

Project Brief: HPV Vaccine Impact Evaluation Study

Title	Impact of 2-dose and 1-dose human papillomavirus (HPV) vaccination schedules on community level HPV prevalence in South African adolescent girls
Purpose	To monitor the effectiveness of a 2-dose and 1-dose HPV vaccination schedules on community level HPV prevalence among South African adolescent girls
Primary Objectives	In South African adolescent girls aged 17–18 years; <ul style="list-style-type: none"> • To measure the population effectiveness of the national 2-dose vaccine schedule, delivered at age 9 years, in protecting against infection with sexually transmitted HPV16 and 18; • To measure the population effectiveness of a 1-dose vaccine schedule, delivered via a demonstration project to girls in Grade 10 of public school, in protecting against infection with sexually transmitted HPV16 and 18; and • To determine whether HIV infection status affects the protective effectiveness of HPV vaccines
Secondary Objectives	<ol style="list-style-type: none"> 1. To measure the extent of vaccine cross-protection and herd protection following the national 2-dose vaccine scheduled delivered at age 9 years; and 2. To identify sociodemographic and behavioural correlates of uptake and impact of the national 2-dose program.
Study Design	Repeat cross-sectional survey methodologies that have been pioneered to assess HPV vaccine effectiveness in Australia will be used. Through a network of sentinel sites in South Africa 3,260 girls aged 17–18, most of whom will be sexually active and therefore potentially exposed to HPV, will be invited to self-collect a specimen for HPV testing. The first round of testing, to take place in 2019, will establish baseline HPV prevalence, in the cohort that was aged 12–13 when the program began in 2014 and therefore too old to receive vaccination. In 2023, the same survey will be repeated at the same sites, to determine the extent to which the first cohort of vaccinees, who will by then have attained age 17–18, have been protected from infection by the 2-dose schedule, taking into account vaccination coverage, HIV positivity and demographic factors. In addition, the same methods to evaluate population effectiveness of a 1-dose schedule, that will be offered in February/March 2019 under a pilot “catch up” program Lwejweleputswa district, Free State to adolescent girls in Grade 10 (who were aged 10–11 in 2014) and therefore just above the age of inclusion when the national program began in 2014.
Study population	For the single dose catch-up, all Grade 10 girls in Free State will be eligible for vaccination For the HPV prevalence surveys. adolescent girls aged 17-18 years would be surveyed in 2019, 2021, and 2023

Study/Programme sites	Free State (Lejweleputswa District), Gauteng (Ward 2), Mpumalanga (Ehlanzeni District), North West (Dr K.K. District)
Study sample size	For the catch-up campaign, approximately 8700 will be eligible for vaccination For the surveys, approximately 850 participants in 2019, 1010 participants in 2021, and 1400 participants in 2023
Expected Outcomes	<ul style="list-style-type: none"> The study will provide the world's first information on population effectiveness of a 2-dose HPV vaccination schedule delivered to 9-year olds in preventing sexually transmitted HPV infection; population effectiveness of a 1-dose HPV vaccination schedule; and population effectiveness of HPV vaccination in adolescents with HIV infection. It will also provide world-first knowledge on the factors that predict vaccine coverage and population-level impact in an LMIC setting of extreme socioeconomic diversity.
Investigator	Prof Sinead Delany-Moretlwe : Principal Investigator
Protocol Team	Prof Helen Rees: Co-Investigator Dr Admire Chikandiwa: Co-Investigator
Other Partners & Collaborators	University of Cape Town National and Provincial Departments of Health National and Provincial Departments of Basic Education Kirby Institute, University of New South Wales (UNSW), Australia
Sponsors/Donors	Bill and Melinda Gates Foundation and Australian National Health Research Medical Council
Key Words	HPV, Vaccine, Adolescents, Population Effectiveness
Progress Update as at January 2019	Protocol has approved by Wits HREC on 21 January 2019 Staff protocol training is underway since 7 January 2019 Community engagement started 14 January 2019 and is ongoing Anticipated single-dose campaign start date is 6 February 2019.
Linked Sub Studies and post grad projects	TBA
Publications/key presentations to date	N/A
Frequency of donor narrative report	Monthly
Contact person (s)	Prof Sinead Delany-Moretlwe (sdelany@wrhi.ac.za) Dr Admire Chikandiwa (achikandiwa@wrhi.ac.za)
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