Use of Acceptability Research for Development and Implementation of Microbicide Prevention Methods

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Microbicides: Background

- Chemical products applied to vagina or rectum with the aim of reducing the spread of sexually transmitted organisms.
  - Cell/pathogen surface disruptive agents (e.g. N-9 spermicides)
  - Maintenance/mobilizers/enhancements of normal vaginal defense mechanisms
  - Inhibitors of viral binding and fusion
  - Inhibitors of HIV replication

- Currently over 65 products development (twenty in Phase I trials, three in Phase II, four in Phase III)

- All phase III trials involved N-9 products
  - N-9 proven to be ineffective as protection against HIV (because of higher incidence of vaginal lesions/epithelial disruption?)
Microbicides: Benefits and Challenges

Potential Benefits of Microbicides:
- Women-controlled preventative option
- Could allow conception and protection simultaneously
- Combat multiple STDs at once
- More discrete?
- Bi-directional protection
- Additional lubrication benefits?

Challenges to Success with Microbicides
- Clinical study and care (SOC dictates condom as well as microbicide distribution, hard to track efficacy, need large N)
- Scientific (better understand mucosal immunity)
- Formulation
- System delivery and support (distribution, education and counseling, ongoing user support)
- Social and cultural barriers (unique to locations and target populations)
- Condom migration concerns?
Thesis

- Microbicides, because they increase the breadth of preventative options and provide women with a preventative option over which they can have greater control, should be pursued for pragmatic and ethical reasons.

- Optimal efficacy of microbicides will depend on their availability, accessibility, the surrounding health support and education systems, involvement of local leadership, and strategies that address the interaction of personal and social/cultural factors that influence product use and non-use.

- Acceptability research provides a platform for understanding how to shape microbicide development on local levels. Thus, a standard form for employing acceptability research concepts to guide implementation should be developed and will minimize concerns over challenges.
In general, acceptability research investigates *how* and *why* people use (contraceptive of prophylactic) products in “real life.”

Past conceptions of “acceptability”
- A quality inherent in the product itself which makes it attractive, pleasing, welcome
- Acceptability research aimed to “modify technology and programs to fit people, rather than modifying people to fit technology and programs.”
- Often conceptualized as a way to estimate the market potential and/or likely patterns of use.

Measurements
- Continuation rates during clinical trials
- Attitudes toward hypothetical measures/after use
- Uptake of a method in context of other choices

Critiqued as lacking clarity in philosophy/purpose and a standard set of guiding measurements
- Often disregarded influence of unique social and cultural contexts
Current Thoughts on Acceptability Research: Reorienting the Paradigm

- Current conceptualizations of “acceptability” should recognize the importance of contextual factors
  - Acceptability as a “complex interplay between a woman, a technology, and a service delivery environment.” Increasingly referred to as “user perspective research”
- Avoid using acceptability research to make broad generalizations about contraceptive or protection method preference
- Obtain user perspectives on existing and prototype technologies
- Explore how and why women make their use/non-use decisions
  - Relationship/partner information
  - Gender/power dynamics in relationship(s)?
  - Sexual experience?
  - Desire for pregnancy?
  - Previous contraceptive use?
  - Perspective of partner, peers, family?
  - Etc.
- Increasingly referred to as “user perspective research”
### Local Resources Survey
- What kind of health care services are available?
- Who can (and does) access these services?
- What are the barriers to access of health services?
- What are the resources (and resource limitations) of health services: money, technology, facilities, trained personnel…
- What are local perspectives/perceptions of the health care services?
- How would local services be prepared to distribute microbicide products?
- What educational facilities/resources are available?
- What CBO or NGOs are in place?

### Survey of Social and Cultural Factors
- What are the unique situations of men and women in terms of economic income, education, job opportunities, social/cultural roles?
- How to different genders, generations, and subgroups perceive:
  - Contraception (different forms)
  - Protection (different forms)
  - Lubrication during sex
  - Men’s and Women’s Roles in relationships and related to sex (different forms of relationships)
  - Seeking health care services and support
  - Sexual Health, STD, AIDS, pregnancy, etc.
Standard Acceptability Research Format

- Women’s User Preference Survey
  - Specific Response to Actual or Hypothetical Products
    - Would you use this product? (Why or why not?)
    - Did you find it satisfactory? (Why or why not?)
    - How does it compare with your experience of other methods?
    - Would you use it again or recommend it to others
  - General Survey to Context of Women’s Lives
    - New or established relationships?
    - Partner characteristics
    - Gender/Power dynamics of relationship(s)
    - Sexual experience? Frequency of sexual encounters
    - Pregnancy desires
    - History contraception experience and perceptions
    - Partner dynamics of contraception and protection

- Identification of Barriers to Optimal Contraception and Protection Use
Suggestions for Future Efforts

- Implement Survey Protocol to be used locally through CBO or NGOs
- Advocate for further scientific R&D on microbicide options
- Collect acceptability research in context of clinical trials
- Broaden scope of acceptability research beyond technological aspects of product design
- Incorporate results from female condom research?
- Refine and utilize hierarchical counseling strategies to minimize condom migration
- Stress community organizing (rather than “health beliefs” model)

Design standard method of measurements
- Quantitative (constellation of continuity rates, efficacy rates, use rates?)
- Qualitative
Selected Resources


Elias C, Coggins C. *Acceptability research on female-controlled barrier methods to prevent heterosexual transmission of HIV: Where have we been? Where are we going?* Journal of Women’s Health & Gender-Based Medicine 2001; 10(2):163-173.

Hordon A. *The needs of women versus the interests of family planning personnel, policy-makers and researchers; conflicting views on safety and acceptability of contraceptives.* 1992. Social Science and Medicine. 35(6):735-766.


