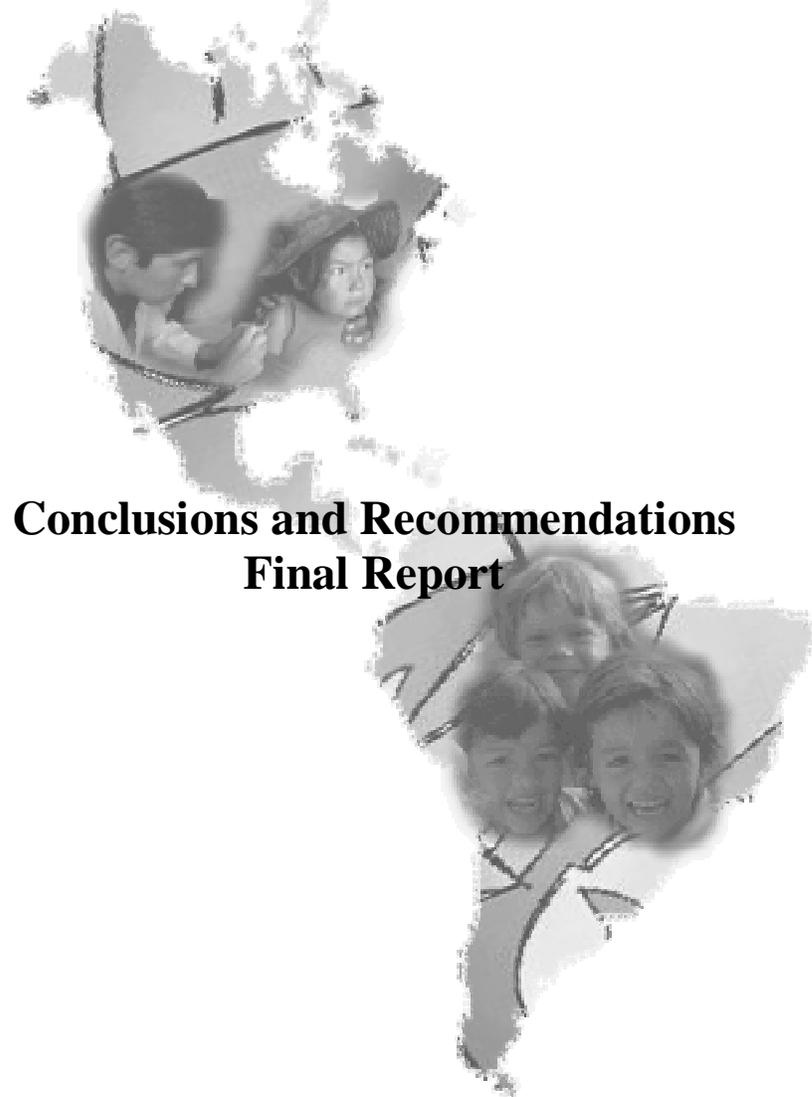


XIII MEETING OF THE PAHO TECHNICAL ADVISORY GROUP ON VACCINE PREVENTABLE DISEASES

HULL, QUEBEC
CANADA
APRIL 12 – 16, 1999



Conclusions and Recommendations Final Report

Division of Vaccines and Immunization



PAN AMERICAN HEALTH ORGANIZATION
Pan American Sanitary Bureau, Regional Office of the
WORLD HEALTH ORGANIZATION



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INTRODUCTION

The Region of the Americas enters the new millenium with great promise and strength. Additional vaccines are being added to the basic schedule every year, and the Region is making progress toward ensuring that these vaccines are of known quality. Much remains to be done, however, especially in reaching those people that are currently not benefiting from immunization services, and those who could already be enjoying vaccination against diseases with a significant health burden. On the other hand, there is a tendency for complacency that goes hand in hand with the success achieved by immunization worldwide. Efforts are needed to wider disseminate the value of vaccines to individuals and the community at large. With the shift towards decision-making on health at the local level, efforts will also be needed to maintain the technical and managerial excellence achieved by all countries in immunization. The process of decentralization should be used as an opportunity to implement equitable immunization programs in all areas of the Americas.

Immunization coverage levels remain at above 80% throughout the Americas, thereby reaching the vast majority of children with the basic vaccination schedule. The strength of these programs lies in a Panamerican approach to tackle important public health programs. The historic poliomyelitis eradication in the Americas was the product of the collective action of collaborating agencies, countries and beneficiaries alike, in the pursuit of a common objective. This collaboration has enabled many countries in the Region to acquire the necessary tools to improve their health situation by themselves.

1. IMPACT OF DECENTRALIZATION AND HEALTH SECTOR REFORM ON NATIONAL IMMUNIZATION PROGRAMS

The processes of health reform and decentralization of health services are well underway in the countries of the Americas. While laws have been enacted that transfer decision-making and resources to the local levels, in practice there is a need to clarify the responsibilities of the various institutions assigned to the delivery of immunization services, as well as mechanisms to transfer and manage resources. These changes are causing delays, especially in the allocation of resources for routine vaccination activities and for emergency outbreak situations in some countries.

Several countries going through the process of decentralization and health reform are showing a decline in process indicators for immunization programs, such as coverage and surveillance. This could have serious implications, both nationally and internationally for immunization programs, especially for measles eradication. National governments should make special efforts to maintain the quality and effectiveness of national immunization programs, so that no areas become a reservoir to seed infection into other communities and countries.

TAG acknowledges the partnership between the Government of Bolivia, the World Bank, and the Pan American Health Organization to strengthen the national immunization program in Bolivia. This collaboration provides the necessary institutional and financial mechanisms that support the equitable and effective implementation of immunization programs and accelerate the introduction of other vaccines of public health importance in the routine schedule. This effort should serve as a model of joint agency collaboration in other countries of the world.

Recommendations:

- Decentralization as part of health system reform is recognized to be a positive step in strengthening health systems. However, assurance is needed of consistent implementation throughout the country for health programs such as national immunization programs, which require adequate performance in all areas.

Financing

- Vaccination and surveillance programs should be considered essential public goods and funded with public resources. National governments must keep the control of the use of resources to fund national vaccination programs coming from outside sources.
- Legislation must be established that supports the creation of a direct budget line to finance recurrent costs associated with vaccination programs.
- Countries must acknowledge the presence of new partners, such as the World Bank, the Inter-American Development Bank, foundations, local community organizations and private sector organizations, and must foster their active participation in national inter-agency committees in discussion of mechanisms for financing and other support for national immunization programs.
- National governments must maintain the authority to monitor the implementation of immunization programs at the state and local level.
- National governments must establish clear mechanisms to transfer and manage financial resources to the local level, to avoid disruptions in vaccination and surveillance activities, and to respond quickly to emergency situations.
- Vaccination services must be protected as an essential activity within a country's basic health package, whenever such definition exists.
- Performance agreements are increasingly being utilized as part of decentralization for the purpose of resource allocation. National governments should ensure that immunization indicators are included in these performance agreements with the local levels.

Delivery of Immunization Services

- Health authorities need to ensure that national technical and managerial capabilities are in place at the local level, especially to conduct surveillance and immunization activities. These steps will be essential to ensure that immunization services remain a priority and that they are delivered in an equitable way.
- The roles and responsibilities of the local and central levels in the delivery of immunization services should be clearly made known to local authorities.
- State authority must develop mechanisms to grant accreditation to public and private health centers prior to them offering vaccination services. Health authorities also have the responsibility of periodically supervising these accredited health centers.

Essential Public Health Functions of National Governments

- National governments must maintain authority for the following key functions: procurement and distribution of vaccines and syringes, programmatic guidelines, national goals and strategies, monitoring and evaluation of program performance at the state level and assurance of quality of vaccines used in national immunization programs.

Programmatic

- Immunization and surveillance indicators should be used for monitoring the impact of decentralization and health sector reform.
- Governments need to ensure that local staff responsible for reporting epidemiological information on vaccine-preventable diseases follow standardized reporting procedures.

2. MEASLES ERADICATION

Great progress has been made towards interrupting measles transmission in most countries of the Americas. However, measles virus continues to circulate in several areas of the Region and only twenty-one months remain until the target date of achieving the goal of hemispheric measles eradication.

PAHO's recommended vaccination strategy (*catch-up, keep-up and follow-up*), where fully implemented, has proven to be highly effective. However, as clearly demonstrated by the 1997 São Paulo measles outbreak, the absence of measles virus circulation during several years does not equal the absence of risk for a measles outbreak. During prolonged periods of low or zero measles incidence, the number of susceptible children gradually increases in a community. These susceptible children can sustain future measles outbreaks should the virus be reintroduced. Achieving and maintaining a measles-free Americas will require ongoing efforts to minimize susceptibility by **fully** implementing the PAHO vaccination strategy in all countries of the Region.

Recommendations:

TAG notes with satisfaction the great progress made towards achieving the eradication of measles in the Americas. Several countries, however, represent weak links that could jeopardize the achievement of this goal, and pose a serious threat of virus introduction to neighboring countries. To reduce the risk of measles outbreaks, PAHO should facilitate special inter-country meetings in high-risk areas to encourage the exchange of information and to help define and plan joint measles vaccination and surveillance activities.

TAG highlights the following areas of concern:

- The large number of susceptible children in Haiti and Guatemala places these countries at very high risk for large measles outbreaks. Efforts are urgently needed in both countries to conduct *follow-up* campaigns and achieve very high coverage.

- With measles virus circulation interrupted in most countries of the Americas, outbreaks provide a special opportunity for the entire Region to obtain information that can be used to prevent future outbreaks. Therefore, investigation reports from all outbreaks, including the 1998 outbreak in Argentina, should be made available to all countries. PAHO should assist in the collection and dissemination of this information throughout the Region.

Vaccination Strategies

- The full implementation of PAHO's recommended vaccination strategy in all countries of the Region is needed to assure the eradication of measles from the Americas.
- Routine vaccination of infants (*keep-up* vaccination) is a critical component of the PAHO measles eradication strategy. Efforts are needed to vaccinate $\geq 95\%$ of infants as soon as possible after their first birthday in every district of every country every year.
- Vaccine coverage must be monitored at the district level or geographic equivalent using appropriate denominators for the target population. Supplemental vaccination (*mop-up*) activities are needed in those districts that do not achieve 95% coverage. These activities may include door to door vaccination.
- *Follow-up* measles vaccination campaigns should be conducted when the estimated number of susceptible children 1-4 years of age approaches the number of children in one birth cohort. In most countries, these campaigns are conducted every four years, but should be conducted sooner if needed (based on coverage obtained in routine programs and other epidemiologic information).
- In countries with rubella/CRS control programs, measles and rubella-containing vaccines should be used for routine infant vaccination, *follow-up* campaigns and outbreak response activities.
- Healthcare workers are at increased risk for being exposed to measles virus and for being a potential source of virus transmission in health facilities. Persons working in healthcare settings who have contact with children and persons with infectious diseases should be vaccinated against measles, regardless of disease history or vaccination status. Rubella containing vaccine should be used.

Outbreak response

- Recent experience from outbreaks in Latin America has demonstrated that certain groups of adults may be at increased risk for measles during an outbreak. These groups have also been responsible for sustaining measles outbreaks and for transmitting measles to susceptible persons of other age groups. Since the epidemiologic situation differs between countries, it is not possible to give blanket recommendations about which groups of adults to vaccinate in all countries. When measles virus circulation is suspected, consideration should be given to quickly vaccinate persons within the following groups: teachers, university students, military personnel and persons living/working within institutions such as prisons, large factories, work camps and chronic care medical facilities.
- To obtain information that can be used to prevent and control future outbreaks, appropriate investigations and analysis must be conducted for all measles outbreaks. Efforts are needed

to determine sources of measles virus introduction, transmission patterns and specific risk factors for acquiring measles.

- Once measles virus circulation has been confirmed by positive measles IgM serology in several patients, it is not necessary to routinely collect blood specimens from every suspected case. Many suspected cases can be confirmed via epidemiological linkage to a laboratory-confirmed case.

Vaccine Stockpile

- PAHO should assure that a stockpile of measles containing vaccine is readily available to deal with emergency situations. Since many countries of the Americas are establishing rubella control/elimination goals, consideration should be given to having a stockpile of MR vaccine.

Surveillance and Laboratory

- Measles surveillance is critical for measuring progress towards the goal of measles eradication in the Americas and for detecting problem areas. Efforts are urgently needed to improve the quality of measles surveillance throughout the Region.
- To monitor progress toward the achievement of measles eradication, all countries should provide data on a weekly basis to the Region-wide measles eradication surveillance system (MESS).
- Each country should periodically have its measles surveillance system objectively evaluated using the standardized evaluation protocol developed by PAHO. Countries should constantly work to improve the quality of the reporting system.
- Virologic surveillance and molecular epidemiology can provide important information to an eradication program. Appropriate clinical specimens for viral isolation should be obtained from every chain of measles transmission. Urine, the most practical specimen to collect for measles virus isolation, should be obtained within 7 days of rash onset and forwarded to a reference laboratory capable of performing measles virus isolation.

3. RUBELLA AND CONGENITAL RUBELLA SYNDROME

Rubella virus continues to circulate freely in most countries of the region. After a complete investigation, many suspected measles cases are ultimately found to be rubella. Moreover, cases of the Congenital Rubella Syndrome (CRS) have been found in all countries of the Region that have established CRS surveillance systems. This suggests that CRS is a major public health problem in all countries of the Americas.

Recommendations:

Vaccination Strategies

- All countries should incorporate rubella-containing vaccine into childhood vaccination programs, both as part of routine childhood immunization at 12 months, and as part of the

follow-up campaigns. Moreover, targeted efforts are needed to reduce the number of rubella susceptible women of childbearing age. Strategies, such as post-partum immunization, immunization in family planning clinics, immunization in schools and the workplace can be used to protect these women.

- There are substantial data available documenting the absence of significant risk of rubella vaccination during pregnancy. However, pregnant women are generally not vaccinated. This is to avoid the risk of the vaccine being implicated should there be an unrelated adverse outcome of the pregnancy. For women who are vaccinated and then subsequently found to be pregnant, abortions are not recommended. Finally, it is not necessary to counsel women to avoid pregnancy for 3 months following rubella vaccination because no known risk of adverse fetal outcomes has been established.
- Countries wishing to prevent and control CRS promptly should conduct a one time mass campaign to vaccinate all females 5-39 years of age with measles and rubella containing vaccine.
- Countries wishing to prevent and control both rubella and CRS promptly should conduct a one time mass campaign to vaccinate BOTH males and females 5-39 years of age with measles and rubella containing vaccine.

Surveillance and Laboratory

- Rubella surveillance should be integrated with measles surveillance. The purpose of rubella surveillance is to detect circulation of rubella virus, not to detect every case of rubella. A separate rubella surveillance system is not needed. All sera from suspected measles cases which test negative for measles IgM antibodies should be tested for rubella IgM antibodies and vice versa.
- CRS surveillance should be initiated throughout the Americas. The purpose of CRS surveillance is to detect new or incident CRS cases in infants; efforts should not be routinely made to confirm CRS in older children.
- The following case definitions are recommended for CRS surveillance:
 - **Suspected CRS case:** A suspected CRS case is considered as any infant less than one year of age in whom a healthcare worker suspects CRS. A health care worker at any level of the health care system should suspect CRS in an infant when:
 1. One or more of the following birth outcomes are detected: congenital cataracts, hepatosplenomegaly, patent ductus arteriosus, purpura or hearing impairment
 2. An infant's mother was known to have had laboratory confirmed rubella infection during pregnancy **AND** after a thorough physical examination, for any reason, there is clinical suspicion of CRS in the infant.

Infants with low birth weight should be specifically targeted for a careful clinical examination for CRS specific birth defects.

- **Laboratory-confirmed CRS case:** A laboratory confirmed CRS case is a patient in whom a healthcare worker initially suspected CRS that is found to have laboratory evidence of rubella virus infection (i.e., rubella IgM positive).
- **Clinically-confirmed CRS case:** A clinically confirmed CRS case is an infant in whom a healthcare worker initially suspected CRS, but laboratory confirmation of rubella infection is not available. This is generally due to the absence of an appropriate clinical specimen. Since presence or absence of rubella infection could not be determined, these cases are considered as failures of the CRS surveillance system.
- **Congenital rubella infection only, without CRS:** This designation is used for an infant born to a woman infected during pregnancy. These infants are IgM positive for rubella, however, there are no clinical findings which are compatible with CRS. These cases should be discarded as not being CRS, and classified as congenital rubella infection (CRI).
- **Discarded CRS case:** A suspected CRS case may be discarded if an adequate serum sample from the infant tests negative for rubella IgM antibodies.
- Similar to measles/rubella surveillance, laboratory confirmation is crucial for the diagnosis of CRS. A blood sample should be collected from every infant with suspected CRS. For surveillance purposes, a single serum specimen is generally considered adequate to either confirm or discard CRS. If, however, the first sample tests negative for rubella IgM and there exists compelling clinical and/or epidemiologic suspicion of CRS, then a second serum specimen may be requested to confirm CRS.
- Little information is available concerning the molecular epidemiology of rubella in the Americas. Similar to measles surveillance, rubella virus surveillance may provide important information concerning the viral sub-types that are currently circulating in the Region. Efforts should be made to collect several appropriate clinical specimens for viral isolation from every documented rubella outbreak. Nasopharyngeal aspirates are the preferred specimens for rubella virus isolation. Specimens should be collected within 4 days of rash onset and forwarded to an appropriate reference laboratory.

4. POLIOMYELITIS

The Region of the Americas remains at constant risk for polio importations from countries where the virus still circulates widely. Poliovirus is now largely confined to South Asia, West Africa, Central Africa and the Horn of Africa. However, there have already been two importations detected in Canada since the confirmation of the last case of acute flaccid paralysis due to wild poliovirus in 1991.

National data continue to show deterioration in the surveillance of AFP in some countries. It is critical that AFP surveillance system remains fully functional to rapidly detect poliovirus throughout the Region, should the virus be re-introduced.

The eradication of polio from the Western Hemisphere is a well-known public health milestone. After seven years of maintaining the Region polio-free, it would be a tragedy if polio is re-established in the Hemisphere. A high level of commitment should be maintained at the

political level in *every* country, to protect the population and prevent the re-establishment of the disease in the Region.

Recommendations:

General

- Countries need to maintain 95% vaccination coverage with OPV in 80% of the districts or equivalent geopolitical area. Countries unable to reach this coverage level should carry out at least two National Immunization Days (NIDs). Measles *follow-up* vaccination campaigns should be used as an opportunity to administer OPV.
- Immunization coverage should be monitored at the lowest geopolitical level. In areas that have discrepancies in terms of target population, there should be verification of information using other sources, such as number of BCG doses applied, or number of DPT1 doses, or results of *mop up* operations, or household census used by malaria programs, or rapid assessment surveys.
- All countries should strengthen the key surveillance indicators of AFP reporting:
 - Surveillance systems must detect at least one AFP case per 100,000 population <15 years of age per year.
 - At least 80% of the AFP cases should have an adequate stool sample collected **within 15 days** of paralysis onset.
- **Oral polio vaccine (OPV)** remains the vaccine of choice for the final phase of the global eradication of polio. OPV is the vaccine recommended for the eradication because it is easier to administer, is inexpensive and it provides better intestinal immunity which constitutes a special barrier to inhibit further spread of wild poliovirus.

Laboratory

- Stool samples must be received in laboratories within 14 days after collection. Once a sample has arrived in a laboratory, results should be available within 28 days.
- All laboratories should implement the use of RD and L20B continuous cell lines.
- Efforts are urgently needed to strengthen communication between polio laboratories and epidemiology units.
- All governments should ensure the implementation of WHO's Guidelines for Implementing Phase I of the Global Action Plan for Laboratory Containment of Wild Polioviruses.

5. NEONATAL TETANUS

Tremendous progress has been made in eliminating neonatal tetanus (NNT) as a public health problem throughout the Americas. In 1998, there were 223 reported cases of NNT from

16 countries in the Region. This represents an 85% reduction in cases since intensive efforts were instituted in 1988.

While there has been a gradual decline in the number of districts that are repeatedly affected, cases continue to be reported. Targeted efforts are needed to increase the level of protection among women of childbearing age (WCBA) living in high-risk districts. Provisional data show that a majority of NNT cases occur in infants born to multiparous mothers. This stresses the need to eliminate missed opportunities to vaccinate.

Recommendations:

- Td is the vaccine of choice among WCBA for NNT prevention.
- In high-risk districts intense efforts (Attack Phase) are needed to achieve 90% Td2 coverage among WCBA. Furthermore, ongoing vaccination efforts are needed to assure that at least 90% of all new cohorts of WCBA receive a dose of Td.
- Missed opportunities to vaccinate can be markedly reduced by administering Td to all mothers who visit a health center for any reason. Women attending prenatal clinics should have their vaccination histories reviewed and should receive vaccination if they had not previously received at least two doses of Td.
- Many NNT cases have occurred in infants born to mothers who have had one or more previous live births. Post-partum Td vaccination in health facilities can be used as an additional opportunity to prevent NNT.
- All cases of NNT should be fully investigated. Case investigations should obtain information about the mother's age, immunization history and recent migration. The mother's migration history may help to identify additional high-risk districts for NNT.
- Tetanus occurring in other age groups should be reported and investigated; this information will help to identify specific risk groups.
- Health professionals and the general population need to be informed about the importance of WCBA maintaining good documentation of their vaccination histories (i.e. vaccination cards).

6. YELLOW FEVER

Although no case of urban yellow fever has been reported in the Region since 1942, more than 1,900 cases of sylvatic (jungle) yellow fever have been notified from Bolivia, Brazil, Colombia, Ecuador, Peru, French Guyana, and Venezuela over the past 10 years. Although all of these infections were acquired in endemic areas, many of the cases were diagnosed and reported in urban environments. The widespread dissemination of the *Aedes aegypti* mosquito throughout the Americas makes the re-urbanization of yellow fever an increasing concern.

The seriousness of the yellow fever problem in the Region requires a commitment by countries at risk to implement appropriate vaccination and surveillance strategies for controlling and preventing the disease. Yellow fever vaccine is highly effective, safe and inexpensive. A

single dose of yellow fever vaccine will confer immunity to at least 95% of persons vaccinated and is protective for at least 10 years.

Recommendations:

- Yellow fever endemic countries must achieve 100% vaccination coverage in enzootic yellow fever zones, as well as in contiguous areas infested with *A. aegypti*. These steps will provide protection to those persons exposed to the sylvatic cycle and will help prevent the introduction of the disease to urban settings.
- Given that it is difficult to predict demographic movements, countries with high migrant movements from non-enzootic to enzootic areas should consider national mass vaccination campaigns to immunize the entire population. Brazil is planning to conduct such a campaign.
- Yellow fever vaccination is also recommended for all travelers entering enzootic areas.
- In order to maintain high levels of population immunity to yellow fever, countries at risk should incorporate yellow fever vaccine into routine childhood vaccination schedules. Yellow fever vaccine should be given, as a separate injection, when measles vaccine is administered.
- Yellow fever surveillance must be strengthened. Timely yellow fever surveillance will allow the rapid implementation of control activities when an outbreak is detected. All suspected cases meeting the WHO surveillance case definition and those with icteric syndrome, in whom other infectious etiologies have been ruled out, should be investigated.
- Countries should prepare emergency rapid response guidelines to be used in the event of a yellow fever outbreak.
- Adequate planning of vaccine supply for routine vaccination and outbreak control is critical. A stockpile of vaccine should be available at *all* times.
- The implementation of a comprehensive vector control and surveillance program will keep the density of *A. aegypti* low in urban environments. This approach will also help to prevent dengue outbreaks.

7. HAEMOPHILUS INFLUENZAE TYPE B VACCINE

Disease burden studies in several Latin American countries have clearly demonstrated that *Haemophilus influenzae* type b (Hib) is an important cause of infant morbidity and mortality. Clinical presentations of Hib infection include meningitis, pneumonia and epiglottitis, among others. Moreover, mental retardation has been shown to be a major sequelae of Hib meningitis. Safe and effective Hib vaccines are available. These vaccines have had a significant impact in reducing Hib disease incidence in countries where the vaccine has been introduced in routine infant immunization programs and high coverage has been obtained. Results from Hib vaccine introduction in Uruguay and Chile have shown an impressive impact on Hib disease and indication of reduction of pneumonia cases.

Remarkable progress has been achieved in the introduction of Hib vaccine in the Americas. By December 1999, PAHO estimates that 81% of all newborns in the Region (75% in Latin America and the Caribbean) will be living in countries where Hib vaccine is included in routine infant immunization schedules.

Given that the price of Hib vaccine remains a major obstacle to introducing the vaccine in all countries, sustainable financing mechanisms will have to be found. In this regard, PAHO's Revolving Fund for Vaccine Procurement can accelerate the introduction of Hib vaccine to all countries by significantly reducing vaccine price through large volume purchases.

Recommendations:

- Hib vaccine should be included in the routine immunization programs of every country in the Region once sustainability has been assured.
- Countries introducing Hib vaccine should monitor and report vaccine coverage.
- Purchase of Hib vaccine or combined vaccines containing Hib antigen through the PAHO Revolving Fund can result in significant cost savings.
- Countries should have surveillance systems to monitor Hib-related illnesses and to measure the impact of vaccine introduction. All countries in the Region should implement hospital-based sentinel surveillance for meningitis and pneumonia due to *H. influenzae* type b and *Streptococcus pneumoniae*. Surveillance should be integrated with and strengthen already existing systems. A network consisting of sentinel hospitals, public health laboratories, and national epidemiology units should be organized in each country.
- PAHO should provide technical support to assure the implementation and coordination of this surveillance system.

Combination vaccines

The availability and use of combination vaccines with DTP vaccine will simplify the administration of vaccine antigens against major childhood diseases. Furthermore, it will result in infants and children receiving fewer injections, fewer visits to health centers and an increase in compliance and coverage.

- Countries that include DTP, Hib and/or Hepatitis B vaccines in their routine immunization programs should consider introducing vaccines that contain either the four or five antigens in combination.

8. ROTAVIRUS VACCINE

Worldwide, rotavirus infection contributes significantly to infant and child morbidity and mortality due to diarrheal diseases. In developing countries, rotavirus accounts for a sizable proportion of all deaths due to diarrhea, especially in children <5 years of age.

A live, orally administered rotavirus vaccine became available in 1998. In limited field trials the vaccine was shown to be protective against severe diarrhea, although it did not prevent infection with rotavirus.

Although rotavirus vaccine is a potential candidate for inclusion in national immunization programs, a better understanding of rotavirus epidemiology and burden of disease in different countries is needed. Each country will eventually need to weigh the economic implications of introducing the vaccine into its immunization schedule.

Recommendations:

- Studies are needed to better define disease burden, define the epidemiology of rotavirus and critically analyze the economic aspects associated with the introduction of rotavirus vaccine.
- Countries should establish strong technical and scientific advisory committees that can advise governments concerning the introduction of rotavirus and other new vaccines. These advisory committees will help assure that only safe, cost-effective and appropriate vaccines are incorporated into national immunization programs.

9. VACCINES OF QUALITY

Using vaccines of proven quality is essential for immunization programs. Although the manufacturer is primarily responsible for assuring vaccine quality, there should be a national authority in each country that performs the six basic regulatory functions: licensing, clinical evaluation, Good Manufacturing Practices (GMP) inspections, lot release, laboratory testing and post-marketing surveillance.

PAHO has been strengthening the vaccine quality control system in the Region by organizing a network of certified national control laboratories responsible for the quality testing of vaccines and by harmonizing regulatory procedures of National Regulatory Authorities of all countries.

Recommendations:

- It is essential that immunization programs use vaccines of known quality according to international standards of safety, potency, efficacy and stability. It is expected that all countries will meet this goal by the year 2000.
- Vaccine producers must implement quality systems that guarantee consistent production of vaccines in compliance with GMP, national regulations, and WHO requirements on vaccine quality and production.
- The fulfillment of international quality standards must be an essential factor to be considered in the economical and technical feasibility studies of vaccine production.
- Governments in the Region must, through their National Regulatory Authorities, assure that they have effective control of the quality of vaccines used in the country: all vaccines used in the country should be licensed and every lot released before usage. In vaccine-producing countries, National Regulatory Authorities should comply with laboratory testing of vaccine lots, GMP inspections and post-marketing surveillance.

- National Control Laboratories should participate in the certification program in order to guarantee the quality of their results and provide analytical support to National Regulatory Authorities and PAHO.

10. HEPATITIS B

It has been estimated that as many as 400,000 new hepatitis B infections occur annually in the Americas. In highly endemic areas, transmission occurs primarily perinatally or in early childhood. In areas with intermediate endemicity, infection occurs in all age groups. In areas of low hepatitis B seroprevalence, most infections occur in adults, especially among persons belonging to defined risk groups. Since the development of chronic infection is age-dependent, children can account for a high proportion of chronic hepatitis B infections. The risk of chronic infection is highest when infection is acquired early in life. Chronic infection is responsible for most HBV-related morbidity and mortality.

Recommendations:

- Routine universal infant immunization should be the primary strategy to prevent HBV transmission.
- In highly endemic areas (hepatitis B surface antigen [HbsAg] prevalence >7%), an area-wide vaccination campaign should be conducted.
- Healthcare workers who are at risk of being exposed to blood or other body fluids should be routinely vaccinated.
- Vaccination coverage should be monitored on a regular basis.
- The feasibility of establishing an “integrated” surveillance system for patients presenting with fever and jaundice should be explored. The purpose of such a surveillance system would be to detect cases of hepatitis B, yellow fever and other tropical diseases, such as leptospirosis and malaria.
- Countries that have introduced hepatitis B (HB) vaccine should consider using combined tetravalent (DTP+HB) or pentavalent (DTP/HB+Hib) vaccines. These vaccines have a similar cost to the monovalent vaccines purchased separately and are easier to administer, thereby reducing the number of injections and visits to health establishments.

11. VITAMIN A

Vitamin A deficiency is a significant public health problem in some countries. Chronic Vitamin A deficiency can result in night blindness, growth retardation and developmental deficiencies. Moreover, even marginal levels of Vitamin A deficiency have been associated with increased rates of morbidity and mortality among infants and children.

Vitamin A deficiency can be prevented through various interventions, including Vitamin A supplementation. To increase coverage of Vitamin A supplementation of children and postpartum women, an innovative approach has been to integrate Vitamin A supplementation with immunization services. Several experiences have demonstrated that supplementation activities can be successfully joined with immunization programs, including in campaigns without adversely affecting vaccine delivery. This linkage represents a creative mechanism to combine financial and human resources to provide two cost-effective interventions.

Recommendations:

- Vitamin A supplementation can be effectively integrated into national immunization programs providing an excellent opportunity to reach children with Vitamin A deficiency.
- Any potential additional health intervention to be integrated into established immunization programs should be carefully evaluated in terms of its impact on its effectiveness before being introduced.

12. SAFE SYRINGE PRACTICES

Non-sterile injection practices remain a problem in some areas. Insufficient supplies of syringes and needles seem to be a major factor. Unsafe injections can result in the transmission of blood borne pathogens from person-to-person.

Recommendations:

- The only way to ensure that used injection equipment is not reused is through the utilization of single use auto-destruct syringes.
- All healthcare workers should be informed about the danger of recapping needles.
- All countries using or introducing single use disposable syringes for the delivery of vaccines must absolutely provide the funds for: procurement of sufficient syringes and safety boxes, supervision to document safe syringe disposal and proper collection/burning of used equipment.
- PAHO should provide support for developmental studies of needle-less injection devices.

13. IMMUNIZATION SAFETY

Immunizations have reduced the incidence of vaccine-preventable diseases throughout the world. Public trust in national immunization programs is important to maintain. Although modern vaccines are safe and effective, no vaccine is entirely without risk and significant adverse events. The regular monitoring of immunization safety will provide technical and scientific assurance of the safety of vaccines utilized.

Recommendations:

- All health care workers and program managers should be well informed on the issues concerning immunization safety.
- Adverse events possibly attributable to vaccination should be promptly reported.
- Health systems should respond promptly and appropriately by conducting careful investigations of such events.
- Information regarding significant adverse events causally related to immunization should be shared between immunization managers and health workers within the Region.
- PAHO should convene a Working Group to propose methodologies for monitoring immunization safety throughout the Americas.

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