Acceptability Studies Contribution to Microbicide Access

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Microbicide Access Forum

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Topics

- Links between acceptability and access.
- Highlights from a range of acceptability research.
- Highlights of recent IPM acceptability studies.
- How acceptability research can contribute to facilitating access to microbicides.
- Draw some conclusions for the way forward.
Access Components

- Availability
- Accessibility
- Acceptability
- Affordability
Microbicide Development Process

Research & Development
- IP rights
- Formulation
- Lab safety
- Community engagement
- Capacity building
- Incidence studies

Site Development
- Safety
- Efficacy
- Acceptability

Clinical Trials
- Clinical trials
- Licensure
- Post-licensure studies

Regulatory Approval
- Manufacturing
- Service delivery
- Marketing

Launch & Access
- Manufacturing
- Service delivery
- Marketing
### Microbicide Acceptability Research Examples

<table>
<thead>
<tr>
<th>Source</th>
<th>Research Examples</th>
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<tbody>
<tr>
<td><strong>(NIH, CDC)</strong></td>
<td>Independent research, microbicide programs and studies ancillary to large research networks (e.g., HPTN, MTN)</td>
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<td><strong>UK DfID</strong></td>
<td>MDP integrated mixed-method design, with comprehensive acceptability assessment</td>
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<td><strong>USAID</strong></td>
<td>Carraguard Phase III exit focus groups (PC) Cellulose Sulfate Phase III study (CONRAD) Tenofovir, CONRAD, CAPRISA</td>
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<td><strong>Gates Foundation</strong></td>
<td>MIRA Phase III diaphragm trial - acceptability sub-study</td>
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<td><strong>IPM</strong></td>
<td>Product acceptability studies, Market Research</td>
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Acceptability studies include investigation of user-experiences and preferences in the following domains:

- Product characteristics
- Sexual relationship effect
- Male partner involvement
- Covert use potential
- Concerns about side effects
- Delivery systems for health care services
IPM Product Acceptability Studies

- Placebo gel formulations (PAS 1)
  - Completed 2006
  - Kenya, South Africa, Zambia

- Placebo vaginal ring (IPM 011)
  - South Africa, Tanzania - ongoing
  - Kenya – follow up

- Placebo vaginal tablet, film, soft gel capsule (PAS 2)
  - Planned 2008-09
  - Burkina Faso, Mozambique, Tanzania, Zambia
Market research conducted Feb-May 2006
- Partners: MR Solutions (US), Research IQ (South Africa), Steadman Group (Kenya)

3 placebo gels of different viscosities
- KY (low), HEC (medium), 002p (high)

7 locations in 3 African countries
- Nairobi, Nakuru (Kenya)
- Johannesburg, Cape Town, Durban (SA)
- Lusaka, Kitwe (Zambia)

543 sexually active women
- ½ single, ½ married or living with partner
- ½ higher, ½ lower socioeconomic status
- 18-30 years, not pregnant.
Primary objectives:
- Which gel do women prefer?
- How do the gels compare (consistency, leakage, sexual pleasure, likelihood of use)?
- What do women like/dislike about the gels?
- How do the male partners react to the gels?

Secondary objectives:
- Value and limitations of market research
- Relationships with market research partners (Africa, US)

Value added:
✓ Introduce market research in developing countries to assess acceptability of potential microbicide products
PAS 1 – Methodology

- Door-to-door recruitment in urban settings

- Each product is used once daily for 1 week
  - At least once right before sex
  - Randomized product placement
  - Condom provision

- 4 interviews with women (at screening and after each product use)
  - Comparative evaluation in final interview
  - In-depth focus groups (SA, Kenya)

- Male partner participation
  - 45 interviews and 2 focus groups (SA, Kenya)
PAS 1 – Results

- **Overall best rating – HEC (medium viscosity)**
  - Among women, too thick was better than too thin
  - 96% liked ‘clear’ gels, but ‘odor’ preferences vastly different
  - For most, gels increased or had no impact on sexual pleasure

- **Likelihood to use – assuming health benefit**
  - More women ‘likely to use’ gels if health benefit

- **40-50 % of male partners aware of gel use**
Placebo ring acceptability and safety study
  • Clinical study (device), initiated Feb 2007

Product: soft silicone ring
  • Attractive technology: 30 days of drug delivery
  • Marketed in US, Europe for other medical uses

200 women participants (18-35 years)
  • HIV-negative, not pregnant, on contraceptives

Research centers in South Africa, Tanzania, Kenya
Assess acceptability of vaginal rings in Africa

- To date, testing & utilization of vaginal rings is largely limited to developed countries
- Gain information on African women & men’s preferences and likelihood of usage

Assess safety of placebo vaginal rings, independent of active drugs

- If safe for use in Africa, can use as potential delivery method for HIV microbicides
Open label, randomized, cross-over design

Acceptability & adherence measurements
- 5 questionnaires administered throughout study
- In-depth focus groups (approx 20 women per site)
- Interviews with male partners (approx 20 men per site)
Questionnaires/discussions cover:

- Adherence
- Product experiences/likes and dislikes
- Vaginal practices
- HIV prevention practices
- Willingness to use product
- Perception of partner preferences
Market research study, planned 2008-09

3 new placebo formulations
  • Vaginal tablet, film, soft gel capsule

8 sites in West, East and Southern Africa
  • Burkina Faso, Mozambique, Tanzania, Zambia
  • 2 sites per country (urban and rural)

600 sexually active women (18-30 years)

Preparations and ethics approvals in progress
Assess acceptability of novel vaginal formulations (film, tablet, soft gel capsule) as potential microbicide delivery systems

Compare products to see which is best received

Determine how acceptability of different methods is influenced by cultural settings
PAS 2 – Methodology

- **Products used once daily for 1 week each**
  - Encouraged to use shortly before sex
  - Randomized block design for product placement
  - Condom provision

- **Evaluation interviews with women**
  - More in-depth focus groups planned

- **Male partner participation**
  - Individual interviews with some partners planned
Duet™ Acceptability – Overview

■ Duet acceptability and safety study
  • Planned enrollment starting Aug 2008

■ Product: Duet (cervical barrier)
  • Reusable, one-size-fits-all, clear barrier
  • Gel is applied on both sides

■ 100 women participants (18-40 years)
  • HIV-negative, not pregnant, on contraceptives
  • Half have previous diaphragm use experience
  • One research site in Zimbabwe
- Assess female and male acceptability

- Assess female and male perspectives and preferences for using Duet daily compared to pre-coital use

- Assess the safety of the Duet among African women, when used daily for 14 days and pre-coitally for 14 days
Acceptability of Microbicide Delivery Methods & Improving Self-reporting and Adherence

Planned Research
- Zambia, placebo gel & inert vaginal ring
- Donors: Swedish Ministry of Foreign Affairs & USAID

Objectives
- Study acceptability & feasibility
- Investigate self-reporting methods to improve adherence including interactive voice response survey (IVRS).
- Assess various recruitment strategies by utilizing community surveys, respondent driven sampling (RDS) and recruitment via male partners

Recent Population Council Studies
- **Nestorone/ Ethinyl Estradiol Contraceptive Vaginal Ring (NES/EE CVR):** safety, efficacy, acceptability
  - Phase 3 Trial; Funded by USAID, NIH, WHO
  - 2300 women: US, LA, Europe, Australia.
  - Acceptability study in 12 sites

- **Progesterone Receptor Modulator Vaginal Ring for estrogen-free, bleed free contraception**
  - Phase 2 Study; Funded by NIH
  - 80 women in LA, US (Chile, Dominican Republic, Oregon)

- **Progesterone vaginal ring for contraception during lactation:**
  In Preparation
  - Phase 3- Safety, Efficacy, & Acceptability
  - To be conducted in India
Dissemination of Results

Multiple audiences:
- Research community
- Community leaders/civil society
- Policy decision-makers
- Advocacy groups
- Media
- Potential users

Dissemination must be appropriate for each
Conclusions

- Acceptability studies provide essential information on preferences and the social context of use that can affect microbicide effectiveness.

- They should be considered an integral part of microbicide development agenda and need to continue.

- Issues of acceptability that need further investigation include: condom migration, impact of partial efficacy, role of male partner.

- There is a need for capacity building in conducting social-behavioral research.