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Acceptability of microbicides as products protecting against STIs and HIV/AIDS: A systematic review

Moisés Matsinhe
Health Development Regional Centre
Maputo, Mozambique

Abstract

Background

With the recognition that women are powerless in making decision on safe sex and the increasing prevalence of STIs and HIV/AIDS, there is a need to understand the socio-cultural barriers that can interfere with the acceptability of new strategies, in particular, Microbicides, on preventing STIs and HIV/AIDS.

Methods

Fourteen studies where screened following the standard methodology for systematic reviews. The studies searched were from 1990 to 2005 addressing the acceptability of Microbicides.

Results

The majority of selected studies were from the USA, followed by Africa with four studies. UK had two studies and India one. The last two studies were from a multi-center. Only one study described how data were collected and analyzed.

Background

Worldwide there are many programs addressing sexually-transmitted infections (STIs) and HIV/AIDS prevention. Parallel to these programs, there are other interventions in the area of pharmaceutical products. Among products available, microbicides are the most promising. Since the early nineties, microbicides were identified as effective in preventing STIs and HIV/AIDS. Microbicides are defined as a range of products, potentially in gel cream, film or suppository form, being developed to prevent transmission of HIV/AIDS and other STIs when applied topically (1). It is clear from the definition that microbicides can prevent getting STIs. Microbicides can provide primary protection to women and couples who can not or do not use condoms (1, 2). Once developed, microbicides and vaccines would be applied as complementary prevention strategies (2). Microbicides can also shift the gender power relations of STIs and HIV/AIDS prevention by empowering women. Women would be able to use microbicide without men consent because it is inserted in the vagina and men can not notice.

There are few studies addressing the acceptability of microbicides. In Sub-Saharan African countries, women do not have power to negotiate for safer sex practice. If an effective microbicide was available, women from this region would be empowered and could make decision on having safe sex. There are several microbicides that have been tested; therefore, acceptability outcome is important in order to be available for the use of all population who are at risk of contracting HIV (3).

Several Randomized Clinical Trials have been done and the problematic of acceptability is one that seems to be less analyzed. In analyzing the acceptability of the use of microbicides in the Sub-Saharan African region, several socio-cultural aspects have to be considered (4). As it was stated before, women in this region are powerless and men take the decision of having protected sex. There is a need for female-controlled methods of HIV prevention (5).

The acceptability of microbicides as a mean to prevent HIV/AIDS is important for several reasons. First, the potential users have to be aware of the new product and know its advantages in comparison with others that are already in place (6). Second, providers such as health care workers have to be able to explain how to use the new product and how it is more effective related to others that have been used before. In the last, community leaders have to be explained from the benefits of the new product so they can advocate its use (7). Assessing acceptability of microbicides not only provides information for further clinical trials and product development, but also, provides the information on socio-cultural factors that can be a barrier for the use of this new product (8).
This systematic review aims to evaluate the acceptability of microbicides in studies done from 1990 to 2005.

Objective

To assess the acceptability of microbicides as products protecting against HIV/AIDS and other STIs.

Criteria for considering studies for this review

Types of studies

Any study measuring the acceptability of microbicides as products protecting against STIs and HIV/AIDS.

Types of participants

Men and women in reproductive age 15-49 years from all over the world, in any type of setting, rural and urban areas, married and unmarried, are included.

Types of interventions

Any study assessing the acceptability of microbicides, users, providers and community leader's perception.

Types of outcomes measure

Studies measuring at least one of the microbicides related outcomes such as user's willingness to consistent use, and socio/cultural implication such as non-user's perception (i.e. provider's perceptions and community leader's perceptions).

Search Strategy for identification of studies

Published studies, in all languages, from 1990 to 2005 were systematically searched through:
a) International agencies involved in HIV/AIDS prevention in Sub-Saharan Africa such as WHO and UNAIDS websites.
b) Data bases: Cochrane Library, Medline, Aidsline.
c) Hand searching of key journals: AIDS, American Journal of Public Health, Sexually Transmitted Disease, The Lancet, Genitourinary Medicine, Journal of American Medical Association, Journal of Acquired Immune Deficiency Syndrome and Human Retrovirology.

Electronic search strategy:

For MEDLINE:

- Microbicide - acceptability AND sub Saharan Africa
- Nonoxynol-9 - acceptability OR microbicides - acceptability AND hiv aids sti prevention
- Microbicides - N-9 AND acceptability
- Nonoxynol-9 - acceptability OR spermicides - acceptability AND hiv aids sti prevention.

For AIDSLINE:

- Nonoxynol-9 - acceptability OR microbicides - acceptability AND sub Saharan Africa
- Microbicides - acceptability AND hiv aids sti prevention

For Cochrane Library:

- Nonoxynol-9 - acceptability OR microbicides - acceptability
- Microbicides - acceptability AND hiv aids sti prevention

For Social Science and Medicine:

- Microbicide - acceptability AND sub Saharan Africa
- Nonoxynol-9 - acceptability OR microbicides - acceptability AND hiv aids sti prevention
- Microbicides - (N-9) AND acceptability
- Nonoxynol-9 - acceptability OR spermicides - acceptability AND hiv aids sti prevention AND sub Saharan Africa

Key words: Microbicides, N-9, acceptability, women, HIV, AIDS, STI, prevention, Sub-Saharan, Africa.

Methods of the Review

Selection of studies

Studies identified in the search were initially reviewed by title and abstract. Those identified as being of potential interest were further assessed using the full text to develop a list of studies focusing on acceptability. Studies that did not provide adequate details on acceptability were excluded.

Table 1: Included and excluded studies

Study	Methods	Participants	Outcome	Included
Bentley M E. & al. 2004 (2)	Quantitative survey data (structured interviews and focus groups)	98 women from 4 countries	STIs and HIV prevention, accepted in the most sites (except India)	Yes
Richardson B A. & al. 2001 (3)	Randomized double-blind placebo controlled trial phase III	278 women	STIs and HIV prevention	No
Niruthisard S. & al. 1992 (4)	Randomized clinical trial	343 women	STIs and HIV prevention	No
Weir S S. & al. 1995 (5)	Cohort study	303 sex workers	STIs and HIV prevention	No
Roddy E R. & al. 2002 (12)	Randomized clinical trial	1251 women at high risk	STIs and HIV prevention	No
Stafford M K. & al. 1998 (6)	Double blind randomization	40 women	STIs and HIV prevention	No
Damme L V. & al. 1998 (7)	Randomized, double blinded, phase with 3 arms	534 women	STIs and HIV prevention	No
Mantell J E. & al. 2005 (8)	Research study	Not applicable	STIs and HIV prevention, perceptions of all stakeholders	Yes
Joshi S. & al. 2003 (13)	randomized clinical trial phase I	23 women	STIs and HIV prevention, Physical properties of the product	Yes
Bax R. & al. 2002 (14)	randomized clinical trial phase I	105 women	STIs and HIV prevention, willingness to use for STD/HIV prevention, sexual pleasure	Yes
Mauck C K. & al. 2004 (15)	Randomized, double blinded, phase I	36 men	STIs and HIV prevention	Yes
Hameeett T M. & al. 1999 (18)	randomized clinical trial	84 drug users women	STIs and HIV prevention, willingness to use	Yes
Bentley M E. & al. 2000 (17)	Structured interviews, participants' diaries, and unstructured exit interviews	27 women	STIs and HIV prevention, product characteristics, effects on sex (pleasure)	No
Ramjee E G. & al. 2001 (19)	Questionnaire	243 men	STIs and HIV prevention, Preference to microbicide compared to condom	Yes

Assessment of methodological quality

All studies having a clear description of the methodology and follow-up rate were accepted. In general all studies had a low statistical power because of the small sample size. The reason for that is related to the phase where the majority of the trials were at the time of the study. Most of the clinical trials were in phase I and II, therefore a small simple size is a characteristic in these phases.
The outcome was reported in a variety of ways. Most studies reported acceptability as individuals' perceptions of potential users when using the nonoxinol-9 (N-9). Other studies provided more information including perceptions of different groups of non

users such as providers and community leaders. Only one study was conducted in a male population in order to collect men's perception of women's microbicides use.

Description of studies

Fourteen studies were included in this review. Seven (50%) studies focused mostly in safety and efficacy of N-9, but did not address acceptability. Seven (50%) of studies referred to acceptability has the result. Among the studies that addressed acceptability, six (42, 6%) had as outcome the willingness to use the product if available. Only one study referred to the need to explore perceptions of all stakeholders. All studies were done in female population except two studies which were conducted among the male population. In one of the studies on male population, the participants were men who have sex with men. The other study on male population was among heterosexual men. This study looked at the male perception and acceptability of female use of microbicides. On women's population, there were four different groups: the first group was composed by low risk women, the second by sex workers, the third one by women at high risk and the last by drugs users. All interventions used one type of microbicide compared to a placebo or another product. Most studies used randomization as a method for assessing acceptability. Two studies used quantitative and qualitative survey data with structured interviews, unstructured exit interviews, and focus groups. A questionnaire was applied in one study.

Results

Fourteen studies were identified for the period from 1990 to 2005. Half of studies focused on the outcome of this systematic review.
The majority, five studies, was from the U S A. Four studies were from Africa, two from UK and one from India. The remaining two studies were from a multi-center (India, Zambia and Malawi). All studies used qualitative methods to assess the acceptability, except one that used both, qualitative and quantitative methods.
In general, the quality of acceptability assessment was low. Almost all studies did not present or describe how data were collected and analyzed.

Discussion

This systematic review discusses the acceptability of microbicides as products preventing STIs and HIV/AIDS. There are barriers in assessing the acceptability of microbicides. The definition of the concept of acceptability is not clear in most studies. Also this concept is not similar from one study to another. For some studies acceptability is related to physical appearance and product characteristics. Once the appearance and characteristics that were discussed in the study are attained, then the product would be acceptable for the users. This point of view does not consider one of the most important factors in acceptability, the perception of the main stakeholders. In addition, these studies can not address socio-cultural problems that can affect the acceptability of microbicides.
Because microbicides are new and studies are ongoing to design an effective microbicide, there is a need of including social scientist in the working teams. This would allow a better understanding of socio-cultural factors that may affect the acceptability of microbicides as products preventing against STIs and HIS/AIDS.

Potential conflict of interest

None declared

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