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Abstract (poster session)

**Independent study on long-term immunogenicity of prophylactic human papillomavirus vaccines: preliminary results**

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**Objectives:** Two prophylactic HPV vaccines, Cervarix™ (HPV-16/18 bivalent) and Gardasil® (HPV-6/11/16/18 quadrivalent) have been licensed in many countries, including Italy. Robust immunogenicity with virtually 100% protection against HPV16/18-related premalignant lesions have been established for both vaccines. In addition, cross-protection against additional HPV types has been reported, especially for the bivalent vaccine. However, most studies were carried on by the manufacturing companies. Our aim was to perform an independent study to assess vaccine-induced neutralizing and cross-neutralizing antibodies in an Italian cohort of vaccinated girls and adolescents. The study, started on December 2011 and ongoing, is done in collaboration with other Italian Regions in order to compare the two vaccines. **Methods:** HPV type-specific neutralizing antibodies (NAbs) were measured in vaccinated subjects from 1 month after completion of the third dose of vaccine by using the pseudovirion-based neutralization assay (PBNA). Eight PBNAs were developed in order to evaluate NAbs against HPV6/11/16/18/31/45/52/58. The presence of NAbs was defined by a titre of 1:40 or higher, according to WHO guidelines. **Results:** Preliminary results were obtained from a group of 100 subjects from Veneto Region, where the quadrivalent Gardasil® vaccine was offered. The study group included 55 subjects investigated within 1-6 month since the completion of the three doses of vaccine and 15, 15, and 15 subjects investigated at 2, 3, and 4 years after vaccination, respectively. At 1-6 months after completion of vaccination, 100% vaccines had NAbs against HPV16, 98% had NAbs against HPV18, while 91% had NAbs against HPV6 and 50% had NAbs against HPV11. The NAbs titer ranged widely from 1:40 to over 1:10240 and was lower for NAbs against HPV6 and HPV11 than for NAbs against HPV16 and HPV18. A progressive reduction of NAbs titer was observed with time from vaccination and, at 4 years from vaccination, 80% of subjects had NAbs against HPV16, HPV18 and HPV6, and 60% against HPV11. Low level 1:40 anti-HPV31 cross-NAbs were detected in 43% of subjects at 1-6 months after vaccination, while no cross-NAbs were detected against HPV45, HPV52, and HPV58. **Conclusions:** High-level NAbs were induced by Gardasil®, but declined with time. Limited cross-neutralization against HPV31, but not against other HPV types, was observed.