First Pan American Vaccine Safety Summit

On 10 May, public health officials from across the Americas converged on the Anschutz Medical Campus at the University of Colorado for the first Pan American Vaccine Safety Summit. The purpose of the two-day summit, organized by the Pan American Health Organization, World Health Organization and the University of Colorado, was to create new ways of delivering immunizations safely.

Country representatives from ten countries defined the framework, mission, objectives and results of a proposed Pan American Vaccine Safety Network. Participants also determined the terms of reference of the Pan American Committee on Vaccine Safety (PACVS), a regional body of experts and institutions in vaccines that will provide evidence based recommendations and guidance to countries dealing with vaccine safety issues. Representatives also discussed how their nations deliver vaccines and the challenges of confronting rumors that can endanger immunization programs. Proactive and honest communication was highlighted as critical measures in managing vaccine-related crisis.

A web-based platform titled e-SAVI was presented during the meeting. The platform allows reporting Events Supposedly Attributable to Vaccines and Immunization (ESA VI), storing and analyzing case information. The e-SAVI platform will be available without any cost to all the countries of the Americas. This platform will also look for effective mechanisms for harmonizing current country-interfaces to capture vaccine safety data. For further inquiries on the system, please contact the immunization program of PAHO.

In addition, representatives recommended preparing a five-year work plan on vaccine safety issues that provide a set of regional strategies and activities to strengthen vaccine safety monitoring as well as crisis prevention and management. This work plan will serve as a tool to effectively identify and mobilize financial resources, and will seek the endorsement of PAHO’s Member States and partners. Finally, representatives recommended continuously fostering the exchange of information and expertise among PAHO’s Member States and partners by establishing formal mechanisms for delivering vaccine safety technical information.


In late 2008, at the request of the Ministry of Public Health, a new component of the operational plan of Uruguay’s National Immunization Program was initiated. This included implementing training courses for new vaccinators in health care institutions across the country, both in the public and private sectors, as a thorough evaluation of all the departments revealed the need to train qualified and skilled vaccination workers.

These courses are conducted free of charge by the Honorary Commission to Fight Tuberculosis and Prevalent Diseases, the entity that operates the immunization program in Uruguay, in coordination with the University of the Republic Medical School and with the endorsement of the Ministry of Public Health and the country office of the Pan American Health Organization (PAHO)/World Health Organization (WHO).

Requirements:

Applicants who meet the following conditions are accepted:

• Over 18 years of age.
• Have a degree in Nursing or Nursing Assistant.

Participants must be registered by the institutions where they provide service and will fulfill tasks as vaccinators, upon passing the course. Individual registrations are not accepted.

A maximum number of students are allowed.

Organization:

The course is divided into two modules:

Theoretical:

Consists of eight modules, each of which is four hours and a ninth module in which students visit the Calmette Laboratory (central level of the Cold Chain) and the Immunization Department of the Honorary Commission to Fight Tuberculosis and Prevalent Diseases.
Diseases. The classes taught by the different professors are later published on the Honorary Commission to Fight Tuberculosis and Prevalent Diseases’ Web page. The minimum attendance required will be 80%. Students who arrive more than 15 minutes late and/or leave before the hour will receive partial credit for attendance.

**Practical:**

Students that pass the theoretical part will carry out an internship with the vaccination services of the Honorary Commission to Fight Tuberculosis and Prevalent Diseases. They must complete a total of 60 hours of practice and have a minimum attendance of 80%.

**Evaluation:**

Each module will be assessed through a questionnaire of 10 multiple choice questions. The final theoretical test will consist of a questionnaire of 30 multiple choice questions. In order to pass the theoretical course, a minimum total of 85 points is required. After completing these hours of practice, students must take a final practical exam.

**Contributed by:** Dr. Fernando Arrieta, Honorary Commission to Fight Tuberculosis and Prevalent Diseases, Uruguay.

**Editorial Note:**

There is clear evidence of the impact health care workers have on health outcomes. It has been shown that the lack of proper training, as well as the lack of motivation from health care workers is one of the main barriers impeding the achievement of the Millennium Development Goals (1).

One of the recommendations to address the shortage of human resources in health at the global level is for the education and training curriculum to focus on the health needs of the country and the community, and that institutions implement innovative ways to increase the capacity of education and training. This recommendation can be found in the WHO workforce report for the expansion of the education and training of health care workers, under the auspices of the Global Health Workforce Alliance (GHWA) (2).

Similarly, the Pan American Health Organization, during the 27th Pan American Sanitary Conference held in Washington, D.C., in October 2007, issued the Regional Plan of Action for Human Resources for Health 2007-2015, through Resolution CE140.R13, in which, among others, urges Member States to “Consider developing a national plan of action for human resources for health, with specific goals and objectives, an appropriate set of indicators and a tracking system, largely intended to strengthen integrated primary health care and public health capacities and ensure access to underserved populations and communities.”

Uruguay’s example shows that these global and regional policies are being addressed, since this course:

1. Is part of a National Immunization Program, which has been developed from the country’s need to further train highly qualified human resources in vaccination.
2. Is in service to the institution where they will fulfill their tasks as vaccinators, in addition to ensuring job security for skilled human resources.
3. Is comprehensive, since the theoretical part covers anatomy, vaccine-preventable diseases, immunology, vaccines and the cold chain, as well as topics covering vaccination center accreditation, regulation and immunization registry. The latter is vital as it allows vaccinators to maintain a commitment to data analysis, permitting evidence-based actions.
4. Has a practical component, which favors developing the skills and abilities of staff in procedures and vaccination techniques. It also facilitates an active learning experience for the trainee instead of only taking notes in class.
5. Makes available a wide range of teaching techniques to the trainee, which facilitates the learning process, with teamwork and discussions being key, among others.
6. Another noteworthy aspect is the availability of the presentations on the Web, allowing students the opportunity to review concepts already seen in class.
7. Considers that it is essential to evaluate participant learning, also being an excellent measurer of training quality.
8. Finally, this course is offered free of charge, encouraging access to trainees to a high quality course, which will be useful to their personal and professional development, with the goal of improving the quality of the vaccination service.

The team in charge of vaccination activities plays a fundamental role not only in administering vaccines, but also in serving the community by providing clear, adequate and sufficient information to the families that come to health centers to receive a vaccine. For this reason, it is essential that the staff is updated on technical components of the immunization program, and qualified to treat and interact with people receiving vaccination, while providing service with quality and warmth.

Workshop to Define the Main Indicators and Visualizations for the Immunization Module of the Regional Health Observatory

From 21-25 May 2012, participants from selected countries of the Americas, WHO, WHO-EURO, PATH-Optimize and UNICEF attended a workshop to discuss indicators and visualizations to be included in the immunization module of PAHO’s Regional Health Observatory held at PAHO headquarters in Washington, D.C. This workshop was one of the many activities aimed at streamlining the integration of immunization programs and surveillance systems, improving data quality and promoting evidence-based decisions in the Region of the Americas.

The objectives of the workshop were:

1. To discuss alternatives to improve immunization data quality and the data collection processes, with a focus on the data collected in the PAHO-WHO/UNICEF Joint Reporting Form (JRF) on Immunization.
2. To define the key performance indicators on immunization for the regional and country levels.
3. To identify the most-useful reports and visualizations to display data and indicators for printed materials, immunization country profiles, and the Web.
4. To propose a roadmap to implement the recommendations provided in phases.

The sessions included presentations from various participants, several work group sessions, plenary discussions and a live demonstration of the data visualizations used for Burden of Disease project of the Institute for Health Metrics and Evaluation (IHME).

Participants discussed how current data included in the PAHO-WHO/UNICEF Joint Reporting Form is collected in centralized and decentralized countries and how the process could be optimized by taking advantage of new information and communication technologies. They also provided PAHO with guidance on what to recommend to countries for improving immunization data quality, analysis, monitoring and evaluation, and use of the information for decision-making. Commonly used immunization indicators, including those used to monitor vaccine-preventable disease (VPD) surveillance performance, were analyzed. New visualizations and informational products, including the immunization module of the Regional Health Observatory [see text box] were discussed and several recommendations were given. Finally, a roadmap for developing the immunization module of the observatory and implementing the recommendations of the workshop was proposed.

Main Recommendations

Improving data quality and the information collection processes for data included in the PAHO-WHO/UNICEF Joint Reporting Form (JRF) on Immunization

- Conduct periodic immunization Data Quality Self-Assessments.
- Conduct periodic evaluations of the Expanded Program on Immunization (EPI).
- Better estimate the staff and equipment needed to correctly vaccinate and collect related data.
- Implement immunization registries, while advocating for the existence and use of unique national IDs.
- Advocate for more frequent censuses.
- Promote more frequent meetings of surveillance committees in order to classify suspected cases systematically and not all at once when previous year data are requested.
- Evaluate and implement tailored strategies and new technologies to improve the data flow based on the different realities within countries, such as energy supply, access to the Internet connection, etc.
- Take advantage of the current development of information systems to include logistics and financial modules, to support better decision-making in the EPI.
- PAHO should document best practices and implement pilot studies in order to better assist Member States in improving data quality and better complete the JRF.
- To this end, the participant from the European Region of WHO (EURO) offered to work with PAHO on this process.

Data Visualizations of Key Immunization Indicators for the Regional (PAHO) Level

- Maintain the publication of the annual brochure Immunization in the Americas (1), maintaining its immunization coverage, VPD data and surveillance sections, but consider adjusting to the demographic and socio-economic data included and adding other managerial and financial data, already collected in the JRF.
- Modify the current PAHO country immunization profiles to include the following sections: 1) Map of the Americas, highlighting the specific country; 2) demographic and socio-economic data; 3) immunization schedule; 4) measles and rubella elimination; 5) polio eradication and acute flaccid paralysis (AFP) surveillance; 6) DTP/ pentavalent coverage and diphtheria, tetanus and pertussis data; 7) new vaccine data including hospital-based sentinel surveillance of meningitis/ pneumonia and rotavirus diarrhea; 8) seasonal influenza vaccine use; 9) managerial and financial data; and 10) yellow fever vaccination data (only for enzootic countries).
- Consider having a 2-page printable version and a more extensive Web version.
- Continue the development of the immunization module of PAHO’s Regional Health Observatory focusing on three potential audiences: general public; technical level (people working on immunization); and political level (country decision-makers, such as ministers). This can be achieved by pro-

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References

viding a general overview and several links to more in-depth pages.

- The structure proposed for the profiles could be used.
- Add information about the impact of vaccination, such as changes in epidemiology; reductions in mortality and in burden of disease, as well as cost-savings related to vaccines currently in use and potential savings associated with new vaccines.
- Link with the key performance indicator dashboard of PAHO’s Revolving Fund for vaccine purchase (2).

Immunization Dashboard to Monitor Key Performance Indicators – Country Level

- Include context indicators (population size, number of births and number of children, urban/rural distribution, health indicators, socio-economic data, etc.).
- Include coverage data, including numerators and denominators, to assess levels and trends for all vaccines recommended in the national immunization schedule.
- Include coverage data from surveys to triangulate this information with administrative data.
- Monitor drop-out rates for different vaccines and doses, at different geographical levels (e.g., DTP/pentavalent 1-2, 2-3 and 1-3; DTP/pentavalent 1-MMR).
- Consider monitoring complete vaccination schedules.
- Define indicators related to vaccine and supplies to monitor inventories, distribution, wastage, etc. at different geo-administrative levels.
- Monitor events supposedly attributable to wastage, etc. at different geo-administrative levels (e.g., DTP/pentavalent 1-2, 2-3 and 1-3; DTP/pentavalent 1-MMR).

The Regional Health Observatory

The purpose of the Regional Health Observatory (RHO) – www.paho.org/rho – is to generate and disseminate data, information, and scientific evidence to support technical cooperation, planning and programming, decision-making and policy in public health in the Region of the Americas. The functions of the RHO include:

1. collecting, standardizing, integrating, and processing of health data and statistics from countries of the Americas and technical programs across the Organization;
2. applying epidemiological methods for documenting health situations and trends, measuring of population health status, inequalities and inequities;
3. monitoring progress of health indicators and the achievement of goals;
4. generating the analytical evidence to support decisions in public health and guide public health policies;
5. evaluating the impact of health interventions at regional and national levels;
6. identifying public health issues; and
7. disseminating health data and information, information products, analytical results, as well as technical and political recommendations.

The RHO is composed of the Health Information and Intelligence Platform (PHIP), the portal of the RHO, and the Health Analysis and Intelligence team. Currently, the Health Data Warehouse contains regional mortality datasets, the Core Health Indicators database and datasets from technical programs, estimates of the world’s population from the United Nations Population Division, World Development Indicators, and Official Development Assistance for Health. In addition, the portal of the RHO facilitates access to health data and statistics, as well as disseminates analytical results, technical and methodological recommendations, briefings of the health situation, and trends generated by the RHO. Most importantly, it is considered a point of entry to comprehensive health data and information from the Region of the Americas. The portal also contains health themes, health data, country statistics, reports and presentations.

References

1. Immunization in the Americas 2012 Summary is available at: http://www.paho.org/immunization
Cold Chain Equipment and WHO Pre-qualification

Since 1979, the World Health Organization (WHO), in collaboration with the UNICEF Supply Division, have developed a series of specifications and test procedures for the pre-qualification of equipment, devices and other cold chain products for vaccine storage. Rigorous procedures are conducted in order to evaluate and pre-qualify each equipment. These results are published regularly through the cold chain equipment catalog, also known as the Performance Quality Safety (PQS) devices catalogue.

This catalog is produced and updated by the WHO Department of Immunization, Vaccines and Biologicals (IVB), Quality, Safety and Standards Unit. This catalog has been developed over the years, in consultation with end users, the industry, and those responsible for testing.

The 2012 edition is available and includes general information on pre-qualified products, as well as specific information on the following aspects: a) technical specifications of the equipment; b) climate and temperature in which each equipment can be used; c) type of coolant; d) energy source; e) dimensions (height x width x length); f) storage capacity; g) energy consumption; h) accessories; i) parts and j) price for procurement through the United Nations system.

Only the products included in the PQS can be acquired by the agencies, funds and programs of the United Nations system.

WHO Pre-qualification

WHO pre-qualification aims to ensure that vaccines, cold chain equipment and supplies related to vaccination, among other products, meet global standards of quality, safety and efficacy. The prequalification process consists of a transparent, scientifically sound assessment, which includes dossier review, consistency testing or performance evaluation and site visits to manufacturers.

Once pre-qualification is met, the product is considered technically satisfactory and safe for procurement by agencies, funds and programs of the United Nations system, such as the PAHO Revolving Fund. However, it should be noted that granting pre-qualification does not guarantee purchase; the manufacturer of the product is solely responsible for ensuring that the quality of the product is acceptable for the buyer.

The product performance is continuously assessed through a PQS revision procedure. The manufacturers maintain the IVB Quality, Safety and Standards Unit informed of any changes made to their equipment, manufacturing process or manufacturing site.

If there are serious problems with a product, the Quality, Safety and Standards Unit reassesses the pre-qualification; if the problem is severe, the pre-qualification can be suspended until it has been resolved. In some circumstances, the pre-qualification can be withdrawn permanently.

Selecting the type of cold chain

Below is a flow chart that facilitates the process of selecting the type of cold chain equipment appropriate for each health facility. However, as new vaccines are introduced into national vaccination schedules, it is necessary for national immunization programs to restructure their supply chain to streamline distribution, minimize wastage or losses, improve requirement forecasts, and ensure the adequate allocation and proper maintenance of cold chain equipment. Therefore, it is recommended that the selection of cold chain equipment best suited for each community form part of a project to optimize the vaccine supply chain. The following aspects should be considered:

- Identifying facilities that require refrigeration equipment, as well as those facilities that because of their location, vaccination tactics, and size of population covered, require only thermoses and cold boxes.
- Development and socialization of a procedures manual for the supply chain of vaccines, syringes and safety boxes.
- Implementation of a logistics module for vaccines, syringes and other program supplies in the health information systems.
- Utilization of an immunization registry so that orders and deliveries are based on actual needs and therefore more accurate, meaning reduced costs and loss factor.
- Technical and administrative staff training on optimizing processes and supplies, as well as defining the most adequate logistics for each facility.
- Equipment maintenance
- Permanent monitoring and supervision.
- Funding and sustainability of processes.

Procedures for purchasing equipment through the WHO/PAHO Revolving Fund

The cold chain equipment acquired through the WHO/PAHO Revolving Fund should meet the International Electrotechnical Commission (IEC) standards for electromechanical and electromedical equipment. These products should also follow the WHO recommendations for cold chain equipment. There should be a preventative maintenance program for the equipment.

For the procurement of cold chain equipment through the WHO/PAHO Revolving Fund, the same operational procedures are applied. The Member States or institutions should identify the type of product required through the code in the catalog (PQS code). If the equipment requested is available, including spare parts, it should be clearly indicated which one is required.

The prices indicated in the PQS catalog do not include transportation and insurance costs or the contribution of 3.5% net product value provided by all Member States and institutions that acquire vaccines, syringes and other related supplies through the Revolving Fund. Of this 3.5%; 3% is placed entirely in the common capitalization fund, which is used by WHO/PAHO as working capital for the credit granted to Member States and institutions; and 0.5% is to cover the administrative cost of procurement activities. Through a price estimate, the unit and total cost will be indicated, as well as the estimated cost for packaging, freight and insurance, plus the 3.5% that will be applied to the net value of the product along with the estimated date of delivery.

In addition to the time required by the manufacturer to guarantee the production of the necessary equipment, it should be noted that this equipment is transported by sea from the country of origin to the client country, which means 5 to 6 months should be given for arrival from the moment the purchase order is placed.

[1] Available at: http://apps.who.int/immunization_standards/vaccine_quality/pqs_catalogue/
Refrigeration equipment is essential for storing and preserving vaccines for national immunization programs. The equipment can work with electricity or with energy derived from liquid fuel or gas (absorption refrigerators). Based on the type of energy that the cold chain equipment uses, they are classified as follows:

- Electric compression equipment: more commonly used in order to store vaccines in health institutions that have regular power supply.
- Absorption equipment (propane or kerosene): appropriate in places where there is no electricity or where there is limited energy resources.
- Solar powered equipment (solar energy): useful in hard to reach places, especially where conventional energy resources do not exist or are difficult to obtain. They function with the energy provided by the sunlight that is stored in batteries, which then power the refrigerator.

Conventional Refrigerators

Conventional refrigerators were the first equipment used for preserving vaccines. Today, this type of equipment continues to be made with improved designs and insulation materials, which allow a moderate cold life within the cooled compartment in case of electric power outages (not very long), compared to older types of refrigerators; however, this autonomy or cold life is subject to the quantity of accumulated ice packs both in the freezer and in the lower compartment (drawers to store vegetables). The more frozen ice packs there are in the freezer, the higher the cold life span will be inside the refrigerator in the event of power outages. See Picture 1. It is important to emphasize that this type of equipment has not undergone the pre-qualification process; therefore it is not included in the PQS.

This equipment by design is useful in areas where electrical energy conditions are unstable. This is due to the fact that the freezer is connected to the lower refrigerator drawer, which allows for a comparatively longer autonomy or cold life span compared to the Non-frost Uni-flow and Multi-flow equipment.

Non-frost Uni-flow and Multi-flow refrigerators

Non-frost Uni-flow refrigerators are types and models that emerged after the conventional ones. Because of their characteristics, these refrigerators can quickly restore proper temperatures for vaccines after opening the door. Furthermore, they also have the advantage of automatically thawing excess ice that is formed in the freezer, (a process that cannot be observed with the naked eye). Picture 2.

Non-frost multi-flow refrigerators are types and models that emerged after the Uni-flow. These refrigerators can also efficiently restore proper temperatures for vaccines in a very short time after opening the door. They have the same design characteristics as the Uni-flow, but with a variation. Instead of injecting cold air through a single duct (Uni-flow), this equipment has several ducts where cold air is led out and distributed within the lower refrigerator drawer through uniform grids. This design, unlike the two previous types, allows the temperature to be the same in any of the two, three or four shelves where vaccines are stored. Picture 3.

The disadvantage of this equipment (Uni-flow and Multi-flow) is that since the freezer is isolated from the refrigerated compartment (where vaccines are stored), the only means of connection between these two parts is a small electric fan, which extracts cold air from the freezer and releases it to the refrigerated drawer through a duct (Uni-flow) or several ducts (Multi-flow). This condition causes the temperature within the interior refrigerator door to increase rapidly during a power outage since the fan comes to a standstill because of the lack of power. For this reason, it is recommended that these refrigerators be used in areas where the electricity supply is permanent. This equipment has not undergone the pre-qualification process; therefore it is not included in the PQS.

Ice-lined refrigerator (ice wall)

Ice-lined refrigerators consist of tubes or ice packs with water, placed around the internal walls of the compartment. One of their main features is that it takes more than 48 hours to heat back up (holdover time1) if power is lost, providing the health care worker sufficient time to salvage vaccines. They can be used in places that do not have permanent electricity supply.

It is recommended that operation tests be conducted prior to using the equipment that is not included in the PQS. Only use the equipment if the results are satisfactory for its intended use.

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1 Holdover time: is the time in hours during which all items in the compartment of a refrigerator are kept below +10 ° C to a maximum external ambient temperature for which it was designed, after the power has been disconnected.
Pre-qualified equipment data sheets
The PQS catalog contains data sheets on currently pre-qualified equipment and supplies, in addition to other products such as syringes, which appear by categories:
Pre-qualified equipments:
E001: Cold rooms, freezer rooms and related equipment;
E002: Transport (guideline only);
E003: Refrigerators and freezers;
E004: Insulated containers;
E005: Ice-packs, cool-packs and warm-packs;
E006: Temperature monitoring devices;
E007: Cold chain accessories;
E008: Single-use injection devices;
E009: (not currently used);
E010: Waste management equipment;
E011: Specimen collection equipment;
E012: (not currently used);
E013: Therapeutic injection devices.
Every data sheet includes a picture and description of general aspects and technical specifications for each equipment. An example of this can be seen in the figure below.
The ProVac International Working Group Begins its First Country Study of the Pilot Phase

Thanks to the recognized success of PAHO’s ProVac Initiative in countries of the Americas, a ProVac International Working Group (IWG) was established to share ProVac tools and methodologies with other Regions. During the two-year pilot phase, this Bill and Melinda Gates Foundation funded project will serve as the platform through which ProVac tools and methodologies developed and implemented in PAHO-countries can be tested and adapted to other regional contexts. The ProVac IWG is con-formed of multiple partners. PAHO’s ProVac Initiative will serve as the secretariat and coordinating agency. Agence de Médecine Préventive (AMP) and PATH will serve as implementing agencies by providing direct technical assistance to country teams using ProVac’s tools and methods. They will provide support for cost-effectiveness evaluations of potential new vaccine introductions in three AFRO countries, two EMRO countries, and two EURO countries and will hold a workshop in each of the before mentioned Regions.

The World Health Organization Headquarters and regional and country offices will also provide direct technical assistance to selected countries, participate in and assist with the planning and implementation of country studies and regional workshops, and serve as liaison between the implementing partners and WHO Regional Offices and Ministries of Health. The Sabin Vaccine Institute is another ProVac IWG partner responsible for the development and piloting of an effective strategy for communicating evidence to diverse stakeholders regarding the decision to introduce a new vaccine. The US Centers for Disease Control and Prevention (CDC) will provide consulting assistance to ProVac IWG partners on potential data sources and data quality issues.

On 22-23 May 2012, one of the ProVac IWG partners, AMP, began the initial country study under the ProVac IWG umbrella. An initial country visit to Albania by the ProVac IWG coordinator, the Technical Officer from WHO European, and two members from the AMP team, project coordinator and health economist and AMP consultant was held in Tirana, Albania. The two-day working visit consisted of a first full day of meetings with the national country team and high level officials from the Albanian Institute of Public Health (IPH) and the Ministry of Health and on the second day an introductory workshop with the national team appointed to perform the study. This visit marked the beginning of Albania’s cost-effectiveness analysis on the potential introduction of the rotavirus vaccine to their national immunization schedule. The study is being conducted by a multidisciplinary national team, using the ProVac tools and methods, with direct technical support from AMP and the WHO Europe, and accompanying expert consultancy of PAHO’s ProVac Initiative. The study is scheduled to be conducted from May-September 2012, and it is led by a national coordinator from the Albanian IPH. The ProVac IWG has high hopes for this initial study, as it will serve as an example for the six studies to come.

The Immunization Newsletter is published every two months, in English, Spanish, and French by the Comprehensive Family Immunization Project 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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