VACCINE/VACCINATION SAFETY IN THE AMERICAS

EXPERIENCES IN SURVEILLANCE OF EVENTS SUPPOSEDLY ATTRIBUTABLE TO VACCINATION OR IMMUNIZATION (ESAVI), AND INTEROPERABILITY OF DATA
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TECHNICAL COORDINATION FOR THE PREPARATION OF THE REPORT

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Claudia Cerón Coral, a social communicator and journalist and PAHO international consultant for the vaccine/vaccination safety project, was in charge of drafting this document.

Graphic design: Ada Fernández.
CHAPTER 1
THE REGIONAL SYSTEM: ITS ORIGINS AND ACHIEVEMENTS

The Manual for Surveillance of Events Supposedly Attributable to Vaccination or Immunization in the Region of the Americas was one of the first steps toward the construction of the regional surveillance system for events supposedly attributable to vaccination or immunization (ESAVIs) and adverse events of special interest (AESIs). This process has had several stages, technological developments, challenges, achievements, and advances.

The manual was developed between 2018 and 2019 by the Comprehensive Family Immunization Unit, under the Pan American Health Organization’s (PAHO) Department of Family, Health Promotion and Life Course, with the collaboration of multiple experts from the ministries of health in the countries of the Region, national regulatory authorities, and international organizations.

Both the development of the manual and the onset of the pandemic allowed us to focus on the construction of a regional ESAVI database for the surveillance of events associated with COVID-19 vaccines, the implementation of active surveillance strategies, and the strengthening of national capacities and ESAVI surveillance systems of the countries of the Region.

In July 2020, PAHO published the first regional guidance for countries to promote the inclusion of the necessary components in national plans for the introduction of COVID-19 vaccines. One of these components was vaccine/vaccination safety, with the following recommendations:

1. Convene the national committee on vaccine/vaccination safety with participation from scientific societies, national regulatory authorities, and the immunization program (ESAVI subcommittee);
2. Strengthen or implement surveillance of ESAVIs and AESIs;
3. Prepare surveillance of potential AESIs to establish background incidence rates, prior to introduction of the COVID-19 vaccine;
4. Define the requirements to strengthen intensified passive surveillance and active surveillance (sentinel hospital network);
5. Participate in the regional ESAVI surveillance system with case reporting from local to national and regional levels;
6. Prepare risk communication and crisis plans.

An event supposedly attributable to vaccination or immunization (ESAVI) is defined as “any untoward medical event that follows immunization and that does not necessarily have a causal relationship with the usage of the vaccine. The adverse event may be any unfavourable or unintended sign, abnormal laboratory finding, symptom or disease.”


With the onset of the pandemic, and with the awareness that vaccines are the first line of defense in response to an emergency of such magnitude, the rapid and safe development of the vaccine became necessary, as did its surveillance.

1.1 The challenge of a new vaccine
Developing a new vaccine and using it for the first time in the midst of the new pandemic created uncertainty, making it essential to build public trust around its use.

By leveraging the resources provided by the United States Centers for Disease Control and Prevention (CDC), the work being done by the PAHO’s Comprehensive Family Immunization Unit (Department of Family, Health Promotion and Life Course), and the contributions of PAHO’s Medicines and Health Technologies Unit (Department of Health Systems and Services), efforts were focused on conducting a study to determine the needs of the countries of the Region of the Americas, and thereby support them.

A cross-sectional study was carried out between January 2020 and October 2021, with online surveys and virtual interviews with 42 countries in the Region, to determine the level of maturity of the systems for the surveillance of adverse events related to vaccines.

1.2 Survey results: A first step
The results of the online surveys and interviews provided information on the types of ESAVI surveillance being carried out in the countries, and enabled an assessment of the situation in the Region.

General findings and recommendations from the ESAVI maturity survey

1. The Region’s national ESAVI surveillance systems have very diverse levels of maturity. It is recommended to strengthen the entire surveillance cycle: detection, reporting, investigation, causality analysis, final classification, and response.

2. In general, coordination among national stakeholders receiving ESAVI notifications is not systematic or consistent. It is recommended that this coordination be strengthened and that a joint approach be taken throughout the surveillance cycle.

3. In general, there is no systematic, consistent reporting of ESAVIs from the national to international level (regional-PAHO and global-WHO), and standardized reports are not being produced. Use of the regional ESAVI surveillance system is recommended, as is close coordination among the actors involved.

4. PAHO will be able to provide a technical cooperation package to each of the Member States to strengthen the entire surveillance cycle, based on the results of the regional survey.
1.3 Formation of the first working group

In April 2021, with financial support from the CDC, the first team tasked with strengthening ESAVI surveillance was formed. The regional team was formed, and five working groups were created, including representatives of national authorities and experts from the Region. The regional survey on the maturity of information systems was finalized, and the Pan American Committee on Vaccine/vaccination safety (PACVASE) was established.

On 23 February 2021, with the launch of the ESAVI and AESI regional surveillance system, Guidance for Implementing the Regional COVID-19 Vaccine AEFI/AESI Surveillance System was also published. This was the first guide that highlighted the need for objective information around the safety of COVID-19 vaccines and how to respond strategically to the situation.
1.4 Creation of the ESAVI surveillance system
The creation of the regional ESAVI surveillance system stems from a November 2020 recommendation from PAHO’s Technical Advisory Group (TAG) on Immunizations. Based on this, the first regional guidelines for the implementation of this system were developed. The objective was clear: to develop a sensitive, timely, standardized, reliable, and integrated regional ESAVI surveillance system with the participation of all stakeholders involved in the vaccine/vaccination safety system, to maintain trust in vaccination and its acceptance throughout the Region.

1. Analyze and classify the different types of ESAVIs in order to establish incidence rates at national and regional levels:
   a) Event related to a vaccine product;
   b) Event related to a deviation in vaccine quality;
   c) Event related to a programmatic error;
   d) Stress event that occurred immediately before, during, or immediately after the vaccination process;
   e) Events coincidental to vaccination.

2. Conduct post-marketing surveillance on the safety of new COVID-19 vaccines through active sentinel surveillance.

3. Coordinate with PAHO’s Revolving Fund for Access to Vaccines for adequate surveillance of ESAVIs related to adverse events due to a vaccine quality deviation, to determine corrective measures.

4. Provide systematic feedback to countries on data collected at the regional level to support their corrective actions and social communication strategies.

Regional strategy for strengthening ESAVI surveillance systems

Implementation of the regional ESAVI surveillance system

February 2021  April 2021  May 2021  August 2021

Note: PACVAS: Pan American Committee for Vaccine/Vaccination Safety; ESAVI: event supposedly attributable to vaccination or immunization; AESI: adverse event of special interest.
1.5 Creation of the PACVAS technical committee

In addition to forming the Vaccine/vaccination safety work team, and designing trainings for officials from the different countries of the Region, PAHO developed a fifth regional strategy, with strategic partnerships. For this, it convened a group of experts from different disciplines to create the Pan American Committee on Vaccine/Vaccination safety (PACVAS).

The purpose of this advisory committee is to provide advice to PAHO, based on the latest scientific evidence, to maintain and strengthen vaccine safety and public trust in the immunization programs in the Region of the Americas.

The Director of PAHO appointed the members of the Committee who are recognized experts from the Region in fields such as epidemiology, immunology, pediatrics, infectious diseases, public health, and drug safety and regulation. Their high levels of expertise and impartiality mean that recommendations are made independently and with scientific rigor.

The Committee officially took up their duties on 17 September 2021.

ANGELA GENTILE Argentina
(President)
Pediatric infectious disease specialist and epidemiologist, specialist in public health and infectious diseases.

JORGE CORTÉS Colombia
Internist, specialist in tropical infectious diseases.

ALEJANDRO CRAVIOTO Mexico
Physician, pediatrician, and PhD in tropical medicine.

TRACY EVANS-GILBERT Jamaica
Pediatrician, specialist in tropical medicine and public health.

PETER FIGUEROA Jamaica
Medical epidemiologist, specialist in infectious diseases.

GLORIA GIRALDO Colombia
Microbiologist and epidemiologist. Oncology nurse.

HERMINIO HERNÁNDEZ Peru
Physician and pediatrician, specialist in infectious diseases and vaccination in children.

NONI MACDONALD Canada
Pediatrician, specialist in pediatric infectious diseases and global health.

MARIA TERESA VALENZUELA Chile
Medical surgeon, epidemiologist, teacher, and researcher.

VERÓNICA VERGARA Colombia
Pharmaceutical chemist, MSc in clinical epidemiology.
1.6 Training stage

After conducting the survey and diagnosing the requirements and needs of the countries of the Region, the need for capacity building at all levels was identified, and the development of practical training workshops began.

The challenge of working virtually during the pandemic meant extra effort both for trainers and participants, since the emergency nature of the pandemic demanded immediate surveillance of COVID-19 vaccines.

Surveillance strengthening began through four- to five-day subregional workshops (with groups of countries), with 60 facilitators; in all, more than 500 officials from the ministries of health and regulatory authorities from the different countries of the Region of the Americas received training.

This was followed by national workshops for each country that requested individual training.

Training activities 2020–2022

- Guidelines launched 26 Feb 2021
- Feb-Mar 2021: Webinars
  - Risk communication
- Apr-Jun 2021: Subregional workshops
  - 500 participants, 60 facilitators
- May 2021 - May 2022: Webinars, Zoom cafe
- Jul 2021 - May 2022: National workshops (full and short)
- Jul 2021 - May 2022: Workshops on national vaccine/vaccination safety committees
- Jul 2021 - May 2022: Workshops and webinars
  - Sentinel surveillance
- Aug 2021 - Jan 2022: Course in data analysis
- Jun 2022: Online courses
- Jun 2022: Online workshops
1.7 Development of virtual courses
A training strategy was designed, with a series of materials based on the regional workshops, so that countries and their officials could take asynchronous courses through workshops available at the PAHO virtual campus.

Workshops were also held with requesting countries. Each had its own specific dynamics with analysis of specific cases, and questions and discussions adapted to each country's needs.

1.8 Materials published
The official publication of the Manual for Surveillance of Events Supposedly Attributable to Vaccination or Immunization in the Region of the Americas in 2021 was followed by the publication of Crisis communication related to vaccine safety: Technical guidance. Both were published in English, French, Portuguese, and Spanish. Development of other materials also continues, to enhance training and the standardization of procedures.

1.9 Communication strategy for risk events
A module was also developed to carry out risk communication activities related to surveillance activities. The development of a permanent risk communication plan helps to maintain public trust and respond to any crisis situation that may arise, including the emergence of an ESAVI.

The objective of the workshops is for teams and the community to be prepared to deal with ESAVI-related situations and know how to respond in a coordinated way to different events that could compromise the operation of the immunization program.

- This helps to maintain and strengthen confidence in vaccination among the population and health personnel.
- It builds a dialogue based on two-way communication that allows for listening and promotes direct feedback to achieve better population health outcomes.
- Each crisis is an opportunity to improve internal processes and consider lessons learned to strengthen the immunization program.
- The communication strategy should be adapted to each context, considering local determinants, differences in risk perception, and specific cultural elements.
Training: a vital component for regional work, 2022

Participating institutions

- National Immunization Program: 25
- National Regulatory Authority: 21
- Epidemiology: 25
- National vaccine safety committee: 14
- Others: 19

Activity required simultaneous interpretation?

- Yes: 11
- No: 30

Geared to personnel at level:

- Regional: 4
- Subregional: 9
- National: 29
- Regions within-country/departmental/state: 9
- National vaccine safety committee: 11
- Others: 6

ESAVI and AESI surveillance training topic

- ESAVI surveillance: 8
- Detection and notification: 10
- ESAVI investigation: 10
- ESAVI causality assessment: 14
- ESAVI sentinels surveillance: 11
- Information systems: 1
- Interoperability standards: 0
- Data analysis: 7
- Detection methods: 0
- Verbal autopsy: 0
- Risk communication: 9

Country participation

- Anguilla: 0
- Antigua and Barbuda: 1
- Argentina: 9
- Aruba: 4
- Bahamas: 1
- Barbados: 5
- Belize: 5
- Bermuda: 4
- Brazil: 9
- British Virgin Islands: 0
- Cayman Islands: 1
- Chile: 6
- Colombia: 7
- Costa Rica: 4
- Cuba: 4
- Curaçao: 0
- Dominica: 4
- Ecuador: 8
- El Salvador: 6
- Granada: 0
- Guatemala: 13
- Guyana: 3
- Haiti: 7
- Honduras: 8
- Plurinational State of Bolivia: 9
- The Bahamas: 1

Type of activity

- Training workshop: 31
- Short workshop: 7
- Webinars: 2
- Zoom cafe: 1
- Other: 2
In parallel with the creation of the vaccine/vaccination safety system, one of the biggest challenges in tackling the pandemic was to develop a technology that would meet emergency requirements. Information was required that could be collected through automated data management systems, rather than manually, using Excel workbooks, a practice that created a great deal of work for officials in the health systems of the Region.

In May 2021 PAHO asked health ministries to share their ESAVI databases with the regional level in order to monitor vaccine safety and the vaccination process. This required improved quality of surveillance data in the subsequent phase.

It was initially determined that a folder with a secure file transfer protocol (sFTP) could be used, allowing countries to transfer files, without overloading them with additional work since they were in the middle of the pandemic and responding to the emergency.
To address data integration needs and support the strengthening of countries’ information systems, a group of engineers needed to be hired for automated data transfer. The status of information in the Region was also analyzed.

Our team of data scientists and IT engineers:

ALEJANDRO BENAVIDES
Systems engineer
South America

ALEJANDRO DONIS
Systems engineer
Regional Database

CARLOS AGUILAR
Systems engineer
Central America

VÍCTOR OSORIO
Systems engineer
English-speaking
Caribbean

DIEGO LEMUS
Analyst
Regional Database

CARLOS FALLA
Data Analyst
Sentinel surveillance
Brazil

Results of the survey on the status of ESAVI surveillance in the Region, 2021:

2.1 Conclusions from the report: three groups of countries

After conducting the survey and diagnosing the status of the methods and information systems used in the different countries of the Region, three large groups were identified, with different levels of maturity with respect to ESAVIs.

The first group included countries with no digital information systems; their information was recorded on paper forms and then transcribed or sent physically to a country office (ministry of health, for example) to be entered into databases. This was the least developed level, representing 60% of the countries in the Region.

The second group comprises countries with their own vaccine safety surveillance systems, with agencies or other bodies responsible for specific levels or provinces. These countries, represented 20% of the total number of countries in the Region. The challenge was how to set them up for information exchange or so that, at least, they could share their database with other national institutions (within each country).

The third group (17%) included countries with a single, country-wide information system, used by the different entities involved in pharmacovigilance.
2.2 Challenges of integrating a homogeneous data system: the DHIS2 tool
The challenge for the Region is to generate not only high-quality national information systems but also the capacity to exchange information using a single regional database. Each possible solution considered the level of maturity and the proposed objectives.

Following the recommendation of the Technical Advisory Group on Vaccine-preventable Diseases, PAHO worked with the countries to begin assembling the regional database and harmonizing internal processes to facilitate transfer to the general database.

Promotional activities were carried out and specific solutions were planned for each maturity level, based on the results of the survey.

For the countries that relied on paper forms, PAHO offered to support national institutions with a digital tool called DHIS2 (District Health Information System, version 2).

The DHIS2 tool is an open-source system whose license is free of charge. It was developed by the University of Oslo, Norway, more than 20 years ago, and is among the most widely used public-health data management systems worldwide. It is currently being implemented in nearly 100 countries, 35 of which are using it as a national, multi-surveillance system.

Work was done directly with the university to adapt the ESAVI module to regional recommendations, incorporating 33 prioritized variables. The WHODrug standard was used to identify and code vaccines and drugs, and the Medical Dictionary for Regulatory Activities (MedDRA) was used to code medical terms from ESAVI reports.

Although DHIS2 is a public and free tool, the costs associated with its implementation and maintenance must be covered, including infrastructure, training, and deployment. It was considered a good option to offer to countries, as it had already been used by PAHO and the World Health Organization (WHO) for other data collection and processing projects.

In fact, this system was promoted by WHO itself for the adoption of different packages configured for streamlined implementation; i.e., as a toolbox that can incorporate almost any type of surveillance and that can be adapted to any country and its particularities.

In order to streamline and adapt the tool to the requirements of ESAVI surveillance, a rigorous business process analysis of ESAVI surveillance was carried out, and functional requirements were established.

To achieve this, a group of support engineers was hired to work in coordination with medical epidemiologists.

The aim was that the regional team, in conjunction with the University of Oslo, would support the countries of the Region in the implementation of projects to adapt the ESAVI module to national systems.

Making this change was a milestone for everyone, including regional and country teams, as it meant changing the way country data were being collected, processed, and shared. In addition to the technological challenge, it was also necessary to overcome some countries’ resistance to sharing data, partly due to the uncertainty
caused by the abundance of fake news during the pandemic. The main concern had to do with reporting information about possible adverse events related to COVID-19 vaccines, which could leak to the media.

In order to overcome this fear, a reasonable amount of time was taken for promotion and information. Approval to share this information rested with the ministries of health in each country of the Region, and work was carried out to address concerns and establish mechanisms aimed at building trust around the collection, security, and objectives of the data provided.

In order to streamline and adapt the tool to the requirements for ESAVI surveillance, a rigorous business process analysis of ESAVI surveillance was carried out, and functional requirements were established.
2.3 The Fast Healthcare Interoperability Resources (FHIR) standard for data transfer

Many countries choose to develop their own systems, and PAHO supports them in addressing their ESAVI surveillance needs. The objective is to ensure that each country’s systems can report data autonomously, which is why the Fast Healthcare Interoperability Resources (FHIR) standard was adopted.

FHIR is based on modern paradigms in the information technology industry, which allow any system to send standardized data to other systems (in this case, the countries to PAHO).

Today, countries transfer their raw databases, and the PAHO team is responsible for analyzing the quality of that information and processing the data to be incorporated into a single database. But getting to this point required a process of coordination, training, and support by the countries so that they could share their data and so that these data could be analyzed and updated.

The information system has a clear objective: it is not only about receiving data, but about being able to diagnose and understand a problem, and strengthen surveillance from the bottom up. Solutions are then offered that make all stakeholders’ work easier.

Training workshops were held on the use of the tools, and a FHIR server was installed at PAHO. A guide was also developed on its use and management so that countries could report their information.

The objectives are to strengthen national information systems by promoting the incorporation of digital tools and the adoption of coding and data exchange standards, and by fostering interoperability with other systems, both internally within each country and with PAHO and the WHO. This will provide robust and collaborative systems to deal with future public health emergencies.
2.4 Teamwork

The benefits of the tool and the training on its use allowed everyone (officials, consultants, and others) to adapt it to different contexts, which was a win-win situation for all.

Since June 2021, 17 countries have begun transferring and sharing their data with the regional ESAVI surveillance system; in April 2023, this number rose to 18.

Although it was an arduous task, with the commitment and dedication of the facilitators and the officials from each country, the databases were consolidated into a system that provides a regional overview.

The regional data model contains 95 variables; migrating countries’ databases to that standardized model takes time. Each variable needs to be thoroughly processed and often discussed with the countries.

In order to have tangible results, sets of variables from the countries needed to be added. Process automation strategies had to be implemented in order to increasingly streamline the entire procedure with each update.

Currently, the regional database has allowed the team to produce two internal reports using 50% of the variables from the regional model. In the meantime, interoperability is growing, processes are becoming more automated, and quality is increasing.
Within the context of the COVID-19 pandemic, PAHO initiated implementation of the regional ESAVI and AESI surveillance system. One of the system’s objectives is to design and implement COVID-19 vaccine safety surveillance through intensified passive surveillance, active sentinel surveillance, and epidemiological studies.

To this end, PAHO began working on forming the regional network of sentinel hospitals as an active surveillance strategy. This was based on the successful experience and lessons learned in more than 10 years of conducting sentinel surveillance on rotavirus, pneumonia and bacterial meningitis, and perinatal health by the Latin American Center of Perinatology, Women and Reproductive Health (CLAP).

This network of hospitals conducts surveillance of severe ESAVIs and also of AESIs, according to the recommendations published in *PAHO’s COVID-19 Vaccines: Safety Surveillance Manual*. The goal is to generate good-quality data (timely, complete, and consistent) on ESAVIs and AESIs that are detected, reported, and analyzed by qualified personnel.
3.1 Selection of hospitals for sentinel surveillance

**Identification of countries meeting the inclusion criteria**
- 18 countries invited
- CLAP hospitals

**Survey application to assess existing capacities in candidate hospitals**
- RedCap platform in three languages: Spanish, English, and Portuguese
- Jan-Jun 2021

**Development of methodology for final classification**
- Four categories

**Evaluation of the questionnaire covering 102 candidates**

**Thirty-seven hospitals; four CLAP hospitals were considered suitable to be part of the sentinel surveillance network**

Note: CLAP: Latin American Center of Perinatology, Women and Reproductive Health

3.2 Inclusion criteria for ESAVI and AESI sentinel surveillance

**COUNTRY**
- Express a political decision and have the human resources available to be part of PAHO’s sentinel surveillance network.
- Have an electronic immunization registry.

**HOSPITAL**
- Participate in the integrated surveillance of severe acute respiratory infections (SARIs) and COVID-19;
- Have unique identification numbers in health care records;
- Have a laboratory, equipment for diagnostic imaging and at least the following medical specialties: pediatrics, general medicine, gynecology and obstetrics, cardiology, and neurology.
3.3 Objectives and benefits of sentinel surveillance

**OBJECTIVES**

- The primary purpose of passive ESAVI surveillance is to identify and respond to events that are temporally associated with immunization.
- In addition, AESI surveillance focuses on the investigation of specific events, regardless of vaccination.
- Assessments are then performed to determine whether the event occurs more frequently in vaccinated individuals than in unvaccinated individuals, and vaccinated cohorts are monitored and their health status is assessed.

**BENEFITS**

- Provides relevant, real-time, and descriptive information of the events observed, compared with the expected events, which may be useful in a risk-benefit assessment of the safety of the use of these vaccines;
- Enables detection, investigation, and analysis of evidence (clinical and epidemiological) of ESAVIs to facilitate the work of the national or subnational vaccine/vaccination safety committees, enabling the causality assessment and final classification of ESAVIs following COVID-19 vaccination;
- Serves as a reference for other health facilities of lower technological complexity (by using higher technologies such as computerized tomography [CT SCAN], electromyography, and other technologies available to study cases);
- Assists ministries of health in conducting controlled studies that make it possible to infer causality of ESAVIs with the vaccine or vaccination, or to indicate a lack of evidence.

The selected sentinel hospitals report to the subnational and national levels, following the information flow established in each country. Data transfer at the regional level is carried out in accordance with the standards agreed on between PAHO and each country.
3.4 ESAVI and AESI active surveillance cycle in sentinel hospitals

- **Detect serious or non-serious special AESIs or ESAVIs**
- **AESI**: Complete the PAHO notification form
- **ESAVI**: Complete the notification form
- **Initiate investigation of the ESAVI. Include additional test in accordance with the case definition**
- **Complete the AESI notification form with discharge diagnosis and progress**
- **Complete the AESI notification form with discharge diagnosis and progress**
- **Weekly data analysis and feedback of information at all relevant levels**
- **Notify the higher surveillance level of serious ESAVIs within 48 hours and non-serious ESAVIs within seven days**
- **If the case poses a high risk to public health, the higher level should be notified immediately**

**Note:** ESAVI: event supposedly attributable to vaccination or immunization; AESI: adverse event of special interest.
PAHO also recommended conducting and intensifying active sentinel surveillance of ESAVIs occurring in pregnant women who are vaccinated against COVID-19.

3.5 Nine countries currently in the network

As part of the sentinel surveillance implementation process, and with the commitment of national authorities and hospitals, support has been provided in different activities:

- Set-up and outfitting of situation rooms in sentinel hospitals;
- Adaptation of the regional protocol for sentinel surveillance;
- Development of procedure manuals;
- Training on the surveillance cycle for ESAVIs and AESIs;
- Technical support (epidemiological/information systems);
- Formation of ESAVI hospital surveillance committees.

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9 countries
23 hospitals
3.6 Sentinel Network Hospitals

**BRAZIL**
- Clinical Hospital at the USP Faculty of Medicine
- São José do Rio Preto Regional Faculty of Medicine Foundation
- Clinics Hospital at the Ribeirão Preto Faculty of Medicine
- Porto Alegre Clinical Hospital
- Professor Júlio Müller University Hospital
- Professor Edgard Santos University Hospital

**ARGENTINA**
- HIGA San Martín Hospital
- Durand Hospital
- SAMIC Hospital, Eldorado
- Castro Rendón Hospital
- Lagomaggiore Hospital

**PERU**
- National Maternal Perinatal Institute
- Dos de Mayo National Hospital
- Pediatric Emergency Hospital
- Goyeneche Hospital

**HONDURAS**
- University Teaching Hospital
- San Felipe Hospital

**GUATEMALA**
- Western Regional Hospital
- Cuiapa Regional Hospital

**PARAGUAY**
- La Costa Hospital
- Central Hospital at the Dr. Emilio Cubas Social Security Institute

**PLURINATIONAL STATE OF BOLIVIA**
- Maternity and Children's Hospital
- obrero Hospital

**DOMINICAN REPUBLIC**
- Hospital San Lorenzo de Los Mina

**ECUADOR**
- Enrique Garcés General Hospital
CHAPTER 4

ACHIEVEMENTS IN COOPERATION AND CHALLENGES TO THE SYSTEM

With the financial resources mobilized during the COVID-19 pandemic, PAHO was able to finance the implementation of the regional ESAVI surveillance system and support countries to build their national surveillance capacities.

The process has made progress and there have been achievements in different countries, each with its own dynamics. This has also led to significant challenges for the system.

Different stages were required to work together with each country. This included initial diagnosis of the status of data collection and processing, subregional and national training, characterization of each country, and its consent for the implementation of more streamlined tools and data transfer. This all represents a significant achievement within the objectives of integrating information, analyzing it, and having real-time data available, as well as a major challenge for the future development of the entire system.

Since the process began in June 2021, 18 countries have begun transferring data. This has not been an easy task, given the work overload in the ministries of health due to the COVID-19 pandemic, the training of teams, and coordination of work with PAHO and other institutions, this exercise has resulted in progress, a diagnosis of difficulties, and analysis of solutions.

For example, in the first stage, more than 90 data variables were analyzed, leading to an arduous process requiring epidemiological validation; it also meant that the associated technological challenges needed to be overcome.

For this reason, when almost a year of work had elapsed with no tangible results (2021–2022), some adjustments needed to be made.

A decision was made to include only the 10 most easily identifiable variables, so that countries that were already submitting data would be able to do this in the simplest way possible. Ten more variables were later incorporated, with an increasing degree of complexity.

National institutions were then encouraged to join forces and increase their national commitment to data transfer and analysis.

This made the progress more evident and the task more homogeneous for the countries that shared their data.

Another major achievement was the reduction in data transmission time: initially this was taking three to four months, but with the transition from manual to digital transfer this period was reduced to between three and four hours.

Despite the difficulty and complexity of developing a new ESAVI information system, this was accomplished in record time. This is also a unique system, used only by the countries of the Region of the Americas, which seeks to produce scientific evidence with timely, integrated, and automated data.

The objective is for the data not to remain isolated, and for the work to strengthen national surveillance with processes that have been evaluated using mature indicators and relying on robust regional cooperation.
### 4.1 Country-PAHO joint activities

**1. Antigua and Barbuda**
- Participation in national ESAVI surveillance training;
- Interest in the implementation of DHIS2.

**2. Argentina**
- Joins the regional ESAVI and AESI sentinel surveillance network with five sentinel hospitals;
- Support for the implementation of the regional protocol for sentinel surveillance;
- Project for updating the electronic reporting form, with incorporation of standards.

**3. Barbados**
- First face-to-face training during the pandemic; national workshop with more than 60 participants;
- Project for the development of a national ESAVI surveillance manual and system consolidation.

**4. Brazil**
- Data transfer at the regional level through an application programming interface;
- Support for the improvement of scripts for local data analysis;
- First draft data quality report;
- Active surveillance operating with six hospitals.

**5. Chile**
- Support for the management of standards licenses for incorporation into information systems;
- Formulation of projects for strengthening data management and automation;
- Development of a standardized operating procedure for data validation;
- First data quality report.
- Plan for risk communication activities.

**6. Colombia**
- Support for the management of standards licenses for incorporation into information systems (WHODrug and MedDRA);
- First data quality report, also shared with the Uppsala Monitoring Centre;
- Formulation of projects to strengthen data management, automation, and national and regional interoperability;
- Support in the formation and training of the National Advisory Committee for the Classification of ESAVI Cases (Vaccine Safety Committee);
- Publication of the synthesis of evidence related to some adverse events following COVID-19 vaccination.

**7. Costa Rica**
- Development of a digital tool to reduce manual workload;
- Exchange of experiences with other countries on the operation of the national vaccine safety committee.

**8. Dominican Republic**
- San Lorenzo de Los Mina Hospital began the sentinel surveillance;
- Continuous training plan on the cycle for the sentinel surveillance hospital;
- Consent to visit the sentinel surveillance hospital.

**9. Ecuador**
- Participation in a national ESAVI surveillance training;
- Support in the formation of the ESAVI Case Classification Committee;
- Training at the subnational level and for the subnational Case Classification Committee (Vaccine/Vaccination Safety Committee);
- Support for the management of standards licenses for incorporation into information systems (WHODrug and MedDRA);
- Formulation of projects to strengthen data management, automation, and national and regional interoperability;
- First data quality report, also released by the Uppsala Monitoring Centre;
- Support in the development of the national protocol for passive and active ESAVI surveillance.

**10. El Salvador**
- Subnational training in ESAVI surveillance;
- Start of discussions on modification of the ESAVI surveillance form in NotiFACEDRA;
- Start of the project for the creation of the National Vaccine/Vaccination Safety Committee.
11. GUATEMALA
- Strengthening and training of the Committee for the Evaluation of Serious Adverse Reactions to Vaccination;
- Implementation of the sentinel surveillance protocol in two hospitals in the country;
- Incorporation of most of the key variables in the national file;
- Support for cooperation processes already established by the national body;
- Implementation of sentinel surveillance forms in the national information system.

12. GUYANA
- ESAVI data transfer;
- Preparation and willingness to participate in ESAVI surveillance training;
- Project for the development of a national manual and of a proposal for the design of digital tools for ESAVI surveillance.

13. HONDURAS
- Joins the regional ESAVI passive surveillance system;
- Continuous training plan on the surveillance cycle for 38 health personnel responsible for subnational and national drug safety monitoring;
- Support in the development of ESAVI and AESI surveillance flowcharts for each of the sentinel hospitals;
- Implementation plan for the ESAVI module in DHIS2;
- Management support for the incorporation of coding standards (WHODrug and MedDRA) into the national authority’s ESAVI and AESI module.
14. JAMAICA
• Agreement to implement DHIS2 as a digital tool to strengthen national ESAVI surveillance.

15. MEXICO
• Participation in subregional ESAVI surveillance workshops;
• Participation in a statistics course, using STATA software;
• Invitation to participate as observers in the National Committee of Experts.

16. NICARAGUA
• Capacity building on national and municipal ESAVI and AESI surveillance for the 38 local comprehensive health care systems;
• Adaptation and development of a virtual educational strategy on regional resources, for health professionals.

17. PARAGUAY
• Joins the regional ESAVI passive surveillance system;
• Continuous training plan for the two sentinel hospitals and the Vaccine/Vaccination Safety Committee;
• Support in the implementation of sentinel surveillance with two procedure manuals, with 80% progress and development of flowcharts;
• Participation of sentinel hospitals from the 18 health regions and the National Immunization Program in the validation of the ESAVI module in DHIS2.
• First report on vaccine/vaccination safety.

18. PERU
• Support for the management of standards licenses for incorporation into information systems (WHODrug and MedDRA);
• Formulation of projects to strengthen data management, automation, and national and regional interoperability;
• First data quality report;
• Peru joins the regional ESAVI passive surveillance system, and four sentinel hospitals join the regional network.

19. PLURINATIONAL STATE OF BOLIVIA
• Support for the development of procedure manuals for ESAVI and AESI sentinel surveillance;
• Joins the regional system for vaccine/vaccination safety, with passive surveillance data submitted starting in October 2021;
• Consent from national authorities to implement the sentinel instance of the DHIS2 tool;
• Training on the use of DHIS2 for surveillance teams from sentinel units at the subnational level, and with national authorities;
• Consent from the country to conduct an on-site monitoring visit for the passive surveillance system and training of the Vaccine/Vaccination Safety Committee.

20. SAINT KITTS AND NEVIS
• ESAVI data transferred to PAHO;
• Start of the project for the development of a national ESAVI surveillance manual.

21. SURINAME
• Agreement to strengthen the national ESAVI surveillance system;
• Adaptation of the regional data model to the national ESAVI database;
• Agreement to implement the DHIS2 digital tool.

22. TRINIDAD AND TOBAGO
• Agreement to strengthen the national ESAVI surveillance system;
• Training of key stakeholders involved in ESAVI surveillance;
• Adaptation of the regional data model to the national digital tool;
• Consent to collaborate on the development of a digital investigation form.

23. URUGUAY
• Authorization for the publication of ESAVI surveillance data.
# Achievements of Technical Cooperation Between PAHO and Countries

## Regional Survey
October 2020 to January 2021

- **92.9%** Personnel available for ESAVI surveillance activities
- **85.7%** Ongoing notification, investigation, and analysis of cases
- **71.4%** ESAVI guide or manual available from the national level
- **64.3%** National standard or set of rules defining how ESAVI surveillance work
- **38.1%** Periodic vaccine safety event reports
- **35.7%** Risk communication plans for vaccine safety events
- **26.8%** Availability of ESAVI national Vaccine/Vaccination Safety Committee
- **14.3%** Active surveillance activities

## Achievements
April 2021 to October 2022

- Overall increase in engagement in ESAVI surveillance activities
- Support in the recruitment of temporary support staff in nine countries
- Training
- Enhancement of surveillance activities
- Advice on specific cases and data management support
- Training
- Updating of Latin American countries' national manuals and advocacy for change
- Development of a national manual in two countries
- Guidance on policy needs to ensure sustainability
- Support in quality management and data analysis
- Delivery of key variables and indicators
- Recruitment of support for risk communication (one country)
- Training and development of materials
- Exchange of experiences and technical guidance on how the committee should work
- Causality assessment training
- Creation of the ESAVI and AESI active surveillance system
- Training and support for the sentinel network and national authorities

Note: ESAVI: event supposedly attributable to vaccination or immunization; AESI: adverse event of special interest.