Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer

CPRIT Innovations in Cancer Prevention and Research Conference

November 10, 2015
Overview

- Mission and Composition of the Panel
- HPV Vaccine Series and Report
- Updates
Mission

The Panel shall monitor the development and execution of the activities of the National Cancer Program, and shall report directly to the President.

Any delays or blockages in the rapid execution of the Program shall immediately be brought to the attention of the President.

Authority: 42 U.S.C. 285a-4; Sec. 415 of the Public Health Service Act, as amended
Members

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Topic Criteria

- Related to functional outcomes that influence resource allocation, organizations, industry practices and, potentially, cancer prevention, detection, and therapeutic interventions
- Affects critical aspects of cancer-related discovery, prevention, early detection, treatment, delivery, control, and policy
- Manageable and focused
- Can lead to actionable recommendations
- Based on sound science and policy
Accelerating Progress in Cancer Prevention: The HPV Vaccine Example

- Nearly 80 million people in the U.S. (1 in 4) are infected with HPV.
- About 14 million people are newly infected every year.
- There are over 100 different serotypes; over 40 can infect the anogenital tract.
- Approximately 15 of those 40 serotypes are oncogenic.
- HPV-16 and HPV-18 are responsible for the vast majority of HPV-linked cancers.
- Two non-oncogenic serotypes (HPV-6 and HPV-11) cause genital warts.
Accelerating Progress in Cancer Prevention: The HPV Vaccine Example

Numbers of U.S. Cancers and Genital Warts Attributed to HPV Infections

- Penis: 400
- Vagina: 500
- Juvenile-Onset RRP: 820
- Vulva: 1,600
- Anus: 1,600, 2,900
- Oropharynx: 5,900, 1,500
- Cervix: 11,500
- Genital Warts: 160,000, 180,000

Accelerating Progress in Cancer Prevention: The HPV Vaccine Example

<table>
<thead>
<tr>
<th>HPV Vaccines</th>
<th>Gardasil</th>
<th>Cervarix</th>
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<tbody>
<tr>
<td>HPV Types</td>
<td>6, 11, 16, 18</td>
<td>16, 18</td>
</tr>
<tr>
<td>Manufacturer</td>
<td>Merck &amp; Co.</td>
<td>GlaxoSmithKline</td>
</tr>
<tr>
<td>Initial US Licensing</td>
<td>2006</td>
<td>2009</td>
</tr>
<tr>
<td>Approved for Prevention of</td>
<td>Cervical cancer &amp; precancers</td>
<td>Cervical cancer &amp; precancers</td>
</tr>
<tr>
<td></td>
<td>Vulvar cancer &amp; precancers</td>
<td></td>
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<tr>
<td></td>
<td>Vaginal cancer &amp; precancers</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Anal cancer &amp; precancers</td>
<td></td>
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<tr>
<td></td>
<td>Genital warts</td>
<td></td>
</tr>
<tr>
<td>Approved for Use in</td>
<td>Females (ages 9 to 26)</td>
<td>Females (ages 9 to 25)</td>
</tr>
<tr>
<td></td>
<td>Males (ages 9 to 26)</td>
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Increasing HPV vaccination is one of the most profound opportunities for cancer prevention.
Series Workshops:

- HPV Vaccination as a Model for Cancer Prevention
- Achieving Widespread HPV Vaccine Uptake
- Creating an Integrated HPV Vaccination and Screening Program
- Global HPV Vaccination: Opportunities and Challenges
Accelerating HPV Vaccine Uptake: Urgency for Action to Prevent Cancer

A Report to the President of the United States from
The President's Cancer Panel

Human papillomaviruses (HPV) cause most cases of cervical cancer and large proportions of vaginal, vulvar, anal, penile, and oropharyngeal cancers. HPV also causes genital warts and recurrent respiratory papillomatosis. HPV vaccines could dramatically reduce the incidence of HPV-associated cancers and other conditions among both females and males, but uptake of the vaccines has fallen short of target levels. The President's Cancer Panel finds underuse of HPV vaccines a serious but correctable threat to progress against cancer. In this report, the Panel presents four goals to increase HPV vaccine uptake: three of these focus on the United States and the fourth addresses ways the United States can help to increase global uptake of the vaccines. Several high-priority research questions related to HPV and HPV vaccines also are identified.

Click below to read more.

HOW TO ACCELERATE HPV VACCINE UPTAKE IN THE U.S.

INCREASE GLOBAL HPV VACCINATION   CONDUCT HIGH-PRIORITY RESEARCH

- Reduce Missed Clinical Opportunities to Recommend and Administer Vaccines
- Increase Parents', Caregivers', and Adolescents' Acceptance of HPV Vaccines
- Maximize Access to HPV Vaccination Services
In 2012:

- 33.4% of girls ages 13-17 completed three-dose series (state rates vary widely and are as low as 12%).
- 6.8% of boys ages 13-17 completed three-dose series.

*Healthy People 2020 goal: 80 percent of girls ages 13-15 complete HPV vaccine series.

U.S. Uptake of Adolescent Vaccines Through 2012

(a) After age 10 years.
(b) ≥ 3 doses HPV vaccine, either Cervarix® or Gardasil®, among females. ACIP recommends either Cervarix® or Gardasil® for females.
(c) ≥ 3 doses HPV vaccine, either Cervarix® or Gardasil®, among males. ACIP recommends Gardasil® for males but some males may have received Cervarix®.

U.S. Uptake Behind That of Several Countries

- **Australia**: 71.2%
- **United Kingdom**: 60.4%
- **United States**: 33.4%

Note: National data on HPV vaccine coverage in Canada are not available. However, Canadian provinces report three-dose coverage among target age groups between 50 and 85 percent.

Sources:
Increasing HPV vaccination rates from current levels to 80%* would prevent an additional 53,000 future cervical cancer cases among girls now 12 years or younger (CDC).

Thousands of non-cervical HPV-associated cancers likely could also be prevented.

A growing proportion of future HPV-associated cancers (esp. oropharyngeal cancers) will occur in males. Benefits of vaccination accrue to males and females.

*Healthy People 2020 goal: 80 percent of girls ages 13-15 complete HPV vaccine series.
Three Goals:

1. Reduce Missed Clinical Opportunities to Recommend and Administer HPV Vaccines

2. Increase Parents’, Caregivers’, and Adolescents’ Acceptance of HPV Vaccines

3. Maximize Access to HPV Vaccination Services
Objective 1.1:

CDC should develop, test, disseminate, and evaluate the impact of integrated, comprehensive communication strategies for physicians and other relevant health professionals.
Objective 1.2:

Providers should strongly encourage HPV vaccination of age-eligible males and females whenever other vaccines are administered.
Goal 1: Reduce Missed Clinical Opportunities to Recommend and Administer HPV Vaccines

**Objective 1.2: Factors Contributing to Providers’ Hesitancy**

- Limited understanding of HPV-associated diseases and benefits of HPV vaccination, particularly for males
- Concerns about safety
- Concerns about inadequate reimbursement for vaccines
- Personal attitudes and beliefs
- Discomfort talking to parents and adolescents about a topic related to sexual behavior
- Concerns about parental resistance
- Preference for vaccinating older versus younger adolescents
- Lack of time or incentives to educate parents and patients about HPV and HPV vaccines
- Lack of systems to remind providers to offer vaccines to age-eligible patients
Goal 1: Reduce Missed Clinical Opportunities to Recommend and Administer HPV Vaccines

Objective 1.3:

Healthcare organizations and practices should use electronic office systems, including electronic health records (EHRs) and immunization information systems (IIS), to avoid missed opportunities for HPV vaccination.
Goal 1: Reduce Missed Clinical Opportunities to Recommend and Administer HPV Vaccines

**Objective 1.4:** Healthcare payers should reimburse providers adequately for HPV vaccines and for vaccine administration and services.

**Objective 1.5:** The current Healthcare Effectiveness Data and Information Set (HEDIS) quality measure for HPV vaccination of adolescent females should be expanded to include males.

**Objective 1.6:** Create a *Healthy People 2020* HPV vaccination goal for males.
Objective 2.1:

CDC should develop, test, and collaborate with partner organizations to deploy integrated, comprehensive communication strategies directed at parents and other caregivers, and also at adolescents.
Goal 2: Increase Parents’, Caregivers’, and Adolescents’ Acceptance of HPV Vaccines

Objective 2.1: Reasons Parents Did Not Intend to Vaccinate Their Adolescents Against HPV

- Vaccination not needed, particularly for males
- Vaccination not recommended by healthcare provider
- Safety concerns
- Lack of knowledge about the vaccines or diseases caused by HPV infections
- Son or daughter not sexually active
- Son or daughter too young to be vaccinated against HPV
- Cost of vaccines
Goal 3: Maximize Access to HPV Vaccination Services

**Objective 3.1:** Promote and facilitate HPV vaccination in venues outside the medical home.

**Objective 3.2:** States should enact laws and implement policies that allow pharmacists to administer vaccines to adolescents, including younger adolescents.

**Objective 3.3:** Overcome remaining barriers to paying for HPV vaccines, including payment for vaccines provided outside the medical home and by out-of-network or nonphysician providers.
Authority of Pharmacists in 2012 to Administer HPV Vaccines to Girls Age 12

- 6% No prior approval required
- 31% Supervision agreement with prescriber required
- 24% Prescription required
- 39% Not permitted to administer

Percentage of U.S. States (including District of Columbia)

Source: Brewer NT, Chung JK, Baker HM, Rothholz MC, Smith JS. Pharmacist authority to provide HPV vaccine: novel partners in cervical cancer prevention. Gynecol Oncol. [Epub 2013 Dec 19]
High-Priority Research to Advance Prevention of HPV-Associated Cancers

1. Investigate More Convenient Dosing Schedules for Current Vaccines (e.g., extended dosing schedules, fewer doses)
2. Develop Next-Generation Vaccines That Provide Broader Protection and/or Are Easier to Store and Administer
3. Explain the Natural History of Oropharyngeal HPV Infections
4. Develop More Effective Ways to Communicate About HPV-Associated Diseases and HPV Vaccines
5. Determine How Best to Integrate HPV Vaccination With Cervical Cancer Screening
The Panel is committed to achieving the vision of increased HPV vaccine uptake. The Panel suggests that a credible organization, such as NVAC [National Vaccine Advisory Committee], be given responsibility for monitoring the status of uptake and implementation of these recommendations.
IAC issued “Dear Colleague” letter encouraging strong HPV vaccine recommendations

Signed by:

- AAFP
- AAP
- ACOG
- ACP
- CDC
- IAC
On June 9, 2015, NVAC voted to approve the 5 recommendations of the NVAC HPV Working Group:

1. Endorse the PCP report and adopt the recommendations therein.*

2. Endorse monitoring “the status of uptake and implementation of PCP recommendations” through an annual progress report from HPV immunization stakeholders.*

*Adopted June 2014
3. ASH* should work with relevant agencies and stakeholders to develop evidence-based, effective, coordinated communications strategies to increase clinician recommendations for HPV vaccination to adolescents.

4. ASH should work with stakeholders to strengthen the immunization system in order to maximize access to adolescent vaccinations, including HPV vaccines.

* Assistant Secretary for Health
5. ASH should encourage the review or development of available data that could lead to a simplified HPV vaccination schedule.
National HPV Vaccination Roundtable (Feb. 2015)

- With support from the ACS and CDC, a national coalition of public, private, and voluntary organizations is collaborating to increase HPV vaccination coverage.

- First meeting held Feb. 23-24, 2015, in Atlanta:
  - Meeting goal: identify and define pilot projects for Roundtable implementation.
  - Pilot projects must be responsive to the PCP’s HPV report recommendations.
  - RFP for first pilot underway: “Identify the factors to success and the challenges impeding the development and implementation of an HPV Immunization Neighborhood.”
Updated communications to providers and parents, based on CDC research:
Research on the HPV Vaccine: Update from NCI

- **Intramural**
  - Proposed trial on single dose (direct evaluation of 2- and 1-dose regimens) is responsive to the Panel’s recommendation to safely reduce number of doses.

- **Extramural**
  - Cancer Center grant supplements were awarded to gather local data on vaccine uptake, barriers, needs, and collaborators.
  - New extramural announcements (in process) address the Panel’s call for research on communication about HPV vaccines.
December 2013: The European Commission approved Cervarix for a two-dose vaccine schedule in girls ages 9 – 14.

Gardasil-9 approved for the prevention of cervical, vulvar, vaginal, and anal cancers caused by HPV types 16, 18, 31, 33, 45, 52, and 58 and for the prevention of genital warts caused by HPV types 6 or 11.

- Approved by US FDA December 10, 2014
- Approved by European Commission June 17, 2015
# Updated MMWR Data from 2014

## Uptake of HPV Vaccine in Adolescents Ages 13-17 (Three Doses)

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<thead>
<tr>
<th></th>
<th>2012</th>
<th>2014*</th>
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<tr>
<td>Females</td>
<td>33.4%</td>
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<tr>
<td>Males</td>
<td>6.8%</td>
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