A Day of Promise, A Day of Reckoning

Making ARV-based prevention work for women

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<table>
<thead>
<tr>
<th>Trial</th>
<th>Product</th>
<th>Population</th>
<th>Dosing</th>
<th>Effectiveness</th>
<th>Notes</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Caprisa 004</strong></td>
<td>Vaginal TDF gel</td>
<td>Heterosexual women in SA</td>
<td>Before &amp; after sex</td>
<td>39% reduction (95% CI: 6-60%)</td>
<td></td>
</tr>
<tr>
<td><strong>iPrEx</strong></td>
<td>Oral TDF/FTC pill</td>
<td>MSM</td>
<td>Daily</td>
<td>42% reduction (95% CI: 15 - 63)</td>
<td>70% among most adherent</td>
</tr>
<tr>
<td><strong>Partners Prep</strong></td>
<td>Oral TDF pill</td>
<td>Discordant couples</td>
<td>Daily</td>
<td>62% for TDF 73% for Truvada</td>
<td>More than 97% of dispensed doses taken</td>
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<td><strong>Treatment as Prevention (HPTN – 052)</strong></td>
<td>HAART initiated at CD4 &gt;350 &lt;550 cells per µL</td>
<td>Discordant couples</td>
<td>Daily</td>
<td>96% (95% CI: 73-99)</td>
<td>28% of cases from non-index partner</td>
</tr>
<tr>
<td><strong>Botswana TDF2 study</strong></td>
<td>Oral TDF pill</td>
<td>Heterosexuals</td>
<td>Daily</td>
<td>63% (95% CI: 21-84)</td>
<td>Re-framed as safety study due to lack of endpoints</td>
</tr>
<tr>
<td><strong>Fem-PREP</strong></td>
<td>Oral TDF/FTC</td>
<td>High risk women</td>
<td>Daily</td>
<td>Trial stopped for futility</td>
<td><strong>CAUTION !</strong></td>
</tr>
</tbody>
</table>
In your packets.....

<table>
<thead>
<tr>
<th>COMPARING ARV-BASED PREVENTION METHODS</th>
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<tr>
<td>Already in widespread use</td>
</tr>
<tr>
<td><strong>Vertical Prevention; Prevention of Mother-to-Child Transmission (pMTCT)</strong></td>
</tr>
<tr>
<td>Typical blood levels</td>
</tr>
<tr>
<td>Present in genital tissue</td>
</tr>
<tr>
<td>Potential for Resistance</td>
</tr>
<tr>
<td>Access issues</td>
</tr>
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</table>

FHI 360

STRIVE

Tackling the structural drivers of HIV
ARV-based prevention methods vary by:

- Which user groups and routes of exposure (e.g. IV drug use, rectal sex, vaginal sex) the method has been shown to work for...
- Level of systemic exposure and hence long term risk
- Potential for encouraging resistance
- Level of routine HIV testing likely to be required
- Dosing (daily; only when having sex, etc)
- Cost (lifetime vs. intermittent use; triple vs. single drug regimens; applicator costs)
- Political, ethical, and gender implications
Reclaiming the vision...

Girls’ and women’s protection strategies

- Social power
- New Tools
- Economic opportunities
Making ARV-based prevention work for women

1. Learn from the past. Don’t underestimate the challenges of implementation.

2. Demand that piloting and roll out of new prevention strategies investigate and address the economic, social, relationship, and rights-based barriers that women face in accessing and using such methods.

3. Ensure that future implementation research includes a strong qualitative component that listens to women.

4. Fight for continued investment into topical gels and other vaginally delivered prevention tools.
1. Learn from the Past....

- Preventive behaviors are harder to adopt and sustain than those linked to symptoms
- Referral alone seldom increases access to care unless supplemented by accompaniment, counseling and subsidies for transport
- People have an abiding need to belong – hence the power of stigma and social norms to hamper protective behavior
- Men often hold the “purchasing power on prevention.” Hence, ARV-based prevention programs will need to address gender and power issues in relationships
Treatment as Prevention (TasP)

- Large and growing momentum for Treatment to be the central pillar of prevention programming
  - “Treatment is prevention. Let’s go with it and you’ll see how we can control HIV within this decade!” (Julio Montaner)
- The LANCET, May 21, 2011:
  - “Agencies such as PEPFAR and the Global Fund to Fight AIDS, Tuberculosis and Malaria need to reassess their prevention portfolios and consider diverting funds from prevention programmes with poor evidence (such as behavioural change communication) to treatment for prevention.”
Can TasP deliver without rethinking our strategies...

- HIV testing is low: From 2005 to 2009 in sub-Saharan Africa a median of 17% of women and 14% of men had ever been tested for HIV infection and knew their results (Measure DHS).

- Early treatment will not prevent the roughly 40% of infections that appear to occur during acute infection (Cohen, et al NEJM; 364: 1943-54).

- Nor will it prevent the 27-33% of infections in discordant couples in East and Southern Africa who become infected from “outside partners.” (Celum et al, NEJM; 362(5), 2010; Dunkel et al, 2010)
Protecting ourselves from uncomfortable truths...

• Not everyone wants to initiate treatment, even those who qualify medically

• Up to one-third of individuals eligible for ART in parts of Kenya and South Africa, actively resist starting treatment despite free access to drugs, regular CD4 testing, referrals to local treatment programmes, and counselling on the importance of ART (Guthrie, BL. JAIDS, 2011; Katz, It, et al. AIDS, 2011)

“They are giving you something that could possibly save your life, so, on one hand why not take it and live with the side effects. On the other hand,...it’s a reminder every day that you’ve got something...and maybe you don’t necessarily want to do that.”
Vertical transmission (PMTCT) as an object lesson

- The proportion of pregnant women in low- and middle-income countries who received an HIV test was only 26% in 2010, up from 7% in 2005 (UNAIDS).

- According to a 4 country study in Africa, even where PMTCT services were available, less than 50% of women who delivered had antiretroviral drugs present in their cord blood. (Coetzee, et al. 2010; PEARL study)

- Overall in high burden countries, only 15-30% of mother-infant pairs complete the entire PMTCT “cascade.” (Paintsil & Anderman, *Curr Opin Pediatr*, 21:2009)

- Community and health worker stigma is a major factor in this attrition
The STRIVE Consortium
A final plea…

Keep the development of topical gels and other vaginal products on the agenda, including non ARV-based products!
For whom? Explicitly identify and prioritise populations on the basis of the epidemic profile. How? Use the human rights approach to achieve dignity and security.

Critical enablers
- Social enablers
  - Political commitment and advocacy
  - Laws, legal policies, and practices
  - Community mobilisation
  - Stigma reduction
  - Mass media
  - Local responses to change risk environment
- Programme enablers
  - Community centred design and delivery
  - Programme communication
  - Management and incentives
  - Procurement and distribution
  - Research and innovation

Basic programme activities
- PMTCT
- Condom promotion and distribution
- Key populations (sex work, MSM, IDU programmes)
- Treatment, care, and support to people living with HIV/AIDS (including facility-based testing)
- Male circumcision*
- Behaviour change programmes

Objectives
- Reduce risk
- Reduce likelihood of transmission
- Reduce mortality and morbidity

Synergies with development sectors
- Social protection, education, legal reform, gender equality, poverty reduction, gender-based violence, health systems (including STI treatment, blood safety), community systems, and employer practices

Figure 1: Proposed framework for the new investment approach