International Partnership for Microbicides

Acceptability Studies Contribution to Microbicide Access

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Microbicide Access Forum

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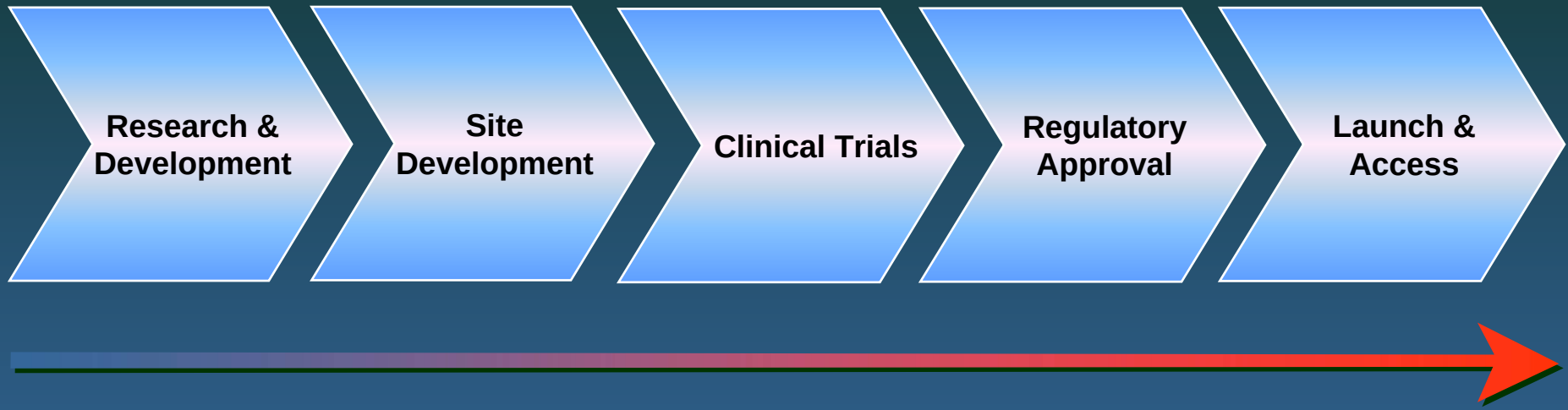
Topics

- 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



- •IP rights
- •Formulation
- • Lab safety

- • Community engagement
- • Capacity building
- • Incidence studies

- • Safety
- • Efficacy
- • Acceptability

- • Clinical trials
- • Licensure
- • Post-licensure studies

- • Manufacturing
- • Service delivery
- • Marketing

Microbicide Acceptability Research Examples

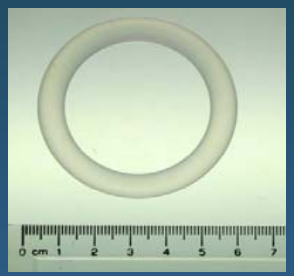
(NIH, CDC)	Independent research, microbicide programs and studies ancillary to large research networks (e.g., HPTN, MTN)
UK DfID	MDP integrated mixed-method design, with comprehensive acceptability assessment
USAID	Carraguard Phase III exit focus groups (PC) Cellulose Sulfate Phase III study (CONRAD) Tenofovir, CONRAD, CAPRISA
Gates Foundation	MIRA Phase III diaphragm trial - acceptability sub-study
IPM	Product acceptability studies, Market Research

Domains of Inquiry

- 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

Gels - PAS 1

- 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.

PAS 1 – Objectives

- 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

Rings - IPM 011

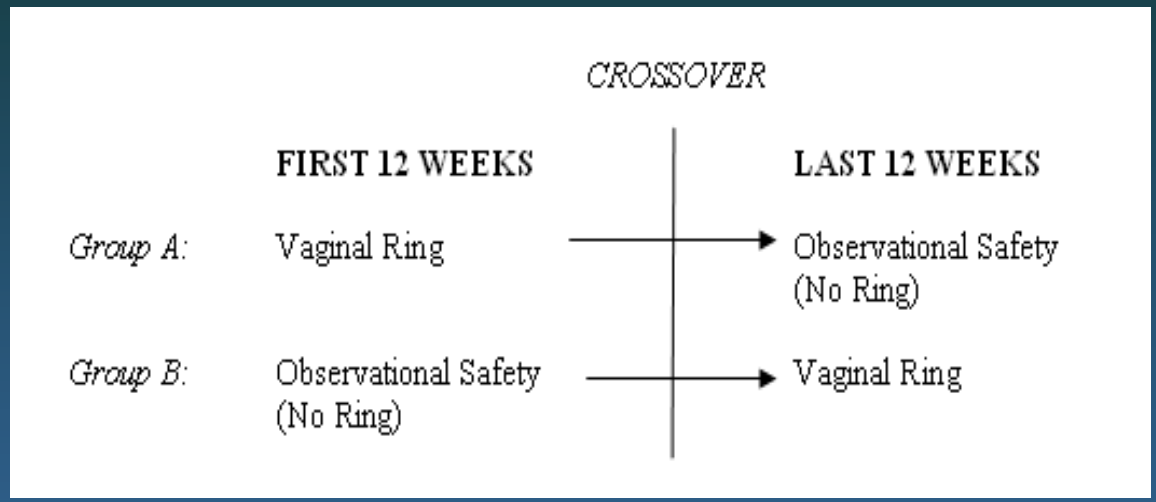
- Placebo ring acceptability and safety study
  - Clinical study (device), initiated Feb 2007
- Product: soft silicone ring
  - Attractive technology: 30 days of drug delivery
  - Marketed in US, Europe for other medical uses
- 200 women participants (18-35 years)
  - HIV-negative, not pregnant, on contraceptives
- Research centers in South Africa, Tanzania, Kenya

IPM 011 – Objectives

- 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

IPM 011 – Methodology

- 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)

IPM 011 – Acceptability

- Questionnaires/discussions cover:
  - Adherence
  - Product experiences/ likes and dislikes
  - Vaginal practices
  - HIV prevention practices
  - Willingness to use product
  - Perception of partner preferences

PAS 2

- 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

PAS 2 – Objectives

- 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

Duet – Objectives

- 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

Recent Population Council Studies

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

Current Hormonal Contraception Trials with Vaginal Rings Population Council

- 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 approptiate 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