

## SYNDROMIC MANAGEMENT VERSUS POINT-OF-CARE, AND LAB-BASED TESTING FOR CHLAMYDIA AND GONORRHOEA: A COST COMPARISON

### Background

*Chlamydia trachomatis* (CT) and *Neisseria gonorrhoea* (NG) infections are two of the most common sexually transmitted infections (STIs) worldwide, and can result in serious long-term sequelae for women and newborns.<sup>1</sup> In South Africa, STIs constitute a significant public health burden. Adolescents and young women are particularly at risk, with prevalence rates of 33.5% for CT and 11.1% for NG reported in 16-24 year old women.<sup>2</sup>

Detection and treatment of CT and NG infections are challenging in many under-resourced settings. In South Africa, syndromic management of STIs is the current standard of care in the public health sector. Syndromic management refers to treatment based on a group of signs and symptoms, referred to as a syndrome. Diagnosis of the exact etiological agent, or pathogen, is not done. Unfortunately, however, many CT and NG infections are asymptomatic, especially in women, and thus many infected individuals never present for treatment.

Recently, the World Health Organization (WHO) recommended that countries with sufficient resources adopt etiological testing for STIs.<sup>3</sup> In this study, we estimated the costs of syndromic management versus point-of-care testing for CT/NG in adolescents.

### Methods

We derived the service information and CT/NG prevalence for this costing study from an NGO-run clinic and youth centre located near Cape Town, South Africa. Syndromic management of STIs was the standard of care at the clinic. However, for a study conducted in 2017, both symptomatic and asymptomatic adolescents were offered on-site point-of-care testing using Xpert CT/NG testing systems (Xpert) (Cepheid, Sunnyvale, CA).<sup>4</sup>

We estimated health system costs, in 2017 US dollars, for three scenarios (Table 1). For (1) syndromic management (SM) and (2) POC testing and treatment (POC), we conducted micro-costing at the study clinic. We visited the study clinic, observed services, and noted the resources required. Costs for the resources were obtained from clinic records and publicly available sources. Costs included were: personnel, consumable supplies, equipment, medications, and overheads (space/utilities, etc). Calculations were done in Excel using a model built for this analysis. We assumed the purchase price for the Xpert instrument was \$18,270, its working life 5 years, and the public-sector price of CT/NG cartridges were \$17.74 each. We used a discount rate of 6.5% for annualising capital costs.

Given the existence of Xpert instruments for tuberculosis (TB) testing in laboratories throughout South Africa, we also estimated costs for a hypothetical scenario: (3) CT/NG testing done using Xpert instruments based in local public laboratories for TB testing (**Lab**). As the Xpert CT/NG test is not currently provided by laboratories, we assumed that the cost of the test would be equal to the current, published cost of Xpert TB testing (\$13.63) by national public laboratories.<sup>5</sup>

For all scenarios, the adolescents were welcomed by a clerk and then seen in a consulting room.

- 1) In the **SM scenario**, a professional nurse asked about symptoms, and if indicated, performed a physical examination. If signs and symptoms were observed, the nurse prescribed treatment, which was dispensed by an on-site pharmacist.
- 2) In the **POC scenario**, a professional nurse asked everyone, regardless of symptoms, to provide a urine sample that was tested using Xpert on the same day in an on-site laboratory by a trained technician. The adolescents were asked to wait 90 minutes for the POC test results. If unable to wait, they were asked to come back another day. A counsellor phoned to remind them to return. If positive, treatment was prescribed by a professional nurse and dispensed by an on-site pharmacist. Symptomatic adolescents with a negative test result were treated with an oral antibiotic and an anti-fungal medication for suspected bacterial vaginosis, *trichomonas vaginalis*, and/or candidiasis.
- 3) The hypothetical **Lab scenario** was the same as the POC scenario with one exception. Urine samples were assumed to be sent to a nearby laboratory for testing, and individuals who tested positive were recalled to the clinic for treatment.

**Table 1: Summary of scenarios**

Scenarios:	SM	POC	Lab
<b>Hypothetical or observed?</b>	Observed	Observed	Hypothetical
<b>Patients tested?</b>	Symp. only	Symp. and asymp.	Symp. and asymp.
<b>Consultation?</b>	Yes	Yes	Yes
<b>Physical exam?</b>	Yes	If symp.	If symp.
<b>Xpert testing?</b>	No	Yes: on-site	Yes: lab-based
<b>Same day Tx?</b>	Yes	If positive	No
<b>Disease-specific Tx?</b>	No	Yes for CT/NG*	Yes for CT/NG*

Symp. = symptomatic; asymp. = asymptomatic; Tx = treatment

\* Treatment was disease-specific for CT/NG, but not for other STIs if symptomatic and CT/NG negative.

## Results

Between February 2016 and July 2017, 535 patients were seen for syndromic management. In contrast, 216 patients were seen for testing with Xpert between February and July 2017.<sup>4</sup>

Table 2 presents the average total cost per patient seen or tested. In the SM scenario, we present the average cost *per patient seen*. In the POC and Lab scenarios, we present the average costs *per patient tested*. Treatment for positive cases is also included.

The cost per patient seen for syndromic management was least costly at \$16.01. Etiological treatment with Xpert cost \$55.70 per patient tested, when done on-site in the POC scenario. Off-site Xpert testing in the Lab scenario was less expensive at \$28.84 per patient tested.

Personnel costs comprised two-thirds of total costs for syndromic management; whereas equipment costs, which were mainly Xpert costs, were two-fifths of the POC scenario costs. For off-site testing, the laboratory charge was nearly 50% of the total cost.

**Table 2: Average total cost per scenario (and per cost component) for CT/NG management or testing (2017 USD)**

	Cost	Uncertainty range*	% of total
<b>Scenario 1: SM – Syndromic management (Cost per case seen)</b>			
Personnel	10.61	(7.96-13.26)	66.3%
Supplies	0.48	(0.36-0.59)	3.0%
Equipment	1.57	(1.18-1.97)	9.8%
Laboratory	-	-	-
Medicine	0.91	(0.91-0.91)	5.7%
Overhead	2.44	(1.83-3.05)	15.2%
<b>Total</b>	<b>16.01</b>	<b>(12.23-19.78)</b>	<b>100.0%</b>
<b>Scenario 2: POC – Point-of-care (Cost per case tested)</b>			
Personnel	11.54	(8.66-14.43)	20.7%
Supplies**	18.73	(14.04-23.41)	33.6%
Equipment**	22.63	(16.97-28.29)	40.7%
Laboratory	-	-	-
Medicine	0.25	(0.25-0.25)	0.5%
Overhead	2.54	(1.91-3.18)	4.5%
<b>Total</b>	<b>55.70</b>	<b>(41.84-69.56)</b>	<b>100.0%</b>
<b>Scenario 3: Lab – Testing at state laboratory (Cost per case tested)</b>			
Personnel	10.36	(7.77-12.96)	35.9%
Supplies	0.78	(0.58-0.97)	2.7%
Equipment***	1.46	(1.09-1.82)	5.1%
Laboratory***	13.63	(10.32-17.04)	47.3%
Medicine	0.25	(0.25-0.25)	0.9%
Overhead	2.35	(1.76-2.94)	8.2%
<b>Total</b>	<b>28.84</b>	<b>(21.69-35.98)</b>	<b>100.0%</b>

\*Cost ranges represent uncertainty analysis (i.e.  $\pm 25\%$  for staff time and supply and equipment costs). Medicine costs are not varied because they are based on published South African tender prices.

\*\*Xpert instrument costs for the POC scenario are included under equipment, and cartridge costs under supplies.

\*\*\*For the Lab scenario, the laboratory costs are the charge for testing. They include the cartridge costs and reflect the shared use of the Xpert instrument at the laboratory. Equipment in the Lab scenario includes other equipment such as the examination bed, desks, etc.

## Policy relevance

In this analysis, syndromic management was the least costly option. It requires skilled personnel but minimal supplies, equipment, and medication.

Comparing the POC and Lab scenarios, the lower cost per patient tested/treated in the Lab scenario (which was estimated based on existing TB test charges by the laboratory) was mainly achieved through assuming higher testing volumes at the off-site laboratory. Similarly, a prior cost evaluation of Xpert testing for TB showed that off-site testing in public laboratories was less costly than on-site point-of-care testing.<sup>6</sup>

The costs presented here are calculated per case seen or tested. To better understand the cost differences between these testing strategies, one must consider the number of positive cases identified and correctly treated. Missed cases, especially in asymptomatic individuals, are a significant problem with syndromic management. In a South African setting, the sensitivity and specificity of diagnosing CT/NG based on self-reported symptoms has been shown to be as low as 50% and 53% respectively.<sup>4</sup>

Despite higher costs per case tested, the WHO has recommended etiological testing in countries that can afford it as part of its 2016-2021 strategy for global STI control.<sup>3</sup> The added cost of etiological testing is possibly less than that of syndromic management if one considers the costs of caring for the many short- and long-term sequelae of untreated STIs, including ectopic pregnancy, pelvic inflammatory disease, and infertility in women, and additional complications for newborns. However, establishing this would require additional analysis.

## References

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**Funding Statement:** This work was funded by United States Agency for International Development (USAID) through co-operative agreement 674-A-12-00029. The authors' views expressed in this publication do not necessarily reflect the views of the United States Agency for International Development or the United States Government.

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*Suggested citation:* Lince-Deroche N, Roseleur J, Leuner R, Kgwedi S, Marcus R, Meyer-Rath G. Syndromic management versus point-of-care and lab-based testing for chlamydia and gonorrhoea among adolescents in South Africa. Johannesburg: HE<sup>2</sup>RO Policy Brief Number 27, Health Economics and Epidemiology Research Office, October 2018.