



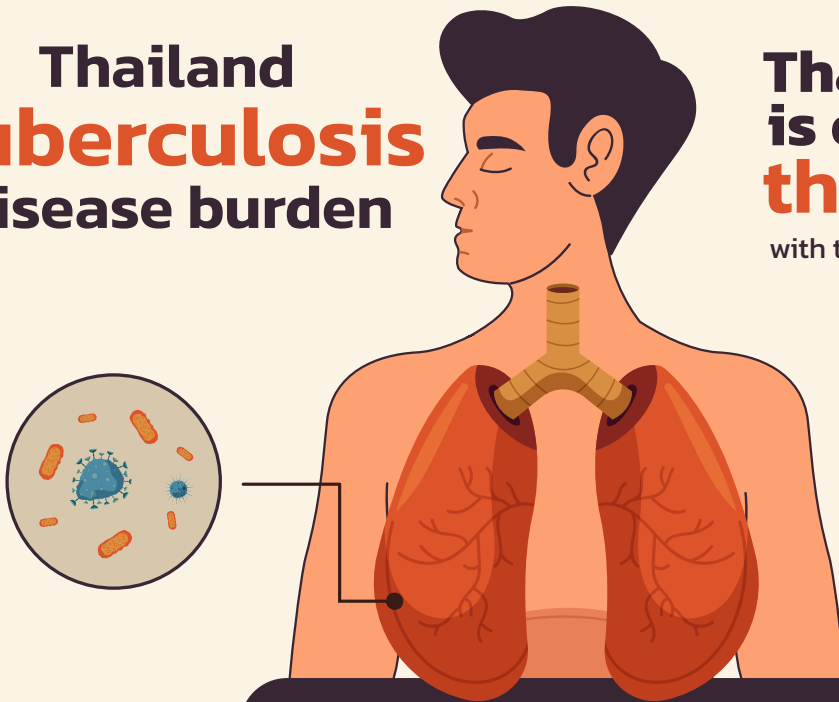
Early HTA: A Guide for Developing Cost-Effective Pulmonary Tuberculosis Tests Fitting the Healthcare Needs

Highlight

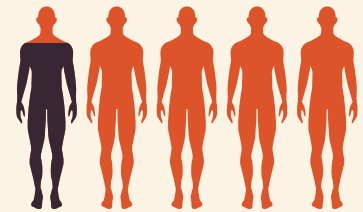
- Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis* (MTB) and represents a significant global health concern. Infectious agents can be easily spread through respiratory droplets, and TB patients face a significant risk of mortality.
- The traditional sputum-based TB screening method is time-consuming, and sensitive populations may be unable to produce sputum for TB screening. Non-sputum-based TB assays can address this issue. Sampling from the tongue (tongue swab) is faster and more applicable for individuals who cannot produce sputum.

Thailand Tuberculosis disease burden

Thailand
Tuberculosis
disease burden



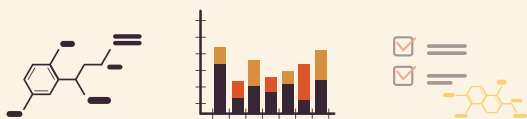
Thailand is one of **30** countries with the highest burden of tuberculosis



contributing approximately **103,000 cases** in the total population

In 2011, Thailand reported **143 cases** of TB per **100,000** individuals

Why Early HTA is Important for Developing TB Tests ?



Early health technology assessment (Early HTA) is a multidisciplinary approach to evaluate an emerging health innovation during the early research and development stages.

At these stages, early HTA can guide the innovators on the direction of their research and development to ensure that the emerging innovations fit the demands of the healthcare system in the future.

About the technology of the test

Tongue swab-based sample collection method for tuberculosis diagnosis is designed to complement, rather to replace, existing diagnostic methods. Its primary aim is to address the **challenges of collecting samples from populations who are unable to produce sputum**, such as children and HIV patients. Samples collected via tongue swabs can be processed for the widely available testing methods, **including advanced molecular techniques like Xpert MTB/RIF, LAMP, and Real-time PCR.**

This innovative approach offers faster results while maintaining similar sensitivity and specificity to traditional culture and sputum-smear microscopy methods, thereby enhancing diagnostic efficiency and accessibility.

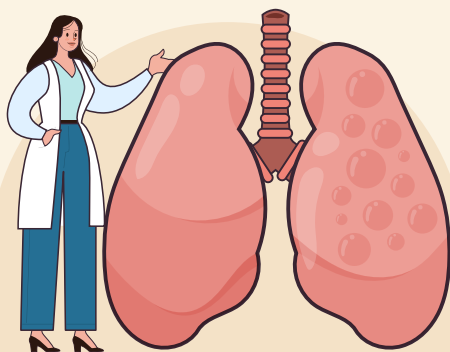


Advantages of Early HTA in Innovation Development

- helping innovator to decide **"to go" or "not to go"**
- helping the structure design of **clinical research**
- evaluating the potential **market value.**
- designing** target product profile.



Target Product Profile to Guide Innovation Development



Early HTA study employed a holistic approach including landscape review, expert elicitation and early health economic modelling. Through continuous interactions between the early HTA researchers and innovators, this study identified useful information for innovators such as the potential value of the tongue-swab sample collection method for Pulmonary TB screening in Thailand.

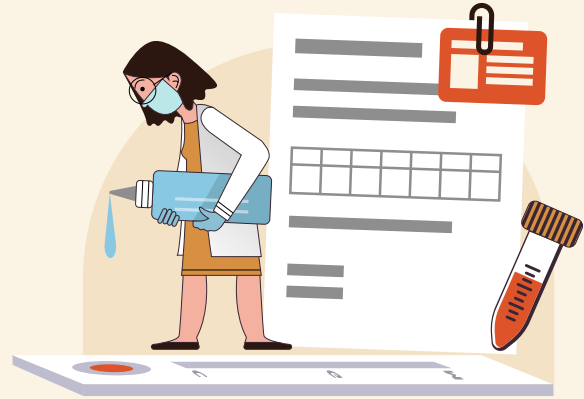
This study also identified a target product profile for non-sputum-based assays for TB screening and treatment monitoring. The target product profile indicated the minimally acceptable and preferred criteria for sensitivity, specificity, and price in order to guide the innovators to develop cost-effective TB screening method.

The results of the study

for non-sputum-based assay matching with

LAMP methods to be cost-effective,

it needs to provide more specificity and sensitivity than traditional method and at a lower cost.



Product Profiles	Base value	Minimum value	Acceptance value	Ideal value
Non-sputum specimen with LAMP technique (TS LAMP)				
Population aged over 5		Superior to AFB&Xpert	Superior to sputum specimen with RT-PCR	Superior to non-sputum specimen with RT-PCR
Sensitivity	0.826	0.816	0.952	1.000
Specificity	0.945	0.937	1.046	1.084
Price (THB)	860	913.45	177.08	-82.97
Sputum specimen with RT-PCR technique (TS RT-PCR)				
Population aged over 5		Superior to AFB&Xpert	Superior to sputum specimen with RT-PCR	
Sensitivity	0.910	0.726	0.862	
Specificity	0.989	0.842	0.951	
Price (THB)	670	1666.41	930.05	

Comparison between sputum-based and non-sputum-based screening

Sputum-based screening	Non-sputum specimen collecting technique (tongue swab)
Time-consuming	Sampling faster
Not applicable for people without sputum	Applicable for all
Expensive	Low cost
Sputum-based assays	Non-sputum-based assays (tongue swab)

Table of cost comparison

Screening method	Sputum specimen (THB)	Non-sputum specimen (THB)
LAMP	1006	860
RT-PCR	789	670

Recommendations

Non-sputum specimen collecting technique (tongue swab) is a method that requires less testing time, lower cost, and applicable for all. This technique aligns with the needs of future healthcare systems and, when evaluated through early health technology assessment (Early HTA), it was found to be a cost-effective technology. Therefore, tongue swab testing techniques are suitable for developing innovations and producing products.

About this project

This study is a collaboration between the Medical Innovation Development Assessment Service (MIDAS) Unit, Health Intervention and Technology Assessment Program Foundation (HITAP Foundation), and the Mahidol-Oxford Tropical Medicine Research Unit (MORU), Mahidol University. This study was supported by Thailand Science Research and Innovation (TSRI). This study aims to develop alternative methods for pulmonary tuberculosis screening and treatment monitoring with the potential for broader population coverage and cost savings for the public health sector. The objectives of this study are 1) Identify the value proposition of the new test 2) Understand the investment required for the new test in the local setting and identify preferred characteristics that would make the test feasible and scalable, such as affordability, quality, and compatibility with Thailand's healthcare systems and 3) Assess economic and health impacts of integrating the new test into the current healthcare system.

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This document is a part of the research titled Early Health Technology Assessment of Non-Sputum-based Assays for Screening and Treatment Monitoring in a Prospective Cohort of Pulmonary Tuberculosis.

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