- In patients with hysterectomy and removal of cervix—no screening is necessary unless prior history for high-grade cervical precancerous lesions or cervical cancer.

Follow-up testing after co-testing with abnormal cytology and/or positive hrHPV is complicated and readers are referred to the ASCCP guidelines for management decisions and the free teaching modules [358].

Significant pending issues for HPV screening include: education to clinicians and laboratorians on guideline recommendations and consistency in implementation moving forward, the use of self-collected vaginal specimens which are not currently FDA-cleared in the United States but have shown promise in difficult to reach patients, acceptability to women and not subject to the issues of inadequate specimen sample seen for cytology analysis, consensus/data on when discontinuation of routine screening occurs, and effect of increased uptake of HPV vaccination and impact for future screening risk in those vaccinated, as a decrease in HPV infections is starting to emerge.

HPV—Genital Warts

Genital warts are a sexually transmitted infection caused by certain types of human papillomavirus (HPV). The main clinical manifestation of genital warts is benign hyperplasia of the skin and mucous membrane in the genitalia, anus and perineum. A variety of HPV types can cause genital warts, but HPV 6 and 11 together account for about 90% of all cases. Most diagnoses are made by visual inspection and/or biopsy. Typing is not commonly performed.

Prevention of HPV and cervical cancer starts with vaccination. CDC now recommends 2 doses starting at ages 11–12, 6–12 months apart, available for both boys and girls. Vaccination can start as early as age 9. Those who start later than age 15–26 need 3 doses. There are currently 3 HPV vaccines licensed by the FDA, but since late 2016, only Gardasil-9 (9vHPV) is distributed in the United States. This vaccine protects against 9 HPV types including types 6, 11, 16, 18, 31, 33, 45, 52, and 58 [359].

Vaginitis/Vaginosis

Significant clinical utility and outcome data has emerged for diagnostics used for detection of the conditions related to vaginosis/vaginitis. These conditions result in millions of visits by women each year, often repeatedly because of misdiagnosis and inappropriate treatment [360]. The diagnoses of bacterial vaginosis (BV), a condition caused by an overgrowth of altered normal vaginal microbiota, and vaginitis caused by fungal organisms (vulvovaginal candidiasis [VVC]) or *Trichomonas vaginalis* (TV) are often considered clinically and diagnostically as a group because of their overlapping signs and symptoms and together account for about 90% of vaginitis (Table 42). The mode of transmission and/or acquisition is not necessarily that of an STI for VVC but may be for BV and is for TV. Inflammation in vaginitis puts patients at increased risk for STI acquisition, including HIV, as well as complications after gynecologic surgery and pregnancy. Several studies identify the high percentage of coinfections among the vaginitis entities (TV, VVC, BV) as well as infections with CT and GC, questioning the need for routine screening for all these entities in women with vaginitis [204, 343, 361–363].

Many guidelines still recommend use of diagnostic tests for BV that are poor in sensitivity and specificity citing lower cost and ability to provide a rapid diagnosis [204, 378]. However, these recommended tests are not commonly available in laboratories or rapid and often not diagnostically valid. In fact, Nugent Gram stain yields indeterminate results 25%–30% with initial smear interpretation and is a high complexity test requiring significant training. *G. vaginalis* cultures are not recommended as 55% of women without BV harbor this organism and reporting this organism alone for BV determination results in poor specificity and overtreatment. Likewise, the Affirm VPIII (Becton-Dickinson), which detects only *G. vaginalis* as the determinant for BV, like culture, has very poor specificity [340, 368]. Although sensitivity for VVC of the Affirm VPIII is adequate compared to culture, that for TV ranges from 63% to 100% compared to the SOC NAAT [361, 368].

Point-of-care tests (POCTs) that can be performed from a vaginal discharge specimen while the patient is in the healthcare setting to meet Amsel's criteria for BV, for example, visualization of thin whitish discharge, vaginal pH strip performed at the POC, potassium hydroxide/whiff test, and wet mount microscopy, have been documented to be rarely performed (only 1 in 5 providers) [340, 343, 369–371]. Also, multiple publications document the unacceptable poor performance of these POCTs by providers when compared to laboratory-based diagnostics, lacking both sensitivity and specificity for making an accurate diagnosis. The overall result with inadequately performed POCTs is that women receive syndromic management and empiric antimicrobials, with nearly 50% of women being incorrectly treated, including both over-treatment and missed treatment [340, 342, 343, 364]. Empiric antibiotic use results in creating alterations in the vaginal microbiome, increases resistance to fluconazole for yeast and metronidazole for TV, an overall decrease in patient satisfaction, continued symptoms, and repeat visits with increased costs [343, 371].

For VVC and TV, whether at POC or in the laboratory, the presence of pseudohyphae in saline wet mount with KOH or motile trichomonads visualized in wet mount, respectively, allows a diagnosis. However, proficiency in microscopic examination is essential given that infections may be mixed and/or present with atypical manifestations. Unfortunately, consistent microscopic exam of vaginal specimens and interpretation are difficult for many laboratories relative to culture and NAAT,