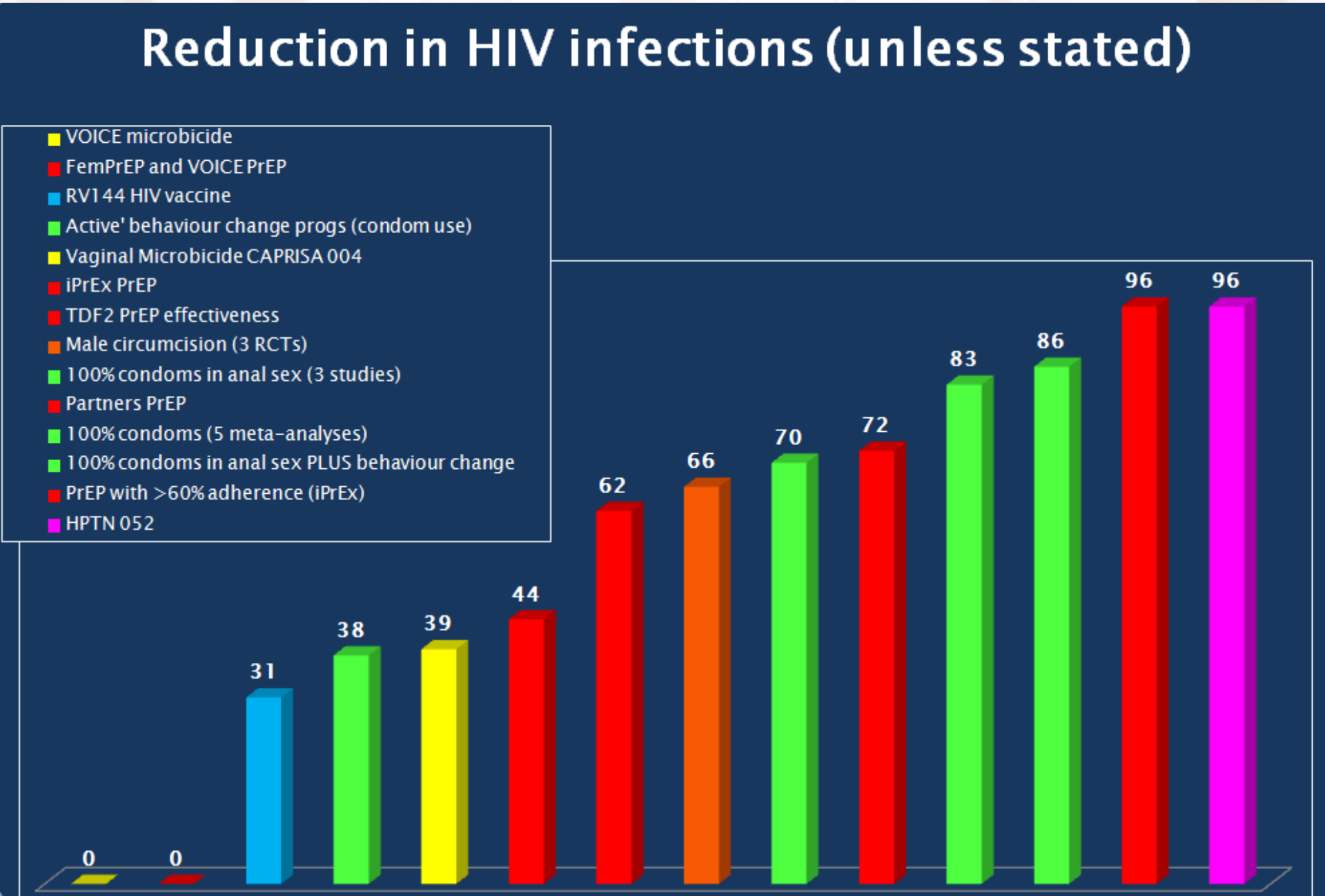
Treatment as Prevention: arriving at community consensus

Gus Cairns, Features Editor, NAM / aidsmap

Opportunity: efficacy in trials

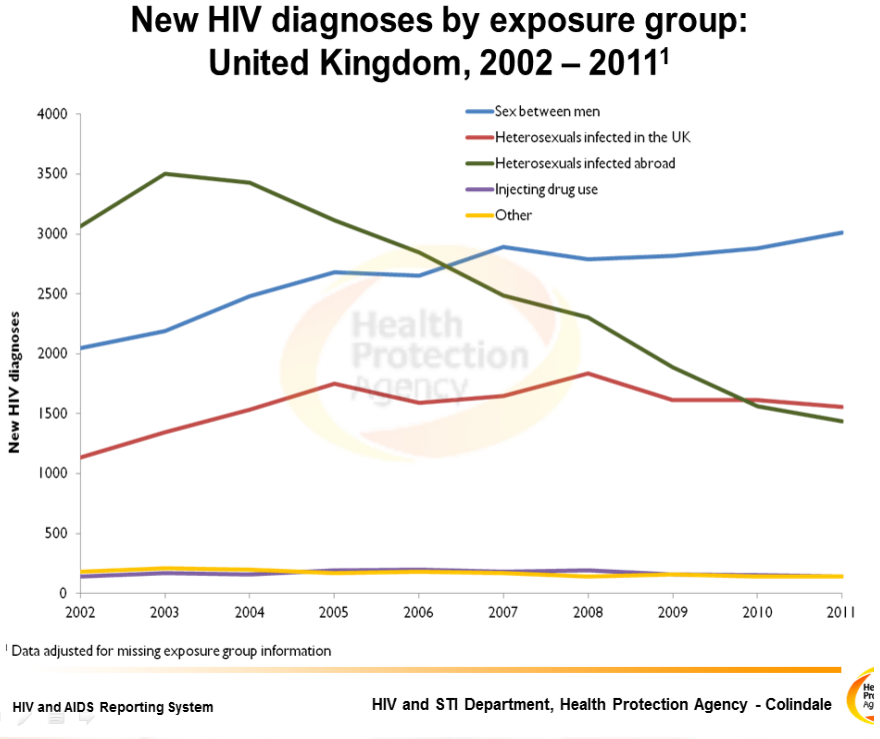


Efficacy in trials references

- **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
- **FEM-PrEP:** Van Damme L et al. *The FEM-PrEP Trial of Emtricitabine/Tenofovir Disoproxil Fumarate (Truvada) among African Women*. 19th Conference on Retroviruses and Opportunistic Infections, Seattle, abstract 32LB, 2012. See this summary.
- **RV144:** Rerks-Ngarm Supachai et al. *Vaccination with ALVAC and AIDSVAX to Prevent HIV-1 Infection in Thailand*. NEJM 361:2209-2220. 2009.
- **Behaviour change programmes:** Albarracin D et al. *A test of major assumptions about behaviour change: a comprehensive look at the effects of passive and active HIV-prevention interventions since the beginning of the epidemic.* Psychological Bulletin 131(6), 856-897, 2005. Abstract here.
- **CAPRISA 004:** Abdool Karim Q et al. *Effectiveness and Safety of Tenofovir Gel, an Antiretroviral Microbicide, for the Prevention of HIV Infection in Women.* Science 329(5996): 1168–1174. 2010.
- **iPrEx:** Grant RM et al. *Preexposure Chemoprophylaxis for HIV Prevention in Men Who Have Sex with Men.* NEJM 363(27):2587-2599. 2010.
- **TDF2:** Thigpen MC et al. *Antiretroviral Preexposure Prophylaxis for Heterosexual HIV Transmission in Botswana.* NEJM 367:423-434. 2012.
- **Male Circumcision (men):** *Auvert B et al. Randomized, Controlled Intervention Trial of Male Circumcision for Reduction of HIV Infection Risk: The ANRS 1265 Trial .* PLoS Medicine 2(11): e298. doi:10.1371/journal.pmed.0020298. **AND** Bailey RC et al. *Male circumcision for HIV prevention in young men in Kisumu, Kenya: a randomised controlled trial.* Lancet 369(9562):643-56. 2007. **AND** *Gray RH et al. Male circumcision for HIV prevention in men in Rakai, Uganda: a randomised trial.* Lancet 369(9562): 657 – 666. 2007.
- **Condoms in anal sex:** Smith D et al. *Condom efficacy by consistency of use among MSM: US.* 20th Conference on Retroviruses and Opportunistic Infections, Atlanta, abstract 32, 2013. **AND** Detels R et al. *Seroconversion, sexual activity, and condom use among 2915 HIV seronegative men followed for up to 2 years.* J Acquir Immune Defic Syndr 2:77–83, 1989.
- **Partners PrEP:** Baeten JM et al. *Antiretroviral Prophylaxis for HIV Prevention in Heterosexual Men and Women.* NEJM 367(5): 399-410. 2012.
- **Condoms (heterosexual).** *Condom effectiveness in reducing heterosexual HIV transmission (Review).* The Cochrane Collaboration, The Cochrane Library 2007, Issue 4. See http://apps.who.int/rhl/reviews/CD003255.pdf.
- **Condoms in anal sex plus behaviour change:** See Smith D above.
- **PrEP with >60% adherence:** Anderson P et al. *Intracellular tenofovir-DP concentrations associated with PrEP efficacy in MSM from iPrEx.* 19thConference on Retroviruses and Opportunistic Infections, Seattle, abstract 31LB, 2012.
- **HPTN052 (TasP):** Cohen MS et al. *Prevention of HIV-1 Infection with Early Antiretroviral Therapy.* NEJM 365:493-505. 2011.

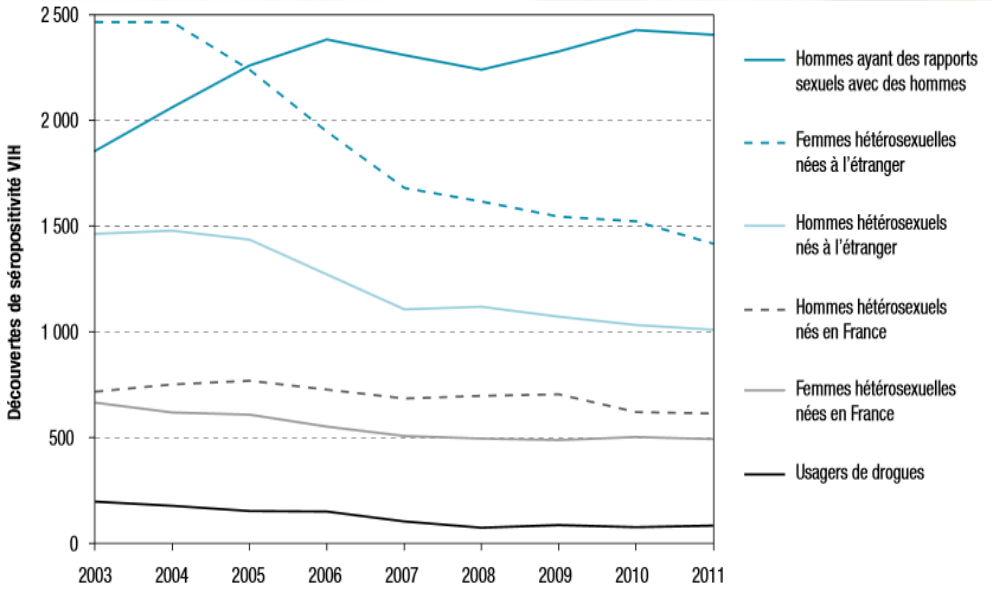
Problem: new diagnoses

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



Health Protection Agency. HIV in the United Kingdom: 2012 Report . HPA, 2012.

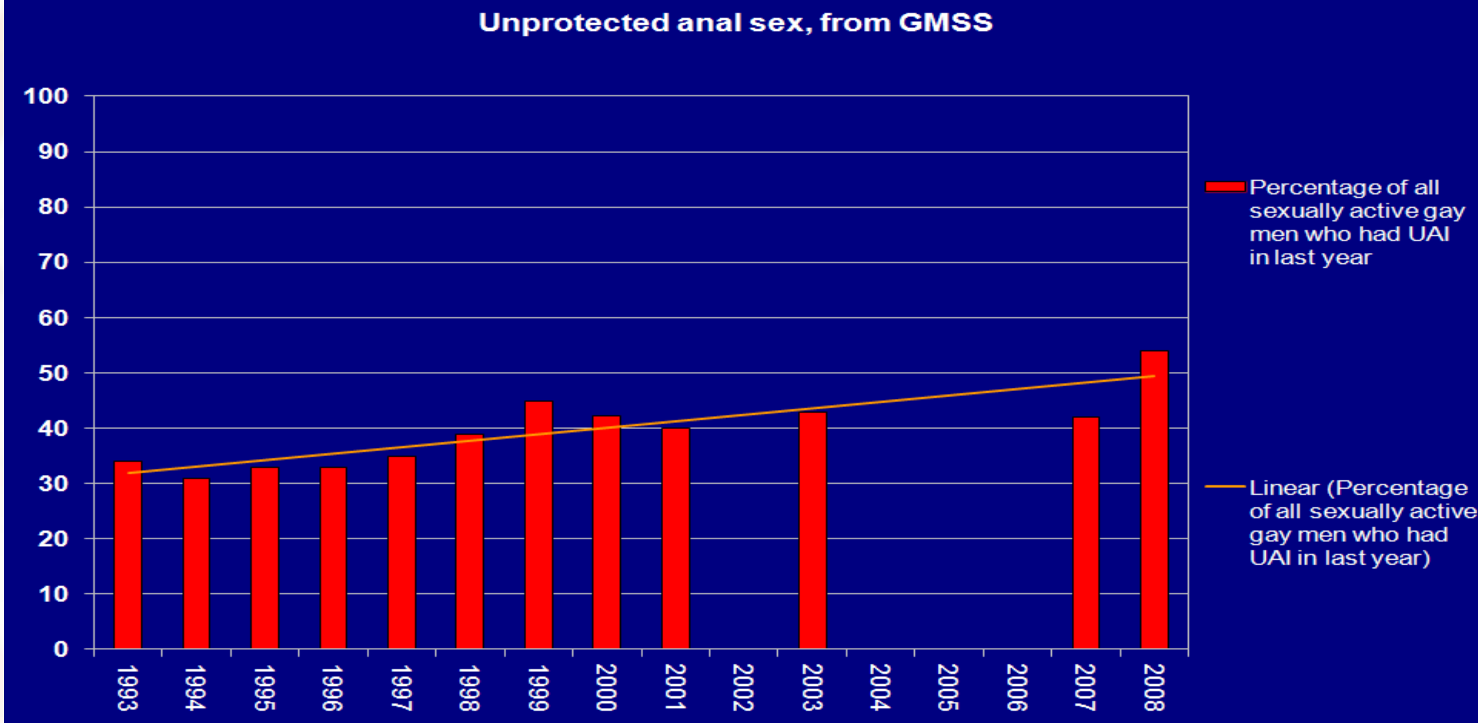
Cazein F et al. Découvertes de séropositivité VIH et sida : France, 2003-2011. Bulletin épidémiologique hebdomadaire 28-29 : 333-340. 2013

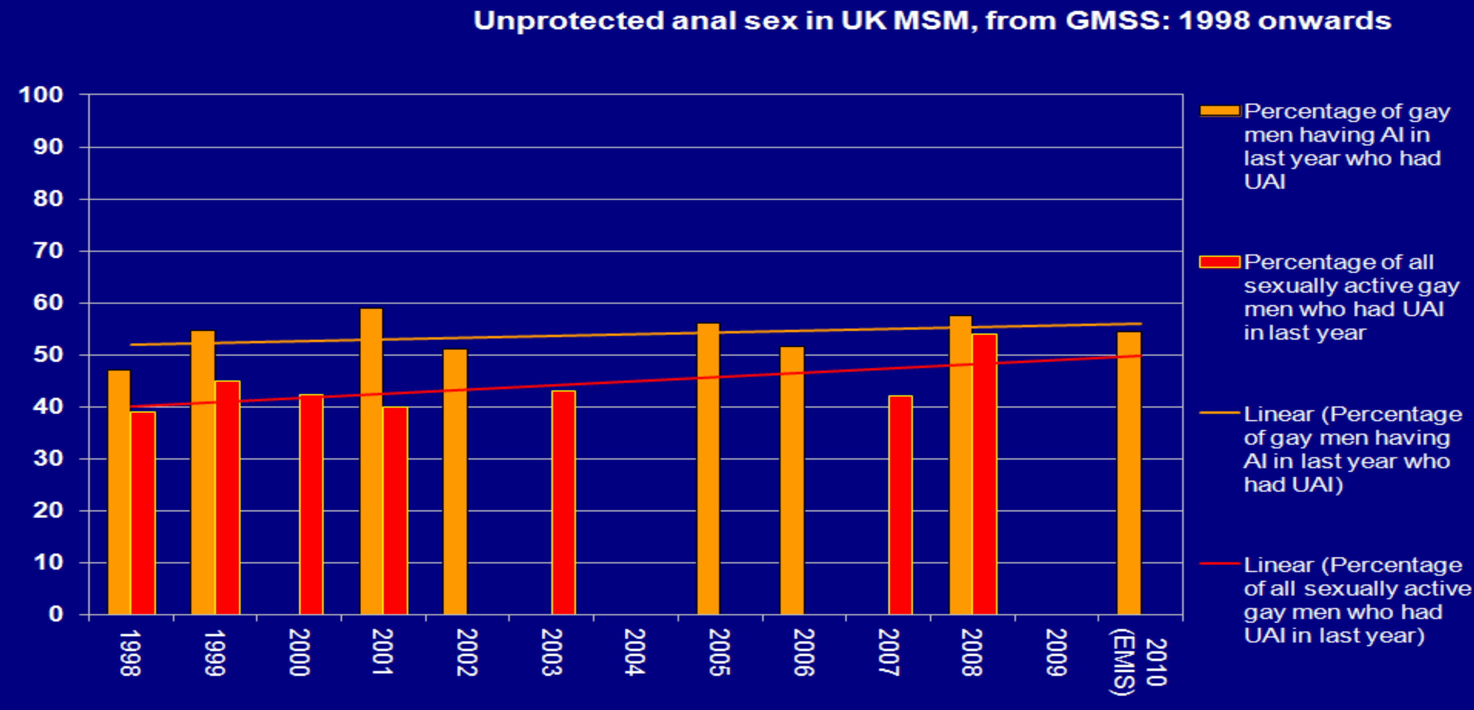


Why? 1: condoms

Data from Gay Men's Sex Surveys, 1993-2008 *and* EMIS 2010: The European Men-Who-Have-Sex-With-Men Internet Survey. Findings from 38 countries

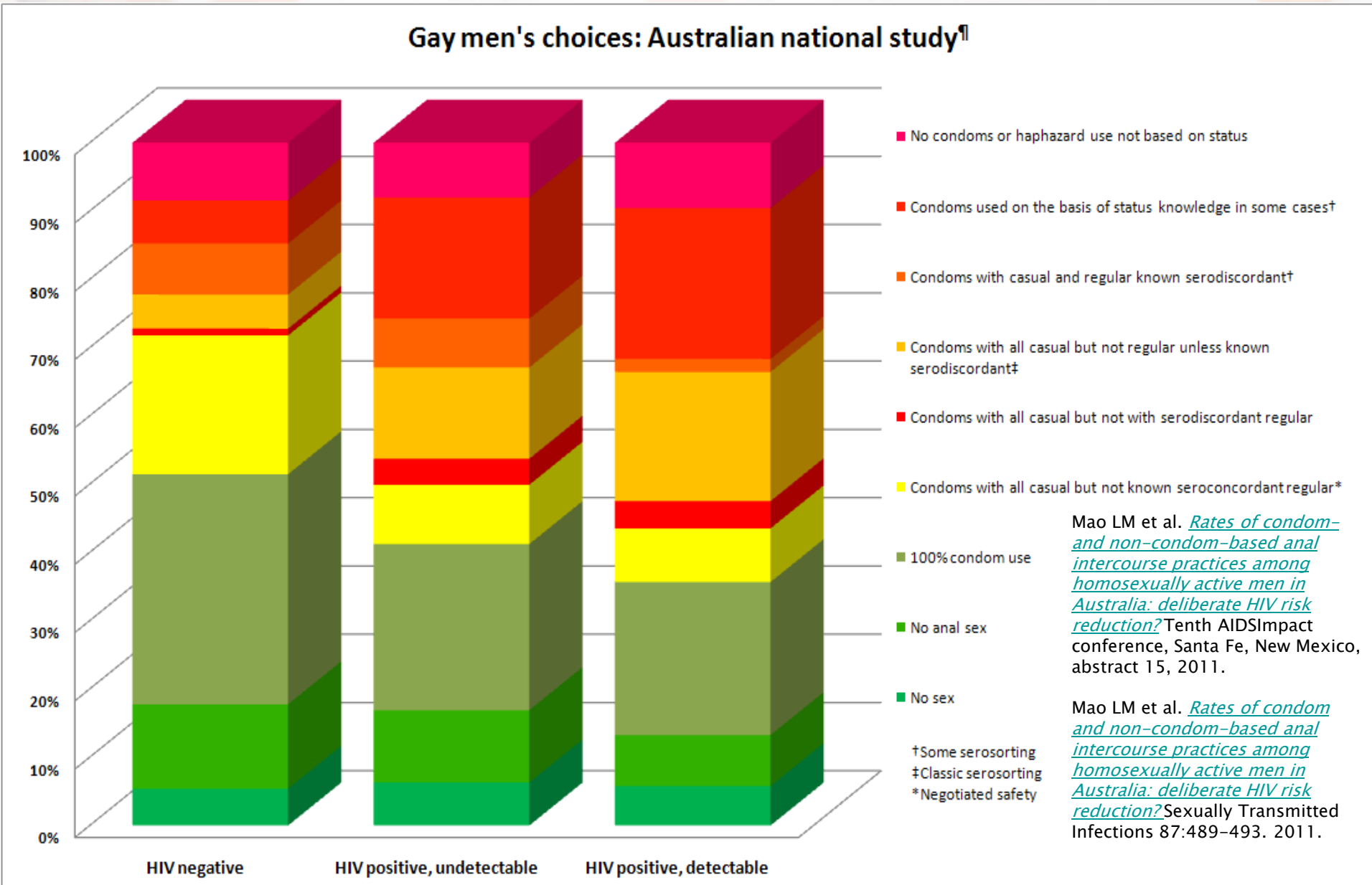
See also Hickson F et al. *HIV Testing and HIV Serostatus-Specific Sexual Risk Behaviour Among Men Who Have Sex with Men Living in England and Recruited Through the Internet in 2001 and 2008.* Sexuality Research and Social Policy 10: 15-23. (Full text available here)





HIV CONT
From

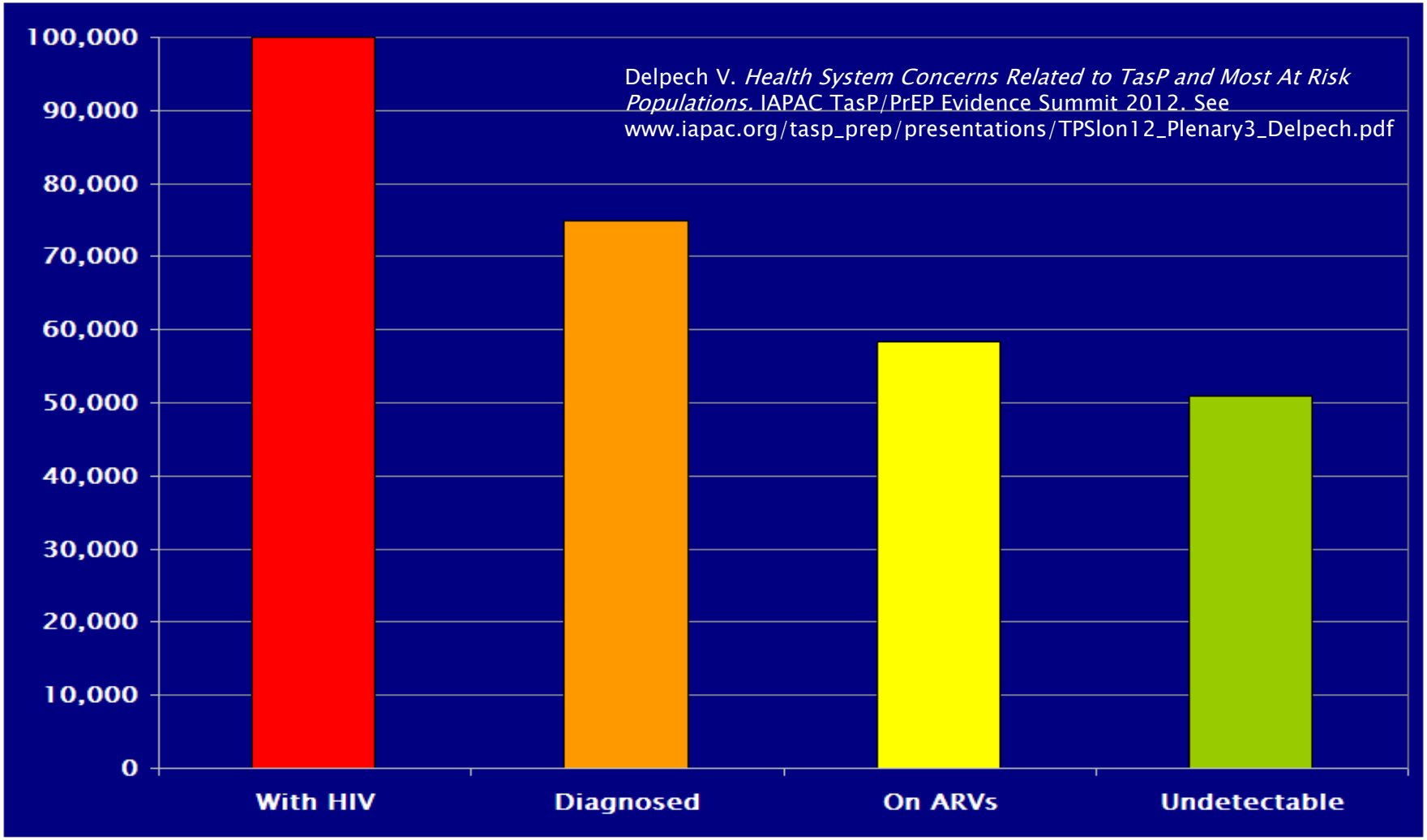
Why? 2: complexity



Mao LM et al. *Rates of condom- and non-condom-based anal intercourse practices among homosexually active men in Australia: deliberate HIV risk reduction?* Tenth AIDSImpact conference, Santa Fe, New Mexico, abstract 15, 2011.

Mao LM et al. *Rates of condom and non-condom-based anal intercourse practices among homosexually active men in Australia: deliberate HIV risk reduction?* Sexually Transmitted Infections 87:489–493. 2011.

Why? 3: the UK treatment cascade

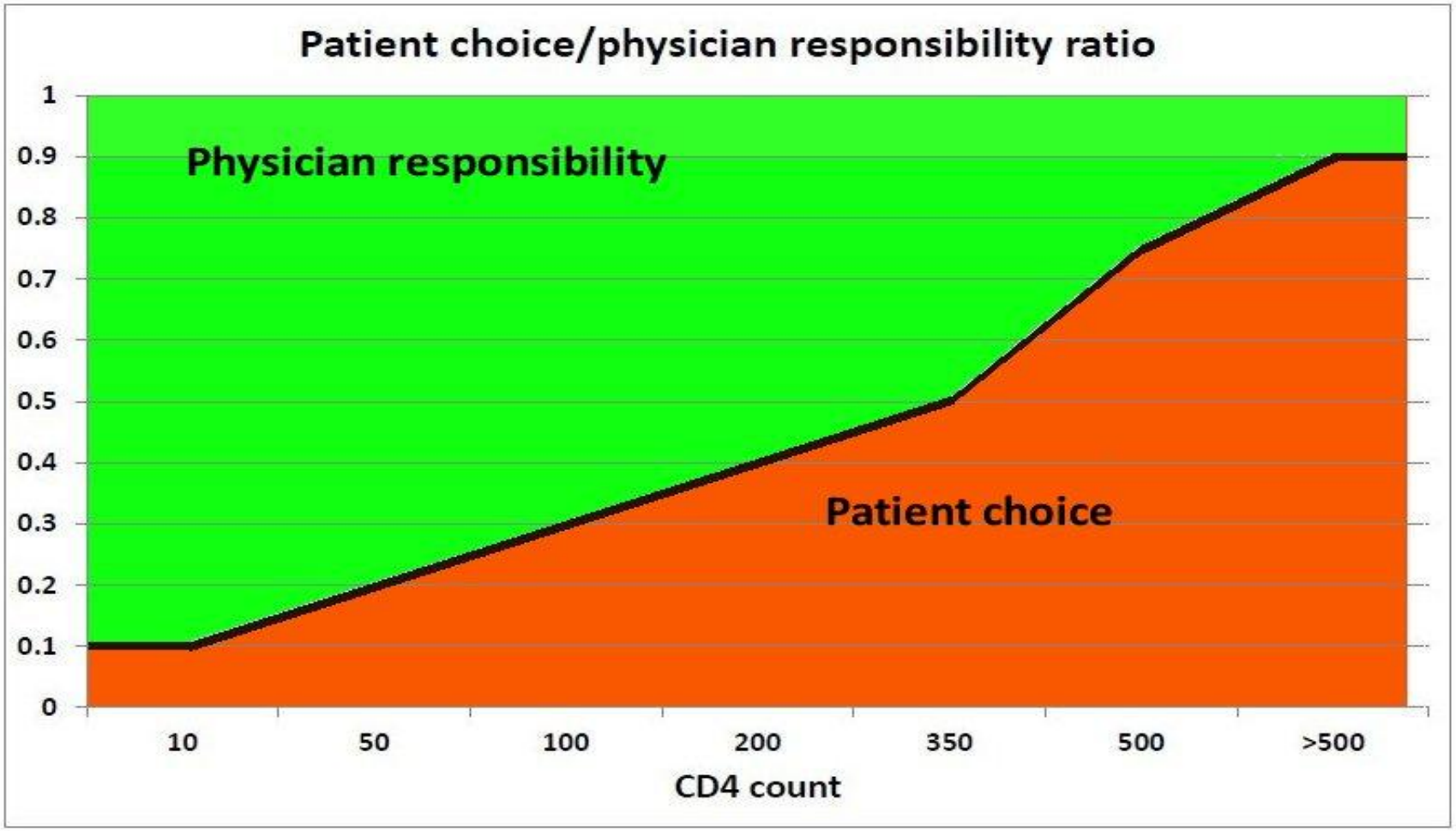


What do the Guidelines say?

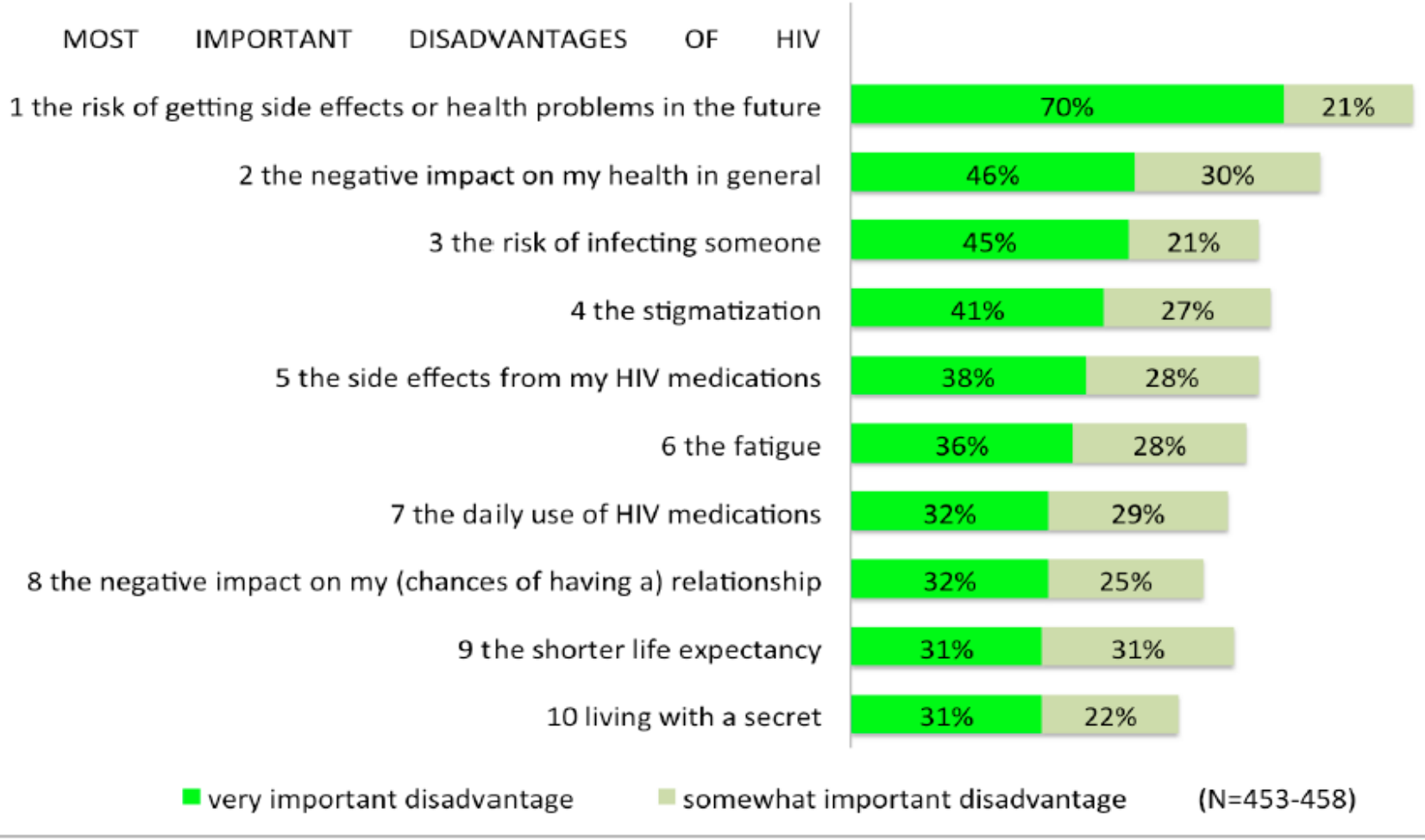
- **US guidelines**: offer ART to all <500 (strong) and >500 (moderate)
- **WHO**: <500 and "to HIV-positive people in serodiscordant relationships"
- **EACS**: <350 and "In serodiscordant couples, early initiation of ART as one aspect of the overall strategy to reduce HIV transmission to the seronegative 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.

DHHS US guidelines - http://aidsinfo.nih.gov/guidelines/html/1/adult-and-adolescent-arv-guidelines/0
IAS-USA guidelines - http://jama.jamanetwork.com/article.aspx?articleid=1221704
WHO guidelines - http://www.who.int/hiv/pub/guidelines/arv2013/en/index.html
EACS guidelines - http://www.europeanaidsclinicalsociety.org/index.php?option=com_content&view=article&id=59&Itemid=41
BHIVA guidelines - http://www.bhiva.org/documents/Guidelines/Treatment/2012/120430TreatmentGuidelines.pdf

Responsibility and Choice



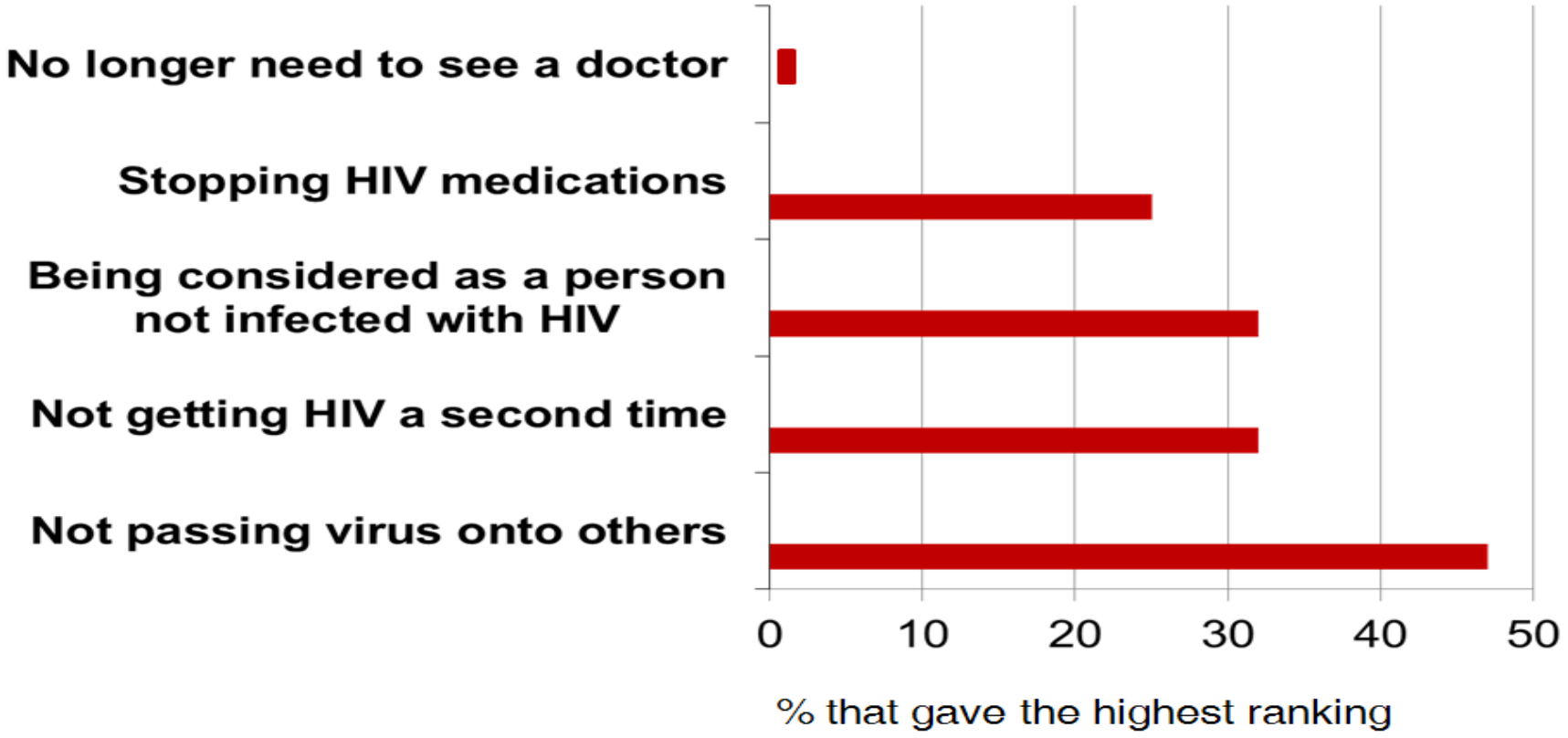
Do people *want* ART as prevention?



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



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

HIV CONTROLLI From Consen

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

FREE HEADLINES: Email • RSS || My Account

BY ALLAFRICA | MYAFRICA | TRAVEL | BLOGAFRICA | SOURCES

HotNow! | Countries | Topics | Development | BizTech | Entertainment | Sport | Africa/World | Governance | Multimedia | Innovation

Tagged: AIDS • External Relations • Health • Human Rights • International Organisations • Southern Africa • Sustainable Development

EMAIL PRINT SHARE

Southern Africa: SADC Considers Universal HIV Testing

19 AUGUST 2013

Like 39 Tweet +1 2

RELATED TOPICS

AIDS
- Kenya: First Lady Roots for More Support...

Southern Africa
- South Africa: Baby's Death Sparks Drive to...

International Organisations
- Rwanda: AUC Chair Approves the Deployment...

Human Rights
- Mauritania: Modern-Day Slave Finds Freedom...

Sustainable Development
- Africa: Building Blocks for Africa's Economy

Lilongwe — Several leaders of the Southern African Development Community (SADC), speaking at the organisation's weekend summit in Lilongwe, called on member states to adopt the principle of universal testing for HIV, rather than leaving it up to each citizen to decide whether to take an HIV test or not.

Among those who called for universal testing were the Presidents of Zimbabwe and the Democratic Republic of Congo, Robert Mugabe and Joseph Kabila, and the chairperson of the African Union Commission, Nkosazana Dlamini-Zuma.

They argued that the AIDS pandemic is such a serious public health threat, that it is no longer an option to allow people to decide for themselves whether they will be tested, and whether they will be treated if they turn out to be HIV-positive.

Mugabe said he could not understand why citizens should be free to take or not take the test, or to submit themselves to treatment or not, when it is the obligation of governments and of public health services to ensure the good health of all citizens. This involves prevention, timely diagnosis and the treatment of all diseases.

Mugabe said it was time to move away from voluntary tests to universal

South Africa

INFOCUS: AIDS »

New HIV Prevention Drug Shunned
Activists have asked the government to rethink its stance after the dismissal ...

Tanzania: HIV Sector Crisis
Major donors supporting the fight against HIV/Aids have announced the withdrawal of ...

Better HIV Treatment for Children
A new study has revealed that babies on antiretroviral treatment may be able ...

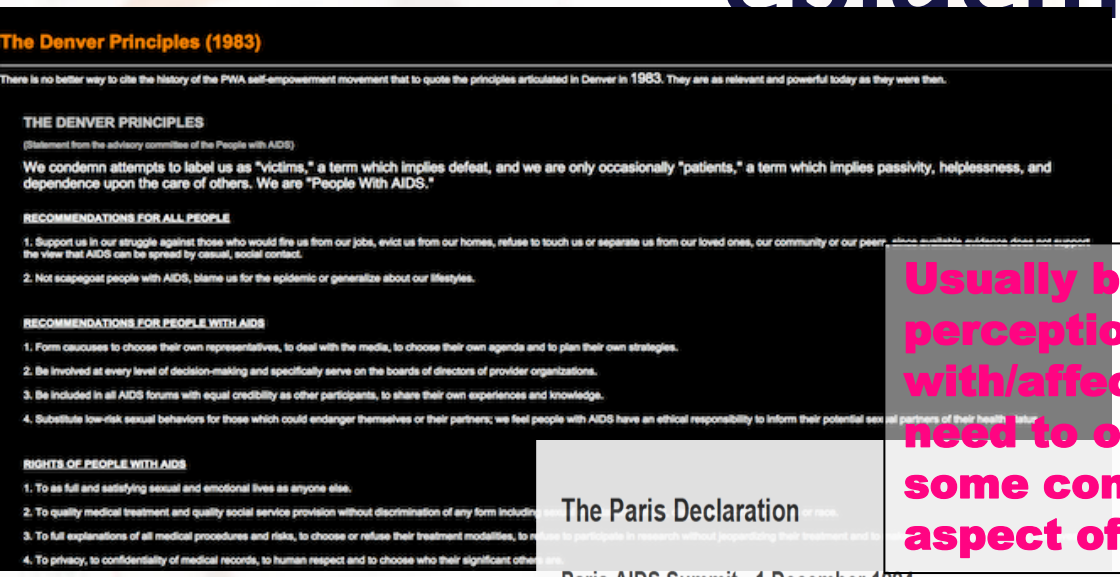
National: political misunderstandings of potential and practicality of 'Test and Treat'

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

RETROVIRALS

Community statements/standards in the epidemic



The Denver Principles (1983)

There is no better way to cite the history of the PWA self-empowerment movement that to quote the principles articulated in Denver in 1983. They are as relevant and powerful today as they were then.

THE DENVER PRINCIPLES

(Statement from the advisory committee of the People with AIDS)

We condemn attempts to label us as "victims," a term which implies defeat, and we are only occasionally "patients," a term which implies passivity, helplessness, and dependence upon the care of others. We are "People With AIDS."

RECOMMENDATIONS FOR ALL PEOPLE

1. Support us in our struggle against those who would fire us from our jobs, evict us from our homes, refuse to touch us or separate us from our loved ones, our community or our peers.
2. Not scapegoat people with AIDS, blame us for the epidemic or generalize about our lifestyles.

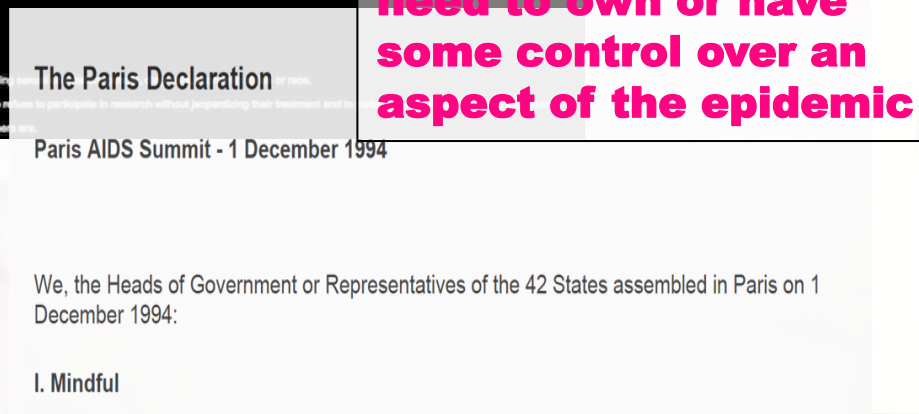
RECOMMENDATIONS FOR PEOPLE WITH AIDS

1. Form caucuses to choose their own representatives, to deal with the media, to choose their own agenda and to plan their own strategies.
2. Be involved at every level of decision-making and specifically serve on the boards of directors of provider organizations.
3. Be included in all AIDS forums with equal credibility as other participants, to share their own experiences and knowledge.
4. Substitute low-risk sexual behaviors for those which could endanger themselves or their partners; we feel people with AIDS have an ethical responsibility to inform their potential sexual partners of their health status.

RIGHTS OF PEOPLE WITH AIDS

1. To as full and satisfying sexual and emotional lives as anyone else.
2. To quality medical treatment and quality social service provision without discrimination of any form including
3. To full explanations of all medical procedures and risks, to choose or refuse their treatment modalities, to
4. To privacy, to confidentiality of medical records, to human respect and to choose who their significant other

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



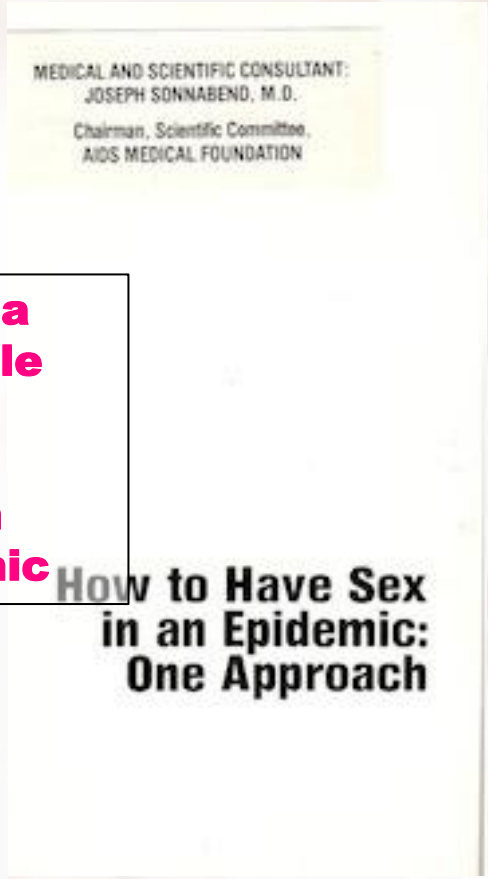
The Paris Declaration

Paris AIDS Summit - 1 December 1994

We, the Heads of Government or Representatives of the 42 States assembled in Paris on 1 December 1994:

I. Mindful

- that the AIDS pandemic, by virtue of its magnitude, constitutes a threat to humanity,
- that its spread is affecting all societies,
- that it is hindering social and economic development, in particular of the worst affected countries, and increasing the disparities within and between countries,
- that poverty and discrimination are contributing factors in the spread of the pandemic,
- that HIV/AIDS inflicts irreparable damage on families and communities,
- that the pandemic concerns all people without distinction but that women, children and youth are becoming infected at an increasing rate,
- that it not only causes physical and emotional suffering but is often used as justification



MEDICAL AND SCIENTIFIC CONSULTANT:
JOSEPH SONNABEND, M.D.
Chairman, Scientific Committee,
AIDS MEDICAL FOUNDATION

How to Have Sex in an Epidemic: One Approach

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."

Community consensus Statement 2

Preface

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 3

Covers:

- Evidence
- Adherence
- Readiness
- Advantages: relief from guilt and anxiety
- Disadvantages: coercion and pressure
- Access and supply of drugs
- Challenge to previously accepted norms (eg 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

- 1st draft written 01 March 2013 (1102 words)
- Sent round EATG writing group
- 2nd major redraft sent round EATG membership 15 May 2013
- 3rd redraft put on Aidsmap and EATG sites for public consultation beginning of June
- 4th 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 **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:

- Caspar Thomson, NAM
- Brian West, EATG
- Zoe Smith, NAM
- Jose Zuniga, IAPAC
- The EATG writing group
- Stephen Head, Gilead Sciences