

Preparing to deliver: introduction of microbicides

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Lilani Kumaranayake, Fern Terris-Prestholt, Charlotte Watts

Health Policy Unit, Department of Public Health and Policy, London School of Hygiene & Tropical Medicine, London, UK.

Background

The HIV/AIDS epidemic is continuing to grow with rapidly emerging epidemics in Eastern Europe and Asia, and a generalised epidemic characterising much of Sub-Saharan Africa (1). Microbicides could be an important addition to current HIV prevention options across all of these settings. Microbicides products are currently in various stages of development and it is anticipated that a number of products will be entering phase III trials in 2004 – 2005 – the crucial stage before the advent of a licensed product.

As clinical development and establishment of efficacy for different microbicide formulations is being undertaken, it is also important to consider and develop potential delivery strategies for microbicides products. This will ensure more rapid utilisation of microbicide products, leading to greater impact on HIV transmission. Concomitant with delivery strategies is the need to consider the costs of alternative delivery mechanisms and hence the implications for resource requirements needed for widespread introduction of a microbicide product. This briefing note summarises the key findings from an economic review of the issues related to development of markets for a number of health products, both contraceptive and as well as broader health products.

Microbicides as public health goods

Public health goods are characterised as products that are used to prevent or treat diseases of public health importance. There are a range of goods which fall under this definition, including condoms for HIV and STI prevention, anti-malarial drugs,

mosquito nets and insecticide treatment for malaria prevention, STI treatment drugs, oral rehydration salts (ORS) for treatment of diarrhoea, and certain contraceptives. The defining characteristic of such public health goods is that their use will benefit both the individual user as well as the wider community, in that they will avert potential further transmission of these diseases within the community.

There are a range of potential methods for delivering these products both within public and private health sectors. For goods that are relatively homogenous and do not require a consultation or service with a health service provider, private providers can play an important role. Homogenous or similar products are often differentiated to consumers through branding and labelling as a way of signalling quality (2). Public health goods can be distributed as over-the-counter products (OTC) or as a prescription product, the latter requiring consultation with a health service provider. It is likely that the first generation of microbicide products will fall into the latter category. Understanding the ways these public health goods have been distributed can provide valuable guidance for future microbicide delivery.

Range of delivery alternatives

Public health goods are currently provided to people in low and middle-income countries via a number of different delivery strategies.

Public sector distribution occurs through various outlets such as health facilities and family planning clinics, depending on the nature of government programmes. Goods tend to be distributed through the public sector free-of-charge or at a nominal fee. Condoms may also be distributed through workplaces and health facilities. The quality of services provided by the public sector is often low, or perceived to be so, and availability may be irregular.

Social marketing (SM). The main objective of SM projects is to increase the availability and use of high quality, low cost commodities. Campaigns usually promote contraceptive use in general and the sale of the social marketing organisation's own brands in particular. The strategy also aims to disseminate messages depending on the nature of the product, e.g. family planning,

STI/HIV/AIDS prevention, safe sexual behaviour, and correct use of contraceptives. SM is generally undertaken by non-governmental organisations. Typically, the prices at which goods are sold cover the cost of the commodities, but not the costs of promotion or distribution.

Commercial provision is undertaken by private for-profit firm or outlets. Goods are provided through private pharmacies and other commercial outlets at market prices that aim to cover costs and include profit margins. Commercial provision is generally targeted at the middle-to-high income population in a country.

Key findings

- In order to establish the efficacy of a product, clinical trials are designed to ensure the best possible delivery of the product being tested. Experience from insecticide re-treatment of mosquito nets shows that uptake and coverage was significantly reduced when delivery moved from trial to actual implementation, due to both people's perceptions about the product as well as characteristics of the delivery channels (3). Similarly, the experience from the introduction of new contraceptive technologies, such as the IUD, has shown that benefits have not always materialised, even with free programmes.
- For contraceptives, most countries where social marketing and commercial sources are now important, began with widespread availability of free commodities. In those countries where there has been a rapid and sustained fertility transition, public sector supply has played an important role. Subsequently, it has been possible to promote commercial suppliers once a minimum level of demand has been created. A number of social marketing programmes have successfully achieved complete cost recovery and transferred activities to a private sector organisation, even in the presence of large public sector condom distribution programmes (4).

Greater emphasis on bringing commercial market and non-governmental players into the process of planning and policy may foster a diverse array of services and

supply points for microbicides, allowing better market segmentation and more precise targeting of different population groups (5). However a mix of delivery methods may be required to reach different population groups. For example, condom social marketing targeted to low income groups is less likely to be effective as they are particularly sensitive to price changes for SM (6).

- A strategic approach to the introduction of new products would go beyond promotion of a single technology, to focussing on a mixture of methods and the capacity to deliver quality services (7). For example, promotional campaigns which accompanied the introduction of the female condom targeted high risk women (generally involved in commercial sex) led to a stigmatisation of the product and low levels of usage among the general population.
- Promotional strategies are important in establishing and sustaining markets (8). Social marketing campaigns which reinforce public health messages and link malaria and mosquito nets saw a five-fold increase in ownership and use of nets in the community (9). Analysis of condom social marketing shows that advertising and promotion has a strong positive impact on male condom sales in both the short and long-term. Initial promotion can affect both the initial start-up but has been found to be significant in explaining subsequent expansion of markets. (10). The results suggest that the introduction of new technologies for HIV prevention activities need to be accompanied by strong promotion activities for sustained market creation.
- There is little analysis on the potential costs for introducing and delivering products. These costs will be dependent on the distribution channels chosen, the ease of reach of the target group, the level of existing service infrastructure and the degree to which cost-recovery is attempted. Different channels will have different implications, with cost-effectiveness traded-off with reaching harder to reach and more vulnerable populations.

Conclusions

1. Introduction strategies take time to develop and need to be considered concurrently with product development and clinical trials. Operational research is needed to identify characteristics of goods and delivery channels which would better lead to more widespread acceptance of a microbicide product.
2. While expanding the role of the private sector has been seen as means of easing financing constraints, experience with contraceptives suggests that the initial introduction by public sector distribution channels has been critical in opening the market and reaching the poor and more vulnerable.
3. Different distribution strategies are required in different countries and settings. In the medium-term it is possible to segment the market so that different distribution channels are being used to reach different target groups.
4. The role of promotion is critical in both the initial introduction as well as developing and sustaining demand.

Recommendations

1. **Tailor product development to potential markets.** Consideration of potential markets should feed into the product development process in order to tailor potential products (including applicators) and delivery channels to have a greater widespread appeal to potential users. Research related to preference and use of different delivery channels by different target groups should be undertaken in order to tailor introduction strategies.
2. **Mix of delivery channels, but public sector a priority.** A range of methods of distribution need to be considered, but initial implementation is likely to focus on public sector methods of distribution. Introduction strategies which will emphasise a mix of methods and messages are likely to have more success.

3. **Broadening delivery channels to reach new people.** Further consideration of the likely target groups for microbicides and delivery channels which are more likely to reach them should be examined. Aiming for women in regular partnerships might mean that a variety of channels beyond the traditional family planning approaches should be considered. Cost recovery at the initial stage of introduction is unlikely for resource poor settings.

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