

ASPIRE ACCRUAL AT MRC HPRU

Building a healthy nation through research

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On behalf of the
HIV Prevention Research Unit
Medical Research Council
(Botha's Hill, Chatsworth, Isipingo,
Tongaat, Umkomaas & Verulam)

MTN Regional Meeting
Cape Town
October 2012



- All CRSs received activation on 28 August.
- Screening visits were initiated between 31 August and 10 September.
- First enrollment visits were conducted from 10 September.

CRS	Date of First Screening Visit (September)	Date of First Enrollment Visit (September)
Chatsworth	31 August	11
Botha's Hill	05	10
Isipingo	10	19
Tongaat	10	17
Umkomaas	07	14
Verulam	04	13

TIME SPENT ON SCREENING PROCEDURES

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Procedure	Average Time (mins)
Registration	15
Informed Consent Process	35
PTID Assignment	10
Behavioural Eligibility, Demographics and urine collection	15
Lab – Pregnancy Test and result entry	10
Pre Test Counselling	20
Blood Collection	10
Lab – HIV test and result entry	30
Post Test Counselling	15
Medical history collection, CRF completion, FP Counselling, Physical Exam and Pelvic Exam	40
Clinicians Review	20
QC1	20
Reimbursement and database updates	15
TOTAL AVERAGE TIME	4 hours 15 minutes

TIME SPENT ON ENROLLMENT PROCEDURES

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Procedure	Average Time (mins)
Registration	15
Informed Consent Process	60
Enrollment Behavioural Eligibility Completion and urine collection	10
Lab – Pregnancy Test and result entry	10
Pre Test Counselling	20
Blood collection, CRF review and update, Targeted Physical Exam, Adherence counselling and Ring Education	40
Lab – HIV Test and result entry	30
Post Test Counselling	15
ACASI, completion of BBA and BVP CRFs	20
Eligibility review and Eligibility Checklist completion (2 staff)	60
Randomisation and prescription completion	10
Recap of ring instructions, ring insertion and digital exam	20
Ring removal and re-insertion, discussion on first ring use and further counselling if required	15
QC1	20
Reimbursement and database updates	15
TOTAL AVERAGE TIME	6 hours

CHALLENGES EXPERIENCED DURING SCREENING & ENROLLMENT VISITS

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CHALLENGES	STRATEGIES
<p>The completion and interpretation of certain CRFs was challenging. For example, determining amenorrhea on the SMH-1 CRF.</p>	<p>Clinical team meetings were held to discuss issues. Queries were sent to SCHARP and clarification was received. Further clarification was received from data communiques.</p>
<p>Some participants were arriving late at the clinics for screening and enrollment visits resulting in a long day for staff and participants.</p>	<p>Participants were fetched for screening visits and encouraged to arrive early for enrollment visits.</p>
<p>Initial screening and enrollment visits were lengthy.</p>	<p>Training and mock visits were conducted with staff resulting in staff becoming more familiar with procedures and better visit flows.</p>

CHALLENGES EXPERIENCED DURING SCREENING & ENROLLMENT VISITS CONT.

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CHALLENGES	STRATEGIES
<p>Eligibility review on the day of enrollment is a long process.</p>	<p>Eligibility review is commenced the day before the enrollment visit is scheduled to occur.</p>
<p>Some participants were initially uncomfortable with the size of the ring during ring education sessions.</p>	<p>Community teams were provided with demonstration rings to use during community education sessions and recruitment. In this way, potential participants were able to assess the size of the ring prior to deciding whether to screen for the study.</p>

- **Pre screening and community education (including use of the demonstration ring).**
 - ✓ Participants had a good background knowledge of the study which aided the IC process and waiting room education sessions.
 - ✓ Use of the demonstration ring provided participants with an understanding of the size and texture of the ring.
 - ✓ This activity also resulted in HPRU CRs being able to compile a list of potential participants for screening visits prior to study start up.
- **Provision of transportation to the clinic for screening participants.**
 - ✓ Screening participants arrived at the clinic early and were able to complete their visits in reasonable time.

STRATEGIES FOR ENHANCED PARTICIPATION CONT.

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- **Conducting ring education and adherence counselling early during the enrollment visit.**
 - ✓ Participants concerns and questions were addressed.
 - ✓ Participants gained insight into what was required with regard to ring use.
 - ✓ Participants were able to see and feel a demonstration ring and practice with a pelvic model. This resulted in participants being able to insert the ring with ease.

- **Will it be possible to choose the ring with the active ingredient?**
 - ✓ Explained to participant that ring assignment is random and also explained the process of randomisation. Further explained that study staff are blinded.

- **Will my partner feel the ring during sexual intercourse?**
 - ✓ Explained to participants that their partners should not feel the ring if it is placed correctly. Previous ring studies have indicated that most partners were not able to feel the ring during intercourse.

- **Will the ring fall out?**
 - ✓ Explained to participants that there is a very small possibility that this may happen but if the ring is placed properly then it is unlikely. Also counselled participant on reinsertion of expelled rings.

- **Will the ring be comfortable to wear considering the size and texture?**
 - ✓ Explained to the participant, with the use of a pelvic model that there is enough room in the posterior fornix where the ring sits so she should not feel discomfort.
 - ✓ Also explained that once the ring is inserted, it will become lubricated and pliable and take the shape of her body.

QUESTIONS FROM PARTICIPANTS

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- **Will wearing the ring for an extended period of time cause an infection?**
 - ✓ Participant reassured that this was unlikely occur.
- **Will the ring stop my menses?**
 - ✓ Explained to participant that the ring would not interfere with her menstrual cycle.
- **Will the ring interfere with the way I walk?**
 - ✓ Participant was reassured that if the ring is placed correctly she should not feel it and it should not interfere with the way she walks.

CURRENT ACCRUAL STATISTICS

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CRS	Total Screened	Total Enrolled
Botha's Hill	63	15
Chatsworth	62	15
Isipingo	34	6
Tongaat	37	5
Umkomaas	49	15
Verulam	50	12
HPRU Total	295	68

Stats as at 27 September 2012

SCREEN OUT REASONS

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CRS	HIV	Abnormal Labs	Clinical	Behavioural
Botha's Hill	15	5	2	2
Chatsworth	6	0	10	2
Isipingo	7	1	3	0
Tongaat	15	2	1	0
Umkomaas	4	0	5	3
Verulam	14	6	3	2
Total	61	14	24	9



Thank You