# Project Accept - HPTN 043

- HPTN 043 : 48 community CRT testing a multi-level HIV prevention intervention with HIV incidence as the outcome.

- Established 4 phase protocol to define community boundaries:
  1. Review existing census data and GIS maps.
  2. Gaining community entry and conducting visits.
  3. Participatory mapping and transect walks.
  4. Identifying and locating fixed and mobile health facilities.

- Well identifies social boundaries and study community matching variables.

Mapping Health Facilities

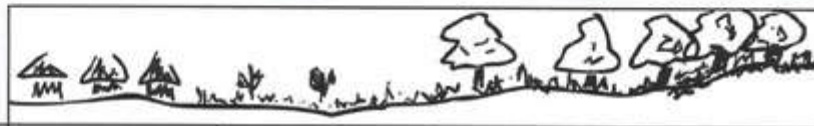Tororo District Health Centers and 2002 Parish Population
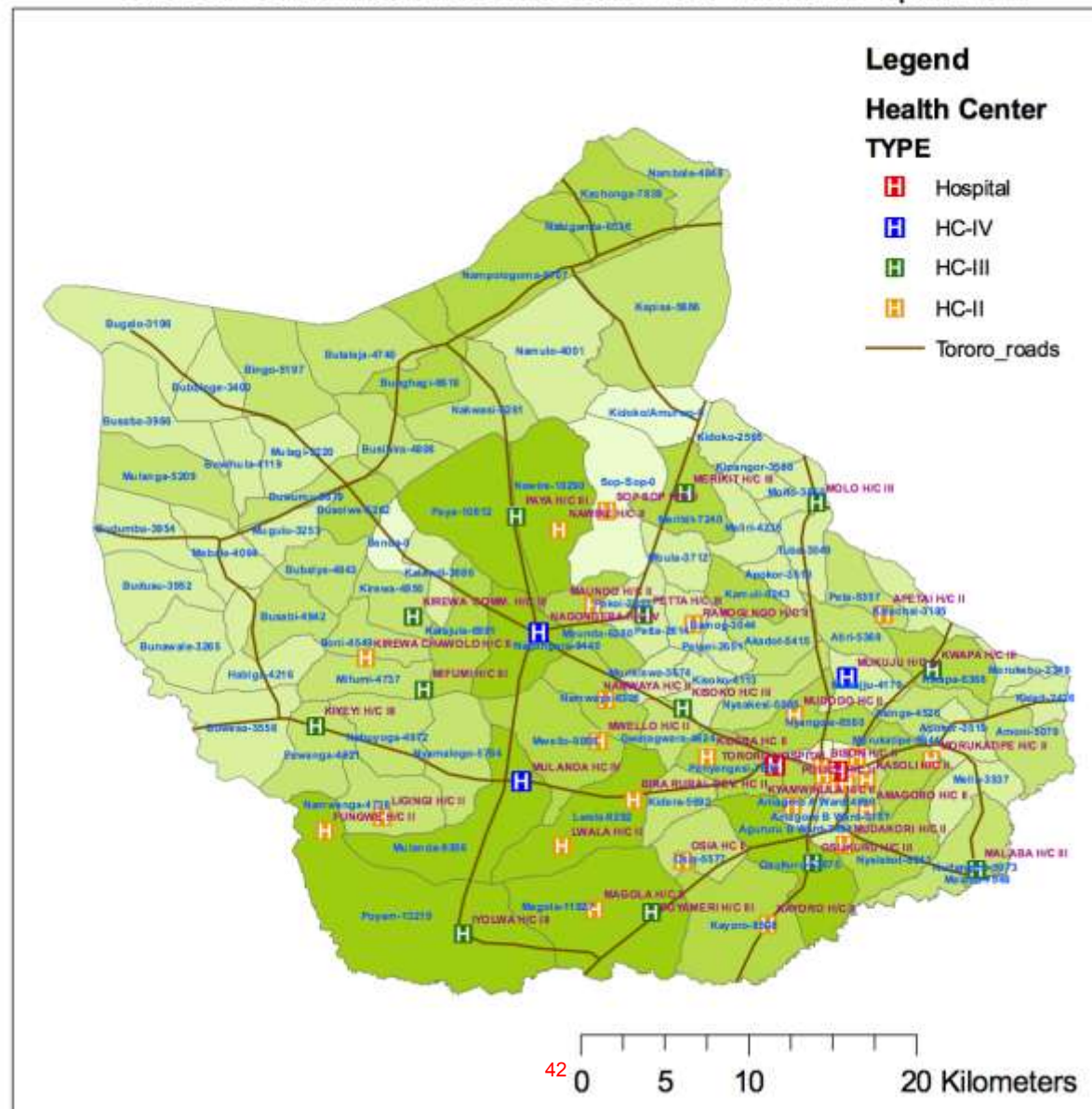
Village Map Example
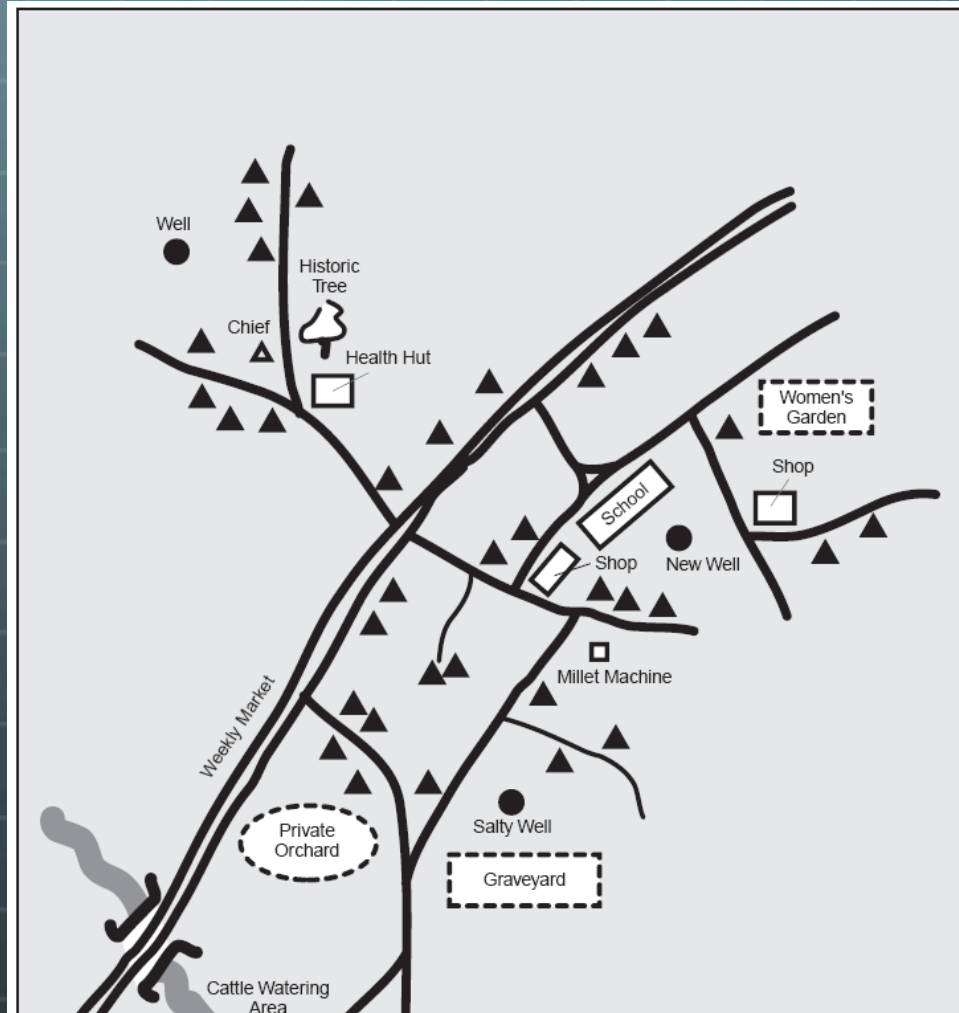
Transect Walk and Social Variables

**Example of a Transect Focused on Food Security and Nutrition Issues**

Zone	Central Village	Inner Fields	Outer Fields	Forest
Food production / gathering	• Household vegetable gardens, chickens, papaya, mango, and orange trees • Goats fenced in during rainy season	• Groundnuts, corn, some hibiscus in women's garden • Some tree products • Small ruminant grazing during dry season	• Millet, sorghum, some rice • Watering holes for animals • Karite trees • Cattle grazing during dry season	• Fruit from baobab, wild date, fig and other wild trees, honey • Cattle grazing during rainy season
Food processing and storage	• Dried vegetables and fruits • Groundnuts in women's fields	• Family granaries in or near fields	• Oil processed from karite nuts	
Health issues	• Some wells unkempt, not sanitary • Health unit lacks trained nurse • No use of mosquito nets			• Many medicinal plants harvested from forest area • River at forest edge is source of XXXXXX

Contamination of intervention & control conditions

Methods to handle potential contamination of experimental conditions:

- New equations to adjust number of clusters to account for contamination - (Slymen & Hovell - Int. J. Epidem.)

- Positioning of study communities with surrounding non-randomized "buffer-Communities".

- Inclusion of contamination estimates in hierarchical modeling of intervention effects.

Buffer Communities Reduce Contamination
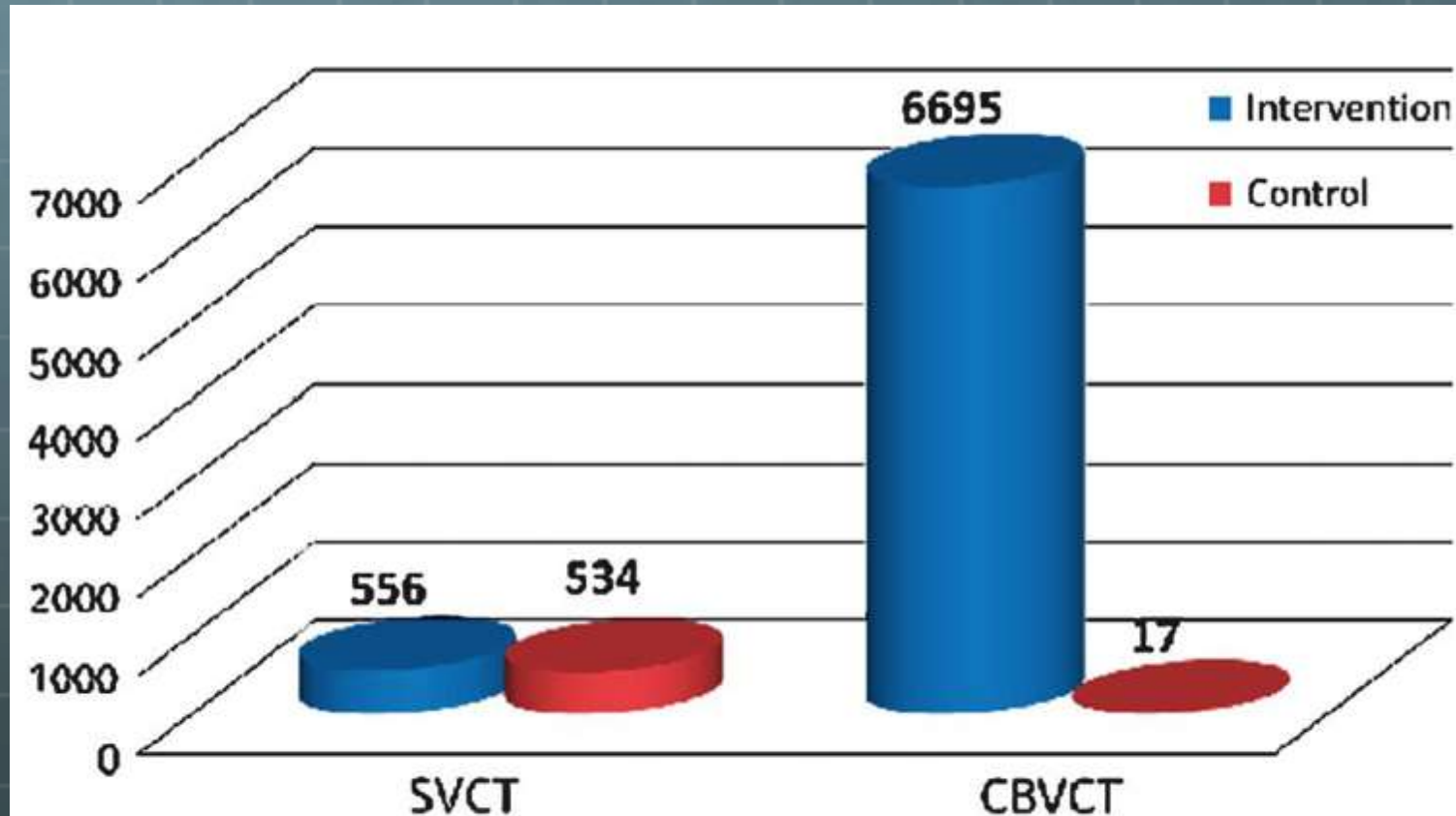
FIGURE 4. Zimbabwe—CBVCT and SVCT utilization by community of origin (initial 24 months).

Identifying Buffer Zones
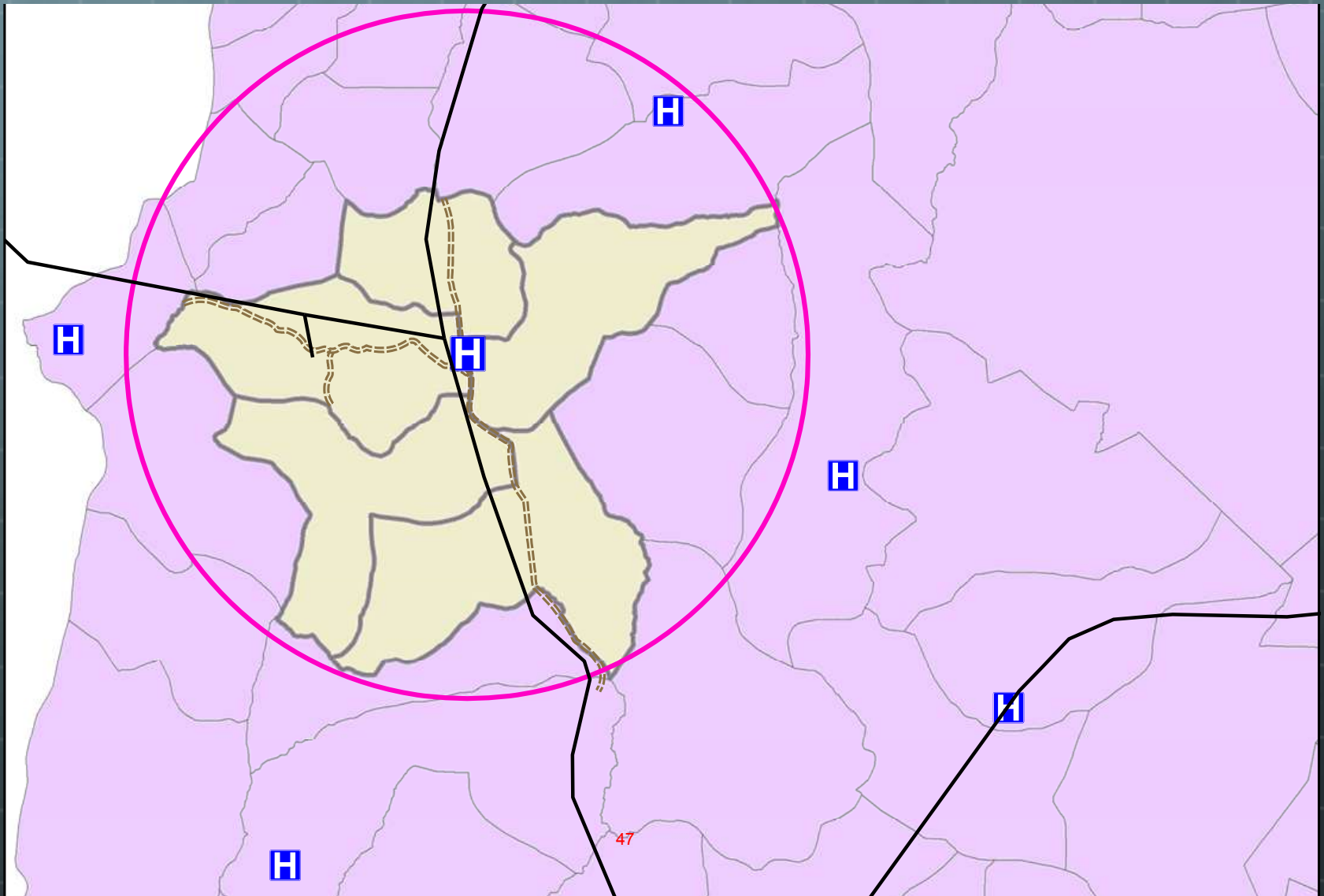
Sample Size Calculation

$$N(1 + \log \hat{\sigma}^2 + \log 2\pi) + (N - k) \log (1 - \rho) + \sum_{i=1}^{k} \log W_i,$$

$$\hat{\sigma}^2 = \left[\sum_{i=1}^{k} \frac{W_i - \rho}{W_i} \sum_{i=1}^{n_i} (X_{ij} - \hat{\mu})^2 - \rho \sum_{i=1}^{k} \sum_{j=1}^{n_i} \sum_{l \neq j}^{n_i} \frac{(X_{ij} - \hat{\mu})(X_{il} - \hat{\mu})}{W_i} \right] \bigg/ N(1 - \rho),$$

$$\hat{\mu} = \left(\sum_{i=1}^{k} \frac{n_i \overline{X}_i}{W_i} \right) \bigg/ \sum_{i=1}^{k} \frac{n_i}{W_i},$$

$$\overline{X}_i = \sum_{j=1}^{n_i} X_{ij}/n_i \quad \text{and} \quad W_i = 1 + (n_i - 1)\rho.$$

- Around 10 clusters per arm and 3000 person-years follow-up per cluster would give 90% power to reject an effect of less than 10% if the true effect is 50%