

Accelerating Progress in Cancer Prevention: The HPV Vaccine Example

Globally, HPV infections cause most cervical cancers (about 500,000 new cases/year and 275,000 deaths), and a substantial proportion of cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancers as well as genital warts and recurrent respiratory papillomatosis. Substantial economic burden is associated with HPV-related conditions. The annual U.S. burden for cervical HPV-related disease alone is as high as \$4.6 billion.

Vaccines protect against infection by the most common strains of oncogenic HPV (e.g., HPV 16, 18). Uptake of HPV vaccines in the United States, however, is sub-optimal. Slightly more than one-third of U.S. females aged 13-17 years and a minimal percentage of U.S. males of the same age received the recommended three doses of vaccine in 2011. These rates are too low to achieve the population-wide potential of HPV vaccines to reduce cancer incidence and mortality. Increasing HPV vaccination rates in the United States and globally could effect a major reduction in HPV-related cancers.

Goals

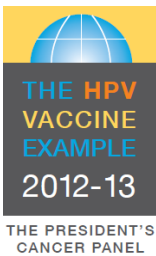
- Develop a finite set of actionable recommendations that focus on effective and/or promising strategies to increase uptake of HPV vaccines in the United States among age-eligible males and females.
- Identify evidence about effective and/or promising strategies to increase vaccine use and lessons learned from HPV vaccine use in the United States and elsewhere.
- Identify topics and issues for which there are knowledge gaps that require further study.
- Identify practice and application issues that require attention.
- Identify issues related to global HPV vaccination strategy.

Approach

In three workshops, the President’s Cancer Panel will assess the scientific basis for, current status of, and continuing efforts for effective vaccination against HPV-related cancers. The focus will include epidemiologic, behavioral, communication, policy, economic, global and other issues that influence effectiveness of HPV vaccines in reducing population cancer risks.

Participants’ provocative questions submitted prior to workshops will help to inform discussions. Each workshop will include a series of short presentations and moderated discussions, with the goal of achieving consensus about key recommendations. Two participants will be invited to co-chair each workshop.

- | | | |
|---|--------------------|-------------------|
| • Workshop 1: <i>HPV Vaccination as a Model for Cancer Prevention</i> | Jul. 24, 2012 | San Francisco, CA |
| • Workshop 2: <i>Achieving Widespread HPV Vaccine Uptake</i> | Sept. 13, 2012 | Washington, DC |
| • Workshop 3: <i>Creating an Integrated HPV Vaccination and Screening Program</i> | Nov. 16, 2012 | Chicago, IL |
| • Workshop 4: <i>Challenges of Global HPV Vaccination</i> | Apr. 23-24
2013 | Miami, FL |



HPV Vaccination as a Model for Cancer Prevention

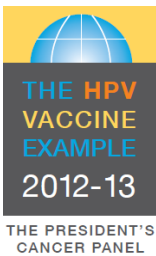
July 24, 2012 • San Francisco, CA

Realization of a preventive vaccine for HPV serotypes most commonly associated with HPV-related cancers (cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancers as well as genital warts and recurrent respiratory papillomatosis) is a major advance in preventive oncology. This workshop will examine questions related to safety, efficacy, duration of protection, population impact, and next-generation vaccines. Broad areas include the following:

- **Fundamental science** that forms the foundation for development of HPV vaccines—specifically, basic, translational, and clinical research that brought vaccine from discovery to approval and practice
- **Surveillance and epidemiology** to assess global distribution of HPV-related cancers; durability of protection; whether booster is needed; number of doses required for immunity; virus latency; safety; cross-protection among multiple oncogenic HPV strains; and baseline incidence of HPV infection and cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancers among vaccinated populations will be examined.
- **Populations that are high priority for vaccination**—should recommended age targets be lowered? Should high-risk populations be specified?
- **Strategies for assessing population impact**, including modeling, designs appropriate for answering questions about population impact, and vaccination registries
- **Next-generation vaccines and improvements in HPV vaccine formulation and delivery** (e.g., circumventing need for vaccine refrigeration and lowering number of doses needed) have implications for future vaccines (e.g., those in development to cover multiple high-risk oncogenic HPV types and those targeting other cancer-related infectious agents). Other considerations include trade-offs regarding number of viruses covered vs. efficacy/safety and other factors. What issues are specific to developing next-generation HPV vaccines, such as combination vaccines? What are the barriers to progress?

Workshop Chairs

- **Doug Lowy, MD**, Chief, Laboratory of Cellular Oncology in the Center for Cancer Research, National Cancer Institute; Deputy Director, National Cancer Institute
- **Cosette Wheeler, PhD**, Professor of Pathology, University of New Mexico



Achieving Widespread HPV Vaccine Uptake

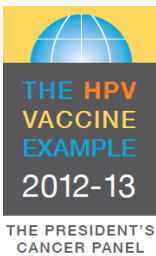
September 13, 2012 • Arlington, VA

HPV vaccination rates in the United States should be increased if we are to achieve optimal population impact from vaccination. Workshop participants will examine a variety of perspectives as part of developing recommendations for increasing vaccine uptake. Perspectives and issues include but are not limited to the following:

- **Policies** that determine price, access and availability, and policies that influence where and by whom vaccines may be administered—and who is eligible to receive them, under what conditions and with what reimbursement—affect their use. Are mandates effective and, if so, under what conditions? What, if any, policy changes are needed to increase use of HPV vaccines?
- **Programmatic initiatives** central to vaccine dissemination include Vaccines for Children Program; AFIX; and initiatives led by state and local public health authorities.
- **Financing, development, and implementation** of a large-scale HPV vaccine efforts
- **Barriers** to greater use of HPV vaccines include the following:
 - ✓ **Programmatic:** there has been a shift of responsibility for immunization from public health departments to private providers who now vaccinate nearly 80% of U.S. children. What problems and benefits have resulted from this change in providers?
 - ✓ **Financial:** copayments for vaccine and physician visits; lack of incentives for parents to have their children vaccinated; burden on providers to keep vaccines stocked on site; and potential for free or low-cost vaccines all affect uptake. Do any of these factors inhibit uptake?
 - ✓ **Behavioral:** vaccine acceptability; among adolescents, perceived likelihood of infection with HPV; beliefs and perceptions about HPV vaccines (e.g., safety, impact on sexual behavior, true or not); perceived barriers to vaccination (e.g., parents' beliefs that vaccination will promote sexual activity among vaccinated children; the vaccine can be given later; cancer is not a major concern)
 - ✓ **Communication:** Physicians and other health providers are important sources of information (in their ability to initiate conversations with patients about concerns, clarify misunderstandings, and recommend vaccine). Can the Internet, social media, and tools like crowd-sourcing be used to inform and improve discussions and decisions about HPV vaccination?
- **Potential benefits and harms of bundling vaccines**—co-administering HPV vaccine with other vaccines for adolescents may increase acceptability and uptake (e.g., Tdap).
- **Lessons from countries** with high-vaccine coverage rates (e.g., Australia).

Workshop Chairs

- **Noel T. Brewer, PhD, MS**, Associate Professor, UNC Gillings School of Global Public Health; Director, Cervical Cancer-Free NC
- **Robert T. Croyle, PhD**, Director, Division of Cancer Control and Population Sciences, National Cancer Institute



Creating an Integrated HPV Vaccination and Screening Program

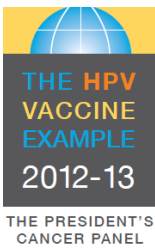
November 16, 2012 • Chicago, IL

The impact of HPV vaccination on cervical, vulvar, vaginal, anal, penile, oral cavity and oropharyngeal cancer rates is not fully characterized. Continued use of available screening methods, even among vaccinated individuals, is needed to minimize cancer incidence and mortality. In this workshop, participants will examine the implications of HPV vaccination on clinical practices, standards, and health economics. The following are some of the issues and topics participants will consider.

- **Potential population health and economic impacts of HPV vaccination**, including the effect of reduced incidence of HPV-related dysplasias, cancers and other outcomes on health care expenditures and the use of modeling to determine cost effectiveness of vaccination.
- **Potential impact of widespread HPV vaccination on cervical cancer screening practices and other aspects of HPV-related care**, including current guidelines for cervical cancer screening and possible needed modifications to guidelines as vaccination uptake increases; impact of changes in cervical cancer screening test itself (e.g., change from Pap test as primary screening test to HPV test); barriers to screening adherence (e.g., shifting intervals of screening); feasibility of dentists as providers to administer vaccine, based on their existing role in providing oral cancer screening; role of managed care organizations/accountable care organizations (MCOs/ACOs) in shaping new models of care; implications of racial/ethnic differences (and other relevant characteristics) in type and frequency of precursor cervical lesions on screening and care for diverse populations; differential screening patterns, delay in screening, and access to screening among diverse populations.
- **Tools and resources needed to support an integrated approach to HPV vaccination and screening, including** a sustainable system of vaccination registries and linkages to existing registries; strengthening and building on existing registries and infrastructure to support collection of needed data; state-based surveillance systems that can measure other disparities (e.g., geographic, racial, ethnic) that might not otherwise be measured; challenges associated with collecting data on preinvasive cancerous lesions; role of MCOs/ACOs and state health departments in monitoring vaccination rates and HPV-related outcomes; technologies that can accelerate efforts to build needed systems and linkages.

Workshop Chairs

- **Marcus Plescia, MD, MPH**, Director, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention
- **Tamera Coyne-Beasley, MD, MPH**, Director, NC Child Health Research Network; Associate Director, Community Engagement NC TraCS Institute - Child Health Core Home of the UNC-CH Clinical and Translational Science Awards (CTSA); Professor of Pediatrics and Internal Medicine, University of North Carolina at Chapel Hill
- **Mona Sarayia, MD, MPH**, Medical Officer, Division of Cancer Prevention and Control, Centers for Disease Control and Prevention



Global HPV Vaccination: Opportunities and Challenges

April 23-24, 2013 ■ Miami, FL ■ Hilton Miami Downtown

Workshop Overview

Cervical cancer is the second-most common cancer among women worldwide, and more than 80 percent of these cases occur among women in developing countries. HPV vaccines are effective in protecting against infection with HPV types associated with more than 70% of cervical cancer cases, along with other HPV-related cancers and genital warts. A worldwide effort to implement HPV vaccination has potential to dramatically reduce rates of HPV infection and associated conditions. The World Health Organization recommends that HPV vaccines be introduced into national immunization programs where prevention of cervical cancer is a public health priority and vaccine introduction is feasible and sustainable. In this workshop, participants will examine a range of topics relevant to the development of a coordinated global strategy to increase HPV vaccine uptake. Data about effective global vaccination programs may inform some U.S. efforts. The following are some of the issues workshop participants will address.

- **Overview of global epidemiology of HPV infection and related conditions**, including differences among countries at varying income levels and regions; projection of trends for cervical and non-cervical HPV-related disease over the coming decades; global capacity for surveillance of HPV infection and related conditions
- **Overview of global HPV vaccination coverage**, including differences among countries at varying income levels and regions; modeling methods to estimate coverage
- **HPV vaccine policy and financing**, including overview of national vaccine program development and financing mechanisms; leveraging established immunization networks to administer vaccines; establishing sustainable financing for national immunization programs; using cost-effectiveness modeling to support decision making
- **HPV vaccination program development and implementation**, including examination of countries that are developing and implementing HPV vaccination initiatives at the national level; opportunities for HPV vaccine delivery (e.g., school-based programs, development of comprehensive adolescent health platform); challenges associated with development and implementation
- **HPV vaccination program monitoring and evaluation**, including examination of countries that are engaging in HPV vaccination program monitoring and evaluation; resources available for countries to monitor and evaluate program activities

Workshop Chairs

- **Rima F. Khabbaz, MD**, Deputy Director for Infectious Diseases, Centers for Disease Control and Prevention
- **Olufunmilayo Olopade, MD, FACP**, Director, Cancer Risk Clinic, Professor of Medicine and Human Genetics, University of Chicago Medical Center
- **Ted Trimble, MD, MPH**, Director, Center for Global Health, National Cancer Institute