

Results Ikajurniq builds on best practices in prevention and treatment of STBBIs in Canada, while recognizing both the particular challenges and the known enablers in reaching, testing and treating Inuit with STBBIs in northern communities.

Conclusions

Inuit experience high rates of STBBIs and face particular challenges in completing the testing and treatment journey. The enablers described in Ikajurniq can greatly increase the number of Inuit who successfully navigate the STBBI cascade of care.

Disclosure No significant relationships.

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ASSOCIATION BETWEEN VAGINAL BACTERIA AND HIV ACQUISITION RISK AMONG AFRICAN WOMEN PARTICIPATING IN THE VOICE STUDY

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Background We previously identified seven vaginal bacteria associated with increased HIV acquisition risk among African women using taxon-directed quantitative PCR (qPCR). We sought to extend the search for high-risk bacteria using a sequential PCR approach.

Methods African women participating in a randomized placebo-controlled trial of daily oral vs. vaginal tenofovir-based pre-exposure prophylaxis for HIV (VOICE study) provided vaginal samples. Cases (177 HIV pre-seroconversion visits from 150 women who acquired HIV) and controls (531 visits from 436 women who remained HIV uninfected) were matched by study arm and site. The vaginal microbiota was characterized using 16S rRNA gene PCR and sequencing to assess associations between relative abundances of bacteria and HIV risk; bacterial taxa were ranked in descending order by score statistic using logistic models run on each taxon until a p-value=0.1. Taxa prevalent at $\geq 5\%$ were selected for measurement of concentrations by qPCR. Relationship between bacterial concentrations and HIV risk was analyzed using Generalized Estimating Equation models, and adjusted for potential confounders.

Results Vaginal bacterial diversity among cases was higher than controls ($p=0.0044$). Analysis of relative abundance data identified 12 bacterial taxa associated with HIV risk that were not previously described. Six of these 12 taxa were selected for taxon-specific qPCR measurements. Concentrations of five of six taxa were significantly associated with increased risk for HIV acquisition. These include bacterial vaginosis-associated bacterium 2 (adjusted odds ratio (aOR)=1.57; 95% CI 0.97, 2.56), Candidate Division TM7 (aOR=2.04; 95% CI 1.14, 3.65), *Prevotella amnii* (aOR=1.53, 95% CI 0.95, 2.46),

Porphyromonas Type 1 (aOR=2.04, 95% CI 1.27, 3.28), and *Peptinophilus lacrimalis* (aOR=1.55, 95% CI 0.98, 2.44). *Dialister microaerophilus* was not associated with HIV risk.

Conclusion A sequential PCR approach facilitated the identification of new bacteria associated with increased HIV acquisition risk. Interventions to decrease high-risk bacteria could be explored as one approach to reduce HIV risk in women.

Disclosure No significant relationships.

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A MULTI-SITE COMPARATIVE STUDY TO UNDERSTAND SOURCES OF VARIABILITY IN STUDIES OF THE VAGINAL MICROBIOTA

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Background The most common approach for describing bacterial communities is amplification of a taxonomically informative gene (e.g. 16S rRNA) followed by amplicon sequencing and taxonomic assignment of the sequences. Variability can arise from numerous steps in this process including DNA extraction, PCR amplification, and bioinformatics approaches for taxonomic assignment. To better understand sources of variation in describing the vaginal microbiota, we conducted a comparative study across four laboratories.

Methods A central laboratory prepared and distributed a specimen set including vaginal swabs from four women with a range of Nugent scores (*in vivo* samples), three mock communities of vaginal bacteria, and positive and negative controls. For *in vivo* and mock communities, each laboratory was also provided specimens that underwent DNA extraction by the central laboratory. Laboratories followed their standard laboratory and bioinformatics processes. Results were analyzed by a central group blinded to laboratory.

Results For mock and *in vivo* communities dominated by a mix of *Lactobacillus* species, all laboratories successfully detected each of the taxa in the sample and reported similar relative abundances. For mock communities containing BV-associated taxa, most laboratories detected all taxa; however, some taxa, including *Prevotella amnii* and *Atopobium vaginae*, were not detected by all laboratories and there was more variation in relative abundances across the laboratories (*P. amnii* relative abundance range= $<1\%$ –17%; mock community proportion of colony forming units=11%). Variations were observed between the relative abundances within laboratories compared to samples that underwent DNA extraction by the central laboratory, highlighting impact of DNA extraction method.

Conclusion Despite differences in methods, in most cases laboratories would have come to the same conclusion regarding dominant taxa in a sample, especially for *Lactobacillus*-dominant samples. Samples with more diverse communities had

more variation in reports of minority taxa and relative abundances. Standardized use of mock communities may improve reproducibility across vaginal microbiota studies.

Disclosure No significant relationships.

P589 THE INFLUENCE OF PRECONCEPTION VAGINAL MICROBIOTA ON PRETERM BIRTH

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Background Preterm birth (PTB) is common worldwide and causes significant neonatal morbidity. Although ascending reproductive tract infection has been implicated in approximately half of spontaneous PTB cases, the microbiologic etiology remains poorly understood and no studies have examined the role of preconception vaginal microbiota in PTB.

Methods We conducted a pilot study comparing bacterial communities among 6 women who experienced a PTB < 34 weeks' gestation and 12 term delivery controls who participated in the Longitudinal Indian Family hEalth (LIFE) study in Telangana, India. Archived preconception vaginal samples were analyzed using broad-range 16S rRNA gene PCR with sequencing. Women with preeclampsia were excluded.

Results Cases had more sequence reads from *Sneathia* spp., *Megasphaera* spp., and *Atopobium vaginae* than controls. Overall, the vaginal microbiota of cases was more diverse than those from controls. Women who delivered at term generally had vaginal microbiota dominated by *Lactobacillus* spp.

Conclusion Our study suggests key differences in preconception vaginal bacterial communities between women who experience a PTB compared to women who deliver at term. Future large scale epidemiologic studies of preconception and prenatal vaginal microbiota and adverse pregnancy outcomes are warranted and may guide PTB interventions.

Disclosure No significant relationships.

P590 VAGINAL MICROBIOTA AND DOUCHING CESSATION: A CROSSOVER PILOT STUDY

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Background Observational studies have demonstrated a dose-dependent association between vaginal douching and bacterial vaginosis. We sought to estimate the effect of douching cessation on the vaginal microbiota in a pilot crossover study.

Methods Thirty-two women self-collected vaginal swabs twice-weekly (n=950) during a douching observational phase ("D", 4 weeks), followed by douching cessation ("DC", 12 weeks). Vaginal microbiota were characterized by 16S rRNA gene sequencing (V3-V4) and clustered into community state types (CSTs). A conditional logistic regression model, adjusted for menstruation and sexual behaviors, allowed each woman to

serve as her own control. Wilcoxon signed-rank tests were used to evaluate paired changes in microbiota between phases. Broad-range qPCR assays provided estimates of bacterial absolute abundance per swab. A piecewise linear mixed effects model was used to assess differences in rates of change in bacterial absolute abundance before and after douching.

Results There was not a statistically significant change in the odds of *Lactobacillus*-dominated CSTs comparing DC to D (aOR 0.54, 95% CI: 0.27–1.11). There were no significant changes for four individual *Lactobacillus* spp. and no meaningful changes in other taxa investigated. The rates of change in bacterial absolute abundance was not significantly different in samples collected 3 days before and after douching (p=0.46). Women who had a *Lactobacillus*-dominated CST at baseline experienced shifts to low-*Lactobacillus* CST in DC, and vice versa for women who had a low-*Lactobacillus* CST at baseline (interaction on entry CST, p-value <0.02), however, these findings were driven by changes occurring in the final weeks.

Conclusion In this pilot study, douching cessation was not associated with major changes in vaginal microbiota. Shifts in *Lactobacillus*-dominance may represent regression to the mean as the shifts occurred late in DC, giving ample time for fluctuations. Disparate findings between this study and prior analyses using Nugent score may be related to low-*Lactobacillus* CSTs receiving low/intermediate Nugent scores.

Disclosure No significant relationships.

P591 THE EFFECT OF HORMONAL CONTRACEPTION ON THE VAGINAL MICROBIOTA OVER 2 YEARS

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Background Despite widespread use, the effect of hormonal contraception (HC) on the vaginal microbiota (VMB) is understudied. We compared VMB in a longitudinal observational study of women during intervals on and off HC.

Methods Women stopping and starting any form of HC and women off HC (controls) collected vaginal swabs twice-weekly for 2 weeks prior to 7 study visits over 2 years. 16S rRNA gene sequencing was conducted, and the VMB was categorized into 7 community state types (CSTs): 4 dominated by *Lactobacillus* spp, and 3 by *Streptococcus* spp (CST VI), *Bifidobacterium* spp (CST VII), or a variety of anaerobes (CST IV). Mixed effects logistic regression models assessed differences in CST proportions. Bayesian double exponential random effects models estimated differences between stability indices within HC and control subjects (measured by median Jensen-Shannon distance [MJSD] from the subject's own centroid and from the centroid of CST I [*L. crispatus*-dominated]).

Results 4185 samples from 105 women (73 HC, 32 controls) were available for analysis. The VMB was more stable in women on HC as compared to controls (MJSD 0.16 vs 0.22, p<0.01) and in oral contraceptive pill users versus controls (MJSD 0.14 vs 0.22, p<0.01). Women had increased stability after being on HC for ≥3 months as compared to <3 months (MJSD difference -0.43, p<0.01). Women on HC for ≥3 months were more likely to be in CST I (51.3% vs 37.3%, p<0.01) and less likely to be in CST IV (11.4% vs 22.5%, p=0.01) than controls. Women on HC ≥3 months maintained