HPTN 043

Funding from NIMH, NIAID and NIDA
NIMH Project Accept
(HPTN 043)

• A **community-level intervention** designed to change:
  – discussion about HIV,
  – disclosure of results when appropriate,
  – community norms and risk reduction for HIV infection among **all** community members, irrespective of whether they participate directly in the intervention

• **Uses 3 strategies:**
  – Remove logistical barriers to VCT; provide rapid and ‘routine’ VCT
  – Engage the community through outreach; and
  – Provide post-test support services
The Three Strategies of Project Accept

Community Mobilization
- Community Buy-in
- Support at the highest levels
- Testimonials from early adopters
- Event testing
- Linkage to other community goals

VCT
- Mobile Vans
- Rapid testing
- Routine VCT
- Adequate counseling

PTSS
- Discussion
- Disclosure
- Partner Referral
- Linkage to Services
Interdependence of the three Project Accept components

COMMUNITY MOBILIZATION

MOBILE VCT

POST TEST SUPPORT SERVICES
Stigma in these settings is rampant
Vulindlela communities, KwaZulu-Natal Province (South Africa)
Political context in Zimbabwe

- **Hyperinflation** (1700%)
  - price and wage distortions
- **High HIV/AIDS burden**
  - prevalence of 20.4% among adults in Motoku
  - >80% of hospital bed occupancy
  - increasing orphan-hood and child-headed households
- **Foreign aid** sanctioned/sidelined/restricted (PEPFAR, GAF)
- **Shrinking resources**
  - health and social safety nets (supplies, drugs and brain drain).
- **Huge challenge** to stem the epidemic
Innovative modifications of PA-THAI intervention needed to reflect local context (methamphetamine and opiate use and trafficking)

Learning by working with people & communities
“Accessible” PA-THAI Communities
Kisarawe District, Tanzania
Community level support: The village drummer announces Project arrival
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Accomplishments (1)

• Study governance determined
• Sites established; contracts negotiated
• Community engagement, advisory boards, involvement of community leadership
• Protocols and SOPs: Project, Intervention, Assessment, Qualitative, QA/QC
• Mapping and enumeration ~125,000 households with no prior census or maps
• Contacted 34,230 households
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Accomplishments (2)

• Regulatory Approvals:
  – DSMB, 14 IRBs, PSRC (DAIDS/NIAID)
  – And harmonization among them

• Staff Training: Ethics, GCP, GLP, Protocol
  Specific operations

• Pilots: Baseline and Intervention

• Quality Assurance: Baseline, HIV Testing,
  Intervention, Qualitative

• Registered as *Lancet* Protocol # NCT00203749
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Accomplishments (3)

- **Baseline**
  - N = 48 communities; n = 14,292
  - 92-99% enumeration response rate
  - 84-94% interview response rate
  - Includes history of licit and illicit drug use

- **Qualitative Cohort (N = 657; 0, 6, 15, 30 mos)**
  - Stigma, testing, how the intervention is working, divergence of testers vs. non-testers

- **Intervention**
  - January 2006: Thailand, Zimbabwe
  - March 2006: Tanzania
  - May 2006: South Africa
  - January 2007: Thulani in Soweto (final community)
“Eye Candy”: Project Accept vans deployed in Soweto
CBVCT Testers by Gender and Site

- Thailand: 48.2% Male, 51.8% Female
- Zimbabwe: 46.4% Male, 53.6% Female
- Tanzania: 48.9% Male, 51.1% Female
- Soweto: 49% Male, 51% Female
- Vulindlela: 68.3% Male, 31.7% Female
HIV Prevalence by Site

Percent HIV+

- Thailand
- Zimbabwe
- Tanzania
- Soweto
- Vulindlela

June, July, August, September, October, November
Figure 1.1: Current and Projected 36 Months VCT Uptake (Age 18-32 years)
PTSS Current and Projected Activity

Figure 1.3: Current and Projected 36 Months PTSS Activities

Current and Projected 36 Month PTSS Activities

- **Soweto**: 9 Months
- **Thailand**: 13 Months
- **Tanzania**: 11 Months
- **Zimbabwe**: 12 Months
- **Vulindlela**: 9 Months

*Site - Time in field*
Getting the support of traditional authorities

Key political leader tests (happily, negative)
Project Accept Endpoint

• Measure 3 markers of infection simultaneously (BED OD-n; Avidity Index; and CD4 count) to account for a longer window period and using the measured values, not cut-points

• CD4 and AI contain information on infection time not in BED, low CD4 can rule out AIDS, and AI will identify recent infections missed by BED to reduce misclassification

• Will provide a measure of incident HIV infection
Final trial outcomes to be released in 2011

Post-intervention assessment with >53,000 randomly sampled community participants

Assessment of drug use on a magnitude never before addressed in Sub-Saharan African communities (where the problem is definitely growing)

Be patient – the results are worth waiting for!