

KEMRI begins Kenya's Single Dose HPV Vaccine Efficacy (KENSHE HPV) Study

Abstract:

Introduction: Cervical cancer is the leading cause of new cancer cases among women in Kenya representing a substantial burden of disease for women. HPV infection is a necessary cause of cervical cancer and preliminary evidence suggests a single-dose of the HPV vaccine would provide efficacy in excess of 95%,¹ supporting HPV vaccination as a scaleable intervention for cervical cancer prevention. An evidence gap exists on the efficacy and durability of single-dose HPV vaccine among young women in Africa.

Objectives: The primary objective is to compare immediate, single-dose bivalent (HPV 16/18) and nonavalent (HPV 16/18/31/33/45/52/58/6/11) vaccination (and delayed meningococcal immunization) with delayed HPV vaccination (and immediate meningococcal immunization) among young women age 15-20 years. We will also conduct costing, budget impact, and cost-effectiveness analyses to provide evidence for decision makers

Methods: Women age 15-20 years old will be randomized to immediate bivalent and delayed meningococcal vaccine (arm 1), immediate nonavalent vaccine and delayed meningococcal vaccine (arm 2), or delayed HPV vaccine and immediate meningococcal vaccine (arm 3) with 36 months of follow-up. The primary study endpoint is persistent vaccine type specific HPV infection at months 18 and 36. The quantitative antibody response will be documented at months 1 and 24 to support immunobridging analyses to girls and adolescents for the single-dose bivalent and nonavalent vaccines. Using the data on persistent infections and health economic models, we will assess the impact on cervical cancer incidence.

Anticipated results: Our study will evaluate whether or not single-dose vaccination impacts the incidence of persistent HPV infections. Our health economic modeling results will help policy planners assess the long-term costs, benefits and budget impact of single-dose HPV vaccine delivery, in terms of cervical cancer deaths prevented and the costs saved relative to the two or three dose HPV vaccine schedule.