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**PART III**

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**Chapter 7**

**EXPANDED PROGRAM  
ON IMMUNIZATION (EPI)**

**Dr. Ciro C. A. de Quadros**

**Dr. Jean-Marc Olivé**

**Dr. Cristina Nogueira**

**Mr. Peter Carrasco**

**Dr. Claudio Silveira**



## I. Introduction

In the early part of this century, communicable diseases of childhood caused the premature deaths of thousands of children in the Region of the Americas. Only one vaccine existed: the smallpox vaccine. In the course of the century, a variety of new vaccines have been produced, and immunization has been shown to be the most cost-effective public health measure for preventing illness and death in children. Today, a few years before the dawn of the 21st century, the dream of completely eliminating several of these diseases—as has already occurred with smallpox—is on the verge of becoming a reality.

In May 1974, the World Health Organization (WHO) established the Expanded Program on Immunization (EPI) in order to extend the enormous benefits of vaccination to a larger number of children. The program focused on six diseases and called for the application of four different vaccines: the measles vaccine; the DPT vaccine against diphtheria, pertussis, and tetanus; the BCG vaccine against tuberculosis; and the oral polio vaccine (OPV). In 1977, when the Pan American Health Organization (PAHO) launched the EPI in the Americas, only 25%-30% of children in the Region were receiving these vaccines.

The EPI supports national immunization services in their efforts to achieve the goal of immunizing all children by their first birthday. Owing to adverse economic conditions, many countries in the Region experienced difficulties in expanding immunization coverage in the first stage, which is to obtain the necessary vaccines. PAHO therefore designed a means of assuring that countries would have a regular supply of high-quality vaccines at the lowest possible cost: the Revolving Fund for Vaccine Procurement, which went into operation in 1979. The fund was capitalized with money from the budget of PAHO, together with substantial donations from UNICEF, the government of the Netherlands, the government of the United States of America, and contributions from other governments. The creation of the fund has prevented interruptions in the supply of vaccines and has also enabled the countries to benefit from the lower costs associated with wholesale procurement. These savings, which are substantial (up to 80% of the price of the vaccines purchased by a country) may be crucial to the success of a national immunization program.

An analysis of the figures on vaccination coverage of children under 1 year of age in the Region makes apparent the notable progress achieved through the creation of the EPI. For the vaccine against measles, coverage rates increased from 23% in 1978 to 80% in 1994; for DPT, from 12% to 79%; for BCG, from 31% to 91%; and for OPV, from 24% to 87%. These increases in coverage translate into millions of cases of illness avoided and young lives saved. As far as poliomyelitis is concerned, as a result of immunization, this terrible illness has been virtually wiped out.

The success of the polio eradication campaign, coupled with the high degree of interagency and intersectoral coordination achieved and the 99% reduction in the transmission of measles between 1984 and 1994, has led to the establishment of other goals.

The Region of the Americas is very close to attaining the goal for control/elimination of neonatal tetanus established by the World Summit for Children and also adopted by WHO—i.e., reduction of the number of cases to less than 1 per 1,000 live births by 1995. This achievement confirms the validity of the strategy of identifying high-risk areas in each country and giving priority to areas in which the largest proportion of cases occur. If resources are maintained, this disease could cease to be a public health problem in the Americas in the very near future.

In September 1994, the Pan American Sanitary Conference adopted a resolution calling for the elimination of measles by the year 2000, as well as strengthening and development of health services and targeting of activities to high-risk groups in the framework of the strategic and programmatic orientations for the 1995-1998 quadrennium. Subsequently, a five-year regional plan of action was formulated and was approved by the XXXVIII Meeting of the Directing Council in September 1995.

Despite significant progress by national programs, much remains to be done in order to achieve the new goals established. It is estimated that in Latin America and the Caribbean, more than 20,000 preventable deaths from measles, pertussis, diphtheria, and neonatal tetanus continue to occur each year. Many deaths attributed to diarrhea or acute respiratory infection are actually caused by measles or pertussis. Moreover, 90% of the children who contract neonatal tetanus die, and more than 25% of those who are infected with measles may die as a result of complications. These figures vary depending on the living conditions of the population, especially with respect to social, geographic, and epidemiological factors that affect specific risk groups and are generally not within the direct control of the health sector.

## **II. Objectives**

The implementation of immunization programs that can be maintained with their own resources in the health services system represents an important step toward the improvement of the overall health of children. Toward that end, the following objectives have been formulated:

### **1. General objectives**

- 1.1 To reduce morbidity and mortality from diphtheria, pertussis, tetanus, and measles by providing immunization against these diseases to all children in the Region (other vaccine-preventable diseases can be included where needed and as resources permit);
- 1.2 To promote the countries' self-sufficiency in the provision of basic immunization services in the framework of integrated health services;
- 1.3 To promote regional self-sufficiency in the production and quality control of vaccines.

### **2. Specific objectives**

- 2.1 To maintain the eradication of wild poliovirus;
- 2.2 To eliminate/control neonatal tetanus by 1995;
- 2.3 To eliminate indigenous transmission of measles virus in the Americas by the year 2000;
- 2.4 To establish a system of epidemiological surveillance of vaccine-preventable illnesses at the regional and national levels so that all suspicious cases can be investigated immediately and appropriate control measures can be applied;
- 2.5 To incorporate new and/or improved vaccines into routine immunization schedules as they become available for use in health services;

- 2.6 To promote other primary health care (PHC) practices whose results might be applicable to the EPI and its target population;
- 2.7 To carry out operations research in order to facilitate achievement of the aforementioned objectives.
- 2.8 To implement health promotion and education activities aimed at encouraging public demand for vaccination programs and ensuring that children receive all their vaccines.

### **III. Immunization Strategies**

In order to achieve the objectives of the EPI, it will be necessary to mobilize human and material resources, community participation, and intra- and extrasectoral coordination. A variety of strategies may be used to ensure vaccination of the target population, depending on the conditions in each country, region, or area; the social and economic situation; and the degree of organization and levels of development attained by the EPI. It should be emphasized that the strategies described below are not mutually exclusive.

#### **1. Routine immunization in health services**

With this strategy, all vaccines are given every day of the year. This is the most common immunization method. Health personnel wait for children to be brought to the health service for vaccination or they take the opportunity to vaccinate them when they are brought to the service for another reason. Vaccination is carried out in response to spontaneous and institutional demand. This strategy requires good health education in the community, as well as sensitization of health personnel to the benefits of vaccination and the relative lack of contraindications.

#### **2. House-to-house immunization**

Health personnel make home visits in the community to identify infants and pregnant women or women of childbearing age and vaccinate them.

#### **3. Mobile brigades or teams**

A team consisting of several health workers travels to communities that are not being served by existing health services in order to carry out immunization activities and other health interventions. In general, the team has some type of transportation.

#### **4. Mass campaigns (national immunization days)**

This approach involves an organized mass mobilization of the population on a given day or over a short period in order to apply the largest possible number of vaccine doses, with the participation of various community groups and intra- and extrasectoral institutions and with strong support from

the mass media. At the local level, intensive vaccination activities may be carried out during brief periods to complement routine immunization programs. This is especially useful in areas in which health services are deficient or coverage is low. Mass vaccination is also useful in cases that require quick action, for example to interrupt an epidemic.

In addition to these initial "catch-up" campaigns, there may be periodic follow-up campaigns aimed at reducing the numbers of susceptible children. These "follow-up" campaigns target all children aged 1-4, regardless of vaccination status or disease history. By supplementing the vaccination coverage obtained through routine vaccination services, this strategy aims to achieve and maintain high population immunity in preschool-aged children.

The interval between "follow-up" campaigns is determined by the vaccination coverage obtained through routine vaccination services. Campaigns are conducted when the estimated number of accumulated susceptible preschool-aged children approaches the number of infants in an average birth cohort.

### **5. Blockade vaccination/mop-up operation (emergency strategy)**

This strategy involves intensive, house-to-house vaccination of the population residing in communities or regions defined as high-risk (due to the presence of cases or to low coverage). The aim is to quickly interrupt transmission of a disease. In order to supervise the activity, visits are made to a randomly selected group of homes.

### **6. Search for susceptibles**

A survey is conducted to detect all susceptibles in a specific area, identifying children and determining their immunization status so that they can be vaccinated, if needed, near their place of residence. The search for susceptibles is carried out house-to-house by health personnel and community members or leaders who have been previously selected and trained.

### **7. Special Strategies**

#### ***7.1 Immunization in hard-to-reach populations***

It may be difficult to carry out immunization activities among certain population groups owing to geographic or sociocultural obstacles.

Populations living in areas that are hard to reach for geographic reasons (i.e., those that are located at a great distance from established health services) can often be vaccinated through a combination of measures, including immunization at home, regular transportation to other locations, more convenient hours of service in health centers, and mobile services. The cost of vaccinating populations in geographically hard-to-reach areas may be quite high. The advantages or disadvantages depend on the tactics applied.

In cases in which there are sociocultural barriers to vaccination, an effort should be made to identify ways of encouraging the community to accept the practice.

### *7.2 Complementary vaccination activities*

It is important to consider not only the way in which vaccination services are to be provided to priority populations, but also the time and place in which these services will be offered. For example, depending on the specific needs and resources available in the area of activity or the program area, it may be advisable to schedule vaccination activities for times and places such as the following:

- Outside of normal working hours: Holding vaccination sessions in the evenings or on the weekend or on market days might make it easier for mothers who work to bring their children to the health service for immunization.
- Monthly or quarterly: It may be preferable to offer intensive immunization services a few days a month or quarter. In this case, greater effort can be put into publicity and community organization activities prior to the immunization days, applying some of the tactics mentioned. This type of programming makes it possible to reduce the number of days during which the vaccines must be kept in the health service, thereby reducing the possibility that they will be improperly handled or stored.
- In-hospital vaccination: Vaccines can be administered to women while they are at the hospital for prenatal checkups or to newborns in maternity wards immediately after birth. Vaccines such as tetanus toxoid can be administered around the fifth month of pregnancy and other vaccines can be given to complete the immunization of women of childbearing age. Newborns can be vaccinated prior to discharge with BCG and also with the hepatitis B vaccine in areas and groups at high risk, provided the vaccine is available.

## **IV. Implementation of the Strategies**

The selection of vaccination strategies is directly related to the level of health infrastructure development. For most countries in the Region of the Americas, it may be best to choose a combination of strategies in order to cover the entire target population. The following factors should be considered:

- Human resources (quality and quantity)
- Material resources
- Financing
- Administrative framework for managing the selected strategy
- Use of human resource non-routine activities
- Training of personnel at the various levels of complexity of the service (Annex 1)
- Status of the cold chain
- Identification of risk areas based on the presence of cases, vaccination coverage levels, status of epidemiological surveillance, "silent" or hard-to-reach areas, impoverished urban and rural areas, border areas, and areas with heavy migration.

These factors should be analyzed before any decision is made. It is possible that the implementation of a strategy will be accompanied by a change in the infrastructure, but it should always be

borne in mind that these strategies are intended to complement, not replace, the services offered regularly as part of primary health care. It may be necessary to strengthen the infrastructure, however, in order to ensure the success of immunization activities.

Regardless of which strategy or combination of strategies is chosen, political commitment and allocation of sufficient resources will be essential to the achievement of the immunization program objectives.

## **1. Stages of implementation**

The implementation of immunization activities comprises the following stages:

- 1.1 Establishment of priorities, always bearing in mind local priorities when setting national priorities;
- 1.2 Formulation of quantitative and qualitative objectives;
- 1.3 Programming of activities;
- 1.4 Selection of strategies;
- 1.5 Calculation of resource needs;
- 1.6 Implementation of the activities;
- 1.7 Control, monitoring, and evaluation.

Immunization activities are generally programmed and managed strategically, which means that, even when it is possible to establish a sequence, that sequence is not rigid, but rather depends on the health conditions in a specific place and population.

Among the stages listed above, programming is crucial to the process of implementing the EPI. It is in this phase that an operational plan is drawn up, based on the epidemiological pattern of the diseases identified in the community, setting objectives and targets for effective control, rationalizing available resources, and systematizing the activities to be carried out. Programming also facilitates the coordination of activities, the formulation of strategies, evaluation, and decision-making.

## **2. Activities to be carried out**

The activities of the EPI fall into various categories of action:

- 2.1 Biologicals and supplies. Programming of all the supplies needed for immunization and their costs.
- 2.2 Cold chain. All matters relating to human, material, and financial resources.
- 2.3 Training. Training activities and production of teaching-learning materials and their respective costs.
- 2.4 Communications. Promotional and community participation activities, for which a budget should be established beforehand.
- 2.5 Operating expenses. Expenditures for wages, fuel, vehicle maintenance, and others.

2.6 Supervision. Supervision is a means of providing ongoing training at the operational level and is also a facet of program evaluation. In health establishments the supervisor can compile information for the evaluation of various aspects of the program, including the following:

- a) Coverage levels achieved and monitoring of epidemiological surveillance indicators;
- b) Vaccine application techniques;
- c) Vaccine storage;
- d) Knowledge of guidelines;
- e) Record-keeping;
- f) Equipment sterilization and disposal methods;
- g) Execution of workshops and other training activities.

Existing problems may be raised with the supervisor, who, together with the personnel, should try to identify all possible solutions. The supervisor can also take advantage of his visit to introduce new concepts and transmit knowledge. Supervisory visits provide a good opportunity to motivate and try to actively involve personnel.

- 2.7 Epidemiological surveillance. Programming of information for activities, guides, case-reporting and investigation, laboratory support, shipping of samples, manuals, and other activities.
- 2.8 Research. Programming of special studies such as studies of missed opportunities, environmental studies, cost-benefit studies, and others.
- 2.9 Evaluation. All programming relating to evaluation, with the respective costs and financing.

## **V. Steps for Implementation**

### **1. General considerations**

Planning for the EPI is based on study and assessment of health conditions in the community or locale and the country, which makes it possible to determine, among other things:

- 1.1 The characteristics of the community in which the service will be provided;
- 1.2 The health risks and problems that affect the population;
- 1.3 The resources available for the activities and the degree to which they are used, as expressed by the delivery of services; and
- 1.4 The services provided.

Based on this information, the instruments with which the health planner can undertake a situation assessment are determined, taking into account the objectives and the general policies in effect. It is important to draw up a plan of action at each local level, establishing the managerial guide-

lines for the program. The plan of action that is prepared for each area or district should include certain activities essential for ensuring success.

Programming should be guided by the simplest possible criteria, but they should be strictly applied. It should be borne in mind that actual formulation and achievement of the coverage goals and the strategies for action takes place at the local level. It is therefore necessary to pay close attention to the needs and problems at this level in order to really increase the efficiency of the health system.

Regardless of the level at which programming is undertaken, it is essential to ensure both intra- and extrasectoral coordination, for example with the education and agricultural extension sectors, neighborhood clubs and associations, mothers' clubs, religious institutions, foundations, and other NGOs. All these institutions and social organizations in the area should be identified in order to program joint activities, ranging from the application of vaccines and surveillance to promotion of vaccination in the community.

## **2. General definition of the area of application**

It is essential to have appropriate data, with the corresponding sources, in order to implement activities in relation to strategies, resources, needed changes, and the goals of the EPI. Information needs are discussed in greater detail below in the section on information systems. Some of the data that are considered important in order for the local level to carry out the activities are:

### ***2.1 Data on demographic structure***

- a) General population;
- b) Population groups by geographic area;
- c) Age and sex distribution of the population;
- d) Population growth;
- e) National and international migration patterns;
- f) Birth rate, fertility rate, and others.

The sources of information are:

- Health facilities of the public, private, and social security sectors;
- General population census;
- Vital statistics registry;
- National statistical and geographic information system;
- The community;
- Demographic surveys.

### ***2.2 Morbidity data (see the section on evaluation)***

### ***2.3 Mortality data (see the section on evaluation)***

### **2.4 Data on vaccination**

- a) Health services;
- b) Type of antigen (trade name and manufacturer);
- c) Lots and expiration dates;
- d) Coverage, based on number of doses applied by age groups and vaccine;
- e) Coverage by geographic area (counties, districts, municipalities), age group, and vaccine;
- f) Number of first and third doses of OPV and DPT applied (drop-out rate);
- g) Missed opportunities;
- h) Adverse events following immunization.

## **3. Development of the operational plan**

### **3.1 Establishment of goals**

In order to plan and ensure efficient functioning of the program, it is necessary to have information systems that are timely, effective, sensitive, and adapted to the objectives. These systems should be tailored to the existing scientific knowledge and the complexity of health structures. In addition, based on existing priorities, they should permit the establishment of the goals to be attained in order to achieve the control and elimination of vaccine-preventable diseases. The EPI has established the following priorities and goals:

- Vaccination of 100% of children under 1 year of age with OPV, DPT, BCG, and measles vaccine;
- Vaccination of 100% of susceptible children between 1 and 4 years of age who were not vaccinated during the first year of life with OPV, DPT, BCG, and measles vaccine;
- Vaccination with tetanus toxoid of 100% of women of childbearing age in all areas at risk for neonatal tetanus;
- Vaccination of 100% of pregnant women with tetanus toxoid.

Several key points and considerations must be taken into account in order to achieve the goals of the program, including the following:

#### **a) Target population**

Vaccination of at-risk populations should be emphasized—for example, children under 1 year of age, pregnant women, and women of childbearing age in areas in which tetanus is endemic. This does not mean overlooking other populations, but rather recognizing that resources are limited and should therefore be used so as to ensure the greatest possible degree of social efficiency and effectiveness.

#### **b) Simultaneous vaccination**

Both children and pregnant women can be vaccinated during a single visit. In order to give three doses of polio vaccine, three of DPT, one of measles vaccine, and one of BCG, only three

contacts are needed between the health service and the child. Similarly, pregnant women can be vaccinated when they come to the health service for prenatal checkups or when they bring their other children to be vaccinated, providing they are within the right period of pregnancy for tetanus toxoid to be administered.

***c) Immunization as an integrated and routine activity of health services***

The immunization program should be integrated into primary health care and into the overall health infrastructure, and it should be maintained through the years. Its strategic importance for strengthening health care at the local level will thus be demonstrated.

**3.2 Budget**

Each health service should have enough vaccines and syringes to immunize all infants and pregnant women in its area of action, in addition to resources for the implementation of other program activities. In particular, there should be sufficient funding to cover the costs of the vaccine distribution logistics system, operating expenses, the cold chain, and epidemiological surveillance, among other expenses.

Needs should be calculated and information should be available on the budget allocations for immunization activities at the various levels of the health system in order to manage the flow of financial resources effectively. The success and sustainability of the program will depend to a large extent on the level of financial decentralization and deconcentration to the local level.

**3.3 Information system**

Described below are the types of information about the area and community that health workers will need to know in order to develop the operational plan.

***a) Epidemiological information***

Based on morbidity and mortality indicators for each area (incidence, mortality and case fatality rates), an epidemiological assessment will be undertaken. It will then be possible to monitor and assess the situation of each of the diseases included in the program. The same data will also be used to establish priorities.

***b) Information on the area of responsibility***

A health center or institution should have updated maps of the area for which it is responsible, indicating its boundaries, the main roadways, and, to the extent possible, the location of housing units. In small cities and towns, it is useful to show the numbers of dwellings and blocks and, where possible, to identify houses, schools, churches, hospitals, and other places where the community may congregate. It is also important to identify access roads and means of transportation. This kind of detailed information will facilitate the development of more appropriate operational plans when the vaccination activities are programmed.

***c) Demographic information***

It is advisable for health service personnel to have updated lists of all newborns, pregnant women, and, in specific cases, women of childbearing age in their area of responsibility. The total popu-

lation and the numbers of individuals in susceptible age groups (under 1 year, 1- 4 years, pregnant women, and other specific groups) can be obtained from the most recent census or can be estimated if the census data are not available. When specific figures are unavailable, the approximate number of people in each age subgroup can be estimated using the following indicators.

TARGET GROUPS	PAHO/EPI INDICATORS (% of the total population)
• under 1 year	3%
• 1 to 4 years	11%
• pregnant women	4%
• women of childbearing age	25%
• 9 months to 14 years	40%

#### *d) Information on infrastructure*

##### **• Physical resources.**

It is essential to have information on the number of vaccination services and their facilities, equipment, and location, as well as on the overall system of services and its makeup. It should be determined whether the geographic distribution of the services makes them accessible to the population. In programming, it is also necessary to consider the possibility of opening new services and extending the hours of existing ones.

##### **• Human resources.**

This information is vital since the execution of the activities depends on the existence of human resources. The information to be compiled includes the numbers of human resources, the times at which they are available, their functions, their level of training, and whether they work exclusively for the EPI or are also involved in other programs. The health care team must be productive and, above all, motivated to carry out immunization activities.

##### **• Cold chain.**

The existence of an effective cold chain is essential to ensure that biological products reach their destination in good condition. A form should be developed for periodically carrying out assessments of resources and equipment in each service unit in order to determine the functionality and the needs of the system. This form should be used to record information on quantities and operating conditions in relation to the cold room, refrigerators per service, volume, source of power, number of coolers and insulated containers, electric generators, maintenance, and other aspects of the cold chain. Information should also be collected on transportation; number of units available; means, use, and funding of public transportation; and costs and financing of the system and its components.

##### **• Availability and delivery of vaccines.**

Vaccines of good quality should be available in sufficient quantities when needed at all levels of the cold chain. One criterion for assessing the availability of vaccines is the number of days per month or year during which a certain vaccine is lacking. In order to determine this, records

must be kept of vaccines that enter and leave national and local storage facilities. These data can be used to plan for the use of vaccines and the ordering of new supplies. It is important know exactly where the various types of vaccine are stored and their respective expiration dates and lot numbers in order to distribute and make timely use of vaccines that are about to expire.

## **VI. Monitoring and Follow-up of the Plan of Action**

Among the activities to be implemented, those relating to the information system and epidemiological surveillance are crucial to monitoring, evaluation, and continual adjustment of the course of the program.

### **1. Epidemiological surveillance**

Epidemiological surveillance is the observation, investigation, and analysis of the occurrence and distribution of diseases and the factors pertinent to their control with a view to facilitating the necessary action. Surveillance makes it possible to collect the information required to assess the status of the program and its progress, identify problems, and implement solutions. It is therefore important that the information be timely and reliable.

Epidemiological surveillance also includes active case-finding, reporting, and recording, as well as comparison, analysis, interpretation, and dissemination of information (feedback). It also provides data about the harm caused by the diseases and the factors that influence their transmission, as well as some indicators for evaluating the performance of health services. The latter are essential for the application, execution, and evaluation of programs.

In order for the action taken to be timely and effective, it is necessary for epidemiological surveillance to be integrated into disease control programs and for surveillance to be carried out at all levels of service delivery.

- 1.1 Determination of the disease that is to be the object of surveillance;
- 1.2 Use of the case definition of the disease under surveillance;
- 1.3 Selection of information sources and of the data to be gathered;
- 1.4 Collection of the data;
- 1.5 Systematic organization of the data;
- 1.6 Analysis of the data for use in decision-making;
- 1.7 Appropriate distribution of the information produced on the disease under surveillance and on the impact of the measures applied (feedback);
- 1.8 Identification of risk areas.

It is the responsibility of health personnel to know and understand the effects that the six diseases targeted by the EPI have on the population living in their area of action. To this end, they must be knowledgeable about the following aspects of these diseases:

- How many cases are there? Why did the cases occur?

- How many deaths occurred?
- Who contracted the disease?
- Where do those who contracted the disease live?
- When did they contract the disease?
- Did they receive the vaccine?
- Are there any contacts? What happened with the contacts?

Varying degrees of health infrastructure development are observed between countries and often even between several local levels within the same country. It is also common for the operational levels of health agencies to have resources of differing degrees of complexity and for not all to have the same capacity to diagnose cases and establish causes of death with the same certainty. Each country must therefore determine which elements of epidemiological surveillance are feasible based on its available resources, its information needs, and the scope and efficiency of its control programs. The way in which the information system will be structured for action is also an important element to be defined.

## **2. Levels of surveillance**

Disease surveillance takes place at all levels of the health system.

### ***2.1 Local level***

It is at the local level that the first contact between the population and the health services takes place. This level constitutes the first link in the processing and interpretation of data and is therefore the level at which the first decisions must be made. The phases of epidemiological surveillance at the local level are outlined below:

#### ***a) Detection of cases and deaths***

The principal tool for detecting cases and deaths is epidemiological investigation. There are several ways of finding cases of the diseases targeted by the EPI. In the case of measles, for example, these include the following:

- Patients with measles are brought to the health center for treatment. When patients are attended in an outpatient clinic, measles cases can be recorded in the patient's file or in the general records of the establishment. However, not all people who contract measles will be brought to the health center, especially those who live far away and those with mild cases.
- Health workers travel to areas without service. In order to extend health services to people who live far from the establishment, health workers make periodic visits to areas in which the "exposed" population lives. The visit serves both as a means of improving services and gathering data on cases and deaths.
- Information is provided by patients and other informants. To supplement the information gathered from patients with any disease and from other people who come to the health center or to mobile units, it is advisable ask those who reside in remote locations whether they know of any cases of measles that may have occurred in their community.

***b) Count and analyze cases***

- Count cases. All cases of the disease that have been detected during a certain reporting period (generally a week or month) are counted, applying the established case definition.
- Determine whether the records are complete. Ascertain the portions of the area served by the health center for which insufficient information is available (age, place of residence, immunization status, date of vaccination).
- Analyze cases. Several important questions need answering:

Are there any cases? Why are these cases occurring?

Can the situation be considered an outbreak of the disease?

Are the cases concentrated in one or more sections of the area or are they evenly distributed across the area served?

If the cases have occurred in vaccinated children, are there indications that the vaccine was ineffective?

Which age group is at highest risk?

***c) Carry out activities***

After detecting and investigating cases, measures such as the following should be taken to protect the community and prevent new cases:

- Conduct a follow-up vaccination operation
- Search for new cases
- Take advantage of the outbreak to raise community awareness of the importance of vaccinating children in accordance with the national immunization schedule
- Take samples for shipment to a laboratory, in accordance with the recommendations for each disease.

If cases are found in vaccinated children, the health team should ask:

- Was the child vaccinated at an appropriate age (9 months or older)?
- Was the vaccine properly stored (in the cold chain)?
- Did the vaccine fail?

If cases occur in unvaccinated children or in children who have not been fully immunized and coverage is therefore low, immunization should be completed, focusing activities in the areas in which the cases were found.

***d) Inform the next level***

The information that has been gathered on cases should be communicated to the next higher level of the health system, in accordance with established guidelines and using the corresponding report forms. If reports are not submitted to the next level on a regular basis, it will be impossible to know what is happening with the EPI diseases in the country's program

areas or areas of responsibility. It is important for the health center to submit weekly reports even when no cases have been detected. Otherwise, those who compile information at the regional level may assume that the report is simply late and that cases do exist (see the section below on the reporting system).

***e) Inform communities***

After gathering data on cases and deaths from diseases included in the EPI, each level has the responsibility to inform the community it serves of its findings and conclusions.

***2.2 Regional level***

Political and administrative divisions (province, region, or state) determine what constitutes the regional level. Personnel at the regional level are responsible for keeping track of what is occurring with the diseases covered by the EPI. At this level, the data on cases and deaths are extracted from the reports of local establishments. If the health centers do not submit reports, it will be impossible for personnel at the regional level to know what is happening in their areas; the same thing will happen if the information is not timely or is incomplete. Several of the phases of epidemiological surveillance corresponding to the local level also apply to the regional level.

***2.3 Central level***

This level generally consists of the ministry of health, which is the entity responsible for immunization policies and control of communicable diseases. The central level is also responsible for maintaining updated information for the entire country on the diseases targeted by the EPI. For data on cases and vaccination activities, the central level depends on reports and supervisory visits. The same general phases of surveillance that apply to lower levels also apply to the central level.

Information sources should maintain ongoing surveillance and should continue to report on possible cases. However, without the stimulus of some kind of response to the information they provide, the sources may lose interest in continued reporting. Feedback can be provided in the form of summaries of data, dissemination of bulletins, investigations of certain cases, or visits to the reporting center to assess special situations or for regularly scheduled supervisory visits.

**3. Reporting system**

Data on the occurrence of cases and deaths from vaccine-preventable diseases are entered into the information system in accordance with the preestablished classification for each disease (i.e. suspected, probable, or confirmed case). This reporting is essential to epidemiological surveillance and case monitoring. In order for the reporting system to function effectively, the following conditions must be met:

- 3.1 The data must be valid. To this end, appropriate forms that specify the exact data to be provided are generally used.
- 3.2 Data must be supplied at regular intervals. The frequency with which information is submitted should be established in accordance with the type of disease and the capacity of the system.

3.3 Personnel must be designated at each level to maintain the flow of information. The reporting form should contain at least the following information:

- a) name
- n) age
- c) place of residence
- d) date of onset
- e) immunization status

It is crucial that reports be sent within established time frames, even if no cases of the diseases targeted by the program occur. In such instances, a report of no cases should be submitted as evidence that surveillance is being carried out. Non-submission of a report by the established deadline does not necessarily mean that there are no cases; rather, it may indicate that the information system is deficient. It is common that not all cases occurring in an area are reported, but it is important for health personnel to understand the causes of this phenomenon. Annex 2 (Figure 1) shows the marked difference that may exist between reported cases and actual cases in a given area, which gives rise to significant underregistration of cases. Some of the reasons identified for this phenomenon are:

- Failure by health services to report regularly;
- Failure by health services to report detected cases;
- Incorrect diagnosis of cases;
- Lack of institutional coordination;
- Cases do not come into contact with the health services system;
- Cases are attended by the private sector and not reported to the national system;
- Cases are attended by other health services (social security, private sector, NGOs).

## **VII. Evaluation of the Program and Indicators**

Among the objectives and goals of the EPI is the development of a system of continuous evaluation. The purpose of this system is to assess the program's degree of development and determine whether it is following its preestablished course.

Evaluation is considered to be the set of methods used to analyze and appraise the development of a program and its objectives, activities, costs, and impact and determine the necessary interventions.

As was note above, the implementation of immunization activities takes place in various stages. For the EPI, evaluation occurs at the same time at which the stages are being implemented. Evaluation is not static, nor does it depend on a sequence; rather, it is a dynamic and continuous process, both in regard to the overall program and to specific aspects.

Some of the evaluation methods used by the EPI are described below.

### **1. Vaccination coverage**

Vaccination is not an end in itself; it is intended to produce immunity and, ultimately, to reduce morbidity and the number of deaths caused by a disease. When naturally acquired immunity is replaced by immunity from vaccination, the epidemiological effect on the pattern of the disease

will depend on the vaccination coverage rate. Coverage should be calculated by age group and geographic area (districts or counties, for example), which makes it possible to direct vaccination activities toward the least-protected groups and the highest-risk areas.

There are several methods of assessing vaccination coverage, and each method has advantages and disadvantages. Vaccination coverage is the percentage of the target population that has been vaccinated. It can be calculated as follows:

$$\text{VACCINATION COVERAGE} = \frac{\text{TOTAL TARGET POPULATION VACCINATED WITH ALL VACCINES}}{\text{TOTAL TARGET POPULATION}} \times 100$$

This formula contains the following components:

- Numerator: Number of doses applied in the target population vaccinated. There are several ways of estimating the numerator. For example, "vaccination with all vaccines" might mean three doses of OPV and DPT, one dose of BCG, and one dose of measles vaccine.
- Denominator: Total target population. Updated census figures and/or estimates by age group are used to determine this number (see the subsection on demographic information in the section entitled "Information system").

The findings of the coverage assessment provide an important basis for decision-making. In the analysis of priority areas, this information indicates whether or not it is necessary to carry out the following actions:

- a) Identify areas with low coverage;
- b) Investigate the causes of missed opportunities (see subsection 8 of this section);
- c) Investigate and report cases of the vaccine-preventable diseases at the local and regional levels;
- d) Identify areas that lack information;
- e) Increase coverage levels where needed.

A basic component of all immunization programs should be a system of continuous evaluation that serves as a warning mechanism, making it possible to identify problems and quickly apply the necessary corrective measures.

For the assessment of coverage, three methods exist:

### *1.1 Administrative method*

This method uses the formula for vaccination coverage, which is estimated in terms of percentage of the total target population. The administrative method is relatively simple because most of the data needed are available within the health care establishment. This is the method recommended by the EPI. One drawback is that the data—for both the numerator and the denominator—may be incorrect or inaccurate for various reasons.

- **Numerator:** Some health establishments may submit inaccurate reports showing an excessive or incomplete number of doses. It is therefore important to periodically analyze the information and the supervisory visits carried out at the local level.
- **Denominator:** Census data are almost always used to estimate the target population. If a census has not been conducted for a certain number of years, the target population can be estimated; however, these estimates are often influenced by subjective factors relating to the individuals who calculate them. In addition, to identify risk areas and ensure a better assessment of vaccination coverage levels, it should be taken into account that people may move from one area to another in search of greater access to health services, which may influence the evaluation of results.

### ***1.2 Household survey***

One way in which a health service can become more familiar with the population for which it is responsible is to conduct a household survey. If possible, it is recommended that the personnel of each health establishment carry out such a survey of the population living in the establishment's program area or area of responsibility. Home visits make it possible to gather data on coverage and draw up a list of women of childbearing age and children under 1 year of age. They also afford health personnel the opportunity to establish a relationship with the population.

### ***1.3 Survey by sampling***

In some situations, it is essential to more accurately determine vaccination coverage in order to reorient the program. In such cases, a sample drawn from the population is surveyed. Support from the regional and/or central level is required for the design of the study and its execution and analysis.

## **2. Relationship between coverage and impact**

Because of the differences in the way the diseases included in the EPI are transmitted, they each require different levels of coverage in order to be kept under control. For example, while vaccination coverage levels of 80% may be enough to control diphtheria, various studies have shown that control of measles requires that more than 90% of the population be immunized.

When high levels of coverage in the susceptible population are achieved, the risk of contracting the disease decreases. These levels vary with the relative communicability of the disease and with certain characteristics of the population, such as population density. In general, the suggested coverage levels produce a significant decrease in the number of cases, and consequently the need for control activities shifts to the individual level—for example, control of contacts in each particular case.

Vaccination coverage should be calculated by age group. Generally, the target group will be children under 1 year of age. Coverage should also be calculated by geographic area (districts, counties), which makes it possible to direct immunization activities toward the least-protected groups. Several factors should be taken into account, including the following:

- 2.1 *Coverage of at least 95% of susceptibles is crucial to the success of the measles elimination program.* In addition, part of the elimination strategy is to interrupt the circulation of the virus within the community at a certain moment. To that end, a mass vaccination campaign should be carried out. It is also necessary to ensure that all children are immunized when they reach their first birthday. A coverage level of at least 95% of this group should be maintained, not only at the national level, but also at the county and district level. The next essential control point should be the moment when children enter nursery or elementary school, for which a system should be developed to rigorously monitor the immunization status of children entering school.
- 2.2 In the consolidation phase of the elimination program, *all children under the age of 15 years should be vaccinated* within a brief period of time. Recognizing that in the first years of execution of the EPI activities there may be failures in the cold chain, as well as errors in diagnosis, *all people in this age group should be vaccinated*, regardless of their history of vaccination or infection with measles in earlier years. Special strategies may be necessary, such as house-to-house vaccination, in order to cover hard-to-reach or problematic areas.
- 2.3 As national systems of disease surveillance are established and cases of acute flaccid paralysis (AFP) are detected during the periods between national immunization days, it will be necessary to institute immediate *mop-up and control activities through mass immunization with trivalent oral polio vaccine*. The mop-up operation may be geographically limited or quite extensive, covering an entire district, county, state, or even a country, depending on the epidemiological features of the outbreak. In order to facilitate logistics and increase the speed with which the control measures are applied, a single antigen should be used during the mop-up operation.
- 2.4 Countries that have been free of poliomyelitis for 3 years or more should do everything possible to ensure continued high coverage levels and should intensify surveillance activities in order to maintain their polio-free status, while also increasing their measles and neonatal tetanus control efforts.

### 3. Drop-out rate

The drop-out rate is the percentage of children who receive a first dose of vaccine but do not complete the minimum vaccination schedule of 3 doses of DPT and OPV, which are necessary to provide full protection.

If this rate is known, the program can be evaluated and the causes that lead to drop-out can be addressed. The following formula can be used to calculate the drop-out rate :

$$\text{Drop-out rate} = \frac{\text{No. of children who received 1 dose} - \text{No. of children who received 3 doses}}{\text{No. of children who received 1 dose}} \times 100$$

#### **4. Morbidity indicators**

Through morbidity data, the following monitoring, evaluation, and impact indicators are obtained:

- 4.1 Incidence
- 4.2 Prevalence
- 4.3 Total and age-specific attack rate
- 4.4 Case fatality rate
- 4.5 Complication and hospitalization rates and others

The information is analyzed on the basis of data from the following sources, which may be in the public, private, or social security sectors:

- a) Weekly reports of new cases
- b) Immediate notification of cases and outbreaks
- c) General morbidity records of outpatient services
- d) Hospital morbidity records
- e) Rehabilitation centers
- f) Nominal case records
- g) Laboratory records
- h) Special health surveys and epidemiological studies
- i) Schools, preschools, military housing, and other institutions
- j) Mass media (radio, TV, press)
- k) Active case-finding

#### **5. Mortality indicators**

The following indicators are obtained from mortality data:

- 5.1 General mortality
- 5.2 Age-specific mortality:
  - a) Neonatal
  - b) Infant
  - c) Adjusted
  - d) Proportional

Mortality is determined by analyzing the data obtained from the following public, private, or social security sources.

- Immediate notification of deaths
- Reports of deaths from communicable diseases

- Hospital mortality
- General mortality
- Vital statistics registry
- Mortality surveys and epidemiological studies
- Mass media

Annex 3 (Table 1) shows some of the key facts revealed by these indicators.

## **6. Vaccine quality control**

The evaluation of the EPI should include careful quality control of vaccines. A minimum of data should be provided on the following aspects of quality control:

### *6.1 Movement of vaccines*

- a) Doses distributed, applied, and lost (loss factor)
- b) Cases of surplus or shortage of vaccines;

### *6.2 Potency of vaccines*

- a) At the time that the vaccine is delivered by the manufacturer, any doubt as to conditions under which it has been stored or transported?

### *6.3 Vaccine storage (cold chain)*

- a) Vaccine storage temperature, taken at various points in the cold chain, and record-keeping
- b) Transportation of vaccines
- c) Condition of equipment (refrigerators and coolers, among others)

### *6.4 Vaccination supplies*

- a) Syringes, cotton, trays, alcohol, and other supplies

## **7. Surveillance of adverse events following immunization**

To ensure the success of the program, it is important to detect any moderate and severe adverse reactions that occur following immunization, because they may influence public acceptance of immunization in the community. Such events do occur occasionally. Some are due to intrinsic properties of the vaccine used. Others can be attributed to problems in immunization programs, such as incorrect handling, improper sterilization, and faulty vaccine administration techniques, among others. Adverse events may also coincide with immunization but be due to other causes.

It is suggested that guidelines for investigation and evaluation of adverse events be established. One of the eventual goals of all programs should be routine collection of information on these events at the local level. Surveillance methods will vary from locality to locality and will depend on the level of development of each program.

Because the objective of this surveillance is to determine whether a non-specific adverse event reported following immunization is occurring at a more frequent rate than expected, it should be emphasized that the estimated rates are only rough calculations of the overall rates of adverse events (vaccine-induced plus coincidental events due to other causes), because even with heightened surveillance only a fraction of all adverse reactions that occur will be reported. Annex 4 (Table 2) shows estimated rates of adverse events following immunization with various types of biologicals.

## **8. Missed opportunities for vaccination**

One of the most important reasons for which satisfactory levels of coverage are not achieved is that children or women are not vaccinated when they visit health services for other reasons. Any circumstance in which children under the age of 5 years or women of childbearing age—who are eligible and need to be vaccinated—do not receive vaccines when they visit a health establishment is termed a "missed opportunity."

Studies conducted in several countries of the region of the Americas have found that the causes for missed opportunities generally fall into four categories:

- 8.1 False contraindications learned in medical and nursing schools, including mild fever, diarrhea, vomiting, and cough or cold;
- 8.2 Attitudes of health service personnel, who fail to offer the vaccine, do not remember to ask whether patients are fully immunized during routine visits to the health service, or are reluctant to open a multi-dose vial of vaccine for a single child, among other reasons;
- 8.3 The logistics and organization of health services and deficiencies in the supply and distribution of vaccines, limited times or days during which some vaccines are administered, and the fact that the person to be vaccinated has not brought his/her immunization card, which are frequent and important causes of missed opportunities;
- 8.4 Public attitudes toward vaccination.

All unvaccinated children under 5 years of age should be vaccinated when they visit a health service, regardless of the reason for the visit and regardless of whether they have an updated immunization card. Annexes 5 and 6 (Tables 3 and 4) provide valuable information which all health personnel should bear in mind in order to address the challenge of developing and implementing strategies to reduce or eliminate missed opportunities for vaccination.

## **9. Special studies**

The national or regional and local levels may undertake the following special studies with a view to expanding the activities and coverage of immunization programs:

- 9.1 Ratio of programmed doses to applied doses;
- 9.2 Ratio of programmed doses to dispatched doses;

- 9.3 Ratio of dispatched doses to applied doses;
- 9.4 Estimates of the cost per child of full immunization;
- 9.5 Costs of treatment and/or rehabilitation of each child who contracts a vaccine-preventable disease;
- 9.6 Number of health workers/days necessary to prevent a case of disease;
- 9.7 Total cost of the program;
- 9.8 Cost of controlling outbreaks;
- 9.9 Cost/benefit analysis.

## **VIII. Conclusion**

PAHO's successful strategy for the eradication of poliomyelitis in the Region, coupled with recent achievements in the effort to eliminate measles and control neonatal tetanus have contributed significantly to the strengthening of health infrastructure. The polio eradication initiative has fostered a true culture of prevention among political leaders, health workers, and members of the community. The involvement of high-level political figures has encouraged the participation of a broad range of personnel from governments, NGOs, and volunteer groups. The proportion of national resources in comparison to external resources contributed to the funding of expanded immunization programs has increased steadily, thereby ensuring the sustainability of immunization programs in general.

A prime example of the political commitment that exists in the Region is the decision to eliminate measles, which was prompted by the success achieved in the eradication of poliomyelitis. This victory was made possible thanks to the enormous combined effort of personnel at the local levels in each country, who worked enthusiastically and unstintingly, despite the difficulties encountered.

## IX. References

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## X. Annexes

### Annex 1 Exercise in Programming Strategies and Tactics

In programming vaccination strategies and tactics at the local level, it may be useful to complete the following exercise with the individual who are responsible for carrying out the activities.

**A. Is there sufficient political commitment and allocation of resources to the EPI in your country or area of activity?**

A1 Yes A2 No

A1.1 Total commitment

A1.2 Partial commitment

Explain your answer in no more than 5 lines.

**B. What immunization strategies and tactics are used in your country and area of activity?**

**C. Based on the material presented in the training unit and your own criteria, what tactic should be applied in order to ensure the success of the EPI?**

**Why?**

Discuss your responses with the rest of the group.

**D. Exercise:**

The groups should split up into subgroups and each one should be asked to select which of the strategies mentioned in the training module (house-to-house immunization, travel to remote areas, mop-up operations) is best suited to the situations presented below. For each strategy, the group should describe the stages necessary for the organization of the activities, including personal, materials, logistical support, time, and mechanisms of evaluation and supervision.

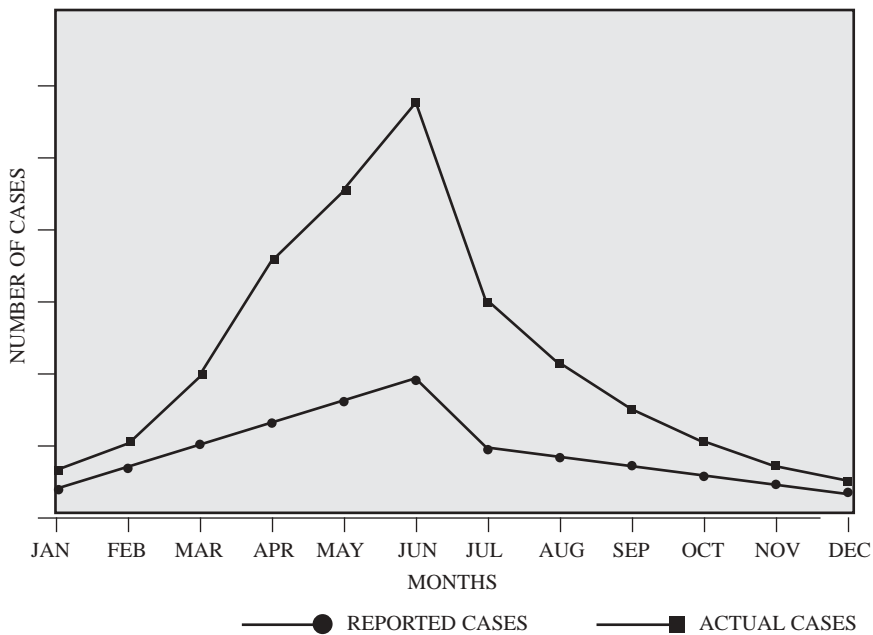
**Which strategy or strategies would you choose?**

1. The city of Oliveland has 20,000 inhabitants and an OPV coverage of 63%. The health service detects warning signs of a possible outbreak of measles.

**Annex 1 (cont'd.)**

2. A country with a population of 15,000 inhabitants, of which 12,000 live in rural areas, has an urban coverage level of 70% and a rural coverage level of 30%. The health service decides to increase the coverage levels.
3. A case of acute flaccid paralysis (AFP) has occurred in Ciropolis, which has 20,000 inhabitants. The coverage level for 3 doses of OPV is 90%. What would you do?
4. A population of 1,300 inhabitants lives in a hard-to-reach area without a health service. The closest health service is 50 km. away. What would you do?

**Annex 2: Figure 1**  
**Difference between reported and actual cases of measles**



Source: Expanded Program on Immunization (EPI), Special Program on Vaccines and Immunization, Pan American Health Organization, Washington, D.C.

**Annex 3: Table 1**  
**Key Facts about Morbidity and Mortality**  
**from the Diseases Targeted by the EPI**

<b>• Paralytic poliomyelitis</b>	In outbreaks, around 70% of cases occur among children under the age of 2 years.
<b>• Measles</b>	30% or more of fatal cases occur during the first year of life.
<b>• Neonatal tetanus</b>	Attacks children during the first month of life, where predisposing causes for its occurrence exist. Mothers should be vaccinated prior to delivery in order to prevent the disease.
<b>• Pertussis</b>	Case fatality and mortality are generally highest during the first 3-6 months of life.
<b>• Diphtheria</b>	The only disease included in the EPI for which morbidity and mortality are low in the first year of life.
<b>• Tuberculosis</b>	Morbidity and mortality from tuberculous meningitis are high during the first years of life.

Source: Expanded Program on Immunization (EPI), Special Program on Vaccines and Immunization, Pan American Health Organization, Washington, D.C.

**Annex 4: Table 2**  
**Estimated Rates of Adverse Events following Immunization**

VACCINE	ADVERSE EVENT	OCCURENCE/ 100,000 CASES OF DISEASE	OCCURENCE/ 100,000 DOSES OF VACCINE
DPT (Pertussiss)	• Permanent brain damage	600-2,000	0.2-0.6
	• Death	100-4,000	0.2
	• Encephalopathy/ • Encephalitis and • Convulsions	600-8,000	0.3-90
	• Shock	—	0.5-30
Measles	• Encephalopathy • Encephalitis	50-400	0.1
	• Subacute sclerosing panencephalitis	0.5-2.0	0.05-0.1
	• Pneumonia	3,800-7,300	—
	• Convulsions	500-1,000	0.02-190
	• Death	10-10,000	0.02-0.3
BCG	• Disseminated BCG infection		< 0.1
	• Suppurative lymphadenitis		100-4.300 (< 2 years)
	• Osteitis • Osteomyelitis		< 0.1-30

Source: Expanded Program on Immunization (EPI), Special Program on Vaccines and Immunization, Pan American Health Orgaization, Washington, D.C.

**Annex 5: Table 3**  
**Minimum Immunization Schedule**

VACCINE	AGE AT WHICH VACCINATION SHOULD BEGIN	DOSE	ROUTE AND SITE OF VACCINATION	MINIMUM INTERVAL BETWEEN DOSES
BCG	Newborn	1	ID** in the shoulder or arm	
DPT (triple)	6 Weeks	3	IM**, preferably in the thigh	4 weeks
OPV*	At birth	1	Oral	4 weeks
	At 6 weeks	3		
Measles	12 months	1	SC** in the left arm	

\* Administer additional doses of OPV to all children during national vaccination days and mop-up operations

\*\* ID = intradermal

IM = intramuscular

SC = subcutaneous

**NOTE:**

- In cases in which this immunization schedule has not been completed at the correct intervals, the first or second dose should not be repeated; rather, the subsequent doses should be given until immunization of the child is complete.

Source: Expanded Program on Immunization (EPI), Special Program on Vaccines and Immunization, Pan American Health Organization, Washington, D.C.

**Annex 6: Table 4  
Immunization Schedule for Women of Childbearing Age**

VACCINE	AGE	DOSE	MINIMUM INTERVAL BETWEEN DOSES	% PROTECTION	DURATION OF IMMUNITY
Tetanus toxoid	12 to 49 years	2	4 weeks	80	3 years
		3	6 months	95	5 years
		4	1 year	99	10 years
		5	1 year	99	Reproductive lifetime of the woman

**NOTE:**

- In places in which cases of neonatal tetanus occur, all women of childbearing age should be vaccinated. All children under 5 years of age and all women of childbearing age who have not been fully immunized should also be vaccinated when they are seen in health services, hospital admissions services, hospital emergency rooms, and health centers, or when they are hospitalized.

Source: Expanded Program on Immunization (EPI), Special Program on Vaccines and Immunization, Pan American Health Organization, Washington, D.C.