

Trip Report: CDC Consultation on the Use of a Partially Effective HIV Vaccine in the U.S.

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I attended this CDC consultation on January 15-16. It occurred in the context of the Vaxgen HIV vaccine trial. The trial will finish at the end of this year. A planned mid-trial data analysis late last year did not result in early termination of the trial, indicating that the lower confidence bound of the vaccine efficacy had not reached previously agreed cutoff of 30%. Details of the analysis were not released. The company has indicated that it would seek FDA licensure for the vaccine if the lower bound of efficacy achieved this level.

The consultants heard presentations modeling the impact of an HIV vaccine on the HIV epidemic in the U.S. Even a partially effective vaccine of 50-60% could have an impact on the long-term course of the epidemic, particularly if used in conjunction with other partially effective HIV prevention measures. However, the models show that a significant relapse to risky behavior in vaccinees could negate the benefits of the vaccine. Issues of implementation of a partially effective vaccine were discussed. Hepatitis B vaccine programs targeting high-risk adults were discussed as a good model for an HIV vaccine program. Greater efforts in piloting hepatitis B vaccination programs were recommended to help develop information for eventual HIV vaccine programs. The need to educate communities at risk for HIV about the vaccine and to promote vaccine readiness were also stressed. This is particularly important in minority and other communities who based on the legacy of Tuskegee and other events may distrust any HIV vaccine, but particularly one labeled as partially effective.

CDC will be publishing the results of the consultation in Clinical Infectious Diseases. I will circulate a copy of any preliminary drafts from the meeting.