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TESTING THE SAFETY OF THE HPV VACCINE IN HIV –INFECTED MEN: AMC STUDY # 052

ROCKVILLE, MD, MAY 11, 2011: A study investigating the safety and immunogenicity (degree of immune response) of the quadrivalent human papillomavirus (4 HPV virus types) vaccine in HIV-infected men was conducted among 112 men. This vaccine (otherwise known as Gardasil[®]) has already been shown to prevent infection with the HPV strains that can cause cervical cancer in women and anal cancer in young men who have sex with men.

The purpose of this study was to see if the HPV vaccine was safe, as well as effective in creating an immune response in HIV-positive men aged 18 years or older. Most of the study volunteers were already taking highly active antiretroviral therapy (HIV medications) and some were not. Men who had precancerous changes on anal biopsy or who had cancer of the anus or surrounding area were not eligible to participate in this study. A total of 109 men in this study received at least one dose of the study vaccine.

Mild redness and pain at the injection site were reported by several volunteers. No serious reactions to the vaccine were reported, and no effect on CD4 counts or HIV viral loads were observed. For each of the 4 HPV virus types targeted by the vaccine, 95% or more of the men in this study developed an antibody (immune) response. An antibody or immune response is important because it may prevent infection with the HPV strains that are most commonly associated with cancer. The information gained from this study will serve as an important building block as we learn more about which HIV-positive people would benefit most from receiving an HPV vaccine.

Reference: Wilkin T, Lee JY, Lensing SY, et al. Safety and Immunogenicity of the Quadrivalent Human Papillomavirus Vaccine in HIV-1-Infected Men. *J Infect Dis* 2010;202:1246-1253.
<http://www.ncbi.nlm.nih.gov/pubmed/20812850>

AIDS Malignancy Consortium Trial # 052: A Single-Arm, Open-Label Pilot Trial of the Safety and Immunogenicity of a Quadrivalent Human Papillomavirus Vaccine in HIV-1 –infected Men

For more information about HIV cancer malignancies, visit the AMC Web site at

<http://www.AIDSCancer.org>