

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