

Meeting Report

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Stop Cervical Cancer

» Accelerating Global Access to HPV Vaccines

London | 12 - 13 December 2006



Meeting organized by



Stop Cervical Cancer: Accelerating Global Access to HPV Vaccines Roundtable 12-13 December 2006

I. Background

Stop Cervical Cancer: Accelerating Global Access to HPV Vaccines was a roundtable meeting held in London on 12-13 December 2006. It was the first civil society gathering to discuss the development of an advocacy agenda that would ensure rapid and equitable global access to HPV vaccines, a critical tool for cervical cancer prevention.

The two-day meeting featured sessions that included brief presentations and extensive discussion on five areas: HPV vaccines and cervical cancer; service delivery; financing for global access; regulatory, supply and demand issues; and awareness, mobilization and political commitment.

Participants at the meeting represented a range of areas of expertise: cancer, sexual and reproductive health, HIV/AIDS, vaccines and immunization. Stakeholders from national governments, donor agencies, advocacy groups, international agencies such as World Health Organization, UNICEF, UNFPA, the GAVI Alliance, PAHO and the pharmaceutical industry were all represented.

The overall objective of the meeting was to lay the foundation for effective advocacy at global, regional and local levels by identifying critical areas for action, potential roadblocks, unanswered questions, and opportunities for progress.

This goal was met through extensive discussion, robust debate and informative presentations from diverse speakers, all of which are summarized in this document. During the two days of discussion, several critical themes and focal points for future work emerged. Section II provides brief thumbnail summaries of each presentation. Section III of this report gives an overview of these themes and a summary of the various perspectives shared during the meeting. Section IV reviews the closing session and planned next steps. Section V, the appendix, contains other relevant documents.

II. Summary of Presentations and Related Questions

SESSION: Opening Session

Dr. Steven Sinding, former Director General of the International Planned Parenthood Foundation; Dr. Geeta Rao Gupta, President of the International Center for Research on Women (in absentia)

Dr. Sinding called the gathering “an historic meeting,” noting that it marked the first time that global civil society had met to discuss the HPV vaccine and the advocacy agenda that would be necessary to help ensure rapid, equitable access to these important tools for cervical cancer prevention.

As Dr. Sinding noted, the purpose of the meeting was to serve as a “forum for collective decision making” about what the various stakeholders might do in their respective roles to help move forward technologies related to cervical cancer treatment and prevention. The meeting’s sessions provided opportunities to share information and to brainstorm on actions that would reduce the time necessary to introduce HPV vaccines, particularly in developing countries. One ultimate goal for the meeting was to develop an advocacy plan which could be used as a common framework for civil society-initiated action that would complement efforts of UNICEF, WHO and other international agencies.

Dr. Sinding also read a message from Dr. Rao Gupta, who was unable to attend the meeting. She described the meeting as a turning point and urged participants to “weave a tapestry of action” that would help accelerate access so that women in the developing world would benefit from the vaccine.

SESSION: Cervical Cancer and HPV Vaccines
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HPV Vaccines: An overview

Dr. Amy Pollack, consultant to The Rockefeller Foundation

The Impact of HPV on Families: A Physician’s View from Africa

Dr. Mike Chirenje, Chairman of the Department of Obstetrics and Gynaecology, University of Zimbabwe and Clinical Director of UZ-USCF Collaborative Research Programme

Merck’s Gardasil®: An Update

Dr. Gregg C. Sylvester, Senior Medical Director, Adolescent Medical Affairs, Merck Vaccine Division

GlaxoSmithKline Biologicals’ Candidate HPV Vaccine: An Update

Dr. Pedro Herzog, HPV Vaccines, GlaxoSmithKline

Speakers in this session provided critical background information on the epidemiology of cervical cancer and connection to human papillomavirus; cervical cancer-related morbidity, mortality and distribution of disease burden worldwide; the profound impact of this disease on women and their families, particularly in developing countries where the availability of screening and treatment is limited; and background data on two HPV vaccines: Merck’s recently-approved Gardasil, and GlaxoSmithKline’s candidate HPV vaccine, which has not yet been licensed in any country.

Cervical cancer is the second greatest cause of cancer death worldwide among women and the leading cause in many developing countries. The relationship between certain types of human papillomavirus and cervical cancer and genital warts is well documented. Out of more than 100 strains of HPV that have been identified, approximately 15-20 are believed to be oncogenic (cancer-causing). The course of HPV infection and progression to dysplasia, pre-cancer and cancer takes place over many years. This has implications for the design of programs to provide cervical cancer vaccines, screening and treatment. In order to maximize the effectiveness of a screening program to detect cervical cancer, the ideal age range to target is 30-35 years of age.

However, the vast majority of women are exposed to and infected with oncogenic strains of HPV shortly after sexual debut. The benefits of an HPV vaccine which blocks infection of the most cancerous strains of HPV would be maximized if the vaccine was delivered to girls prior to their sexual debut.

Burden of disease is highest in the developing world where there also is a severe lack of resources for diagnosis and treatment of cervical cancer. Untreated disease can be a source of stigma and social isolation for women and their families. The paucity of screening and treatment options leads to a high number of preventable deaths and burn-out among providers who are left with no treatment options for victims. It was noted that one East African study found that just 3-5 percent of women surveyed were covered by any cervical cancer screening program.

Two new HPV vaccines represent powerful tools for preventing cervical cancer, but these vaccines will not cure disease or remove the need for treatment in women who are already infected with HPV or diagnosed with cancer or pre-cancerous lesions.

Merck's quadrivalent HPV vaccine, Gardasil[®], is now licensed in more than 45 countries for use in 9- to 26-year-old girls; it is also licensed for 9 to 15-year-old males in many of these countries. Gardasil[®] provides protection against HPV 16 and 18, which are responsible for the majority of cases of cervical cancer worldwide, and against types 6 and 11, which cause genital warts. It is administered at 0, 3 and 6 months.

GSK's candidate HPV vaccine is not yet licensed in any countries. The company has submitted its vaccine to the EMEA for regulatory approval. It uses a different adjuvant from Gardasil[®], called ASO4, which is designed to strengthen and sustain immune responses. This vaccine also targets HPV strains 16 and 18.

GSK and Merck are investigating whether their vaccines provide any "cross-protection" against other oncogenic strains of HPV, and if so, what level of protection.

Both companies stated that they are committed to providing their vaccines to developing countries at "dramatically lowered" prices; neither has established a tiered pricing scheme or set prices for the products in different markets. Ongoing research will also explore safety and efficacy in HIV positive women.

SESSION: Service Delivery of HPV Vaccines

Overview of Key Issues

Dr. Jacqueline Sherris, Strategic Program Leader, Reproductive Health, PATH

Panelists: Dr. Merle Lewis, Public Health Specialist, PAHO; Dr. Arletty Pinel, Chief, Reproductive Health Branch, UNFPA; Dr. Issa Makumbi, National EPI Manager, Ugandan Ministry of Health; Dr. Helene Sancho-Garnier, Strategic Leader for Prevention and Early Detection, International Union Against Cancer (UICC)

Speakers in this session explored some of the challenges and opportunities around building or expanding cervical cancer prevention programs to include HPV vaccines. At this stage, many of the challenges center on lack of awareness of and demand for HPV vaccines in many parts of the world, and the lack of ongoing organized health services targeting 9 to 14-year-old girls that could be used as entry points for HPV vaccine introduction.

In addition to infrastructure challenges, the issues of positioning and messaging were also discussed at this session. It was noted that HPV vaccination will impact a number of important health areas including: sexual and reproductive health, cancer prevention, adolescent health, women's health, and HIV/AIDS. Different programs may choose to focus on different issues; this is both a challenge in terms of cohesive global messaging and an opportunity for innovation and exploration of new interventions for an under-served age range.

There are several ongoing access initiatives which will shed light on service delivery strategies. PATH has conducted formative research in several countries which culminated in the formation of plans for demonstration projects in India, Peru, Vietnam and Uganda. These projects are ongoing and will be an important source of information, potentially offering service delivery models for introduction in other countries.

PAHO is moving forward with HPV vaccine introduction in Latin America. It will build on the successes of previous programs including delivery of rubella, measles and tetanus-toxoid vaccines. PAHO will recommend immunization to young girls prior to sexual debut; no recommendation about immunization of boys is expected to be made in the near term. In the PAHO analysis, HPV vaccines could be effectively and efficiently delivered via the school system and at fixed locations for those not attending school.

In addition to sharing lessons learned from PATH-supported pilot projects and PAHO, developing countries will require technical support and assistance to evaluate need and optimal introduction strategies for HPV vaccines. Areas where countries may require assistance include: burden of disease and epidemiological data; information on financing and cost effectiveness of the intervention compared to other interventions; assistance in evaluating EPI and other program capacity and infrastructure as they relate to the requirements for new vaccine introduction; assistance in addressing socio-cultural aspects of vaccine introduction; assistance in program design and supply chain management.

Decisions about vaccine introduction will be made in countries with limited or no existing programs to screen for and treat cervical cancer. While HPV vaccines may be introduced in these settings, they will not address the needs of women already infected with oncogenic types of HPV or those who have progressed to cancer. Comprehensive approaches which set mid- and long-term goals in terms of expanding overall cancer-prevention programming are also important.

SESSION: Financing Global Access for HPV Vaccines
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Overview of Key Issues

Rob Hecht, Senior Vice President of Public Policy, International AIDS Vaccine Initiative

Panelists: Dr. Lieve Fransen, Head of Human and Social Development, European Commission; Dr. Julian Lob-Levyt, Executive Secretary, the GAVI Alliance; Dr. Jan Agosti, Senior Program Officer, Infectious Disease Program, the Bill & Melinda Gates Foundation; Dr. Howard Zucker, Assistant Director General, Health Technology and Pharmaceuticals, World Health Organization

Speakers in this session discussed challenges and opportunities around securing funding for HPV vaccine purchase and program implementation, and placed the task of securing this funding into the broader context of immunization funding worldwide. Global expenditures on immunizations are approximately USD \$20 per child per year, a figure which reflects the costs of service delivery as well as purchase of the vaccines themselves. The GAVI Alliance has the potential to become “the most important source of external financing” for HPV vaccines, should the vaccine be approved as a priority by the GAVI board and advocated for by developing countries. While GAVI commitments could be instrumental, they will not be sufficient in and of themselves. Additional sources of funding, including the World Bank, the European Commission, and national health insurance schemes, will be necessary to ensure equitable coverage.

Funding will need to be secured by working in coalition across disease and health interests (cancer prevention, HIV/AIDS, sexual and reproductive health, etc.). A strong coalition is also needed to focus on mobilizing demand in the global South, where the vaccine is so urgently needed by poor women and girls.

On the demand side, establishing a clear and significantly tiered pricing structure will help guide countries’ expectations and budgetary calculations. Beyond the cost of the vaccine itself, service delivery costs need to be considered. Different service delivery strategies at the country level will impact these costs.

Long-term commitments (ten years or more) from donors create a situation of shared risk between the country and the donor and a more stable environment for adding a new product to a country’s immunization program.

It was noted that there is a high level of interest in HPV vaccines at GAVI, including from board members, but more needs to be done. Needed action includes developing an investment case and exploring advocacy strategies which emphasize and utilize politically persuasive arguments about additional benefits of the vaccines in terms of impact on gender equity, outreach to adolescent girls, etc., as well as data on the vaccines themselves.

The EU and the EC are focusing on health spending within the overall budget of countries, and are working to increase the fiscal space used for health allocations. Raising the ceilings for health budgets would help reduce the sense of competition among various critical health interventions and new vaccines.

The Bill & Melinda Gates Foundation is also committed to working on cervical cancer prevention, including promotion of low-cost screening, treatment and diagnostic tools, as well as support for the PATH pilot projects.

Securing a recommendation from the WHO Strategic Advisory Group of Experts is a critical milestone on obtaining donor support and pre-qualification for purchasing by UNICEF and other entities. The WHO SAGE committee is likely to have HPV on the agenda in April 2007.

SESSION: Regulatory, Supply and Demand

Overview of Key Issues

Mitchell Warren, Executive Director of the AIDS Vaccine Advocacy Coalition

Panelists: Stephen Jarrett, UNICEF Supply Division; Dr. David Salisbury, Head of Immunisation, UK Department of Health, and Chair of the WHO Strategic Advisory Group of Experts and Immunization Policy; and Dr. N.K. Ganguly, Director General, Indian Council of Medical Research. Prof. Helen Rees O.B.E., Executive Director, Reproductive Health and HIV Research Unit, University of Witwatersrand, South Africa and Former Chair of the South African Medicines Control Council was unable to attend.

Mobilizing and quantifying demand for new products are critical activities which must be accompanied by simultaneous supply-side work to ensure sufficient supplies of doses are available. At the same time, regulatory action is taken as needed to prevent delays in access. This session provided perspectives on the various aspects of planning required to introduce vaccines in successful programs.

Focusing on securing funds for program costs is critical, since in most cases, these far outstrip the costs of procuring the vaccines themselves. For EPI vaccines, the expenditure ratio of procurement costs to delivery costs is 1:20.

As countries are encouraged to introduce the vaccine, steps must also be taken to ensure that there is an adequate supply. The inter-relationships among supply, demand, quality assurance and long-term sustainability of successful programs require a strategic approach to supply chain management.

Looking specifically at HPV vaccines, advocacy for introduction must be accompanied by a scientific plan for addressing unknowns including duration of protection (beyond five years); flexibility of dosing; the lack of information on how the vaccine works in people with different immune profiles (higher level of activation due to parasite burden, endemic disease found in many developing countries); and the issue of delivering a three-dose vaccine without information on efficacy of abbreviated regimens. The absence of data in these areas could be a hurdle for

regulatory agencies considering the vaccine and for developing countries considering introduction.

SESSION: Awareness, Mobilization, and Political Commitment

Overview of Key Issues

Susan Perl, Consultant, Rockefeller Foundation

Panelists: Dr. Nono Simelela, Director, Technical Knowledge and Support, International Planned Parenthood Federation; Ms. Anjali Nayyar, Vice President of Country and Regional Programmes, International AIDS Vaccine Initiative; Ms. Michelle Beg, Director of Campaigns and Communications, Young Women's Christian Association; Ms. Johanna Ralston, Vice President of Global Strategies and Marketing and Managing Director of International Affairs, American Cancer Society; Dr. Diarmuid McClean, Development Specialist, Irish AID.

This final session considered opportunities for building a broad coalition to advocate for introduction of HPV vaccine, and provided the donor perspective on how successful advocacy might proceed. (Note: This session took place on the final day and much of the discussion was continued in the closing session; additional critical points are found in the following section).

Panelists emphasized that it is not going to be possible to look at this vaccine as a single intervention owned by any specific constituency. Instead, it will be critical to build a broad-based and inclusive coalition with strong, flexible partnerships. This coalition can work with governments to strengthen programs, including screening and treatment, through vaccine roll out.

Youth organizations and cancer survivor groups have potentially critical roles to play in mobilizing grassroots support for the vaccines in both developing and developed countries.

These and other groups must work closely with developing countries to make a case to donors that there is significant and compelling evidence that introducing HPV vaccine is public health imperative.

Section IV. Closing Session and Planned Next Steps

Dr. Steven Sinding chaired the final session and began by providing an overview of some of the critical points made during the preceding two days of panels and discussions. These are summarized below according to five core themes, which are also found in the draft Advocacy Plan for Access (see attached), which provided a framework for the meeting.

Mobilization

- There is a limited awareness of cervical cancer and its impact in the developing world, and cancer of any kind is not on the agenda at the country level.
- Education must precede mobilization: What is at stake? What are the benefits of this new strategy? There is a need for materials to inform and educate. A certain level of

awareness is necessary *before* HPV advocacy can be effective in changing decision-making.

- Political and strategic positioning will be at least as important as evidence-based arguments in garnering support for expanded cervical cancer prevention programs which include HPV vaccines.
- There is a need to create champions at all levels.
- There is a need to frame the HPV vaccine as a global vaccine.
- There is a need for flexibility in positioning HPV vaccines depending on country priorities: cancer, sexual and reproductive health, adolescent health, etc.
- There is a need for clarity and transparency about outstanding research questions, and about how and when will they be answered.
- There is a need to clarify the differences between the two vaccines, assuming GSK's candidate is licensed. How will countries make choices between the two vaccines, and on what basis?
- HIV activism and other initiatives which have helped bring new resources to public health problems in the global South can provide important lessons.
- All the advocacy tasks should be organized in terms of achieving a comprehensive "supply management strategy."
- There is a need for a mechanism for sharing best practices, advocacy goals and campaigns. Information dissemination is essential.

Financing

- There is a need for tools for policymakers to help prioritize "innovation pileup."
- There is a need to collect information about integrated and/or vaccine delivery costs.
- There is a need for *new* funding, so as not to drain off other programs.
- Strategic messaging and political will for roll-out of HPV vaccines could affect GAVI's decision to finance HPV vaccines.
- Predictability of financing encourages country level investment/demand and is critical to successful programming.
- There is a need to re-examine and learn from factors which drove other vaccines: Hepatitis B, Hob.

Demand

- Pharmaceutical companies need predictability in demand to react with supply and price.
- There is a need for mechanisms to better estimate demand.
- Demand has a political component, and it will not be driven by disease burden alone.
- There is a need to have a better understanding of supply capacity: what can pharmaceutical companies supply now and in five years? How does that correspond with demand?

Political Will

- Political will is critical in mobilizing support and can be a critical factor in influencing decisions, irrespective of cost-effectiveness analysis data, etc.

- Messages need to convey short-term gain and focus on 10-20 year view of financing commitments.
- Support at the country level is essential to creating demand to purchase vaccines at both country and donor levels.
- There is a need for finance messaging efforts that position HPV vaccines in a different way (women's cancer, relation to HIV vaccines, etc.) since the disease burden alone will not carry weight in many countries.

Regulatory Action

- Evidence is needed to gain a WHO SAGE recommendation for broad use of the HPV vaccine.
- WHO pre-qualification of HPV vaccines should proceed as rapidly as possible.
- Clear statements on how unanswered questions, such as duration of protection, will be answered are needed.

Participants closed the meeting by discussing how to move forward as individual institutions and as a coalition. There was consensus that flexibility and inclusiveness were critical to success of such a coalition, and that it would be important to have some form of organizational structure such as a secretariat or loosely-coordinated network to further the advocacy points identified in the meeting.

Participants reviewed a draft Call to Action statement and agreed on plans for finalizing the statement by March 2007. The co-conveners agreed to prepare and distribute a draft memo outlining possible strategies to release the Call to Action.

It was agreed that the Advocacy for Access Plan would also be updated based on the input from the meeting, and re-circulated as a first step towards a global strategy which would be implemented on multiple levels—global, regional, national and programmatic.

Thanks were expressed to Global Health Strategies and the co-conveners of the meeting (the Rockefeller Foundation, the International Planned Parenthood Federation, PATH, the International AIDS Vaccine Initiative, the International Union Against Cancer and the AIDS Vaccine Advocacy Coalition) for organizing the event. As one participant said in the final minutes of the session:

It is an amazing vaccine. It is that different and we have that much of an opportunity around gender and rights and activism and doing something that is global – we can't afford not to stand on the table and stomp our feet a little bit. On a national level we need to do everything we can to be realistic about what is happening in countries. We need to be realistic: we may not see another vaccine that is this effective in our lifetimes. If we get too encumbered by the barriers we all know exist then we will lose track of what we need to do. This is not business as usual.