Update on Bacterial Vaginosis 2025

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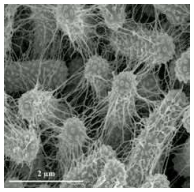
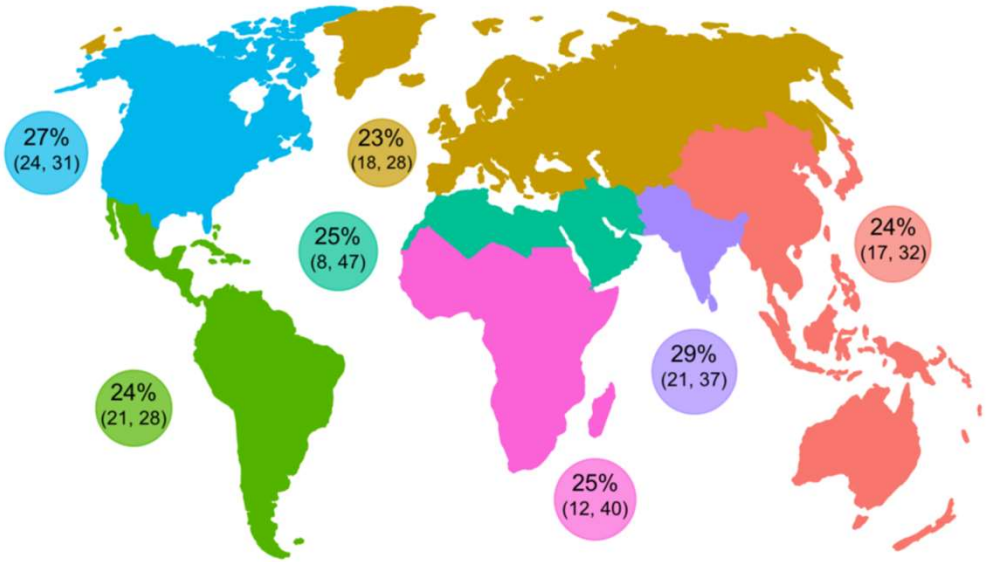
Bacterial Vaginosis (BV)

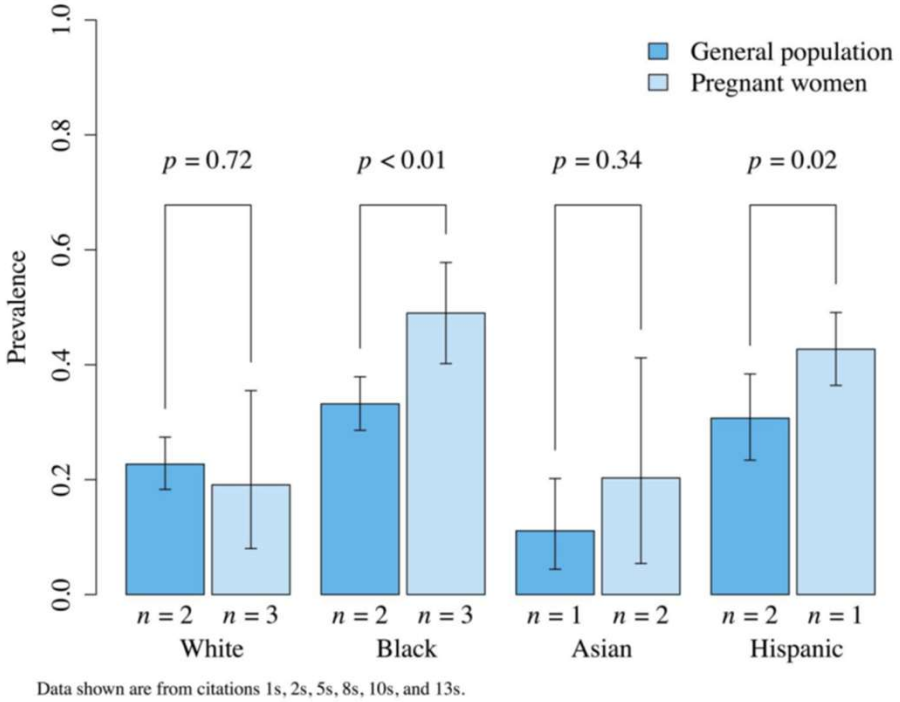


- Most common vaginal cause of vaginal discharge[1]
  - U.S. prevalence 30% per NHANES data
- Associated with preterm birth, low birth weight, post-operative gyn infections, and increased risk for acquisition and transmission of HIV and STIs[2]
- Characterized by depletion of lactic acid-producing lactobacilli and increases in BV-associated bacteria (BVAB) (*Gardnerella vaginalis*, *Prevotella* spp., *Atopobium vaginae*, BVAB1-3, *Megasphaera* spp., *Sneathia* spp., etc.)[2]

[1]*Obstet Gynecol* 2007;109(1):114-20; [2]Bacterial Vaginosis, STD 4th edition

Global Burden of BV





Annual global economic burden of treating symptomatic BV is US $4.8 (95% CI, $3.7-$6.1) billion

Sex Transm Dis 2019;46(5):304-311

Epidemiology of BV Strongly Supports Sexual Transmission of BV-Associated Bacteria (BVAB)[1]

- BV associated with inconsistent condom use and increased numbers of recent and lifetime sexual partners[2]
- Women with BV have an earlier median age of sexual debut than women without[2]
- Most significant risk factor for incident BV is a new sexual partner while that for recurrent BV is a regular sexual partner[2]
- High level of concordance of BV found in women and their female sexual partners[3]

[1]*Curr Infect Dis Rep* 2013;15:130-135; [2]*J Infect Dis* 2016:214 (Suppl 1); [3]*J Infect Dis* 2002;185:1307-13

Epidemiology (2)

- Men with community state types (CSTs) 4-7 in their penile microbiota significantly more likely to have a female partner with a high Nugent score[1]
- Penile microbiota of male partners significantly more similar to the vaginal microbiota of their female partners, compared to other non-partner women, regardless of circumcision status[2]
- Detection of PSA among women positively associated with BV recurrence[3]

[1]*MBio* 2015; 6(3):e00589; [2]*Microbiome* 2016; 4:16; [3]*Sex Transm Dis* 2016;43(3):172-6

Epidemiology (3)

- Partner concurrency significantly associated with prevalent BV[1]
- Among WSW with incident BV versus those without, the relative rate of any sexual activity prior to incident BV was 40% higher ($p=0.010$), digital-vaginal sex 57% higher ($p=0.005$), and digital-anal sex 5.6 times higher ($p<0.001$)[2]
- In a systematic review of male circumcision and STIs & BV, male circumcision was found to result in lower BV prevalence in women[3]

[1]*Sex Transm Inf* 2018; 94(1):75-77; [2]*Sex Transm Infect* 2019, Mar 14 e-published online; [3]*Front Public Health* 2019; 7:4

Key BV-Associated Bacteria[1]

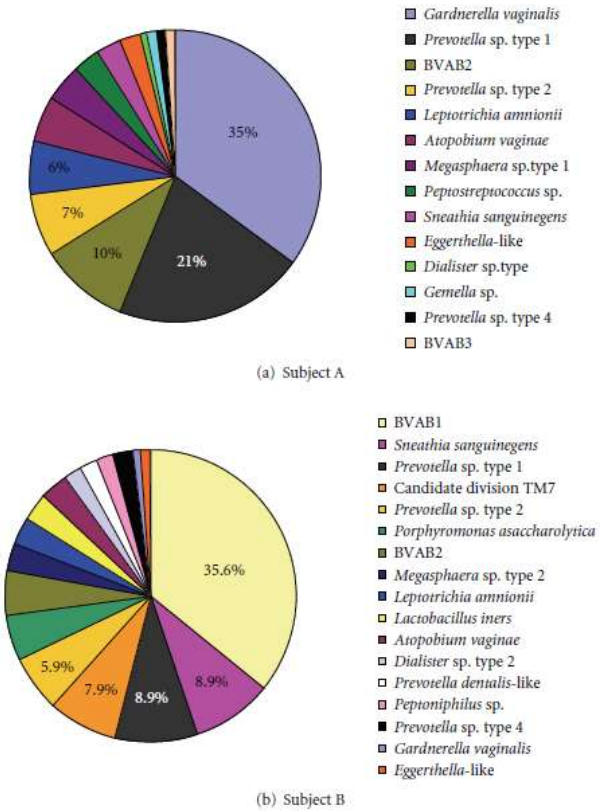
- *Gardnerella vaginalis, Fannyhessea vaginae*, *Prevotella* sp., *Leptotrichia* sp., *Megasphaera* type I, *Sneathia* spp., and the Clostridia-like bacteria BVAB1, BVAB2, and BVAB3 (*M. indolicus*)
  - All have high specificity for BV
  - *G. vaginalis* present in 95-100% of BV cases

- More common in BV compared to normal flora however only *G. vaginalis*, *F. vaginae*, *Megasphaera* type 1, and BVAB2 are found to be independently associated with BV

- *G. vaginalis, Megasphaera* type I, BVAB2, BVAB3, *Sneathia*, and *Leptotrichia* rare or absent in sexually-unexposed women
- Multiple clades of G. vaginalis with variable virulence and antimicrobial resistance
- G. vaginalis and Prevotella synergy

[1]*PLoS One* 2012;7(2):e30633

In addition, the microbiology of BV is heterogeneous…

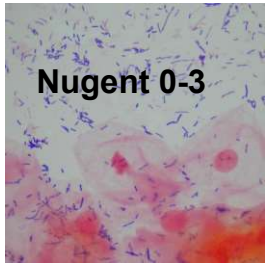


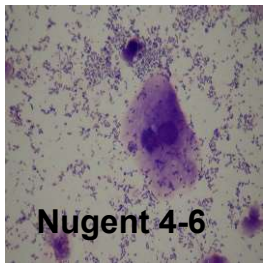
- BV is a syndrome, not a pathogen
- Presuming sexual transmission of BV presumes that any number of organisms could lead to the same effect…

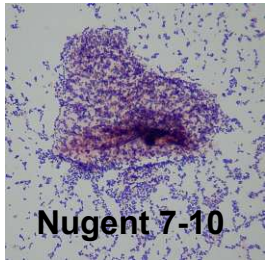
Interdiscip Perspect Infect Dis 2008;2008:750479

Traditional Diagnosis of BV

- Amsel criteria[1] (clinical criteria)
  - Homogenous vaginal discharge, vaginal pH>4.5, positive whiff test, >20% clue cells/hpf
  - 3 out of 4 criteria needed for diagnosis
  - Sensitivity 37-70%, specificity 94-99% compared to Nugent
- Nugent score[2] (vaginal Gram stain criteria)
  - **0-3**: lactobacillus predominate vaginal microbiota
  - **4-6**: intermediate microbiota with emergence of *G. vaginalis*
  - **7-10**: disappearance of lactobacilli with numerous *G. vaginalis* and strict anaerobes
  - Mainly used in research settings







[1]*Am J Med* 1983;74:14-22; [2]*J Clin Microbiol* 1991;29:297-301; Photos taken by Charles Rivers, PhD, MSPH

Markers for Consideration in BV Nucleic Acid Amplification Tests

- Targeted PCR assays were developed for 17 vaginal bacterial species
  - Species selected based on their abundance in broad-range rRNA gene clone libraries, their initial apparent specificity for BV, or their novelty
- Applied to 264 vaginal fluid samples from 81 subjects with and 183 subjects without BV
- Results compared to Amsel, Nugent

Results compared to Nugent:

Bacterium	Sensitivity (%) (95% CI)		Specificity (%) (95% CI)	
Gardnerella vaginalis	97.3	(90.6 – 99.3)	45.5	(37.5 – 53.6)
Atopobium spp.	95.9	(88.6 – 98.6)	84.6	(77.8 – 89.6)
Megasphaera Type 1	94.5	(86.7 – 97.9)	94.4	(89.4 – 97.1)
Megasphaera Type 2	6.9	(3.0 – 15.1)	100	(97.4 – 100)
BVAB2	80.8	(70.3 – 88.2)	96.5	(92.1 – 98.5)
Either *Megasphaera* Type 1 or BVAB2	95.9	(88.6 – 98.6)	93.7	(88.5 – 96.7)
Lactobacillus crispatus	8.2	(3.8 – 16.8)	6.3	(3.4 – 11.5)
Lactobacillus iners	94.5	(86.7 – 97.9)	11.9	(7.6 – 18.2)

J Clin Microbiol 2007; 45:3270-3276

BV Nucleic Acid Amplification Tests

5 quantitative multiplex PCR tests are currently available that detect certain BVAB as well as *Lactobacillus* spp.[1-4]

	BD MAX™ Vaginal Panel	Hologic Aptima® BV	LabCorp NuSwab® VG	Quest Diagnostics™ SureSwab® Bacterial Vaginosis	MDL OneSwab® BV Panel PCR w/ Lactobacillus Profiling by qPCR
Regulatory	Market Authorized	Cleared	LDT	LDT	LDT
Gardnerella vaginalis	Y	Y	-	Y	Y
***Lactobacillus* spp.**	Y	Y	-	Y	Y
Atopobium vaginae	Y	Y	Y	Y	Y
BVAB-2	Y	-	Y	-	Y
Megasphaera-1 *(& -2)	Y	-	Y	Y*	Y*
Reported as	BV	BV	Species w/ interpretation guidance for BV	Species w/ interpretation guidance for BV	Species w/ interpretation guidance for BV
Reportable results	POS NEG	POS NEG	Score: Negative for BV (0-1) Indeterminate (2) Positive for BV (3-6)	Not supportive of BV Equivocal Supportive of BV	Normal microflora Transitional microflora Abnormal microflora

[1]*J Clin Microbiol* 2012; 50: 2321-2329; [2]*Obstet Gynecol* 2017; 130:181–189; [3]*J Clin Microbiol* 2016; 54:1017–1024; [4]ISSTDR 2019

Table 3. Test Characteristics of Select Clinical Diagnostic Tests for BV				
Test	**Sensitivity**	**Specificity**	**Positive Predictive Value**	**Negative Predictive Value**
Point-of-care tests				
Wet mount	37-70%	94-99%	-	-
OSOM BV Blue [34]	88%	95%	93%	91%
FemExam card [36]	91%	61.5%	69.8%	87.5%
Multiplex PCR tests				
NuSwab® [45]	96.7%	92.2%	94%	95.6%
SureSwab*	-	-	-	-
BD MAX Vaginal Panel™ [46]	90.5%	85.8%	89%	87.7%
MDL BV Panel [47]	99%	94%	94%	94%
Footnote: reference standard is Nugent score and/or Amsel's criteria. *No published test characteristics found in the literature.				

Although multiplex PCR assays have an improved accuracy of diagnosing BV, a possible limitation of their performance is the reference standard to which they are compared.

J Clin Microbiol 2018;56(9)

BV and Risk of Acquisition of Other STIs (1)

- Additional data supports the previous finding that BV increases the risk of *T. vaginalis* and *C. trachomatis*[1]
- BV may also enhance susceptibility to *M. genitalium*[2]
- HSV-2 associated with an increased risk of incident BV (not new however not captured in the 2015 guidelines)[3]
- Vaginal dysbiosis associated with an increased risk of incident HPV as well as high grade cervical lesions and cancer related to persistent HPV[4]

[1]*Int J STD AIDS* 2016;27(14):1283-1288; [2]*Am J Epidemiol* 2017;186(2):194-201; [3]*AIDS Behavior* 2018; 22(7): 2172-2180; [4]*Am J Obstet Gynecol* 2018, Dec. 12 e-published online

Vaginal Dysbiosis and Elevated HIV Risk[1-3]

- Multiple studies have shown that the presence of certain BVAB (i.e. *Prevotella bivia*, *Leptotrichia/Sneathia, Parvimonas* spp. types 1&2, *Gemella asaccharolytica*, *M. hominis*, *Eggerthella* spp. type 1; *Megasphaera* spp.) may increase susceptibility to HIV, even in the absence of a BV diagnosis
  - In a murine model[1], high-risk BVAB increased numbers of activated CD4+ cells in the genital tract
- Only *L. crispatus* has been associated with a reduced likelihood of HIV

[1]*Immunity* 2017; 46(1): 29-37; [2]*Lancet Infect Dis* 2018; 18(5): 554-564; [3]CROI 2018, Poster #268

BV and Vulvovaginal Candidiasis (VVC)

- BV, especially RBV commonest cause of RVVC.
- Association: Simultaneous – Mixed infection

  Consecutive – Follows BV
- Mechanism of ↑ VVC???
- High risk of fluconazole resistance in C. albicans participating
- Therapeutic implications!

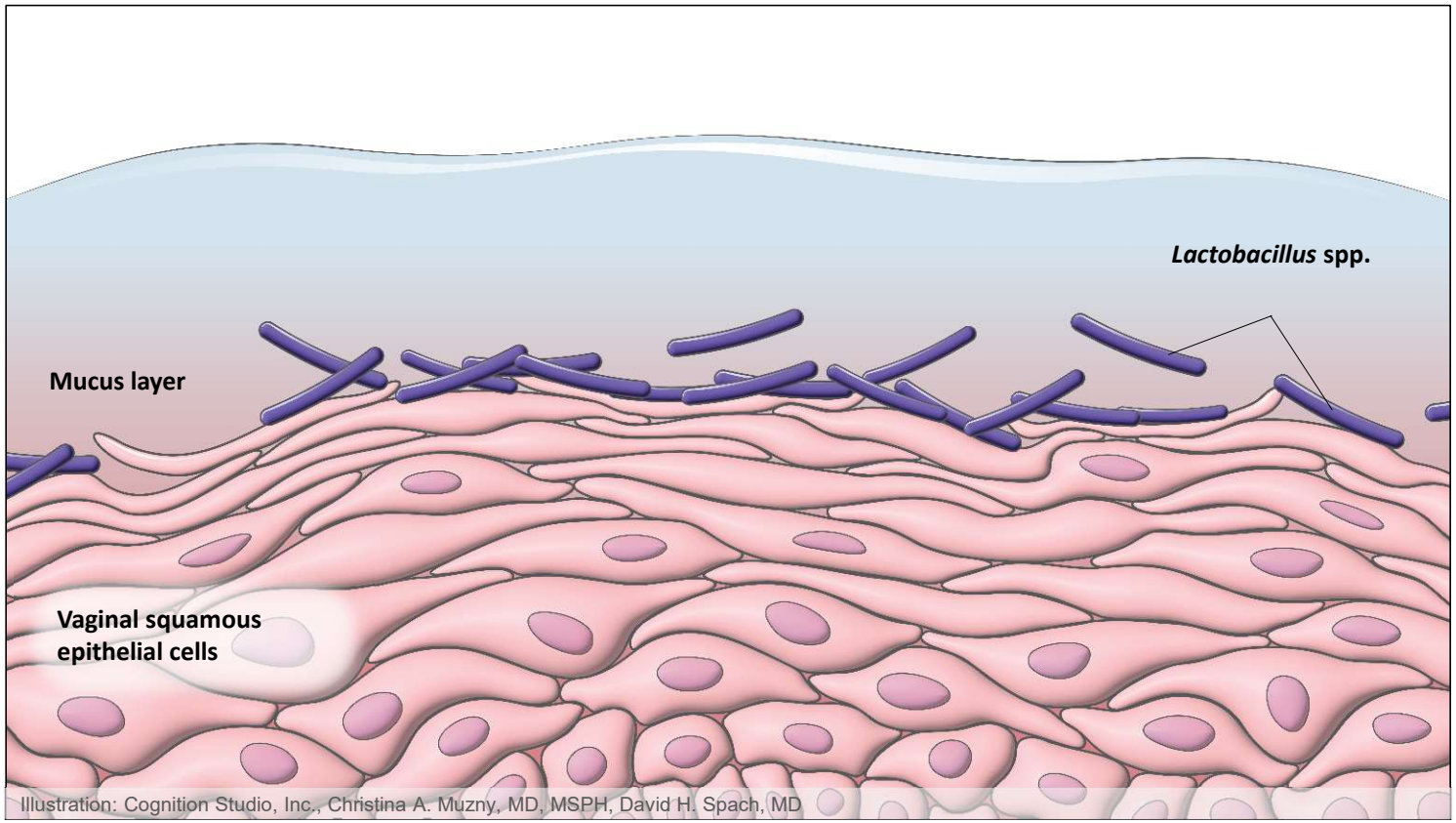
Sobel JD Microorganisms…2024

BV Pathogenesis Research and the Role of the Biofilm

- BV strains of *G. vaginalis* have the greatest propensity to form biofilms compared to 29 other BVAB[1]
- *G. vaginalis* biofilm cells alter their gene expression profiles significantly which may contribute to antimicrobial resistance and BV biofilm persistence, promoting the recurring and chronic nature of BV[2]
- Biofilm-disrupting agents (i.e. TOL-463) may enhance the likelihood of BV cure relative to current therapies[3]

[1]*J Infect Dis* 2014; 210(4):593-6; [2]*NPJ Biofilms Microbiomes* 2017;3:3; [3]*Clin Infect Dis* 2019;68(5):803-809

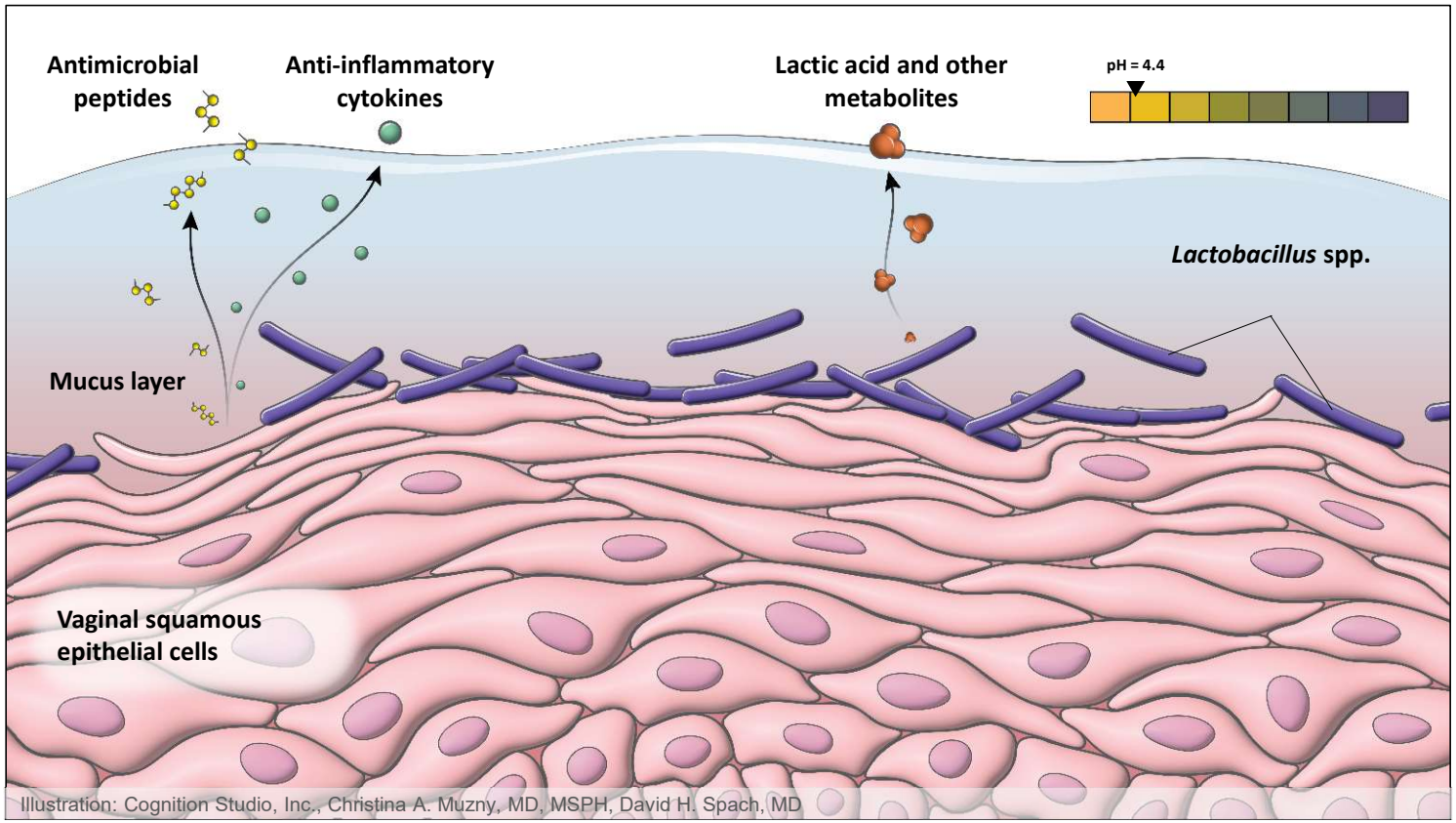
“Optimal” *Lactobacillus*-Dominated Vaginal Microbiota



Source: (1) Muzny CA, et al. J Infect Dis. 2019;220:1399-405. (2) Muzny CA, et al. Curr Opin Infect Dis. 2020;33:59–65.

National STD Curriculum

Lactobacillius-Dominated Microbiome Creates Healthy Vaginal Environment



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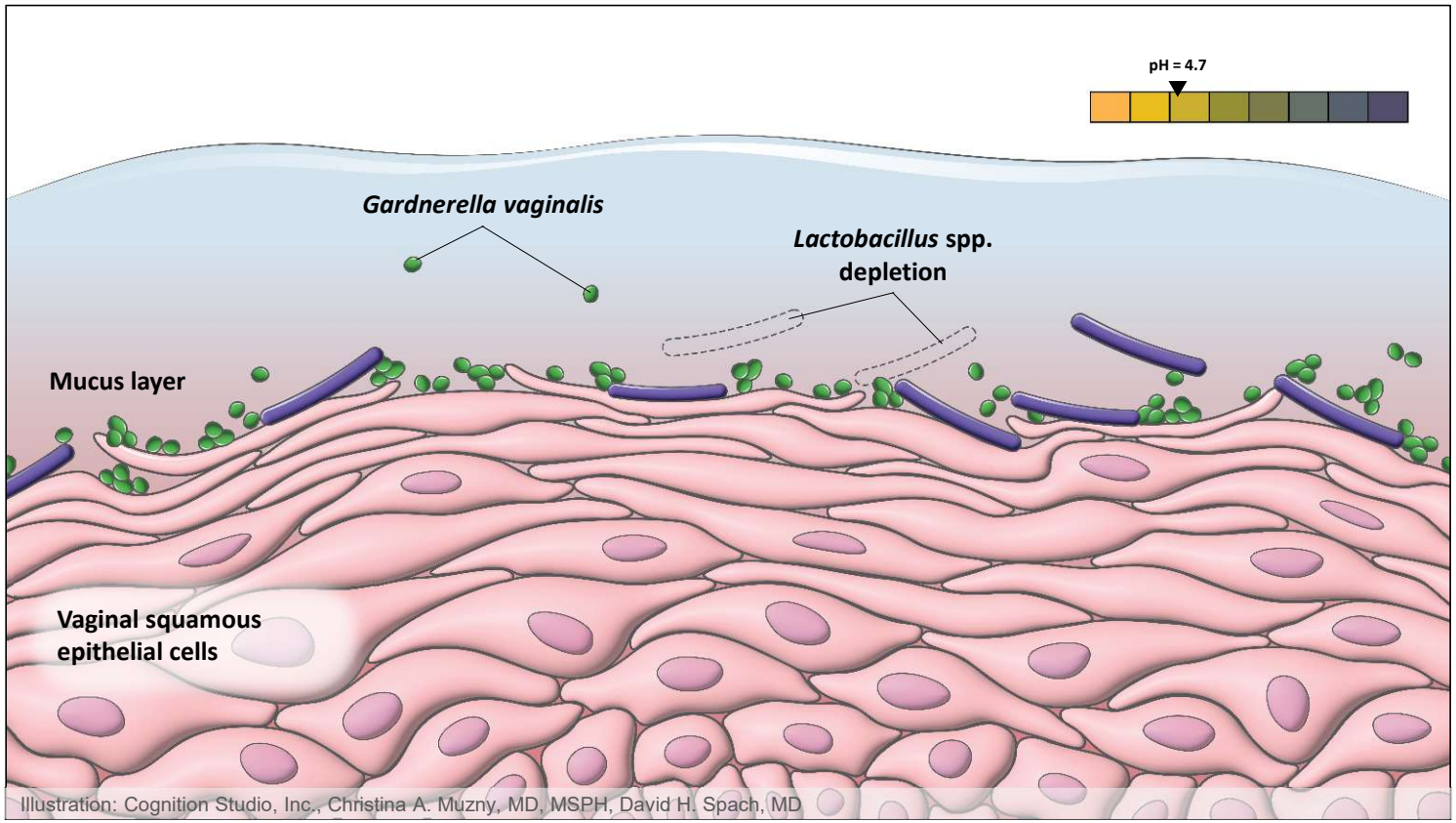
Gardnerella vaginalis Colonization Displaces Vaginal *Lactobacilli*



Source: (1) Muzny CA, et al. J Infect Dis. 2019;220:1399-405. (2) Muzny CA, et al. Curr Opin Infect Dis. 2020;33:59–65.

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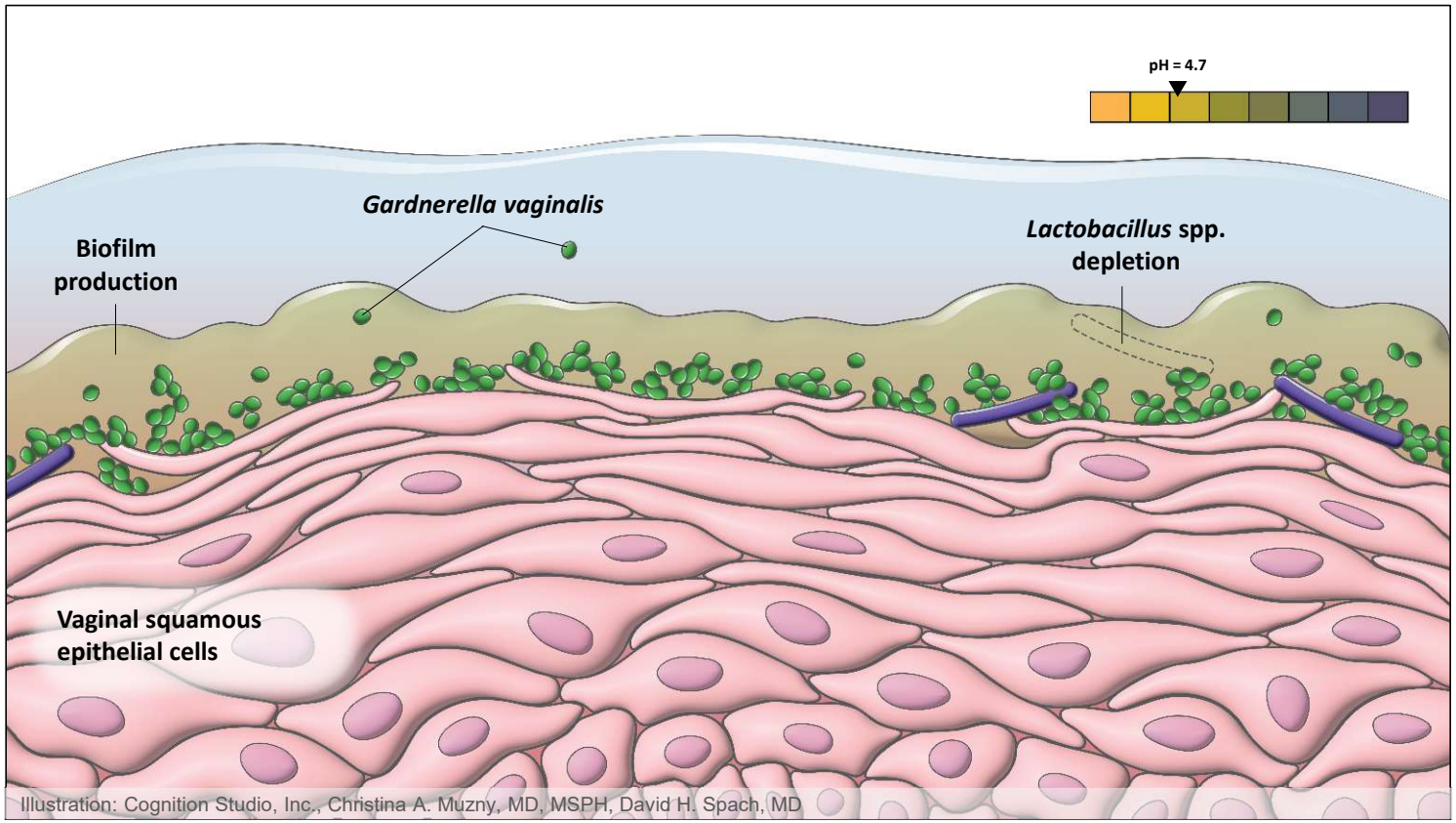
Gardnerella vaginalis Provides Initial Scaffolding for BV Biofilm Formation



Source: (1) Patterson JL, et al. Am J Obstet Gynecol. 2007;197:170. e1–7. (2) Castro J, et al. J Biofilms Microbiomes. 2017;3:3.
(3) Muzny CA, et al. Curr Opin Infect Dis. 2020;33:59–65.

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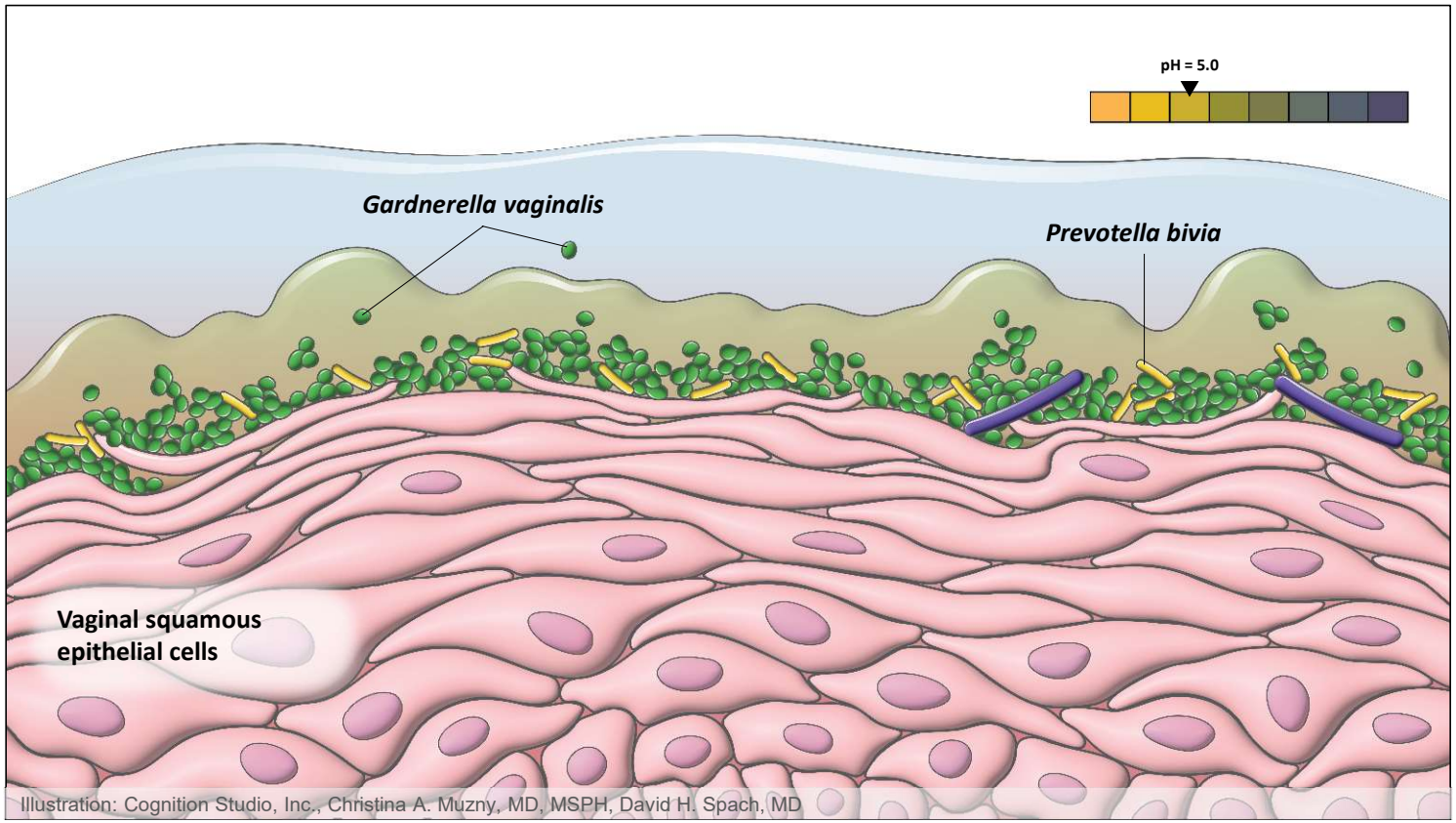
Synergy Between *Gardneralla vaginalis* and *Prevotella bivia*



Source: Pybus V, Onderdonk AB. J Infect Dis. 1997;175:406–13. (2) Hyman RW, et al. Proc Natl Acad Sci USA. 2005;102:7952–7. (3) Muzny CA, et al. J Infect Dis. 2019;220:1399-405. (4) (2) Muzny CA, et al. Curr Opin Infect Dis. 2020;33:59–65.

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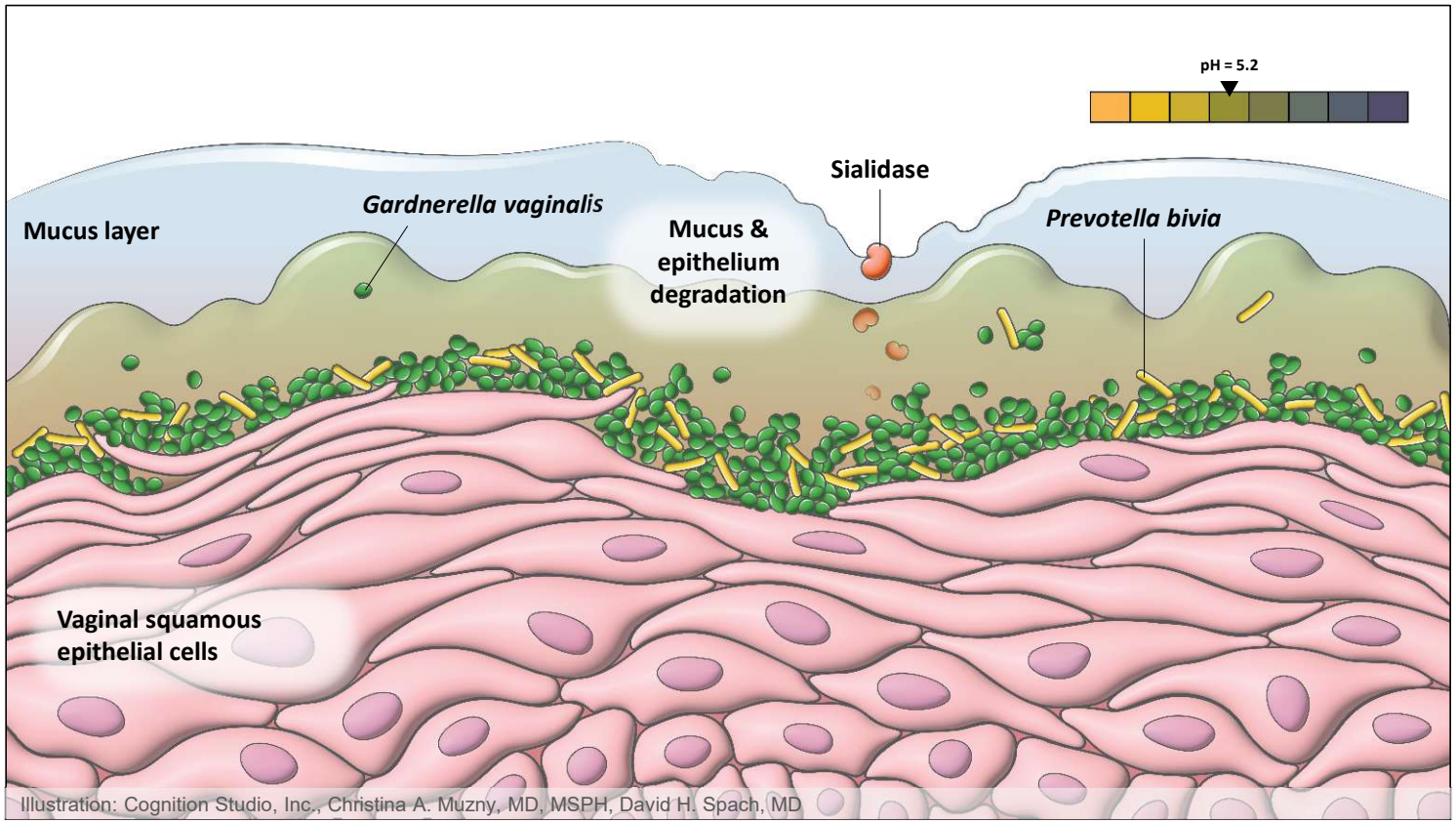
Production of Sialidase Degrades the Protective Mucus Layer



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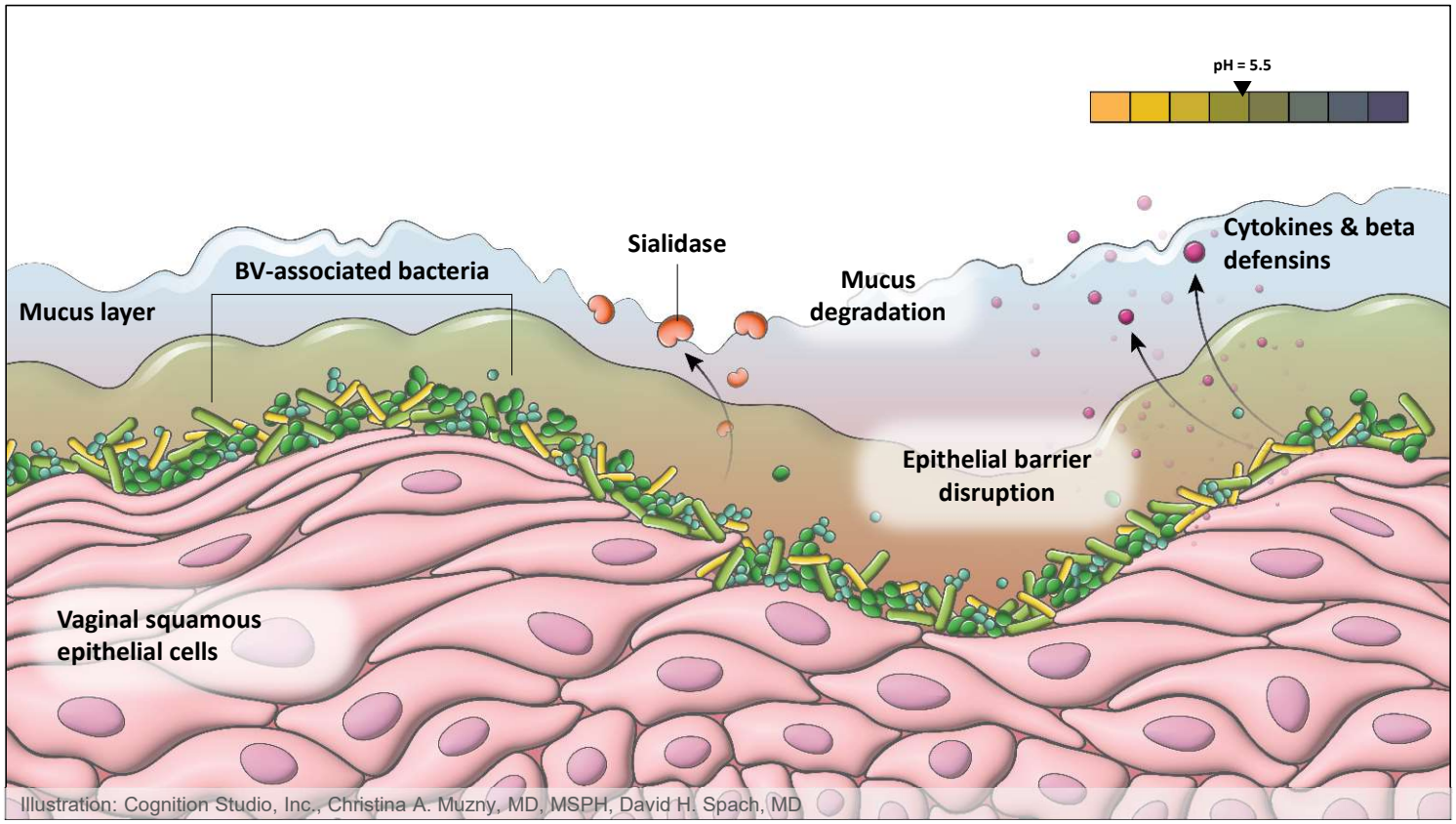
Loss of Mucous Layer & Increased Adherence of BV-Associated Bacteria



Source: (1) Muzny CA, et al. J Infect Dis. 2019;220:1399-405. (2) Muzny CA, et al. Curr Opin Infect Dis. 2020;33:59–65.

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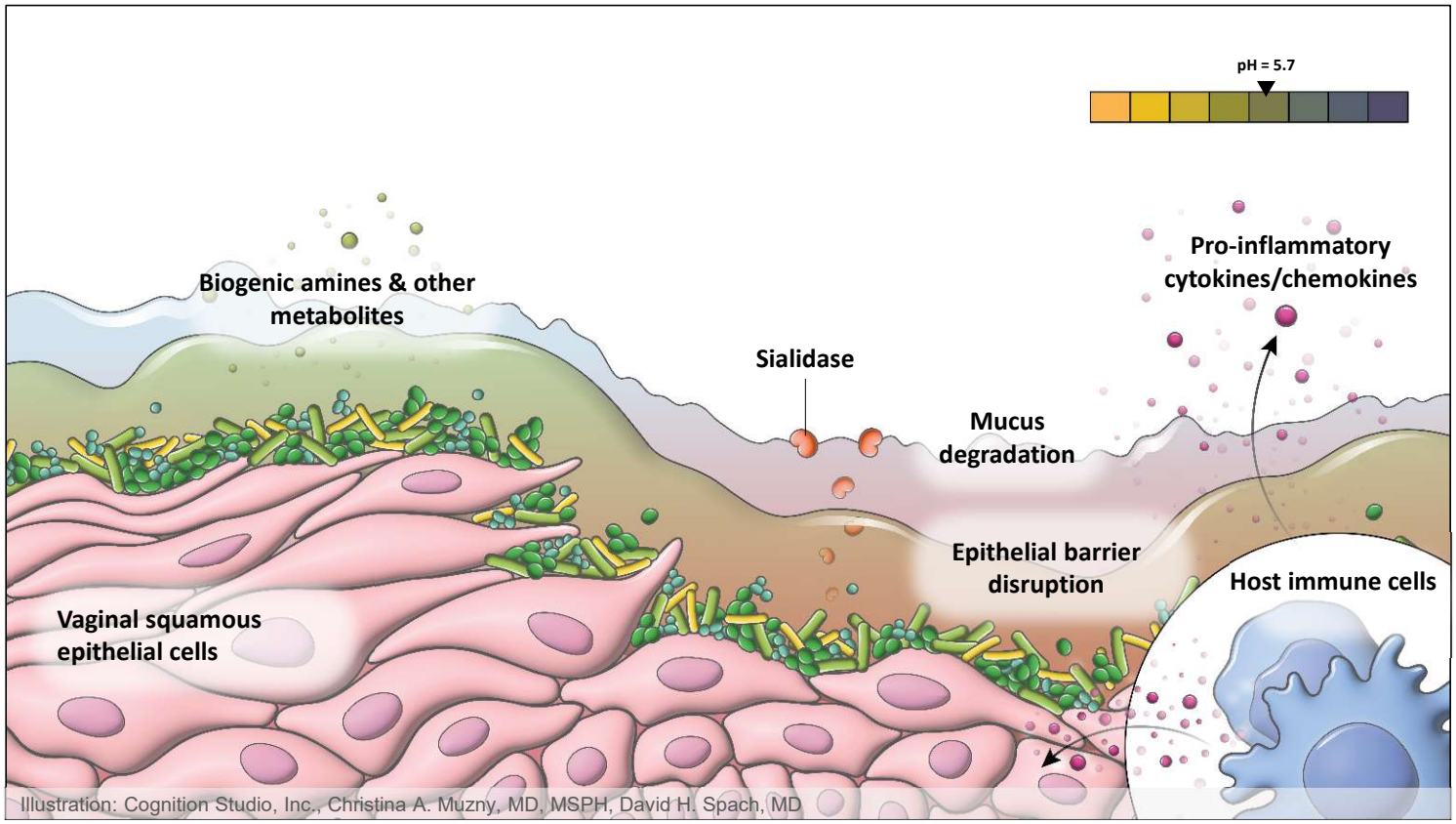
Secondary Colonizers of BV Biofilm Stimulate Host immune Responses



Source: (1) Muzny CA, et al. J Infect Dis. 2019;220:1399-405. (2) Muzny CA, et al. Curr Opin Infect Dis. 2020;33:59–65.

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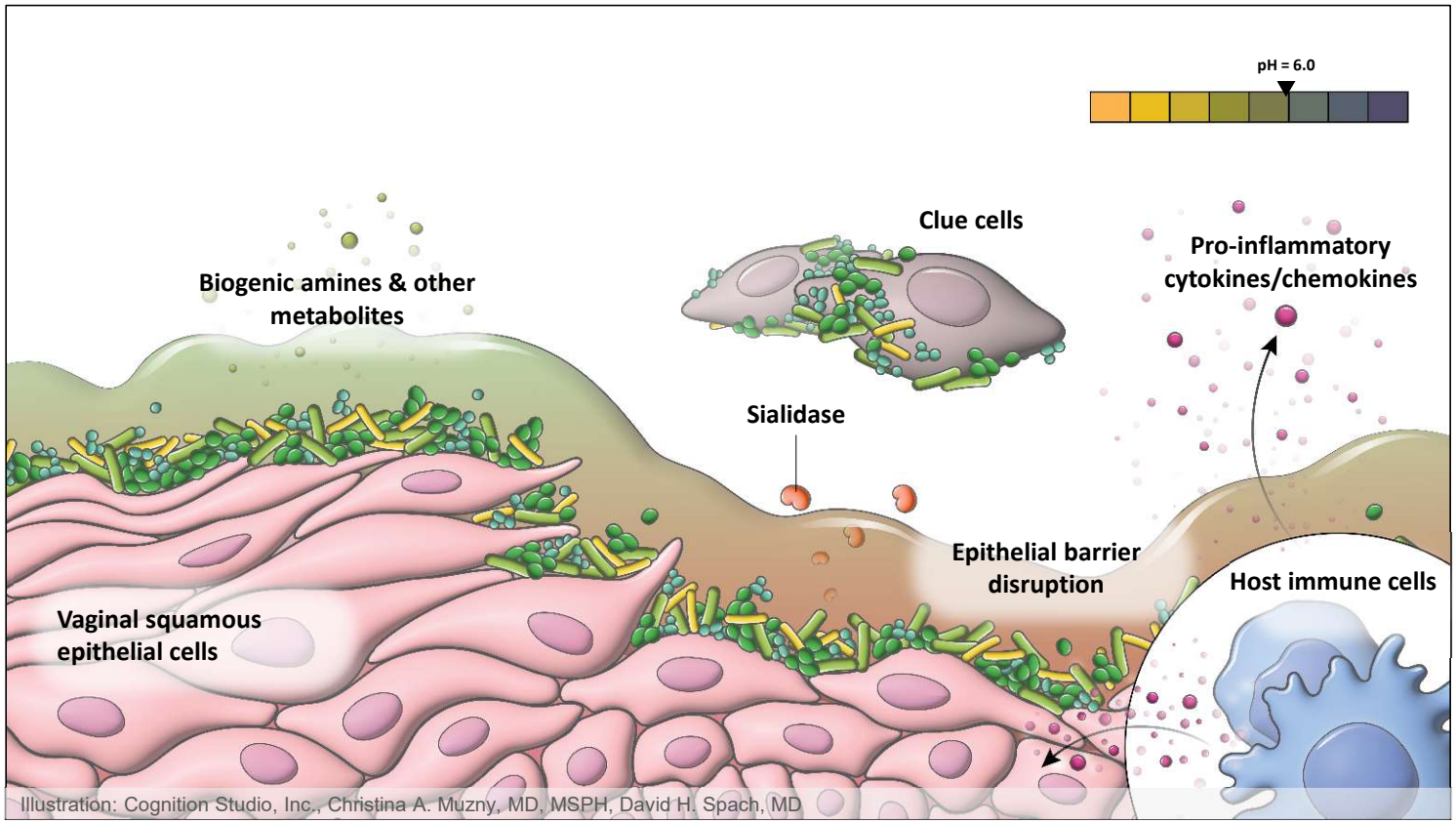
Final Stage of BV and Characteristics of Symptomatic BV



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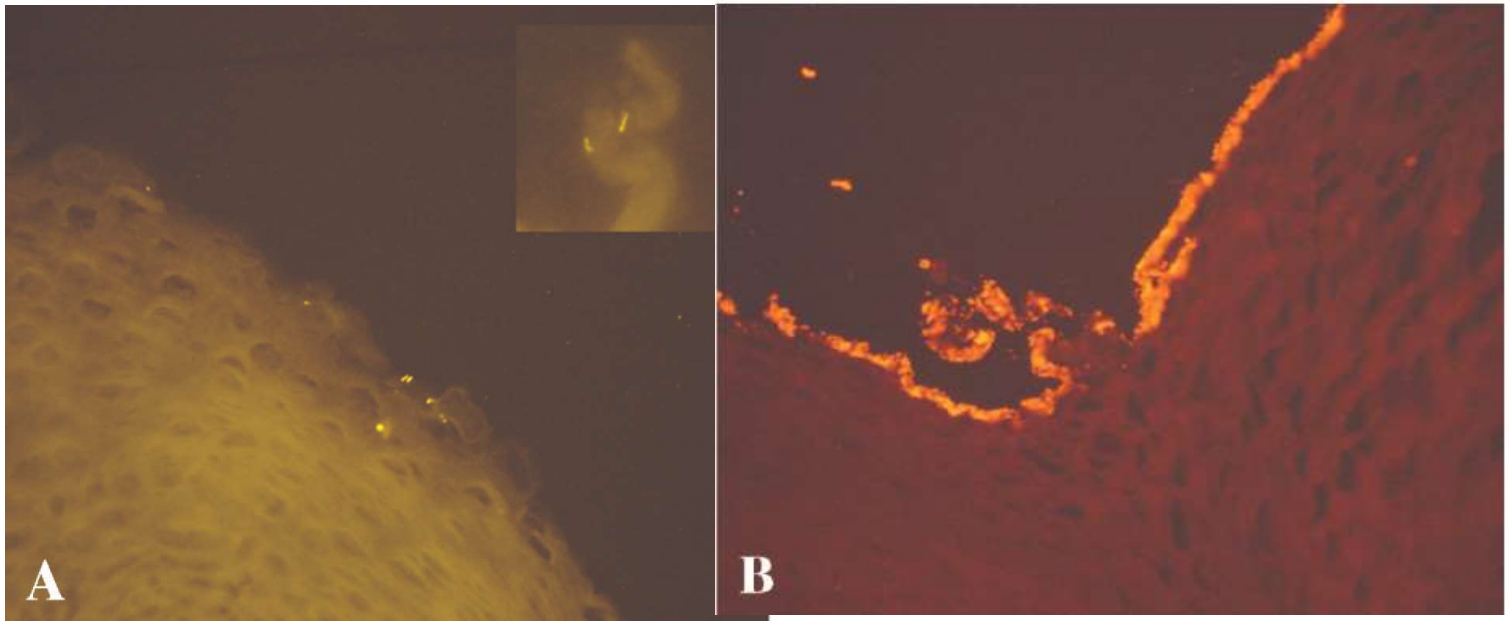
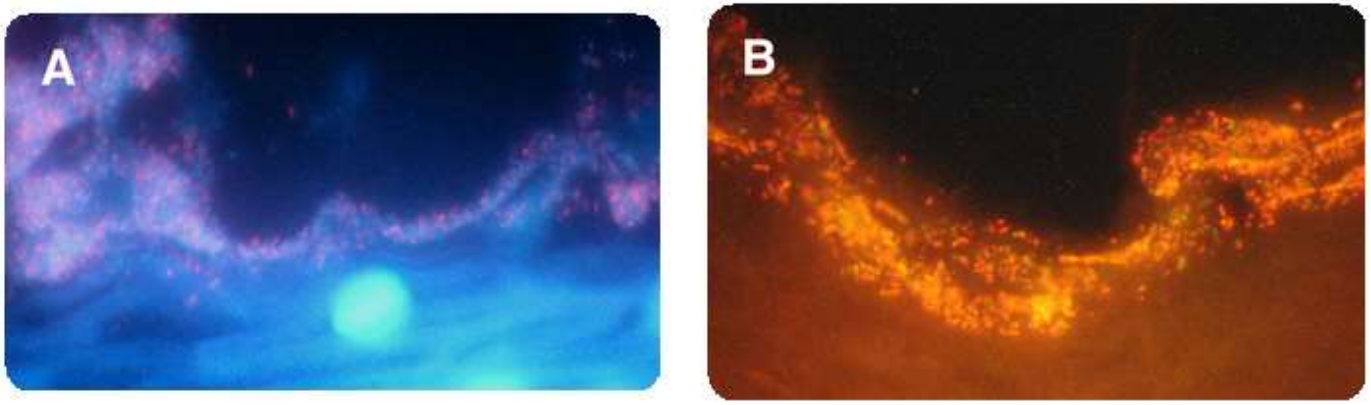
Adherent Biofilms in Bacterial Vaginosis



Swidsinski A et al Obstet Gynecol 2005 ; 106: 1013-23

Adherent Biofilms After MTZ

FIGURE 2
FISH microscopy of the bacterial biofilm during and after treatment with metronidazole



Swidsinski A et al Am J Obstet Gynecol 2007;197:

2021 Recommended and Alternative BV Treatment Regimens

Recommended Regimens for Bacterial Vaginosis

Metronidazole 500 mg orally 2 times/day for 7 days

or

Metronidazole gel 0.75% one full applicator (5 g) intravaginally, once daily for 5 days

or

Clindamycin cream 2% one full applicator (5 g) intravaginally at bedtime for 7 days

Alternative Regimens

Clindamycin 300 mg orally 2 times/day for 7 days

or

Clindamycin ovules 100 mg intravaginally once at bedtime for 3 days*

or

Secnidazole 2 g oral granules in a single dose†

or

Tinidazole 2 g orally once daily for 2 days

or

Tinidazole 1 g orally once daily for 5 days

* Clindamycin ovules use an oleaginous base that might weaken latex or rubber products (e.g., condoms and diaphragms). Use of such products within 72 hours after treatment with clindamycin ovules is not recommended.

† Oral granules should be sprinkled onto unsweetened applesauce, yogurt, or pudding before ingestion. A glass of water can be taken after administration to aid in swallowing.

2021 CDC STI Treatment Guidelines

Newest Antimicrobials for BV

- Clindesse
- Xachiato
  - Single dose – 2% clindamycin phosphate
- Metronidazole – 1.3% vaginal gel (Nuvessa)

Key Question: Do any changes need to be made to currently recommended BV therapy in pregnant women?

- There are no new data to suggest superior efficacy of new medications compared to currently recommended medications.
- There are no adequate and well-controlled studies of Clindesse in pregnant women. The FDA package insert for Clindesse states that it should only be used during pregnancy if clearly indicated.
- There are no adequate and well-controlled studies of 1.3% MTZ vaginal gel in pregnant women.
- There are no adequate and well-controlled studies of SEC in pregnant women.

Should pregnant women with asymptomatic BV who are at low risk for preterm delivery be treated?

- PREMEVA study: a large, multi-center RTC, concluded that low-risk asymptomatic pregnant women should not be screened or treated for BV[1]

- RCT of pregnant women with elevated vaginal pH ≥5.0 randomized to Clindamycin 300mg po BID for 5d vs. placebo[2]
  - Preterm birth (PTB) rates were similar in both arms: 13.9% Clindamycin vs. 13.1% placebo.
  - This study concluded that oral Clindamycin does not prevent PTB in women with elevated vaginal pH.
- No new data to suggest alteration of current guidance.

[1]*Lancet* 2018; 392(10160):2171-2179; [2]*BJOG* 2018; 125(12):1601-1609

Should pregnant women with asymptomatic BV who are at high risk for preterm delivery be treated?

- No new data.
- 7 trials have previously evaluated treatment of pregnant women with asymptomatic BV at high risk for preterm delivery (mixed results) and are listed in the 2015 guidelines: one showed harm, two showed no benefit, and four demonstrated benefit.

Recurrent Bacterial Vaginosis - How Common?

- Hay (1998):[1]

  20%-30% recurrence within 30 days

- Blackwell (1982):[2]

  30% recurrence within 3 months

- Hillier/Holmes (1999):[3]

  80% recurrence within 9 months

[1] Hay PE. *Dermatol Clin.* 1998;16:769-773.
[2] Blackwell A, Barlow D. *Br J Vener Dis.* 1982;58:387-393.
[3] Hillier S, Holmes KK. In *Sexually Transmitted Diseases.* 2nd ed. New York: McGraw-Hill; 1999.

Recurrent Bacterial Vaginosis

- Recurrence at 12 m
  - BV (NS 7-10) 58%
  - Abnormal flora (NS 4-10) 69%
- Recurrence associated with:
  1. Past history of BV
  2. Regular sex partner
  3. Female sex partner
  4. Copper IUD
  5. Smoking

Bradshaw CS, JID 2006

Current Theories: Etiology of Recurrent BV

- Failure to recolonize vagina with protective *Lactobacillus* spp.
  - Failure of vaginal acidification
- Failure to reduce numbers of *G. vaginalis*, anaerobic GNR + GPC, mycoplasma, *Mobiluncus* spp.
  - Protective biofilm haven
  - Antimicrobial resistance of overgrowing microorganisms
- Persistence of initial precipitating/trigger pathogen
- Reinfection with, or recolonization of, triggering pathogen/agent

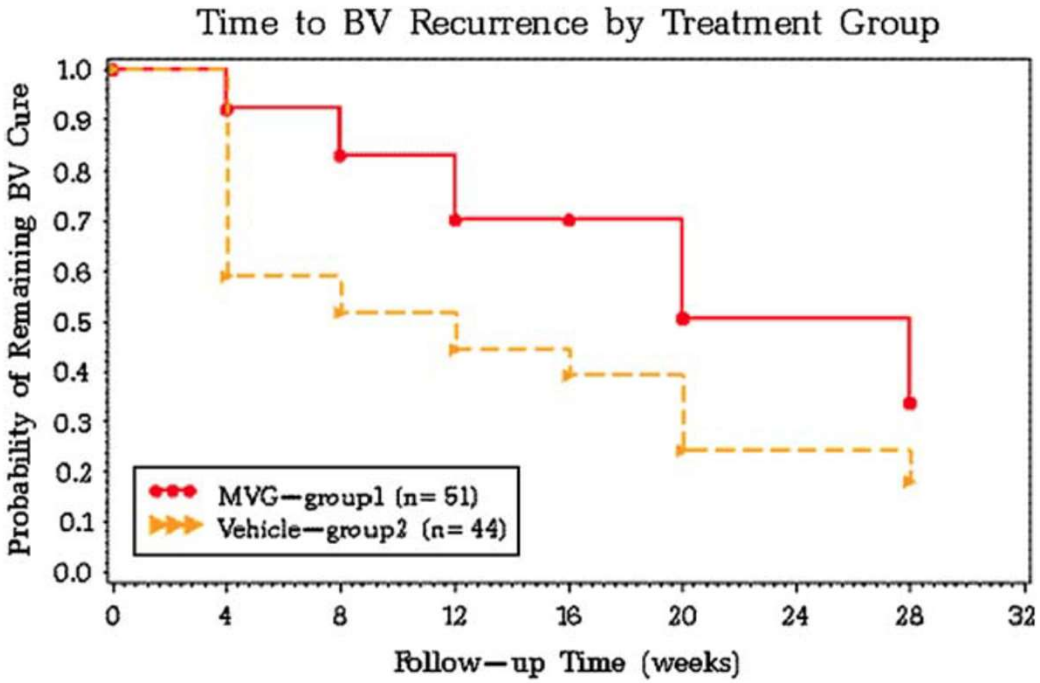
Recurrent Bacterial Vaginosis

Does ↑ duration of antimicrobial therapy ↓ recurrence?

NO!

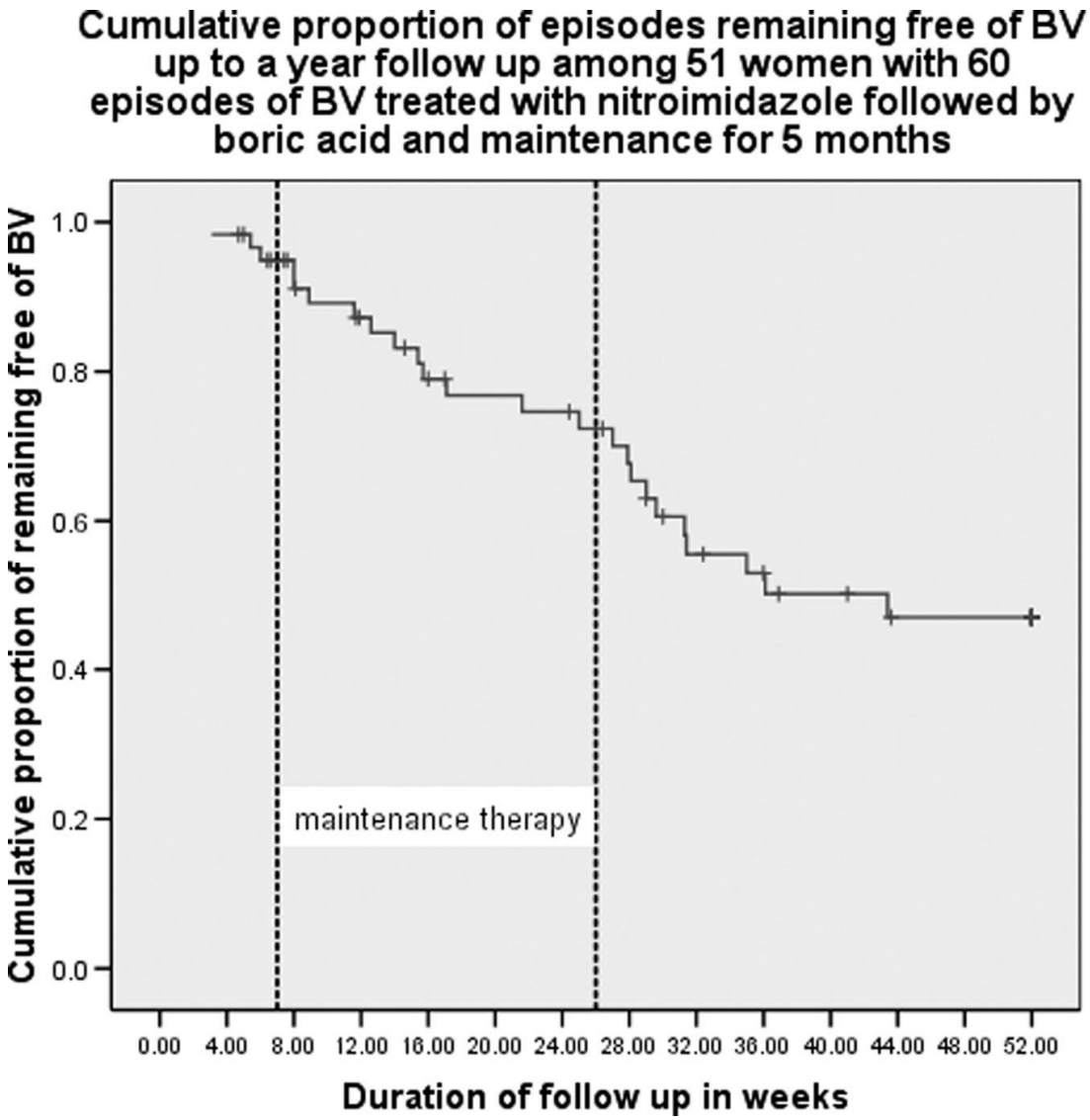
Schwebke J…2010

Despite Treatment, BV Recurrence Is Common



At 28-weeks, BV recurrence occurred in **75%** of women on placebo compared to **51%** of women on suppressive metronidazole therapy

Sobel JD Am J Obstet Gynecol 2006; 194(5): 1283-9



Reichman O, Sobel JD 2012

Treatment of Recurrent BV

- Avoid single dose nitroimidazole
- Switch class-MTZ → clindamycin
- Barrier contraception/ condom
- Minor- IUD removal
  - Quit smoking

OPEN

Recurrent Bacterial Vaginosis: An Unmet Therapeutic Challenge. Experience With a Combination Pharmacotherapy Long-Term Suppressive Regimen

Sarvani Surapaneni, MD, Robert Akins, PhD,† and Jack D. Sobel, MD**

Detroit Study for Recurrent BV

Oral nitroimidazole- 7 days

+

Simultaneous vaginal Boric acid – 30 days

Followed by- Twice weekly Metrogel 0.75% for 5 months

Surapaneni et al 2021

Detroit Study for Recurrent BV

- Outcome day 30-35- BV cure (92/93)
- Breakthrough BV during Metrogel (5 months)- 30.4% ……

  70% remained remission
- Post-treatment BV
  - A further 30% recurred (Reinfection vs Relapse) by one year

Surapanei et al 2021

Treatment of Recurrent BV

Initiate combination and maintenance Rx

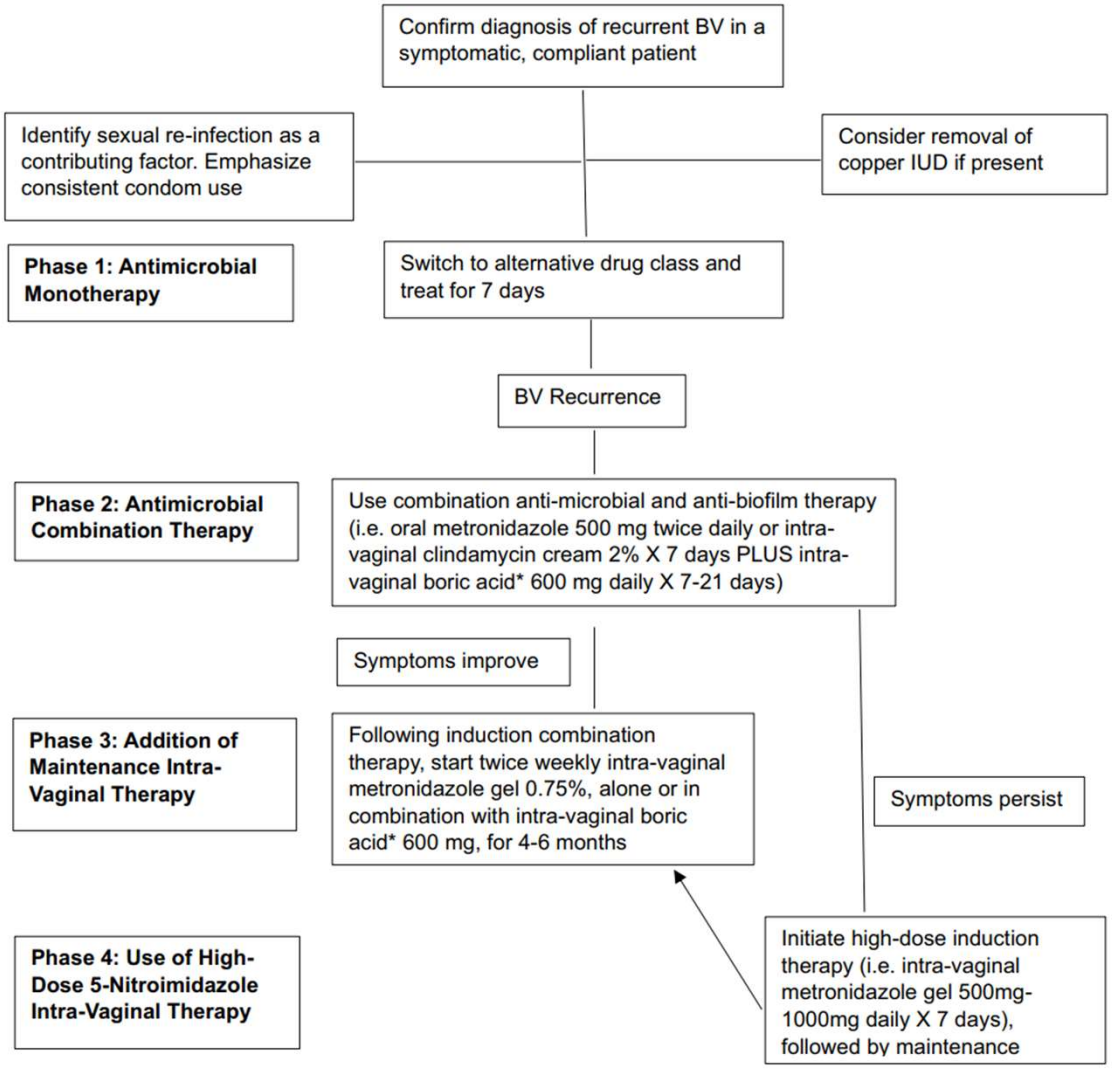


Figure 1 Recommended, sequential treatment algorithm for women with recurrent BV. Bolded text represents different phases of anti-microbial treatment during recurrent BV. *Intra-vaginal boric acid may not be available and/or is forbidden in some countries.

Is there a role for vaginal probiotics in BV treatment?

- A previous Cochrane systematic review[1] and *Clin Microbiol Infect* 2007;13(7):657 did not find sufficient evidence for or against probiotics for BV treatment
- There have been several small studies recently published regarding the use of vaginal probiotics (i.e. Elsharkawy et al. *J Matern Fetal Neonatal Med* 2019), many of which did not have a control group or were poorly powered.
- LACTIN-V (CTV-05 *L. crispatus*) (Cohen CR, et al NEJM 2020)
- There is no recently published data on *L. crispatus* CTV-05 (LACTIN-V).
- The use of vaginal probiotics in the treatment of BV cannot be made at this time.

[1]*Cochrane Database Syst Rev* 2009 Oct 7;(4):CD006289

LACTIN-V (CTV-05 *L. crispatus*)

Response to antibiotic treatment of BV predicts effectiveness of LACTIN-V in preventing recurrent disease

Hemmerling A et al...STD 2024

Clinical Infectious Diseases

MAJOR ARTICLE

Treatment of Male Sexual Partners of Women With Bacterial Vaginosis: A Randomized, Double-Blind, Placebo-Controlled Trial

- This study minimized several of the limitations of prior male partner treatment trials
  - Sufficient power calculation
  - Randomization of men face-to-face to the currently recommended MTZ 500 mg orally twice daily for 7 days
  - Improved monitoring of male partner adherence (pill bottle review)

Schwebke J, Sobel JD 2020

Clin Infect Dis 2021; 73(3):e672-e679

Unfortunately, similar to prior studies, this trial also found that male partner treatment with metronidazole did not reduce BV recurrence in female partners.

Table 2. Analysis of Primary Outcome

	BV Treatment Failure,[a] % (n/N)	
	Intent-to-Treat Population (n = 214)	Per-Protocol Population[b] (n = 133)
Population/arm		
Metronidazole	81 (87/107)	72 (50/69)
Placebo	80 (86/107)	75 (48/64)
Two-sided *P* value[c]	>.999	.844

Abbreviation: BV, bacterial vaginosis.

[a]Participants with recurrence/persistence through the third follow-up visit (day 112–119) were added to the cumulative failures for the study. Participants who did not return for their test-of-cure visit were also considered treatment failures.

[b]Includes women whose partners completed treatment and excludes pre-existing protocol violations of entry criteria.

[c]Fisher's exact test. Note: In the intent-to-treat population, 51 who did not attend the last visit were treated as failures; this includes 31 without any BV testing and 20 with negative BV tests at follow-up visits 1 and/or 2.

Clin Infect Dis 2021; 73(3):e672-e679

Treatment of Male Sexual Partner (RBV)

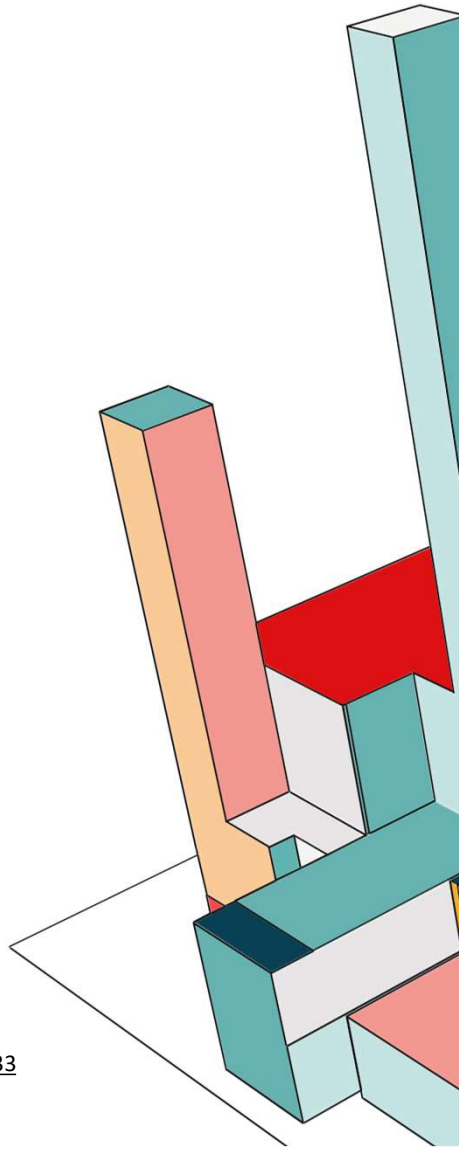
- Post-hoc analysis – “Some benefit to partner metronidazole treatment.”

  (i) Compliant partner – Consistent condom use.

  (ii) Compliant partner – Completed oral MTZ therapy.

Penile Microbiome and Incident BV

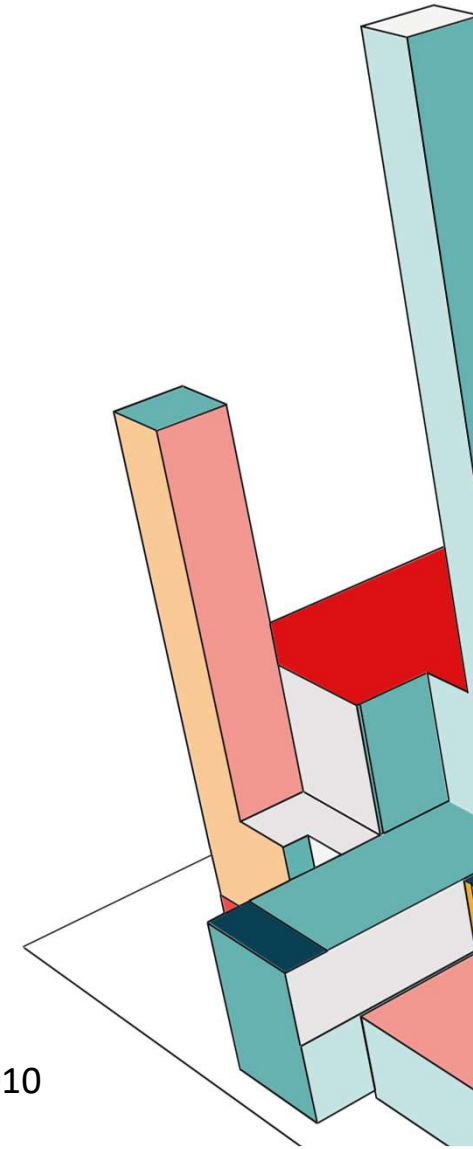
- Kenyan men 18-35 and female partners ≥ 16 years recruited
- BV assessed at baseline, 1, 6 and 12 months by Nugent score
- Amplification of V3-V4 region of 16S rRNA gene performed on meatal and glans/coronal sulcus swab samples
- Incident BV= 31% among 168 couples where female partner did not have BV at baseline: 37.3% if male uncircumcised, 26.3% if circumcised
- Predictive capacity of meatal taxa was high: sensitivity (80.7%), specificity (74.6%), accuracy (77.5%), area under the curve (88.8%).



Mehta S et al. Front. Cell. Infect. Microbiol., 03 August 2020
Sec. Microbiome in Health and Disease
Volume 10 - 2020 | https://doi.org/10.3389/fcimb.2020.00433

Cohesive vs Dispersed gardnerella

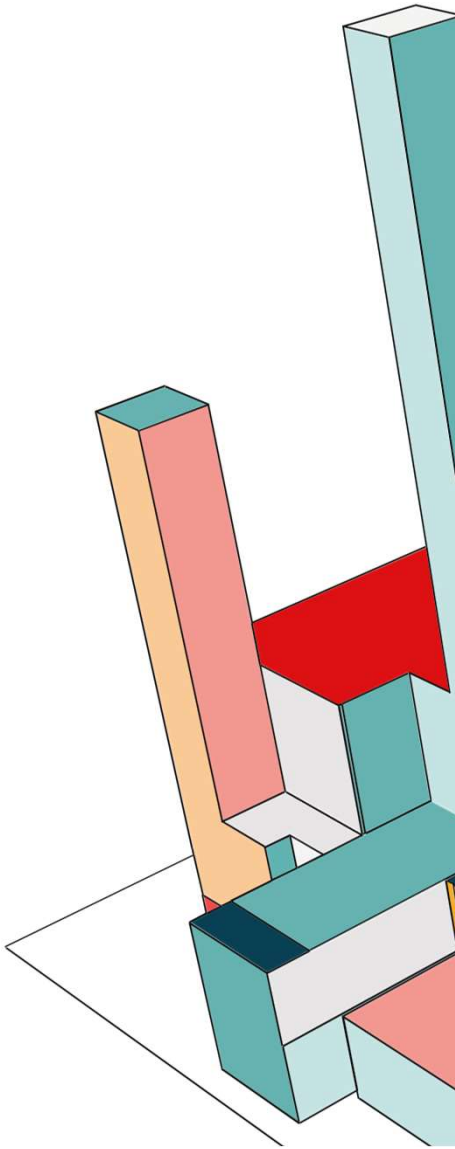
- Spontaneously voided urine samples
- Urinary sediment analysed by FISH (fluorescent *in situ* hybridization) for Gardnerella
- Population studied:
    - Women with typical BV symptoms (n=20) and sex partners (n=10)
    - Randomly selected men (n=100), women (n=100), girls aged 4-10 (n=50) hospitalized for non-BV concerns
    - 72 married pregnant women and sex partners (none circumcised)
    - Healthy volunteers: 10 females, 5 uncircumcised males, 5 children
    - 2 women with BV: asked to provide daily urine sample x 4 weeks



Swidsinksi et al 2010

Vodstrcil et al, 2025

- RCT was stopped early due to efficacy of the treatment group
- N= 164 couples enrolled, trial stopped after 150 completed
- Enrollment: regular sex partner of at least 8 weeks
- Females whose male partner was assigned to the male-partner treatment group had a significantly lower risk of BV recurrence at 12 weeks compared to standard BV treatment for the female partner only:
    - RR: 35% in treatment group, rate of 1.6 per person-year; 95% CI 1.1-2.4 vs
    - 63% in control group, recurrence rate of 4.2 per person-year; 95% CI, 3.2-5.7].



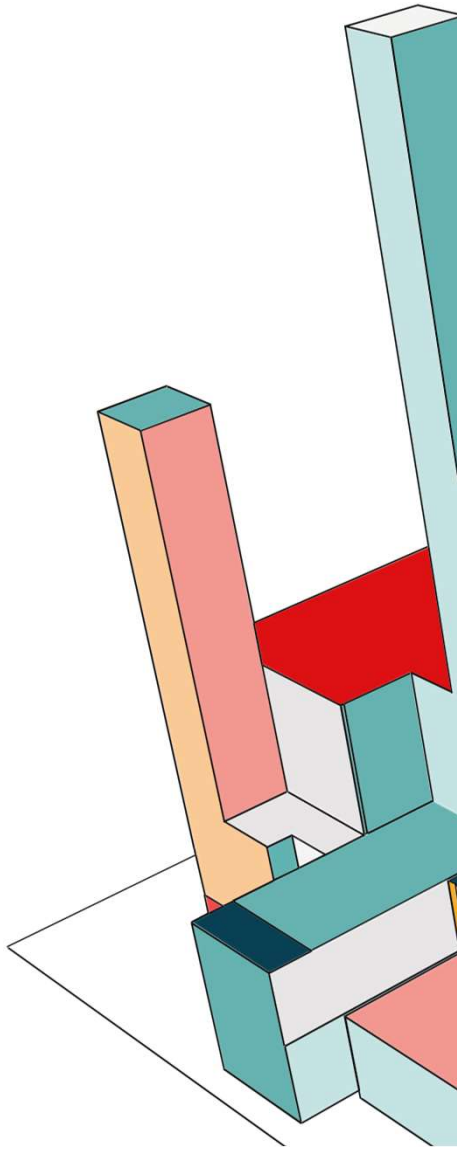
Vodstrcil et al 2025

Adverse events:

- There were no severe adverse events reported for either female or male partners undergoing BV treatment.
- Oral metronidazole may cause nausea, headaches and a metallic taste in the mouth; 26 of 56 men (46%) in the trial reported such side effects.
- Only 4 male participants reported any penile skin irritation.

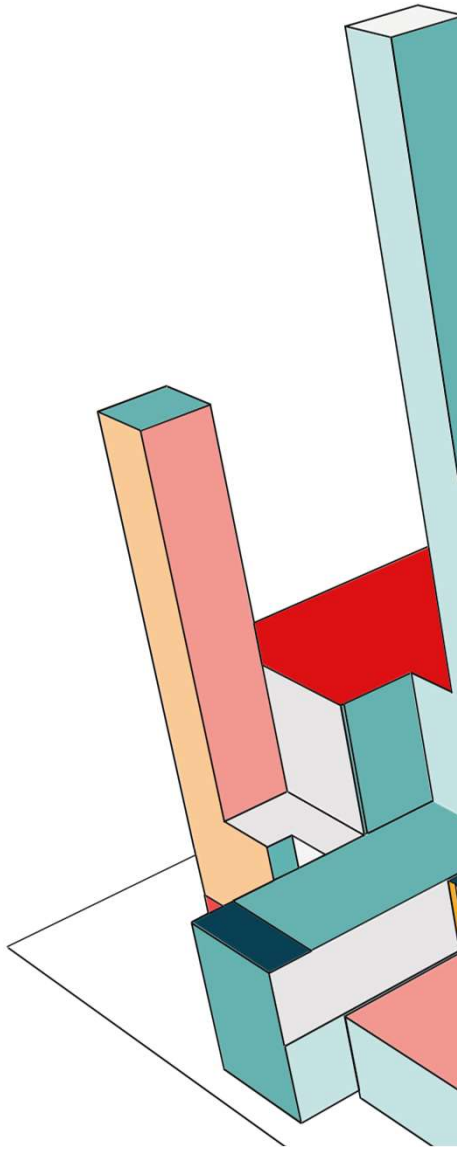
Adherence:

- 86% of male partners reported taking ≥70% of medication doses



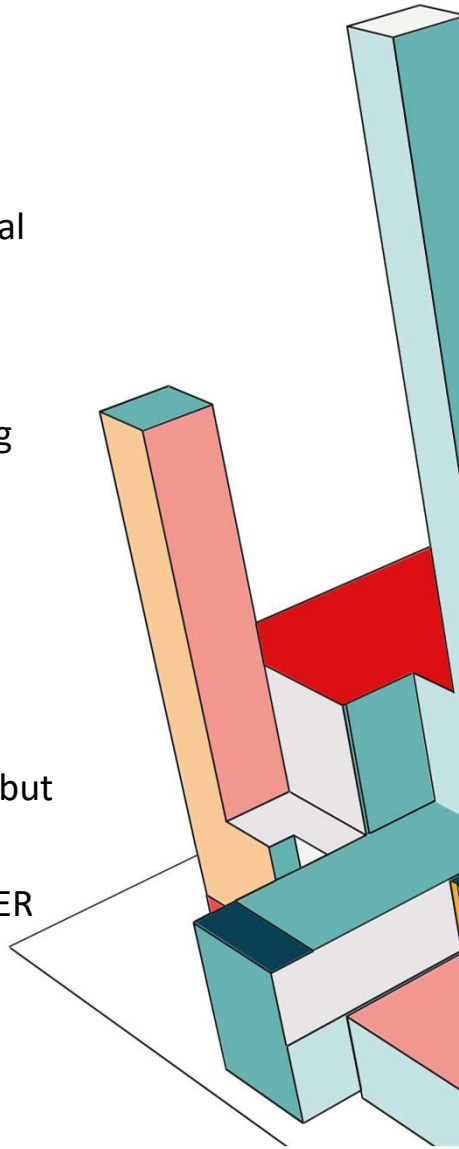
Key differences from prior trials

- Oral and topical MPT
- Oral nitroimidazole alone may not have cleared BV-associated bacteria from penile microbiome and/or prostatic vesicle reservoirs
- Different treatments by circumcision status? IUD status?
- Intervention may be more likely to work in subset of couples practicing consistent condom use (male partner adherence is KEY)



BV messaging

- Sexually transmitted; prior studies limited by misdiagnosis or false information about sexual activity
    - Biofilms are difficult to treat
    - Impossible to distinguish recurrence from **reinfection** vs **relapse** unless no sex during treatment
- Management of recurrent BV will likely still require maintenance antibiotic regimens
- Adherence with medications and condoms is critical for success
- **Condom use guidance** during treatment:
    - Australian study messaging: avoid ALL sexual contact throughout treatment period (but if you do, use condoms)
    - Expert opinion: no sex during concurrent partner treatment, condom use x 30d AFTER treatment



Important considerations

- **Must be written into national/societal Guidelines**
  - CDC and ACOG currently working on guidance
  - Strength of recommendations→ liability if not treating male partners at first BV episode?
- **Need legal expansion of expedited partner therapy to cover BV treatment**
- **Insurance coverage for medications**
  - May get pushback if not explicitly stated in Guidelines

Operational standpoint:

- See male partners via telemedicine
- Provide educational material to index patient and they provide suggested treatment/educational materials to partner to take to their provider

Limitations

- **No male screening test** for BV outside of research trials (16S rDNA swabbing)
- **Clinical endpoints**: resolution of symptoms? No evidence that test of cure would be indicated/helpful
- **Duration and type of treatment**- would topical penile treatment be sufficient? No prior clinical data.
- Guidance for **female partner recurrences ISO successful MPT**-> when should MPT be repeated if ever?
  - 2ndary analysis of Australian trial will be presented at ISSTDR Montreal July 2025
- **BV pathogenesis research** is desperately needed to identify the exact etiology of BV
  - Anticipate this will improve diagnostics, treatment and prevention

Alcohol Abstinence is Nitro-Imidazole Therapy

New Recommendation

NOT REQUIRED

Role of VAGINAL FLUID TRANSPLANTATION.

nature medicine

BRIEF COMMUNICATION

https;\\doi.org/10.1038/s41591-019-0600-6

Vaginal microbiome transplantation in women with intractable bacterial vaginosis

Ahinoam Lev-Sagie, Debra Goldman-Wohl, Yotam Cohen, Mally Dori-Bachash, Avner Leshem, Uria Mor, Jacob Strahilevitz, Allon E. Moses, Hagit Shapiro, Simcha Yagel & Eran Elinav

SUMMARY

- BV burden worldwide is enormous
- BV is at least initially sexually transmitted
- Biofilm a critical factor
- Diagnosis moving towards molecular methods
- Treatment – little progress especially cure. Recurrence is common
- Future – V.F.T. …..??