EPI Newsletter

Expanded Program on Immunization in the Americas

Volume XXVII, Number 2 **IMMUNIZE AND PROTECT YOUR CHILDREN** April 2005

Meeting of the Interagency Coordinating Committee for Immunization, Guatemala, March 2005: Pushing the Unfinished Immunization Agenda

From early on, the Interagency Coordinating Committees (ICCs) for immunization have been a cornerstone in the success of immunization programs in the Region of the Americas. ICCs channel efforts by international agencies, governments, and the civil society to help countries strengthen their immunization programs and control vaccine-preventable diseases. ICCs are charged with the task of ensuring coordination of all inter-agency inputs. They review the progress made and the needs for additional assistance. They also play a critical role in the implementation of immunization Plans of Actions.

In March 2005, Guatemala held an ICC meeting. The meeting brought together prominent Guatemalan authorities, including the Minister of Health and the Vice-Minister of Finances, and major international partners. It also included the participation of Pan American Health Organization Director, Dr. Mirta Roses Periago. As she stated in her presentation, the primary focus of the meeting was to complete the unfinished immunization agenda: the conviction that in spite of the Region's great strides in the fight against vaccine-preventable diseases (eradication of poliomyelitis, elimination of endemic measles transmission), new challenges loom ahead, and much remains to be accomplished. The participants also recognized that immunization plays a significant role in reaching the Millennium Development Goals of reducing child mortality and improving maternal health, and is a key tool for the promotion of socioeconomic development.

From left to right, Dr. J. Andrus, Chief, Immunization Unit, PAHO; Dr. J. Molina Leza, PAHO/WHO Representative, Guatemala; Dr. M. Roses Periago, Director, PAHO; Mr. M. Tulio Sosa, Minister of Health, Guatemala; and Dr. E. Asturias, International Cooperation Advisor, Ministry of Public Health and Social Assistance, Guatemala.

Dr. Roses Periago praised Guatemala for its achievements in immunization over the last 25 years. She particularly commended the country for the introduction of the pentavalent vaccine[1] into its childhood immunization schedule in 2005. Dr. Roses Periago summarized future challenges to be: eliminating rubella and congenital rubella syndrome from the Americas; sustaining immunization programs as they introduce new vaccines; and achieving equity by striving to immunize every child. To achieve these goals, Dr. Roses Periago emphasized the importance of partnerships for external cooperation, and mobilization of resources under the umbrella of the Ministry of Health.

Dr. Roses Periago made an appeal to ICC members to enact an Immunization Law ensuring a budget line for vaccines and operational expenses of the immunization program. This would help ensure program sustainability, and would assist the Guatemalan Government in guaranteeing the right of its people to immunization.

[1] Pentavalent vaccine: Combination vaccine against diphtheria-pertussis-tetanus-*Haemophilus influenzae* type b-hepatitis B

In this issue:

The Minister of Health, Mr. Tulio Sosa thanked the participating partners for their technical cooperation, particularly in the areas of social communication, strengthening of the surveillance system for vaccine-preventable diseases (including the national laboratory capacity), and support to activities aimed at increasing vaccination coverage, all leading to improved health for the people of Guatemala.

The participating embassies, technical cooperation agencies, and non-governmental agencies congratulated Guatemala for the achievements of its immunization program. They pleaded for a stronger strategic alliance between immunization partners to promote an Immunization Law, called for innovative modalities to involve the private sector, asked that alternatives be considered to exempt vaccination supplies from taxes, and called for an increase in social investment for prevention through immunization. Similarly, participants expressed the need to follow up, in subsequent ICC meetings, on the topics discussed. They also suggested that a similar approach be adopted to channel the cooperation in other health areas.

Current Developments in HPV Vaccination

Numerous international epidemiological and molecular studies have confirmed human papillomaviruses (HPV) as the aetiologic agents responsible for the development of cervical neoplasia. This significant development in the understanding of cancer biology paved the way for the subsequent development of a vaccine against cervical cancer. There is sufficient evidence to indicate that a cancer of infectious origin can be prevented by immunization. The declining incidence of hepatocellular carcinoma following the introduction of hepatitis B vaccine provides excellent proof of this possibility.

Human papillomaviruses are small, non-enveloped, double-stranded DNA viruses, which infect man exclusively. They are entirely epitheliotropic, infecting the skin or the anogenital and oropharyngeal mucosa. Roughly 70 percent of HPV exposures result in spontaneous clearance without clinical manifestations. It has been estimated that the median duration of these transient infections can range from 4.8 to 8 months, depending on the infecting virus type. The most frequently associated HPV lesions are warts, which can be flat (sub-clinical), papular or cauliflower-like. Sometimes, however, HPV infections can persist, inducing cytologic abnormalities. These cytologic abnormalites can become progressively worse and result in malignant changes. Latent infections, which are only detectable through the presence of HPV DNA, also occur.

Close to 100 HPVs have been completely sequenced and characterized, of which forty are known to primarily infect the genital epithelium. On the basis of extensive molecular epidemiological evidence, these genital HPVs have been sub-divided into low-risk and high-risk oncogenic types. Low-risk types, such as HPV 6 and 11, are found predominantly in genital warts (condylomata acuminata) occurring on external surfaces of the vulva, anus, and vagina. High-risk, oncogenic types, of which there are at least thirteen (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 68), are more frequently associated with invasive cervical cancer. Of these, HPV type 16 is by far the most common type worldwide, being present in 50 percent of cervical cancers. In Latin America and the Caribbean, in addition to HPV 16, virus types 18, 45, 33 and 31 are also observed as dominant types.

Cervical cancer is the HPV infection sequela of greatest public health importance. The International Agency for Research in Cancer has estimated that each year nearly half a million new cases and over 230,000 deaths occur worldwide. Approximately 80 percent of this estimated burden is borne by women in less developed countries, where cervical cancer is the leading cause of malignancy among women. Within the Region of the Americas, it has been estimated that 92,136 incident cases and 37,640 deaths due to this malignant neoplasm occur annually, with Latin America and the Caribbean contributing 83.9 and 81.2 percent, respectively, of the total estimated cases and deaths.

It is important to emphasize that in addition to cases of invasive cervical cancer, estimates of the total HPV burden must also include women with high and low grade cervical intraepithelial lesions, as well as those with HPV infections without evidence of cytological abnormalities (Figure 1).

To date, HPV vaccine development has progressed along two lines: prophylactic vaccines to prevent de novo HPV infections and therapeutic vaccines to induce viral clearance and regression of existing pre-cancerous lesions have been explored. This review will be limited to prophylactic vaccines.

Because HPVs are DNA tumor viruses that contain oncogenes, the theoretical argument exists that the presence of such genes in a vaccine could disrupt normal cell growth controls and result in vaccine-induced carcinogenesis. Hence, the HPV vaccine developed is a sub-unit vaccine composed solely of a major capsid protein, L1, which has the intrinsic capacity to self assemble into virus-like particles (VLPs) that are morphologically indistinguishable from authentic virions. The full length L1 capsid gene of HPV 16 is inserted into a bacculovirus, which is then used to express L1 VLPs in insect cells or yeasts. L1 VLPs induce the production of neutralizing antibodies, which prevent infection upon subsequent exposure.

In a landmark study published in 2002, Koutsky and her colleagues reported on the findings of a double-blind, randomized, multi-centre clinical trial, which was conducted in the United States using an HPV 16 L1-VLP vaccine. The study population consisted of 2,392 women, aged 16-23 years, who were both HPV 16 DNA as well as antibody negative at enrollment. Women were randomly assigned to receive

0.5mls of either placebo or vaccine administered intramuscularly at day 0, month 2, and month 6, respectively. Each dose of vaccine contained 40µg of HPV 16 L1 virus-like particles formulated on an aluminum adjuvant. This vaccine was shown to be 100 percent effective in preventing persistent HPV infection as well as the development of precancerous cervical lesions. A quadrivalent HPV vaccine (6,11,16,18) is also being evaluated in a Phase 2 trial in Brazil. To date, these vaccines have also been demonstrated to be safe, well tolerated and highly immunogenic.

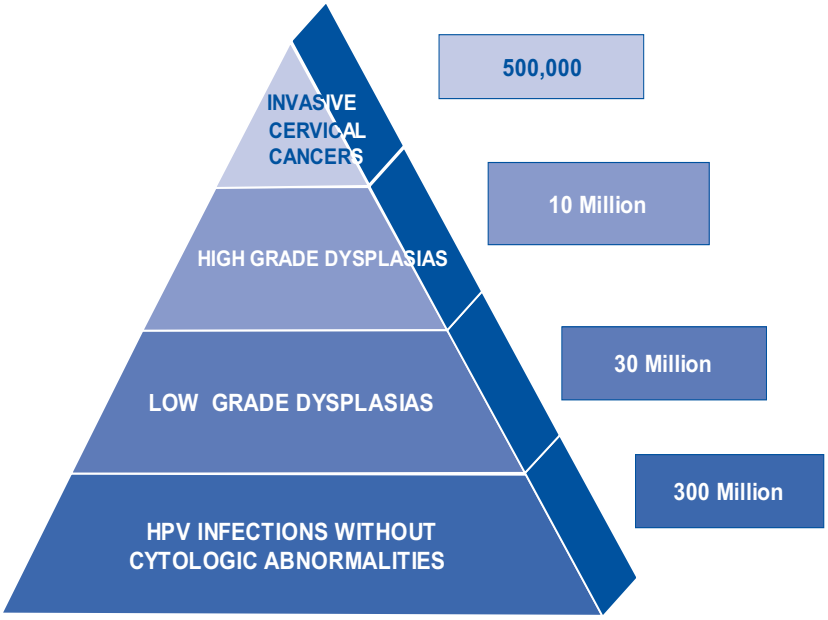
In 2004, Harper and her associates reported the findings of a randomized controlled trial, which had been conducted among 1,113 women, aged 15-25 years, in Brazil, Canada, and the USA, utilizing an HPV 16-18 L1 VLP vaccine. This vaccine was delivered with an adjuvant, ASO4, in a three-dose schedule at months 0, 1, and 6, respectively. This bivalent vaccine was demonstrated to be generally safe, well-tolerated, and highly immunogenic, with a vaccine efficacy of 100 percent against persistent infection with HPV 16 and 18 infections. Vaccine efficacy against cervical cytological abnormalities associated with HPV 16-18 infections was recorded at 92.9 percent. Additionally, this vaccine induced antibody titres, which were 80-100 fold-higher than those elicited by natural infection.

In summary, the results of the Phase I and II trials undertaken, to date, and utilizing different HPV types, demonstrate that these prophylactic vaccines are highly efficacious against persistent HPV infection; are able to reduce the incidence of type-specific associated cervical abnormalities; are well tolerated by subjects; and can elicit significant humoral antibody responses and robust cell mediated immune responses at levels higher than those observed in natural infections. Systemic immunization with a sub-unit VLP HPV vaccine, even without adjuvant, can induce protective immunity against a sexually transmitted mucosal viral infection.

HPV vaccines are currently undergoing international Phase III trials. The bivalent HPV 16-18 VLP vaccine is being tested in 90 centers across 14 countries (including Brazil and Mexico), among 13,000 women, aged 15-25 years. Prevention of CIN (cervical intraepithelial neoplasia) 1 and 2 as well as of persistent HPV infection will be the end points to be evaluated. The quadrivalent HPV 16,18, 11, 6 vaccine is also being tested in 25,000 subjects in an international Phase III trial, which includes the participation of Brazil, Colombia, Mexico, and Peru.

Despite the tremendous progress achieved to date in the development of cervical cancer preventing HPV vaccines, a number of outstanding issues remain to be addressed. One issue is the unknown duration of immunity induced by these L1-VLP vaccines. Preliminary data from several Phase II trials have indicated that antibody titres fall from peak levels achieved after immunization to low but measurable levels that persist for at least 36 months post-vaccination. Since the window of observation of subjects in these vaccine trials has been relatively short, the duration of L1-VLP vaccine-induced protection and whether or not boosting may be required remain to be determined.

Figure 1. Estimated Global HPV Burden



Although there is great optimism for the introduction of HPV vaccines for the primary prevention of cervical cancer, it will be critical to continue to emphasize that secondary prevention through screening must still be available for women, particularly those already infected with these high-risk oncogenic viruses, and for those who may be infected with virus types not contained in the early vaccines.

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2005 Immunization Schedules for Selected Vaccines – Latin American Countries

	1 BCG		2 OPV							3 DPT					5 DPT-Hep B+Hib				6 DPT+Hib				7 Hep B**				8 Hib				9 M	10 MMR			11 MR	12 TT/dT***					13 Yellow Fever		14 Influenza	15 Varicella
	Number of doses																																			Number of doses								
	1	2	NB§	1	2	3	4	5	6	1	2	3	4	5	1	2	3	4	1	2	3	4	1	2	3	4	1	2	3	4	1	1	2	3	1	1	2	3	4	5	1	2	1	1
ARG	NB	6y		2m	4m	6m	18m	6y						6y					2m	4m	6m	18m	NB	2m	6m	11y						1y	6y	11y	pospartum	16y	every 10y							risk groups; >65y	
BOL*	<1y			2m	4m	6m									2m	4m	6m						NB*									1y				WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	1y			
BRA	NB	6-10y*		2m	4m	6m	15m						15m	4-6y					2m	4m	6m		NB	1m	6m							1y	4-6y		WCBAs	11y	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	≥9m	10y	risk groups; >60y	indigenous population
CHI	NB			2m	4m	6m	18m						18m	4y					2m	4m	6m			2m	4m	6m						1y	6y			7y								risk groups; >65y; pregnant women; health workers	
COL	NB		NB	2m	4m	6m	18m	5y					18m	5y	2m	4m	6m						NB									1y	5y			WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	1y	10y		
COR	NB			2m	4m	6m	4y				4m	15m	4y		2m	6m							NB					4m	15m			15m	7y			10y	every 10y							risk groups; 6m to <5y; ≥65y	risk groups >15m to <14y
CUB*	NB			2 doses (<1y)	2 doses (1y)	2 doses (2y)	1 dose (9y)						18m	6y*	2m*	4m*	6m*						NB				2m	4m	6m	18m		1y	6y			14y								>65y	
DOR	NB			2m	4m	6m	18m	4y					18m	4y	2m	4m	6m						NB									1y				WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs				
ECU	NB			2m	4m	6m	18m						18m		2m	4m	6m						NB	school children at risk								1y				WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	1y	every 10y		
ELS*	NB			2m	4m	6m	18m	4.5y					18m	4.5y	2m	4m	6m															1y	4y			≥10y	every 10y; pregnant women					>1y*		risk groups; 6m-23m; >60y	
GUT	NB			2m	3m	4m	18m	4y					18m	4y	2m	4m	6m															1y				WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs				
HAI	NB		NB	1.5m	2.5m	3.5m	1y+3m	2y+3m		1.5m	2.5m	3.5m	1y+3m	2y+3m																9m					WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs				
HON*	NB		NB	2m	4m	6m	<5y						18m	4-5y	2m	4m	6m															1y				11y	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	>1y*		risk groups; >60y	
MEX*	NB			2m	4m	6m	1 dose*	1 dose*	1 dose*				2y	4y	2m	4m	6m															1y	6y		13-39y	12y	WCBAs	WCBAs	WCBAs	WCBAs			6m-2y; 60y-64y at risk; ≥65y	
NIC*	NB			2m	4m	6m	1 dose*	1 dose*					18m		2m	4m	6m															1y				6-9y	10-14y	15y +	15y +	15y +				
PAN	NB		NB	2m	4m	6m	18m	4-5y						4-5y	2m	4m	6m					18m	NB									1y	4-5y			≥15y	every 10y				≥1y	10y	<2 and >65y	
PAR*	NB			2m	4m	6m	18m	4y					18m	4y	2m	4m	6m															1y	4y			WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	>1y*			
PER	NB			2m	3m	4m					3m				2m	4m							NB					3m				1y			women 16-20y	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	1y			
URU*	NB			2m	4m	6m	12m							5y	2m*	4m*	6m*	12m*					12y	12y+1m	12y+6m							1y	5y			12y	every 10y					>1y*		risk groups; 6m-2y; >55y	1y
VEN*	NB		NB	2m	4m	6m							18m		2m	4m	6m						NB									1y				WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	WCBAs	1y*			

** This table only includes the hepatitis B vaccine used in children national schedules. Vaccination of at-risk groups is not included.

*** TT/dT use reported as indicated by countries in the EPI Indicator Tables.

§ Doses administered to newborns do not count towards completion of the primary series.

NB: Newborn
WCBA: Women of Childbearing Age

Please advise the editors of the EPI Newsletter of any discrepancies and/or changes in your national immunization schedule.

Immunization schedules for the rest of the countries of the Region will be published in the August issue.

* BOL: Hepatitis B for newborns only in sentinel hospitals.
* BRA: BCG at 6-10 years only in some states.
* COL: Yellow fever vaccine in children >1 year administered in at-risk areas.
* CUB: DT pediatric administered at 6 years; vaccine used is tetravalent DPT+Hep B starting in 2005.
* ELS: Yellow fever vaccine administered to travelers to endemic areas.

* MEX: Additional OPV doses for children during National Health Weeks.
* NIC: Additional OPV doses for children during National Health Weeks.
* PAR: Yellow fever vaccine administered to population in border areas.
* URU: Yellow fever vaccine administered to travelers to endemic areas.
* VEN: Yellow fever vaccine administered to population in at-risk municipalities, in addition to recruits and travelers to endemic areas.

Immunization and HIV: The Case of the English-speaking Caribbean

After almost twenty years living with the AIDS epidemic, the Caribbean, as the rest of the world, now has a generation that has grown up in a world with HIV. These young people come of age, initiate sex, and enter parenthood as members of communities in which HIV transmission, through mainly heterosexual contact, defines the Caribbean as the location with the second highest HIV prevalence rate in the world.

Caribbean territories have responded to HIV not only at the community and national levels, but also at the regional level. Countries have sought to strengthen their collective energies and, through the Caribbean Community (CARICOM), founded the Pan Caribbean Partnerships against HIV/AIDS (PANCAP) in February 2001. PANCAP seeks to garner the financial resources to respond to HIV, and to facilitate collaboration and political will essential for ensuring Caribbean development.

It is against this background that initiatives for the prevention of mother to child transmission are gaining acceptance, support, and funding throughout the Caribbean Region. As an example, CARICOM decided in 1992 to support such initiatives and reduce vertical HIV transmission by at least 50% by 2005. Today, many countries are at various stages of integrating initiatives into their traditional family health or maternal and child health programs to prevent HIV infection and reduce its transmission. Immunization programs, which are an important component of family health programs, must now refine vaccination strategies for addressing children and adults who are known or suspected to be immunocompromised due to HIV infection.

HIV presents several challenges to the Expanded Program on Immunization. In an HIV-positive person, the immune response to vaccines may not provide adequate protection and there is a risk that some live vaccines may themselves cause progressive infection among immunocompromised persons. For this reason, guidelines (see Table below) for administering vaccines in the context of HIV exist and need to be implemented in the Caribbean and elsewhere.

Authors: *Dr. Beryl Irons, Epidemiologist, PAHO Caribbean Epidemiology Center (CAREC), Trinidad & Tobago; Ms. Sheila Samiel, Communication Specialist, CAREC.*

Reference:

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Guidelines for Immunizing HIV-infected Persons

Some important considerations:

- With some notable exceptions, immunization is generally safe and beneficial for HIV-infected persons;
- Routine screening for HIV status before vaccination is not recommended;
- The efficacy of immunization is variable for HIV-infected individuals, and the proportion of responders declines with progression from HIV infection to AIDS;
- HIV-infected individuals of any age who are well controlled on combination anti-retroviral therapy (undetected or low viral load with good preservation of CD4 lymphocyte count) are likely to respond well to vaccines;
- Most HIV-infected children have the capacity to mount both cellular and humoral immune responses during the first two years of life; decline in these two responses occurs during the next two years;
- Severely ill HIV-infected children should not be vaccinated.

Vaccines that should continue to be offered routinely to all HIV-positive persons, both symptomatic and asymptomatic, according to the country's standard schedule:

- Diphtheria-pertussis-tetanus (DPT) vaccine
- *Haemophilus influenzae* type b (Hib) vaccine
- Tetanus and tetanus-diphtheria vaccines (including childbearing-age and pregnant women)

Vaccines that should continue to be offered routinely to HIV-positive children with some specific considerations:

- Measles-mumps-rubella (MMR) vaccine: MMR should be routinely administered to HIV-infected children unless they are severely immunosuppressed (see Table 1). MMR should be administered as early in life as possible, according to the nationally recommended schedules. In outbreak situation, HIV-infected (known or suspected) infants at increased risk of exposure to measles should receive a first dose of measles-containing vaccine at 6 months of age and a second at 9 months of age.

- Oral polio vaccine (OPV): OPV has not been found harmful when administered to asymptomatic HIV-positive children. However, if available, inactivated polio vaccine (IPV) is preferred, especially for symptomatic individuals. IPV is preferred for HIV-positive individuals and their household contacts due to the theoretical risk of OPV's neurovirulent effect on immunocompromised persons.
- Hepatitis B vaccine: Recombinant hepatitis B vaccines are safe to use and are recommended following the country schedule for non-HIV infected individuals. Early immunization is especially important as the risk of becoming a chronic carrier is higher for HIV-infected persons than for uninfected ones. The immunological response may be poor among HIV-positive individuals but not enough information is available to provide firm recommendations on dosage at this time.

Table 1. Age-specific CD4 T-lymphocyte count indicating severe immunosuppression in HIV infection

Age	<12 months	1-5 years	≥6 years
CD4 count	<750† ($0.75X10^9$/L)	<500† ($0.50X10^9$/L)	<200† ($0.20X10^9$/L)

† Or <15% of total lymphocytes

Source: Red Book, 2003

Vaccines that should NOT be administered routinely to symptomatic HIV-infected persons (i.e., AIDS):

- BCG: In persons known or suspected to be infected with HIV, BCG vaccine is contraindicated if the risk of tuberculosis is considered low. However, in countries with a high prevalence of HIV, BCG is recommended at birth or as soon as possible thereafter, following the country's schedule if the risk of tuberculosis is high, since BCG will protect the infant against extrapulmonary forms of TB.
- Yellow fever vaccine: Where the risk of yellow fever is high, yellow fever vaccine may be considered for HIV-positive persons.
- Live attenuated typhoid vaccine
- Varicella vaccine

Vaccines to be considered for HIV-infected persons given their increased risk of disease:

- Pneumococcal
- Influenza

Use of Immune Globulin in HIV-infected persons:

- Immune Globulin (IG)
  - Symptomatic patients exposed to measles regardless of immunization status
  - Persons exposed to hepatitis A or traveling to endemic areas
- Varicella Immune Globulin (VZIG)
  - Susceptible children and adults after significant exposure to varicella zoster (chickenpox or zoster)
- Tetanus Immune Globulin (TIG): Same as for non-immunocompromised persons
- Hepatitis B Immune Globulin (HBIG): Same as for non-immunocompromised persons
- Rabies Immune Globulin (HRIG): Same as for non-immunocompromised persons. Similarly, rabies vaccine is safe and can be used following the usual recommendations

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Third Annual Vaccination Week in the Americas

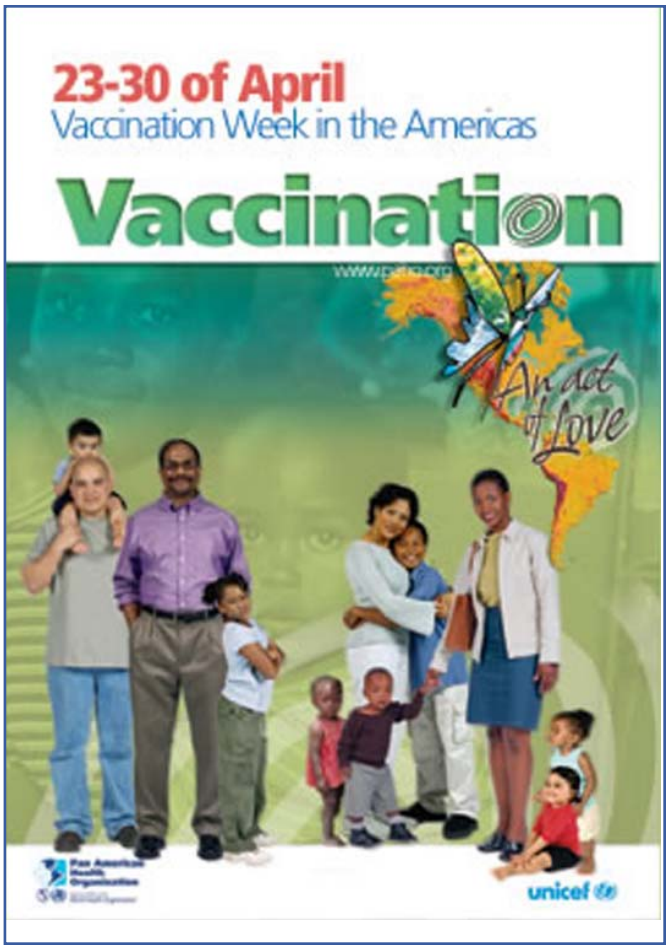
The third Vaccination Week in the Americas (VWA) will take place from 23-30 April throughout the Region of the Americas. The VWA is a regional initiative of the Pan American Health Organization (PAHO) that aims to strengthen national vaccination programs throughout the Region. Its main principals are equity, access, and Pan Americanism.

The VWA specifically targets populations without access to immunization because they are located in remote or urban fringe areas. The VWA also targets from indigenous communities and other ethnic minorities. Governments of the Region have shown a high degree of political commitment to maintain immunization as a regional public good, and have made the VWA a political priority.

Countries can participate in different ways. They can target high-risk populations for *follow-up* measles compaigns and rubella, yellow fever, or influenza campaigns. They can also intensify vaccination efforts in low-coverage municipalities. A number of countries are planning to provide vitamin A and parasiticides to children and folic acid to pregnant women. Some plan to offer eye exams and general health education to the population. The United States' National Infant Immunization Week 2005, sponsored by the Centers for Disease Control and Prevention (CDC) is being conducted as part of the VWA. Canada's National Immunization Awareness Week will also coincide with the region-wide event.

PAHO's role in the VWA will be to provide technical support to countries, through its Regional Headquarters and country field offices, for resource mobilization, organization of border activities, evaluation of VWA impact, and evaluation of social communication strategies.

An important goal of the VWA is to form strategic partnerships and expand interagency cooperation at regional level.



PAHO, the CDC, the Canadian International Development Agency (CIDA), the United Nations Children's Fund (UNICEF), the Red Cross, the Sabin Vaccine Institute, the March of Dimes, Rotary International, and other organizations have combined technical and financial efforts to support the initiative.

The EPI Newsletter is published every two months, in Spanish, English and French by the Immunization Unit of the Pan American Health Organization (PAHO), Regional Office for the Americas of the World Health Organization (WHO). The purpose of the EPI Newsletter is to facilitate the exchange of ideas and information concerning immunization programs in the Region in order to promote greater knowledge of the problems faced and possible solutions to those problems.

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