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Introducing a Microbicide – Factors Impacting Country Adoption: Zambia and South Africa

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health
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africa

Background

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- In South Africa IPM contracted HDA, SFH and GAF to perform a study on access to microbicides
- In Zambia JHPIEGO did a similar study
- These studies were done through document reviews, informant interviews and stakeholder workshops

Focus areas

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- Regulatory approval
- Requirements for importation
- Policy and decision-making processes
- Financing
- Procurement
- Local manufacture and commercial distribution
- Distribution channels, logistics and distribution
- Marketing, communication and branding
- Community preparedness: are communities ready for microbicides?

Key Findings 1 – Delays are real!

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- Delays in registration with regulatory authorities may be a key impediment
 - ⌘ In South Africa even “fast track” registration can take up to a year, unclear what products can be fast tracked. Cost data are becoming important!
- Manufacture takes time to scale up
- In South Africa the Department of Health can make funding available, but there will have to a process of decision making and application within government
- In Zambia it was clear that both the Ministry of Health and the donors would have to be convinced about the cost-effectiveness of microbicides

Delays continued

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- Even if Ministries of Health and Donors are committed and provide funding for a microbicide, there may be other significant delays:
 - ☒ Procurement
 - ☒ Training
 - ☒ Distribution

Key Findings 2: There are also opportunities

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- South Africa has a strong Regulatory Body (The MCC) that could be used by other countries in the region
- There are 2 manufacturers in South Africa that could manufacture a microbicide for the country and the region, and the South African government has financing tools to support them
- South Africa already funds a large HIV programme (\$350 million per year), and would be willing to include microbicides into this funding envelope. It would help if the product was researched and manufactured in South Africa!
- Both countries already have experience of segmenting the condom market to get maximum distribution of a product – private, public and socially marketed products
- In both countries decision makers are highly motivated to introduce new HIV prevention methods, especially women initiated

But remember....

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- The best microbicide with the best access plan will not change all the underlying societal issues that make this epidemic such a challenge.
- So, we still need prevention messages and to challenge unequal gender relationships, and strengthen health systems

Other issues

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- Concerns over the possible impact on promiscuity, early sexual debut, increased 'risky' behavior / sexual disinhibition should be clearly addressed
- Women's perceptions of men's attitudes and preferences may be important
- Urban and rural communities are likely to have different profiles and require different strategies

Recommendations

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- A lot of the detailed planning needs to wait until a microbicide candidate shows efficacy
- However, we can and should:
 - ↻ Ensure that clinical trials are rigorous, and also look at cost-effectiveness and acceptability
 - ↻ Strengthen regulatory bodies
 - ↻ Keep our governments and other stakeholders up to date on developments
 - ↻ Start negotiating with manufacturers

Recommendations Cont.

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- ↻ Try and get consensus within the scientific community
- ↻ Look at alternative distribution channels
- ↻ Start to examine models of microbicide manufacture, financing, cost-effectiveness, that will allow informed decision making when the results of clinical trials are known
- All this is necessary if we don't want excessive delays

Thanks

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