|  |
| --- |
| **Title:** Analysis of factors associated with adherence on second-line antiretroviral therapy (ART) in the Johannesburg Inner City, South Africa: A mixed method cohort study |
| **Short Title:** Second-line ART adherence study (SAS) |
| The aim of the study is to understand/recommend what the ultimate profile of enhanced second line ART regimens should be, from the patients on second-line therapy, to improve adherence, patient clinical outcomes and possibly avert progression of disease. |
| **Design and Study Population** | The study will employ a mixed method phased approach: **Phase I: (Quantitative):**Using the South African ART monitoring and evaluation system TIER.Net a database will be developed of all clients on/switched to second-line therapy between 01 January 2014 and 31 December 2015. The patients will be disaggregated according to whether they are active or inactive in the ART programme with the active patients being further disaggregated into whether they are virally suppressed or failing. This period was therefore chosen because a 12 month viral load reading post switching will be used to categorise/classify patients. Some active patients will be selected for Phase II.**Phase II (Mixed method):** 150 Active patients from Phase I will be invited to participate in semi-structured interviews to explore variables including (but not limited to) reasons for switching from a first-line regimen, experience with the ART – especially the current regimen (i.e. size and number of the pills, frequency of taking medication, tolerability), disclosure, living conditions, co-morbidities, nutritional status, level of education, employment status, distance to health facility and cultural beliefs. |
| **Primary Objectives** | To determine factors (e.g. socio-demographic; disclosure; nutrition) associated with viral load suppression (and treatment failure).To understand acceptability and adherence in second-line patients who are virologically suppressed and those who are not virologically suppressed. |
| **Secondary Objectives** | To describe patients on second line ART in selected City of Johannesburg Region F facilities. |
| **Participating Site/s** | This study will be conducted in eight health facilities in City of Johannesburg Region F facilities. This includes all levels of care**:** **1) Primary Health Care**: 80 Albert Clinic, Jeppe Clinic, Joubert Park Clinic, Malvern Clinic, Rosettenville Clinic**2) Community Health Centre:** Hillbrow Community Health Centre and **3) Hospitals**: Charlotte Maxeke Johannesburg Academic Hospital (CMJAH) and South Rand Hospital (SRH) |
| **Duration** | September 2017 – December 2018 |
| **Key Milestones** | Completion of Phase I - September 2018Completion of study - December 2018/January 2019 |
| **Partners & Collaborators** | City of Johannesburg Region F facilities |
| **Progress Update as at August 2018** | Phase I (Quantitative): Draft manuscript circulated for comment Phase II (Mixed method): Data analysis |
| **Publications**  | Planned submission for final study results in December 2018 |
| **Overall Study/Project Contact** | Samanta Lalla-Edward (slalla-edward@wrhi.ac.za) )  |
| **Updated on**  | 20 August 2018 |