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"Determining the Efficacy of the Gardasil-9 Vaccine in HIV-Positive Individuals"

Background: Cancer in the anal and cervical regions is caused by specific genotypes of the human papillomavirus (HPV). The Gardasil-9 vaccine is an effective vaccine that prevents HPV infection as well as decreases the chances of cancer development in the anogenital tract - specifically targeting oncogenic HPV genotypes. The vaccine has been tested to be effective in HIV-negative individuals as they have been observed to produce an antibody response to the vaccine. However, there are relatively few studies conducted that evaluate the vaccine response in people diagnosed with HIV. A higher prevalence of HPV infection, as well as pre-cancerous and cancerous lesions, are seen in the HIV-positive population so it is unclear if this is due to lack of efficacy of the vaccine or other outside factors. This study's goal is to test for HPV genotype-specific infections in the anogenital tract in well-controlled HIV individuals, as well as test the antibody response to the HPV vaccine. This project is interested in a diverse racial and socioeconomic background of individuals who have not received or fully received the Gardasil-9 vaccine.

Methods: Following the informed consent of eligible individuals for this study, a cotton swab was used to collect cellular materials from the anogenital region. Genomic DNA from the samples was extracted by lysing the cell to free the DNA from the cell nucleus and then washing it with appropriate buffers to have the DNA suitable for storing before testing. The extracted samples were nano-dropped to measure the DNA concentration using the 260/280 specific absorbance range. For testing, a polymerase chain reaction (PCR) was utilized with primer set MY09/MY11, commonly used for identifying the presence of HPV, regardless of genotype. An additional β-globin primer set, PC04/GH20, was used to ensure human DNA was present. After completing the PCR, the product was analyzed through gel electrophoresis. The DNA fragments were separated by the base pair length of the specific primer sets - detecting a band around the 450 bp range signified a positive result.

Results: Approximately 105 samples were collected, and out of those, 48 samples have been extracted and tested for HPV. From the tested samples, 34 were male and 13 were female, and the e age ranged from early 30s to late 40s. The individuals from the tested samples consisted of a majority Black/African American population (81%), with the remaining being of a white population. In total, 21 samples (44%) were positive with HPV, and of those, more than half did not receive the HPV vaccine prior to enrollment.

Discussion: This study will continue to enroll this at-risk population. The sponsor company, Merck will be testing the collected samples for serum antibodies against the 9 types of HPV in Gardasil. The high rates of HPV positivity at 44% underscores both the need for HPV vaccination and follow up screening to prevent anogenital malignancies in people living with HIV.