TasP - Individual versus Public Health Benefit versus Both.

Kevin Fisher
Policy Director, AVAC
June 2012
“We now have powerful tools for treating and preventing HIV. And lo and behold, they are the same thing.”

— Wafaa el-Sadr, November 2011
“HERE is now, for the first time, hard clinical evidence of an effect that AIDS doctors have suspected for years: If you are HIV-positive, being on antiretroviral drugs will probably save not only your life, but also the lives of your sexual partners.”

TasP is a win-win. It can be both individual and public benefit, but not without much, much more work and careful communication in the coming years.
Where is the TasP field?

• Clinicians and Researchers: Moving forward as additional questions are answered.
• Funders: Funding gaps to be filled
• Advocates: Priorities to be set
• Community?
“Wider ART use is likely to have benefits in reducing transmission through other routes, but this policy cannot be employed for ART initiation in all people with diagnosed HIV without understanding whether there is a benefit for personal health. However, there is a strong rationale for a new policy whereby all people with high CD4 count - such that they are not currently considered to require ART for their own health - have this potential benefit of ART explained to them, along with the substantial caveats, and ART offered for this indication if the individual so wishes.”
In this graphic, we’ve highlighted, in darker blue, the areas where biomedical HIV prevention research has the most experience to date. The “gap” between positive effectiveness data and access for trial participants and their communities is less familiar territory—as are the steps in lighter blue.

Global TasP Research

Total Trial Participants by Region

- North America
- Asia & SE Asia
- Africa
- South America

Total Trial Participants by Technology Type

- Microbicides
- PrEP
- TasP
- Vaccines

When participants by country were not specified by trial sponsors, funders, and/or implementers, total trial participants are divided evenly among countries.
Antiretroviral Therapy in Prevention of HIV and TB: Update on Current Research Efforts

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HIV Prevention Options Timeline

* Trial end-dates are estimates; due to the nature of clinical trials the actual dates may change. For full trial details, see www.avac.org/trials.
** Not all trials included are effectiveness trials. Trials included on this list are mainly phase II/IIb, III/IIIb and IV trials.

** TIMELINE LEGEND **
- Oral TDF
- Oral TDF/FTC
- TFV gel
- Rectal TFV gel
- DPV ring
- EARliest regulatory submission
- Planned
- Final results pending
- DNA/Ad5
- DNA/Ad5 Injectable
- Pox-Protein

<table>
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<tr>
<td>2005</td>
<td>Bangkok Tenofovir Study/CDC 4370</td>
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<tr>
<td>2008</td>
<td>Partners PrEP</td>
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<tr>
<td>2009</td>
<td>VOICE/MTN 003</td>
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<tr>
<td>2007</td>
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<td>CAPRISA 004</td>
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<td>ASPIRE/MTN 020</td>
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* For full trial details, see www.avac.org/trials.
Individual Benefit > 350 CD4?

- HPTN 052 is a biological experiment in viral load reduction, not implementation research—and it is still collecting data.
- Some HPTN 052 health benefit data expected at IAC in DC.
- START results won’t be available until 2015.
- HPTN 052 doesn’t address important populations such as gay men and other MSM and people who use drugs. But see WHO review.
Individual Choice – Next Steps

• Implementers, clinicians and communities have to be comfortable with people not choosing the early treatment route.

• TasP is already combination prevention. Testing and linkage to care provide benefit even if people opt not to begin ARVs.

• TasP is being recommended based upon optimized regimens. First-line regimens in some countries include drugs like AZT, which are not favored by patients.
Would you take ART early to prevent transmission?

Top concerns about initiating early ART for HIV-1 prevention (among 77 people unwilling):

- Side effects (51.4%)
- Stigma (20.8%)
- Pill burden (19.4%)
- Potential for earlier development of antiretroviral resistance (18.1%)

Heffron et al. CROI 2012
What do clinicians tell individuals as TasP is implemented and before research is completed?

- People living with HIV who are in serodiscordant couples and who are started on ART for their own health should be advised that ART is also recommended to reduce HIV transmission to their uninfected partner (WHO guidance 2012)

- Gay men and other MSM, people who use drugs.
• Loss to care in cascade of treatment currently reduces TasP impact even in ideal circumstances

• Path forward where resources are limited unclear
  – Antiretroviral therapy for HIV-positive partners with >350 CD4 cells in serodiscordant couples should be offered to reduce HIV transmission to uninfected partners. *(WHO Guidance 2012).*
  – A concern about queue jumping. *(WHO consultation)*
  – Definition of couples *(WHO)*

• Ensuring access to TasP for all populations *(MSM, PUD)* even as the field awaits data.
Of all with HIV infection in the US, only 328,000 (28%) have suppressed HIV RNA.
Real World TasP: San Francisco

- United States (Gardner, et al. CID 2011)
- United States (Cohen, et al. MMWR 2011)
- San Francisco (SF Dept of Public Health, 2009)*

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<td>HIV+ Population</td>
<td>100%</td>
<td>79% 80% 80%</td>
<td>79% 80% 80%</td>
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<tr>
<td>HIV diagnosis</td>
<td>100%</td>
<td>68%</td>
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<td>Linked to Care</td>
<td>62%</td>
<td>59%</td>
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<tr>
<td>Retained in Care</td>
<td>57%</td>
<td>40% 41%</td>
<td>40% 41%</td>
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<td>Need ART</td>
<td>32%</td>
<td>36%</td>
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<td>On ART</td>
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<td>Undetectable VL</td>
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• AVAC has begun surveying HIV+ MARPs in Peru, Kenya, Ukraine, South Africa and US to identify next steps.

• Preliminary Results:
  – Excitement and Support for TasP
  – Concern about cost and access
  – Questions about evidentiary basis for benefit of early treatment
  – Concern about social or clinical pressure to initiate treatment
Next Steps

- Greater clarity on benefits from early treatment.
- Implementation research to establish feasibility.
- Clinician education in context of higher demand for services.
- Adapting treatment discussions to focus on patient health and choice and prevention.
- Public acceptance of the right to forgo treatment.
- Access to treatment for all populations.
Agenda for Ending AIDS

**Deliver** proven tools for immediate impact
- Model successful programs
- Mobilize demand for new tools
- Reprogram resources for impact
- Fund evidence-based scale-up
  - Testing
  - Treatment
  - Male Circumcision

**Demonstrate** proven tools for immediate impact
- Plan for rollout in different settings
- Prioritize use of tools for greatest impact
- Pilot to guide real-world implementation
  - PrEP
  - Microbicides

**Develop** long-term solutions to end the epidemic
- Sustain research funding to capitalize on new scientific insights
  - Other ARV-based px
  - Vaccines
  - Functional Cure

**GOAL:** A sustained decline in HIV infections (now at 2.7 million/year)