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Performance of a Rapid Self-Test for Detection of *Trichomonas vaginalis* in South Africa and Brazil

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Women participating in studies in Brazil ($n = 695$) and South Africa ($n = 230$) performed rapid point-of-care tests for *Trichomonas vaginalis* on self-collected vaginal swabs. Using PCR as the gold standard, rapid self-testing achieved high specificity (99.1%; 95% confidence interval [CI], 98.2 to 99.6%) and moderate sensitivity (76.7%; 95% CI, 61.4 to 88.2%). These tests may be considered an alternative to syndromic management in resource-poor settings.

Trichomonas vaginalis is highly prevalent (1), is frequently asymptomatic (2), and may cause pelvic inflammatory disease in women (3). *T. vaginalis* appears to facilitate HIV acquisition (4), and *T. vaginalis* treatment reduces genital shedding of HIV (5). Yet health professionals in many settings continue to rely on syndromic management or wet mount for diagnosis, with well-established low to moderate sensitivity of both, generally 50 to 70% (2, 6, 7), with some estimates as low as 36% (6), and poor specificity for syndromic management, as low as 56% (8). A rapid immunochromatographic *T. vaginalis* test has performed well in the United States (9, 10) and in Canada (11). We evaluated this test, the XenoStrip *T. vaginalis* test (Xenotope Diagnostics, San Antonio, TX), now the OSOM *Trichomonas* rapid test (Sekisui Diagnostics, San Diego, CA), in two developing countries—Brazil and South Africa.

As part of two studies comparing home- and clinic-based screenings (12, 13), women randomized to either a clinic or a home arm self-collected two vaginal swabs in their respective setting. The first Dacron swab was transported dry to a laboratory for in-house PCR for *T. vaginalis* (6). Women used the second cotton swab to perform the rapid *T. vaginalis* test, a dipstick test that takes approximately 10 min to perform, on their own. In the home group, women mailed (South Africa) or brought to the clinic (Brazil) a completed self-sampling kit, which included the Dacron swab to be used for PCR and their interpretation of the rapid-test result on a questionnaire. In the clinic group, women gave the first self-collected swab, to be used for PCR, to the provider and performed and read the rapid-test results using the second self-collected swab on their own, with the provider available to answer questions and review their interpretation of the rapid-test result. The rapid *T. vaginalis* test included an internal control, seen as a single red line, which verified that sufficient fluid was absorbed and that the capillary flow worked properly. A second red line indicated positivity for *Trichomonas* antigen.

In both studies, women were recruited from the communities surrounding two participating public clinics. Study staff visited local community-based organizations and employers to describe the study and invite women to attend recruitment sessions held at the clinics. In South Africa, participants were ages 14 to 25 years, while in Brazil, participants were 18 to 40 years old. Women in both the home and clinic settings responded to questions about vaginal symptoms, including unusual vaginal discharge, genital itching, pain on urination, and lower abdominal pain. Women who reported any of these symptoms were coded as symptomatic.

Based on PCR, the prevalence of *T. vaginalis* among women whose first self-collected swab had valid results was 10% in South Africa ($n = 230$) and 3% in Brazil ($n = 695$). As seen in Table 1, the specificity for self-testing using the rapid *T. vaginalis* test was high in both settings. The point estimate for sensitivity was higher in South Africa (83.3%) than in Brazil (68.4%); given the small number of *T. vaginalis* cases, this difference was not statistically significant (z-test $P = 0.2$). The pooled sensitivity was 76.7% (95% confidence interval [CI], 61.4 to 88.2%), and the pooled specificity was 99.1% (95% CI, 98.2 to 99.6%).

In South Africa, 27% (63/230) of women reported at least one vaginal symptom. The point estimate for the sensitivity was higher among symptomatic women (sensitivity of 7/8, 87.5%; 95% CI, 47.3 to 99.7%) than asymptomatic women (sensitivity of 80%; 95% CI, 51.9 to 95.7%). The point estimates for test performance in Brazil did not change by symptom status. Despite being a low-risk population, 75% of the women in Brazil reported symptoms, most commonly abnormal discharge (41%), suggesting that self-reports on "unusual" vaginal discharge may not be useful to distinguish symptoms in this setting. The test had a slightly higher estimated sensitivity in the clinic setting, where staff were available to answer questions, than at home, although this difference was not statistically significant (Table 1).

In our studies, women were able to use the point-of-care test and achieve similar or higher estimated sensitivity than with wet mount (7) and higher sensitivity and specificity than with most estimates for syndromic management (2, 6), although we cannot

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TABLE 1 Performance of self-testing using rapid XenoStrip *T. vaginalis* tests with self-collected vaginal swabs, with in-house PCR on self-collected vaginal swabs as the gold standard, in South Africa and Brazil

Group of women and self-test result	No. of positive and negative cases and PPV/NPV with in-house PCR for each self-test result					
	Gugulethu, South Africa			São Paulo, Brazil		
	No. of positive cases[a]	No. of negative cases[b]	PPV/NPV (95% CI)[c]	No. of positive cases[a]	No. of negative cases[b]	PPV/NPV (95% CI)[c]
Among all women who self-tested						
Positive	20	7	74.1 (53.7–88.9)	13	1	92.8 (66.1–99.8)
Negative	4	199	98.0 (95.0–99.5)	6	675	99.1 (98.1–99.7)
Sensitivity/specificity (95% CI)	83.3 (62.6–95.3)	96.6 (93.1–98.6)		68.4 (43.4–87.4)	99.9 (99.2–100.0)	
Among women who self-tested at the clinic						
Positive	12	2	85.7 (57.2–98.2)	8	0	100.0 (59.0–100.0)
Negative	2	114	98.3 (93.9–99.8)	3	376	98.9 (97.3–99.7)
Sensitivity/specificity (95% CI)	85.7 (57.2–98.2)	98.3 (93.9–99.8)		72.7 (39.0–94.0)	100.0 (99.0–100.0)	
Among women who self-tested at home						
Positive	8	5	61.5 (31.6–86.1)	5	1	83.3 (35.9–99.6)
Negative	2	85	97.7 (91.9–99.7)	3	299	99.0 (97.1–99.8)
Sensitivity/specificity (95% CI)	80.0 (44.4–97.5)	94.4 (87.5–98.2)		62.5 (24.5–91.5)	99.7 (98.2–100.0)	

[a] Or sensitivity (95% CI), in specified rows.
[b] Or specificity (95% CI), in specified rows.
[c] CI, confidence interval; PPV, positive predictive value; NPV, negative predictive value.

rule out the possibility of equivalence given the wide confidence intervals in this small study. Treatment based on syndromic algorithms for *T. vaginalis* can lead to severe overtreatment (8). Given possibly increasing prevalence of metronidazole-resistant strains of *T. vaginalis* (14), overtreatment is a risk that should not be ignored. On the other hand, given the potential for *T. vaginalis* to increase the risk of HIV acquisition (4) and/or HIV transmission (5), missing infections due to the low to moderate sensitivity of both syndromic management and wet mount should also not be ignored.

These results require confirmation in a larger trial; nevertheless, this study suggests that rapid point-of-care tests may be integrated into health systems, such as that in South Africa, that rely on syndromic management, with the potential to improve diagnostic capacity, and thus appropriate treatment, of *T. vaginalis* in resource-poor settings. Additionally, rapid point-of-care tests, either alone or in combination with wet mount, may be considered alternatives to wet mount alone in settings in which microscopy is available, such as parts of Brazil. Rapid *T. vaginalis* tests are likely to increase sensitivity (9–11) and, when combined with wet mount, can do so without reducing specificity.

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