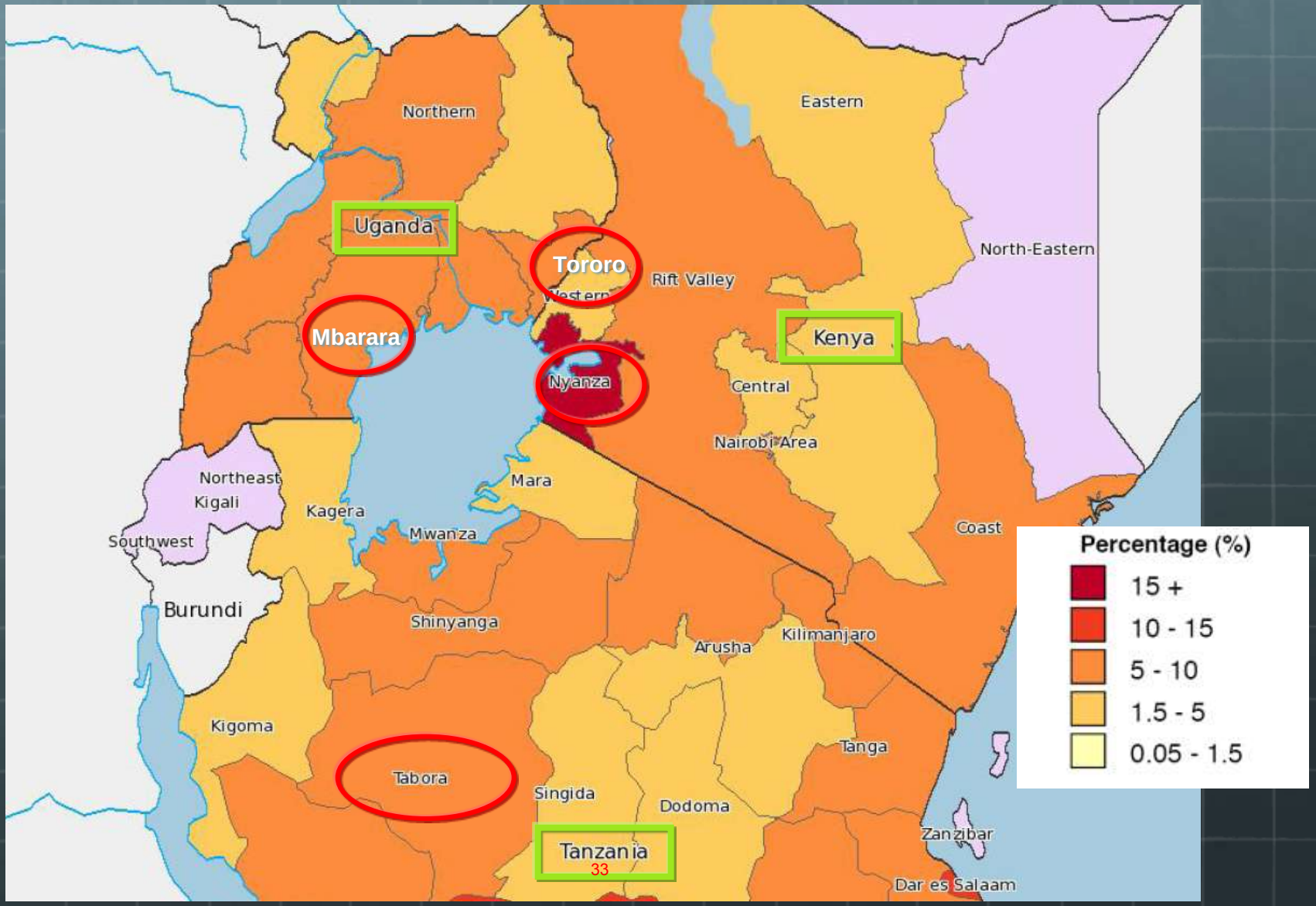
East Africa Sites



Study Endpoints

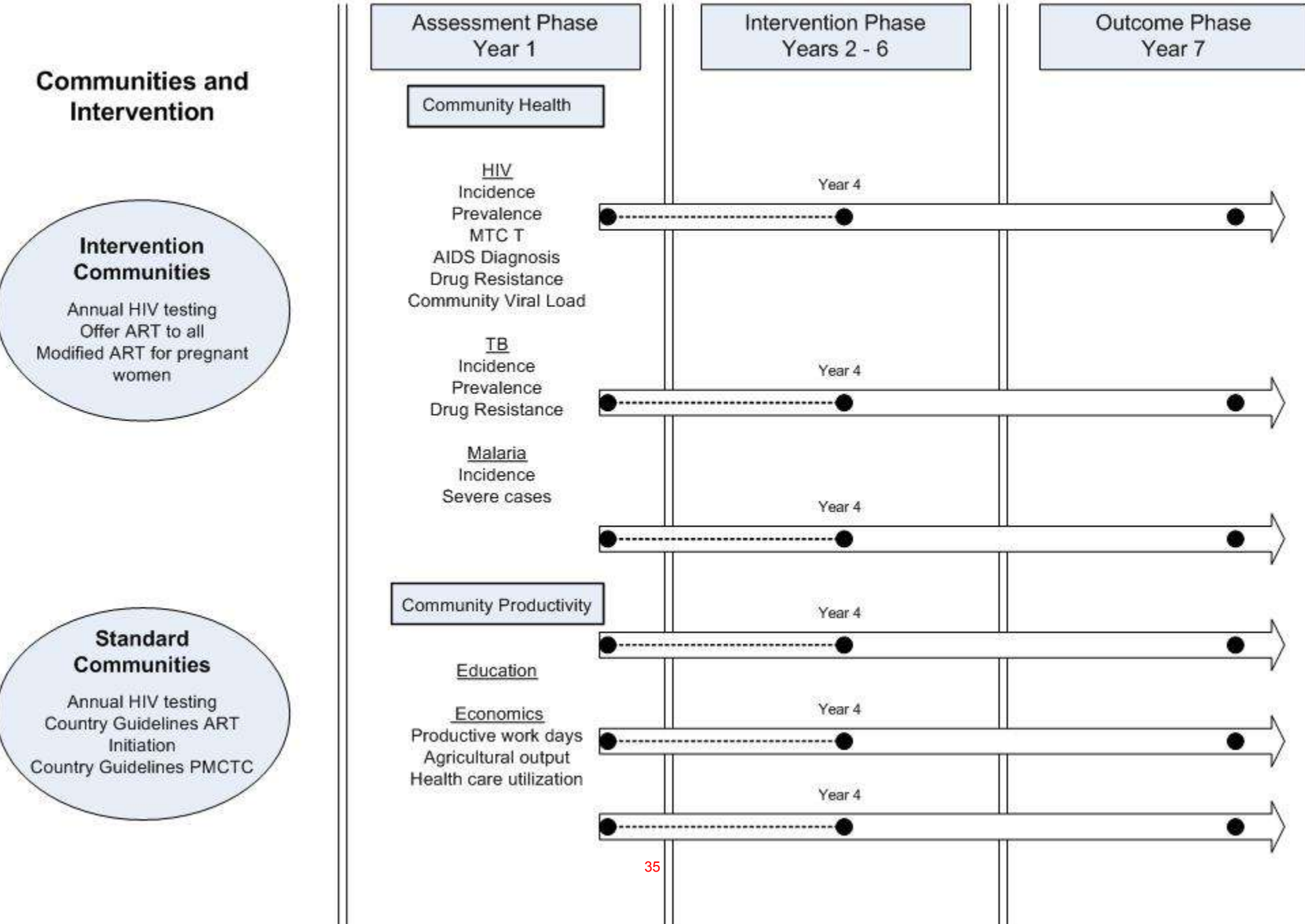
HEALTH OF THE COMMUNITY

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

+

Community Productivity
Employment
Productivity
Education

COMMUNITY BASED OUTCOMES OF EARLY HIV TREATMENT



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 (eg. 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 geo-spatial mapping with ethnography and participant information gathering techniques.