


Risk-based screening to identify reproductive tract infection among HIV-infected women desiring use of intrauterine contraceptives

Nontokozo Langwenya ^{1,2}, Catherine S. Todd,³ Heidi E. Jones,⁴ Donald R. Hoover,⁵ Nai-Chung Hu,^{1,2} Agnes Ronan,² Landon Myer^{1,2}

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¹Division of Epidemiology and Biostatistics, University of Cape Town, Cape Town, South Africa

²Centre for Infectious Diseases Epidemiology and Research, University of Cape Town, Rondebosch, Western Cape, South Africa

³Global Health, Population, and Nutrition Department, FHI 360, Durham, North Carolina, USA

⁴Department of Epidemiology & Biostatistics, City University of New York, New York, New York, USA

⁵Department of Statistics and Biostatistics, Rutgers University, New Brunswick, New Jersey, USA

Correspondence to

Nontokozo Langwenya, Division of Epidemiology and Biostatistics, University of Cape Town, Rondebosch 7925, South Africa; ntokozolangwenya@gmail.com

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ABSTRACT

Background Reproductive tract infections (RTIs) are a major cause of morbidity and mortality, yet RTI testing remains limited in resource-constrained settings. We assessed performance of an existing RTI risk assessment screening tool among women living with HIV (WLHIV) considering intrauterine contraceptive (IUC) use.

Methods We conducted a cross-sectional analysis among WLHIV screened for participation in an IUC trial in Cape Town, South Africa (NCT01721798). RTI testing included *Neisseria gonorrhoeae*, *Chlamydia trachomatis*, *Trichomonas vaginalis* and bacterial vaginosis. Tool scoring was based on five separately scored criteria: (1) age under 25 years, (2) cohabitation with a partner, (3) secondary education, (4) self-reported intermenstrual bleeding and (5) number of current sexual partners and condom use frequency (score 0–5). We assessed tool performance in detecting RTI at 0 vs 1–5, 0–1 vs 2–5 and 0–2 vs 3–5 score thresholds.

Results Of 303 women, 52% (n=157) reported antiretroviral therapy use and median age was 31 years. The prevalence of any RTI was 38% (gonorrhoea=7%, chlamydia=11%, trichomoniasis=12% and bacterial vaginosis=18%) and 8% of women had multiple RTIs. Overall, 4%, 27% and 69% of women had screening tool scores of 0, 1 or 2+, respectively. At a threshold of at least one scored criterion, the tool demonstrated high sensitivities (95%–97%) but low specificities (3%–4%) for detecting any RTI. Increasing the score threshold and/or inclusion of abnormal vaginal discharge marginally improved specificity.

Conclusion The prevalence of RTIs observed in this population was high, and the screening tool had no discriminatory power to detect prevalent RTIs.

INTRODUCTION

Reproductive tract infections (RTIs), which are genital tract infections including sexually transmitted pathogens and excessive growth of lower genital tract commensal bacteria like bacterial vaginosis, cause considerable morbidity in sub-Saharan Africa. Annually, an estimated 63 million new cases of curable RTIs, including chlamydia (*Chlamydia trachomatis*), gonorrhoea (*Neisseria gonorrhoeae*), syphilis (*Treponema pallidum*) and trichomoniasis (*Trichomonas vaginalis*) occur among adults aged 15–49 years living in Africa.¹ In South Africa, the prevalence of bacterial vaginosis in clinic and community-based populations may reach 42% among women of reproductive age.² The burden of RTIs is compounded by high prevalence of HIV; RTIs are associated with increased risk of HIV acquisition and sexual transmission of HIV.^{3 4}

While laboratory testing is considered the gold standard for RTI diagnosis, RTI screening using sociodemographic and behavioural algorithms and syndromic management are a simplified and affordable approach in many resource-limited settings.^{5–7} Syndromic management is based on providing treatment for symptoms and recognised clinical signs resulting from pathogens most commonly responsible for producing the syndrome.^{7 8} However, syndromic management has poor specificity for RTI diagnosis, often resulting in overtreatment, particularly for women.⁹ Additionally, syndromic management fails to treat asymptomatic infections, which comprise 57%–61% of RTIs among women.¹⁰

Hypothetically, RTI screening tools with high sensitivity and specificity can be

used to identify both symptomatic and asymptomatic infections and, if used in conjunction with syndromic management, improve diagnostic accuracy.¹¹ In Kenya and Thailand, risk screening had a sensitivity of 60%–61% and a specificity of 57%–71% in predicting gonorrhoea and chlamydia infection, with sensitivity increasing to 69% with addition of clinical symptoms in a family planning clinic population of unknown HIV status.^{12 13} However, both studies focused nearly exclusively on organisms causing cervicitis, which have a different syndromic management symptom profile compared with pathogens causing vaginitis.

Although intrauterine contraceptives (IUCs) are highly effective and safe contraceptives for women, provider and patient concerns about RTIs and possible ascending infection likely limit IUC use in sub-Saharan Africa.^{14 15} Data suggest that the risk of pelvic inflammatory disease (PID) related to IUC use depends on background RTI prevalence for a given population.² The WHO recommends RTI testing and treatment prior to IUC insertion for women at increased RTI risk.¹⁴ Thus, IUC use among women living with HIV (WLHIV) remains low, partly due to these concerns.

Among WLHIV, we evaluated the performance of a validated RTI risk screening tool intended to identify women at low RTI risk who may be offered IUC insertion at the same visit.¹⁶

METHODS

Study population

We analysed screening data from a clinical trial assessing the safety and acceptability of the copper T-380 intrauterine device and levonorgestrel intrauterine system among WLHIV in Cape Town, South Africa (NCT01721798) between November 2013 and December 2016. Per local antiretroviral therapy (ART) eligibility guidelines, non-pregnant WLHIV were identified as ART-eligible based on CD4 cell count <500 cells/uL and/or WHO clinical stage III/IV.¹⁵ Eligible participants were: (a) 18–40 years, (b) not pregnant or intending to become pregnant in the next 30 months, (c) had no history of ectopic pregnancy or sterilisation, (d) diagnosed with HIV, (e) currently using ART with viral load <1000 copies/mL within 12 months *or* not ART-eligible per local guidelines and (f) desiring IUCs for contraception. Clinical data were abstracted from medical records and collected through face-to-face interviews conducted in the local language, isiXhosa. Ethical review and approval were received from the institutional review boards of the University of Cape Town (Reference: 283/2012) and FHI 360 (Reference: 10369). All participants provided written informed consent prior to participation.

Risk screening

During screening, participants completed the risk assessment screening tool for IUC insertion (online supplementary table 1) prior to pelvic examination,

and urine pregnancy and genital specimen RTI testing. Algorithms used in the screening tool were developed with data from HIV-negative women, aged 15–44 years, attending family planning clinics in Jamaica, Kenya, Zimbabwe and the United States.¹⁶ In these data, the sample size ranged from 615 (Kenya) to 1400 (Zimbabwe) and prevalence of either gonorrhoea or chlamydia (cumulatively regarded as cervical infection) ranged from 4.9% to 14.1%.^{17–19} The tool was validated using data from HIV-negative women from Uganda (n=1731, cervical infection prevalence=4.3%) and Thailand (n=1525, cervical infection prevalence=5.8%). The tool performed reasonably well identifying women at low risk of cervical infection; the change in odds of having an infection given a score of 1+ was 1.03 to 2.60.¹⁶ The tool identifies five indicators associated with increased cervical infection risk: (1) age less than 25 years, (2) lives separately from partner, (3) lack of secondary education, (4) bleeding between periods or after sex and (5) any current sexual partner(s) and, if sexually active, frequency of condom use. Each indicator is assigned a value of 1 if present and points are added to give the overall risk score (minimum score 0, maximum score 5). In our study, the tool was translated into isiXhosa, piloted on a small sample of WLHIV, and the final translated version was administered by a trained study nurse.

RTI testing

Consenting women were tested for gonorrhoea and chlamydia with NG/CT Xpert (Cepheid Diagnostics, Sunnyvale, CA, USA) nucleic acid amplification testing (NAAT), and for trichomoniasis and bacterial vaginosis with OSOM BV Blue and Trichomonas (Sekisui Diagnostics, Lexington, MA, USA) rapid diagnostic tests for genital tract specimens. Women diagnosed with any RTI were treated using single-dose regimens where possible and offered partner treatment and notification slips. At pelvic examination, providers evaluated each participant for potential signs of RTI and anatomical contraindications to IUC use. Vaginal discharge was considered abnormal if the colour was not white or clear (eg, green or grey), there was a foul odour and/or the consistency was not smooth (eg, frothy).

Statistical methods

Analysis was restricted to WLHIV who completed the risk assessment screening tool prior to RTI testing and were tested for RTIs within 35 days of screening. Prevalence was described for each pathogen and for coinfections, using proportions with 95% confidence intervals (95% CIs). The association between each screening tool indicator and RTI test result was examined using chi-square and Fisher's exact tests, and we examined the relative odds of having any RTI for each indicator. Based on prevalence of chlamydia and gonorrhoea,

Table 1 Frequency distribution of the clinical characteristics and reproductive tract infections among women living with HIV screened for participation in an intrauterine contraceptive trial, Cape Town, South Africa

Parameter	Total (n=303) n (%)
Reporting ART use	157 (52)
Median years since HIV diagnosis (IQR)*	5 (2–8)
Abnormal vaginal discharge†	42 (14)
Prevalence of RTIs	
Gonorrhoea‡	20 (7)
Chlamydia‡	33 (11)
Trichomoniasis	37 (12)
Bacterial vaginosis	54 (18)
Any RTI	116 (38)
Coinfection (>1 RTI)	23 (8)

*Date of HIV diagnosis missing for seven participants.

†Not recorded for six women.

‡Five women were not tested for gonorrhoea and chlamydia.

ART, antiretroviral therapy; RTI, reproductive tract infection.

the overall risk score was initially categorised into 1–5 versus 0 to estimate high versus low risk of infection for the primary analysis, based on the original instrument testing.¹⁶ To evaluate tool performance, we used the receiver operating characteristic (ROC) curve analysis and calculated the sensitivity, specificity, positive predictive value (PPV) and negative predictive value (NPV) for any RTI, infection restricted to gonorrhoea and/or chlamydia and any RTI other than bacterial vaginosis. We then explored alternate cut points and inclusion of abnormal vaginal discharge for improving the tool's RTI detection performance.

Patient and public involvement

Patients were not involved in the development of the research question and study design.

RESULTS

Of 374 women screened for RTI using the risk assessment tool, 72 were excluded from analysis due to not returning for pelvic examination and RTI testing despite multiple follow-up attempts (n=41), returning after 35 days which necessitated re-screening (n=27) or only being tested for syphilis (n=3). Of 303 eligible women, approximately half (52%) reported ART use, and median time since HIV diagnosis was 5 years (IQR 2–8) (table 1).

Overall, 38% (95% CI 33 to 44, n=116) of women had at least one RTI, with prevalence ranging from 32% in those aged >30 years to 49% in those aged 18–24 years. The most prevalent RTI was bacterial vaginosis, followed by trichomoniasis, chlamydia and gonorrhoea (table 1). Forty-six women (15%) were positive for either gonorrhoea or chlamydia, of whom seven were infected with both pathogens and 15 (5%;

95% CI 3 to 8) had at least one other RTI. Coinfection rates increased as age decreased, with 4% for ages >30 years, 6% for 25–30 years and 13% for 18–24 years. Among women with documented pelvic examination (98%, n=297), abnormal vaginal discharge was observed in 42 women, of whom 26% had at least one RTI (95% CI 17 to 34) (online supplementary table 2). RTI prevalence and coinfection was higher among non-ART compared with ART-using women (43% vs 34%, p=0.149 and 12% vs 3%, p=0.003, respectively).

Risk screening tool

Overall, 4%, 27% and 69% of women had screening tool scores of 0, 1 or 2+, respectively; the median score was 2 (IQR 1–3) (figure 1). The proportion of women with at least one detected RTI or abnormal vaginal discharge did not differ by score group compared with women with no RTI or normal pelvic examination. Most (89%, n=254) women reported being sexually active in the preceding 3 months, of whom 6% (n=14) reported having multiple sexual partners (table 2). There was no difference in reported condom use between women with one sexual partner versus multiple partners; 41% versus 43% reported consistent condom use. Nearly two-thirds (64%) were living separately from their sexual partner and 5% had experienced spotting between menstrual periods or after sex.

Two of five screening tool indicators were associated with RTI; being age below 25 years and being sexually active (table 2). Women with gonorrhoea and/or chlamydia infection had five times the odds of being younger than 25 years of age compared with those aged 25 years or more. This association persisted with inclusion of trichomoniasis (OR 2.81, 95% CI 1.39 to 5.63) but not bacterial vaginosis (OR 1.64, 95% CI 0.83 to 3.21). Although being sexually active was associated with increased odds of having an RTI, there was

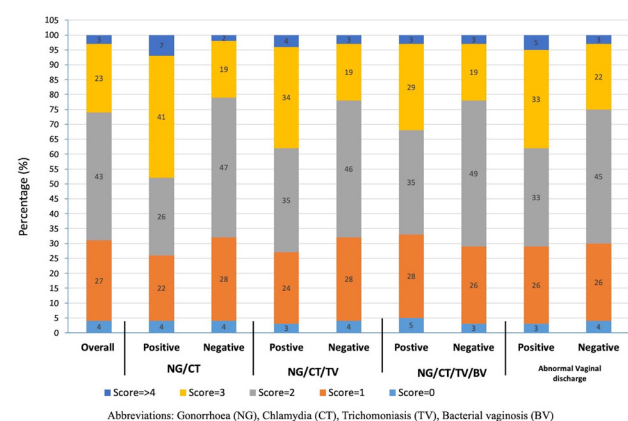


Figure 1 Distribution of risk screening scores for all women, by detectable reproductive tract infection and by vaginal discharge. BV, bacterial vaginosis; CT, chlamydia; NG, gonorrhoea; TV, trichomoniasis.

Table 2 Univariate logistic regression of the association for each item of the screening tool, clinical signs of infection, and detected reproductive tract infections

Parameter	All women (n=303)		NG and/or CT (n=298)		NG, CT, TV (n=303)		NG, CT, TV, BV (n=303)	
	n (%)		Negative n (%)	Positive n (%)	OR (95%CI)	Negative n (%)	Positive n (%)	OR (95%CI)
Age (years)								
≥25	264 (87)		228 (91)	32 (70)	Ref.	207 (90)	57 (77)	Ref.
<25	39 (13)		24 (10)	14 (30)	4.54 (2.12 to 9.83)	22 (10)	17 (23)	2.81 (1.39 to 5.63)
Live separately from partner								
No	109 (36)		94 (37)	13 (28)	Ref.	86 (38)	23 (31)	Ref.
Yes	194 (64)		158 (63)	33 (71)	1.51 (0.76 to 3.03)	143 (63)	51 (69)	1.36 (0.76 to 2.33)
Spotting/bleeding after sex								
No	289 (95)		241 (96)	43 (93)	Ref.	218 (95)	71 (96)	Ref.
Yes	14 (5)		11 (4)	3 (7)	1.52 (0.41 to 5.71)	11 (5)	3 (4)	0.84 (0.22 to 3.09)
Secondary schooling								
Completed	63 (21)		52 (21)	30 (22)	Ref.	43 (19)	6 (8)	Ref.
Not complete	240 (79)		198 (79%)	35 (79)	0.92 (0.43 to 1.99)	186 (81)	68 (92)	1.30 (0.66 to 2.57)
Sexually active								
No	49 (16)		45 (18)	2 (4)	Ref.	43 (19)	6 (8)	Ref.
Yes	254 (84)		207 (82)	44 (96)	4.78 (1.1 to 20.45)	186 (81)	68 (92)	2.62 (1.06 to 6.43)
Condom use*† (n=254)								
Consistent	147 (58)		121 (58)	25 (57)	Ref.	106 (57)	41 (60)	Ref.
Inconsistent	107 (42)		86 (42)	19 (43)	1.07 (0.55 to 2.00)	80 (43)	27 (40)	0.84 (0.50 to 1.54)
Abnormal vaginal discharge								
No	255 (86)		218 (88)	35 (76)	Ref.	201 (90)	54 (73)	Ref.
Yes	42 (14)		31 (12)	11 (24)	2.2 (1.02 to 4.79)	22 (10)	20 (27)	3.38 (1.72 to 6.65)

*Condom use is a follow-up question for women who report being sexually active. A value of 1 is assigned for inconsistent condom use with partner(s).

†Observed by clinician at screening and not part of the screening tool.

BV, bacterial vaginosis; CI, confidence interval; CT, chlamydia; NG, gonorrhoea; OR, odds ratio; Ref, reference group; TV, trichomoniasis.

Table 3 Performance of the screening tool in predicting risk of reproductive tract infection among women living with HIV (WLHIV) who were living in Cape Town, South Africa

Parameter	Categorisation of the risk score		
	1–5 vs 0	2–5 vs 0–1	3–5 vs 0–2
NG, CT, TV or BV			
Sensitivity (%)	95 (89–98)	67 (57–75)	32 (24–41)
Specificity (%)	3 (1–7)	29 (23–37)	78 (71–84)
PPV (%)	38 (32–44)	37 (31–44)	47 (36–59)
NPV (%)	50 (21–79)	59 (49–69)	65 (58–71)
NG, CT, TV or BV (risk assessment tool + abnormal discharge)			
Sensitivity (%)	96 (90–99)	76 (67–83)	49 (40–59)
Specificity (%)	3 (1–7)	28 (21–35)	74 (67–80)
PPV (%)	39 (33–45)	40 (33–47)	55 (45–65)
NPV (%)	55 (23–83)	64 (52–75)	69 (62–78)
NG, CT or TP			
Sensitivity (%)	97 (91–99)	73 (61–83)	38 (27–50)
Specificity (%)	4 (2–8)	32 (26–38)	78 (72–83)
PPV (%)	25 (19–30)	26 (20–32)	36 (25–48)
NPV (%)	83 (51–98)	79 (69–86)	80 (74–85)
NG and/or CT			
Sensitivity (%)	96 (85–99)	74 (59–85)	47 (32–63)
Specificity (%)	4 (2–7)	32 (26–38)	78 (73–83)
PPV (%)	15 (11–20)	17 (12–22)	29 (18–40)
NPV (%)	83 (51–97)	87 (78–93)	89 (84–93)

95% confidence intervals included for each estimate in parentheses. BV, bacterial vaginosis; CT, chlamydia; NG, gonorrhoea; NPV, negative predictive value; PPV, positive predictive value; TV, trichomoniasis.

no difference in the relative odds of RTI for inconsistent versus consistent reported condom use.

There was no cut point within the screening tool that produced both a reasonable sensitivity and specificity (table 3 and online supplementary figure 1). At the recommended threshold of 1+ for high RTI risk, the tool demonstrated high sensitivity (89%–98%) but low specificity (1%–7%) and failed to discriminate between infected and uninfected women. Use of the screening tool in conjunction with presence of abnormal vaginal discharge did not improve the tool's sensitivity or specificity. Excluding the detection of bacterial vaginosis alone increased the probability of not having gonorrhoea, chlamydia or trichomoniasis if scoring below the threshold. Increasing the threshold to 2+ and 3+ progressively decreased the sensitivity with a concordant increase in specificity for detecting any RTI. Restricting tool use to the prediction of gonorrhoea and/or chlamydia infection resulted in marginal improvements in sensitivity at all cut-off points, and the tool performed best at identifying gonorrhoea and/or chlamydia uninfected women at a threshold of 3+. When high RTI risk was defined as being younger than 25 years and sexually active (the two indicators most

strongly correlated with RTI), the negative predictive value for any RTI was 64%.

DISCUSSION

We detected high RTI prevalence among WLHIV screened prior to IUC insertion, but a validated risk-based screening tool did not discriminate RTI status among this population.¹⁶ At the recommended threshold, the screening tool failed to identify 97% of women without an RTI who could receive immediate IUC insertion, and, based on tool score, all women younger than 25 years would receive presumptive RTI treatment despite lower documented RTI rates.

In this cohort, bacterial vaginosis and trichomoniasis are the most prevalent RTIs, consistent with data from women at risk for HIV infection in sub-Saharan Africa, with some variation in individual estimates.^{20–22} In Uganda, gonorrhoea prevalence among WLHIV interested in IUC use was similar to our findings, but chlamydia prevalence was lower than reported in our South African population (1% vs 11%).²⁰ This difference may result from excluding women with a known RTI in the previous 3 months and/or who reported that their partners had other sexual partner(s) or a history of RTI in the Ugandan study, in addition to regional differences.²⁰ In a separate study of WLHIV in Cape Town, South Africa the prevalence of chlamydia and trichomoniasis were comparable to our findings, but BV prevalence was three-fold higher.²¹ In Johannesburg, South Africa the prevalence of any RTI (gonorrhoea, chlamydia or trichomoniasis) was 21% among WLHIV with no vaginal discharge, comparable with 25% observed in our data.²² A study among young (ages 16–22 years) HIV-negative women in Cape Town, South Africa, found very high RTI prevalence (47%), driven by chlamydia prevalence of 42%, comparable to our finding of 36% among WLHIV aged <25 years.²³ However, coinfection rates were lower than those of the general South African population and HIV-negative women of the same age group.^{21 24}

The tool's poor performance may be attributable to having only one of five indicators, being aged <25 years, associated with RTI detection in this population. Although this indicator is an established RTI risk factor, our finding of non-discriminatory power of these factors for RTI diagnosis is consistent with literature evaluating RTI screening based on a combination of age and reported condom use.^{7 23 25}

To our knowledge, this is the first study to evaluate this tool among WLHIV, which may be a possible explanation for the observed difference in the tool's performance, although the sociodemographic characteristics of the populations used to develop the risk tool did not vary considerably from our study population.¹⁶ The RTI prevalence was twice that of the population used to develop the tool, possibly accounting for the low specificity observed.¹⁶ However, the diagnostic accuracy of the risk scores did not increase

significantly when various thresholds were explored or when restricted to ART use status or RTI type.

Our findings should be considered amidst several limitations. Our data are limited to women considering IUC insertion and participation in a clinical trial, and thus may not be representative of WLHIV of reproductive age in this or other settings. Due to the nature of the screening tool we did not collect sociodemographic data from all women, which may limit important risk distinctions that may be drawn from these data. However, the tool captured age range and educational attainment, of which young age was a critical RTI predictor. Although behavioural and demographic data were collected by a trained nurse, some screening items are susceptible to social desirability bias, particularly self-reported condom use and number of sexual partners. This bias may have resulted in under-reporting of inconsistent condom use or having one or more sexual partners, contributing to the poor tool performance by decreasing specificity. However, one strength of our study is use of validated laboratory tests for definitive RTI diagnosis, providing the ability to measure the tool against multiple pathogens known to increase PID risk in the presence of an IUC.

CONCLUSIONS

In summary, we documented a high prevalence of RTIs among WLHIV interested in receiving an IUC. While using a risk assessment tool for RTI screening and management among women interested in IUC use appears feasible, this tool offers no additional value for RTI screening prior to IUC receipt in this population. However, women and their providers need to discuss balancing contraceptive need and RTI risk as many women may perceive risk of mistimed pregnancy from not receiving an IUC as outweighing the risk of PID with IUC insertion. There is an urgent need for development and expansion of innovative, affordable and robust point-of-care RTI tests.

Key messages

- ▶ There is a high prevalence of reproductive tract infections (RTIs) among women living with HIV and desiring long-term contraception in South Africa.
- ▶ Risk-based screening to identify RTIs in this population was of little value, even when used in conjunction with presence of symptoms such as abnormal vaginal discharge.
- ▶ There is an urgent need for development and expansion of innovative and affordable point-of-care RTI tests.

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Contributors NL managed data collection, conducted the analysis, and wrote the manuscript. CT developed the protocol and provided input on analysis and manuscript development. HJ assisted with analysis, protocol development, and manuscript preparation. DH contributed to analysis and manuscript development. N-CH contributed to the data cleaning and manuscript preparation. AR supervised data collection and study coordination. LM supervised data collection, analysis, and assisted with manuscript development. All authors commented extensively, reviewed the manuscript critically, and approved the final version.

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ORCID iD

Nontokozo Langwenya <http://orcid.org/0000-0001-7883-621X>

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