Introducing a microbicide - factors impacting country adoption

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Introduction

• With funding from the EC, IPM commissioned Futures to:
• 'identify mechanisms, critical pathways and key procedures to accelerate the availability of microbicides in developing countries'
• 'and to make recommendations for research and policy development'
• Four Country Profiles - India, Nigeria, Rwanda, and Tanzania
• South Africa and Zambia reports already prepared by other consultants
• This is 'work-in-progress', due for completion end-September
IPM requirements for country profiles

1. Demographic information
2. HIV epidemiological information
3. Health system
4. Regulatory capacity
5. Local manufacturing capacity
6. Procurement systems
7. HIV programming
8. Institutional Mapping
9. Recommendations for microbicide planning and research

Initial observations

1. Stakeholders prefer existing mechanisms & terminology
2. Innovations almost always take longer than you hope
3. Capacity constraints are real
4. Research & statistics are not neutral
5. Country ownership and participation are not just slogans
1. Stakeholders prefer existing mechanisms

- We all find it easier if new things fit into our existing ‘map’
- Microbicides are new, but they are ‘most like’ contraceptives
- Well-established players, mechanisms & terminology
- For example:
  - Use the WHO ‘Strategic Approach’ for repro health
  - Fit into the national HIV/AIDS strategic plan and planning
  - Think and talk ‘ongoing prevention programme’, not ‘product’
  - Make the comparison to contraceptives

Existing mechanism 1
WHO Strategic Approach

- Not rocket science, simply three sensible stages
- assess the situation; pilot and show results; then scale-up
- look at the system as a whole, and include all stakeholders,
- WHO role as ‘technical expert’ widely accepted by Ministries of Health and related agencies such as drug regulators
- 25 countries experience, fairly well documented, on the web
- Does not have to led by or even involve WHO very much
Existing mechanism 2
The national HIV/AIDS strategic plan

- Almost every country now has one
- And a process for reviewing and revising it
- Some countries even have budget lines linked to the plan
- Donors & GF-CCM increasingly expected to align to it
- So get microbicides into the prevention plan
- If the plan includes prioritising of target groups, then risk to discordant couples will make microbicides high priority

Existing mechanism 3
It’s the programme, not the product

- 30 years of experience of introducing contraception generally, and specific contraceptive methods
- Well-established people and processes to introduce new products and approaches, and to then scale up
- ‘Cafeteria’ approach discourages ‘magic bullet’ optimism
- Same issues of rights, gender, choice, confidentiality
- Same differences between regions, faiths, groups
- Familiar obstacles – poor distribution, provider bias
Existing mechanism 4  
Make the comparison to contraceptives

- Widely-accepted hierarchy of contraceptive effectiveness
- And ways to measure and explain it
- In terms which both providers and users can understand
- HIV transmission risk is more complicated than pregnancy
- And ‘partial efficacy’ issue is difficult to explain in lay terms
- But some contraceptive methods are ‘partially effective’

Hierarchy of contraceptive effectiveness
How many women will get pregnant in a year?

<table>
<thead>
<tr>
<th>Method</th>
<th>Perfect use</th>
<th>Typical use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sterilisation</td>
<td>0%</td>
<td>0%</td>
</tr>
<tr>
<td>IUD</td>
<td>0%</td>
<td>1%</td>
</tr>
<tr>
<td>Injectable</td>
<td>0%</td>
<td>3%</td>
</tr>
<tr>
<td>Pill</td>
<td>0%</td>
<td>8%</td>
</tr>
<tr>
<td>Breast-feeding</td>
<td>1%</td>
<td>3%</td>
</tr>
<tr>
<td>Male condom</td>
<td>2%</td>
<td>15%</td>
</tr>
<tr>
<td>Female condom</td>
<td>5%</td>
<td>21%</td>
</tr>
<tr>
<td>Withdrawal or calendar</td>
<td>5%</td>
<td>27%</td>
</tr>
</tbody>
</table>

Trussell et al, Contraceptive Technology, 2000
Hierarchy of HIV prevention
How many women will get HIV in a year?

<table>
<thead>
<tr>
<th>Perfect use</th>
<th>Typical use</th>
</tr>
</thead>
<tbody>
<tr>
<td>Abstinence</td>
<td></td>
</tr>
<tr>
<td>Fidelity</td>
<td></td>
</tr>
<tr>
<td>Male condom</td>
<td></td>
</tr>
<tr>
<td>Female condom</td>
<td></td>
</tr>
<tr>
<td>1st generation microbicide</td>
<td></td>
</tr>
<tr>
<td>Male circumcision</td>
<td></td>
</tr>
<tr>
<td>2nd generation microbicide</td>
<td></td>
</tr>
<tr>
<td>Something we haven’t yet thought of</td>
<td></td>
</tr>
</tbody>
</table>

2. Innovations take time

- True almost everywhere, of every innovation
- Raising hopes too high exposes them to risk of ‘failure’
- One lesson of the female condom experience
- Easier to expand a modest success, than to rescue what appears to be a disappointment
- Some innovations can be successful ‘on the quiet’
- Intermediary service providers such as nurses are key, and one of the reasons that things often move slowly
3. Capacity constraints are real

- Over-stretched and under-paid staff, weak management
- New demands on them because of HIV, and because of massive new funding – and not just for HIV
- HIV programming is complicated – and made even more complicated by demands of donors and programmers
- Not conducive to innovation, risk-taking, decision-making
- Paying lip-service is not enough – must confront this reality
- And the reality of private sector provision

4. Research and statistics are not neutral

- People doing the science are often poor at explaining
- Politicians and policy-makers driven by other agendas
- Scientific ‘results’ can and will be exploited for mischief
- Even the experts do not agree what ‘partial efficacy’ means
- North-South inequalities of money & power & prestige
5. Country ownership is more than a slogan

- Resentment of donor-driven HIV/AIDS agendas
- Trial participants are the best advocates of all
- Engaging ordinary people can stop mischief-makers
- National scientists and experts in each country need to take, and be seen to take, a leading & supportive role
- Demands for 'local' evidence, clinical and behavioural

Acknowledgments

- Team Leader - Carol Bradford
- Plus Jo Heslop, Beth Mbaka, Sally Pollard, Hilary Vaughan
- Country profiles - Jessie Mbwambo (Tanzania); Grace Muriithi (Rwanda); Yomi Oduwole & Morenike Ukpong (Nigeria), Bobby Ramakant (India), plus Crown Agents staff
- London Meeting - Kim Dickson & Tim Farley, WHO; Sheena McCormack, MDP, MRC; Tony Mitchell, Origin Pharmaceuticals; Anne Philpott, DFID; Steven Sinding & Naana Otoo Oyortey, IPPF; Charlotte Watts, LSHTM