Methodology for the International Evaluation of the Expanded Program on Immunization



REGIONAL OFFICE FOR THE Americas

METHODOLOGY FOR THE INTERNATIONAL EVALUATION OF THE EXPANDED PROGRAM ON IMMUNIZATION



Comprehensive Family Immunization Unit (IM) Family, Gender and Life Course Department

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This methodology and its instruments should be implemented under the permanent guidance of the Pan American Health Organization. It should be supervised by a group of immunization experts. This methodology is exclusively for evaluating the Immunization Program.

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ACRONYMS

AFP Acute flaccid paralysis

BCG Bacillus of Calmette and Guérin-vaccine against severe forms of tuberculosis

CDC Centers for Disease Control and Prevention (United States)

DPT Diphtheria-pertussis-tetanus vaccine (whole cell pertussis, wP)

DQS Data quality self-assessment

EPI Expanded Program on Immunization

ESAVI Events supposedly attributable to vaccination or immunization

GTZ German Development Service (German acronym GTZ)

Hib Haemophilus influenzae type bID Intradermal injection

IDB Inter-American Development Bank

IgG Immunoglobulin G
ILI Influenza-like illness
IM Intramuscular injection

IMCI Integrated Management of Childhood Illness

JICA Japanese International Cooperation Agency

MDG Millennium Development Goals
MDI Municipal development index
MERCOSUR Southern Common Market

MMR Measles, mumps and rubella vaccine

MR Measles and rubella vaccine
NGO Non-governmental organizations

NNT Neonatal tetanus

OPV Oral vaccine against polio
ORAS Andean Health Agency

PAHO Pan American Health Organization

PCR Polymerase chain reaction

RESSCAD Special Meeting of the Health Sector of Central America and Dominican Republic

RF Revolving Fund

SARI Severe acute respiratory infections

SC Subcutaneous injection

TAG Technical Advisory Group on Vaccine-preventable Diseases
Td Tetanus and diphtheria vaccine (for people >=7 years)

UNASUR Union of South American Nations
UNDP United Nations Development Program

UNICEF United Nations Children's Fund

USAID United States Agency for International Development

VPD Vaccine-preventable diseases

VWA Vaccination Week in the Americas

WB World Bank

WHO World Health Organization

INTRODUCTION

Since its creation in 1977, and in accordance with the global vision and strategy of the World Health Organization (WHO), the Expanded Program on Immunization (EPI) in the Americas continues to make valuable contributions to reducing infant morbidity and mortality and exemplifies organization, commitment, solidarity, equity, and quality.

Due to the coverage levels attained by the EPI, the Region of the Americas has been free of wild poliovirus cases since 1991, has had no cases of indigenous measles since 2002, and has not reported a single case of endemic rubella since 2009. The EPI has also contributed to the control of diseases such as diphtheria, yellow fever, severe childhood tuberculosis, hepatitis B, invasive infections by Haemophilus influenzae type b (Hib), and pertussis (whooping cough).

While laudable progress has been made in the field of immunization in the Americas, new strategies must be adopted to preserve the achievements made, address the unfinished agenda, and confront new challenges, in order to contribute to the achievement of the Millennium Development Goals (MDGs).

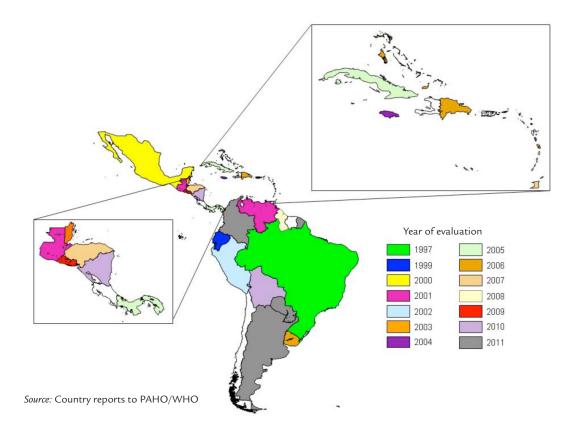
In this context, the methodology for the evaluation of the EPI is an instrument for technical cooperation that can be used to monitor the progress programs have made, as well as to assess their level of development and technical and financial capabilities. The evaluation also serves as a managerial tool for strengthening the EPI during the transition from child vaccination to family vaccination.

1. **BACKGROUND**

International evaluations of the EPI (previously known as "external evaluations") have been conducted in the Americas since the 1980s, under the coordination and technical guidance of what is now the Comprehensive Family Immunization Unit of the Pan American Health Organization/ World Health Organization (PAHO/WHO).

While the evaluations focused specifically on the epidemiological surveillance system for measles in the 1990s, they were later expanded to cover all components of the EPI. A map of the region showing all of the evaluations carried out in the past 14 years is provided in Figure 1.

FIGURE 1. YEAR OF THE LATEST EPI EVALUATION, LATIN AMERICA AND THE CARIBBEAN, 1997-2011



An exhaustive review of the evaluation's methodology was carried out in 2007 and in 2010 in order to incorporate new components, taking into account past experiences, lessons learned, new challenges such as the introduction of new vaccines and technologies, underutilized vaccines, and new donor requirements.

2. DEFINITION

The evaluation is a set of procedures based on qualitative and quantitative methods that is implemented periodically to analyze the evolution of a national EPI and to obtain information regarding the fulfillment of its objectives, activities, costs, results, and impact. The evaluation results are used to maintain, correct, or modify program activities.

The following bullets summarize the main characteristics of the evaluation:

- It is a value judgment on the part of a team of EPI experts, rather than just a set of measurements. This value judgment is supported by the use of the methodology.
- It is integrative: Its inter-programmatic approach takes into account the transition from child immunization to family immunization.
- It is multidisciplinary: It requires the involvement of various health professionals from other participating institutions and agencies, including general practitioners, public health professionals, pediatricians, epidemiologists, nurses, microbiologists, nutritionists, community health workers, statisticians, educators, and administrators.
- It is participatory: International organizations such as PAHO, the United Nations Children's Fund (UNICEF), the Centers for Disease Control and Prevention (CDC), and the World Bank (WB), as well as national institutions, including non-governmental organizations (NGOs), are involved in implementing the evaluation.
- It utilizes teamwork: The final product is the result of the application of the evaluation instruments and joint analysis by the evaluators.

3. PURPOSE

The purpose of the evaluation is to scrutinize the EPI in the context of the health system and its broader setting. The evaluation looks at the program's strengths and weaknesses, the efficiency and effectiveness of its activities, and its impact on disease. It also assesses the program's capacity to adapt to new demands, both those generated from health sector reform and decentralization, as well as those arising in response to the population's need for access to new vaccines and technology.

4. OBJECTIVES

- 1. To characterize the degree of development of the program, including its achievements, and compare the progress made since the previous evaluation.
- 2. To become acquainted with the lines and mechanisms for program financing and sustainability.
- To describe managerial and administrative capabilities at the national, subnational (region, state, province, department or their equivalent) and local (municipal, district or its equivalent) levels.
- 4. To evaluate the program's information system and data quality at all levels.

- 5. To evaluate the epidemiological surveillance system, that is, its capacity for the timely detection and control of the circulation of measles and rubella viruses and for the surveillance of flaccid paralyses and vaccine-preventable diseases, including those prevented by new vaccines.
- 6. To evaluate the cold chain and its capacity to accommodate the introduction of new vaccines, as well as the logistical aspects of moving vaccines and supplies.
- 7. To evaluate safe vaccination practices with an emphasis on the quality of vaccines and syringes, the monitoring of events supposedly attributable to vaccination or immunization (ESAVI), and biosafety in the handling and final disposal of used syringes and vials.
- 8. To find out about mass communications activities and the degree of user satisfaction.
- 9. To characterize the program's integration into the health services system and within the family and community health approach.
- 10. To detect problems and provide recommendations regarding the actions necessary to address them, taking into consideration the national context, and the specific needs of the country.
- 11. To draft a five-year/multi-year plan of action, identifying feasible, relevant activities for the efficient management of the EPI.

5. CHARACTERISTICS

The following are critical elements needed for the success of an international EPI evaluation.

5.1 Political will

The country, through its Ministry of Health, officially notifies the PAHO/WHO Representation of its interest in carrying out the evaluation, given that an evaluation requires commitment from a high level in order to provide the technical and logistical support for the evaluation process; political will is also required for decision-making and implementation of the recommendations coming out of an evaluation.

5.2 Type of evaluation

The evaluation is both qualitative and quantitative and can therefore assess the EPI's processes, results and impact.

5.3 Evaluation team and responsibilities

PAHO/WHO will form an external evaluation group comprising international experts in the field of immunizations. This group will be comprised in each country by civil servants from different levels and by representatives of cooperation agencies, NGOs, and bilateral entities working with the EPI. The number of national and international officials required will depend on the size and specific needs of each country, keeping in mind that one member of the evaluation team will have to be assigned exclusively to data quality assessment.

PAHO/WHO is responsible for assisting with technical and logistical coordination of the evaluation, working in conjunction with the team from the Ministry of Health. PAHO/WHO will also mobilize the team of international evaluators, share experiences from other countries, and provide the materials and methodologies that will be used in carrying out the evaluation. PAHO/WHO is also responsible for presenting the findings to the national authorities, proposing

recommendations, and helping to draft the five-year/multi-year plan of action with feasible,

The international evaluation team is responsible for reviewing the documentation on the health system of the evaluated country, for the analysis of the health situation, the national EPI standards, and the previous evaluation reports, and for tailoring the methodology to the particular context of the evaluated country.

The evaluated country coordinates the organizational and logistical aspects of the evaluation, with PAHO's support. It also makes available all relevant technical documentation and information on the health system and the EPI, as well as the most recent EPI plan of action, including an estimate of the unit cost of each activity included in the plan. Finally, the EPI coordinates the drafting and implementation of the five-year/multi-year plan of action.

The focal point for the country evaluation in PAHO's regional headquarters office and the focal point for immunization in the PAHO/WHO Representation in the country evaluated will coordinate the process of drafting the final report and presenting the results to the relevant authorities.

6. METHODOLOGY

relevant activities and a budget.

The multidisciplinary EPI evaluation is designed to assess the current conditions that are influencing the efficient achievement of the program's objectives. It also aims to identify social and public health trends that should be taken into account in the short and medium terms to ensure the success of the EPI.

Since the mid-2000s, the methodology has included elements for an in-depth evaluation of the quality of information systems of immunization programs, based on the WHO Data Quality Self-Assessment (DQS). Just as with other aspects of this methodology, the DQS tools should be adapted to the national context of the immunization program, the scope considered desirable and feasible, and the information flow established in the country.

The methodology is flexible and can be tailored to the conditions in each country where it is applied. This should be done taking into account existing social and health policy, the model of healthcare, and the way in which the EPI is coordinated and integrated within that model, in order to articulate recommendations that help strengthen the EPI. The proposed methodology is described in detail below.

6.1 SCOPE

The evaluation will be carried out at every political and administrative level of the evaluated country: national, subnational, and local. At each level, interviews should be conducted in the health sector and with cooperation agencies, subnational and local governments, organized civil society, and users.

6.2 METHODS AND INFORMATION COLLECTION INSTRUMENTS

Data should be collected at the national, subnational and local levels using the following methods:

- Review of existing technical and legal documents; some of these are listed in Annex 1.
- Review and analysis of relevant data at the national level, such as vaccination coverage, surveillance indicators for vaccine-preventable diseases (VPD), and maternal and child mortality indicators, among others.
- Structured interviews using guides and/or instruments designed for key EPI actors at the political, managerial and operational levels of the program, as well as for cooperation agencies, NGOs, etc. A list of institutions and individuals at each level should be created to organize these interviews (Annex 2).
- Surveys with closed questions to elicit quantitative information on user satisfaction with immunization services.
- Forms to review the concordance of the immunization data generated and reported and whether this data is reported in a complete and timely manner, including questions designed to evaluate the monitoring system.
- Specific forms to evaluate the sensitivity and performance of the VPD surveillance system.
- Direct observation during health facility visits; the results of these observations will supplement the final results and recommendations.

The following specific instruments will be used for data collection (Annex 3).

- Interview guide for the political level, specifically for decision-makers; it takes approximately
 one hour to apply.
- Interview guide for the managerial level, designed for EPI managers and coordinators at the national, subnational, and local levels; it takes approximately two hours to apply.
- Interview guide for other (non-EPI) managers; it takes approximately 45 minutes.
- Interview guide for the operational level, designed for health workers providing immunization services; it takes approximately two hours.
- Interview guide for laboratories, designed for laboratory directors; it takes approximately two hours.
- Interview guide for the National Technical Advisory Committee on Immunization, the national regulatory authority, international cooperation agencies, NGOs, funders, and other institutions; it takes approximately 30 minutes.
- Forms for sentinel surveillance of VPDs related to new vaccines
- Forms for active institutional searches of suspected cases of certain VPDs.
- Forms for data concordance and complete and timely reporting.
- Interview guide to evaluate the quality of the monitoring system, specifically for the person in charge of vaccination data.

Interview guide for users of immunization services; it takes about 15 minutes to apply.
 Because of the type of sampling, this activity is intended to be informative, rather than purporting to offer a representative and exhaustive portrayal of users' perceptions at the national level.

Note: The instruments for use at the management, operational, and user levels include evaluation criteria articulated as questions that are meant to be answered through evaluator observations rather than directly asked of the interviewee. The table below offers examples of evaluation criteria that should be observed rather than asked. This saves time when applying the instrument.

	Evaluation criteria
Observe	1. Is the refrigerator correctly installed (15 to 20 cm from the wall, level, with nothing beside or on top of it, and shielded from the sun)?
Observe	Does the refrigerator contain anything other than EPI vaccines?

6.3 SITE VISIT SELECTION CRITERIA AND PROCEDURES

The steps for selecting site visit locations are described below. They may be modified or adapted as the evaluated country deems necessary.

Step 1

Site visit locations are chosen taking into account the different levels of complexity and operation of the EPI, as well as the social and economic development of the regions, states, or provinces, depending on the country's geopolitical divisions.

Step 2

In order to select which regions, states, or provinces will be evaluated, a description of their municipalities or districts must be undertaken, taking into account factors such as risk, equity, and vulnerability. Other useful criteria include the EPI Tables that each country completes and submits annually to PAHO.

In order to achieve the recommended stratification, it is necessary to establish selection criteria based on the available information, assigning priority to criteria inherent to the EPI and the VPD epidemiological surveillance system. For example:

- EPI performance indicators, such as coverage of the third dose of diphtheria, whooping cough and tetanus-containing vaccine (DPT3/pentavalent3) and the measles, mumps, and rubella (MMR) vaccine
- VPD surveillance system indicators, such as the reporting rate for diseases in process of elimination (poliomyelitis, measles and rubella)
- The presence of VPD cases or outbreaks

- 8
- Social indicators such as unmet basic needs, human development index, etc.
- Geographical access, population density, strong presence of tourists and foreigners, existence of indigenous groups, etc., which are taken into account in the final selection.

Step 3

After the municipalities or districts have been characterized, each criterion is subdivided into categories and points are assigned to each, based on their importance for the EPI (more points are assigned to the worst category). A table is created listing the criteria in order of importance (most to least) for subsequent stratification of the municipalities. The scoring is arbitrary and may vary from country to country based on the adaptations or modifications that each deems appropriate. See Table 1 for an example.

TABLE 1. CRITERIA AND CATEGORIES FOR CLASSIFICATION OF MUNICIPALITIES

No.	Criterion	Category	Score
		Average 95% and over for the last 2 years.	0
1	Coverage of DPT3/pentavalent3 vaccine less than 95% in children less than 1 year of age	Average 80% to 94% for the past 2 years	10
		Average under 80% for the past 2 years	15
		Average 95% and over for the past 2 years	0
2	Coverage of MMR vaccine less than 95% in children aged 1 year.	Average 80% to 94% for the past 2 years	10
		Average under 80% for the past 2 years	15
	Percentage of the population less than 1 year of age that live in municipalities with DPT3/pentavalent3 coverage less than 95% (among children less than 1 year of age).	Over 15% in the past year	0
3		6% to 15% in the past year	10
		5% or lower in the past year	15
4	Epidemiological silence in measles/	Zero suspected cases reported in the past year	15
4	rubella surveillance.	Minimum of one suspected case reported in the past year	0
5	Presence of cases or outbreaks of	Presence of cases or outbreaks	15
5	vaccine-preventable diseases.	Absence of cases or outbreaks	0

(Continued)

TABLE 1. (CONTINUED)

No.	Criterion	Category	Score
6	Municipality with disadvantaged urban population groups, tourism or border areas, or high levels of human migration.	Has border or tourism municipalities or internal migration	5
0		Does not have municipalities with any of these characteristics	0
7	Existence of indigenous groups.	Yes	5
/		No	0
8	Urban or rural area, according to the national statistics institute or its equivalent in each country.	Urban	0
0		Rural	5
9	Unmet basic needs (the strata are defined based on the criteria used in	The municipality falls into the poorest stratum	5
9	each country).	The municipality falls into the least poor stratum.	0

After each municipality has been scored, they are grouped into one of three categories: low, medium, and high risk. The categories can be differentiated by color, such as a traffic light, to facilitate interpretation of the results. The color code is shown in the table below.

TABLE 2. CLASSIFICATION OF MUNICIPALITIES ACCORDING TO THEIR SCORE FOR EACH CRITERION

Total score	Selection category	Risk	Color assignment
More than 50 points	1	High	Red
Between 30 and 50 points	2	Medium	Yellow
Less than 30 points	3	Low	Green

Once the municipalities have been grouped into these three categories, the ones that will be evaluated can be selected taking into account other important logistical factors such as distance and the availability of transportation and human resources. Selecting municipalities with high, medium, and low ratings is recommended.

After selecting the municipalities that will be visited, the next step is to select the health facilities, taking into account the following criteria:

- 1. Each facility's level of complexity
- 2. Each facility's coverage area
- 3. Who provides the health services, i.e., private or public facilities, insurance companies, NGOs, and so forth

- 4. Geographical access and availability of transportation.
- 5. Facilities experiencing difficulties providing immunization services
- 6. Facilities that have adopted innovative immunization delivery strategies

6.4 EVALUATION COMPONENTS

The evaluation includes the following components:

Political priority assigned to the program and legal framework

- What level of political priority is assigned to the program?
- Is the national EPI mentioned spontaneously as one of the country's priorities?
- Is it easily identifiable as a priority and backed with resources?
- Are laws or decrees in place to support vaccination as a public good?
- Are laws or decrees in place to ensure national budget resource allocations?

Planning and programming

- Is there an annual and a five-year/multi-year plan of action?
- To what degree are they evaluated and carried out?
- Are targets, goals, and priorities clearly articulated?
- Are there plans for the introduction of new vaccines?
- How have decisions been made about the introduction of new vaccines?
- · Are the population data reliable?

Organization and coordination

- Where is the EPI situated within the Ministry of Health (Ministry organigram)?
- What is the EPI's structure (EPI organigram)?
- Is this structure conducive to meeting the targets and goals?
- Are activities coordinated with the laboratory(ies) and other health care programs? Are they
 adequate?
- · Are coordination mechanisms in place with the national regulatory authority?
- Are coordination mechanisms in place with agencies, with other institutions or sectors, or with professional associations?
- Is there a national advisory committee on immunization?

Implementation

- What immunization strategies and tactics are employed?
- What types of campaigns have been scheduled for this and the coming years?

- Are there specific interventions for municipalities with coverage levels less than 95%?
- What promotion and prevention activities are carried out in an integrated manner with the immunization program?

Human, management, and financial resources

- Does the EPI have an adequate technical team at the central level and throughout the country?
- Does it have adequate logistical and management resources (vaccines, syringes, transportation, communication, laboratory resources, etc.)?
- Is the program costed?
- Does the EPI have a specific, exclusive and adequate budget?
- Is a mechanism in place for the procurement of vaccines and supplies?
- Was there any shortage of the DPT vaccine the previous year?

Training and supervision

- Are technical standards, instruments, and a training plan in place?
- Are there instruments and a plan for supervision?
- Have biosafety standards been established for handling and disposal of used syringes and vials?

Information system

- Is up-to-date information available on coverage and the incidence of vaccine-preventable diseases?
- Is a risk analysis carried out for each municipality or community?
- Are there risk maps for areas with coverage levels below 95%?
- · Has the quality of the data or information system been evaluated?

Epidemiological surveillance and laboratory

- Are technical standards in place?
- Is the weekly reporting network adequate?
- Are surveillance indicators for measles, rubella and Acute Flaccid Paralysis (AFP) complied with?
- Are surveillance subsystems in place for diseases prevented by new vaccines?
- Is a surveillance system in place for ESAVI?
- Is there follow-up on sentinel surveillance of new vaccines?
- Have areas of risk and epidemic potential been identified?
- Is there up-to-date information on cases and their laboratory results?

Cold chain

- Is there an up-to-date inventory?
- Does current capacity allow for the introduction of new vaccines?
- Is there an equipment maintenance and replacement plan?
- Are resources allocated for this?

Evaluation and research

- Have periodic national evaluations been conducted?
- Have they been used to inform decision-making?
- Have operational studies been carried out? On what? When?
- Have studies been carried out on the burden of disease, cost-effectiveness, and the impact of the introduction of new vaccines?

Social communication, social mobilization, and user satisfaction

- Is there a social communications plan?
- Is it financed?
- Is the routine program widely publicized?
- Are there community networks that support the EPI?
- Is there support for the EPI on the part of the private sector, social groups, or the community?
- Is user satisfaction evaluated periodically?

Vaccine safety

- Is a surveillance system in place for ESAVI?
- Is feedback given at the local level on the findings of investigations into ESAVIs reported to the national level?
- Is there a committee for the review and classification of ESAVI?
- Is there a crisis prevention and management plan?

When drafting their five-year/multi-annual plan of action, the countries may group these components or address them separately depending on their needs.

7. **EVALUATION STAGES**

The international evaluation lasts two weeks and is implemented in the stages outlined below:

ORGANIZATION OF THE EVALUATION

If the evaluation is to be successful, it is important to begin preparing for it four to six weeks in advance. The organization process occurs at two levels: a) organization of technical aspects and b) organization of logistical issues.

a) Technical aspects

It falls to the Ministry of Health to coordinate the technical aspects of the evaluation, and PAHO is available to assist with this. The national EPI manager, the focal point for immunization in the PAHO/WHO Representative Office in the country to be evaluated, and the focal point for the country evaluation in PAHO's regional office should jointly oversee the coordination of this area.

Technical coordination includes the following activities, each of which involves specific tasks.

Organizing the evaluation team

The evaluation team will include international and national experts on immunization. The Ministry of Health of the country to be evaluated should put together a team comprising technical personnel with expertise in maternal and child health, primary health care, epidemiological surveillance, laboratory services, etc. from the various divisions and levels of care in the country and from other entities such as international cooperation agencies and non-governmental organizations. The number of technical personnel on the evaluation team will depend on the size and complexity of the country and of the geographical areas to be visited. National team members should be assigned to the evaluation full-time for as long as it lasts.

The international team will be made up of technical personnel from PAHO's representative office in the country to be evaluated and from its regional office, as well as experts on immunization, epidemiological surveillance and laboratory services from other countries. In order to strike a balance between the national and international team members, the latter should be limited to 5 to 7 people depending on the number of geographical areas to be visited. As mentioned earlier, one team member should be assigned to work exclusively on the data quality component.

Adapting the methodology

PAHO provides each country to be evaluated with a standard, flexible methodology, along with a set of instruments (guides, forms, checklists) that can be adapted or tailored to each country's needs.

Questions may be added to or eliminated from any of these instruments based on the health priorities and needs that have been identified. The EPI team is responsible for doing this. Ideally, a pilot should be conducted to field test the changes made to the methodology. The pilot should be carried out in a geographical area that will not be selected for the international evaluation.

The criteria for selecting site visit locations and the minimum numbers of management, operational and user interviews should be determined in conjunction with the EPI. Once the methodology has been adapted, it should be submitted to the EPI national evaluation team for review. The adapted instruments should be forwarded in advance (one to two weeks before the evaluation is scheduled to begin) to the international and national evaluators so that they can familiarize themselves with the materials.

Organizing and preparing the information before commencing the field work

A health situation assessment of the country to be evaluated must be drafted, including a baseline of the EPI's situation in the past five to ten years. This information will be presented at the first plenary meeting and an executive summary of the documentation will be distributed to each member of the evaluation team. The EPI baseline will be included in the evaluation's final report. Annex 4 offers a proposal of the information to include in the baseline and Annex 1 has a list of documents and information that should be reviewed and available during the course of the evaluation.

It is recommendable to hire a consultant to organize and prepare the information for the baseline, as long as the country to be evaluated so requests.

b) Logistical issues

Just as with technical coordination, the EPI and the PAHO office in the country to be evaluated are jointly responsible for logistical coordination. Setting up the logistics for the evaluation is among the more time-consuming activities and requires close coordination with other areas. Therefore, this process should ideally begin four to six weeks in advance of the evaluation. It is also important to assign responsibilities to each member of the teams from the PAHO/WHO Representative Office of the country to be evaluated and from the national EPI.

The following is a basic list of the material and human resources required for the evaluation.

- Materials and supplies
 - ✓ The following office supplies should be available for the field work and for each member of the evaluation team: briefcases, files, separators, USB drives, pencils, erasers, pens, notebooks, portfolios, stationery, bags, and manila envelopes for questionnaires, staplers, staples, clips, and identification badges.
 - ✓ Copies of all evaluation questionnaires; the number will depend on the number of evaluation teams and areas to be visited.
 - ✓ Vehicles and fuel for the evaluation team's transportation in the capital of the country
 to be evaluated and for travel to the locations selected for the site visits.
 - ✓ Cell phones with a cash balance for every international member of the evaluation team and a list of useful telephone numbers, including those of the evaluation team members and for use in case of emergency.
 - ✓ Hotel rooms in the capital for the international members of the evaluation team.
 - ✓ Hotel rooms for all members of the evaluation team in cities and towns outside the capital where the evaluation will be conducted.
 - ✓ Meeting room (in the hotel in the capital) equipped with microphones, a multimedia projector, and a computer.

- ✓ Work rooms (in the hotel in the capital) equipped with computers, black-white and color printer, photocopier, Internet access, plenty of paper and water bottles. These work rooms will be needed for the second week of the evaluation and the number will depend on the size of the evaluation teams.
- ✓ Secretarial room also equipped with a computer, printer and Internet access. This room is required for the second week the evaluation.
- ✓ Refreshments in the work rooms (morning and afternoon breaks) for the evaluation team. Refreshments are required for the first day and for the second week when the evaluation team is busy analyzing the information compiled.
- Human resources (not including the evaluators)
 - √ Full-time secretarial support assigned exclusively to this task in the PAHO/WHO Representative Office of the country to be evaluated; this person is responsible for supporting the logistical aspects of the evaluation.
 - ✓ Full-time secretarial support assigned exclusively to the evaluation in the hotel in the capital where the information will be analyzed during the second week.
 - ✓ Authorized drivers for all vehicles assigned permanently to the evaluation during the implementation period.
 - ✓ Photographer and videographer to document key moments of the evaluation (optional).
 - ✓ Master of ceremonies for the evaluation's closing event (optional).

The following instruments are suggested for planning and evaluating technical and logistical issues:

- · A work timetable that includes a detailed description of each activity, the person responsible, and the dates for following up on completion. The entire team involved in organizing the evaluation should participate in creating and reviewing the timetable and should meet periodically to review completion of tasks so as to avoid delays or difficulties during the implementation period.
- · A checklist to confirm that logistical tasks have been carried out (Annex 5). Ideally, this checklist should be created before the timetable to make sure that it includes all of the administrative tasks.

7.2 Presentation of the methodology for the evaluation, the national HEALTH SYSTEM AND THE EPI

Although the evaluation does not officially begin until the first Monday, it is useful to hold a preparatory meeting the day before with the international members of the evaluation team and the PAHO immunization focal point in the country to be evaluated. The objective of this meeting is to introduce the international evaluators, briefly review the methodology-especially if it has been modified—and go over the logistical aspects of the evaluation.

The following daily schedule of activities is proposed to facilitate the implementation of this stage.

Day 1 (Monday): 8:00 a.m. - 12:00 p.m.

Activities:

- · Opening of the meeting
- Plenary session with all the participants.
- Presentation on the country's health system to provide a frame of reference.
- Presentation on the current state of the EPI in the country, its objectives, priorities, and resources.
- Presentation on the various administrative areas related to EPI components and activities. The national authorities are responsible for these presentations, which are intended to introduce the international members of the evaluation team to the national health system and the EPI's operations.

Day 1 (cont'd): 1:00 p.m. - 6:00 p.m.

Activities:

- Presentation on the evaluation's objectives and methodology Information on:
 - ✓ Distribution of the evaluation teams by geographical area to be visited (subnational and national).
 - ✓ Individuals or authorities who should be interviewed in each area.
 - ✓ Type of transportation that will be used to travel to the assigned area and for local transportation. It might be useful to create a chart of routes for each team that includes the institutions they will visit and contact numbers.
- · Review of and training in the instruments.
- · Printing and distribution of materials.

Day 1 (cont'd): 6:00 p.m. on

Activities:

- · Ideally, responsibilities for drafting each section of the final report, assembling, presenting and photocopying it, and elaborating the five-year/multi-year plan should be assigned from the beginning of the evaluation. Advance planning will save time and will help to avoid unnecessary stress.
- The teams can travel to the subnational locations that same afternoon or evening, according to the schedule that has already been established.

7.3 FIELD WORK

The following daily schedule of activities for this stage is intended to facilitate the field work. If the teams did not leave for the site visits the previous evening, they should do so on the second day.

Day 2 (Tuesday)

The field work begins on day two of the evaluation with the following activities:

- Introduction of the evaluation team to the health authorities in their assigned subnational areas.
- Meeting with the health authorities to explain the work which will be carried out.
- Interviews at the subnational/local levels.
- Final decision as to the selection of the health facilities that will be visited.
- The evaluation team assigned to the capital will conduct interviews with the authorities, sector chiefs at the national central level, representatives of international cooperation agencies, financing organizations, NGOs, the national laboratory, census and statistics offices, the national regulatory authority, and other relevant institutions.

In each subnational area, the evaluation team can divide into groups of two or three people in order to visit as many health facilities as possible. Staff from the subnational area should be included in these visits and participate in the evaluation. As stipulated, each team should visit at least 10 to 12 health facilities, depending on travel times and accessibility.

The team should meet at the end of each day and prepare a summary of the progress made, challenges, and recommendations for each component that has been evaluated (Annex 6). This daily summary should be prepared in a participatory manner in order to facilitate the assessment of the program in the area visited.

How to consolidate information in the subnational areas

- Review all the interviews that were done and consolidate the common **achievements** and **challenges** for each component.
- These achievements and challenges will be written in the standard report format for the subnational area visited (Annex 6).
- Recommendations should be drafted to address any challenges identified in a particular component in order to propose solutions to the problems detected.

Keep in mind the following definitions of achievements and challenges:

It is an achievement: if the standards are met. For example, if health workers are familiar with the geographic boundaries of the area and have a map.

It is a challenge: if a problem is found in the majority of the health facilities. For example, there are no maps and staff is unfamiliar with the geographic boundaries of their catchment area.

Components should be evaluated based on compliance with technical standards or guidelines and with the management and surveillance indicators established by the Ministry of Health and PAHO/WHO.

Each component should be examined in an integrated manner, never in isolation, in order to get a sense of the degree of compliance. Since the components being evaluated are inter-related, there will be some overlap. For example, the evaluation of the epidemiological surveillance component includes checking whether trained staff are in place for active case-finding. Similarly, the evaluation of the training component includes verifying plans for training health workers in active case-finding.

Days 3 and 4 (Wednesday and Thursday).

The evaluations continue as scheduled in the selected departments and municipalities, by applying the interview guides at the political, management, and operational levels, and conducting interviews of users, agencies, NGOs, and cooperation organizations. The main findings should be presented to the local team at the end of each day.

Day 5 (Friday).

This is the final day of interviews in the selected areas and services. Just as before, the main findings should be presented to the municipal team at the end of the day.

Day 6 (Saturday).

Activities: 8:00 a.m. to 6:00 p.m.

The evaluation team provides the subnational health authorities with an overview of the main findings and conclusions from all of the visits and interviews. If possible, the evaluation team should leave a preliminary report in the area visited.

Each team also finalizes and consolidates its report at each level based on the evaluation components, including achievements, challenges and recommendations. The team finalizes the written report and prepares the presentation for day one of the second week (Monday).

With good leadership and group work, the presentation and the report should take at most eight hours. The team returns to the capital in the afternoon.

7.4 Analysis and presentation of results and elaboration of the five-year/multi-year plan

Week two of the evaluation

Day 8 (Monday).

Activities: 8:00 a.m. to 6:00 p.m.

- Plenary presentation by each team on the evaluations conducted in the subnational areas, the capital, and at the national central level, using the standard formats provided in Annex 7.
 The suggested length of each presentation is 20 minutes.
- Submission of the preliminary reports from each geographical area visited to the technical coordinator, who will deliver them to the administrative coordinator to make photocopies for distribution to the work teams and inclusion in the final report.
- Organization of the work teams that will consolidate the data for each component at the national level. Each team is usually assigned three to four components.

How to consolidate and analyze the data at the national level

For each of the assigned components, the evaluation group will compile the standardized subnational reports prepared by the teams (Annex 6) and synthesize the main achievements, challenges, and recommendations in the areas of the country that were evaluated.

During the plenary, the most appropriate recommendation can be identified in light of the main challenges and recommendations for a particular component.

The recommendations will be used as the basis for identifying the activities that should be implemented to improve weaknesses and contribute to the program's progress. Those activities will be included in the five-year/multi-year plan of action.

In order to ensure proper compliance, each component of the EPI evaluation should use Ministry of Health and PAHO recommended guidelines, technical standards, and procedures as a reference for interpretation and analysis of findings.

Day 9 (Tuesday).

Activities: 8:00 a.m. to 6:00 p.m.

- Team work to consolidate the achievements (progress), challenges (difficulties), and recommendations (solutions), by component.
- Presentation of the consolidated data to the entire team.

Day 10 (Wednesday).

Activities: 8:00 a.m. to 6:00 p.m.

After examining the achievements and challenges and drafting the recommendations, the next step is to prepare the five-year/multi-year plan of action. The plan's activities should be aligned with the recommendations and objectives set out in the evaluation and should take into account the following guidelines:

- Identify appropriate activities to address, mitigate, and surmount problems (difficulties, limitations).
- Create a timetable for implementing the activities.
- Estimate the costs of carrying out the activities.
- Identify potential funding sources and assign responsibilities for implementing the activities.

Plan of action activities should be organized into the following components: political priority and legal frameworks, planning and coordination, biologicals and supplies, cold chain, training, communication and social mobilization, operational expenses, supervision and monitoring, epidemiological surveillance and laboratory, information system, research, and evaluation. For further guidance on developing an plan of action, definitions of each component and an Excel template, please see the PAHO document, "Instructions for Developing the Annual Plan of Action of the Expanded Program on Immunization" and its associated annex.

Day 11 (Thursday).

Activities: 8:00 a.m. to 12:00 p.m.

• Drafting the plan of action (cont'd).

From 2:00 p.m. on:

- Preparation of the final report and plan of action (cont'd).
- Drafting of the presentation for the national authorities.
- At the end of the day during a plenary session, the team will review together the final version of the evaluation, the five-year/multi-year plan of action by component, and the presentation.
- Printing of the draft final report and five-year/multi-year plan of action to present to the Minister of Health.

Activities: 8:00 a.m. to 12:00 p.m.

 Presentation of the evaluation results to the Minister of Health, other health authorities, representatives of the administrative and technical units that participated in the evaluation, representatives of the Congressional Committee on Health, scientific societies, representatives of international cooperation agencies, and EPI directors and subnational coordinators, among others.

A model agenda for the two work weeks is provided below.

TABLE 3. AGENDA FOR THE INTERNATIONAL EPI EVALUATION

Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Opening meeting of the international EPI evaluation. Distribution of teams at the subnational level. Review and analysis of the instruments.	Travel to subnational areas. Presentation of the methodology to the subnational authorities. Application of the instruments at the central, subnational, and local levels. Planning of site visits to the selected facilities.	Evaluation at the subnational and local levels. Analysis and drafting of preliminary reports. Evaluation at the central level (interviews).	Evaluation at the subnational and local levels. Analysis and drafting of preliminary reports. Evaluation at the central level (interviews).	Evaluation at the subnational and local levels. Analysis and preparation of the preliminary report. Evaluation at the central level (interviews). Presentation of an overview of the evaluation to the subnational directors.	Finalization of the report for the subnational level. Presentation of the main findings and recommendations to the team at the subnational level. Travel to the capital.
Monday	Tuesday	Wednesday	Thursday	Friday	Saturday
Presentation of the evaluations conducted at the national and subnational levels by each evaluation team. Submission of subnational reports.	Drafting of each component of the national report. Presentation of the consolidated national data on achievements, challenges, and recommendations for each	Drafting of the five-year/ multi-year plan of action. Drafting of the final report.	Five-year/ multi-year plan of action completed. Final report completed.	Presentation of the final evaluation report to the Ministry of Health and technical personnel at the central and subnational levels.	International and national evaluators depart.

8. EVALUATION FOLLOW-UP

The EPI evaluation in a country sets in motion a process that involves implementing the recommendations. It is therefore necessary to develop a system for monitoring compliance with the recommendations and to schedule a follow-up evaluation within no more than five years.

The Ministry of Health, through the EPI manager—and working in conjunction with other sectors and with PAHO's support—will be responsible for implementing and monitoring the proposed activities in order to achieve the objectives set out in the evaluation.

Joint meetings should be held periodically to look at how the activities are being carried out and whether the dates and deadlines established in the timetable are being met. A progress report on compliance with the recommendations at each level should be prepared every six months as a supplement to the national evaluation.

The plan of action is an instrument for negotiations that should be presented to the Inter-Agency Coordinating Committee, the National Advisory Committee on Immunization and other relevant entities responsible for mobilizing resources and providing support.

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 - http://www.who.int/vaccines-documents/DocsPDF05/777_screen.pdf.

10. ANNEXES

ANNEX 1: LIST OF DOCUMENTS TO REVIEW

- 1. Technical vaccination manuals
- 2. VPD surveillance protocols in the country
- 3. Research protocols and studies carried out
- 4. National EPI surveillance bulletins
- 5. Meeting minutes from the Inter-Agency Coordinating Committee, the National Advisory Committee on Immunization, etc.
- 6. Vaccine laws, resolutions or other related documents
- 7. Sectoral health plan (most recent)
- 8. Annual EPI plan of action (most recent)
- 9. New vaccine introduction plans
- 10. Final report from the last international evaluation implemented in the country

ANNEX 2: LIST OF SUGGESTED INTERVIEWS FOR EACH LEVEL

Political level:

National:

- Ministers of Health, Education, and Finance
- Vice Ministers of Health and Finance
- Chief Medical Officer
- Office of the First Lady
- Directors-general of the Ministry of Health
- Director of hospitals
- Director of the health regions
- National regulatory authority
- Director of the central laboratory of the Ministry of Health
- · Director-general of the armed forces and national police
- Members of the national health council
- · Technical secretariat of planning
- · President of the congressional committee on health
- President of social security
- Health superintendence
- Private sector
- Others

Subnational:

- Governor
- Government health secretaries
- Departmental board chair
- Education secretary
- · Regional health director
- Regional social security director
- Education supervisors
- Others

Local:

- Mayors
- President of the local health council
- Others

Management Level:

National:

- EPI Manager
- Chief, Epidemiological Surveillance Department
- EPI Manager of the Social Security Institute
- EPI coordinator, military and police health
- Association of private hospitals
- Head of statistics, health promotion, maternal and child health, communications, laboratory, programming and evaluation units

Subnational:

- Hospital director
- · Chief of nursing
- EPI manager
- Epidemiological surveillance manager
- Regional educators
- Director of the public health area
- Laboratory director
- · Statistician in charge of data management

Local:

- Hospital director
- Health facility director
- Chief of nursing

Operational Level: Institutions and personnel that offer vaccination services.

- Laboratory director
- · Health facility directors
- Laboratory technician
- Nurses
- · Nursing assistants
- Statisticians
- Obstetricians
- Midwives
- Health promoters
- Others

Agencies, Financing institutions, NGOs, and other entities: national, subnational, and local:

- PAHO
- USAID
- UNICEF
- JICA
- · Rotary International
- IDB
- World Bank
- Plan International
- GTZ
- Pediatrics society
- President of the National Technical Advisory Committee on Immunization
- · Society of obstetrics and gynecology
- Society of infectious diseases
- Chair of pediatrics
- Catholic Conference, bishops and priests
- School of nursing
- National board of physicians (association, circle, committee or however it is known in the country)
- School of medicine
- National coordinator of farmers
- Social ministries coordinator
- Community leaders
- Others

ANNEX 3: INTERNATIONAL EVALUATION INSTRUMENTS

The international evaluation instruments are available on the PAHO website. To access them, simply click on the instrument you wish to download.

- 1.1 INTERVIEW GUIDE FOR THE POLITICAL LEVEL
- 1.2 INTERVIEW GUIDE FOR THE MANAGEMENT LEVEL OF THE EPI
- 1.3 INTERVIEW GUIDE FOR THE OPERATIONAL LEVEL
 - 1.3.1 CHECKLIST BY KEY COMPONENT OF THE EPI (OPTIONAL)
- 1.4 INTERVIEW GUIDE FOR THE MANAGEMENT LEVEL—OTHER (NON-EPI) MANAGERS
- 1.5 INTERVIEW GUIDE FOR LABORATORIES
- 1.6 Interview guide for the national regulatory authority
- 1.7 Interview guide for the National Technical Advisory Committee on Immunization
- 1.8 INTERVIEW GUIDE FOR COOPERATION AGENCIES AND NGOs
- 1.9 EPI USER SURVEY
- 1.10 FORM FOR ACTIVE SEARCH OF SUSPECTED VPD CASES
- 1.11 INTERVIEW GUIDE FOR SENTINEL SURVEILLANCE
- 1.12 Instruments for quality assessment of immunization information systems

IMMUNIZATION INFORMATION SYSTEM QUALITY ASSESSMENT — NATIONAL

 $\underline{\text{Immunization information system quality assessment} - Departmental}$

ANNEX 4: EPI BASELINE INFORMATION

1. Poli	tical priority, programming, and planning
1.1	Resolutions, directives, laws on vaccination
1.2	Annual action plan
1.3	Population database by province, district, and age group (note the source)
1.4	Document with the EPI mission and objectives
2. Org	anization and coordination
2.1	Health department organization chart
2.2.	Intersectoral support committee: minutes
3. EPI	resources
3.1.	Logistical
	a. Vehicles
	b. Computers
	c. Telephones
	d. Fax
	e. Modem
3.2	Staff
3.3	Laboratory (reference and support): fax, computer, telephone, reagents
3.4	Budget
	a. Per diem
	b. Vaccines
	c. Syringes
	d. Operations
	e. Overhead
	f. Fleets
	g. Maintenance
4. Sup	ervision and training
4.1	Supervision guides
4.2	Program norms and standards (vaccination, surveillance, cold chain, bio-safety)
5. Info	ormation System
5.1	Up-to-date information
	a. Population by district and age cohort
	b. Demographic data: population pyramid
	c. Vaccination coverage by district
	d. Disease incidence
	e. At-risk districts:
	Due to vaccination coverage
	Due to incidence rate
	Due to susceptible population clusters
	Due to epidemiological silence
	(Continued)

(Continued)

ANNEX 4: (CONTINUED)

9.5

Crisis prevention and management plan

		Due to ecological criteria (e.g. yellow fever endemic areas)
		Due to migration
		% of urban and rural population
		 Accessibility
		Borders
	5.2	Information system structure and flow chart
	5.3	Bulletins, publications, and feedback
6.	Epid	lemiological surveillance
	6.1	Structure of the reporting network: map
	6.2	Compliance with AFP, measles, and NNT surveillance indicators
	6.3	Standards and manuals
	6.4	Risk areas: epidemiological maps
	6.5	Case files of laboratory results
	6.6	Case information according to laboratory classification
	6.7	Active case-finding (vaccine-preventable diseases)
7.	Colc	I chain
	7.1	Up-to-date inventory
	7.2	Maps
	7.3	Maintenance plan
	7.4	Resources
		a. Logistical
		b. Human
_	- 1	c. Financial
8.		uation/Research
	8.1	National and departmental evaluation reports
	8.2	Evaluation report on bacterial pneumonias and meningitis (departments with sentinel hospitals)
	8.3	Evaluation report on Yellow Fever (endemic areas)
	8.4	Subregional meeting reports
	8.5	Operational research on the quality and reliability of EPI information
	8.6	Risk and poverty research
9.	Safe	Vaccination
	9.1	Number of severe ESAVI reported in the last year
	9.2	Final classification of the severe ESAVI reported (vaccine-related, programmatic error, inconclusive, coincidental).
	9.3	System for solid vaccination waste disposal
	9.4	National open vial policy
	7. 4	National open vial policy

ANNEX 5: LOGISTICS CHECKLIST

Task	Yes/No	Comments
Key meetings		
Meeting with the PAHO Representative and the administrative area in the country to be evaluated in order to coordinate the organization of the international evaluation.		
Meeting with national health authorities to decide on the content of the EPI presentations and the presenters.		
Letters/Invitations/Lists		
Letters of invitation from the PAHO office in the country to be evaluated notifying the participating national evaluators that PAHO will cover travel expenses and per diems. It is important to confirm that the national evaluators have received the invitation and have permission from their supervisors in order to issue per diem and transportation checks in advance.		
Letters of welcome from the PAHO/WHO Representative Office in the country evaluated, which should include\$		
 list of telephone contacts PAHO's office hours After hours contact information for staff (PAHO IM focal point, administrator, PAHO and United Nations safety focal point) 		
Letters of invitation to the inauguration of the international evaluation signed by the Minister of Health.		
Letters to subnational health authorities identifying the municipalities to be evaluated, the dates of the evaluators' visits, and appointments with governors, mayors, municipal health secretaries, and/or other authorities.		
List of participants prepared including: passport or identify document numbers, cell phone numbers, departments and/or municipalities to visit, and travel information including flight itineraries. This information should be used for the purposes of creating an emergency contact list and for hotel reservations.		
List of medical contacts with mobile telephone numbers in case of emergency.		
Appointments schedule for interviews with authorities and/ or staff at the national and subnational level. This schedule should be handed out on the first day of the evaluation.		
Basic information sheet for international evaluators with the following data: weather, currency exchange, use of credit cards, acceptance of dollars for paying bills, airport-hotel transportation, hotel services, restaurants near the hotel, etc.		

(Continued)

ANNEX 5: (CONTINUED)

Task	Yes/No	Comments
Hotels/Rooms		
Hotel reservations for evaluators: In the capital of the country to be evaluated In the areas they will visit		
Hotel meeting rooms reserved and completely equipped.		
Access to computer and printing equipment, Internet, stationery, flip charts, markers, overhead projector, microphones.		
Contracts for the provision of refreshments for the second week of the evaluation.		
Evaluator transportation		
Ticket purchases for national evaluators.		
Per diem checks issued to distribute on the first day of the evaluation.		
Vehicles rented, with fuel and drivers, permanently assigned to the evaluation team, and routes established.		
Materials/Information to distribute		
Briefcases or backpacks packed with evaluator files containing information organized with dividers, interview guides, office supplies, etc.		
Folders prepared with color copies of the final report for the key stakeholders and guests that will attend the final ceremony.		
Other		
Press release or executive summary for the political authorities and the PAHO Representative Office officially announcing the beginning of the international evaluation in the country.		
Preparation of the two-week agenda, the first day's agenda, and the evaluation's closing event.		
Identification and allotment of funds for editing and publication of the final report.		

ANNEX 6: FORMAT FOR SUBNATIONAL REPORTS

Subnational	Level	

Components	Achievements	Challenges	Recommendations	Comments
Political priority and legal framework				
Planning and programming				
Organization and coordination				
Budget and financial resources				
Human resources				
Physical and material resources				
Logistics and supplies				
Implementation				
Epidemiological surveillance and laboratory				
Information system and data quality				
Training and supervision				
Monitoring and evaluation				
Cold chain				
Vaccine safety				
Communications, social mobilization, and user satisfaction				
Research				

ANNEX 7: FORMAT FOR NATIONAL REPORTS BY COMPONENT

COMPONENT:

ACHIEVEMENTS					
	1				
CHALLENGES	RECOMMENDATIONS				

ANNEX 8: FORMAT FOR INTER-AGENCY COOPERATION REPORTS

COMPONENTS	ACHIEVEMENTS	CHALLENGES	RECOMMENDATIONS	COMMENTS
Priority of the cooperation				
2. Cooperation with the EPI				
3. Perception of the EPI				

ANNEX 9: NUMBER OF INTERVIEWS CARRIED OUT BY LEVEL AND AREAS VISITED

	National Level	Capital	Subnational level A	Nivel Subnacional B	Nivel Subnacional C	Nivel Subnacional D	Total
No. of interviewees							
No. of evaluators							
No. of subnational areas visited							
No. of municipalities visited							
No. of political interviews							
No. of management interviews							
No. of operational interviews							
No. of interviews with users							
No. of hospitals visited							
No. of health centers visited							
Laboratories							
No. of cooperation agencies/ scientific associations /NGOs interviewed							
Total population of provinces visited							
Total population of districts/ municipalities visited							
Percentage of the district population by province							

