

Measuring the Impact of the HPV Vaccine in the U.S.: What CDC's Division of Cancer Prevention and Control is doing in collaboration with Central Cancer Registries

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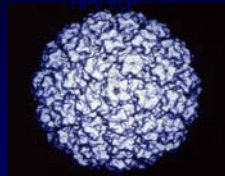
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Prevention of HPV infection

HPV Vaccines

- ◆ Made from proteins on the outside of the virus
- ◆ Contains no mercury
- ◆ Contains no infectious material



HPV Vaccines

Vaccine/ Manufacturer	HPV Types	Schedule	Progress of trials
Quadrivalent <i>Merck</i> GARDASIL®	6/11/16/18	3 doses 0, 2, 6 mos	Licensed in June, 2006
Bivalent <i>GSK (not yet out)</i> CERVARIX®	16/18	3 doses 0, 1, 6 mos	Phase III ongoing



How well does the Quadrivalent HPV vaccine work? (Keep in mind who was studied)

Endpoint	Efficacy
Vaccine type Cervical cancer precursors	100
Vaccine type genital warts	99

Package insert: Gardasil®*



HPV Vaccine Other studies that are ongoing

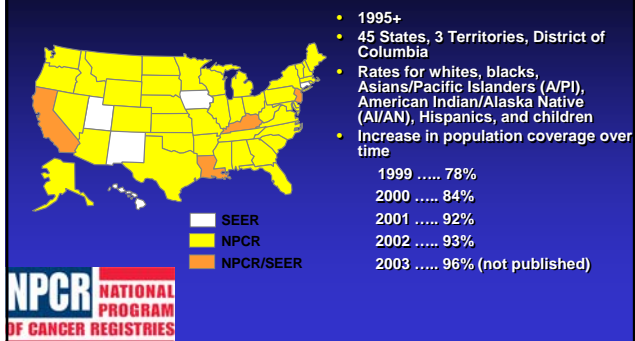
Vaccine/ Manufacturer	Efficacy in Females >26	Long Term Follow-up	Efficacy in Men
Quadrivalent <i>Merck</i>	X	X	X
Bivalent <i>GSK</i>	X	X	



Measuring Impact is Multidimensional

- Vaccine Coverage/Safety
- **Biological Outcomes**
- Provider Practices
- Cost Effectiveness
- Population Behavior
- Communication and Education

National Program of Cancer Registries



Assessment of Burden of HPV-related Cancers in the U.S. (ABHACUS)

2008 Supplement in ACS' Journal Cancer

Cancers Attributable to Infection with Oncogenic HPV Types, U.S., 2002

Site	Total Cancers*	% Estimated HPV Attributable Fraction*
Cervix	12,085	100
Anus	3,703	85
Vulva/Vagina	4,480	40
Penis	985	40
Oral/Pharyngeal	10,088	15

*2002 US Cancer Statistics, CDC/NCI, 2005

+Parkin M. International Papillomavirus Conference, Vancouver, Canada, 2005/Trotter H, Franco E, Vaccine; 2006 in press

Supplement in ACS' Cancer Journal

- 23 Peer-reviewed articles
 - Most involve cancer registries
 - Behavioral Surveillance System
 - HPV epidemiology
 - Natural History of Cervical Cancer
- Authors include
 - Central Cancer Registry Staff
 - ACS
 - NCI
 - Academia/HPV experts

HPV Typing of Cervical Cancers in the U.S.

Background

- IARC studies have established HPV types associated with invasive cervical cancer
- North America not well represented in IARC studies
- Concerns about type-replacement
- Concerns about cross-protection of vaccines
- Need for baseline in the U.S. important

Aims

- Conduct a pilot study on HPV typing in cervical cancer cases obtained from 3 population-based cancer registries to determine the feasibility of establishing infrastructure for the systematic monitoring of HPV in incident cervical cancer in representative samples of the United States.
- Determine the baseline distribution of HPV types associated with cervical cancer in the U.S. pre-HPV vaccine licensure in the cancer registries selected to represent areas with high burden of disease and racial ethnic diversity.

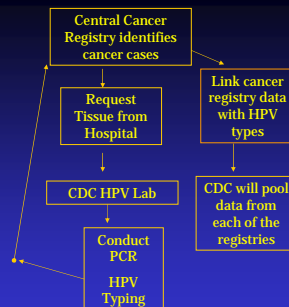
Design

- Identify central cancer registries
- Establish a common protocol to obtain tissues from identified cases
- HPV detection and typing
- IRB/HIPAA

Cancer Registries-Criteria

- 3 NPCR/SEER Cancer Registries
 - States with high burden of disease (a sample or all cervical cancers over 3 years prior to vaccine introduction)
 - Racial/ethnic diversity
 - Geographic diversity
 - Urban/rural composition
 - Interest and cooperative Path labs
 - HIPAA regulations/IRB restrictions

Schema



Anticipated Results

- HPV type of invasive cervical cancer
 - grade and stage
 - histology
 - By race/ethnicity
 - By county level
 - By age

Advantages and Disadvantages

- Establish infrastructure in sites with high burden of disease
- Ability to add other cancer sites for HPV typing
- Population-based
- Data based on rigorous standards
- Comprehensive demographic, clinical, and path information
- Standard HPV lab
- Does not allow examination of in situ cancers or CINII/CINIII
- New added burden to state registries
- Better to work via path laboratory through a different network
- Currently HPV vaccination status not in basic data but can be easily added
- Cx carcinoma in situ discontinued as a requirement in 1996

Timeline

- Summer 2007-identify at least 3 central cancer registries
- Fall 2007-finalize protocol
 - Subcontract with Batelle and Central Cancer Registries
- Fall/Winter 2007-submit CDC IRB/state IRBs
- Spring 2007-start data collection



www.cdc.gov/cancer

The findings and conclusions in this presentation are those of the author(s) and do not necessarily represent the views of the Centers for Disease Control and Prevention