Safety assessment in primary Mycobacterium tuberculosis smear microscopy centres in Blantyre Malawi: a facility based cross sectional survey

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ABSTRACT

Introduction

Tuberculosis (TB) is caused by Mycobacterium tuberculosis and is transmitted mainly through aerosolization of infected sputum which puts laboratory workers at risk in spite of the laboratory workers' risk of infection being at 3 to 9 times higher than the general public. Laboratory safety should therefore be prioritized and optimized to provide sufficient safety to laboratory workers.

Objective

To assess the safety for the laboratory workers in TB primary microscopy centres in Blantyre urban.

Methodology

TB primary microscopy centers in Blantyre urban were assessed in aspects of equipment availability, facility layout, and work practice, using a standardized WHO/AFRO ISO 15189 checklist for the developing countries which sets the minimum safety score at ≥80%. Each center was graded according to the score it earned upon assessment.

Results

Only one (1) microscopy center out nine (9) reached the minimum safety requirement. Four (4) centers were awarded 1 star level, four (4) centers were awarded 2 star level and only one (1) center was awarded 3 star level.

Conclusion

In Blantyre urban, 89% of the Tuberculosis microscopy centers are failing to provide the minimum safety to the laboratory workers. Government and other stake holders should be committed in addressing the safety challenges of TB microscopy centres in the country to ensure safety for the laboratory workers.

Recommendations

It is recommended that the study be conducted at the regional or national level for both public and private laboratories in order to have a general picture of safety in Tb microscopy centres possibly across the country.

Introduction And Background

Tuberculosis (TB) is caused by Mycobacterium tuberculosis (M.Tb). This disease is a major global health problem. Each year, there are around 9 million new cases of TB and close to 2 million people die from the disease and all countries are affected but 85% of cases occur in Africa (30%) and Asia(55%) while India and China alone represent 35%1.

TB cases in Malawi have recently gone downward, decreasing from nearly 28,000 notified cases in 2003 to about 23,000 notified cases in 2010. In 2007, Malawi declared TB a national emergency2. This means that TB still remains a health problem in Malawi despite the notable efforts and strategies put in place in the previous years to combat the disease by National Tuberculosis Program (NTP). Since TB is chiefly spread through inhalation of droplet particles (nuclei) containing virulent human strains of "Mycobacterium tuberculosis" in crowded places or rooms with limited air flow; prisons, hospitals and any large gathering for a prolonged time, this overcrowding poses a risk of transmitting the bacilli3. In a hospital setting, this leaves clinicians, nurses, ward attendants, laboratory workers and other health workers at risk of Tuberculosis infection. "Health care workers and other staff are also at particularly high risk of infection with TB because of frequent exposure to patients with infectious TB disease"4

Another study conducted in Malawi in 1998 found that Laboratory conditions and safety procedures were poor. In the findings, out of 38 hospitals in the sample frame, 17 (45%) had an area of less than 25 m2, eight (21%) had a separate room for tuberculosis work, and five (13%) had a safety cabinet. All laboratory personnel wore gloves, but in several hospitals there were no white coats, face masks, protective aprons or soap for washing hands5. As such, it is crucial to determine how safe the Laboratories are for the workers therein if we are also going to scale down the overall case mortality rate of Tuberculosis which currently stands at 24% in health care workers against the general population.6

Therefore, it is imperative to use a conventional checklist devised by the World Health Organisation (WHO) which is called 'World Health Organisation / African Region Office International Systems Organisation 15189 accreditation checklist', in short the WHO / AFRO ISO 15189 accreditation checklist. It contains items and protocols that are supposed to be available in the laboratory in order to recognize it and be allowed to participate in international laboratory quality schemes. And since most African countries have limited resources, the WHO recommends an aggregate score of 80% or above to be considered for accreditation.7 In 1995, Sewell D, conducted a study in the United States of America to identify laboratory-associated infections and bio safety. It was reported that the risk of exposure to infectious agents tends to be lower in laboratory workers than other groups of health care workers (HCW) but the risk of laboratory-associated infection in employees of clinical and research laboratories is greater than in the general population.8

This study was aimed at assessing the safety for the laboratory workers in TB microscopy centers in Blantyre urban.

Methodology

All primary TB microscopy centres in Blantyre urban (Lirangwe, Chilomoni, South Lunzu, Ndirande, Limbe, Zingwangwa, Mpemba, Chileka and Bangwe Health centres) that perform TB microscopy were included in the study. All referral, private and research laboratories were excluded.

Two methods were employed to collect data in this study. The 'observational method' and a 'Checklist' were used to assess the availability and utilization of safety facilities especially to find out the necessary Personal Protective Equipment available (PPE) and how the available PPE were

used. On observational data collection, visual comparison of the TB microscopy centre was done by the investigators. Information such as, if the TB laboratory was isolated, if entry to the laboratory was restricted, laboratory air flow, and how PPE were used was collected through observation. A Checklist contained some recommendations from the WHO and investigators used such information to compare the available PPE and other safety measures at each facility.

All TB microscopy centers were evaluated using WHO / AFRO ISO 15189 accreditation checklist. It was standardized to meet the objectives of the project. The elements of this checklist are based on ISO standard 15189:2007(E) and, to a lesser extent, CLSI guideline GP26-A37.

A score of 2 points was awarded for each item available; 1 point for unsatisfactory outcome and no (0) point when the item was not available or the procedure was not followed as shown on supplementary data. Procedures which were assessed comprised sputum reception, transportation, smear preparation and slide staining.

The checklist was divided into sections; Reagents and Consumables which had a possible total score of 34; Items and Design had a total possible score of 78 and Procedures (sputum reception, transportation, smear preparation and slide staining) which had a possible total score of 40.

The aggregate score for all the sections was 152. Therefore each microscopy center was calculated a percentage from the aggregate score and ranked according to the corresponding star level indicated on table 1.

Table 1: a sample of WHO/AFRO checklist grading

0 STAR (<55%)	1 STAR (55-64%)	2 STAR (65-74%)	3 STAR (75-84%)	4 STAR (85-94%)	5 STAR (>95)

The specific safety aspect such as the general work practice, the suitability of the facility to perform TB microscopy and finally the status of the laboratory equipment for each health centre were also assessed.

Results

The findings revealed that eight of the nine TB microscopy centres lacked proper safety facilities as indicated in Table 2

Table 2: Results for all Blantyre urban health centers following WHO/ AFRO grading system

HEALTH CENTRE	PERCENTAGE	STAR
NDIRANDE	57	1
CHILEKA	63	1
CHILOMONI	65	2
MPEMBA	67	2
BANGWE	71	2
LIMBE	73	2
SOUTH LUNZU	63	1
LIRANGWE	61	1
ZINGWANGWA	80	3

Summary of the findings for all the TB microscopy centres in Blantyre Urban. source: J.Majamanda, P.Ndhlovu and I.T. Shawa

Since the first objective involved taking note of the items and protocols at the site, the specific observations which directly contributed the star level of each health centre are given in much detail below:

Ndirande Health Centre had a dysfunctional biosafety cabinet fan. When in use it was incapable of sucking air out of the safety cabinet but rather pushed the air towards the worker. The exhaust duct was blocked by the iron sheets. There were no biohazard bags, which made the disposition of laboratory wastes risky. There were no ideal sputum transportation boxes; as such the cartons were improvised, as shown in the figures 1 below;

Figure 1: Improvised transportation boxes

Chileka Health Centre had no disinfectants. The already prepared reagents were not properly labeled. And the biosafety cabinet was not working properly.

Mpemba Health centre had no sample reception area. The centre did not have biohazard bags, and equipment for preparing reagents for smear preparations.

At South Lunzu health centre, the biosafety cabinet was not available; as such TB smear preparation was done on open benches. There was no ideal sample transportation box; therefore a carton was also improvised just like Ndirande health centre. There were no disinfectants and hand washing soaps. Patients were seen carrying their own sputum samples into the laboratory, passing through a crowd of other waiting patients, exposing not only the laboratory workers to potential TB infection, but also the other patients.

Limbe Health Centre did not have sample transportation boxes; as such cartons were also improvised. The biosafety cabinet exhaust duct faced the patients' waiting area as shown in figure 2 below.

Figure 2: Improperly placed exhaust ducts at Limbe Health Centre.

At Lirangwe Health Centre, there was no electricity

connection, no reagent preparation materials such as weighing balance, staining racks and proper glassware. However this health center had a proper sputum transportation box as recommended by the Ministry of Health as shown in the figure 3 below;

Figure 3: An ideal sputum transportation box at Lirangwe Health Centre

At Zingwangwa Health Centre there were no biohazard bags. The direction of air in the biosafety was from dirty to clean area. There were no biohazard bags and some staining reagents such as phenol solution.

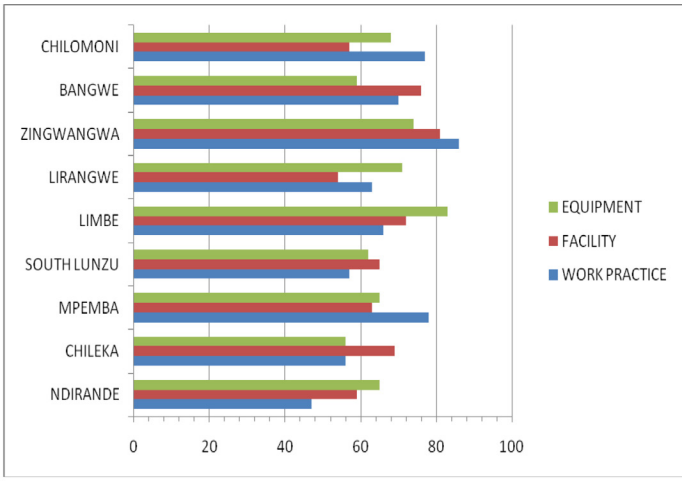
Bangwe Health Centre had no biohazard bags. Exhaust ducts placed close to open windows.

In the absence of a designated sample reception area at Chilomoni Health Centre, patients brought their own sputum samples to the laboratory, passing through a crowded waiting area. No soap for disinfection was seen. The samples were processed in a tiny and congested (not spacious) laboratory room.

The three aspects of safety (work practice, facility layout, and equipment) for all the health centers revealed that all the aspects of safety in the laboratory were affected, but facility layout was affected the most. Figure 4 shows how each health centre performed. For example, the study shows that safety related to work practice at Zingwangwa health centre was above 80% which means that the laboratory personnel are striving to ensure safety in the laboratory. The infrastructure at the centre was rated at 80% to provide safety in the laboratory while status of the laboratory equipment was 60% which calls for some improvements.

Safety aspects such as work practice, infrastructure and status of laboratory equipment: source J.Majamanda, P.Ndhlovu and I.T. Shawa

Figure 4: The Bar graph showing specific safety aspect for each health centre



The mean score for all the 9 centers is 66.67% which is far too low from the minimum requirement of 80%. Eight (8) out of the nine (9) centres in the study population have scored less than the minimum safety requirement of ≥80% which represent 89% unsafe centres.

Discussion

This cross-sectional facility based analytical survey was designed to assess the safety in primary Mycobacterium tuberculosis smear microscopy centres in Blantyre urban. The minimum safety requirement as established by the WHO/AFRO for each primary microscopy centre is ≥80% using the ISO 15189 standardised checklist for developing countries. The findings of this study show that only one microscopy centre (Zingwangwa) out of nine centres scored 80%, which is the minimum safety requirement while the rest of the health centres were below the required minimum set standards. All the aspects that offer safety in the laboratory (facility layout, equipment and work practice) have been affected, but the most affected is the facility layout. This does not only put the laboratory workers at risk of infection, but also the patients and any other person accessing the laboratory services.

The findings correlate with another study conducted in Malawi in 1998 by Nyirenda TE, which concluded that laboratory conditions and safety procedures in TB smear microscopy in Malawi are poor3. The health centres provide easy access for TB testing and assist in early detection of smear positive cases which enhance the prompt treatment and management of patients. From the findings, Zingwangwa health centre would be considered safe (borderline) to perform smear microscopy according to the used guidelines. There is need to ensure safety in all the laboratory facilities where TB smear microscopy is performed. The study indicated that the health centres lack proper infrastructure. The laboratories were too small and crowded.

Conclusion And Recommendations

In Blantyre urban, 89% of the Tuberculosis microscopy centres were failing to provide the minimum safety to the laboratory workers. All the microscopy centres except one (11%) that were included in the sample frame had scored less than the minimum safety requirement (80%). This means that 89% of the microscopy centres in Blantyre urban failed to provide the minimum safety to the laboratory workers. Government and other stake holders should therefore be committed in providing safety in the laboratories in the country (in primary Tb microscopy centres and other referral centres which face the same challenges).

It is recommended that the study be conducted at the regional or national level in order to have a general picture of safety in Tb microscopy centres possibly across the country. Both public and private laboratories should be included in future studies.

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