Honorable Minister
Permanent Secretary
Chief Medical officer
Senior officials of the Ministry of Health
Media Personnel
Colleagues,

Events Supposedly Attributable to Vaccination or Immunization (ESAVI)

It gives me a great pleasure to be part of this important session this morning on behalf of PAHO and NWHO. My talk will be very specific on one item. It is about the events supposedly attributable to vaccination or immunization, in particular the HPV vaccine.

One of the greatest achievements in public health has been infectious disease prevention through immunization. Few interventions in this field that have prevented as many deaths and diseases as vaccinations administered through organized immunization programs. PAHO and WHO supports the decision of the Ministry of Health to introduce the HPV vaccination to adolescent girls in Trinidad and Tobago.

Extraordinary progress has been made in the introduction of new vaccines, which will save lives and avert diseases and expenditures in the health system. By 2010, 15 countries and territories had added the rotavirus vaccine to their regular series, 18 had the pneumococcal vaccine, vaccine for pneumonia and then at least 5 countries have introduced the HPV vaccine and Trinidad will join them in 2012. These countries have also been able to introduce continual surveillance centers systems to assist the impact of the vaccination programme in the population.

Through the ProVac Initiative, PAHO we continue to assist countries in the Member States in the aspects of decision-making, why and how and when to introduce vaccines.

All vaccines obtained through the World Health Organization (WHO) and PAHO which Trinidad and Tobago also obtain some of the vaccines, through PAHO, actually have to meet the following criteria.

- examination of their characteristics
• adherence to the standards of good manufacturing practices, and
• approval by regulatory authorities in those countries. (NRA).

WHO certifies that a vaccine is of good quality if only approved by the national regularity authorities and then this vaccine has to meet at least six criteria. They have to:

• Publish a set of clearly written licensing requirements (for products and manufacturers) and ensure compliance.
• Present an analysis of the results of the use of the vaccine in the field about their safety and effectiveness.
• Have a system to track by having a batch or a note when it is released.
• Present laboratory test results also if necessary.
• Permit regular inspections. WHO also goes to those facilities and do inspections of the facility as well, in keeping with the good manufacturing practices
• And finally the manufactures have also to show and evaluate clinical results through authorized clinical trials.

The existence of many events that are supposedly related to a given vaccine indicate that there may be a problem with its application rather than to be from the vaccine. For this programme’s operations we encourage the countries to look into:

• If there is a contamination,
• improper injection,
• proper cold chain programmes,
• dosage errors,
• or dilutions problems or administration of vaccine.

These problems can be corrected easily through the training and supervision of health workers which Trinidad and Tobago is doing through the campaign as I know.

The purpose of a vaccine is to induce immunity (to form antibodies) through the reaction of the immune system of the vaccinated person. It is not surprising that vaccines generate certain mild side effects. A local reaction at the place where the vaccination is given, fever, and general symptoms may be part of the normal immune response. Sometimes the individual may overreact from this vaccination. Furthermore, some of the components of the vaccine which are added like the
preservatives and others may produce reactions to the individuals. An effective vaccine however minimizes this kind of reactions, while at the same time inducing maximum immunity.

So what is it about the HPV vaccine? A review of data generated throughout 21 countries was reviewed by WHO. This review of available evidence of the safety of both the 4-valent HPV vaccine commercially known as Gardasil® and the 2-valent HPV vaccine which is Cervarix® was presented and then assessed. This data was from pre-licensure randomized controlled trials and post-licensure surveillance reports from the 2 vaccine manufacturers, as well as from the European Medicines evaluation agency, the United States Food and Drug Administration, the United States Centers For Disease Control were include in the review.

The current evidence on the safety of HPV vaccines is very reassuring. The reviewed data covered local and systemic events in short-term, and long-term events up to 6 years after vaccination, including during and after pregnancy events. Remember the vaccine is now approved for the last 6 years. The data has shown that there will be no effects at all or there will be mild effects. A common observation was the occurrence of injection site reaction and minor muscle pain. During adolescent vaccine campaigns, some mass sociogenic illnesses such as post-vaccination dizziness and syncope have been reported. These events have been prevented by observing adolescents for sit for about 15 minutes or to be monitored for about 15 minutes. These are isolated incidents than to be a reaction that is common. Overall, no concerns with the safety profile were identified. With this I will assure you all that the HPV vaccine is safe to be administered in the population in this country based on our data provided on the different entities and institutions.

PAHO again supports the decision of the Ministry of Health to introduce the HPV vaccination which is also lifesaving and then preventing diseases and then necessary expenditure in the health system. Once again as the CMO mentioned HPV IS 100% preventable.

Thank you very much

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