Poor Immunogenicity of the H1N1 2009 Vaccine in Well Controlled HIV-infected Individuals: Interim Results of an Immunogenicity Trial

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Background: Individuals with HIV infection are at increased risk of serious illness from 2009 H1N1 influenza. Current US guidelines for A(H1N1) 2009 vaccination for adults recommend the use of a 15 micrograms dose of the H1N1 vaccine. However, there is no information about the immunogenicity of this vaccine in HIV-infected adults.

Methods: We evaluated the immunogenicity, safety, and tolerability of a single intramuscular 15 micrograms dose of the monovalent, unadjuvanted, inactivated, split virus H1N1 vaccine (Novartis, Basel, Switzerland) in HIV-infected adults attending a single clinic at the University of Pennsylvania, Philadelphia. We measured antibody titers at baseline and week 3 post-immunization using the hemagglutination-inhibition assay against the H1N1 (A/California/04/2009) strain (Bioqual, Inc). Tolerability and reactogenicity were evaluated using the HVTN questionnaire.

Results: A total of 120 participants were enrolled in the trial; 71% were male, 68% were African American, and the median age was 46 years (range 21 to 77). All participants but one (99%) were on ART, with a median current CD4 of 502 (IQR 307 to 640) cells/mm³, and a nadir CD4 of 132 (IQR 38 to 253) cells/mm³. The HIV RNA level was < 400 copies/mL in 92% and BLQ in 86% of the subjects. As of December 21st, 2009, 39 participants had completed 3 weeks of follow up. At week 3, 61% of subjects achieved antibody levels above 1:40. Nine of the 39 (23%) subjects had antibody HIA titers greater than 1:40 at baseline. Among participants without evidence of previous exposure to H1N1, only 53% (95%CI 35% to 71%) develop protective titers by week 3 of the study. In this interim analysis, non-responders had lower current (P <0.05) and nadir CD4 cell count than responders. Only 1 of 4 subjects with detectable HIV viral load at baseline developed protective antibody titers. Age and race were not predictors of the response to the vaccine. The vaccine was well tolerated with grade 1 local reactions at the site of injection observed in 18% of the participants. There were no serious adverse events.

Conclusions: These preliminary results suggest that only half of well-controlled HIV-infected individuals without pre-existing immunity to H1N1 develop protective antibody titers after immunization with the recommended dose of the H1N1 flu vaccine. Alternative vaccines, dosing, adjuvants, or schedule strategies are needed to achieve effective immunization of this vulnerable population.