

Information Systems for the EPI

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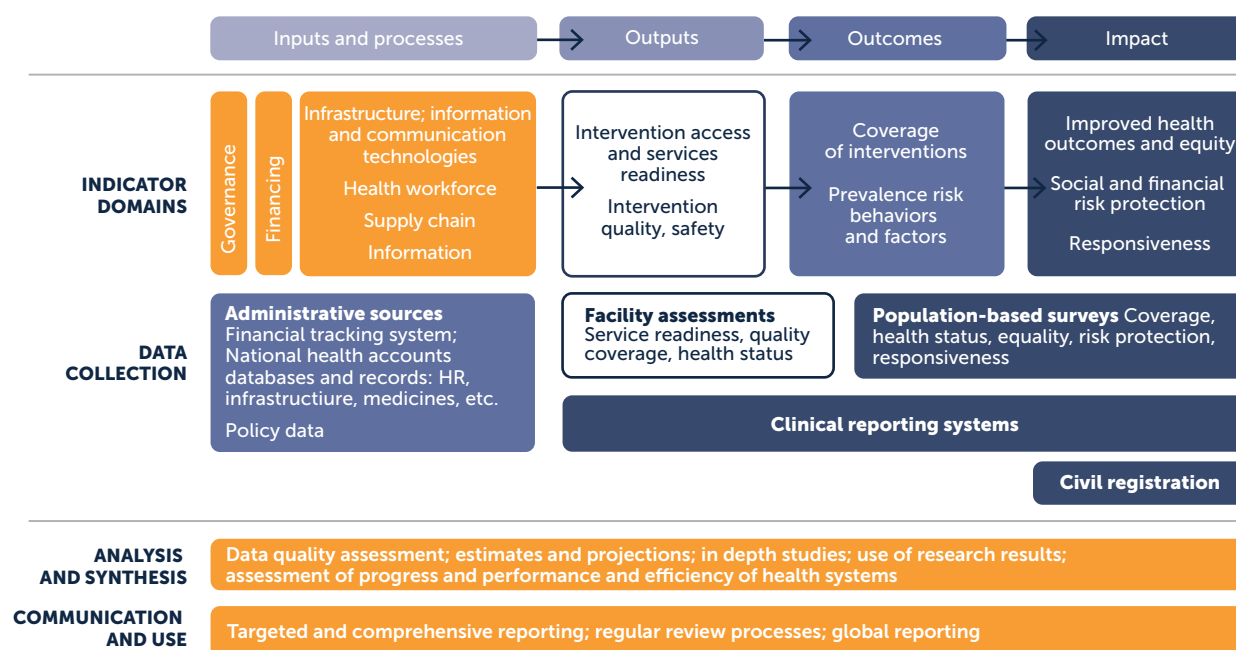
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Introduction

Information systems are key to producing the information that will guide the strategic, managerial, and operative decision-making process within the Expanded Program on Immunization (EPI). Moreover, essential data for monitoring and accountability, from the administrative to the managerial level to the general target population, will be created. The ultimate goal of having proper information is for EPI to make adequate decisions that contribute to reducing the morbidity and mortality of vaccine-preventable diseases (VPD) and improve Program performance.¹⁻³

The data-centered strategic and policy decisions within the EPI include focusing vaccination strategies and methods on reaching vulnerable and undervaccinated populations, communications, community education and outreach, as well as adjustments to vaccination schedules. Managerial decisions relate to the vaccine and supply inventory at all levels, secure cold chains and trained vaccinators to provide safe and quality vaccination services covering all of the population. Finally, operative or routine decisions include the determination of an approximate number of vaccinees every week/month, tracking of individual schedules and the strategies necessary to attain them as well as the required vaccines and supplies for vaccination at the medical facilities and in the community.

Progress and accountability are monitored through the analysis of wide-ranging performance data and indicators. The International Health Partnership, or IHP+, has proposed a theoretical framework for monitoring and managing inputs, processes, outputs, outcomes, and impact of health programs,⁴ as shown in Figure 1.

Figure 1. Theoretical Framework for Monitoring and Managing Impact in Health Programs

Source: International Health Partnership or IHP+

In the area of vaccination, the four indicator categories include the following:³

- 1. Inputs and processes:** Resources such as vaccines, supplies, staff, and financial resources, and processes that make them available where needed.
- 2. Outputs:** Availability for the provision of safe and quality vaccination services for the population and the informed population requesting the service.
- 3. Outcomes:** The main EPI indicator of this type is vaccination coverage, to be measured through facility reports or coverage surveys. This indicator results directly from the availability of vaccination service supply and the demand of the population under item 2 (outputs).
- 4. Impact:** Improvements to health, for instance through the reduction of the morbidity and mortality of vaccine-preventable diseases, to be detected through the epidemiological surveillance of vaccine-preventable diseases (VPD).

The information systems for EPI should monitor the above-mentioned indicators. Often times an information system is mistakenly equated with software. However, information systems include a range of elements focused on data management and administration to produce information. These elements include individuals, data, activities or work techniques, and material resources (typically, though not necessarily, information and communication resources).

In general, EPI requires at least four types of information systems or subsystems for decision-making: 1) vaccines administered (mainly used to estimate vaccination coverages), 2) the supply chain, 3) VPD epidemiological surveillance, and 4) surveillance of events supposedly attributable to vaccination or immunization (ESAVI). This list includes only information obtained regularly rather than from specialized studies or surveys, neither does it include information on finances or human resources as this type of information is usually within the health system in general. This chapter focuses on the first two types of information, i.e., vaccination coverage and the supply chain as well as the use of information and communication technologies (ICT) for EPI.

Vaccination Coverage

As previously mentioned, vaccination coverage is the most widely used outcome and performance indicator to monitor an immunization program. This indicator is measured and monitored systematically and periodically at the various management levels since it allows to detect problems and to implement corrective actions wherever and whenever required.

Coverage should be considered as an indicator that is estimated rather than measured directly. This is done by dividing the number of vaccine doses administered (persons vaccinated) for each vaccine type and dose (first, second, third) at a specific place and period, by the target population at that place and period, expressed in percentage form, as presented in the formula below.

$$\text{Administrative coverage (\%)} = \frac{\text{(Number of vaccine doses administered)}}{\text{(Target population)}} \times 100$$

Despite the fact that some countries derive coverage estimates from surveys only, most of the countries use the administrative method whereby EPI uses aggregated data on vaccine doses administered. Under the administrative method, the determination of the number of vaccine doses administered, i.e. the **numerator** to estimate coverage, typically starts with the recording of the number of doses for each biological and the doses (for instance, first, second, third) administered on one day at a health clinic or community-based vaccination activity. Then the data are consolidated based on the tier (district, regional, or similar), up to the national tier with aggregated data for the vaccinated total for a specific vaccine and dose in a specific time period.

The **denominator** to estimate coverage will be the target population for each vaccine and dose. This data is usually derived from population estimates based on census projections or recorded births, even though some countries have comprehensive immunization registries used as population denominators.

The information system to estimate coverages is the vaccination record that, in general, includes several tools for data collection, including vaccination cards, individual vaccination records and home-based records of vaccine doses administered.^{2,3}

Vaccination cards, either only including data on vaccines administered or where vaccines are included in health cards or records of other data such as growth, are provided to the user. The cards record the vaccination and doses administered and the date and, in many cases, provide information on the upcoming visits.⁵ To see a global repository of vaccine cards, go to: <http://www.immunizationcards.org/>.

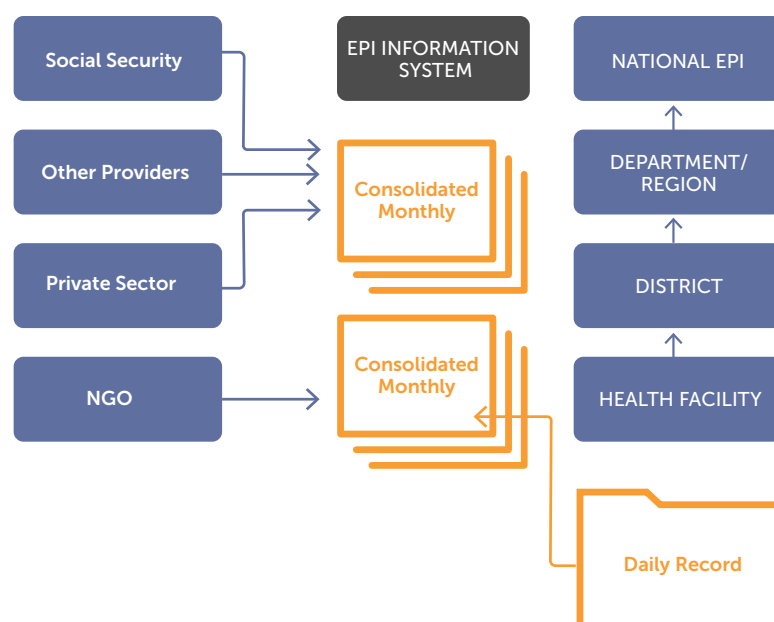
Individual vaccination records include information on the vaccinee and data on each vaccine administered. They may be books or copies of the vaccination cards organized by date of birth, by date of first contact with vaccination or by ID number. The most important characteristic of these records is their sorting to readily identify the user and to monitor the individual vaccination schedule, allowing for the identification of the vaccines received and others still pending based on their age or risk group.

Tickler files (picture below) are very practical systems to organize vaccination cards showing at the beginning of each month the cards of the individuals requiring vaccination and, by the end of the month, the individuals requiring vaccination who failed to attend the health clinic to be vaccinated are readily identified.

Daily records or tally sheets of doses administered are sheets or books to capture each vaccine dose administered, in general organized by age group and, in some cases, by hospital or community-based strategy and/or place of residence of the user. The main goal of this record is to facilitate counting and consolidation of doses administered every month (or every week, in some countries). This data is later reported on a **consolidated monthly form** (Figure 2).

In some countries, a daily paper vaccination registry has been developed whereby each line includes data on the vaccinee, such as name and date of birth. However, contrary to the individual vaccination records in tickler files described above, the records are ordered by vaccination date, limiting their use for monitoring the vaccination of each individual. Their role, as any non-individualized daily record, is to allow counting for consolidation of doses administered monthly. This type of record is not advisable since a simpler daily record or tally sheet fulfills the same function. Even worse, if this type of record or book replaces the individual vaccination record or tickler file mentioned above, the health clinics are left without a simple mechanism to identify and follow-up defaulters, i.e., individuals with outdated schedules.

Figure 2. A typical Data Flow for Vaccines Administered



There are flow variations, with more or fewer levels of data aggregation and computerization from various levels. Data entry into EPI information systems, usually into Excel sheets, or into health information systems for data on vaccines administered as well as other health interventions may take place at various levels, but the trend is to computerize at the level of the health clinic.

Data entered into the information system on coverages should at least include all of the vaccines and doses (first, second, third, and boosters) disaggregated by age group (or by indication, for example, influenza for pregnant women, patients with chronic diseases, etc.); the reporting period (weekly, monthly); and information on the facilities and geographical location data. They should also include the denominator used for each vaccine and dose.

Electronic Immunization Registries

Electronic Immunization Registries (EIRs) are confidential, population-based computerized information systems or databases, which include and consolidate vaccination data (doses administered) with information for each person. Electronic records facilitate the timely follow-up of individual vaccination schedules in addition to monitoring coverage according to vaccine, dose, geographical area, age, and provider (health clinic).⁶⁻⁸

Data shows that the EIRs help improve coverages through the following functionalities: patient reminders (upcoming vaccine and dose, overdue vaccines and doses); performance monitoring according to facility and feedback; and support for individual decision-making.^{9,10} In addition to facilitating data for decision-making, the EIRs may also introduce useful data for research, such as vaccine effectiveness, equality, vaccine safety, Program efficiency, and vaccine hesitancy data.

Currently, many countries, in particular in the Americas and Europe, are developing and implementing EIRs.¹¹ The rationale for this trend includes increasingly complicated vaccination schedules given the rapid introduction of new vaccines; mass use of new information and communications technologies (ICTs), and rapid increase in availability of computers, connectivity, and other devices.

An EIR should ideally have the following features:

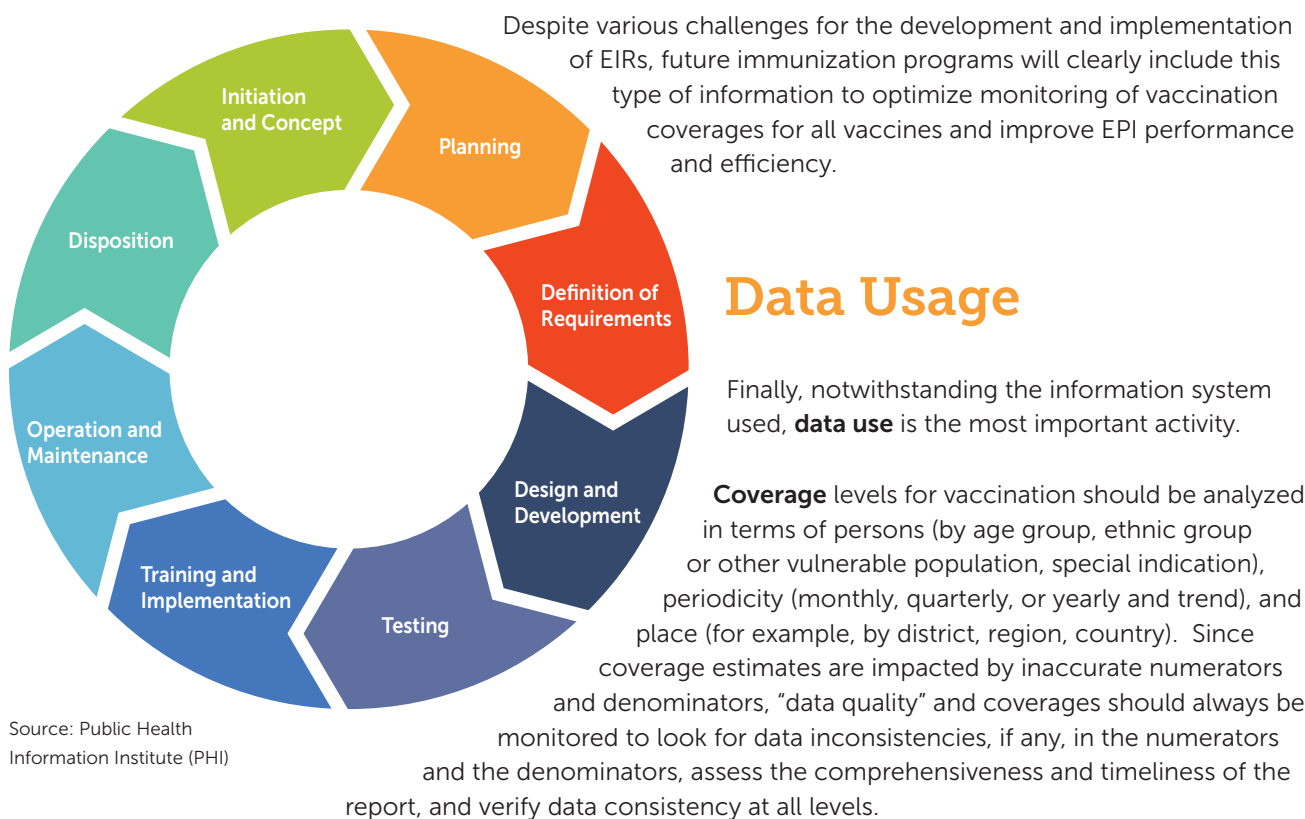
- Inclusion of all persons at birth, or as early as possible.
- Unique identifier, i.e. national identifier number or birth registration ID; a unique combination of variables (names, mother's name or her ID, date and place of birth); or biometric data (fingerprints, iris)
- Information about the vaccine given as close to the vaccination date as possible (in time and place)
- Data security and protection of patient confidentiality
- Flexibility to allow adjustment to changes in the vaccination schedules
- Information about each person, including information on geographical area of residence.
- Information about the vaccines given, dates and provider.
- Record deactivation features (deaths, migration)
- Timely individualized follow-up of vaccination schedules
- Aggregation of data by various geographical levels, age groups, and other relevant variables.

Several lessons are being learned from the increased development and use of EIRs:^{12,13}

- As with every information system, the development has a life cycle (Figure 3). Ignoring or incorrectly implementing a step impacts on quality and/or costs and/or time.
- The implementation of an EIR is a time-consuming process requiring adequate resources not only for its development but also for its operation and maintenance.
- The EIR design should take into account the operational levels and be useful for vaccinators. Design should be based on a clear understanding of vaccination processes and data registries. Consideration should also be given to the possibility of optimizing processes with this technology, i.e. it goes beyond replacing the individual vaccination registry form on paper with an electronic registry since processes can be re-designed and re-engineered.

- Properly defined processes need to be established to identify and manage potentially repetitive registries. They include:
 - » mechanisms intended to prevent duplicated registries (search/verify before creating a new registry and system checks), and
 - » processes for deduplication (system logs to detect registries suspected of being duplicate, establish how the registry is determined to be duplicated, how data are consolidated from two or more registries into one, etc.)
- The EIR development and implementation shall be monitored and assessed systematically and thoroughly. The following monitoring areas should be considered at minimum:
 - » Infrastructure and equipment;
 - » Integration and interoperability with other relevant systems;
 - » Software performance and quality certification;
 - » Trained human resources;
 - » Most frequent consultations and problems;
 - » User satisfaction at the various levels and in the various roles;
 - » Compliance with the implementation schedule;
 - » Management of information generated by the EIR and data quality;
 - » Thoroughness of the registry. This is key to use registry data as a denominator for coverage estimation.

Figure 3. Life Cycle of Information Systems Development



In addition to coverages, other indicators associated with the vaccinees should be monitored. The **dropout** rate is the most important supplementary indicator for individuals who start but do not complete their vaccination schedules. A significant advantage of this indicator is that it is not impacted by denominator inaccuracies, since it only analyzes numerator data. The most-widely used dropout rate is between the first and the third doses of the diphtheria-tetanus-pertussis (DTP) vaccine or the DTP-Hib-Hep B (pentavalent) vaccine, estimated as follows:

$$\text{DTP1-DTP3 (\%) Dropout} = \frac{(\text{DTP1 Dose \#} - \text{DTP3 dose \# in children <1 year}) \times 100}{(\text{DTP1 dose \# in children <1 year})}$$

The dropout rate should be lower than 5% in a country or region with a good follow-up system.

Supply Chain

The supply chain for immunization is defined as the **processes and elements** to ensure the vaccine and the vaccination supplies are in proper condition, where they should be, whenever needed and in adequate quantities. The supply chain processes include vaccine and supply **reception, transportation and distribution**, as well as proper **preservation**. As previously mentioned, the elements of the information system for supplies include human resources, financial resources, and equipment.¹⁴

Given the varied organization of the supply chain depending on the country, this section is intended only as an overview of the processes and some indicators, for processes and equipment, to consider when designing or restructuring the information system for the immunization supply chain.

Typically, data for the immunization supply chain are developed at vaccine storage sites, ranging from the national warehouses to the refrigerators at health clinics. Most countries have national (and sometimes regional) warehouses with capacity to maintain vaccines refrigerated or frozen for long periods of time, and to freeze cold packages. At the subnational levels, there is equipment to maintain vaccines refrigerated for shorter periods of time than at the national warehouses. Finally, at the operational levels there are refrigerators, or cold boxes, with capacity for fewer vaccines for limited periods. Similarly, the storage capacity for vaccination supplies depends on the level.

Currently, the type of data used for managing the supply chain is varied and dependent on the supply chain level. Some of the most frequently used data include vaccine and supply inventory balance sheets; forecasted demand (monthly, quarterly, yearly); cold chain equipment inventory (with information to plan maintenance and replacement); and data on temperature.^{3,15} The tools used for data collection range from kardex or requisition books for vaccines and supplies, and untabulated temperature control sheets to computerized inventory records and electronic temperature monitoring.

To conceptualize the information systems for the supply chain, it is important to consider the data purpose and to define the key performance indicators to monitor for guiding the process for strategic, managerial, and operative decision-making. Information systems for the supply chain should allow for:

- **Adequate Planning**
 - » Vaccine and supply needs (what and how much to request)
 - » Financial needs
 - » Vaccine and supply acquisition (when and how)
 - » Vaccine distribution

- **Efficient and Effective Management of Resources**
 - » Anticipate shortage of vaccines and/or supplies
 - » Anticipate excessive burden on cold chain equipment (since this impacts adequate preservation and heightens the risk of products reaching their expiry date while in storage)
 - » Reduction and prevention of unnecessary waste
- **Vaccine Access Improvement**
 - » Ensure supply meets the needs.
- **Ensuring User Safety**
 - » Traceability of the products used
- **Performance Monitoring**
 - » Using standardized data and indicators, with complete and timely statistics.

Below follows a list of the elements to consider when defining key performance indicators for the immunization supply chain:¹⁵

- Stock levels (by dose/month)
 - » Back-up stock
 - » Minimum and maximum stock
- Supplies
 - » Distributed versus needed
 - » Used vs. received
- Vaccine waste
 - » Open vials
 - » Closed vials
 - » By product, presentation, and place.
- Storage capacity
 - » Required vs. available
- Storage and transportation temperatures
 - » Continuous vs. twice daily
 - » Freeze indicators
 - » Alarm indicators
- Cost indicators
 - » Requested vs. used and wasted

Recently, the *Gavi Data for Management* task force proposed some standard indicators,¹⁶ as follows:

- **Full stock availability:** The time range between vaccine and supply arrival and availability of all vaccines and supplies (or trace vaccines/supplies) at a warehouse or a health facility, i.e. without shortage periods (stock=0). This indicator is contrary to shortages which could have a negative connotation.
- **Stocked according to plan:** Health center ratio with vaccines and supplies at levels between minimum and maximum stock defined.
- **Closed vial wastage:** Ratio of closed vials discarded in a warehouse or at the health center. Vials are discarded based on expiry date, interruption of the cold chain (warming up or freezing), breakage of vials, diluent loss or damage, or because they were taken to a community activity.
- **On-time and in-full delivery (OTIF):** Ratio of orders completely delivered as planned and on time, at the national level or from the national level to lower levels, etc.
- **Temperature alarm ratio:** This indicator can be estimated with a digital device to measure temperature and generate alarms provided alarm occurrence is recorded. These alarms occur when temperature drops below -0.5 degree Celsius for at least 60 minutes (low temperature alarm), or when the

temperature increases above 8 degrees Celsius for 10 or more continuous hours (high temperature alarm). Despite that the goal of the alarms is to immediately correct the problem, their frequent occurrence might signal equipment problems and the need to have them assessed and repaired.

- **Operability of the cold chain equipment:** Ratio of functional cold chain equipment (cold chambers, refrigerators, freezers, cold boxes, thermoses) over the cold chain equipment total in a specific area; it can be estimated by equipment type.

The above-mentioned indicators are baseline and should be adapted according to the organization of the supply chain and the needs of the immunization program in each country.

Use of Information and Communications Technologies Under EPI

Currently, information and communications technologies (ICTs) play a very important role in the monitoring of health programs in terms of data collection and transmission online or through mobile devices, as well as the analysis and generation of dashboards and visualizations. Examples of ICT use under EPI include electronic immunization registries (EIRs), vaccination recall/reminders delivered through a short message service (SMS); development of mobile applications for health education; remote monitoring of temperature and integrated systems for stock and supply chain management, including the use of bar codes to facilitate traceability of supplies.^{15, 17} Some of the uses are described below:

Data collection: Recording doses administered, or vaccinees, vaccine or supply stock transactions directly on a mobile device or an information system, for example an EIR.

Data transmission: Online or through mobile devices to have data at a higher level of the system, in real time.

Analysis: Automatic production of graphs, tables, maps, and interactive views which were not possible in the manual systems. ICTs allow for integrating data from various systems, including with geographic information systems (GIS), and the creation of **dashboards**.

EPI management dashboards: Offer simultaneous views of various indicators, such as the supply chain; coverage and dropout rates at specific places, time and based on specific individuals; and the impact as measured through the epidemiological surveillance indicators for VPD, among others.

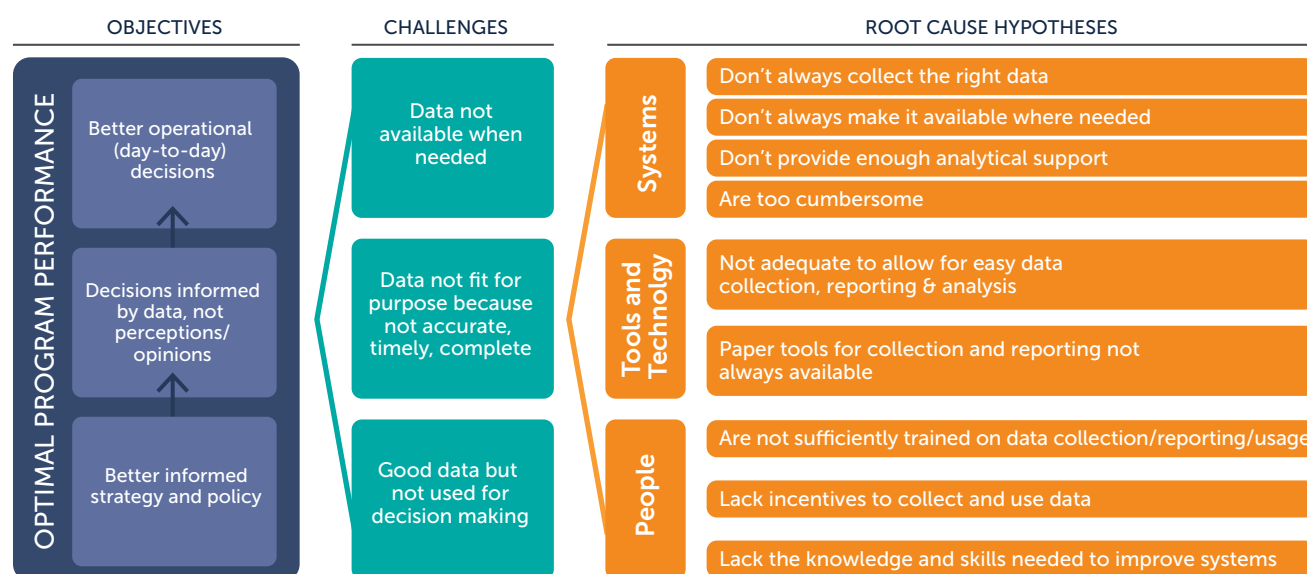
Geographic information systems (GIS) are part of a technology which is still underused but very promising for EPI management. GIS systems are designed to capture, store, manage, analyze, administer, and present all sorts of spatial or geographic data. They have been used successfully for risk analysis; microplanning of Program activities; campaign planning and follow-up (estimation of target population, progress follow-up); and to support the management and strategic planning of the immunization supply chain, among others.

Technology in itself cannot modify incentives or the behavior of users. However, the ICTs may motivate and empower skilled individuals to do a better job. The use of ICTs will only lead to improved information systems once technology and individuals work together to improve EPI performance.

Conclusion

The information system used by EPI, whichever it is, should be monitored and assessed systematically to understand the challenges and root causes impacting its performance and the quality of the data produced to allow for continuous improvement. Figure 4 below introduces a framework to assess challenges and root causes that may impact EPI information systems.

Figure 4. Challenges and Root Causes Affecting the Performance of Information Systems and Data Quality



Finally, coordination amongst countries and across the region to harmonize the immunization indicators used and to share data is key. This coordination allows for regional and global analyses to inform and guide strategies for the elimination and control of vaccine-preventable diseases.^{18,19}

For more information associated with information systems and ICTs for EPI, the *TechNet Resource Library* comprises more than one thousand resources on this topic: <https://www.technet-21.org/en/library/main>. This library is available in English, Spanish, and French. To register, visit: <http://www.technet-21.org/>.

References

1. World Health Organization. Global Framework for Immunization Monitoring and Surveillance. 2007 WHO/IVB/07.06. Available at: http://www.who.int/immunization/documents/WHO_IVB_07.06/en/
2. World Health Organization. *Immunization in Practice – A Practical Guide for Health Staff. Module 6: Monitoring and Surveillance*. 2015 Available at: <http://www.who.int/immunization/documents/training/en/>
3. World Health Organization. *Collecting, Assessing, and Using Immunization Data. Reference guide*. Draft. February 2016.
4. International Health Partnership (IHP+) and World Health Organization. *Monitoring, Evaluation and Review of National Health Strategies*. Available at: http://www.internationalhealthpartnership.net/fileadmin/uploads/ihp/Documents/Tools/M_E_Framework/M%26E_framework.2011.pdf
5. World Health Organization. Practical Guide for the Design, Use and Promotion of Home-based Records in Immunization Programmes. 2015 WHO/IVB/15.05. Available at: http://apps.who.int/iris/bitstream/10665/175905/2/WHO_IVB_15.05_eng.pdf
6. Linkins, RW. Immunization registries: progress and challenges in reaching the 2010 national objective. *J of Public Health Manag Pract*. 2001;7(6):67 - 74.
7. Gostin, LO, Lazzarini Z. Childhood immunization registries. A national review of public health information systems and the protection of privacy. *JAMA*. 1995;274(22):1793 - 9
8. Danovaro-Holliday MC, Ortiz C, Cochi S, Ruiz-Matus C. Electronic immunization registries in Latin America: progress and lessons learned. *Pan American Journal of Public Health*. 2014; 35(-6):453 - -7.
9. Jacobson Vann JC, Szilagyi P. Patient reminder and recall systems to improve immunization rates. Cochrane Database of Systematic Reviews. 2005 Available at: <http://onlinelibrary.wiley.com/doi/10.1002/14651858.CD003941.pub2/abstract>
10. Groom H, Hopkins DP, Pabst LJ, Murphy Morgan J, Patel M, Calonge N, Coyle R, Dombkowski K, Groom AV, Kurilo MB, Rasulnia B, Shefer A, Town C, Wortley PM, Zucker J; Community Preventive Services Task Force. *Immunization information systems to increase vaccination rates: a community guide systematic review*. *J Public Health Manag Pract*. 2015 May-Jun; 21(3):227-48. doi: 10.1097/PHH.000000000000069.
11. World Health Organization. Immunization and Vaccine-related Implementation Research Advisory Committee (IVIR-AC): summary of conclusions and recommendations, 30 May – 1 June 2016 meeting. *Weekly Epidemiological Record (WER)* 19 August 2016, vol. 91, 33 (pp. 389–396). Available at: <http://www.who.int/wer/2016/wer9133/en/>
12. Pan-American Health Organization. Technical Advisory Group on Vaccine-preventable Diseases. Data Quality Final Report, 2011. Available at: http://new.paho.org/hq/index.php?option=com_content&view=article&id=1862&Itemid=2032&lang=en
13. Pan-American Health Organization. National computerized nominal immunization registries: workshop to share lessons learned. *Immunization Newsletter*. 2011; 32(1):4. Available at: www.paho.org/immunization/newsletter
14. Ministry of Health of Peru. General Human Health Office. National Health Immunization Strategy. Practical Guide on the Cold Chain. 2005 Available at: <http://www.slideshare.net/sofphyazul/guia-de-cadena-de-frio>
15. World Health Organization. Using Information and Communication Technology (ICT) to Improve Immunization Programs: Stakeholder Consultation Summary Report. Istanbul, Turkey | 11-13 November 2014.
16. GAVI's Data for Management Strategy. Available at: <http://bidinitiative.org/blog/gavis-data-for-management-strategy/>
17. Pan-American Health Organization. *Immunization Newsletter*. December 2010. Available at: www.paho.org/inmunizacion/boletin
18. Tambini G, Andrus JK, Fitzsimmons JW, Roses Periago M. Regional immunization programs as a model for strengthening cooperation among nations. *Pan American Journal of Public Health*. 2006 Jul; 20(1):54-9. Available at: <http://www.scielosp.org/pdf/rpsp/v20n1/31726.pdf>
19. Pan-American Health Organization. 54th Directing Council – Working Document (CD54.R8): Action Plan on Immunization 2015. Available at: http://www.paho.org/hq/index.php?option=com_content&view=article&id=11087%3A2015-54th-directing-council&catid=8080%3A54th-session-28-sep-2-oct&Itemid=41537&lang=en