International Workshops on Injection Safety

To strengthen the Regional Plan for Quality Control and Safety of Syringes, PAHO conducted two international workshops on injection safety in 2008, one in Nicaragua (July) and the other in Honduras (November). The objectives of the workshops were to train health professionals and managers of the Expanded Program on Immunization (EPI) on Good Storage Practices (GSP), discarding and final disposal of sharp waste, injection safety, and proper use of medical devices. Sessions on auto-disable (AD) syringe use and the Regional Plan for Quality Control and Safety of Syringes were also conducted. In addition, the workshops sought to promote the use of the regional incident reporting system for syringes.

Good Storage Practices

GSP are guidelines developed by the World Health Organization (WHO). GSP are derived from the Good Manufacturing Practices (GMP). One objective of GSP is to reduce the risks of contamination and confusion, for example in the improper labeling of a product. These practices apply to immunization supply storage, such as central and regional storage warehouses, and hospital and community pharmacies. The objectives of GSP are to guarantee the quality, efficacy, safety, and performance of supplies.

GSP address the flow of supplies and personnel, storage conditions, hygiene norms, arrival and return of supplies, and market recalls, among others. The GSP guidelines highlight the importance of temperature and humidity monitoring (technical mapping) of refrigerators, freezers, and cold rooms. For this purpose, all measurement instruments must be calibrated. Staff working in storage facilities must have well-defined and written roles and responsibilities, and benefit from continuing education.

Trained staff must verify that the products received correspond to what has been ordered, check product quality, and keep written records of all transactions. The reception area must be secure so product quality is not compromised. Each storage facility must have its own equipment for material transportation, weighing, and measuring.

GSP recommendations encompass inventory management, supply turnaround, and product identification. As products are shipped from the central storage unit to regional storage facilities, the accompanying information must allow for the tracking of quantities of any specific lot or batch number (traceability). This will facilitate product recall in case of quality problems or non-conformity.

During the discussion about GSP, it was noted that weaknesses exist at country level regarding storage practices. All stakeholders should commit to having impeccable storage facilities, in spite of financial constraints. This issue must be handled in coordination with national regulatory authorities. Guidelines are being developed.

Discarding and Final Disposal of Sharp Waste

Final disposal of sharps and solid waste remains a challenge for the EPI. Several criteria for dangerous waste management and treatment, from product acquisition to final disposal, have been established. Some of the technologies more commonly used for solid waste disposal are needle destroyers, sterilizing equipment (dry heat, vapor, gas, microwaves), shredding devices, incinerators, chemical disinfection, and encapsulation.

Measles and Rubella Laboratory Network in the Americas

During the verification phase of the interruption of endemic transmission of measles and rubella viruses, it is essential to maintain high quality laboratory surveillance. The role of the laboratory is to provide the essential data to classify suspected cases and to provide molecular epidemiologic information about the viruses circulating in the Region of the Americas. The information should be analyzed and reported in an effective and timely manner to allow implementation of adequate public health measures.

The measles and rubella laboratory network in the Americas was established in 1995 and is part of the World Health Organization (WHO) Global Measles and Rubella Laboratory Network. The network has implemented standardized diagnostic and testing methods, as well as a comprehensive quality assurance program, which includes proficiency testing, confirmatory testing, an accreditation process, and weekly notification of the laboratory performance indicators. Laboratory results are reported to the Pan American Health Organization (PAHO) in a timely manner.

The laboratory surveillance guidelines were reviewed by a group of representatives from the Global Specialized Laboratory (GSL), the Regional Reference Laboratory (RRL), and national laboratories during a meeting at PAHO Headquarters on 27 August 2008.
2. Case Classification and Laboratory Testing:
In an elimination setting, case classification can sometimes be challenging and often requires additional testing and clinical specimens. In this regards it is imperative that countries strengthen virological surveillance. An adequate specimen for virus isolation can improve the sensitivity of the serology in the first days of the disease when serology results can be inconclusive. It allows for the genetic characterization of the virus, which is fundamental for an elimination program in the Region. A negative virus isolation result does not rule out measles or rubella infection because the test is much affected by the timing of specimen collection and specimen quality, which can be affected by storage and transportation. In this situation a second serum specimen (convalescent phase) is indicated to verify seroconversion.

Countries should be aware of the limitations of laboratory testing. To detect IgM to measles and rubella, all laboratories are using commercial EIA assays that have been fully validated and have excellent sensitivities and specificities. Still, no serologic test will be sufficient for all cases. Collection of additional samples for viral detection provides another means to confirm a case and the genetic information provides valuable information about the transmission pathways of the virus. Though these samples are requested, they are difficult to obtain for many cases because of the problems associated with specimen collection, transport, and storage. A second serum sample can also help to improve the laboratory’s ability to classify cases, but many cases are unfortunately lost to follow-up.

Accurate case classification depends on careful review of all laboratory results and epidemiologic data.

a. Cases should be classified after the laboratory and epidemiologic teams have reviewed all laboratory and epidemiologic data.

b. The laboratory and epidemiologic teams from each country should develop a country-specific testing algorithm for case classification. The laboratory components of the algorithm must include additional testing measures to be used to classify sporadic cases (isolated case with no travel history or known epidemiologic links) to rule out false positive or false negative IgM test results. The algorithm should include:

- Protocol for confirming an IgM test result;
- Adequate sample for virus isolation from as many suspected cases as possible; in addition, laboratories should obtain genetic data from all outbreaks;
- Guidance for determining when to attempt collection of a second serum specimen;
- Instructions for use of additional serologic tests: rise in IgG titers and avidity testing;
- Guidance on whether to perform testing for other etiologic agents at the national laboratory or the RRL, considering available capacity and resources.

c. The laboratory should provide guidance to field staff for adequate specimen collection, storage, and transportation.

d. The laboratory testing algorithm must include a provision for laboratories that do not perform virus isolation to forward clinical specimens from confirmed cases to the designated regional reference laboratory for virus isola-
HPV Vaccine Introduction in Panama

On 27 October 2008, the President and the Minister of Health of Panama presided over a ceremony to celebrate the introduction of the human papillomavirus (HPV) vaccine in the country’s immunization schedule for girls aged 10 years. This was a historic moment, as Panama became the first country in Latin America to introduce the HPV vaccine in routine vaccination activities. A new chapter in the history of chronic disease prevention is being written. Only a few years ago, few could have imagined the possibility to prevent cervical cancer with a vaccine.

A few HPV types are responsible for almost all cases of cervical cancer, which is one of the main causes of mortality in women of Latin America and the Caribbean (LAC). Each year, the disease claims the life of an estimated 33,000 women in LAC countries (Figure 1). It is estimated that the number of deaths could double by 2030. Cervical cancer mostly strikes vulnerable populations, such as poor or indigenous women. Health authorities throughout LAC countries are deeply concerned by the high disease burden, the highest mortality rates of cervical cancer in the world, and the economic impact the disease will have on their countries. However, hope is in sight thanks to the availability of vaccines that prevent 70% of HPV infections.

It is expected that the HPV vaccine introduction in Panama will yield many lessons for other LAC countries, that will in turn introduce the vaccine in their schedules and provide their populations with increased opportunities for disease prevention and health. To prevent and control cervical cancer, PAHO recommends a comprehensive strategy that includes the programmatic integration of immunization, cancer control and prevention, adolescent health, and reproductive health.

### References:

### Figure 1. Cervical Cancer Age-standardized Incidence and Mortality Rates per 100,000 population, the Americas, 2002

<table>
<thead>
<tr>
<th>Country</th>
<th>Age-standardized Rate</th>
<th>Age-specific Incidence Rate</th>
<th>Age-specific Mortality Rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Haiti</td>
<td>87.3</td>
<td>30.4</td>
<td>2.3</td>
</tr>
<tr>
<td>Bolivia</td>
<td>55</td>
<td>26.1</td>
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<tr>
<td>Paraguay</td>
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<td>24.6</td>
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<tr>
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<td>48.2</td>
<td>22.2</td>
<td>2.2</td>
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<tr>
<td>Peru</td>
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<td>22.3</td>
<td>2.1</td>
</tr>
<tr>
<td>Guyana</td>
<td>47.2</td>
<td>23.5</td>
<td>2.1</td>
</tr>
<tr>
<td>Nicaragua</td>
<td>45.6</td>
<td>21.1</td>
<td>1.7</td>
</tr>
<tr>
<td>El Salvador</td>
<td>38.7</td>
<td>18.2</td>
<td>1.4</td>
</tr>
<tr>
<td>Ecuador</td>
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<td>16.8</td>
<td>1.1</td>
</tr>
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</tr>
<tr>
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<td>0.8</td>
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<tr>
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<td>17.2</td>
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<td>17.2</td>
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<td>0.7</td>
</tr>
<tr>
<td>Mexico</td>
<td>28.2</td>
<td>12.9</td>
<td>0.7</td>
</tr>
<tr>
<td>Panama</td>
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<td>10.7</td>
<td>0.6</td>
</tr>
<tr>
<td>Trinidad &amp; Tobago</td>
<td>27</td>
<td>10.9</td>
<td>0.6</td>
</tr>
<tr>
<td>Suriname</td>
<td>25.8</td>
<td>9.4</td>
<td>0.6</td>
</tr>
<tr>
<td>Chile</td>
<td>24.9</td>
<td>9</td>
<td>0.6</td>
</tr>
<tr>
<td>Barbados</td>
<td>24.6</td>
<td>10.2</td>
<td>0.6</td>
</tr>
<tr>
<td>Brazil</td>
<td>23.6</td>
<td>7.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Argentina</td>
<td>23.2</td>
<td>7.8</td>
<td>0.5</td>
</tr>
<tr>
<td>Costa Rica</td>
<td>21.5</td>
<td>12</td>
<td>0.5</td>
</tr>
<tr>
<td>Cuba</td>
<td>20.2</td>
<td>8.3</td>
<td>0.5</td>
</tr>
<tr>
<td>Uruguay</td>
<td>18.8</td>
<td>8</td>
<td>0.5</td>
</tr>
<tr>
<td>Bahamas</td>
<td>16.7</td>
<td>6.2</td>
<td>0.5</td>
</tr>
<tr>
<td>Puerto Rico</td>
<td>8.8</td>
<td>2.8</td>
<td>0.3</td>
</tr>
<tr>
<td>Canada</td>
<td>7.7</td>
<td>2.5</td>
<td>0.3</td>
</tr>
<tr>
<td>USA</td>
<td>7.7</td>
<td>2.3</td>
<td>0.3</td>
</tr>
</tbody>
</table>

In 2009, the PAHO Revolving Fund (RF) is offering a total of 46 vaccine presentations to participating countries. This year, the RF added pneumococcal 7-valent vaccine and liquid rotavirus vaccine (3-dose schedule). Also, as per the RF principle of promoting equity, new suppliers who have received prequalification status from the World Health Organization participated in the bid solicitation.

Table 1 shows 2009 prices for vaccines offered through the RF. Compared to 2008, the average price of 24 vaccine presentations has decreased: BCG multidose (-4.0%); DTP multidose (-4.2%); Td adult multidose (-6.4%); DT pediatric multidose (-8.1%); pentavalent (DTP-Hepatitis B-Hib) liquid single dose (-10.1%) and lyophilized single dose (-8.2%); Tdap triple acellular adolescent/adult single dose (-21.3%); pneumococcal 23-valent adult (-19.1%); hepatitis A pediatric single dose (-2.0%); pneumococcal 7-valent pediatric (-17.5%); Hib lyophilized single dose (-3.0%); hepatitis B recombinant adult single dose (-2.5%) and multidose (-15.0%); measles and rubella multidose (-2.3%); rabies human use Indian origin single dose (-4.4%); influenza Southern Hemisphere adult prefilled syringe (-7.5%), adult multidose (-10.2%), pediatric multidose (-5.9%), and pediatric prefilled syringe (-10.5%); yellow fever 10-dose (-19.4%); and influenza Northern Hemisphere pediatric prefilled syringe (-22.9%), pediatric multidose (-20.0%), adult single dose (-32.5%), and adult multidose (-19.7%).

Price reductions were facilitated by new supply sourcing and efficient working relationships between Member States, PAHO, and suppliers to manage changes in demand forecasting and production process during 2008.

Price increases, however, also occurred in 2009 for 6 vaccine presentations: hepatitis B recombinant pediatric single dose (+6.4%); MMR multidose Zagreb strain (+2.2%); polio plastic 20-dose vial (+6.7%), rabies human French origin multidose (+6.7%), varicella single dose (+7.6%), and polio inactivated single dose (+20.6%).

Table 2 shows 2009 prices for syringes offered through the RF.
The most commonly used practice for final waste disposal in Latin American and Caribbean countries is "on-site" burial, whether in a protected burial pit or in a concrete pit. Concrete pits are often preferred in small communities. An important distinction must be established regarding the technical difference between incinerating and burning. Incineration is a process that transforms something into ashes, and results from achieving temperatures above 1200ºC. At lower temperatures, waste is only burnt, with the risk of producing toxic substances such as furans and dioxins. During the workshops, countries were advised to analyze the cost of the different options and choose the most appropriate technologies for their needs.

In the particular case of the pneumococcal vaccine syringe (made of plastic, glass, paper, and rubber, see Photo 1), current disposal options include incineration, burial in protected pits, encapsulation, autoclaving, and shredding.

During the discussion, it was noted that it is essential to consider vials containing biological residue, such as vaccine vials, as dangerous materials to be disposed. Glass vial recycling is only appropriate when vials are inactivated through high-temperature sterilization.

**Injection Safety**

WHO defines an injection as safe when it does not harm the recipient, the health worker, or the community. While 90% of injections administered in the world are for therapeutic purposes, only 5% to 10% are given for preventive services, including immunization.

Two speakers presented the epidemiology of needlestick accidents and occupational exposure to blood-borne pathogens, and the efficacy of measures to prevent such accidents. Regarding the occupational exposure of health workers to blood-borne pathogens, unsafe injections are responsible for 39% of the new hepatitis B virus (HBV) infections, 37% of hepatitis C virus (HCV) infections, and 4.4% of HIV infections. The risk of infection following a percutaneous injury in a health care worker is 6–30 per 100 people for HBV, 3–10 per 100 people for HCV, and 1 per 300 people for HIV.

Preventative measures for needlestick injuries include the following: (1) risk elimination (needle-free IV systems, elimination of sharps, and elimination of unnecessary injections); (2) engineering solutions (retractable needles, needle removal, and special containers for sharps material disposal); (3) administrative controls and good work practices; and (4) personal protection equipment. A reduction in needlestick injuries will be achieved by reducing procedures requiring sharps, providing education, using safer devices and conveniently located rigid containers, using standard precautions, and promoting a positive work environment.

**Table 2. Prices for Syringes Purchased Through the PAHO Revolving Fund, 2009**

<table>
<thead>
<tr>
<th>Disposable Syringes, Plastic with Attached Needle</th>
<th>Auto-disable Syringes, Plastic with Attached Needle</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Size</strong></td>
<td><strong>Packed per Case</strong></td>
</tr>
<tr>
<td>1cc 22G x 1-1/2”</td>
<td>3600</td>
</tr>
<tr>
<td>1cc 23G x 1”</td>
<td>3600</td>
</tr>
<tr>
<td>1cc 25G x 5/8”</td>
<td>2000</td>
</tr>
<tr>
<td>1cc 26G x 3/8”</td>
<td>3600</td>
</tr>
<tr>
<td>1cc 27G x 3/8”</td>
<td>800</td>
</tr>
<tr>
<td>5cc 22G x 1-1/2”</td>
<td>3000</td>
</tr>
<tr>
<td></td>
<td>1300</td>
</tr>
</tbody>
</table>

* Prices FCA for each syringe.

**INJECTION from page 1**

The most commonly used practice for final waste disposal in Latin American and Caribbean countries is "on-site" burial, whether in a protected burial pit or in a concrete pit. Concrete pits are often preferred in small communities. An important distinction must be established regarding the technical difference between incinerating and burning. Incineration is a process that transforms something into ashes, and results from achieving temperatures above 1200ºC. At lower temperatures, waste is only burnt, with the risk of producing toxic substances such as furans and dioxins. During the workshops, countries were advised to analyze the cost of the different options and choose the most appropriate technologies for their needs.

**Raising Awareness Regarding the Risk of Unsafe Injection Practices**

It has been established that the most hazardous maneuver during injection activities is the recapping of needles after use, and that up to two-thirds of accidents due to inadequate syringe use could be prevented if used needles were not recapped.

A testimonial video was shown at the workshop that featured two persons who were victims of occupational needlestick accidents while using syringes. These persons recount their experience, stating their errors while using unsafe practices, and describing the events following the accident. The video ends by stressing that 60-80% of needlestick injuries are not reported. The strong emotional content was useful to motivate and mobilize the audience.

Photo 1. Pneumococcal vaccine syringe.
Finally, the importance of reporting needlestick accidents was highlighted because timely reporting ensures proper treatment and follow-up, guarantees a financial compensation where appropriate, and stimulates procedure changes or engineering modifications. There are barriers to reporting needlestick injuries, such as lack of proper training on reporting procedures, fear to be punished or fired, lack of awareness regarding the risk of HIV, HBV, or HCV infections, lack of guaranteed confidentiality, and in some cases a lack of post-exposure treatment or prophylaxis.

**Medical Devices**

The technical aspects of medical devices were discussed in depth, in particular their cost implications for the health sector. The importance for countries to consider regulatory mechanisms to ensure the efficacy, safety, and quality of medical devices was also emphasized. Aspects to be regulated should include market introduction, post-marketing surveillance, quality assurance systems, including GMP, and manufacturing and distribution monitoring. In addition, regulatory requirements should be harmonized. Other essential aspects include regulation regarding used and donated devices, and the practice of reusing medical devices designed for single use (to be disposed and not reused), which is common and represents a risk to the patients.

Finally, the work of the Global Harmonization Task Force for medical devices (GHIF; for more information see at www.ghif.org) was presented. The Task Force provides guidelines and standards for medical devices. Medical devices are classified according to their risk and the place where they will be used. Workshop participants expressed concern regarding the high prices of these technologies. Country participants made a commitment to apply the acquired knowledge in their country and to share the information received with their national EPI.

**PAHO’s Next Steps**

- Follow-up on the recommendations of the workshops to evaluate results and injection safety practices.
- Strengthen the exchange of experiences and lessons learned between countries regarding good practices on injection safety and mechanisms for final disposal of sharps waste.
- Continue the training workshops on safe injections.
- Expand the use of AD syringes in the Americas.
- Strengthen the use of the incident reporting system for syringes at country level.

**References:**

Key Training Messages for Injection Safety

- Use a sterile AD or disposable syringe and needle to vaccinate each person.
- Use a disposable syringe and needle to reconstitute each vaccine.
- Prevent contamination of injection equipment and vaccine.
- Prepare each injection in a designated, clean area where blood or body fluid contamination is unlikely.
- Always pierce the septum of multi-dose vials with a sterile needle.
- Do not leave a needle in the stopper.
- Protect fingers with small gauze pad when opening ampoules.
- Discard a needle that has touched any non-sterile surface (hands, environmental surfaces).
- Anticipate and take measures to prevent sudden patient movement during and after injections.
- Prevent needlestick injuries by not recapping needles, and placing used needles attached to the syringes directly into safety boxes located in a convenient location (Photo 2).
- Ensure that safety boxes are only ¾ full and that they are sealed after reaching that level. Never overfill a safety box and never transfer contents of safety boxes to other containers.
- Seal safety boxes for transport to a secure area. Do not open, empty, or reuse them (Photo 3).
- Manage injection waste in an efficient and environment-friendly way.
- Prevent accidents to personnel in charge of waste disposal.
- Do not place empty vials in the safety box, they may explode while burning.
- Put only potentially contaminated injection equipment in the safety boxes. Do not put empty vaccine vials, cotton pads, compresses, etc. in the safety boxes.

Adapted from World Health Organization. “First, do no harm” Introducing auto-disable syringes and ensuring injection safety in immunization systems of developing countries. WHO/V&V/02.26.

Checklist of Resources for an Emergency Vaccine Retrieval and Storage Plan

- Designated primary and backup vaccine coordinators with emergency contact information.
- Emergency staff contact list in order of contact preference.
- Vaccine storage unit specifications (type, brand, model number, serial number).
- Alternate vaccine storage facility or facilities.
- Written protocols, vehicles, and drivers for transporting vaccine to and from the alternate vaccine storage facility.
- Written instructions for entering your facility and vaccine storage spaces in an emergency if the building is closed or if it is after hours. These instructions should include the building security/after-hours access procedure, a floor diagram and the locations of the following:
  - Doors
  - Flashlights
  - Spare batteries
  - Light switches
  - Keys
  - Locks
  - Alarms (including instructions for use)
  - Circuit breakers
  - Packing materials
- Appropriate packing materials to safely transport or temporarily store vaccine.
- Prioritized vaccine packing list.
- Written protocol for vaccine packing.
- Written protocol for appropriately storing vaccine at the alternate storage facility.
- Up-to-date list of manufacturer quality control office telephone numbers.

A New Face for Rubella Watch

Thanks to Rubella Watch, readers of the Region of the Americas have been witnesses to the impressive progress achieved towards eliminating rubella and congenital rubella syndrome (CRS). Today, the Region is on the cusp of reaching the goal of elimination, while it still faces multiple challenges to protect the achievements of countries and maintain measles elimination.

In this context, Rubella Watch puts on a new face, with a clearer and more streamlined design that reflects the permanent watch countries of the Region and the world have led over measles and rubella. Rubella Watch will continue to publish reports on the efforts all countries of the Americas are making to quickly respond to constant importations. It will also report on the ongoing implementation of strategies to maintain the elimination of both the rubella and measles virus.