

ACCEPTABILITY STUDIES IN DURBAN, SOUTH AFRICA:

Past, Present and the Future



DR GITA RAMJEE
HIV Prevention Research Unit
Medical Research Council
Durban, South Africa

INTRODUCTION

- **Worldwide escalating number of HIV infections among women**
- **Urgent need for female controlled methods, e.g.:
Microbicides**
- **Product acceptability – ultimately determines use**

Critical to determine acceptable product characteristics, barrier to use and cultural factors influencing use in parallel to clinical trials

OBJECTIVES

- **Determine product acceptability in different population groups**
- **Determine product acceptability among microbicide-experienced women and their partners, and microbicide-naïve women**
- **Conduct randomized control trials (RCT's) of novel microbicide – inform pharmaceutical industry**
- **To identify facilitators and barriers to the introduction of microbicides in the public/private health care systems**
- **To identify barriers to the introduction of microbicides among potential users**

PRODUCT ACCEPTABILITY IN VARIOUS POPULATIONS (Past Research)

Sexworkers participating in COL 1492 trial

- **Product acceptable**
- **Did not interfere with cultural practice of “dry sex”**
- **Enhanced sexual pleasure** Ref: Ramjee et al. SAMJ 1999, 89: 673-676

Non-sexworker population

- **Product acceptable**
- **Enhanced sexual pleasure**

MEN FROM STD CLINICS, GENERAL POPULATION & UNIVERSITIES

- **80% wanted protection from HIV/STD for female partners**
- **77.87% preferred partners to use vaginal microbicide**
- **66-82% involved in decision making process**
- **Desire a non-contraceptive product**
- **58-67% excess lubrication not desired product characteristic**

Ref: Ramjee et al. Int Family Planning Perspectives, 2001, 27(4): 164-170

DISCLOSURE OF MICROBICIDE USE BY WOMEN

Voluntary Disclosure:

- long-term steady relationship
- Fear of discovery

Non-disclosure:

- Fear of partner suspecting HIV/STD infection
- Clients may decline condom use
- Right to protect themselves
- Violence
- Forced to leave study by partners

Ref: Morar et al. Poster Presentation, Microbicide 2002 Conference, Antwerp, 2002



SEXWORKERS' BELIEFS, EXPERIENCES AND PERCEPTIONS OF COL 1492 IN DURBAN

- **Mixed reaction to beliefs of the efficacy of the product**
- **Majority participants accepted product**
- **Highlighted urgent need for effective microbicide**

Ref: Qwana et al. Oral Presentation, Microbicide 2002 Conference, Antwerp, 2002



CURRENT STUDIES

Randomized Controlled Trial to determine acceptable volume and product characteristics of inert formulation of PRO2000 among rural men and women

OBJECTIVES

- **To determine most appropriate and acceptable volume and texture of the product**
- **Cultural factors influencing use of product among rural women**
- **Inform the pharmaceutical industry of the desired product volume and texture**
- **Determine adherence to product use**

STUDY DESIGN



Viscosity 1	Period 1	Volume 1	Volume 2
		A	B
	Crossover	WASHOUT PERIOD	
	Period 2	Volume 1	Volume 2
		A	B
	WASHOUT PERIOD		
Viscosity 2	Period 3	Volume 1	Volume 2
		A	B
	Crossover	WASHOUT PERIOD	
	Period 4	Volume 1	Volume 2
		A	B
	WASHOUT PERIOD		

FUTURE STUDIES

Identification of facilitators and barriers to introduction of microbicides into public/private health sectors

Open-ended Interviews:

- **Risk assessment**
- **Perception of different level of protection by various prevention strategies**
- **Preferences of prevention methods**
- **Perceptions and beliefs about microbicide use**
- **Willingness to endorse method**
- **Developing strategies of disseminating information on microbicides at various levels within health sector**

FUTURE STUDIES

Barriers to introduction of microbicide among potential users

- Focus groups to discuss knowledge on microbicides
- Develop appropriate microbicide promoting material with advertising and marketing agencies
- Market research – appropriate microbicide distribution for different target groups

CONCLUSION

- **Microbicide acceptability studies are relevant and important**
- **Need a standardized tool for measuring acceptability**
- **Comprehensive programme on product acceptability – research focus – potential providers, potential users, social marketing, clinical trial of desired product characteristics, male, female and couple perceptions, cultural values and attitudes, etc.**
- **Acceptability studies and clinical trials of new products in parallel**

ACKNOWLEDGEMENT

**Studies on acceptability of vaginal microbicides
funded by NICHD grant 5 R01 HD4015**

