East Africa Sites

[Map showing sites such as Tororo, Mbarara, Uganda, Nyanza, Kenya, Tabora, Tanzania, with color coding for percentage values.]
Study Endpoints

HEALTH OF THE COMMUNITY

Community Health
HIV, TB, Malaria
Mortality: overall, maternal, child

Community Productivity
Employment
Productivity
Education
COMMUNITY BASED OUTCOMES OF EARLY HIV TREATMENT

Communities and Intervention

Intervention Communities
Annual HIV testing
Offer ART to all
Modified ART for pregnant women

Standard Communities
Annual HIV testing
Country Guidelines ART initiation
Country Guidelines PMCTC

Assessment Phase Year 1
Community Health

HIV Incidence
Prevalence
MTC T
AIDS Diagnosis
Drug Resistance
Community Viral Load

TB Incidence
Prevalence
Drug Resistance

Malaria Incidence
Severe cases

Intervention Phase Years 2 - 6

Community Productivity

Education

Economics
Productive work days
Agricultural output
Health care utilization

Outcome Phase Year 7
Year 4

35
Cluster Randomized Trials

Key feature of CRT is randomization at the level of an identified group (cluster).

Outcomes are generally measured at the group level, but not exclusively (e.g., mortality rates, community viral load or household income measures).

Number of groups often limited

Complex hierarchical design & analysis
Key Design Issues for the Community Randomized Trial

- Number of clusters (communities) to randomize?
- How to define communities uniformly
- How to handle contamination of intervention & control conditions
- Recent applicable advances in CRT design, power calculation and analysis
Number of Clusters (Communities) to Randomize

Minimum number of clusters to be randomized is driven by:

- Magnitude of outcome difference to be detected - *we set this*.
- Prevalence or rate of outcome(s) - *directly observable or estimated*.
- The degree of group level clustering of responses to be measured cross-sectionally and over time (intra-class correlation - ICC) - *most often unknown and difficult to measure*. 
Number of Clusters (Communities) to Randomize?

Rare to have a CRT with less than 20 randomized groups, >40 is the rule.

Recent push to publish ICCs from trials
- HIV incidence ICCs from HPTN-043 will be available by end of 2011.

Refinements of CRT power-calculations now published.

Randomizing within matched or stratified clusters can increase power.
The Community as the Cluster

How to define communities uniformly

Traditional methods relying on artificial geographic boundaries have been found lacking.

Advances in graphical information systems (GIS) useful in Africa to understand malaria and tuberculosis.

Recent success in Africa in combining geospatial mapping with ethnography and participant information gathering techniques.