**Trials of vaginal live biotherapeutics should include molecular outcomes**

The Lactin-V trial by Cohen et al offers hope for prevention of bacterial vaginosis.1 The protective effect was modest, similar to twice-weekly metronidazole,2,3 but the *L. crispatus* CTV-05 strain could still be detected in 48% of participants 13 weeks after last administration. This is encouraging, but in order to interpret Lactin-V effects properly, we would like to see additional data. First, past trials of lactobacilli-containing vaginal probiotics have shown large variability in outcomes between women, and fluctuations within women, over time.4 Cohen et al present a cumulative incidence per trial arm, thereby overlooking these variabilities. Second, sequencing or other molecular vaginal microbiome composition data, preferably (semi-)quantified, are essential for interpretation.3,4 Molecular methods, unlike microscopy, can differentiate between autologous and biotherapeutic lactobacilli, which enables microbiome data from all study visits, including during product use, to be used in longitudinal modelling. Molecular methods also enable estimation of (relative) abundances of lactobacilli and bacterial vaginosis-associated anaerobes over time. Clinical symptoms are important outcomes in their own right, but microscopy-based Amsel/Nugent criteria should be accompanied by molecular data.

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