Welcome!

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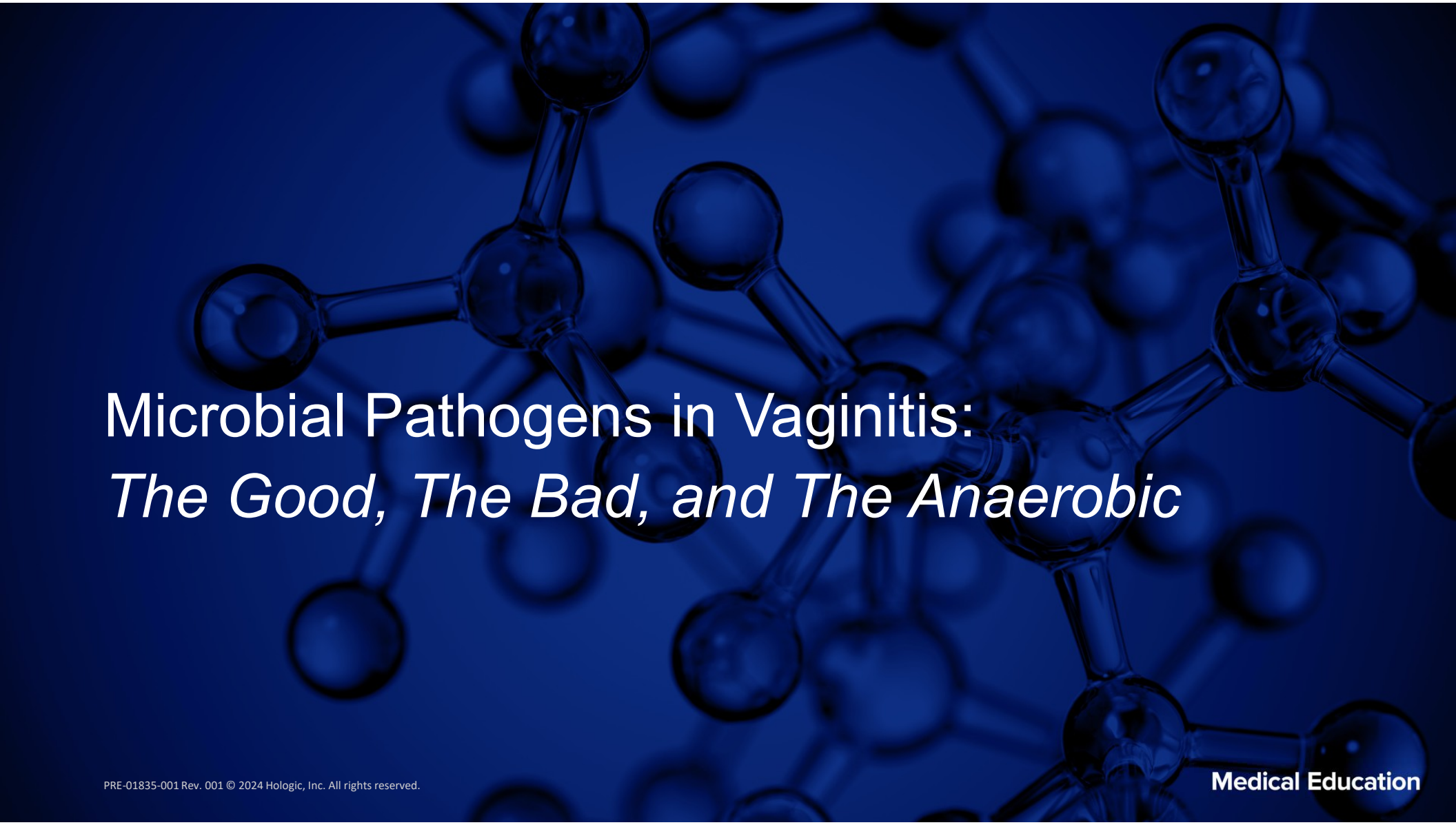

Microbial Pathogens in Vaginitis:
The Good, The Bad, and The Anaerobic

Medical Education

Agenda

Review of Vaginitis
- What is vaginitis
- How vaginitis contributes to overall health
- Why vaginitis is so challenging to identify

Overview of Individual Conditions
- Bacterial vaginosis (BV)
- Candida vaginitis (CV)
- *Trichomonas vaginalis* (TV)

Diagnostic Options and Considerations
- Bacterial vaginosis (BV) Diagnostic Methods
- Candida vaginitis (CV) Diagnostic Methods
- *Trichomonas vaginalis* (TV) Diagnostic Methods

Discussion of Nucleic Acid Amplification Testing (NAAT)

Treatment for Vaginitis

Vaginitis is a Leading Reason for OB/GYN Visits[1,2]

Most women experience an episode of vaginitis at least once in their lifetime[3]

Bacterial vaginosis alone impacts

21 million

women in the United States[4,5]

1. Kent HL. Epidemiology of Vaginitis. Am J Obstet Gynecol. 1991 Oct;165(4 Pt 2):1168-76. 2. ACOG Vaginitis Frequently Asked Questions. Updated September 2023. Accessed January 24, 2024. https://www.acog.org/womens-health/faqs/vaginitis 3. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70 4. Koumans EH. The Prevalence of Bacterial Vaginosis in the United States, 2001-2004; Associations with Symptoms, Sexual Behaviors, and Reproductive Health. 5. CDC Bacterial Vaginosis (BV) Statistics. Last updated February 10, 2020. Accessed January 24, 2024. https://www.cdc.gov/std/bv/stats.htm

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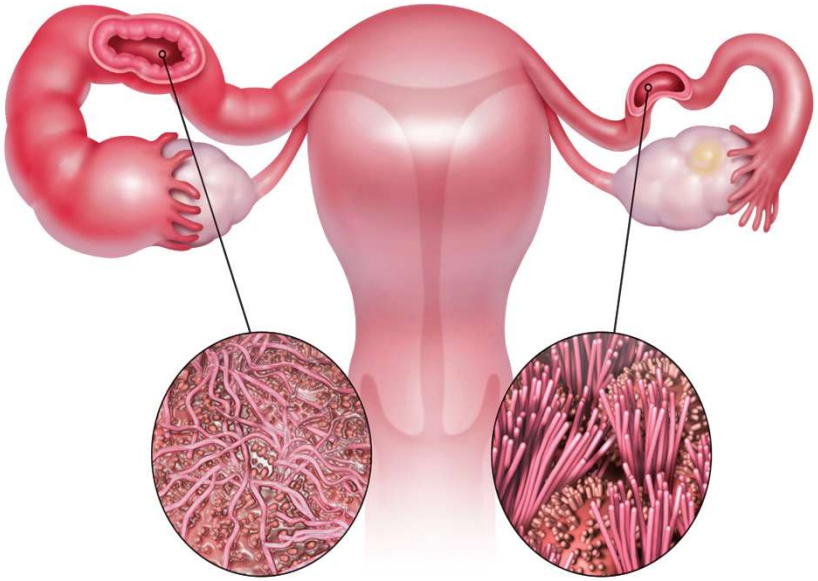
What is Vaginitis?

"Vaginitis is defined as inflammation or infection of the vagina and is associated with a spectrum of symptoms, including vulvovaginal itching, burning, irritation, dyspareunia, 'fishy' vaginal odor, and abnormal vaginal discharge."

ACOG Practice Bulletin. Vaginitis in Nonpregnant Patients. Washington; DC: American College of Obstetricians and Gynecologists; 2020:135(1)e1-e17. No. 215

The Risks of Delayed or Misdiagnosis



Microscope image of fallopian tube lining **after PID**.

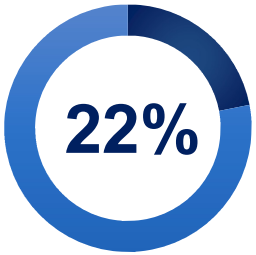
Microscope image of **normal** fallopian tube lining.

Vaginitis can be associated with an increased risk of:

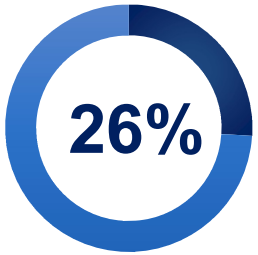
- Endometritis[1]
- Pelvic inflammatory disease (PID)[1,2]
- Sexually transmitted infections (STIs)[3,4]
- Transmission and acquisition of human immunodeficiency virus type 1 (HIV-1)[5]

1.Catherine L. Haggerty, Sharon L. Hillier, Debra C. Bass, Roberta B. Ness. PID Evaluation and Clinical Health (PEACH) Study Investigators, Bacterial Vaginosis and Anaerobic Bacteria Are Associated with Endometritis, Clinical Infectious Diseases, Volume 39, Issue 7, 1 October 2004, Pages 990–995. 2. Ness RB, Kip KE, Hillier SL, et al. A Cluster Analysis of Bacterial Vaginosis–associated Microflora and Pelvic Inflammatory Disease, American Journal of Epidemiology, Volume 162, Issue 6, 15 September 2005, Pages 585–590. 3. Van Der Pol B, Daniel G, Kodsi S, et al. Molecular-based Testing for Sexually Transmitted Infections Using Samples Previously Collected for Vaginitis Diagnosis, Clinical Infectious Diseases, Volume 68, Issue 3, 1 February 2019, Pages 375–381. 4. Bautista CT, Wurapa EK, Sateren WB, et al. Association of Bacterial Vaginosis With Chlamydia and Gonorrhea Among Women in the U.S. Army. American Journal of Preventive Medicine Volume 52, Issue 5, May 2017, Pages 632-639. 5. Atashili J, Poole C, Ndumbe PM, Adimora AA, Smith JS. Bacterial vaginosis and HIV acquisition: a meta-analysis of published studies. AIDS. 2008;22(12):1493-1501.

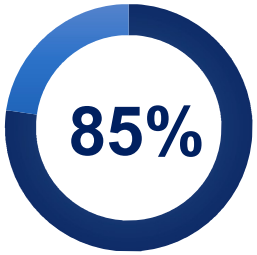
The Risks of Delayed or Misdiagnosis



of women testing positive for BV and/or *Candida* spp. were **coinfected with an STI**[1]



increased risk of acquiring gonorrhea with each additional episode of BV[2]



of individuals positive for any STI were also **positive for BV or *Candida* spp**[1]

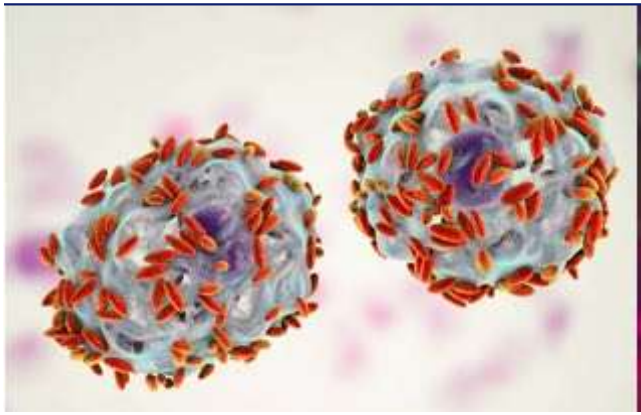
2021 CDC Recommendation	All women with BV should be tested for HIV and other STIs[3]

1. Van Der Pol B, Daniel G, Kodsi S, et al. Molecular-based Testing for Sexually Transmitted Infections Using Samples Previously Collected for Vaginitis Diagnosis, Clinical Infectious Diseases, Volume 68, Issue 3, 1 February 2019, Pages 375–381. 2. Bautista CT, Wurapa EK, Sateren WB, et al. Association of Bacterial Vaginosis With Chlamydia and Gonorrhea Among Women in the U.S. Army. American Journal of Preventive Medicine Volume 52, Issue 5, May 2017, Pages 632-639. 3. Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187

Common Causes of Vaginitis

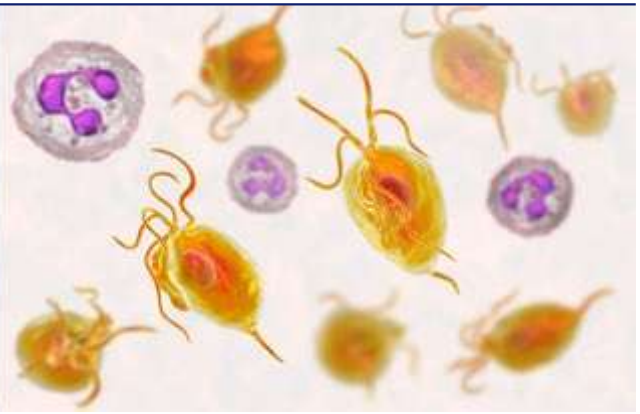
Vaginitis has multiple etiologies

Majority of vaginitis is caused either individually or in combination by:



Bacterial vaginosis (BV) ~50%

Candida vaginitis (CV) ~25%



Trichomonas vaginalis (TV) ~15 %

Paladine HL. Vaginitis: Diagnosis and Treatment. Am Fam Physician. Am Fam Physician. 2018 Mar 1;97(5):321-329. Sobel J. Approach to females with symptoms of vaginitis. UpToDate. Updated May 25, 2021. Accessed August 2021. www.uptodate.com

Mixed Infections and Overlapping Symptoms Make Diagnosis a Challenge[1]

37% of women with BV are also infected with TV and/or *Candida* species[1]

Similar Symptoms[2-11]						
	Bacterial Vaginosis	**Candida**	**Trichomoniasis**	**Chlamydia**	**Gonorrhea**	***Mycoplasma genitalium***
Abnormal Discharge	✓	✓	✓	✓	✓	✓
Vaginal Odor	✓		✓			
Vaginal Irritation	✓	✓	✓	✓	✓	✓
Pain During Urination/Sex	✓	✓	✓	✓	✓	✓

1.Belley-Montfort L, Lebed J, Smith B, et al. Sensitivity of the Amsel's Criteria compared to the Nugent Score in absence and in presence of Trichomonas vaginalis (TV) and/or Candida SPP among women with symptomatic vaginitis/vaginosis. Sex Transm Infect: first published as 10.1136/sextrans-2015-052126.290 on 18 May 2015. 2. Kent H. Epidemiology of vaginitis. Am J Obstet Gynecol. 1991;165(4):1168-1176. 3. Manhart LE, Gaydos CA, Taylor SN, Lillis RA, Hook EW 3rd, Klausner JD, Remillard CV, Love M, McKinney B, Getman DK. Characteristics of Mycoplasma genitalium Urogenital Infections in a Diverse Patient Sample from the United States: Results from the Aptima Mycoplasma genitalium Evaluation Study (AMES). J Clin Microbiol. 2020 Jun 24;58(7):e00165-20. doi: 10.1128/JCM.00165-20. PMID: 32321783; PMCID: PMC7315021. 4. Hainer BL, Gibson MV. Vaginitis. Am Fam Physician. 2011 Apr 1;83(7):807-15. PMID: 21524046. 5. Bautista CT, Wurapa EK, Sateren WB, Morris SM, Hollingsworth BP, Sanchez JL. Association of Bacterial Vaginosis With Chlamydia and Gonorrhea Among Women in the U.S. Army. Am J Prev Med. 2017 May;52(5):632-639. doi: 10.1016/j.amepre.2016.09.016. 6. CDC. Trichomonas Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. https://www.cdc.gov/std/trichomonas/stdfact-trichomoniasis.htm 7. CDC. Bacterial Vaginosis Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. https://www.cdc.gov/std/bv/stdfact-bacterial-vaginosis.htm 8. CDC. Candida Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. https://www.cdc.gov/fungal/diseases/candidiasis/genital/index.html 9. CDC. Chlamydia Fact Sheet. Center for Disease Control and Prevention website. Last reviewed February 15, 2023. Accessed February 15, 2023. https://www.cdc.gov/std/chlamydia/stdfact-chlamydia.htm 10. CDC. Gonorrhea – CDC Detailed Fact Sheet. Center for Disease Control and Prevention website. Last reviewed April 11, 2023. Accessed July 11, 2023. https://www.cdc.gov/std/gonorrhea/stdfact-gonorrhea-detailed.htm 11. CDC. Mycoplasma genitalium – CDC Detailed Fact Sheet. Center for Disease Control and Prevention website. Last reviewed December 5, 2022. Accessed June 1, 2023. https://www.cdc.gov/std/mgen/stdfact-Mgen-detailed.htm

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Contributing Factors for Vaginitis

- Antibiotic use[1]
- Changes in hormone levels due to conditions such as pregnancy or menopause[1]
- Douching[1,2]
- Spermicide use[1]
- Infection[1]
- Lack of condom use[2]
- HSV-2 seropositivity is a factor for BV[2]
- Sexual intercourse, multiple partners, or new partners are factors for BV and TV[2]
- BV more common among women with female partners[2]

1. ACOG Vaginitis Frequently Asked Questions. Updated September 2023. Accessed November 9, 2023. https://www.acog.org/womens-health/faqs/vaginitis. 2. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70

ACOG Recommendations for Reducing Risk of Vaginitis

DO NOT USE

- Scented products like hygiene sprays
- Douche

USE

- Plain, warm water to clean the vulva
- Condoms
- Potential preventative treatments if antibiotic use is indicated
- Clean products such as diaphragms after each use

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ACOG Vaginitis Frequently Asked Questions. Updated September 2023. Accessed January 18, 2024. https://www.acog.org/womens-health/faqs/vaginitis


Bacterial Vaginosis: Microbial Imbalance
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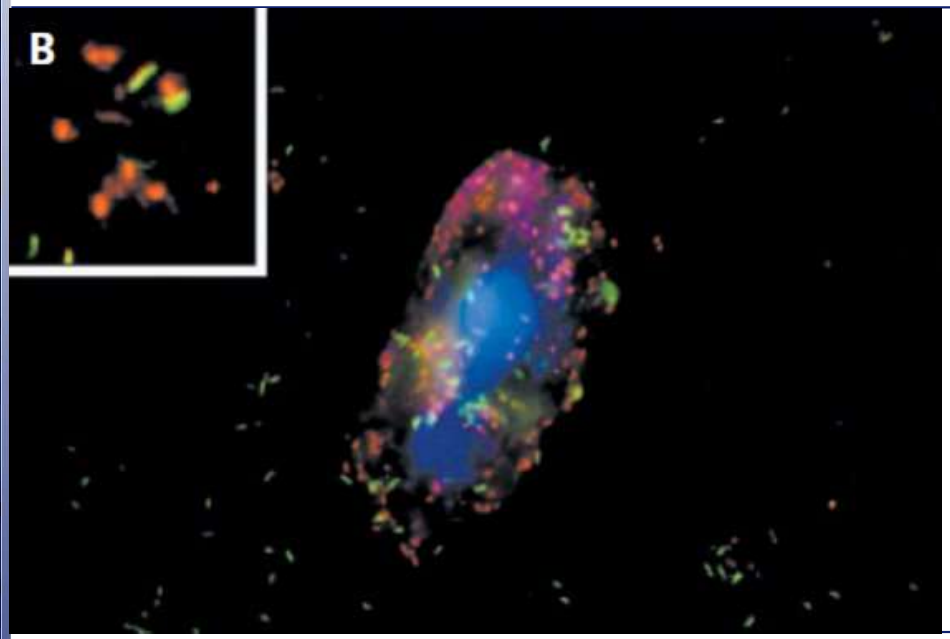
Bacterial Vaginosis (BV)

A highly prevalent condition and the most common cause of vaginal discharge worldwide



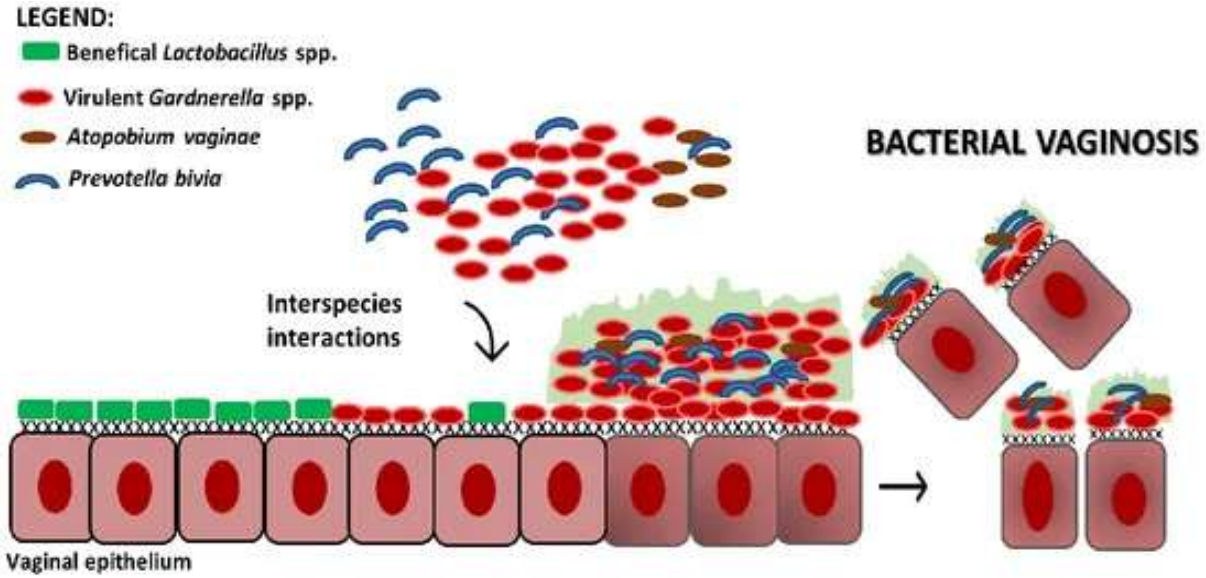
- Patients with BV are at an increased risk of post-procedural gynecologic infections and have increased susceptibility to STIs such as HIV and HSV-2.
- PID is associated with BV infections.
- BV is not sexually transmitted, but rare in women who do not have a sexual partner.
- Treatment for BV is recommended for women with symptoms.
- The CDC recommends that women with BV should be tested for other STIs such as HIV.

Image adapted from Fredricks, DN et al. 2005.

Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70

Changes to Vaginal Microbiome in BV

BV results in a biofilm which sticks to cells in the vagina[1,2]



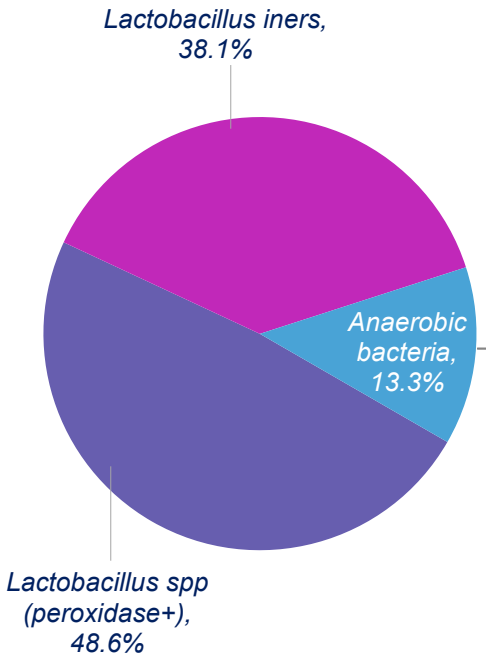
- Biofilm displaces hydrogen-peroxide producing *Lactobacillus*[2]
- Biofilm includes an overgrowth of commensal anaerobic bacteria[3]
- *Gardnerella vaginalis* and *Atopobium vaginae* (also known as *Fannyhessea vaginae*[4]) were found to comprise greater than 80% of studied biofilms[5]

Image adapted from Castro, J., et al., 2021

1. Gottschick C et al. Screening of Compounds against Gardnerella vaginalis Biofilms. 2016. PLOS ONE 11(4): e0154086. https://doi.org/10.1371/journal.pone.0154086. 2. Muzny CA et al. An Updated Conceptual Model on the Pathogenesis of Bacterial Vaginosis. J Infect Dis. 2019 Sep 26;220(9):1399-1405. doi: 10.1093/infdis/jiz342. PMID: 31369673; PMCID: PMC6761952. 3. Shipitsyna E, Roos A, Datcu R, Hallen A, Fredlund H, Jensen JS, et al. Composition of the vaginal microbiota in women of reproductive age--sensitive and specific molecular diagnosis of bacterial vaginosis is possible? PLoS One. 2013;8(4):e60670. 4. Nouioui, I., et al. Genome-Based Taxonomic Classification of the Phylum Actinobacteria. Frontiers in Microbiology. 2018:9:1-119. doi: 10.3389/fmicb.2018.02007 5. Hardy L, et al. Hardy. Sex Transm Infect 2016;92:487–491. doi:10.1136/sextrans-2015-052475

Importance of Multiple BV Targets

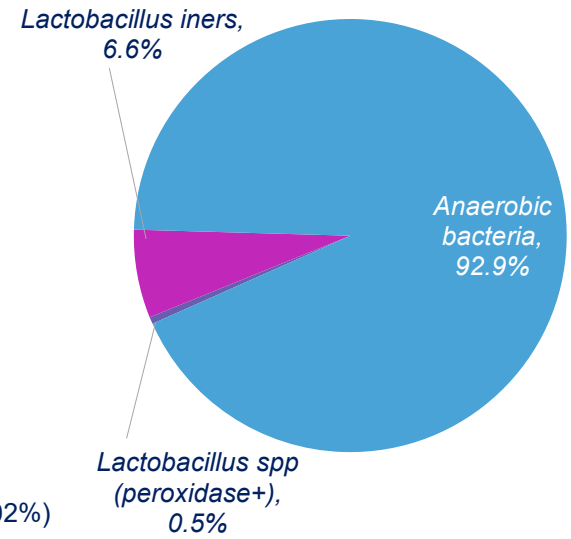
Normal Vaginal Flora



Anaerobic Bacteria

- Gardnerella vaginalis (7.2%)
- Atopobium vaginae (0.6%)
- Eggerthella (0.001%)
- Prevotella (0.2%)
- BVAB 1 (0.02%)
- BVAB 2 (0.01%)
- Finegoldia magna (0.1%)
- Megasphaera type 1 (0.2%)
- Megasphaera type 2 (0%)
- Sneathia sanguinegens (0.1%)
- Leptotrichia amnionii (0.1%)
- BVAB-TM7 (0.002%)
- Mobiluncus curtisii/mulieris (0.002%)
- Other non-Lactobacillus species (4.8%)

BV



Anaerobic Bacteria

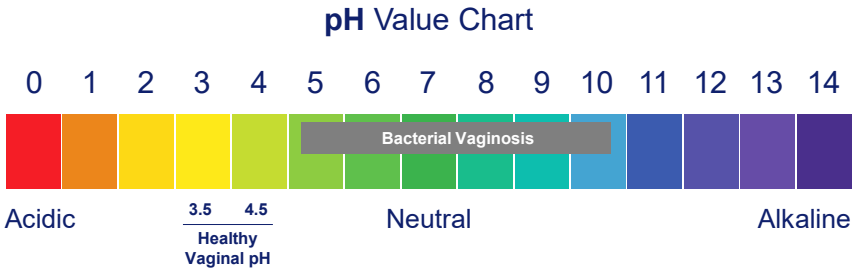
- Gardnerella vaginalis (29.1%)
- Atopobium vaginae (7.1%)
- Eggerthella (1.2%)
- Prevotella (13.2%)
- BVAB 1 (6.1%)
- BVAB 2 (6.3%)
- Finegoldia magna (0.1%)
- Megasphaera type 1 (9.8%)
- Megasphaera type 2 (0.1%)
- Sneathia sanguinegens (4.3%)
- Leptotrichia amnionii (6.8%)
- BVAB-TM7 (0.8%)
- Mobiluncus curtisii/mulieris (0.2%)
- Other non-Lactobacillus species (7.9%)

Medical Education

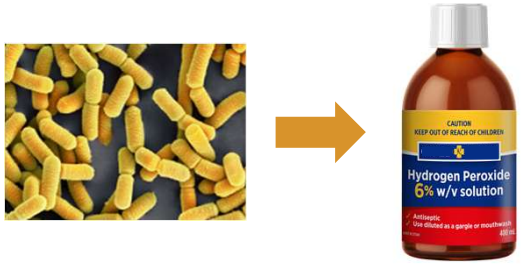
Figure adapted from Shipitsyna E, Roos A, Datcu R, Hallen A, Fredlund H, Jensen JS, et al. Composition of the vaginal microbiota in women of reproductive age--sensitive and specific molecular diagnosis of bacterial vaginosis is possible? PLoS One. 2013;8(4):e60670.

The Good Indicator: *Lactobacillus spp.*

Lactic acid produced by lactobacilli is thought to maintain a **healthy, acidic environment**[1,2]

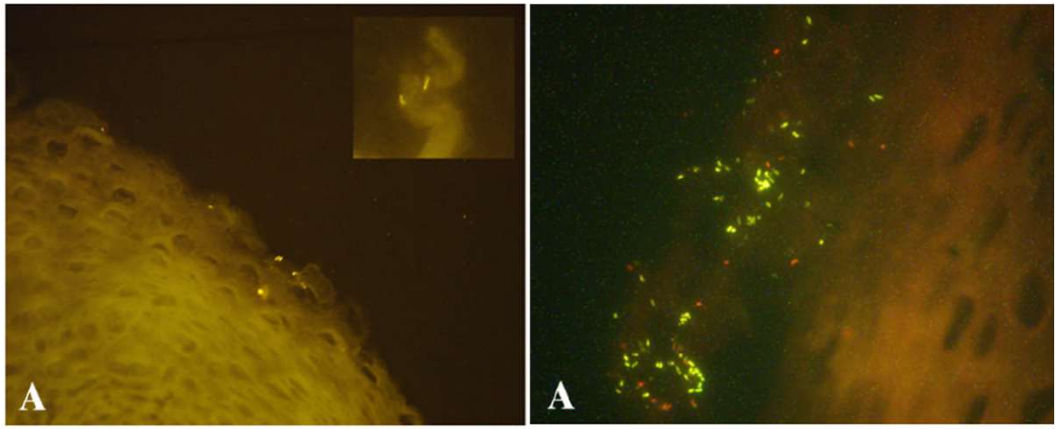


Also, lactobacilli produce H_2O_2 which is well-known for **inhibiting growth** of microorganisms[3]

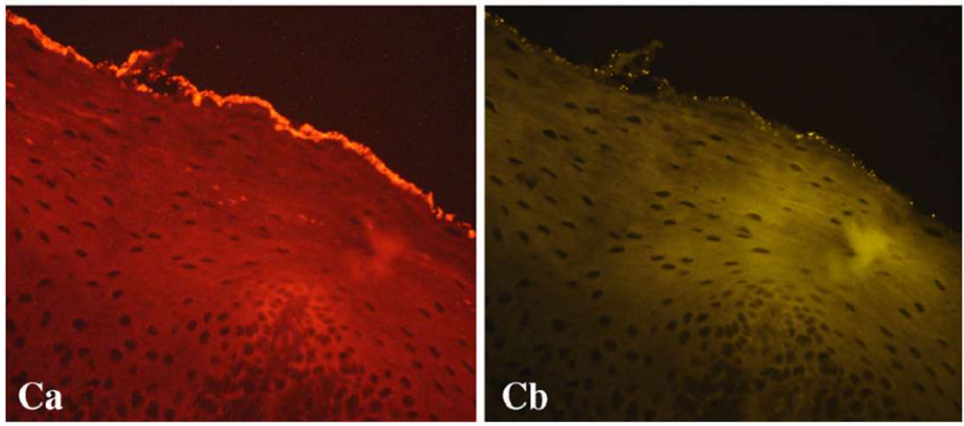


1. Tachedjian G, Aldunate M, Bradshaw CS, Cone RA. The role of lactic acid production by probiotic Lactobacillus species in vaginal health. Res Microbiol. 2017 Nov-Dec;168(9-10):782-792. doi: 10.1016/j.resmic.2017.04.001. Epub 2017 Apr 20. PMID: 28435139. 2. O'Hanlon DE, Moench TR, Cone RA. Vaginal pH and microbicidal lactic acid when lactobacilli dominate the microbiota. PLoS One. 2013 Nov 6;8(11):e80074. doi: 10.1371/journal.pone.0080074. PMID: 24223212; PMCID: PMC3819307. 3. Hawes SE, Hillier SL, Benedetti J, Stevens CE, Koutsky LA, Wolner-Hanssen P, Holmes KK. Hydrogen peroxide-producing lactobacilli and acquisition of vaginal infections. J Infect Dis. 1996 Nov;174(5):1058-63. doi: 10.1093/infdis/174.5.1058. PMID: 8896509.

Pathogenic Displacement: *Lactobacillus spp.*



Normal vaginal epithelium

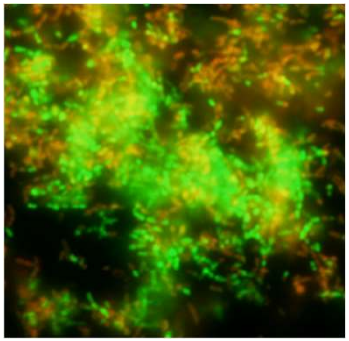


Vaginal epithelium in BV

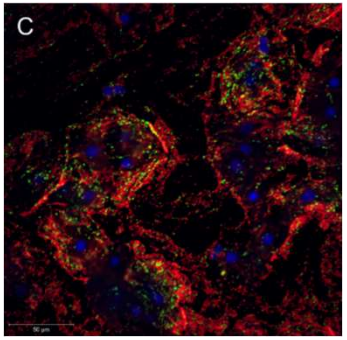
Image adapted from Swidsinski, et al. 2005

Pathogenic Overgrowth

Simultaneous detection of *G. vaginalis* and *A. vaginae* is highly predictive of BV[1]



Gardnerella vaginalis

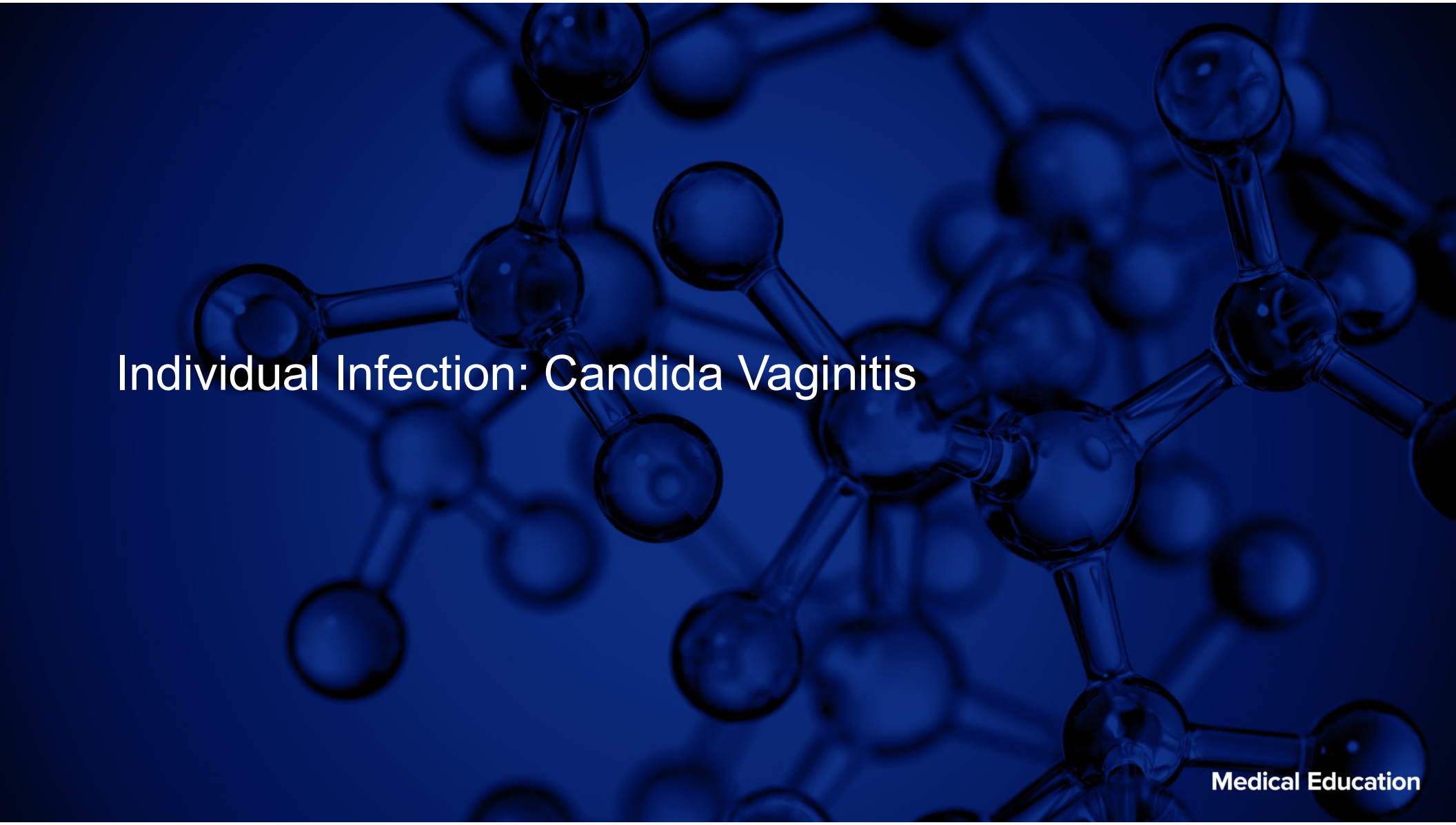


Atopobium vaginae

- *G. vaginalis* is the **predominant** organism in this biofilm[2,3]
- *A. vaginae* was rarely found without *G. vaginalis*[1]
- 86% detection in BV(+) women and only 13% within BV(-) women[1]
- "…other organisms may be relatively avirulent opportunists that colonize after initiation of infection by *G. vaginalis*"[3]

Image on right adapted from Gottschick, C et al. 2016. Image on left adapted from Hardy L, et al. 2016

1. Hardy L, et al. Sex Transm Infect 2016;92:487–491. doi:10.1136/sextrans-2015-052475 2. Muzny CA et al. An Updated Conceptual Model on the Pathogenesis of Bacterial Vaginosis. J Infect Dis. 2019 Sep 26;220(9):1399-1405. doi: 10.1093/infdis/jiz342. PMID: 31369673; PMCID: PMC6761952. 3. Patterson JL, Stull-Lane A, Girerd PH, Jefferson KK. Analysis of adherence, biofilm formation and cytotoxicity suggests a greater virulence potential of Gardnerella vaginalis relative to other bacterial-vaginosis-associated anaerobes. Microbiology (Reading). 2010 Feb;156(Pt 2):392-399.


Individual Infection: Candida Vaginitis
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Candida Vaginitis

Inflammation and infection of the vagina with *Candida* species caused by overgrowth

Second most common cause of vaginitis after BV

- Causes symptoms such as:
  - Burning
  - Itching
  - Pain
  - Swelling
  - Redness
  - Dysuria
  - Dyspareunia
  - Abnormal discharge
- Hallmarked by thick, curdy discharge

Medical Education

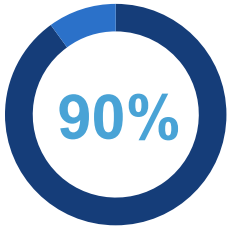
Vaginitis. ACOG Practice Bulletin No. 72. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2006;107:1195-206.

Candida Vaginitis

- Vulvovaginal candidiasis (VVC) is uncommon in prepubescent girls and post-menopausal women (not using estrogen) and is **often over-diagnosed in these populations**[1]
- Although VVC is **usually not sexually transmitted,** it is included in this section because it is frequently diagnosed among women who have vaginal symptoms or are being evaluated for an STI[2]
- Most women with uncomplicated yeast infections have **no precipitating factors**[2]

1. Vaginitis. ACOG Practice Bulletin No. 72. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2006;107:1195-206. 2. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70

Understanding *Candida* Species



Candida albicans is most prevalent – responsible for up to 90% of CV cases[1]

Candida glabrata is 2nd most prevalent[1]

- *C. glabrata* is associated with antifungal (azole) resistance and can require a different treatment pathway than *C. albicans*

Some amount of *Candida* is typically found in healthy vaginal flora – important to identify clinically significant levels for infection[2]

1, Vermitsky JP, Self MJ, Chadwick SG, Trama JP, Adelson ME, Mordechai E, Gygax SE. Survey of vaginal-flora Candida species isolates from women of different age groups by use of species-specific PCR detection. J Clin Microbiol. 2008 Apr;46(4):1501-3. 2. Bauters TG, Dhont MA, Temmerman MI, Nelis HJ. Prevalence of vulvovaginal candidiasis and susceptibility to fluconazole in women. Am J Obstet Gynecol. 2002 Sep;187(3):569-74.

Candida Vaginitis

Most common cause of vaginal complaints after BV[1]

Estimated

75%

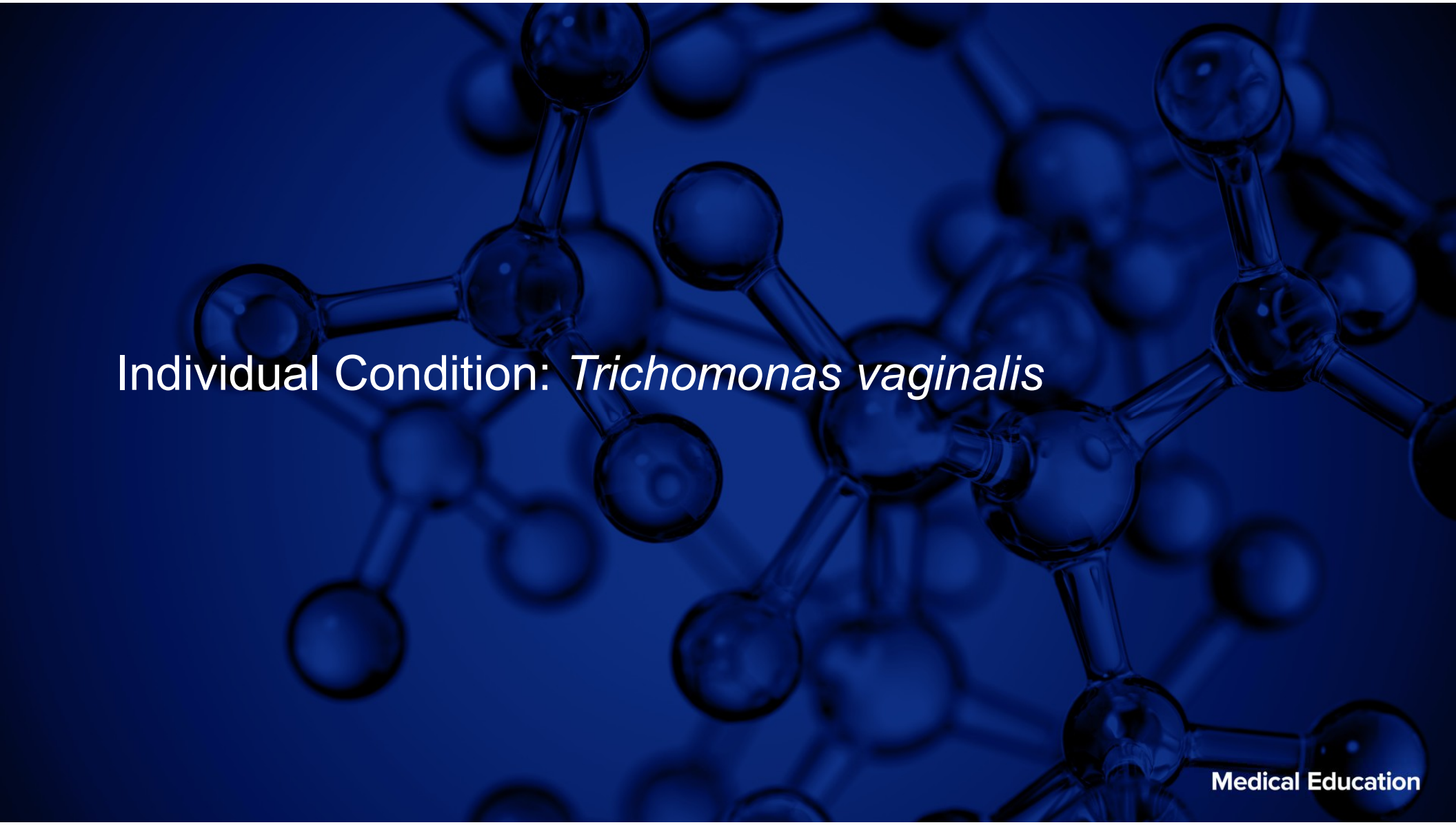
of women will have at least one episode of CV in their life[2]

Up to 5%

of women have recurrent CV[2]

Many patients self-diagnose and use OTC treatment only to have reoccurrence[3]

1. Vaginitis. ACOG Practice Bulletin No. 72. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2006;107:1195-206. 2. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70. 3. Ferris DG, Net al. Over-the-counter antifungal drug misuse associated with patient-diagnosed vulvovaginal candidiasis. Obstet Gynecol. 2002 Mar;99(3):419-25.


Individual Condition: *Trichomonas vaginalis*
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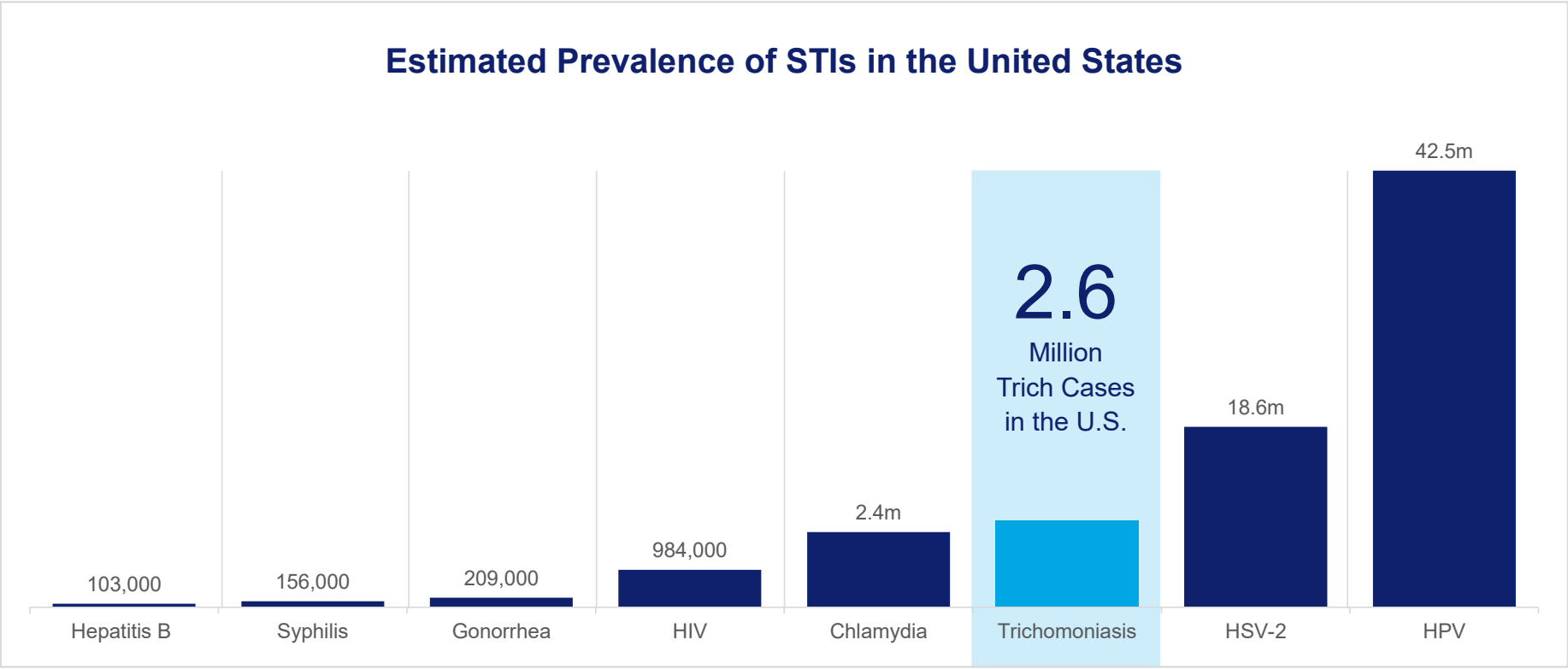
The Most Common Curable STI

Trichomoniasis (Trich) is as prevalent as Chlamydia and Gonorrhea combined

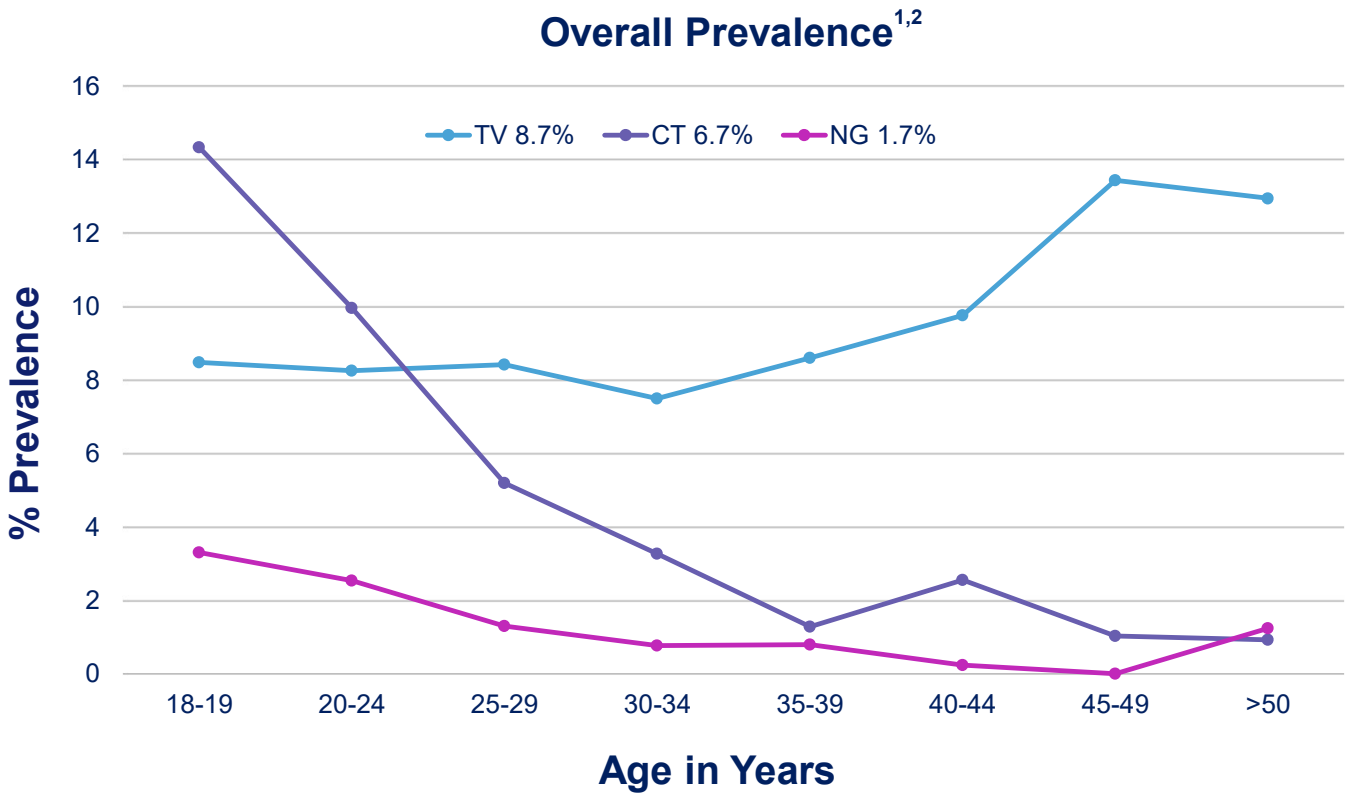


Medical Education

Graphic adapted from: CDC. Incidence, Prevalence, and Cost of Sexually Transmitted Infection in the United States. Last reviewed: March 16, 2022. Accessed August 24, 2023. https://www.cdc.gov/nchhstp/newsroom/fact-sheets/std/STI-Incidence-Prevalence-Cost-Factsheet.html

Estimated Prevalence Across All Ages

Trich is prevalent in women across a wide range of ages



"Detection rates of T. vaginalis were found to be highest among women aged 46 to 55 years and may be due to T. vaginalis infiltrating the subepithelial glands and being detected only during hormone-induced or antibiotic-induced changes in the vaginal flora." [3]

–Stemmer et.al

1. Graph adapted from: Ginocchio CC, et al. Prevalence of Trichomonas vaginalis and coinfection with Chlamydia trachomatis and Neisseria gonorrhoeae in the United States as determined by the Aptima Trichomonas vaginalis nucleic acid amplification assay. J Clin Microbiol. 2012;50(8):2601-2608. 2. Graph adapted from: Ginocchio CC, et al. Prevalence of Trichomonas vaginalis and Co-Infection with Chlamydia trachomatis and Neisseria gonorrhea in the United States as Determined by the APTIMA Trichomonas vaginalis Nucleic Acid Amplification Assay. 19th International Society for Sexually Transmitted Diseases Research (ISSTDR). July 10-13, 2011, Quebec City, Quebec, Canada. Oral presentation O3-S2.05. 3. Stemmer SM, et al. Detection Rates of Trichomonas vaginalis, in Different Age Groups, Using Real-Time Polymerase Chain Reaction. J Low Genit Tract Dis. 2012;16(4):352-357.

Trichomoniasis Infections are Often Asymptomatic

The latest CDC estimates reported more than

26

MILLION

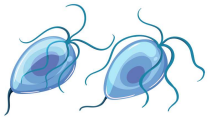
NEW sexually transmitted infections[1]

AND

6.9

MILLION

incidences are from Trich[1]



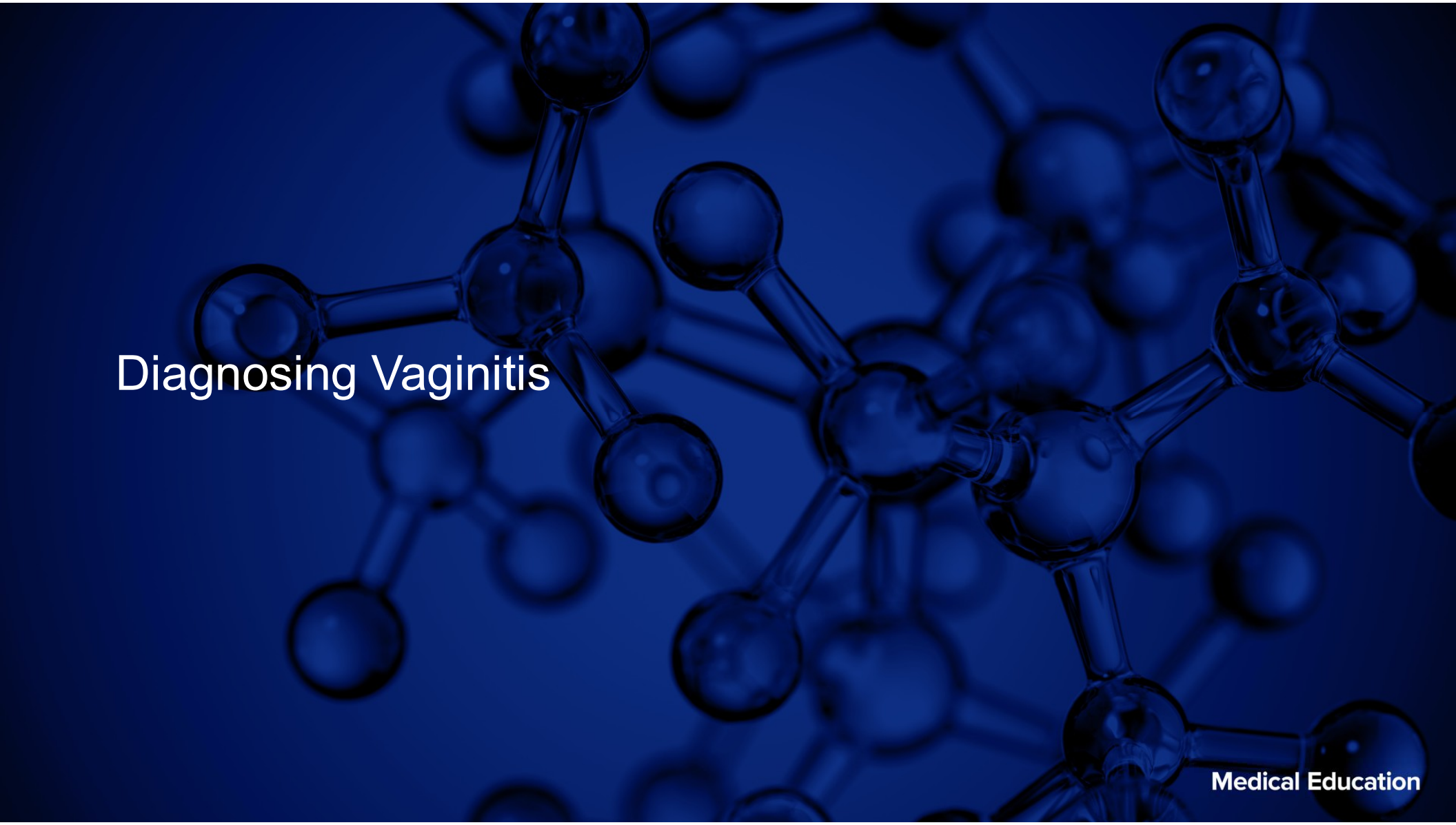
About 70% of people with the infection have minimal to no signs or symptoms.[2] When there are symptoms, many different conditions may cause symptoms similar to Trich, and co-infections can be common.[3]

1. CDC. Incidence, Prevalence, and Cost of Sexually Transmitted Infection in the United States. Last reviewed: March 16, 2022. Accessed August 24, 2022. https://www.cdc.gov/nchhstp/newsroom/fact-sheets/std/STI-Incidence-Prevalence-Cost-Factsheet.html 2. Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. 3. Allsworth JE, et al. Trichomoniasis and other sexually transmitted infections: results from the 2001-2004 National Health and Nutrition Examination Surveys. Sex Transm Dis. 2009;36(12):738–744

Consequences of Untreated Trichomoniasis

- Concurrent STIs, including chlamydia, gonorrhea and HSV types 1&2[1]
- Increased time to clear HPV infections[2]
- Possible connection with preterm birth and low birth weight[3]
- Increased risk of HIV transmission[3]
- Pelvic Inflammatory Disease (PID)[3]
- Endometritis[3]

1. Allsworth JE, et al. Trichomoniasis and other sexually transmitted infections: results from the 2001-2004 National Health and Nutrition Examination Surveys. Sex Transm Dis. 2009;36(12):738–744. 2. Shew ML, et al. Association of condom use, sexual behaviors and sexually transmitted infections with the duration of genital human papillomavirus infection among adolescent women. Arch Pediatr Adolesc Med. 2006;160(2):151-156. 3. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines, 2021. MMWR Recomm Rep. 2021 Jul 23;70(4):1-187.


Diagnosing Vaginitis
Medical Education

Office Exam

Finding the underlying cause of vaginitis starts with the patient

- Obtaining a medical history alone has been reported to be insufficient for accurate diagnosis of vaginitis and can lead to inappropriate administration of medication.[1]
- Patient history: medicine, hygiene practices, sexual behaviors, sex of partners.[2]
- Examine the vulva and skin around the anus for signs of inflammation.[3]
- Physical appearance of discharge may provide some clues, but not considered diagnostic.[3]

1. Hillier SL, Austin M, Macio I, Meyn LA, Badway D, Beigi R. Diagnosis and Treatment of Vaginal Discharge Syndromes in Community Practice Settings. Clin Infect Dis. 2021 May 4;72(9):1538-1543. 2. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70. 3. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. *Obstet Gynecol*. 2020;135(1):e1-e17. doi:10.1097/AOG.0000000000003604

Typical Methods for Diagnosing Vaginitis

From the established to the emerging

Method	Typical Setting	BV	CV	TV
Wet Prep[1]	POC[1]	X	X	X
Amsel[1]	POC[1]	X		
Gram Stain with Nugent[1]	Lab[1]	X		
Direct Probe[1,2]	Lab/POC[2]	X	X	X
Yeast Culture[1]	Lab[1]		X	
NAAT[1]	Lab[1]	X	X	X

Medical Education

1. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70. 2. Brown HL, Fuller DD, Jasper LT, Davis TE, Wright JD. Clinical evaluation of affirm VPIII in the detection and identification of Trichomonas vaginalis, Gardnerella vaginalis, and Candida species in vaginitis/vaginosis. Infect Dis Obstet Gynecol. 2004;12(1):17-21.

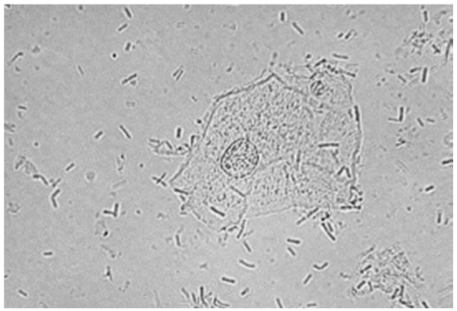
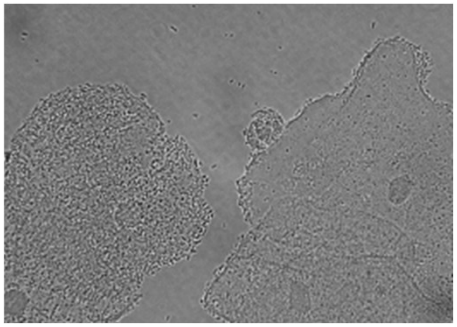
Wet Mount

Saline and KOH Mounts

- Two swabs should be taken of the posterior fornix
- Saline Prep: Add Swab to 1mL of saline, mix, and place a drop of this on a slide
- KOH Prep**:** Repeat with a drop of 10% KOH
  - KOH breaks apart the clue cells and WBCs
  - KOH does not interfere with fungi making it easier to visualize

Kelly KG. Tests on Vaginal Discharge. In: Walker HK, Hall WD, Hurst JW, editors. Clinical Methods: The History, Physical, and Laboratory Examinations. 3rd edition. Boston: Butterworths; 1990. Chapter 179.

Potential Findings of Wet Prep

	Saline Only	KOH Prep
	**Normal:** a few WBCs, normal epithelial cells[1]	**Normal:** No yeast or hyphae[1]
	**Abnormal:** Many WBCs, yeast, mobile Trichomonas, clue cells[1]	**Abnormal:** Budding yeast or hyphae[1]

Candida glabrata does not form pseudohyphae or hyphae and is not easily recognized on microscopy[2]

Images adapted from Mylonas, I and Bergauer, F., 2011

1. Kelly KG. Tests on Vaginal Discharge. In: Walker HK, Hall WD, Hurst JW, editors. Clinical Methods: The History, Physical, and Laboratory Examinations. 3rd edition. Boston: Butterworths; 1990. Chapter 179. 2. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70.

Performance of Wet Mount Microscopy in the Diagnosis of Vaginal Infections

	Sensitivity	Specificity	Agreement between observers (Cohen k)
Trichomoniasis	25% - 82%	98% - 100%	0.38
Bacterial vaginosis	82% - 100%	93% - 97%	0.81
Candidiasis	43.9% - 78%	75% - 88.9%	0.77

k interpretation: values $\leq$ 0, no agreement; 0.01-0.20, none to slight; 0.21–0.40, fair; 0.41-0.60, moderate; 0.61-0.80, substantial; 0.81-1.00, almost perfect

NOTES

- Examination must be performed immediately.
- All wet mount microscopy criteria must be evaluated.
- Detection of *Candida* species does not mean infection – clinical evaluation is necessary.

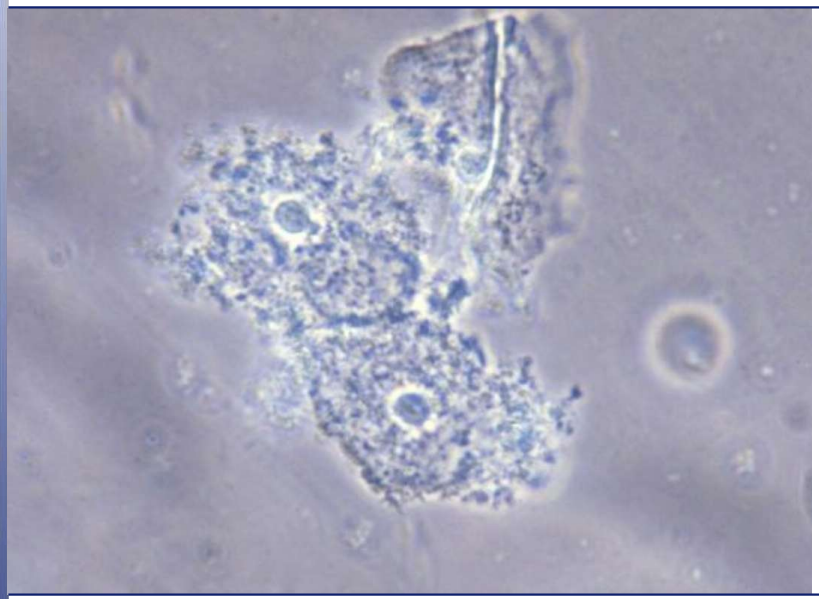
Vieira-Baptista P, Grincevičienė Š, Oliveira C, Fonseca-Moutinho J, Cherey F, Stockdale CK. The International Society for the Study of Vulvovaginal Disease Vaginal Wet Mount Microscopy Guidelines: How to Perform, Applications, and Interpretation. J Low Genit Tract Dis. 2021 Apr 1;25(2):172-180

Wet Mount Testing: Pros and Cons

PROS	CONS
Potential for detection of 3 major causes of vaginitis[1]	Up to 45% of TV infections are missed by wet mount[2]
Near patient and quick TAT[1]	TV detection declines over time after collection[3]
Minimal start up equipment or cost[1]	Low to moderate sensitivity for *Candida* (49.3-78%)[1]
	Microcopy is regulated in office by CLIA[1]

1. Vieira-Baptista P, Grincevičienė Š, Oliveira C, Fonseca-Moutinho J, Cherey F, Stockdale CK. The International Society for the Study of Vulvovaginal Disease Vaginal Wet Mount Microscopy Guidelines: How to Perform, Applications, and Interpretation. J Low Genit Tract Dis. 2021 Apr 1;25(2):172-180. 2. Nye MB, et al. Comparison of APTIMA Trichomonas vaginalis transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women. Am J Obstet Gynecol. 2009;200(2):188.e1-7. doi: 10.1016/j.ajog.2008.10.005. 3. Workowski, et al. Sexually Transmitted Infections Treatment Guidelines 2021. MMWR Recomm Rep 2021;70.

Applying Amsel's Criteria for BV



Bacterial vaginosis can be diagnosed based on the presence of 3 of the following 4 Amsel Criteria:

1. Homogeneous, thin, white-gray discharge that smoothly coats the vaginal walls
2. More than 20% clue cells on saline microscopy
3. A pH of vaginal fluid greater than 4.5
4. Positive KOH whiff test result

Medical Education

Vaginitis. ACOG Practice Bulletin No. 72. American College of Obstetricians and Gynecologists. Obstet Gynecol. 2006;107:1195-206

Current Testing Standard is Complex and Subjective

Amsel's Criteria

PROS	CONS
Point of Care and rapid	The sensitivity ranges between 37%–70%[2,3]
High specificity[1]	Microscopy training and competency required[4]
	Not all offices have microscopes
	Subjective interpretation of odor (whiff test) component[5]

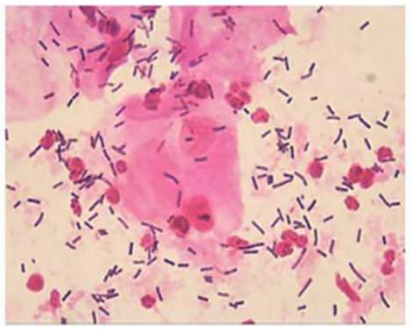
1. Landers DV, Wiesenfeld HC, Heine RP, Krohn MA, Hillier SL. Predictive value of the clinical diagnosis of lower genital tract infection in women. Am J Obstet Gynecol. 2004;190(4):1004-1010. 2. Sha BE, Chen HY, Wang QJ, Zariffard MR, Cohen MH, Spear GT. Utility of Amsel criteria, Nugent score, and quantitative PCR for Gardnerella vaginalis, Mycoplasma hominis, and Lactobacillus spp. for diagnosis of bacterial vaginosis in human immunodeficiency virus-infected women. J. Clin. Microbiol. 2005 Sep;43(9):4607-12. 3. Schwebke JR, Hillier SL, Sobel JD, McGregor JA, Sweet RL. Validity of the vaginal gram stain for the diagnosis of bacterial vaginosis. Obstet Gynecol. 1996 Oct;88(4 Pt 1):573-6. 4. Miller JM, Binnicker MJ, Campbell S, et al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. Clin Infect Dis. 2018;67(6):e1-e94 5. Gutman RE, Peipert JF, Weitzen S, Blume J. Evaluation of Clinical Methods for Diagnosing Bacterial Vaginosis, Obstetrics & Gynecology: March 2005 - Volume 105 - Issue 3 - p 551-556.

Gram Stain with Nugent Score

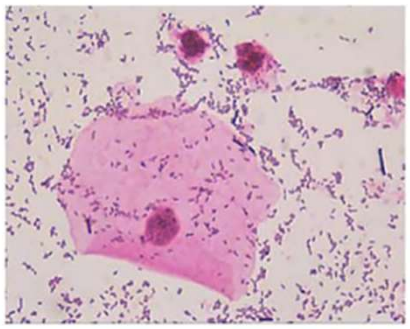
Reference standard for the diagnosis of bacterial vaginosis

Nugent scoring assigns a value to different bacterial morphotypes seen on Gram Stain of vaginal secretions

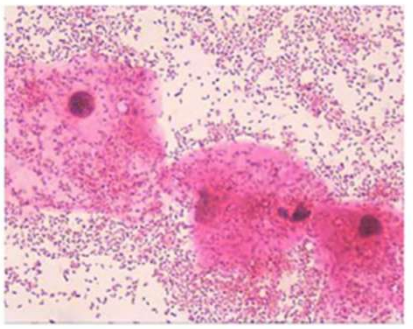
- 0 - 3 normal flora
- 4 - 6 intermediate flora
- 7 - 10 bacterial vaginosis



(i) Normal Vaginal Flora



(ii) Altered Vaginal Flora



(iii) BV

Score	*Lactobacillus* morphotype per field	*Gardnerella* morphotype per field	Curved bacteria (*Mobiluncus*) per field
0	>30	0	0
1	5 - 30	<1	1 - 5
2	1 - 4	1 - 4	>5
3	<1	5 - 30	5 - 30
4	0	>30	>30

Images from adapted from Wang, Z. et al., 2021

Nugent RP, Krohn MA, Hillier SL. Reliability of diagnosing bacterial vaginosis is improved by a standardized method of gram stain interpretation. J Clin Microbiol. 1991 Feb;29(2):297-301. doi: 10.1128/jcm.29.2.297-301.1991. PMID: 1706728; PMCID: PMC269757.

Current Testing Standard is Complex and Subjective

Nugent Scoring System

PROS	CONS
Considered the gold standard for BV[1]	Microscopy training required[2]
Standardized method of interpretation[1]	Consensus scoring to improve accuracy and in one study up to 24% requiring a third reader to obtain consensus[3]
	Laboratories have difficulty in retaining competency[2]
	Nugent scoring includes an intermediate, which is neither positive or negative[3]

1. Nugent RP, Krohn MA, Hillier SL. Reliability of diagnosing bacterial vaginosis is improved by a standardized method of gram stain interpretation. J Clin Microbiol. 1991 Feb;29(2):297-301. doi: 10.1128/jcm.29.2.297-301.1991. PMID: 1706728; PMCID: PMC269757. 2. Miller JM, Binnicker MJ, Campbell S, et al. A Guide to Utilization of the Microbiology Laboratory for Diagnosis of Infectious Diseases: 2018 Update by the Infectious Diseases Society of America and the American Society for Microbiology. Clin Infect Dis. 2018;67(6):e1-e94 3. Schwebke JR, Taylor SN, Ackerman R, et al. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. J Clin Microbiol. 2020 Feb; 58(2): e01643-19.

Direct Probe Assay (BV, CV, TV)

- Directly detect nucleic acids from *G. vaginalis*, *Candida* species and *T. vaginalis*[1]
- Individual collection device[1]
- No target amplification prior to detection[1]
- Designed for use in doctor's office or laboratory setting, but not waived[2]
- Final step is interpreting results of color development[1]

1 BD Affirm™ VPIII Microbial Identification Test. US package insert 670160JAA. Becton, Dickinson and Company, 2019.. 2. Brown HL, Fuller DD, Jasper LT, Davis TE, Wright JD. Clinical evaluation of affirm VPIII in the detection and identification of Trichomonas vaginalis, Gardnerella vaginalis, and Candida species in vaginitis/vaginosis. Infect Dis Obstet Gynecol. 2004;12(1):17-21. doi: 10.1080/1064744042000210375. PMID: 15460191; PMCID: PMC1784585.

Current Testing Standard is Complex and Subjective

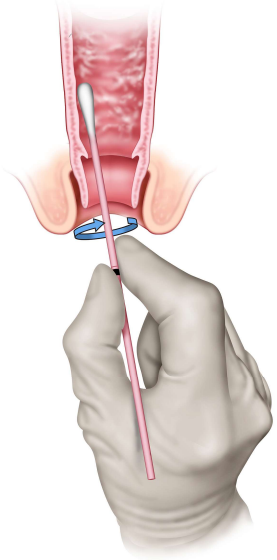
Direct Probe

PROS	CONS
Detects three main causes of vaginitis[1]	Requires separate collection[1]
Rapid, POC test[2]	Interpretation required[1]
	Single organism (*G. vaginalis*) used to diagnose complex, multi organism syndrome of BV[3]

"*However, because a single sentinel organism has not been found that accurately identifies patients with bacterial vaginosis, the diagnostic utility of a test that identifies only a single organism (eg, G vaginalis) is still being investigated and is not currently supported.*"[2]

1. Brown HL, Fuller DD, Jasper LT, Davis TE, Wright JD. Clinical evaluation of affirm VPIII in the detection and identification of Trichomonas vaginalis, Gardnerella vaginalis, and Candida species in vaginitis/vaginosis. Infect Dis Obstet Gynecol. 2004;12(1):17-21. doi: 10.1080/1064744042000210375. PMID: 15460191; PMCID: PMC1784585. 2. Dessai F, Nyirenda M, Sebitloane M, Abbai N. Diagnostic evaluation of the BD Affirm VPIII assay as a point-of-care test for the diagnosis of bacterial vaginosis, trichomoniasis and candidiasis. Int J STD AIDS. 2020 Mar;31(4):303-311. doi: 10.1177/0956462419895684. Epub 2020 Feb 12. PMID: 32050856. 3. ACOG Practice Bulletin, Number 215. Obstet Gynecol. 2020 Jan;135(1):e1-e17

Traditional Culture for *Candida* Species[1-4]

1 Vaginal Swab	2 Culture on Sabouraud Agar or other selective/ differential media	3 Stain	4 Speciation
			
	• Selective media prevents growth of bacteria, allowing for yeast to grow • Chromogenic agar may allow for species information • Incubation at 30°C, 24-48h		• Manual: biochemical reactions, Candifast, germ tube (18-24h), cornmeal (18-24 h), Chromagar (24-48h) • Semi-automated: Vitek II (18h) • MALDI-TOF MS (10 min)

1. Erdem H, Cetin M, Timuroglu T, Cetin A, Yanar O, Pahsa A. Identification of yeasts in public hospital primary care patients with or without clinical vaginitis. Aust N Z J Obstet Gynaecol. 2003 Aug;43(4):312-6. doi: 10.1046/j.0004-8666.2003.00089.x. PMID: 14714718. 2. Alizadeh M, Kolecka A, Boekhout T, Zarrinfar H, Ghanbari Nahzag MA, Badiee P, Rezaei-Matehkolaei A, Fata A, Dolatabadi S, Najafzadeh MJ. Identification of Candida species isolated from vulvovaginitis using matrix assisted laser desorption ionization-time of flight mass spectrometry. Curr Med Mycol. 2017 Dec;3(4):21-25. doi: 10.29252/cmm.3.4.21. PMID: 29707675; PMCID: PMC5917097. 3. CHROMagar™ Candida. NT-EXT-001. CHROMagar, 2022. 4. Vitek® 2 YST. US package insert. 043908-02. bioMerieux, 2016.

Current Testing Standard is Complex and Subjective

Yeast Culture

PROS	CONS
Allows for speciation of *Candida*[1]	Requires up to 48h for yeast to grow[3]
Allows for additional susceptibility testing[2]	Interpretation required if using chromogenic media or biochemicals[3]
Useful in recurrent VVC[2]	Further testing might be required for speciation[3]

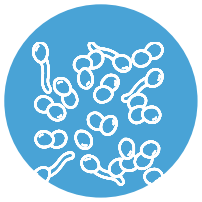
1. Vaginitis in Nonpregnant Patients: ACOG Practice Bulletin, Number 215. Obstet Gynecol. 2020 Jan;135(1):e1-e17. doi: 10.1097/AOG.0000000000003604. PMID: 31856123.2. Rolo J, Faria-Gonçalves P, Barata T, Oliveira AS, Gaspar C, Ferreira SS, Palmeira-de-Oliveira R, Martinez-de-Oliveira J, Costa-de-Oliveira S, Palmeira-de-Oliveira A. Species Distribution and Antifungal Susceptibility Profiles of Isolates from Women with Nonrecurrent and Recurrent Vulvovaginal Candidiasis. Microb Drug Resist. 2021 Aug;27(8):1087-1095. doi: 10.1089/mdr.2020.0139. Epub 2021 Feb 26. PMID: 33646045. 3. Ozcan K, Ilkit M, Ates A, Turac-Bicer A, Demirhindi H. Performance of Chromogenic Candida agar and CHROMagar Candida in recovery and presumptive identification of monofungal and polyfungal vaginal isolates. Med Mycol. 2010 Feb;48(1):29-34. doi: 10.3109/13693780802713224. PMID: 19191167.

NAAT Testing for Vaginitis

- Allows for consideration of multiple targets indicative of vaginitis disease state[1,2]
- Additional STI testing such as chlamydia or gonorrhea may be run off of the same collection[3]
- Tests may be performed on clinician collected or self collected vaginal swab depending on approval[2,4,5]
- BV tests are based on the detection of specific bacterial nucleic acids and have high sensitivity and specificity for BV and/or certain lactobacilli[1,2,5]

1.Schwebke JR, Taylor SN, Ackerman R, Schlaberg R, Quigley NB, Gaydos CA, Chavoustie SE, Nyirjesy P, Remillard CV, Estes P, McKinney B, Getman DK, Clark C. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. J Clin Microbiol. 2020 Jan 28;58(2):e01643-19. doi: 10.1128/JCM.01643-19. PMID: 31748322; PMCID: PMC6989072. 2. Coleman JS, Gaydos CA. Molecular Diagnosis of Bacterial Vaginosis: an Update. J Clin Microbiol. 2018 Aug 27;56(9):e00342-18. doi: 10.1128/JCM.00342-18. PMID: 29769280; PMCID: PMC6113459. 3. Van Der Pol B, Daniel G, Kodsi S, Paradis S, Cooper CK. Molecular-based Testing for Sexually Transmitted Infections Using Samples Previously Collected for Vaginitis Diagnosis. Clin Infect Dis. 2019 Jan 18;68(3):375-381. doi: 10.1093/cid/ciy504. PMID: 30084883; PMCID: PMC6336912. 4. Coorevits L, Traen A, Bingé L, Van Dorpe J, Praet M, Boelens J, Padalko E. Identifying a consensus sample type to test for Chlamydia trachomatis, Neisseria gonorrhoeae, Mycoplasma genitalium, Trichomonas vaginalis and human papillomavirus. Clin Microbiol Infect. 2018 Dec;24(12):1328-1332. doi: 10.1016/j.cmi.2018.03.013. Epub 2018 Mar 17. PMID: 29559392. 5. Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. CDC MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968.

NAAT Testing for Vaginitis



NAAT may allow for the speciation of *Candida* species that are associated with azole resistance.[1]

NAAT detection of TV is superior to wet mount microscopy.[2]

NAAT detects 3 times more mixed infections cases than clinical diagnosis with wet mount and Amsel's Criteria.[3]

NAAT detects mixed infections more frequently than either clinical evaluation[3] or probe testing.[4]

1. Schwebke JR, Taylor SN, Ackerman R, Schlaberg R, Quigley NB, Gaydos CA, Chavoustie SE, Nyirjesy P, Remillard CV, Estes P, McKinney B, Getman DK, Clark C. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. J Clin Microbiol. 2020 Jan 28;58(2):e01643-19. doi: 10.1128/JCM.01643-19. PMID: 31748322; PMCID: PMC6989072. 2. Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. CDC MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968. 3. Schwebke JR, Gaydos CA, Nyirjesy P, Paradis S, Kodsi S, Cooper CK. Diagnostic Performance of a Molecular Test versus Clinician Assessment of Vaginitis. J Clin Microbiol. 2018 May 25;56(6):e00252-18. doi: 10.1128/JCM.00252-18. PMID: 29643195; PMCID: PMC5971525. 4. Sobel JD, Subramanian C, Foxman B, Fairfax M, Gygax SE. Mixed vaginitis-more than coinfection and with therapeutic implications. Curr Infect Dis Rep. 2013 Apr;15(2):104-8. doi: 10.1007/s11908-013-0325-5. PMID: 23354954.

NAAT Based Testing

PROS	CONS
Can potentially perform BV, CV and TV testing at one time[1]	Not a POC test
Highly accurate compared to gold standard[1]	Individual FDA clearance/approvals or LDTs make comparisons challenging
Objective and reproducible[1]	

1.Schwebke JR, Taylor SN, Ackerman R, et al. Clinical Validation of the Aptima Bacterial Vaginosis and Aptima Candida/Trichomonas Vaginitis Assays: Results from a Prospective Multicenter Clinical Study. J Clin Microbiol. 2020 Feb; 58(2): e01643-19.


How do these methods compare?
Medical Education

NAAT Compared to Probe for BV

Assay	Sensitivity (%)	Specificity (%)	Targets	Reference Standard
NAAT – TMA[1]	95.0	89.6	*Lactobacillus spp. (crispatus, jensenii, gasseri), Gardnerella vaginalis, Atopobium vaginae*	Nugent and Amsel's Criteria
NAAT – PCR[2]	90.5	85.8	*Lactobacillus (crispatus, jensenii), Gardnerella vaginalis, Atopobium vaginae, Megasphaera 1, BVAB2*	Nugent and Amsel's Criteria
Direct Probe[3]	84.0	100	*Gardnerella vaginalis*	Gram Stain

Values are for clinician collected vaginal swabs. See NAAT package inserts for patient collected vaginal swabs.

1. Hologic Aptima BV Assay. US package insert AW-18811-001. Hologic, Inc.; 2019 2. BD Max™ Vaginal Panel. US package insert P0223 Rev 06. Becton, Dickinson and Company, 2019. 3. BD Affirm™ VPIII Microbial Identification Test. US package insert 670160JAA. Becton, Dickinson and Company, 2019.

Superior Specificity of NAAT Compared to Probe for BV

Comparison of BV molecular assays to NS Gram Stain for 111 specimens [a,b]

a BV, Bacterial Vaginosis; NS, Nugent Score; TP, true positive; FP, false positive; TN, true negative; FN, false negative; PPV, positive predictive value; NPV, negative predictive value. Values in parentheses are 95% confidence intervals.

b Intermediate NSs (4-6) were considered positive for BV if ≥2 of Amsel's criteria (positive whiff test, clue cells on Gram stain, and vaginal pH of >4.5) were present.

c The specificity of Aptima IVD was higher than BD Affirm ($P = 0.0002$).

Assay	TP	FP	TN	FN	Sensitivity (%)	Specificity[c] (%)	PPV (%)	NPV (%)
Aptima IVD	38	9	57	7	84.4 (70.9 - 92.6)	86.3 (75.9 - 92.9)	80.9 (67.2 - 89.8)	89.1 (78.8 - 94.9)
BD Affirm	39	26	40	6	86.7 (73.5 - 94.1)	60.6 (48.5 - 71.5)	60.0 (47.8 - 71.0)	87.0 (74.0 - 94.3)

Figure adapted from Richter SS, Otiso J, Goje OJ, Vogel S, Aebly J, Keller G, Van Heule H, Wehn D, Stephens AL, Zanotti S, Johnson T, Leal SM, Procop GW. Prospective Evaluation of Molecular Assays for Diagnosis of Vaginitis. J Clin Microbiol. 2019 Dec 23;58(1):e01264-19.

NAAT Results in More Accurate Diagnosis and Better Clinical Management

NAAT molecular tests detect 3x more co-infection cases than clinical diagnosis with wet mount, culture, and Amsel's Criteria[1]

3x more
Candidiasis + BV co-infections

3x more
Candidiasis + TV co-infections

4x more
BV + TV co-infections

Schwebke JR, Gaydos CA, Nyirjesy P, Paradis S, Kodsi S, Cooper CK. Diagnostic Performance of a Molecular Test versus Clinician Assessment of Vaginitis. J Clin Microbiol. 2018 May 25;56(6):e00252-18. doi: 10.1128/JCM.00252-18. PMID: 29643195; PMCID: PMC5971525.

Recommendation for Trichomoniasis Diagnosis

ACOG

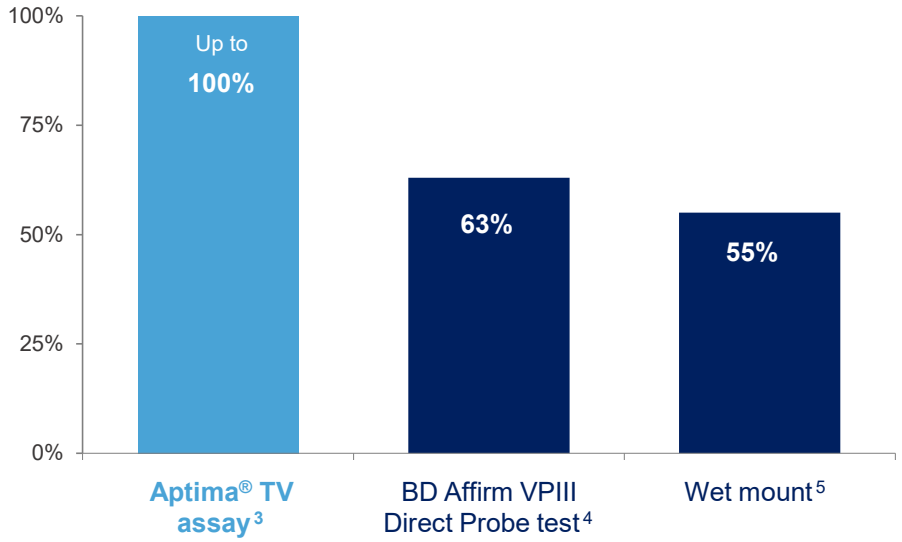
The American College of Obstetricians and Gynecologists

"Nucleic acid amplification testing (NAAT) is recommended for the diagnosis of trichomoniasis."[1]

CDC

Center for Disease Control and Prevention

"NAATs are highly sensitive, detecting more T. vaginalis infections than wet-mount microscopy among women."[2]



This chart is a representation of clinical data from multiple published sources. The clinical studies represented within these sources were conducted using different study designs with various assays.

1. ACOG. Vaginitis in Nonpregnant Patients. ACOG Practice Bulletin. Number 215. 2020;135(1):e1-e17. 2. Centers for Disease Control and Prevention. Trichomoniasis Treatment and Care. Last reviewed: September 21, 2022. Accessed August 24, 2023. https://www.cdc.gov/std/treatment-guidelines/trichomoniasis.htm 3. Aptima Trichomonas vaginalis Assay. US package insert AW-27552. Hologic, Inc., 2023. 4. Andrea SB and Chapin KC. Comparison of Aptima Trichomonas vaginalis Transcription-Mediated Amplification Assay and BD Affirm VPIII for Detection of T. vaginalis in symptomatic women: Performance Parameters and Epidemiological Implications. J Clin Microbiol. 2011;49(3):866-869.5. Nye MB, et al. Comparison of APTIMA Trichomonas vaginalis transcription-mediated amplification to wet mount microscopy, culture, and polymerase chain reaction for diagnosis of trichomoniasis in men and women. Am J Obstet Gynecol. 2009. 200(2):188 e1-7.


Treatment for Vaginitis
Medical Education

Available Testing Methods are Poor, Often Leading to Misdiagnosis and Incorrect Treatment

Misdiagnosis

63% of women with BV are **incorrectly diagnosed with Amsel's criteria**[1]

50% of women with VVC are **misdiagnosed with clinical and conventional testing approaches**[2]

52% of vaginitis diagnoses showed **no evidence of testing**[3]

Inappropriate Rx

34% of women **WITHOUT BV, VVC or TV** were prescribed antibiotics and/or antifungals[4]

47% of women with vaginitis received **1 or more inappropriate prescriptions**[4]

1. Schwiertz A, Taras D, Rusch K, Rusch V. Throwing the dice for the diagnosis of vaginal complaints? Ann Clin Microbiol Antimicrob. 2006 Feb 17;5:4. doi: 10.1186/1476-0711-5-4. PMID: 16503990; PMCID: PMC1395331. 2. Brown H, Drexler M. Improving the Diagnosis of Vulvovaginitis: Perspectives to Align Practice, Guidelines, and Awareness. Popul Health Manag. 2020 Oct;23(S1):S3-S12. doi: 10.1089/pop.2020.0265. PMID: 32997581; PMCID: PMC7591372. 3. Kong AM, Jenkins D, Troeger KA, Kim G, London RS. Diagnostic Testing of Vaginitis: Improving the Value of Care. Popul Health Manag. 2021 Aug;24(4):515-524. doi: 10.1089/pop.2021.0143. PMID: 34406089. 4. Hillier SL, Austin M, Macio I, Meyn LA, Badway D, Beigi R. Diagnosis and Treatment of Vaginal Discharge Syndromes in Community Practice Settings. Clin Infect Dis. 2021 May 4;72(9):1538-1543. doi: 10.1093/cid/ciaa260. PMID: 32350529; PMCID: PMC8248297.

Treatment Differs Among the Three Main Causes of Vaginitis

Bacterial Vaginosis[1]	Yeast Infection[1]	Trichomoniasis[1]
Metronidazole 500 mg orally 2 times/day for 7 days **OR** **Metronidazole** gel 0.75% one full applicator (5 g) intravaginally once a day for 5 days **OR** **Clindamycin** cream 2% one full applicator (5 g) intravaginally at bedtime for 7 days	**Butoconazole** 2% cream 5 g intravaginally in a single application **OR** **Terconazole** 0.4% or .8% cream 5 g intravaginally daily for 7 days or 3 days **OR** **Terconazole** 80 mg vaginal suppository one suppository daily for 3 days **OR** **Fluconazole** 150 mg orally in a single dose	**Metronidazole** 500 mg orally 2 times/day for 7 days for women **OR** **Tinidazole** 2 g orally in a single dose

In one study, 47% of women with a laboratory-diagnosed cause of vaginitis received at least one inappropriate treatment[2]

1. Workowski KA, Bachmann LH, Chan PA, Johnston CM, Muzny CA, Park I, Reno H, Zenilman JM, Bolan GA. Sexually Transmitted Infections Treatment Guidelines, 2021. CDC MMWR Recomm Rep. 2021 Jul 23;70(4):1-187. doi: 10.15585/mmwr.rr7004a1. PMID: 34292926; PMCID: PMC8344968. 2. Hillier SL, Austin M, Macio I, Meyn LA, Badway D, Beigi R. Diagnosis and Treatment of Vaginal Discharge Syndromes in Community Practice Settings. Clin Infect Dis. 2021 May 4;72(9):1538-1543. doi: 10.1093/cid/ciaa260. PMID: 32350529; PMCID: PMC824829

Key Takeaways

Vaginitis	BV, CV, TV	Testing	Treatment
• Vaginitis is common and a leading reason women visit their OBGYN – BV, CV, and TV are the underlying causes of most vaginitis • Vaginitis symptoms and sequalae can range from mild to serious complications – Overlapping symptoms make diagnosis challenging	• BV is hallmarked by dysbiosis of flora and is a leading cause of vaginitis • CV is the second most common cause of vaginitis • TV is the least frequent cause of vaginitis, but is more prevalent in older women	• A variety of testing may be used to diagnose with BV, CV, TV, all of which have pros and cons – Wet prep, Amsel, Nugent, Direct Probe, yeast culture, and NAAT are common ways to test for vaginitis	• Treatment is tailored for the underlying cause of vaginitis

Please complete the evaluation using the link or QR code.

https://bit.ly/vaginitis_microbial_eval_25

Microbial Pathogens in Vaginitis Evaluation (510-604-25)