



Safety Assessment in Primary Mycobacterium Tuberculosis Smear Microscopy Centres in Blantyre, Malawi: A Facility Based Cross Sectional Survey.

Blantyre, Malawi'de Bulunan Yayma Mikroskopi Merkezlerindeki Primer Mycobacterium Tüberkülozis vakalarının Güvenlik Değerlendirmesi: Merkez Bazlı Kesitsel Çalışma

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ABSTRACT

Purpose: Tuberculosis (TB) is caused by Mycobacterium tuberculosis and is transmitted through coughing, sneezing, laughing and singing. Laboratory workers' risk of infection is 3 to 9 times higher than the general public as they handle potentially infectious samples. Laboratory safety should therefore be prioritized and optimized to provide sufficient safety to laboratory workers. The aim of this study was to assess the safety of the laboratory workers in TB primary microscopy centres in Blantyre urban.

Material and Methods: 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 $\geq 80\%$. Each center was graded according to the score it earned upon assessment.

Results: The safety hoods were not functional in Ndirande, Lirangwe and Chileka microscopy centres. No safety hood was found in South Lunzu. In Ndirande and Limbe the exhaust ducts face the patients' waiting area and door to the laboratory, putting them (patients and laboratory technicians) to a greater risk of infection when smear preparation begins. Bangwe, Chilomoni, Ndirande, Chileka, South Lunzu and Limbe microscopy centres had no sputum transportation boxes.

Conclusion: There is a great compromised safety in the TB microscopy centers in Blantyre urban. Only one (1) microscopy center out of nine (9) reached the minimum safety requirement representing an 89 percent (%) failure of TB primary microscopy centers to provide safety to laboratory workers. Laboratory conditions and safety procedures in TB primary smear microscopy centres in Blantyre urban are poor. Government and other stake holders should therefore be committed in addressing the safety challenges of TB laboratories in the country (in primary Tb microscopy centres and other referral centres which face the same challenges) to ensure safety to the laboratory workers.

Key Words: Mycobacterium tuberculosis (MTB); Blantyre; Malawi; Microscopy; Laboratory Safety

ÖZET

Amaç: Tüberküloz (TB) mycobacterium tuberculosis tarafından oluşmakta ve öksürme, hapşırma, gülme ve şarkı söyleme yoluyla yayılmaktadır. Laboratuvar çalışanları normal popülasyona göre 3-9 kat daha fazla enfeksiyon riski altındadırlar. Laboratuvar çalışanları için gerekli güvenliği sağlamak için laboratuvar güvenliği öncelikli hedefler arasında alınmalı ve laboratuvar koşulları optimize edilmelidir. Blantyre şehri TB primer mikroskopi merkezi laboratuvar çalışanlarında işçi güvenliğini değerlendirmek.

Materyal ve Metod: Blantyre şehri TB primer mikroskopi merkezi ekipman uygunluğu, tesisin yerleşimi ve iş pratiği açısından değerlendirildi. WHO/AFRO ISO 15189 un standardize edilmiş kontrol listesi kullanıldı ve gelişmekte olan ülkeler için minimum güvenlik skoru >80 dir. Her merkez bu skor kullanılarak aldığı puanlara göre derecelendirildi.

Bulgular: Ndirande, Lirangve ve Chileka mikroskopi merkezlerindeki güvenlik kabinleri fonksiyonel değildi. South Lunzuda güvenlik kabini bulunamadı. Ndirande ve Limbe de hastaların bekleme odası ve laboratuvar kapılarında bulunan havalandırma kanalları özellikle yayma hazırlama sırasında enfeksiyonun bulaş riskinin artmasına neden olmaktadır. Bangwe, Chilomoni, Ndirande, Chileka, Güney Lundzu ve Limbe mikroskopi merkezleri balgam taşıma kutularına sahip değillerdi.

Sonuç: Blantyre kenti TB mikroskopi merkezlerinde büyük bir güvenlik tehlikesi vardı. Dokuz merkezeden sadece bir tanesi minimum güvenlik şartlarını karşılamıştır ki bu incelenen merkezlerde toplam %89'luk bir başarısızlığı işaret etmektedir. Sonuç olarak Blantyre şehir merkezindeki TB yayma mikroskopi merkezleri laboratuvar koşulları ve güvenlik prosedürleri oldukça zayıftır. Hükümet ve diğer ilgili makamlar bir araya gelerek ülkedeki TB laboratuvarlarının ve benzer sorunlar yaşayan diğer merkezlerin güvenlik sorunlarını ele alarak laboratuvar çalışanlarının güvenliğini sağlamalıdır.

Anahtar Kelimeler: Mycobacterium tuberculosis (MTB); Blantyre; Malawi; Mikroskopi; Laboratuvar Güvenliği

INTRODUCTION

Tuberculosis (TB) is caused by Mycobacterium tuberculosis (*M.Tb*). People who have Tuberculosis in their lungs can release tiny

particles containing *M. Tb* into the air by coughing, sneezing, laughing or singing. Figure 1 below shows the amount/quantity of *M.Tb* microbes that can be transmitted through coughing, talking and singing.

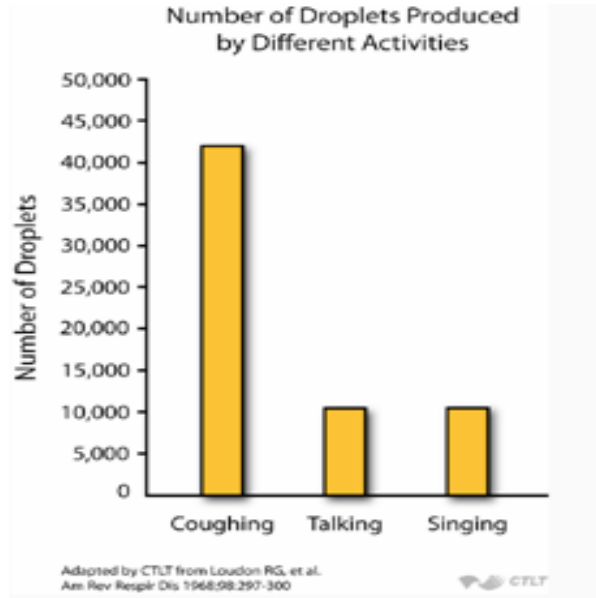


Figure 1. Quantity of *M.tb* transmitted by different activities



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Tuberculosis is still one of the leading causes of morbidity and mortality in Malawi despite the fact that it can be cured with adequate treatment. The emergence of multi drug resistant tuberculosis (MDR-TB) is one of the challenges in our efforts to control TB¹.

Health care workers in most facilities are at high risk of becoming infected with tuberculosis (nosocomial transmission) especially when they have immune-suppression due to the human immunodeficiency Virus (HIV). Preventive and control measures to reduce the risk of TB infection and protection of health care workers should be given highest priority in health care planning and development¹.

This study was aimed at assessing the safety of laboratory workers in TB microscopy centers in urban Blantyre. All health centers that do TB microscopy in urban Blantyre were included.

In 1995, Sewell D, conducted a study 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.² This was suggested that unique risks were associated with the laboratory work site. Another study conducted in Malawi in 1998 found that Laboratory conditions and safety procedures in Malawi 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 hands³.

In 2005, a cross-sectional study conducted in North-western Ethiopia aimed at assessing the physical conditions and current laboratory practice, pertaining to handling sputum specimens in the

health-care laboratories carrying out sputum smear microscopy, found that the laboratories had an area of less than 25 m². None of them had separate rooms or safety cabinets for sputum smear preparation. Only three laboratories used facemasks. Decontamination of sputum specimens prior to disposal was reported in only 2 laboratories and incineration as a means of sputum specimen disposal was used in only six laboratories⁴.

In 2006, a Situation analysis of TB microscopy centres in Ghana revealed that out of 114 laboratories visited between 2000 and 2001, 97 centres (85.3%) were using the recommended TB laboratory register for recording though they were not filled accurately or completely. The majority of the available microscopes had mechanical or optical faults. Availability of other materials for smear preparation and staining ranged from 44% to 82 %⁵. Working conditions such as shared laboratory and air space, inadequate ventilation, accidents with biological specimens, and inadequate disposal of biological waste present risks of TB transmission to laboratory workers and other staff⁶.

Tuberculosis (TB) 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%⁷. The overall case mortality rate of Tuberculosis in health care workers of all types in Malawi is 24% compared with the adult general population aged > or = 15 years with a relative risk [95% confidence interval (CI)] of TB 11.9 [9.8-14.4], of smear-positive PTB 5.9 [3.9-9.0], of smear-negative PTB 13.0 [9.5-17.7] and of extra pulmonary TB 18.4 [13.8-24.6], $P < 0.05$ ⁸.

As of 2007, the Malawi National Tuberculosis Programme (NTP) manual stipulated an increased annual TB case notification rate (all forms) of 5000 to 27000 in Malawi collected between 1985 and 2006⁹. 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 bacilli¹⁰. In a hospital setting, this leaves doctors, 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"¹¹

This project focused on evaluating the safety of laboratory workers in handling sputum specimens from reception, transportation, smear preparation and staining compared to the standard set by World Health Organization (WHO) as minimal laboratory safety requirements for developing countries.

MATERIAL and METHODS

Table 1: A sample of WHO/AFRO checklist.

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

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

From the results presented in table 2 above as well as on graph (figure 1) below, only Zingwangwa Health centre has reached the minimum safety requirement with a 3 star. The minimum requirement as set by WHO/AFRO checklist is 80%.

These results have better been represented in the bar graph below:

The results indicate that eight out of nine primary TB mycobacterium smear microscopy

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

The observational method and a checklist were used to assess the availability and utilization of safety facilities. On observational data collection, visual comparison of the TB microscopy centre was used. 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-A3¹⁵. 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. Procedures which were assessed comprised sputum reception, transportation, smear preparation and slide staining.

centres had not reached a minimum safety score of 80% as set by the WHO standards. The specific observations of each health centre are as follows;

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 3;



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

HEALTH CENTRE	SCORE	PERCENTAGE	STAR
NDIRANDE	0.57	57	1
CHILEKA	0.63	63	1
CHILOMONI	0.65	65	2
MPEMBA	0.67	67	2
BANGWE	0.71	71	2
LIMBE	0.73	73	2
SOUTH LUNZU	0.63	63	1
LIRANGWE	0.61	61	1
ZINGWANGWA	0.80	80	3

Summary of the findings for all the TB microscopy centres in Blantyre Urban.

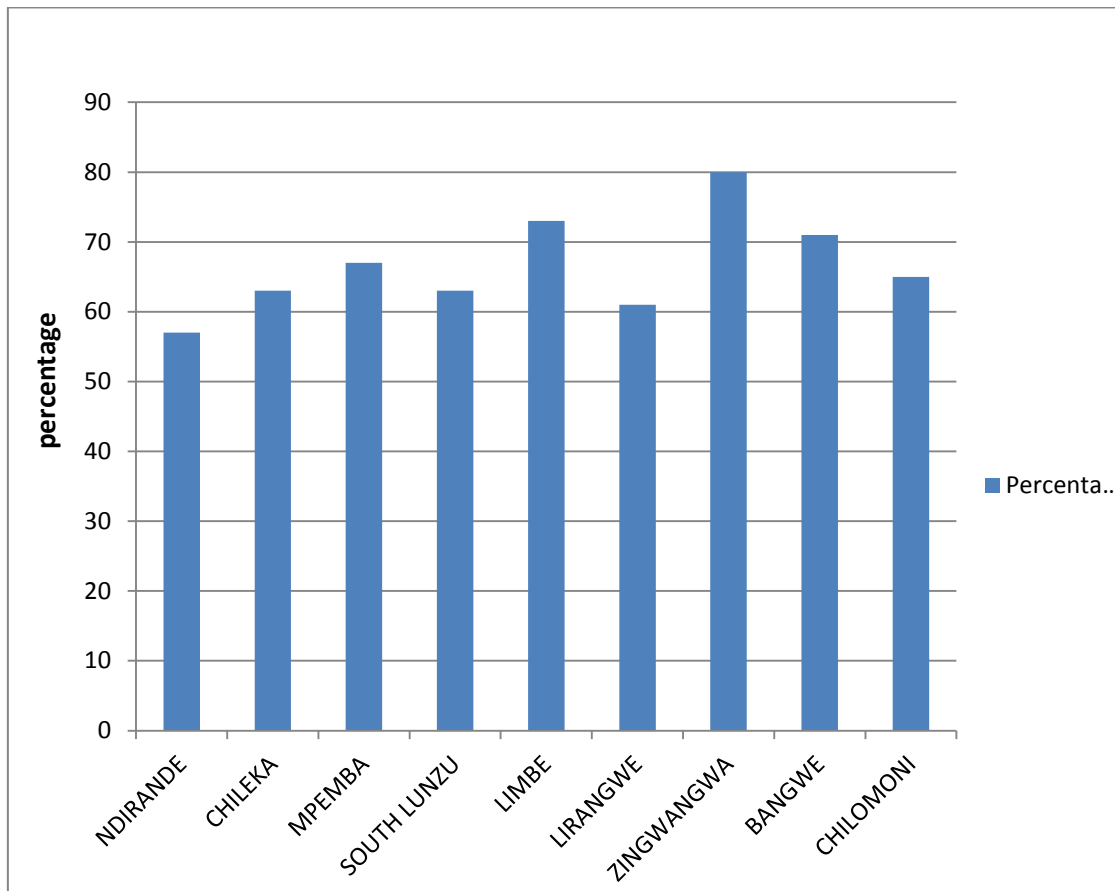


Figure 2. Bar graph of the performance of each TB primary Microscopy centre
The bar graph showing the performance of each health centre.



Figure 3. Improvised transportation boxes
Sputum box: lack of ideal box (courtesy of Jonathan Majamanda and Philmon Ndhlovu)

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 improved. The biosafety cabinet exhaust duct faced the patients' waiting area as shown in figure 4.



Figure 4. Improperly placed exhaust ducts at Limbe Health Centre.
Exhaust duct facing the patients' waiting area (courtesy of Jonathan Majamanda and Philmon Ndhlovu)

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 5 below;



Figure 5. An ideal sputum transportation box at Lirangwe Health Centre

Ideal sputum transportation box as recommended by the Ministry of Health (courtesy of Jonathan Majamanda and Philmon Ndhlovu).

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) from all the health centres were assessed and Zingwangwa health centre had the highest score as per WHO requirement as presented in the line graph below;

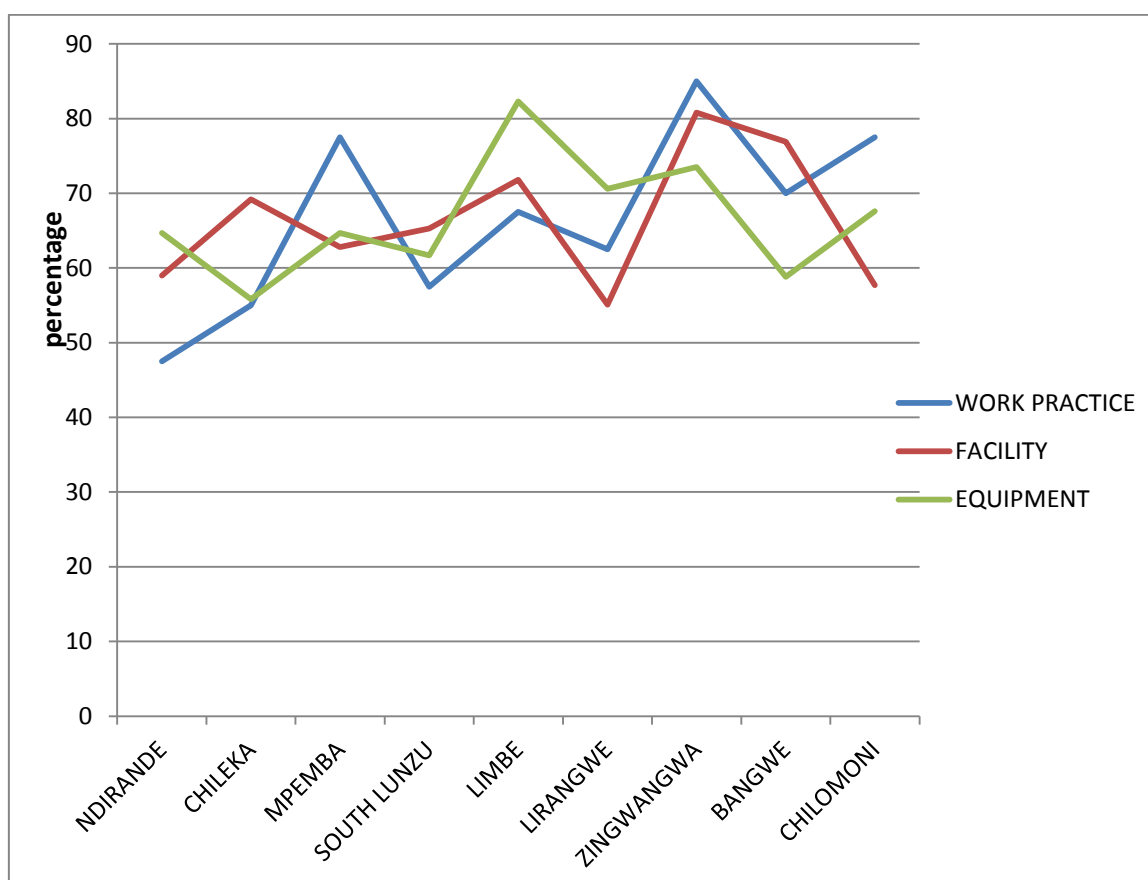


Figure 6. Line graph of specific safety aspect for each health centre

This line graph shows that all the aspects of safety in the laboratory are affected, but facility layout is affected the most.

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 was $\geq 80\%$ using the ISO 15189 standardised checklist for developing countries. From the findings, only one microscopy centre (Zingwangwa) out of nine centres scored 80%, which was the minimum safety requirement while 8 scored less than 80%. The mean score for all the 9 centres was 66.67% which is far too low from the minimum requirement of 80%. All the aspects that

offer safety in the laboratory (facility layout, equipment and work practice) had been affected, but the aspect most affected was the facility layout.

The results 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.

CONCLUSION and RECOMMENDATIONS

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. Therefore this study rejects the null hypothesis which states that the safety in all Blantyre urban TB smear microscopy centres is $\geq 80\%$.

From the findings of this study, all the three aspects of safety in the laboratories handling Tb specimens were affected. Of much concern was the facility layout which not only put the laboratory workers at risk of infection, but also the patients and any other person accessing the laboratory services. 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).

For future research, 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 referral and private laboratories should be included in similar future studies.

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