



J. Jeff McConnell



Pedro

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J. Jeff McConnell

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About

Project Director, Grant Lab Epidemiology and Clinical Studies at The Gladstone Institutes
2001 to present

Studied Sociology at SUNY at Stony Brook
Past: University of Alberta and Fort Lewis College, Durango, CO

Lived in San Francisco, California

From Athabasca, Alberta

The sociologist who did the budgets

Jeff, the sociologist who did the budgets

-----Original Message-----

From: Jorge Sanchez [mailto:jsanchez@impactaperu.org]
Sent: Thursday, March 18, 2004 5:09 PM
To: Jeff McConnell
Cc: rgrant@itsa.ucsf.edu; Jose Ojeda
Subject: Re: Enrollment and clinical visit estimates

Yes, we are working with excel files. Please send your file to compare with what we are doing. Thanks for your help
Jorge

Jeff McConnell escribió:

Hi Pepe,

I am working with Bob Grant to develop the overall budgets for the chemoprophylaxis proposal. For example, based on the clinical plan outline not distributed yesterday (about and specific assumptions about enrollment

Jeff McConnell

To: Pedro Goicochea <pgoicochea@gladstone.ucsf.edu>, Grant Lab
RE: Thank you

August 30, 2013 12:43 PM

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TE QUERMOS PEDRO!
WE WERE A PART OF SOMETHING BIG
AND YOU SHOWED US HOW.
PUENTES

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Various intermittent dosing concepts have been discussed by various members of our communities. This lexicon attempts to establish a common vocabulary so that we literally can understand what we are talking about. The intent is to facilitate a discussion about the intermittent PrEP research agenda. Hopefully, it will also facilitate a dialogue among community and research leaders to understand if the growing community interest in PrEP fits with research questions under consideration by sponsors. The discussion about oral prep assumes the agent will be tenofovir or Truvada, although their efficacies in humans are still unknown. Even if the current therapies are proven safe and effective, future PrEP and PrEP studies may involve other agents and considerations of their safety, efficacy, and cost. This lexicon is a work in progress that will develop along with these discussions.

ONCE-DAILY DOSING

Tenofovir or Truvada taken orally once daily (as it is current licensed for use as treatment) without regard to the timing of exposure to HIV. **Currently, all completed and on-going trials are based upon once-daily dosing strategies.** Some animal model studies in macaques (a type of primate) and mice have incorporated daily dosing.

WEEKLY-BASED DOSING

Tenofovir or Truvada taken orally based on a weekly schedule that might include 1, 2, 3, 4, or 5 doses per week, independent of the timing of exposure to HIV. The optimal strategy for timing the doses is unclear. Undoubtedly, this strategy would attempt to balance cost, adherence, and drug levels, but the optimal balance is not known. Small planned pharmacokinetic (PK) studies in seronegative humans and in human tissue-culture models might provide clues to how many weekly doses will provide adequate prophylaxis, if any. Animal model studies have generally followed exposure with a specifically timed post-exposure dose and may not provide relevant information about weekly dosing that is completely independent of exposure.

EVENT-BASED DOSING

Tenofovir or Truvada taken orally based on exposure events, whether anticipated or completed (i.e., before sex is anticipated and/or after it happens.) Presumably this strategy would depend upon a single pre-exposure dose and one or more post-exposure doses. Although PrEP use in the community appears to be rare, terms such as “disco dosing” or “Taking a T” probably envision this type of strategy. Some experiments in animal models (macaques) provide data relevant to event-based dosing. A “Pocket-PEP” study in Brazil provided data about how well individuals who are at risk can identify or act on significant exposure events by self-administering post-exposure antiretrovirals that are readily available.

ROUTINE PLUS EVENT-BASED DOSING

Tenofovir or Truvada taken orally based on a weekly schedule that might include 1, 2, or 3 routine doses, independent of anticipated or completed exposure. Exposures would be followed by one or more specifically timed post-exposure doses, independent of the routine weekly dose schedule. Small-scale PK studies might be informative. Many animal model experiments have used variably-timed pre-exposure doses with specifically timed post-exposure doses.

PERIODIC DOSING

Tenofovir or Truvada taken orally, based on any one or more than one of the dosing strategies above during periods of potential sexual or IV exposures. Disruptions in access to a regular partner or partners, voluntary or involuntary periods of abstinence, carefully planned periods of serosorting, including seroconcordant monogamy, or other life events may effectively reduce or avoid exposure, even among individuals frequently at high risk for exposure to HIV. Animal model data may indicate how long before or after exposure prophylactic efficacy is required and may be informative for planning periodic dosing studies.

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I have been looking at this tree for several hours now. I think that it does the job.

Enjoy!

Jeff McConnell

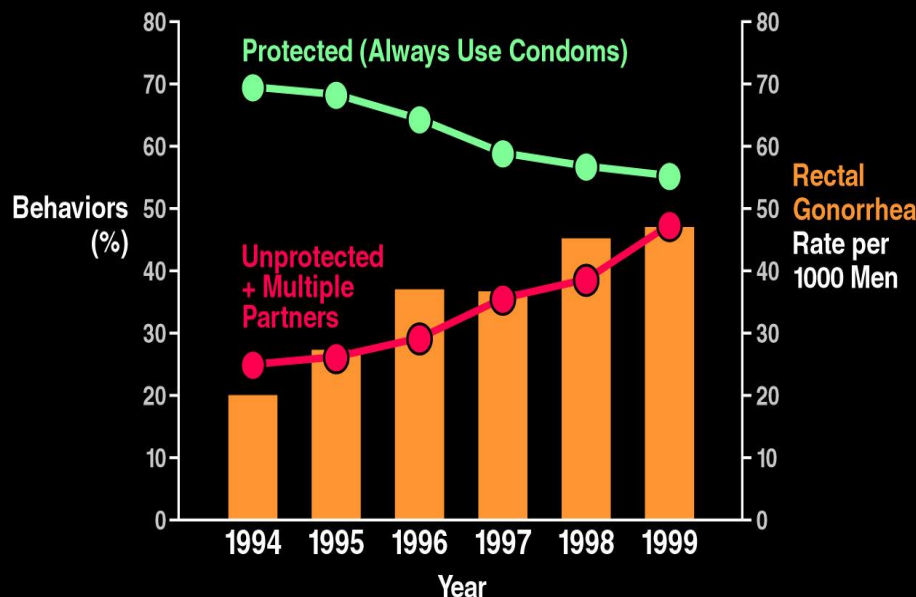
April 12th, 2009, 1:08 am





Studies in SF 1994 – 1999 Show Indicators of Risk for Epidemic Spread on the Rise

Reported Sexual Behaviors among Men Who Have Sex with Men and Male Rectal Gonorrhea Cases: San Francisco, 1994–1998

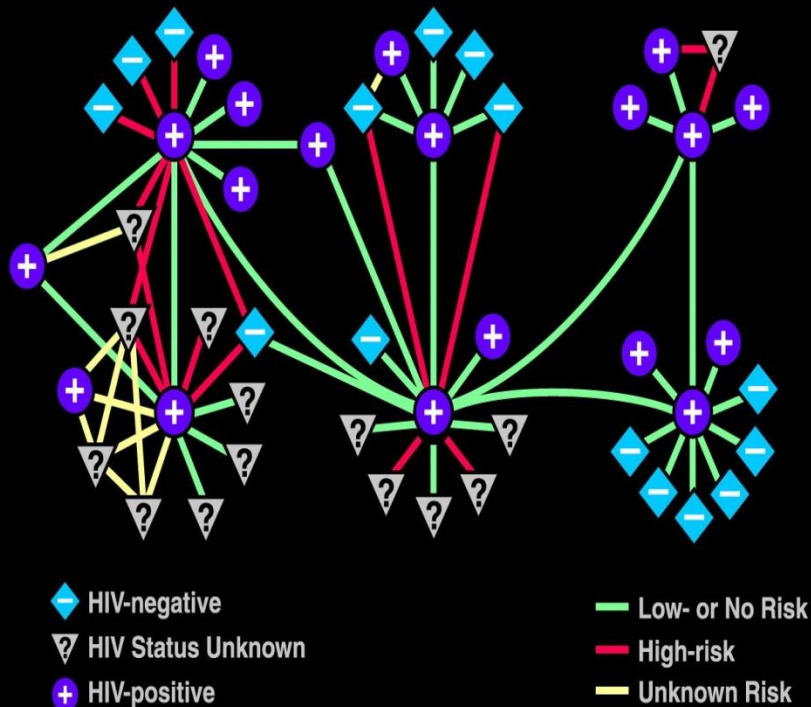


03.036D

- Consistent condom use fell from 70% in 1994 to 54% in 1999
- MSM reporting UAI with multiple partners grew from 23% to 43%
- Rates of RGC grew from 20 to 45 cases per 100,000

A New Way to Look at Sexual Risk

A Bay City Sexual Network



Our HIV-positive study participants reported risk on a *partner-by-partner* basis (last 3 months).

We learn...

- partner's HIV status
- specific sexual practices per partner
- about relationships between partners

03.037A1















We will miss you, Jefe!



Prevention: latest news

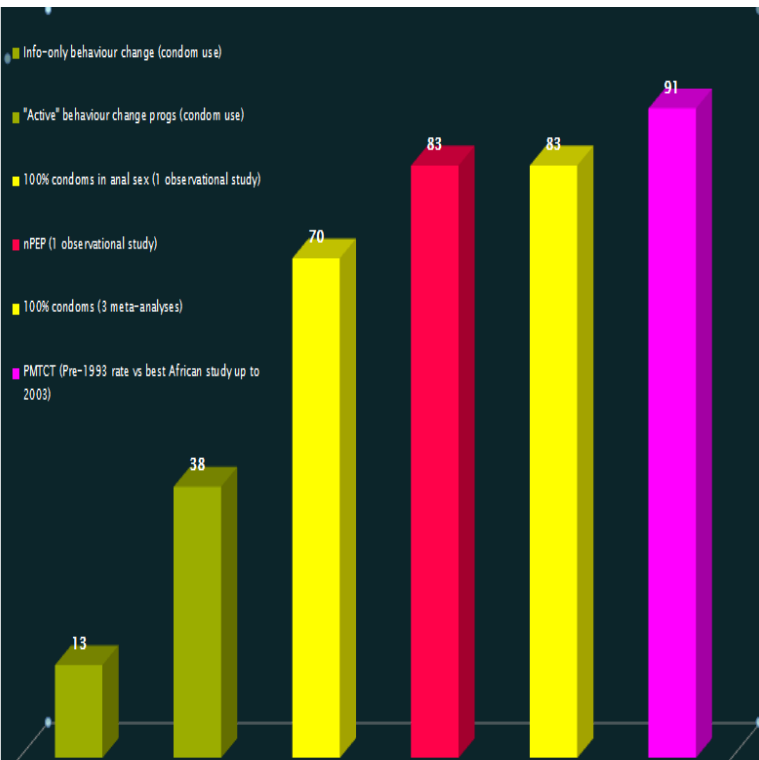
Gus Cairns, Editor, NAM (www.aidsmap.com)

Policy Working Group, EATG

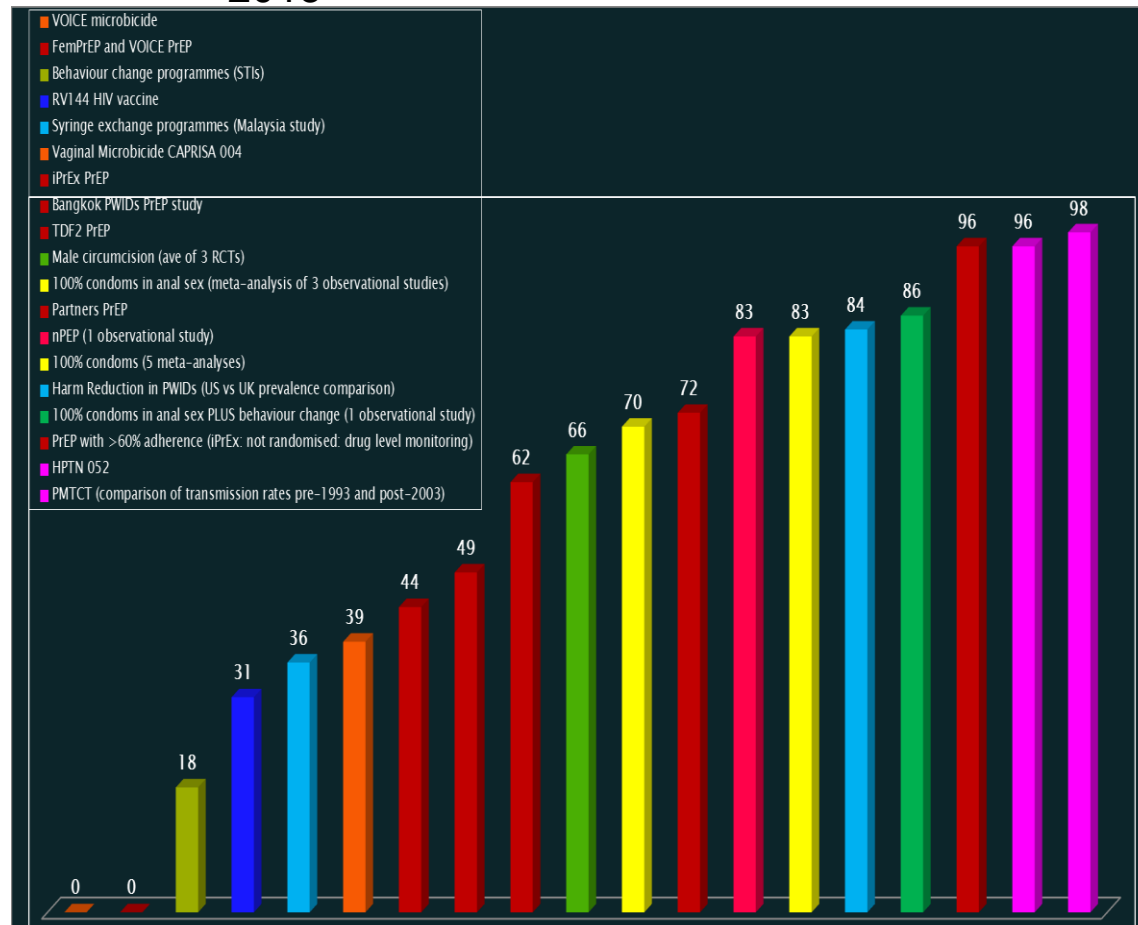
See www.hivt4p.org

What we know – then and now

Known efficacy of prevention methods, 2003



Known efficacy of prevention methods, 2013



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What we've learned

- Adherence is all
- Community investment is essential
- Prevention methods must fit lifestyles
- People won't use PrEP like TasP: adherence may be lower
- People will adjust usage to risk
- *Youth*, gender, emotional health, lifestyle affect adherence

HPTN052 – reminder

- Randomised placebo–controlled study,
 - 1763 serodiscordant African/Thai couples (3% gay): 886 immediate ART, 877 delayed
 - Delayed went on ART when $<250\text{cells}/\text{mm}^3$
 - Transmissions = 39.
 - Linked = 28
 - 27 not on treatment
 - 1 person who transmitted on treatment did so around the time they started treatment
 - **11 unlinked transmissions = 28%**

PARTNER Study

- Longitudinal cohort study
- 1110 (so far) serodiscordant couples, Europe. HIV+ partners all on treatment
- 40% gay
- Interim results at CROI 2014
- **Zero** linked transmissions* in 44,000 occasions of sex, 16,400 of them between men
- 50–100 (median: 86) would be expected from partners not on ART
 - *Linked transmissions *exclude* couples where the HIV+ partner had a VL over 200 copies/ml
- **Figures for unlinked transmissions not yet available, but may be a lot**

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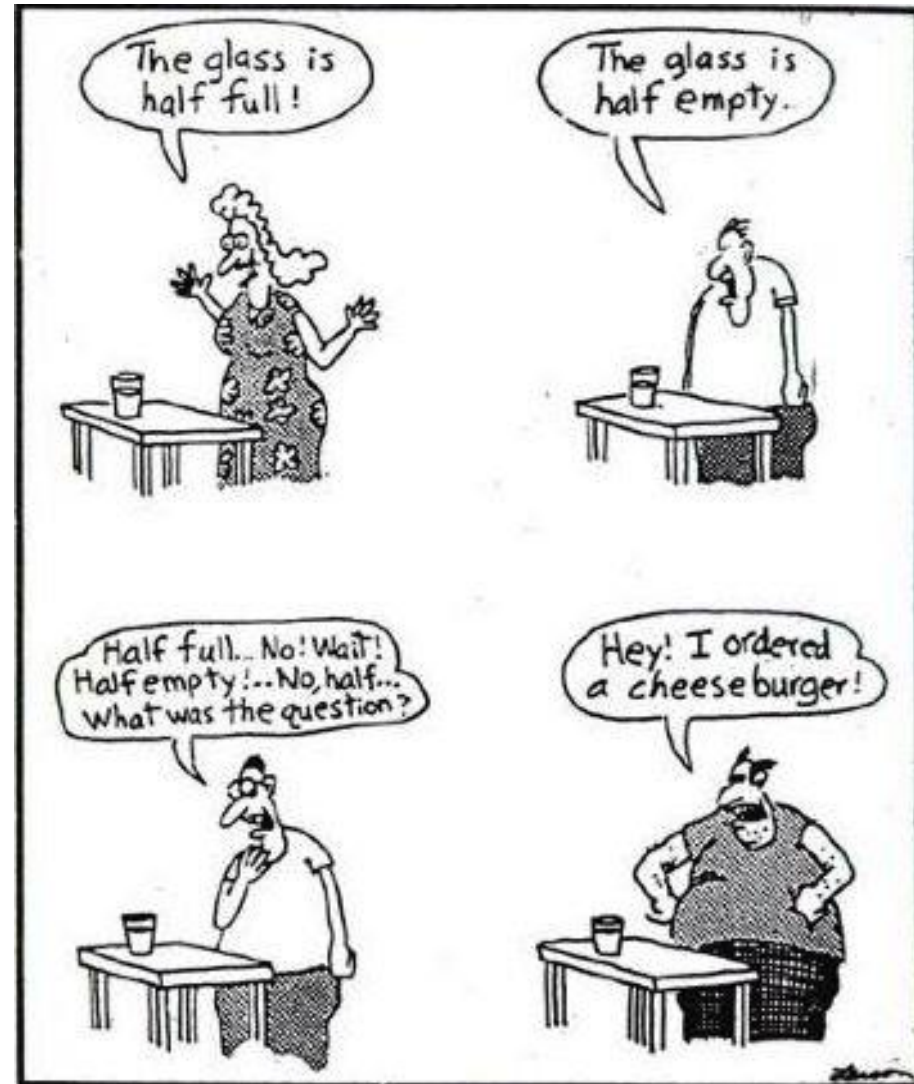
Partner Study – what does ‘zero’ tell us?

- 95% confidence interval
 - “If we repeated this study 100 times, we’d expect the results to lie outside this range in 5% of them”
 - Not “There is a bird in this picture” but: “The chance that dot is a bird and not a stray pixel is x%”
 - About resolution, not results: so the more data, the narrower CIs get
- 95% CI for annual risk of transmission:
 - All sex: zero to 0.45%
 - Anal sex: zero to 1%
 - Vaginal sex where HIV+ partner ejaculates: zero to 2%
 - Anal sex where HIV+ partner is top: zero to 2.5%
 - Anal sex where HIV+ partner is top and ejaculates: zero to 4%
- NB Double-side confidence interval so 2.5% chance of actual risk lying above the upper bound
- ‘Point estimate’ = usually in the middle of the confidence interval, but sometimes isn’t esp if lower bound is zero (or upper bound is 100%)
- Best guess is that as more results come in upper bound of 95% CI will draw closer to zero (but will never reach it)

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Optimist vs pessimist

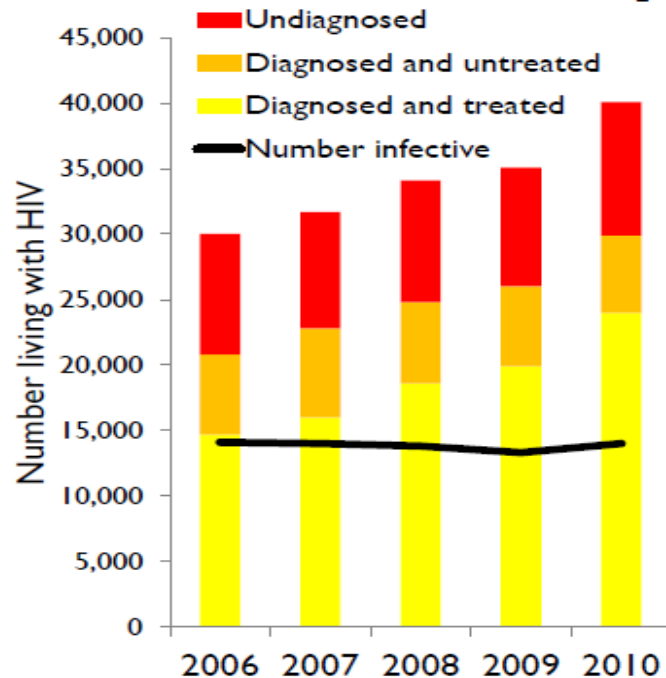
- Glass full: 'real' chance of transmission probably zero
 - CI will edge closer to zero with more data
 - Only 1.17 years of F/U so far: more gay men being recruited and followed for 3 more years
- Glass empty: chance of transmission between gay men may be 40% in ten years if HIV+ partner is bottom
 - But even this is at least 20x better than chance of transmission from untreated partner (per-event chance 1.4% = 40% after 28 exposures)



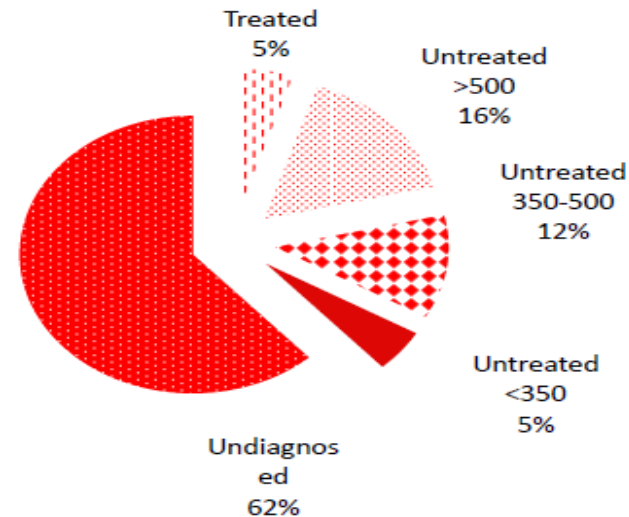
The four personality types - Gary Larson

Implications for community

Why is HIV transmission continuing in MSM?



Among 14 000 men who are infectious



Slide from Valerie Delpuch, 2013 IAPAC TasP meeting



Public Health England

Brown et al HIV_Med. 2013 HIV treatment as prevention among men who have sex with men in the UK: is transmission controlled by universal access to HIV treatment and care?

HIV and AIDS Reporting Section

- In areas with good treatment access like UK, most transmissions are now from the undiagnosed and nearly all from the untreated
- → maximise testing and treat everyone?

Don't forget: www.hivt4p.org

312 SUPPORTERS

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Share  

 **aidsmap**

 European
AIDS Treatment
Group

Community consensus statement on the use of antiretroviral therapy in preventing HIV transmission

READ

the community consensus statement

SIGN

and add your support

Introduction to the statement

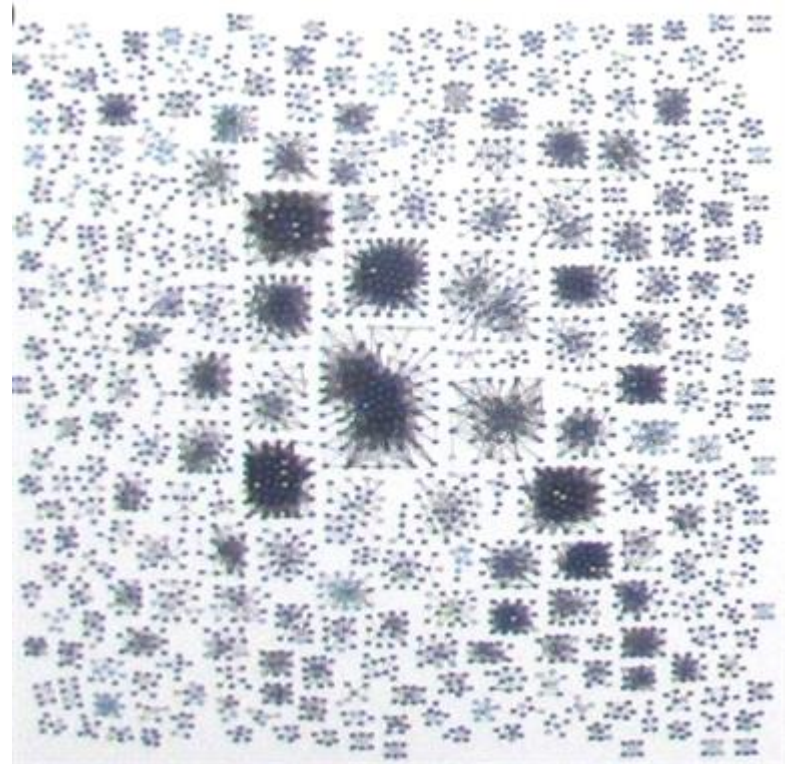
1. This is a community consensus statement on the use of antiretroviral therapy (ART) to reduce the risk of HIV transmission from people living with HIV. It does not cover the provision of antiretroviral drugs to people who are HIV negative to reduce their risk of acquiring HIV (pre-exposure prophylaxis, PrEP). It is also not specifically about access to ART in general.

[Listen to the podcast](#)



If test-and-treat isn't enough → PrEP?

- Test-and-treat may not be enough to control high-incidence, highly-connected epidemics
- Brian Williams model: PrEP cost-effective where HIV incidence >6% a year
- Community-level incidence in YBMSM in Atlanta = 12%
- In Kenya MSM (Mombasa) = 39%
- In PROUD participants = over 6% cf general UK MSM incidence = 0.5%



Pic: HIV transmission clusters in NYC, from Wertheim JO et al. *Risk Factor Predicts Geographic Spread Within New York City HIV-1 Transmission Network and Beyond*. CROI 2014 Abstract 214

PrEP studies: latest news

- PROUD: Open-label randomised immediate-vs-deferred, high-risk MSM
 - Pilot stage N=546. Now fully recruited
 - 50% offered PrEP for 2 years, 50% after the first year
 - Largely well-educated white gay men
 - Median 10 AI partners in last 3m but used condoms with c 2/3 of them
 - Very high rate of PEP usage pre-PROUD: 40% in a year and 21% more than once (has cost-effectiveness implications)
 - Drug usage: 50% mephedrone etc, 43% GHB, 35% cocaine, 24% meth
 - 25% each had rectal, oral or urethral gonorrhoea (often together)
 - These baseline data suggest incidence will be higher than national estimate of 2.7/100 pyrs
 - Hep C cases: 5 so far diagnosed with acute hepatitis C even though there has been no systematic HCV testing
 - Participant Involvement Meeting: strong preference for daily dosing

More PrEP studies

- US Demo project
 - San Francisco, Washington DC, Miami
 - Very different adherence: 4x a week adherence 92% in SF, 78% in DC, 53% in Miami
 - 37% entering trial proactively asked for PrEP - 56% of those who ended up taking it had asked.
 - 69% had heard of PrEP: cf. New York and Denver studies 2011, only 22% had heard of it
 - Miami participants younger, more non-whites, more uninsured, lower risky sex and drug use
 - Disappointingly-few Afro-Americans – only 8%. May improve as DC recruitment catches up.

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More PrEP studies

- Kenya MSM and FSW studies IAVI E001 and E002
 - Short (6m) acceptability studies of intermittent PrEP
 - Daily cf. before-and-after: one c.12h before anticipated sex, one 2h after
 - Adherence very much higher with daily dosing: problem was post-sex dose
 - Travel an issue if staying at a friend's house
 - Concern about being mistaken for HIV+: wanted a clearly different appearance for PrEP pills (NB cited as an issue in PROUID too)

More PrEP studies

Fem-PrEP: zero efficacy, <26% adherence

Qualitative interviews with participants – main reasons for non-adherence:

- Told by someone [most often a family member] not to take the pills: 15%
- Deterred by the non-adherence of other participants: 22%
- Feeling that pills were only to be taken when one was sick: 21%
- Felt at low risk of HIV: 28%
- **Forgot: 29%**
- Was travelling: 21%
- Too busy: 16%
- **As an investigational drug, it will probably not be of benefit: 47%**
- Perception one might be on placebo: 27%
- Fear of side effects: 26%
- Experience of side effects: 14%
- **Daily pill-taking is too difficult: 32%**
- The pills are too large: 27%

Corneli A et al. *FEM-PrEP: Participant Explanations for Non-Adherence*. 21st Conference on Retroviruses and Opportunistic Infections (CROI), Boston. Abstract 959LB. 2014.

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What we've learned

- Adherence is all
- Community investment is essential
- Prevention methods must fit lifestyles
- People won't use PrEP like TasP: adherence may be lower
- People will adjust usage to risk
- *Youth*, gender, emotional health, lifestyle affect adherence

Thank you!

- Sheena McCormack
- Lut van Damme
- Amy Corneli
- Alison Rodger
- Bob Grant
- Mark Hubbard
- Marc-André le Blanc
- ...and many others.



for hiv information



How we are changing the language of prevention

Suraj Madoori, HIV PJA

Background

- CDC: a November 2013 *Morbidity & Mortality Weekly Report* titled "Sexual risk lower among U.S. gay and bisexual men who accurately know their HIV status".
- Use of language and placement of emphasis we both potentially stigmatizing and blaming, including a focus on rising rates of men reporting sex without condoms.
 - *"unprotected sex" was used as a synonym for "condomless sex" or "sex without condoms"*

CDC Letter

- Advocates and allies authored a detailed sign-on letter in response
 - 50+ organizations sign-on
 - Demanded clarity of terms
- Some media coverage in HIV/AIDS and gay press

Process and CDC Response

- Submitted open letter
- Quick agreement for phone meeting; CDC definitively agrees to language change
- Post-call letter and meeting with advocates at CROI 2014 to clarify scope of agreement.
- Agreed to changes across agency communications

Next steps: building on Jeff's legacy

- How do we build on the success?
 - Wider systems advocacy (SAMSHA, DHS, DoE)
 - Continuing engagement w/ CDC
 - Acute need for guidance/resources for CBOs / ASOs / providers to update materials, change language use and program/counseling practices
- Remaining issues from letter:
 - HIV testing policy and recommendations (increase to every 3 months for gay and bisexual men?)
 - Inclusion & exclusion of transgender people in data (including NHBS) and surveillance