



Immunization Unit
Family and Community Health Area



PARTNERING FOR HPV VACCINE INTRODUCTION

FINAL REPORT

Washington, D.C. – 5 October 2005

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PARTNERING FOR HPV VACCINE INTRODUCTION

Introduction

On 5 October 2005, the Pan American Health Organization (PAHO) conducted a meeting, in Washington, D.C. The theme was *Partnering for HPV Vaccine Introduction*. The specific purpose of this meeting was to accelerate and strengthen the dialogue between invited partner agencies regarding their interests and plans related to the introduction of Human Papillomavirus (HPV) vaccines.

Nine partner agencies and two vaccine suppliers participated in this meeting, which was chaired by Dr. Jon Andrus, Chief, Immunization Unit, PAHO. PAHO attendees included an Area Manager, Regional Advisors and Technical Officers from the Areas of Family and Community Health; Disease Prevention and Control; Strategic Health Development; and Technology and Health Services Delivery. A list of participants is appended in Annex 1.

In his welcome address, Dr. Andrus used the opportunity to frame the day's discussion by reviewing some of the challenges associated with the introduction and sustainability of new vaccines, such as their costs; national realities regarding budgets and public health priorities; inequities between developed and developing countries regarding the pace of new vaccine adoption; and insufficient vaccine supplies for satisfying the global demand. He further pointed to some important requisites for success, which included:

- The need for creation of effective global partnerships, not only in support of vaccine research and development but to specifically enhance the likelihood that new vaccines would become available at affordable prices;
- The need for Governments to create fiscal space in their national budgets in order to address sustainability issues; and
- The continued need to promote the development of the PAHO Revolving Fund as a regional vaccine procurement mechanism.

Dr. Gina Tambini, Manager, Area of Family and Community Health, addressed the meeting on behalf of PAHO Assistant Director, Dr. Carissa Etienne. Dr. Tambini noted that in preparation for the introduction of this new primary preventive tool, PAHO had already embarked upon a series of activities which involved:

- Engaging HPV vaccine suppliers in an ongoing technical dialogue;

- Assembling all of the relevant internal stakeholders around the topic of HPV vaccine introduction and developing a joint work-plan;
- Strengthening National Regulatory Authorities in order to ensure the quality of products;
- Initiating advocacy efforts in order to heighten awareness about HPV vaccines through publications and oral presentations; and
- Exploring avenues and mechanisms for building effective partnerships with external agencies and organizations.

Dr. Tambini further emphasized that it was essential for PAHO to strengthen its existing partnerships with vaccine suppliers, donors and Members States in order to ensure that these vaccines would be affordable and their availability equitable in the true spirit of Pan Americanism.

The Vaccine Suppliers

Both vaccine suppliers described their products; presented the results of their Phase I and II clinical trials conducted to date, including antibody responses; and discussed their plans for future trials. Early data from GlaxoSmithKline (GSK) indicated that an HPV vaccine containing serotypes 16 and 18 might afford some degree of cross protection against other HPV types that are phylogenetically related. Merck and Company reported that its vaccine appeared to exhibit enhanced immunogenicity in younger populations, aged 10-15 years old, when compared to older cohorts. Acceptability studies conducted by GSK suggested that physicians in Mexico were more likely to highly recommend use of a cervical cancer vaccine (94%) than their counterparts in other countries such as Australia (84%) and Canada (77%). There was also a high acceptance among Mexican women (92%) to be vaccinated against cervical cancer.

The following questions and answers resulted from the presentations of the vaccine suppliers:

QUESTION 1

How would vaccine efficacy be assessed in young children in the absence of CIN lesions?

ANSWER 1

Both vaccine suppliers are conducting immuno-bridging research to extend the results from studies in older adolescents and adults to the pre-teen age group.

QUESTION 2

How will the issue of consent for HPV vaccine trials in adolescents be handled?

ANSWER 2

Both vaccine suppliers indicated that they required consent from the parent (or legal guardian) as well as assent from the subject, when trials were being undertaken with subjects below the age of legal consent.

QUESTION 3

What is the duration of protection conferred by these vaccines?

ANSWER 3

Information on duration of protection is unavailable at this time, but both suppliers are conducting long term follow-up studies to assess this variable.

QUESTION 4

What level of antibody is actually protective?

ANSWER 4

There are currently no established serologic correlates of protection.

Presentations from Partner Agencies

The Pan American Health Organization (PAHO)

Dr. Merle Lewis in her overview noted that from PAHO's organizational perspective, the overriding objective of HPV vaccine introduction was the improvement of the health of the family. Recognizing that there will be two differently formulated vaccines in the marketplace, she noted that the goal of HPV vaccine application would be to reduce the burden of cervical cancer, or cervical cancer and genital warts, in Member States.

The PAHO plan would contribute to its Member States having an improved capacity to determine the feasibility of HPV vaccine introduction; to formulate effective public health policies related to this issue; and to develop satisfactory program and financial plans to support HPV vaccine introduction. Dr. Lewis also fully recognized that HPV vaccine introduction offered a unique opportunity to address the issue of secondary cervical cancer prevention via screening.

The pillars of the PAHO HPV vaccine introduction plan are as follows:

1. Building political will through multi-dimensional and cross-cutting advocacy efforts;
2. Creating synergistic partnerships to complement our initiatives in support of technical and investment advocacy and resource mobilization;
3. Disseminating relevant technical information and knowledge, packaged in culturally sensitive and linguistically appropriate formats for multiple audiences;

4. Conducting appropriate research especially related to the economic impact of the problem, vaccine cost-effectiveness as well as vaccine acceptability;
5. Formulating and implementing appropriate evidenced-based surveillance strategies and ensuring that relevant measuring tools are available;
6. Developing social marketing, communication and promotional strategies that facilitate increased awareness of HPV vaccine among community-based groups;
7. Strengthening the regulatory environment at the national level in order to ensure the quality of products and to facilitate the conduct of pharmaco-surveillance; and
8. Strengthening national expertise and capacity to facilitate efficient logistics and supply management.

The World Health Organization (WHO)

Dr. Teresa Aguado of WHO, Geneva, reviewed the new Global Immunization Vision and Strategy (GIVS), outlining its key strategic elements as:

- (a) Protecting more people in a changing world;
- (b) Introducing new vaccines and technologies; and
- (c) Positioning immunization together with other health-linked interventions and surveillance within a health systems context.

Dr. Aguado highlighted the initiatives undertaken by WHO since 1999, in an effort to accelerate the development of HPV vaccines for global use. Some of these activities included the conduct of international collaborative studies for the harmonization of HPV reagents for diagnostic testing; the updating of HPV type-specific prevalence data in collaboration with the International Agency for Research on Cancer (IARC); the provision of expert advice for regulatory pathway decisions regarding endpoints for HPV clinical trials; raising interest in HPV vaccines through different audiences and fora; and the convening of an expert consultative group on HPV vaccines. Additionally, she detailed how the grant from the Gates Foundation to the WHO would focus on three specific areas, which included:

- (1) The establishment of a global HPV laboratory network together with standardized laboratory procedures for measuring vaccine effects;
- (2) The creation of a web-based repository of HPV-cancer related epidemiologic data; and
- (3) The development of an international, multidisciplinary policy platform for setting a global agenda.

Dr. Aguado reviewed some of the major public health questions that would be asked by decision-makers in relation to HPV vaccine introduction. Some of these were related to the burden of disease and proportion due to HPV types contained in the vaccine; the target age group(s) for vaccination; the required vaccine schedules; the cost and cost-effectiveness of the vaccine; and the capacity of the health system to deliver this vaccine.

Some areas of work for possible joint collaboration with PAHO were identified, and these included conducting studies to address possible vaccine delivery strategies (for example, primiparous women in Brazil); the rolling out of the HPV laboratory networking in the Americas; developing specific guidelines for HPV vaccine introduction in the Region of the Americas; and the strengthening of the regulatory environment at the country level.

Dr. Aguado noted that an optimal communication strategy should address the following questions:

- How will this anti-cancer vaccine be positioned, in agreement with the available scientific evidence and regulatory requirements?
- How will this vaccine be presented within the context of existing secondary cervical cancer prevention?
- Which will be the target population groups for vaccination? Pre-adolescents, adolescents, adults?
- Will parental consent always be required for vaccination?
- Will vaccination of females only, initially, be recommended, and at some subsequent future time, both sexes?

WHO will develop a position paper on HPV vaccines, the essential content of which would address the following topics:

- The public health impact;
- The pathogen;
- The justification for vaccines as a measure of cancer control;
- A review of the existing vaccine candidates and products;
- Potential delivery strategies with a country analysis; and
- The WHO's position on HPV vaccines.

The International Union Against Cancer (UICC)

Pursuant to the vision of a world in which cancer is eliminated as a major life-threatening disease, UICC has been engaged in information and knowledge sharing; transferring scientific findings to clinical settings; reducing and eliminating disparities in prevention, early detection and treatment; and

delivering the best possible care to all cancer patients. Ms. Maria Stella de Sabata gave an overview of the UICC's four strategic directions and detailed those activities related to prevention and early detection as follows:

1. The promotion of cancer registration and hospital-based cancer registries through software developed in collaboration with the US Centers for Disease Control and Prevention (CDC) and IARC;
2. The development of country profiles to serve as a practical tool for guiding decision-making in cancer control activities;
3. Undertaking activities in national cancer control planning, including the provision of technical advice and the development of resource material;
4. The promotion of evidenced-based cancer prevention strategies among NGOs through an ad-hoc publication; and
5. The provision of support for evidence-based interventions, including within the Global Women's Cancer Initiative (GLOW), which focuses on breast and cervical cancer.

Within the context of partnering for HPV vaccine introduction, Ms. de Sabata indicated that the UICC could provide assistance with the implementation of evidence-based programs as well as intervention pilot projects for technologies that will be evaluated under scientific conditions. Additionally, she pointed out that through its membership, it could play a role in communication and information dissemination to the public, health care personnel, and other authorities, and raise awareness in order to increase participation rates.

Ms. de Sabata noted that the UICC would be hosting the World Cancer Congress in Washington, D.C. in July 2006 and solicited the participation as well as the submission of abstracts from the agencies assembled.

The American Cancer Society (ACS)

Dr. Debbie Saslow described the mission of the ACS as one of preventing cancer, saving lives, and diminishing suffering from cancer through research, education, advocacy and service. She also defined the lines of action pursued by the ACS in relation to cervical cancer prevention and these included the development of screening guidelines; the provision of information for patients and providers; keeping abreast with emerging science and technologies; facilitating collaboration; increasing access to service; and reducing disparities. It was further noted that the ACS' policy regarding the initiation of cervical screening now recommended that this intervention should commence at three years after the onset of sexual activity. The role of HPV DNA testing as a complement to cytological screening was also cited. Although Dr. Saslow stated that the ACS could provide no position statement on a product, such as HPV vaccine, that was

not currently available in the marketplace, she did suggest that, in the United States, the application of HPV vaccines would certainly be considered for women, who were not being screened.

The United States Agency for International Development (USAID)

Dr. Jeff Spieler of USAID noted that although there has been a long history of collaboration between USAID and PAHO, cervical cancer prevention was not currently on their listing of priorities at this time. He, however, suggested that there may be other avenues for collaboration, which could be explored.

The United States National Cancer Institute (USNCI)

Dr. Edward Trimble indicated that NCI was actively working to eliminate suffering and death due to gynecologic cancers both in the United States and around the world. He noted that NCI investigators had developed a new vaccine approach to prevent the transmission of the human papillomavirus and had subsequently licensed this technology to two large pharmaceutical companies. The further development and application of this technology had resulted in the successful formulation of current HPV vaccines. It was pointed out that NCI is a current collaborator in an HPV 16.18 vaccine trial, which is being conducted in Guanacaste, Costa Rica. Dr. Trimble emphasized that NCI is striving to encourage and promote the development of therapeutic cervical cancer vaccines. As regards secondary prevention activities, NCI has been directing much effort towards making screening for cervical cancer less expensive and more accessible, as it was stressed that there were still geographic regions of excess cervical cancer mortality in the USA. The NCI has established a Center for the Reduction of Cancer Health Disparities in recognition of the need to minimize these health inequities. The NCI, is also one of a number of agencies (IGCS, UICC, ASC) that have partnered together to facilitate the Global Women's Cancer Initiative (GLOW).

The United States Centers for Disease Control and Prevention (USCDC)

Dr. Lauri Markowitz emphasized that even though CDC had no definitive position on HPV vaccines at this time, recommendations for its introduction, program implementation and impact monitoring were currently under discussion. She pointed out that the responsibility for those final decisions and policies rested with the Advisory Committee on Immunization Practices (ACIP) and that an ACIP HPV Working Group had already been convened. The issues for consideration by the HPV Working Group included (a) the safety, efficacy and duration of

protection; (b) programmatic issues; (c) vaccine acceptability; (d) the impact of vaccination; and (e) cost issues and cost effectiveness. The deliberations of the ACIP are based on the assumption that a quadrivalent HPV vaccine will be licensed in the USA for use in females, aged 9-26 years, in 2006.

Dr. Markowitz noted that even though the universally recommended vaccines were provided at no cost to eligible children less than 19 years of age under the Vaccine for Children Program, CDC contract costs for those recommended vaccine packages had risen from US \$45 per capita in 1985 to \$570 in 2005. The potential increased costs of an expanded package would not be insignificant as the three-dose schedule of HPV vaccine has been estimated to be about \$200-300.

With regard to program implementation, key issues for consideration revolve around what strategies should be employed to successfully reach and vaccinate adolescents and whether adolescent vaccination could be integrated with other approaches or initiatives already directed to that group. In the context of monitoring impact, Dr. Markowitz acknowledged that this vaccine presented some peculiar challenges, especially because there are multiple outcomes, which could be measured. Some of these would include the prevalence of HPV types, the incidence of cervical cancer precursors, cervical cancer, and genital warts. While the SEER (SURVEILLANCE, EPIDEMIOLOGY, AND END RESULTS) Program of the National Cancer Institute and the National Program of Cancer Registries (NPCR) would provide long-term data on changing cervical cancer incidence in the U.S. population, there are currently no registries of cervical cancer precursor lesions. Regardless of the outcome being measured, HPV typing would still be essential. The use of self-collected vaginal swabs may have to be explored further.

Program for Appropriate Technology in Health (PATH)

Dr. Jacqueline Sherris described that agency's mission as one of improving the health of people around the world by advancing technologies, strengthening health systems and encouraging healthy behaviors. The work of the Alliance for Cervical Cancer Prevention (ACCP), of which PATH is a member, was highlighted and some of the salient findings summarized as follows: (a) demand for cervical cancer prevention services is strong among women and communities; (b) organized prevention programs are feasible and can be integrated into existing services; and (c) the single-visit screen-and-treat approach is safe and effective in low-resource settings. The areas of focus within the START Project (Screening Technologies to Advance Rapid Testing) were briefly noted.

PATH is developing a plan to accelerate the introduction of these new vaccines, while simultaneously promoting evidence-based cervical cancer prevention

approaches in developing countries. The major objectives of this plan are as follows:

1. To build partnerships with industry;
2. To plan for the development of an HPV vaccine investment case;
3. To identify potential early introducer countries;
4. To conduct country assessment missions in four countries (India, Peru, Vietnam, and Uganda), which have been identified as possible candidates for early HPV vaccine introduction; and
5. To identify available HPV information and information needs.

A number of challenges to effective HPV vaccine introduction were highlighted, some of which include the under-representation of certain population groups and geographical regions in current clinical trials; a limited range of existing strategies for reaching adolescent girls; the difficulty in predicting both the magnitude and timing of long-term vaccine impact; and the potential competition between HPV vaccines and other new vaccines and health needs. Dr. Sherris envisaged that the results gained from the execution of this plan will feed into program design and product registration, add to the global evidence base, provide data for investment advocacy, and create an enhanced local capacity for vaccine introduction.

Bill and Melinda Gates Foundation

Dr. Jan Agosti systematically detailed each strategy which had been identified as important in relation to HPV vaccine introduction and identified the associated activity and the agencies to which support had been specifically provided. Some of these strategic areas included:

- The epidemiology of HPV, including age-specific incidence, prevalence and strain distribution in developing countries;
- The development of country profiles related to the immunogenicity, safety, efficacy and effectiveness of HPV vaccines in general as well as in HIV-infected populations;
- The cost effectiveness of HPV vaccination, particularly within the context of screen-and-treat approaches;
- The social acceptability of a vaccine targeted to young women as well as the development of appropriate messages;
- Mathematical modeling of the impact, the likelihood of epidemiologic replacement and changes in attributable benefit; and
- Financing mechanisms to support vaccine introduction.

Pursuant to these goals, the Foundation had already earmarked grants to support the work of a number of agencies, including PATH, IARC, Harvard University, and WHO. Further, it was noted that some strategic challenges existed, and that these related to (i) negotiating with the industry; (ii) working with potential customers such as GAVI, UNICEF, and PAHO, in order to build the investment case for HPV vaccines; and (iii) integrating vaccination with cervical cancer screening and treatment.

Recommendations and Agreements

One of the recurrent themes emerging from this meeting was that the introduction of HPV vaccination must be viewed as complementary to cervical cancer screening in a post HPV vaccine era. This topic was mentioned by the ACS, NCI, PATH, PAHO, and WHO.

The salient recommendations and agreements arising from this meeting's discussions are summarized below.

Recommendations

- PAHO should proceed to consolidate this group of partners and formalize this partnership as a consortium.
- In an effort to further solidify PAHO's position with regard to HPV vaccine introduction, a follow-up technical workshop of this group of partners should be convened with the members of the Technical Advisory Group (TAG) on Vaccine-preventable Diseases in May 2006. The proceedings of this workshop would be published in the *Panamerican Journal of Public Health*.
- The consortium should focus on those areas of work that are complementary between partners and avoid duplication of effort and resources. In this regard, it was suggested that an activity matrix could be developed, so as to reflect both countries of interest and activities being undertaken by the different partners.
- This partnership should review the WHO's Technical Position Paper on HPV vaccines, when the latter becomes available during the first quarter of 2006.
- Countries in this partnership should be adequately represented.

- The report of this meeting should be shared with all of the PAHO Member States and published in the *Immunization Newsletter* of the Immunization Unit.
- The opportunity should be taken to promote the recommendations emerging from this meeting at the UICC sponsored World Cancer Congress, which is scheduled to take place in July 2006, in Washington, D.C..
- The possibility should be explored for having the issue of HPV vaccine introduction and other new vaccines and technologies placed on the agenda of the Summit Meeting of Presidents.

Agreements

1. The NCI indicated that it would be willing to contribute to this partnership in the area of surveillance development as well as on the issue of screening within a post-HPV vaccine era so as to enhance the possibilities for comprehensive cancer control.
2. The two vaccine suppliers, Merck and GlaxoSmithKline, stated that they would be willing to share data from clinical studies and mathematical modeling exercises in order to contribute evidence for advocacy and public health decision-making.
3. The ACS disclosed that it would be interested in working through outreach programs to gain access to underserved populations and reduce cancer burden disparities.
4. PATH expressed a specific interest in establishing an ongoing dialogue with PAHO around the subject of the Revolving Fund.
5. CDC declared an interest in working in the areas of implementation, surveillance development, and other aspects of impact monitoring.

Other Items

1. The CIDA representative suggested that PAHO's Regional Immunization program should review the lessons learned from other PAHO-CIDA interactions (i.e., the Infectious Disease Project) and utilize these as a basis for initiating next steps.
2. It was suggested that the NCI and UICC web sites could provide additional avenues for information dissemination.

Conclusion

The Chairman thanked the members of the audience for their active participation, constructive comments and willingness to work together towards successful HPV vaccine introduction.

The meeting was adjourned at 3.00pm



Annex 1

PARTNERING FOR HPV VACCINE INTRODUCTION

LIST OF PARTICIPANTS

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13 NOVEMBER 2005



Annex 2

PARTNERING FOR HPV VACCINE INTRODUCTION

**PAHO HEADQUARTERS, ROOM C (SECOND FLOOR)
5 OCTOBER 2005**

AGENDA

CHAIRPERSON - DR. JON ANDRUS

- | | | |
|-------------------|---------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------|--------------------------------------------------------------------------------------------------------------------------------|
| 9:30 a.m. | Welcome
Setting the Stage for New
Vaccine Introduction | Dr. Jon Andrus
Chief, Immunization Unit, PAHO |
| 9:45 a.m. | HPV Vaccines - A New Public
Health Tool: A PAHO Perspective | Dr. Carissa Etienne
Assistant Director, PAHO |
| 10:00 a.m. | Current Status of HPV Vaccines and Introductory Plans | |
| | GlaxoSmithKline Biologicals
Merck & Company | Dr. Gary Dubin
Dr. Elaine Esber |
| <i>10:30 a.m.</i> | <i>Coffee Break</i> | |
| 10:45 a.m. | Individual Agency Interests and Plans | |
| | Pan American Health Organization
American Cancer Society
International Union Against Cancer
United States Agency for International Development
United States National Cancer Institute
World Health Organization | Dr. Merle Lewis
Dr. Debbie Saslow
Ms. Stella de Sabata
Dr. Jeff Spieler
Dr. Edward Trimble
Dr. M. Teresa Aguado |

12:00 p.m. *Lunch Break*
In House: Chess Room, Third Floor (next to the Cafeteria)

12:45 p.m. **Individual Agency Interests and Plans** (continuation)

US Centers for Disease Control and Prevention
Program on Appropriate Technology in Health
The Gates Foundation

Dr. Lauri Markowitz
Dr. Jacqueline Sherris
Dr. Jan Agosti

1:15 p.m. Agreements on Joint Areas of Work

2:30 p.m. Next Steps & Wrap-Up

3:00 p.m. *Meeting Adjourned*