

EPI Newsletter

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October 2001

Haiti's Ongoing Efforts to Halt the Polio and Measles Outbreaks

After almost a decade with no confirmed cases and declining levels of immunization, both polio and measles returned to Haiti in 2000. To date, there have been 8 confirmed cases of paralytic polio caused by a vaccine-

derived virus while for measles there have been 1,148 confirmed cases. Similar epidemics have occurred in the Dominican Republic.

Strategies for the control of these two diseases and lessons learned were major themes of the XV EPI Managers Meeting for Central America, Mexico and the Caribbean held at Port au Prince, Haiti on 12-14 August 2001. Other objectives of the meeting, which was held in Haiti for the first time, examined the quality of disease surveillance in countries, reviewed laboratory quality control procedures, as well as the epi-



over 120 immunization health staff participated at the XV EPI Managers Meeting in Haiti. each of the participating From left to right, Mr. Carlos Canseco, Rotary International; Dr. Ciro de Quadros, PAHO; Dr. countries, reviewed laboratory quality control pro-

children). It was initiated in mid-September and is scheduled to end by mid-November. A previous polio vaccination campaign carried out in May and June 2001 using the same methodology reached well over 85% of the target population. This level of coverage was confirmed by conducting 659 coverage surveys in those areas where coverage was thought to be the lowest. The methodology for the campaign is based on a carefully-designed plan of door-to-door vaccination that is enhanced by:

• intense supervision in

the field;

demiological situation of rubella and neonatal tetanus.

Vaccination

A national vaccination campaign based almost exclusively on door-to-door vaccination, and a separate 2-week vaccination campaign in kindergartens and primary schools,

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• the use of two visits to each small geographic sector, the first for general vaccination, and the second, usually on the following day, for vaccination of those children missed during the first visit;

is designed to deliver measles vaccine to every child be-

tween the ages of 6 months and 5 years in Haiti (approxi-

mately 1.5 million children), and oral polio vaccine (OPV)

to all children under the age 10 (approximately 2.9 million

• monitoring of vaccine coverage in a sample of sectors to verify an adequate level of vaccine coverage.

Recommendations on Polio and Measles from the XV Subregional Meeting

Following a review and discussion of recent information on polio and measles, recommendations for vaccination, monitoring of vaccine coverage, surveillance, and active case search were presented:

- attain a vaccination coverage of at least 90% for 3 doses of OPV; and, for measles, at least 95% in all areas of each country;
- implement door-to-door vaccination as the preferred strategy;
- add measles vaccination in the next vaccination campaign for polio in Haiti;
- monitor vaccination coverage in areas where coverage is suspected to be low;
- · conduct follow-up vaccination campaigns in areas where coverage is below recommended levels;
- carry out periodic active case search in all areas with poor surveillance, recent cases, or where coverage is suspected to be low;
- use PAHO investigation methods that include household census, collection of blood specimens and nasopharyngeal or throat swabs for measles, and stool specimens for polio. When cases are identified, carry out investigation within 48 hours;
- include weekly negative reporting from at least 80% of selected health care centers;
- find at least 1 case per 100,000 persons below age 15 for AFP surveillance;
- include private and public health professional in surveillance network.

Surveillance

Routine reporting of measles and cases of acute flaccid paralysis (AFP) from all health care facilities in the country is being improved through a collaboration between the Ministry of Public Health and Population (MSPP) and PAHO for training of all health care personnel in the use of new surveillance guidelines. Planning is also underway between MSPP and PAHO to identify a group of key health care institutions that will send negative reports weekly to the Ministry. Responsible individuals within each center will be identified and a means of communication with each person will be established. In addition, PAHO has established a U.S. \$100 reward for the reporting of each case of laboratory-confirmed polio, as well as for the reporting of the first case of laboratory-confirmed measles after completion of the current vaccination campaign. Finally, in the past month presentations have been made to a number of groups, including two Haitian medical societies, Peace Corps volunteers, and the Cuban Medical Brigade, to encourage their participation in surveillance.

Active case search

Personnel from MSPP and PAHO have conducted active case searches in all major health care facilities in 8 of the 9 departments of the country. These visits will be continued until the surveillance system is performing adequately. Additional cases of suspected measles and AFP have been found during these searches, and each of these cases has been investigated within 48 hours.

MSPP, PAHO, and a task force of collaborating nongovernmental organizations and concerned individuals have made major commitments to the current national vaccination campaign and anticipate that this effort will successfully end the two epidemics.

Editorial Note: Over 70 health workers from Haiti's nine regions joined participants from 10 countries in the XV EPI Managers Meeting for Central America and were able to discuss the results and lessons learned from the vaccination strategies used in previous campaigns. The meeting also provided an opportunity to strengthen the partnership of all actors involved in the efforts to eradicate measles and to prevent further circulation of the Sabin-1 vaccine-derived virus. As seen in Figure 1, great progress has been made. Continued efforts are needed to successfully complete the current vaccination campaign, restart the use of negative reporting in the surveillance system, and continue the active search of cases at all major health facilities. Once the vaccination campaign is completed, mop-up campaigns should be conducted in all areas where new cases are detected by either surveillance or active case search, or where monitoring reveals inadequate coverage. Concurrently, immediate action is needed to enhance Haiti's system of routine immunization in all areas of the country.



*Data as of epidemiological week 38 (22 September, 2001)

Analysis of the Performance of Argentina's National Poliomyelitis Eradication Program during 1999-2000

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During the first months of 2001, PAHO carried out an assessment of country risk of failing to detect poliovirus circulation, based on the performance of national surveillance systems in the last five years and the level of annual vaccination coverage with oral polio vaccine reached during those same years. It was recommended that all countries in the Region undertake a similar evaluation of their surveillance systems. The following analysis was performed by the Ministry of Health of Argentina, covering the years between 1999-2000 and using the criteria of OPV coverage during the first year of life and surveillance indicators in 24 jurisdictions.

For the evaluation, the goal of 90% national coverage in children under 1 year of age was utilized in conjunction with the following 5 indicators:

- Notification rate of acute flaccid paralysis (AFP) in children under 15 years of age of 1 per 100,000;
- Case identification within 14 days of onset of paralysis: ≥80%;
- Case investigation reported within 48 hours: $\geq 80\%$;
- Adequate stool samples taken within 14 days: $\geq 80\%$;
- Viral isolation in stool samples: $\geq 15\%$.

Of the 6 criteria (one related to vaccination coverage with three doses of OPV, four related to surveillance and one to laboratory) utilized in the evaluation, two are of particular relevance: Vaccination coverage with three doses of OPV and AFP notification rate among children under the age of 15 years.

Table 1 shows the compliance with the criteria in the different national jurisdictions in a descending order: 66%

Table 1.
Level of compliance of the polio eradication program by
jurisdiction, Argentina 1999 - 2000

	1. Coverage		2. Notification rate		3. Case identification		4. Case investigation		5. Sample taken		6. Viral isolation	
JURIS	Annual coverage		Rate 1/100,000		80% ident. <u><</u> 14 days		80% invest <u><</u> 48 hrs		80% <u><</u> 14 days		15% viral isol.	
	1999	2000	1999	2000	1999	2000	1999	2000	1999	2000	1999	2000
JRS1												
JRS2												
JRS3												
JRS4												
JRS5												
JRS6												
JRS7												
JRS8												
JRS9												
JRS10												
JRS11												
JRS12												
JRS13												
JRS14												
JRS15												
JRS16												
JRS17												
JRS18												
JRS19												
JRS20												
JRS21												
JRS22												
JRS23												
JRS24												

(16/24) and 58% (14/24) complied with the vaccination coverage criteria between the years 1999 and 2000, respectively. A total of five jurisdictions failed to reach the coverage criteria during the two-year period of the analysis. In terms of the notification rate, it was above 1 in 46% (11/24) of the analyzed jurisdictions during 1999, and 58% (14/24) in 2000. A total of seven jurisdictions failed to comply with the established AFP notification goal during the 1999-2000 biennium. With regard to all 6 criteria used in the analysis (i.e., coverage and 5 surveillance and/or laboratory indicators), no jurisdiction met all the criteria during both years. In fact, only half of the country's jurisdictions complied with 50% of the criteria during the two years.

Table 2 shows the 24 jurisdictions organized in a descending ranking, based on the level of compliance with the criteria for vaccination coverage as well as that for the annual notification rates. Two jurisdictions failed to reach both criteria.

In summary, PAHO has brought forward a series of criteria to evaluate the Poliomyelitis Eradication Programs. Formost, this analysis shows the importance of carrying out evaluations at the local level. The indicators and coverage levels when evaluated at the national level were satisfactory in Argentina. However, the national levels only represent an average of the country and do not show regional variations within the country. These evaluations are valuable to determine areas at risk, in order to correct possible gaps in existing levels of vaccination, and to ensure that resources are allocated towards these areas and efforts towards polio eradication are optimized.

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Table 2. Compliance level of coverage and notification rate per jurisdiction, Argentina, 1999 - 2000

JURIS	Annual	coverage	Notification r	Compliance level	
	1999	2000	1999	2000	Rate + Coverage
JRS1					4
JRS3					4
JRS8					4
JRS4					3
JRS5					3
JRS7					3
JRS11					3
JRS16					3
JRS18					3
JRS20					3
JRS17					3
JRS6					2
JRS2					2
JRS16					2
JRS9					2
JRS12					2
JRS13					2
JRS15					2
JRS24					2
JRS19					1
JRS22					1
JRS21					1
JRS14					0
JRS23					0

Measles Case Classification: Frequent Dilemmas in the Field

The interpretation of a positive-IgM test for measles in countries without known endemic transmission and vaccine-related rash illnesses

As we approach eradication of measles from the Americas, epidemiologists will be faced with the interpretation of a positive IgM laboratory test in a suspected case of measles in the setting of greatly-reduced disease transmission. Indeed, national authorities will be faced with the dilemma of how to classify an IgM-positive case when no cases have been confirmed in their country for numerous weeks or months. Since no laboratory test is 100% sensitive nor specific, laboratory false-positives will occur. Furthermore, the predictive-value positive of a laboratory test decreases as the prevalence decreases. Thus, we should expect falsepositive laboratory results to occur. In addition, as countries maintain high levels of vaccination activity, one should anticipate the notification of recently vaccinated persons who present with a febrile rash illness. The dilemma in this situation is to determine if a IgM-positive result is occurring because the individual 1) has a non-measles rash illness and was incidentally vaccinated, 2) has an acute measles infection and was incidentally vaccinated, or 3) has a vaccinerelated rash reaction. Here, we discuss the interpretation of an IgM positive test and revisit the definition of a vaccinerelated rash.

First, unless there is clear evidence to the contrary as discussed below, *all suspected measles cases that are found IgM-positive should be considered laboratory-con-firmed cases*. However, the finding of isolated measles cases with little or no secondary transmission does not, in any way, imply that a resurgence of endemic measles transmission is occurring in a country with no known transmission. Moreover, in such settings, the finding of isolated measles cases with little or no secondary transmission, as has occurred in Peru, El Salvador, the United States, Canada, and Mexico, suggests that surveillance was sufficiently sensitive to detect the case and that local vaccination coverage levels were sufficient to prevent an outbreak.

(a) How should one interpret a positive IgM test in an individual with a febrile rash illness in the setting of no known transmission?

One must assume that it is measles infection until proven otherwise. Since measles is so highly contagious (it has been considered by many as the most contagious infectious disease known), the failure to identify the source of infection or secondary cases, even after a thorough search for cases, does not imply that it is a false-positive laboratory case. It is always possible that the individual was infected by a stranger while on a bus, in town, etc. However, in these exceptional circumstances, the individual can be tested at a reference laboratory for IgG anti-measles antibody. The lack of a significant rise in IgG titers between two properly spaced specimens is sufficiently strong evidence to conclude that the positive-IgM result is a false positive. However, even if tests for IgG antibody levels suggest that a recent measles infection has not occurred for surveillance purposes, an interpretation of a false positive IgM is acceptable only if a thorough active search failed to identify other cases and local coverage (verified by house-to-house monitoring) is sufficiently high, i.e., at least 95%.

(b) How do we interpret a positive IgM test in a recently vaccinated individual with a febrile rash illness?

In this situation it is not possible to determine if the positive IgM is from the vaccination or from a recent measles infection. The case should not be dismissed as vaccine-related based solely on the history of recent vaccination. A thorough case investigation and active search for other cases in health facilities and in the community is warranted as well as a detailed evaluation of coverage. As stated above, the positive-IgM laboratory result could represent either a response to a vaccination in an individual with a non-measles infection, or in an individual with a vaccinerelated rash. However, it could also have nothing to do with the individual's recent vaccination but represent a true acute measles infection (i.e., the vaccination was given during the period of incubation and did not prevent an infection). One could test for rubella IgM antibodies, and if positive, the (+) IgM results for rubella and measles could represent a response to a recent MMR or MR vaccination. However, unless the case meets the criteria stated below for a vaccinerelated case, in almost all situations the case must be confirmed.

(c) In what circumstance can we classify a recently vaccinated suspected measles case as a vaccine-related rash?

One will not be able to conclusively determine if it is vaccine-related, but based on the principles described above, and for surveillance purposes, a case can be discarded and classified as a vaccine-related rash if it meets **ALL** of the following criteria:

- 1. Has a rash illness, with or without fever, but does not have cough or other respiratory symptoms related to the rash, **and**
- 2. Rash onset began 7-14 days after vaccination with a measles-containing vaccine, **and**
- 3. Serum sample, taken between 8 and 56 days after vaccination, is positive for measles, **and**
- 4. Thorough field investigation did not identify the index case or any secondary cases, **and**
- 5. Field and laboratory investigation failed to identify other causes (including the failure to identify wild measles virus in culture).

Editorial Note: The definition of what constitutes a vaccine-related rash was discussed during the XIV Meeting of the PAHO Technical Advisory Group on Vaccine Preventable Diseases (TAG) in Foz de Iguazu, October 2-5, 2000 (The final report can be found at: <u>http://www.paho.org;</u> Search: TAG). In addition, a field was created in the MESS database under "Final Diagnosis" for countries to code

whether a case's rash and laboratory result were vaccinerelated. According to the MESS database in the Regional office, as of week 37 of 2001, 8 countries have reported 27 cases that have been discarded as vaccine-related. Evaluation of these 27 cases reveals that 3 were <1 year of age, 22 were 1-year of age, and 2 were 2-years of age. All had a history of vaccination. However, to be classified as vaccinerelated, the interval between vaccination and the onset of the rash must be 7-14 days. Studies suggest that, in general, an interval less or greater than this may not be consistent with a reaction to vaccination. Of the 27 vaccine-related cases in the database, only 13 had intervals of 7-14 days. Four cases have intervals of <7 days and 10 cases have intervals of >14days. The four cases with intervals <7 days were from different countries and none had a history of all 3 respiratory symptoms of measles (i.e., cough, coryza and conjunctivitis). However, 3 of the 4 had at least one of the 3 respiratory symptoms. The 10 cases with an interval of >14 days were reported from 7 countries and there was no clustering of cases in any country. Five of the 10 had at least one respiratory symptom and of these, 2 had two symptoms and one case, with onset of rash 18 days after vaccination, reportedly had conjunctivitis, cough and coryza.

This preliminary analysis suggests that not all countries have implemented the case definition for what constitutes a vaccine-related rash as discussed during the recent TAG meeting. Countries should ensure that cases meet the above criteria prior to classifying it as a vaccine-related rash case. In addition, countries should take this opportunity to review their "vaccine-related" cases and determine whether they truly are consistent with a vaccine reaction. It is acknowledged that by using the criteria described above, a few false-positives or vaccine-related IgM-positive rash illnesses will be confirmed as wild measles cases. In the current phase of the eradication process, this is an acceptable compromise to ensure the highest sensitivity in measles surveillance.

Strengthening Laboratory Diagnosis for Poliomyelitis in the Americas

A meeting of the Poliomyelitis Laboratory Network of the Americas was held August 7-8, 2001, in Rio de Janeiro, Brazil. The meeting sought to strengthen the participation of laboratories that are part of the network in polio epidemiological surveillance. A timely laboratory diagnosis is critical to support ongoing efforts towards polio eradication worldwide, as well as for maintaining the Americas polio free.

Working sessions included the review of indicators that monitor the proportion of viral isolates obtained from samples, accreditation procedures, communication and feedback mechanisms with countries and epidemiologists, standardization of techniques and containment plans for wild poliovirus and material that can be potentially infectious in the countries of the Americas. There was also discussion of the implications that the recent vaccine-derived polio outbreak in Haiti and the Dominican Republic may have on the work of laboratories.

What follows are selected conclusions and recommendations of the meeting which will have an immediate impact on the work of laboratories, as well as on the work of epidemiologists who are directly involved in the polio eradication efforts and in the surveillance of acute flaccid paralysis (AFP):

- All communication towards and from laboratories related to samples of AFP cases should be accompanied by an EPI number (identification number of specimens which includes country-year-case number; example: COL-00-015/case No. 15 of Colombia of the year 2000). Laboratories should acknowledge the receipt of samples to countries. Country epidemiologists should make the necessary follow-up of these samples to confirm their arrival at the laboratories and to obtain laboratory results.
- PAHO reiterates that it is not recommended to take samples from contacts of AFP cases. This recommenda-

tion is reiterated to prevent the unnecessary work overload at laboratories. Laboratories of the Network will not process samples from contacts on a routine basis. This will only be done following an explicit request from epidemiologists.

- Virologists will be responsible for identifying those specimens that have remained at the laboratories for over six weeks without results; as well as for those specimens that have pending intra typic differentiation for over four weeks. All discrepancies between the information appearing in the *Polio Surveillance Bulletin*, published weekly by PAHO, and that of national laboratories should be communicated by virologists to the assigned epidemiologists, with a copy to PAHO/ Washington.
- The *Polio Surveillance Bulletin* will change the columns in Table 1, to reflect the samples that are pending results at laboratories for over 6 or under 6 weeks (currently it appears as pending results for over or under 10 weeks).
- All samples sent to the Laboratory Network should always be accompanied by the following basic information: EPI number, name of the case, age, date the sample was taken; date sample was sent, date of onset of paralysis, number of OPV doses received, and date of last OPV dose.
- Laboratories need to comply with the following three conditions in order to obtain annual accreditation: a) complete and comply with the list of requirements that monitor laboratory conditions; b) pass the proficiency test; and c) comply with the indicators that monitor the proportion of viral isolates obtained from samples.

For a copy of the complete report, please contact the Division of Vaccines and Immunization at PAHO in Washington D.C.

The Importance of Cleaning Up Data

The following article is the first in a series on the topic of data quality to be published by the **EPI Newsletter**. In this issue discussion will center on the data published in PAHO's weekly **Measles Bulletin** to aid health workers and health authorities at the country level make policy decisions and take action. Data appearing in the **Bulletin** originate from the Measles Eradication Surveillance System (MESS) database developed by PAHO in 1996, to support the collection of standardized case information that show the state of Measles Eradication in the Americas and an up-to-date

evaluation of measles surveillance as measured by surveillance and laboratory indicators.

A frequent question received at PAHO's Headquarters' offices has to do with the discrepancy between data published in PAHO's weekly *Measles Bulletin* and those held by countries. This discrepancy can be attributed to various factors and has been an issue of discussion on several occasions.

Using the data received from the countries through epidemiological week 37 (September 15, 2001), data from sixteen countries were reviewed to identify duplicate case entries and coding errors. The countries evaluated included three countries in the Caribbean, six countries in Central America and Mexico, as well as seven countries of South America. Of these 16 countries, ten had sent weekly MESS downloads showing multiple entries for a case when comparing "NAME" fields. In one country, the same case had

been entered three times. The number of duplications per country ranged from 1 (3 countries) to 13 (one country). It is important to understand that duplications, or double entry, distort the information contained in the regional database, which are used for critical programmatic decisions.

Next, a review was performed of Case Numbers (CASE_ID field in the database) and its relation to the onset date of the case's eruption. Six of the 16 countries under review showed codes that were written incorrectly. Therefore, these cases could easily be overlooked for updates and possibly result in multiple entries. For example, a country had a case with Case Number "110-2001" instead of "01-0110." Another country had a case with Case Number "10-2001" instead of "01-0110." Another country had a case with Case Number "0-968" instead of "01-968." Yet another country had three cases showing Case Numbers for the year 2001, namely "01-####", but with dates of onset of rash in the year 2000. It is important to highlight that the *Measles Bulletin* uses the date of onset of rash as the primary selection criteria for all reports. Therefore, a case with the date of onset coded as

"2000" will not be taken into account for the bulletin even though it was reported in 2001 and has a year 2001 Case Number assigned to it.

This analysis demonstrates the importance of reviewing the information before it is sent to Washington. Human errors while entering data can occur. In fact organizations often require double entry for all data, to minimize human error. While the task of double entry is not recommended, all countries should review their database on a weekly basis to

avoid case duplications, among other potential errors.

A simple way to do this is to print summary case listings. From the Reports menu in MESS, select Cases, then Lists and finally Case Summary Listing; at Order, click By Case Number and then Print. This will produce a case listing ordered by Case Number, which will help you identify errors. Also, print a Case Summary Listing as before but at Order click By Name to help identify duplicate entries.

All cases identified through these means need to be reviewed carefully; those that are determined to be duplicate entries need to be erased from the database using the Delete function and cases with errors in the Case Number and or location need to be corrected using the Move function. The Modify function cannot be used to correct errors in Case Number or location.

Another important data cleaning step involves the use of the Filter function. From the Data Menu, select the Cases option. Clear all default values and enter 01 in the Onset Week field then click on Filter. This will list all cases with onset in the year 2001. One can then click on the different column headers and the list of cases will be sorted on that field allowing you to quickly identify mistakes. Repeat these steps but with onset in year 2000 to determine if there are any cases still classified as suspected or that mistakenly have a year 2001 code in their Case Number. Also look for cases Reported in 2001 that have no date of Onset. Please keep in mind that the Date of Onset of Rash is the key to placing cases in a time frame, not the Case Number.

The information in the Bulletin represents the information received in Washington. Ultimately, countries are responsible for the quality and precision of the information.

The *Measles Bulletin* can be obtained at http://www.paho.org Search Measles Bulletin.

Coverage Rates: DPT-3, OPV-3, Measles, BCG Region of the Americas, 1999 and 2000 (Revised)

Region/Country	DPT		OPV		Measles		BCG	
Rogion, Country	1999	2000	1999	2000	1999	2000	1999	2000
Anguilla	96	92	99	94	99	99	99	99
Antigua & Barbuda	99	95	99	96	99	90	n/a	n/a
Argentina	88	80	91	85	97	91	99	99
Bahamas	82	99	82	91	86	93	n/a	n/a
Barbados	87	94	86	86	86	94	n/a	n/a
Belize	87	89	84	89	82	96	96	95
Bermuda	58	30*	58	30*			n/a	n/a
Bolivia	87	89	89	89	99	99	95	95
Brazil	94	98	98	99	98	99	99	99
British Virgin Islands	90	99	92	99	92	99	99	99
Canada							n/a	n/a
Cayman Islands	94	93	94	92	90	89	92	90
Chile	94	97	95	89	95	97	94	99
Colombia	73	74	75	78	76	75	79	86
Costa Rica	86	88	84	79	89	84	89	92
Cuba	94	99	96	99	99	96	99	99
Dominica	99	99	99	99	99	99	99	99
Dominican Republic	83	78	84	67	94	88	90	90
Ecuador	80	89	70	83	99	89	99	99
El Salvador	94	99	93	98	75	97	72	99
Grenada	88	97	87	97	94	92	n/a	n/a
Guatemala	86	95	86	94	93	98	91	97
Guyana	83	88	83	78	87	86	91	93
Haiti	59	59	58	58	85	80	58	57
Honduras	95	88	95	90	98	99	93	99
Jamaica	84	86	84	86	82	88	89	94
Mexico	96	89	96	89	94	96	99	99
Monserrat	99	85	99	85	99	99	99	99
Nicaragua	83	89	93	94	97	99	99	99
Panama	92	98	96	99	73	97	99	99
Paraguay	77	80	74	73	70	92	87	79
Peru	99	98	96	93	92	97	97	93
St. Kitts & Nevis	99	99	99	99	99	99	99	99
St. Lucia	89	70	89	70	95	89	99	91
St. Vincent & Grenadines	95	99	99	99	87	96	99	99
Suriname	85		84		85		n/a	n/a
Trinidad & Tobago	90	90	90	90	88	90	n/a	n/a
Turks & Caicos	83	99	89	99	94	99	99	99
Uruguay	93	88	93	88	92	90	99	99
Venezuela	79	77	82	86	79	84	96	99

* Data incomplete

n/a Data not applicable

... Data not available

First International Course on Regulations for Biological and Biotechnological Products

The first international course on regulations for biological and biotechnological products was held from 7 May to 1 June 2001, at the Instituto Nacional de Higiene Rafael Rangel in Caracas, Venezuela. Its objective was to update and standardize the criteria for evaluation and regulation of biological and biotechnological products in the Region. Sponsors included the Organization of the American States (OAS), the Program for Fellowships from the Office of Planning and Development, and the Ministry of Foreign Affaires in Venezuela, and the Pan American Health Organization.

The course was divided into modules and workshops, which aimed to cover the six basic functions related to the regulation of biological and biotechnological products, in accordance with recommendations issued by the Pan American Health Organization and the World Health Organization:

- Module I: Philosophical, legal and technical aspects of the regulation of biological and biotechnological products.
- Module II: Regulatory issues of vaccines.
- Module III: Regulatory issues of Blood Products.
- Module IV: Regulatory issues of Recombinant Products.
- Workshop I: Good Manufacturing Practices in the production of Biological Products.

Workshop II: Clinical Studies of Biological Products. Workshop III: Lot Release of Biological Products.

Participants had the opportunity to acquire the philosophical, legal, and technical knowledge that will allow them to handle the literature related to the production, quality control, management, use, and regulation of biological and biotechnological products, such as vaccines, blood derivatives of human and animal origins, and those obtained through genetic manipulation. They took part in practical exercises related to quality control and evaluation of licensing documents, summary protocols for production and control, and certificates of lot release.

There were 14 international professors coming from various organizations, such as the Pan American Health Organization, the World Health Organization, the Food and Drug Administration of the United States (FDA), the European Economic Community, the Center for Genetic Engineering and Biotechnology of Cuba and from the industry representing the areas of biological and biotechnological product. Fifty national professionals from regulatory, academic, legal, clinical areas, along with the pharmaceutical industry participated in the preparation and conduction of the workshop.

The areas of responsibilities of national and international participants included licensing and control of biological and biotechnological products, purchasing processes, distribution and use of biological and biotechnological products and academia. The 12 international participants came from Cuba, El Salvador, Bolivia, Paraguay, Panama, Nicaragua, Costa Rica, Brazil, Ecuador, and Guatemala and close to a total of 200 people participated at the various section of the course.

All efforts and resources placed in order to achieve and maintain high immunization coverages to control and eliminate diseases can be jeopardized by the use of vaccines that are no potent or even of low potency. The Division of Vaccines and Immunization has been working on ensuring the quality of the vaccines used in the immunization programs. The objective of this workshop fits within the general frame of activities being promoted at the regional level to train personnel from the NRA on licensing, lot release, GMP inspections and post-marketing surveillance, as well as update them with new technologies and products being developed.

The *EPI Newsletter* is published every two months, in Spanish and English by the Division of Vaccines and Immunization (HVP) of the Pan American Health Organization (PAHO), Regional Office for the Americas of the World Health Organization (WHO). Its purpose 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 their possible solutions.

References to commercial products and the publication of signed articles in this *Newsletter* do not constitute endorsement by PAHO/WHO, nor do they necessarily represent the policy of the Organization.



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