EXPANDING HIV PREVENTION OPTIONS FOR ADOLESCENT GIRLS AND YOUNG WOMEN

(PROJECT ENGAGE)

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Program Overview

Project Engage contributes to the advancement of new HIV prevention methods, especially for adolescent girls and young women (AGYW), and is funded by a Global Development Alliance between USAID, Gilead Sciences, CONRAD and a dedicated consortium of partners in both Africa and the US. Research activities are focused on evaluating the acceptability of and adherence to the new Descovy® (F/TAF)-based oral PrEP regimen compared to Truvada® (F/TDF) in AGYW at risk of HIV acquisition in Africa, as well as advancing innovative adherence support and monitoring tools essential to facilitating effective implementation of oral PrEP in this population. Data on barriers and facilitators to oral PrEP uptake and adherence in AGYW will be gathered to inform future decision-making and programming. Project Engage will also generate effectiveness and implementation data on an AGYW tailored adherence support intervention via a newly-designed smartphone app, *Vuka+*. Furthermore, we will develop and validate a new point-of-care (PoC) adherence monitoring assay and conduct pilot implementation studies of new PoC adherence assays in African settings. Altogether, Project Engage will provide evidence supporting the implementation of HIV oral PrEP regimens for AGYW in Africa.

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Activities – Project Updates

Acceptability Study of Oral F/TAF vs F/TDF for the Prevention of HIV Acquisition in AGYW

In partnership with MatCH Research Unit (MRU) and CAPRISA in South Africa, and Harare Health and Research Consortium in Zimbabwe, we are conducting a study to assess AGYW acceptability and adherence to daily regimens of F/TAF and F/TDF. The study will recruit 330 participants (aged 15-24) who will be randomized 1:1 to receive F/TAF or F/TDF orally once daily for 6 months. The main endpoint of the study is acceptability measured by discontinuation rate, attendance at follow-up visits, responses to quantitative assessments, and qualitative data collected through in-depth interviews and focus group discussions. Secondary and exploratory endpoints include adherence, measured through dried blood spot (DBS) analysis and behavioral assessments, and validity of psychometric adherence scales.

Status: As of October 2023, two of three sites have completed all follow-up visits, and the last participant last visit (LPLV) for the final site is planned for December 2023. Preliminary study results are expected mid-2024.

Refinement & Testing of a Novel Smartphone-Based Adherence Support Intervention

This activity aims to assess the effectiveness and implementation of a new mobile health (mHealth) PrEP adherence support intervention designed specifically for AGYW in Africa. In collaboration with Desmond Tutu Health Foundation (DTHF) in South Africa, University of North Carolina and Florida State University (FSU), CONRAD is conducting a two-phase testing of the new adherence support smartphone app, ***Vuka+.*** The first phase is a 4-week ***pilot study*** that recruited ~30 AGYW to assess the usability and acceptability of the intervention app. After refinement of the app based on the pilot data, phase 2 includes a Type I Hybrid ***effectiveness and implementation study*** in 330 participants (aged 15-24) in South Africa. Participants will take daily oral F/TDF and be randomized 1:1 to ***standard of care (SOC) counseling vs SOC plus app intervention***. The primary endpoints are adherence measured by DBS, acceptability and usability of the app, and feasibility of app implementation in a research setting.

Status: The pilot study was completed in 2022, and the Vuka+ app was refined based on those pilot results. As of October 2023, the Effectiveness and Implementation study is fully enrolled and LPLV is expected in April 2024. Preliminary data from this study are expected in Q3 2024.

Adaptation of the Vuka+ app to a text format within the WhatsApp platform is currently ongoing, in collaboration with FSU and One Cow Standing.

Clinical Validation & Implementation of Point-of-Care Adherence Diagnostics

To address a gap in implementation and increase adherence to oral PrEP, Project Engage will clinically test new point-of-care (PoC) antiretroviral monitoring assays, as well as conduct a ***pilot implementation study*** in a service delivery clinic in South Africa. ***CONRAD-150***, the clinical validation study, is being conducted at EVMS in the US in collaboration with Old Dominion University (CONRAD's partner in the development of a novel TFV and FTC assay called SAM, or Spectral Antiviral Monitoring), and University of Colorado (LC-MS/MS of DBS, the gold standard comparator), and will also generate data supporting SureQuick urine test kit for TFV and University of Washington's RESTRICT assay for TFV-DP and FTC-TP.

Status: A pilot implementation study of the SureQuick assay was completed in 2022 in collaboration with MRU. The CONRAD-150 clinical validation study is in progress with results expected in 2025.

Capacity Building, Research Utilization & Community Engagement

Working closely with Project Engage's Global North + South partners and considering local research community needs, the program aims to strengthen research capacity focusing on innovative aspects of each of the program's activities, including webinar-based training series on psychometric scales (available at https://engage.avac.org/courses/project-engage/) and mHealth (ongoing). With AVAC support, we aim to strengthen awareness, local community engagement, and dissemination of Project Engage activities to broad stakeholders, including local, regional and national HIV PrEP advocates and civil society representatives. Critical to this effort was the establishment of a dedicated Project Advisory Group comprised of 14 AGYW and young men from South Africa and Zimbabwe who serve as an ongoing, independent mechanism for bidirectional stakeholder engagement and program input starting as early as protocol design stages.

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