

VOICE :Challenges and lessons learnt at the Durban MRC CRSs

MTN Regional Meeting 2010

Cape Town





Presentation Outline

- Challenges Implementing VOICE
- Strategies to Address These Challenges
- Lessons Learned
- Unresolved Challenge

Challenges Implementing VOICE

- Stringent clinical inclusion criteria – i.e.—exclusion criteria of dipstick findings—unexplained hematuria common findings
- High screening to enrolment ratios – expected, ongoing
- Community challenges regarding PrEP – expected, resolved, but addressing as issues arise
- Highly mobile population (effect on retention) – expected, ongoing
- Recruitment and training of new staff – unexpected, ongoing
- Long duration of study visits – has improved as the staff have become more familiar with the trial, unexpected, resolved
- High HIV prevalence –at selected CRSs (currently at Overport ,Botha’s Hill, Tongaat)



Strategies to Address These Challenges

- Have been very active in terms of community entry and education. CWG has been of assistance with this as well. The need to be proactive in this regard is critical
- The population is highly mobile and this is unfortunately beyond our control and is not something we can change
- We have embarked on major recruitment drives to get most staff into the organization at the same time – but competitive salaries in many other sectors have proved challenging for us in this regard
- Reduction of waiting time in the clinic: ppts are more comfortable with the visits and staff are more confident and faster with visits—hence reduction of waiting time



Lessons Learned

- Correct staffing ratios and well trained staff are critical in ensuring successful trial implementation
- Well trained staff with experience in the clinical trial environment lead to improved clinic flows and reduced length of study visits
- Role of the CWG is important in terms of community involvement, and gaining buy in from the community is critical to ensuring successful trial implementation
- The communication of inclusion and exclusion criteria, especially in terms of behaviour to potential ppts is critical so time is not wasted on ppts who may be ineligible – some women know they are ineligible but still come for a screening visit



Lessons learnt contd

- Due to the high screening to enrolment ratios, it is clear that a massive drive in terms of recruitment is required across all sites, but finding women who are eligible is still proving to be a challenge
- General health of our population is not as high as expected, as many are being screened out due to clinical issues that they themselves were not aware of and have never seek care for



Unresolved Challenge

- Highly mobile population who are actively seeking employment – when participants relocate, how should we proceed in terms of study participation, study product and follow-up? Considering this is often unpredictable, and most often can not be anticipated at during screening and enrolment, how can we move forward with these participants and still accomplish the trial objectives