Terms of Reference

Sub-contract of study: Tuberculosis case yield of risk group screening using optimized screening and diagnosis algorithms in Indonesian primary health care centers

July-December 2017

A. Background

The national TB prevalence survey has shown that Indonesia is missing notifications for about 670,000 cases per year, resulting in a current estimated case detection rate of only 33%. To halt and reverse the TB epidemic in Indonesia, there is an urgent need for strategies that increase case detection of TB. With the current screening and diagnosis algorithm, it is possible that a significant number of TB cases are missed at Puskesmas level due to the algorithm's low sensitivity and specificity. Considering the wide coverage of primary health care centers (*Puskesmas*) in Indonesia, optimising TB case detection using more sensitive and specific diagnostic tools at Puskesmas level is important. Once developed, such tools can also be used in the private sector. Enhanced case finding using a sensitive screening algorithm combining risk, signs and symptoms of TB with sensitive diagnostics (i.e., Xpert MTB/Rif) is required to detect more TB cases.

In collaboration with the National TB Program (NTP) and local researchers, Challenge TB will conduct a study which aims to maximize case finding in Puskesmas against affordable cost by 1) assessing which groups among Puskesmas clients have higher risk of TB (and should thus be prioritized for active screening) and 2) using a more sensitive screening algorithm which may include X-ray and more TB symptoms than currently included. Since the NTP intends to roll out Xpert MTB/Rif as the test of first choice for all persons suspected of having TB in the near future, any case finding algorithm will include Xpert as the diagnostic tool. The identified enhanced case finding algorithm(s) will be compared to passive case finding ('business as usual') using Xpert MTB/Rif as the diagnostic test. However, it is currently not known if there are high TB risk groups among Puskesmas clients, and it is also not known what the incremental yield of adding X-ray and/or more symptoms to the screening algorithm is on case finding. Therefore, the operational research will be conducted in two phases:

- Phase I will concentrate on finding the most optimal algorithm(s) for enhanced case finding among Puskesmas clients, based on combinations of client characteristics, symptoms and signs of TB, optimizing the (health system) cost per case detected against the incremental number of TB cases detected (will be conducted in 2017). In this phase, all Puskesmas clients will be screened for TB symptoms and risk and will undergo CXR and will further be tested for Xpert and sputum smear microscopy (Figure 1). A maximum of 10 Puskesmas that represents the maximum variation will be

selected. Puskesmas sampling will be conducted purposively. Aiming to include a minimum of 10-15 TB patients for each Puskesmas, and assuming a 2-3% TB prevalence among clients and 85% of clients can provide sputum, minimal 6000 clients will be screened within the duration of 2-3 weeks per Puskesmas (600 clients per Puskesmas per week).

Figure 1. Flow of screening and diagnostic of TB patients at Phase I

- Phase II of the study will subsequently test the feasibility, acceptability and cost-effectiveness of the most promising algorithm selected from Phase I, scaled-up and implemented in routine practice (will be conducted in 2018). Phase II will be carried out as a cluster-randomized trial, in which clusters are defined as Puskesmas. The most optimal symptom-risk group combinations for screening of clients of PKM will be randomly assigned to multiple Puskesmas (intervention group) while other Puskesmas serve as the control group (Figure 2). Sample size calculation in Phase II depends on the choice of algorithm defined from phase I. This is because different risk groups will have different baseline notification rates of pulmonary TB and this will result in different expectations about the potential incremental increase in case notification that can be achieved after implementing the chosen screening algorithm.

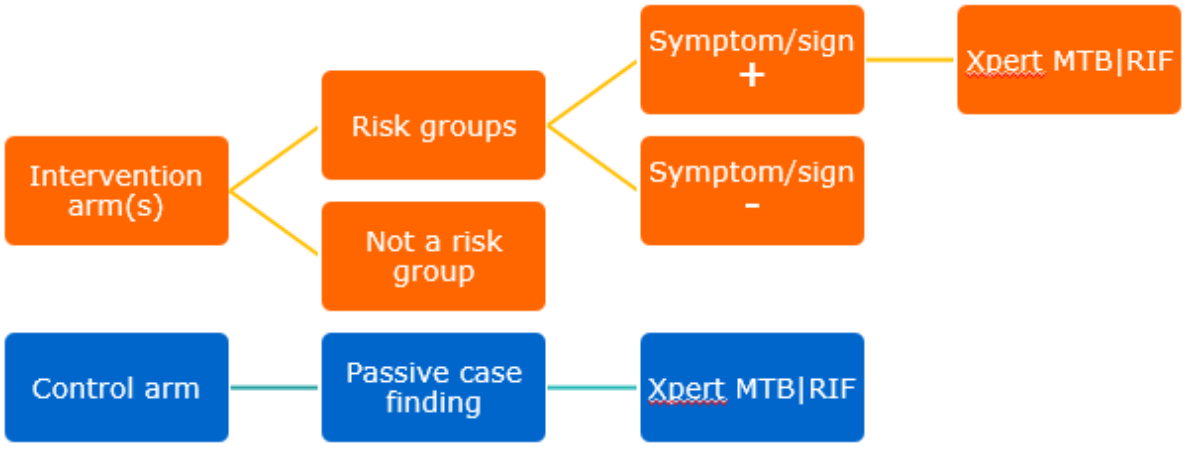

Figure 2. Flow of screening and diagnostic of TB patients at Phase II. Puskesmas form the units of intervention.

In order to ensure quality implementation of this operational research, Challenge TB will sub-contract local researchers/institutions to coordinate with different stakeholders, closely supervised the implementation of the study and at the same time give valuable recommendation and input to the study. This collaboration is expected to encourage local ownership as well as part of capacity building for young researchers who are expected to take part on this sub-contract. Moreover, it will ensure on time implementation of the study which will result in early and prompt recommendations to the NTP.

B. Objective

General

1. To Ensure quality implementation of Operational Research on Tuberculosis case yield of risk group screening using optimized screening and diagnosis algorithms in Indonesian primary health care centers
2. To increase local ownership of the study implementation and to encourage adoption of the study results
3. To build collaboration with local researchers
4. To encourage capacity building through the involvement of young researchers or students or graduates within the study team

Specific

1. To coordinate with all stakeholders and relevant authorities matters related to the study
2. To support study development and preparation (including study permits)
3. To oversee the study implementation (including supervision and M&E)
4. To provide recommendation and input for data analysis and study result
5. To hire and supervise study coordinator
6. To facilitate phase-I and phase-II training (curriculum and expertise)

C. Methodology

This terms of reference will be announced publicly. Interested researchers should submit the following documents:

1. Brief plan or method of work to achieve the objectives and deliverables

2. Curriculum vitae

Completed applications must be submitted in English and no later than 5:00 p.m. August 5, 2017, by email to ctbindonesia@kncvtbc.org with email subject: subcontract OR ICF Bogor_[researcher name or instution].

Criteria of selection are the following:

1. Expert in conducting operational research
2. Strong experience in tuberculosis researches, supported with oustanding international publications
3. Established network and collaboration with TB program and related stakeholders
4. Willing and feasible to conduct close supervision in study area (Kabupaten Bogor)

Selected researchers are recruited and engaged in the development of a detailed proposal and the sub-contract. As part of the capacity building, the researchers are encouraged:

1. To recruit young researchers or students or graduates from local universities to be involved in data collection, data analysis and report writing
2. To involve Puskesmas staff during data collection analysis and interpretation of the results

D. Key activities

Under close collaboration with KNCV/Challenge TB and the Ministry of Health, the researchers are requested to do the following :

1. Prepare and finalise the data collection tools
2. Prepare and finalise guidelines for data collection and analysis
3. Conduct data collection
4. Conduct supervision and monitoring & evaluation
5. Conduct data analysis
6. Attend all study related meetings both with KNCV/Challenge TB, NTP and other stakeholders
7. Support the pilot and training as part of the preparation of the study implementation
8. Communicate regularly with KNCV/Challenge TB in regards to study progress

9. Increase capacity of young researchers or students or graduates and Puskesmas staff related to data collection, analysis and interpretation of the results through on the job training
10. Produce a report (as part of and to be integrated with the final study report)
11. Produce a financial report of consultancy

E. Deliverable

At the end of the contract, the researchers have to deliver documents which written in English and Bahasa Indonesia as follow:

1. Quality study implementation
2. Recommendation for data analysis, interpretation and study result
3. Develop advocacy plan to relevants policy maker related to implementation & scale up of study results
4. Supervision report and M&E report
5. Financial report of the consultancy

F. Schedule:

	2017																								
	July				August					September				October				November					December			
Activities	1	2	3	4	1	2	3	4	5	1	2	3	4	1	2	3	4	1	2	3	4	5	1	2	3	4
Training pilot																										
Pilot																										
Pilot evaluation																										
Training for phase I																										
Data collections																										
Supervisions																										
M&E meeting																										
Data analysis																										

Report writing																								

G. Data ownership and patient confidentiality

Data collected and processed during the study including data management and analysis generated will remain under the ownership of researchers and NTP. The results of the study may be published or otherwise publicly announced. An acknowledgement shall be made for the contributions of the researchers. Before further analysis or utilisation of the data outside of the study purpose by sub-contract researchers, formal notification and approval of all involved researchers, NTP and KNCV/CTB should be sought.

This study is sponsored by the USAID through KNCV/Challenge TB (CTB) project. Therefore, an acknowledgement for USAID and KNCV/CTB support should be made visible in any publications resulted from this study.

All data collected during the study is linked to a Unique Participant Identification Code (UPICs) that does not enable direct identification of participants. Data linking UPICs to confidential information (i.e., name and address information of participants) will not be digitized and will only be used for confirmation of linkage of data in case of linkage problems.

H. Place of study

The study will be conducted in Bogor district. However, meetings in Jakarta or West Java Province might be possible.