

# From Vaccines to Microbicides : The shift in focus for a CTU



THE AURUM  
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KT Mngadi  
The Aurum Institute  
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# Overview

Major differences

Key factors and their impact on  
site focus

Conclusion



# Major Differences

	Vaccines	Microbicides
Target population	Males and females	Females
Community Outreach		
Messages/awareness	Gender generic	Targeted at females/partners and families
Venues	General community Health care facilities (STI , FP )	Gathering points for women's groups; Females at health care facilities (FP,STI clinics))
Research Facilities	Gender generic	User friendly for females Accessible to partners and families

# Differences (contd.)



Study product	Vaccines	Microbicide
<b>Storage</b>	In pharmacy , freezer	Bulk storage at research site At home, room temperature
<b>Administration</b>	By research staff	Self administered
<b>Dosing</b>	Once monthly for up to max of 4 mnths	Daily [or before sexual intercourse]
<b>Dispensing</b>	Counseling on adverse events	Detailed counseling on product use/storage/compliance/medication returns/adverse events
<b>Accountability</b>	No participant involvement	Return of empty dispensers [pill containers]

# Differences (contd.)

	Vaccines	Microbicide
<p><b>Retention- Visit frequency</b></p> <p><b>Visit duration</b></p>	<p>Frequency decreases with time</p> <p>Duration shorter</p>	<p>Currently intense monthly reviews; Longer on average</p> <ul style="list-style-type: none"> <li>• Behavioral questionnaires</li> <li>• Compliance checks</li> <li>• Partner involvement</li> </ul>
<p><b>Adverse events</b> Biomedical</p>	<p>Fears of infn from vaccine</p> <p>False HIV positivity</p>	<p>Possible ARV resistance</p>
<p>Social harms</p>	<p>False positive results</p>	<p>Partner issues</p> <p>“High risk “ = promiscuity labeling</p> <p>Myths around study product :</p> <ul style="list-style-type: none"> <li>• HIV/STI treatment</li> <li>• Thinks partner is HIV positive</li> <li>• Contraceptive method</li> </ul>



# 1. Study Population

- High risk population ( gender inequality)
- Females (reproductive years)
  - Vulnerable population
  - Marginalised in developing countries (culture, religion, legal framework, social)
  - Unable to fully influence or control contraception and HIV/STI prevention in relationship
  - Lower income (less mobile, less free time, less choice)

## 2. Community Outreach

- Take into account:
  - Increased health seeking behaviour of females (a plus)
  - Requiring permission from partners to be screened and enrolled
  - Risk of social harm (being seen as high risk, “myths” associated with vaginal gels e.g. prevention of HIV, treatment of STI’s, abortifacient, lubricant = promiscuity)
  - Recruitment from venues indicative of “unprotected” sexual activity:
    - STI, FP and PNC clinics (breastfeeding)
    - Sex workers



# Implications for site



- Adapt :
  - Community outreach strategy and activities
  - Know your community
- Consider the following:
  - Marketing of onsite medical services
  - Sensitivity training for male recruiters
  - ? Exclusive use of female recruiters
  - Changing usual recruitment points
- Study clinic : comfortable, friendly , inviting environment, sensitive to female needs , accommodate women with children
- Teamwork and brainstorming vital

### 3. Study Product: Microbicides

- Cheaper , easier to use , female controlled
- Volume of product ( daily use):
  - Storage and dispensing
  - Accountability ( return unused study product)
- Participant-controlled usage:
  - Comprehensive instructions
  - Compliance and self report
  - Reporting and management of side effects

# Microbicide as IP- implications

- More storage space for IP :
  - Assess pharmacy capacity and plan accordingly
- Handover of bulky product packages:
  - Dedicated dispensing area
  - IP to be placed in carrier that is discrete
- Detailed counseling on usage, compliance, side effects and storage
  - Dedicated dispensing area
  - Pharmacist to dispense and advise in addition to nurse
  - Use of other vaginal products and possible interactions
- Accountability
  - Return of unused product/ empty containers per visit
  - Documentation of returns
  - Time periods and instances guiding product return e.g. if pregnant, or adverse events, admission



## 4. Adverse events and Microbicides

- Participant administered product
  - Rely on participant driven report of adverse events, pregnancy etc between visits
    - Challenges of beliefs re receipt of active product vs placebo:
      - Distort balance between risk of side effects vs possibility of benefit
      - Increased risk behaviours ; reduced risk behaviour reporting
    - Reporting bias:
      - “expected” rather than actual use to please study staff
      - pleasant/enhancing side effects to convince staff of compliance
- Possibility of resistance to antiretrovirals



# Adverse events of microbicides- implications

- Research staff awareness and training:
  - Awareness of factors affecting accurate reporting
  - Creating an environment conducive to accurate product use / reporting ( non – judgemental, non – threatening)
  - Risk reduction and other counseling skills
  - Awareness of expected side – effects
  - Protocol knowledge with regards to resistance data and how to answer FAQ's

## 5. Partners and Families of Microbicide Trial Participants and Implications for site

- Product is detectable during storage at home – may lead to questions from partners and families:
  - Staff awareness and training on:
    - How to counsel participants on management of incidents; what answers to give if any
    - How to handle partners/families that present to study site and demand explanations
    - Reporting of social harms consequent to incidents
    - Follow up support for participants experiencing social harms



**MEDICAL CARE**

**Walk-In MEDICAL CARE** \$113.00

**Walk Care**

- General Check-up
- Skin Treatment/Prescription
- Urinal Infection
- Cough/Sore Throat
- Urinary Tract Infection
- Ear/Acute Otitis Media
- Allergic Rhinitis
- Rash
- Sinus Infection
- Acute/Chronic Conjunctivitis
- Joint Pain
- Head Congestion
- Pink Eye/Itchy
- Back Pain
- Headache/Migraine
- Over The Counter
- Call Item
- X-ray/Procedure

**Minor Exam Care Services** \$145.00

\*You may incur charges for supplies and/or additional testing.

**Annual Care** \$199.00

- Year Exam
- Year Vaccination
- Year X-ray
- X-ray/Body Removal
- Skin For Year Exam
- Silver Spoon (Adult/Preschool Food)
- Allergic Diagnosis
- Health & Wellness Screening
- General Check-up and all tests listed

**Walk & Wellness Services**

- Flu
- Blood Sugar
- Cholesterol
- Tuberculosis (TB)
- Urinalysis

\*May not be covered or an additional charge with General Check-up.

**Prescriptions**

\*Prescriptions will be charged separately. Following a General Check-up.

**Insurance**

Patients are responsible for their own insurance coverage. Patients with insurance should contact their insurance provider for details. Patients without insurance should contact their insurance provider for details. Patients with insurance should contact their insurance provider for details. Patients without insurance should contact their insurance provider for details. Patients with insurance should contact their insurance provider for details. Patients without insurance should contact their insurance provider for details.

## 6. Microbicide trials – Management of Pregnancy and Implications for site

- Pregnancy prevention :
  - Counseling ( partner buy in)
  - Provision of on site contraception
- Report and confirmation of pregnancy :
  - Enrolment into sub protocol with ICF's for both mother and infant
- Staff must be vigilant and aware:
  - Avoid missing opportunities for enrolment to sub protocols
  - Impact of change in scheduled procedures
  - Synchronise study visits
  - Referral to ANC (retrieval of ultrasound reports)
  - Paediatric assessments to be scheduled



## 6. Microbicide trials -Retention

- Frequency of visits (monthly)
- Bringing minor children to the site (no alternative caregiver at home)
- Withdrawal of permission from partner to continue visits (social harms)



# Retention with Microbicide Trials - Implications

- Staff training in and awareness of :
  - Barriers to retention
  - Value of assisting participants with forward planning :
    - Allocating funds and time to follow-up visits
    - How to manage detection by partner/ family
    - Suggestions for alternative caregiver for minor children on visit days
  - Site resources to assist with :
    - Disclosure of study participation
    - Care for minor children ( without setting a precedent)

# 7. Social Harms - Implications

- High risk cohort - perceptions by community, partner, family - labeling and rejection
- Reinforce the perception that prevention is a female issue
- Myths about study product
- Violence by partner

Staff awareness, training and competence:

- Recognition of harms and how to address
- When and to whom to refer for assistance – site resource list

Site considerations:

- Screener protocol ( all ppts undergo standard screening)
- One clinic facility for all protocols

# Conclusion



- Staff tuned into gender issues and cultural , religious and social constructs of the population
- Staff awareness , training and competencies are vital – employing a higher level of staff tuned into the nuances of microbicides, able to preempt problems and address proactively or know when to refer/report
- Staff that are non- judgemental, know themselves and their prejudices and how to accommodate for the same.



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# THE AURUM INSTITUTE

To seek, to find, to share, to care