

PRODUCTION OF VACCINES FOR THE PREVENTION OF ARI: A REGIONAL OUTLOOK

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I. INTRODUCTION

The spectacular victory achieved by public health with the eradication of smallpox worldwide and of wild poliovirus in the Western hemisphere (1) has had enormous impact on preventive medicine. These accomplishments have demonstrated that vaccines are basic tools for the prevention of vaccine-preventable diseases and that vaccination constitutes one of the most cost-effective health interventions (2).

In recent years, with the strengthening of immunization programs in the countries of Latin America and the Caribbean, equally spectacular results have been registered, such as the elimination of measles achieved by the Expanded Program on Immunization (EPI) of the Pan American Health Organization (PAHO) (3). At the same time, non-selective vaccine campaigns have been carried out among children from 9 months to 14 years of age, resulting in coverage of the majority of the susceptible population. This strategy was initiated in Cuba, continued in the English-speaking Caribbean, and later extended to all the countries of Latin America.

Recent data show a sharp decline in the number of measles cases. In some countries, no cases have been reported for a prolonged period, which may indicate that the chain of virus transmission has been interrupted. To maintain this situation and eliminate measles from the Western Hemisphere, it is proposed that two basic activities be strengthened. The first is epidemiological surveillance through the network of laboratories and the use of advanced technologies for serological and virological tests. The second is periodic mass vaccination of certain age groups of children (generally children under 5), chosen on the basis of data on the epidemiological situation of measles in each country (4).

During the last 15 years, the Region of the Americas has seen a notable increase in immunization coverage against all diseases covered by EPI, with substantial decreases in mortality and morbidity from these diseases.

Morbidity from other vaccine-preventable diseases associated with upper respiratory infections (ARI) in 1980 and 1994 were 20.68 and 2.58, respectively, per 100,000 population for whooping cough; 0.98 and 0.11 for diphtheria; and 66.61 and 3.12 for measles (5). The impact of vaccination efforts can be clearly seen in Figures 1, 2, and 3, which show data from various countries of the Region obtained through the Special Program on Vaccines and Immunization (SVI) of PAHO.

Figure 1 shows the annual number of reported measles cases and immunization coverage from 1960 to 1994. Figures 2 and 3 show the annual number of reported cases of whooping cough and diphtheria, respectively, with immunization coverage among children under 1 year of age from 1978 to 1994.

High coverage levels were also achieved for BCG, which is administered to newborns in the region and is well known for its importance in the prevention of tubercular meningitis (6).

In addition to the vaccines routinely used in immunization programs, there are other important vaccines that provide protection against the etiologic agents of diseases associated with ARI. The major ones are the vaccine against *Streptococcus pneumoniae* with its 23 serotypes, which is recommended for the elderly and immunocompromised persons (7); the conjugate vaccine against *Haemophilus influenzae* type b (Hib) (8), which has recently been incorporated into the routine vaccination program in the United States; the vaccine against influenza virus, prepared with inactivated whole virus or subunits of the virus (9), which is used especially in countries with temperate or cold climates; the rubella vaccine, given in combination with the measles and mumps vaccine; the polysaccharide vaccine against *Neisseria meningitidis* serogroups A, C, W135, and Y, which is recommended for travelers in epidemic or hyperendemic areas, or in case of outbreaks or epidemics (10).

The Finlay Institute of Cuba has developed a vaccine against meningococcal meningitis serogroup BC, which has been shown to be 75 to 85% effective in children over the age of 4 but less effective in children under 4 (11, 12).

Acellular pertussis vaccine has been used routinely since 1981 among children over 18 months in Japan (13). This vaccine has also been approved for use in the United States, but only for boosters. The results of clinical studies currently under way will decide the future of this vaccine.

An important trend in vaccine development is the use of new combined vaccines, such as the DPT vaccine combined with conjugate Hib, which has been approved in the United States (14). The combination of several antigens in a single vaccine facilitates the immunization operation, since it reduces the number of vaccine injections and consequently reduces the operating costs associated with vaccination.

Figure 1. Number of reported cases of measles and coverage of measles vaccination among children under the age of 1. Countries of the Americas, 1978-1994

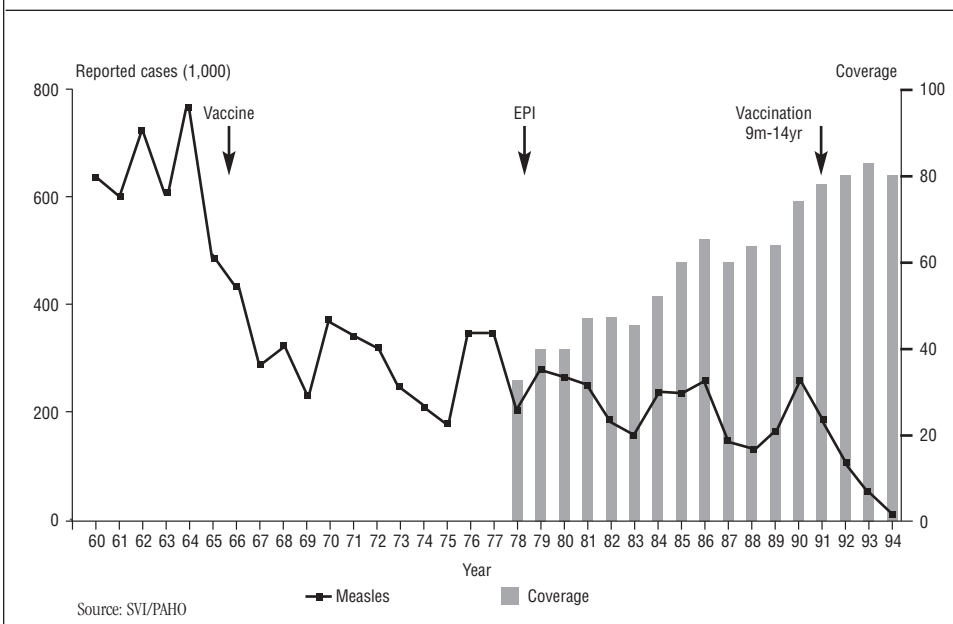


Figure 2. Number of reported cases of whooping cough and coverage with three doses of DPT among children under the age of 1. Countries of the Americas, 1978-1994

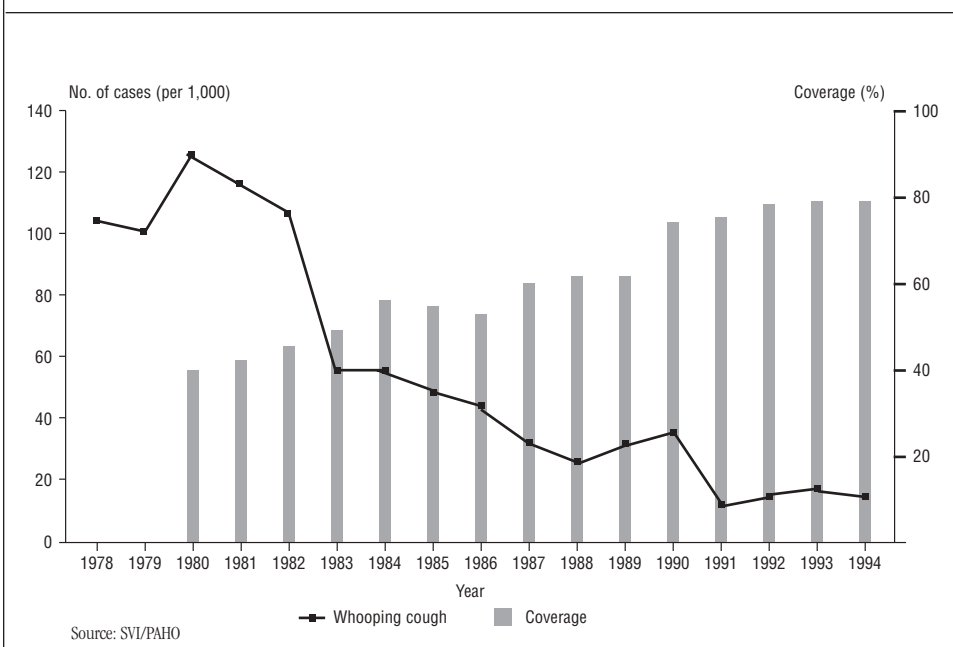
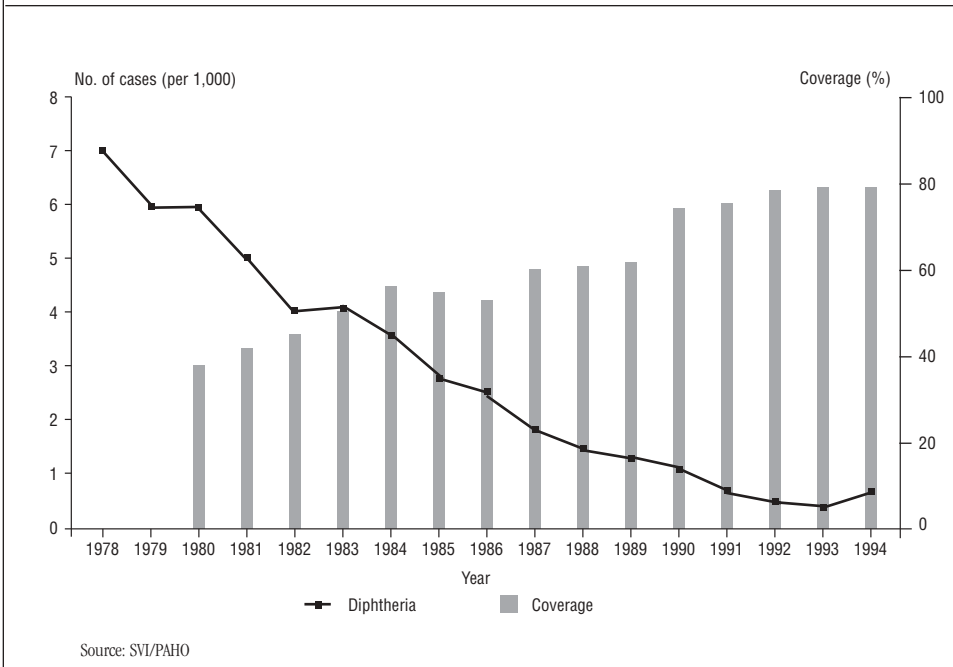


Figure 3. Number of reported cases of diphtheria and coverage with three doses of DPT among children under the age of 1. Countries of the Americas, 1978-1994



II. VACCINE RESEARCH AND TECHNOLOGICAL DEVELOPMENT

Work in this area has focused on both enhancing existing vaccines and developing new ones. In the first case, one example is the significant improvement achieved in recent years in the heat stability of the measles vaccine. As a result, most of the vaccines currently on the international market will maintain their potency and immunogenic capacity even when they are subjected to improper storage temperatures. The accelerated heat-stability test, in which the vaccine is subjected to a temperature of 37° C for 7 days, has been included in the quality control of these vaccines to ensure their heat stability (15). Other studies have examined the use of vaccines with high virus titers (10-100 times higher than the titers of routine vaccines of the Edmonston-Zagreb and Schwarz strains) to overcome maternal immunity in children 6 months of age, but the results were not favorable, given the high mortality that occurred among children inoculated with this type of vaccine (16).

Studies aimed at the development of new measles vaccines have focused on the use of recombinant viruses as vectors, including vaccinia, fowlpox, and baculovirus, which express the structural proteins H (hemagglutinin) and F (fusion) of the measles virus (17, 18, 19), in addition to the development of genetically attenuated strains. The protection provided by experimental vaccines made from viral glycoprotein incorporated into immunostimulating complex-

es (ISCOMs) (20) has been demonstrated in laboratory animals. Given the importance of this disease and the new knowledge acquired about the pathology and about the measles virus, both measles control and immunization practices have recently received extensive review and discussion in the context of the Children's Vaccine Initiative (CVI) (21, 22).

The acellular pertussis vaccine has received special attention in the last few years. Efficacy studies on the new formulations of this vaccine have recently been completed in Sweden and Italy. The results of these studies, which involved children aged 2, 4, and 6 months, were made public simultaneously in July 1995 by the National Institute of Allergy and Infectious Diseases of the United States, the Institute of Infectious Disease Control of Sweden, and the National Institute of Health of Italy. The efficacy study was a random, double-blind study of four acellular vaccines, using a placebo. Three acellular pertussis vaccines yielded 84-85% protection and produced a significantly lower number of adverse side effects than the vaccine made of inactivated whole *Bordetella pertussis* cells. A fourth acellular vaccine provided 58% protection. In recent efficacy studies in Italy, Germany, Sweden, and Senegal, the acellular vaccine provided protection similar to that obtained with the inactivated whole-cell vaccine. The acellular pertussis vaccines all contained inactivated pertussis toxin. Other components included agglutinogens, filamentous hemagglutinin, and pertactin or protein 69kD, an outer-membrane protein (23-27).

Despite these advances, the existence of more than a hundred viral and bacterial agents that may cause ARI hinders the development of a specific vaccine for each etiologic agent of the various illnesses classified as ARI. Some of these agents have numerous serotypes, including *S. pneumoniae*, with 84; parainfluenza virus, with 4; *H. influenzae*, with 6 serotypes, including type b and the nontypeable strains; streptococcus, classified in groups A to O depending on the chemical composition of the specific antigen/group, which in turn is classified in types ranging from 1 to 80 according to the antigenic differences in the outermost membrane of the bacteria (28).

Theoretically, it would be necessary to develop a specific vaccine for each of the types and subtypes to provide total immunological protection. Nevertheless, in practice there is no interest in developing vaccines against all the infectious agents that may cause IRA; rather, vaccine development efforts focus on the agents that cause the greatest morbidity and mortality.

With regard to *S. pneumoniae*, it is important to note that the existing vaccine, which contains polysaccharides of 23 serotypes, is recommended for adults, but it does not protect children under the age of 2—the age at which pneumococcal pneumonia is most critical. The selection of the serotypes was made taking into account the results of epidemiologic studies conducted in the United States and several countries in Africa. The most important serotypes affecting children tend to be different from those that affect adults. Hence, it can be inferred that it is not known with certainty whether the most important serotypes for Latin America are present in the existing vaccine or whether other serotypes should be included in any vaccine to be used in the region.

PAHO, through the Special Program on Vaccines and Immunization (SVI) and with the support of the Canadian International Development Agency (CIDA), is conducting a study to determine the distribution of the *S. pneumoniae* serotypes that cause pneumonia in children under age 5 in six countries of Latin America (Argentina, Brazil, Chile, Colombia, Mexico, and

Uruguay). Only partial information is available at present, but by late 1995 it is expected that results will be available that will facilitate identification of the most important serotypes with a view to formulating a vaccine against *S. pneumoniae* in the countries of the region.

As with other polysaccharide vaccines, these antigens are not capable of inducing an immune response in children under the age of 2. This lack of response is probably due to the fact that these polysaccharides are T-independent antigens and they therefore do not use the helper T lymphocytes to stimulate the immature B cells (29). In recent years, an alternative technology has been used to convert these T-independent antigens into T-dependent antigens. Covalent conjugation of a polysaccharide with a carrier protein—as was done in the case of the capsular polysaccharide of *H. influenzae* type b with various proteins—has produced very effective and useful vaccines for children under 2 (30, 31).

A series of proteins, such as tetanus toxoid (32), diphtheria toxoid, diphtheria protein CRM₁₉₇ (cross-reacting mutant 197 of *Corynebacterium diphtheriae*) (33), and the outer-membrane protein complex of *Neisseria meningitidis* group B (OMP) (34) have been used as carrier proteins to conjugate the polysaccharide of *H. influenzae* type b. This same principle is being applied by various research groups to produce vaccines against *S. pneumoniae* (35, 36).

The particular difficulty of developing a conjugate vaccine in the case of *S. pneumoniae* is that it is not simply a matter of preparing a single serotype. The formulations of this vaccine must include multiple serotypes, including at least 70-80% of the serotypes responsible for invasive *S. pneumoniae* illnesses. For example, two proposed formulations would include serotypes A4, 6, 9, 14, 18C, 19F, and 23F and B1, 5, 6, 14, 18C, 19F, and 23F. On the basis of the preliminary results of the study of distribution of *S. pneumoniae* serotypes in the region, the A formulation would cover 50% of the serotypes and the B, 70%.

Although the intent is to produce a single-dose vaccine, several polysaccharide-protein conjugates—that is, several individual vaccines—must be prepared, produced, and tested. Because the production of polysaccharide-protein conjugates is complicated, these vaccines are expected to be expensive. Moreover, a number of scientific and technical issues must be addressed, including the number of polysaccharide-protein conjugates that can be combined using the same carrier protein, problems of interference between the different antigens, dosage, and the immunization schedule.

The need to include several serotypes in a conjugate vaccine against *S. pneumoniae* has led to the search for other options. In recent years, several investigators have worked with common antigens, i.e., identical or similar antigens, present in all the pneumococcal serotypes. The use of these antigens would make it possible to confer broader protection. In the case of proteins, recombinant methods could also be used to obtain them in larger quantities, and because of their T-dependent nature they would confer protection at an early age. The results thus far obtained in animals with three antigens, in particular—namely, PspA (surface protein A) (37), pneumolysin (38), and pneumococcal protein 37kD (39)—are very promising.

The Jordan Report (40) describes studies being carried out for the development of other vaccines such as, for example, vaccines against groups A and B streptococcus, *Mycoplasma pneu-*

moniae, *Pseudomonas aeruginosa*, and the development of a new strain for immunization against tuberculosis, the *Mycobacteriae vaccae* strain, the inactivated form of which is being studied for use as an adjuvant to BCG or as a candidate vaccine. In field studies conducted in Romania, one dose of the *M. vaccae* strain, in combination with chemotherapy, was also shown to be quite effective in treating patients with drug-resistant tuberculosis.

Significant advances have been made in the development of a vaccine against group B streptococcus, of which 6 serotypes corresponding to 6 different polysaccharides have been identified. In children, the group most affected by this disease, these polysaccharides are not immunogenic. Consequently, the vaccine should be administered to women during pregnancy, or an effective vaccine for children should be developed. Studies aimed at conjugating the polysaccharides with a protein, as in the case of the Hib conjugate vaccine, are currently under way (41, 42).

The strategy for development of a vaccine against parainfluenza virus (with 4 serotypes) comprises two approaches. In one, purified outer-membrane protein, glycoprotein F (fusion), H (hemagglutinin), and N (neuraminidase) are used as immunogens. The second approach seeks to attenuate the viral strain, and clinical studies of several currently available candidate vaccines are aimed at carrying out this process. One of the strains under study is derived from a bovine virus and the others are attenuated strains, on which the technique of virus adaptation through cell cultures in successive stages at low temperatures is used.

The first vaccines developed against respiratory syncytial virus (RSV) in the 1960s, using formalin-killed RSV, caused major adverse reactions (43). Several of the viral components, such as the purified viral glycoproteins F (fusion) and G (adhesion), are currently being studied and have shown immunogenic capacity in animal models.

Influenza vaccine exists in an inactivated form and an attenuated virus form. The inactivated vaccine may be made from formalin-killed whole virus or from disassembled virus. In the United States only inactivated vaccines are used, whereas in Europe, especially Russia, live attenuated virus vaccines are used. However, existing vaccines produce only short-term immunity, and frequent changes in the antigenicity of the virus mean that vaccination must be repeated each year with the strains indicated by the World Health Organization (WHO). The antigenic variations (antigenic drift and, less frequently, antigenic shift) of influenza virus type A (which has three subtypes), type B, and type C mean that an annual review must be undertaken to determine the composition of the virus strain to be used in the vaccine for the next influenza season. In 1995-1996, the recommended vaccine strains are A/Johannesburg/33/94 (H3N2), A/Singapore/6/86 (H1N1), and B/Beijing/184/93 (44).

Several groups are working on the development of a more potent influenza vaccine (45). Some are seeking to develop attenuated virus strains adapted through culture in successive stages at low temperatures (46). Other techniques currently in use are based on methods of molecular biology and genetic engineering. Viral genes have been inserted into bacteria or yeasts to produce peptides with the amino acid sequence of the specific epitopes (i.e., recognized sites of an antigen) of the virus, which can be purified for use as vaccines (47-49).

Genetic engineering technology and biotechnology are being used in the development of new vaccines and in the enhancement of existing vaccines (50). In addition, enormous advances in the basic sciences such as biochemistry, chemistry, immunology, and molecular biology have yielded a tremendous body of new knowledge, especially in recent decades. This, in turn, has resulted in better understanding of the biology of etiologic agents and host immune response at the molecular level.

Utilizing this new knowledge and modern techniques, investigators are exploring several different ways of enhancing the quality of existing vaccines and developing new forms of combined vaccines with a greater variety of protective antigens. Numerous groups are working on the development of vaccines made from synthetic peptides (51) as a logical extension of studies conducted to identify the sites on microorganisms responsible for the induction of protective immune response (epitopes). Determination of the amino acid sequence of the epitopes makes it possible to produce these segments of the protein molecule in synthetic form for use in the production of the vaccine.

Mastery of the technology of molecular-level manipulation has enabled investigators to design and construct antigens of such genetic stability that reversion to their prior virulence is practically impossible (52). Studies are also examining the possibilities for using viruses as vectors of other genes of interest by inserting one or several genes of other infectious agents in the non-essential region of the viral genome, which results in the development of immune response and also provides additional protection against the genes inserted in the genome of the vector (53).

Advances in molecular biology and genetic engineering are increasingly being reflected in the development of new immunization forms such as genetic vaccines. It was recently demonstrated that, when inoculated intramuscularly in mice, the hemagglutinin genes of influenza virus inserted in plasmids produce antibodies against the hemagglutinin and protect against the lethal "antigenic challenge" using homologous virus, but they do not protect against the challenge of the heterologous virus. However, when the gene of the nucleoprotein of the influenza virus is inoculated, protection is obtained against both the homologous and heterologous virus challenge (54). Preliminary observations indicate that if the right gene is used, this method may offer an enormous advantage over other vaccines, given its ability to protect, with a single dose, against several subtypes or serotypes of the infectious agent of a given disease.

Another notable advantage of genetic vaccines is their ability to induce longer-term and more effective cell-mediated immunity through the process of synthesis and assembly of the antigens that develop intracellularly in the region in which the class I molecules of the major histocompatibility complex (MHC) are coded, resulting in stimulation of the cytotoxic T cells and development of cellular immunity. At the same time, viral or bacterial antigens injected in the tissues synthesize and assemble with the class II MHC molecules, stimulating primarily the helper T cells and humoral immunity.

With regard to DNA vaccines, the principal obstacles to their development are regulatory authorities, who require extensive documentation and guarantees that the genetic material

injected into the muscle is transient and will not be incorporated into the genes of somatic cells, which could have unforeseen consequences.

Another new method utilizes transgenic plants as a system for the production of antigens and immunogenic proteins. Many groups of investigators are conducting research in this area and have presented results suggesting that it is possible to use genetically treated plants and plant viruses to produce vaccines against human diseases such as cholera, typhoid fever, hepatitis B, and AIDS, among others (55-57). Someday, it is believed that it will be possible to include some vaccines in plants that are consumed as part of a normal diet. Although research in this area is still in the earliest stages, production of vaccines in plants for human use could offer significant advantages over current methods of vaccine production, given the potential for increasing output and thereby reducing the costs associated with the production process. In addition to vaccines, it is also feasible to produce monoclonal antibodies in genetically treated plants (58).

With some rare exceptions, these studies have been conducted in the industrialized countries in accordance with the priorities assigned within their spectrum of needs. Thus, for the foreseeable future the countries of Latin America and the Caribbean will continue to be passive recipients of products developed and produced in technologically advanced countries.

Investment in the industrialized countries in vaccine research, technological development, and production, both by private laboratories and by the public sector, is enormous. In the United States, the public sector alone invests US\$250 million, while the private sector spends close to US\$100 million on such activities (59). The Program for Accelerated Vaccine Development within the National Institute of Allergy and Infectious Diseases in the United States coordinates these activities.

Few international agencies support vaccine development programs. The Rockefeller Foundation is one of the nongovernmental institutions that contribute in this area. For many years, often in conjunction with developing countries, this foundation has supported the development of vaccines such as the yellow fever vaccine. Currently, together with the Armand Frappier Institute of Canada, the Veterinary Laboratory of Colombia (VECOL), and the National Institute of Health of Colombia, it is providing support for the development of a rabies vaccine in a high-density cell culture system.

The Special Program for Research and Training in Tropical Diseases (TDR) (60), the Program on Control of Diarrheal Diseases (CDD) (61), and the Global Program for Vaccines (GPV) (62), all WHO programs, and the Special Program on Vaccines and Immunization (SVI) of PAHO are among the few sources of support at the international level for vaccine development activities.

The World Summit for Children and the Declaration adopted in New York in September 1990 (21) led to the Children's Vaccine Initiative, which is cosponsored by WHO, the United Nations Children's Fund (UNICEF), the Rockefeller Foundation, and the United Nations Development Program (UNDP). The Summit recognized that millions of children die each year from diseases that could be prevented. To prevent these deaths, however, it is necessary to broaden the spec-

trum of diseases for which vaccines are available, simplify the requirements governing vaccine supply, and reduce the costs of vaccination.

Achieving the higher objective of universal immunization will require the establishment of mechanisms for making rapid use of the latest scientific knowledge in the development of new and better vaccines, which will benefit children in all countries. The ideal vaccine would have the following characteristics:

- it would require a single application or two applications rather than multiple doses;
- it would be administered in early childhood;
- it could be combined in new forms, different from those that currently exist, thereby reducing the need for numerous injections and visits to health care practitioners;
- it would be heat-stable, retaining its potency during transport and storage, particularly in tropical climates;
- it would be effective against a variety of diseases that are not currently covered by immunization programs but are serious public health problems, such as AIDS, acute respiratory infections, diarrheal diseases, and important parasitic diseases; and
- it would be affordable.

The Children's Vaccine Initiative represents a major landmark in the prevention of communicable diseases. To achieve its goals will require substantial investments of money, time, and many types of efforts on the part of the scientific and technological community throughout the world.

The bulk of the capacity to participate in this scientific and technological "revolution" is located in the developed world, where existing laboratories are in a better position to direct their attention toward this effort. It is necessary to strengthen the scientific and technological capabilities of the developing countries so that they can participate actively in the process of vaccine development, instead of remaining passive beneficiaries of the external production of these biologicals.

In response to this need and at the request of several of its member countries, several years ago PAHO began to organize a regional program for the development and production of vaccines, taking advantage of the existence of several centers of scientific and technological excellence in the region. The centerpiece of this effort is technical cooperation among countries and the implementation of multicenter projects for research and development of vaccines that are important for the region.

In 1994 the Pan American Sanitary Conference formally approved the Regional System of Vaccines (SIREVA) (63), and since March 1995 it has been part of the Special Program on Vaccines and Immunization (SVI), together with the PAHO/WHO Expanded Program on Immunization.

III. VACCINE PRODUCTION

Because immunization programs in most countries of the region depend heavily on imported basic vaccines, they are highly vulnerable to fluctuations in the market and the international political situation. It is therefore important to give due attention to vaccine production and try to strengthen laboratories in the region in order to increase the number of vaccine-producing laboratories, diversify sources, and maintain a continuous supply of the essential vaccines for immunization programs in several countries. In light of these concerns, the last part of this chapter will briefly examine some of the problems involved in vaccine production.

The major vaccine-producing laboratories are located in the developed countries. Many of these laboratories also engage in drug production, a far more profitable activity. Vaccine production in these laboratories is organized so as to permit a return on investments and generation of sufficient funds to continue research and development of new vaccines.

With the advent of biotechnology, hundreds of small laboratories have appeared. They are almost always organized by investigators who have knowledge of technology, and they are established to exploit this technology. However, the majority of these small enterprises concentrate on the development of products for laboratories or for therapeutic use, such as monoclonal antibodies or laboratory diagnostic kits, because less time is required to develop and market these products.

In recent years, an important market phenomenon has been observed in vaccine production, namely, the trend toward oligopoly, with the vaccine market dominated by a few laboratories, most of them transnationals. The most direct and visible causes of this phenomenon are the increase in production costs associated with greater technological complexity and the need for large investments in plant, equipment, and human resources to meet technical requirements such as the so-called Good Manufacturing Practices (64) established by regulatory authorities. In the United States, the high cost of insurance, due to payment of damages to consumers who suffer adverse reactions to a vaccine, is another reason for the high price of vaccines in the U.S. market.

The size of the investment needed for the incorporation of new technologies and the development of any new vaccine poses a problem for laboratories that engage solely in vaccine production activities and do not have large amounts of capital. For example, to develop the recombinant hepatitis B vaccine, a European laboratory invested some US\$60 million and over 6 years of effort. This vaccine is protected by 14 patents, which are held by several different institutions. Such circumstances have obliged international laboratories to strengthen their strategies through market globalization and at the same time to seek to boost profits and productivity. For these laboratories, producing economical lots of vaccine and ensuring medium- and long-term market share are essential to the continuity of their activities.

IV. REGIONAL PRODUCTION

Very few private laboratories in the region produce vaccines for human use. Those that do are generally small and have little market impact. There are several reasons for the absence of large private laboratories in the region, including:

- Immunization programs are generally organized and implemented by governments and, since vaccination coverage is very high, private market demand for vaccines is minimal in the majority of countries.
- Governments are also responsible for the procurement of all vaccines for their respective national immunization programs. Procurement is done through a competitive bidding process, which is always extremely time-consuming. In addition, the selection process favors the laboratory that submits the lowest bid.
- Both the United Nations Children's Fund (UNICEF) and the PAHO Revolving Fund for Vaccine Procurement¹ promote bidding on large volumes of vaccines to meet the needs of groups of several countries. This makes supplying the vaccines very attractive to producing laboratories, which can schedule delivery of the vaccine far in advance at very low prices.

In addition, private laboratories obtain their earnings by selling in private markets in developed countries, and they offer their production surpluses to programs such as UNICEF and the PAHO Revolving Fund at marginal cost.

Generally speaking, in the region there are few competitive vaccine-producing laboratories. Most are state-run or public, and they almost always have a limited production line, aimed solely at satisfying spontaneous demand in their own countries. They do not generally seek to expand their markets. Moreover, their structure and form of organization do not allow the flexibility and responsiveness necessary for appropriate management of productive activities.

These laboratories produce some of the vaccines used for the prevention of diseases associated with ARI, such as whooping cough and diphtheria, which are combined with tetanus toxoid to form the DPT vaccine. Only two laboratories produce measles vaccine (Table 1).

Current production is not sufficient to meet the needs of the existing market in the region. In addition, there are technical problems such as obsolescence of methodologies, processes, and production equipment, which lead to low productivity and deficient quality in the vaccines of some producers. In general, the production facilities of these laboratories do not fulfill the requirements of the Good Manufacturing Practices.

Most of these laboratories have adapted facilities, and the flow of work is therefore not always optimal. They adopt classic production methodologies in a static culture, which is an enormous constraint on their production volume. Owing to numerous economic difficulties, they do not

¹ An administrative mechanism established in 1979 that consolidates the countries' vaccine requirements for their immunization programs to obtain, through negotiation with various laboratories, high-quality vaccines at low cost.

Table 1. Production of DPT and measles vaccine in countries of the Region (number of doses x 1,000 for the year 1994)

Country	DPT	Measles
Mexico (1)	9,500	12,000
Brazil (2)	5,000	15,000
Chile	2,400	000
Venezuela	4,000	000
Colombia	2,600	000
Cuba (3)	000	***
Argentina (4)	***	000
Uruguay	160	000
Ecuador	750	000

*** Production suspended or no information available.
000 Not produced.

(1) In the process of modernizing and expanding production facilities.
(2) The national self-sufficiency program is making large investments in three institutions. Once completed, the country will have the capacity to produce 40 million doses of DPT vaccine per year.
(3) New facilities with a large capacity for production of bacterial and viral vaccines are being completed.
(4) All bacterial vaccine production facilities are currently being modernized.

have appropriate equipment or facilities and are therefore limited to the production of very small lots. They generally do not perform cost-benefit studies to encourage cheaper production. Only a few conduct research and development activities on a regular basis. This situation hinders any programs aimed at modernizing and implementing new technologies. Nevertheless, some laboratories develop and maintain continuous production of vaccines for years, which shows that there are human resources sufficiently trained in production techniques, who are capable of responding to and meeting demand when adequate support is forthcoming.

In Mexico, the General Bureau of Biologicals and Reagents has modernized its facilities and equipment and is in the process of expanding its production of vaccines. This entity, through its two institutions, the National Institute of Public Health and the National Institute of Virology, is the only one in Latin America that produces all the vaccines included in the Expanded Program on Immunization (EPI). In Brazil, through a Ministry of Health program aimed at achieving self-sufficiency in immunobiologicals, sizable investments are being made in new facilities for the production of DPT vaccines in three different laboratories (Butantán Institute, Bio-Manguinhos/Oswaldo Cruz Foundation, and Technology Institute of Paraná/TECPAR), which are estimated to have a total potential production capacity of over 120 million doses of DPT vaccine a year. The Public Health Institute of Chile is a traditional producer of DPT vaccine and

totally satisfies national demand for this vaccine. The Rafael Rangel National Health Institute in Venezuela has also modernized its facilities, and both the Malbrán Institute in Argentina and the National Institute of Public Health in Colombia are engaged in an enormous effort to reestablish production activities to meet national requirements. Cuba is the country that has invested most heavily in the areas of research and development of immunobiologicals, biotechnology, and vaccine production.

Considering the importance of immunization activities, which in recent years have become essential to the implementation of programs for the control and eradication of vaccine-preventable diseases, it is also necessary to adopt policies oriented toward strengthening vaccine development and production activities to satisfy the demand for essential vaccines for national immunization programs in the Region and avoid total dependence on imported vaccines, which weakens and limits disease control policies. Some strategic considerations that should be borne in mind here include:

- Modern vaccines need to be more technologically complex, more potent, and less prone to cause adverse reactions, and they should produce immunity with one or two doses. They will also have to be combined with many antigens and have fewer adverse side effects. However, with these characteristics, new vaccines are likely to be much more expensive than current vaccines and their high cost will therefore make their use prohibitive in our countries.
- Those who are most interested in the development and production of vaccines against the diseases prevalent in the Region should be the countries of the Region themselves.
- Productive activity should go hand in hand with technological development to permit the most appropriate use of technology. If production is not linked to a program of research and technological development, it will soon become obsolete.
- It is necessary to formulate medium- and long-term policies that will provide a logical and dynamic approach to production activities, from aspects relating to organization, administrative structure, and technological development to quality control and management of all these activities. As part of this development, it is imperative to strengthen national quality control systems (65) to ensure the quality of local production.

In some countries of the region, important progress has been made in the development of new vaccines, including the rabies vaccine developed by Fuenzalida and Palacios (66); the more recent vaccine against *Neisseria meningitidis* serogroups B and C developed by C. Campa and associates (11); the vaccine against hepatitis B developed by M. Limonta and associates using recombinant DNA technology (67) (the latter two groups from Cuba); and the malaria vaccine developed by M.E. Patarroyo and associates from Colombia (68), which is in the final phase of development.

Notwithstanding these significant achievements in the region, it should be emphasized that all the other vaccines have originated in developed countries, and it is expected that very soon improved, more technologically complex vaccines will be available on the international market.

This situation points to the need to strengthen technical cooperation among countries in the region to develop and enhance vaccines by using new technologies. The PAHO initiative creating the Regional System of Vaccines by (SIREVA) and its incorporation into the Special Program on Vaccines and Immunization (SVI) is intended to respond to this need.

The system seeks to strengthen a network of affiliated institutions, which coordinate activities for the development and improvement of vaccines. The system incorporates an innovative approach that integrates all activities related to vaccine development, including research and epidemiological surveillance, basic and applied research, technological development, scale of production, quality control, and clinical and field trials.

V. CONCLUSION

The spectacular victory for humanity achieved with the eradication of smallpox in the 1970s, the success of the wild poliovirus eradication program in 1994, and the anticipated elimination of measles in the near future have spurred government authorities in various countries to strengthen vaccination programs.

PAHO, WHO, UNDP, and UNICEF are also endeavoring to motivate funding organizations and member governments to make large-scale investments in projects for research and development of more potent and effective vaccines that will cause fewer adverse reactions.

This problem will probably confront two different worlds: one will have the capacity to progress toward generation of the scientific knowledge required to address problems through technological means, while the other will be increasingly prevented from finding solutions due to its limited capacity to generate local expertise and its dependence on products developed in other countries for purposes other than protection of children in countries in which ARIs are endemic.

With the current availability of vaccines against some of the etiologic agents of ARI (for example, *H. influenzae* type b, *S. pneumoniae*, and acellular *B. pertussis*) and the expected availability of others in the near future, governments will be under pressure to include these vaccines in immunization programs. Unfortunately, high costs will significantly limit their use and may even threaten the functioning of programs, unless the governments of the region take part in the initiative and promote the development and production of these new vaccines.

The Special Program on Vaccines and Immunization (SVI), through SIREVA, expressly seeks support to accelerate scientific and technological development as part of its commitment to guide and direct regional and national approaches aimed at the production of vaccines for the prevention and control of diseases preventable through immunization in the Region of the Americas. This commitment is offered as a response to an increasingly difficult challenge: helping the countries of a developing region to progress in the scientific and technological fields to ensure their access to the benefits of modern science in the prevention and control of diseases. The system also proposes to attract the collaboration of the developed countries to consolidate and strengthen institutions in the Region for the joint achievement of substantial improvements in conditions in the Americas that cannot be achieved by the individual countries.

The international donor community must be mobilized to commit the necessary resources and to support the development of the system over the next 10 years, but especially in the initial phase. The proposed goals are feasible from the scientific, economic, administrative, and political standpoints. The value of the investment is indisputable; what remains to be seen is whether the will to carry out the necessary actions exists.

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VII. APPENDICES

Table 1. Explanatory model for Quwari

DISEASE	SEVERITY	SYMPTOMS	CAUSES	TREATMENT
<i>RAMARISU</i>	mild	<ul style="list-style-type: none"> • <i>acbbis accbis ninbku</i> • <i>singanmanta qbyña mana sijetanchu</i> • <i>k'ajan</i> • <i>mana valorcitur kanchu</i> 	cold or catarrh contagion	herbal teas rubs baths pills
<i>PESTE</i>	mild/intermediate	<ul style="list-style-type: none"> • <i>k'ajan</i> • <i>rumarisu</i> • <i>kusiyanku</i> • <i>kunkitan k'aran</i> 	relapse carelessness	herbal teas rubs baths
<i>K'AJA UNQUY</i>	mild/intermediate	<ul style="list-style-type: none"> • <i>simisitun cb'akin</i> • <i>k'ajan</i> • <i>caloruan kanku</i> • <i>ansaqin</i> 	colds carelessness	herbal teas baths poultices fomentations
<i>CH'UJU UNQUY</i>	intermediate/severe	<ul style="list-style-type: none"> • <i>kunkitan k'aran</i> • <i>k'ajan</i> • <i>libre ansaqin</i> • <i>cbu'uju apuran</i> • <i>caloruan kanku</i> 	mother's milk cold drinks <i>mancharisqa</i>	herbal teas rubs baths poultices
<i>COQUELUCHE</i>	severe	<ul style="list-style-type: none"> • <i>asivan cb'ujunku</i> • <i>libre ansaqin</i> • <i>kunkitan k'aran</i> • <i>tuta mana puñuy atinkucbu</i> • <i>tusisqampi cb'i'iny arparin</i> 	colds <i>pachamama</i> <i>jap'iqua</i>	herbal teas poultices fomentations symbolic treatments
<i>T'UKU UJU</i>	severe	<ul style="list-style-type: none"> • <i>kullillata wijch'ukum</i> • <i>kasqallampi ujilata estrirakuna</i> • <i>k'ajan</i> • <i>cb'uju apuran</i> • <i>tusisqampi cb'inyarparin</i> 	<i>jap'iqua</i> <i>ayasqa</i> <i>unquy purin</i>	herbal teas symbolic treatments ritual baths
<i>CH'AKI UJU</i>	severe	<ul style="list-style-type: none"> • <i>q'iya bolasta thuqhamun</i> 	colds	herbal teas

Table 2. Relationship to clinical signs	
CLINICAL SIGN	QUECHUA EXPRESSION
Fast breathing	<ul style="list-style-type: none"> • <i>ansaqin</i> (is panting) • <i>sayk'un</i> (tires) • <i>apurata saman</i> (fast breathing) • <i>wisitan apurata kuyun</i> (the little belly sinks and rises)
Difficult breathing	<ul style="list-style-type: none"> • <i>n'akayta saman</i> (barely can breathe) • <i>samaynin ch'usajchakun</i> (stops breathing)
Noisy breathing (wheezing, stridor)	<ul style="list-style-type: none"> • <i>arqbin</i> (sound of exhaustion) • <i>qburqusan</i> (sounds similar to hoarseness, but sharper) • <i>aras</i> (sound produced by obstruction from frothing in the mouth)

Table 3. Recommendations in Quechua for home-care of a child with cough**DANGER SIGNS**

If the child presents any of the following symptoms, take him or her to the physician immediately.

- | | |
|---------------------------------|---|
| • <i>Ñak'ayta saman</i> | (barely can breathe) |
| • <i>Apurata saman</i> | (fast breathing) |
| • <i>Ansaqin</i> | (is panting) |
| • <i>Samaynin ch'usajchakun</i> | (stops breathing) |
| • <i>Sayk'un</i> | (tires) |
| • <i>Wisitan untuj kuyun</i> | (the little belly sinks and rises) |
| • <i>Wisitan apurata kuyun</i> | (the little belly moves quickly) |
| • <i>Aras</i> | (sound produced by frothing in the mouth) |
| • <i>Arqbin</i> | (sound indicating exhaustion) |
| • <i>Qburqusan</i> | (sound similar to hoarseness, only sharper) |

If the mother believes the child has *ayasqa*, *saxra*, or *mancharisqa*, she should immediately take child to the physician and the *jampiri* (healer). Treatment by the two is preferable.

FEEDING

- Nurse more frequently;
- Child over 4 or 6 months, should receive more liquids; e.g., herbal teas of eucalyptus, water-cress, or *muni*;
- When child improves, he/she should receive additional food for a week;
- Clean out child's nose with drops of milk, chamomile, and salt water;
- NEVER use *tawañu* or *phusuqullu* to unclog the nose.

FOR COUGH

- Give child herbal teas of eucalyptus and *muni*;
- Use poultices and cataplasms, fomentations of water and eucalyptus leaves.

DANGER!

- NEVER use kerosene or creosote to treat children. These materials are poisonous and very dangerous;
- NEVER dilute mentholated ointments to give children or apply inside the nose. They may only be used as rubs. If ingested they are poisonous.

Table 4. Explanatory model for Jayuma Llallagua

DISEASE	SEVERITY	SYMPTOMS	CAUSES	TREATMENT
<i>PISTI</i>	mild	<ul style="list-style-type: none"> • <i>jacb'is jacb'is jurmanikiv</i> • <i>p'iqi usu</i> • <i>tumpa calentura</i> • <i>aliq' ch'uxu</i> 	<ul style="list-style-type: none"> • cold • contagion 	<ul style="list-style-type: none"> • rubs • baths
<i>CH'UXU</i>	mild/intermediate	<ul style="list-style-type: none"> • <i>manqha calentura</i> • <i>mall'q'a ch'ejantata</i> • <i>pisti</i> • <i>janiw ñuñixiti</i> • <i>janiw ch'ixusuñ puecxiti</i> 	<ul style="list-style-type: none"> • cold • contagion 	<ul style="list-style-type: none"> • herbal teas • poultices • baths
<i>K'AJA CH'UXU</i>	severe	<ul style="list-style-type: none"> • <i>k'aj k'aj ch'ixususa muraduki tuku</i> • <i>watsamaqi</i> • <i>walja manqha calentura</i> • <i>wilamp ch'uxumi</i> • <i>janiw sum samsuniñ puecxiti</i> 	<ul style="list-style-type: none"> • cold • contagion 	<ul style="list-style-type: none"> • rubs • herbal teas • baths
<i>KUSTIPA</i>	severe	<ul style="list-style-type: none"> • <i>wilamp ch'uxumi</i> • <i>nasat wilaw sari</i> • <i>janiw sum ch'ixsunxiti</i> • <i>ratukiw samanix</i> 	<ul style="list-style-type: none"> • cold 	<ul style="list-style-type: none"> • herbal teas • rubs • ritual baths
<i>SAXRA</i>	severe	<ul style="list-style-type: none"> • <i>lakapa muraduki tuku</i> • <i>manqha calentura</i> • <i>ratukiw samanix</i> • <i>picbupaw pbaraqi</i> • <i>qayumpi</i> • <i>ch'uxña wicb'uchu</i> 	<ul style="list-style-type: none"> • a spirit that comes to take the life of the child 	

Table 5. Relationship to clinical signs	
CLINICAL SIGN	AYMARA EXPRESSION
Fast breathing	<ul style="list-style-type: none">• <i>walsamaqi</i> (takes many breaths)• <i>ratukiw samanix</i> (fast breathing)
Difficult breathing	<ul style="list-style-type: none">• <i>janiw sum samsuniñ puedxiti</i> (can no longer breath well)• <i>pichupaw pharaq</i> (child's chest heaves)
Noisy breathing	<ul style="list-style-type: none">• <i>qburqbuski</i> (acute hoarseness)• <i>ayquski</i> (groaning and wheezing)• <i>aras</i> (wheezing with foaming)
Cyanosis	<ul style="list-style-type: none">• <i>lakapax muraduki tuku</i> (the mouth turns purple)

Table 6. Recommendations in Aymara for the home care of a child with cough

DANGER SIGNS	
<p>If the child presents with any of the following danger signs, he/she should be taken immediately to a physician:</p>	
<ul style="list-style-type: none"> • <i>Wak samaqi</i> • <i>Janiw sam sansuniñ puedxiti</i> • <i>Lakapax muraduki</i> • <i>Ratukiw samanix</i> • <i>Pichupaw pbaraqi</i> • <i>Janiw ñuñun munxiti</i> • <i>Qburqbuski</i> • <i>Ayquski</i> • <i>Aras</i> 	<ul style="list-style-type: none"> (breathes a lot) (can no longer breathe well) (mouth is purple or bruised) (fast breathing) (his/her chest “jumps”) (won’t nurse any more) (acute hoarseness) (grunting with wheezing) (wheezing with foaming)
<p>If a child suffers from <i>saxra</i>, a healer and a physician should be consulted immediately. It is preferable to seek treatment from both.</p>	
FEEDING	
<ul style="list-style-type: none"> • Nurse more frequently; • Child over 4 or 6 months, should receive more liquids; • When child improves, he/she should receive additional food for a week; • If <i>t’isi</i> (dry mucus) makes feeding difficult, clean out child’s nose with drops of milk, chamomile, and salt water. 	
FOR COUGH	
<ul style="list-style-type: none"> • Give child herbal teas using <i>wira wira</i>, eucalyptus, <i>chuqi kaylla</i>, barley grain, and <i>salwiya</i>; • “Cure” the cough with poultices and cataplasms made from <i>lik’imp ch’iyar t’arwampi</i> and <i>untu sinsil ch’iyar t’arwampi</i>. 	
DANGER!	
<ul style="list-style-type: none"> • NEVER use kerosene or creosote to treat children. These materials are poisonous and very dangerous. • NEVER dilute mentholated ointments to give children or apply inside the nose. They may be used only as rubs. If ingested or rubbed inside the nose they are poisonous. 	

Table 7. Explanatory model for the city of El Alto de la Paz

DISEASE	SEVERITY	SYMPTOMS	CAUSES	TREATMENT
COUGH	severe intermediate	<ul style="list-style-type: none"> • audible throat (snoring) • inflamed throat • spitting phlegm • stopped-up throat • sunken chest 	<ul style="list-style-type: none"> • breath or exposure • sudden chill • excessive exposure to sun • drink or play in cold or non-boiled water • eat ice cream or orange 	herbal teas baths and fomentations cataplasms ointments and injections syrups and pills
TEMPERATURE	severe intermediate	<ul style="list-style-type: none"> • temperature • burning breath • strong breath • heart is jumping • it is as if he or she were swallowing air 	<ul style="list-style-type: none"> • <i>saxva</i> (evil being) • fright or <i>ajayu</i> (spirit) • cold • cough and gripe 	herbal teas baths and aromatic smoke suppositories pills poultices
<i>K'AJA CHUXU</i>	severe	<ul style="list-style-type: none"> • suffers from <i>arasa</i> (foamy saliva that appears with wheezing) • silenced by cough • turns purple and strong cough • <i>palerilljata</i> (sunken chest) 	<ul style="list-style-type: none"> • from cold • the disease “walks” • cough left untreated too long • eat orange or banana 	herbal teas poultices and baths rubs syrups and injections

Table 7. (continued)				
DISEASE	SEVERITY	SYMPTOMS	CAUSES	TREATMENT
COUGH WITH GRIPPE	severe	<ul style="list-style-type: none"> • has mucus • cough • stuffy nose or <i>t'isi</i> (dried mucus) 	<ul style="list-style-type: none"> • cold • playing in cold water • contagion • head exposed • bath in cold water in open air 	herbal teas vaporization baths poultices tablets suppositories ointments
WHOOPIING COUGH (<i>COQUELUCHE</i>)	severe	<ul style="list-style-type: none"> • his/her little chest hurts • is vomiting • won't breathe • <i>ayquski</i> (groaning with constant pain) 	<ul style="list-style-type: none"> • cough not cured in time • play in water • heat • as if relapsed 	herbal teas rubs fomentations syrups injections ointments

Table 8. Relationship to clinical signs	
CLINICAL SIGN	EXPRESSION USED BY THE MOTHERS IN EL ALTO DE LA PAZ
Accelerated breathing	<ul style="list-style-type: none"> • breathes hard or a lot • <i>samaqiskiw</i> (is breathing a lot) • is panting • heart or little belly is throbbing strongly • breathes very tired
Difficult breathing	<ul style="list-style-type: none"> • stuffy nose or <i>t'isi</i> (dried mucus) • blocked throat • muffled cough inside • cannot breathe well • as if swallowing air
Noisy breathing	<ul style="list-style-type: none"> • the throat sounds like the lungs • <i>arasa</i> (foaming from the mouth) • <i>ayquski</i> (groaning with constant pain) • <i>qbataqi</i> (onomatopoeia for sound coming from the throat) • <i>qbuthuqi</i> (sound that occurs with thick saliva or phlegm) • breathes with noise in the throat
Indrawing	<ul style="list-style-type: none"> • <i>jaqukipstata</i> (jumping heart or stomach) • heart is jumping or throbbing • his/her little chest is moving • <i>pbatbanka sillaranti</i> (his/her little belly sinks) • <i>paletilljata</i> (sunken sternum) • sunken chest

Table 9. Recommendations for home care of children with cough in the city El Alto La Paz

DANGER SIGNS	
A child presenting any of the following symptoms should be taken immediately to the physician:	
<ul style="list-style-type: none"> • Breathes a lot • Breathes with the belly or chest • <i>Samaqiskia</i> (is breathing strongly) • Breathes with fatigue • Throat is blocked • Smothered cough • Cannot breathe through throat • As if swallowing the air • The throat makes sounds like the lungs • <i>Arasa</i> • <i>Qbathaqi</i> • <i>Qbutbuti</i> • Breathing with sound from throat • <i>Jaqukipstata</i> • Heart is jumping or throbbing a lot • <i>Phatbanka sillaranti</i> • <i>Palettiljata</i> • Sunken chest 	<ul style="list-style-type: none"> (frothing accompanying wheezing) (onomatopoeia for throat sounds) (sound accompanying thick saliva) (bouncing heart or stomach) (sunken belly) (sunken sternum)
If the condition of a child with cough worsens and presents <i>arasa</i> , <i>qbututi</i> , or <i>qbatati</i> or the throat makes noises, the child should be taken to a health center while there is still time for physicians to cure him or her.	
FEEDING	
<ul style="list-style-type: none"> • Feed the child; • Give child more to drink; • Administer a reliable remedy to soothe the throat and alleviate the cough. 	
FOR COUGH	
<ul style="list-style-type: none"> • If the child has a sore or burning throat, apply poultices of eucalyptus, rub on mentisan or chicken fat; • If the child has cough, <i>k'aja ch'uxu</i>, or whooping cough, give him or her eucalyptus tea or herbal teas of <i>wira wira</i> or <i>chbuqi kaylla</i> with honey every day until the disease has subsided; • When children are sick with cough, temperature and <i>k'aja ch'uxu</i>, they should be given liquids to alleviate thirst, such as herbal teas made from chamomile, linseed, cinnamon, or eucalyptus. 	
DANGER!	
If the throat is blocked or swollen, avoid the following treatments:	
<ul style="list-style-type: none"> • Do not have children ingest mentisan; • Do not use motor oil for rubs; • Do not apply kerosene rubs; • Do not bathe in alcohol; • Menthol ointments ingested or rubbed in the nose are poisonous. 	



SECTION V

CONTROL OF ARI AT THE LOCAL LEVEL



PLANNING ACTIVITIES FOR CONTROL OF ARI IN THE CONTEXT OF INTEGRATED CARE FOR CHILDREN

Dr. Yebuda Benguigui

I. INTRODUCTION

An analysis of the issue of acute respiratory infections (ARIs) encompasses the same four major areas that are the focus of the planning of control activities: mortality, morbidity, the quality of care, and the prevalence of risk factors.

a) Mortality

Among the many diseases grouped together as ARI, pneumonia is responsible for 85% of all deaths from these diseases. It is therefore the focus of most information available on ARI-related mortality. Just the same, diagnoses of other ARIs (influenza, bronchitis, and bronchiolitis) must also be considered in focusing on mortality among children in developing countries, in part because specific causes of death are often mislabeled.

These classification problems, which are particularly severe in records of deaths in children under 5 years of age, are only one of the detrimental factors affecting the quality of general mortality statistics in the developing countries of the Americas.

The estimates of the Pan American Health Organization (PAHO) indicate that ARI-related mortality in children under 5 ranges from a low of 16 per 100,000 live births in the case of Canada to 3,072 in the case of Haiti, where ARI-related mortality accounts for 20-25% of all deaths; in children under 5, one of every four.

Even though the level of ARI-related mortality in most countries is lower, there is still a marked contrast between the situation in the more economically developed countries in the Region (such as Canada and the United States) and in the developing countries. But among the latter considerable differences exist, particularly in mortality from pneumonia and influenza in children under 1 year. Just the same, Costa Rica and Cuba, which boast some of the lowest rates in the developing countries of the Region, still have rates seven times higher than Canada.

These estimates are quite different than the official statistics in most countries. Belize and Peru are extreme cases in that the estimates are eight and three times higher, respectively, than the official figures. Whereas in most countries of the Region the estimates of mortality are around double, simply because the data recorded systematically to describe pneumonia and influenza are so limited that the estimates present a more realistic picture.

In a great number of developing countries with high numbers of cases of mortality from pneumonia and influenza, there has not been a decline in these cases in recent years. Comparing the estimates for 1985 with the results for 1994, one can observe that in various countries the estimated cases in 1994 are higher than those in 1985, and in others the difference between the two does not reach 20%, which represents an annual diminution of less than 3%.

The gap existing between mortality rates from pneumonia and influenza in the developing countries compared with the developed countries is wider and wider, taking into account that in Canada and the United States the number of cases decreased 20% or more in the period between 1985 and 1994 (20% and 26.3%, respectively).

The reasons for these differences are complex and include considerations of matters extrinsic to health as well. Nevertheless, the major factors susceptible to control are the following:

- Limitations in access to service are responsible for many domestic deaths of children who failed to receive personal care.
- A lack of adequate antibiotics for treatment in the early phase is another common factor in these deaths.
- Poor quality care in many health centers that fail to use standardized criteria for the early detection of warning signs of pneumonia on the part of health personnel and the community at large.

b) Morbidity

Many studies conducted on the incidence of ARI in children under 5 conclude that annual incidence is similar in developing countries and developed countries. All of the studies found that an average child under 5 residing in an urban area will suffer six to eight bouts of ARI annually, including cough, cold, rhinorrhea, bronchitis, bronchiolitis, and pneumonia, whereas the same child in a rural area will suffer from three to five such episodes. The different incidence is attributed to the presence in rural areas of fewer environmental contaminants that irritate respiratory mucosa.

Moreover, the incidence of pneumonia is notably higher in developing countries, where between 150 and 200 cases of pneumonia for every 1,000 children take place. Furthermore, the etiology of these is mainly bacterial in developing countries as compared to the mainly viral origin of the cases in more economically developed countries.

There is scarce information available on morbidity for the countries of the Region, and the quality of this information is undercut by the absence of a record-keeping and analytical system for morbidity data in the countries and health regions in contrast to mortality records, which do exist.

The available data profiles are based on special studies and reflect a high incidence of ARI in children, which is the basis of 40-60% of pediatric doctor's visits at health centers. However, the portion of visits due to pneumonia (under 10% in most studies) is low, which leads to the conclusion that their number is small because they are not carried out in a timely fashion.

Hospital records, however, indicate pneumonia is one of the principal ARI-related causes of pediatric hospitalization, along with manifestations of severe bronchial obstruction. ARI represents 20-40% of all pediatric hospitalizations in developing countries. These are mainly for pneumonia and to a lesser degree bronchitis, bronchiolitis, and bronchial obstruction syndrome (1).

c) Prevalence of risk factors

The high incidence of pneumonia in children, in conjunction with their other risk factors (malnutrition, overcrowding, poor care in the home) contribute to the higher incidence of complications and mortality in the pneumonia cases in developing countries. Certain risk factors stand out in particular—low birth weight, scarce or absent breastfeeding, vitamin A deficiency, incomplete vaccinations, poor air quality in the home, and exposure to chills.

d) The quality of case care

The quality of care that children under 5 receive at health centers is a factor of the high mortality rates and is associated with an important problem in ARI control, which is the use of drugs in treatment.

ARI is the major reason for antibiotic prescription in children under 5. Most studies indicate that in at least half of the ARI cases treated at health centers antibiotics were prescribed, although in most cases they were not required.

Moreover, other medications are often used to treat ARI in children, including cough syrups and cold remedies that may often have harmful effects due to their suppression of the child's natural defense mechanisms.

In short, the principal factors that characterize the problem of ARI in children in the Region of the Americas are its importance as the cause of mortality, hospitalizations, sequelae, visits, and inappropriate use of antibiotics and other drugs for coughs and the common cold.

II. THE OBJECTIVES AND STRATEGY OF ARI CONTROL

The main goal of ARI control activities is to reduce mortality from pneumonia in children under 5 years of age. Three other objectives are also sought:

- Reduce the inappropriate use of antibiotics and other drugs used to treat ARI.
- Reduce severity and avoid other complications in the upper airways (deafness secondary to otitis media, rheumatic fever, and heart problems secondary to streptococcal pharyngitis).
- Reduce ARI complications in the lower airways (pneumonia and bronchiolitis) through early diagnosis and effective case management.

Standard case management (SCM) is the main focus of the strategy being used to accomplish the objectives of ARI control. However, other efforts can also contribute significantly to accomplishing the objectives, including vaccinations against measles and whooping cough and the prevention of other risk factors (2).

a) Standard case management

SCM stresses the reduction of mortality from pneumonia in children and the reduction of the inappropriate use of antibiotics in treatment. It uses a decision tree to systematize the three stages of case management: evaluation, classification, and treatment. The strategy proposes a set of signs and symptoms that offer a high predictive value and allows for the classification of children with ARI according to the probability of their contracting pneumonia. It also includes a series of recommendations for standardized treatments of proven effectiveness to be administered to the children in accordance with their classification.

The following are components of SCM:

1. Treatment in hospitals for cases of very severe disease and pneumonia in infants under 2 months of age.
2. Treatment in hospitals for cases of very severe disease and pneumonia in children from 2 months to 4 years of age.
3. Treatment of pneumonia cases in children from 2 months to 4 years of age.
4. Treatment of non-pneumonia cases presenting cough or colds.
5. Treatment of cases of children with wheezing.
6. Treatment of cases of ear infections.
7. Treatment of cases of sore throat.
8. Education for mothers (or other responsible caretakers) on warning signs and treatment techniques in the home.

The tables on case management included in Appendix 1 of this chapter cover diagnosis, classification, and treatment.

Adapting SCM to local characteristics may necessitate choosing between several options that are generally contained in the national rules and policies for ARI control. These decisions include the following areas:

- Antibiotics provided for standard treatment of pneumonia. Four antibiotics are recommended in particular: cotrimoxazole, amoxicillin, ampicillin, and procaine penicillin. Selection will depend on the local situation, cost, frequency of doses, and the need for disposable elements in the case of injectable antibiotics.
- Health personnel other than physicians who are authorized to use antibiotics to treat pneumonia and bronchodilators to treat wheezing.

When part of the population lacks access or has only restricted access to professional medical care, pneumonia cases run the risk of becoming severe and leading to death unless antibiotic treatment can be received. In these situations, it may be appropriate to train personnel who are not physicians to detect and manage cases classified as pneumonia under the standard care criteria. Such personnel require strict supervision to ensure against the excessive or unnecessary use of antibiotics, which is also an objective of ARI control.

Cases of wheezing can be managed in a similar fashion, if a trained nonprofessional can offer bronchodilator treatment at the primary care level and obviate the need to obtain care at a health center.

- Home remedies recommended to mothers for treating symptoms of cough and cold. Because the contents of many cough medicines and cold remedies may be potentially harmful to children, it is important to decide at the local level which medicines mothers may give their children without risk. Similarly, there are several concoctions prepared at home that are often used to treat cough and colds. These need to be examined at the local level to determine which ones are harmful, to discourage their use, and to promote the use of remedies that are not harmful for the child.

The course offered by PAHO on the organization of ARI control activities includes a module on national policies that examines these issues in greater detail.

b) Immunization against measles and whooping cough

Immunization against measles and whooping cough is an important part of the preventive strategy now recommended to avoid certain cases of pneumonia. Pneumonia is a common complication of measles and whooping cough, and it is estimated that 15% of the pneumonia deaths in children under 5 are the result of complications from these diseases. Clearly, vaccinations against these diseases will also reduce many pneumonia cases and related deaths.

Specific details on the planning and implementation of programs for measles and whooping cough vaccination are found in Chapter 8, "Production of vaccines for the prevention of ARI: A regional outlook."

c) Reduction of risk factors

Reducing the prevalence of risk factors that contribute to pneumonia (and other diseases) is an important component in the strategy to bring down the incidence and severity of pneumonia cases and related mortality. These factors include low birth weight, bottle feeding at birth, poor weaning practices, poor air quality inside the home, and exposure to drafts and colds.

Some of these factors are addressed elsewhere in this and other PAHO publications (3).

III. STAGES IN THE IMPLEMENTATION OF CONTROL ACTIVITIES

Four stages are proposed here for a more efficient implementation of ARI control. They are geared toward greater effectiveness in health centers prior to receiving patient visits. It is hoped that these measures will head off difficulties that may arise when a greater number of children are being checked for ARI before the health personnel have become effectively trained to implement the recommended strategic activities (1, 4).

The four stages and their corresponding activities are detailed below:

a) Stage 1

Providing SCM for severe pneumonia and other ARI at the primary level and in public and private hospitals.

Activities:

- Increase access to SCM for ARI through efforts to train personnel at health centers and supply appropriate drugs and equipment. SCM includes efforts to teach mothers who seek health services how to care for ARI cases in the home.
- Increase access to SCM for severe pneumonia and very severe disease by training hospital personnel and supplying appropriate drugs and equipment.

b) Stage 2

Provide SCM for ARI through community health workers.

Activities:

- Increase access to SCM for ARI by training community health workers and providing them with supplies and supervision.

c) Stage 3

Encourage proper care in the home for children with ARI, including early recognition of pneumonia signs by mothers and other caretakers to ensure that they are brought to the health worker as soon as is needed.

Activities:

- Educate the family about care for ARI in the home, detection of pneumonia signs in children, and when to seek assistance outside the home. Promote the use of health services.

d) Stage 4

Provide specialized treatment for ARI cases that fail to respond to SCM or that otherwise would benefit from specialized care.

Activities:

- Increase access to specialized case management in referral hospitals at the secondary and tertiary levels.

These stages are not intended to be performed in strict sequence. Some stages may take place simultaneously depending on the local characteristics, but regardless of the circumstances in the site that the stages are applied, the proposed sequence facilitates a focus on those areas where greatest control and responsibility is possible. Commencement of implementation with provision of SCM in primary level health centers will lead to reductions in ARI mortality, improvements in early recognition of pneumonia and other severe diseases by health personnel, and more timely and appropriate treatment.

IV. STEPS TO FOLLOW IN IMPLEMENTATION

The following steps are among those required for implementation of ARI control strategy at the local level:

a) Description of the geographic area of implementation

The first step in the implementation of the strategy is to clearly define the geographic area where ARI control activities will be implemented. This will facilitate calculations of the demographic demand for health care, in particular the size of the under-5 population and the distribution of more specific age cohorts (under 2 months, 2-11 months, 1-4 years). This information is useful in figuring the requirements for drug supplies, as is described below.

The map of the implementation area should include the major concentrations of population, transportation and communication routes, and geographic features that may impede access. It should also include the different available health centers, as specified in section IV. c below (5).

b) Up-to-date description of ARI situation in the area of implementation

Prior to undertaking any planning, it is important to understand the magnitude of the ARI problem in the corresponding area, particularly the aspects that will be targets of control; i.e., mortality, morbidity, and the quality of care. Information will need to be gathered on the following:

- Mortality from pneumonia in infants under 1 and in children 1-4 years old in the last year for which information is available. When mortality data are unavailable or the diagnostic quality of information on cause of death is in doubt, estimates can be based on the total number of deaths in the age cohort and the knowledge that in most developing countries pneumonia is responsible for 10-30% of all deaths of children under 5. It is also useful to learn the place of death (whether at home or at a health center), the care received prior to death, nutritional status, and birth weight of the deceased, all of which can help to strengthen the strategy and implementation of ARI control. Information on at-home deaths can be sought through records of health centers and posts in the area of implementation or through household visits.
- The number of hospital admissions for pneumonia involving children under 5 during the last year for which information is available. As a complement to this information, it is also useful to learn further aspects of hospitalizations, such as average length of hospital stays, whether patients were referred by peripheral services or taken to the hospital directly by parents, lethality rate of the establishment, and nature of treatment provided.
- The number of doctors' visits by children under 5 for pneumonia and other ARIs at area health services (including both peripheral health posts, outpatient clinics, and emergency room arrivals) and the proportion of visits that resulted in antibiotic treatment.

This last information will be more useful if it can be correlated to diagnosis, given the importance of reducing the unnecessary use of antibiotics in non-pneumonia cases (cough, common cold, bronchitis) or pharyngitis.

Information can also be gathered on the proportion of visits due to cough or difficult breathing that received chest X-rays and the proportion that received cough syrups and common cold treatments. To obtain this information, it may be necessary to review available data on mortality, morbidity, medical visits, and hospital admissions. The formats proposed for operational studies that are included in the PAHO publication "Priority Operational Investigations for Evaluating the Impact of ARI Control Activities" are recommended. They include study protocols that are designed to assess the results of control strategies and that provide baseline information, which is particularly important to depict the actual situation prior to the interventions (6).

c) Establishment of the health network available for implementation

After the geographical area and the ARI situation have been detailed, identification should be made of the available structure for implementation of control strategies. This network consists of all the health units and personnel that are involved in ARI control, including hospitals, health

centers, health posts, and community health workers located in specific areas that lack a health post. The health structure may also include private as well as public health offices, social security offices, churches, and nongovernmental organizations, among others. Nongovernmental components may be included from the start or at a subsequent stage.

The description of the health network should proceed in the following manner:

- Inventory the existing health centers in the area, define their level of complexity according to their ARI-treatment capabilities—e.g., handling capacity for very severe cases of disease, very severe pneumonia cases, regular pneumonia cases, or only cases of cough and colds (not pneumonia). The level of complexity should also include the availability of a vehicle for cases referrals and communications infrastructure (radio, telephone, etc.).
- Locate the centers on the area map and identify them by level of complexity as specified above.
- Establish routes of referrals and counterreferrals between the different health levels and centers.

This procedure will help to show clearly what the access of the population to different health centers is, which is a key step in defining the capabilities for caring for cases of different levels of severity for different sectors of the population. It will also indicate the average time needed to complete a referral between different levels to demonstrate the access of cases to hospitals. Using this information, an informed decision can be made on aspects of SCM, such as which health professionals can prescribe antibiotics to control pneumonia and bronchodilators to control wheezing, where different hospitals will keep drugs and other supplies for severe cases that cannot be referred. These decisions will also depend on the access and case referral capabilities of different health workers.

The health network tally should also include the number and category of health personnel that will take part in the planning and supervision of strategic implementation (area chief, health center director, supervisor, statistician), as well as of the personnel responsible for care for children with ARI under 5 years of age (7).

d) Planning implementation of ARI control activities

The implementation of ARI-control activities in the given area should be conducted in sequence and organized to ensure that the proposed objectives are met as efficiently as possible. Thus, it is essential to plan specifically to ensure:

- Access to SCM for ARI is available to the under-5 population in the geographical area.
- Access to SCM for pneumonia is available to the under-5 population in the geographical area.

These objectives will require three activities:

- Health personnel training.
- Provision of drugs and other necessary supplies for treatment.
- Supervision of health personnel to ensure effective performance and operations.

Access to SCM is not a guarantee that cases will be treated effectively, because mothers may choose not to seek out health services or professional treatment. Thus, social communication and health education is also important.

- Social communication and health education geared to better knowledge, attitudes, and practices in the community in relation to care for children with ARI. Particular emphasis is recommended on early detection of warning signs of pneumonia, timely health center visits, and appropriate handling of children with ARI in the home.

In addition, planning should also include two other activities intended as follow-up for the process and the results thereof:

- Monitoring and surveillance of activities and results.
- Regular assessment of results of both the implementation process and the impact of activities on the health situation.

d.1) Health personnel training

Training health personnel is the first activity that should be conducted in implementing ARI control strategies and covers two main areas: the organization, planning, and supervision of activities; and ARI case management.

The personnel responsible for implementation of ARI control such as the area chief or director and the health center supervisors should receive training in organization, planning, and supervision. The training should cover situation analysis, setting priorities, calculating goals and objectives, and planning and organization for strategic implementation. Training should also cover familiarization with the aspects of strategy to be implemented, including SCM. This area is of particular importance for supervisors who need to ascertain that the health personnel conduct implement the strategy correctly.

The training of supervisory personnel should precede that of the health personnel responsible for case management to ensure that SCM is introduced in the health network institutions in a well-planned way and that that the personnel will have supervisors who can assist them in identifying and addressing problems.

Training in case management, however, is aimed at all personnel involved in pro-

viding care to children with ARI under 5 in the health centers (in the first stage) and in the community (in the second stage). These personnel include doctors and nurses at referral hospitals, health centers, health posts, and other establishments in the area, and with time, the community health workers.

In setting priorities in this process, the referral hospital personnel should receive training before or simultaneously to the personnel in the peripheral health centers. This order will help to ensure that cases referred to hospitals by peripheral services will not be sent away because of inconsistencies in the care policies of the two types of health services.

As personnel training progresses, private sector personnel can also receive training, along with personnel from social security offices and NGOs that operate on the local and intermediate levels. These inclusions will help improve access to SCM for ARI and reinforce standardization of care criteria.

The need to train personnel in SCM should prepare them to evaluate, classify, and treat children with ARI, so it is important that training emphasize praxis. Therefore, it is recommended that 50% of the training time be devoted to in-service training or praxis, and the rest of the time devoted to the study of materials that describe and analyze the SCM strategy.

To this end, ARI treatment training units have been created in centers that have a large number of visits or admissions of children with ARI under 5 years of age. These training units allow a large number of health workers to attend courses of training practice.

Appendix 2 presents a breakdown of the training materials available and the different types of courses that are suggested for implementation of the ARI control strategy.

d.2) Provision of drugs and other supplies

The ongoing availability of drugs at the health centers is an essential condition for SCM of ARI and includes antibiotics, antipyretics, and bronchodilators.

The availability of antibiotics to treat pneumonia is essential in reducing mortality in children under 5, which is one of the main objectives of ARI control.

Planning for the provision of drug supplies must cover several areas, including the calculation of the necessary quantities, distribution, and surveillance of their use. These aspects are detailed in the breakdown of the course on organizing ARI control activities and in other technical documents (see Appendix 3.)

The drugs must be available before training begins to ensure that health services are immediately available as personnel are trained and that once personnel identify pneumonia cases they can provide immediate treatment. A lack of drugs would undercut training by preventing recommended control activities from being performed. On the other hand, unless personnel to whom drugs are distributed have been properly trained, the supplies are likely to soon be used up because of inappropriate and unnecessary prescriptions.

Other necessary supplies include case management charts (“Care for the child with cough or difficult breathing” and “Care for the child with ear problems”) and care records. Timers are also needed to track respiratory frequency and are particularly useful in these cases if no other equipment is available to count a minute.

Economic factors may make it difficult in certain cases to provide timely and regular antibiotics. At such times, promotion is needed of a “revolving fund” of drugs that is set up for ongoing cost recovery through community support and contributions from representative institutions (9).

d.3) Supervision of health personnel

The supervision of SCM for ARI is of primary importance to guarantee effective access to adequate pneumonia case management. Supervision should be conceived of as an essential complement to training and as a way to assess and evaluate, together with the personnel, possible problems that may crop up as control strategies are practiced and adapted on a daily basis. Thus, supervision should help resolve doubts and areas that were not made satisfactorily clear in training.

Therefore, trained personnel should receive a supervisory visit within the first two months of having completed training, so that potential problems can be reviewed. This visit will be of key importance and will ensure personnel that they can count on the necessary assistance to address problems and implement activities effectively.

Supervision should always be on a regular basis and address the following points:

- The quality of care for children with ARI under 5, to detect possible problems in implementing the control strategy. The supervisory visitor can observe how health personnel handle a child with ARI, ask the health worker questions, review records of the latest cases treated, and question mothers who bring their children to the health service.
- Proper availability and storage of drugs and other necessary supplies for treatment. This area can be ascertained through observations and consultations with health workers on recent requests and prescriptions of drugs. Records on the inventory and use of drugs should also be reviewed.
- Current situation and the trends in indicators of ARI control. The health workers can be consulted on deaths, particularly from pneumonia, in children under 5 in the area of service, the referral of severe cases to hospitals, and control activities performed.

To ensure that all essential aspects are covered, a supervisory doctors’ visit guide is recommended to have at hand the main questions to be asked and activities performed at the health service in relation to the above recommendations. Sample questions are included in the reference document in Appendix 4.

d.4) Social communication and health education

Social communication and health education are intended to teach mothers early recognition of pneumonia warning signs in a child with ARI, so that a health worker will be immediately consulted. In addition, health education is intended to teach mothers and other caretakers about appropriate home management of a child with ARI and thereby encourage correct practices and discourage harmful or potentially harmful ones that may exist in the home.

Given the importance of the early consultation with the health worker, it is essential that the health personnel be well versed in SCM and receive regular supervision and the drugs that are required.

Communication may be either specifically targeted or mass communication. In starting control activities, communication should target population groups that already have access to health workers who can provide SCM. This will ensure that demand for care is not created in sites where personnel lack training, drugs for treatment, and supervision. At this stage emphasis is placed on providing education to mothers or caretakers at the time of medical visits, either during the actual consultation or in the waiting rooms of the hospitals and health centers or posts where standardized care is provided. Education may also be offered in schools in the local area corresponding to the health services.

Mass communication, however, should be limited to situations in which SCM has mass coverage, so that people are not encouraged to seek out nonexistent services.

If communication and educational efforts are carried out in this way, they will constitute a proper response to situations of high domestic mortality resulting from the inability of mothers and families to consult health services in a timely manner. In these cases, activities must focus on raising mothers' awareness of warning signs and ensuring their access to health services capable of offering SCM.

Therefore, these activities must adapt materials and methodologies to local cultural characteristics and develop local materials that convey the main educational points contained in the SCM strategy.

In some regions or areas it may be necessary to tailor messages according to different languages, cultures, or ethnographic features of specific local groups of population. Guides have been prepared to help execute the studies that will orient the required adaptations.

d.5) Monitoring activities and results

Ongoing verification is important to guarantee the success of planned activities. Since the activities are geared to achieving the objectives of ARI control, proper performance can be ensured only by updating activities as advancements are made in relation to the problem.

The purpose of the surveillance or monitoring is to ensure prompt detection of any

problem that may arise, whether in terms of performance or meeting objectives, to avoid any delay in designing the best solutions to the problems identified. In this way, monitoring can prevent resources and efforts from being devoted to activities that do not achieve results.

Monitoring should be done on a regular basis (monthly or bimonthly) because of the need for prompt detection of problems. At the same time, monitoring should take account of the indicators that need to be measured, activities that are geared to increasing access to control activities, and application of the strategy among the population; that is, it must focus on health personnel training, supplies, supervision, and communication. It must also focus on the impact that the activities have on the problem.

Several basic indicators need to be tracked when monitoring ARI control activities and their results. These indicators, which are normally made available by health services in developed countries, are listed in Appendix 5, along with information on how to calculate them and where to obtain them.

d.6) Assessment of results

The assessment is a process to review activities and results and is intended to establish the degree to which the activities being performed and the original objectives have been accomplished. Although there is much overlap in the focus of assessment and monitoring, monitoring involves more continuous attention to specific indicators and more follow-up of the activities and the objectives to be accomplished.

The assessment takes a more thorough and comprehensive view of the activities, allowing a more effective and efficient analysis that can identify different options and strategies for treating the problems.

Assessment, like monitoring, involves the measuring of indicators that will reflect changes in the status of the problem and the objectives of ARI control, as summarized in Appendix 5.

V. PROPOSED GOALS AND OBJECTIVES FOR ARI CONTROL

In view of the effectiveness of the control strategies and the capabilities of countries throughout the Americas to proceed with their implementation, goals and objectives have been proposed within the framework of international commitments to improve maternal and child health. These country-level goals are to be adapted according to the actual situations in each country, and they should help to orient national authorities responsible for ARI control in the gradual implementation of control strategies (10).

The national goals and objectives are valuable and applicable domestically at the national, inter-

mediate, and local levels. The following are the goals and objectives proposed for the year 2000:

1. Training

- Train 100% of national officials and ARI coordinators and their administrative departments (national, provincial, departmental) in organization, programming, and supervision of ARI control activities.
- Provide training to at least 80% of health personnel responsible for treating children at primary-level health services in effective ARI case management.
- Ensure that at least one training unit for ARI treatment is in proper operation in each state, province, or department.

2. Access to and use of SCM for ARI

- Provide at least 80% of the population with access to health services that offer SCM for ARI (including trained personnel with adequate supplies and supervision).
- Provide standardized treatment for at least 80% of the pneumonia cases in children under 5 years of age (including outpatient antibiotic treatment and hospital referrals and treatment for cases that require them).
- Provide education on home care for children with ARI to 100% of the mothers that bring children to the health services.

3. Program impact (Goals of the World Summit on Children)

- Reduce the level of pneumonia mortality in children under 5 that existed in 1990 by 30% by the year 2000.

VI. OPERATIONAL PLANS

To implement the ARI control strategy, it is suggested that detailed national operational plans be developed that would take into account the points covered in Section IV above. The plans would also specify goals and objectives appropriate for the actual situation in the corresponding country and would include a schedule of activities that could be monitored and assessed by national authorities. These operational plans are of considerable value for guiding the implementation of activities, organizing the ARI control responsibilities of responsible officials, and as a baseline for following up on results.

In addition to their usefulness at the national level, operational plans are valuable at inter-

mediate and local geographic level. Appendix 6 presents a local-level operational plan.

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VII. APPENDICES

Appendix 1. Tables on Standard ARI Case Management

**Care for Children with Cough
or Respiratory Difficulty**


ASK:

- What is child's age?
- Is child coughing? Since when?
- For 2-month to 4-year-old: Can he or she drink?
- Under 2 months: Has he or she stopped eating?
- Does child have fever? Since when?
- Does child have convulsions?


OBSERVE and LISTEN:

(child should be still)

- Count breaths per minute.
- Observe whether child is indrawing or has retractions.
- Observe and listen for stridor.
- Observe and listen for wheezing. Is it recurrent?
- Check to see if child is normally sleepy or hard to awaken.
- Check for low-grade fever with hand or thermometer.
- Check to see whether child suffers from severe malnutrition.

THE YOUNG INFANT (AGE LESS THAN 2 MONTHS)		
SIGNS:	<ul style="list-style-type: none"> • Stopped feeding well, • Convulsions, • Abnormally sleepy or difficult to wake, • Stridor in calm child, • Wheezing, or • Fever or low body temperature. 	
CLASSIFY AS:	VERY SERIOUS DISEASE	
TREATMENT:	<ul style="list-style-type: none"> ▶ Refer URGENTLY to hospital. ▶ Keep young infant warm. ▶ Give first dose of an antibiotic. 	
SIGNS:	<ul style="list-style-type: none"> • Severe chest indrawing, or • Fast breathing (60 per minute or MORE) 	<ul style="list-style-type: none"> • No severe chest indrawing, or • No fast breathing (less than 60 per minute).
CLASSIFY AS:	SEVERE PNEUMONIA	NO PNEUMONIA: COUGH OR COLD
TREATMENT:	<ul style="list-style-type: none"> ▶ Refer URGENTLY to hospital. ▶ Keep young infant warm. ▶ Give first dose of an antibiotic. <p>(If referral is not feasible, treat with an antibiotic and follow closely)</p>	<ul style="list-style-type: none"> ▶ Advise mother to give the following home care: <ul style="list-style-type: none"> ▶ Keep young infant warm. ▶ Breastfeed frequently. ▶ Clear nose if it interferes with feeding. ▶ Return quickly if: <ul style="list-style-type: none"> ▶ Breathing becomes difficult. ▶ Breathing becomes fast. ▶ Feeding becomes a problem. ▶ The infant becomes sicker.

THE CHILD AGE 2 MONTHS TO 4 YEARS

SIGNS:	<ul style="list-style-type: none"> • Not able to drink, • Convulsions, • Abnormally sleepy or difficult to wake, • Stridor in calm child, or • Severe malnutrition 	
CLASSIFY AS:	VERY SEVERE DISEASE	
TREATMENT:	<ul style="list-style-type: none"> ▶ Refer URGENTLY to hospital. ▶ Give first dose of an antibiotic. ▶ Treat fever, if present. ▶ Treat wheezing, if present. ▶ If cerebral malaria is possible, give an antimalarial. 	

SIGNS:	<ul style="list-style-type: none"> • Chest indrawing (If also recurrent wheezing, go directly to: <ul style="list-style-type: none"> ▶ <i>Treat Wheezing</i> 	<ul style="list-style-type: none"> • No chest indrawing, and • Fast breathing (50 per minute or more if child 2 months up to 12 months; 40 per minute or more if child 12 months up to 5 years). 	<ul style="list-style-type: none"> • No chest indrawing, or • No fast breathing (Less than 50 per minute if child 2 months up to 12 months; less than 40 per minute if child 12 months up to 5 years).
CLASSIFY AS:	SEVERE PNEUMONIA	PNEUMONIA	NO PNEUMONIA: COUGH OR COLD
TREATMENT:	<ul style="list-style-type: none"> ▶ Refer URGENTLY to hospital. ▶ Give first dose of an antibiotic. ▶ Treat fever if present. ▶ Treat wheezing, if present. (If referral is not feasible, treat with an antibiotic and follow closely). 	<ul style="list-style-type: none"> ▶ Advise mother to give home care. ▶ Give an antibiotic. ▶ Treat fever, if present. ▶ Treat wheezing, if present. ▶ Advise mother to return with child in 2 days for reassessment, or earlier if the child is getting worse. 	<ul style="list-style-type: none"> ▶ If coughing more than 30 days, refer for assessment. ▶ Assess and treat ear problem or sore throat, if present (see chart). ▶ Assess and treat other problems. ▶ Advise mother to give home care. ▶ Treat fever, if present. ▶ Treat wheezing, if present.

Reassess in 2 days a child who is taking an antibiotic for pneumonia:			
SIGNS:	WORSE	THE SAME	IMPROVING
	<ul style="list-style-type: none"> • Not able to drink. • Has chest indrawing. • Has other signs of danger 		<ul style="list-style-type: none"> • Breathing slower. • Less fever. • Eating better.
TREATMENT:	▶ Refer URGENTLY to hospital.	▶ Change antibiotic or refer.	▶ Finish 5 days of antibiotic.

SORE THROAT

Assess

ASK:

- Is the child able to drink?

LOOK, FEEL:

- Feel the front of the neck for nodes.
- Look for exudate on the throat.

CLASSIFY THE DISEASE

SIGNS:	<ul style="list-style-type: none"> • Not able to drink. 	<ul style="list-style-type: none"> • Tender, enlarged lymph node on neck and • White exudate on throat. 	<ul style="list-style-type: none"> • Nasal secretion or obstruction. • Throat red. • Pain or burning of throat.
CLASSIFY AS:	THROAT ABSCESS	STREPTOCOCCAL SORE THROAT	VIRAL PHARYNGITIS
TRATAMIENTO:	<ul style="list-style-type: none"> ▶ Refer to hospital. ▶ Give benzathine penicillin (as for streptococcal sore throat). ▶ Treat fever, if present. ▶ Give paracetamol for pain. 	<ul style="list-style-type: none"> ▶ Give an antibiotic for streptococcal throat. ▶ Give safe, soothing remedy for sore throat. ▶ Treat fever, if present. ▶ Give paracetamol for pain. 	<ul style="list-style-type: none"> ▶ Indications for home care. ▶ Give soothing harmless remedy for throat pain. ▶ Treat the fever or pain. ▶ Instruct mother to return if child's condition worsens. ▶ Offer child additional liquids.

▶ Treat fever

<ul style="list-style-type: none"> • High fever ($\geq 39^{\circ}\text{C}$) 	<ul style="list-style-type: none"> • Fever is not high ($38\text{--}39^{\circ}\text{C}$) 	In a falciparum malarious area: <ul style="list-style-type: none"> • Any fever, or, • History of fever 	<ul style="list-style-type: none"> • Fever for more than five days
<ul style="list-style-type: none"> ▶ Give paracetamol 	<ul style="list-style-type: none"> ▶ Advise mother to give more fluids. 	<ul style="list-style-type: none"> ▶ Give an antimalarial (or treat according to your malaria program recommendations) 	<ul style="list-style-type: none"> ▶ Refer for assessment

PARACETAMOL doses

→ Every six hours

AGE or WEIGHT	100 mg tablet	500 mg tablet
2 to 12 months 6-9 kg	1	1/4
12 months up to 3 years 10-14 kg	1	1/4
3 to 5 years 15-19 kg	1 1/2	1/2

FEVER ALONE IS NOT A REASON TO GIVE AN ANTIBIOTIC EXCEPT IN A YOUNG INFANT (AGE LESS THAN 2 MONTHS). GIVE FIRST DOSE OF AN ANTI-BIOTIC AND REFER URGENTLY TO HOSPITAL.

▶ Give an antibiotic for streptococcal sore throat

▶ Give benzathine penicillin

BENZATHINE PENICILLIN IM
A single injection

< 5 years	600,000 units
≥ 5 years	1,200,000 units

OR

▶ Give amoxicillin, ampicillin, or penicillin V for ten days.

▶ Soothe the throat with a safe remedy.

▶ Give paracetamol for pain or high fever.

EAR PROBLEM

Assess

ASK:

- Does the child have ear pain?
- Does the child have pus draining from the ear? For how long?

LOOK, FEEL:

- Look for pus draining from the ear or red, immobile ear drum (by otoscopy)
- Feel for tender swelling behind the ear.

CLASSIFY THE DISEASE

SIGNS:	<ul style="list-style-type: none"> • Tender swelling behind the ear. 	<ul style="list-style-type: none"> • Pus draining from the ear LESS than two weeks, or, • Ear pain, or, • Red, immobile ear drum (by otoscopy). 	<ul style="list-style-type: none"> • Pus draining from the ear two weeks or MORE. 	
	CLASSIFY AS:	MASTOIDITIS	ACUTE EAR INFECTION	CHRONIC EAR INFECTION
	TREATMENT:	<ul style="list-style-type: none"> ▶ Refer URGENTLY to hospital. ▶ Give first dose of an antibiotic. ▶ Treat fever, if present. ▶ Give paracetamol for pain. 	<ul style="list-style-type: none"> ▶ Give an oral antibiotic. ▶ Dry the ear by wicking. ▶ Reassess in five days. ▶ Treat fever, if present. ▶ Give paracetamol for pain. 	<ul style="list-style-type: none"> ▶ Dry the ear by wicking. ▶ Treat fever, if present. ▶ Give paracetamol for pain.

TREATMENT INSTRUCTIONS

- ▶ Give an oral antibiotic for an ear infection
 - ▶ Give the first dose of antibiotic in clinic.
 - ▶ Instruct mother on how to give the antibiotic for five days at home.

AGE or WEIGHT	COTRIMOXAZOLE Trimethoprim + sulfamethoxazole ▶ Two times daily for 5 days			AMOXICILLIN ▶ Three times daily for 5 days		AMPICILLIN ▶ Four times daily for 5 days	
	Pediatric tablet (20mg trimethoprim + 100 mg sulfamethoxazole)	Syrup (40mg trimethoprim + 200 mg sulfamethoxazole per 5 ml)	Adult tablet single strength (80mg trimethoprim + 400 mg sulfamethoxazole)	Tablet 250 mg	Suspension 125 mg in 5 ml	Tablet 250 mg	Suspension 250 mg in 5 ml
Less than 2 months (<5kg) [♦]	1*	2.5 ml*	1/4*	1/4	2.5 ml	1/2	2.5 ml
2 up to 12 months (6-9kg)	2	5 ml	1/2	1/2	5 ml	1	5 ml
12 months to 5 years (10-19kg)	3	7.5 ml	1	1	10 ml	1	5 ml

♦ Give oral antibiotic for 5 days at home only if referral is not feasible.

* If the child is less than 1 month old, give 1/2 pediatric tablet or 1.25 ml syrup twice daily. Avoid cotrimoxazole in infants less than one month of age who are premature or jaundiced.

▶ Dry the ear by wicking

- ▶ Dry the ear at least 3 times a day:
 - ▶ Roll clean, absorbent cloth into a wick.
 - ▶ Place the wick in the child's ear.
- ▶ Remove the wick when wet.
- ▶ Replace the wick with a clean one until the ear is dry.

Appendix 2. Training Materials Available for Training Health Personnel in ARI Control Activities at the Local Level

TYPE OF COURSE	PERSONNEL TO BE TRAINED	MATERIALS AVAILABLE
ARI program management training course	Coordinators or personnel responsible for ARI control at the national, regional, state, provincial, departmental levels	Modules: Introduction, Management of the Young Child with an Acute Respiratory Infection, National Policies, National Goals, Planning and Monitoring Activities, Evaluation, Course Director's Guide, and Facilitator's Guide
Supervisory skills course	Local, area, and regional supervisors with supervisory and monitoring functions	Modules: Introduction, Management of the Young Child with an Acute Respiratory Infection, Goals, Planning and Monitoring Activities, Training, Community Involvement, Course Facilitator's Guide
Outpatient management of ARI in children	Physicians, nurses, nursing auxiliaries, and other personnel from outpatient health services (health centers and posts, outpatient clinics, and hospital emergency services)	Modules: Participant's Manual, Management of the Young Child with an Acute Respiratory Infection, Instructor's Guide Audiovisual support material
Course on the management of children with ARI	Personnel from health services at the local and regional levels	Modules: Management of the Young Child with an Acute Respiratory Infection, Course Director's Guide, Facilitator's Guide, Clinical Course Instructor's Guide
Course on the management of children with ARI in the community	Personnel responsible for instructing community health agents	Modules: Guide for the Coordinator of ARI Control Activities, Course Director's Guide, Instructor's Guide, Learning Materials
Course for community health agents	Community health agents (health promoters, health visitors, and other community health workers)	Modules: Monitor's Guide, Training Module for Health Workers Audiovisual support material

Note: Information on the training materials is included in the list of technical documents on ARI. Reference publication OPS/HMP/IRA/94.08 (Annex 6)

Appendix 3. Model for Estimating Drug Amounts Needed for the Treatment of ARI in Children (*)**Introduction**

Calculation of drug needs for treatment of ARI cases is an important activity which must be undertaken in all health services in order to ensure the availability of sufficient materials to cover the needs of the service. In making this calculation, the estimated amounts should be adjusted as much as possible to real needs. The aims are to ensure that drugs will be available continuously, to avoid stockpiling excessive amounts of drugs, and to avoid increasing the cost of care unnecessarily.

Drug needs in a particular health service can be calculated on the basis of past consumption, on the basis of an adjustment to real needs to cover treatment requirements, or on the basis of an estimate of the annual incidence of diseases that will require the use of each drug. The latter method is recommended for calculating the drug needs for the treatment of ARI in children under the age of 5 years.

Steps for calculating drug needs

Calculating drug needs based on estimated morbidity requires the following steps:

1. Estimate the number of cases that occur in the population in a year.
2. Estimate the number of cases that will be treated.
3. Estimate the number of units of drug (ampoules, tablets, bottles of syrup) that will be required for each treatment.
4. Estimate the amount of drug required.
5. Estimate the cost of the drug.

The following model summarizes the 5 steps for calculating drug needs for the treatment of pneumonia and wheezing in children under the age of 5. To calculate antibiotic needs for the treatment of otitis and pharyngitis, the same model as for pneumonia can be used, modifying the variables as necessary.

(*) Additional considerations relating to the use of this estimation model at the local level are included in reference document OPS/HMP/IRA/94.09, which may be obtained from the Pan American Health Organization.

CALCULATION SHEET

Drug needs for treatment of ARI

DISTRICT/AREA: _____ YEAR _____

ESTIMATED FORMULA TOTALS
PERCENTAGE (No. x %)

Number of pneumonia cases that occur in the population in a year

Example:

1. Total population	-	-	100,000
2. Population aged under 5 years	15.0%	1 x 0.15	15,000
3. Estimated number of pneumonia cases	15.0%	2 x 0.15	2,250

Number of pneumonia cases that will be treated

4. Pneumonia cases that will have access to standard case management (access)	60.0%	3 x 0.60	1,350
5. Pneumonia cases with access that will actually receive standard case management (use)	50.0%	4 x 0.50	675

Number of units of drug (ampoules, tablets, bottles of syrup) that will be required for treatment

6. Cases of severe and very severe pneumonia in children under the age of 2 months	10.0%	5 x 0.10	68
6.1. Cases that will receive inpatient treatment	90.0%	6 x 0.90	61
6.2. Cases that will receive outpatient treatment	10.0%	6 x 0.10	7
7. Cases of pneumonia (total) in children aged 2 months to 4 years	90.0%	5 x 0.90	608
7.1. Cases of very severe pneumonia	3.0%	7 x 0.03	18
7.1.1. Cases that will receive inpatient treatment	90.0%	7.1 x 0.90	16
7.1.2. Cases that will receive outpatient treatment	10.0%	7.1 x 0.10	2
7.2. Cases of severe pneumonia	12.0%	7 x 0.12	73
7.2.1. Cases that will receive inpatient treatment	90.0%	7.2 x 0.90	66
7.2.2. Cases that will receive outpatient treatment	10.0%	7.2 x 0.10	7
7.3. Cases of pneumonia	85.0%	7 x 0.85	517

CALCULATION SHEET Drug needs for treatment of ARI

DISTRICT/AREA: _____ YEAR _____

	ESTIMATED PERCENTAGE	FORMULA (No. x %)	TOTALS
Number of cases of wheezing that occur in the population in a year			Example:
1. Total population	-	-	100,000
2. Population aged under 5 years	15.0%	1 x 0.15	15,000
3. Estimated number of wheezing cases	15.0%	2 x 0.10	1,500
Number of cases of wheezing that will be treated			
4. Wheezing cases that will have access to standard case management (access)	60.0%	3 x 0.60	900
5. Wheezing cases with access that will actually receive standard case management (use)	50.0%	4 x 0.50	450
Number of units of drug (ampoules, tablets, bottles of syrup) that will be required for treatment			
6. Cases of severe and very severe wheezing	10.0%	5 x 0.10	45
6.1. Cases that will receive inpatient treatment	90.0%	6 x 0.90	41
6.2. Cases that will receive outpatient treatment	10.0%	6 x 0.10	4
7. Cases of wheezing (not severe)	90.0%	5 x 0.90	405

Calculation of Drug Needs and Estimated Cost							
DRUG TO BE USED	TYPE OF CASE TO BE TREATED	NO. OF CASES	AMOUNT PER CASE	TOTAL AMOUNT	PLUS 20% TO COVER LOSSES	UNIT COST	TOTAL COST
Cotrimoxazole suspension	Cases of pneumonia (not severe) in children aged 2 months to 4 years	517	1 bottle	517	620	0.67	415.00
Crystalline penicillin	Very severe and severe cases of pneumonia in children under 2 months of age	68	5 ampoules	705	846	0.123	104.00
	Severe cases of pneumonia in children aged 2 months to 4 years	73					
Chloramphenicol	Very severe cases of pneumonia in children aged 2 months to 4 years	18	5 ampoules	90	108	0.3585	38.72
Nebulized salbutamol	Very severe and severe cases of wheezing	45	1 bottle	45	54	3.30	178.20
Oral salbutamol	Cases of wheezing (not severe)	405	1 bottle	405	486	0.50	243.00

Appendix 4. Guide for Supervision of ARI Case Management						
Region: _____			Date: ___/___/___			
District: _____			Type of health worker: _____			
Health Service: _____			Trained in ARI: Yes [] No []			
1. Observe the health worker as he/she cares for children under the age of 5 years with ARI, and answer the following questions:						
	CHILD 1		CHILD 2		CHILD 3	
	YES	NO	YES	NO	YES	NO
Did the health worker correctly assess:						
- danger signs?						
- chest indrawing?						
- respiratory frequency?						
Was the child correctly classified based on the health worker's assessment?						
Was the child's illness classified as very severe disease or severe pneumonia?						
Were antibiotics given if the child's illness was classified as pneumonia, acute ear infection, or streptococcal sore throat?						
Were antibiotics given if the child's illness was classified as not pneumonia?						
Were any potentially harmful cold or cough remedies recommended?						
Was the child's immunization status checked?						
Was the mother instructed about:						
- how to use an antibiotic?						
- how to care for the child at home?						
- when to bring the child back to the health service?						
Were the diagnosis and treatment recorded in a case log or file?						

2. Ask the health worker the following questions:

2.1. How do you assess a child under the age of 5 years with cough or difficult breathing?

2.2. When do you refer a child with ARI to a hospital?

2.3. When do you prescribe antibiotics for a child with cough or difficult breathing?

2.4. What signs and symptoms do you take into account in order to classify a child with cough or difficult breathing as pneumonia?

2.5. How do you treat a child with pneumonia?

2.6. What instructions or recommendations do you give to mothers or those responsible for caring for children with pneumonia?

3. Analyze with the health worker any problems detected in the health service at the time of the visit in relation to ARI control.

4. Interview some mothers or caregivers of children with cough or difficult breathing who have been treated by the health worker (do not interview mothers of children who were referred to a hospital or were hospitalized).

4.1. Were you advised to give any kind of drug treatment at home? Yes [] No []

If yes, ask whether an antibiotic was prescribed.

4.2. If an antibiotic was prescribed, ask the mother the following questions:

How much antibiotic will you give the child?

How many times a day? _____

For how many days? _____

4.3. Did the health worker tell you when to bring the child back? Yes [] No []

If yes, ask the mother when she will return with the child.

4.4. Did the health worker tell you how to care for the child at home? Yes [] No []

If yes, ask the mother how she will care for the child at home.

DRUG	AVAILABILITY	AMOUNT	MATERIAL IN THE LAST 12 MONTHS		HOW LONG?	
			Yes []	No []	m___	w___
Cotrimoxazole	Yes [] No []		Yes []	No []	m___	w___
Amoxicillin	Yes [] No []		Yes []	No []	m___	w___
Ampicillin	Yes [] No []		Yes []	No []	m___	w___
Procaine penicillin	Yes [] No []		Yes []	No []	m___	w___
Benzathine penicillin	Yes [] No []		Yes []	No []	m___	w___
Paracetamol	Yes [] No []		Yes []	No []	m___	w___
Salbutamol	Yes [] No []		Yes []	No []	m___	w___
Others:	Yes [] No []		Yes []	No []	m___	w___

5. Check to see that the health services has adequate supplies of the materials needed for standard case management.

5.1. Drugs

5.2. Are the ARI case management charts prominently displayed in the place in which ARI cases are assessed, classified, and treated?

Yes [] No []

5.3. Are there enough forms and records to log the ARI cases treated during the next 2 months?

daily case record:

Yes [] No []

case referral form:

Yes [] No []

education pamphlets for mothers:

Yes [] No []

6. Review the records of ARI cases treated in the health service.

Summarize the findings of a review of 20 or more cases of ARI in children under 5 years of age using the calculation sheet on the next page. Check the records for the following:

- Was the following data recorded: age of the child, classification/diagnosis, and treatment?
- Were cases of severe pneumonia and very severe disease referred (these cases may be recorded as sepsis, pneumonia, meningitis)?
- Were antibiotics administered to pneumonia cases that were not referred?
- Were antibiotics used unnecessarily to treat non-pneumonia cases (cough, common cold, bronchitis, non-streptococcal pharyngitis)?

Appendix 5. Proposed Monitoring and Evaluation Indicators for Control of Acute Respiratory Infections		
INDICATOR	FORMULA FOR CALCULATION	SOURCE OF INFORMATION
Mortality from pneumonia among children under the age of 1 year	$\frac{\text{Number of deaths of children under the age of 1 year due to pneumonia in a given place and period}}{\text{Total number of live births in the same place and period}} \times 1000$	Deaths: Vital statistics registry or another agency; Births: Vital statistics registry, Department of Statistics, or another agency responsible for recording births
Mortality from pneumonia among children aged 1-4 years	$\frac{\text{Number of deaths of children aged 1-4 years due to pneumonia in a given place and period}}{\text{Total number of children aged 1-4 in the same place and period}} \times 1000$	Deaths: Vital statistics registry or another agency responsible for registering deaths Population aged 1-4: Department of Statistics, Census Bureau, or another agency responsible for population statistics
Hospital mortality from pneumonia	$\frac{\text{Number of deaths from pneumonia in children under the age of 5 years occurring in a hospital in a given place and period}}{\text{Total number of deaths from pneumonia in the same place and period}} \times 100$	Hospital deaths: Hospital statistics registry Total deaths: Vital statistics registry or another agency responsible for registering deaths
Hospital case fatality rate from pneumonia	$\frac{\text{Number of deaths from pneumonia in children under the age of 5 years occurring in a hospital in a given place and period}}{\text{Number of cases of pneumonia in children under the age of 5 hospitalized in the same place and period}} \times 100$	Hospital statistics registry
Use of antibiotics to treat cases	$\frac{\text{Number of ARI cases in children under the age of 5 years classified as not pneumonia and treated with antibiotics in a given place and period}}{\text{Total number of ARI cases in under-5 children classified as not pneumonia in the same place and period}} \times 100$	Daily record of cases treated in health services

Appendix 5 (continued)		SOURCE OF INFORMATION
INDICATOR	FORMULA FOR CALCULATION	
Access to standard case management in health services	<p>Number of children under the age of 5 years who have access to standard case management by health personnel in a given place and time</p> <p>_____ x 100</p> <p>Total number of children under 5 living in the same place and time</p>	Children with access: Health services survey Population: Department of Statistics, Census Bureau, or another agency responsible for population statistics
Maternal knowledge about when to seek assistance	<p>Number of mothers of children under the age of 5 years who know the signs that indicate that a child with ARI should be taken to a health service</p> <p>_____ x 100</p> <p>Total number of mothers of children under the age of 5 years</p>	Community survey
Appropriate treatment of pneumonia in health services	<p>Number of pneumonia cases in children under the age of 5 years seen in health services who received standard case management</p> <p>_____ x 100</p> <p>Total number of pneumonia cases in children under 5 seen in health services</p>	Health services survey
Rate at which assistance from a health worker was sought when needed for a child with ARI	<p>Number of children under the age of 5 years with ARI who needed to be assessed by a health worker and for whom assistance was in fact sought by the mother or caregiver</p> <p>_____ x 100</p> <p>Total number of children under the age of 5 with ARI who should have been assessed</p>	Community survey

Appendix 6

Operational plan for conducting ARI control activities at local level

A. INTRODUCTION

1. General characteristics of area
2. Current status of problem
3. Health care infrastructure available

B. ASSESSMENT OF CURRENT SITUATION

C. OBJECTIVES

D. STRATEGY OF STANDARD CASE MANAGEMENT (SCM)

E. GOALS AND OBJECTIVES

F. IMPLEMENTATION ACTIVITIES

1. Training plans
2. Drugs and equipment required
3. Supervision plans
4. Communication plans
5. Monitoring plans
6. Assessment

G. ACTIVITIES SCHEDULE

H. BUDGET



EVALUATING CONTROL MECHANISMS FOR ACUTE RESPIRATORY INFECTIONS

Dr. Jorge Toro Alborno

I. INTRODUCTION

The success of a well-implemented health program requires close attention to the performance of administrative and operational personnel as well as to the participation from the community. It is also necessary to know what resources are used for different activities, such as promotion and support for central and local health authorities and program implementation, particularly in the case of ARI control.

For the sake of both the health team and the target population, the indicators used to assess intermediate or final results should be made consistent. An evaluation provides valuable information for current activities and future programming (1-3). The use and dissemination of evaluations will give health services and the ARI control program a solid foundation.

Evaluation is important due to the need to know how far one has advanced towards the set goal and which factors should be adjusted, or to verify that the set objectives have been met and therefore new ones need to be set. On a broader level, and to summarize the direction to be followed in the evaluation of a control program, principal objectives among others could be the following:

- Determine how far one has come, i.e., what has been achieved in comparison to what had been expected.
- Establish which problems were overcome to achieve the proposed goals.
- Redefine the direction in view of the problems encountered.

- Show that the activities carried out benefit the community despite the problems which may arise.
- Provide feedback to the participants, sharing the achievements, analyzing the problems encountered, and underlining the importance of working in depth with the program.
- Justify the need for the activities and the inherent cost, to both the authorities and the community (4).

II. CONTROL MEASURES AND EVALUATION STRUCTURE

Evaluation is a process by which results obtained from the implementation of a program are evaluated and compared to the objectives set out for a given period—normally a year—in a specific geographic area, and whose purpose is to critically analyze all the information which is useful and available, to support, reinforce, and re-elaborate the activities and strategies previously established (1-3, 5-7).

Control or monitoring is also a structured process, of greater periodicity and constancy, whose aim is to systematically verify that the stages contributing to achievement of the objectives have been fulfilled. The sum of the various objectives achieved would allow for a specific goal to be reached.

Control or monitoring is carried out through the administration by gathering precise information on selected indicators, resources, the activities of personnel and health workers, the health centers, the local municipalities and community, and through direct observation on field trips to the area (6, 7).

To meet the goals through fulfillment of specific objectives, activities should be planned and implemented with priority criteria throughout the run of the ARI control program, and the parameters or indicators to be controlled and evaluated should be established beforehand. Selected information should be gathered, analyzed, and distributed throughout the different program levels with a periodicity that has been established previously. The use of forms is helpful in the transcription of data, permitting criteria to be put together to consolidate the local information from health establishments or units from a same area, municipality, district, region, or country.

The main goal of the ARI control program is to reduce the annual pneumonia mortality rate in children under 5 years of age (8). However, in many areas where there is regular information on pneumonia deaths, it may not be necessary to wait a year or even more to learn the results of a given effort. The possibility of analyzing the trend of this indicator in shorter time periods, for example a month, according to geographic distribution or the number of deaths at home, allows efforts to be concentrated on those social groups or places with a higher mortality, thus being able to adjust the annual goal with action directed at the problems detected by the control process. When evaluating any control program, it is important to have its organizational chart in mind, which basically means answering two questions:

What will be evaluated?

This first question can be answered by viewing the grouping of the elements that make up the evaluation according to the classic criteria (9, 10). In this way the evaluation can be charted as it is made:

- a) Evaluation of the process, which means evaluation of the “process” of implementation, i.e., the activities carried out and their effect on the population’s request for attention. This is done by comparing the results with the proposed objectives.
- b) Evaluation of the impact, i.e., the result of the activities carried out on the effect of ARI on the population; this is observed directly by measuring the reduction in “harm” in the community. The reduction of this “harm” is what is intended when planning the activities, and the evaluation consists in comparing the damage at the time of evaluation with the situation set by the goals. In the majority of ARI control programs, the main “harm” to be reduced is mortality.

**What will be the means used for the evaluation, i.e.,
Which are the parameters that more truly reflect
the present state of the situation evaluated?**

This second question entails selecting the best indicators to be used to characterize the situation and that most clearly reflect the advances made (4, 11, 12). In this sense the most convenient indicators are not always of the same kind and depend on what is being evaluated and the level at which the evaluation is being made, as well as the information available for putting them together.

The following criteria should taken into account in the selection of each indicator:

- usefulness, in terms of contributing to reaching the goal;
- availability or feasibility of obtaining it systematically;
- reliability, and
- priority.

The priority requirement refers to the need to define the basic indicators which the health units or establishments should provide (3).

Within the defined framework for determining the instruments that allow or facilitate evaluation, it is important to take into account the difficulties in obtaining the information and how to overcome them. The lack of reliable, timely information with a wide scope, mainly for evaluating the effect reached, is one of the problems which most limits the possibilities and scope of the evaluations, above all at the central levels. This difficulty is eased if the information sys-

tems are organized in such a manner that the personnel responsible for the activities being carried out have a clear idea as to which is the necessary information.

Great importance should be given to the gathering and consolidation of information, as well as establishing the hierarchy of those in charge of this task. In some countries, the motivation and thus the collaboration of personnel in charge of gathering information has been achieved through developing ARI epidemiology and control supervision courses, thus facilitating evaluation (see more following that refers to training).

The majority of countries have one or several kinds of registers on the services which their health establishments provide, the vital data verified in a determined zone (civil registers, cemeteries in the case of deaths, and others) and other aspects which are useful when carrying out the evaluation. These sources of information should be taken into account even if they are of doubtful quality, when putting together the evaluation indicators. On the other hand, it should be considered that the best way of solving registration system problems, and thus to improve them, is by using them, thus learning their weaknesses and limitations.

One of the specific objectives (3, 5), training, is of extreme importance. From it indicators are chosen for the control of ARI. Training is important in helping achieve the goal of reducing pneumonia deaths, because trained and motivated personnel will take the proper measures for prevention, diagnosis, and treatment of cases, and thus reduce ARI deaths. In view of this, the completion of the scheduled courses and determining the number of trained officers and the categories to which they belong should be checked. Control of the activities and difficulties in carrying it out allows for timely recognition of the types of problems encountered to find ways of solving them and providing support.

Elements to be controlled could include activities, resources, and the program's administrative elements, such as regularly providing antibiotics, supervising education, and community participation. The following section details the indicators and parameters presently used in evaluating ARI control activities.

III. EVALUATION SYSTEMS

Evaluations may be quantitative and qualitative, given that in some cases the necessary quality is expressed numerically (2). On the other hand, operational and sociological research can also be quantified and be qualitative (2, 3, 5, 6, 8, 13, 14). The following proposal for classifying evaluations according to their nature and the elements taken into account is especially pragmatic:

a) Periodic and systematized evaluation

a.1) Epidemiological evaluation

For the program's main goal, which is to reduce the pneumonia and ARI-related deaths in children less than 5 years of age, the quantitative epidemiological evaluation

indicates in numeric form how many children of specific ages (less than 1 year and 1 to 4 years) have died due to these pathologies in a specific period and comparing these figures to the total dead of the same age due to other causes, which allows their relative importance to be established. In comparing these figures with the specific population, the rates for a specific period and geographic area can be obtained.

Obtaining an area's or country's periodic rates allows for comparison in a specific period, between themselves and those of other regions or countries, to establish the evolution, magnitude, and location of this severe child health problem. At least one previous year is needed as a reference to compare that mortality information and to verify whether the indicator shows an increase or decrease in deaths. To have a larger picture, one would have to have the data from six or more years, which allow one to study a trend, including years of epidemics—for example, respiratory viruses—and reduce the influence of randomness and interepidemic periods or other phenomena. This six-year period allows an annual five-year average in the reduction of the problem to be calculated.

Another quantitative indicator is the number of children who have died at home by age group, which is shown in Table 1 as a control and evaluation proposal. The possibility of evaluating the number of pneumonia and other severe ARI releases from hospital, hospital pneumonia lethality expressed in percentages, and the number of children who received standard treatment, among others, could also be considered.

a.2) Administrative evaluation

By means of the administrative evaluation, the achievements and problems encountered in the activities and the logistic support to the program will be determined. An administrative analysis should, for example, indicate the degree to which the proposed time frame was met for handing in information and comments. Other indicators are knowledge of the number of courses and trained persons; the number of establishments they originate from and the category to which they belong; the number of trained community workers; the number of educational sessions held among the population in general or among the mothers, among others. Likewise it may be necessary to have data on the availability of transportation and travel allowances; acquisition and distribution of supplies for the program, such as antibiotics, forms, educational and audiovisual material, among others.

b) Sporadic evaluation

b.1) Operational studies

These studies are extremely useful in consolidating the program, as they provide practical information on how activities are carried out, showing the weaknesses and strengths of a wide range of aspects of interest to the persons developing the process

(3, 6, 13). The technical, therapeutic, administrative, epidemiological, and other studies provide valuable elements to a variety of specialists, such as bacteriologists, clinicians, students, health workers and administrators, various health professionals and technicians, and to community volunteers.

At present, the study of biomedical and social risk groups, as is the case with some of the factors contributing to ARI: low birth weight, malnutrition, congenital irregularities, immunodepression, and other diverse pathologies, is considered very important. For example, a geographic area where malnutrition is prevalent would probably have a higher incidence of severe cases or deaths from ARI. Knowledge of this fact should be used in considering prevention and control measures for this problem which go beyond those considered in the ARI program.

Various risk factors could be investigated in these operational studies, such as the causes of morbidity and mortality and the relative importance of some diseases accompanying ARIs. Studies could be conducted on intrahospital outbreaks of respiratory diseases, their prevalence or incidence by clinical service; the kinds of manipulations or the equipment used in treating infections.

It might be important for the administrators of some specific regions to have knowledge of the coverage and access to health services, rejection of visits, analysis of referrals and their replies, self-medication, prescription and administration of medication by pharmacists or other workers, standard treatment of cases, and the study of autopsies in determining the causes. This evaluation of the intermediate steps in the evolution of a child's pathology tend to explain the causes for success or failure in the term of his illness, and consequently the program's degree of effectiveness.

Due to the fact that these studies require human resources, time, and special records, it is not always possible to carry them out in a constant fashion, and thus they should be scheduled and carried out sporadically and often based on a team's motivation or with the participation of outside groups.

As well as a broader knowledge of how the program is running, operational studies try to provide precise information and to motivate personnel and the community to find solutions to problems as they are detected. Receiving and disseminating these reports, which have been processed and analyzed according to selected variables, has the purpose of improving technical and administrative aspects over time. Some may ask for more extended periods for solving the problem, especially if more complex resources are required, as would be broadening the coverage.

- **Clinical studies**

Clinical field research is especially aimed at establishing the effectiveness of the activities included in the program. The results of the quality evaluation and the diagnostic criteria according to the levels of ARI treatment and the therapy used in each one provide substantial elements for training personnel. The quali-

ty of the diagnosis could be compared to the exams provided by the clinical support services, such as lab, X-rays, and the pathological anatomy. Likewise, the criteria presently used to diagnose the gravity of a case, or the inference charts, could be evaluated and eventually modified in light of the new information obtained thanks to these studies.

- **Therapeutic studies**

Various investigations have provided a working basis standardized by level for therapeutic aspects ranging from the choice of antibiotics according to their effectiveness, their availability and cost, and in order of priority indicated by their dose, secondary effects, and bacterial resistance. These investigations also indicate the use and recommendations for inhaled bronchodilators, antipyretics, and analgesics in specific doses and concentrations.

However, therapies are dynamic, and new medications and antibiotics are constantly being discovered; at the same time, an ever more powerful bacterial stock becomes resistant to current antibiotics (15). Thus the proposals of therapeutic charts are of value for the present but may become obsolete after a certain time.

Although these studies are more complex and costly, an evaluation of this kind can be made from the viewpoint of fulfilling the standards for the use of medications in this program, which indicates among its specific objectives a reduction in the use of antibiotics and cough suppressants. Their rational use would allow them to be available for those children truly needing them (13). Table 2 provides a proposal for evaluating their use.

- **Epidemiological studies**

There are various examples of this kind of study, such as the description and analysis of their incidence, according to the climate, environmental temperature, and the etiology, as well as the correlation with atmospheric pollutants and other causes, which would help health teams to more adequately face the variables in play.

As to mortality, as well as the classic indicators annual rates by age group, it is interesting to learn in detail the description of the variables, their correlations, and the study on causality in the geographic area under consideration. Bacteriology, histopathology, clinical and social sciences, and others could also greatly contribute to this epidemiological work. The sociocultural profile related to mortality indicates epidemiological risk groups which should be evaluated at length, given that public health attention modifies the risks, providing a certain dynamism to the problem.

- **Educational studies**

Training the personnel and educating the community is a relevant activity in the control of ARI (16, 17). Its purpose is to increase knowledge and appropriate action in these groups through different methodologies.

The resources of time, money, and personnel employed in these activities can be considerable, making it necessary to evaluate the methods and teaching-learning techniques used to achieve optimal results. An educational process should above all be a follow-up of the set objective. It should be confirmed whether the training efforts are resulting in effective action for the care of sick children; whether the mothers learned from and interacted with the health teams; or whether the community volunteers had learned to recognize the signs and symptoms of severe disease in their children.

Likewise the community's educational material, such as videos, brochures, posters, or others should be assessed to measure the degree of understanding and acceptance by those interviewed, as well as to consider their suggestions. At the end of any educational program, an evaluation of the mothers', or groups of the population interacted with, learning and behavior can be planned.

b.2) Sociological evaluation

The programs and the resources mobilized are to have a positive impact on the population. However, there is little attention given to the factors of human behavior, culture, language or idiom, customs, religion, and beliefs (2, 6). There exist innumerable instances throughout the world of interventions that failed precisely because they did not consider these important elements of conduct.

Sociological studies take these aspects into account to incorporate them in the program. Many questions, determining the causes and evolution of ARIs, can be asked in this type of evaluative research: What and how much do mothers know about the signs and symptoms of severe disease in their children's pneumonia? Are they capable of identifying acute respiratory infections? What name do they know them by? What practices do they have with regard to them? What do they think of the health team? What do they know about prevention? What is the child's environment? Do they have the means of getting to a health center?

Any educational program in the control of ARI should take into account these sociological variables in the persons and communities, to manage the available resources effectively. For example, an element that should be taken into account is that related to the drawings and colors used in the posters and brochures, as well as the contents aimed at delivering information and education. For some indigenous cultures in America, red is a good and positive color, which is contrary to our cultural notions. Likewise, the messages and words normally used, and apparently clear to health technicians, may be interpreted differently by some communities.

Sociological studies may be complex or difficult to carry out, but the wealth of information they provide on the program's evolution, which with its messages tries to increase knowledge and bring about adequate changes in behavior, contributes in creating a profile of the population that should be adapting as the program develops. That is why it is necessary to repeat sociological measurements and evaluations which permit the correction of errors or reinforce lines of action. The preceding chapter "Results from Ethnographic Studies on the Control of Acute Respiratory Infections in Bolivia" provides a clear example of this kind of evaluation.

IV. QUALITATIVE EVALUATION

If the quantification of the activities and its results is useful and necessary, even though at times difficult to compile, there is always the question of how have said figures arisen, what are the deficiencies, how can they be overcome, and how do the principal actors (personnel, volunteers, and community members) perceive and relate to the development of the program.

Generally, qualitative studies are postponed or not carried out due to the diverse social, economic, psychological, cultural, political, and environmental factors, which interact to cause the facts there is an interest in analyzing (2).

As for the principal indicator and goal, which is the reduction of mortality due to pneumonia and ARI, it would not suffice to simply indicate a decrease or increase, though from the quantitative point of view this would be valid in some kinds of evaluative studies. It would also be extremely important to learn the quality and reliability of said information, as well as its causality. It is probable that many observers (doctors and other witnesses) participated in generating these figures, which is why it would be useful to validate the quality of the diagnosis and registers, even if it were in a sample of total deaths.

An infant death is irreversible and lamentable from the social point of view, but it also has to do with the end of the natural evolution of various stages of a disease, which could be interpreted as a failure of the program, as it had not been prevented and treated through primary, secondary, or tertiary prevention. Qualitative research may provide valuable retrospective information on this process and reveal to what degree it could have been avoided and what action needs to be taken in the future for similar situations.

Consequently it is important to learn and explain the reasons for death due to pneumonia in a group of children, for example, from a specific area; at the same time one should ask oneself if the mothers recognized the signs and symptoms of severe disease in their children in time, and if they made the decision to consult the services. Likewise, it would behoove one to determine whether the parents had difficulty in accessing the health services and to pose other questions pertinent to the program, such as, What was the quality of the diagnosis of the children? What indications, which specific treatment, and in which dosage was it provided? In which diagnosis were antibiotics used and what kind were they? Were cough suppressants or expectorants used? Was there an indication of hospitalization? Did the trained human and mate-

rial resources, which are indispensable for an adequate treatment, exist? To explain these problems in a manner similar to that provided by the quantitative methods, these questions are aimed at providing more precise information to make the correct decisions and thus improve the programs.

The evaluation studies and proposals presented in this chapter are not exclusive. On the contrary, each one of them provides valuable information for the ARI control program. The experience of the administrators and the rest of the personnel allow the models deemed necessary and viable to be proposed or modified through the length of the course. At the same time it is necessary that the national coordinators and those responsible at the local level establish their priorities and the resources which would be used to carry out any evaluative study.

V. DISSEMINATION AND FEEDBACK

At the end of an evaluation period and whatever its results, it is important to complete the process as quickly as possible by means of feedback to the personnel involved and the health authorities of the area evaluated with regard to the program's scope, achievements, and weaknesses. The processed information delivered to the different levels of execution will demonstrate that the data provided are used and appreciated, which helps to improve the systems (1, 3, 14).

Some parameters which the feedback should include are the following:

- Meeting the deadlines for the delivery of local information
- Coherence of the information provided
- Comparison of the information from different geographic areas
- Results of specific goals and objectives, as well as their trends
- Information on the achievements, difficulties, and means of solving the problems
- Comprehensive analysis of the program in the period evaluated
- Proposals for new strategies and activities or for reinforcing the restricted ones and those not carried out.

A crucial aspect of the evaluation process feedback is to stimulate the personnel, congratulating them for the initiatives undertaken in the periodic evaluations and in the supervision visits.

There are various methods for disseminating the evaluations in brochures or information letters on a monthly, trimonthly, six-month, or annual basis. The seminars or national or regional evaluation meetings also contribute to the active participation of those involved. The chances for direct communication and exchange of experiences, educational material, and publications between local coordinators, national officers, and in some occasions international advisors personalizes the program and makes its activities dynamic, contributing positively to the formation of a human chain concerned with resolving these important problems.

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Table 2. Use of antibiotics, syrups and antipyretics according to diagnosis

Diagnosis	Antibiotics								Syrups			Antipyretics						
	Amoxicillin	Ampicillin	Cotrimoxazole	PNS	PNB	Erythromycin	Cloxacillin	Other	TOTAL	Cough suppressants	Expectorants and mucolytics	TOTAL	YES		NO		TOTAL	
													Fever	TOTAL	Yes	No		Yes
Cold																		
Flu																		
Pharyngitis																		
Laryngitis																		
Bronchitis																		
Rhinitis																		
Bronch. obstruct																		
SUBTOTAL:																		
Adenoiditis/sinus																		
Acute otitis																		
Purulent bronch.																		
Purulent rhinitis																		
SUBTOTAL:																		
TOTAL:																		

Establishment: _____ Period: _____

PNS = Penicillin sodium PNB = Penicillin benzathine NQ = Not quantified



INDICATORS AND PARAMETERS TO ASSESS ACTIVITIES AT THE LOCAL LEVEL TO CONTROL ACUTE RESPIRATORY INFECTIONS

Dr. Sergio J. Arias

I. INTRODUCTION

Proper implementation of a program to control acute respiratory infections (ARI) means that program goals and objectives must be clearly defined. The goals will indicate to what extent objectives are achieved within a given timeframe.

To achieve the goals, the specific activities that are planned beforehand need to be carried out. The success anticipated in reducing the problem is specified in the major and subordinate goals.

To ascertain the extent to which proposed goals are achieved, the processes known as monitoring and assessment are performed on a regularly scheduled basis and at the conclusion of the period that is scheduled for the activities (1, 2).

The assessment of the activities and the course of ARI control is attempted through verifying the status and relationship of the following aspects (3-5):

- The original situation that prevailed before control activities were conducted (situational analysis);
- The current situation at the time the assessment is conducted;
- What was anticipated for the current moment, in terms of what was originally specified in the major and subordinate program goals.

This process allows the progress of ARI control actions to be gauged. Major program goals and subordinate goals provide the framework for the assessment since they are compared to the kind of impact that has resulted.

Both the processes of planning and of assessment have different characteristics at the local level. Activities performed at the local level will also be somewhat different than at the national or central level. It is at the local level that actions performed and the target population are most closely understood. This proximity presents advantages in performing the assessment at the local level as compared to the central level (6-8):

- More thorough analysis because more specific data are available;
- Veracity in the direct, reciprocal relationships between those who issue information and those who analyze it;
- Timeliness of data analysis—i.e., far briefer time span between when the data are issued and when they are analyzed;
- Greater flexibility and speed in responding to problems that are detected;
- Participation in the assessment process by the personnel who are direct providers of care and by the community.

Based on this general plan for the main assessment areas and their different characteristics as they are applied at the local level, this chapter presents an assessment proposal for ARI control actions at the local level.

It may be advisable to use average indicators of the situation—that is, the ratios between the number of times a phenomenon is observed and the total population in which the phenomenon applies. These indicators are known as rates, percentages, or proportions; examples include disease incidence, the percentage of antibiotic use, the proportion of health centers or posts that have oxygen available, just to name a few.

In other cases, particularly at the local level, accurate representation of average health indicators may not be feasible. Under these circumstances, it is advisable to conduct individual case analysis to estimate, for example, pneumonia mortality in a given area or to use the data to supervise health services where cases of meningitis are found.

Organization of and assessment of data collection and analysis are covered in the preceding chapter, “Evaluating Control Mechanisms for Acute Respiratory Infections.”

The following section describes the indicated model assessment, along with indicators suggested for specific aspects.

II. THE ASSESSMENT PROCESS

The assessment process concerns the evaluation of what may be called “executed activities,” or the activities that are performed or conducted. In other words, the assessment is intended to verify whether all activities planned or provided for have indeed been carried out and, if so, to what extent.

This section will consider the assessment of activities that should be carried out—specifically: training, supplies, communication, supervision, monitoring, and assessment. The purpose of these activities, which constitute steps to be followed in the implementation of ARI con-

trol, is to offer a greater number of health services and health personnel to the community to afford greater access to standard ARI case management in the community (1, 2).

The performance of these activities and the greater access that is expected to be made available do not, on their own, ensure that the population will in fact use the health services to address problems that affect a child's health. Thus, the progress anticipated must also be expressed in terms of the actual use the population makes of these health services. Thus, the results to be assessed are examined within two kinds of parameters that are defined in the planning process as the access goal and the usage goal.

a) Training

Training health personnel in standard ARI case management is the first step in the process to increase access to the strategy, and is normally an activity planned in great detail. The training assessment must verify whether the number of personnel provided for in the planning stage were trained in the corresponding time period. Two basic indicators are proposed:

a.1) Proportion of health personnel in the area who have received training in standard ARI case management.

This indicator is the most direct reflection of results from training. A high proportion would indicate that training was properly performed during the period of time in question.

A breakdown of the type of personnel may be advisable (e.g., physicians, nurses, aides, and community health workers), particularly because the kind of personnel performing health services varies widely in the countries of the Region. This disaggregation can reinforce training efforts by indicating which personnel have missed the training and how different categories compare.

In addition, the assessment can indicate how many of the personnel received practice in care of children with ARI. The assessment of this aspect is of great importance to establish if the trained personnel were instructed in the specific skill of case management, which is one of the major goals of the program.

a.2) Proportion of health services in area that have available at least one staff member trained in standard ARI case management.

This indicator is also related to the access of the population to standard ARI case management and takes into account the previous indicator as well. And, as in that instance, this indicator can also reflect each category of health personnel that has received the training. In many countries only the physician is capable of prescribing drugs, in which case the benefits of the training would be limited if nurses, for example, were the only health personnel to receive it. Thus, one may wish to further refine this indicator by tracking the number of services in which at least one member in each professional category (physician, nurse, aide) has received this training.

Comparisons of the two proposed indicators can illuminate the following kinds of situations:

- When the first indicator reflects a high value (i.e., the corresponding goal has been nearly accomplished), but the second indicator reflects a low value (i.e., only a small proportion of the health services have benefited), the health services and personnel are then acutely concentrated in a few centers. In such instances, a conscious attempt may be required to ensure a greater number of health centers and posts are covered by the training.
- When a low percentage of personnel have received training but a high percentage of centers have specifically trained personnel, the training efforts may likely be excessively dispersed in response to an attempt to cover the greatest number of health centers and posts. Such a situation is likely to require more thorough coverage of personnel in each category.

In any event, the individuals responsible for the assessment will need to recall that the significance of the relationship between the indicators will depend on several factors, such as the number of health centers available, the demand for care that each of the centers must ideally meet, and the concentration of personnel.

To arrive at a clear demonstration that problems exist, which means that training goals have not been fulfilled, a thorough analysis of different aspects should be made to find the origins of the problems. Such an analysis requires the following indicators:

a.3) Obtain the proportion of scheduled courses that were conducted effectively and indicate whether all of the courses scheduled were actually held. If some were not, study the reasons for it.

a.4) Obtain the proportion of aides among the total number of personnel invited to participate. If attendance is low, the reason should be investigated.

Other indicators can be found that also demonstrate problems that may occur in the series of training activities. In all cases, it is important to establish what the problems are and propose realistic solutions.

b) Provision of supplies

The provision of supplies is the second essential element to consider in ensuring that health centers provide standard ARI case management. Certain additional aspects should be covered by the assessment:

- In general, providing supplies, particularly drugs, is not an area of responsibility incumbent on the personnel in charge of coordinating ARI control activities, but rather is under the section responsible for purchasing or supplies. Thus, special coordinating efforts are required to afford an uninterrupted and sufficient supply of essential drugs.
- Often, the provision of supplies is not regarded as warranting close attention, since it is regarded as the responsibility of other offices or personnel. This attitude may occasion severe scarcity of essential drugs in the medical services.
- The supply of drugs and other essential materials is the area of ARI activities that represents the greatest monetary expense. Therefore, its assessment is of key importance in demonstrating that budgeted resources have been used appropriately or that allocations have been insufficient.

When executing ARI control activities, it is essential at all times to motivate health personnel and the community. Therefore, the lack of adequate supplies is the source of greatest frustration and complaint among health personnel and the community.

The following indicators are proposed for the assessment of supply activities:

b.1) Proportion of health centers that have a regular supply of antibiotics.

This indicator directly demonstrates the extent of coverage achieved in the supply of antibiotics. Its priority reflects the fact that the antibiotics are the most important of the supplies.

“Regular supply” in this context means that there would never be a shortage of antibiotics. If at some time they were lacking, the situation would represent an “accident” that would not normally occur. It is also important that the antibiotics recommended for ARI control are included in the supply as per the current standards for case management in the country or region.

b.2) Proportion of health centers that have a regular supply of other drugs.

The importance of antibiotics in no way negates the considerable need to have other essential drugs available.

b.3) Proportion of health centers that have a regular supply of other materials.

The supply of other key materials is often overlooked. The supply of charts for maintaining standard case management in the health centers and forms for medical and data records must also be well planned. Certainly, the major supplies are the antibiotics. However, without these other materials monitoring and assessment activities would be severely hampered by the lack of information. The provision of supplies other than drugs is usually the responsibility of the ARI control program.

The above three indicators should give an accurate idea of the coverage of supplies. At the local level, where information is more readily available and supervision more direct, the task is made easier.

If a failure to meet supply goals is found, more detailed study of each step in the supply chain will be required—budgeting, requests for bids from suppliers, purchasing, storage, distribution, and use. To the extent that it is possible, these areas should be evaluated in conjunction with the personnel responsible for the supplies.

Other aspects that can be reviewed include:

- time devoted to formulating the requests for purchases;
- time elapsed between the request for supplies to be purchased and the actual acquisition;
- time elapsed between the arrival of supplies at the storage site and the actual distribution to the services;
- regularity of deliveries;
- amounts (whether adequate or not) of each delivery;
- miscellaneous losses due to various causes (expiration of shelf life, inadequate storage, etc.)

Given that one of the objectives of the program is to decrease the inappropriate use of antibiotics and other drugs (see Section III. b in this chapter), the lack of drugs in health services may reflect excessive prescription rather than a problem in supply. Dwindling supply may also reflect antibiotic use of non-ARI pathologies or by persons over 5 years of age. In these circumstances, training must be reinforced to avoid inappropriate antibiotic use.

c) Supervision

The supervision of health services should ensure constant availability of trained personnel and adequate supplies for effective application of the strategy of standard ARI case management. But these two factors will not ensure effective implementation without regular and appropriate supervision, which is particularly effective at the local level. This supervision is also needed to detect failures and problems that call for a quick and effective response.

Thus, a detailed assessment of the supervisory work will help to make needed improvements in the later stages of the program cycle. The assessment of supervisory activities should focus on both the qualitative and quantitative aspects of supervision (9). The proposed indicator for assessing supervision in quantitative terms is as follows:

c.1) Proportion of health centers in the area that receive regular supervision.

This indicator directly reflects the extent of supervision offered in the time period under assessment. The importance of this first step is that if regular supervision cannot be exercised, other aspects of the services cannot be meaningfully examined. Detailed attention to shortfalls in fulfilling supervisory goals is required if the sources of problems are to be located.

What is meant by “regular supervision”? There is no universal definition of what constitutes “regularity,” because it is dependent on a plethora of circumstances that are specific to particular regions or geographical areas—the number of health centers in the jurisdiction, the distances that have to be covered, the means of transportation available, and the number of personnel under supervision, just to name a few. At the local level, regular supervision may simply mean the greatest number of site visits possible in the time allotted. In any case, planning an assessment of supervisory activities should always take account of the regularity of visits.

The quality of supervision is less amenable to gauging with a single indicator that will account for all pertinent factors. Some of the issues that the assessment of supervisory quality should consider are (9):

- Was a written guide prepared for the supervision? If so, does it cover all areas that should be assessed? Will the structure of the guide permit a conclusive determination of whether the standard case management strategy is being properly implemented?
- Were the personnel responsible for the supervision properly trained? Did the training include standard case management? What other areas subject to supervision were covered?
- Among the health centers that have trained personnel and adequate supplies available, to what extent is the standard case management strategy being applied?
- How long does it take from the time a problem is detected through the supervision until it gets resolved?

Whereas these areas are often murky when studied at the central level where spot testing or sampling must be used to exercise supervision, at the local level more opportunities are found to exercise detailed and more effective supervision.

Just as occurs in other areas, problems detected in supervisory activities through the assessment should spur an effective response that will correct them.

d) Access and use

Increasing access and use is an “intermediate goal” of the ARI control activities. Success in the area of access means the population will have greater opportunities to resolve health problems that affect the child; access means a greater supply of services offered to the community.

For its part, greater use of services means more likely and extensive utilization of this care. This is the most important indicator of whether the activities performed will have a real impact on the problem.

An assessment of access and use acts as a “quality control” check on the other assessments performed. This is because appropriate performance and a corresponding favorable assess-

ment in the areas of training, supplies, communication, and supervision should be reflected in an increase in access and use of the services that offer appropriate care for children with ARI. Access can be assessed according to the following indicators:

d.1) Proportion of health services prepared to offer standard ARI case management.

This indicator will reflect which health centers have trained staff, adequate antibiotic supply, and regular supervision of the standard ARI case management strategy. When personnel are trained, adequate supplies are available, and correct supervision is exercised, then the health centers with problems will be identified and their problems resolved. The supervisory process is the most accurate source of information used to develop this indicator. When supervision is appropriate, the centers listed as capable of offering standard ARI case management will in fact be doing so.

d.2) Proportion of the population in the health service area that practice standard ARI case management.

This is one of the most revealing of the indicators. The official in charge of health services in a given area must cover several health centers and types of personnel, which in turn are responsible for providing health care to the community. This indicator therefore reflects the activities conducted in the community and provides a check for the assessment. Just the same, however, frequently a large health center will not be able to accurately define the coverage area and population level it serves.

Unlike the other indicators, in this case the health centers to which the population has access must be those that effectively implement practice standard case management. To ensure this is the case, regular, appropriate supervision is required, not only to ascertain regular antibiotic supplies and the proper performance of trained personnel, but to ensure the proper practice of standard case management.

d.3) Proportion of mothers or relatives that know when to seek care from a health worker for a child with ARI.

This indicator gauges the mothers' awareness of the ARI problem, particularly with regard to childhood pneumonia. It reflects the level of success of communications efforts to increase this awareness and with it, efforts to seek care for the sick child. It also gives an indication of true access to the population; that is, leaving aside the features of transportation and geography, the indicator shows the "cultural access" to the strategy that mothers and other relatives of the child have.

This indicator is developed through community surveys in which mothers are questioned about their awareness of urgent warning signs of disease in the child, which should lead her to seek medical care at a health center. The signs that the mothers should recognize are the same ones that should be taught to the community either when they bring their children in to be seen or during special sessions designed for this purpose.

In addition, in countries where there is high demand for care and the level of concern is also high, it is important to also evaluate whether communication efforts result in fewer unnecessary appointments sought out for everyday matters, particularly in those centers intended to handle emergencies. Communication activities should be geared to increasing the number of medical visits in a rational manner (12).

Use of care can be assessed with the following indicator:

d.4) Effort to obtain care from a health worker for a child with ARI.

This indicator gauges the ratio between the total number of children with ARI who require a diagnosis and the number who are in fact taken to the doctor. It is an indicator of the use of the health services offering standard ARI case management by the mothers or other family members of pediatric patients. Whether the care that was actually provided was effective is another important question, given the reduction in mortality that the consultations can have.

This indicator is particularly comprehensive in assessing the progress from the entire set of activities undertaken, because greater effort by mothers to seek proper treatment is possible only when other elements are conducted in a well-coordinated manner.

Indirect information for this indicator can be obtained through household surveys in which the mother or other caretaker is asked about the signs the child exhibited during his or her last bout of respiratory disease and whether or not health services were sought.

The most sensitive phase in the entire process of the activities assessment is the calculation and detailed analysis of these indicators. A low level of access and use duly assessed using the indicators proposed above should immediately lead to a thorough analysis of the activities conducted in order to find out where the weaknesses lie.

III. ASSESSMENT OF IMPACT

This assessment is the most important step in verifying the success of the activities. To obtain a positive final result from ARI control activities, all efforts made must be guided by the objectives proposed at the onset—the reduction of harm in the community from ARI.

The framework for these objectives was put forth by the Pan American Health Organization with regard to its ARI control programs as follows (12):

- a) Reduce mortality from pneumonia in children under 5;
- b) Reduce the excessive and inappropriate use of antibiotics and other drugs in treating ARI;
- c) Reduce the complications from acute infections in the upper airways, particularly partial and total hearing impairment, secondary to acute otitis media.

The assessment of the level of accomplishment vis-à-vis these objectives is the most pertinent reflection of this process. The final purpose is to reduce specific health problems affecting the community and the human suffering they bring. At the same time, increased availability of health services means a better quality of life for the community. Thus, it should never be overlooked that the assessment of the impact of the health services is the most important of all; no other assessment will directly reflect true improvements in the health conditions of the population.

The minute and detailed study of activities is important, but is no substitute for thorough analysis of the impact. It is the relationship of the health inputs to health outcomes that needs to be established.

In certain circumstances, the absence of an analysis of impact is due to the difficulty in obtaining an assessment. The impact may be measured according to the proposed indicators during different time periods in which activities are conducted. And these may not translate into a measurable impact.

Nevertheless, every assessment should expressly state the impact anticipated and if the time frame following the implementation of activities is too brief to afford a measurable impact, the assessment can make note of the time constraint, so that at the appropriate time in the future, the issue can be studied.

At the local level, the time constraint should not be as great because of the ongoing monitoring of activities and the opportunity to assess individual cases.

Thus, the rules that apply at national or regional levels do not necessarily hold at the local level, where the impact of increased efforts can be tracked on a short-term basis, and goals, such as eliminating unnecessary deaths as a result of improper case management, are entirely feasible.

Not only can local planning, performance, and effective use of opportunities achieve optimum impact from available resources, but a more direct method of assessment and control are also possible at the local level, so problems detected can be quickly addressed.

The following are methodologies to assess the anticipated impact as set forth by the objectives of the activities. Specific indicators for each case are also provided.

a) Reductions in pneumonia mortality in children under 5.

Pneumonia mortality in children under 5 (which is the age group where the strategy is most effective) is the worst effect of all from ARI. Thus, the prevention of unnecessary deaths is the most important goal set for the activities.

Assessment of this impact requires a view of two fundamental aspects:

- the number of deaths produced; and
- the causes of their occurrence.

The number of deaths can be more reliably ascertained at the local level than on the national level. A survey of deaths should be taken to have the most current data possible. Information on deaths depends on the coordination of different data sources from local civil registries,

immediate notification from referral hospitals where deaths are common, data from community health workers, and other sources. Whatever methodology is used, all deaths should be reported within less than one month of the time they occur, and the mortality data should be examined for trends in causes, so that possible responses will be immediately forthcoming.

The characteristics of the deaths should be classified according to one of the following categories:

- Deaths that occur despite the use of effective standard case management and available technology (unavoidable deaths);
- Deaths that occur without the patient consulting health services (domestic death);
- Deaths that occur because the patient is not treated until his or her condition becomes severe (death due to delayed search for care);
- Deaths that occur after one or several patient visits with health worker(s), who fail to provide standard ARI case management.

This proposed scheme for classifying deaths attempts to determine the level of “responsibility” of the health services to specify weaknesses that may have contributed to or caused the deaths. The information can be gathered by local officials from records (e.g., clinical chart of hospitalized children who die) and community research and surveys.

It is important to make every effort to discriminate in the determination of the cause of death between the underlying cause and contributing factors or secondary causes. This is not always a simple matter, which is the reason that “undefined” is an important category. However, other information on pneumonia cases can be obtained such as basic and associated causes and whether infections had a nosocomial etiology or were secondary to other disease.

These assessments at the local level are among the most important activities conducted. It should be noted that these assessments will have a strong effect on the health personnel involved in the fatal cases, due to any awareness arising from the assessment of the role their actions played in the deaths. The purpose here, however, is not to assign blame, except in cases of negligence, but to reveal the current situation and the major problem areas that need to be addressed. Thus, the following indicator is proposed for local assessments to determine the impact on mortality of ARI control activities:

a.1) Individual analysis of deaths in children under 5 to determine the cause of death and actions taken to prevent it.

In general, the higher up the organizational ladder one travels in ARI control programs, the more difficult or impractical it becomes to assess individual cases. At the central level, the personnel have available the traditional tools of infant mortality, mortality in children under 5, and mortality from pneumonia in children under 5 and over 5. The study of these variables requires an analysis of the quality and reliability of the data, and their magnitude and evolution over time.

Although the quality of the data may not be the direct responsibility of those using it here, their input is critical to efforts to improve their content. A detailed awareness of the weakness and limitations in the data can contribute significantly to eventual improvements.

Undercounting and underreporting are not uniform in countries throughout the Region, many of which do a fine job. Thus, the assumption that the impact on mortality from ARI control efforts cannot be assessed because of problems in data quality should not be made without a prior evaluation to confirm the belief. Moreover, methodologies exist to adjust for undercounting or underreporting and they may provide a more accurate picture of the true situation.

With these constraints in mind, the following indicators are proposed for assessing the impact of ARI control activities at the central, national, or regional level.

a.2) Mortality from pneumonia in children under 1 year and 1-4 years or 5 years.

This indicator expresses the magnitude of the problem. Whenever possible, mortality figures from official records should be adjusted on the basis of available estimates of underreporting of deaths in each country. One of the reasons these adjustments are needed is that the goals of health programs are expressed in terms of the impact sought on specific kinds of mortality. And the situation as reflected in these magnitudes will largely determine the actions taken.

a.3) Mortality from all causes in children under 1 year and under 5 years.

This indicator reveals the ratio of pneumonia deaths to total deaths in each cohort, which are key data needed to establish the magnitude of the problem. This indicator can be used to check figures that suffer from classification problems to improve their accuracy.

a.4) Trends in mortality from pneumonia.*

The trend in mortality from pneumonia helps to define the magnitude of overall mortality. Average or even relatively low mortality from pneumonia should not give rise to complacency; if rates have been stable for some time, actions can still be taken to decrease the rates, and these actions should be reflected in declining trends.

For this purpose, indicators such as hospital lethality can be used, although in the early phases of a program this particular indicator is likely to appear high because severe cases are being properly referred. The percent of all infant mortality due to

* With regard to methods for calculating decreases in mortality from pneumonia or trends in other proposed indicators, see the PAHO publication *Acute respiratory infections in children in the Countries of the Americas: Mortality in the Andean area* (HMP/ARI-013/89).

pneumonia is another indicator that can reveal the impact of ARI control efforts.

These indicators should be routinely evaluated at all levels of national, intermediate, and local ARI control programs. Because impact cannot always be measured opportunistically, these surveillance efforts will afford much information about program progress.

Even though these data do not evaluate the program itself, the health personnel and community should be aware at all times of the characteristics and trends of the problem they are addressing.

b) Reduction in the excessive or inappropriate use of antibiotics and other ARI control drugs.

Reduction of needless use of these drugs is another program objective and should be reviewed regularly to assess impact. Although many of the same difficulties found at the central level in obtaining these data exist also at the local level, the status of the problem is more easily assessed locally. The following indicators are proposed for this area of assessment.

b.1) Proportion of ARI cases in children under 5 years that received antibiotic treatment from the health services.

This is the most comprehensive indicator of antibiotic use in the health services and measures antibiotic use in outpatient facilities and by patients of community health workers in those countries or areas where they are certified to prescribe antibiotics.

In planning ARI control activities, the objective is put forth in relation to the total number of ARI cases. Ordinary medical records do not always indicate the treatment prescribed. However, the supervision of health services can play an important role in this collection, whatever way it is carried out. Again, collection of this information at the local level is far simpler than at the national level.

Possible data sources include daily logs of medical visits (if treatment is listed), pediatric outpatient clinical histories, individual patient charts, supervisory reports, medical prescriptions presented to pharmacies, or any other records that allow the treatment provided to children who are diagnosed with ARI to be identified.

Generally speaking, an acceptable average proportion of patients with ARI who are treated with antibiotics is 20 to 30%. This range is the goal that ARI control programs should take on both a short- and long-term basis. If average prescription rates exceed this range, detailed analysis of potential problems should be conducted.

To begin, a determination should be made of the pathologies for which antibiotics are prescribed to find out whether excess medication is being prescribed for routine pathologies or if mistaken diagnoses are reached of pathologies that require antibiotic treatment. This information provides key feedback on areas that need reinforcement in training sessions and from supervisory activities.

Other potentially useful indicators of inappropriate or excessive antibiotic use are:

b.2) Proportion of cases of pneumonia or otitis media in children under 5 treated with antibiotics.

This indicator reflects whether pathologies that requiring antibiotic therapy are treated accordingly. The proportions should approach 100% (they may be less due to some cases being diagnosed after the fact).

b.3) ARI cases in children under 5, other than pneumonia and otitis media, treated with antibiotics.

This indicator reflects whether antibiotic use is excessive in viral and routine pathologies such as common cold and most pharyngitis. The proportion should be 20 to 30% or lower. Depending on the level responsible (physicians, nurses, or community health workers) higher proportions indicate the need for additional training to reinforce concepts concerning pathologies that do require antibiotic treatment, such as streptococcal pharyngitis.

b.4) Proportion of overall ARI in children under 5 represented by each pathology.

This indicator identifies whether the distribution of diagnoses is correct and whether severe pathologies that require antibiotic treatment are being overlooked. The general distribution of each pathology follows a relatively well-known pattern in which the vast majority of consultations are for routine pathologies, with pneumonia representing no more than 5% of the total and otitis media 20%.

Regardless of whether there is in fact a greater level of pneumonia and otitis media cases or classification problems are evident, the situation will warrant further review to reinforce personnel training, particularly areas of supervision and case assessment.

A close study of inadequate or excessive antibiotic use will help to resolve critical problems. Assessment of the reduction in antibiotic use is easier to measure than mortality-related data and can be tracked with the information forthcoming from the health centers or community health workers.

This information lends itself to simple graphic representations that can be shared with the entire health service staff to follow monthly trends. This technique has been successful in many countries where it has helped personnel to become strongly motivated in the accomplishment of related goals.

c) Reduction of complications from acute infections of the upper airways, especially hypoacusis and deafness secondary to otitis media.

Not many details are provided for this indicator, given that few countries have carried out specific activities for this objective. The lack of specific knowledge concerning this problem has prevented specific goals from becoming formulated, although some countries have attempted to define the basic situation through studies, while conducting activities for the appropriate management of acute and chronic otitis media.

Studies that attempt to track the prevalence of hypoacusis in the population and correlate it with histories of acute or chronic otitis media require complex efforts and special equipment for tympanometry to determine the extent of hearing loss. Many health services simply lack such equipment and its acquisition is overshadowed by other priorities.

To the degree that the prevalence of hypoacusis can be determined in the pediatric population and correlated to otitis media episodes, another component to control this problem can be established and subsequently assessed in the ARI program. At a minimum, this is an area that can be assessed a priori to indicate whether cases of otitis media are being properly treated. Tracking and treating otitis media would constitute a reasonable preliminary attempt to address the problem.

This component would be assessed using the following indicators:

c.1) Proportion of cases of acute otitis media in children under 5 that are properly handled.

Notwithstanding the problems in collecting reliable information, this indicator can be assessed indirectly. In the absence of numerical accuracy, a hypothesis that standard case management for acute otitis media contributes to reductions in the incidence of hypoacusis and deafness in the pediatric population is quite reasonable. Thus, an accounting should be made of the proportion of all cases of acute otitis media that receive antibiotic treatment.

c.2) Reduction of the cases of hypoacusis (annually or in other time frame) secondary to otitis media.

As is clear, accurate assessment of this indicator requires baseline information that is not easy to obtain in many countries. However, proper treatment of otitis media will certainly reduce hearing loss problems in the infant population and have a significant impact on the problem.

Tables 1 and 2 in the appendix of this chapter provide a list of proposed indicators for the assessment process as well as of the impact on the population. Calculation methods and data sources are also suggested.

IV. PRESENTATION OF THE ASSESSMENT AND PARTICIPATION OF HEALTH PERSONNEL IN THE PROCESSES OF MONITORING AND ASSESSMENT

How the results of monitoring and assessment are handled and how health personnel take part in discussing these results are every bit as important as the prior steps involved in the collection and tabulation of information on the process and its impact. Thus, whenever ARI control activities are assessed in a limited or comprehensive manner, the persons concerned must be brought into the process.

The participation of personnel can take many forms, including: meetings to review progress

in activities, updates and bulletins that publish results, integration of the results into the course materials used for personnel training, and conferences or seminars held by medical professionals during which results are examined and problems concerning scientific knowledge are discussed.

An assessment meeting held on at least an annual basis is essential to allow health personnel themselves an opportunity to show the results of their activities. During these meetings, the accomplishment of proposed goals is studied and related to the actual impact that has taken place. It is essential for the information to be presented, even when goals and objectives have not been achieved for the period in question. This procedure will allow personnel to feel that they are participants in the assessment process and enable them to examine the reasons that proposed goals have been missed. Not only should personnel participate who provide direct care for children with ARI, but supervisory staff and personnel responsible for the collection and management of records should also take part.

When these review sessions are held locally, it is important that higher-level officials at the regional or national level also attend. Regular reports to higher-level health officials are needed to keep them abreast of the course of ARI control activities, both progress made and problems encountered. This communication facilitates institutional support from higher management levels and engages them in the solution to problems where their assistance and intervention may be useful.

Finally, the review meetings should be followed up with a summary report that is distributed as broadly as possible among health personnel, community groups, and other organizations. This feedback will help make activities better known, earn them greater support, and fulfill the major objectives of the general assessment: to make known the progress of activities conducted, specify the shortfalls in the results anticipated, and evaluate the factors that need improvement to achieve the goals set forth.

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Table 1. Indicators proposed for the "Assessment process" of ARI control activities

AREA	INDICATORS	CALCULATION	DATA SOURCE
TRAINING	<p>Proportion of health personnel trained in standard ARI case management</p> <p>Proportion of health services in area that have at least one staff member trained in standard ARI case management</p>	<p>Number of health personnel trained in standard ARI case management</p> <hr/> <p>Total number of health personnel working in the area</p> <p>Number of health services in area that have at least one staff member trained in standard ARI case management</p> <hr/> <p>Total number of health services in area</p>	<p>Numerator: list of those who have attended training sessions or courses during the period in question</p> <p>Denominator: list of all personnel in all health centers</p> <p>Numerator: list of those who have attended training sessions or courses, according to health center where they work</p> <p>Denominator: list of all health services in the area</p>
PROVISION OF SUPPLIES	<p>Proportion of health services in area that have regular supply of antibiotics</p> <p>Proportion of health services in area that have regular supply of other drugs</p> <p>Proportion of health services in area that have regular provision of other supplies</p>	<p>Number of health services in area that have regular adequate supply of antibiotics</p> <hr/> <p>Total number of health services in area</p> <p>Number of health services in area that have regular adequate supply of other drugs</p> <hr/> <p>Total number of health services in area</p> <p>Number of health services in area that have regular adequate provision of other supplies</p> <hr/> <p>Total number of health services in area</p>	<p>Numerator: the data sources for these indicators may be:</p> <ul style="list-style-type: none"> • If the supervision of the health services is regular and of good quality, this information should be provided directly in the supervisory reports, which should note the level of drugs and other inputs available. If these conditions are met, these reports will be the best way to demonstrate regular provision of these supplies. • If the supervision of the health services is not regular or is deficient, the most reliable source of this information may be the reports or records on the delivery of drugs and other supplies that the pharmaceutical or other divisions keep. Even though this information may not be as meaningful as a specific report on availability, it will be useful in calculating realistic estimates. <p>Denominator: list of area health services, as with the other three above indicators</p>

Continued on the following page

Table 1. (continued)

AREA	INDICATORS	CALCULATION	DATA SOURCE
SUPERVISION	Proportion of health services in area that are regularly supervised	Number of health services in area that are regularly supervised Total number of health services in area	Numerator: supervisory reports on health centers in area Denominator: list of all health services in area
ACCESS	Proportion of health services in area that can offer standard ARI case management Proportion of population in area that have access to health services that offer standard ARI case management Proportion of mothers in area that know when to seek care from a health worker for a child with ARI	Number of health services having trained personnel, adequate supplies, and regular supervision Total number of health services in area. Population of children under 5 covered by health services that use standard ARI case management Total population of children under 5 in area Mothers of children under 5 in area who recognize ARI danger signs that require them to seek professional care Total number of mothers of children under 5 in area.	Numerator: supervisory reports if they are done regularly and properly Denominator: list of all health services in area This is a composite indicator. Thus, the population of the service area must be calculated if it is not already known, and the corresponding services must be known. Once these two data are obtained, a calculation should be made first of the population covered by health services that provide standard case management for ARI (numerator) and then of the total population in the service area (denominator). The information for the latter may be found in local supervisory reports or surveys of the local services; the information for the numerator should be available as part of the basic information used by the services. To obtain the information to calculate this indicator, a household survey is needed that will determine mothers' knowledge of danger signs. The numerator is the number of mothers who respond correctly to the survey and the denominator is the total of mothers surveyed in the area
USE	Attempt to obtain needed care for a child with ARI from a health worker	Number of children with ARI who should have received care from health service and were in fact taken to a service that provides standard case management Total number of children with ARI who should have received care from health personnel	Calculation of this indicator requires a household survey that will determine the signs and symptoms of the child's last bout with ARI that required treatment and which children were brought to a service that provides standard ARI case management.

SOURCE: Pan American Health Organization. *Infecciones respiratorias agudas: Guía para la planificación, ejecución y evaluación de las actividades de control dentro de la atención de primaria de salud*. PAUTEX Series for health program managers. No. 17. Pan American Health Organization. 1988.

Table 2. Proposed indicators for the "Impact assessment" of ARI control activities

AREA	INDICATORS	CALCULATION	DATA SOURCE
MORTALITY	<p>Individual analysis of deaths of children under 5</p> <p>Mortality from pneumonia in children under 1 year, 1-4 years, or under 5</p> <p>Mortality from all causes in children 1-4 years and under 5 years</p>	<p>Number of pneumonia deaths in children under 1, 1-4, and under 5 years in the region in a given year</p> <hr/> <p>Total population of children in the region in that year</p> <p>Total mortality in children under 1, 1-4, and under 5 years in the region in a given year</p> <hr/> <p>Total population of children under 1, 1-4, and under 5 years in the region in a given year</p>	<p>The individual analysis of each death requires information on deaths in the region that can normally be obtained from hospital records, health service offices, civil registers, notaries, local courts and judges' files, cemeteries, funeral parlors, and any other available source that records deaths.</p> <p>Numerator: the same data sources for deaths that is used above should be used here as well. In addition, health statistics at the regional and central level may be helpful.</p> <p>Denominator: Estimates and census data, preferably official, may also be used. If they are not available, data from health personnel or other institutions may be helpful.</p> <p>The data for both the numerator and denominator may come from the same sources mentioned above.</p>
ANTIBIOTIC USE	<p>Proportion of all ARI cases in children under 5 received in health services who were treated with antibiotics</p>	<p>Number of all ARI cases in children under 5 received in health services who were treated with antibiotics in a given year</p> <hr/> <p>Number of all ARI cases in children under 5 received in health services in the same year.</p>	<p>The information for all the indicators in this area (ANTIBIOTIC USE) may be obtained from health service records, which should indicate the diagnosis for each case received and the type of treatment prescribed.</p> <p>These records can provide information to formulate the indicators in two main ways:</p> <p>a) Using ongoing information systems, either previously existing ones or those created specifically for this purpose. These systems allow data to be gathered regularly (on a monthly, bimonthly, or semester basis) to formulate the indicators.</p>

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AREA	INDICATORS	CALCULATION	DATA SOURCE
ANTIBIOTIC USE (Continued)	<p>Proportion of all pneumonia and acute otitis media cases in children under 5 received in health services who were treated with antibiotics.</p> <p>Proportion of all ARI cases other than pneumonia and acute otitis media in children under 5 received in health services and treated with antibiotics</p> <p>Proportion of each pathology in relation to total ARI cases in children under 5</p>	<p>Number of all pneumonia and acute otitis media cases in children under 5 received in health services who were treated with antibiotics</p> <p>Number of all pneumonia and acute otitis media cases in children under 5 received in health services in the area in the same time period</p> <p>Number of all diagnosed cases, other than pneumonia and acute otitis media, in children under 5 received in area health services and receiving antibiotic treatment in a given year</p> <p>Number of all diagnosed cases, other than pneumonia and acute otitis media, in children under 5 received in area health services in a given year</p> <p>Number of cases of each diagnosis in children under 5 received in health services in a given year</p> <p>Number of all ARI cases in children under 5 received in health services in the same period</p>	<p>b) The supervisory reports, which should demonstrate that the supervisory guides provide for the retrospective review of records to practice case management.</p> <p>Any data source should include the patient's age, diagnosis, and treatment.</p>
REDUCTION IN HYPOACUSIA	<p>Proportion of cases of acute otitis media in children under 5 that are properly cared for</p>	<p>Number of cases of acute otitis media in children under 5 that are properly cared for</p> <p>Total number of cases of acute otitis media in children under 5</p>	<p>The data sources for this indicator are the same ones used for tracking antibiotic use.</p>

SOURCE: Pan American Health Organization. *Infecciones respiratorias agudas: Guía para la planificación, ejecución y evaluación de las actividades de control dentro de la atención de primaria de salud*. PAITEX Series for health program managers, No. 17. Pan American Health Organization, 1988.

