Immunization Data Quality Self-assessment: The Costa Rica Experience

The immunization Data Quality Self-assessment (DQS) methodology was created by the World Health Organization (WHO) to evaluate the different aspects of the immunization “monitoring system” (1). Immunization monitoring refers to the regular ongoing measurement of vaccination coverage and other program indicators. This methodology was adapted from the Data Quality Audit (DQA) methodology that was launched within the framework of the Global Alliance for Vaccines and Immunization.

The objectives of the DQS are to evaluate the quality, timeliness and accuracy of data produced by the immunization monitoring system in a given country. The DQS is meant to be flexible. It assists managers in identifying problems and proposing tailored recommendations for improvement. The DQS is to be used by staff collecting and using immunization data at the national, provincial, or local levels. These persons define the parameters to be evaluated, develop the questionnaires, conduct the evaluation in the field, analyze the findings, and propose recommendations.

The first DQS in the Region of the Americas took place in Costa Rica from 3 to 12 November 2005. A team of 19 persons, including representatives of the Ministry of Health (MOH), the Social Security (Caja Costarricense del Seguro Social or CCSS), PAHO, WHO, and representatives from Bolivia and Honduras participated in the evaluation. The team included primary health care technicians, regional and local epidemiologists, public health nurses, statisticians, immunization program managers, and other high-level health system managers.

The Immunization Monitoring System in Costa Rica

In Costa Rica, the main provider of immunization services is the CCSS. The CCSS includes over 800 primary Health Units and 29 hospitals, distributed in 104 administrative Health Areas and seven Health Regions. The CCSS uses a computerized system for recording of vaccination doses administered (SISVAC). SISVAC has been implemented in all Health Regions and Areas, and most primary Health Units. While the CCSS is the main provider of immunizations, the MOH is the regulatory entity. Administratively, the MOH is organized in 99 Areas and nine Regions. Each Area of the MOH receives immunization data from its counterpart CCSS Health Area and from private institutions. The Area consolidates the information, and conducts appropriate epidemiological analysis. It is important to note that Health Areas do not necessarily correspond to the

Data Quality Self-assessment (DQS) Methodology

The three main components of the DQS are:

- The quality of the immunization monitoring system is evaluated using questionnaires designed by the team.
- Data accuracy is assessed by comparing the data available in data collection forms at the different levels. Data from the daily listings of vaccines administered in Health Units are compared with aggregated data reported to the local and provincial levels, and data available at the national level.
- Reporting timeliness is evaluated by noting whether the units reporting or receiving reports record dates of submission and/or receipt.

2005 Caribbean EPI Managers’ Meeting

The 22nd Meeting of the Caribbean EPI Managers was held in Bermuda, from 29 November to 2 December 2005. The meeting brought together over 70 health officials from 24 countries of the English-speaking Caribbean, Aruba, Canada, the Netherlands Antilles (Bonaire, Curacao, Saba, St. Eustatius, and St. Martin), Suriname, and the United Kingdom. PAHO Immunization staff, representatives from the Caribbean Epidemiology Center (CAREC), the Caribbean Program Coordination Office, the Caribbean Community (CARICOM), the Christian Children’s Fund, and UNICEF also attended.

Measles and Rubella Elimination

The last case of indigenous measles in the Caribbean Community was reported in 1991, and the last importation (from a European tourist), in 1998. Experience in several countries shows that, when high coverage with measles-containing vaccine exists, reliable detection and aggressive follow-up of suspect cases will limit the consequences of measles virus importations.

Rubella vaccination campaigns have been highly successful in the Caribbean. There has been no laboratory-confirmed rubella case since 2001. No confirmed rubella cases were reported between 2002 and 2005. In
geographical borders of the districts (cantón or second administrative geographical level, province being first). The MOH does not use SISVAC, but uses Excel workbooks and a DOS-based system in some Regions and at the central level. All coverage information is stratified by district of residence from its collection at the local level.

Over the last few years, the administrative coverage levels reported have been irregular in the different districts. Health authorities have been unsure if this situation was a reflection of the immunization program performance, or resulted from deficiencies in the immunization monitoring system. Against this background, Costa Rica requested support from PAHO to conduct an evaluation.

Quality of the Immunization Monitoring System

In Costa Rica, the aspects evaluated included the quality of recording and archiving practices, data analysis, planning and training, and supervision. One specific form was designed for each level of the health system (Health Unit, hospital, Area, and Region). Questionnaires were designed for dichotomous answers and scored accordingly. By dividing the score obtained by the maximum score possible for that component, the quality index was then obtained for each site visited.

To display the quality indexes, expressed in percentages, for the components evaluated and facilitate comparisons across equivalent levels (Health Units, Areas, and Regions), radar graphs were created using an MS-Excel tool created for this purpose. Figure 1 shows an example of these graphs for a Health Area. In the example, the score was as high as 100% for recording and archiving, and as low as 20% for the supervision component.

Data Accuracy

To evaluate the accuracy of the data, data available at the local level were compared with data found in the Health Area, then with data at the regional and national levels, when feasible. The accuracy ratio (see box below), expressed as a percentage, was used as a measure of data accuracy. This ratio is defined as the number of vaccine doses verified or counted at a more local level (numerator), divided by the number of vaccine doses reported by that level to higher levels (denominator).

Accuracy Ratio for data sent by a Health Unit =

\[
\frac{\text{No. of counted DTP3 doses (infants <1 year of age) found in reports for that Health Unit at the Health Area for the same given month}}{\text{No. of DTP 3 doses (infants <1 year of age) found in reports for the Health Area}} \times 100
\]

If not all reported doses reported to a higher level can be verified at a lower level, the accuracy ratio will be <100%, indicating over-reporting. This would be the case if more doses are found in the Region than in the registries of the Health Area or the Health Unit in question. Similarly, if more doses are found in the daily reports of a Health Unit, than in the Health Area or Region, the accuracy ratio would be >100% indicating under-reporting.

Aggregating the accuracy ratios (same level) to obtain a district or provincial ratio is possible by weighting according to population size, for example. However, aggregating should be done with caution, as the result could falsely suggest accurate data hiding simultaneous over- and under-reporting.

The vaccine doses verified were BCG for hospitals, DTP1 and DTP 3 (first and third dose of the diphtheria-tetanus-pertussis vaccine respectively), and MMR (first dose of measles-mumps-rubella vaccine) for January through June 2005.

Timeliness

Data was also collected to evaluate timeliness. To consider a report as timely, the deadlines for monthly data reporting established by the MOH were considered. This component could only be evaluated when a date stamp or date registry was present.

DQS Implementation in Costa Rica

The DQS was divided in three stages:

1. Initial Workshop. The evaluation group devoted the first three days of the assessment to define the scope of the evaluation, develop the evaluation questionnaires and forms, and pilot the forms in the field to fine-tune them.

2. Field work. During the subsequent three days, four teams visited 10 Health Region administrations (4 from the CCSS and 6 from the MOH), 26 Health Areas (12 from the CCSS and 14 from the MOH), 21 Health Units, 9 hospitals, and 3 private institutions.

3. Analysis workshop. During the last two days, each team analyzed their findings and presented them to the rest of the group. A summary of the main findings and proposed recommendations were presented to the national authorities in a final closing meeting.

Main Findings

A final report with detailed results and recommendations was prepared and distributed to all relevant stakeholders and to all the sites visited. The results were presented as common strengths and weaknesses by each level. However, consolidating the results was difficult because strong aspects found in some sites were the weakest in others. Also, the selection of sites was not random, restricting the ability to generalize the findings.

Regarding the quality of the immunization monitoring system, strengths and weaknesses were found at each level. In general, recording and archiving practices were adequate at all levels, with some notable exceptions at the national hospitals and some private institutions. The form for primary recording of daily doses does not include the variable “sex” (although this is captured in the computerized SISVAC system available in most Health Units), and the age grouping does not include a category for persons >65 years, limiting the ability to...
to monitor the impact of seasonal influenza vaccination, in the schedule since 2004. Areas for improvement regarding SISVAC use were identified. Immunization data analysis is done to some degree at all levels. However, the analysis is usually restricted to BCG, OPV3, DTP3, and MMR 1 vaccines, and the use of indicators such as drop-out rates (see box above) is limited. Data are seldom presented in graphs or maps.

Immunization activities were always included in planning and training on immunization topics considered. However, high level support on data collection and reporting, as well as SISVAC use, was weak. Finally, supervision for the information component of immunization is incipient, usually limited to an evaluation of timeliness of data transmission.

Regarding data accuracy, Costa Rican legislation makes reporting of vaccine doses administered compulsory for all providers. However, under-reporting was noticed, mostly in hospitals and private institutions. In one hospital where under-reporting could be quantified, accuracy ratios were as high as 141% for BCG and 143% for hepatitis B, representing 41% and 43% under-reporting, respectively. The Regions do not receive reports accounting for all the doses administered in their Health Areas. There is no standard mechanism to manage reports regarding persons receiving vaccines outside their district of residence. Therefore, vaccine doses administered to non-residents could not be monitored.

As for timeliness of reporting, most sites visited record the dates of receipt of reports. Delays were found mostly from hospitals. Data reporting could be quantified, accuracy ratios in less than 5 days. In 2001, 2003, and 2004, the rate was 15%, 23%, and 29%, respectively. In 2005 (Week 43), 31% of specimens arrived at the regional laboratory in less than 5 days. In 2001, 2003, and 2004, the rate was 15%, 23%, and 29%, respectively. In 2005 (Week 43), 31% of specimens arrived at the regional laboratory in less than 5 days.

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Countries place high priority on achieving high coverage in every district and avoiding importations and circulation of Sabin vaccine-derived viruses.

Eradication strategies must be sustained. These strategies are:

- Effective and timely AFP surveillance; and
- Maintaining vaccination coverage >95% for polio vaccines for each birth cohort.

In the Western Hemisphere, polio eradication was achieved in 1991 and the Region was certified free of indigenous wild poliovirus circulation in 1994. The last case of poliomyelitis in the CARICOM countries was reported in 1982. Recent outbreaks in previously polio-free countries have highlighted the fact that countries with pockets of susceptibles are at risk of wild-poliovirus reintroduction and vaccine-derived polio circulation.

After fourteen years of maintaining the Americas polio-free, the Region continues to sustain surveillance of acute flaccid paralysis (AFP).
Influenza Pandemic Preparedness

Another influenza pandemic is inevitable, possibly with H5N1 virus, which is "new" to humans. During the pre-pandemic phase, surveillance should be conducted on birds and humans. During a pandemic, vaccines and antivirals will probably NOT play a major role in the initial response. Public health measures, including hand-washing, limiting gatherings, and quarantine, will form the major part of community control measures. Hospital infection control will also be crucial.

All countries have received WHO, PAHO, and CAREC guidelines on developing plans for influenza pandemic preparedness, and sample plans from countries such as the United Kingdom and Canada. A draft SARS (Severe Acute Respiratory Syndrome) simulation exercise was disseminated to the countries in 2005. This exercise has been reviewed and amended for use with influenza pandemic preparedness.

The CARICOM countries are taking the threat seriously and planning accordingly. Currently, 17 of 21 countries have held at least one planning committee meeting and have a draft plan or a plan outline. The committees are multidisciplinary and multileveled, and, in most countries, include national surveillance and response teams. The next steps will include further preparation activities, such as confirmation of laboratory networks in the sub-region, finalization of country plans, hosting of a sub-regional meeting, training, and conducting simulation exercises.

Finally, meeting participants unanimously endorsed the activities outlined in the PAHO Strategic and Operational Plan for responding to Pandemic Influenza.

New vaccines

1. Rotavirus: PAHO, in collaboration with Member States, has been designing and developing surveillance systems for diarrhea that would capture rotavirus (RV) gastroenteritis, and to date such systems are being piloted in five Latin American and four Caribbean countries. Within the four Caribbean surveillance sites in Guyana, St. Vincent & the Grenadines, Suriname, and Trinidad & Tobago, the proportion of stool specimens found to be positive for RV ranges from 25% to 56%.

2. Human Papilloma Virus: Every year over 233,000 women die from cervical cancer worldwide. In the Region of the Americas, where over 92,000 cases and 33,000 deaths of cervical cancer are recorded annually, significant sub-regional disparities exist, as incidence and mortality rates in Latin America and the Caribbean are 4-5 times higher than those for North America. The International Agency for Research on Cancer has estimated the age-adjusted incidence and mortality rates for cervical cancer in the Caribbean at 35.8 and 16.8 per 100,000 population, respectively.

Two prophylactic vaccines against Human Papilloma Virus (HPV), composed of sub-unit virus-like particles, have undergone extensive clinical trials in human subjects with excellent results. These vaccines will provide a significant opportunity for enhanced comprehensive cervical cancer prevention.

In order to assemble the evidence to support rational and effective decision-making for HPV vaccine introduction, studies on the economic impact of cervical cancer, the cost-effectiveness of vaccination, and the acceptability of vaccination by health care providers and the general population will be required.

Ensuring Compliance with Vaccination

Ensuring compliance with vaccination must be an on-going EPI activity, requiring the dedication and commitment of all health workers. While specific immunization legislation on compulsory vaccination are beneficial, countries must have a detailed protocol outlining the procedures to be implemented for identification and management of defaulters or refusals for vaccination.

The health staff in countries must also appreciate that the current cohort of mothers in the Caribbean are young and have had little experience with vaccine-preventable diseases. Hence, the fears and concerns of these young parents are focused on adverse events that may occur as a result of vaccination. On-going honest and open communication with parents will help them to better understand the benefits of vaccination and alleviate their fears about vaccines. This is the most effective method of ensuring compliance with vaccination.

Note: For complete report and recommendations, please contact the Immunization Unit at fch-im@paho.org.
Classification of Suspect Measles/Rubella Cases as “Vaccine-related”: Compliance with PAHO Recommendations

In a setting of low or absent transmission of the measles/rubella virus, surveillance will detect patients with eruptive febrile illnesses who have positive serological results for measles or rubella but no wild-type measles/rubella virus infection. One explanation for such occurrence is a reaction to the measles-mumps rubella vaccine (MMR). In 2000, the PAHO Technical Advisory Group on Vaccine-preventable Diseases defined five criteria for concluding that a rash-illness is related to a measles/rubella-containing vaccine. A case can be classified as having a vaccine-related rash if it meets ALL of the following criteria:

1. Presence of rash illness, with or without fever, but no cough or other respiratory symptoms related to the rash;
2. Rash onset began 7–14 days after vaccination with a measles-containing vaccine;
3. Serum sample, taken between 8 and 56 days after vaccination, is positive for measles;
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 failure to identify wild measles virus in culture).

As part of periodic data quality reviews of the Measles Elimination Surveillance System (MESS), the compliance of cases classified as vaccine-related has been checked against the criterion defining the acceptable time period between vaccination and rash onset (criterion 2). The MESS database included a total of 38,894 suspect measles/rubella cases with rash onset between 2003-2005 (as of epidemiological week 9, 2006). Of those cases, 259 (0.67%) were classified as vaccine-related. Figure 1 shows the distribution of cases classified as vaccine-related by the number of days between vaccination and rash onset. For the years 2003–2005, only 34% of the cases classified as “vaccine-related” met the criterion of rash onset 7–14 days following MMR vaccination.

To prove whether evidence existed supporting the onset of MMR-related rash beyond the 7–14 day period following vaccination, a literature review and discussions with experts were conducted. This process showed overwhelming evidence of MMR-related rash occurring specifically between 7 and 14 days following vaccination.

Two placebo-controlled clinical trials are the main basis for defining the 7-14 day period. In these studies, the authors followed groups of MMR vaccinees after injection and found that the peak period for vaccine-related rash onset was during the second week after vaccination. Additionally, several other prospective studies and case reports reached the same conclusion. A few studies report cases of rash occurring beyond 14 days after MMR vaccination, but such cases are the exception rather than the rule. Importantly, these studies were not placebo-controlled. The above-mentioned placebo-controlled clinical trials showed that the proportion of rash cases beyond the second week after MMR vaccination was not significantly different between the group receiving MMR and the placebo group. This finding suggests that rash seen in MMR vaccinees 14 days or later after MMR vaccination is not likely related to the vaccine.

For those MESS cases classified as vaccine-related but with rash onset beyond 7–14 days following vaccination, the etiology is likely to be other rash illnesses that typically occur in the pediatric population, such as parvovirus B19 and human herpes virus 6, or could represent missed cases of measles or rubella. The “vaccine-related” MESS cases are being evaluated to determine if this may be the case. The Immunization Unit recommends that countries review the definition of a vaccine-related case as recommended by PAHO and classify potential vaccine-related cases accordingly.

Acknowledgement: This summary was prepared with assistance from Dr. Riyadh Muhammad, Preventive Medicine Resident, Johns Hopkins University.

Selected References:


Figure 1. Days between Vaccination and Rash Onset in MESS Cases Classified as “Vaccine-related”, 2003–2005

- 0-6 days: 7%
- 7-14 days: 11%
- 15-21 days: 34%
- 22-30 days: 11%
- 31-60 days: 11%
- >60 days: 6%
- Unknown: 20%

N=259

Source: Measles Elimination Surveillance System (MESS)

* Preliminary data as of Week 10 2006
Update on Rotavirus Surveillance in the Americas

Rotavirus is the most frequent cause of gastroenteritis and severe dehydration in young children, in both developed and developing countries. Rotavirus infection manifestation can range from an asymptomatic infection to severe diarrhea with dehydration, which could lead to hospitalization and death. Recent studies have estimated that rotavirus causes approximately 111 million gastroenteritis episodes requiring home care, 25 million clinic visits, 2 million hospitalizations, and between 352,000-592,000 deaths in children aged <5 years.1 A study sponsored by the World Health Organization showed that 20-70% of hospitalizations and 20% of deaths due to diarrhea in children aged <5 years were attributable to rotavirus.2 Although rotavirus distribution is universal, affecting the rich and the poor, a relationship exists between the socioeconomic level and the rate of hospitalizations and deaths. Children in the poorest countries account for 82% of rotavirus deaths.3

Given the imminent availability of rotavirus vaccines, it is imperative to understand the local epidemiology of rotavirus infection. Estimating the burden of disease and conducting cost-benefit and cost-effectiveness studies will certainly provide valuable information for decision-making regarding the introduction of rotavirus vaccine into routine infant immunization schedules. Additionally, information on the burden of disease will allow the evaluation of the vaccine impact. To this end, the Pan American Health Organization (PAHO) and partners such as the U.S. Centers for Disease Control and Prevention, PATH (Program for Appropriate Technology in Health), and the Sabin Vaccine Institute are collaborating to assist countries in the implementation of sentinel, hospital-based rotavirus surveillance.

Ten countries have implemented rotavirus surveillance and are reporting to PAHO on a monthly basis. Table 1 presents the data reported and indicators from these countries. It is expected that all countries in the Americas would have rotavirus surveillance implemented by the end of 2006. This will establish a baseline for rotavirus disease burden and foster a better understanding of the epidemiological profile of the disease in the pre-vaccine era. ■

References:

Regional Workshop on Rotavirus Surveillance

A Regional workshop on rotavirus surveillance was conducted in Rio de Janeiro, Brazil, from 12-16 December 2005. Over 100 persons participated in the event, including surveillance and laboratory professionals from 18 countries and panelists from PAHO partner organizations. The objectives of the workshop were to:
• Standardize case definitions regarding sentinel hospital-based surveillance;
• Standardize indicators for evaluation of surveillance activities;
• Plan surveillance activities in preparation for the introduction of new rotavirus vaccines; and
• Train participants on clinical, epidemiological, and laboratory aspects of rotavirus disease.

The main outcomes of the workshop were national plans of action for rotavirus surveillance and an operational field guide for surveillance implementation including contributions from participating countries. This field guide is being finalized by the Immunization Unit and will be available shortly.

Table 1. Data and Indicators of Rotavirus Sentinel Hospital-based Surveillance in Reporting Countries, Region of the Americas, 2005

<table>
<thead>
<tr>
<th>DATA AND INDICATORS</th>
<th>COUNTRIES</th>
<th>TOTAL</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Bolivia</td>
<td>CAREC a</td>
</tr>
<tr>
<td>Number of hospitalizations in children aged &lt;5 years</td>
<td>743</td>
<td>552</td>
</tr>
<tr>
<td>Number of hospitalizations due to diarrhea in children aged &lt;5 years</td>
<td>141</td>
<td>183</td>
</tr>
<tr>
<td>Percentage of hospitalizations due to diarrhea</td>
<td>19%</td>
<td>33.2%</td>
</tr>
<tr>
<td>Number of children aged &lt;5 years that meet the case definition</td>
<td>81</td>
<td>63</td>
</tr>
<tr>
<td>Percentage of suspect rotavirus cases</td>
<td>57.5%</td>
<td>34.4%</td>
</tr>
<tr>
<td>Number of children with complete form and stool sample collected</td>
<td>80</td>
<td>86</td>
</tr>
<tr>
<td>Percentage of suspect cases with complete form and stool sample collected</td>
<td>98.8%</td>
<td>136.5%</td>
</tr>
<tr>
<td>Number of cases with result positive for rotavirus</td>
<td>NA</td>
<td>41</td>
</tr>
<tr>
<td>Percentage of confirmed rotavirus cases</td>
<td>NA</td>
<td>47.7%</td>
</tr>
</tbody>
</table>

a The 4 countries reporting rotavirus data to the Caribbean Epidemiology Centre (CAREC) are Guyana, Saint-Vincent and the Grenadines, Suriname, and Trinidad & Tobago.

b This indicator includes outpatient data.

NA: not applicable.

Source: Country Reports to Rotavirus Database of Immunization Unit, PAHO.
PAHO Revolving Fund Vaccine Prices for 2006

In 2006 the EPI Revolving Fund for Vaccine Procurement (RF) is offering a total of 39 vaccine presentations to participating countries in the Region. New vaccines included this year are pneumococcal, varicella, hepatitis A, IPV, DTPa, and meningococcal. The RF promotes equity and helps ensure that the immunization programs of participating countries benefit from a continuous supply of vaccines at affordable prices. This is especially beneficial to smaller countries that would otherwise have to pay higher prices for lower quantities of vaccines required.

Table 1 shows 2006 prices for vaccines being offered through the RF. In summary the weighted average of price increase for 2006 compared to 2005 is 1.8%. Some vaccine prices have decreased, such as yellow fever (-10%) and hepatitis B (-13%). This was facilitated in part by a close working relationship between participating countries, suppliers, and PAHO to manage changes in demand forecasting during 2005 followed by the necessary adjustments in production of supply. Price increases, however, occurred for dT 10 (+15%) and MMR 1 (+7%), due to lower accuracy in demand forecasting. A 2.5% increase for Pentavalent is the result of supply pressures and a sole source.

In anticipation of possible supply shortages in 2006 for MMR, yellow fever, polio, and Pentavalent, the Immunization Unit will continue to strengthen its working relationships with countries and suppliers. It will focus on improving management of changes in demand and supply to ensure a smooth and constant flow of vaccines in the supply chain.

Participating countries will soon receive a new tool for forecasting and budgetary purpose. The tool’s function is to assist countries in managing and monitoring their budget requirements. The resulting improvements in the supply’s chain efficiency and effectiveness will enhance the RF’s performance and help reducing costs, ultimately facilitating the introduction of new vaccines.

Note: The 2006 vaccine and syringe price lists can also be consulted on the Immunization Unit’s webpage, at http://www.paho.org/english/ad/fch/im/Vaccines.htm

<table>
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<th>Vaccine Doses per Vial</th>
<th>Average Cost</th>
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<tr>
<td>DPT 10</td>
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<tr>
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<tr>
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<tr>
<td>Hib Lyophilized 10</td>
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<tr>
<td>Hib Liquid 1</td>
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2006 Vaccination Week in the Americas

The 2006 Vaccination Week in the Americas (VWA) will take place from 22 to 29 April. This is the fourth consecutive VWA, featuring inter-border activities and integrated health services delivery. Thirty-nine countries and territories in the Region of the Americas will join efforts to vaccinate almost 38 million people against polio, measles, rubella, influenza, diphtheria, mumps, tetanus, *Haemophilus influenzae* type b, hepatitis A and B, and yellow fever.

The objectives of the VWA vary by country (Figure 1). The 2006 VWA will focus on the transition from child immunization to family immunization. Countries will put an emphasis on social communication and mobilization campaigns to raise awareness about immunization among the community and health professionals.

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The *Immunization Newsletter* is published every two months, in English, Spanish, 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 *Immunization 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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