

MTN Regional Meeting

Pharmacy Session
October 29-30, 2013



Tuesday October 29th

12:30 PM to 1:30 PM	LUNCH (Restaurant Thirty7)		
1:30 PM to 2:00 PM	Welcome and Objectives		
2:00 PM to 2:30 PM	Ring manufacturing and supply chain		Kathie Windle
2:30 PM to 3:00 PM	ASPIRE Progress Update		Cindy Jacobson
3:00 PM to 3:30 PM	BREAK (Old Harbour Lobby)		
3:30 PM to 4:00 PM	Pharmacists		Site
4:00 PM to 4:30 PM	Role in ASPIRE		Presentations
4:30 PM to 5:00 PM	Cont.		Site Presentations
5 : 0 0 P M	Meeting adjourned		

Wednesday October 30th

12:30 PM to 1:30 PM	LUNCH (Restaurant Thirty7)		
1:30 PM to 2:00 PM	Welcome and Objectives		
2:00 PM to 2:30 PM	Product complaint		Kathie Windle
2:30 PM to 3:00 PM	Used Rings to Lab		Group Discussion
3:00 PM to 3:30 PM	BREAK (Old Harbour Lobby)		
3:30 PM to 4:00 PM	Dispensing >1 ring Protocol Deviations		Group discussion
4:00 PM to 4:30 PM	Off-Site visits		Cindy Jacobson Site Presentation
4:30 PM to 5:00 PM	Wrap-up		Cindy Jacobson
5 : 0 0 P M	Meeting adjourned		

Pharmacy Session Overview Day 1

- Dapivirine Ring: Kathie Windle (IPM)
 - ➡ Manufacturing & Supply Chain Process
 - ➡ Next plans/future
- ASPIRE Progress Update
 - ➡ Enrollment
- Pharmacists Role in ASPIRE
 - ➡ Site Presentations

Pharmacy Session Overview Day 2

- Product Complaint Review
 - ➔ Reporting Process
 - ➔ Summary of Reports
- Used Ring Clinic to Lab vs. Destruction Process
- Protocol Deviation Reporting
- Off-Site Visits: Site Presentation
- Wrap up



Kathie Windle

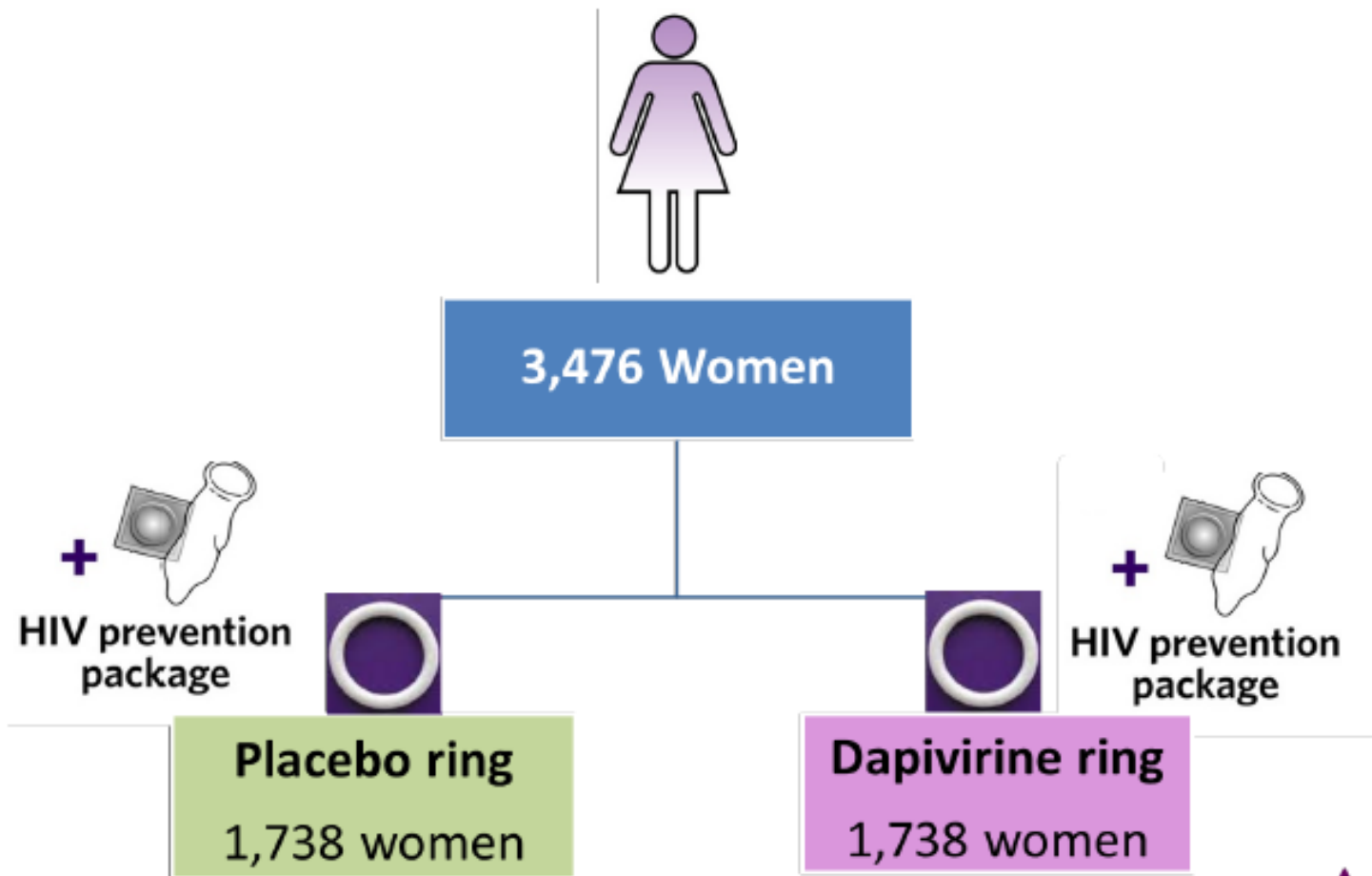
- International Partnership for Microbicides (IPM)
- Materials Planning and Supply Chain Lead
- Extensive experience in trial supply management including forecasting, packaging and global distribution.
- Prior to joining IPM Kathie was with Human Genome Science Inc.



Kathie Windle

- Currently manages drug supply chain from drug substance, manufacturing and drug product through packaging and distribution.
- Clinical drug supply management and oversight.

ASPIRE Study Design



Timeline

2011

- Initiate site IRB and regulatory approval process

2012

- IRB/regulatory approvals, trainings, start

2013

- Enrollments, follow-up

2014

- Follow-up

2015

- Results

**MTN 020 - A Study to Prevent Infection with a Ring for Extended Use (ASPIRE)
Data as of October 25, 2013**

Accrual Summary by Site

Site	Activation Date	First Enrollment Date	Last Enrollment Date ¹	Duration of Accrual ² (weeks)	Enrollment Target ³	Total Screened	Total Enrolled	Screen/Enroll	Average Enrolled per Week	Percent Enrolled ⁴
Malawi - Blantyre	22MAY2013	13JUN2013	22OCT2013	19.3	150	59	40	1.5	2.1	26.7%
Malawi - Lilongwe	24MAY2013	17JUN2013	21OCT2013	18.7	150	64	43	1.5	2.3	28.7%
SA - Cape Town	04SEP2012	19SEP2012	15OCT2013	57.4	150	196	150	1.3	2.6	100.0%
SA - CAPRISA eThekweni	13SEP2012	10OCT2012	02OCT2013	54.4	250	481	150	3.2	2.8	60.0%
SA - MRC/Botha's Hill	28AUG2012	10SEP2012	14JUN2013	58.7	216	297	120	2.5	2.0	55.6%
SA - MRC/Chatsworth	28AUG2012	11SEP2012	25JUN2013	58.6	216	314	115	2.7	2.0	53.2%
SA - MRC/Isipingo	28AUG2012	19SEP2012	24JUN2013	57.4	216	308	117	2.6	2.0	54.2%
SA - MRC/Tonga	28AUG2012	17SEP2012	14JUN2013	57.7	216	340	103	3.3	1.8	47.7%
SA - MRC/Verulam	28AUG2012	13SEP2012	25JUN2013	58.3	216	273	114	2.4	2.0	52.8%
SA - MRC/Umkomaas	28AUG2012	14SEP2012	14JUN2013	58.1	216	217	87	2.5	1.5	40.3%
SA - WRHI	16OCT2012	30OCT2012	21OCT2013	51.6	200	250	142	1.8	2.8	71.0%
Uganda - Kampala	19JUL2012	21AUG2012	16OCT2013	61.6	300	321	205	1.6	3.3	68.3%
Zimbabwe - Seke South	22OCT2012	01NOV2012	17OCT2013	51.3	225	289	156	1.9	3.0	69.3%
Zimbabwe - Spilhaus	22OCT2012	30OCT2012	23OCT2013	51.6	225	271	152	1.8	2.9	67.6%
Zimbabwe - Zengeza	23OCT2012	13NOV2012	17OCT2013	49.6	225	261	146	1.8	2.9	64.9%
All Sites	19JUL2012	21AUG2012	23OCT2013	61.6	3171	3941	1840	2.1	29.9	58.0%

¹ Date of most recent enrollment as of October 25, 2013.

² Duration of accrual based on first enrollment date.

³ 305 out of 3476 enrollment slots are currently unassigned to sites.

⁴ Calculated based on the current target of 3171 which excludes the 305 enrollment slots that are currently unassigned to sites.



Pharmacists Role in ASPIRE

- What was discussed last year
- What is really happening - Site presentations
- Discussion – what changes can we make at our site?



Pharmacists Role in ASPIRE

□ Education

Participant meetings

Waiting room

Dispensing 2 rings

Information about non-study products

Review product use instructions



Pharmacists Role in ASPIRE

□ Counseling

- Provide ring adherence counseling.
- Conduct counseling and
- Provide information regarding contraception and/or STI treatments.



Pharmacists Role in ASPIRE

□ Other

Periodic check-ins with pharmacists during specified follow-up visits to maintain relationship.

Participant may accompany clinic staff to pharmacy or pharmacist may accompany participant to clinic staff when study product is dispensed.



Pharmacists Role in ASPIRE

□ Other

Reminder calls to participants between Enrollment and Month 1 (and/or other study visits) to answer questions, gather information, and remind of next appointment.



Pharmacists Role in ASPIRE

Uganda - Prior to start:

Participants will be referred to pharmacists by clinic staff when questions arise that could be best answered by pharmacy staff.

Pharmacists will educate participants about relevant issues, such as results from other related studies, during any participant meetings held on site.

RM 2012

Ordering, proper storage, dispensing, information/education when called upon, and product destruction.



Pharmacist role at the Kampala site

Rebecca Sakwa



What does the pharmacist do?

- ❑ Orders for study product and the zip lock bags
- ❑ Maintains the study product at the recommended (15-30) ° C
- ❑ Prepares and dispenses study product to the filing clerk or designee on receipt of a prescription from an authorized prescriber
- ❑ Maintains study product accountability records




What does the pharmacist do?

- The pharmacist carries out quality control activities by performing real time review of study product preparations by another pharmacist before the study product leaves the pharmacy
- The pharmacist does quality assurance through review of all participant specific pharmacy files before they are placed back in the cabinets after the day's work is done




What does the pharmacist do?

- The pharmacist maintains an adequate supply of male condoms for issue to the participants
- The pharmacist participates in weekly team meetings




Has the role of the pharmacist
changed since the last visit?

The pharmacist role has not
changed




Is there anything that could be done differently in the study and if so why?

No, nothing could be done differently




How does the pharmacist impact adherence/retention?

There is a plan for different team members to talk to participants in the waiting area on a rotational basis and the pharmacists have a slot in the future



What works well in the study and what should be changed for future studies?

The double check system works well; no need for any changes



How often has the pharmacist dispensed more than one ring to a participant?

This has happened once at our site



Thank you



Pharmacists Role in ASPIRE

MRC – Prior to start

Pharmacists may be involved in the counseling of participants for whom a second ring is dispensed (e.g. how to store the second ring or what to do with the used ring until the participant returns to the clinic).

Pharmacists could also be involved in counseling and providing information regarding damaged rings and procedure to be followed.

RM- 2012

Study Product Management and Accountability

QA/QC

STIs and emergency drugs, destruction, temperature monitoring

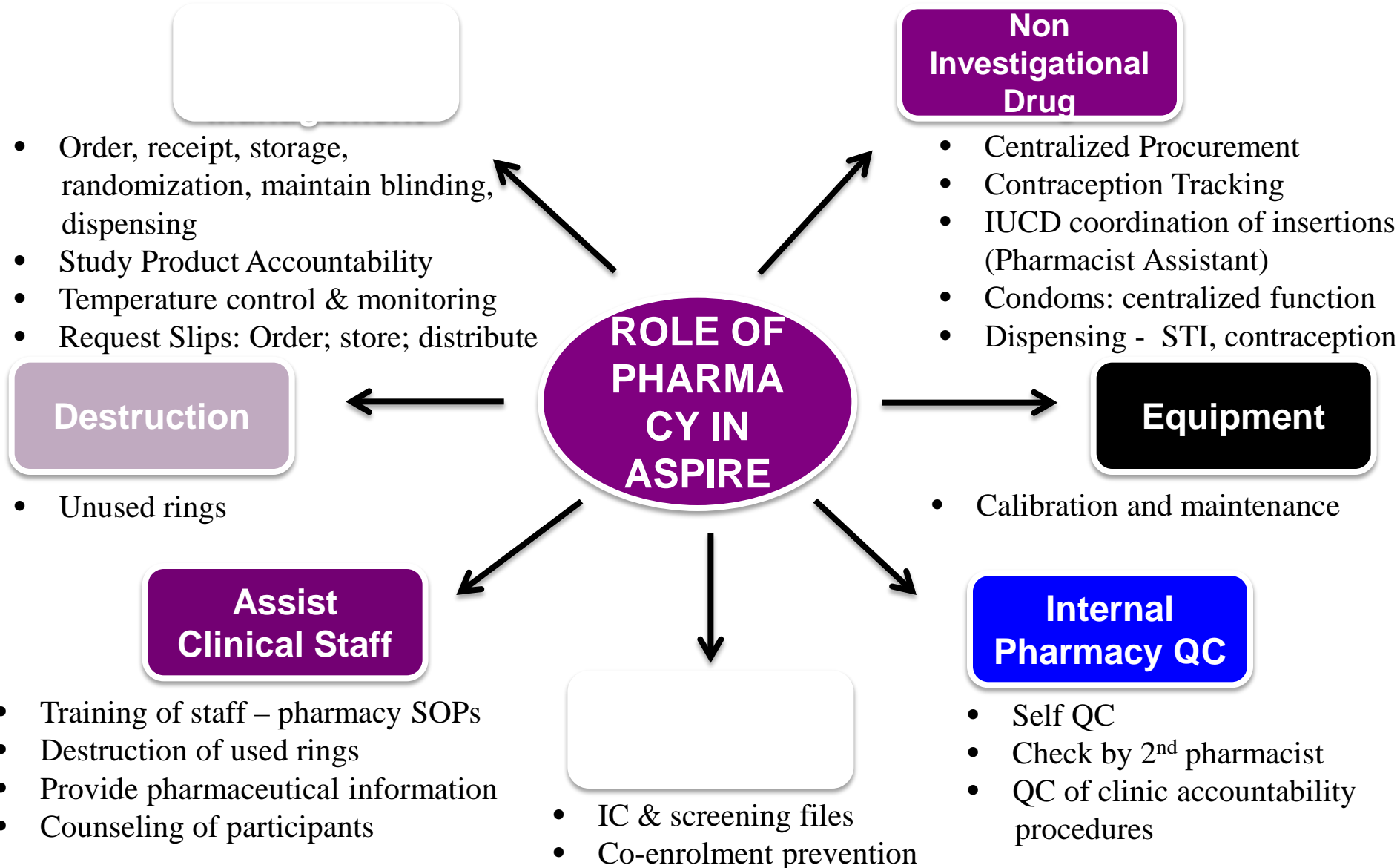


ASPIRE
PHARMACY BREAKOUT SESSION

Presented by Faeza Arbee
Pharmacist – Chatsworth CRS
HIV Prevention Research Unit
South African Medical Research Council

MTN Regional Meeting
Cape Town
October 2013

ROLE OF PHARMACY IN ASPIRE



HOW HAS PHARMACIST'S ROLE CHANGED FROM VOICE

Role is more participant centered and we are part of the team focusing on :

- ✓ Retention
- ✓ Adherence
- ✓ Product coverage
- ✓ Data Quality



WHAT WE WOULD DO DIFFERENTLY & WHY

- Adherence :
 - ✓ Restrict ring insertion/removal training – this can encourage manipulation by some participants
 - ✓ Document ring appearance per participant over time (e.g. on clinic accountability record).
 - ✓ Identify adherence support for each participant - “buddy system”
 - ✓ Objective measures of adherence from study start – PK analysis at each visit, validated ring inspection procedures
 - ✓ Adherence monitoring – starts at month 1, with intense counseling support for all participants with <80% adherence
 - ✓ Provide demo ring to participants at screening to determine acceptability for long term use
 - ✓ Regular adherence workshops where participants share strategies and discuss problems regarding adherence

ROLE ON ADHERENCE & RETENTION

Retention and product coverage

- Retention tracking – create a weekly list of expected participants for follow up
- Ring use tracking – prior to LoA#2 – decreased the number of PD's.

Waiting Room Education

- Posters
- Address anonymous queries
- Address comments on HIV



Adherence Counselling

- Clearly Non-adherent ppt
- Difficult cases



Social Events

- Partner testing and treatment
- Women's Day/ Heritage Day Celebration
- Singing Competition; Fashion Show
- Refreshments served
- Participant tokens

ASPIRE – WHAT WORKS

- Pharmacy System - works well
 - ✓ Dispensing process:
 - Well thought-out
 - ✓ Label concept (on PSDR):
 - Excellent idea
 - Minimizes dispensing errors
- Study Product Request Slip
 - ✓ Covers all scenarios

FUTURE TRIALS

Randomization Envelopes

- Worked well in VOICE
- Lowers chance of errors
- PSDR self-separated in ASPIRE

Randomization Tracking Record

- Include Bin codes: Ease of summary

Randomization number

- Include on flip-side of participant dispensing record
- Quick reference

FUTURE TRIALS

Product Use Counselling

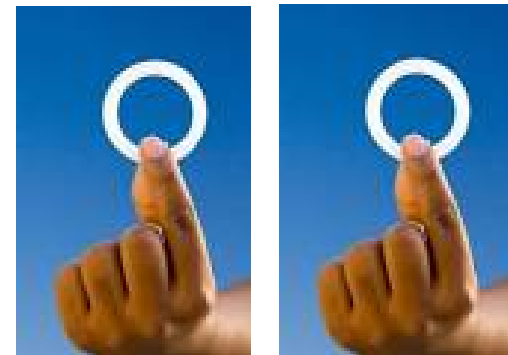
- **Pharmacist involvement – team approach to improve adherence**

Ring Use

- **Pharmacist involvement in ring inspections**
- **Document trends per participant over time**

DISPENSING MORE THAN 1 RING

- When does this occur:
 - ✓ In December for participants travelling away from site over the festive period
 - ✓ At some sites this is utilized for participants who plan to be away from the research site for more than a month e.g. students, visiting family.
- Special considerations:
 - ✓ Special labeling and counseling regarding dates to discard used ring/insert new ring





Тяк си ти!



Pharmacists Role in ASPIRE

eThekwini – Prior to start

Pharmacists will provide counseling and information to participants during group education sessions in the clinic waiting room.

RM-2012

????



ASPIRE – Pharmacist's Role

Microbicide Trials Network Regional Meeting, Cape Town 2013

Atika Moosa

Research Pharmacist, CAPRISA eThekweni CRS- 31422 (Durban)



OVERVIEW

- Pharmacists Role
 - Maintaining the integrity of randomisation
 - Adherence - Enrolment counselling - on ring use at the enrolment visit*
 - Retention - Participation in retention meetings*

- Dispensing > 1 ring

*new



DAILY RETENTION MEETINGS

- PI, clinician, nurses, study coordinator, trackers & pharmacist
- Missed appointments/visits for the day and ongoing from previous
- Review and strategize



RETENTION MEETINGS -Pharmacist Input

- iDART missed appointment report
- 35 day date post-ring insertion



DISPENSING MORE THAN 1 RING

- ❑ Instruction label on 2nd ring
- ❑ Counselling points for nurse –
Communication & Action Log
- ❑ Reminder sent to team for ppt to be contacted to remove ring 1 and insert ring 2 (day 27/28)
- ❑ Pharmacy log kept of all dispensations for more than 1 ring

MS OUTLOOK CALENDAR REMINDER

The screenshot shows the Microsoft Outlook Appointment window. The title bar reads "Appointment". The ribbon includes "File", "Appointment", "Insert", "Format Text", and "Review". The "Appointment" ribbon has several groups: "Actions" (Save & Close, Delete, Calendar, Forward, OneNote), "Show" (Appointment, Scheduling Assistant), "Attendees" (Invite Attendees), "Options" (Show As: Busy, Reminder: 15 minutes, Recurrence, Time Zones), "Tags" (Categorize, Private, High Importance, Low Importance), and "Zoom" (Zoom).

Below the ribbon, a message states: "Conflicts with another appointment on your Calendar." The appointment details are as follows:

- Subject: PID:
- Location: Clinic
- Start time: Thu 2013/09/12, 09:00 AM, All day event
- End time: Thu 2013/09/12, 09:30 AM

The main body of the appointment contains the following text:

2 rings dispensed on 16 Aug 13

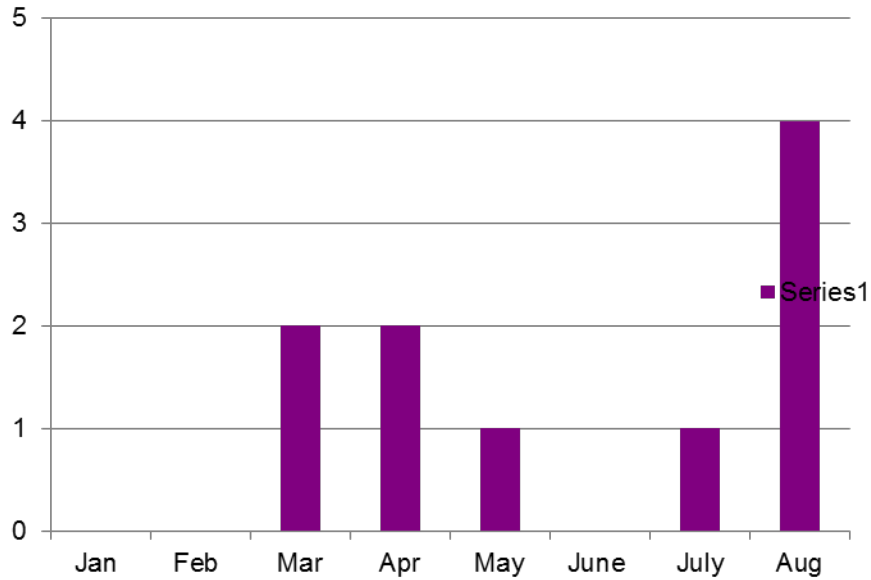
28 day for removal of Ring 1 and insertion of Ring 2 is 12 Sep 13.

35 day expiry for Ring 1 is 19 Sep 13.

LIST OF PARTICIPANTS FOR 2 RINGS DISPENSED:

DATE	PTID	28 DAY FOR RING REPLACEMENT	FIRST 35 DAY EXPIRY	REMIND CLINIC TO PHONE PT ON/BY (ADD TO EMAIL CALENDER)	COMMENTS

Number of ppts that received > 1 ring





ACKNOWLEDGEMENTS

- MTN is funded by NIAID (5UM1AI068633), NICHD and NIMH, all of the U.S. National Institutes of Health
- University of KwaZulu-Natal - CAPRISA HIV/AIDS Clinical Trials Unit (5U01AI069469).



Pharmacists Role in ASPIRE

Zimbabwe – Prior to Start

Pharmacists will provide information to participants about the provision of any prescribed primary care drugs.

RM – 2012

Regulatory, SOP development, staff training, QA/QC, contraception counseling, destruction, all issues related to study product



ASPIRE REGIONAL MEETING

27 October- 01 November 2013
E.C. Nyawera and K Hlahla

ZIMBABWE SITES



ROLE OF PHARMACIST IN ASPIRE

1. STUDY PRODUCT MANAGEMENT

- This involves the procurement, receiving, storage and dispensing of study product.
- The pharmacist is accountable for the study product including its quarantine and destruction

2. Formulation and Implementation of SOPs

ROLE OF PHARMACIST IN ASPIRE

3. Liaising With Regulatory Bodies

- Ensuring that the site pharmacy complies with all local and international regulatory rules and regulations

4. Contraception and primary care provision and counselling

5. Staff training


6. QA/QC



Changes since the last meeting

Pharmacy staff now :

- Work together with the clinic manager and MO in the management of clinic activities.
- Give Protocol overviews to participants during screening visits.
- Actively involved in group adherence sessions and participant retention meetings.



Areas that we would like to do differently.

- We are currently satisfied with the system in place.



ASPECTS OF ASPIRE THAT WORK WELL

- Structure of the pharmacies limit access to other clinic staff thus ensuring blinding.
- Checklists for enrolment and follow-up are detailed and easy to follow and contain all the required steps for dispensing study product.
- Doing QA/QC procedures in real time


ASPECTS OF ASPIRE THAT WORK WELL

- Having "pre-loaded" binders for enrolment. This is good because it avoids confusion, saves time on dispensing during enrolment.
- Routine random checks on study product inventory in addition to monthly inventory ensures effective study product accountability.



CHANGES IN FUTURE TRIALS

- Pharmacists should have interviews with participant regarding study product experiences quarterly.



Dispensing more than one ring at a time:

- So far each site has dispensed two rings for one participant at some point.
- With the number of incidences we have had it's difficult to calculate the frequency.
- We anticipate that this may increase especially during the festive season and as the participant's number of visits increase.

THANK YOU





Pharmacists Role in ASPIRE

WRHI

The pharmacist may provide counselling about the administration, storage, and side effects of any concomitant medications issued during the study.

The pharmacists will be available at follow-up visits for counseling sessions should the participant have any specific questions around the ring (its formulation, possible discomforts) or at the request of the clinician or nurse.

RM -2012

??????



The Pharmacist's Role in ASPIRE

Cape Town, October 2013

By Clare Dott, MPharm

**Wits Reproductive Health &
HIV Research Institute**



Role in ASPIRE

- Most important: provision of study product.
- Control of study product: dispensing, accountability, appropriate storage, assessing need for stock, and ordering and receiving stock.
- Maintain blinding – restrict access to pharmacy and pharmacy records.
- Regulate dispensing, ensuring that all applicable documentation is present and complete.
- Contribute pharmaceutical aspect to multi-disciplinary discussions with site research team.



Change of Role in ASPIRE since 2012

- Role in ASPIRE only started in June 2013.

What I would like to do different and why

- More pharmacist-participant involvement. Due to the nature of the study and the study product chain of custody at Wits RHI, it is very seldom that participants visit the pharmacy, excepting the rare occasions when a participant collects her own con-meds.

Impact on Adherence and Retention

- Ensuring that provision of study product happens efficiently so as not to disrupt clinic flow and keep participants waiting unnecessarily.
 - Impacts retention by assisting to create a better clinic experience for the participant.
- Providing drug information in multi-disciplinary discussions or training sessions with the site team, and thus facilitating adherence discussions between participants and clinical, community or other personnel.
 - Participants tend to understand the importance of adherence better when they gain an understanding of how the ring releases the active substance continuously while inserted.



What works well in ASPIRE and what should be changed for future trials

- Dispensing, documentation and product return procedures are relatively simple. Little room for error.
- Participant perspective: simple regimen to follow – insert ring and forget about it. No need to remember to use product every day or when required. This should therefore enhance adherence.
- Concomitant medication management would be less complicated if prescribing and recording could be done using active ingredient names as opposed to trade names as this requires the clinical team to be updated every time a different generic is received.



Dispensing of >1 Ring at a time

- 2 Rings were issued at approximately 1.63% of visits where study product was dispensed.
- Reasons: participant travelling, clinician not going to be on site or clinic closed for a period.




Pharmacists Role in ASPIRE

Lilongwe

Pharmacists may meet with participants to discuss drug dispensation and adherence issues that may come up related to the study product.

RM – not yet activated



MTN O2O ASPIRE

PHARMACY ROLES
BY GLADYS CHITSULO
UNC
LILONGWE



Role in ASPIRE

- Not only to dispense vaginal rings but develop and maintain investigational product control system.
- Thus IP ordering, receiving, storing and account for the IP.
- Assessing adherence with regards to study visit compliance



Role in ASPIRE

- Help the clinic strategize issues of adherence and retention and how to deal with loosing rings.
- Provide contraceptives to clinic as well as primary care for participants and their families.
- Training of new staff on ASPIRE protocol and SOP's



Roles in ASPIRE

- The system of ordering and accountability works better.
- Though at times it is difficult to have two dispensing pharmacists at the same time, it works better to avoid dispensing errors.
- Monthly dispensation of one ring is the routine way.



Challenges in ASPIRE

- Dispensing of more than one ring has never been anticipated as it has its own challenges
- The challenge being site has to write to get an approval from the protocol chair
- The participant's HIV status as we are dealing with a very high risk group of sexually active women those older are those that were recruited from STI clinic with STI



Pharmacists Role in ASPIRE

Blantyre

Pharmacists will not take on additional roles to increase interaction with participants as clinic staff will be able to provide sufficient information and adherence counseling.

RM – Not yet activated



Pharmacist Role in ASPIRE

COLLEGE OF MEDICINE- JOHNS
HOPKINS RESEARCH PROJECT-
BLANTYRE SITE



Pharmacist role Overview

□ STUDY PRODUCT MANAGEMENT

- Ordering
- Receiving
- Storage
- Dispensing of study drugs and non study drugs
- Drug Accountability

□ SOP Development

□ QA/QC



Ordering and receiving

- A pharmacist is responsible for ordering and receiving of study drugs and making sure there are no out of stocks.
- Once study drugs are received, they are stored at the recommended temperature.
- Temperature is maintained by two air conditioners and pharmacists always make sure that the temperature is within range.



Dispensing and accountability

- Only pharmacists are responsible for dispensing study rings to the clinic staff/runner following dispensing SOP
- All study drugs received and dispensed are accounted for on the accountability logs.
- Most of the non study drugs are dispensed to the study staff on behalf of the patient



SOP Development

- All Pharmacy SOPs
- Helping the clinic to develop clinic accountability and offsite SOPs



Pharmacist –Clinic staff relationship

- Working hand in hand with the clinic on proper storage and documentation of used rings. (For the first two months, now are being transferred to laboratory).
- We are always available anytime for any issues relating to study rings



QA/QC

- All study drugs received and dispensed are entered on accountability.
- Prescriptions once received are checked by two pharmacist before dispensing
- Study rings are checked every time dispensing is done and Physical inventory is done every month and documented

Pharmacist-participant relationship

- Pharmacist and participant do not meet
 - We ASPIRE to create such an opportunity
 - We ASPIRE to take part in adherence counselling



ASPIRE!!!!!!!!!!!!!!!!!!!!!!!!!!!!!!

BLANTYRE PHARMACY
TEAM



Pharmacists Role in ASPIRE

Cape Town – Prior to Start

Pharmacists provide adherence counseling and information on side effects related to contraception and STI treatments.

Pharmacists may also revisit procedures for ring insertion with the participant, ensure participant understanding of what to expect and when the next ring will be inserted, what to do if the ring comes out, ring use during menstruation, and why it is important to return used rings to the clinic.

The pharmacist may accompany the participant to see the clinician during ring dispensation.

RM -2012

Contraception counseling, STIs, develop relationship with ppt, ring instructions-information-education, adherence counseling, retention, destruction



Desmond Tutu HIV Foundation

Masibambane Ngezandla

Desmond Tutu HIV Foundation

Emavundleni CRS

Melanie Maclachlan



Role in ASPIRE

Contraception Counselling and Provision

STI Counselling and Treatment

Development of Relationship with ppts

Enrolment Ring use instructions

Ring information

Ring use education

Destruction

Ensure waste destruction certificate with all required info.

Assist the SCO with the destruction requirements.

Assist with destruction processes

QC destruction logs

Follow up on Destruction certificates



Role in Aspire (continued)

Adherence Counselling

- Main pharmacy focus
- Using examples from previous studies
- Addressing ppt concerns
- Checking the BBA CRF's and discussing
- Focus on forgetting the ring till the next visit
- What the participant finds easy and difficult
- Checking and discussing RW-1 concerns

LOA 2 – discussing changes, testing and adherence

How has your role in ASPIRE changed since the meeting last year?

1. Greater focus on Adherence
2. Looked at different ways of counselling to improve adherence
3. Development of retention events to help improve adherence

How do you impact adherence?

- Pharmacy staff do adherence counselling
- Play a supportive and encouraging role to participants, always reminding them of the importance of open and honest communication in all counselling sessions.
- Helping to ensure that they can make follow up visits, if not, strategizing with them to aid in a solution.
- Training on adherence

How do you impact Retention?

- All staff responsible for retention
- Building relationships with ppt's
- Work closely with the study coordinator for visits

- Retention events
 - M6 events
 - Movie day at Month 12
- Buddy system

What aspects work well in ASPIRE?

- Randomisation assignment is easy to use
- Risk profile for the women is broader allowing a wider range of women to be represented
- Testing dapivirine levels to link up with what participants say
- Comprehensive STI Screening
- Good safety profile for ring
- Potentially allow women to take greater responsibility for health

What should be changed for future trials?

- Allowing dispensing of ring directly to the participant
- Terminated ppts should not be counted as part of adherence
- Allowing ppts to be replaced if they are terminated from the study
- Missed visits counted per month when the visit window is still open

How frequently would you estimate that you dispense >1 ring at a time for a participant?

At most 1 participant needs more than 1 ring every second month

Frequency increases significantly over holiday periods especially December/January

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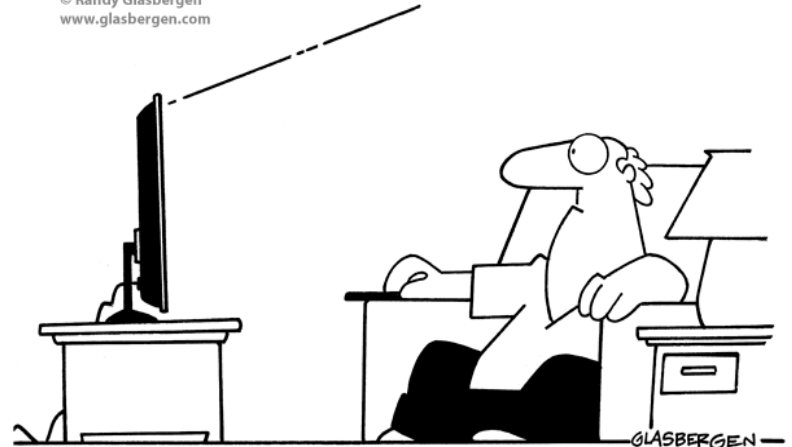
"Well there's a side effect I've never seen before!"

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**"Life gave me lemons, so I made lemonade.
Unfortunately, Vitamin C doesn't cure depression."**

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"Ask your doctor if Placebos are right for you!"