



HPV-IMPACT: Human Papillomavirus Vaccine Impact Monitoring Through Surveillance of Cervical Precancerous Lesions in California

Summary

In 2007, the Centers for Disease Control and Prevention (CDC) funded a collaboration between the California Department of Public Health-STD Control Branch (CDPH) and the California Emerging Infections Program (CEIP) to develop a comprehensive plan to conduct systematic, population-based surveillance of cervical intraepithelial neoplasia (CIN) 2/3 and adenocarcinoma in situ (AIS). The pilot phase of this project will be conducted in Alameda County.

Rationale

The recent introduction of a highly effective vaccine against human papillomavirus (HPV) exposed the need for population-based surveillance of HPV-related diseases. Although it will take decades to measure the impact of the vaccine on cervical cancer incidence, the short term impact can be assessed through surveillance of cervical cancer precursor lesions (CIN 2 and 3 and AIS). These lesions occur with greater frequency and are detectable much earlier than cancer with a peak incidence in the late 20s and early 30s. Beyond monitoring trends in CIN 2/3 and AIS incidence, a multi-faceted approach to understanding vaccine impact will involve examining vaccine penetration in the population, monitoring any changes in specific types of HPV associated with CIN 2/3 and AIS, and monitoring Pap utilization.

Objectives

1. Determine the burden of CIN 2/3 and AIS in the catchment area and collect basic demographic and clinical data on all cases. Monitor trends in CIN 2/3 and AIS incidence.
2. For a representative subset of cases, collect additional case data and obtain biologic specimens for confirmation of pathologic diagnosis and identification of HPV types.
3. Explore development of infrastructure for statewide surveillance to evaluate the impact of the HPV vaccination program, including disease surveillance, immunization registry, and behavioral surveillance.

Target population

Females 18 years of age or older residing in Alameda County

Case Identification and Data Collection

- Primary case reporting through pathology laboratories
- Supplemental demographic and clinical data collected via a standardized case report form

Human Subject Protection

- Protection of human subjects will be emphasized with Institutional Review Board (IRB) applications to the California Health and Human Services Agency, the University of California at Berkeley, Public Health Foundation and any other applicable institutions

Data/Specimen Collection on Subset of Cases (N=250 total per year)

- Biologic specimens (tissue blocks or slides) from subset of cases will be sent to the CDC for confirmation of the pathologic diagnosis and HPV typing
- Supplemental clinical data elements will be collected: HPV vaccine status; gynecologic history, previous HPV-related diagnoses, other relevant medical conditions

Evaluation

Standard epidemiologic methods will be employed to evaluate patterns of disease over time and across populations. The impact of HPV vaccination will be assessed by correlating vaccine status, disease outcome, and HPV type involvement. Data reports will be generated and disseminated with careful attention to protecting confidentiality.

Timeline

2008—Complete the planning and design phase of the project, establish relationships with local laboratories and providers, ensure human subjects approvals are in place

2009—Begin active case surveillance, data collection, and reporting

2010—Continue data quality monitoring and improvement, coordinate pathology specimen collection, data analysis and report generation

Anticipated Role of Laboratories

- Identify cases of CIN 2 or 3 and AIS
- Using existing data systems, collaborate with CDPH to identify a workable and sustainable reporting mechanism
- Collaborate with CDPH to send a subset of tissue specimens to the CDC

National Collaborating Surveillance Sites and Participating Institutions

Connecticut Emerging Infections Program and Yale University

Tennessee Dept of Health, Tennessee Emerging Infections Program, and Vanderbilt University

New York Emerging Infections Program and University of Rochester

Oregon Emerging Infections Program and State of Oregon Department of Human Services

Kaiser Permanente Northern California

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