

## RESEARCH BASED TEMPLATE

Submissions must not exceed 300 words (excluding title & authors). The document **must not** be password protected or saved as read only as this may result in your abstract failing to upload successfully. Use Arial 12 point type only. Please structure your submission using the subheadings below. If the abstract does not fit the headings, please put full abstract beneath introduction and we will remove the headings once submitted.

## **DIFFERENTIATING BACTERIAL VAGINOSIS PERSISTENCE FROM REINFECTION**

### **Authors:**

Vodstrcil LA<sup>1-3</sup>, Plummer EL<sup>1,2</sup>, Doolabh A<sup>1,2</sup>, Wild N<sup>1,2</sup>, Matthews LG<sup>1,2</sup>, Htaik K<sup>1,2</sup>, Hocking JS<sup>3</sup>, Petoumenos K<sup>4</sup>, Bateson D<sup>5</sup>, Sweeney S<sup>6,7</sup>, Bradshaw CS<sup>1-3</sup>

<sup>1</sup>School of Translational Medicine, Monash University, Melbourne, Victoria

<sup>2</sup>Melbourne Sexual Health Centre, Alfred Health, Carlton, Victoria

<sup>3</sup>Centre for Epidemiology and Biostatistics, Melbourne School of Population and Global Health, The University of Melbourne, Melbourne, Victoria

<sup>4</sup>Kirby Institute, UNSW Sydney, New South Wales

<sup>5</sup>Cancer Elimination Collaboration, University of Sydney, New South Wales

<sup>6</sup>School of Medicine & Public Health, University of Newcastle, New South Wales

<sup>7</sup>Brightwell Health, Newcastle West, New South Wales

### **Background:**

More than 50% of women treated for bacterial vaginosis (BV) experience “recurrence” within 3-6 months post-treatment, rising to 60-80% in women with an ongoing partner. Our randomised controlled trial (RCT) found concurrent male-partner treatment (MPT) with combination oral and topical antimicrobials improves BV cure by mitigating reinfection, but some women did not achieve cure. This study aimed to understand the factors associated with a repeat-BV diagnosis (i.e., failing to achieve cure) within 4-weeks of concurrent MPT.

### **Methods:**

Data were pooled from couples receiving concurrent MPT across two pilots, the RCT, and a post-RCT extension trial. Women with BV received first-line therapy and male partners received combination therapy with oral metronidazole 400mg and topical 2% clindamycin (penile application) twice daily for 7-days. Women provided vaginal smears for Nugent scoring (NS) post-treatment (day-8) and prior to resuming sex and were assessed at week-4 for BV (Amsel and NS). We used Cox regression to assess factors associated with repeat-BV by week-4.

### **Results:**

Across 188 concurrently treated couples, 39 (21%, 95%CI:15-27%) women had repeat-BV at week-4 (rate of repeat-BV=2.2 per person-year, 95%CI:1.6-3.0). On day-8, 63% of women had an optimal vaginal microbiota by Nugent score (NS=0-3), 30% intermediate-BV (NS=4-6) and 7% Nugent-BV (NS=7-10). Repeat-BV at week-4 was associated with having a non-optimal vaginal microbiota by Nugent score (NS=4-10) at day-8 (adjusted-HR=4.22, 95%CI:1.93-9.23, p<0.001). Women with both an IUD and day-8 Nugent score of 4-10 had the highest rate of repeat-BV (5.3 per person-year, 95%CI:2.7-10.7).

### **Conclusion:**

## RESEARCH BASED TEMPLATE

Submissions must not exceed 300 words (excluding title & authors). The document **must not** be password protected or saved as read only as this may result in your abstract failing to upload successfully. Use Arial 12 point type only. Please structure your submission using the subheadings below. If the abstract does not fit the headings, please put full abstract beneath introduction and we will remove the headings once submitted.

MPT significantly reduces reinfection and improves BV cure; however, our data show that BV persists after treatment in a proportion of women with concurrently treated partners, and persistence might be associated with IUD-use. High levels of BV cure could be achieved by identifying women with persistent BV after treatment who may benefit from intensive/alternative female-directed interventions.

### **Disclosure of Interest Statement:**

The trials were funded by the National Health and Medical Research Council (APP1138165 and APP1173361 to Professor Bradshaw). The funder had no role in trial design, data collection or analysis, or manuscript preparation.