Original Article

Cost and affordability analysis of TB-LAMP and Xpert MTB/RIF assays as routine diagnostic tests in peripheral laboratories in Malawi and Vietnam

Hojoon Sohn ,¹ Lehka Puri ,² Ngoc Anh Thi Nguyen ,³ Anja H. Van't Hoog ,^{4,5} Van Anh Thi Nguyen ,³ Marriott Nliwasa ,^{6,7,8} Pamela Nabeta ⁹

¹Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, Baltimore, MD, USA

²McGill University, Montreal, Canada

³National Institute of Hygiene and Epidemiology, Hanoi, Vietnam

⁴Department of Global Health, Academic Medical Center, University of Amsterdam, Amsterdam, Netherlands

⁵Amsterdam Institute for Global Health and Development, Amsterdam, Netherlands

⁶Helse Nord Tuberculosis Initiative, Department of Microbiology, University of Malawi College of Medicine, Blantyre, Malawi

⁷Malawi-Liverpool-Wellcome Trust Clinical Research Programme, Blantyre, Malawi

⁸Clinical Research Department, London School of Hygiene & Tropical Medicine (LSHTM), London, UK

⁹Foundation for Innovative New Diagnostics (FIND), Geneva, Switzerland

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Correspondence to

Hojoon Sohn

Department of Epidemiology, Johns Hopkins Bloomberg School of Public Health, 615 N Wolfe St, Baltimore, MD 21205, USA.

E-mail: hsohn6@jhu.edu

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ORCID iDs

Hojoon Sohn

<https://orcid.org/0000-0001-5837-3844>

Lehka Puri

<https://orcid.org/0000-0002-0208-2076>

Ngoc Anh Thi Nguyen

<https://orcid.org/0000-0001-9124-2336>

Anja H. Van't Hoog

<https://orcid.org/0000-0002-6358-0394>

Van Anh Thi Nguyen

<https://orcid.org/0000-0002-5662-9954>

Marriott Nliwasa

<https://orcid.org/0000-0002-3100-5512>

<https://e-jghs.org>

ABSTRACT

Background: While the incidence of tuberculosis (TB) is declining globally, the rate of decline is far too slow to meet the 2035 end TB targets. Use of rapid molecular diagnostics that can be deployed in peripheral settings has the potential to address gaps in TB care cascade, improve case detection, and ultimately limit the on-going transmission of the disease.

Methods: We assessed the costs and affordability of 2 commercial nucleic acid amplification test (NAAT)—loop-mediated isothermal amplification assay for TB (TB-LAMP) and Xpert MTB/RIF (Xpert)—used at the peripheral laboratories in Malawi and Vietnam. Costs were assessed from the health service provider perspective using bottom-up method. Categorized documentation of resources uses for each diagnostic test was done using a standardized time-and-motion form directly observing each laboratory procedure. Affordability was assessed as a proportion of total first-year implementation and operational costs of respective diagnostics against the national TB program budget for 2014.

Results: Unit costs of TB-LAMP and Xpert varied depending on the daily test volumes and the test kit costs were the primary cost driver. Unused equipment capacity costs were also an important cost driver at low testing volumes and was more significant for Xpert. Weighted average per-test cost of nationwide implementation of respective diagnostics was between \$14.37–\$15.85 for TB-LAMP and \$20.06–\$26.86 for Xpert for Vietnam and Malawi. Both NAATs would account for a significant portion of or exceeded the national TB program budget if complete nationwide roll-out to peripheral laboratory were considered.

Conclusion: While TB-LAMP is a lower cost alternative to Xpert as an upfront NAAT for TB in peripheral settings, cost-utility against Xpert and other alternatives and optimized implementation strategies must be carefully evaluated through additional model-based studies to better inform policy and program decisions to expand the coverage of rapid diagnostics for TB.

Keywords: Cost analysis; Affordability; Diagnosis; Nucleic acid amplification techniques; Tuberculosis

Pamela Nabeta <https://orcid.org/0000-0002-5395-6191>**Conflict of Interest**

No potential conflict of interest relevant to this article was reported.

Author Contributions

Conceptualization: Sohn H, Nliwasa M, Nabeta P; Data curation: Sohn H, Puri L, Nguyen NAT, Nliwasa M; Formal analysis: Sohn H, Puri L; Funding acquisition: Sohn H, Nabeta P; Investigation: Sohn H, Van't Hoog AH, Nguyen VAT, Nliwasa M; Methodology: Sohn H, Puri L, Nguyen NAT, Van't Hoog AH, Nliwasa M; Project administration: Sohn H, Nguyen VAT, Nliwasa M, Nabeta P; Resources: Sohn H, Nguyen VAT, Nliwasa M, Nabeta P; Software: Sohn H, Puri L; Supervision: Sohn H, Van't Hoog AH; Validation: Sohn H, Puri L, Van't Hoog AH, Nliwasa M, Nabeta P; Visualization: Sohn H, Puri L; Writing - original draft: Sohn H; Writing - review & editing: Sohn H, Puri L, Nguyen NAT, Van't Hoog AH, Nguyen VAT, Nliwasa M, Nabeta P.

INTRODUCTION

Although the global incidence of tuberculosis (TB) is declining, it continues to be the top single most infectious disease cause of deaths globally, with more than 10 million people impacted by the disease and an estimated 1.6 million people dying from TB (300,000 among human immunodeficiency viruses [HIV]-positive people).¹ This phenomenon is largely driven by countries with highest TB burdens where delays in diagnosis and linkage to proper care continue to fuel disease transmission and undermine TB control efforts.² Likewise, introduction of novel technologies and public health interventions that can improve delays in the TB care cascade are critical in achieving the 2035 end TB targets.³

The majority of countries facing the highest TB disease burden are low-and-middle income countries where sputum smear microscopy (SSM) remains as a primary bacteriologic diagnostic tool in peripheral settings. While it is relatively cheap to perform,⁴ its performance is highly variable based on a technician's experience, quality of the sample, and has limited diagnostic value for children, HIV-positive patients, and those suspected of drug-resistant (DR) TB.⁵ Xpert MTB/RIF assay (Xpert; Cepheid, Sunnyvale, CA, USA)—the first World Health Organization (WHO) approved commercialized cartridge-based nucleic acid amplification test (NAAT) utilizing a common GeneXpert testing platform⁶—has widely been adopted by high TB burden countries,⁷ but its coverage and utility is limited to centralized locations (intermediate level laboratories or higher).^{8,9}

As an alternative to Xpert and as a replacement test for SSM, the LoopampTM MTBC Detection assay (loop-mediated isothermal amplification assay for TB [TB-LAMP], developed by Eiken Chemical Co., Ltd. Tokyo, Japan), a closed-tubed rapid NAAT for the detection of *Mycobacterium tuberculosis*, also received conditional recommendation by the WHO in 2016.¹⁰ Furthermore, testing procedures and hands-on involvement of laboratory personnel is no more complicated than that of Xpert. Considering its comparable diagnostic performance and favorable operational characteristics,¹¹ TB-LAMP has the potential to address important gaps in the TB diagnostic cascade in high TB burden countries.

In this study we evaluated and compared the economic costs and affordability of nationwide implementation of TB-LAMP assay with that of Xpert in peripheral TB laboratories in 2 high TB burden countries—Malawi and Vietnam.

METHODS**Settings**

We conducted a comprehensive cost analysis of TB-LAMP and Xpert assays performed in peripheral laboratories in Malawi and Vietnam from the health service provider perspective. We incorporated a time-and-motion (TAM) study to directly observe and quantify all resource use for every relevant laboratory procedure for each diagnostic.¹² Empiric cost data of respective NAATs were collected at select peripheral TB laboratories operating within multi-functional primary care clinics (Ndirande in Malawi and Ung Hoa in Vietnam). Both laboratories performed 10–20 SSM tests per day (5 working days for Ung Hoa and 2 days for Ndirande for TB), which were medium to high workload laboratories. As independent diagnostic performance evaluation sites for TB-LAMP, these laboratories were the only laboratories in respective countries that were concurrently performing Xpert assays at the

time of our assessment (At Ndirande site, Xpert was being offered as a routine test for select patients based on national diagnostic guideline).

Identification, measurement, and valuation of resources used

We assessed the costs of each diagnostic test using a bottom-up costing method.^{12,14} Between February and April of 2015, we collected all data on relevant resources used to perform each test, including overhead (utilities, furniture, administrative, and operational costs) and building costs, staff salaries, laboratory equipment and capital assets, procurement costs of laboratory chemicals and consumables (**Appendix 1**). Actual resource-use data for each laboratory procedure was assessed based on the TAM study, using a standardized form completed by study staff directly observing and quantifying time and resources used for each step of the procedure diagnostic tests (**Fig. 1**). As laboratory staff members at the study sites did not experience with TAM study, our study staff provided a brief overview of goals and methods of the study prior to engaging in the data collection. The TAM study was conducted multiple times over several working days at each laboratory to observe varied batch sizes of patient samples under routine working conditions. To overcome generalizability and representativeness of our study site, we observed a range of minimum to maximum testing volumes reflective of daily workloads at a wide range of peripheral TB laboratories (between 1 and 14 tests) for the 2 diagnostics.

Cost analysis

For each batch size observed, unit cost was assessed based on the ‘ingredients’ approach multiplying the quantities of resource-use collected from TAM observations by unit cost/prices of each resource. Costs associated with the use of laboratory equipment, building space, and other capital assets directly and indirectly utilized for each test were assessed as time-associated costs (annuitized) based on their purchased-new prices (in 2014), expected useful life years (**Appendix 2**), and an annual discount rate of 3%.¹⁵ Overhead costs were allocated based on the total staff hands-on time (for administrative overheads) and total procedural time (for infrastructural overheads). For each testing volume, we assessed and added unused daily equipment processing capacity (56 for TB-LAMP and 16 for Xpert) to calculate overall unit cost of each diagnostic test. For example, if only 2 tests were performed

Fig. 1. Laboratory procedures for TB-LAMP and Xpert assays observed using TAM method. Sample preparation methods and testing/reaction steps for TB-LAMP and Xpert involved multiple procedural steps that were generalized to the ‘squares’ represented in the diagram above. Each ‘square’ represented independently observable continuously performed laboratory procedure for each diagnostic test. Resource-use data for each procedural step were collected based on direct observation and standardized time and motion forms. LAMP = loop-mediated isothermal amplification; TB-LAMP = loop-mediated isothermal amplification assay for tuberculosis; Xpert = Xpert MTB/RIF.

per day on average, we assumed a total of 6 hours out of possible 8 hours (75%) of useful equipment operations as both tests have a total equipment run-time of 2 hours per batch/test. The daily fraction of annual unused equipment capacity was then multiplied by the daily cost of relevant laboratory equipment (e.g. GeneXpert IV system, \$15.13 per day) to calculate daily costs associated with unused equipment capacity ($0.75 \times \$15.13 = \11.34). All costs were evaluated based on 2014 United States Dollars (USDs); where data was available in local currency, and conversion was done based on average UN exchange rate to the USD.¹⁶

To estimate weighted average per-test costs post nationwide roll-out of the test, we first estimated the total number of peripheral laboratories in the respective countries: 160 in Malawi and 920 in Vietnam, based on the WHO guideline for diagnostic coverage of microscopy centers (1 per 100,000 population). Then we summarized workload categories into 3 categories based on mean daily testing volumes: low (less than 4 tests), medium (between 5 and 9 tests), and high (10 or more tests). Distribution of laboratories in respective workload categories were assumed to be at 60%, 30%, and 10%, respectively, and were varied for sensitivity analyses. We then multiplied volume-based average unit cost with estimated proportion of peripheral laboratories in each workload category and summed these estimates to compute weighted per-test cost.

Affordability analysis

Affordability of nationwide roll-out of TB-LAMP or Xpert was assessed as a percentage of the total first-year operational costs of the nationwide implementation out of the reported annual national budget for TB for 2014. For each test, the total first-year operational cost per laboratory workload category was assessed using the budgeting table adapted from the WHO Xpert implementation manual (**Appendix 3**),¹⁷ the estimated annual testing volume, and the total number of peripheral laboratories in each workload category. The first-year operational cost included procurement of necessary laboratory equipment (e.g. LF-160 incubator for TB-LAMP and GeneXpert systems for Xpert), testing kits and laboratory consumables only. For Xpert, we assumed all peripheral laboratories would procure 1 GeneXpert IV (GX4, with capacity to test 16 test per day) system. We excluded costs associated with implementation and recurrent training and quality assurance program costs as data was unavailable at the time of our assessment.

Ethics

This study received approvals from local government authorities and organizations to review financial records. No Institutional Review Board approval was needed as the study did not utilize patient relevant information nor recruited patients for the study. Eiken Chemicals Co., Ltd. and Cepheid did not provide any financial support and had no role in the designing, analyzing, and writing of this manuscript.

RESULTS

Per-test costs for TB-LAMP and Xpert varied depending on daily testing volumes (**Table 1**). Factoring all laboratory-based procedures, TB-LAMP cost between \$10.39–\$19.25 in Malawi and \$10.08–\$17.55 in Vietnam for samples processed between 2 and 14 per operating day. Differences in per-test costs for Xpert was greater between the low (1 sample) and high volumes (14)—\$13.40–\$48.01 in Malawi and \$13.49–\$30.60 in Vietnam—due to high costs associated with unused equipment capacity at lower testing volumes. Per-test costs were

Cost and affordability of TB-LAMP and Xpert assays

Table 1. Unit-cost, unused equipment capacity costs, and overall per-test costs of TB-LAMP and Xpert by varied daily testing volumes

Daily testing volume	Malawi						Vietnam					
	TB-LAMP ^a			Xpert			TB-LAMP ^a			Xpert		
	Unit cost	Unused equipment capacity	Total per-test cost	Unit cost	Unused equipment capacity	Total per-test cost	Unit cost	Unused equipment capacity	Total per-test cost	Unit cost	Unused equipment capacity	Total per-test cost
1	-	-	-	17.32	30.69	48.01	-	-	-	17.83	12.77	30.60
2	17.88	1.37	19.25	14.56	13.64	28.20	16.98	0.57	17.55	14.69	5.67	20.37
4	13.38	0.68	14.06	13.02	6.82	19.84	12.96	0.28	13.24	13.09	2.84	15.93
6	11.74	0.46	12.20	13.79	3.79	17.58	11.51	0.19	11.70	13.89	1.58	15.47
7	11.54	0.39	11.93	14.96	1.30	16.26	11.25	0.16	11.41	15.21	0.54	15.75
10	10.65	0.27	10.92	13.53	0.91	14.44	10.45	0.11	10.57	13.63	0.38	14.01
14	10.19	0.20	10.39	13.40	0.00	13.40	10.00	0.08	10.08	13.49	0.00	13.49

We assessed per-test costs based on the fraction of total TB laboratory operational days (2 days for Malawi and 5 days for Vietnam per week) out of possible 250 annual operational days.

TB-LAMP = loop-mediated isothermal amplification assay for tuberculosis; Xpert = Xpert MTB/RIF.

^aComplete laboratory procedure for 1 sample testing for TB-LAMP was not observed during the time-and-motion study.

higher in Malawi as a result of lower number of operating days for TB diagnosis (2 days per week) compared to Vietnam (5 days per week). This led to much greater unused equipment capacity costs in Malawi, where for Xpert, this figure was as high as \$30.69 per test (more than twice the estimate for same test volumes in Vietnam).

The weighted national average per-test cost was significantly higher for Xpert than TB-LAMP in both countries: in Malawi, Xpert per-test cost was \$11 more expensive (70% higher) than TB-LAMP. The differences in costs were mainly driven by high costs associated with unused equipment capacity for the GX4 system in low volume laboratories. As GX4 system can simultaneously test up to 4 samples per run (2 hours per run), daily test volumes higher than 4 tests requires for multiple runs. This resulted in consistently higher overhead, building space use, and staffing costs than TB-LAMP. For both tests, reagent and chemicals (mainly TB-LAMP test kit and Xpert cartridge) were the single largest cost driver (Table 2).

First-year implementation and operational costs of TB-LAMP were \$8,427, \$14,170, and \$26,348 at a low, medium, or high-volume laboratory, respectively. For Xpert, these costs were more than 3 times higher (\$27,627; \$40,621; and \$57,775, respectively) than for TB-LAMP, largely due to high equipment cost of the GX4 system. When assuming complete roll-out at all peripheral laboratories, the TB-LAMP first-year cost accounted for 35% of total national TB program budget for 2014 in Malawi while it exceeded the budget by more than

Table 2. Weighted national average per-test cost (US\$ 2014) of TB-LAMP and Xpert test for Malawi and Vietnam, inclusive of unused equipment daily testing capacity

Costs per resource category	Malawi		Vietnam	
	TB-LAMP	Xpert	TB-LAMP	Xpert
Overhead	0.30	0.53	0.18	0.29
Building space	0.03	0.09	0.01	0.01
Equipment use	0.47	2.65	0.08	1.03
Unused equipment capacity	0.77	11.04	0.32	4.59
Staff	0.24	0.40	0.16	0.26
Reagents and chemicals	11.82	11.48	11.82	11.48
Consumables ^a	1.13	0.93	1.18	0.97
Registration	1.03	1.03	0.49	0.49
Repeat test cost ^b	0.16	0.17	0.14	0.13
Weighted national average	15.85	26.86	14.37	20.06

TB-LAMP = loop-mediated isothermal amplification assay for tuberculosis; Xpert = Xpert MTB/RIF.

^aFor both TB-LAMP and Xpert, we assumed 1% rate for invalid, uninterpretable result requiring repeat testing;

^bFor TB-LAMP, 1 of the 3 test kits required (pipette 60 set, approximately \$0.50 per test) was classified as consumables, instead of reagents and chemicals.

Table 3. Total cost and affordability of national roll-out of TB-LAMP compared to Xpert assay in Malawi and Vietnam

Workload categories	Malawi					Vietnam				
	No. of labs	TB-LAMP		Xpert		No. of labs	TB-LAMP		Xpert	
		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)
Low (≤ 4 tests per day)	96	\$808,994	14	\$2,652,200	47	460	\$4,651,715	64	\$15,250,150	209
Medium (> 4 and < 10 tests per day)	48	\$680,167	12	\$1,949,850	34	280	\$3,910,963	54	\$11,211,638	154
High (≥ 10 tests per day)	16	\$421,584	7	\$924,400	16	180	\$2,424,106	33	\$5,315,300	73
Total	160	\$1,910,745	34	\$5,526,450	97	920	\$10,986,784	151	\$31,777,088	435
Total national TB program budget (reported to WHO in 2014)		\$5,700,000					\$7,300,000			

We further varied the distribution of low (50%–70%), medium (25%–35%), and high volume (5%–15%) labs. These results are available in **Appendix 4** and **Appendix 5**.

TB = tuberculosis; WHO = World Health Organization; Lab = laboratory; TB-LAMP = loop-mediated isothermal amplification assay for tuberculosis; Xpert = Xpert MTB/RIF.

50% for Vietnam (**Table 3**). For Xpert, complete roll-out at low volume laboratories alone accounted for more than 47% of total TB budget for Malawi and exceeded the budget in Vietnam by more than 100%. While restricting roll-out to high volume laboratories would significantly reduce overall burden on the budget, it would still constitute more than 30% of the Vietnam's TB budget for TB-LAMP and 73% for Xpert (**Table 3**).

DISCUSSION

In this study, we evaluated the cost and affordability of TB-LAMP and Xpert assays as potential upfront bacteriologic tests for TB deployed at peripheral laboratory level in high TB burden, low resource settings represented by Malawi and Vietnam. TB-LAMP cost between \$10.39–\$19.25 in Malawi and \$10.08–\$17.55 in Vietnam) and \$13.40–\$48.01 in Malawi and \$13.49–\$30.60 in Vietnam for Xpert. Test kit costs were the single most important cost driver for both tests, but at lower testing volumes, costs associated with unused equipment capacity became an important cost driver. Given significantly more expensive equipment costs for Xpert, TB-LAMP was consistently cheaper to operate and implement at peripheral laboratories than Xpert. However, given the high up-front costs of equipment and significantly more expensive test kits compared to SSM, complete roll-out of TB-LAMP or Xpert to peripheral laboratories will likely put a significant burden on and could far exceed the annual national TB program budget.

Variabilities in the unit-costs of diagnostic tests, clinical services, or public health interventions resulting from differences in operations, implementation practices, service volumes and economies of scale have been reported previously.^{18–21} In our study, we further describe this variability along with an assessment of key cost drivers at different daily testing volumes. However, at lower testing volumes, Xpert costs were considerably more expensive due to the low utilization rate of the GeneXpert system (almost ten times the cost of TB-LAMP equipment). Furthermore, depending on the amount of TB laboratory operational days, unused equipment capacity costs can account for more than \$30 per-test (i.e. the laboratory in Malawi with 2 operating days per week for TB) at very low-test volumes. This was further reflected in the weighted national average per-test cost of the 2 tests, resulting in at least \$5 to \$10 higher in cost for Xpert compared to TB-LAMP.

In an earlier global assessment of costs associated with Xpert implementation, increasing Xpert coverage to test all presumptive TB patients was reported to be approximately 5 times the cost of conventional diagnostics in most of the countries assessed, but the affordability

was dependent on how much the country spent on TB care and control.⁸ Similarly, our current analyses indicate that the magnitude of the budget-impact of nationwide roll-out of each of the tests is further dependent on the overall coverage (assessed as total number of implementing peripheral laboratories). Likewise, in Vietnam where the TB program budget relative to population size (surrogate for total number of peripheral laboratories) is vastly small compared to Malawi, costs of the first-year operations of the nationwide TB-LAMP roll-out would far exceed the annual TB program budget despite it being a considerably cheaper alternative to Xpert. Given the significance of the budget implications of the nationwide roll-out of TB-LAMP or Xpert, decision-makers should further seek evidence on optimized placement strategies and their associated costs, operational and epidemiologic impact as countries aim to modernize TB diagnostics at the peripheral level.

There are several important limitations that should be noted for interpretation and generalizability of our findings. First, representativeness of the laboratories in which we collected empiric cost data may not be generalizable to other peripheral laboratories in Malawi and Vietnam. Furthermore, our estimates for weighted average per-test costs and assessment of affordability were based on a hypothetical distribution of peripheral TB laboratory network estimates based on the WHO's recommendation of 1 microscopy laboratory per 100,000 population. Likewise, our cost estimates may be an over estimate of the actual costs of procurement of equipment and test kits required for the first-year operation at peripheral laboratories. However, given that our affordability assessment does not include costs associated with quality control programs and implementation training, the degree of over-estimation may likely be offset by these additional programmatic costs.

Second, we did not assess costs against the diagnostic performance, relevant TB epidemiology, and other important factors associated with increasing the coverage of NAATs in these 2 countries. Given TB-LAMP's limitation in diagnosing DR TB, ongoing global efforts to scale-up Xpert coverage,²² and the development of simpler, innovative NAATs with capacities to detect DR-TB,²³ cost-utility of TB-LAMP must be evaluated against Xpert and other alternatives in additional modeling studies to better inform the position and utility of TB-LAMP in high TB burden settings. This is particularly important as new tool uptake has proven to be slow and technological innovation alone will not likely address many gaps in the TB care cascade in high burden countries.²⁴⁻²⁶

In conclusion, our study provides a comprehensive assessment of costs and affordability of TB-LAMP compared to Xpert as a potential alternative upfront peripheral NAAT in high TB burden countries. While TB-LAMP costs are considerably lower than that of Xpert, its lack of DR-TB detection capacity and on-going scale-up efforts of Xpert may limit the cost-utility of TB-LAMP, particularly in settings with high DR-TB prevalence. Furthermore, given high costs associated with increasing coverage of NAATs as primary diagnostics for TB in high TB burden settings, overall utility of NAATs and their placement strategies to address highly variable and copious health system gaps for TB must be assessed to better inform resource allocation in low resource and high TB burden settings.

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Cost and affordability of TB-LAMP and Xpert assays

Appendix 1. TB diagnostics cost data elements and relevant data sources

Data element	Cost items	Source of data collected
Physical infrastructure	Building construction	Construction contractors/government estates and building planning office/recent laboratory construction budget
	Maintenance contracts for all laboratory equipment requiring periodic maintenance	Laboratory financial records/laboratory or hospital accounts office/service contractors
Capital assets	Laboratory equipment	Manufacture catalogues, purchase records, FIND concessionary price list
	Medical equipment	Manufacture catalogues, purchase records
Chemicals, reagents, consumables & drugs	All types of chemicals and reagents utilized for diagnostic methods evaluated/drugs used for TB specific and non-specific clinical practice	Laboratory and clinic financial records/manufacture catalogue (must include all costs associated with procurement, usually at 25% of the catalogue price)
	All types of general laboratory and medical consumables (e.g. latex gloves, syringe, etc.)	Laboratory financial records/manufacture catalogue (must include shipping costs)
Human resources	Laboratory staff salaries	Government salary scale/laboratory or hospital accounts office
	Laboratory staff allowances and benefits	Government salary scale/laboratory or hospital accounts office
	Staff training off-site	Laboratory records/interview
Training & quality assurance	Relevant internal and external quality assurance program	Estimated at 5% of per-test cost, tested in sensitivity analysis for ranges between 2%–10%

TB = tuberculosis; FIND = Foundation for Innovative New Diagnostics.

Appendix 2. Assumed expected life years for laboratory capital assets

Types of capital asset	Examples	Expected/depreciable life (range ^a)
Buildings	Building structures/infrastructures	30 yr
Equipment	Powered laboratory or medical equipment	10 yr (5–15 yr)
	Non-powered multi-purpose equipment	2 yr (1–5 yr)
	Laboratory glassware	2 yr (1–5 yr)
	Administrative equipment and computers	5 yr (2–10 yr)

^aA 1-way sensitivity analysis was conducted using this range.

Appendix 3. A worked-out example annual budget for complete roll-out of TB-LAMP into peripheral laboratories in Vietnam, including initial implementation costs

Row label	Category	Item	Cost (USD)	Comment
A	Equipment	LF-160 incubator (LAMP)	\$2,002.21	
B	Equipment	Shipping	\$450.82	Estimated cost for shipment to Vietnam
C	Consumables	MTBC detection kit	\$11,437.42	Cost of 12.5 kits needed to run tests for 1,500 samples (96 tests/kit)
D	Consumables	PURE DNA extraction kit	\$15,011.73	Cost of 20 kits needed to run tests for 3,500 samples (90 tests/kit)
E	Consumables	Pipette-60 set	\$1,429.46	Cost of 12.5 kits needed to run tests for 1,500 samples (1 pipette + 385 pipette tips/kit)
F	Consumables	Per test	\$7.97	To run 1 sputum sample
G	Consumables	Average number of working days per year	250	Number varies depending on country
H	Consumables	Average number of patients per day (medium volume labs)	14	Number varies depending on working hours and country
I	Consumables	Average number of tests per year	3,500	Number varies depending on working hours and country
J	Estimated total cost for installation		\$2,453.03	A + B
K	Estimated running costs/year		\$27,878.61	C + D + E
L	Total per lab		\$30,331.64	J + K

USD = United States Dollar; LAMP = loop-mediated isothermal amplification; lab = laboratory.

Cost and affordability of TB-LAMP and Xpert assays

Appendix 4. Total cost and affordability of national roll-out of TB-LAMP compared to Xpert assay in Malawi and Vietnam, lower distribution of low volume laboratories

Workload categories	Malawi					Vietnam				
	No. of labs	TB-LAMP		Xpert		No. of labs	TB-LAMP		Xpert	
		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)
Low (≤ 4 tests per day)	80	\$674,162	12	\$2,210,167	39	460	\$3,876,429	53	\$12,708,458	174
Medium (> 4 and < 10 tests per day)	56	\$471,913	8	\$1,547,117	27	280	\$2,713,500	37	\$8,895,921	122
High (≥ 10 tests per day)	24	\$202,248	4	\$663,050	12	180	\$1,162,929	16	\$3,812,538	52
Total	160	\$1,348,323	24	\$4,420,333	78	920	\$7,752,858	106	\$25,416,917	348
Total national TB program budget (2014)			\$5,700,000					\$7,300,000		

TB = tuberculosis; TB-LAMP = loop-mediated isothermal amplification assay for tuberculosis; Xpert = Xpert MTB/RIF; Lab = laboratory.

Appendix 5. Total cost and affordability of national roll-out of TB-LAMP compared to Xpert assay in Malawi and Vietnam, higher distribution of low volume laboratories

Workload categories	Malawi					Vietnam				
	No. of labs	TB-LAMP		Xpert		No. of labs	TB-LAMP		Xpert	
		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)		Total 1st yr cost	National TB budget (%)	Total 1st yr cost	National TB budget (%)
Low (≤ 4 tests per day)	112	\$943,826	17	\$3,094,233	54	644	\$5,427,001	74	\$17,791,842	244
Medium (> 4 and < 10 tests per day)	40	\$337,081	6	\$1,105,083	19	230	\$1,938,215	27	\$6,354,229	87
High (≥ 10 tests per day)	8	\$67,416	1	\$221,017	4	46	\$387,643	5	\$1,270,846	17
Total	160	\$1,348,323	24	\$4,420,333	78	920	\$7,752,858	106	\$25,416,917	348
Total national TB program budget (2014)			\$5,700,000					\$7,300,000		

TB = tuberculosis; TB-LAMP = loop-mediated isothermal amplification assay for tuberculosis; Xpert = Xpert MTB/RIF; Lab = laboratory.