate activities, and support initiatives for the use of such technologies. Figure 6 shows the advantages of using an EIR.

Annex 2 ("*Benefits of an EIR*") includes a detailed description of each of the benefits described above and related studies.

FIGURE 6.
Advantages of using an electronic immunization registry (EIR)



2.4 CHARACTERISTICS OF AN IDEAL EIR

According to PAHO, and according to the experiences of different countries of the Region of the Americas [14], an ideal EIR has some specific characteristics (Figure 7).

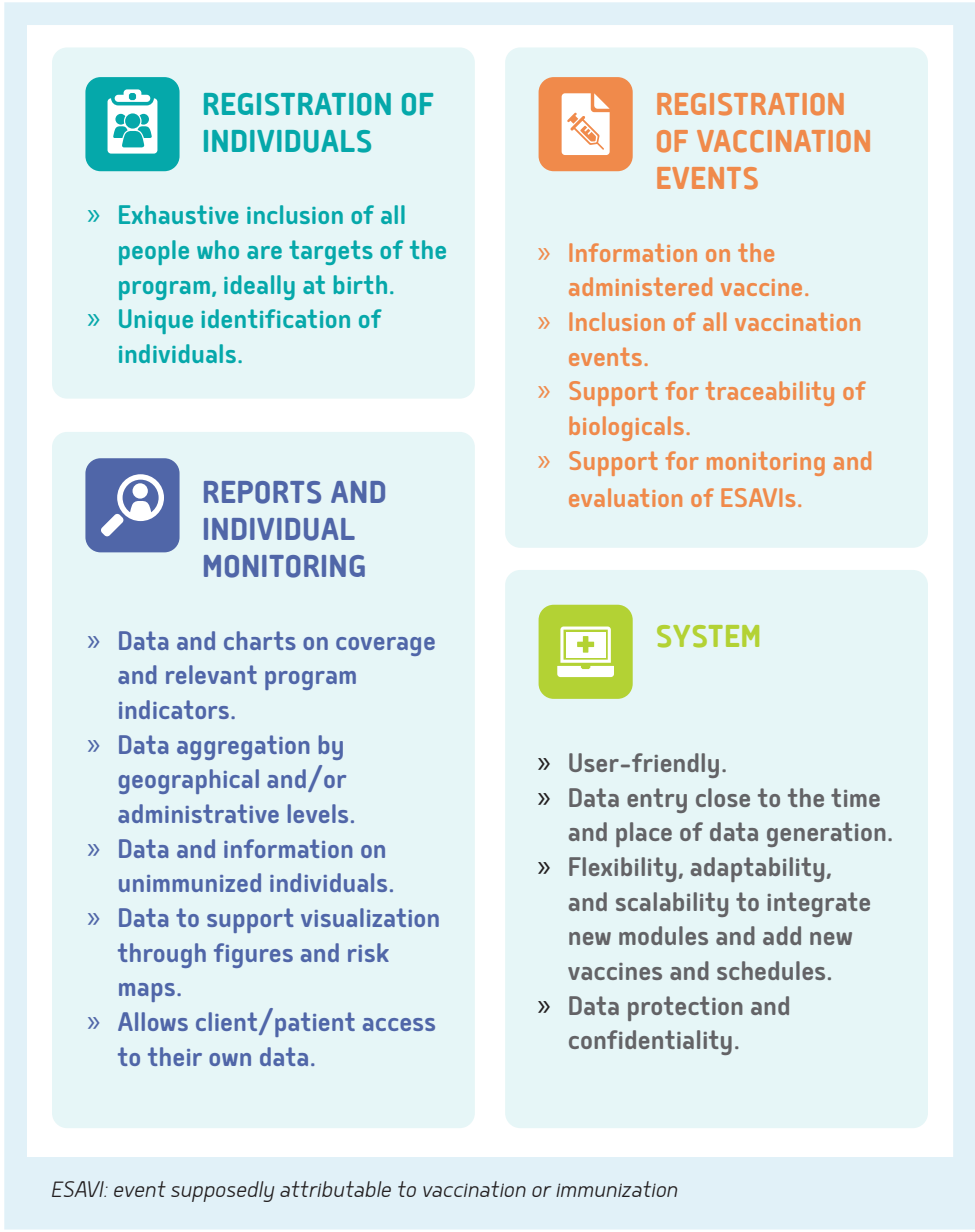
2.4.1 REGISTRATION OF INDIVIDUALS

2.4.1.1. Exhaustive inclusion of all people who are targets of the program, ideally at birth

An EIR should allow the inclusion of all people within the age group defined as the target population, regardless of whether they have been vaccinated. As a result, it should have mechanisms to capture marginalized populations. Its use should be considered by all actors of the health sector: social security, private sector, nongovernmental organizations (NGOs), among others (Figure 8). This aspect is of vital importance, since an EIR can only be used as a population denominator if it is as exhaustive and accurate as possible. In this regard, it is important to consider the possibility of establishing intersectoral cooperation agreements to ensure access to the country's most complete and current population databases.

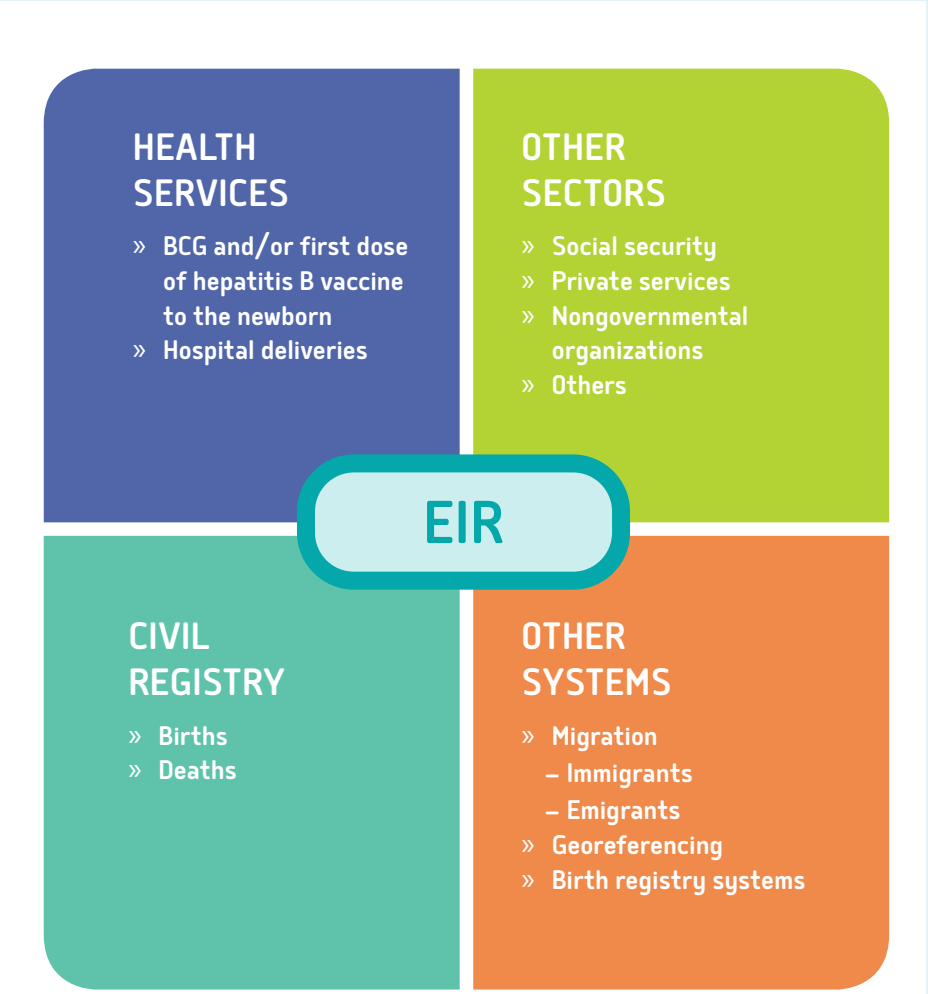
Inclusion should be early, coordinating actions with the unit responsible for birth registration – either the registry of live births and/or the civil registry (especially in countries with a high level of institutional birth registration). In other cases, inclusion will take place at the time of administration of the BCG vaccine and/or of the first dose of the hepatitis B vaccine in newborns, or upon explaining the reason not to administer the recommended vaccines to the newborn. Ideally, the system would also coordinate with the department in charge of migration so as to include immigrants and exclude emigrants, according to the definitions established by the country. The completeness of the denominator should be confirmed to ensure that the whole population is being considered.

FIGURE 7.
Characteristics of an ideal EIR



ESAVI: event supposedly attributable to vaccination or immunization

FIGURE 8.
Relationship of an EIR with other sectors



BCG: Bacillus Calmette-Guérin (vaccine against serious forms of tuberculosis)

COUNTRY CASE STUDY

CHILD REGISTRY OF PERU

The "validated and up-to-date district individualized registry (or census) of girls and boys under 6" of Peru is a goal of the "Plan of Incentives for Improved Management and Municipal Modernization." This registry will be useful for government programs, particularly social programs, by providing reliable information which can be used to support budgetary planning and programming, as well as to identify gaps in insurance and identification for access to health and education services, among others. Furthermore, the registry can serve as a list of beneficiaries of delivery of health services, such as the National Strategy of Immunization of Peru, and as a major population database for an EIR.

The objectives of the individualized registry are:

» To provide an up-to-date, standardized registry of children under 6 at the district level.

» To identify children who do not receive their national identity document (DNI) or unique identification code (CUI) within the established period, in order to bring them closer to the entities responsible for the identification process.

» To provide regional governments with a tool for the management of interventions designed to improve the health of children under 6.

Finally, having an individualized registry is the first step in the implementation of social monitoring, as it will permit local governments to know the infant and child population for which they are responsible and to conduct the necessary monitoring so that the outputs of budget programs reach the citizens within their jurisdiction in a timely, sustainable fashion for local management.

Source: Ministry of Health of Peru.

2.4.1.2.
Unique identification of individuals

The unique identification of vaccine recipients is essential to avoid the duplication of registries for the same person, which leads to imprecise coverage and inadequate monitoring of individual immunization schedules. Unique identifiers (UIDs) can be:

» National ID numbers or analogous codes, whether the own individual's or the mother or parents' (in the case of children, once a unique ID has been assigned to the child, the immunization registry must be edited to replace the mother's or parents' ID with the child's own).

» Assignments of codes or unique IDs based on names, initials, the minor's date of birth or the date of birth of the person responsible for the child (mother, parent, other), place of birth or place of first vaccination.

» Biometric records (e.g., fingerprints and iris scans).

Individual demographic data should also include: first and last names, sex, date of birth, ethnic group or ethnicity (if applicable), name and contact information for the legal guardian (mobile number, e-mail address, etc.), and place of residence (this should be an editable field), which will provide information for the calculation of vaccine coverage in a given territory and facilitate the efficient identification and monitoring of the unvaccinated population (see Section 4.1). In all cases, relevant ethical and legal provisions should be taken into account with a view to ensuring the confidentiality and appropriate use of data (see Chapter 8).

2.4.2

REGISTRATION OF VACCINATION EVENTS

2.4.2.1.
Information on the administered vaccine

It is important that any EIR includes data on the biologic administered, since they provide relevant information for program management and monitoring of recipients' vaccine history. Recommended variables include:

» **Type of biologic:** information on the type of vaccine administered. The potential differences between biologics provided by the public sector and those offered by the private sector should be considered: e.g., children vaccinated with 13-valent versus 10-valent pneumococcal vaccine. Both types of vaccines are counted for calculation of administrative coverage, but the vaccine recipients would be protected against different pneumococcus serotypes.

» **Dose:** data of the number of the dose administered (first, second, third, etc.) are important, as they allow follow-up of the immunization schedules of different system users and calculation of coverage on the basis of dose type, simultaneity, and dropout rates. However, a correct design and use of the system should establish which dose was applied according to the individual's vaccine history. The software should be designed to include critical alerts that ensure correct definition of which dose was administered.

» **Date of administration:** this parameter is particularly essential, as it allows analysis of whether vaccination was timely and valid, postponement of booster doses (when applicable), and serves as a necessary input and resource for implementing reminders.

» **Vaccine batch number:** this parameter is important because it links the vaccine recipient with the administered vaccine. It allows traceability of batches, e.g., in case of an event supposedly attributable to vaccination and immunization (ESAVI) which requires monitoring of all people who received that particular batch, and even allows connection between IIS subsystems or modules for better inventory control.

» **Manufacturer of the biologic:** this can be relevant to allow better monitoring and traceability of administered doses; furthermore, it provides accurate information for integration with other modules within the IIS, e.g., the ESAVI module.

» **Place of administration:** this data allows analysis of productivity, calculation of immunization coverage by place of vaccine administration, and programming for each vaccination center's needs. Furthermore, it allows detection of potential program errors amenable to intervention.

» **Strategy:** registration of the type of strategy used to deliver the vaccine to the recipient population allows documentation of the scope of the different strategies and more efficient planning. Possible strategies include routine immunization based at intramural and extramural health centers, national campaigns, special immunization campaigns, school-based immunization, etc.

» **Vaccinator:** data on the vaccinator allow analysis of productivity and traceability of program errors, among other advantages.

For more detailed information on the variables that an EIR should include, see Chapter 4.

2.4.2.2.
Inclusion of all immunization activities

EIRs and their data repositories should be exhaustive in their inclusion of all immunization activities carried out in the country, including the following:

- Immunization carried out in the public, private, social security, and other sectors (e.g., the armed forces, private clinics, etc.).
- Vaccines administered to foreign nationals who are immunized in the country and information on people immunized abroad, whose vaccine histories should be updated accordingly.
- Vaccines administered during immunization campaigns, including school-based immunization drives, nationwide campaigns, and others.
- All vaccines administered at the country's various health facilities (both those included in the national schedule and those that are not part of the schedule, including vaccines for special populations), so as to prevent health facilities from using any system other than or in addition to the EIR.

In any of the aforementioned cases, it is important to establish a guideline for reporting of immunization data in the different sectors, in order to ensure the comprehensiveness and timeliness of information. During vaccination campaigns, it is important that the system be flexible enough in order to incorporate these immunization strategies in the EIR.

With the information thus provided, the EIR should generate reports in which the vaccine history of each individual can be visualized, including information on the administered vaccines regardless of the type of biologic, place of administration, and immunization strategy (routine scheduled campaigns, etc.).

COUNTRY CASE STUDY

BOGOTÁ, COLOMBIA

The EIR of Bogotá, Colombia, known as the Nominal Vaccination Information System (SINV in Spanish), is installed in 100% of public and private health facilities in its area of responsibility. Health facilities that deliver babies enter all newborns (vaccinated or otherwise) into the EIR and into the Single Registry of Affiliates (RUAF in Spanish) simultaneously; 100% of public health facilities are online and carry out real-time data entry, i.e., information is updated in the EIR at the exact time immunization is administered. In 2016, the system coverage rate in private health facilities was 98%; this makes it possible to know the doses of each vaccine administered to each child. The Bogotá EIR facilitates data analysis and generation of outreach indicators by place of residence or immunization, as well as of vaccination by month of birth (cohort monitoring); supports rapid monitoring of coverage and calculation of dropout rates; and enables identification of children with incomplete immunization schedules. Furthermore, it provides easy online access to vaccination records to parents and caregivers, who can download the vaccination card and keep a hard copy.

The comprehensiveness of input of immunization activities carried out in the area of responsibility of the Ministry of Health of Bogotá, which has been confirmed through monthly comparisons with other data sources (such as the RUAF), means that analyses based on the system are reliable and representative of immunization performance in Bogotá.

Source: Ministry of Health of Bogotá, Colombia, 2016.

2.4.2.3.
Support for traceability of biologics

One of the reasons to have an EIR is so that the EPI can achieve traceability of biologics, from the time they arrive in the country through their transport all the way to administration. If the EIR is intended to support vaccine traceability, it should either interoperate with an inventory system or a logistics module should be added to the EIR, so as to allow monitoring of the vaccine from its arrival at the EPI up to its administration. The traceability of biologics plays an essential role in immunization safety.

Interoperability or integration of a logistics system with an EIR must take into account matters of semantics and interoperability standards (for further detail on this subject, see Chapter 5). Batch numbers, quantities, dates of manufacture and expiry, and processes inherent to the distribution of vaccines at different levels (national, subnational, municipal/district, and local) should be considered, and stock adjustments should be made as necessary to account for loss of the cold chain, broken bottles, expiration, and other events. Provisions should be included for the management of vaccines administered in other sectors, such as the private sector.

2.4.2.4.
Support for monitoring and evaluation of ESAVIs

The monitoring of events supposedly attributable to vaccination and immunization (ESAVIs) is a relevant process within immunization programs; thus, IISs must provide information to facilitate monitoring of these events from different perspectives: regarding the biologic itself (type of vaccine and batch), regarding the user (family history and clinical history), programmatic errors, and other relevant data for investigation and final classification of each case. EIRs provide an important support for an ESAVI notification system, as they provide timely information on immunization activities. Furthermore, the EIR can include information on user reactions, flag contraindications, and use the data obtained for studies of causality.

2.4.3
REPORTS AND INDIVIDUAL MONITORING

2.4.3.1.
Data and charts on coverage and relevant program indicators

The information provided by EIR systems should support program management at all its levels of responsibility and allow monitoring and assessment of the achievement of vaccination coverage and relevant program indicators, such as dropout rates, coverage by vaccine, dose, cohort, timeliness, and simultaneity, among others, in addition to information for decision-making. In view of the foregoing, it is important that the EIR make information available in a timely fashion, to make the respective analyses possible, and support visualization of these indicators through dashboards and relevant, tailored reports.

The data provided by an EIR system can be used to generate different analyses in greater detail than possible with a non-individualized information system. One such function is cohort analysis, i.e., verification of the vaccination status of individuals according to the exact year and/or month of birth of a birth cohort, which enables precise analysis of a specific cohort and closer monitoring at the individual level. Analysis of a live-birth cohort over time, also known as "cohort monitoring," should be consistent and systematic, with strict evaluation of the doses applied concerning the number of doses for age and the adequacy of intervals between doses, i.e., adherence to the schedule and timeliness of vaccination. The purpose of cohort monitoring is to detect which children are up to date on their vaccines, which are behind on their schedules, which have received inadequate vaccines, and which should be subject to localization and contact. Systematic cohort monitoring on a monthly basis reveals (in)consistency in outcomes, administration of vaccine doses, and changes or variations in adherence, and allows evaluation of the results of any implemented strategy.

2.4.3.2.
Data aggregation by geographical and/or administrative levels

An EIR should allow consolidation of the number of doses applied by type of biological, dose, and age, thus contributing to analyses to improve the performance of the program at all management levels (local, municipal, subnational, and national). The following list highlights some benefits of having this information available (for more detail, see Chapter 4):

» Monitoring and evaluation of vaccination coverage at different levels, to allow comparison of performance between two or more organizations in a single level and support supervision and performance management processes, campaign planning, etc.

» Support estimation and planning by health facilities of needs for supplies and biologics based on accurate utilization information. This would also allow evaluation of vaccine wastage and determine compliance with the recommendation (implemented in the majority of countries) regarding the opening of a new vaccine vial even for administration of a single dose.

2.4.3.3.
List of vaccine defaulters

The EIR should consider including a module or similar structure that allows extraction or generation of a monthly plan of individuals requiring immunization (individuals who are due to receive one or more vaccines on a day of the current month according to the immunization schedule) [1] and a list of vaccine defaulters (individuals who did not attend immunization at the scheduled date and are thus behind on their immunization schedule). This can be used to design reminder strategies, e.g., via phone calls, text messages, etc., to locate these individuals. This information will make it possible to carry out various analyses of the reasons for vaccine default, which, in turn, can then support actions to address said problems, in addition to validating information on individual vaccine history.

2.4.3.4.
Data to support visualization through figures and risk maps

One of the relevant aspects to consider is the analysis of immunization data at the geographical level and risk mapping, through which areas and communities with pockets of unvaccinated individuals can be identified. These analyses will allow targeting of high-risk areas through maps created for each organizational level of the country and thus permit the optimization of strategies for intramural and extramural vaccination. Furthermore, they foster action at different levels of responsibility, and even provide adequate information for micro-level planning.

2.4.3.5.
Provide recipients and caregivers access to their data

Information on immunization is important not only for health providers, but also for vaccine recipients themselves and their parents or caregivers. In this regard, an important aspect to consider is the access to general immunization information according to the needs of each associated profile (e.g., vaccination card) through Web-based system interfaces and under the security parameters determined by the country.

2.4.4
SYSTEM

2.4.4.1.
User-friendly

The system should be visually attractive and user-friendly, so that users are comfortable with it and find it simple to use.

2.4.4.2.
Data entry close to the time and place of data generation

An ideal EIR ensures the proximity in time and place of registration of immunization activities:

» **Place**: data should be entered into the system in the same place where immunization is carried out or in a nearby area. This provides a safeguard for proper management of files and records and allows any doubts to be cleared up immediately.

» **Time**: data entry should be carried out immediately after immunization, to ensure timely registration. In the event that data entry cannot be performed immediately, it should be performed on a daily basis, so that the information is available in the system when the following dose of vaccines is administered.

» In the case of offline systems, it is essential that the system issues reports of the dates of file and data upload, to allow evaluation of timeliness at different levels (the municipal level evaluates reporting by facilities it manages, the state level evaluates municipalities, and so on) and define the dates of data transmission to the other levels. It is recommended that data be conveyed as soon as possible, within a maximum delay of 30 days. It is important to stress that data feedback is essential for vaccinators. If the country has an online system, it is easier to provide such feedback through the same system; however, when the country has an offline system, alternative methods for feedback on information about defaulters, individuals behind on schedule, etc. should be sought.

2.4.4.3.
Flexibility, adaptability, and scalability to integrate new modules and add new vaccines and schedules

Immunization programs constantly review their vaccination schedules through the incorporation of new vaccines into the compulsory schedule, vaccines for scheduled campaigns and vaccines in response to contingencies, modification of age recommendations, and updated number of doses for some vaccines, among others. Given the foregoing, the EIR should be a flexible, parameter-based information system that allows adaptability to the changes defined by country programs in a timely manner. This is relevant both for data collection and for analysis of cohorts transitioning from one schedule to another.

COUNTRY CASE STUDY

A country had an EIR system that, in its early stages, responded to all the information requirements of its immunization program at all levels of responsibility. Nevertheless, the immunization program was becoming more complex by incorporating new vaccines and changing the doses in the immunization schedule, in a shift from five to 12 vaccines. All these changes required a sufficiently flexible EIR system that would allow timely incorporation of these modifications. Unfortunately, the country's EIR system did not meet these criteria, as it depended on a third party to make all modifications. Furthermore, updates to its architecture were not taken into account, which led the system to become obsolete; ultimately, it was dropped altogether by the local and intermediate levels of government, which used parallel information flows instead and did not conduct systematic monitoring of data quality. As a consequence, when the time came to make vaccine coverage levels public, the country found it did not have a reliable data source and, thus, its numerators could not be corroborated, which caused a decline in coverage.

In this process of transparency, the country was brave enough to expose the reality of its data and formulated a plan to improve the data quality in order to reverse this situation, including analysis and improvement of its information systems.

2.4.4.4.
Data protection and confidentiality

An EIR should fulfill the guidelines established in the country's eHealth policy or other relevant regulations establishing confidentiality policies for individual health information. The information captured by an EIR is individualized, and safeguards are thus required to ensure it is not used improperly. It is relevant to ensure that data security and professional ethics policies are formulated, implemented, and enforced (see Chapter 8). Furthermore, user management with password protection strategies is important as a means of restricting access to information. On the other hand, the system should meet data security standards in order to prevent loss of data. It is recommended that user audits be conducted to reveal who performed each transaction and when, and to ensure protection of the system and its information.

2.5 THE BEST TIME TO DEVELOP AN EIR

The countries of the Region of the Americas and of other regions of the world have made unequal progress in the implementation of electronic immunization records. However, when a country makes the decision to set up such a system, it is important that expectations be realistic and that the necessary technical, financial, and social backing be in place to facilitate better results and ensure the system is used to the fullest.

On the other hand, there are several motivating factors concerning the needs involved in transitioning from a paper-based immunization registry to an EIR, which can be of a technical, infrastructure-related, financial, social, or managerial nature. Table 1 presents the main factors that should be taken into account when deciding whether implementation of an EIR system is feasible.

KEY CONSIDERATIONS

★ If all of the essential criteria are met, implementation of an EIR system is recommended.

X If some of the essential criteria are not met, it is recommended that investment in EIR technology be reevaluated or reconsidered, as the minimum requirements for implementation of systems of this nature are unlikely to be present.

TABLE 1. Factors that determine the feasibility of developing an EIR

FACTOR	DESCRIPTION	ESSENTIAL	CRITERION MET (YES/NO)
Technical	A sufficient supply of electrical power is available at 95% of health facilities	Yes	
	Constant, sufficient Internet connectivity (or appropriate to the needs of the system) is available in 100% of districts or municipalities and in 95% of health facilities	Yes	
	Personnel and technical support resources and/or resources to support training in use of the information system are or will be available	Yes	
Financial	A budget has been set aside to design, develop, or adapt and implement a new EIR (front-end costs)	Yes	
	A budget has or will be set aside to ensure the long-term sustainability and maintenance of the system, hardware resources, infrastructure, human resources, and their adequate upkeep	Yes	
Social and political	Health workers are willing to incorporate use of these information systems into their practice	Yes	
	There is sufficient political and social stability in the country	Yes	
	There is a clear understanding of what an EIR requires and all the necessary resources to develop, implement, and maintain it (human resources, budget, infrastructure, etc.) are available or can be obtained	Yes	
	There is political priority for the use of new technologies and/or a specific information system	No	
	There is a verifiable commitment from the authorities (through a standard or formal approval of the project) to EIR implementation	Yes	
	There is a specific contextual opportunity that favors implementation of an EIR	No	
	The teams involved in implementation of this type of system are willing to do so	Yes	
	There is an appropriate legal framework in place for such health information systems	No	

FACTOR	DESCRIPTION	ESSENTIAL	CRITERION MET (YES/NO)
Program management requirements	A high volume of resources (biological, human effort, time) are being expended to find unvaccinated individuals, and there is a need to make these interventions more efficient. For example: indiscriminate campaigns are being conducted in the hope of immunizing unvaccinated individuals.	No	
	Overestimations or underestimations of population parameters are leading to low or high coverage. For example: the system is looking for people who do not exist (the EIR can help collect a population-wide census) and/or it is believed that some areas have good immunization coverage when that is not actually the case. There is a need for more reliable coverage.	Yes	
	There is little trust in the accuracy and/or security of the data of the current immunization information system or registry	Yes	

3

Strategic and operational planning and estimation of associated costs

The planning stage is vital when developing any information system. In the case of an electronic immunization registry (EIR) system, it is particularly essential, as it represents the stage at which the core aspects of the system are defined, such as the multidisciplinary team that will be involved in its development, costs, responsibilities, system requirements, and the necessary political commitment, among others. This chapter reviews the most important aspects that must be addressed when entering the planning stage of EIR development.

By the end of this chapter, you will be able to define:

- How to formulate a work plan and define timelines and the key considerations for implementation of an EIR.
- The scope of the project.
- What resources and competencies are required for implementation of an EIR.
- Which stakeholders and players are part of the team.
- What costs are associated with the cycle of an EIR.
- Whether a formal transition stage from a non-individualized information system to the EIR should be implemented.

3.1 USEFUL STRATEGIC PLANNING ELEMENTS FOR THE IMPLEMENTATION OF AN EIR SYSTEM

The formulation of a plan allows:

1. Implementation of activities consistent with the defined objectives and strategies within the defined timelines.
2. Harmonization of actions and actors around a common objective.
3. Mobilization and allocation of the necessary resources.
4. Monitoring and evaluation of progress toward the proposed objectives, so that any necessary adjustments can be made.

Strategic planning proposes a framework for the management and implementation of EIRs. Such a plan will allow the team established for the management of the EIR to define national goals, results, indicators, and targets to develop and strengthen the EIR during a given period. Furthermore, it enables integration of the IIS with the HIS and its inclusion within the national eHealth strategy's framework. The main objectives of strategic planning are to:

» Document the importance of strengthening information systems in order to have individualized immunization registries in the country, making this requirement clear to the national authorities with decision-making power to achieve their support, commitment, and priority.

» Generate external and internal analyses of the relevant aspects that will have an impact on development and implementation of the EIR system, considering this as a system cycle over the long run.

» Harmonize the objectives of the different participants in the process of EIR development, design, and implementation.

The proposed methodology for strategic planning combines elements of situation and context analysis, SWOT (strengths, weaknesses, opportunities, and threats) analysis, and a logical framework for planning, adapting them to the context of health information systems. This method should be led by a project manager, ideally from the EPI or directly affiliated with it. Either way, the established team must maintain an active level of participation. This team should consist of:

» Head of the immunization program or equivalent

» Immunization data management area within the Ministry of Health and related institutions (within the EPI, from the statistics agency, or others)

» Epidemiological surveillance area

» Health information systems and/or information and communication technologies area

» Other immunization service providers

This methodology raises the following reference questions for the definition of the information system's mission, which should be answered by the team:

» Why is this EIR needed?

» Why is it important to have a system with these characteristics?

» What is the country's current immunization registry information system and which are the systems used by different providers (social security, private sector, NGOs, etc.)?

» What are the results and functions of the EIR?

» What is the vision of the program in terms of information systems and data quality?

» What is the forecast for the immunization program for the next 15 years?

» What are the MoH's strengths and weaknesses at the internal level that might affect achievement of these objectives?

» What opportunities and threats come from the external context?

» What are the strategic lines of action that the strategic plan encompasses?

» What are the strategic objectives that should be proposed to fulfill the vision of the EIR information system?

» What is the political priority of the authorities with regard to information systems?

» Is any restructuring in the health system and/or organization expected to occur?

» Is there an eHealth strategy to guide health information systems-related guidelines?

» Is relevant legislation in place or being drafted?

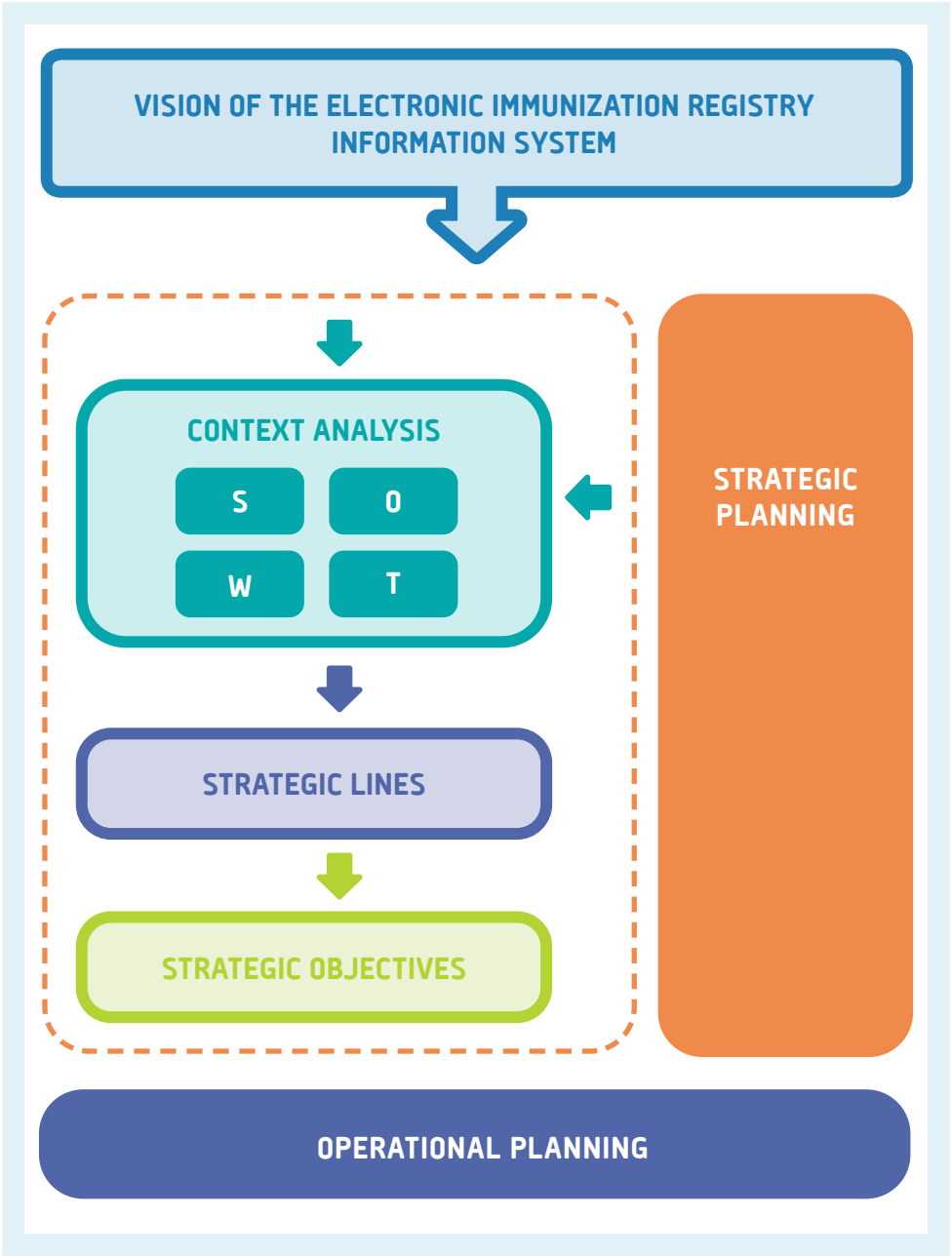
This EIR strategic plan should be supplemented by an operational plan, which is an instrument for the management of the activities and necessary resources for implementation of the strategic plan that will allow monitoring and follow-up of adherence to the defined timelines and the financing of said activities, with national resources and from international cooperation agencies, if applicable. Figure 9 presents the proposed general methodology.

TOOLS

For more information on planning an information system, review and use the tools made available in the document "Planning an information system project: A toolkit for public health managers":

http://www.who.int/immunization/programmes_systems/supply_chain/optimize/planning_information_systems_project.pdf

FIGURE 9.
General methodology for EIR planning



3.2 SCOPE OF THE SYSTEM

The scope of the system is an essential point to consider within planning, since its complexity determines which activities are to be developed in the future and their associated costs. **When defining the scope of a system, one must define both what is included and what is not**. Defining the scope is important because:

» It provides the necessary stability for the whole cycle of the information system

» It allows the program to take control of the project and be clear when addressing personnel involved in development of the information system

» It helps manage expectations regarding the information system

» It enables definition of indicators for measurement of the success of the project

The scope of a system is established in three dimensions:

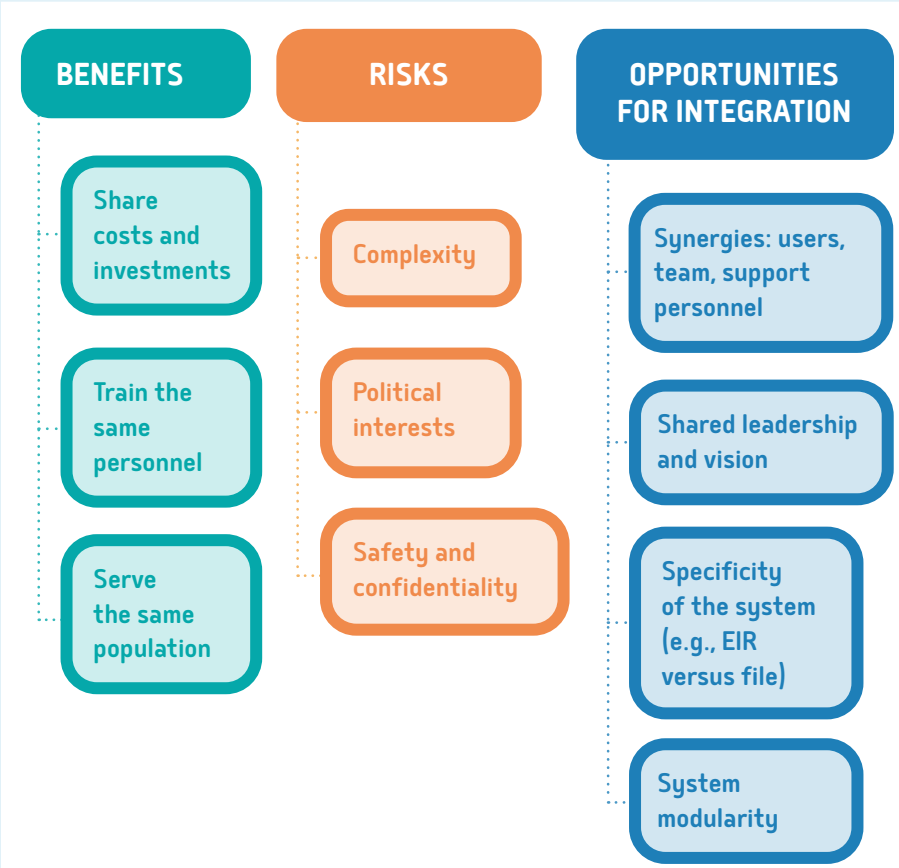
1. **Functional:** this dimension refers to what the system does. One must determine if the system will be used as a registry of immunized individuals, for storage of vaccine histories, for ESAVI surveillance, for supply management and logistics (vaccines and other related supplies), for promotion and dissemination activities, for financial and/or accounting transactions, and/or for the management of human resources, for instance.

   If the system is defined to be an EIR, certain activities must be prioritized. For example, in its early days, the EIR can focus only on the population of children under 5 years of age and then later start to include records of older individuals. Another example is if the decision is made to design the immunization information system in a modular fashion. In this case, system deployment can begin with the EIR module and, at a later stage, add ESAVI and logistics modules. From the start, there should be a complete overview of the system and which modules it will include, so as to facilitate interoperability and step-by-step progress toward achievement of this vision. Associated key documentation should be created and formalized, such as the operating plan, the survey of requirements, and technical specifications.

2. **Programmatic:** this dimension of scope refers to the public health programs that will use the system. It must be defined a priori whether the system is going to be designed for a specific program or whether it will be part of an integrated public health system. If the final objective is integration into the public health system, this should be done progressively. However, this should be clearly stipulated from the start. To answer this question, one must first think about the end users. Will they end up having to use several systems to do their jobs? If so, it would be necessary to coordinate their needs with regard to system development. This is a relevant step, as some countries choose to implement integrated public health systems. This integration can involve benefits, risks, and opportunities that should be evaluated according to each country's decision. Figure 10 presents each of the potential characteristics.

3. **Geographical:** the geographical dimension states where the system is going to be used and by whom. It is necessary to determine whether it will be deployed nationwide, at which levels of the health system, and whether it will be used in hospitals, district offices, or community health centers. Furthermore, it is essential to know the structural conditions of each area, as different strategies can be defined for different contexts (e.g., online vs. paper-based/offline system; who should key in or enter data into the information system; depending on size, access, information, structure, volume of immunization recipients, etc.). Data may be entered at the local, municipal, departmental, or mixed level. One must also consider the entire health sector that contributes to the immunization process, with actors such as the private sector, social security, communities, NGOs, and the armed forces, among others.

FIGURE 10.
Potential benefits, risks, and opportunities for system integration and interoperability



TOOLS

For more information on functional scope documentation, review and use the tools contained in "Planning an information system project: A toolkit for public health managers":

http://www.who.int/immunization/programmes_systems/supply_chain/optimize/planning_information_systems_project.pdf

KEY CONSIDERATIONS

- Formulate questions about what is expected of the information system. The answers to these questions should define the scope of the system:
  - » What is needed and wanted from the system?
  - » What problem(s) is (are) being solved?
  - » Who will solve these problems?
  - » Who will use the system?
  - » Where will the system be used?
- Consider that a health information system should not necessarily be deployed as a system that does everything for everyone from the start. One solution can be to "modularize" the system or deploy the project in phases. A cost estimate should be calculated for each module. In this way, decision-makers will have a clear notion of the additional costs of each one.
- It is best to start at the pilot stage, with reduced scope, so that system implementation will be easier and deficiencies can be detected and corrected before expanding the functional, programmatic, or geographical scope.
- At the start of any important ICT project, the management team should prepare an implementation roadmap or a document summarizing the key characteristics of the project, what it should enable, and when and where it will be deployed. Thus, there will be no doubts as to its goals, targets, and scope.
- A plan for monitoring and evaluation should be agreed upon and implemented, in order to determine systematically what is working well and what is not, so the necessary adjustments can be made in a timely fashion.
- It is important to achieve a common language among the EPI professionals and the IT staff, to ensure a shared vision of the project.

3.3 DEVELOPMENT OF AN OPERATIONAL PLAN

Once the elements of strategic planning and the scope have been defined, an operational plan must be formulated for management of project activities and of the necessary resources for their implementation. This plan will enable monitoring and follow-up of compliance with the objectives, defined time frames, and allocated funding for such activities, considering both domestic resources and those of international cooperation agencies, if applicable. It is also important to define the team that will be involved throughout the process and authorize its participation.

For this reason, a diagnosis of competences, resources, and capacities is essential to evaluate the country's state of investment at the time of deciding on the implementation of an EIR system. In each case, the advantages and disadvantages provided by different alternatives should be analyzed and, at the very least, the following elements should be considered:

- » Context of health information systems already in place or under development
- » Human resources
- » Data entry and information flow processes
- » Technical infrastructure
- » Financial resources available
- » Monitoring of implementation (system follow-up)
- » Stakeholders and actors participating in the working group

3.3.1

CONTEXT OF HEALTH INFORMATION SYSTEMS ALREADY IN PLACE OR UNDER DEVELOPMENT

The national eHealth strategy (or equivalent), the state of development of health information technology in the country, and associated regulations should be taken into account, as these will provide the framework into which the EIR system will be implemented. It is important to determine if implementation of some form of individualized immunization registry has already been attempted in the past or is already in place (e.g., at the provincial level, in the social security system, or by another provider) and, if so, how long it has been in place and whether it is part of a larger information system. Progress on implementation of electronic medical records or other similar individualized systems should also be assessed. The successes and failures of existing systems can provide the basis for selection of which type of registry to implement. A series of recommended questions to help clarify this aspect are presented in the following table.

KEY QUESTIONS

?	Does the country have an eHealth strategy?
?	Does the country have legislation that affects or influences decisions on development of the EIR? For example, does it consider interoperability standards, confidentiality of health data, etc.?
?	Does the country have a paper-based individualized immunization registry or information system? If so, at which level?
?	Does the country have some form of EIR or information system already in place?
?	Have other EIR projects been implemented previously, at the pilot level or otherwise? If so, what happened?
?	How can experience with individualized immunization registries at the local level be leveraged for the process of EIR implementation?
?	How can an EIR information system help implementation of immunization strategies?
?	What is the current process for registration of immunization activities? How would it or could it change (to increase efficiency) with implementation of the EIR system? Are there areas in the country where this would work and others where it would not? Why?
?	Should processes be reengineered at some level?

3.3.2

HUMAN RESOURCES

One of the core elements for implementation of an EIR is the empowerment and commitment of human resources, which should be in sufficient number and sufficiently skilled at each level in which the system will operate. In some cases, the responsibility for data entry and reporting of immunization lies with the same person who administers vaccination; in other cases, there is a data entry clerk who performs this task. On the other hand, in the early stages of an EIR system and during the transition period (see Section 3.6) of implementation, the EIR and the old non-individualized system are likely to be used in tandem, which means additional workload for vaccinators and/or data entry clerks. A list of questions to help elucidate this aspect is presented below.

KEY QUESTIONS

- Who participates in the registry and in the flow of information to the EIR?
- Is the EIR intended for use in a vaccination room or in a data entry room? Do the personnel have the necessary computer skills?
- If the EIR system is intended for implementation in a data entry room, do the typists/entry clerks have the necessary knowledge about the immunization schedule and registry?
- Do all intended users have the computer skills needed to use the system?
- Will sufficient training be provided not only in use of the system, but also in computer skills? What strategy will be used for the training (e.g., online vs. in-person)? What is the cost of each training strategy?
- Will provisions be made for a strategy to solve problems that arise (e.g., a help desk)?
- How will the potential burden of using two parallel systems in the early stages of EIR implementation be handled?
- How can the pilot stage be supported so this transition is as smooth as possible?
- Are health providers accepting or even enthusiastic about the change?
- What is the current workload of health providers? What value will an EIR add to their work?
- Is staff turnover an issue? If so, what provisions are in place to ensure new personnel have the necessary competencies?
- Will personnel have to be allocated for historical data entry?

3.3.3

INFORMATION ENTRY AND FLOWS

A diagnosis should be made of the flow of information and the records associated with this flow, to provide a picture of which data are currently collected and which registries are used. This information can be used to evaluate whether the system should include the variables already collected and used in the current system or should use others instead, always taking into account that variables that will not be analyzed should not be included.

Sometimes, data collection instruments must be changed completely. For example, if lists of people to vaccinate are generated every month in an offline EIR, there would no longer be any need for a ledger or log in which each individual's information is recorded whenever they are vaccinated; only the data on the vaccination itself (vaccine, date, vaccinator, facility) will have to be filled in each time, thus increasing the efficiency of the recording process. Only when people who were not included in the previous monthly list (i.e., those receiving their first vaccination, those vaccinated previously in another facility, etc.) present to the facility will their data be entered, either to search for their existing records in the registry or to create a new record if none exists. In an online EIR system, the procedure is the same, with the added advantage of preventing duplicate entries. Another case involves extramural immunization activities, which, depending on the situation of each country, can be recorded using a paper-based system (and the resulting information keyed into the EIR) or on a mobile device that allows immediate data entry during the immunization activity. Following is a list of questions to help elucidate this aspect.

KEY QUESTIONS

- What are the instruments and procedures used to collect immunization information in each immunization strategy (forms, computer equipment, etc.)?
- What is the flow and periodicity of immunization data entry at each level of organization?
- How would the roles of the different levels of organization change with the implementation of an EIR?
- How would data quality validation activities change?

3.3.4

INFRASTRUCTURE AND TECHNOLOGY

The implementation of a health information system should include the necessary conditions for its proper operation and proper utilization by users. Infrastructure needs (temperature control, desks, chairs, shelves, surge protectors, etc.) should be taken into account. On the other hand, the EIR is a component of a complete immunization information system. Health information systems are increasingly taking advantage of Internet connectivity to provide remote access, entry, and storage of data online, which means that the technical infrastructure is an important aspect at the time of considering implementation of an EIR [15].

KEY QUESTIONS

- Is an adequate physical space available for data entry (desks, in/out trays for forms to be entered and already entered into the system, air conditioning in warm climates, etc.)?
- What infrastructure and tools (computers, surge protectors, servers, printers, others) are needed and to what extent are these available?
- How many immunization/data entry facilities have an Internet connection?
- What are the limitations of those connections (speed, frequent downtime, etc.)?
- How many immunization/data entry facilities have a constant supply of electricity?
- How many immunization/data entry facilities have adequate hardware (based on the system requirements)?
- Does the Ministry of Health or another government agency of the state provide a hosting and storage service or must the system resort to cloud services or virtual servers?
- What provisions will be made for the security of IT teams and equipment?

3.3.5 FINANCIAL RESOURCES

A financial mechanism must guarantee availability of the necessary resources throughout the cycle of the EIR system, from the initial investment to routine system maintenance and updates. The following list of questions can help elucidate this aspect.

KEY QUESTIONS

- Does the country have a clear and realistic estimate of the capital cost required for the EIR? What information is available and what is lacking?
- Does the country have a clear and realistic estimate of the maintenance cost of an information system similar to the proposed EIR? What information is available and what is lacking?
- Does the country have its own funds available for the implementation of an EIR?
- Are there possibilities of applying for external funds for development and/or implementation of an EIR?
- Do funds (domestic and/or external) cover the entire cycle of the system and its technical requirements?
- What provisions will be made to ensure the sustainability of the EIR in the future?

3.3.6

MONITORING OF IMPLEMENTATION (SYSTEM FOLLOW-UP)

Monitoring and evaluation are essential for follow-up of EIR system implementation throughout the cycle. Thus, it is relevant to define parameters clearly and assign a team to take charge of this monitoring. The following series of recommended questions can help elucidate this aspect in terms of time and budgeted financial resources.

KEY QUESTIONS

- Does the country have a team or focal point responsible for monitoring and evaluation of the EIR information system?
- How is implementation taking place with regard to the original plan?
- How is implementation taking place with regard to the allocated resources?
- Are periodic meetings for monitoring of the information system being held?

3.3.7

INTEREST GROUPS AND STAKEHOLDERS PARTICIPATING IN THE WORKING GROUP

All phases of the EIR information system cycle involve the participation and contributions of a multidisciplinary team, in addition to interest groups that hold stakes in the information generated by the system. It is advisable to define, from the very start, the roles, duties, and responsibilities of each participant and formalize their status as a part of the work team.

Table 2 lists potential stakeholders that should be considered, either as active participants during the system cycle and/or as part of interest groups involved in defining information requirements.

TABLE 2. List of potential participants in development of an EIR

LEVEL	RELEVANT PLAYERS
Operational (immunization facility)	Vaccinator (public or private sector, other institutions that vaccinate)
	Recorders and data entry clerks
	Community; mothers, parents, or guardians; schools
	Head or director of the institution/facility
	Person in charge of the immunization program
	Data entry clerks
	Head or director of the institution/facility
	Health personnel (physicians, nurses, aides, epidemiologists, among others)
	Statisticians
	IT engineers
	Communication personnel
	Situation room or liaison center staff
	Other health programs

TABLE 2. continued

LEVEL	RELEVANT PLAYERS
Intermediate	Person in charge of the immunization program
	Head of the institution/facility
	Data entry clerks
	Other health programs
	Health workers, including statistics personnel
	Planners and budget managers
	Person in charge of the vaccine stockpile/office supply distribution center
	Political authorities (mayors, governors, etc.)
	Communication personnel
	Situation room or liaison center staff
National	Person in charge of the immunization program
	EPI team
	Statisticians
	Persons/agencies in charge of health surveillance
	Institutional or departmental authorities
	Persons/agencies in charge of ICTs and/or eHealth
	Regulatory authorities
	International organization staff, donors, investigators, and scientific societies
	Planners and budget managers
	Other immunization providers: private sector, social security, armed forces, among others
	Ministry of Finance
	Communication personnel
	Persons in charge of other programs
	Situation room or liaison center staff
	Political authorities (Minister of Health, Presidency, lawmakers, etc.)

TOOLS

For more information on operational planning, review and use the tools made available in the document "Planning an information system project: A toolkit for public health managers":

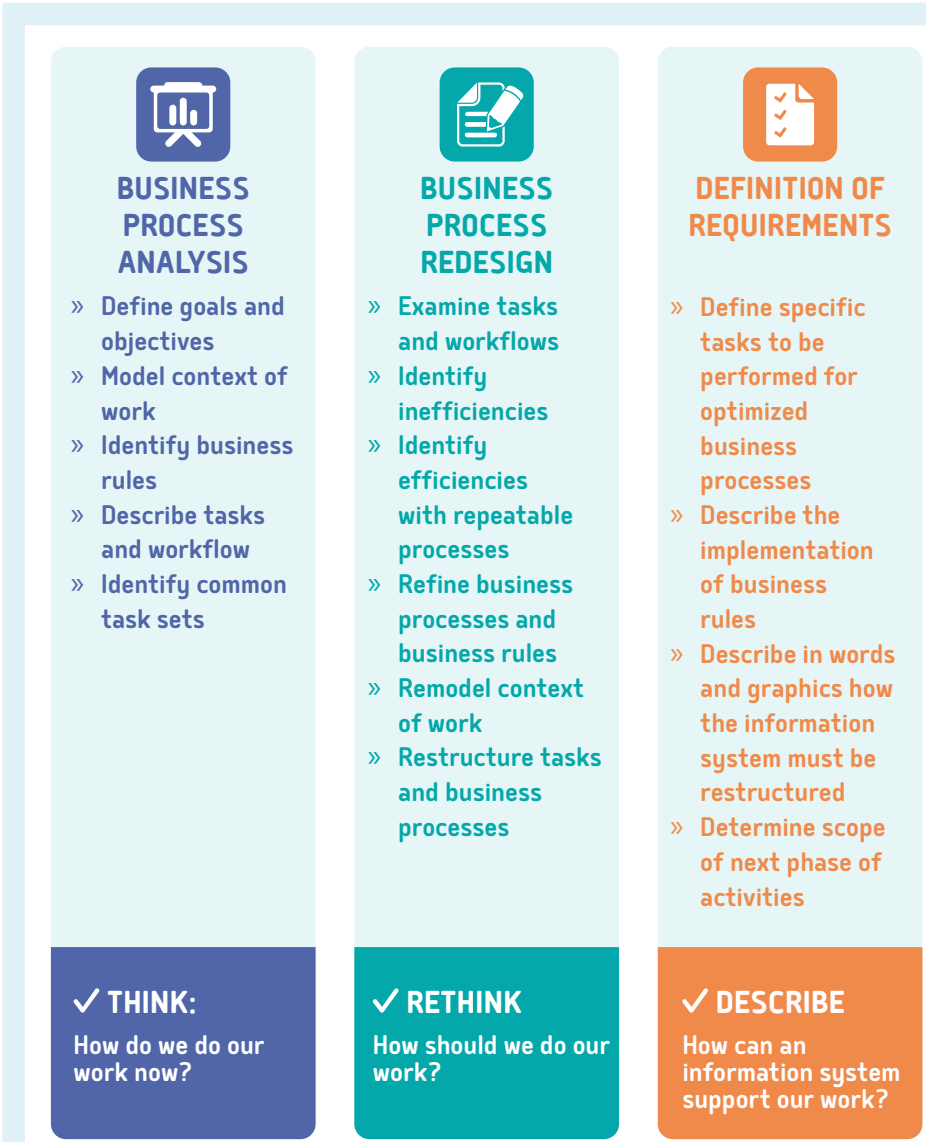
http://www.who.int/immunization/programmes_systems/supply_chain/optimize/planning_information_systems_project.pdf

3.4 CURRENT INFORMATION FLOWS

The purpose of information systems is to make processes more effective and efficient. A process survey is the starting point to define what the EIR must do, as it enables identification of the essential elements for the specific context. In general, during implementation of information systems (including EIRs), health providers should work together with IT personnel. These two groups have completely different training backgrounds, and communication between them does not always flow well. Thus, it is important to find a clear methodology for work that ensures understanding among all stakeholders, with a view to identifying the requirements the information system should meet. This will prevent or reduce potential causes of project failure.

The Public Health Informatics Institute (PHII) uses a best-practices methodology known as the Collaborative Requirements Development Methodology (CRDM), designed to keep projects on time and within the established scope [16]. Figure 11 describes the stages of this methodology.

FIGURE 11.
Collaborative Requirements Development Methodology (CRDM)



Defining processes can help think about how people work before making changes to the process through the introduction of an information system. This increases the possibilities of incorporating the needs and requirements of the users who are actually going to utilize the tool. For example:

» If the EIR system is installed in the immunization room, health providers can incorporate a review of the child's vaccine history and of any contraindications into the process.

» If the system has clinical-decision support capabilities, the same system will indicate the correct immunization schedule for each individual.

» Definition of a monthly immunization plan in accordance with the number and type of people to be immunized each month can also be different with an EIR in place, since data can be obtained directly from the system.

» In extramural campaigns or activities, a list of children to be immunized in each area can be printed out and taken into the field.

» Another option for extramural campaigns is the use of mobile technologies, through which vaccinators can have access to information on unvaccinated persons and can update this information with real-time data.

In a process survey, it is important to diagram the flow of activities and those responsible for their implementation. This activity flow follows up the entire process and constitutes a coordinating element that provides a clear, consensus-based definition of the process to the members of the group and other stakeholders.

KEY CONSIDERATIONS

- The design of the EIR should take into account the operating levels and should be useful for vaccinators. It should be designed with a clear understanding of the vaccination and data recording processes. It should also take into account that processes can be optimized with this technology, i.e., it is not about simply switching from existing paper-based immunization registry forms to electronic ones, but rather a true reengineering of the processes themselves.

- Seek out channels for communication between program technical staff, IT personnel, and all participants, with a view to ensuring that all parties understand the requirements and objectives of the system.

TOOLS

For more information on processes, review and use the tools made available in the document "Planning an information system project: A toolkit for public health managers":

http://www.who.int/immunization/programmes_systems/supply_chain/optimize/planning_information_systems_project.pdf

For more information on CRDM, visit: http://phii.org/crdm

3.5 COSTS ASSOCIATED WITH THE CYCLE OF AN EIR

The costs of EIR implementation go beyond the initial capital cost of the information system. In fact, its maintenance can be more expensive than the initial development and implementation; if these expenditures are not provided for, the system may be abandoned.

In the field of information system management, a concept known as total cost of ownership (TCO) is used. This refers to a comprehensive audit of the costs associated with information systems and ICTs. The TCO considers all organizational costs related to the subject: procurement of hardware and software, management and technical support, communications, training, system maintenance, updates, operation costs, networks, safety, licensing costs, opportunity costs of system downtime, etc. It is important to understand the TCO because it prevents underestimation of costs, considers all needs for funding, and allows allocation of an adequate budget for the short, medium, and long term. The following questions are particularly relevant when the time comes to define costs:

» Is an EIR a good investment?

» What are the main cost categories involved and what variables affect these costs?

3.5.1 IS AN EIR A GOOD INVESTMENT?

According to published literature and to the opinions of experts and countries that operate this type of system, an EIR can be considered a good investment for the country, provided that the necessary conditions for implementation of the system are ensured [17-22]. It is important to note that, according to these experiences, no return on investment is seen in the short term, only once the system is fully set up and its use has matured. Annex 3, "*Why an EIR is a good investment,*" provides evidence in this regard.

3.5.2

COST CATEGORIES

The main cost categories of an electronic immunization registry (EIR) are listed in Table 3.

TABLE 3. Cost categories and examples

COST CATEGORY	EXAMPLES OF ASSOCIATED COSTS
Administrative support	» Wages of administrative personnel who provide support for related processes » Office supplies » Travel and meetings
Development	» Developer costs » System customization costs, in the event that a ready-made system is being adapted for the country » Costs of pilot deployment and subsequent modifications to the system
Scale-up	» Cost of technical support at the national level » Travel and meetings » Training
Hardware	» Computers » Central processing units (CPUs) » Printers » Surge protectors
Software	» System software licensing (per user, per environment, free, etc.) » Licensing of other necessary software products
Network infrastructure	» Internet connectivity costs
Security	» System security costs (antivirus, firewall, etc.) » Backup costs
Physical infrastructure	» Proper space for hardware and data entry
Training	» Costs of travel and meetings for personnel in charge of training and participants » Hours devoted to staff training
Data servers	» Servers for data storage and protection
Management and technical support	» Help desk/call center » Wages of personnel assigned to answer user queries » Time devoted to the formulation of registry guidelines
Maintenance	» 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	» Wages of data entry clerks (if a new position is created or overtime is required) » Wages of personnel in charge of the system
Communications	» Strategy for communication and dissemination of EIR use
Monitoring and evaluation	» Wages of HR professionals (with different profiles) » Data quality assessments » Field inspections » Periodic data quality evaluations at all levels

3.6 TRANSITION STAGE FROM A NON-INDIVIDUALIZED INFORMATION SYSTEM TO AN EIR: YES OR NO?

The transition period from a non-individualized information system (one based on consolidated data) to an EIR system is critical. The implementation of the new system should be progressive and parallel; this ensures the comprehensiveness and comparability of the system and allows detection of challenges in EIR implementation. To prevent information loss and reduce workloads, it would be desirable that, during the transition stage, EIR data could be incorporated automatically for the construction of indicators in the non-individualized system. It is advisable that the non-individualized system remain in operation until certain requirements are met (Table 4).

TABLE 4. Checklist for compliance with requirements during construction of non-individualized system indicators

ACTIVITY	DONE
Training of all health personnel in the operation of the EIR and guaranteed acceptance at all levels.	☐
Creation and dissemination of a standard to support implementation and compliance at all levels.	☐
Quality assurance of the information generated by the EIR through comparisons between the two systems, data quality assessments, and other field studies.	☐
Satisfactory correction of system and/or user errors by the health personnel.	☐
Similar administrative immunization coverage reported by both systems.	☐

Another important aspect in the transition period is to decide whether historical vaccination records will be entered into the system or whether data will only be entered starting from a given date. Table 5 describes some options.

TABLE 5. Options for data entry into a non-individualized system

OPTION 1. ENTER NEW DATA ONLY, ONCE THE SYSTEM HAS BEEN IMPLEMENTED.	
Description Start entering data only from a certain date onward, making no attempt to update the system with information on vaccines administered before that date.	
Advantages	**Disadvantages**
» Simpler process. » Does not require additional cost or effort.	» Limits data analysis for continuous monitoring of immunization schedules and coverage, as historical records will not be available.

TABLE 5. continued

OPTION 2.
ENTER ALL HISTORICAL IMMUNIZATION DATA OR DATA FOR A GIVEN PERIOD

Description

During the implementation process, the immunization schedule of each person entered into the system will be updated from the paper-based records of each facility. The purpose of this update is to provide online information on the vaccine history of the target population of the immunization program, which will allow consolidation of information for later analysis processes that will become inputs for decision-making by program leaders. This implies that, from the date of application rollout, the following should be entered into the system:

» New cohorts of live births or infants receiving their first immunizations, which will allow consolidation of the population in the EIR.

» Information from the vaccination cards of vaccine recipients who belong to a cohort from before system implementation or who attend an immunization facility to receive one or more vaccines, and who will then continue their regular vaccination schedule as appropriate.

» Existing vaccination records for previous periods from each facility, in order to compile retrospective information. Human resources at the local level or at senior management (municipal or departmental) levels should be reinforced for this purpose.

» Immunization data for foreigners or people vaccinated in other countries, using their respective vaccination cards or books as a source. It is important to recognize differences in immunization schedules and their equivalence to the national schedule, in order to record reliable information that will allow these patients to continue their schedules subsequently. This will prevent unnecessary administration of vaccine doses already received.

Advantages	Disadvantages
» The vaccine history of the population will be entered into the EIR information system. » The system can be tested with real data, which can allow detection of flaws or deficiencies.	» Requires additional effort, time, and resources on the part of health providers or other personnel hired to carry out this activity. » Requires training for personnel who will enter historical records into the system. » Vaccine recipients can become frustrated if they are not included in the new system.

During the transition period between systems, it is important to monitor the acceptability of the EIR by users and by the population and understand its impact. The following factors should be analyzed:

» Health personnel and system users
  - Resistance to change.
  - Workload brought on by the new data entry procedure and by incorporation of the process into their established workflow (who will key in data, who will coordinate, who will review information in the system, etc.).
  - Time to register a new vaccine recipient in the system.
  - Use of reports by different user profiles.

» Population
  - Perception of confidence in data security.
  - Amount of data requested.
  - Wait times per new system procedure.
  - Use of reports made available to the population; e.g., online printout of vaccination card.
  - Programmatic errors.
  - Beneficiary's satisfaction with access to their own personal data through the Internet (from a computer or personal mobile device).

KEY CONSIDERATIONS

- When formulating plans for implementation of information systems, organizations should consider the maintenance and update stage of the system, which can be very costly.
- It is important to establish business rules in the system to facilitate its use by vaccinators and data entry clerks. However, such business rules should not be so restrictive as to prevent staff from logging program errors, if these occur.
- At the time of EIR design, it is important to consider making the system amenable to parametrization, so as not to depend on a third party for evolutionary maintenance.
- It is important to define the maintenance schedule in advance (except for corrective activities), as maintenance can be lengthy and lead to system downtime.
- If evolutionary maintenance is carried out, it is important that data entry personnel and system users be well informed of the changes implemented and, if applicable, how to use new system functions. Furthermore, in the case of an offline EIR, a mechanism should be implemented to ensure that each system installation in use is the most up-to-date version of the software.
- The maintenance stage should always be considered in planning, as, regardless of how it is carried out (i.e., by an internal developer or an external service provider), maintenance activities and types must be established in advance.
- These concepts apply to both software and hardware maintenance of the information system.
- Two important issues that will ensure the success of EIR implementation should also be considered during planning: the training strategy and the communication strategy. These two aspects inevitably require time and effort, but have massive impact.

4

Necessary elements for electronic immunization registry (EIR) implementation and achievement of results

By the end of this chapter, you will be able to define:

- Which variables must be considered in an EIR.
- Which are the functions of an EIR.
- How can an EIR help implement immunization strategies.
- How will the success of the system be measured.

Defining the expected results of an electronic immunization registry is an important step in the design of the information system, as the requirements, functionalities, and demands of the system must be stipulated clearly. The present chapter describes relevant aspects in this regard, based on a review of the literature and on the experience of countries that already have such systems in place.

4.1 VARIABLES TO CONSIDER FOR AN EIR

When deciding which data to collect, it is important to take into account information needs for program management, evaluate the costs and benefits of the efforts needed to obtain such information, and assess the workload that this can represent for health workers. It also is important to note that, the greater the number of variables included, the greater the resulting workload, which can affect the quality of input of key data (Table 6).

Countries will define their own basic data sets for collection; however, the following categories are considered essential for an EIR, according to the literature and to the expert opinion of countries with existing systems.

TABLE 6. Variables to consider in an EIR

CATEGORY	VARIABLES	PURPOSE
Demographic data of the user or vaccine recipient	Unique identifier of the vaccine recipient, if available in the country (e.g., national ID card, social security number, national health system number, passport, or similar ID)	These variables are necessary for unique identification of each vaccine recipient, and thus allow follow-up of individual immunization status. Furthermore, these variables allow generation of different analyses, e.g., of data quality, inequalities, and coverage by place of residence, and enable active search of unvaccinated individuals or defaulters as required. On the other hand, they also allow implementation of monitoring activities and vaccine reminders through telephone calls and/or text messages.
	First name, middle name, last name(s)[a]	
	Date of birth	
	Place of birth (health facility, city)	
	Sex	
	Ethnicity	
	Contact telephone number (landline and/or mobile)[b]	
	Home address	
	Municipality (or similar) of residence	
	Landmarks or directions to user's place of residence	
	Coordinates or georeferences to user's place of residence	
	Nationality	
	E-mail	
	Occupation	
	Status (active/inactive, e.g., in case of migration or death)	
Parent or legal guardian of vaccine recipient	Complete name and surname of the mother and/or father and/or guardian of the patient	These variables enable complete identification of the individual, especially of children, and allow implementation of monitoring activities and reminders through telephone calls and/or text messages.
	Phone number (landline and/or mobile)	
	Municipality of residence	
	Unique ID of patient's parents (e.g., national ID card, social security number)	

TABLE 6. continued

CATEGORY	VARIABLES	PURPOSE
Immunization activity and description of the biologic agent	Biologic[c]	Necessary for establishing a detailed history of the immunization activity. This provides a complete vaccine history for each individual and thus allows follow-up in accordance with the established immunization schedule. On the other hand, data related to the biologic agent or vaccine itself allow various analyses of data quality, stock traceability, reasons for not vaccinating (e.g., contraindications vs. refusal of certain vaccines), and monitoring of ESAVIs.
	Dose[d]	
	Date of administration	
	Batch number	
	Batch expiration date	
	Commercial formulation (e.g., hexavalent, pentavalent)	
	Manufacturer	
	Condition of the vaccine recipient, if applicable	
	Reason for not vaccinating (includes contraindications, history of ESAVI, etc.)	
	Vaccination-emergent adverse reactions (reported ESAVIs)	
Immunization strategy and technique	Name and address of health facility	These variables provide a detailed background of the facility where the vaccine was administered and who administered it, and allow analyses of productivity of the immunization strategy used.
	Identification code of health facility	
	Type of health facility	
	Sector (public, private, or other)	
	Type of strategy (intramural, extramural, etc.)	
	First name, last name, and ID number (or assigned code) of vaccinator	

ESAVI: event supposedly attributable to vaccination or immunization

[a] The use of separate fields for first name and last name facilitates later search of the database.

[b] More than one field may be used, to record additional telephone numbers and e-mail addresses.

[c] If there is no catalog or formulary of biologics connected to the system, the information in this field should be used instead.

[d] The EIR can be programmed to calculate the number of the dose administered. For instance, if a user known to the immunization 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.

KEY CONSIDERATIONS

- Given the wide range of providers of immunization services and the availability of data at different levels, it is recommended that the EIR implementation team categorize which variables are mandatory and which are optional regarding the vaccine recipient (beneficiary), the beneficiary's parents or guardians, the vaccine itself, etc.
- It is essential that these basic fields describe as best as possible **who, what, when, how,** and **where** the biologic agent was administered to each person.
- Mandatory variables are indispensable for unique identification of vaccine recipients and definition of each vaccine administration.
- Another important consideration is that, whatever the defined elements, data collection should be carried out in a consistent, uniform, standardized manner, aligned with other health information systems, taking into account that the data will be used for population statistics.
- The system should be user-friendly and efficient, and the number of variables should thus be adequate to the workflow of health providers.
- It is important to mention that an EIR is only as useful as the quality of the entered data; as a result, efforts should be made to ensure that the data collected, recorded, and stored in the system meet minimum coverage and quality standards.
- The lowest level of geographical disaggregation for purposes of analyses should be clearly defined.

4.2 EIR FUNCTIONS

The minimum functional requirements of an "ideal" EIR information system (see Section 2.4) and the responsibilities of the program are defined in Table 7.

TABLE 7. EIR functions

EIR FUNCTION	LOCAL LEVEL	INTER-MEDIATE LEVEL	NA-TIONAL LEVEL	COMMU-NITY
Data entry				
Recording of each immunization event[a]	X			
Storage of individualized vaccine histories	X	X		

TABLE 7. continued

EIR FUNCTION	LOCAL LEVEL	INTER-MEDIATE LEVEL	NA-TIONAL LEVEL	COMMU-NITY
Calculation and report of vaccination coverage				
By vaccine	X	X	X	
By dose	X	X	X	
By age	X	X	X	
By geographical area (place of residence and place of vaccination)	X	X	X	
By condition (chronic disease, pregnancy, etc.)	X	X	X	
By immunization strategy (intramural, extramural, school-based, etc.)	X	X	X	
By population group (ethnicity and other groups as required by each country, etc.)	X	X	X	
By sex	X	X	X	
By health system affiliation (social security, health insurance, private, etc.)	X	X	X	
Report management				
Predefined reports[b] (e.g., coverage, dropout rate, timeliness and simultaneity of vaccination, etc.)	X	X	X	
Special reports (cohort monitoring, specific requirements, etc.)	X	X	X	
Data visualization (dashboard with relevant indicators)	X	X	X	
Monitoring of potential programmatic errors	X	X	X	

EIR FUNCTION	LOCAL LEVEL	INTER-MEDIATE LEVEL	NA-TIONAL LEVEL	COMMU-NITY
Traceability of the administered biologic agent				
By expiration date	X	X	X	
By manufacturer	X	X	X	
By batch number	X	X	X	
By facility or vaccinator	X	X	X	
Interoperability with other systems				
EIR systems of other regions, provinces, etc.	X	X	X	
Other information systems (electronic medical records, civil registry, other modules of the immunization information system, etc.)	X	X	X	
Individual immunization schedule monitoring				
Access to vaccine history	X	X	X	
Automatic generation of reminders (calls, text messages, etc.)	X			
Daily, weekly, or monthly scheduling (list of unvaccinated individuals)	X	X		
List of defaulters	X	X		
Business rules to support clinical decision-making (rules are optional at the country's discretion, but this functionality is essential)	X			
Search and management of duplicate entries (de-duplication protocols)	X	X	X	

TABLE 7. continued

EIR FUNCTION	LOCAL LEVEL	INTER-MEDIATE LEVEL	NA-TIONAL LEVEL	COMMU-NITY
Access to information by external stakeholders, according to security clearance parameters				
Generation of vaccination card				X
Access to consolidated data				X
Communication between the EPI and EIR users (one-way or two-way)	X	X	X	
Alert management (validation, contraindications, precautions, etc.)	X			
Flexibility to update the structure (schedules, providers, etc.)			X	
Offline data entry	X	X	X	

[a] If paper-based for later inclusion in the system, records should be designed to facilitate data entry. For individuals who are already registered in the EIR, the use of lists where the only parameters updated are vaccine, dose, and date of immunization minimize errors and make data entry more efficient than having to collect all user data every time the same person receives a vaccine.

[b] See Annex 4, "*Essential EIR reports*".

4.3 HOW CAN AN EIR HELP IMPLEMENT VACCINATION STRATEGIES?

EIRs are designed to collect data and thus contribute to the improvement of quality and timeliness of health information. They are a useful tool for the EPI at all levels of responsibility. Table 8 lists the various practical advantages that an EIR system can provide for definition of immunization strategies, according to system functionalities.

TABLE 8. Practical benefits of the use of EIR systems

OUTCOME AND FUNCTIONALITY	PRACTICAL UTILITY
Coverage calculation	» Data collected by the system make it possible to define the numerator for program coverage calculation for a given period. » If the denominator for each level is added periodically to the system, coverage reports can also be generated; otherwise, the system only provides the numerator for external calculation. » Immunization coverage can be assessed both by place of residence and by occurrence of vaccination.
Coverage calculation by cohort	» The information provided by the system by birth cohort can be very precise; this allows analysis of coverage monitoring by cohort (monthly, annual), biologic agent, dose, and area of residence. » There can be some degree of interoperability with the live-births registry system, which would support coverage calculation by cohort to supplement the official denominator.

TABLE 8. continued

OUTCOME AND FUNCTIONALITY	PRACTICAL UTILITY
Monitoring of immunization status by cohort	» Once a user has been entered into the system, immunization status can be monitored for compliance with the compulsory vaccination schedule. » Based on the population of live newborns, the system can be used to find out who has not been vaccinated; this, in turn, allows formulation of vaccination strategies targeting the unvaccinated population.
Reminders	» The address, e-mail, and phone number of intended vaccine recipients can be used to generate a system of reminders through telephone calls, text messages, announcements on local radio, e-mail, and letters.
Lists of monthly vaccine recipients and absentees	» The EIR can generate monthly lists of individuals due for vaccination, so that vaccination centers know who should attend during that month in their catchment areas. » The system can also generate lists of absentees and defaulters, which can then be used by local government to initiate active search and targeted actions.
Monitoring of relevant data quality and program variables	» One important role of EIR systems is that relevant information can be used to construct and monitor different program indicators, such as: – Dropout rates – Timeliness and simultaneity of vaccination (adherence to the recommended schedule) – Completeness of registration – Vaccine refusals – Performance by immunization strategy – Performance by vaccination center/vaccinator – Programmatic errors » The information collected by the EIR can support generation of reference maps for immunization program indicators. » The EIR can generate a consolidated report of different indicators and relevant information through dashboards. These are especially advisable for simple analyses at the local level, which enable assessment of how immunization data entry has an impact on program activities.
Identification of low-coverage areas and pockets of unvaccinated population	» The system can provide georeferenced information from each immunization area and coverage status to identify pockets of unvaccinated individuals, with a view to guiding vaccination strategies.
Extramural immunization activities	» The system can support definition of extramural activities and immunization campaigns, according to the obtained data, to best identify who and where to vaccinate. For example: create lists of intended vaccine recipients and define routes for home visits. » If the system is deployed in the field, the immunization status of each user can be reviewed and vaccinations recorded during the extramural activity.

TABLE 8. continued

OUTCOME AND FUNCTIONALITY	PRACTICAL UTILITY
Mass vaccination campaigns	» The EIR system is very useful for mass vaccination campaigns, as its data can be used to support: – Detection of pockets of unvaccinated individuals – Definition of immunization strategies – Search for target population, individually and by cohort – Calculation of vaccination coverage over a given period (day, week, month, or total campaign), geographical area, dose, etc.
Support for rapid monitoring of vaccination (RMV)	» Corroboration of individual immunization status through the EIR allows rapid, effective searching (when the system integrates all information from the country).
Data analysis for routine vaccination	» Generate lists of data cross-referencing databases on the administration of different vaccines given simultaneously. » Generate lists of data cross-referencing databases with other sources of individualized information, as available in the country (e.g., lists of chronic patients, vital statistics, etc.). » Analysis of reasons for vaccine refusal. » Analysis of timeliness of immunization.
Support during outbreaks	» During outbreaks, it is important to know the immunization status of individuals and areas; this information is readily provided by an EIR.
Analysis of vaccine losses	» The information obtained from the system would allow analysis of vaccine losses. This analysis requires cross-referencing information from the EIR and from the inventory system module.

4.4 ROLES AND RESPONSIBILITIES OF THE TECHNICAL TEAM FOR EIR IMPLEMENTATION AND MONITORING

Having an EIR system in place entails a number of new roles and responsibilities within the EPI, since it requires constant review of the system itself, its data, processes, and utilization. Table 9 describes these roles and their main responsibilities.

Regardless of whether technical support is provided by the EPI, by a Ministry of Health IT team, or by an outside contractor, it is important that technical support activities be structured according to the complexity of user queries or incidents. In the early stages of implementation of an information system, user queries are very common; this should be taken into account. Over time and as users gain practice, queries become less frequent and can be addressed faster. Monitoring of incidents is particularly important, as it reflects how the system is improving and how users are adapting to its utilization.

Once the EIR system has been planned, designed, and developed, a pilot project should be designed for deployment in a specified area. The team responsible for its implementation will conduct system monitoring, evaluate how the system behaves in a production environment (i.e., in the health facility), and provide close follow-up of some aspects. All these activities will help generate the corresponding documentation:

» Compilation of most frequent errors

» User requirements

» Potential improvements

» Gaps in training

» Time and workload control

» Two-way feedback

TABLE 9. List of roles and responsibilities created by an EIR

ROLE	RESPONSIBILITY	LEVEL OF RESPONSIBILITY
Data entry clerk	Person responsible for entering individualized immunization data into the EIR system (directly or from paper-based records). This role can be taken on by the vaccinator or by another person, depending on the established information flow.	Local
Data quality manager	National EPI staffer in charge of monitoring data quality and taking potential actions in this regard.	National
Data quality monitoring and system modification team	Team of EPI personnel in charge of data quality assurance and Ministry of Health statistics personnel who periodically review the quality of EIR data. This team can be set up at all program levels. This team is also in charge of planning and requesting modifications or evolutionary maintenance to the system (in light of changes in vaccination or campaign schedules) and defining requirements.	National, subnational, and local
Technical support team	According to the organizational structure and the availability of resources of the information system, it is important to have different tiers of technical support for system users, as follows: » First-tier support: direct contact with the user; addresses basic incidents and queries. » Second-tier support: staffed by specialists in information systems, databases, networks, operating systems, etc., who address incidents of a more complex nature. » Third-tier support: these teams provide more specialized technical support than the second tier, i.e., when support from information-systems specialists is required for more complex incidents.	National and subnational

EIR: Electronic Immunization Registry; EPI: Expanded Program on Immunization.

Once necessary adjustments or modifications have been made to the pilot, system implementation can proceed at a broader scale. During this stage, it is important that the team in charge of implementation monitor the health facilities of the regions, municipalities, and areas in which the system was set up. This can be done via:

- Standards
- Video conferences
- Field visits
- Call centers
- Instant messaging-based helpline
- E-mail helpline (depending on the technical support tier)
- Frequently asked questions
- Manual on use of the information system
- Local facilitators
- Process support Web page
- Meetings
- Training workshops:
  - In-person
  - Virtual
- Facilitator training

TOOLS

For more information on monitoring of EIR project implementation, review and use the tools made available in the document "Planning an information system project: A toolkit for public health managers":

http://www.who.int/immunization/programmes_systems/supply_chain/optimize/planning_information_systems_project.pdf

KEY CONSIDERATIONS

- The system plan should be clearly defined and continuously updated according to the progress made toward system implementation.
- Consider resources to support monitoring of the testing and training stages and implementation of the information system cycle.
- Set up an implementation team composed of immunization program, IT, and statistics personnel (as appropriate to the reality of each country).
- Devise accountability mechanisms for the various responsibilities assigned to each member of the team.
- Development and implementation of an EIR should be monitored and evaluated in a systematic, detailed fashion. It is advisable to formulate a work plan that identifies the main activities and tasks, milestones, budget, and time frames, as well as the persons responsible for each of these activities. At the very least, the following areas should be considered for system implementation monitoring:
  - Infrastructure and equipment.
  - Integration and interoperability with other relevant systems.
  - Software performance and quality assurance.
  - Trained human resources.
  - User queries and most frequent problems.
  - User satisfaction at different levels and in different roles.
  - Management of the information generated by the EIR and data quality.
  - Completeness of the registry: this is essential if registry data are intended to be used as denominators for calculation of immunization coverage.

4.5 HOW SYSTEM SUCCESS IS MEASURED

One of the responsibilities of the implementation and monitoring team is measurement of system success through the achievement of the specific objectives defined for the system (Table 10).

TABLE 10. System objectives and their measurement

SYSTEM OBJECTIVES	INDICATORS
Improve data quality	» Database completeness or comprehensiveness – Compare with population estimates – Triangulate with other population bases – Compare with surveys and rapid monitoring of vaccination – Compare with non-individualized system » Timeliness – Review the timeliness of data entry with respect to the date of immunization » Consistency – Number of duplicate entries – "Gaps" in immunization schedules (e.g., skipping from the first dose of a DPT vaccine to the third dose of the same vaccine without having a second dose recorded in the system) – Gaps in simultaneity of vaccine administration
Improve immunization schedule monitoring	» Dropout rate » Timeliness of administration of all biologic agents in the immunization schedule » Delay in relation to the established immunization schedule » Proportion of completed schedules for age » Proportion of refusals by vaccine, geographical area, or other variable(s) of interest
Increase immunization coverage	» If historical data are available, compare before/after schedule completeness and timeliness » Triangulate data with immunization surveys » Compare with the non-individualized system
Make work easier for health providers	» Results of time and movement studies » Survey results » Interview results » Results of focus groups » Vaccinator productivity » Immunization strategy productivity » System downtime
Ensure and monitor equity	» Baseline of inequalities and progress over time » Coverage by different interest groups, according to the available information
Improve accountability	» Comparison of doses administered with the established target populations » Analysis by strategy » Number of program errors (e.g., doses outside the recommended immunization schedule)

DPT: diphtheria/pertussis/tetanus vaccine

5

By the end of this chapter, you will be able to define:

- Criteria to evaluate for the development of an EIR.
- Non-functional requirements for technology selection.
- Information on the relevant external context.
- Software procurement models.
- Assessment of supplier selection.

Finding the right solution

This chapter will address relevant aspects from a technological standpoint for the selection of an appropriate system and model for the electronic immunization registry (EIR). It is essential that, before seeking alternatives for system procurement or development, the factors that help determine the desirability of establishing an EIR have been evaluated (see Section 2.2). The objectives of this section are to identify and select the best technological solution for an EIR in the context of each country.

To identify the best selection from a technological standpoint, several factors should be considered:

a. **Context assessment:** the first aspect that should be taken into account is the eHealth, legislative, and governance context of the country. As mentioned in Chapter 1, the sustainability of any solution only will be achievable if it is integrated into the framework of a country's eHealth (or equivalent) strategy.

b. **Definition of requirements:** subsequently, the functional and non-functional requirements of the system should be determined and documented.

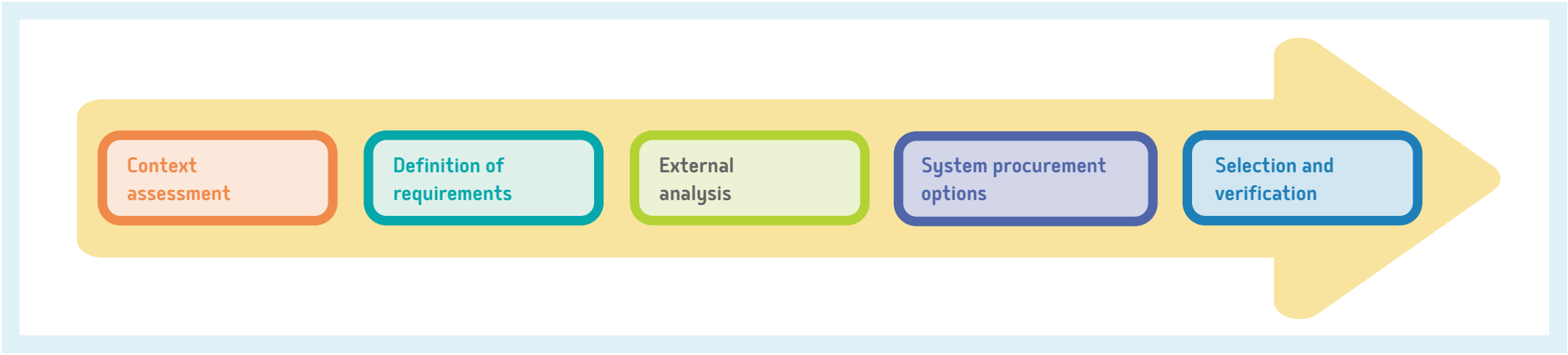
c. **External analysis:** the next step is to seek the most appropriate solution considering both already existing systems and the possibility of developing a new system. The vast range of available software, the different acquisition models available, and the many technology options make for a complex selection process. The next step is to define and document which non-functional requirements are mandatory for the system. These requirements are the essential components for investigation and evaluation of whether an existing system (e.g., in a province or sector) is suitable for implementation as a solution or whether a new system must be developed from scratch.

d. **System procurement options:** the next step is to decide which software procurement model is most indicated, taking into account existing resources and restrictions.

e. **Selection and verification:** the last step is to confirm whether the system selected for procurement or development meets the defined requirements and is aligned with the country eHealth strategy, and that the necessary resources are available for EIR implementation.

Figure 12 lists the steps necessary for finding the solution that best fits the specific context of each country.

FIGURE 12.
Steps for selection of the optimal EIR solution.



KEY CONSIDERATIONS

- An essential part of this process is the availability of a multidisciplinary team with experience in leadership, technology, and immunization processes.
- The support of people or organizations with experience in eHealth strategies should be sought. If such a strategy is already implemented in the country, it is highly advisable to approach the technical group in charge of the strategy and ensure alignment with its principles.
- It is important to document the functional and non-functional requirements to support selection of the most appropriate solution.
- It is important to investigate the entire information systems environment, both within and outside the country, to leverage experiences and lessons learned from others and avoid making the same mistakes.
- Additional support should be sought from local experts, online resources, and relevant communities of practice in the subject of ICTs in health [23-28].

5.1 CRITERIA TO EVALUATE IN THE EHEALTH CONTEXT BEFORE DEVELOPING AN EIR

Before reviewing possible solutions, it is essential that the country context be understood as it pertains to:

» **eHealth solutions:** according to WHO, eHealth consists of "the cost-effective and secure use of ICTs in support of health and health-related fields, including healthcare services, health surveillance, health literature, and health education, knowledge and research" [5].

» **Infrastructure:** in this context, the term refers both to the physical/technological infrastructure and to the software services and platforms that support the exchange of information in the health sector.

» **Standards and interoperability:** identify the required standards and accurate, consistent exchange of information across the various health sectors and different geographical areas; without these, data could not be collected consistently and could lead to misinterpretations. Furthermore, it would be difficult or impossible to share due to incompatibilities in data structure and terminology.

» **Legislation, policies, and certification:** the existing laws, policies, and requirements that support development and operation of health information systems. This category includes standards and policies for data security and confidentiality.

This information can be used to answer essential questions, such as:

» Is there an existing system to which the new system must be connected?

» What types of technology, software, and hardware are already being used in the country?

» Is there a reference parameter for the use of data and communications standards?

» Are there policies or regulations in place to regulate data security and privacy?

Ideally, this information is found in the country eHealth strategy documentation. If the information is available, options can be narrowed down to only those which meet current standards and policies. For example, if country policies mandate the use of open-source technologies, only those solutions developed using this type of technology will be evaluated; if encryption is required for data transmission between client and server, an infrastructure that meets this criterion must be set up. Furthermore, if legislation requires that databases containing individualized information be stored within the country, cloud-based solutions would not be appropriate. Other regulations outside the eHealth strategy can also be important. For example, if text messages can only be sent to people who explicitly authorize their receipt, the EIR should be designed to include a function that allows identification of which users authorize contact via text message (Table 11).

KEY CONSIDERATIONS

- When there is no national eHealth strategy to guide the necessary criteria and requirements of health information systems, attempts should be made to design the new system in line with existing systems and use common standards and policies.

TABLE 11. Common components within the national eHealth strategy that must be evaluated before selection of a new EIR

CATEGORY	COMPONENT	DEFINITION	EXAMPLE EVALUATION QUESTIONS
Infrastructure	**Connectivity**	Network and data connectivity infrastructure needed to support priority eHealth services and applications and the general concept of national eHealth.	» What is the current status of the network connectivity infrastructure? » Is the network infrastructure sufficient for an online system to operate? » What is the scope of the institutional internal data network (Intranet)? » Is mobile phone coverage adequate enough to consider implementation of a mobile component within the system? » Are there plans for expansion of the data network?
	Computer infrastructure	Physical computer infrastructure where software and databases are stored.	» What hardware and software is available for implementation of the EIR? » Is the computer equipment needed to implement an EIR available? » If the system will include mobile components, is the necessary equipment (phones, tablets) available? Are there resources to ensure connectivity? » Is the necessary server infrastructure available and are there adequate data management protocols, including backups, for EIR deployment?
	Identification and authentication services	Determines whether there is a centralized service to identify and authenticate users within the health information systems.	» Is there a centralized service to authenticate users within the health systems? » If so, which protocols are used by this centralized authentication service? » What procedures have been established for user management and credential management in the authentication service?
	Directory services	Reference tables necessarily used by all health systems; e.g., lists of medicines and of health providers, directory of the health services network, catalog of geographical areas, list of available vaccines, active vaccination schedules, etc.	» Is there a service from which the EIR should retrieve common listings used in the health systems? » If so, how is access to this service obtained? » What procedures are in place for maintenance of these listings?
	Common application services	Applications to which the other systems should be connected; e.g., a vital records system.	» Is there a repository of individual electronic medical records to which the EIR should connect? » Are there other systems in place with which the EIR should interoperate? For example: – Birth registry – Death registry – Electronic medical records – Other systems, independently of region or province EIR – Other modules of the immunization system, such as ESAVI, stock management, and epidemiological surveillance – Private EIR systems

TABLE 11. continued

CATEGORY	COMPONENT	DEFINITION	EXAMPLE EVALUATION QUESTIONS
Standards and interoperability	**Data structure standards**	The format in which the health dataset should be stored. Definition of a standard in the structure allows applications to present data consistently.	» Is there documentation of the standards to be used for storage together with the information compiled in the EIR? » Are there standard forms for EIR data collection?
	Common terminology	Defines the use of a common language to describe symptoms, diagnoses, and treatments in electronic communications.	» Has a standard been defined to use as a common language and ensure interoperability between systems? » Have clinical nomenclature standards been defined? » Have medical terminology standards been defined? » Have drug terminology standards been defined? » Examples: – International Classification of Diseases, 10th edition, for diagnoses (ICD-10) – Systematized Nomenclature of Medicine (SNOMED)
	Messaging standards	Define the structure of messages so that data can be sent and received through the messaging infrastructure.	» How should messages shared across information systems be structured? » What is the protocol for data transmission and acknowledgment of receipt when exchanging messages? » Example: – HL7 (Health Level Seven, a standard-developing organization for the field of health)
	Software accreditation standards	Define the criteria that software and services must meet to be validated for use within the national eHealth environment.	» What criteria must the EIR meet to become part of the eHealth ecosystem? » Are there instruments in place for evaluating the EIR in terms of quality, safety, and interoperability?
Legislation, policy, and certification	**Legislation**	The policies and regulatory elements that govern storage, access, and sharing of health information by all the sectors and across all geographical areas.	» Are there national eHealth standards and other interoperability requirements? » What policies have been defined for the privacy, protection, storage, and retention of health information? » Are there regulations in place that restrict the physical storage medium of health information (own servers, cloud servers, etc.)? » Are there provisions for the use of a unique health ID? » What are the established procedures for auditing of health information systems? » Are there any requirements related to software licensing?
	Policy	Policies needed for the general public to support development of a national eHealth environment.	» Are there policies in place for access and utilization of health information? » What policies are in place to promote and manage innovation, risk, evaluation of feasibility, and assess the utility of technology services?
	Certification	Elements required for accreditation of eHealth products and services.	» What criteria should be met for accreditation of eHealth products and services?

EIR: Electronic Immunization Registry; ESAVI: Event Supposedly Attributable to Vaccination or Immunization

5.2 NON-FUNCTIONAL REQUIREMENTS FOR SELECTION OF APPROPRIATE TECHNOLOGY

The term non-functional requirements describes system attributes related to the technical characteristics and restrictions of the environment, which should be taken into account for selection of the optimal technology to be used in the EIR. They tend to be grouped into five major categories:

» Operability

» Usability

» Compatibility

» Security

» Maintainability

5.2.1 OPERABILITY

Operability defines how the system should work in terms of performance, availability, and reliability. Within this category, special attention should be given to the requirements related to connectivity options that the system should be capable of offering as alternatives.

Depending on environmental restrictions related to the availability of Internet connections in the area of EIR implementation, it is essential to determine whether the system should provide the necessary flexibility for online implementation, offline implementation, or a combination of both based on synchronization, portable storage, or both. In accordance with the type of system already in place in the country, different scenarios should be considered for data updating and incomplete data management. This is of the utmost importance for maintaining the quality of immunization data; at all levels of responsibility, there must be assurances that data at the local level are the same data contained in the EIR. All processes related to this activity should be incorporated into program guidelines for EIR data updating and editing. Table 12 lists advantages and disadvantages of different EIR implementation modalities with regard to connectivity, as well as points that should be taken into account for data management.

TABLE 12. Advantages, disadvantages, and data management characteristics of different options according to the degree of connectivity of the system

	ADVANTAGES	DISADVANTAGES	DATA MANAGEMENT
Offline	» Does not require any investment in connectivity for the information system to use. » Provides the necessary information for organization of local immunization activities. » As the database is local, it does not require expensive equipment. This makes the volume of information very small.	» The immunization history of vaccine recipients is not available online, nor are complete immunization data. This can lead to duplication of vaccine and person records if the user is not always vaccinated in the same facility and does not bring a vaccination card. » Clear and formal coordination is required for collection of all immunization data and late data. » The software is difficult to maintain and update, as it is distributed across many points. » Local response ability is required in case of system failure. » Maintenance of a decentralized system can be slower and more expensive.	» Unique, well-known flow: all system users should be familiar with the flow of the information system, which should be formalized through regulations. » Procedure: should also be known to all to ensure that, if any editing or modification is required at the local level, it will be reflected at all subsequent levels. » Set dates: cycle closure and upload dates should be established for each level of responsibility (local, subnational, and national), as well as dates for database modification and transmission. Protocols for late data management should also be defined.

TABLE 12. continued

	ADVANTAGES	DISADVANTAGES	DATA MANAGEMENT
Online	» All individualized immunization data and individual vaccine histories are available in real time. » Immunization data can be extracted for follow-up of routine vaccination and vaccination campaigns, as well as to establish timely actions as needed. » Maintenance and updating are centralized.	» Requires investment to ensure adequate connectivity levels. » Requires major investment in infrastructure to support large numbers of simultaneously connected users. » System complexity is greater, which means they can be more expensive and difficult to develop. » Additional infrastructure and a dedicated team to respond to system failures are required. » Clear guidelines on how to record vaccination if the system is down are needed.	» If the system is online and has a data update function, there must be a mechanism to control who carries out these modifications and when, as established by the country. » The system is "closed" at a given time, i.e., there are deadlines for data editing, modification, and/or new data entry. This is done to establish a set value for indicators that are extracted from the system and reduce their variability.
Mixed	» The entire immunization history of vaccine recipients is available in real time for all connected regions/provinces. » Immunization data can be extracted for follow-up of routine vaccination and vaccination campaigns, as well as to establish timely actions as needed, but only in areas that have online systems. » There is no need for connectivity in 100% of areas in which the system will be implemented, which can be a great advantage in areas with major network infrastructure challenges. » Mobile applications can be used for data entry in areas with limited connectivity. These applications keep a local database stored in the device, which is then synchronized with the centralized database when a connection becomes available.	» The system requires a greater degree of complexity for synchronization and updating processes. » In limited-connectivity areas, additional development of offline applications is required. » In limited-connectivity areas, full immunization histories and online immunization data are not available. » Additional infrastructure and a dedicated team to respond to system faults are required. » Clear guidelines on how to record vaccination when the system is down are needed.	» Independent processes should be implemented for online and offline locations. » Synchronization procedures must be established to allow updating of the online system database with data from offline locations.

KEY CONSIDERATIONS

- Due to connectivity limitations in some countries, it is advisable that a new EIR be able to operate in a mixed model (both online and offline). As infrastructure barriers are overcome, one should aspire to a fully centralized, online system to reduce maintenance costs.
- Mobile technology coverage is increasing progressively in the majority of countries. Thus, an interesting strategy is to develop mobile applications which can work on offline devices and synchronize with the central server periodically to reduce data transfer costs.
- When updates are made to the database of an offline system, these should be carried out at the local level, the modified database sent to the subnational level, and both databases consolidated at the national level. Updating at the local level and failing to send the update along to higher levels is not enough and can lead to data loss or incomplete data at the national level. Mechanisms must be in place to ensure that all levels have the same information.

5.2.2 USABILITY

Usability establishes the clarity of application design according to ISO 9126 (the international standard for evaluation of software product quality). According to this standard, "usability refers to the capability of a software product to be understood, learned, used, and attractive to the user, when it is used under specified conditions" (Table 13). Based on this concept, the core principles of usability are:

» Ease of learning

» Ease of use

» Flexibility

» Sturdiness

TABLE 13. Example list of non-functional requirements related to usability

CATEGORY: USABILITY					
	Requirement	**Met**	**Partly met**	**On-going**	**N/A**
1	Allows flexible configurations depending on the context of use, including the physical and social environment.	☐	☐	☐	☐
2	Relays information in wording (or a sequence of voice commands) easily understood by users.	☐	☐	☐	☐
3	Places emphasis on ease of use and learning in order to reduce training costs.	☐	☐	☐	☐
4	Is easy for users to learn and thus meet specific objectives of system effectiveness and efficiency.	☐	☐	☐	☐
5	Enables streamlined data collection, organization, and dissemination.	☐	☐	☐	☐
6	Focuses on the mobile user experience, with secondary use on larger screens.	☐	☐	☐	☐
7	Allows users to carry out actions in two clicks or fewer.	☐	☐	☐	☐
8	Provides a search interface to reduce the data entry burden.	☐	☐	☐	☐
9	Allows validation of real-time input and provides feedback to prevent input errors.	☐	☐	☐	☐
10	Allows automatic calculation of values, obviating the need to carry out mathematical operations.	☐	☐	☐	☐
11	Recalculates the personal immunization schedule or provides clinical decision support in the event that the intended vaccine recipient does not receive vaccines on time or has contraindications to their administration.	☐	☐	☐	☐

N/A, not applicable.

5.2.3

COMPATIBILITY

This concept establishes the criteria that the system should meet in order to ensure interoperability with other systems in operation, as well as its flexibility to operate with different existing technologies. Table 14 lists these criteria.

TABLE 14. Example list of non-functional requirements related to compatibility

CATEGORY: COMPATIBILITY					
	Requirement	**Met**	**Partly met**	**On-going**	**N/A**
1	Open standards are used to promote interoperability.	☐	☐	☐	☐
2	Actionable data are exchanged between systems to meet semantic interoperability requirements.	☐	☐	☐	☐
3	Access is available via Internet-enabled devices.	☐	☐	☐	☐
4	Support is provided for flexible data collection (e.g., paper-based forms, online forms, SMS, text messages, bar codes, etc.).	☐	☐	☐	☐
5	Enables streamlined data collection, organization, and dissemination.	☐	☐	☐	☐
6	Meets industry standards for data exchange.	☐	☐	☐	☐
7	Can operate with third-party and open-source reporting tools.	☐	☐	☐	☐
8	Provides a pleasant and satisfactory user experience.	☐	☐	☐	☐
9	Meets industry standards for monitoring and tracking of supplies.	☐	☐	☐	☐

N/A, not applicable.

5.2.4

SECURITY

This concept covers security requirements for access to data and to the various functions provided by the software product, including user validation and user access control (authentication) requirements. It also covers security aspects concerning access to physical locations, data integrity requirements, fraud control, and means of data communication through the corresponding channels, as well as encryption and nonrepudiation requirements for data transmitted through different communication channels (Table 15).

KEY CONSIDERATIONS

- Security requirements should be taken into account for all EIR modules, including mobile applications.
- Due to their local databases, mobile applications require special attention to security procedures. Passwords should be defined for use by teams and database encryption should be ensured.

TABLE 15. Example list of non-functional requirements related to security

CATEGORY: SECURITY					
	Requirement	**Met**	**Partly met**	**On-going**	**N/A**
1	Prevents unauthorized access to confidential information on vaccine recipients.	☐	☐	☐	☐
2	Prevents partial changes to the database, which can cause more problems than rejecting the entire form.	☐	☐	☐	☐
3	Keeps a log of data changes made by the system and by users (updates, deletions, and additions).	☐	☐	☐	☐
4	Allows the administrator to establish access and priority privileges.	☐	☐	☐	☐
5	Allows definition of multiple roles and assigns degrees of clearance for data viewing, input, editing, and auditing.	☐	☐	☐	☐
6	Requires role-based authentication of each user before providing access to the system.	☐	☐	☐	☐
7	Provides a flexible password control strategy that allows alignment with national policy and with standard operational procedures.	☐	☐	☐	☐
8	The system can be configured to comply with the country's existing health information storage policies.	☐	☐	☐	☐

N/A, not applicable.

5.2.5

MAINTAINABILITY

Maintainability is "the ability of an item, under given conditions of use, to be retained in, or restored to, a state to perform as required, under given conditions of use and maintenance" [29] (Table 16). For more detail, see Chapter 3.

TABLE 16. Requirements related to the maintainability of an information system

CATEGORY: MAINTAINABILITY					
	Requirement	**Met**	**Partly met**	**On-going**	**N/A**
1	The system is modular.	☐	☐	☐	☐
2	The system source code is reusable.	☐	☐	☐	☐
3	The system has the necessary documentation to enable easy analysis.	☐	☐	☐	☐
4	The system has the necessary documentation to enable easy modification.	☐	☐	☐	☐
5	The system has the necessary documentation to enable easy testing.	☐	☐	☐	☐

N/A, not applicable.

KEY CONSIDERATIONS

- These lists are basic examples of non-functional system requirements. They are intended as a guide for development of specific requirements.
- When formulating non-functional requirements, it is essential to seek the opinion of the IT bureau in the Ministry of Health or of the agency in charge of information systems in the country.

5.3 RELEVANT INFORMATION ON THE EXTERNAL CONTEXT TO SUPPORT DECISION-MAKING

Once the context in which the EIR should operate has been determined, the next step is to figure out how these and other types of systems work elsewhere in the world, in the country, in other regions, or in other health programs, with particular focus on development and implementation. An all too common issue in the world of software is imitation of existing models, which leads to duplication of efforts and resource expenditures. It is thus advisable to search for published prior experiences, even when requirements mean a bespoke system will probably be necessary.

TOOLS

Valid resources for this review are scarce, as there is no centralized repository of all published experiences in public health, and many publications are designed to report on success stories rather than failures. Very few publications shed light on challenges, lessons learned, or important technical details needed to make correct decisions. However, some resources are available:

» Technical Network for Strengthening Immunization Services [24]
http://www.technet-21.org/

» mHealth database
http://www.africanstrategies4health.org/mhealth-database.html

» USAID Deliver Project
http://deliver.jsi.com/

5.4 OPTIMAL SOFTWARE PROCUREMENT MODEL FOR AN EIR

The next step is to determine under which model the new EIR could be acquired. There are several alternatives, each with its own advantages and disadvantages which must be taken into account. In addition, it is essential that the basic requirements be understood to be able to determine which option is most feasible in each context (Figure 13 and Table 17).

FIGURE 13.
Software procurement models

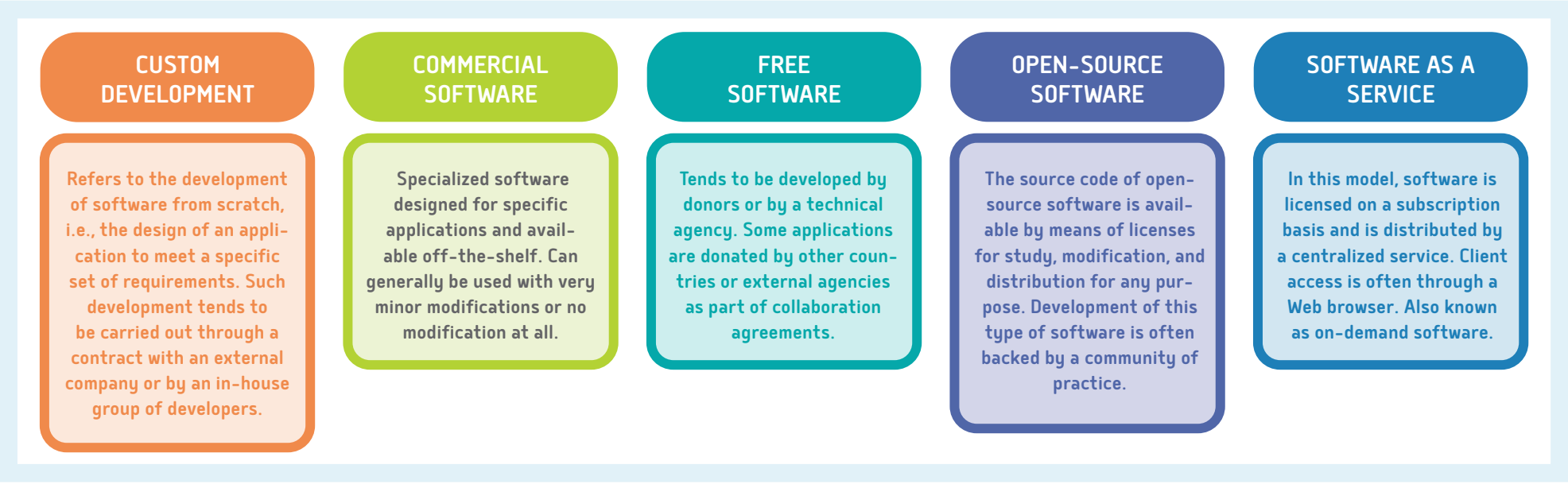


TABLE 17. Advantages, disadvantages, and needs of different software procurement/delivery models

MODEL	ADVANTAGES	DISADVANTAGES	NEEDS
Custom development	» Provides control over technology, design, and functionality » The development experience generates a sense of belonging and improves sustainability » Easier to connect with existing systems in the country » Provides possibility of involving the local IT sector » All system requirements can be personalized, including reports	» Very time- and resource-consuming. Tends to take longer than planned » Almost always requires more funds than originally allocated » Having control over the design does not ensure satisfaction with the end product; this depends largely on the capacity of the development team and its interaction with the technical team » Long-term maintenance depends on the continuous availability of the development team, which means the project can stall halfway or be difficult to update	» In-house development requires trained staff » External development requires appropriate funding for system development and future maintenance (sustainability) » In both cases, adequate communication with technical personnel (including health workers at the local level) is required to ensure correct interpretation of project requirements » Clearly defined roles, ownership, and access to data
Commercial software	» Time from software selection to implementation is short » In most cases, a trial period is available before purchasing the software » The product is maintained and updated by a company (for a price that can vary over time) » Tends to be a product that has already been tried and improved by previous clients	» Specific solutions tend to be very expensive » In some cases, costs are not completely clear, e.g., cost per number of users (type of licensing) » Design does not tend to take into account the more complex requirements and processes of the EPI, but is rather based on the requirements of the private sector » Updating to new versions carries additional costs » If it is not updated, the system can become obsolete and lose technical support » Possibility of losing support if the software seller closes down » Long-term maintenance depends on continuous availability of the supplier	» Initial funds for software purchase » Although the product is maintained and updated by the company, trained IT staff within the Ministry of Health are still required » Clearly defined roles, ownership, and access to data
Free software	» Can be evaluated and deployed quickly » No front-end costs (only for maintenance or customization if required)	» No service agreements and, therefore, no guarantee of rapid problem-solving » There are always costs involved once the system is operational » The source code is not always available » Support may be discontinued (sustainability)	» Allocated budget to cover system operating expenses » Trained IT personnel within the Ministry of Health are needed to update and operate the system

TABLE 17. continued

MODEL	ADVANTAGES	DISADVANTAGES	NEEDS
Open-source software	» Software can be modified, as the source code and appropriate permissions are available » Users, programmers, and companies can become involved in the development process (community of practice) » Error detection and correction and implementation of new features are efficient » No investment required to purchase licenses, only for staff training » No dependence on a specific provider for maintenance tasks	» No external technical support; community support can vary over time » The solution of any problem depends on the community of practice or on the in-house IT staff, which entails unplanned expenditures » The customization of an open-source system is time-consuming, tends to be difficult to plan and, as a result, difficult to budget for	» In-house support requires trained IT staff » Budget allocation to cover system customization, operation, and maintenance expenses » Country legislation must allow the use of such software; provisions must be made for the event of a change in regulations
Software as a service	» Very easy to implement and maintain » Implementation and operation costs are defined clearly » No installation or client-side maintenance required » Investment in software improvement can be shared between clients	» Data must be stored in remote servers (in some cases, this goes against national policy) » Ministries of Health do not tend to allocate payment for this type of service in their budgets » Costs can increase without prior notice upon renewal of the service agreement	» Budget allocation to cover monthly license/subscription costs » Trained IT personnel within the Ministry of Health are required for system implementation » Country legislation must allow the use of such software; provisions must be made for the event of a change in regulations

5.5 EVALUATION OF THE SELECTED MODEL

Ideally, at this point in the process, there will be a list of options. These possible solutions must be compared on the basis of all the crucial factors that have been reviewed in this document, including those listed in Chapter 3 and Chapter 4. The easiest way to conduct this assessment is to assign scores for each criterion through a selection matrix (Table 18).

KEY CONSIDERATIONS

- There are many factors to take into account when evaluating existing options from a cost standpoint. Savings in the short term do not necessarily represent a better solution from the standpoint of long-term cost-effectiveness. On many occasions, there are hidden costs not included in front-end prices, such as maintenance, updates, training, etc.

TABLE 18. Example table for confirmation of model selection

FACTOR	POSSIBLE POINTS	SYSTEM 1	SYSTEM 2	SYSTEM 3
Does it meet or will it meet the defined requirements?				
To what extent does the system meet the needs of the user?				
Does this system meet or will it meet technical infrastructure requirements?				
Is the appropriate hardware in place to acquire, adopt, or develop this system?				
Does this system use or will it use recommended standards for health information systems?				
Is or will the system be interoperable with other information systems, both health and otherwise (e.g., identification systems)?				
Does the system meet or will it meet country regulatory requirements for health information systems?				
Is this system certified or certifiable according to existing standards?				
Are the development, implementation, and operation costs of this system within the planned and estimated budget?				
Are the necessary funds available to ensure the scalability and sustainability of this system?				
Are Ministry of Health personnel trained in the appropriate technology to acquire, adopt, or develop this system?				
Total score				

5.5.1

SUPPLIER ADEQUACY

On many occasions, the Ministry of Health lacks internal capability for the development of a new project. This means a solution has to be sought within the private IT sector or from specialized providers. Regardless of modality, deciding which company or supplier is adequate can be a difficult task, especially when there are many alternatives and little experience in this type of process.

The process of writing an invitation to bid is very important when seeking an adequate supplier to meet the needs of the institution. The possibility should be left open for the largest possible number of bidders; this increases the odds of finding a company or consultant that meets the needs of the project. Furthermore, the bidding or tender process has several added values, including transparency and the opportunity to conduct a thorough review of the needs that must be addressed to compile a robust list of project requirements.

Conducting an invitation for bids is essential when the policies of the institution, the project funders, or government regulations require it. However, even when there is no such requirement, this process is always a good idea in order to increase the effectiveness of the search for suppliers.

The usual steps of this process can be summarized as follows:

1. Define the project plan and scope, as described in Chapter 3. At this point, it is important to consult decision-makers about any restrictions to the project. Subjects to consider include budgetary limits, flexibility in deadlines, and non-negotiable technical requirements.
2. Identify key partners and advisors. Evaluation of the answers provided by this process is a complex, demanding undertaking that requires deep knowledge of the institution, as well as some level of understanding of how companies or consultants work.
3. Conduct an in-depth review of functional and non-functional project requirements before publishing the invitation for bids.
4. Draft an invitation for bids.
5. Determine how offers will be evaluated and include this in the invitation for bids.
6. Publish the invitation for bids in accordance with the country's procurement method.
7. Review proposals.
8. Research new technologies contained in the proposals as needed.
9. Conduct a background check of potential suppliers.
10. Prepare, review, and sign a contract.

There are many guidelines of what information should be included in an invitation for bids or tender. In general, including the following information is advisable:

» Information on the institution, including its legal and financial status and the background and experience of key personnel.

» Brief description of the project.

» Project requirements and objectives: this tends to be the longest part of the document, as it describes the characteristics that will determine a successful result. As a rule, specific closed-ended questions are easier to evaluate and score than open-ended questions.

» Project budget, broken down by component, including pay-per-use and hosting costs.

» Milestones and deadlines.

» Questions and information required of the supplier, including prior experience in similar projects.

» Contact information and deadline for proposals.

6

Monitoring and evaluation of EIR data quality

Data quality assessments, whether of paper-based or electronic information systems, play a key role in validating that the information on which the EPI, the health authorities, and all those involved in the use and analysis of immunization data rely are indeed reliable for proper decision-making and program management.

By the end of this chapter, you will be able to define:

- What are data quality assessments.
- Why management of data quality monitoring and evaluation is important.
- Evaluation of performance indicators for identification of inconsistencies.
- How to avoid, reduce, or address data duplication in the EIR.
- How to manage data updates and incomplete data.

Data quality can be assessed in two ways: by evaluating the quality of system operation and by evaluating the quality of data produced by the system.

6.1 DATA QUALITY ASSESSMENT

The quality of immunization data is an important component within management of an EPI [30-34]. The concept of data quality has been widely discussed and is defined, in simple and practical terms, as data that represent the reality of what is hoped to be described. To measure the representativeness of data through different indicators of the quality, countries use different methods:

» Data quality self-assessment (DQS) [35]

» Data quality audit (DQA)

Both methods allow analysis and evaluation of immunization registries or information systems and provide information relevant for the improvement of data quality. Generally, these assessment methods measure the following data quality criteria:

» **Completeness of reporting:** the degree to which all reported results are included. This indicator represents the extent to which information contains a complete list of people or units of analysis and not only a part of the population or universe of interest.

» **Timeliness of reporting:** data are timely when the information is available on time, i.e., within the date and time deadlines established for reporting.

» **Accuracy of data:** seeks to prove the coverage data entered into primary registries, i.e., to compare data from a given level of reporting (form, report, etc.) with the same information compiled or reported at a more central or hierarchically higher level.

6.2 THE IMPORTANCE OF MANAGING DATA QUALITY MONITORING AND ASSESSMENT

Electronic immunization registries play an essential role in the management of national immunization programs. Therefore, the data contained in these systems must be verifiable and must reflect reality. This means that, for EIRs to be useful and reliable, the entered data must be of high quality in terms of timeliness, precision, and accuracy. To ensure this, it is important to understand the process of sending and consolidating information from the local level up to the national level, through several intermediate entities, according to the information flow proposed by each country.

EIR management entails processes of review, analysis, and systematic measurement of data quality, with periodic reviews of databases, reviews of potential programmatic errors, data entry errors, and presentation errors, and verification of the dates of receipt of local databases (in offline EIRs), among others. It is important that these data quality monitoring activities be conducted by dedicated teams at each level of responsibility, as mentioned in Chapter 4.

6.3 EVALUATION OF PERFORMANCE INDICATORS FOR IDENTIFICATION OF INCONSISTENCIES

In countries with an EIR, it is recommended that quality assessment be adapted to local needs, with the incorporation of evaluation of the EIR system component. For this purpose, the following items should be included.

6.3.1

DESCRIPTION OF THE NATIONAL EIR

An exhaustive review of the EIR information system should be conducted, including the following components:

» System scope

» Normative and legal context

» System architecture

» System maintenance and sustainability.

» Human resources

» Modules included in the system

» Functionalities

» EIR user satisfaction

Annex 5, "*Criteria for EIR system evaluation,*" provides a checklist of the main aspects that should be evaluated.

6.3.2

ANALYSIS OF THE INFORMATION SYSTEM

All levels of responsibility, as well as paper-based or electronic tools involved in the information flow are included in the analysis:

» Evaluate whether all the immunization providers enter information and whether it is indeed registered in the system.

» Confirm if reports are available at all levels as established.

» Assess whether there are major differences in doses recorded in the system for biologic agents that are administered simultaneously.

» Confirm that all functionalities are operational.

6.3.3

EIR DATA ANALYSIS

Monitoring and evaluation of data quality in an EIR system should consider the review of certain general aspects, which will serve as an important input to determine review standards. These aspects include:

» Review the immunization schedule, considering the following variables of analysis:
  – Age at vaccine administration.
  – Minimum and maximum age, and interval between doses and vaccines.
  – Vaccine and dose.

» Identify the data sources that feed or interoperate with the EIR system (e.g., electronic medical record, Excel spreadsheets, etc.).

» For offline EIRs: review the dates of transmission of local immunization data, in accordance with current regulations.

» Special cases for immunization as established in the country (business rules and specific analyses may not apply to these cases).

» Determine which analyses allow detection of potential program and/or data entry errors.

» Send databases with potential errors found at the local levels and request that the registry be modified at the local level:
  – In case of a recording error, confirm it against the defined means of verification.
  – In case of a program error, strengthen training and reporting in order to avoid errors in data recording.

Once these aspects have been considered, analyses should be generated taking into account all stages of the data flow process.

6.3.3.1.
Data input into the EIR system

Certain business rules can be defined for this purpose and should be taken into account when designing an EIR so as to provide assurances for data quality at the time of input into the system. These business rules are listed in Annex 6, "*Business rules to ensure EIR data quality at the time of data entry.*" It is important to note that, although these business rules are recommended for the warning system, insofar as they can prevent recording errors, data entry into the registry should not be so restrictive as to conceal a potential program error (e.g., the system should allow recording of HPV vaccine administration to a man, even though the immunization policy only covers girls).

Mechanisms for cleaning of duplicate entries should be considered when designing EIR data quality activities and processes. This prevents inflation of immunization statistics and improves the quality of data, thus providing reliable information to support decision-making. Ensuring that information is not duplicated and that a single immunization event is not counted more than once is essential. Duplicate entries can be generated because of a multiplicity of information sources, by data entry errors, multiple and/or unclear data flows, population mobility (e.g., the same person being vaccinated at different health facilities), or by the existence of local databases (offline systems). Other common causes of duplicate data are when data entry is not done in the immunization center, but elsewhere, or because recipient names or the surnames sound alike (e.g., Marie, Mary, Mery; Daisy, Daisi; John, Jon, Yon), among others.

DUPLICATE ENTRIES CAN BE CLASSIFIED INTO TWO CATEGORIES:

» **Duplicate recipient:** two or more records describe a single recipient (e.g., when there is no mechanism to search for individuals and identify them in the system before administering a vaccine); and

» **Duplicate immunization:** two or more records describe the same vaccine administration event.

Duplicate recipient

Possible causes:

a. The country does not use a unique individual identifier, or this identifier is not issued at birth.

b. The system allows registration of the same individual twice.

Within this context, it is important to consider some mechanisms to prevent and handle duplicate entries. Annex 7, "*Recommended actions to avoid duplicate entries,*" provides some examples of duplicate recipient identification.

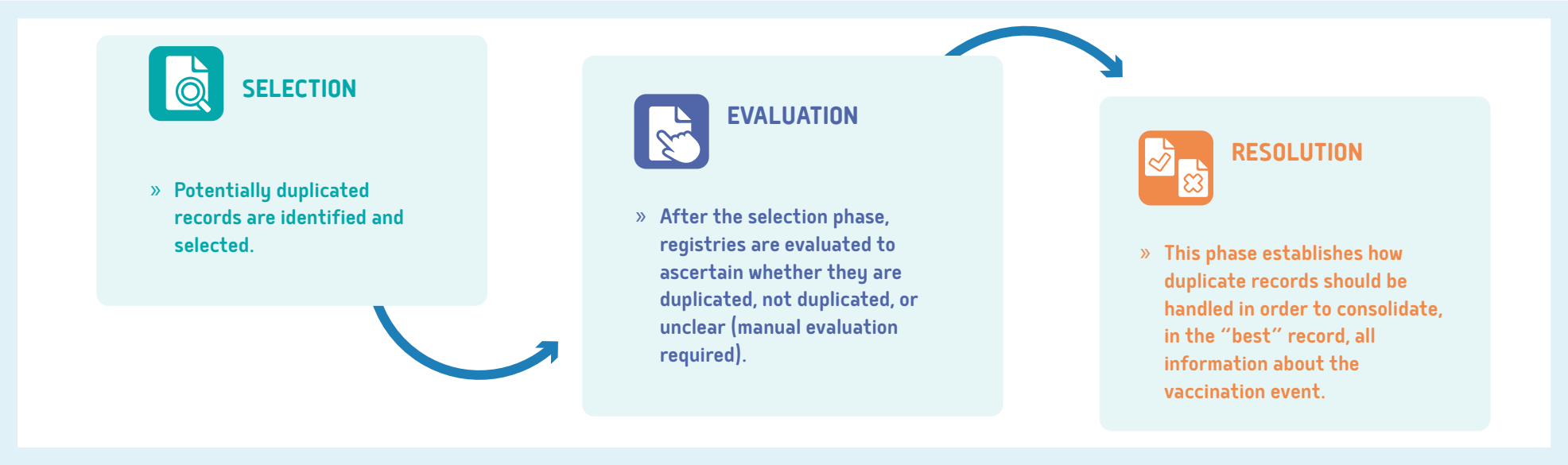
Duplicate immunization

Records can come from different information sources (e.g., national registry, private providers, other interconnected systems, registries of different immunization facilities, etc.). The American Immunization Registry Association (AIRA) has established a procedure for de-duplication of vaccination records. It consists of three phases: selection, evaluation, and resolution (Figure 14). Furthermore, certain components should be considered for this process of analysis: variables, principles, and business rules, which should be taken into account and will vary from country to country.

6.3.3.2. Data upload for consolidation

Data quality analyses should take into account the existence of different systems that interoperate with the EIR within the country. Thus, mechanisms must be in place to ensure that all data from these different systems are included in the nationwide database according to the data network defined for its interoperability, in a timely and complete fashion.

FIGURE 14.
Procedure for de-duplication of vaccination records in the system



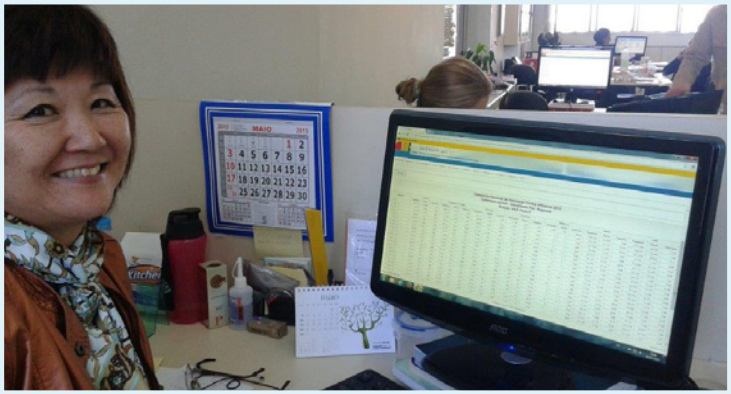
Furthermore, it is important to carry out a systematic review of system algorithms, formulas, and parameters to make sure that the reports, vaccines, and doses considered are adequate for the national situation. This is of vital importance whenever changes are made to policies, to recommended vaccines (e.g., different valence) and to the range of vaccines available in the private sector, and to immunization schedules.

EXISTING DATA IN THE CONSOLIDATED DATABASE AT THE SUBNATIONAL AND NATIONAL LEVELS

Certain database analyses can be carried out to evaluate data quality on the basis of country vaccination schedules for a given period. Annex 8, "*Examples of EIR analyses for data quality monitoring,*" presents some examples of recommended analyses for data quality monitoring in individualized databases. These example analyses can be carried out and expanded to other vaccines, according to the business rules established by the country.

KEY CONSIDERATIONS

- There must be an established procedure for detection and de-duplication of duplicate records as part of the data quality assurance process.
- Health workers should be involved in the de-duplication process, as they are the ones who know vaccine recipients best.
- Entries with errors should be returned to the local level for correction.



TOOLS

Review the data quality self-assessment tool:

http://apps.who.int/iris/bitstream/10665/69034/1/WHO_IVB_05.04.pdf

7

By the end of this chapter, you will be able to define:

- Future challenges concerning:
  - » eHealth policies
  - » ICT utilization
  - » Data quality

Facing future challenges

The challenges involved in EIR information are varied and of varying complexity; however, many of the countries that have implemented EIRs have known how to overcome many of the challenges described herein. It is important to consider these challenges, because they can jeopardize system sustainability.

7.1 eHEALTH POLICIES AND THEIR IMPACT ON EIRs

Countries have made great strides in the formulation and adoption of eHealth policies, considering national alliances between different sectors: civil society, civil service, and the private sector. Nevertheless, eHealth-related challenges persist and have a direct impact on EIR systems. Tables 19, 20, and 21 describe some of these challenges.

TABLE 19. Challenges related to eHealth policies that affect EIR implementation

CHALLENGE	DESCRIPTION
Inter-operability	A major challenge is how the countries manage to establish interoperability between different EIR systems in a single country and/or with other health information systems.
Connectivity	Connectivity is one of the barriers to the implementation of online information systems. Many countries have initiated, within the framework of their national eHealth strategy, efforts to expand health-sector connectivity through policies and intersectoral agreements, including the private sector and local governments. This challenge is most pressing at the time of deciding which type of system will be developed (online, offline, or mixed).
Technological equipment	The lack of technological equipment can be a pressing challenge when computerizing systems. Nevertheless, countries have overcome this challenge through policies at the national level, but also with the support of local governments, which have invested in technological infrastructure to support the implementation of health information systems at health facilities. However, health workers are often the ones who arrange for the provision of technological equipment, using their own resources (e.g., when they use their own mobile devices for data entry or connect via Internet cafés).
Changing technologies	Changes in technology are a relevant aspect, as they can render an information system (whether in development or existing) obsolete.
Legal framework for the health system and EIR	The legal framework that underpins use of information and communication technologies in health has been undergoing development in several countries, and facilitates the exchange of clinical information while protecting the privacy of personal data. However, these legal frameworks should be available in all countries and disseminated across all stakeholders. Changes in regulations can have direct effects on EIRs already in use.
Infra-structure	An EIR system requires some basic infrastructure, such as an adequate physical space for data entry, electricity, temperature control, etc. However, these conditions are often difficult to achieve.

EIR: Electronic Immunization Registry.

7.2 USE OF INFORMATION AND COMMUNICATION TECHNOLOGIES

TABLE 20. Challenges in the use of information and communication technologies that affect EIR implementation

CHALLENGE	DESCRIPTION
Use of mobile technologies	Although there are some experiences with the use of mobile technologies, countries have not fully exploited their use. For example, the use of mobile technologies jointly with an EIR system is an opportunity to improve program performance, whether for monitoring of individuals through text messages or reminders, to facilitate data entry, or, e.g., through the use of tablets for extramural activities and/or rapid monitoring of vaccination.

EIR: Electronic Immunization Registry.

7.3 DATA QUALITY AND USE OF DATA BEYOND TYPICAL ANALYSES

TABLE 21. Challenges in data quality and use that affect EIR implementation

CHALLENGE	DESCRIPTION
Record completeness	Assurances must be made that the entire target population of the program is recorded. Ideally, the EIR will be connected to the population databases of the national civil registry, registry of live births, etc. Furthermore, the immigrant population that seeks vaccination should be entered into the system. This is important because, if the EIR is to be used to calculate coverage on the basis of the population registered in the system, it is essential to ensure that the entire population is indeed captured. The capture-recapture method can be used by comparing two systems and evaluating the coverage of both.
Unique identifier	A unique identifier is one of the main components that can ensure data quality and prevent duplication, as well as support technical sustainability for the interoperability between systems. Unique ID is also key for individual vaccination monitoring.
Consistency of records	It is important to monitor and evaluate data so that records are consistent with reality. Aspects that should be taken into account include: » Duplicate records » Simultaneity of immunization » If there is a third dose, there should be records of a first and second dose (in case the recipient's record has been started from scratch or incorporated historical data) » Different formulations of the same biologic agent within a single country (e.g., when the Ministry of Health administers pentavalent vaccine but private clinics offer the hexavalent vaccine, how should doses be calculated in the EIR?)
Monitoring of inequalities	This is an essential aspect of public health actions, to ensure that the entire target population of public health programs is being reached. In the case of immunization, inequality monitoring is a relevant aspect that is strengthened by the use of EIRs, which can incorporate variables useful for analysis of equity. These data can be used to detect gaps, assess evolution over time, etc., and determine strategies to bridge potential existing gaps.
Vaccination campaigns	The use of the EIR in vaccination campaigns is a challenge that some countries have already overcome. The information provided by the system via cross-referencing of different vaccine databases, population databases, other campaigns, etc., with a view to determining the target population of a campaign, enables vaccinators to reach unvaccinated individuals and formulate strategies to capture them. It is also useful to collect immunization information from this type of strategy.
Management control	Another relevant aspect is how the EIR can provide information on the traceability of vaccines and permit calculation or estimation of vaccine losses, which can help the program improve its planning of vaccine procurement and utilization, thus increasing efficiency.
Process efficiency	It is important to consider that the adoption of EIR systems seeks not only to replace paper-based forms, but also to optimize the processes related to immunization registries. As a result, it is a challenge to change this perception and conduct studies related to process optimization, such as time-movement, use of resources, workload by vaccinator and by weekday, costs, etc.
Coordination of EIRs between countries	Due to migratory movements between countries, one particularly pressing challenge concerns the sharing of immunization information across borders. When this is achieved, people who continue their immunization schedules in other countries can be followed up there.
Shared databases	The EPI should have access to the databases of the EIR system, which entails having staff trained to do so or working hand in hand with other units that have this capability. Some examples are: vaccination by residence versus by place of vaccination or production, by cohort, simultaneity, rejections, etc., according to the variables incorporated in the system.

EIR: Electronic Immunization Registry; EPI: Expanded Program on Immunization.

8

By the end of this chapter, you will be able to define:

- Whether it is ethical to obtain nominal data from users of the health services.
- The ethical obligations of the authorities who set up an EIR toward the people from whom data are obtained and toward the general population.
- The ethical obligations of those in charge of an EIR regarding management and maintenance of the collected data.
- The concept of ethical use of the data collected through a national electronic immunization registry.

Ethics

Ethics is a cornerstone of performance of the essential health functions, which means it should be present in all activities.

In the case of electronic immunization registries, this entails an ethical responsibility throughout the data life cycle.

1. **Collection of individualized vaccination data:** time point at which health workers obtain individualized data from vaccine recipients.
2. **Data management and maintenance:** this phase includes all processes involved for correct transfer, preservation, and security of individualized data.
3. **Data use:** time at which health workers use individualized immunization data for management process that requires their analysis.

As mentioned before, an immunization registry allows monitoring of the immunization status of each individual, monitoring of immunization coverage at the population level to improve the performance and management of immunization programs at all levels of responsibility, and supports the control and/or elimination of vaccine-preventable diseases (VPDs). Furthermore, such registries help prevent and respond to outbreaks, assist in monitoring of vaccine safety, and provide information for the decision-making process. Unlike non-individualized records, which group data according to ranges of variables, nominal vaccination records include data on each vaccinated person. This allows not only a more effective, timely, and accurate response to the needs of the program, but also facilitates individualized follow-up to improve immunization of each vaccinated person. It is in this framework that the ethical considerations necessary to establish, collect, manage, maintain, and use EIR data will be analyzed. This analysis uses a framework for public health ethics [36] and WHO's ethical orientation for public health surveillance [37] as references.

8.1 IS IT ETHICAL TO OBTAIN INDIVIDUALIZED DATA FROM HEALTH SERVICES BENEFICIARIES?

The authorities responsible for the health of the population must strengthen surveillance capacity to ensure rapid responses when control of specific health problems or risks is required. The entire population benefits from said surveillance, and must demand that health authorities work efficiently and effectively on the mandate of protecting our health, especially by addressing problems that no single individual is in any position to address. Obtaining individualized data from users of the health services is ethically justified if: 1) it is done by the authority in charge of protecting the health of the population (directly or through mechanisms established for this purpose), 2) the information is used to improve the health of the population, and 3) the benefits that result from obtaining these data outweigh the costs, risks, and inconveniences of obtaining and preserving them. This entails that it is not acceptable, from an ethical standpoint, to collect data (individualized or otherwise) that will not help protect the health of the population, nor is it acceptable to collect non-actionable data. For example, it is not ethically acceptable to obtain individualized data if the health authority will only act on consolidated data.

Acquisition of individualized data (instead of non-individualized data) is more onerous for the population, implies a greater risk (for example of breaks in confidentiality or improper use of data), and is more financially costly. This greater burden is only ethically justifiable if it implies greater benefit for the population, e.g., through more diligent and effective action in the event of an outbreak or for monitoring of vaccine recipients who have not completed their vaccination schedules. As previously mentioned, the EIR can provide various benefits, which can have a positive impact on population health, by being a useful tool for program management and information analysis, facilitating the availability of information, supporting outbreak and public health emergency response, improving equity, and improving vaccine safety surveillance, among others.

8.2 ETHICAL OBLIGATIONS TOWARDS PEOPLE FROM WHOM DATA ARE OBTAINED AND THE GENERAL POPULATION

Individualized data acquisition creates a series of obligations on the part of those who establish an EIR:

1. First, those responsible for EIR implementation have the obligation to ensure that the use of data actually benefits the population, as it was this benefit that justified the acquisition of individualized data in the first place. This benefit can only be actualized if data collection has been carried out rigorously. Furthermore, these managers have the ethical obligation to ensure that only those individualized data truly necessary for the EIR to improve the health of the population are collected (see Section 4.1).
2. Those responsible for an EIR also have the ethical obligation to obtain information respectfully, which entails informing the person from whom data will be obtained (which data will be obtained, for what purpose, how they will be used and stored, and even who will be responsible for preserving them). However, this does not mean requesting permission to obtain these data or obtaining informed consent. In other words, the informed consent of the person from whom data are obtained is not indispensable for ethical data collection for an EIR. The authorities responsible for the health of the population have the power to obtain individualized information to be able to carry out their task of protecting the health of the population. However, in public health, it is advisable to encourage voluntary social cooperation and resort to compulsory actions only when necessary. Thus, it is advisable to consider mechanisms to generate a social consent built on communication with the population – e.g., by means of information campaigns and public consultations – and a long-term public commitment by the health authority. In any case, the population should be informed of the existence of the EIR, its features, and its impact on health.

3. The ethical obligation to protect the confidentiality of the people whose data are obtained mandates that those responsible for the EIR adopt all reasonable necessary measures to ensure that both individual data and consolidated data are protected. Collecting sensitive information carries the risk that confidentiality may accidentally be broken, or that the information may be used for other ends than originally intended. The people responsible for the EIR should take all reasonable necessary measures to minimize these risks by specifying beforehand clear and rigorous roles and rules for accessing and managing the data, as well as for each task, by adapting, coding and anonymizing data in such a way that it can respond to the specific information needs while not providing more information than is required to perform the task.

4. Finally, those responsible for the EIR have the obligation to ensure that obtaining the necessary data does not place an additional burden on the most vulnerable population; for example, disadvantaged populations that live in remote rural areas should not have to travel to faraway health facilities at a prohibitive cost (of both time and money). The same burden that can be light for people in urban areas can be extremely burdensome for rural populations. Therefore, measures to ensure that burdens are distributed fairly should be sought. An EIR can significantly contribute to the reduction of inequities. However, it is necessary that it at least does not deepen existing inequalities. At the same time, it should be thoroughly thought through how data will be collected from people who may be in a particular situation of vulnerability, such as undocumented workers or people living in irregular migratory situations and their families, in order to avoid exposing those populations to unnecessary harm.

8.3 ETHICAL OBLIGATIONS OF EIR MANAGERS TOWARD MANAGEMENT AND PRESERVATION OF COLLECTED DATA

The parties responsible for the EIR have the obligation to ensure the respectful and responsible management of the data collected therein. This implies, in addition to keeping the population continuously informed on what data are collected and why they are collected, implementing mechanisms to ensure a holistic and responsible handling of the data. In addition, those responsible for the EIR must ensure that the data are effectively used for their intended purpose, i.e., to benefit the population. When using EIR data in activities to benefit the population, those responsible for the EIR have an ethical obligation to ensure that discrimination and stigmatization are avoided, for example in the case of those populations or ethnic groups that exhibit very low vaccination rates. In general, those responsible for EIRs have to actively seek to minimize risks that may arise when handling the data collected, such as possible breaks in the confidentiality of the information.

Ethical management of EIR data requires transparency in their use and, specifically, with regard to sharing of data with other actors. Because what justifies data collection for an EIR is the health benefit for the population, there is an ethical rationale for those responsible for the EIR to share the data with other public health agencies that are part of the health authority, with the provision that these agencies will also use the data for the benefit of population health and will ensure at least the same level of protection of confidentiality that the EIR ensures. Sharing data under these conditions makes it possible to generate a greater health benefit for the population while maintaining the same level of risk, which means it is ethically justified. However, it is not ethically acceptable to share data with other government agencies that are not devoted to public health protection, e.g., law enforcement agencies such as the police. Sharing EIR data with such entities would only be justified under extraordinary circumstances involving a substantive risk to the public good and only after rigorous ethical and legal scrutiny.

8.4 ETHICAL USE OF COLLECTED DATA

The ethical use of data collected through an EIR means that the relevant authority uses the data for the benefit of the health of the population, that the data were obtained in an ethically acceptable manner, and that the data are handled ethically. Furthermore, from a procedural standpoint, ethical use of EIR data implies transparent governance of the EIR itself. This requires clear supervision mechanisms to ensure strict accountability, which, in turn, will foster trust among the population.

EIR data can be used for a valuable purpose other than for the direct benefit of the population from which the data were gathered, for example to do research. Research is like other public health activities – such as surveillance tasks which are made possible by the EIR – because it also involves systematic data collection. However, unlike these other activities that seek the direct benefit of the population, research aims to produce generalizable knowledge. Conducting research is valuable because it can provide accurate and relevant evidence to guide health activities and therefore can benefit everyone indirectly.

When EIR data are to be used for research, the parties responsible for the EIR must ensure that the research is conducted in an ethical manner in accordance to national legislative and regulatory frameworks, as well as international ethical guidelines such as the Helsinki Declaration [38] and the international ethical guidelines for health-related research involving humans (CIOMS) [39]. These provisions include the approval of the protocol by an ethics review committee before starting a study including human subjects. It can sometimes be difficult to differentiate activities that constitute research with human subjects from those that are public health tasks and are not subject to the same provisions. In general, research that is conducted with data that are entirely unidentifiable is not considered research with human subjects. Regardless of how difficult it can be, the determination of what is and is not research with human subjects should be carried out by an appropriate entity, such as an ethics review committee. Furthermore, there are several guidelines that help to distinguish research with human subjects from other public health activities [40-44] In the end, those responsible for the EIR have an ethical duty to proceed in an ethical manner when conducting activities related to the regular use of EIR data for the direct benefit of the population as well as for research.

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Annex 1. LESSONS LEARNED FROM HEALTH INFORMATION SYSTEMS THAT HAVE FAILED

REASONS	DESCRIPTION	ACTIONS NEEDED TO FACE THE CHALLENGE
Inadequate survey of requirements	✗ In the definition of requirements, the processes and procedures associated with the immunization program are often unclear, which means that, when the survey is conducted, these factors are not clearly structured and the developed systems do not meet program needs.	✓ Carry out a survey of requirements with personnel knowledgeable on the processes of each level of the system. ✓ Ensure that the person who carries out said survey is knowledgeable on the definition of requirements.
System design	✗ Managers take short cuts through the use of already-established system development methodologies and do not devote sufficient time to analysis and system design at the beginning of the project, which increases the time and effort needed to develop the system.	✓ Formulate an adequate, participatory planning process. ✓ Study the different methodologies and systems available and establish the advantages and disadvantages that are consistent, or not, with the reality of the country and each level of management. ✓ Take into account ease of use, interface user-friendliness, and optimal operation when designing the system.
System architecture	✗ The architecture of the system does not adjust to the expected scale and scope or context in which the system is going to be implemented. ✗ The design and architecture of the system are complex; the information system was planned as a complex system from the start and does not work in a modular fashion.	✓ The objectives and requirements of the system should be defined clearly in the planning and design stage. This will avoid a disconnect between the actual design and the expected one, understanding that the chosen system architecture can increase the costs of system implementation. ✓ Work on system design and architecture from a modular standpoint, incorporating all system requirements.
Lack of documentation of the stages	✗ The pilot projects are not documented or evaluated sufficiently well as to demonstrate the increases in efficiency, improvements in health outcomes, and cost-benefit ratio needed to justify expansion to the national scale.	✓ Document the entire process of implementation of the information system, including the strategic and operational plans, the survey of requirements, and all processes up to its use.

Annex 1. continued

REASONS	DESCRIPTION	ACTIONS NEEDED TO FACE THE CHALLENGE
Commitment from the authorities	✗ Lack of commitment from the authorities; failure to give formal approval to the team responsible for the project and to the plan created by this working group. ✗ Changes in political authorities at the Ministry of Health.	✓ Establish a formal multidisciplinary working group with entities that should participate in the project. ✓ Ensure project governance by the national authorities and demonstrate the benefits that can come from information systems. ✓ Consider international experiences that can support governance, showing the different experiences of countries of the Region and worldwide. ✓ In case of a change in administration, present the project to develop the information system, its current stage of progress, and the benefits the system will provide, so that the new authorities are committed from the start to support the system and give formal approval. ✓ Use different methodologies to plan activities within an established timetable, meet deadlines, conduct monitoring, hold periodic team meetings, and make systematic progress reports to the pertinent authorities.
Different interests	✗ The agendas of the technical support providers and cooperation agencies do not coincide with the interests of the system users.	✓ Strengthen governance by the ministry itself with international organizations/ suppliers to present a project that meets country requirements and context within the necessary time frame.
Budget	✗ Budget commitments are made prematurely and the project timetable is not flexible enough to allow the adjustments required by the system.	✓ The planning process is essential, and the plan and budget thus obtained should be reviewed constantly and adapted to system changes and requirements.
System maintenance	✗ As noted in Chapter 4, failure to consider the human-resource costs and requirements of system maintenance can cause the system to fail. When support actions are not carried out for lack of planning, the system promptly becomes obsolete. ✗ Need for updates, modifications, and/or evolutionary maintenance that are not easily parameterized or depend on a third party.	✓ The budget should include all costs and expenditures associated with the entire cycle of the information system, including system maintenance activities. ✓ Ensure the continuity of software development and maintenance not only in terms of processes, but also in human resources, as this ensures agile results in establishment of the information system. ✓ Consider update needs (e.g., to include a new vaccine) and maintenance from the very start of the planning stage. Clearly define how these services will be delivered and who will be responsible for said activities.
Training	✗ Lack of user training.	✓ Seek different training strategies for future system users, including video conferences, a help desk hotline, field visits, and training of facilitators that can extend knowledge to others.

Annex 1. continued

REASONS	DESCRIPTION	ACTIONS NEEDED TO FACE THE CHALLENGE
Transition to the new system and acceptance thereof	X Lack of an agenda for switching to the new system. Failure to consider the period of transition and processes that will ensure acceptance by system users.	✓ Consider a transition agenda during which users will be closely followed to provide a better understanding of their concerns regarding the new system. ✓ Include a transition agenda in the system planning stage.
Confidentiality and privacy	X Potential use of individualized data from vaccine recipients outside of ethical standards.	✓ Establish clear standards which stipulate responsibilities and ethical and legal considerations for the use of system data. Provide for sanctions against individuals who misuse data. ✓ Define roles or user profiles which can receive clearance to check or view certain data.
Monitoring and follow-up of the information system	X Lack of monitoring and follow-up of the information system and the data it generates without reviewing whether the variables, algorithms, formulas, reports, etc. are adequate with regard to the latest system updates.	✓ Assign a team in charge of monitoring and follow-up of the information system and its data, who should conduct constant reviews of the system, its architecture, its business rules, and the information stored in the databases. ✓ Conduct periodic surveys of end users' perceptions to determine whether the system is meeting the needs of the different levels of the immunization program.

Annex 2. BENEFITS OF AN EIR

A2.1

BENEFITS FOR PROVIDERS, PATIENTS, AND USERS

The following table lists the benefits of an EIR for providers, patients, and users of the immunization service:

BENEFIT	DESCRIPTION
Access to immunization status and relevant immunization-related information	If the EIR has a Web interface for end users, parents, and/or guardians, they can access users' immunization history online and even download an electronic version of their vaccination card or certificate. Furthermore, the Website can serve as an environment for communication, providing information on vaccine-preventable diseases, contraindications, possible adverse reactions and what to do, next vaccination dates, and locations of vaccination centers, among others.
Users' immunization history is available to health care providers	The health professionals responsible for vaccination can access immunization history of the beneficiaries of vaccination services, which allows clear definition of the corresponding dose according to age, background, and schedule. This ensures a correct process and avoids potential program or process errors. On the other hand, in many countries, few people take their vaccination cards to the immunization center or even have a card at all, which hinders identification of the proper dose according to the user's immunization schedule. In this context, an EIR with integrated databases for different vaccination providers is very useful to ensure administration of proper doses, reduce the probability of missed opportunities for vaccination, and prevent revaccination.
Immunization strategies centered on patient care	The information provided by EIR systems allows implementation of different immunization strategies according to the presence of "pockets" of unvaccinated individuals. These strategies can be: » Telephone calls » Text or e-mail messages » Letters through the post » Extramural activities in defined areas » Rapid vaccination monitoring in predefined areas

A2.2

BENEFITS FOR DECISION-MAKERS IN PUBLIC HEALTH

EIRs bring the following benefits to decision-makers in public health:

BENEFIT	DESCRIPTION
Adequate immunization service	The immunization service can be more precise, timely, and complete. This ensures the right patient gets the right dose at the right time according to immunization schedules.
Reliable immunization coverage	Reliable estimates of immunization coverage are needed to formulate recommendations and make adjustments to immunization strategies, as well as to improve the efficiency of the immunization systems by better understanding when and where people are vaccinated. Evidence suggests that better measurement of coverage results in an increase in the coverage itself [45-48]. More reliable numerator data – as has been seen in Uruguay and Chile – allow valid measurement of coverage, unlike traditional interventions [49].

A2.3

BENEFITS FOR IMMUNIZATION PROGRAM MANAGERS

EIRs provide the following benefits for immunization program managers:

BENEFIT	DESCRIPTION
Traceability of vaccines (inventory management, vaccine management, and vaccine safety)	The EIR provides information related to the stage of the process of vaccine administration to system users. If this stage is linked to inventory management information systems since the time vaccines reach the country until they are delivered to health facilities, the path of each vaccine could be entirely traceable. This information is relevant for accountability of the immunization program, as well as to improve program safety, as it makes it possible to know who has received each batch of vaccine in case an evaluation is required in response to an ESAVI.
Program management control	Through the EIR information system, immunization program managers can have access to information relevant for program management control at all levels. Thus, key indicators are measured, such as immunization coverage, productivity, performance, program errors, utilization of supplies, and compliance with immunization schedules, among others. Potential actions and initiatives are also better designed, and planning of program activities and resources is enhanced.
High-quality information that improves the decision-making process	Automated functions can improve the quality of data entry and reduce data duplication, while integration with specialized systems provides greater accuracy, real-time epidemiological surveillance, complex decision-making, and scientific evidence for compliance with international requirements. If the EIR information system is used correctly, it can be reliable, as registries would meet the operational definitions used for data quality analysis as defined by the "Toolbox for Coverage Monitoring of Integrated Public Health Interventions": accuracy, precision, completeness, timeliness, integrity, reliability, and confidentiality.

Annex 2.3. continued

BENEFIT	DESCRIPTION
Process efficiency	The benefits of using technology in the field can increase the efficiency of cold-chain monitoring and optimize the deployment of resources and the monitoring of vaccinated and unvaccinated individuals, which reduces the administrative work burden. It is well known that EIRs enhance administrative efficiency, as do other health technologies [17, 21, 50]. Electronic data entry and storage result in significant time savings and provide real-time access to local and district providers and program managers. It also improves communication of vaccination data among key actors, which enhances program efficiency. A clear example was provided by an evaluation of the national individual registry system of Uruguay, which concluded that "Overall system performance was excellent (proper archiving and recording of form data, sufficient supply of forms, timely flow of information, adequate defaulter tracing practices and computer system security)" [49].
Improved communication	EIRs take advantage of mobile applications and Web-based platforms, which helps bridge communication gaps among providers, patients, and users. » A review of 41 studies showed that EIR-issued telephone reminders were more effective than other vaccination reminders (letters, cards, etc.) [45]. » The systematic issuing of EIR reminders to mothers is a useful way to identify child vaccination status [51].

BENEFIT	DESCRIPTION
Support during response to outbreaks and public health emergencies	EIR information systems can be a valuable source of information during outbreaks and emergencies, as they provide timely access to individualized information, which reduces search time and allows a rapid response to the emergency. EIRs that interact with hospital systems, pharmacy or birth registries, and data recordings provide greater access and availability of information for patients during an emergency, which enables provision of adequate care to the target population. Furthermore, EIR systems can support emergency or outbreak response by incorporating response campaigns.

A2.4

BENEFITS FOR RESEARCH

Vaccine effectiveness

Since EIRs are integrated with other applications in the immunization and health information systems (e.g., electronic medical records, inventory systems, etc.), they contribute to the national health information network and are considered additional variables that provide a reliable data source that can be used to improve different analyses. There is mounting evidence that immunization information systems can be used to carry out vaccine efficacy studies.

The availability of an EIR with good coverage of the target population can be a source of very valuable information to conduct vaccine effectiveness studies, as it combines immunization history with clinical and epidemiological data from other sources, such as epidemiological surveillance.

Vaccine safety

In vaccine safety studies, EIRs facilitate the collection of data, which are also more timely, as they are already available in existing databases. Furthermore, it allows generation of analyses according to different relevant variables, and can support research into ESAVIs.

Equity

In the Region of the Americas and in other regions, considerable inequalities persist due to various factors that limit access to immunization services. These factors include a lack of human resources, infrastructure, and equipment; physical and cultural distance between immunization services and target populations; and income inequality. Therefore, income level, geographical location, and ethnicity are determinants of the vulnerability and exclusion of populations from health services.

In this regard, EIRs allow different immunization centers to conduct follow-up to users who did not access the immunization services, with a view to conducting close monitoring and seeking capture strategies for individuals who did not present to the immunization services or who presented but failed to complete their immunization schedule.

Annex 3. WHY AN EIR IS A GOOD INVESTMENT

REASON	DESCRIPTION
Positive cost-benefit ratio	EIRs provide administrative efficiencies and potentially significant savings [17]. » According to a seminal study by the State Health Department of Utah, USA, individualized registries save substantial time in administrative tasks, with a consequent annual savings potential of US$11,740 on average [52]. » In 1998, the immunization registry of Boston, Massachusetts, USA, saved US$26,768 in comparison with manual costs, and an immunization information system was predicted to save US$689,403 in comparison with manual registries [17]. The cost-effectiveness and cost-benefit ratios of registries are expected to vary with population and system complexity. These cases may not be relevant for development in the regions where needs and resources are different. However, a parametric cost analysis provides a predictable cost structure both for development and for maintenance of immunization registries [21]. Preventive evaluations of workflow, system, and preparation of human resources can ensure equally successful results in developing countries. Investments in EIR technology can provide benefits in the long run, in which the return on investment may not be immediate. As a result, long-term performance should consider the costs of implementation, staff training, maintenance fees, service fees, and system customization (e.g., interfaces with mobile technology applications). Furthermore, it should be taken into account that measurable returns are likely to be dispersed between the Ministry of Health, the subnational level, the local level, and the clinical personnel who use the EIR. Positive externalities, such as the individual social benefit to patients, are hard to measure, despite efforts to plan cost and evaluate return.
Utility in emergencies	Given the inherent difficulties of evaluating the cost-effectiveness of an EIR in daily practice, the social and capital benefits of an EIR in emergencies are worth considering. There is evidence of the utility of EIRs by offering significant returns in such situations: » An evaluation of the immunization information system of the U.S. state of Louisiana after Hurricane Katrina revealed significant savings when more than 18,000 immunization registries were recovered. The immediate access to these registries represented an estimated savings of more than US$1.6 million in vaccines alone and of US$3.04 million in vaccine administration fees [53]. » EIRs that interact with hospital systems, pharmacy or birth registries, and data registries offer greater access and availability of information for patients during an emergency.
Investment in developing countries	As described above, the immunization information system is part of a health technology platform. There is substantial evidence that technology is a promising tool for investment in developing countries [15].

Annex 4. ESSENTIAL EIR REPORTS

The reports generated by an EIR provide relevant support for monitoring of key management indicators and information at all levels of responsibility. The following reports are essential:

TYPE OF REPORT	DESCRIPTION
Daily log	Report on daily data entries disaggregated by: » Date » Biologic agent » Dose » Individual (immunization history) » Age or indication (e.g., influenza) » Health facility and vaccinator » Sex (optional, if there are no systemic differences)
Consolidated registry	Consolidated report of daily entries disaggregated by: » Biologic agent » Period » Dose » Type of facility » Level of responsibility (municipal, regional, national, and/or other administrative level) » Age of the target group or indication » Sex (optional, if there are no systemic differences)
Immunization program indicators report	Indicators are measurements that allow monitoring of program performance. Every EIR should include the following basic indicators: » Vaccination coverage by vaccine, according to time, place, and person variables – Time: over a defined period – Place: by place of residence – Place: by occurrence of vaccination (output) – Place: matrix of vaccinated individuals cross-referenced to output data or health facility data and residence data – Person: coverage by birth cohort – Person: complete and incomplete schedules according to age » Default rate (for various biologics) » Timeliness of administration » Simultaneity of administration for biologics that should be administered at the same time » Access to the immunization service
Lists of pending vaccine recipients or follow-up of immunization schedules	The EIR should generate lists of interest such as: » Dropouts or defaulters: individuals who should have been vaccinated at a time previous to the period of analysis but have not been vaccinated » Pending recipients: individuals who are due to be vaccinated in the period of analysis (e.g., in a given month) » Next appointments: a visualization dashboard for health workers and users and/or their parents or guardians so they can see when their next vaccination appointment has been scheduled, if applicable These lists can be linked to immunization reminders (automated or otherwise).
Maps	An EIR can have the function of generating maps or, at least, provide information for map generation. These maps can be used to identify the following aspects: » Areas with individuals pending vaccination » Areas with unvaccinated individuals » Vaccination coverage, among others

Annex 5. CRITERIA FOR EIR SYSTEM EVALUATION

EVALUATION CRITERIA	RESPONSE
System scope	
Year of implementation	
Unique identifier (Yes/No)	
Included population (children under 5, entire population, etc.)	
Vaccine types included (regular schedule, vaccination campaigns, vaccines not included in the regular vaccination schedule, vaccines applied in the private sector, etc.)	
Used during extramural activities (Yes/No)	
Incorporates vaccines given previously (Yes/No)	
Includes previous cohorts (from paper-based or electronic systems) (Yes/No)	
Geographical level (national, subnational, local)	
Normative and legal context	
Country has an eHealth strategy (Yes/No)	
System is compliant with country standards	
EIR use will be compulsory (including private sector and others)	
Country has a legal framework for privacy and data confidentiality	

EVALUATION CRITERIA	RESPONSE
System architecture	
Integration with other health information systems	
Integration with other EPI information systems	
Type of software	
Type of database	
Type of system connectivity (online, offline, or mixed)	
Periodicity of data updating and database synchronization	
Location of the database servers	
Technical requirements for computers to run the system	
Inclusion of a module for text messaging or mHealth	
Maintainability and sustainability	
Institution in charge of running the system	
Plans for scale-up and availability of hardware, software, and telecommunications infrastructure	
Data security (backup protocols, procedures, etc.)	
Management of software updates and improvements	
Help desk support	
Updating of system documentation	
Funding for the EIR	
Human resources	
Profile of personnel who enter data into the system	
Profile of personnel responsible for the data validation and monitoring of duplicate records	
Profile of external and internal software developers	
Profile of training personnel	
Profile of personnel in charge of hardware and telecommunications maintenance	
Profile of database administrator	
Whether EPI has access to databases or depends on a third party	

Annex 5. continued

EVALUATION CRITERIA	RESPONSE
Modules included in the system	
Immunization registry	
Logistics and supply chain management (Yes/No)	
Cold chain inventory	
Surveillance of ESAVIs	
Surveillance of vaccine-preventable diseases	
Training module	
Others	
Functionalities	
Storage of individualized vaccine histories	
Calculation and reporting of immunization coverage:	
» By vaccine	
» By dose	
» By age	
» By geographical area (place of residence, occurrence of immunization, place of immunization)	
» By condition (chronic disease, pregnancy, etc.)	
» By immunization strategy (intramural, extramural, etc.)	
» By population group (ethnicity, minority, etc.)	
» By sex	
» By health system affiliation (social security, health insurance, private, etc.)	
Report management	
» Predefined reports	
» Special reports	
Immunization safety monitoring	
» By expiration date	
» By batch number	

EVALUATION CRITERIA	RESPONSE
Interoperability with other systems	
» EIR systems of other regions, provinces, etc.	
» Other information systems	
Individual schedule monitoring	
» Automatic generation of reminders	
» Daily and monthly scheduling (list of unvaccinated individuals)	
» List of defaulters/dropouts/neglected populations	
» Business rules to support clinical decision-making	
Search and management of duplicate entries (de-duplication protocols)	
Access to information by external stakeholders (e.g., parents) according to security clearance parameters	
Communication between the EPI and EIR users (one-way or two-way)	
Alert management (contraindications, etc.)	
Parameterization of variables (schedules, providers, etc.)	
Return of information to the operational level (dashboard with coverage and default rates by level, etc.)	
Offline data entry	

Annex 6. BUSINESS RULES TO ENSURE EIR DATA QUALITY AT THE TIME OF DATA ENTRY

	EXAMPLES OF POTENTIAL ERRORS	BUSINESS RULE
1	A child has had an immunization event recorded with a date prior to her date of birth. For example: » Date of birth: 3 April 2015. » Date of BCG administration: 1 April 2015.	The date of vaccine administration cannot precede the date of birth of the patient.
2	A child has had an immunization event recorded with a date of administration after her date of death. For example: » Date of administration of pentavalent vaccine: 20 April 2015. » Date of death: 20 March 2015.	The date of vaccine administration cannot be later than the date of death of the patient.
3	An influenza vaccine dose was administered to an adult and the immunization event was recorded as follows: » Date of influenza vaccine administration: 14 October. » Date of EIR entry: 13 October.	The date of vaccine administration should precede or be the same as the date of immunization event input into the system.
4	The same immunization event has been recorded twice (duplicate record).	Each administered vaccine should be recorded as a single event.
5	First name, last name, identification number, date of birth, vaccine, dose, date of administration, etc. are compulsory variables. However, a review of databases reveals that the identification field is not completed.	Each immunization event should include all the compulsory data required by the system (verify the conditions under which data entry takes place).
6	A neonate has a date of birth of 20 August. On that same date, there is a record of administration of the BCG vaccine, neonatal hepatitis B vaccine, and DPT vaccine.	The date of birth of the vaccine recipient can only coincide with the date of administration of the BCG vaccine and the neonatal hepatitis B vaccine. Other vaccines should not have dates of administration coinciding with the date of birth. Analysis of administration of the BCG and hepatitis B vaccines should be in accordance with the vaccination schedule of each country.
7	A child has received the MMR vaccine twice on the same day at different health facilities.	The same patient should not receive the same vaccine more than once on the same day.
8	The expiration date of a batch of vaccine is 15 January 2016. The date of administration of this batch of vaccine was 30 January 2016.	The date of administration of a vaccine should not be later than the date of expiration of the vaccine batch in question.
9	Vaccines have been administered that do not correspond to the recipient's age, or extra/unnecessary doses have been administered.	A patient should not have more than X vaccinations before age 5, Y vaccinations before age 2, and Z vaccinations before age 1.
10	An infant has received the DPT vaccine at age 1 month.	Doses should not be administered before the minimum age established in the immunization schedule.

BCG Bacillus Calmette-Guérin (vaccine against serious forms of tuberculosis); DPT: diphtheria/pertussis/tetanus vaccine; EIR: electronic immunization registry.

Annex 7. RECOMMENDED ACTIONS TO AVOID DUPLICATE ENTRIES

ACTION	DESCRIPTION
Connection to the civil registry system, live births registry, or others to provide a real reference base for the population of the country and allow cross-referencing between databases.	This will ensure the incorporation of all target vaccine recipients in the immunization program, in addition to providing a base population that ensures the quality of individual identification data*. This is very useful both for the health sector and for the civil registry system, by sharing data from individuals that can be used to complete both records as necessary.
Include multiple IDs, such as: » National ID number » Passport number » Certificate of live birth number » Data on mother, father, and/or guardian » Social security number or health insurance number	The system should provide for different IDs, especially in a country that does not necessarily have a unique ID. In such cases, all sources of identification should be considered in order to ensure that a given record refers to the same person and facilitate the search.
Define different data fields to establish a combination that identifies every individual uniquely. Some such fields include: » First and last name of the individual » First and last name of the mother, father, and/or guardian » ID number of mother, father, and/or guardian » Place and date of birth » Time of birth (in case of multiple deliveries) » Place of residence	The system should provide for different ID variables, since the country does not necessarily have a unique ID. The EIR should have a search function that covers different key variables (e.g., first and last name, date of birth, place of birth) before allowing input of a person into the system in case a unique ID number is not available at the time of immunization. This makes it possible to filter data and minimize duplication of records.
Algorithms for identification and management of duplicate entries in the system.	De-duplication processes (system algorithms to detect records suspected of being duplicated, determine who defines whether a record is duplicated, how to consolidate data from two or more registries into one, and who has clearance to make changes in the database).
Carry out all necessary software validations, either in the user interface or in the database, to ensure information quality and minimize the risk of data duplication.	When the EIR is being developed, it is important to consider validation mechanisms that will allow easy detection of duplicate vaccine and person records in the system. This will facilitate management of duplicates.
Periodic (e.g., monthly) follow-up and search for potentially duplicate records.	The team in charge of EIR data quality should review the database periodically, analyze potential duplicates, and arrange for their correction.

* In countries where this population database is robust.

Annex 8. EXAMPLES OF EIR ANALYSES FOR DATA QUALITY MONITORING

VACCINE	TYPE OF ANALYSIS	PURPOSE
BCG and neonatal hepatitis B	BCG or neonatal hepatitis B vaccine administered to individuals older than the age defined in the immunization schedule.	Search for records of BCG or neonatal hepatitis B vaccination in individuals older than the age defined in the immunization schedule. Check against the country immunization schedule.
	BCG or neonatal hepatitis B vaccine administered to individuals with a "negative age."	Search for records of people who have received BCG or neonatal hepatitis B vaccine with a date prior to the date of birth.
DPT or polio	First dose of DPT1 or polio vaccine before age 2 months.	Search for records of people who have received the first dose of DPT or of polio vaccine before age 2 months, which can correspond to recording error or program error. Bear in mind that, in some situations, such as during whooping cough outbreaks, a rapid schedule can be used in which the DPT series is started at age 6 weeks.
	DPT or polio vaccine after the recommended age.	Search for records of people who were given DPT or polio vaccine after the age defined in the immunization schedule.
Influenza	First dose of influenza vaccine. Children who have received only one dose of the pediatric influenza vaccine.	Search for records of children who were being vaccinated for the first time and received only one dose of the influenza vaccine. If the dose was administered less than 28 days before, this is not a problem, as this is the minimum interval between the two doses in the same flu season.

BCG Bacillus Calmette–Guérin (vaccine against serious forms of tuberculosis); DPT: diphtheria/pertussis/tetanus vaccine.

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Health
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ISBN: 978-92-75-11953-2