

**P3-S3.06** QUANTIFYING LACTOBACILLAE SPECIES WITH REAL TIME PCR METHODS FOR HIV PREVENTION TRIALS

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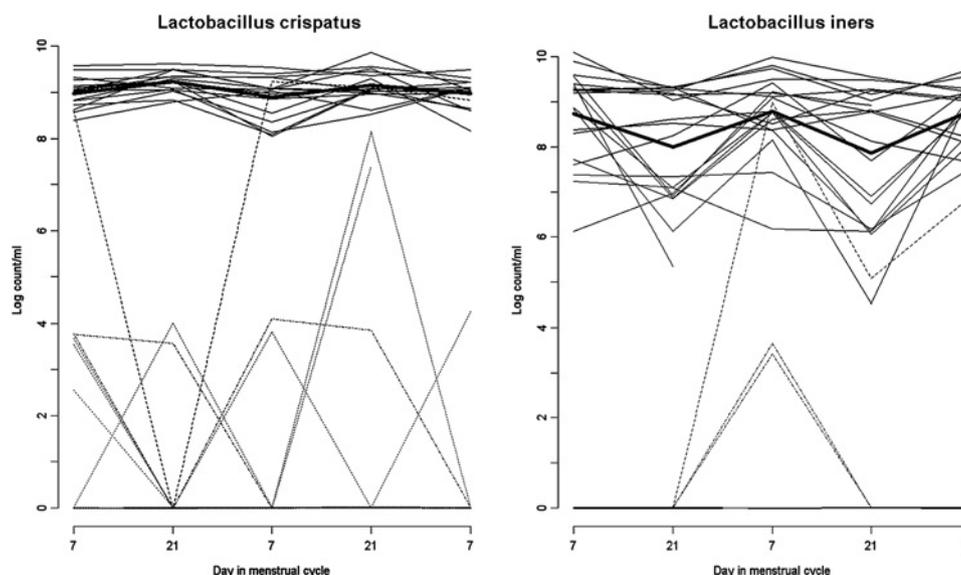
**Background** The vaginal flora plays an important role in the defence against HIV infection. It is thus important to assess the impact on the vaginal milieu of products that are developed to protect women against HIV acquisition.

**Objectives** Using Real Time PCR, describe and quantify *Lactobacillae spp.* in healthy European women who enter microbicide phase I studies.

**Methods** Thirty healthy women who don't use hormones and have a regular menstrual cycle, were sampled with a COPAN flocked vaginal swab on days 7 and 21 of the cycle for a total of 5 visits. Real Time PCR was used to quantify bacterial cells for four *Lactobacillus spp.* at all visits.

**Results** *L. crispatus*, *L. iners*, *L. jensenii*, and *L. gasseri* were present at least once in 93%, 77%, 73% and 70% of women, respectively. High counts ( $\geq 8$  log for *L. crispatus*,  $\geq 6$  log for other species) were consistently present in 60%, 67%, 53%, and 53% of women. We labelled these latter women "L. species-positive". Using logistic regression we modelled the probability of belonging to this group. The temporal variation of the log counts within this group was modelled using random effects linear regression. No predictors of being "L. species-positive" for any of the studied *Lactobacillae* were identified. Longitudinal analysis showed that *L. crispatus* counts were 0.22 log higher ( $p < 0.001$ ) and *L. iners* counts were 0.83 log lower ( $p < 0.001$ ) at the end of the menstrual cycle. Furthermore, *L. crispatus* counts decreased by 0.40 log after intercourse (PSA present) ( $p = 0.002$ ), while *L. iners* (+0.73 log,  $p = 0.033$ ) and *L. gasseri* (+0.58 log,  $p = 0.052$ ) increased see Abstract P3-S3.06 figure 1.

**Conclusion** The menstrual cycle and sexual activity have a significant effect on *Lactobacillus sp.* counts. This should be taken into account when assessing safety of products in HIV prevention trials.



Abstract P3-S3.06 Figure 1 Log counts of bacterial cells per ml by day in the menstrual cycle: Note: Lines connect consecutive counts for individual women. Bold line is overall trend in "L. species-positive" women.

**P3-S3.07** ANALYSIS OF PATIENTS WHO DO NOT KEEP OR CANCEL APPOINTMENTS AT A UNIVERSITY BASED HIV/AIDS CLINIC

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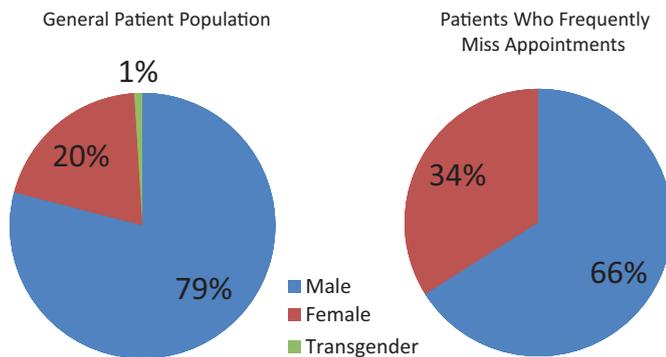
**Background** The Bluegrass Care Clinic (BCC), a university based HIV/AIDS clinic, has an annual average patient no show rate of 13.6% to medical appointments. Treatment adherence greater than 95% is needed to obtain maximum benefits of therapy and minimal disease progression requiring attendance to regularly scheduled medical appointments throughout the patient's lifespan. Missed appointments are not only known to interfere with appropriate care but to mispend medical and administrative resources. The BCC sought to identify demographic trends, interpret perception and identify barriers unique to those individuals who frequently do not attend appointments.

**Methods** Quantitative and qualitative data were collected through focus groups, phone surveys and data from Resource Scheduling Software. Descriptive statistics (frequencies and means) were derived.

**Results** During a 29 month period the BCC expended roughly \$3864 per month due to patients who did not show for appointments. 68 individual patients did not show for more than eight appointments. These 68 patients accounted for 21% of missed appointments, while 1053 patients accounted for the other 79% of missed appointments see Abstract P3-S3.07 figure 1. 13 patient focus groups were held where members cited transportation/coping/stress as potential barriers to attendance. During a phone survey of the 68 individuals only one individual correctly estimated the average number of appointments they missed per year. Female clients seem to disproportionately become frequent non-attenders as compared to their male counterparts. Female clients make up only 20% of the general BCC population, while they make up 34% of the clients who frequently miss appointments. There is a disproportionate effect in black clients. These individuals make up 21% of the BCC's total

client population, while they make up 29% of the clients that frequently do not attend appointments.

**Conclusions** Surprisingly, a disproportionate percentage of individuals account for 1/5 of patients who do not attend or cancel appointments. Individuals surveyed by phone the majority had no actual perception of the average number of appointments they miss without cancelling. Interestingly, although the BCC serves 63 counties, 78% of those who frequently miss appointments live in the immediate area (within 30 miles of the BCC)- so transportation barriers that were identified during focus group sessions may not have a significant impact on those who frequently miss appointments.



Abstract P3-S3.07 Figure 1 Bluegrass care clinic: gender.

**P3-S3.08 SENSITIVITY AND SPECIFICITY OF RAPID HIV TESTING IN A COMMUNITY SETTING**

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**Background** It was estimated in 2005 that 13% of men who have sex with men (MSM) in Montréal were HIV-positive, and that 23% of these were not aware of their diagnosis. Clinique l'Actuel introduced a pilot rapid HIV testing program using the MedMira kit in 2008. The objective of this study was to describe the sensitivity and specificity of rapid HIV tests in a community based, high HIV risk setting.

**Methods** An advertising campaign encouraged MSM and others at risk for HIV to undergo testing through dedicated clinics offering rapid HIV tests. Patients calling for testing deemed at high risk were given appointments within 2 weeks, where they filled out a short questionnaire, received medical consultation routine STI screening, pre- and post- test counselling and their HIV test results within the hour. Those consenting received with a MedMira or and INSTI rapid test and regular HIV screening. Any positive result was confirmed by Western blot.

**Results** 2500 individuals were tested: 98% men with a median age of 34 (IQR: 26–41). For the MedMira test there were 43 true positives, 2295 true negatives, 13 false positives and four false negatives. 145 patients received the finger-prick INSTI test giving two true positives and 143 true negatives. For MedMira, sensitivity was 91.5% and specificity 99.5% while both figures were 100% for INSTI. The four false negatives were also negative by standard ELISA but positive for P24 antigen. Patients testing positive for HIV had significantly more history of previous STI than those testing negative ( $p=0.041$ ).

**Conclusion** In this setting sensitivity and specificity of the rapid tests used was comparable to standard testing. Acute seroconversion likely explains the four false negatives. As with conventional testing, rapid testing requires adequate counselling about the possibilities of

a false negative test. In high-risk populations, routine STI screening should always be performed together with HIV screening.

**P3-S3.09 NEW DRUGS TARGETING TOXICITIES HAVE HIGHEST HOPE OF IMPACTING PATIENT PROGNOSIS**

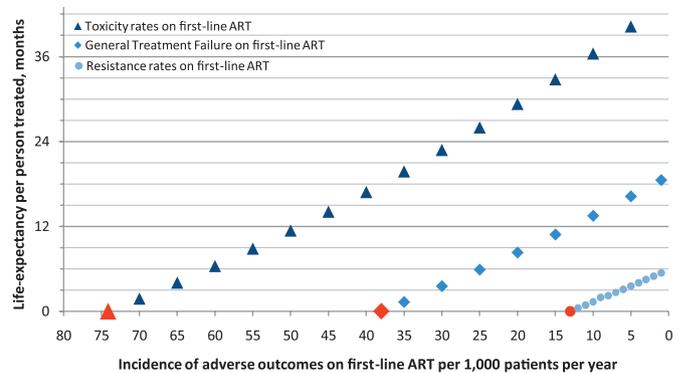
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**Background** As more HIV drugs enter the market there is a need to evaluate the effect of various antiretroviral therapies (ART) on patient outcomes. We aim to quantify the impact of different first- and second-line ART strategies on patient outcome including TMC278, an investigative non-nucleoside reverse-transcriptase inhibitors, thought to have low toxicity rates.

**Methods** A deterministic model was developed representing a cohort of 100 000 HIV-infected individuals. The model was parameterised using data from Athena; a cohort encompassing all patients infected with HIV-1 followed longitudinally since 1996 at 25 HIV treatment centres in the Netherlands. Clinical, biological and immunological data for HIV-infected patients are collected upon entry and at each follow-up visit. The model allows comparison of different ART strategies and of the impact of adverse outcomes: (I) toxicity; (II) general failure and (III) resistance on time on ART and life-years saved per person treated.

**Results** One of the main reasons for switching treatment is toxicity; therefore, new drugs aimed at reducing toxicity will be valuable. The model shows that if TMC278 can reduce incidence of toxicity leading to discontinuation of first-line ART from 74 to 49 per 1000 patients per year (34%) compared with current treatment then this would equate to one additional life-year saved per patient (Abstract P3-S3.09 figure 1). In comparison, a reduction in general failure from 38 to 25 incidences per 1000 patients per year (34%) adds 6 months and a reduction in resistance from 13 to 1 incidence per 1000 patients per year (92%) adds only 5 months (Abstract P3-S3.09 figure 1). For second-line, reducing incidence of toxicity from 143 to 53 per 1000 patients per year (63%) will add one life-year to per patient. This compares favourably with empirical estimates of toxicity for TMC278 in clinical trials (70% reduction in toxicity leading to discontinuation of first-line ART compared with efavirenz). The model also shows that by reducing rates of toxicity for first-line ART, consequently improving patient prognosis, patients on average spend more time on first-line ART before switching. Decreasing toxicity by 34% equates to an additional 18 months on first-line ART and a 61% decrease in toxicity equates to about five additional years on first-line ART.



Abstract P3-S3.09 Figure 1 Increase in life-expectancy per person treated with reduced annual incidence of adverse outcomes per 1000 patients for first-line ART. The red markers indicate empirical data; the blue markers indicate simulated estimates.