



Integration of the Adherence Ancillary Study with the PrEP Trial: The Kabwohe Experience.



Alex Kintu, Nicholas Kamara, Deo Agaba, Godwill Wana, Eugene Rukundo, Elioda Tumwesigye, Stephen Asiimwe

BACKGROUND

KCRC is one of the nine sites conducting the Partners Pre-Exposure Prophylaxis (PrEP) Study. Since site activation in July 2008, KCRC is now conducting a number of ancillary studies to the PrEP study namely: the Adherence Study, the Fertility Intention Study and the Daktari Study. To maintain site efficiency, the different studies' activities have been integrated following each study protocol. This poster details challenges, lessons learnt and the way forward for the integration of the ancillary adherence study (AAS) into the PrEP Study.

OBJECTIVE

To highlight the challenges and benefits of enrolling PrEP trial participants into the adherence ancillary study

DESCRIPTION

A number of study activities are cross cutting for the two studies. Below are some of the areas of integration;

Clinic:

- Concurrent consenting and monthly follow up of participants.
- MEMS cap wake up and download along with scheduled PrEP pharmacy activities.
- Processing and shipping of blood samples from home visits
- CRF binder assembling, filling, QC and faxing.

Community:

Community activities for the two studies that are in same geographical regions are scheduled on the same day. These include retention and recruitment activities, AE follow-up, community sensitization, unannounced pill counts, unannounced blood draws and locator updating.



Fig 3: Kabwohe Site Staff with Prof C.Celum and Dr. P.Ndase

APPROACHES TO INTEGRATION

- Sharing resources; personnel, vehicles, office space, etc
- Joint trainings for all staff
- Weekly general, departmental and Heads of Department meetings.
- There is collective responsibility, teamwork and multi-tasking by all staff involved in research

ACHIEVEMENTS

- Over 488 couples have been enrolled in the PrEP study and over 260 in the AAS
- All research staff trained in both studies.
- Improved adherence for participants who have received intervention counseling
- Better coordination of the two studies community activities.
- Budgetary support for activities that share resources for the two studies.

"Being home visited encouraged me to honor my clinic appointments and swallow my pills because it showed that Kabwohe staff have gone the extra mile by coming to my home just like I travel to the clinic every month to pick my study pills"

PrEP partner participant

Fig 1: Comparison of PrEP and AAS milestones

	PrEP	AAS
Site activation	July 2008	November 2009
Target study size	528	400-800
Number enrolled*	489	262
Clinic retention*	95	93%
Home visit retention*	N/A	77%

*August 2010

Fig 2: Unannounced home visit for pill counts



CHALLENGES

- Large numbers for follow-up in the community for both studies.
- Inability to enroll PrEP participants who would like to participate in the AAS at a particular time. A pre-set number of participants is enrolled to ensure optimal follow up at home visits.
- Increased clinic waiting times.
- Challenges in coordinating different studies' activities even when they are in the same region. This is due to conflicting priorities.
- Risk of unwanted disclosure during unannounced home visits.
- Short turn around time for delivery of home visit blood samples.
- Specimen handling for samples delivered beyond working hours.

WAY FORWARD

- Lower and planned enrolments into the AAS.
- More training of staff so as to be competent in all studies' activities.
- More planning and integration of community activities to maximize output using the available resources.
- Maximize retention for the two studies.

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