Treatment as Prevention: arriving at community consensus

Gus Cairns, Features Editor, NAM / aidsmap
Opportunity: efficacy in trials

Reduction in HIV infections (unless stated)

- VOICE microbicide
- FemPrEP and VOICE PrEP
- RV144 HIV vaccine
- Active' behaviour change progs (condom use)
- Vaginal Microbicide CAPRISA 004
- iPrEx PrEP
- TDF2 PrEP effectiveness
- Male circumcision (3 RCTs)
- 100% condoms in anal sex (3 studies)
- Partners PrEP
- 100% condoms (5 meta–analyses)
- 100% condoms in anal sex PLUS behaviour change
- PrEP with >60% adherence (iPrEx)
- HPTN 052
Efficacy in trials references

- **VOICE:** Marrazzo J et al. *Pre-exposure prophylaxis for HIV in women: daily oral tenofovir, oral tenofovir/emtricitabine or vaginal tenofovir gel in the VOICE study (MTN 003).* 20th Conference on Retroviruses and Opportunistic Infections, Atlanta, abstract 26LB, 2013. See www.mtnstopshiv.org/news/studies/mtn003


- **RV144:** Rerks-NGarm Supachai et al. *Vaccination with ALVAC and AIDSVAX to Prevent HIV-1 Infection in Thailand.* NEJM 361:2209-2220. 2009.


- **Condoms in anal sex plus behaviour change:** See Smith D above.


Problem: new diagnoses

HIV diagnoses in UK 2002–11 and France 2003–11

Why? 1: condoms


Why? 2: complexity


Why? 3: the UK treatment cascade

What do the Guidelines say?

- **US guidelines**: offer ART to all <500 (strong) and >500 (moderate)
- **WHO**: <500 and “to HIV–positive people in serodiscordant relationships”
- **EACS**: <350 and “In serodiscordant couples, early initiation of ART as one aspect of the overall strategy to reduce HIV transmission to the seronegative partner should be considered and actively discussed”
- **BHIVA**: <350 and it is a matter of good clinical practice to discuss the prevention possibilities of ART with all patients [not just couples] and prescribe it if requested for this reason.

Responsibility and Choice

Patient choice/physician responsibility ratio

Physician responsibility

Patient choice

CD4 count

CONTROLLING THE HIV EPIDEMIC WITH ANTIRETROVIRALS
From Consensus to Implementation
Do people **want** ART as prevention?

<table>
<thead>
<tr>
<th>MOST IMPORTANT DISADVANTAGES OF HIV</th>
<th>Very Important</th>
<th>Somewhat Important</th>
</tr>
</thead>
<tbody>
<tr>
<td>1 the risk of getting side effects or health problems in the future</td>
<td>70%</td>
<td>21%</td>
</tr>
<tr>
<td>2 the negative impact on my health in general</td>
<td>46%</td>
<td>30%</td>
</tr>
<tr>
<td>3 the risk of infecting someone</td>
<td>45%</td>
<td>21%</td>
</tr>
<tr>
<td>4 the stigmatization</td>
<td>41%</td>
<td>27%</td>
</tr>
<tr>
<td>5 the side effects from my HIV medications</td>
<td>38%</td>
<td>28%</td>
</tr>
<tr>
<td>6 the fatigue</td>
<td>36%</td>
<td>28%</td>
</tr>
<tr>
<td>7 the daily use of HIV medications</td>
<td>32%</td>
<td>29%</td>
</tr>
<tr>
<td>8 the negative impact on my (chances of having a) relationship</td>
<td>32%</td>
<td>25%</td>
</tr>
<tr>
<td>9 the shorter life expectancy</td>
<td>31%</td>
<td>31%</td>
</tr>
<tr>
<td>10 living with a secret</td>
<td>31%</td>
<td>22%</td>
</tr>
</tbody>
</table>

Fred Verdult, From IAS cure workshop, Washington DC 2012: “**CURE:** The point of view of people living with HIV.”
Do people want ART as prevention? 2

Participant’s priorities on outcomes of cure research

- No longer need to see a doctor
- Stopping HIV medications
- Being considered as a person not infected with HIV
- Not getting HIV a second time
- Not passing virus onto others

Sharon Lewin, From IAS cure workshop, Kuala Lumpur 2013: “Experience from an HDACi trial: implications on ethics and patient expectations.”
### Things that matter to doctors and patients

#### Doctor
- CD4 count
- Viral load
- OIs
- Hepatitis status
- Side effects
- Adherence
- Behaviour change
- STDs
- Onward infections
- Public health?

#### Patient

**I must take ART because:**
- otherwise I’ll have to use a condom and then my partner will know I’m positive
- I can then prove to my partner that I’m not infectious and she won’t insist we use condoms
- condoms make me lose my erection
- once I’m on the pills they won’t be able to send me back home to where it’s not available
- someone told me HIV gives you cancer
- it means I’m a good, responsible citizen
- I want to live long enough to see my son graduate

**I can’t take ART because:**
- my partner will see the pills and he’ll know I’m positive
- they’re sending me back home and I won’t be able to get it and then I’ll become drug resistant

**I’m scared to take ART because:**
- if my partner finds out he’ll use it to insist we don’t use condoms any more

**I mustn’t take ART because:**
- someone told me that it makes you impotent
- someone told me the pills give you cancer
- my pastor tells me I should trust in God
- I know I’ll forget to and then I’ll be twice as ill
Reservations about TasP (and PrEP) in community
(quotes from recent news, mail list and Facebook discussions)

• Side effects “Antiretroviral therapy is a lifelong regimen with potential irreversible side effects”

• **Efficacy** “Reducing the viral load of HIV-positive individuals may reduce their potential infectivity. But this is an important but secondary issue, and it should always be noted that the extent of this reduction of infectivity remains the subject of considerable uncertainty.”

• **Behaviour change and public health effect:** “With gonorrhoea fuelling HIV transmissions, and with drug resistant gonorrhoea round the corner, making pills and condoms compete is a disaster in the making.”

• **Perception of ART:** “When you Septrin you consider yourself to be in another stage, you have not reached the final stage of the ARVs... if these stages are brought forward and I start taking them, this person will know now I am in the last stage. So even the benefits... which is very good, but then we will have the negative effect, the psychological effect. That I am now heading to the grave.”*

• **Public health ethics** “There is no precedent outside the criminal justice system where individuals are given drugs for purposes other than their direct benefit.”

• **Morals** “Medications were not introduced to allow men of either status more condom-free sex: They were introduced to save lives.”

*Curran K et al. ‘If I am given antiretrovirals I will think I am nearing the grave’: Kenyan HIV serodiscordant couples’ attitudes regarding early initiation of antiretroviral therapy. AIDS 27, 2013.
Enforced TasP: the threat of coercion

National: political misunderstandings of potential and practicality of ‘Test and Treat’

National/Local: enforced testing as part of control of minorities seen as threats (FSWs, PWIDs, MSM) or of prisoners

NB: withholding treatment also commonly used against prisoners
Community statements/standards in the epidemic

Usually borne out of a perception that people with/affected by HIV need to own or have some control over an aspect of the epidemic.
Community Consensus Statement

- Originally borne out of need to revise EATG Prevention Policy Paper in general.

- Last version appeared in May 2009 after Swiss Statement but before HPTN 052.

- It said: “EATG therefore believes that there is a need for epidemiological and clinical research, amongst gay men in particular, to establish whether people with undetectable plasma viral loads are able to transmit HIV and if so how often.”
This is a community consensus statement on the use of antiretroviral therapy (ART) for people living with HIV to reduce their risk of transmitting HIV ... [it] is issued with an underlying principle in mind: that of safeguarding people’s choices and well-being, whether they choose to take ART or not.
Community consensus statement

Covers:

- Evidence
- Adherence
- Readiness
- Advantages: relief from guilt and anxiety
- Disadvantages: coercion and pressure
- Access and supply of drugs
- Challenge to previously accepted norms (e.g., condom use, stigma)
- Continued condom supply supported *but* noted not everyone uses them
- Support and education needs of HIV+ and HIV− people
- Unanswered questions and research needs
Consensus statement 4

A couple of quotes

• “In many countries the vulnerable populations that need ART most have the worst access to HIV services in part due to criminalisation and stigma. The prevention benefits of ART cannot be realised until these are addressed.”

• “Providing ART for prevention must not in any way impede efforts to make ART available as treatment to anyone who needs it for clinical benefit. Prevention and treatment need not be in competition for resources and should not be set in opposition to one another”
Consensus statement 5

Research gaps

- Anal sex
- Needle and drug equipment sharing
- Network effects
- STIs and infectiousness
- Clinical risks and benefits of ART for people with high CD4 counts
- Risk compensation
Process

- 1\textsuperscript{st} draft written 01 March 2013 (1102 words)
- Sent round EATG writing group
- 2\textsuperscript{nd} major redraft sent round EATG membership 15 May 2013
- 3\textsuperscript{rd} redraft put on Aidsmap and EATG sites for public consultation beginning of June
- 4\textsuperscript{th} redraft 15 July 2013: had expanded to 2861 words
- Sent to external editor 24 July 2013
- Returned 02 August: now 2035 words
- Started process of inviting community to meeting, concentrating on Europeans, geographical spread
- Purpose of meeting to help shape \textbf{final} version
- No further envisaged revision after incorporating input from meeting:
  - Envisaged to send it round as sign–on statement (cf. Denver Principles) to as wide a section of the community as possible.
Community meeting

- Fifty attendees from all over Europe and a few from US
- Representing various populations, (MSM, sex workers, PWIDs)
- Plenaries on
  - Evidence (Montaner)
  - Health systems (Anderson)
  - Access (Stefanyshyna)
  - Background to statement (this presentation!)
- Breakout groups
- Feedback
Community meeting feedback

- Place statement in context of human rights: underlying values
- TasP is an example of ‘Think Global, Act Local’; should support the need to reflect location-specific issues
- Need to always speak to the science, but too biomedical in language at present
- It emphasises “safeguarding people’s choices”, but some people have none. Rights and dignity precede choice
- Be explicit about what the statement is about and is not about (e.g. treatment access in general, PrEP)
- Is this statement transferable to a non-European context?
- TasP must not supplant or impoverish prevention methods that work just as well/better but are less politically acceptable, eg harm reduction
- Strengthen emphasis that TasP for some must not endanger existing programmes for all
- Mention gender inequality and violence, esp. as it impacts on adherence
- Adherence is an attribute of communities, as well as individuals
- Advocate for integrated prevention and treatment services
- Implementation research into the exact mix that is most effective for specific locations, populations and people
- Another research gap: iterative cost-effectiveness models based on real data
- What ‘community’ is issuing this statement?
Next steps

- Merge feedback into document and then send to external editor
- Finished document anticipated by 12/2013
- Circulate for sign–on in early 2014
Special thanks to:

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