Late breaker oral session

LBO-1.1 ACYCLOVIR ACHIEVES LOWER CONCENTRATION IN AFRICAN HIV−, HSV-2+ WOMEN COMPARED TO NON-AFRICAN POPULATIONS, POSSIBLY EXPLAINING LOWER HERPES SUPPRESSION

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Background Two trials of acyclovir (ACV) 400 mg twice daily as daily suppressive therapy against herpes simplex virus type 2 (HSV-2) proved ineffective for prevention of HIV acquisition. Explanations for this lack of efficacy are unclear. In one of these trials, HPTN 039, ACV was modestly effective in reducing genital ulcers due to HSV-2; however, there was less reduction in the frequency of genital ulcers and higher HSV-2 DNA quantity in breakthrough lesions in women from African sites than in men from US sites. Pharmacokinetic differences of ACV have been proposed as one explanatory variable for these findings.

Methods Sixty-eight HIV-negative, HSV-2 seropositive women participated in a pharmacokinetic study of ACV after completion of HPTN 039 (a phase III, randomised clinical trial of daily acyclovir 400 mg p.o. twice daily). Following a single oral dose of 400 mg of acyclovir, blood was collected over an 8 h period. An LC/MS/MS-based assay determined ACV concentrations. PK parameters were estimated using non-compartmental methods.

Results Sixty-six African women had complete PK data for evaluation. Mean (range) age was 36 (21–54) years and weight was 70 (40–129) kg. The geometric mean (95% CI) for PK parameter estimates were: Cmax 0.31 ug/ml (0.28, 0.34), AUC0-inf 1.59 ug*hr/ml (1.43, 1.76), Tmax 1.56 h (1.40, 1.80), and half-life 2.8 h (2.5, 3.0). This Cmax was lower than 8 comparable single dose ACV PK studies in non-African populations, mean 46% lower (range 28%–59% lower, all p values <0.006). Similarly, AUC was lower than all other studies, mean 38% lower (range 26%–62%, all p values <0.001). In some studies, Tmax was earlier and the half-life was shorter. Subject weight did not explain the differences.

Conclusion Acyclovir exposure in black African women was lower than in comparable ACV studies of non-African populations. These statistically significant differences in drug exposure (Cmax and AUC) may be clinically significant and partly explain the modest effects of ACV on HSV-2 recurrence in these African women.

LBO-1.2 THE POTENTIAL IMPACT OF PRE-EXPOSURE PROPHYLAXIS FOR HIV PREVENTION AMONG MEN WHO HAVE SEX WITH MEN (MSM) IN LIMA, PERU

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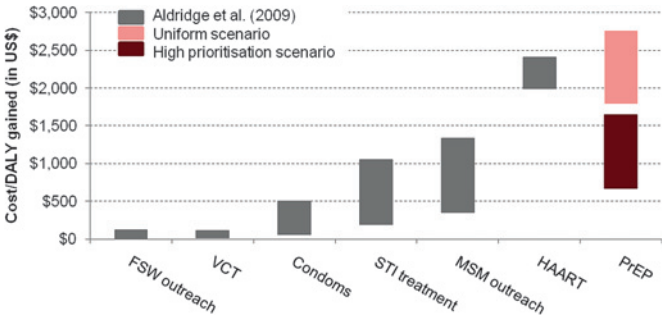
Background HIV Pre-exposure prophylaxis (PrEP), the use of antiretroviral drugs by those HIV uninfected individuals to prevent HIV infection, recently demonstrated effectiveness in preventing acquisition in a high risk population of men who have sex with men (MSM). There is a need to understand if and how PrEP can be used cost-effectively. This study examines the programmatic implications of the iPrEX study: the only randomised controlled trial of PrEP among men who have sex with men (MSM) published last December in the New England Journal of Medicine.

Methods We developed a mathematical model representing the HIV epidemic among Men who Have Sex with Men (MSM) and transgender people in Lima, Peru as a test-case. It considers differential infectiousness by stage, including the impact of antiretroviral treatment and different sexual practices, such as partnerships type and sexual positioning. The model was used to investigate the population-level impact, cost, and cost-effectiveness of PrEP under a range of implementation scenarios, and to develop possible strategies by which PrEP could be implemented.

Results The epidemiological impact of PrEP is largely driven by programme characteristics—coverage, prioritisation strategy and time to scale up—as well as individual's adherence behaviour. If PrEP is prioritised to key groups, it could be a cost-effective way to avert infection and save lives (up to 8% less new infections with 5% coverage). Across all our scenarios the estimated highest cost per DALY gained (US$2755) is below the WHO recommended threshold for cost-effective interventions for the region (<US$4608/DALY gained) see Abstract LBO-1.2 Figure 1. The impact of PrEP is reduced if those on PrEP decrease condom use, especially if the program has low coverage; but only extreme behaviour changes and a low PrEP efficacy would adversely impact the epidemic overall. However, PrEP will not arrest HIV transmission in isolation, due to its incomplete effectiveness, dependence on adherence, and the high total cost of programmes limiting attainable coverage levels.

Conclusions This study quantifies the epidemic and financial implications of different programmatic scenarios. While the implementation of a strategic PrEP intervention has potentially important financial implications (a substantial expenditure would likely be required to generate significant reductions in incidence), PrEP among vulnerable populations could be a cost-effective option comparable to currently available interventions for Men who Have Sex with Men (MSM) populations.



Abstract LBO-1.2 Figure 1

LBO-1.3 SYPHILIS INFECTION AND ASSOCIATED BEHAVIOURS AMONG TRANSGENDER WOMEN, CHICAGO 2010

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Background Transgender women are an underserved and understudied population with unique medical and behavioural risk profiles. High rates of STIs and HIV in this population have been reported, although accurately quantifying STI rates and associated risks is difficult because of limitations in measurement of gender identity, lack of standardised reporting measures, and conflation between Men who Have Sex with Men (MSM) and transgender identities. In 2009 we reported a substantial increase in syphilis among transgender women at our clinic (from two cases in 4 years to ten cases in 1 year); in 2010 we identified 20 new cases, another substantial increase. We

sought to describe morbidity and behavioural characteristics of these cases to better understand trends among this population.

Methods Data were gathered using clinic-based sentinel surveillance systems and through abstraction of Interview Records completed upon DIS interview.

Results Transgender women represented an increasing proportion of total syphilis cases identified from 2009 (3.7% or 10/269) to 2010 (6.4% or 20/313). The 20 cases identified in 2010 were among 19 transgender women; one client was re-infected. Of these, 2 (10%) were primary, 12 (60%) were secondary, 5 (25%) were early latent, and 1 (5%) was latent of unknown duration syphilis. The mean age increased slightly from 21.4 years (range 19–24) in 2009 to 24.9 years (range 19–41) in 2010. Reported race/ethnicity included: 13 (65%) non-Hispanic black, 3 (15%) Hispanic, 2 (10%) non-Hispanic white, 1 (5%) Asian/Pacific Islander and 1 (5%) American Indian/Alaskan Native. HIV co-infection was similar to rates observed in Men who Have Sex with Men (MSM) populations (60%); 25% of HIV-positive clients had been diagnosed in the prior year. Forty-five per cent had a history of STI (non-HIV). High rates of transient housing (30%), unemployment (55%), incarceration (25%), and transactional sex (40%) in the prior 12 months were reported. Median number of sex partners in the past year was 10 (range 0–60). No common sex partners were named during case investigation interviews during 2009 or 2010.

Conclusions Increases in syphilis among transgender women in Chicago highlight a need for enhanced screening and targeted prevention messages for this population. High levels of risk and HIV co-infection reflect potential for ongoing transmission of both HIV and other STIs.

LBO-1.4 INCREASING MACROLIDE RESISTANCE IN *MYCOPLASMA GENITALIUM*

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Background To evaluate therapy outcome in *M genitalium* infection with standard chlamydia treatment doxycyclin 9 days and azithromycin 1 g stat compared to extended azithromycin 15 g for 5 days and to evaluate macrolide resistance.

Methods Patients attending the STD-clinic in Falun, Sweden between January 1998 and December 2005 with a positive PCR test for *M genitalium* routinely had a test of cure. Response was determined to doxycycline, azithromycin 1 g as a single dose and 15 g extended treatment primary and secondary when persistence after doxycycline. Macrolide resistance was monitored at base as well as after treatment in those testing positive after treatment with azithromycin. Macrolide resistance also was monitored yearly 2006–2010 in patients with newly detected *M genitalium* infection.

Results Totally 313/407 (77%) had a test of cure, 254/313 (81%) within 12 weeks. The eradication rate with doxycycline was 43% totally, 46% for women and 38% for men, with azithromycin 1 g 92% totally, 96% for women and 89% for men and with azithromycin extended dosage 96% totally, 100% for women and 93% for men. Confirmed macrolide resistance developed in 7/7 (100%) of those testing positive after azithromycin 1 g. In 2006–2007 we found no, in 2008 and 2009 1/year and in 2010 11 patients with macrolide resistance in newly detected *M genitalium*.

Conclusions These findings confirms the results from other studies that doxycycline is inefficient in eradicating infection with *M genitalium*. Although the treatment outcome with azithromycin 1 g was not significantly lower than with extended dosage for 5 days it was in this study associated with 100% induced macrolide resistance in those with treatment failure. A remarkable higher proportion of macrolide resistance in 2010 than earlier years was found. We will try to monitor yearly prescription of azithromycin 1 g in our county and all Sweden last years. Is there an increase explaining the higher proportion 2010? Azithromycine 1 g should be avoided as recommended therapy for *M genitalium* as well as for chlamydia and non-gonococcal urethritis. Specific diagnostics for *M genitalium* as well as monitoring of resistance is urgent.

LBO-1.5 MEN WHO HAVE SEX WITH MEN (MSM) HAVE A 140-FOLD RISK FOR HIV AND SYPHILIS COMPARED WITH OTHER MEN IN NEW YORK CITY

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Background While men who have sex with men (MSM) comprise the majority of new HIV and new syphilis cases in the U.S.,

Abstract LBO-1.5 Table 1 Annual HIV Incidence among 229 HIV-Negative Men who Have Sex with Men (MSM) Diagnosed with Rectal Chlamydia or Gonorrhoea at New York City STD Clinics Between January 2008 and December 2009

	Number of patients	%	Person-years at risk	Number of HIV seroconversions by STD clinic diagnoses	Total number of HIV seroconversions after HIV registry cross-match	Annual HIV incidence	95% CI
Overall	229	100%	368.29	16	22	5.97	3.84 to 8.90
Age (years)							
<20	25	11%	37.07	4	4	10.79	3.42 to 26.00
20–29	148	65%	239.90	9	13	5.42	3.01 to 9.03
30–39	42	18%	69.56	2	5	7.19	2.63 to 15.93
40+	14	6%	21.75	0	0		
Race/ethnicity							
Non-Hispanic White	71	31%	116.63	2	3	2.57	0.65 to 7.00
Non-Hispanic Black	44	19%	63.44	6	9	14.19	6.92 to 26.03
Hispanic	83	36%	135.40	5	5	3.69	1.35 to 8.18
Asian	12	5%	20.23	1	1	4.94	0.25 to 24.38
Other/multiple	19	8%	32.59	1	4	12.27	0.15 to 15.13
Rectal infection							
Chlamydia	158	69%	252.62	10	14	5.54	3.15 to 9.08
Gonorrhoea	49	21%	80.85	4	5	6.18	2.27 to 13.71
Both	22	10%	34.82	1	3	8.62	2.19 to 23.45
Early syphilis concurrently or in last 2 years							
Yes	31	14%	50.33	3	4	7.95	2.52 to 19.17
No	198	86%	317.96	12	18	5.66	3.46 to 8.77