The costs of accessible quality assured syphilis diagnostics: informing quality systems for rapid syphilis tests in a Tanzanian setting

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Objectives To determine the costs of Rapid Syphilis Test (RSTs) as compared with rapid plasma reagin (RPR) when implemented in a Tanzanian setting, and to determine the relative impact of a quality assurance (QA) system on the cost of RST implementation.

Methods The incremental costs for RPR and RST screening programmes in existing antenatal care settings in Geita District, Tanzania were collected for 9 months in subsequent years from nine health facilities that varied in size, remoteness and scope of antenatal services. The costs per woman tested and treated were estimated for each facility. A sensitivity analysis was constructed to determine the impact of parameter and model uncertainty.

Findings In surveyed facilities, a total of 6362 women were tested with RSTs compared with 224 tested with RPR. The range of unit costs was $1.76–$3.13 per woman screened and $12.88–$32.67 per woman treated. Unit costs for the QA system came to $0.51 per woman tested, of which 50% were attributed to salaries and transport for project personnel.

Conclusions Our results suggest that rapid syphilis diagnostics are very inexpensive in this setting and can overcome some critical barriers to ensuring universal access to syphilis testing and treatment. The additional costs for implementation of a quality system were found to be relatively small, and could be reduced through alterations to the programme design. Given the potential for a quality system to improve quality of diagnosis and care, we recommend that QA activities be incorporated into RST roll-out.

Keywords Diagnosis, economic evaluation, sexually transmitted infections, maternal and child health, quality control
KEY MESSAGES

- Rapid syphilis diagnostics are very inexpensive in this Tanzanian setting, and may help to improve access to screening for syphilis in antenatal care.
- The incremental costs for a quality assurance (QA) system were found to be relatively small, and further cost reductions can be found through programme design alterations.
- Rapid diagnostics are currently being implemented in many low-resource settings. We argue that roll-out should include a robust QA system in order to ensure validity and quality of diagnosis and care.

Introduction

The burden of curable sexually transmitted diseases remains high in many low-income countries. According to a World Health Organisation (WHO) estimate, 12 million people are infected with syphilis each year, and 90% of infections take place in low-income countries (World Health Organization 2007). Syphilis in pregnancy is a leading cause of adverse birth outcomes, and is believed to contribute to 650,000 fetal and neonatal deaths each year in developing countries (Kamb et al. 2010).

Adverse outcomes attributable to maternal syphilis infection can be prevented with a single dose of benzathine penicillin (Hawkes et al. 2011; Watson-Jones et al. 2002b). As symptoms of primary syphilis are often unnoticed in women and later stages are often asymptomatic, universal screening for syphilis during pregnancy is the preferred intervention for control of congenital syphilis and is policy in most sub-Saharan African countries (Hook and Peeling 2004; Peeling et al. 2006b; Peeling and Ye 2004; Mabey et al. 2001).

The traditional lab-based diagnostic for detection of syphilis, the rapid plasma reagin (RPR) test, has achieved low coverage in low-resource settings due to a number of implementation barriers such as lack of electricity, equipment and training; according to Gloyd et al. (2001), only 38% of all pregnant women are screened for syphilis in sub-Saharan Africa. The RPR test cannot be performed on whole blood, and requires a refrigerator for the reagents and a rotator for test processing (Hook and Peeling 2004; Peeling et al. 2006b; Peeling and Ye 2004; Mabey et al. 2001). Furthermore, even where screening is available, diagnostics such as RPR are commonly carried out by users without lab training and in the absence of a quality system or supportive supervision. While RPR has good sensitivity and specificity when performed in a lab setting, ranging from 86% to 100% and 93% to 98%, respectively (Mabey et al. 2006), environmental and infrastructural factors can compromise the validity of the tests or lead to variability in test results.

Rapid diagnostics could drastically improve access to and quality of syphilis screening programmes in low-resource settings (Loubiere and Moatti 2010; Bates and Maitland 2006). Unlike RPR, Rapid Syphilis Test (RSTs) can be stored at room temperature, performed using whole blood, give results within 30 min, and do not require additional laboratory infrastructure (WHO/TDR Sexually Transmitted Diseases Initiative 2006). Diagnostic accuracy of RSTs varies by type; sensitivity and specificity of the SD Bioline using whole blood in clinic based trials were found to range from 85.2% to 100% and 98.1% to 99.4% respectively (Mabey et al. 2006).

As with many other diagnostics, however, RST validity and accuracy can be compromised due to exposure to high temperatures or humidity, manufacturing issues, or operator errors. In order to ensure accuracy of diagnosis and quality of care, implementation of a quality assurance (QA) system alongside rapid diagnostics is widely advocated (Peeling et al. 2006a,b; Schmid 2004; TDR 2009). A QA system will often be made up of several components (LSHTM 2011), including but not limited to: an in-built control in the test device to verify the specimen was adequate (Internal Quality Control); an incoming inspection of test kits to ensure their accuracy has not been compromised during transport; regular testing with known positive and negative samples to evaluate accuracy of the test kits (External Quality Control); and regular proficiency testing of the operator with blinded positive and negative samples (External Quality Assessment). In addition, adequate training and re-training, monitoring and supervision are essential to ensure the quality of diagnostic testing. Each component of a QA system can be implemented at differing frequencies and intensities, in order to match the specific need of the health system in question; the ideal mix of QA components will vary by setting.

The costs of monitoring and supervision, training and QA as part of rapid diagnostic test implementation are often overlooked (TDR 2009), with very little information available on these components in the literature. The objective of this study is to estimate and compare the costs of RSTs with RPR in this Tanzanian setting, and to determine the relative impact of a QA system on the cost of RST implementation.

Methods

The setting and intervention

Geita District is primarily rural, with a large mining community and with an estimated syphilis prevalence of 8% in antenatal care (ANC) attendees (Watson-Jones et al. 2002a). The district has a total of 52 facilities; we purposively selected nine facilities for cost data collection which varied in size, remoteness and scope of services provided within ANC. Facilities chosen included three dispensaries (D), five health centres (HC) and one district hospital (DH), which is the highest level of referral within the district. Facilities varied from 16 to 73 km from Geita Town (with the district hospital within Geita Town). Number of staff working in ANC varied from 2 to 8; and number of days per week on which ANC was offered varied from 2 to 5.

Prior to the introduction of RSTs, RPR tests were conducted within maternal and child health (MCH) units by staff nurses, with no regular training or QA in place. Testing was
intermittent in most facilities, likely due to frequent stockouts of reagent or testing kits, and problems with test batching. The typical RPR testing process in Tanzania is described in further detail by Terris-Prestholt et al. (2011).

In September 2009, a pilot programme for RST implementation in Geita District was established by the National Institute for Medical Research (NIMR), Mwanza. All health workers conducting screening were given intensive training at the start of the project, and routine monitoring and supervision were conducted by NIMR staff to assess compliance and ensure quality of diagnosis and patient care. In addition, a robust QA system was introduced in February 2010 to ensure diagnostic accuracy. The QA system included each of the components described above. External quality control was conducted with dried tube specimens—prepared from whole blood at the NIMR lab in Mwanza and known positive and negative serum samples, which were described above. External quality control was conducted with dried tube specimens—a relatively new approach to quality control specimens which does not require cold-chain support and can be easily produced from whole blood (Parekh et al. 2010). These were also produced at the NIMR lab and delivered alongside serum samples.

**Cost analysis**

Cost data were collected using a combination of standard step-down accounting and micro-costing methods (Kumaranayake et al. 2000; Creese and Parker 1994; Drummond et al. 2005; Terris-Prestholt et al. 2010). The incremental costs of adding RPR and RST screening and treatment onto existing antenatal services were estimated; i.e. all extra costs to run syphilis screening and treatment were included, while general administrative or overhead costs required to run the health facilities were not included (Terris-Prestholt et al. 2010). Economic costs were collected retrospectively from a provider’s perspective, considering both the Tanzanian Ministry of Health and the NIMR as providers. All research costs were excluded. Annual capital costs were annualized using a 3% discount rate. Primary start-up and training were estimated to have a life of 3 years, while RPR equipment was given a life of 10 years. Costs were collected over a 9-month period, first for RPR in 2007/08, later for RST in 2009/10. RPR costs were collected retrospectively from six of the nine facilities; three facilities were excluded from the RPR analysis due to unavailability of output data (D2, HC5 and DH). As RPR had been previously initiated, it was not possible to collect training and start-up costs. Where syphilis screening was conducted alongside HIV screening, costs such as personnel time and building space were considered to be ‘shared costs’ and divided equally between HIV and syphilis screening (Terris-Prestholt et al. 2011).

Costs are summarized into three activity based categories: start-up and training costs, quality costs, testing and treatment costs. Within testing and treatment, costs are presented by input (e.g. personnel, supplies, etc.). Costs were collected in Tanzanian shillings (TZS) and converted to US dollars (USD) using the average exchange rate for 2010 (TZS 1569.04 = 1 USD) (OANDA 2010), then adjusted to 2012 USD using inflation rates from the Consumer Price Index (Bureau of Labor Statistics 2012). All costs are presented in 2012 USD. Cost components include capital and recurrent costs for testing and treatment at the health facility level, as well as start-up, capital and recurrent costs for RST implementation and QA.

**Project outputs and unit costs**

Project outputs were collected retrospectively from patient registers for RST and RPR over the same periods as the costs. Project outputs include number of pregnant women tested, reactive tests and women treated. Unit economic costs per woman tested and per woman treated were calculated for each facility, and for all facilities combined.

**Sensitivity analysis**

A univariate sensitivity analysis was constructed to determine the impact of uncertainty in cost and output collection. We analysed factors in the sensitivity analysis which could not be directly observed, or which varied significantly amongst facilities, including clinic opening hours, supply wastage, staff time taken for testing, staff salaries, building costs and discount rate. In addition, we conducted a multivariate analysis of cost and output factors, simultaneously varying all factors above with uniform distribution between the minimum and the maximum values observed over 1000 iterations.

**Results**

**Project outputs**

Over a period of 9 months in 2007–08, a total of 838 women were screened with RPR in six facilities. Disaggregated ANC attendance rates during this period were not available; however, we found that testing rates overall for Geita District during this time were 17.8% (Mabey et al. 2012). Assuming that ANC attendance rates remained relatively constant from 2007/08 to 2009/10 for the facilities included in this analysis, this would represent about 12% of women attending ANC at these facilities. Outcome data were unavailable from two facilities, and one facility conducted no testing during this period; these three facilities were therefore dropped from RPR cost analysis. A total of 230 women (27%) were recorded as reactive, although reactivity rates at the clinic level varied from 9% to 59% of all women presenting for screening (Table 1). As there was no retesting of samples with a gold standard, the true prevalence of syphilis in these facilities is unknown; however, a study conducted in 2001 found an average of 8% RPR reactivity in the area (Watson-Jones et al. 2002a). This suggests that some facilities had high false-positive rates. Treatment rates for RPR also varied widely (11–90%) but overall only 66% of those testing positive were treated.

Over a similar time period in 2009–10, a total of 9372 pregnant women were tested with RSTs in the nine surveyed facilities, covering 87% of women attending antenatal care. Of women tested, 10% (912 women) tested positive, of which 92% (841 women) were treated. At some facilities, more women were screened than were enrolled in ANC—these women were either residents outside the ANC catchment area and not captured by the recording system or had been previously enrolled in ANC but not tested until the introduction of RSTs.
Costs

Total economic costs for screening and treatment using RPR ranged from $207 to $512. Personnel accounted for 23–34% of costs, while supplies accounted for 35–47%. A significant proportion of costs were incurred due to refrigeration of the reagent for RPR; combined equipment and operation/maintenance costs represented 13–34% of costs (Figure 1). Costs were not collected for start-up/training or QA as these activities did not occur under the observation period for RPR costing.

Total economic costs incurred for screening and treatment using RSTs over a 9-month period ranged from $751 to $5863 per clinic. RST costs at the health facility level were driven by the high unit costs of the diagnostics ($1.10 per test kit); test kits accounted for 41–73% of total health facility costs. Personnel time accounted for 11–32% of costs.

Total costs for the QA system ranged from $513 to $554 by health facility over the 9-month costing period. Costs varied due to differences in transportation costs associated with reaching more remote clinics and differences in staff salaries. An incoming inspection of test kits costs $36 at the district level for each shipment of kits, or an average of $0.70 per health facility. One external quality control panel costs an average of $23 per health facility, whereas one external quality assessment panel costs an average of $33 per health facility. Salaries and transport for NIMR personnel accounted for 61% of costs for external quality control, and 50% of costs for external quality assessment. One monitoring and supervision visit from NIMR personnel costs an average of $24 per health facility. Finally, start-up and training costs ranged from $184 to $401 per facility, dependent on the number of nurses trained. Inclusion of start-up and training, monitoring and supervision, and QA costs increased total costs for RST screening to $1540–$6777.

Costs incurred in district supervision were excluded from both RST and RPR cost analysis due to unreliability of reported

### Table 1  Screening and treatment output

<table>
<thead>
<tr>
<th></th>
<th>D1</th>
<th>D2</th>
<th>D3</th>
<th>HC1</th>
<th>HC2</th>
<th>HC3</th>
<th>HC4</th>
<th>HC5</th>
<th>DH</th>
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<tr>
<td>Total ANC clients</td>
<td>196</td>
<td>594</td>
<td>735</td>
<td>707</td>
<td>792</td>
<td>723</td>
<td>1667</td>
<td>1412</td>
<td>3885</td>
<td>10711</td>
</tr>
<tr>
<td>RPR</td>
<td></td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>Total tested</td>
<td>85</td>
<td>38</td>
<td>81</td>
<td>197</td>
<td>217</td>
<td>110</td>
<td>110</td>
<td>0</td>
<td>N/A</td>
<td>838</td>
</tr>
<tr>
<td>Total positive</td>
<td>50</td>
<td>14</td>
<td>27</td>
<td>95</td>
<td>21</td>
<td>13</td>
<td>10</td>
<td>0</td>
<td>N/A</td>
<td>230</td>
</tr>
<tr>
<td>Total treated</td>
<td>23</td>
<td>N/A</td>
<td>3</td>
<td>85</td>
<td>19</td>
<td>8</td>
<td>5</td>
<td>0</td>
<td>N/A</td>
<td>143</td>
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<tr>
<td>% of ANC tested</td>
<td>43</td>
<td>6</td>
<td>10</td>
<td>28</td>
<td>27</td>
<td>15</td>
<td>7</td>
<td>0</td>
<td>12</td>
<td></td>
</tr>
<tr>
<td>% reactive</td>
<td>59</td>
<td>37</td>
<td>33</td>
<td>48</td>
<td>10</td>
<td>12</td>
<td>9</td>
<td></td>
<td>27</td>
<td></td>
</tr>
<tr>
<td>% of positive treated</td>
<td>46</td>
<td>11</td>
<td>89</td>
<td>90</td>
<td>62</td>
<td>50</td>
<td></td>
<td></td>
<td>62</td>
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<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Total tested</td>
<td>240</td>
<td>481</td>
<td>666</td>
<td>809</td>
<td>819</td>
<td>517</td>
<td>1135</td>
<td>1371</td>
<td>3334</td>
<td>9372</td>
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<tr>
<td>Total positive</td>
<td>23</td>
<td>53</td>
<td>105</td>
<td>74</td>
<td>122</td>
<td>58</td>
<td>107</td>
<td>102</td>
<td>268</td>
<td>912</td>
</tr>
<tr>
<td>Total treated</td>
<td>23</td>
<td>52</td>
<td>88</td>
<td>70</td>
<td>116</td>
<td>51</td>
<td>105</td>
<td>102</td>
<td>234</td>
<td>841</td>
</tr>
<tr>
<td>% of ANC tested</td>
<td>122</td>
<td>81</td>
<td>91</td>
<td>114</td>
<td>103</td>
<td>72</td>
<td>68</td>
<td>97</td>
<td>86</td>
<td>87</td>
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<tr>
<td>% reactive</td>
<td>10</td>
<td>11</td>
<td>16</td>
<td>9</td>
<td>15</td>
<td>11</td>
<td>9</td>
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<td>10</td>
</tr>
<tr>
<td>% of positive treated</td>
<td>100</td>
<td>98</td>
<td>84</td>
<td>95</td>
<td>95</td>
<td>88</td>
<td>98</td>
<td>100</td>
<td>87</td>
<td>92</td>
</tr>
</tbody>
</table>

supervision rates and topics addressed during supervision. The total economic cost of one supervisory visit from district co-ordinators was found to be $111.09 (Table 2).

**Unit costs**

Unit costs for RST screening at the health facility level were $1.92 per woman screened and $21.40 per woman treated. Costs per woman screened varied from $1.74 at HC4 to $2.75 at D1. QA costs varied from $0.15 to $2.25 per woman tested. Inclusion of start-up, training and QA costs increased unit costs to $2.32 per woman screened (ranging from $1.76 to $3.02) and $12.96 per woman treated ($6.02–$74.26) per woman treated. Variations in RPR unit cost did not reflect facility size, but appear to be rather a reflection of test batching and frequency of testing.

**Sensitivity analysis**

We conducted a univariate sensitivity analysis in order to understand the impact of assumptions made in collection of cost data and output measures on unit costs at the health facility level. RST costs were sensitive to estimates surrounding staff time and supply wastage, while RPR costs were highly sensitive to staff time estimates. Decreasing staff time by 50% reduced the average unit cost per woman tested with RPR to $1.93. Increasing the estimated supply wastage by 50% increased the estimated unit cost per woman tested with RST to $2.42, higher than the base case scenario for RPR.

A multivariate sensitivity analysis was conducted varying staff time and working hours, supply wastage, salaries and discount rate, as well as output factors including testing rates, syphilis prevalence, and treatment rates for positive women and their partners. All factors were varied over a uniform distribution between the minimum and the maximum values observed. Over 1000 iterations, unit costs for RST testing were lower than those for RPR 83% of the time (Figure 2). Lower cost is largely related to economies of scale achieved through higher utilization under RST; further research is needed to determine whether this increased access is sustained in the longer term (Figure 2).

**Discussion**

**Cost of screening**

This analysis found the average unit cost at the health facility level for routine screening with RSTs to be $1.92 per woman screened. This was lower than the estimated unit cost for RPR ($2.32 per woman screened), although direct comparisons varied by health facility. Our results suggest that rapid syphilis diagnostics are very inexpensive in a Tanzanian setting, and less expensive than RPR, even where RPR is feasible.

Previously published costs per woman screened with RSTs vary between $1.25 and $4.87 depending on prevalence rates and costs included in the analysis (Blandford et al. 2007; Levin
et al. 2007; Schackman et al. 2007; Rydzak and Goldie 2008). Our finding that RST costs for testing and treatment are lower than those for RPR is unique; previous studies have reported RST costs per woman screened to be $0.17–$1.07 higher than those for RPR. The lower costs for RST are largely a reflection of economies of scale in implementation—greater access allows fixed costs to be spread over a larger number of women. This may also reflect higher personnel costs for RPR testing in Tanzania than those previously recorded, incurred through manual completion of tasks which could be performed by equipment in settings with better laboratory infrastructure. However, if supply shortages, or other barriers to testing re-occur, leading to lower numbers of women screened, it is not as clear which strategy is the most cost-effective. Unit costs are likely to be similar, and the relative cost-effectiveness will then depend on the respective tests’ ability to identify active cases of syphilis, and ensure high levels of treatment for women with reactive test results.

The Tanzanian Ministry of Health and Social Welfare (MOHSW) has expressed plans to scale up RST implementation throughout the country following this demonstration project, and has accordingly changed the national syphilis screening guidelines. We found the start-up and training costs to vary between $184 and $401 per facility. Implementing start-up and training at all government-owned primary care facilities (2916 facilities total) (World Health Organization 2006) would cost an estimated $750 000, though costs are expected to be far lower when integrated into the context of a national programme. Assuming a linear relationship between testing inputs and outputs, testing and treatment covering 70% of pregnant women in Tanzania would cost roughly $3 000 000. A coverage rate of 90% would cost roughly $3 800 000.

**Access to screening**

During the study period, syphilis screening rates for women in antenatal care increased under RST implementation. In surveyed facilities, the total number of women screened under RSTs was 88% of total ANC attendees, as compared with only 12% of ANC attendees screened with the RPR method. The increase in number of women tested may be attributable to increased acceptability of the tests by health care workers, additional monitoring by project staff, or a reduction in stock outs of essential supplies during the RST period. Because they can be ordered in bulk and stored for long periods of time without refrigeration, RSTs may be less susceptible to stockouts than RPR test supplies. RSTs were preferred by both health care workers and ANC clients and found to motivate staff, who were happy to provide a diagnostic service and immediate treatment to patients (Mabey et al. 2012).

This study did not evaluate whether increased access to screening was sustained after the project period completed; further research is therefore needed to determine the long-term utilization patterns of RST as compared with RPR.

**Access to treatment**

Treatment of reactive patients also increased under RST implementation. The introduction of RST witnessed a 30% increase in the number of reactive cases treated compared with RPR. Due to the rapid nature of the tests, RST results are available the same day, reducing loss-to-follow up and increasing access to treatment. Follow up in the study communities is needed to disentangle this from any potential study effect related to stocks of benzathine penicillin.

Increased access to prompt treatment has the potential to greatly reduce adverse pregnancy outcomes. A single dose of penicillin in pregnancy has been proven to reduce the likelihood of adverse birth outcomes due to syphilis. A study conducted in 2002 in a neighbouring district in Tanzania found that following treatment, there was no increased likelihood of adverse outcomes among women with high-titre active syphilis, which was thought to be correlated to adverse pregnancy outcomes (Watson-Jones et al. 2002a), as compared with RPR-negative women. A more recent panel of experts with the WHO/child health epidemiology reference group (CHERG) has evaluated the literature on maternal syphilis and estimated that treatment can avert adverse outcomes in 48.7% of all women with untreated syphilis in pregnancy, regardless of titre (Newman et al. 2011). In this study setting, this would mean that treatment has prevented 111 stillbirths, 68 miscarriages, 163 cases of congenital syphilis, and 106 neonatal and infant deaths.

**Cost of QA**

The QA costs reported reflect current QA implementation for the quality system alongside RST in Tanzania. This includes joint monitoring and supervision/QA visits to all health facilities once per month, with external quality control and external quality assessment conducted simultaneously. QA costs were not observable for RPR testing, and therefore not reported in this study. However, QA should be a component of any syphilis screening programme, and a robust QA system supporting screening with RPR would likely carry similar costs.

The costs and effects of QA are variable according to implementation, and a QA programme can be designed for different settings with different disease prevalence levels and to suit different budgets. In areas of high disease prevalence, WHO guidelines recommend that quality controls and monitoring are performed weekly or even daily to ensure high
Increasing the frequency of on-site external quality control samples to a weekly basis would increase external quality control costs from $21.79 to $35.52 per month. In areas of low disease prevalence, periodic external quality assessment at a lower frequency is advisable as part of a continuous proficiency assessment of personnel, thereby reducing retraining events and increasing confidence of operators. Decreasing the frequency of external quality assessment schemes from monthly to quarterly would reduce costs by a third, assuming samples are also manufactured quarterly.

Altering the frequency of QA activities will influence the cost of the programme, although care should be taken to ensure the scheme is sufficient to meet the needs of the system. Reduced intensity of QA could lead to inaccuracy in testing, especially in areas where there is high turnover of staff. This might result in high numbers of false-positive or false-negative test results, considering that under the RPR testing without QA, reactive rates of up to 59% were seen, thus leading to over-treatment or cases missed. The importance of QA in ensuring the quality and accuracy of testing is further discussed by Mabey et al. (2012).

The number of events necessary to validate the test kits after shipment can be reduced by centralizing the supply and inventory system, reducing the number of actors in the distribution channel, and ensuring adequate temperature monitoring, although minimum performance requirements should be established to avoid unnecessary time-consuming and unproductive testing.

Decentralization of QA responsibilities to the district level and integration with other projects can also influence QA cost. The majority of costs for both external quality control and external quality assessment presented reflect transport and personnel costs associated with bringing NIMR personnel from Mwanza for delivery of QA materials, monitoring and supervision. Where district co-ordinators are already conducting monitoring and supervision for other programmes, the incremental cost of integrating a QA component would be minimal.

Finally, QA is a fixed cost at clinic level and therefore exhibits economies of scale in implementation. Unit costs for QA activities varied from $0.15 per woman tested at the largest health facility (DH) to $2.25 per woman tested at the smallest health facility (D1). Given the economic gains from implementing QA at larger health facilities, a valid interim solution may be to implement QA at larger health facilities first, expanding to smaller health facilities when economically possible. However, it is often the small clinics that need it most.

**Limitations**

There are a number of limitations to this study which may affect generalizability of the results. Primarily, it is difficult to determine the potential changes in access to and cost of services upon scale-up of rapid testing and transfer of QA responsibility to the MoHSW. Although the pilot project was designed to maintain minimal impact on the health system, NIMR did provide support that may not be sustainable by the Tanzanian government. For example, NIMR provided additional support to the supply chain throughout the project, decreasing the frequency of supply stockouts and thereby increasing access to screening and treatment for syphilis. It is also possible that frequency and intensity of monitoring/supervision will change substantially if decentralized to the district level, possibly impacting the success of the QA system.

This study also did not confirm diagnoses with a gold standard, making it difficult to estimate health outcomes (such as Disability Adjusted Life Years). The lack of a gold standard also prevented confirmation that the introduction of RSTs along with a robust quality system improved the accuracy of testing.

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**Table 3 Univariate sensitivity analysis**

<table>
<thead>
<tr>
<th>Parameters varied</th>
<th>Minimum</th>
<th>Maximum</th>
<th>RPR Base case $2.21</th>
<th>Minimum</th>
<th>Maximum</th>
<th>Minimum</th>
<th>Maximum</th>
</tr>
</thead>
<tbody>
<tr>
<td>Observed values</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Discount rate</td>
<td>1%</td>
<td>6%</td>
<td>2.30 (1%)</td>
<td>2.30 (1%)</td>
<td>1.92 (0%)</td>
<td>1.92 (0%)</td>
<td></td>
</tr>
<tr>
<td>Working hours per day</td>
<td>7</td>
<td>4</td>
<td>2.20 (5%)</td>
<td>2.20 (5%)</td>
<td>1.85 (3%)</td>
<td>2.06 (7%)</td>
<td></td>
</tr>
<tr>
<td>Supply wastage</td>
<td>0%</td>
<td>50%</td>
<td>2.23 (4%)</td>
<td>2.23 (4%)</td>
<td>1.80 (6%)</td>
<td>2.42 (26%)</td>
<td></td>
</tr>
<tr>
<td>Staff time (±50%)</td>
<td>−50%</td>
<td>+50%</td>
<td>1.93 (17%)</td>
<td>1.93 (17%)</td>
<td>1.77 (8%)</td>
<td>2.07 (8%)</td>
<td></td>
</tr>
<tr>
<td>Staff salaries/month</td>
<td>$139</td>
<td>$624</td>
<td>3.32 (44%)</td>
<td>3.32 (44%)</td>
<td>1.76 (8%)</td>
<td>2.37 (24%)</td>
<td></td>
</tr>
</tbody>
</table>

**RST outcomes**

- Syphilis prevalence: 7% – 16%
- % positives treated: 84 – 100
- % partners treated: 14 – 100

**RPR outcomes**

- % ANC tested: 7 – 43
- Syphilis prevalence: 9% – 59%
- % positives treated: 11 – 90
diagnosis. We also found some gaps in cost data for RPR testing. We used original RPR cost data from a previously published study in Gitea District (Terris-Prestholt et al. 2003) where data were lacking, inflated to 2012 USD (Bureau of Labor Statistics 2012). Finally, the impact of QA on total costs of RST screening per woman is likely underestimated. QA activities were not started in Tanzania until February 2010 after the screening programme had been running for 3 months, thus potentially underestimating costs by up to a third. Table 3 provides the building blocks to estimate the replication costs of QA under different configurations.

As noted by McIntyre et al. (2009), access to health care or health services is a multidimensional concept and not directly measurable from utilization data. Further dimensions of access include hours and location of services, expectations and attitudes between providers and patients, and range of services provided relative to need. Mabey et al. (2012) further discuss acceptability of RSTs amongst clients and health care workers in this setting; however, this project was not designed to estimate other components of healthcare access.

Conclusions
The cost-effectiveness of RSTs has been previously proven. This study reports the relative costs of a quality control system, when implemented alongside RST testing in a Tanzanian setting. We find that QA has a small additional cost to rapid syphilis screening, but potentially improves quality of diagnosis considerably. QA costs could be further reduced through alterations in the programme design, including changes in frequency of QA activities, integration with other programmes and decentralization to the district level. Rapid syphilis screening services are currently being expanded throughout the country as part of the Ministry of Health’s efforts to increase access to syphilis screening in antenatal care. Given the small incremental costs and potentially significant improvements in quality of diagnosis, we argue that roll-out of RSTs should include a QA and monitoring/supervision system in order to improve the validity and quality of diagnosis and treatment.

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Conflict of interest
None declared.

References


