Measles, Rubella, and CRS Elimination: Costa Rica Makes History

On 14 May 2008, Costa Rica became the first country of the Region to create a national commission for documenting the elimination of measles, rubella, and congenital rubella syndrome (CRS). The independent body will be comprised of national advisors and consultants who will collect and examine available country data as a step towards declaring Costa Rica free from measles, rubella, and CRS. At the conclusion of this process, the commission will submit its final report to the Minister of Health who will officially present it to an international Expert committee (see *Immunization Newsletter*, February 2008).

From May 2007 to April 2008, Costa Rica also served as pilot country to test the regional protocol on elimination that PAHO developed to assist countries with data collection and analysis. In May 2008, national and international participants convened in San José to (1) discuss the regional protocol and incorporate recommended modifications based on the lessons learned during the initial collection of evidence on measles, rubella and CRS elimination in Costa Rica, and (2) determine the next steps to implement to achieve the goal of elimination certification in Costa Rica. Meeting participants included representatives from Costa Rica’s Ministry of Health, Social Security Fund, and Birth Defects Registry Center; country experts in the field of neonatology, ophthalmology, and cardiology; international experts from the World Health Organization, the U.S. Centers for Disease Control and Prevention, PAHO, and the Oswaldo Cruz Foundation; and the former president of the American Academy of Pediatrics.

A key recommendation for improving the regional protocol was to develop a document providing countries with additional guidance on how to inter-relate all the pieces of evidence—including detailed information on the national immunization program, epidemiological analysis of measles, rubella, and CRS, surveillance quality, molecular epidemiology, and population immunity—to support the argument of elimination.

Dr. Oscar Árias Sánchez, President of Costa Rica, signing the executive decree creating the national commission on 14 May 2008. To his left is Rodrigo Árias, Minister of the Presidency, and to his right Dr. María Luisa Ávila Agüero, Minister of Health.
These forms are submitted to the Immunization Unit (FCH/IM) no later than 15 July of the prior year. Information provided must also include updated delivery addresses and a schedule of national holidays for the coming year. To ensure sustainability of supply, Member States prepare a projection of vaccine and syringe requirements for one additional year through PAHO Forms 173-1 and 173-2.

Upon receipt of PAHO Forms 173-1 and 173-2 from Member States, FCH/IM consolidates requirements by country (for vaccine type and vial size, and for syringes) into a regional forecast. This information is forwarded in summary form to PRO to initiate the bid process in August.

FCH/IM will ask the Member State to confirm quarterly requirements and/or changes five months in advance of the quarter in question. For example, faxes/e-mails confirming vaccine and syringe requirements for the third quarter (July-September) will be sent out on 15 February to be returned by the Member State no later than 15 March. This will help to ensure a reliable and sustainable procurement of vaccines and syringes on a timely basis as suppliers require a minimum lead time of three months to adjust their production plan.

Vaccine and Syringe Procurement

Once the bidding process has been completed, PRO establishes annual arrangements with suppliers for the forthcoming year. These arrangements will provide terms, conditions, and prices for the coming year and will guide placement of individual orders to meet the specific quarterly needs of each participating Member State.

Vaccines will be supplied with an expiration date no less than 12 months unless otherwise specified by Member States on their PAHO Form 173-1. If any shipment does not meet this expiration date guideline, the Member State would be asked to authorize the shipment, prior to the order being placed.

Participating Member States will be charged for any vaccine or syringe orders placed by PAHO on their behalf pursuant to PAHO Forms 173-1 and 173-2. If a participating Member State decides to cancel or reduce a requirement after the orders have been placed with the supplier, it must notify PRO 45 days before the vaccine or syringe is scheduled to be shipped. If notification is not received on time by PRO to cancel/amend the order, then the Member State requesting the vaccine or syringe will be responsible for any charges up to the full value of the order.

Vaccine, Syringe, and Related Supplies Delivery

PRO will make the necessary arrangements with the suppliers and their freight forwarders to ship and deliver, on a timely basis, all vaccine and syringe requests specified by Member States on properly submitted PAHO Forms 173-1 and 173-2.

PAHO does not allow partial shipments from suppliers unless prior authorization is obtained from PRO. Depending on the circumstances, PAHO may request written authorization from the Member State or Institution to proceed with such a shipment.

PRO will send copies of each vaccine, syringe and/or related supplies’ purchase order to each Member State concerned.

Depending on the product, the following documents will be provided to the Member State or Institution, as Consignee, prior to shipment:
- Air waybill or bill of lading, commercial invoice and packing list;
- Insurance certificate;
- License from the National Regulatory Authority (NRA) of the country of origin;
- Certificate of release per lot from the NRA;
- Certificate of analysis per lot;
- Free sale certificate; and
- Summary protocol of production and quality control based on WHO standards.

Upon arrival of the vaccines, syringes or any related supplies to the final destination, the Member State or Institution is solely responsible for completing customs clearance procedures.

Acknowledgment of Receipt and Claim Process

The Member State or Institution should formally notify acknowledgment of receipt of shipment to the local PAHO/WHO Representative’s (PWR) office within 3 working days of arrival of the product:

1. When goods arrive at destination with visible damages, the consignee must complete customs clearance, take possession of the cargo, and report in writing the damages to the airline. The consignee should also inform the insurance company and PRO of its intention to file a formal claim and proceed with the claim according to the instructions specified in the insurance certificate.

2. When goods arrive at destination with hidden (not visible) damages, the consignee must complete customs clearances and immediately upon arrival at their warehouse inspect the goods. The consignee should also inform the insurance company and PRO of its intention to file a formal claim and proceed with the claim according to the instructions specified in the insurance certificate.

In both instances, it is imperative to report the damages immediately and send written notice to the insurance company of the intent of filing a formal claim. Most insurance policies establish very short periods of time for filing a formal claim. If the claim is not reported within the time limits set by the insurance company, the claim may be denied.

The consignee should evaluate, based on the total value of the goods damaged whether or not filing a formal claim justifies the time and efforts required to comply with the specifications set forth by the insurance company to accept a claim. PAHO cannot file a claim on behalf of the consignee.

In the case of specific problems reported by the Member State or Institution (short expiration date, broken product, mislabeling, or instability) with the receipt of vaccine flasks or any related supplies (needles, syringes, cold boxes and thermal flasks) the PWR will contact PRO when it is informed of the problem by the Member State. PRO will in turn address the problem with the supplier and proceed accordingly. The PWR should notify PRO within 3 working days after receiving the formal acknowledgment of receipt from the Member State. Upon receipt of the acknowledgement, PRO authorizes payment to the supplier and closes the order. PRO must pay the supplier upon presentation of a commercial invoice and a transport title as proof of shipment within the time limit stated in the purchase order.

Technical Clearance

Final acceptance of vaccine shipments shall be subject to technical clearance of production and control protocols by the receiving country’s NRA and/or PAHO. Upon receipt of the product at destination, the Member State shall have ninety (90) days to inspect and test products and to reject all products that do not conform to the specifications, terms and conditions of the order.

PAHO will notify the supplier in case of discrepancies between laboratory results from the NRA and the supplier. Thereafter, for a prequalified product, PAHO will request WHO to have the
product re-tested in a WHO reference laboratory; the expenses will be covered by the WHO prequalification budget. For vaccines not included in the WHO prequalification system, PAHO will arrange to have the product re-tested in a reference laboratory designated by PAHO; these expenses will be covered by the supplier. PAHO may also request the supplier to furnish additional samples to the reference laboratory for testing. The decision of the reference laboratory will be considered final. Upon notice of rejection, and destruction or return certificate, the supplier will either replace the shipment, or refund the payment, as requested by PAHO and pay all laboratory expenses.

Note: This article is adapted from PAHO’s document Operating Procedures for the Revolving Fund for Vaccine and Syringe Procurement. The full document is available at the following electronic address: www.paho.org/immunization.

Regional Plan for Quality Control and Safety of Syringes

(This article is an update of the Plan following the article published in the Immunization Newsletter of October 2005)

In 2004, the Pan American Health Organization (PAHO) developed a plan to verify compliance of disposable and autodisposable (AD) syringes with ISO international quality and safety standards (see box) and with World Health Organization (WHO) guidelines. The plan was meant to ensure the quality, efficiency, and safety of syringes and other products used by immunization programs. Additionally, it was meant to develop institutional capacity within National Regulatory Agencies (NRAs) to conduct tests and verify product quality.

The plan includes all aspects of syringe procurement, from purchase until final disposal. Its objectives are as follows:

- Ensuring syringe quality, efficiency, and safety;
- Developing and strengthening in-country laboratory capacity to verify quality and compliance with standards;
- Promoting syringe standardization;
- Training on new technologies, such as AD syringe use;
- Training on safe syringe use and disposal;
- Promoting safe injection practices; and
- Strengthening mechanisms for syringe purchase, distribution, and storage.

Quality Control

PAHO has established a strategic alliance with the Emergency Care Research Institute (ECRI, see box) to verify quality. ECRI is a PAHO/WHO Collaborating Center and serves as reference laboratory. PAHO collaborated with ECRI to develop the protocols and requirements for laboratory design and equipment. During a training workshop on the evaluation of syringe quality (October 2006), the protocols were reviewed and approved. They were then translated into Spanish and sent to the countries to be used as reference documents.

PAHO is organizing a Regional laboratory network to verify the conformity of syringes and needles with quality standards. Initially, six individuals from NRAs in Argentina, Chile, Colombia, Jamaica, Mexico, and Nicaragua were trained in how to conduct tests, organize the laboratories, and certify them. The training program will be extended to staff from six other countries. PAHO provided the laboratories with the equipment, norms, and protocols required. The first six laboratories are currently evaluating the testing protocols.

Each year, PAHO acquires syringes on behalf of the Region’s national immunization programs through its Revolving Fund. For 2007, over 110 million syringes were purchased at a cost of US $4.56 million while, for the first half of 2008, over 41 million syringes were purchased at a cost of US $1.75 million. For 2007 and the first half of 2008, AD syringes account for 10.5% and 20.5%, respectively, of the total of syringes purchased. As part of the control for quality and compliance with regulations, laboratory testing was conducted to verify the compliance of syringes submitted to the 2007 Revolving Fund bid (Figure 1). The evaluation showed several deviations from standards ISO 7886-1, ISO 7886-3, ISO 7864, and ISO 594/1. PAHO also conducted a follow-up on syringes received by the countries, with a random sampling to control quality and the conditions in which the syringes were received. PAHO will continue its follow-up activities to verify compliance with quality standards, in conjunction with the laboratory network.

Safety

Following the discovery of problems with the syringes purchased through the Revolving Fund, PAHO implemented the Regional Incident Report System (RIRS), whose objective is to follow-up and investigate incidents due to quality or any problems related to syringes and needles. The reporting system is internet-based and the portal serves the following objectives:

- Providing guidelines on quality and safety issues;
- Performing follow-up and investigation of reported incidents;
- Circulating alerts based on investigation results;
- Announcing investigation results;
- Providing a forum for members to exchange information;

The International Organization for Standardization (ISO) is the world’s largest developer and publisher of international standards. ISO standards are universally accepted and ensure desirable characteristics of products and services. Among others, ISO develops international quality standards to certify design, management, and manufacturing processes, thereby ensuring that all three processes are safe and efficient. ISO’s output ranges from standards for traditional activities, such as agriculture and construction, to mechanical engineering, manufacturing and distribution, transport, medical devices, and information and communication technologies. ISO also develops standards for good management practice and for services.

ECRI Institute is a nonprofit organization dedicated to draw on the discipline of applied scientific research to determine the best medical procedures, devices, drugs, and processes, and improve patient care. ECRI Institute is a center for health technologies engaged in the areas of consulting, research, analysis, and training. It serves as an information repository and a laboratory for the evaluation of medical devices.

1. See article Design and Use of AD Syringes on page 4.
• Creating an information repository on products, documents, and services, for use by immunization programs; and
• Circulating news and a calendar of events.

The RIRS was tested and implemented at Regional level. The next step involves testing at country level before the official launch. PAHO provided training on portal use to staff in countries at central level and to PAHO focal points in the PAHO/WHO Representations (PWRs). The portal is currently only available in Spanish, but an English version will soon be added.

Syringe Standardization

PAHO has been disseminating information to the countries regarding syringe standardization, based on the WHO recommendations on syringe type and needle caliber for each vaccine dose. Through subregional meetings and information provided to the PWRs, PAHO has been educating countries on the use of disposable (standard) syringes. The sizes of disposable syringes has been matched to those of AD syringes recommended for use by WHO, in accordance with the vaccines used. Changes are reflected in the PAHO Form 173-2 for 2009 Revolving Fund requirements. Among the benefits of syringe standardization are improved volume control and delivery system management, economies of scale, and improved shipping, storage, product handling, and inventory capacity.

Conclusion

With the Regional Plan for Quality Control and Safety of Syringes, PAHO is expecting to make it easier for countries to purchase high-quality and safe products. And, as standardization becomes more universal, the shift to AD syringe use will be facilitated.

A key component of the plan is the RIRS. Strengthening this system and widening its use will benefit both regional immunization programs and NRAs. Staff will benefit with training on procedures for product registration, follow-up of product performance, post-marketing surveillance, and auditing.

Finally, organizing and supporting laboratory capacity to conduct quality testing of syringes and needles, along with training professionals in good practices for the safe use and storing of syringes and needles, should contribute to increased injection safety.

References:

Design and Use of AD Syringes

Managers of immunization programs have long recognized the benefits of safe injection practices, which have led to better infection control, procurement of safe and quality products, and appropriate waste disposal strategies. However, new technologies introduced without appropriate training have often been rejected by health workers, as is the case for autodisable (AD) syringes. As a result, vaccine wastage and non-use of syringes have occurred.

AD syringes are designed in such way that they can only be used once. After the administration of a single vaccine dose, they become permanently deactivated (blocked) and any risk of blood-borne infection is eliminated. For this reason, AD syringes are the preferred equipment for administering vaccines, both in routine immunization and for mass campaigns.

The AD syringes available on the market vary according to their design (See Table 1).

1. Some AD syringes have a fixed needle with a metallic clip that locks the plunger after a single use.
2. The K1 design features a security plunger that blocks/breaks after one use. The inconvenience associated with the K1 design is that the plunger is not at the zero dosage marking. Since most health workers are not familiar with this design, they push the plunger in too far, causing it to block itself and disable the syringe prematurely.
3. Some syringes are manufactured with a detachable needle that can only be used with the AD syringe it comes with, thereby eliminating the possibility of reusing a needle.
4. Syringes with a retractable needle prevent re-use and eliminate accidents due to needle sticks occurring when health workers recap the needle after administering the vaccine, a practice that is unsafe but still in use.

Other technologies are available, such as intradermal vaccination with a jet gun that does not require a needle. This technology is not yet commercially available.

Each type of AD syringe requires that health workers carefully follow the manufacturer’s instructions. Below is a description of the general steps to be taken for the safe and adequate use of AD syringes.

1. Check the expiration date before opening the wrapper.
2. Check that the wrapper is in good condition.
3. Open the wrapper as indicated.
4. Remove the syringe from the wrapper.
Calculating Needs for Vaccines and Syringes at Local Level

1. Budget permitting, use one syringe per vaccine dose ordered and one reconstitution syringe per vial to be reconstituted. This may lead to ordering more syringes than will be used with those vaccines.
2. The number of syringes can be calculated based on true vaccine and syringe wastage factors in each facility (Table 1).
3. A wastage factor of 1.11 (assuming a 10% syringe waste) can be used to order AD syringes.

<table>
<thead>
<tr>
<th>Table 1. Calculating the Wastage Factor for Vaccines and Syringes</th>
</tr>
</thead>
<tbody>
<tr>
<td>Syringe Wastage Factor = ( \frac{\text{Number of Syringes Used}}{\text{Number of Persons Vaccinated}} )</td>
</tr>
<tr>
<td>Vaccine Wastage Factor = ( \frac{\text{Number of Doses Used}}{\text{Number of Persons Vaccinated}} )</td>
</tr>
<tr>
<td>Syringe Wastage Rate = ( \frac{\text{Number of Syringes Used} - \text{Number of Persons Vaccinated}}{\text{Number of Syringes Use}} )</td>
</tr>
<tr>
<td>Vaccine Wastage Rate = ( \frac{\text{Number of Doses Used} - \text{Number of Persons Vaccinated}}{\text{Number of Doses Used}} )</td>
</tr>
</tbody>
</table>

Converting the Wastage Rate to the Wastage Factor:

\[ \text{Vaccine Wastage} = \frac{1}{1 - \text{Wastage Rate}} \]


Table 1. Autodisable Syringe Designs

<table>
<thead>
<tr>
<th>Type</th>
<th>Packaging</th>
<th>Requires Activation</th>
<th>Disabled by</th>
</tr>
</thead>
<tbody>
<tr>
<td>Fixed Needle</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>SoloShot IX</td>
<td>Individual Paper package</td>
<td>No</td>
<td>Metal clip</td>
</tr>
<tr>
<td>Destroke</td>
<td>Bulk-packed with plunger caps</td>
<td></td>
<td>Ratchets on plunger</td>
</tr>
<tr>
<td>Uniject</td>
<td>Prefilled, single dose: individual foil package</td>
<td>Push port into needle shield</td>
<td>Reservoir (bubble) cannot be refilled</td>
</tr>
<tr>
<td>K1</td>
<td>Individual paper or plastic package</td>
<td>Remove tab or twist plunger (depending on style)</td>
<td>Plunger breaks off</td>
</tr>
<tr>
<td>Detachable Needle</td>
<td>Individual paper package</td>
<td>No</td>
<td>Metal clip</td>
</tr>
<tr>
<td>Retractable Needle</td>
<td>Currently available on the market, this AD syringe is blocked when a mechanism cuts the needle after injection. The needle remains within the syringe and the plunger is blocked after use.</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

# Estimating Needs for Injection Waste Management

## Table 1. Calculating the Total Number of Safety Boxes to Be Used in a Month

<table>
<thead>
<tr>
<th>Calculate the Number of Syringes to Be Used</th>
<th>Calculate the Number of Safety Boxes Necessary</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Nb. of Injection Performed</strong></td>
<td><strong>Total Number of Syringes [S]</strong></td>
</tr>
<tr>
<td>+ Safety Margin (10 %)</td>
<td>/</td>
</tr>
<tr>
<td></td>
<td><strong>Capacity (Sharps/Box) [C]</strong></td>
</tr>
<tr>
<td></td>
<td>= Theoretical Nb. + Safety Margin (10 %)</td>
</tr>
<tr>
<td></td>
<td>= Total Number of Safety Boxes [B]</td>
</tr>
</tbody>
</table>

## Table 2. Calculating the Daily Production of Filled Safety Boxes

The disposal of the safety boxes on a daily basis must be ensured in each health care facility. The calculation of the daily production of safety boxes helps in organizing the everyday logistics. It could be on weekly basis according to the number of injections performed.

- Number of staff providing injections: \( S = \) 
- Average number of injections performed per staff per day: \( I_d = \) 
- Total number of syringes used daily: \( S_d = S \times I_d \) 
- Capacity of a safety box: \( C = 100 \text{ or } 400 \) 
- Daily number of safety boxes to be disposed of at the focal centre: \( B_d = S_d / C \) (boxes/day)

## Table 3. Estimating the Costs for Waste Treatment and Disposal

### 3.1. Sharp Collection Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost/Box</th>
<th>x</th>
<th>Nb. Boxes</th>
<th>=</th>
<th>Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Safety Boxes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td>Total</td>
</tr>
</tbody>
</table>

### 3.2. Waste Handling Costs

<table>
<thead>
<tr>
<th>Item</th>
<th>Cost / Unit</th>
<th>x</th>
<th>Nb. Units</th>
<th>=</th>
<th>Sub-Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Protective Clothes</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plastic Bags</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adhesive Tape</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>etc…</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

### 3.3. Minimum Investment Costs for Waste Treatment and Disposal Equipment

- Incinerator: \((S_d / 1000) \times 15\) (ratio plan 15 $ / 1000 syringes disposed of) 
- Autoclave etc.

### 3.4. Minimum Recurrent Costs

<table>
<thead>
<tr>
<th>Human Resources</th>
<th>Nb. of workers</th>
<th>Daily Rate ($ / day)</th>
<th>x</th>
<th>Nb. of Days</th>
<th>=</th>
<th>Sub-Total</th>
</tr>
</thead>
<tbody>
<tr>
<td>Combustible (wood, fuel, etc)</td>
<td>Quantity Used / Day</td>
<td>Unit Price ($)</td>
<td>x</td>
<td>Nb. of Days</td>
<td>=</td>
<td>Sub-Total</td>
</tr>
</tbody>
</table>

**Total Costs (3.1 to 3.4)**

Management of Waste from Injection Activities

1. Disposal of the Whole Syringe

2. Separation of Needles and Plastic Syringes

* Several countries are currently managing needles and syringes according to this procedure. However, pilot projects are being carried out to allow a validation from WHO regarding the ease of use and safety of needles removers which may carry a risk of needle stick injuries.

Laboratory Containment of Wild Poliovirus: Group B Countries Workshop

The American Regional Commission for Certification of Poliovirus Laboratory Containment and Verification of Polio-free Status (AMR RCC) held a Workshop for Laboratory Containment of Wild Poliovirus in Panama City, Panama, from 20-22 May 2008. The workshop was organized to comply with the commitments made during the second meeting of the AMR RCC, in February 2008. The workshop specifically targeted Group B countries of the Region. During its February 2008 meeting, the AMR RCC concluded that countries could be divided into two general groups (A and B) based on assessment of available information and perceived compliance with requirements of Phase I of the WHO Global Action Plan for laboratory containment of wild polioviruses. Group B countries (i.e., Argentina, Brazil, Colombia, Cuba, Ecuador, Guatemala, Panama, Paraguay, Peru, and Venezuela) are those where much work remains towards completion of Phase I requirements. Phase I, implemented under the guidance of National Certification Committees, includes drafting a list of laboratories in the country, conducting a survey to find out whether laboratories are storing wild poliovirus or potentially infectious materials, and, based on the survey’s findings, establishing an inventory showing what types of samples are stored in which laboratories.

The conclusions of the workshop were as follows:

1. The AMR RCC recognizes the progress of Group B countries and their enthusiasm towards completing the task. They are requested to present a preliminary or final report by 30 September 2008, using the model format.
2. The final report should be signed by the National Committee and sent by the national authorities to PAHO/WHO, who acts as secretary of the AMR RCC. Final reports should be submitted to PAHO by 31 December 2008.
3. Countries are requested to describe in detail the process followed to prepare the list of laboratories in each country, as well as the process followed to classify them in groups of high-, medium-, or low-risk. All (100%) high- and medium-risk laboratories should be surveyed. Countries that chose to survey only a sample of low-risk laboratories should explain whether the result of the survey in this sample confirms that the classification was adequate. If not confirmed, the sample should be increased.
4. Countries should include their laboratory database in this process (Phase I), in electronic format.
5. PAHO/WHO offers its support to countries to complete Phase I of the containment plan.

The AMR RCC was established by the Director of PAHO/WHO in February 2004 in order to independently document that the requirements for wild poliovirus laboratory containment have been fulfilled, and to verify that the polio-free status of the Region remains unchanged.

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