

Current Concepts in Screening and Assessment of Vulvovaginitis

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W E L C O M E

Dear Colleague:

Welcome to the first issue of the *Vagisil® Vaginal Health Initiative* Newsletter Series, "Current Concepts in Screening and Assessment of Vulvovaginitis." In this issue you'll find an in-depth presentation of current clinical thinking about vaginal infections, including differential diagnosis, prevalence, and potential consequences and preventable liabilities of misdiagnosis. Of particular interest, we believe, is a discussion concerning the importance of accurate diagnosis in the treatment of vulvovaginitis and the utility and practicality of a new, easy-to-use patient self-screening tool.

The newsletter is the first in a series of publications developed by the Advisory Board of the *Vagisil® Vaginal Health Initiative*, a group of clinicians, educators, and women's health experts organized by Combe Incorporated. These publications reflect Combe's ongoing commitment to women's health. In December 2006, the Advisory Board met in New York City to define its mission and discuss current thinking regarding the diagnosis and treatment of vulvovaginitis.

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Both the Board and Combe Incorporated are committed to the goals of:

- Educating healthcare providers and women about the importance and value of patient self-screening for vaginal infections
- Encouraging healthcare providers to recommend pH testing to appropriate patients under appropriate clinical circumstances
- Educating and enabling women to be proactive regarding their vaginal health

The principal purposes of the *Vagisil® Vaginal Health Initiative* include: 1) optimizing care of vulvovaginitis, and 2) integrating patient vaginal pH determinations with evidence-based care of this common condition. Look for subsequent issues of the *Vagisil® Vaginal Health Initiative* Newsletter Series, and please refer to the *Vagisil®* professional website (www.vagisilhealth.com) for information and tools that are part of this ongoing educational effort. We also ask you to comment and to make suggestions for future topics.

On behalf of the *Vagisil® Vaginal Health Initiative*, we thank you for your interest and for your ongoing participation in these educational initiatives. We hope that you'll find the information in this newsletter both useful and stimulating.

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Overview of Vulvovaginitis

Vulvovaginitis means inflammation of the vagina and vulva. It can affect females of all ages and accounts for about 10 million office visits annually in the United States.¹ The condition can result from microecological abnormalities or infections caused by microorganisms, such as bacteria, fungi, protozoa, or viruses, as well as local irritants. In some cases, vulvovaginitis results from microorganisms that are passed between sexual partners.²

Symptoms of vulvovaginitis include abnormal vaginal discharge, soreness, irritation, itching, burning, discomfort, and pain with sexual activity.^{3,4} Because these symptoms are common to several types of vaginal infection, a healthcare provider should be consulted promptly after symptoms begin so that an accurate diagnosis may be made and appropriate treatment provided.

Even though vulvovaginitis is common, many women need to learn more about vaginal health and disease. Approximately 90% of vulvovaginitis cases are caused by either bacterial vaginosis (BV), vulvovaginal candidiasis (“yeast infection”), or trichomoniasis.^{5,6} The term “yeast infection” is what most women think of when they hear the word vaginitis, but, as noted above, a yeast infection is only one type of vaginal infection. Microbial vaginitis can be caused by a number of microorganisms other than those associated with BV, vulvovaginal candidiasis, and trichomoniasis. In addition, infectious vaginitis can be caused by more than one microorganism, which may be present simultaneously. **Table 1** lists the more common infectious causes of vulvovaginitis. Some noninfectious conditions that can cause vulvovaginitis include contact dermatitis, allergic reactions, irritant vulvitis, atrophic vaginitis, vulvar dermatoses, and, possibly, desquamative inflammatory vaginitis.

Table 1: Other Infectious Conditions That Can Cause Vulvar or Vaginal Symptoms^{4,7,8}

• Vulvitis or Vulvar Complaints	• Vaginitis or Vaginal Complaints
<ul style="list-style-type: none">• Vulvovaginal candidiasis• Human papilloma virus (HPV)• Syphilis• Herpes simplex virus (HSV)• Molluscum contagiosum• Chancroid• Granuloma inguinale• Lymphogranuloma venereum	<ul style="list-style-type: none">• Vulvovaginal candidiasis• BV• Trichomoniasis• Gonorrhea• Chlamydia• Miscellaneous (eg, <i>Escherichia coli</i>, group B streptococci, staphylococci)• Cervicitis• HSV• HPV

Ecology of the Vagina: Arrangements and Derangements of Microflora

To better appreciate the range of causes of vulvovaginitis, it is important to understand the normal vaginal environment. In reproductive-aged women, the normal vaginal ecology is maintained by the interaction among lactobacilli and other constituents of the normal bacterial flora, the metabolic by-products of these bacteria, estrogen levels, intracellular glycogen concentrations, and the vaginal pH. With respect to metabolic by-products, some species of vaginal lactobacilli produce hydrogen peroxide (H₂O₂), which is toxic to many potential vaginal pathogens, and all vaginal lactobacilli produce lactic acid, which maintains the vaginal pH at a healthy level of 3.8 to 4.5. When potentially pathogenic organisms are introduced into the vagina or when changes in the normal vaginal environment allow pathogens to multiply, the vaginal flora is altered and vulvovaginitis can occur.⁹

Concentrations of lactobacilli are relatively constant in the vagina throughout the menstrual cycle, but glycogen levels are highest during the week before menstruation. The concentration of bacteria other than lactobacilli in the vagina is highest during days 1 to 5 of the menstrual cycle. The concentration of *Candida*, a genus of fungi that includes *Candida albicans*, is highest just before

menstruation; overgrowth of *Candida* can result in vulvovaginal candidiasis. Oral contraceptives are associated with only a minor decrease in estrogen and are not typically associated with an altered vaginal flora. Diaphragm use is associated with an increase in vaginal colonization with *Escherichia coli*. Semen interferes with the ability of H₂O₂-producing lactobacilli to inhibit the growth of other bacteria. The immune-altering properties of semen enable microbes such as *C. albicans* to increase in number.

Bacterial Vaginosis: Pathogenic Imbalances

BV Is Common

BV is the most common cause of vaginal discharge in the United States, accounting for up to 50% of cases of vaginitis in women of childbearing age.⁹ BV has been found in approximately 15% to 19% of ambulatory gynecology patients, in 10% to 30% of pregnant women, and in 24% to 40% of patients in sexually transmitted infection clinics.⁹ In the 2001-2004 National Health and Nutrition Examination Survey, almost 1 in 3 pregnant or nonpregnant women 14 to 49 years of age in the general population of the United States tested positive for BV by self-collected vaginal smear.¹⁰ BV is characterized by an alteration of the vaginal microflora, exemplified by an increase in the vaginal pH to a level always above 4.5, an increased

number of microorganisms per milliliter of vaginal fluid, and characteristic patterns of mycoplasmas and anaerobic and aerobic microflora. Lactobacilli, including H_2O_2 -producing species, are greatly reduced, but concentrations of other bacteria are drastically increased, particularly facultative and obligate anaerobes (Figure 1).^{9,11} Some women with BV have no discharge or odor, but in others BV is associated with:

- Thin, white or dull gray vaginal discharge
 - Adherent to the vaginal wall
 - Amine odor, more prominent after unprotected sex, during menstruation, or after douching with a non-pH-adjusted solution

Vulvovaginal Candidiasis: Yeasty Rider

Vulvovaginal Candidiasis Is Common, Too

Vulvovaginal candidiasis is usually caused by an overgrowth of *C. albicans*, the species of *Candida* present in 80% to 90% of women with vulvovaginal candidiasis. It is the second most common cause of abnormal vaginal discharge in the United States, accounting for up to 30% of cases.⁴ Approximately 75% of women of childbearing age will experience at least one episode of vulvovaginal candidiasis in their lifetimes, and, of those, about 50% will have two or more episodes.⁴

Vulvovaginal candidiasis is common after antibiotic treatment.

Most women will experience one or more vaginal yeast infections in their lifetimes

In a recent study, vaginal *C. albicans* was recoverable in 21% of 275 women before antibiotic therapy and in 37% of 233 after antibiotics were used.¹² Vulvovaginal candidiasis is classified as uncomplicated (infrequent and mild) or complicated (recurrent and severe).¹³ Typical symptoms of vulvovaginal candidiasis include:

- Thick, white, curd-like, usually odorless but sometimes yeasty-smelling discharge adherent to the vaginal wall
- Vulvar and/or vaginal swelling and/or erythema
- Pruritus
- Vulvar fissures (cracks in the skin)
- Possible dysuria
- The vaginal pH is characteristically normal (ie, ≤ 4.5)

Trichomonal Vaginitis: Sex and the Single Protozoan

Trichomonal vaginitis, or trichomoniasis, is an infection that is transmitted through sexual intercourse by a protozoan called *Trichomonas vaginalis*. It is the third most common cause of vaginitis.⁹ Symptomatic trichomonal vaginitis is characterized by:

- Vulvar irritation
- Burning
- Possible dysuria
- Yellow-green, “frothy” discharge with an abnormal odor
- Inflammation
- Vaginal pH > 4.5

Approach to Assessment of Vulvovaginitis

Patient Evaluation

The sooner the correct etiologic diagnosis of vulvovaginitis is made, the earlier targeted, effective treatment can be initiated. The early initiation of targeted treatment reduces vulvovaginal discomfort quickly, decreases the risk of upper reproductive tract infection, and minimizes associated costs.

Evaluation of vulvovaginitis begins with a medical/sexual history and physical examination, followed by focused laboratory studies.¹⁴

History-related questions should include the onset, extent, and severity of symptoms; any change in sexual partner; recent or chronic illnesses; medication use; other products being used; and hygienic habits, such as douching.¹⁵ The healthcare provider should inspect the external genitalia, vaginal walls, and cervix.^{4,9} External fissures are seen in about 25% of patients with vulvovaginal candidiasis but rarely in women with BV or trichomonal vaginitis.⁴ The nature of the discharge (amount, consistency, color, odor) and accompanying pruritus, if present, may also provide important clues. The source of the discharge (vaginal or cervical) should also be identified. The pelvic examination is often followed by: a wet mount preparation with saline to identify “clue” cells, white blood cells, and *T vaginalis*; 10% potassium hydroxide (KOH) testing for yeast; the “whiff” test to detect amines; and pH testing (Table 2). Other vaginal tests such as cultures and nucleic acid-based probes should also be obtained as determined by local findings.

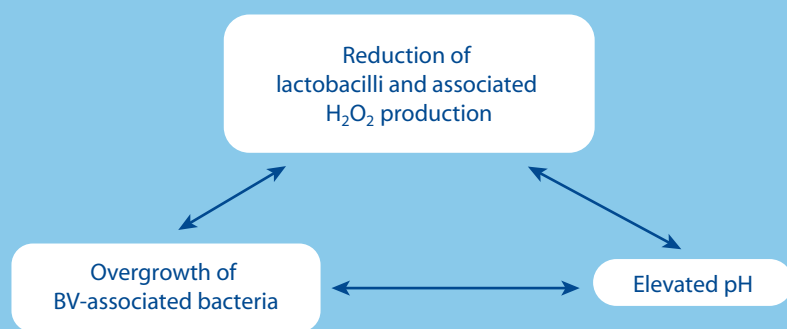


Figure 1. Interaction among vaginal lactobacilli, pH and BV

Table 2: Suggested Diagnostic Criteria for Vulvovaginitis

Diagnostic Criterion	Normal	BV	Vulvovaginal Candidiasis	Trichomonal Vaginitis
pH	3.8–4.5	>4.5	≤4.5	>4.5
“Whiff” test	Negative	Positive	Negative	Variable
Pseudohyphae and/or blastospores*	Absent	Absent	Present	Absent
“Clue” cells*	Absent	Present	Absent	Absent
Motile trichomonads*	Absent	Absent	Absent	Present

*On microscopic analysis of a wet mount of vaginal fluid.

Cost Savings

Decision and cost-effectiveness analyses were performed by Carr and colleagues to assess follow-up testing in patients with symptoms of vaginitis who remained undiagnosed after a pelvic examination was performed and a wet mount, KOH and “whiff” tests, and pH were obtained at the initial office visit.¹⁴ The authors

Vaginal pH testing is a simple but important diagnostic tool. Patients can now measure their own vaginal pH at home, before the office visit

compared the diagnostic efficiency of vaginal pH at the initial visit with that of follow-up Gram’s stain of vaginal secretions for BV, vaginal cultures for *Candida* and *Trichomonas*, or DNA probes for gonococci and Chlamydia. The results showed that considerable cost savings can be achieved by using vaginal pH to guide subsequent diagnostic assessment. Use of pH testing is cost-effective because a pH ≤4.5 usually rules out BV and trichomonal vaginitis, although the pH is typically normal in vulvovaginal candidiasis.

In the same cost-effectiveness study, the least expensive diagnostic strategy was found to be the most comprehensive: begin with pH testing and submit specimens for yeast cultures and DNA probes for *Neisseria gonorrhoeae* and *Chlamydia trachomatis* for all patients, but perform Gram staining for BV and submit specimens for culture of *Trichomonas* only when the vaginal pH exceeds 4.9. Other diagnostic strategies increased average costs by \$5 to \$81 per patient and increased the duration of symptoms by up to 1.3 days. The investigators concluded that a comprehensive, pH-guided testing strategy at the initial office visit was less expensive and more effective than ordering tests sequentially.¹⁴

Role of Vaginal pH in Assessment of Vulvovaginitis

Although it is tempting for physicians to treat vulvovaginitis empirically based on the clinical features alone, studies show poor correlation between symptoms and the final diagnosis. The cost of diagnosing vulvovaginitis can vary substantially depending on the amount of testing conducted at the initial visit, as noted by Carr and associates.¹⁴ Vulvovaginitis is often diagnosed and treated incorrectly, even when Amsel’s criteria or

microscopy are employed.¹⁶ Amsel’s criteria for BV include:

- Thin, homogenous vaginal discharge
- Vaginal pH >4.5
- Positive “whiff” test
- “Clue” cells on microscopic evaluation of saline wet mount

Because incorrect etiologic diagnosis of vulvovaginitis can result in treatment failure, it is important for healthcare providers to assess patients carefully so that appropriate anti-infective therapy can be initiated. Measurement of the vaginal pH is a key component of the diagnostic evaluation of vulvovaginal symptoms.¹⁷ A vaginal pH >4.5, particularly when associated with abnormal findings on microscopy, helps establish the correct etiologic diagnosis. However, patients with symptoms of vulvovaginitis are often assessed without a Gram’s stain of vaginal secretions. In this case, an elevated vaginal pH alone strongly suggests the need for further testing. **Figure 2** (page 5) shows an algorithm for the assessment of vulvovaginitis based on an initial determination of vaginal pH.¹⁸

The pH level of the vagina is measured by placing a strip of pH test paper on the lateral wall of the vagina—or swabbing the lateral vagina and placing a strip of pH test paper in the swabbed vaginal fluid—and then comparing any color change against a standard chart. A vaginal pH level >4.5 indicates an imbalance in the vaginal ecosystem and often signals BV, but it may also indicate trichomonal vaginitis; a vaginal pH ≤4.5 is normal, but if there is an abnormal vaginal discharge, it suggests candidiasis.

Benefits of Patient Self-screening for Vaginal pH

Measurement of vaginal pH can now be performed by providers in the office or by patients at home before an office visit using the commercially available, simple-to-use Vagisil™

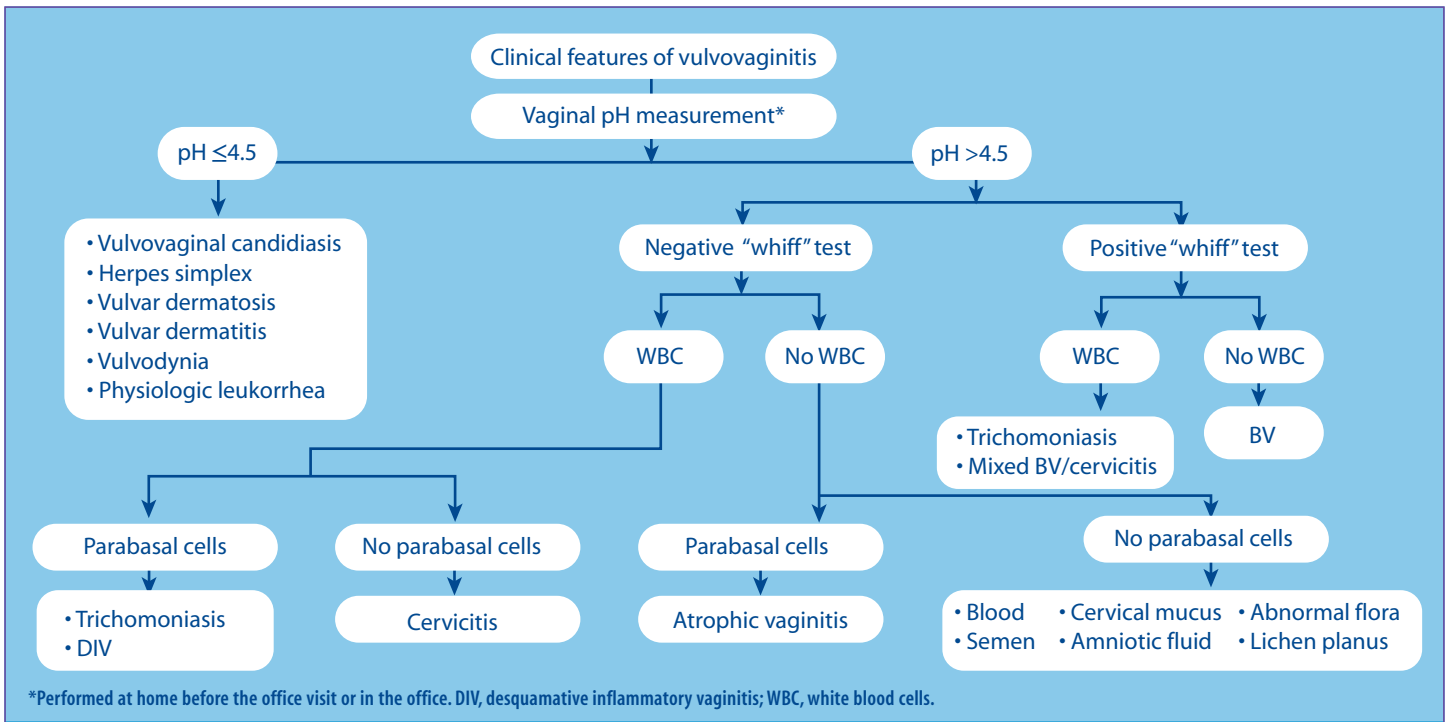


Figure 2. Vaginal pH-based approach to the assessment of vulvovaginitis (adapted from Nyirjesy and Sobel)¹⁸

Screening Kit. The Vagisil™ Screening Kit is quick, providing results in minutes. Recommending that women with symptoms of vulvovaginitis self-screen with the Vagisil™ Screening Kit increases the likelihood that they receive appropriate treatment sooner and more efficiently. The person making the appointment or the nurse practitioner or another medical professional providing telephone triage can ask the patient if she has already self-screened for vaginal pH and suggest that she do so before her appointment. Self-screening at home offers advance information to the healthcare provider's office, facilitating triage and thereby speeding targeted treatment. It can also allow the patient to obtain symptomatic relief before therapy is started.

A study conducted to determine whether women could learn about

the role of vaginal pH by reading the package insert for a pH self-test device showed that:

- Women correctly understand the role of the vaginal pH level as an aid to self-screening of symptoms of vaginitis when using an over-the-counter (OTC) vaginal pH self-test device¹⁹
- Women can learn how to use an OTC vaginal pH self-test device correctly by reading the package insert¹⁹

Another study showed that women with symptoms of vaginitis can understand and use a vaginal pH self-test device as a screening tool. The women obtained the same pH readings as those obtained by healthcare professionals.²⁰

By providing women with a screening tool such as the Vagisil™

Screening Kit, women with symptoms of vulvovaginitis may better determine what is causing their vaginal discomfort. Since BV and not candidiasis is the most common cause of vulvovaginitis, vaginal pH screening at home could reduce the inappropriate use of OTC antifungal medication by as much as 50%.²⁰

Vagisil® Vaginal Health Initiative

In its continuing commitment to patient education, Combe Incorporated, creator of the Vagisil® line of feminine care products, has implemented the *Vagisil® Vaginal Health Initiative*, a new program for healthcare providers. Through Advisory Board meetings, a website featuring patient materials, key opinion leader newsletters, and the National Initiative for Clinical Experience (N.I.C.E.), the *Vagisil® Vaginal Health Initiative* will:

- Educate healthcare providers about the importance and value of patient self-screening for vaginal infections
- Encourage healthcare providers to recommend self-screening to appropriate patients

Women from diverse demographic, ethnic, and educational backgrounds can accurately use the pH screening tool. Measurement of vaginal pH can be performed at home before an office visit using the commercially available, simple-to-use Vagisil™ Screening Kit

- Educate and empower women to be proactive regarding their own vaginal health

N.I.C.E.ly Done (National Initiative for Clinical Experience)

N.I.C.E. is an office-based survey that provides the healthcare team with valuable experience with respect to recommending and acting on the

information that patients can provide after self-screening with the Vagisil™ Screening Kit. Physicians, nurses, and other healthcare professionals responsible for patient education, counseling, or triage should find the results of this survey to be interesting.

The overall goal of N.I.C.E. is to lend support to the value, ease, and reliability of patient self-screening, as gathered through the course of a typical medical practice.

If a member of your practice is interested in participating in the

survey, he or she can contact us via the Combe Incorporated website at www.vagisilhealth.com. Everything required to gather and submit the requested information on five patients is included in the N.I.C.E. Program Kit—Vagisil™ Screening Kits, brief survey instruments with return envelopes, and “N.I.C.E. Patient” reminder flags/stickers for patient files. Results of the survey will be prepared for publication and will add to the body of knowledge concerning the use, reliability, and value of patient screening for vulvovaginal infections. ■

Educating Consumers

As part of its commitment to empower women to take charge of their health, Vagisil® conducted a consumer survey of Ivy League-educated women on the extent of their knowledge of their own bodies. The results were enlightening, providing a benchmark for the kind of consumer education needed to help women and clinicians better manage feminine health concerns. As part of your practice and work with women, you may find that many of the survey results ring true. Highlights of the survey include:

- Four out of five women (80%) surveyed say yeast is the most common vaginal infection, not BV
- Forty-two percent of the women do not know what BV is
- Nearly 90% equate vulvar itch with poor hygiene
- Women assume they have a yeast infection when they have feminine itching—yet studies have shown that this self-diagnosis is inaccurate more than 50% of the time

These misperceptions often lead to a delay in treatment, or to ineffective treatment. Women waste time and money and suffer needlessly while searching for a solution. Providing tools that help women choose correctly between an OTC remedy and a visit to a clinician can help them manage their health more effectively. In addition, self-screening for vaginal infection allows women to provide valuable information to their healthcare provider, thus streamlining office calls and visits.

These survey results will be used in educational messages in monthly women’s magazines, newspapers, TV news reports, and other consumer news outlets where women often seek lifestyle information. Vagisil® will offer resources to address common myths and misperceptions and a description of products and tools—including the Vagisil™ Screening Kit—that will help women find the right course of treatment for their symptoms.

Knowledge and tools are only one part of this equation, however.

Vagisil® recognizes that women can be uncomfortable talking about feminine hygiene and/or health issues with their healthcare providers or even among themselves. Thus, the Vagisil® website has recently been restructured to create an information destination. The new site’s resources include the V-ictionary, a basic dictionary containing information about the female body and common feminine health concerns. Women can also take a guided tour of the vulva via an illustration that clearly identifies key anatomic areas and provides simple definitions—a much needed resource, as the survey results showed more than 50% of women rarely or never look “down there.” In addition, experts answer specific questions and provide perspectives on medical concerns and lifestyle topics. The goal is to help women start and continue healthy conversations and practices—with their doctors, mothers, and daughters—for better feminine health, now and in the future. ■

REFERENCES: 1. Weisberg M. Considerations in therapy for vulvovaginal candidiasis: when and whom to treat. In: Sobel JD, ed. *Clinical Perspectives: Terconazole, an Advance in Vulvovaginal Candidiasis Therapy*. New York, NY: McGraw-Hill; 1988:1-8. 2. National Institutes of Health. National Institute of Child Health and Human Development. Research on gynecological disorders. Available at: <http://www.nichd.nih.gov/womenshealth/research/disorders/gyne.cfm>. Accessed February 16, 2007. 3. Anderson MR, Klink K, Cohrsen A. Evaluation of vaginal complaints. *JAMA*. 2004;291:1368-1379. 4. Eckert LO. Clinical practice. Acute vulvovaginitis. *N Engl J Med*. 2006;355:1244-1252. 5. Sobel JD. Vulvovaginitis in healthy women. *Compr Ther*. 1999;25:335-346. 6. Sobel JD. Vaginitis. *N Engl J Med*. 1997;337:1896-1903. 7. Mitchell H. Vaginal discharge—causes, diagnosis, and treatment. *BMJ*. 2004;328:1306-1308. 8. Jones HW III. Benign diseases of the vulva and vagina. In: Jones HW III, Wentz AC, Burnett LS, eds. *Novak's Textbook of Gynecology*, 11th ed. Baltimore, MD: Williams & Wilkins; 1988:570-596. 9. Egan ME, Lipsky MS. Diagnosis of vaginitis. *Am Fam Physician*. 2000;62:1095-1104. 10. Allsworth JE, Peipert JF. Prevalence of bacterial vaginosis, 2001-2004 National Health and Nutrition Examination Survey data. *Obstet Gynecol*. 2007;109:114-120. 11. Fredricks DN, Fiedler TL, Marrazzo JM. Molecular identification of bacteria associated with bacterial vaginosis. *N Engl J Med*. 2005;353:1899-1911. 12. Pirota MV, Garland SM. Genital *Candida* species detected in samples from women in Melbourne, Australia, before and after treatment with antibiotics. *J Clin Microbiol*. 2006;44:3213-3217. 13. Workowski KA, Berman SM, for the Centers for Disease Control and Prevention. Sexually Transmitted Diseases Treatment Guidelines, 2006. *MMWR Recomm Rep*. 2006;55 (RR11):1-94. 14. Carr PL, Rothberg MB, Friedman RH, et al. “Shotgun” versus sequential testing: cost-effectiveness of diagnostic strategies for vaginitis. *J Gen Intern Med*. 2005;20:793-799. 15. Stewart EG. The dilemma of diagnosing vaginal infections. *Practical Strategies in Women's Health* [serial online]. 2006;1:7. Available at: http://www.womenshealthexperience.com/pdf/PSIWH/PSWH_Summer2006.pdf. Accessed February 16, 2007. 16. Schwiertz A, Taras D, Rusch K, Rusch V. Throwing the dice for the diagnosis of vaginal complaints? *Ann Clin Microbiol Antimicrob*. 2006;5:4. 17. ACOG Practice Bulletin. Clinical Management Guidelines for Obstetrician-Gynecologists; Number 72; May 2006: Vaginitis. *Obstet Gynecol*. 2006;107:1195-1206. 18. Nyirjesy P, Sobel JD. Advances in diagnosing vaginitis: development of a new algorithm. *Curr Infect Dis Rep*. 2005;7:458-462. 19. Roy S, Caillouette JC, Faden JS, Roy T. The role of an over-the-counter vaginal pH self-test device package insert: can subjects learn what the device is for and how to use it? *Am J Obstet Gynecol*. 2005;192:1963-1969. 20. Roy S, Caillouette JC, Faden JS, Roy T, Ramos DE. Improving appropriate use of antifungal medications: the role of an over-the-counter vaginal pH self-test device. *Infect Dis Obstet Gynecol*. 2003;11:209-216.