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The potential impact of microbicides in Bagalkot District, Karnataka, India: model projections and implications for product promotion

Background

There were five million HIV infections globally in 2002. After South Africa, India has the highest number of people living with HIV [1]. The National AIDS Control Organisation (NACO) estimate that 3.82-4.58 million people were living with HIV in India in 2002 [2]. Several microbicide products are about to enter phase III trials. If the vaginal microbicides currently being developed are shown to be effective against HIV and/or other STI, they would offer women an important additional method of HIV prevention.

However, at present it is hard to know what impact a microbicide may have on HIV transmission in different settings. In practice this will depend upon context specific factors, the degree to which microbicides reduce the risk of HIV and STI transmission, levels of distribution, and their acceptability and ease of use. Mathematical modelling, in combination with site-specific data, can be used to project the extent to which a microbicide would reduce HIV transmission in that setting, and to identify key factors influencing impact. This briefing note summarises the key findings from a modelling analysis which estimates the impact of a partially effective microbicide that is widely accessible in the urban areas of three talukas (sub-districts) within Bagalkot District, in the Southern Indian State of Karnataka.

Setting the scene: Bagalkot District and Karnataka

Bagalkot District is in northern Karnataka [3] and is divided into six talukas [4]. The India-Canada Collaborative HIV/AIDS Project (ICHAP) works with local partners in three talukas in Bagalkot District - the demonstration project area (DPA) [3]. ICHAP conducted a baseline community survey in 2003 [3] and are developing a range of HIV programmes. This analysis estimates the impact of introducing a microbicide into the urban localities within the DPA - a population with approximately 93,000 males and 89,000 females aged 15-49. In this setting commercial and casual sex are commonly reported by men, with an estimated 1,000 sex workers and 19,000 clients [3, 5-7]. There are several forms of concurrent sexual partnerships - with some married men having other partners, and over a third of sex workers being married or having other non-commercial partners [3, 5, 8, 9]. Sex workers report very high levels of condom use with their last client (90%), but use is much lower in marital partnerships, with 4% of urban males reporting using a condom at last sex with their wife [3, 5, 8, 9].

Epidemiological data from this area and surrounding districts suggest that the HIV epidemic is starting to become generalised. An HIV prevalence of 17% among male STD clinic attendees in Karnataka was reported in 2003 [10], and an estimated 2% of the urban population in the DPA are HIV infected [3]. Using this data, we estimate that the sex worker HIV prevalence is 54%.

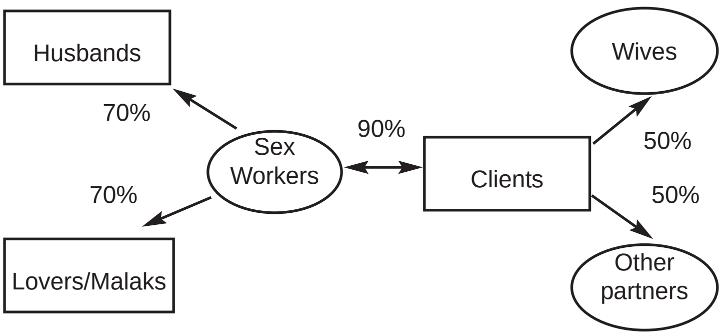
Key findings

- In this setting, for the specific baseline assumptions about microbicide distribution and use:
    - A 40% HIV and STI efficacious microbicide would avert 18% of the 5150 expected HIV infections - mostly averting infections among clients and their non-commercial sexual partners.
    - A 60% HIV and STI efficacious microbicide would avert 35% of the 5150 expected HIV infections - almost twice the impact of a 40% efficacious microbicide.
- Microbicides reduce the extent to which the non-commercial partners of clients become infected both directly - by their own use of microbicides, and indirectly, by reducing the rate at which clients become infected.
- Reductions in condom use following microbicide introduction - termed 'condom migration' - will primarily be a concern if sex workers are using condoms with very high consistency (90%), microbicide efficacy is low (40%) and microbicide use is low (50% of non-condom-protected sex acts).

Model description and aims

The impact of microbicide use is simulated using a dynamic mathematical model and site-specific data. The model simulates HIV and STI transmission between sex workers and their clients, and from sex workers and clients to their non-commercial sex partners. Figure 1 shows the behavioural sub-groups included in the model. The arrows denote possible directions of HIV or STI transmission included.

Figure 1. Model structure and baseline assumptions about consistency of microbicide use in non-condom-protected sex acts

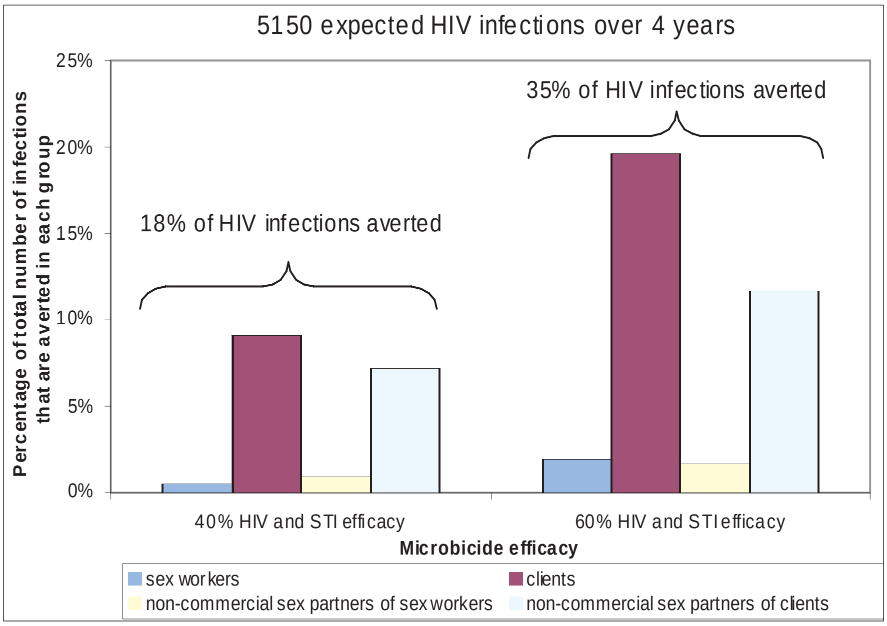


The model is used to project how HIV transmission may change over four years if an efficacious microbicide was made accessible to 75% of the urban DPA population who are sex workers, clients or non-commercial partners of either. The baseline scenario considers a 40% HIV and STI efficacious microbicide. The consistency of use in non-condom-protected sex acts is taken to be: 90% for commercial sex, 70% for sex workers with their non-commercial partners, and 50% for clients with their non-commercial partners. Microbicide users are assumed to reduce their level of condom use by 5% (5% migration).

Projections of microbicide impact

The model projects that over four years 5150 HIV infections will occur among the sex workers, their clients and the non-commercial partners of each. For the baseline microbicide scenario the model projects that 18% of these HIV infections would be averted - with the majority of averted infections being among the clients and their non-commercial sex partners. At 60% HIV and STI efficacy, 35% of the 5150 HIV infections are averted - an almost two fold greater impact than a 40% efficacious microbicide (Figure 2).

Figure 2. Microbicide impact over four years for a 40% and 60% HIV and STI efficacious microbicide



Condom migration, consistency and efficacy trade-offs

The model was used to explore how impact varies with different levels of condom migration, and for different assumptions about the efficacy of microbicides and their consistency of use. The results relate to the baseline scenario values unless otherwise stated.

- The greatest potential negative impact of migration is likely to be in commercial sex, where condoms are used with highest consistency. With 10% migration there is a 5% reduction in HIV infection overall, but a small (1%) increase in the number of HIV infections amongst sex workers.

- The extent to which migration is a potential concern is influenced by the efficacy of the microbicide, and the extent to which microbicides are used. Even 5% migration increases the number of HIV infections among sex workers and clients if a 40% efficacious microbicide is used in only 50% of non-condom-protected sex acts. However, for a 60% efficacious microbicide the impact is not negative in these groups.

- There is the possibility that sex workers over-report condom use. If sex workers actually use condoms 20% less consistently than reported then, even with 20% migration, microbicides will reduce the overall transmission by 13%, and will have a positive impact in each group.

- Given the potential concerns of condom migration in commercial sex, it has been proposed that microbicides should be marketed primarily for use in non-commercial, or long-term relationships. If the model is used to project the impact of microbicides being used only in casual and long-term partnerships, we project that this pattern of use would avert 6% of infections (with no infections averted in sex workers or clients). In contrast, if microbicides were only used in commercial sex as a fall-back to condoms, and not in other forms of sexual partnership, then 12% of infections would be averted overall - primarily among clients. This illustrates the extent to which the overall impact projections of microbicides result both from their use as a fall-back to condoms in commercial sex, and from their use in non-commercial partnerships.

Conclusions

1. Microbicides could be an important addition to current HIV prevention options in India.

2. In settings such as Karnataka, where HIV is largely concentrated in the most vulnerable populations, microbicide use could help reduce transmission to the wider population.

3. If there is little condom migration then, even when condom use in commercial sex is high, microbicides used as a fall-back to condoms with commercial and non-commercial partners could have a substantial impact on HIV transmission - particularly among clients and their non-commercial partners.

4. Condom migration could be a concern among groups who are able to use condoms with high levels of consistency - such as those engaging in commercial sex - particularly if microbicide efficacy and uptake are low.

5. The impact of microbicides will depend upon the extent to which women find them accessible, and easy and convenient to use consistently.

Recommendations

1. Mechanisms to facilitate the regulatory review process and to help the rapid distribution of any efficacious microbicide product should be identified.

2. Methods to promote microbicides for use by people most vulnerable to HIV infection with their non-commercial sexual partners need to be investigated.

3. Different strategies to promote microbicides to different groups need to be considered. Strategies to promote the use of microbicides within primary partnerships need to ensure that their use is not associated with infidelity or lack of trust.

4. Hierarchical messages to separately promote microbicides for use in commercial sex as a fall-back to condoms, without undermining condom use, need to be explored.

5. While products are in development it is important to identify what programmatic and product-related characteristics may affect a microbicide's acceptability, price and ease of use.

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