

MTN ANNUAL MEETING - MTN 003

LESSONS LEARNT FROM IMPLEMENTATION OF VOICE AT MRC DURBAN SITES

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BUILDING A HEALTHY NATION THROUGH RESEARCH





CURRENT STATS –Durban sites
SCREENING FAILURES
COMMUNITY AND EDUCATION
RECRUITMENT AND ACCRUAL
IMPLEMENTATION
TRENDS
RETURNS
ADHERENCE
DATA COLLECTION
WAY FORWARD



CURRENT STATS:DURBAN SITES

	Chatsworth	Botha's Hill	Verulam	Isipingo	Tongaat	Overport	Umkomaas
Date 1st screening:	10 Nov 09	18 Nov 09	15 Feb 10	18 Feb 10	17 Feb 10	22 Feb 10	16 Mar 10
Date first enrollment	25 Nov 09	07 Dec 09	08 Mar 10	10 Mar 10	09 Mar 10	09 Mar 10	-
Screened	156	107	61	69	64	32	2
Screened Out	77	55	25	20	33	22	-
Enrolled	33	22	5	1	3	2	-
In the pipeline	46	30	31	48	29	8	-

REASONS FOR SCREENING FAILURE

Building a healthy nation through research

	CHATS	BH	VER	TON	OVERPORT	ISP	UMK
HIV	14	21	18	19	15	8	
Window Closed	32	9					
Pregnant	7	3	1	2	2	4	
Low Haemoglobin	3	3		2	1		
Grade 2 Pelvic Exam Finding	-	3			1	1	
Abnormal Pap	1	2					
Elevated AST/ALT; Other Labs	1	2	2	2			
Hypophosphataemia	-	1					
Breastfeeding	4	1		3		1	
Planning on moving away from area	3	2			3		
Latex Allergy	-	2					
Chronic Uncontrolled Disease	2	1		1		1	
Low Platelets	-	1					
Hepatitis B Positive	2	2	3	2		3	
Not Sexually active	1	1	1				
Not suitable to continue in the study	7	1		1		2	



COMMUNITY AND EDUCATION

- Community and participant buy in requires good understanding of novel concepts and products – *ARV based compounds, Pre-Exposure Prophylaxis, resistance, placebo-controlled trials.*
- Difficulties explaining and teaching concepts - *multi-disciplinary team required at community meetings with input from clinicians, nurses and pharmacists.*
- Dispelling myths and misconceptions around ARVs amongst members of the community and other health care workers.



RECRUITMENT AND ACCRUAL CHALLENGES

- Fear of HIV Testing
- Fear of Side Effects of ARVs – general info in the field and more intense in the clinic where fears can be addressed by clinical staff
- Recruiting in Dec/Jan holidays – participants not honoring visits after Screening Part 1, difficult to distinguish school pupils, most people away from the area during the holiday.
- Screen out due to HIV
- Women booked for pre-screening not honoring visits.
- More field staff and vehicles as accrual intensifies

Lessons that were learnt from recruitment challenges in MTN 001 helped with early recruitment at Botha's Hill (entry into more areas, intensive pre-screening procedures, engage health service providers)



IMPLEMENTATION CHALLENGES

- First sites in South Africa to implement VOICE - putting theory into practice is more challenging than it seems.
- New teams assembled to implement the protocol – staff who have not worked together previously.
- New MRC staff– adjust to MRC and MTN and DAIDS systems.
- Experience from previous microbicide trial implementation- staff who worked on trials conducted by other sponsors had to adjust to requirements of MTN trials, documentation, CRFs.



CLINICAL CHALLENGES

Stringent eligibility criteria

- Transient lab abnormalities (AST,ALT, dipstick, Phosphate)
- Anaemia
- Higher levels of abnormal paps (higher rate of cervical abnormalities in South African women)



COMMON TRENDS IDENTIFIED

- **PROCEDURAL**

- Administration of Hepatitis B at Screening Part 2 rather than Enrollment
- Inconsistent use of the Safety Flow sheets
- Inconsistent reporting of reportable and non-reportable AEs

- **LAB**

- Site specific lab forms – names of HIV test kits
- Creatinine clearance worksheets (convert vs no convert)



COMMON TRENDS IDENTIFIED

PRODUCT RETURNS

- Unused product returns – more explanation required from pharmacy in comments to explain differences between product returned and available for re-issue.
- Inconsistent use of the Product Ordering Tool. Need to determine date of next scheduled visit prior to completing.
- Product to be returned to pharmacy as early as possible in the visit-after registration.
- Pharmacy requires information on last product use- to chart note and communicate to pharmacy.



COMMON TRENDS IDENTIFIED

ADHERENCE COUNSELLING

- Unused product returns slip from pharmacy – review prior to Adherence Counselling.
- Counselling to be tailored based on comparing reported returns and actual returns. More probing about barriers/challenges required to explain inconsistencies.
- Adherence Counselling Worksheet – mark off each box to indicate that each counselling point has been addressed.
- More documentation required for participant's experience of first product use.



DIFFERENCES BETWEEN MTN 001 AND VOICE

- Panty liners not required for participants on the oral arm.
- Reminders to record date and time of last dose only required prior to quarterly and PUEV visits.
- Not all AEs are reportable on AE log CRFs but all AEs to be documented and followed until resolution.
- Pregnancy Tests at interim visits - only if clinically indicated.



DATA COLLECTION

- **Contraceptives Log** – record date started and stopped of each contraception injection since started on study, not prior doses.
- **Demographics CRF** – site specific recruitment codes for each recruitment area.
Careful consideration- overlapping of recruitment areas
- **Safety Lab Results** – record leucocytes and nitrites as well even when not indicated – Multistix 9 testing these parameters.
- **Follow up Visit (FV-1)** – Question 2 – new AEs refers to reportable AEs only. To update if new AEs reported from lab results.
- Review interviewer administered forms carefully.
- **Screening and Enrollment Pelvic Exam** – if ppt is amenorrheic, data required- at minimum, the year of last menstrual period.



The Way Forward.....

- Standard, consistent approach across all 7 sites
- Community messaging—restructure key messages
- Peer educators to assist with community education – Ppts relate thier personal experience on MTN 001
- Adherence messages—morning waiting room sessions, restructured key counselling messages
- Defining key concepts of “blinding” and “placebo”



The Way Forward.....

- Team building—monthly meetings with all teams
- Silo meetings—e.g. laboratory, clinical, pharmacy
- Identified errors early before trends develop- ongoing staff training. Refresher trainings and error trend analysis
- Communication— enhancing an interactive open environment to alert us of site challenges and implementing solutions
- Practising - mock visits, clinic flows ,working with CRFs
- Data communiques and SSP updates – ongoing training of staff on updates.



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MRC VOICE Motto.....



.....Team work can make the
dream work.



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THANK YOU