

From Launch to Success “Lessons Learned”

Patrick Ndase
Regional Physician, MTN

Regional Meeting 2009, Cape Town

Context

- Prevention field is dynamic with multiple players
- Findings in one study could impact other studies
- Swift & efficient implementation of study protocols is critical
 - Other PrEP trials rapidly accruing (iPREX, Partners' PrEP)
 - Want VOICE results to be timely & relevant

We do have a need!

- To implement VOICE in a Swift & Efficient way
 - VOICE results to be timely & relevant

Lessons Learned?

- Meeting timelines
 - Protocol development
 - Site Regulatory approval process
- Implementation
 - Recruitment
 - Retention
 - Product Adherence
- Final points for overall success of the network studies

Meeting timelines

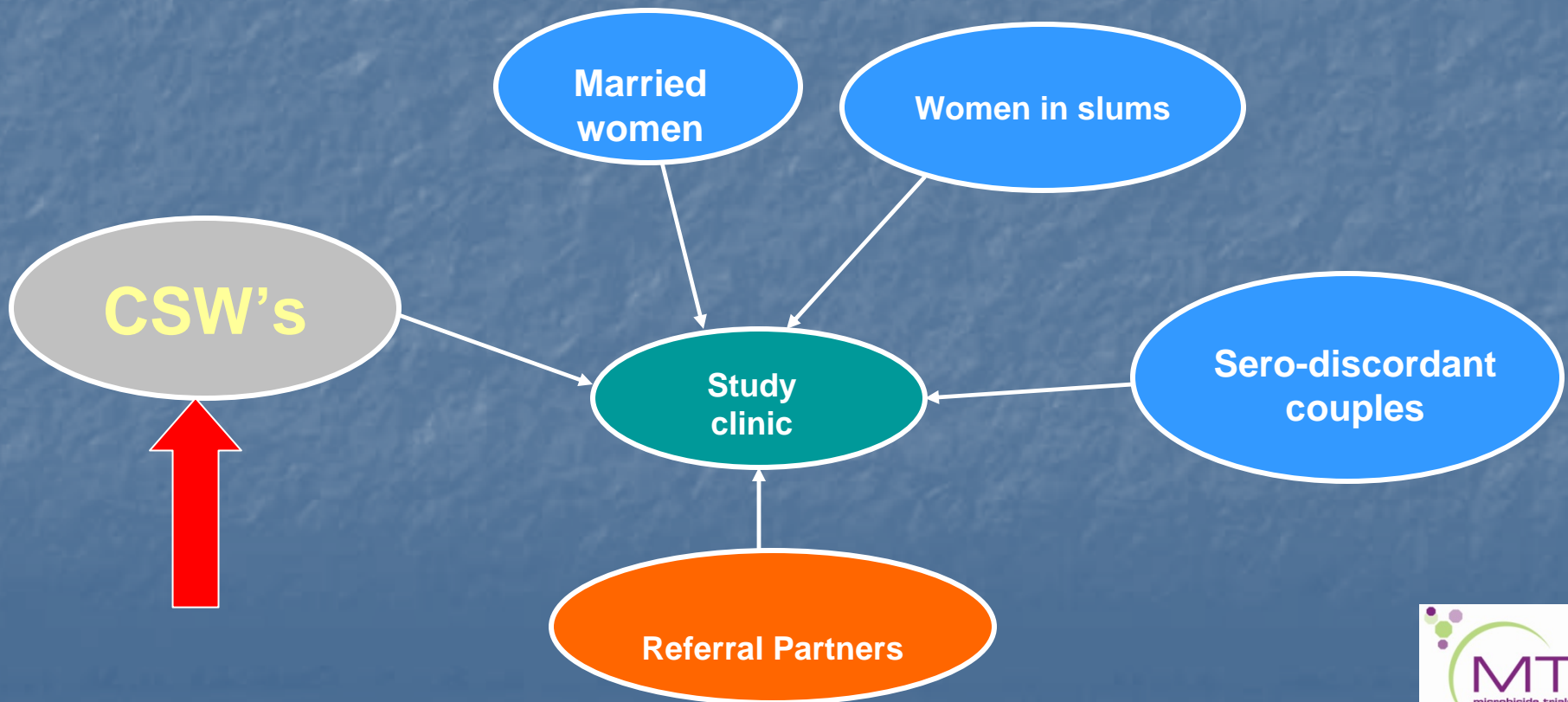
- Protocol Development
 - Flexible Protocol language to avoid LoA's
 - Definition of Protocol support materials for regulatory approval prior to site initial submission
 - Marked delays at local regulatory agencies
- Regulatory approvals
 - Advance preparations
 - As part of stakeholder engagement (often initially requires neutral convener)

Implementation: Recruitment

- Need to target high risk
 - 'Event-driven' trials are completed sooner
 - Key to efficient implementation of efficacy trials
- Risk criteria are typically broad
 - Build on lessons from prior studies at site
 - Track local HIV prevalence & incidence trends
- Incidence rate critical to site selection
- Monitor recruitment sources & risk levels

Recruitment & site viability

- Define your target population based on anticipated HIV risk levels



Implementation 2

■ Retention:

- High recruitment means heavy participant flow
- Clinic flow operations
 - Optimize staff time
 - Identify bottlenecks ,
redundancy, staff inefficiencies



Retention: cont.

- Need to anticipate retention challenges: holiday, planting seasons, disclosure issues, client needs etc
- Participant events
- Sharing across sites of strategies & lessons learned

Always be eager to learn from others



- Find right spin to approaches proven to work elsewhere
- Peer retention model may be worthy trying in highly mobile population
 - ❖ Participants in same locality often know each other

Product Adherence

“Messaging on Safety critical”

- “The Messenger” must be convinced of the safety message
 - ❖ Address underlying staff reservations about safety
 - ❖ Comfort with less clinically significant signals (phosphate, bone density)



Fine line to walk about safety messaging

- Execution of scientific rigor Vs instilling fear of study product?
- If likely safe; why the rigor?



Study drug Adherence

- Peer support model: Participant events a good way to discuss adherence challenges & strategies
- Participant events
 - If well orchestrated, can be well attended
 - Partners PrEP experience:
 - ❖ Kampala site: >200 discordant couples attended
 - ❖ Eldoret in Kenya had >60% ppt attendance
 - Staff moderated, participant led
 - Topics center on product adherence, retention, visit schedules, FP, etc

Pillbox Organizers Are Associated with Improved Adherence to HIV Antiretroviral Therapy and Viral Suppression: A Marginal Structural Model Analysis

Maya L. Petersen,¹ Yue Wang,¹ Mark J. van der Laan,¹ David Guzman,² Elise Riley,² and David R. Bangsberg^{2,3}



CID 2007:45 (1 October) • HIV/AIDS

Adherence: Pill carrying methods

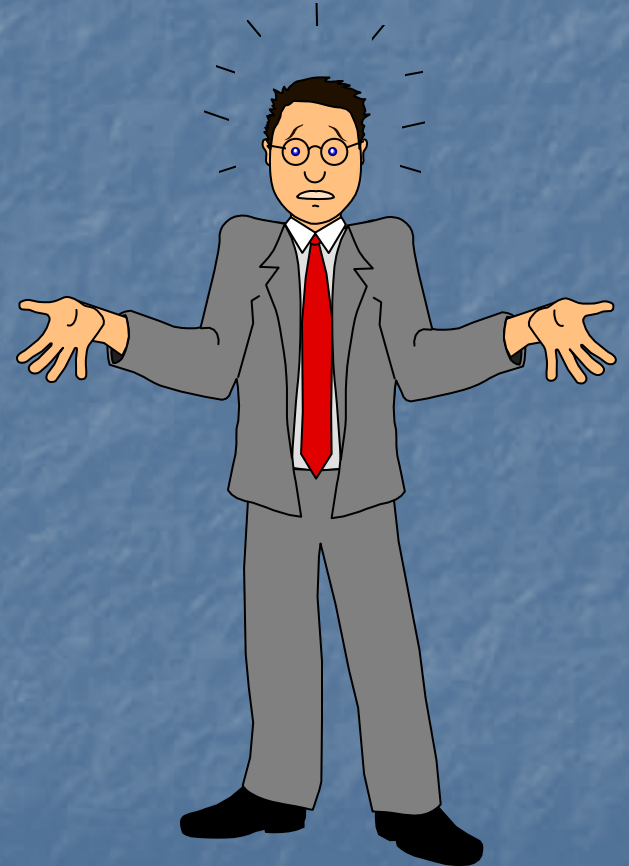
ADDRESS ADHERENCE BARRIERS:

- Travel
- Hectic work schedule
- Stigma
- Alcohol binges
- Lilongwe experience
(little blue gel carrier bag)



Question in VOICE?

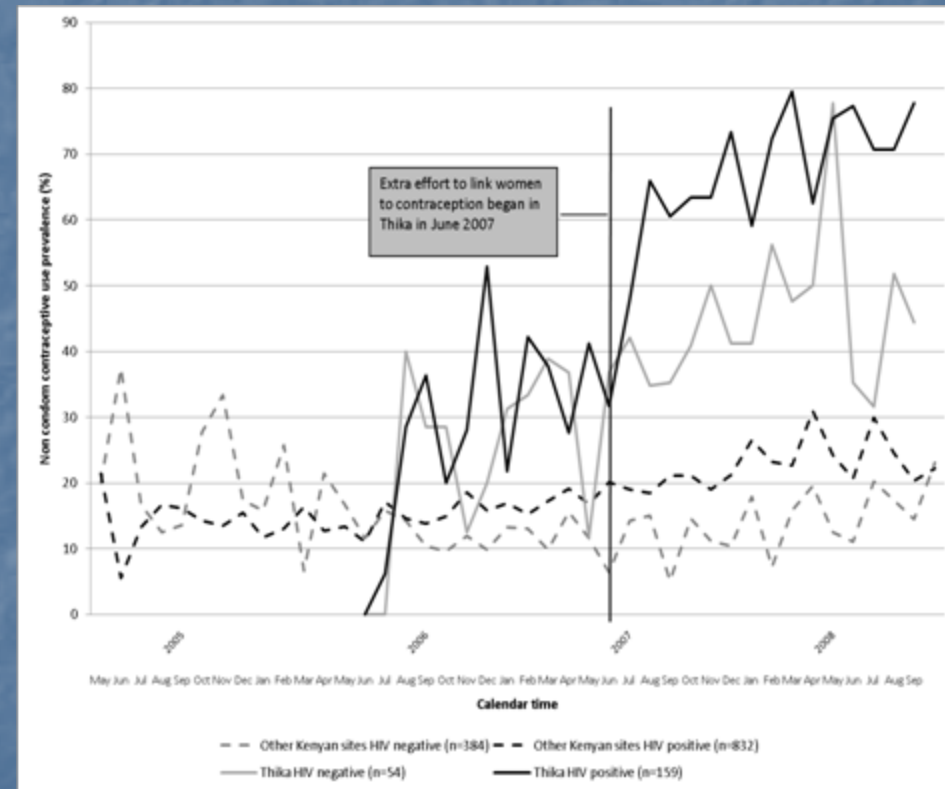
- What level of adherence interventions would be allowable?
- Need to roll out similar interventions across all VOICE sites
 - Addresses differential adherence concerns



Summary points

Inter-site cross pollination: “Improving Contraceptive Uptake”

- Minimal time off product:
 - Reduces power if high pregnancy rates
 - Thika, Kenya: multi-pronged FP intervention (Partners HSV/HIV trial)
 - Blantyre, with highest Pregnancy rate in HPTN 035



Ngure, K et al. AIDS, in press

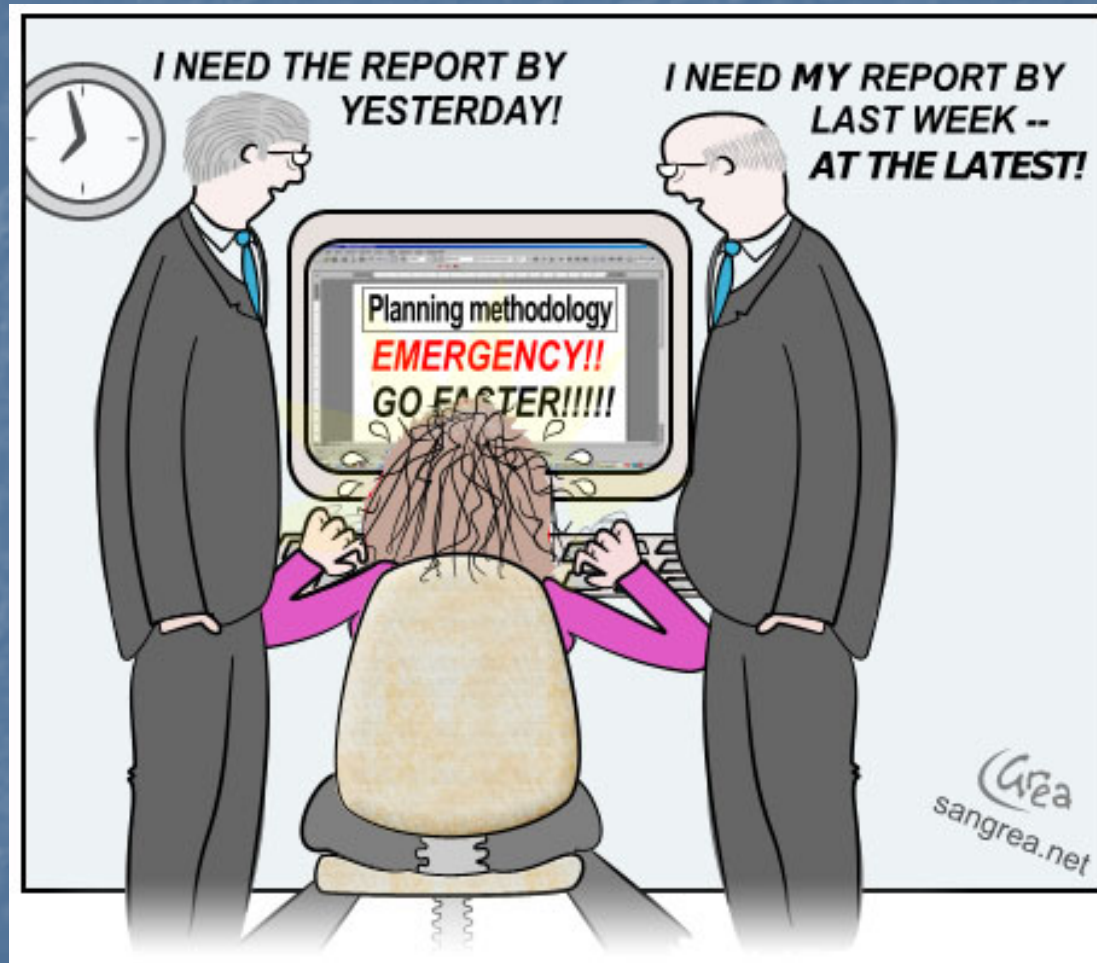
Gauge your site against the best

Thika site, a Partners PrEP site had an increment in adherence rate of 7% through:



- Participant seminar (peer model)
- Programmed telephone calls 3-4 post-enrollment
- Tailor made adherence counseling on feared side effects

Learning to work under pressure is key



“Input” must be talking to “processing” & vice versa

Thank you very much