



July 14, 2011

Norma Erickson
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Dear Ms. Erickson:

Thank you for your recent email to me at the Centers for Disease Control and Prevention (CDC) regarding the effectiveness and safety of human papillomavirus (HPV) vaccines. CDC currently has several efforts ongoing to monitor HPV vaccine impact, as well as HPV vaccine safety. Efforts to monitor the impact of HPV vaccine include evaluations of a variety of different HPV-associated outcomes. Some of these evaluations include the determination of specific HPV types. CDC has selected an optimal method for HPV DNA typing that detects and types HPV accurately.

Beginning in 2003, cervicovaginal swabs have been collected from women participating in the National Health and Nutrition Evaluation Survey (NHANES). These swabs are tested to determine individual HPV types. Types will continue to be monitored to evaluate changes after vaccine introduction.

In addition, CDC is participating in two ongoing special projects to evaluate HPV types in women who have cervical precancer lesions. Sites in five states (California, Connecticut, New York, Oregon and Tennessee) have developed a population-based system for monitoring cervical intraepithelial neoplasia (CIN) grade 2 or 3 and adenocarcinoma in situ and associated HPV types. In addition to collecting standard basic surveillance data on all reported cases, this project is determining HPV types in the precancers. CIN grade 3 is also being monitored by CDC through special projects being conducted in several state-based cancer registries funded by CDC's National Program of Cancer Registries (NPCR).

HPV typing of cancers is conducted using data from registries supported by CDC's NPCR. A pilot study to identify cancer cases and to obtain paraffin block tissues for HPV typing to establish a pre-vaccine distribution of HPV types in cervical cancer and non-cervical cancer cases has been conducted in four cancer registries (Louisiana, Kentucky, Florida, and Michigan) and in three sites using discarded tissue repositories (Hawaii, Iowa, and Los Angeles). Future periodic typing is planned to evaluate cancers and HPV types after vaccine introduction.

Your letter requests that CDC issue a directive to the vaccine manufacturers, vaccine distributors, state health departments, and healthcare providers to report the HPV genotype DNA sequence derived from the cervicovaginal cell suspension in cytology samples from women with cancer or precancer. Since HPV genotyping is not done in clinical practice, it is not feasible to have HPV genotypes from all patients with Pap test results indicating cervical precancer or cancer reported to CDC.

With respect to vaccine safety, CDC monitors post-licensure vaccine safety using two well established systems: the Vaccine Adverse Event Reporting System (VAERS) and the Vaccine Safety Datalink (VSD) Project. A research paper published by Brotherton, et al did find an increased rate of anaphylaxis (severe allergic reaction) in Australia's school-based HPV vaccination program; however, that study had several limitations which CDC considers may have led to imprecise estimates. The VSD has monitored over 600,000 doses of Gardasil and identified only one anaphylaxis case. Our findings do not suggest that Gardasil vaccine is associated with an increased risk of anaphylactic reactions.

Syncope has been among the most frequently reported adverse events to VAERS. However, syncope has been reported after administration of other adolescent and adult vaccines, so it is not unique to the Gardasil. In addition, post-licensure vaccine monitoring of Gardasil in the VSD has found no increased risk of syncope following HPV vaccine when compared to the risk of syncope following other adolescent vaccines. Because of the recognized occurrence of syncope following all adolescent vaccines and the potential for subsequent serious injury, the Advisory Committee for Immunization Practices (ACIP) has recommended that providers should consider observing patient for 15 minutes after vaccination.

CDC considers that the systems mentioned above, as well as other systems previously referenced, form a reliable, science-based, post-licensure monitoring system for evaluation of HPV vaccine impact and safety.

Thank you for your letter and for the concerns you expressed. We appreciate your interest in this important public health issue.

Sincerely,
/Lauri Markowitz/

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