Project Brief: DAISY – Specific Aim 3

Full Title of Study/Programme	Delivery of Antiretrovirals via Implantable System for Young Children (DAISY) Specific Aim 3
Technical Focus Area/Key Words	HIV-infected children, antiretroviral treatment, long-acting treatment approaches, implant, acceptability
Rationale	SA reports one of the highest populations of HIV-infected young children and of the 55% of children that receive ART only 67% are virally suppressed. Adherence and retention in care are affected by multiple challenges with formulation and dosages for children, including poor palatability of drugs, high pill burden, and difficulty in swallowing. Simplified dosing regimens and long-acting (LA) ART formulations are needed to improve treatment success for children who face a lifetime of ART. Delivery of ART via implantable system for young children (DAISY) is one such formulation currently in development. Integrated research on product development and end-user preferences is critical for successful product development. For technology optimization and future implementation of the DAISY into clinical practice, research is needed on end-users' perspectives on (1) acceptability and preferred characteristics of the DAISY system for pediatric treatment, (2) considerations for future implementation within the existing health care system in SA, and (3) biodegradability of the inserted implants.
Primary Objectives	To measure acceptability of, and preferences for the DAISY drug delivery platform among two key end-user groups in South Africa (SA): caregivers of HIV-positive children receiving antiretroviral therapy (ART) and health care providers. These end-user perspectives are linked to the Target Product Profile (TPP) and will inform design of the DAISY, including device and applicator characteristics.
Secondary Objectives	N/A
Primary Endpoint/Outcome	N/A
Secondary Endpoint/Outcome	N/A
Study Design	Iterative qualitative study
Study arms	N/A
Study population	Health care providers serving pediatric HIV-infected populations and caregivers of HIV-infected children aged 2-5 who have been treated with antiretroviral treatment for at least 6 months.
Study sample size	24 Healthcare providers and 16 caregivers for in-depth interviews; 34 caregivers participated in 8 focus group discussions
Follow up/duration	No follow-up
Study/Programme sites	Hillbrow Community Health Centre, Yeoville Clinic, Harriet Shezi Children's Clinic and Tembisa Hospital Paediatric HIV Clinic
Study/Programme duration	2 Year funding period: January 2020 – February 2022
Investigators	• Lee Fairlie, Wits RHI • Elizabeth Montgomery, RTI International • Fiona Scorgie, Wits RHI

Other Partners & Collaborators	RTI
Sponsors/Donors	NIH
Linked Sub Studies and post grad projects	Nil
Publications/key presentations to date	1. One manuscript using the HCP data has been published. The tittle of the manuscript: Acceptability of Implants for HIV Treatment in Young Children: Perspectives of Health Care Providers in Johannesburg, South Africa. AIDS Patient Care STDS. 2022 Oct;36(10):389-395. doi: 10.1089/apc.2022.0087.PMID: 36286579 2. Second manuscript using caregivers' data is still in progress
Progress Update as at 04/2024	Protocol approved by HREC Staff hired
Frequency of donor narrative report	Quarterly reports were submitted to NIH programme officer
Overall Study/Project Contact	Lee Fairlie
Briefing owner and date	Fiona Scorgie, 15/10/2020