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Rapid Point-of-Care Testing for Genital Tract Inflammatory Cytokine Biomarkers to Diagnose Asymptomatic Sexually Transmitted Infections and Bacterial Vaginosis in Women: Cost Estimation and Budget Impact Analysis

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Background: Screening for genital inflammation can reveal asymptomatic cases of sexually transmitted infections (STIs) and bacterial vaginosis (BV), useful in settings where only syndromic management is available. This study aimed to estimate the incremental cost of screening using a new cytokine biomarker rapid test and determine the budget impact of providing this service in primary health facilities in South Africa.

Methods: Costs of adding genital inflammation screening to existing family planning services were estimated for women (15–49 years) attending 3 different family planning clinics in US $2016. The predicted unit cost per patient screened from a provider's perspective was calculated using bottom-up and top-down approaches and was used to analyze the budget impact of scaling up and providing this service in primary health facilities countrywide. Univariate sensitivity analyses tested the robustness of the findings.

Results: The incremental cost per woman screened for genital inflammation ranged between US $3.19 and US $4.79. The scaled-up costs ranged between US $7,245,775 and US $22,212,636 countrywide, annually. This was based on the number of women of reproductive age currently seeking contraceptive care at all primary health care facilities, as a proxy for those most susceptible to asymptomatic STIs/BV. The cost estimates were sensitive to changes in personnel costs, utilization rate, and population coverage rates.

Conclusions: This screening tool is likely to increase case detection, contributing to better STI/BV management and control, in addition to reducing women's risk of HIV acquisition. The incremental cost estimates could make implementation affordable.

Globally, sexually transmitted infections (STIs) and bacterial vaginosis (BV) remain a major public health concern, with 357 million new cases of curable STIs (chlamydia, gonorrhea, trichomoniasis, and syphilis) occurring in individuals aged 15 to 49 years annually.[1] It is estimated that developing countries account for 86% of the disease burden.[2,3] Studies have shown that STIs/BV increase HIV risk, which may partly be due to genital inflammation associated with these conditions.[4–8] Previous studies have found that 87% of STI cases and 90% of BV cases are asymptomatic in South Africa,[9,10] which is important because STIs/BV are managed syndromically, using a clinical algorithm based on presumptive clinical diagnosis by a healthcare practitioner, in resource-limited settings. Asymptomatic women will therefore not usually be treated. However, levels of genital inflammation tend to be similar in both symptomatic and asymptomatic women, suggesting a high risk of acquiring HIV and/or reproductive complications in asymptomatic women.[7,9,10]

Substantial effort has been put into developing and implementing strategies for improved diagnosis and management of STIs/BV and to accurately detect asymptomatic cases.[11–13] Although syndromic management has been widely adopted in Africa and globally, this approach has some important limitations, including poor sensitivity and specificity in diagnosing asymptomatic cases, coupled with high rates of overdiagnosis or misdiagnosis (and hence overtreatment with antibiotics and potential for increased drug resistance), and reliance of algorithms or flowcharts for diagnosis, which requires trained service providers.[14] Consequently, development of rapid point-of-care (POC) tests has become a major focus in the field, to replace or improve/complement syndromic management.[9,14,15] Point-of-care tests have considerable potential to provide prompt results and facilitate treatment within the same clinic visit as testing, on the same day.[16] In resource-limited settings, POC testing has been found to be time efficient and beneficial in patient retention for treatment, and a cost-saving strategy contributing to improved STIs management.[17–19] Contrarily, some of the POC tests in use are limited by poor sensitivity and specificity, and complexity in their utilization demonstrating the need to develop new POC tests with improved accuracy and comparability to laboratory testing.[13,20,21] The rapid cytokine biomarker POC test is a newly developed screening test that detects cytokines IL-1β and IP-10, which have been found to be predictive of an active STI, with 77% sensitivity, 72% specificity, 82%

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positive predictive value, and 65% negative predictive value.[22] Compared with the sensitivity of clinical signs (19%) of asymptomatic STIs and BV infections in HIV-uninfected women,[22] the 2 cytokine biomarkers have considerably improved sensitivity. This study estimates the predicted incremental costs of genital inflammation screening using a new cytokine biomarker rapid POC test (called the Genital Inflammation Test [GIFT]), developed by researchers at the University of Cape Town,[23] empirical cost of family planning services, and the budget impact of the implementation of GIFT in primary health facilities countrywide.

MATERIALS AND METHODS

Study Design

The GIFT screening intervention would be made available as part of the routine service provision; therefore, the study includes economic costs from the provider's perspective of the current family planning services in addition to the incremental cost of the GIFT screening intervention based on expected implementation. This incremental cost estimate for per woman screened was then used to analyze the budget impact of scaling up this intervention countrywide.

Study Setting and Population

Three health facilities in Cape Town were selected using convenience sampling: Desmond Tutu HIV Foundation Youth Centre (DTHF; Cape Town) managed by a nongovernmental organization (NGO), the University of Cape Town (UCT) Student Wellness Services Clinic funded by private sources and the government, and a South African government health clinic (Spencer Road Clinic, Woodstock, Cape Town). The study population included women 15 to 49 years of age attending family planning services at each of these clinics. The utilization data for the study population who attended the family planning clinics in the 3 facilities was collected from electronic clinic records.

Description of the Screening

We described the screening procedure and test to potential patients (woman of reproductive age attending the family planning) hypothetically, as the prototype of the GIFT device is currently being developed. We proposed that the nurse or doctor would explain the genital inflammation screening process to the patient during the clinic visit and obtain informed consent. The nurse would then collect a lateral vaginal wall swab, which would be applied to the lateral flow cytokine test device, in a tube containing buffer. The end of the swab would be snapped off, the lid closed, and the tube would be shaken vigorously. The swab would then be removed, and the end of the GIFT test strip dipped into the tube and taken out. The test strip would incubate for 5 minutes after which the results would be readable and interpreted to the patient. If the test was positive, either another sample collected for STIs/BV etiologic laboratory testing for the cause of inflammation or that broad spectrum antibiotics would be administered directly. Currently, if the patient were offered etiologic testing for STIs/BV after a positive inflammation test result, she would be contacted to return to the clinic for the results and appropriate treatment. This screening process is predicted to take an average of 10 minutes per patient.

TABLE 1. Methods and Data Used in Estimating Costs: Identifying and Measuring CAPITAL Costs

Type of Cost	Identification	Measurement			Valuation	
Capital Costs	Categories	Costing Method	Related Information for Allocation Purposes	Source of Data	Valuation Method	Source of Data
Building	Consulting room, waiting room, toilet	Current replacement cost (CSIR building costs per m^2 × square meter of facility) 20-y life span. 3% discount or annuitization	Space (square meters) Number of consultations and type of service	Observation and record reviews	Replacement and contract prices	Department of Public Works, building contractors
Medical equipment	Weighing scale, blood pressure machine, stethoscope, examination couch, bed screen, trolley	Actual current replacement cost 5-y life span 3% discount rate for annuitization	Resources used by family planning clinic Number of consultation and type of service	Observation and record reviews	Replacement and contract prices for equipment	Clinic expenditure records, commercial price lists
Furniture and other equipment	Tables, chairs, cabinets, office stationery, computer, printer, telephone	Actual current replacement cost. 15-y life span for furniture and 5-y life span for equipment 3% discount rate for annuitization	Resources used by the family planning clinic Number of consultation and type of service	Observation and record reviews	Replacement and contract prices	Clinic records and contracts, commercial price lists
In-service training	Personnel; doctors and nurses	Actual current cost of training 5-y life span 3% discount rate for annuitization	Number of staff trained Time spent on different services by these staff	Management, training records	Course fees; for in-house training—staff remuneration	Remuneration packages of trainers (nurses)

CSIR indicates Council for Scientific and Industrial Research of South Africa; m^2, meters squared.

TABLE 2. Methods and Data Used in Estimating Costs: Identifying and Measuring Recurrent Costs

Type of Cost	Identification	Measurement			Valuation	
Recurrent Cost	**Categories**	**Costing Method**	**Related Information for Allocation Purposes**	**Source of Data**	**Valuation Method**	**Source of Data**
Overheads	Electricity, water, and other utilities Rent (where applicable) Telephones, faxes, and postage Stationery, computer consumables, and photocopies	Actual costs from facility records	Number of consultations per type of service Space (square meters) used by each cost center for utilities and rent	Procurement records, observation	Expenditure records	Expenditure records
Personnel	Direct staff (doctors, nurses) Support staff (counselor, administration, receptionist, manager, cleaning staff, data capturer)	Total remuneration costs (salary and all benefits) Calculate separately for each category of personnel listed	Number of consultations per type of service Time spent on different types of services	Observation (clinic visits per facility) and financial record reviews	Gross salary per annum, including benefits (cost to clinic)	Clinic facility salary packages
Medical and surgical supplies	Relevant medical supplies	Actual costs from facility/service records (where "internal") Unit costs to be obtained from supplier (e.g., provincial depot) where "external"	Detailed list of types, quantities, and unit costs of all medical supplies required	Observation (clinic visits per facility) and financial records reviews	Tender contract prices and expenditure records	Supply chain management: records, contracts; medical supplies services: contracts, records
Diagnostic test (cytokine biomarker test)	Cytokine biomarker test device	Cost estimation from manufacturing company	Number of consultations per type of service	Expert opinion	Manufacturing company price list	Manufacturing company price list
Maintenance		Actual costs of supplies related to maintenance activities	Number of consultations per type of service	Observation, record reviews	Clinic expenditure records	Clinic expenditure records

Costing Methods

We adopted top-down and bottom-up approaches to calculate the incremental cost of the screening during a family planning clinic visit. The incremental cost of all cost categories (for capital [building, furniture and equipment, and procedure training] and recurrent costs [personnel, medical supplies, overheads, and maintenance]) was calculated using the proportion of the time taken for genital inflammation screening in a family planning visit as summarized in Tables 1 and 2 as well as the Supplementary Appendix (http://links.lww.com/OLQ/A760). We included the GIFT diagnostic test estimated to cost less than US $0.30 per test by the manufacturing company.

Cost data were collected for the period March 2016 to February 2017. We observed family planning consultations, interviewed staff, and reviewed facility and financial reports to estimate the resources used for all inputs of the current family planning and additional GIFT screening process. On-site training on the GIFT screening process was based on the time spent on training by the nurse and valued using gross salary. Capital costs were annuitized at a 3% discount rate using a useful life of 20 years for buildings, 15 years for furniture, and 5 years for equipment and training.[24,25] Test costs were calculated by multiplying the quantity of anticipated inputs used by their price. Using a full costing approach for existing services, we estimated the incremental unit cost per patient screened for each facility for a 1-year period. The costs were estimated in 2016 South African Rand (ZAR) and then converted to US dollars using an average exchange rate of US $1 = ZAR14.72 derived from oanda.com and accessed on April 5, 2016.

Budget Impact Analysis

An expenditure-based model was developed in Microsoft Excel to estimate the budget impact of the intervention. The modeling was done using a 2-step approach. First, the size of the target population was determined using available demographic and contraception coverage rate data.[26,27] The target group based on the contraception prevalence rate within South Africa reflects women of reproductive age who are most susceptible to asymptomatic STIs/BV, resulting in genital inflammation. Second, the incremental unit cost of estimate from the study was used to scale up and provide national annual estimates under various coverage rates based on the estimated number of women in 2016.

Assumptions

Based on the prospective nature of the study, for the baseline costs, we assumed that (1) the contraception coverage rates were representative of the number of women aged 15 to 49 years attending family planning clinics, with an average of 57% in South Africa[28]; (2) this would be a once-off screening for every woman per year in addition to currently used primary prevention interventions for HIV prevention[29]; (3) women would attend a government, semiprivate, or NGO-funded primary health facility; (4) the screening program occurs at a primary care level as the scaling up is modeled at this level; and (5) the screening intervention would be made available as part of the routine service provision; therefore, no additional scaling-up costs would be included.

Data Analysis

Data were analyzed using a costing-based model in Microsoft Excel 2013. The total costs at the facility level were added up and divided by the total number of female patients attending the family planning clinic in 2016/17. The budget impact analysis was based on the South African national health budget estimates for 2016. With no evident specific budget for STIs services, the total public health expenditure estimate was used to analyze the budget impact of this screening service.[30]

Sensitivity Analyses

The robustness of the findings was explored by performing univariate sensitivity analyses using alternative assumptions on parameters that had uncertainty. For the cost estimates, we varied the total personnel costs, the test device price, and the service utilization figure by 50%. For the budget impact analysis, the coverage rate of 57% in the base case analysis was increased by 5% to assess the difference with increased family planning coverage. In addition, the eligible population was limited to a potential high-risk group (<25 years),[31s] to provide insight into the most feasible level of implementation.

Ethical Considerations

The UCT, Faculty of Health Sciences, Human Research and Ethics Committee granted ethical approval for this study (HREC 787/2016, HREC 365/2017).

RESULTS

Unit Cost Estimates

The unit cost of genital inflammation screening per woman at the Spencer Road government clinic (US $3.19) was lowest followed by the UCT Student Wellness Services (US $4.16) and the DTHF Youth Centre (US $4.79; Table 3). The total capital costs for the Spencer Road government clinic were significantly lower at US $0.12 compared with US $0.15 and US $0.70 at the UCT Student Wellness Services Clinic and DTHF Youth Centre, respectively.

TABLE 3. Incremental Unit Costs of Genital Inflammation Screening in 2016 US $

Cost Category	Youth Center (n = 2137)	Student Wellness Center (n = 1687)	Government Clinic (n = 4815)
Capital costs			
Buildings	0.57	0.05	0.08
Equipment and furniture	0.08	0.04	0.01
Procedure training	0.05	0.06	0.02
Total capital costs	0.70	0.15	0.12
Recurrent costs			
Personnel	2.14	2.09	1.37
Medical supplies	0.97	0.97	0.97
Diagnostic GIFT test	0.30	0.30	0.30
Overheads and maintenance	0.68	0.66	0.44
Total recurrent costs	4.08	4.01	3.07
Total unit cost	4.79	4.16	3.19

GIFT indicates Genital Inflammation Test; n, number; US $, US dollar.

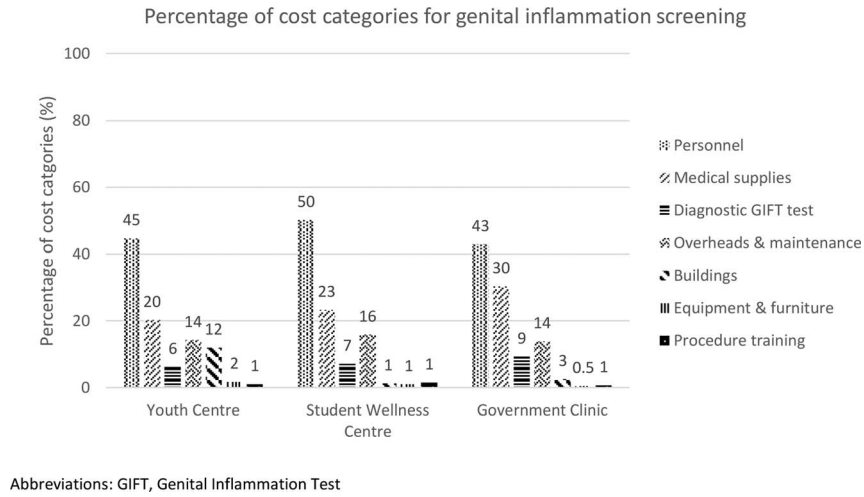

Figure 1. Percentage of cost categories for genital inflammation screening at different study sites.

At all facilities, the personnel costs were the main cost driver and accounted for 43% to 50% of the budget, followed by overhead costs ranging between 14% and 16% of costs. The training costs were 1% for all facilities (Fig. 1).

Budget Impact Analysis

At an estimated coverage rate of 57%, a total of 6,959,537 and 956,936 women would be screened in public and private health facilities, respectively, countrywide (Table 4). The estimated annual expenditure for screening differs by the type of health facility that the women would attend for screening, ranging from US $22,212,636 (Spencer Road; government), to US $3,985,176 (UCT Wellness; public-private), to US $4,579,947 (DTHF Youth Centre; NGO). Because the screening intervention would be made available as part of the routine service provision at a primary health care level, no additional scaling-up costs would be incurred. With the total target population of 6,959,537 women to be screened, the total annual resources required for this service provision in government clinics (US $22,212,636) are 0.85% of the annual total health budget (US $2,619,789,402).[30]

Sensitivity Analyses

The unit costs were not sensitive to variation in the test device price (approximately 3%–5% of the unit cost) but were sensitive to changes in the total personnel costs and changes in the utilization rates, which carried a higher proportion of the total cost. For the budget impact, the total cost of screening was sensitive to the variation of the target population coverage (Table 5).

DISCUSSION

To our knowledge, this is the first costing study to assess the cost implications of implementing a novel cytokine POC test in public sector reproductive health clinics, to test for genital inflammation associated with asymptomatic and symptomatic STIs/BV in women aged 15 to 49 years in South Africa. This is important because introduction of a novel inflammation POC cytokine test would address a major gap in diagnosis of asymptomatic cases of STIs or BV, which are the majority. The incremental unit cost estimates varied between the 3 types of primary health facilities, being lowest at the government health facility (US $3.19 at the Spencer Road clinic) compared with the public-private health facility (US $4.16 at UCT Wellness Centre), or an NGO-funded health facility (US $4.79 at DTHF Youth Centre), in the Western Cape. As we anticipated, the unit cost of the actual test made up a negligible fraction of the estimated unit cost estimates (US $0.30 per POC test). A strength of this analysis was that comprehensive cost data were collected from a provider's perspective and from health facilities offering different primary health services. The range in the unit costs could be attributed to 3 main factors. First, both the public sector and the public-private facilities receive government subsidies for resources used in the screening intervention, whereas the NGO clinic does not. Second, the public sector and the public-private facilities are public entities that offer comprehensive health services and therefore benefit from economies of scale in terms of facility operating costs, and also purchasing health service inputs at the government level. The DTHF Youth Centre, in contrast, is a single-entity NGO operating at a lower

TABLE 4. Estimated Expenditure of Genital Inflammation Screening in Women in 2016 US $

		Source	
Total women (15–49 y), n	15,262,143	Stats SA (2016)[26]	
Contraception coverage rate, %	57	SADH (2016)[44s]	
	Target Population to Be Screened, n	**Total Cost of Screening, US $**	
Population using public health facilities (80%), n SADH (2016)[26]		Government clinic	
12,209,714	6,959,537	22,212,636	
Population using private health facilities (11%), n SADH (2016)[26]		Youth center	Student wellness center
1,678,836	956,936	4,579,947	3,985,176

n indicates number; SADH, South Africa Demographic and Health Survey; Stats SA, Statistics South Africa; US $, US dollar.

TABLE 5. Univariate Sensitivity Analyses for the Unit Cost Estimates in 2016 US $

	Unit Costs, US $					
Parameter	**Youth Center**	**% Change**	**Student Wellness Center**	**% Change**	**Government Clinic**	**% Change**
Base case	4.79		4.16		3.19	
Test device price						
−50%	4.64	−3	4.02	−3	3.04	−5
+50%	4.93	+3	4.31	+3.6	3.34	+5
Utilization rate						
−50%	4.45	−7	3.83	−8	2.98	7
+50%	5.13	+7	4.49	+8	3.42	7
Personnel costs (total)						
−50%	3.72	−22	3.12	−25	2.51	−21
+50%	5.85	+22	5.21	+25	3.88	+21

Coverage Rate	**Eligible Population**	**Total Cost, US $**	**Budget Impact, %**
Base-case scenario (15–49 y)	6,959,537	22,212,635.93	0.85
Increase CPR (5%)	7,570,023	24,161,112.76	0.92
High-risk population (15–25 y)	2,314,757	7,387,969.63	0.28

CPR indicates contraception prevalence rate; US $, US dollar.

scale. Third, the public-private and NGO entities have salary scales slightly above the public sector salaries contributing to the varied personnel costs across the entities. In addition, the personnel cost is depended on the health worker cadre conducting the screening.

There is a paucity of data estimating the costs associated with STI/BV screening using rapid tests (including nucleic acid amplification tests against specific etiologic agents), particularly in low- and middle-income countries. A study of a new POC test for *Chlamydia trachomatis* infection in the United States (in 2011) estimated the testing cost per patient to be US $33.48.[32s] Another study in 2014 estimated the cost per patient of rapid testing for chlamydia and gonorrhea to be $24.46.[32s,33s] Although these costs are similar to our findings in the NGO setting, both were conducted in developed countries and therefore may not be generalizable to this study. In comparable settings, a cost-effectiveness study of rapid tests for antenatal syphilis screening showed the cost per patient screened (in 2012) to range between $1.9 and $6.5 in Tanzania, $2.2 and $5.6 in Zambia, and $2.63 and $4.95 in Peru.[34s] Similarly, studies analyzing costs for rapid POC tests used for detection of maternal syphilis found costs to range between $1.26 and $5.79 in Brazil (2006 US dollars, $1 = 2.14 Reais), $0.83 and $0.85 in Mozambique (2004 US dollars $1 = 23,500 Metical), and $1.14 and 1.43 in Bolivia (2004 US dollars, $1 = 8 Bolivians.[35s,36s] For BV, rapid POC testing (in 1999) ranged between $4.24 and $8.32 in Gambia (37), although very few BV rapid tests have shown good sensitivity and specificity. Each of these tests, however, tests for the individual etiologic agent (of which there are many) compared with this test, which aims to measure the common feature of all of these infections/conditions—genital inflammation. It is important to note that most of these studies excluded more substantial cost categories in the analysis (facility fees, staff) and excluded the economic costs of screening, contrary to our study.

Other studies have shown that rapid STI/BV POC tests, despite costing more than syndromic management, both are cost saving in the long term and have improved health outcomes by minimizing loss to follow-up, reducing false diagnosis, improving case finding (asymptomatic infections identified), and averting additional cases of disease complications.[19,32s,37s] This screening test detects cytokines IL-1B and IP-10, which have been found to be predictive of an active STI, with 77% sensitivity, 72% specificity, 82% positive predictive value, and 65% negative predictive value.[22] In line with this, scaling up the service of genital inflammation screening for women within family planning clinics would increase identification of asymptomatic women, have an impact on overtreatment, and improve STI/BV treatment and access of STI health services to women.

Despite the fact that the current standard of care (syndromic management) is not picking up the majority of infections, the affordability of any health intervention is central to decision makers in prioritizing and choosing between interventions.[38s,39s] The findings from the budget impact analysis indicate the budgetary need of the proposed genital inflammation screening test in relation to the national health budget, which needs to be carefully balanced against the cost of not capturing/treating asymptomatic STIs/BV with associated health risks (most importantly HIV and pregnancy complications). We have shown that the costs for providing the screening service in primary health facilities countrywide would amount to 0.85% of the total health budget if provided at a government health facility. It is important to note that this proposed GIFT aligns with the South Africa's HIV/STI prevention targets by 2022, which aim to increase identification of asymptomatic STI infections and reduce new HIV and STI cases.[40s]

Our study presents some limitations. First, because the cytokine biomarker POC test is yet to be piloted, we collected data from 3 potential pilot sites and in 1 urban setting only. Therefore, the findings can only be generalized to similar settings within South Africa. In our budget impact analysis, we assumed that all the women would be screened at these facilities, and this might not account for the limited access of such facilities to most women. Second, the time estimation may differ from the actual observation of the genital inflammation screening process. Third, the DTHF Youth Centre provides services to youth, which represents only a small subset of women of reproductive age. However, younger women are at higher risk for STIs/BV and HIV, so it is possible that an inflammation POC test for asymptomatic STIs/BV would be most impactful in younger-aged women. In addition, we assumed that women would be screened once per year (not accounting for costs of a repeat screening within the same year), which may lead to underestimation of the budget in forecasting future costs.

The policy recommendations for South Africa are outlined hereinafter, with the main caveat in making these recommendations being that the rapid POC test is yet to be piloted in health facilities. First, the target population is well defined, and implementation of the screening program to achieve 57% coverage may be feasible

within the current budget. However, it may be cost-effective to restrict the inflammation POC test to younger women (<25 years) who are at higher risk for STIs/BV.[32s] Therefore, it would be important to compare the cost-effectiveness of this screening intervention to other possible STI diagnostic interventions in similar settings. Subsequently, shifting of financial resources within HIV and tuberculosis programs or an increase in the national health budget would need to happen to avail more funds. Although we would argue that prevention of HIV infection by better management of STIs/BV should be seen as a priority. Accordingly, the estimated costs could inform immediate decisions about investments for STIs control programs in South Africa. Establishment of national funds specific to STI services would ensure efficient financial planning and budget allocation for these services. Third, the implementation of the screening program could be integrated into family planning services as a means to improve STI asymptomatic case detection and achieve the prevention targets for HIV and STI infections, as per the South African national strategic plan on HIV, tuberculosis, and STIs from 2017 to 2022.[40s] There is a clear need to address the massive HIV burden and risk in Southern Africa, to which asymptomatic STIs/BV contribute substantially,[11] and focusing genital inflammation screening during the period maximum risk for HIV infection, less than 25 years of age,[41s] would be a potential option in its implementation. Moreover, with the estimated unit costs of adult antiretroviral treatment per patient year at $249.15 (2017/2018) and female adolescent antiretroviral treatment per patient year at $122.42 (2071/2018),[42s,43s] genital inflammation screening would potentially save costs associated with lifetime HIV treatment.[42s]

In conclusion, we have presented incremental unit cost estimates of this genital inflammation POC test and have provided an indication of the budgetary requirements for national implementation. However, it would be important to additionally compare the costs per age category and also establish the cost-effectiveness of this screening intervention to compare the costs and health outcomes of other STI/BV diagnostic interventions in current use and to appreciate this cost in terms of HIV infections or adverse birth outcomes averted.

REFERENCES

1. World Health Organization. Sexually Transmitted Infections: Implementing the Global STI Strategy. Geneva, Switzerland: World Health Organization, 2017.
2. Toskin I, Peeling RW, Mabey D, et al. Point-of-care tests for STIs: the way forward. Sex Transm Infect 2017; 93:S1–S2.
3. Wi TE, Ndowa FJ, Ferreyra C, et al. Diagnosing sexually transmitted infections in resource-constrained settings: Challenges and ways forward. J Int AIDS Soc 2019; 22(Suppl 6):e25343.
4. Fleming DT, Wasserheit JN. From epidemiological synergy to public health policy and practice: The contribution of other sexually transmitted diseases to sexual transmission of HIV infection. Sex Transm Infect 1999; 75:3–17.
5. Mayer KH, Venkatesh KK. Interactions of HIV, other sexually transmitted diseases, and genital tract inflammation facilitating local pathogen transmission and acquisition. Am J Reprod Immunol 2011; 65:308–316.
6. Cohen CR, Lingappa JR, Baeten JM, et al. Bacterial vaginosis associated with increased risk of female-to-male HIV-1 transmission: A prospective cohort analysis among African couples. PLoS Med 2012; 9:e1001251.
7. Masson L, Mlisana K, Little F, et al. Defining genital tract cytokine signatures of sexually transmitted infections and bacterial vaginosis in women at high risk of HIV infection: A cross-sectional study. Sex Transm Infect 2014; 90:580–587.
8. Masson L, Passmore JA, Liebenberg LJ, et al. Genital inflammation and the risk of HIV acquisition in women. Clin Infect Dis 2015; 61:260–269.
9. Wilkinson D, Abdool Karim SS, Harrison A, et al. Unrecognized sexually transmitted infections in rural South African women: A hidden epidemic. Bull World Health Organ 1999; 77:22–28.
10. Mlisana K, Naicker N, Werner L, et al. Symptomatic vaginal discharge is a poor predictor of sexually transmitted infections and genital tract inflammation in high-risk women in South Africa. J Infect Dis 2012; 206:6–14.
11. Mayaud P, McCormick D. Interventions against sexually transmitted infections (STI) to prevent HIV infection. Br Med Bull 2001; 58:129–153.
12. Bowden FJ, Tabrizi SN, Garland SM, et al. Infectious diseases. 6: Sexually transmitted infections: New diagnostic approaches and treatments. Med J Aust 2002; 176:551–557.
13. Eden PR, Johnson J. Point-of-care testing and its implications for STIs. MLO Med Lab Obs 2016; 48:22, 24.
14. Sonko R, McCoy D, Gosa E, et al. Sexually transmitted infections: priority programmes. South African Health Rev 2002; 2002:257–277.
15. World Health Organization. Sexually Transmitted Infections (STIs): The Importance of a Renewed Commitment to STI Prevention and Control in Achieving Global Sexual and Reproductive Health. Geneva, Switzerland: WHO, 2013:8.
16. Pai M, Ghiasi M, Pai N. Point-of-care diagnostic testing in global health: What is the point. Microbe 2015; 10:103–107.
17. Swain GR, McDonald RA, Pfister JR, et al. Decision analysis: point-of-care chlamydia testing vs. laboratory-based methods. Clin Med Res 2004; 2:29–35.
18. Drain PK, Hyle EP, Noubary F, et al. Diagnostic point-of-care tests in resource-limited settings. Lancet Infect Dis 2014; 14:239–249.
19. Herbst de Cortina S, Bristow CC, Joseph Davey D, et al. A systematic review of point of care testing for *Chlamydia trachomatis*, *Neisseria gonorrhoeae*, and *Trichomonas vaginalis*. Infect Dis Obstet Gynecol 2016; 2016:4386127.
20. Campbell L, Woods V, Lloyd T, et al. Evaluation of the OSOM *Trichomonas* rapid test versus wet preparation examination for detection of *Trichomonas vaginalis* vaginitis in specimens from women with a low prevalence of infection. J Clin Microbiol 2008; 46:3467–3469.
21. Watchirs Smith LA, Hillman R, Ward J, et al. Point-of-care tests for the diagnosis of *Neisseria gonorrhoeae* infection: A systematic review of operational and performance characteristics. Sex Transm Infect 2013; 89:320–326.
22. Masson L, Arnold KB, Little F, et al. Inflammatory cytokine biomarkers to identify women with asymptomatic sexually transmitted infections and bacterial vaginosis who are at high risk of HIV infection. Sex Transm Infect 2016; 92:186–193.
23. Masson L, Barnabas S, Deese J, et al. Inflammatory cytokine biomarkers of asymptomatic sexually transmitted infections and vaginal dysbiosis: A multicentre validation study. Sex Transm Infect 2019; 95:5–12.
24. Walker D, Kumaranayake L. Allowing for differential timing in cost analyses: Discounting and annualization. Health Policy Plan 2002; 17:112–118.
25. Drummond MF, Sculpher MJ, Claxton K, et al. Methods for the Economic Evaluation of Health Care Programmes. Oxford, United Kingdom: Oxford University Press, 2015.
26. Statistics SA. Mid year population estimates. Pretoria, South Africa: Statistics South Africa, 2016. Contract No.: P0302. Available at: statssa.gov.za. Accessed April 6, 2020.
27. Chersich MF, Wabiri N, Risher K, et al. Contraception coverage and methods used among women in South Africa: A national household survey. S Afr Med J 2017; 107:307–314.
28. Chola L, MacQuilkan K, Winch A, et al. Projecting the fiscal impact of South Africa's contraceptive needs: Scaling up family planning post 2020. S Afr Med J 2019; 109:756–760.
29. Steen R, Wi TE, Kamali A, et al. Control of sexually transmitted infections and prevention of HIV transmission: mending a fractured paradigm. Bull World Health Organ 2009; 87:858–865.
30. National Treasury SA. Estimates of National Expenditure. Pretoria, South Africa: National Treasury SA, 2017. Report No.: 09/2017.

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