ASSESSING TB UNDER REPORTING IN ZAMBIA THROUGH AN INVENTORY STUDY

TERMS OF REFERENCE

1.0 Background

The World Health Organization (WHO) estimated that more than four million tuberculosis (TB) cases are missed by national TB surveillance systems annually (WHO, 2017). Although the WHO declared that finding these missed TB cases is a top priority to reach Global End TB targets, still the number and characteristics of missed cases are largely unknown in most high TB burden countries (WHO, 2015).

In Zambia, TB remains a significant public health problem and one of the leading causes of morbidity and mortality. Following an exponential increase in the number of new and relapse TB cases notified to the National TB program from the mid-1980's that peaked in 2003 to 504/100,000 population, there has been a gradual decrease in the number of cases and the notification rate reduced to 231/100,000 population in 2016.

However, the first National TB Prevalence Survey in Zambia, conducted from 2013 – 2014, found that the prevalence of bacteriologically confirmed TB in the adult population was 638/100,000 (range 502–774). For all forms of TB in all age groups the prevalence was 455/100,000 population. These rates are much higher than previously estimated by the World Health Organization (WHO, 2013), implying that more TB cases are being missed. For instance, in 2016, despite WHO estimating 62,000 incident TB cases in Zambia, only 38,326 new and relapse TB cases were notified.

The reason for the declining TB notifications can be as a result of under-diagnosis or underreporting of TB cases to the national program. Under-reporting can be due to TB cases being diagnosed but are not started on anti-TB treatment (pre-treatment lost to follow-up) or TB patients are on TB treatment but are not reported to the National TB Program.

In responding to these challenges of the missed TB cases, the World Bank in collaboration with the East, Central and Southern Africa Health Community (ECSA-HC) is supporting the implementation of the Southern Africa TB and Health Systems Support (SATBHSS) Project. The project is being implemented in Lesotho, Malawi, Mozambique and Zambia with the main objectives of:

(i) Improving coverage and quality of TB control and occupational lung disease services; and
(ii) Strengthening the regional capacity to manage the burden of TB and occupational diseases.

Under the SATBHSS Project, funds have been made available for technical support for regional innovation through generation and sharing of knowledge and evidence from TB prevention and control interventions. The Ministry of Health through the National Tuberculosis and Leprosy Program (NTLP), therefore seeks to recruit a suitably qualified and experienced consulting firm to assess and quantify the level of TB underreporting in Zambia through an inventory study.
2.0 Rationale

The Ministry of Health through the NTLP has developed and launched a new TB National Strategic Plan (2017-2021). This National Strategic Plan, which is aligned with the National Health Strategic Plan (2017-2021), the Global End TB Strategy and Sustainable Development Goals (SDGs), has outlined ambitious milestones and targets towards ending the TB epidemic in Zambia by 2030. To achieve this goal, the NTLP should find all the missed TB cases and put them on treatment. In addition, Zambia being one of the 30 high TB burden countries in the world, assessing underreporting through an inventory study is a requirement to meeting one of WHO benchmarks for TB surveillance.

3.0 Objectives

The main objective of the study is:

To determine the level of under-reporting of diagnosed TB cases in Zambia

The specific objectives are:

a) To evaluate the level of diagnosed bacteriologically confirmed TB cases who are not starting anti-TB treatment (pre-TB treatment lost to follow-up)
b) To quantify diagnosed bacteriologically confirmed TB cases put on anti-TB treatment but were not reported to the national program
c) To define the characteristics of the under-reported TB cases
d) To identify risk factors associated with under-reporting of bacteriologically confirmed TB cases in Zambia
e) To identify possible gaps in the national TB surveillance system
f) To develop recommendations to minimize initial default and subsequent under-reporting, and thereby improve TB surveillance approaches

4.0 Methodology

The inventory study will be conducted retrospectively using already existing data in the TB laboratory registers, TB treatment registers, health facility quarterly and annual reports, and national TB data. Study period will be from January, 2017 to December 2017.

The study will include districts randomly selected from the list of all districts in Zambia, while some districts in Lusaka and Copperbelt Provinces shall be purposively selected. All the TB diagnostic centers, public or private, in the selected districts shall be included in the study, whilst private health facilities in Lusaka and Copperbelt Provinces will be purposively selected.

Data on pre-treatment lost to follow-up will be extracted from the TB laboratory registers and compared with data recorded in the TB treatment registers. Data on TB cases who were put on anti-TB treatment but not reported to the national level will be extracted from the TB treatment registers,
health facility quarterly and annual reports and compared with the data reported to the national level. Data on TB diagnosis will also be retrieved from GeneXpert machines reports in the study sites. All data will be cross-matched using a combination of unique (TB number) and non-unique personal identifiers to the TB cases which were reported to the national TB program at district, provincial and national levels.

In addition, drug consumption data at each pharmacy will also be used to assess whether more drugs were consumed compared to the number of TB patients recorded and reported to the national level.

In addressing objective c), the methodological approach shall encompass identification of gaps at all levels of the health system: national, provincial, district, facility and community. Additionally, the gaps in the surveillance system to detect TB, initiate treatment, provide supportive care and report treatment outcomes shall be identified for each of the following to be achieved:

i) Bacteriological confirmation of TB,
ii) Siting of disease (PTB or EPTB),
iii) History of previous treatment,
iv) HIV status,
v) Treatment outcome,
vi) Drug resistance, etc.

The overall methodological approach for the study should be established and detailed according to the guidance described in the WHO 2012 report ‘Assessing TB under-reporting through inventory studies’.

5.0 Scope of the Assignment

A consulting firm will be recruited to carry out this assignment whose scope will include, but not be limited to the following activities:

a. Present to the Ministry of Health an inception report outlining the study methodology, milestones and timelines;
b. Assemble and organize the inventory study team comprised of the appropriate number of experts to design, implement and analyse the study, in collaboration with the MOH NTP lead team
c. Develop a comprehensive plan for the appropriate inventory study design and methods to be used according to the guidance described in the WHO 2012 report ‘Assessing TB under-reporting through inventory studies’ and other relevant literature
d. Development of inventory study protocols and submission for ethical approval
e. Ensure methodologies and approaches for record-linkage of cases with the national TB surveillance databases
f. Pilot the study to identify issues and strengthen the training phase of the study
g. Orientation and training of field team members and data collectors in the study sites
h. Retrospective data collection, reporting on progress and discuss deliverables at each stage as may be required and agreed upon.
i. Conduct monitoring and data quality assurance through supervisory visits.
j. Data collation and cleaning.
k. Conducting data analysis according the recommended WHO approaches.
l. Develop and submit a preliminary report highlighting the main findings with proposed recommendations.
m. Submit all the study materials to the MOH NTP which shall include data base, technical report and do-files for the cleaned data base.
n. Develop strategies for dissemination of key findings and recommendations through presentations at stakeholder meetings.
o. Develop and submit a final report with recommendations after obtaining input from all relevant stakeholders at country and regional level.
p. Develop a policy brief based on the key findings of the study in collaboration with the MOH.
q. Perform all the above listed activities in close collaboration with the MOH NTP.

The consulting firm may engage or collaborate with other key experts required for the scope of works aforementioned.

6.0 Duration of the Consultancy

It is envisaged that the assignment will be undertaken in 45 consultant days spread over a maximum period of three (03) calendar months including the time for consultation and report writing, and the preparation and submission of deliverables including clients/Bank staff reviews and clearances.

Table I: Timeframe for conducting the study

<table>
<thead>
<tr>
<th>Milestones</th>
<th>Expected Timelines</th>
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<tbody>
<tr>
<td>Initial meetings with MOH NTLP lead team to agree on study focus and methodologies</td>
<td>Within 7 days of being awarded the contract</td>
</tr>
<tr>
<td>Inception report detailing the sampling procedure of health care facilities and areas, study methodology, milestones and timelines</td>
<td>Within 7 days of signing the contract</td>
</tr>
<tr>
<td>Develop study protocols, including inventory study design tools, data management and quality assurance plans</td>
<td>Within 7 days of approval of the inception report.</td>
</tr>
<tr>
<td>Submission of study protocols for review and validation by MOH</td>
<td>Within 5 days of review of inception report</td>
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<tr>
<td>Seek ethical approval</td>
<td>21 days after submission to Ethics Committee</td>
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<tr>
<td>Retrospective data collection in sampled health care facilities/providers</td>
<td>21 days</td>
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<tr>
<td>Data cleaning and analysis</td>
<td>Within 14 days completion of the data collection</td>
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<tr>
<td>Draft report</td>
<td>10 days after completing the data analysis</td>
</tr>
<tr>
<td>Dissemination of key findings and recommendations and development of a policy brief</td>
<td>20 days after completing the data analysis</td>
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<tr>
<td>Final report</td>
<td>5 days after receiving feedback from MOH NTLP on the draft report</td>
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### 7.0 Expected Outputs/Deliverables

The following are the key deliverables:

1. Detailed inception report
2. Comprehensive study protocol
3. Draft report and data set
4. Final report and data set

Other expected outputs include:

1. Participation in initial meetings with MOH NTLP lead team and detailed minutes of the discussions
2. Inventory study data collection tools and data-base
3. Pilot study report
4. Orientation/Training report
5. Report of dissemination of the study findings in national and regional consultative meetings to obtain stakeholders views and comments
6. Policy brief on addressing under-reporting of TB cases in Zambia

### 8.0 Payments

The payment will be based on the guidance from the Zambia Public Procurement Authority (ZPPA) for similar assignments and directly linked to the deliverables as indicated below:

<table>
<thead>
<tr>
<th>Payments</th>
<th>Deliverables</th>
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<tr>
<td>15% of total contract value</td>
<td>Signing of contract</td>
</tr>
<tr>
<td>45% of total contract value</td>
<td>Submission of Inception report acceptable to the NTLP</td>
</tr>
<tr>
<td>25% of total contract value</td>
<td>Submission of draft report acceptable to the NTLP</td>
</tr>
<tr>
<td>15% of total contract value</td>
<td>Submission of final report acceptable to the NTLP</td>
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All deliverables will be quality assured by the Ministry of Health through the NTLP. Should the deliverables not be satisfactory due to the consultants’ fault, remaining deliverables will be completed without any additional payment.
9.0 Profile of the Consultant

A consulting firm consisting of qualified and experienced team members, shall be selected using procedures agreed between the Government of the Republic of Zambia and the World Bank. The lead consultant, who will be the principal investigator, should have the following qualifications, competencies and abilities:

- At least a Master of Public Health or MSc in Epidemiology, Medical Statistics or related discipline
- Proven experience and track record in conducting rigorous epidemiological studies, including advanced statistical analysis.
- Demonstrate the following expertise;
  - Evidence of at least 8 - 10 years of Professional experience in the relevant fields related to these TORs such as public health, biostatistics and analytical epidemiology
  - Work experience in the Zambia health care delivery system or similar settings will be an added advantage
- Added advantages will include:
  - Having conducted a similar assignment: conducting TB prevalence and inventory studies
  - A PhD in Public Health or MSc in Epidemiology, Medical Statistics or related discipline
  - Extensive knowledge and understanding of the principles of TB prevention and control, and surveillance systems,
  - Experience working with international health organizations.

In addition, the consulting firm’s core team members should comprise of the following key staff with the following minimum qualifications and experience:

<table>
<thead>
<tr>
<th>POSITION</th>
<th>MINIMUM QUALIFICATION</th>
<th>WORK EXPERIENCE</th>
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<tbody>
<tr>
<td>Epidemiologist</td>
<td>A PhD or MSc degree in epidemiology, and/or public health with a strong focus on analytical epidemiology</td>
<td>At least five years’ work experience in population-based epidemiological studies, preferably studies on TB, work experience and knowledge of health care systems in the African Region or similar settings</td>
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<tr>
<td>Biostatistician/Data Manager</td>
<td>A master's degree in Statistics, Biostatistics or related field</td>
<td>At least five years’ work experience in data management in the context of research studies, database management, and work experience and knowledge of health care systems in the African Region or similar settings</td>
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<tr>
<td>Medical Laboratory Specialist</td>
<td>A Bachelor of Science degree in Laboratory Biomedical Sciences or related field</td>
<td>At least three years’ work experience in laboratory based medical sciences with a focus on TB, and work experience and knowledge of health care systems in the African Region or similar settings</td>
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10.0 Supervision and reporting

The consulting firm shall work under the supervision of the Ministry of Health National TB Program, and shall hold regular meetings with the NTLP personnel who will be part of the inventory study team to plan the work and review progress reports.