LAUNCH OF THE EAPoC VL STUDY

STUDY SITE RECRUITMENT

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EAPOC- VL is part of the EDCTP2 programme supported by European Union under grant agreement *RIA2019IR-2873*

Specific Objective 1

To assess effectiveness of PoC for HIV viral load (VL) monitoring on improving VL suppression among children and adolescents living with HIV.

- The objective will be achieved by conducting a cluster randomized trial (WP1).

In particular the study will:

- Assess whether the use of PoC VL testing will improve VL suppression among children and adolescents.
- Determine if the use of PoC VL testing can improve the VL monitoring schedule by eliminating missed opportunities.

Distribution of Sites/ Clusters

- Twenty (20) sites / clusters will be selected from four countries with the proportion depending on the number of participating institutions per country:

-Uganda will have **six (6) sites** from two partners: MUL and UVRI.

- Tanzania will have **six (6) sites** from three partners: NIMR, KCRI and KI.

- Rwanda will have **four (4) sites** from one partner, UoR.

- Kenya will have **four (4) sites** from one partner, KEMRI.

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Randomization of Clusters

- The 20 clusters (units of randomization) will be randomly assigned in a 1:1 ratio to either the intervention or control arm.

- **Intervention Arm:** Routine HIV VL monitoring will be done using PoC VL testing i.e. m-PIMATM HIV-1/2 VL test on the m-PIMA Analyzer, in addition to the standard of care.

- **Control Arm:** Routine HIV VL monitoring will be centralized (standard of care).

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Participants per Cluster

- We will recruit 1,200 children and adolescents (≤19 years) living with HIV and having unsuppressed viral load.

- Each cluster will enroll 60 participants as follows:

  - <5 years (20 participants)

  - 6-12 years (20 participants)

  - 13-19 years (20 participants)

Implementation Plan

Work Package 1 Lead(s)	Activities for Site Identification (To be discussed further)	Responsible Institution(s)	Timeline
MUL (Lead) **KEMRI (Co Lead)**	Partner institutions identify potential sites for the study. Partner institutions to communicate if identified sites have adequate numbers of unsuppressed children and adolescents in each age group (see Excel). Partner institutions to communicate numbers of children and adolescents missing VL bleeds in the past quarter (Jan-Mar 2021). Partner institutions to communicate new numbers of unsuppressed children and adolescents that potential sites identify on a monthly basis.	Kenya; (KEMRI) Rwanda (UoR) Tanzania (KCRI; NIMR; KI) Uganda (MUL; UVRI)	Activities completed by 25th April 2021

Unsuppressed Numbers from Selected sites

Facility	Unsuppressed				Missing/ Lost to Follow Up			
	<5 yr	6-12 yr	13-19 yr	TT	<5 yr	6-12 yr	13-19 yr	TT
TASO- Masaka	8	31	12	51	4	43	24	71
Uganda Cares- Masaka				83				
Mild May								
TASO- Entebbe				28				

Challenges and Way Forward

Current Challenges

- Small numbers of unsuppressed children and adolescents at some proposed sites.

- Very small numbers of unsuppressed children in the <5 years age group.

Way Forward

- Discuss challenges with team at the EA PoC VL study launch
- Harmonize suppression (and other) criteria across sites

Activities at site level for WP2

- Implemented only in intervention sites.
- Coordinator activities: PhD student KCRI.
- Training Research Asisstants (1 in each country/partner).
- (T0-before intervention): Participant observation & In-depth interviews HCW - different levels

Activities for WP2 cont'd

- In-depth interviews/focus group discussions with children / adolescents / caregivers (T1-one month after/T2-six months after)
- Survey (Year 3)
- Interviews with policymakers (year 3)
- Data will be collected by research assistants
  - Trained in mixed methods data collection
- Needed: trained research assistant (MSc), topic guides, database (both for qualitative and quantitative data), software

Activities for WP3

- Partners & organisation
  - Level A engagement: 4 partners (UVRI, KEMRI, KCRI, UR)
  - Level B engagement: contributors to WP3
- Task 0: Preparation

- RW: Establish WP3 Implementation Group (LEVEL A) and WP3 Advisory Group (LEVEL B)
- LEVEL A (Obl): Hiring and identifying staff (+ data collection teams) at different sites
- LEVEL A (Opt/Obl) + LEVEL B (Opt): Identify and list standardized questionnaires to be adapted and used in formative phase, including stigma (for adolescents/children only?) + sample size calculations
- LEVEL A (Opt/Obl) + LEVEL B (Opt): Identify/Adapt/Create standardized tool to capture 'Best Existing Practice': look into successes and frustrations of the health professional-child/adolescent-caregiver interactions from a youth centred perspective
- LEVEL A (Opt/Obl) + LEVEL B (Opt): Finalize sit-in observations methodology, including creation of observation sheet
- LEVEL A (Opt/Obl) + LEVEL B (Opt): Finalize qualitative research methodology to study the psycho-social impact of coping with the care process, including stigma, using free listing interviews (Quinlan, 2017), experience sampling (Fazeli et al., 2017), semi-structured exit interviews, and FGD.
- RW: Create detailed data collection plan in collaboration with other WPs

Activities for WP3 cont'd

- Task 1: Formative Research Phase
  - LEVEL A (Obl) + LEVEL B (Opt): Sit-in observations in 4 sites
  - LEVEL A (Obl) + LEVEL B (Opt): Running quantitative questionnaires in 4 sites
  - LEVEL A (Obl) + LEVEL B (Opt): Use tool to capture 'Best Existing Practice' in 4 sites
  - LEVEL A (Obl) + LEVEL B (Opt): qualitative research in 4 sites
  - RW: Psychometric validation
- Task 2a: Development of tool
  - RW: Identify software developer
  - RW: Develop draft tool
  - RW + LEVEL A (Opt): Test the tool alongside 'baseline' quantitative questionnaires + power calculations + psychometrics in Rwanda sites + eventual adaptation
  - LEVEL A (Obl) + LEVEL B (Opt): Share inputs on tool development throughout the process
- Task 2b: Development of micro-interventions
  - LEVEL A (Obl) + LEVEL B (Opt): Based on 'Best existing practices', propose list of micro-interventions
  - RW: Develop and fine-tune micro-interventions through action research
  - LEVEL A (Obl): local adaptation + test feasibility of micro-interventions in four sites
- Task 3: Test Proof-of-concept (integration in RCT in 4 intervention sites for final six months)
  - LEVEL A (Obl): 'baseline 2' measurement in 4 sites, using 'baseline quantitative questionnaires' and newly developed tool
  - LEVEL A (Obl): Implement micro-interventions and use of newly developed tool for 6 final months of the project in 4 interventions sites, 1 per country
  - LEVEL A (Obl): 'endline 2' measurement in 4 sites, using 'baseline quantitative questionnaires' and newly developed tool

Implementation Plan cont'd

WP Lead(s)	Activities for data collection	Responsible	Timeline
MUL (WP1) AIGHD (WP2) UoR (WP3) KEMRI (WP4) UVRI (WP6)	**Personnel issues: who will be hired where?** **Management and analysis of qualitative / mixed data** **Challenges** -Online training: role plays are a challenge -language and translation -common means of data collection -regular briefing from the field	**AIGHD & UoR**	To be discussed

Community Engagement (WP6)

- Identify/map and analyze stakeholders.
- Build rapport and obtain consents & acceptances to support recruitment & retention of study participants.
- Engage stakeholders to inform & obtain feedback.
- Facilitate and support communication among WPs, study participants, and stakeholders.
- Facilitate dissemination and advocate for adoption/exploitation of study findings.

Activities at site level for WP6

- **Engage stakeholders to inform & secure buy-in to conduct the implementation research in East Africa (Kenya, Rwanda, Uganda& Tanzania)**

  - Research approval boards- Institutional Ethics boards, National approval institutions
  - Policy makers – Ministries of Health, HIV Implementing Partners, Development partners/donors
  - Local Government officers providing oversite to study sites – Regional & District Health Officers
  - Study site – health facility management, HCWs involved in HIV care
  - Study Participants - care givers, children & adolescents
  - Support structures and mechanisms for study participants

Activities at site level for WP6 Contn.

- **Coordinate the collaborative effort among partner institutions & Research teams**

  - Conduct prerequisite engagements to ensure readiness of study teams to recruit study participants, support mobilization for short training of research teams and stakeholders.
  - Support synchronization and logical flow of research activities across work packages
  - Provide platforms and mechanisms for information sharing and feedback among work package teams
  - Advocate for adoption of POC VL monitoring

Implementation Plan cont'd

WP Lead(s)	Outline of community engagement Activities (To be discussed further)	Responsible	Timeline
MUL (WP1) AIGHD (WP2) UoR (WP3) KEMRI (WP4) UVRI (WP6)	Community Engagement to involve selected sites, reach out to missing children for possible enrolment into the study, prepare for site activation and trainings Challenges	**UVRI**	To be discussed

Implementation Plan cont'd

WP Lead(s)	Outline of Other Activities (To be discussed further)	Responsible	Timeline
MUL (WP1) **AIGHD (WP2)** **UoR (WP3)** **KEMRI (WP4)** **UVRI (WP6)**	Electronic data capture. Data collected by site staff at ART clinics Data cleaning: Data queries generated by KEMRI and sent to partner institutions who then liaise with site staff at ART clinics to resolve queries and partners feedback to KEMRI. **Needed:** Project RA to liaise with sites for data cleaning or site staff to do the data cleaning. **Communication methods**: Use of shared folders, emails, etc..?	**KEMRI & NIMR** MUL (ensure timely data mgt)	To be discussed

THANK YOU

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