

Involvement of the Retail Pharmacies in Pakistan Tuberculosis Control:

Assessment of the knowledge of the retail pharmacy staff about tuberculosis and public tuberculosis Control Programme, and sale practices of anti-tuberculosis drugs in DI Khan city, Khyber Pukthoon Khwa Province, Pakistan

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This thesis is submitted in partial fulfilment of the requirements for the degree of

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Abstract

Introduction: Tuberculosis is the second leading cause of death globally from a contagious disease. Pakistan is at 4th position among the twenty two high TB burden countries. National tuberculosis control programme (NTP) Pakistan has achieved 100 % directly observed treatment short-course coverage in public sector but large proportion of TB patients take care from private sector, generally outside the system of NTP. NTP had taken various initiatives in TB control, including the engagement of the private sector. One of the important part of the private sector is retail pharmacies that has been mostly left out of public private mix activities. The NTP programme can get benefit from engaging private retail pharmacies for; screening of individuals with symptoms suggestive of TB and referring them to the TB control programme (case detection), supervised treatment, education, counselling and awareness. In order to attain these goals a baseline assessment of the knowledge, attitude and practices of the staff at the pharmacies is an essential pre-requisite.

Methods and materials: The study was a cross-sectional survey which employed a questionnaire to collect the data from 82 private retail pharmacies through interviewing one staff member from each pharmacy with the longest experience by the principal investigator. SPSS was used for data entry and analysis.

Results: All the staff members were male and only 4/82 pharmacies had a person with five year professional degree in pharmacy, 27/82 had received 2 years formal training as a pharmacy assistant, while 51/82 had not received any formal training in pharmacy. The majority of the pharmacies lacked records of the medicines sold to the patients and informational materials relevant to TB were present in only 38% pharmacies. The majority of pharmacy staff had reasonable good information about TB prevention, anti-TB drugs administration and persistent cough as TB symptom but 66% lacked knowledge about MDR-

TB and associated factors and no one had received any training about TB in the last two years. All the interviewed staff answered that frequently sold anti-TB drugs were combination preparation of 4 drugs (4-FDC-RHZE) or 2 drugs (2-FDC-RH) combinations. Almost 83% retail pharmacy staff answered that patients purchasing anti-TB drugs belong to a low socioeconomic class. Only 57% of pharmacy staff were aware of NTP while only 30% had heard of the TB DOTS strategy. Almost 80% of staff referred the suspected TB patients to chest physicians and no one referred suspected TB patients to TB DOTS center. Nearly 66% of the pharmacy staff wanted to know more about NTP and 83% were willing to be involved in TB control efforts by getting training and referring patients to the DOTS delivery facility. The results also revealed that there was a significant positive association between knowledge of TB, and the duration of working experience of pharmacy staff with the exception of MDR-TB related factors and duration of TB treatment.

Conclusion: The research study revealed that it is feasible to involve private retail pharmacies in TB control and they can play a potential role in TB control by detecting and referring suspected TB patients to NTP DOTS centres, providing patient oriented services like adherence to the treatment, proper counselling regarding administration and side effects of anti-TB drugs. However proper training, clear and feasible guidelines is an essential pre-requisite as majority of the staff are not professionally trained pharmacists.

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Acronyms and Abbreviations

BCG	Bacilli Calmette Guerin
CDR	Case Detection Rate
DOTS	Directly Observed Treatment Short-course
EPTB	Extra Pulmonary Tuberculosis
FDC	Fixed dose combination
GPs	General Practitioners
HIV	Human Immunodeficiency Virus
MDR-TB	Multi Drug Resistance-tuberculosis
M.TB	Mycobacterium Tuberculosis
NGO	Non Governmental Organization
NTP	National Tuberculosis Control programme
PI	Principal Investigator
PPM	Public Private Mix
SNPT	Smear Negative Pulmonary Tuberculosis
TB	Tuberculosis
TST	Tuberculin Skin test
WHO	World Health Organisation
ZN	Ziehl Neelson

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CHAPTER ONE: INTRODUCTION

1 Background

1.1 Tuberculosis:

Tuberculosis (TB) is an infectious or contagious, airborne disease caused by micro-organisms called *Mycobacterium tuberculosis* (M.TB). It usually affects the lungs in two third of TB patients which is called pulmonary TB but can also affect sites other than lungs which is called extra pulmonary TB. The TB disease is spread through air droplets when individuals with pulmonary TB are sick and expel M.TB, for example by coughing, talking and sneezing. Mostly infected people develop TB disease within five years after initial TB infection but sometimes it takes many years to develop TB. Generally, a comparatively small proportion (about 5-10%) of individuals infected with M.TB develop TB disease. On the other hand, the possibility of developing TB disease is very high among people with human immunodeficiency virus (HIV) infection. TB mainly affects adults an economically productive and care-giver group in the society contributing towards perpetuation of poverty (1-4).

1.2 History of Tuberculosis:

TB history is very long and old. It is believed that mycobacterium genus is originated more than 150 million years before and was documented in china, India and Egypt 2300, 3300, 5000 years before respectively (5). In definite Egyptian mummies, findings clearly shows that spinal caries were present around 2400 BC. Around 460 BC to 370 BC TB was described with the name of consumption or Phthisis by Hippocrates famous Greek physician as it was the most common disease of that time and for the first time tubercles "Phymata" observed in the tissues of pigs, sheep and cattle (6).

On 24th March 1882 Robert Koch declared that he had discovered the agent which causes TB called M.TB (2, 7) and this day is still celebrated as TB day every year. In 1895 X-Ray was discovered by Wilhelm Konrad von Rontgen which contributed a lot in diagnosis of TB. In 1921 BCG discovery (2) and TB medicines like Streptomycin discovery in 1944, Para-amino-salicylic acid discovery in 1949 and isoniazid discovery in 1952 brought revolution in the treatment of TB disease (6, 8). TB disease was considered under control till 1980s but the epidemic of AIDS threw fuel on the fire (9).

The International Union against Tuberculosis and Lung Disease made collaborations with World Health Organization (WHO) and some other international partners in 1998 to form the Stop TB Initiative, which was a defining moment in the reorganization of worldwide efforts to control TB (2).

By 2050 WHO Stop TB Strategy aims to reach each and every TB patient and accomplish the goal under the MDGs and have planned to eradicate TB as a public health problem.

1.3 Pathogenesis of tuberculosis:

The most common causative agent of TB is M.TB in human. *Mycobacterium microti* and *Mycobacterium bovis* causes TB in animals but can also cause disease in humans. Humans are the main reservoirs for M.TB. TB transmit from infected person to another person through airborne droplet nuclei, when an infected person with pulmonary TB sneezes, cough, sings or speaks. The first implant of bacilli is in lung at alveolar level, when a healthy individual inhales the bacilli. In the start innate immunity tries to control the infection but if macrophages do not have the ability to kill the bacilli then delayed type hypersensitivity and cell mediated immunity reaction become activated. The multiplication of bacilli and production of primary parenchymal lesion causes some of the bacilli movement into hilar lymph nodes which then causes enlargement of lymph node. The draining lymph nodes and

the parenchymal exudates lesion together are called Ghon complex. M.TB can affect any other organ system because M.TB spreads from one part to another body part through the lymphatic system, the blood stream or through the airways and can cause serious complication of pleura, lymph nodes, bone and joints, genitourinary tract, central nervous system, pericardium, gastrointestinal tract, skin and peritoneum. Development of hypersensitivity to organism take 6-8 weeks and the infected individual becomes positive to tuberculin test. It is estimated that approximately 50 percent of immune compromised individuals infected with M.TB develop TB during 2 years after infection and remaining may develop TB many years later. Around 10 percent immune compromised individuals infected with M.TB develop TB disease during life time (10).

1.4 Pulmonary Tuberculosis:

Pulmonary TB is the most frequent form of the TB disease and occur more than 80 % of the cases (11). Pulmonary TB with cavity formation is the most dangerous and infectious form of pulmonary TB (12). About two third smear positive TB patients will die within eight years if they are left untreated (13). Contacts of sputum positive TB patients are at higher risk of being infected with M.TB and a single untreated smear positive TB patient can transmit TB disease to 10-15 contacts in one year (14). Patients with pulmonary TB, where micro-organisms are seen on microscope examination of sputum specimens, are labelled as smear positive cases (11) and the main keys to control TB are early identification of smear positive cases and rapid initiation of TB treatment (15).

When sputum specimen is negative through microscopic examination, it is termed as smear negative pulmonary TB . Thirty to eighty percent of the cases are smear negative pulmonary TB among the entire pulmonary TB cases (16). According to NTP Pakistan smear negative pulmonary TB is presently defined as symptomatic illness with a minimum of three negative

sputum smear examinations on direct microscopy for acid fast bacilli, radiological abnormalities on chest x-ray and persistence of symptoms after use of a broad spectrum antibiotic for 7 days. It is an increasing epidemiological and clinical problem (17). smear negative pulmonary TB diagnosis is a difficult job and majority of these type of cases are treated on the basis of radiographic and clinical findings in developing countries. These causes the under or over diagnosis of the TB cases because x-rays reports are reader dependent and non-specific (18,19).

TB is generally asymptomatic in the start but becomes symptomatic as the condition is advanced. TB symptoms are most often restricted to the site of the disease. More common systemic symptoms include persistent cough for more than two weeks, low grade fever, weight loss, fatigue, night sweats, malaise and loss of appetite, while chest pain, bloody sputum and shortness of breath are less common symptoms.

1.5 Extra-pulmonary tuberculosis:

Extra Pulmonary TB add up to about 20 percent of all cases of TB patients and account for more than 50 percent of the cases in HIV positive individuals (20, 21). It has an effect on organs other than lungs like pleura, peritoneum, joints and bones, genitourinary tract, skin, lymph nodes and pericardium. It can also be suspected in patients who present with fever with site specific symptoms and signs or fever of indefinite origin, or in patients whose biopsy report show granulomatous inflammation.

1.6 Diagnostic approaches in tuberculosis:

Diagnosis of the TB involves manifestation of M.TB by microbiological, histopathological, or cytopathological methods. Diagnosis of TB in children under age of 15 years is very challenging and more complicated than in adults and primarily depends on history, tuberculin

skin testing, chest radiography and mycobacterial culture/staining, even though these investigations may not be positive all the time because of less cavity formation and low bacillary load (22, 23).

1.6.1 Sputum smear microscopy:

The most common diagnostic tool used for the TB diagnosis is examination of smears through microscope for the presence of mycobacteria. Sputum smear microscopy is reliable, cost effective, fairly quick and specific test for the infectious pulmonary TB diagnosis in adults (24). Two types of staining are used in acid fast bacilli procedure. One is Ziehl Neelson (ZN) method which actually involves staining mycobacterium cell wall with carbolfuchsin dye which retain this dye. The second type involves fluorescent stains, like auramine and rhodamine, which are more superior than ZN stain (25). But the advantages of ZN technique over other methods include rapidity, low cost and that it can be performed within hours. But its sensitivity is very low because it requires bacilli in large number (5000-10,000 per ml of sputum) (2, 26).

1.6.2 Culture:

Diagnosis of TB disease depends on the isolation of M. TB by means of a culture technique of liquid or solid media (10). Culture technique is more sensitive as compared to smear microscopy, as it requires only 10-100 bacilli per ml but its sensitivity depends on several factors including the culture medium and specimen processing method (26), requires 6-8 weeks for results and also specialized personnel equipments (27).

1.6.3 Chest x-ray:

In the low-income countries diagnosis of TB is based upon radiological findings on chest x-ray and clinical presentation but the cavities are very rarely present (23). Lung parenchymal changes and mediastinal or hilar lymphadenopathy indicates pulmonary TB. Pleural effusion, alveolar consolidation, empyema and segmental hyperinflation are the main common parenchymal changes. Many lung diseases have same radiographic appearance that can simply mimic TB disease when used alone and can result in over diagnosis of TB (10). For example, children with pneumonia and with TB have very few distinguishing features and have many common features (28).

1.6.4 Histology:

In Extra pulmonary TB cases, bacteriological techniques have low sensitivity and histology is a vital aid (29, 30). However samples are obtained by surgical interventions and biopsy.

1.6.5 Tuberculin skin test (TST):

The evidence of TST is actually based on the infection with M.TB that produces a delayed type of hypersensitivity skin reaction to a few components of the mycobacterium (10). A positive TST indicates present or past primary infection with M.TB, but it does not obligatory indicate the TB disease. Tuberculin reactivity becomes obvious in three to six weeks in most children, but some time it can take up to three months behind initial infection (23). A positive test in children is the feature of primary infection (22) and can support TB diagnosis in adults as well as in children (31). Fifty percent false negative results can also occur in those with advanced HIV infection and up to 25% may have negative test with active TB whereas false positive results can take place in infection with error in interpretation of the test, non

tuberculous mycobacteria or BCG immunization (22). In developing countries, Mantoux method is use as the recommended TST (32).

The other alternatives for TB diagnosis include; serology, Interferon-gamma Release Assays, imaging, Gene xpert, Immunocytochemical and Immunohistochemical methods.

1.7 Global burden of tuberculosis:

According to WHO, the global burden of TB is huge (1) and remains a major public health problem worldwide (33). TB is the second leading cause of death globally from a contagious disease, after the HIV. There were an estimated 9 million incident cases of TB and 1.5 million people died from the disease (0.4 million deaths occur among those people who were HIV positive and 1.1 million deaths occur among those people who were HIV negative) in 2013 (1). There were an estimated 170,000 deaths from multi drug resistant tuberculosis (MDR-TB), a relatively high total compared with 450,000 incident cases of MDR-TB (34).

In 2013, the Western Pacific Regions and south-East Asia collectively responsible for 56 % of the total world's TB cases (1)

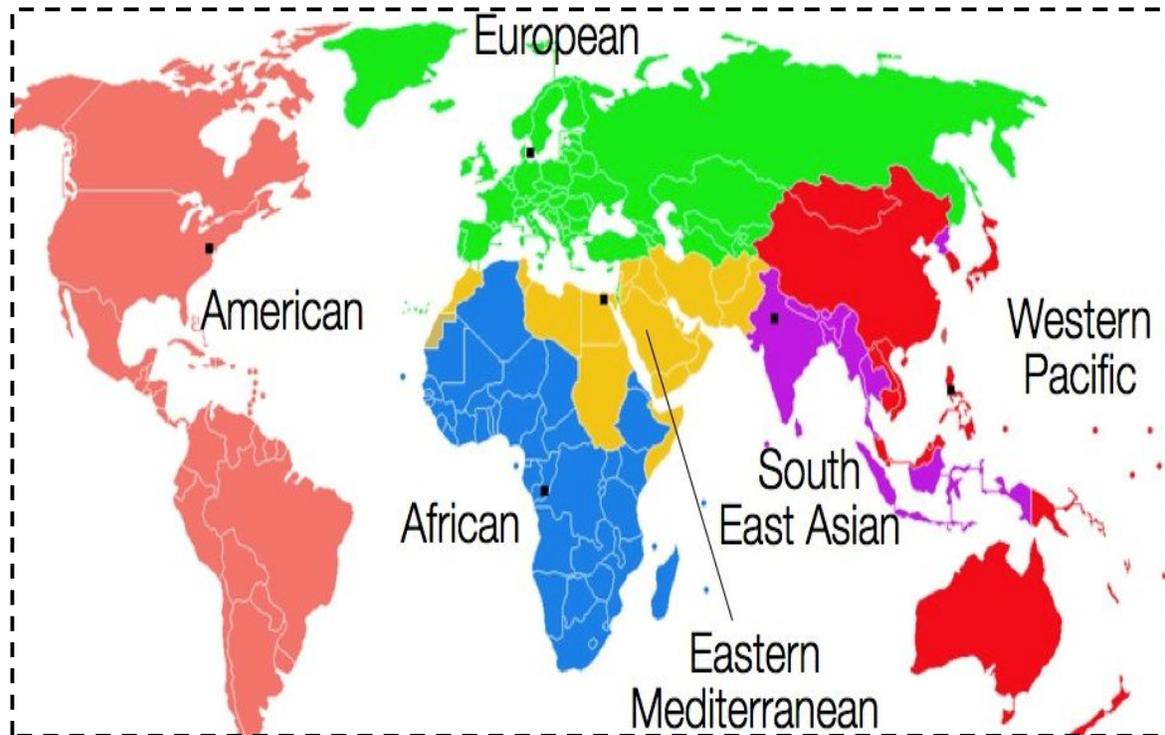


Figure 1: Shows the map of world by region indicating the location of Pakistan.

Source: Google images

1.8 Tuberculosis burden in Pakistan:

Pakistan is at 4th position among the twenty two high burden countries of TB and also at 4th position among twenty seven MDR high burden countries in the world. In the Eastern Mediterranean Region, Pakistan contributes approximately 61% percent to the TB burden. The incidence is 97/100,000 per year for sputum positive TB cases in Pakistan and for all cases the incidence is 275/100,000 each year according to WHO. The estimated prevalence of the TB disease is 342/100,000 population. In 2013, estimated mortality due to TB was 56/100,000 population (1).

TB is accountable for 5.1 % of the entire countrywide disease burden in Pakistan (35). A large percentage of cases take place in women in their child-bearing age and younger age group ranging from 15 to 49 year age with poverty being the major driving force. Poor

domestic conditions, inequalities and poor nutritional status of individuals and ambient environmental conditions are the main predisposing features accountable in the spread of TB and incidence of TB (36).

1.9 National tuberculosis control programme of Pakistan:

NTP is a nationwide body, which is under the Ministry of Health (MOH). In 1995 NTP Pakistan is formed in response to the announcement of TB global emergency by WHO in 1993. National strategies were developed and piloted under this program in different regions of Pakistan, but in 1996 the program was halted when the Federal Directorate for TB Control was dissolved in 1996. TB control activities were resumed in 1998 based on an agreement between the provincial and federal TB control programs (37). In 2001 the NTP was revived when TB was declared a nationwide health emergency through the Islamabad Declaration (38).

The NTP of Pakistan is well-respected internationally and is constantly trying to expand and maintain TB control activities by using DOTS strategy country wide. In the beginning the programme faced the most important challenge of providing standardized TB care services country wide to sputum smear positive cases. To tackle this major challenge the NTP was active in gathering the essential political commitment at each and every single level including developing training materials and guidelines for managers and other health care providers, evolving mechanisms to harmonize TB care services into primary health care and using international and national assets for procurement of anti-TB drugs. In the near past further initiatives were introduced in the country by the NTP, including external quality assurance system to improve peripheral laboratories, control of TB through public-private mix, performance through a system of regional and national reference laboratories, hospital DOTS linkage, management of TB which is difficult to diagnosis, and control of MDR-TB.

In public sector like basic health units (BHUs), district headquarters (DHQs), rural health centers (RHCs) and tertiary care hospitals, NTP has achieved 100 % DOTS coverage. Since 2001, NTP has been provided free treatment and diagnostic facilities to 1.5 million TB patients through 4000 treatment centers and 1500 diagnostic centers in Pakistan (39).

Mission of NTP is to attain country wide TB control by DOTS approach and by ensuring good quality TB care through public sector health services and develop the role and responsibility of other partners, including Non-Governmental Organizations (NGOs) and private sector (40).

1.10 Directly observed treatment-short-course (DOTS) strategy for tuberculosis control:

DOTS is a policy recommended by WHO for effective control of TB disease in all low income countries. NTP Pakistan has also adopted this policy. The key principle of the strategy is to split the transmission chain of TB disease by curing and diagnosing people with contagious TB. The DOTS strategy has 5 important components and all these 5 components are essential for an effective TB control programme (41).

- 1) Government commitment.
- 2) Use of sputum smear microscopy for diagnosis.
- 3) Treatment of TB patients with standardised regimens, which includes observation of treatment directly in the serious phase for all smear positive cases and throughout the retreatment course of therapy.
- 4) Continuous and regular supply of medicines from the nearby health care facility.
- 5) Standardized monitoring and recording and reporting of outcomes of treatment and management.

1.11 Public private partnership (PPM) in tuberculosis control:

It is mostly acknowledged that a large proportion of TB patients take care from private sector, generally outside the system of NTP. These include para statal health care institutions and private health care providers for profit and they do not always follow the suggested DOTS approach for management of TB, hence depriving patients to get good quality care, treatment and management (42).

Currently Pakistan is undergoing health sector modification and various initiatives in TB control include the engagement of private sector. The Public health sector in Pakistan provides health care facilities to only 30% of the population and private sector provides health care facilities to 70% of the population (43). A study was conducted in Thatta district which demonstrated that by involving private practitioners in TB control by collaboration with the NTP Pakistan, case detection rate (CDR) may be considerably increased (44). A survey of private physicians in Karachi was done in 2003, which is a densely populated city area of Pakistan, showed a lack of confidence and knowledge on TB diagnosis, a lack of knowledge about main TB symptoms, over dependence on chest X-rays for diagnosis of TB rather than sputum microscopy and extensive use of inappropriate treatment regimens, representing private practitioners un-mindfulness to the public health implications of a TB patient's sputum status (45). In Pakistan the major contributing factor is inappropriate treatment regimens which give rise to MDR-TB in community. The findings of this research study also pointed to the need for advanced training of private practitioners and permitting them the use of subsidized or free sputum examination facilities to control TB as part of a PPM approach (45).

In 2005, Pakistan attained near universal DOTS coverage in all the districts, following the Islamabad Declaration. A 5 year federal work plan was also approved in 2006, that supported numeral TB relevant activities together with extension of the PPM approach to TB control.

The NTP of Pakistan has been committed to partnership building and has utilized technical support for the activities of the program, and the Interagency Coordinating Committee to make possible support of donors and there is joint program annually to review TB care and control with all of the involved partners. Sustaining this commitment to involving the private sector is particularly important given that private practitioners in Pakistan have poor knowledge of TB and do not follow guidelines of NTP. The NTP involved four non profit organizations in 2010, to execute PPM DOTS pilot projects in thirty districts. Another PPM strategy named "Hospital DOTS linkage" is also initiated by the NTP. In about forty percent of private and public sector, this program has been executed, which build up a referral system between DOTS treatment centers and hospitals, improves laboratory services and also introduces standardized treatment. Data was collected in 2009 which showed there was a fifty percent increase in case detection and notifications in areas in which the hospital DOTS linkages had been initiated (38).

To use a PPM approach as part of their strategy , the NTP has worked in collaboration with an NGO named Green Star Social Marketing Pakistan Ltd (GS) that has involved to engage the private sector in TB control by delivering good quality TB care services to low-income customers and has improved access to TB treatment and diagnostic services in this population (46).

The NTP of Pakistan has also implemented numerous innovative programs for TB control through private-public partnerships as a component of the Stop TB Partnership's TB REACH initiative in Karachi (47). One of the program involves bringing camps for chest screening in urban areas as an approach to educate the societies about TB and TB control, raise awareness, help to reduce stigma and increase case detection (47). The program seeks to engage the private sector by giving training to general practitioners in TB case management (48). More than 30,000 patients of TB were screened in the first 3 months and 350 cases of the most

contagious form of TB were detected (47). Another public private partnership was also implemented in district Karachi which used conditional cash transfers and mobile phone technology for general practitioners (GPs) and community health workers (CHWs) to improve TB case management and increase case detection (48). In the first nine months after the program implementation, there was almost 500% of increase in paediatric case notifications and 300% increase in TB case detection through Indus Hospital (48). Indus Hospital has also implemented a public-private partnership through their TB Program Team, which aimed directly at scaling-up of community based MDR-TB programs and supporting the establishment (49).

While there is definitely need for more work to be done in expanding and sustaining adherence to the NTP guidelines and DOTS implementation in the private sector, PPM has been revealed to make a huge contribution to TB control, accounting for almost 20 percent of total TB case detection in 2007. One of the important part of the private sector is retail pharmacies that has been mostly left out of PPM activities. Experiences in many countries have revealed that with proper training, the retail pharmacy staff have the potential to play an important role in TB case management and detection (50).

1.12 Engaging private pharmacies in tuberculosis control:

Pharmacists represent a vital and crucial part of the health care team and they are at the frontline when it comes to patient counselling and mass awareness in case of different diseases. The treatment plan of TB is quite complicated and runs for a length of time which makes adherence to prescribed regimens a critical factor in the control of this epidemic. The involvement of pharmacists therefore is a prerequisite to achieve ideal results in the care and control of TB. Keeping in view the importance, WHO has recognized pharmacists as one of the six pillars for providing efficient TB care with International Pharmaceutical Federation

and have stressed the point of intense collaborative exercise to be practiced in order to meet the desired goals of TB care and control throughout the world (51).

Moreover, private sector retail pharmacies usually have close links to the society, and often the first point of contact when a person with early un-specific signs and symptoms of TB seeks help from health care services. Unfortunately, pharmacies often miss the chance to detect and identify a case of suspected TB and thereby do not refer the patient to the correct health care facility, which contributes to delays in TB management and diagnosis. Furthermore anti-TB drugs are most likely dispensed uncontrolled to the people with or without TB. It has been accounted that private drug sale markets in four countries i.e. Indonesia, India, Pakistan and Philippine had the biggest relative sales volumes per annum. These countries sold large amount of first line anti-TB drugs to supply 65 to 117 percent of the annual incident TB cases with a standard 6 to 8 months regimen (52).

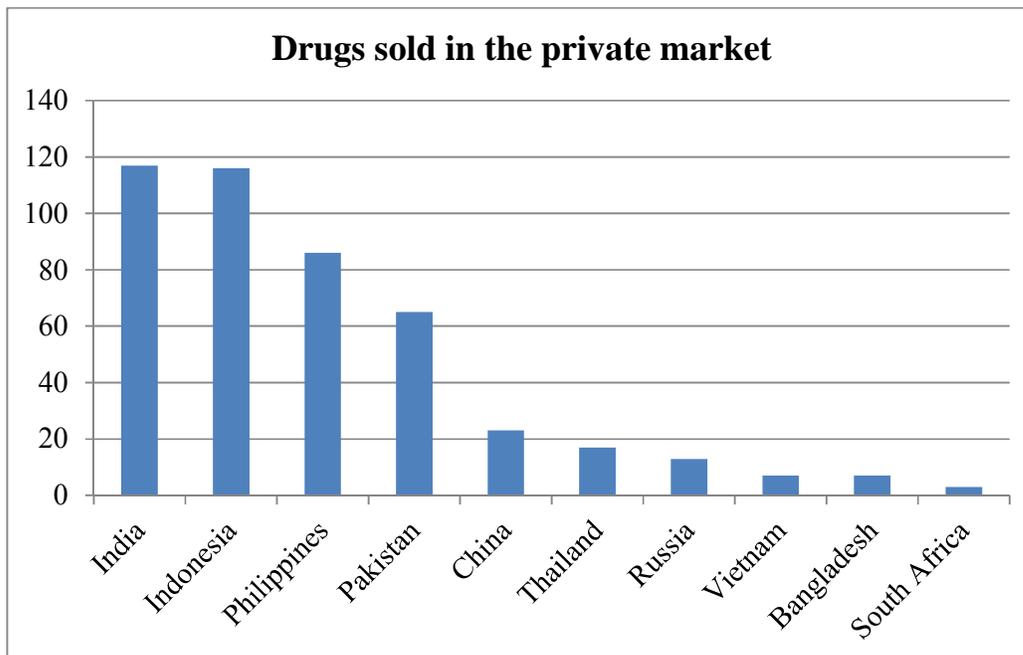


Figure 2: Percentage of anti-TB drugs sold in private market.

Source: Global Alliance for TB Drug Development, Annual Report, 2009.

Retail pharmacy staff/ Pharmacists have not been utilized in TB control, care and prevention in Pakistan. An impact assessment study in Pakistan found that giving training to common people in the society to screen for TB in private sector clinics and then connecting patients to free treatment and diagnosis from a NTP accepted private health care facility was one of numerous interventions that amplified case recognition 2 fold over that observed in the control area (53). Extending these efforts further to connect private retail pharmacies in TB control, recently the NTP in partnership with DEV-NET and Pakistan Pharmacists Association (PPA) initiated the project to “Engage Pharmacists in TB Control and care in Pakistan (54). The results from this project have not yet been published.

1.12.1 Role of pharmacists in tuberculosis control:

TB can be cured if the patients are counseled well enough and the medication is taken without any interruption and if the medications are taken as directed by the physician. Being drug experts pharmacists can play a productive role in the management and control of TB particularly in following areas which are discussed individually::

- (i) Improving drug availability and ensuring easy accessibility
- (ii) Patient education
- (iii) Achieving better adherence to recommended therapy, and
- (iv) Developing a private-public sector collaboration

(i) Improving drug availability and ensuring accessibility:

Drug resistance is a threat which is usually encountered during management of TB and it occurs because of inconsistent and incomplete treatment resulting in failure to control TB. The factors involved in the development of drug resistant TB include; irregular drug supply, use of expired drugs and/or substandard drugs (55). A critical role can thus be

played by pharmacist in drug acquirement, distribution and allocation, drug information and appropriate use by ensuring:

- The availability of good quality and appropriate quantity of all essential drugs including anti-TB medicines
- Avoidance of stock-out situations
- Ordering and purchase of medicines under the supervision of a pharmacist
- Proper storage conditions of medicines
- Use of fixed dose combination (FDC) medicines of established efficacy.

(ii) Patient education

Pharmacists whether in community, retail or hospitals are in direct contact with a large population on a daily basis and are therefore a key figure to disseminate information to the patient regarding treatment of TB and its prevention. It is necessary that pharmacists should actively counsel the patients who are receiving anti-TB medications in order to get ideal results. They can act as patient's source of information regarding their disease and the recommended treatment plan. Pharmacists can help control the spread of this epidemic by providing health education either directly or through provision of health information literature to the patients and general population (56).

(iii) Achieving better adherence to recommended therapy

The duration of TB treatment spans over months and the medication is taken regularly which create issues of non adherence and patients need some encouragement in order to follow the regimen as directed. Numerous factors play a role in creating barriers to adherence i.e. regular and prolonged treatment plan, adverse effects, complicated regimen and serious drug interactions.

Complying with the advised treatment course by taking the right drug by the right patient at the right time means good adherence which ultimately leads to successful disease eradication. Community pharmacies having trained pharmacists can act as direct counselling and treatment centres for DOTS therapy usually for local TB patients, ensuring adherence and help fighting drug resistance. Pharmacists can use both direct and indirect methods in order to assess adherence and identify factors which are responsible for divergence from the prescribed regimens. Direct methods include blood and urine analysis while conducting patient interviews, analyzing health outcomes, pill counts and review of refill records come under indirect methods of assessing adherence (57). In low-resource settings indirect methods are more feasible.

Pharmacists can also advance patient compliance and adherence by adopting various strategies i.e. Maintaining patient medication diary, Alarm watches and reminders to avoid medication errors, provision of pill boxes storing scheduled doses of medication

(v) Developing a private-public sector collaboration

The private and public sector need to build and maintain a close collaboration and quarterly reports should be generated based on records kept in TB registers assisting government bodies in TB control (56). Pharmacists working in private healthcare centres can support and encourage TB patients in recognizing TB control centres set up by government so that the cases are well recorded and reported. Well updated TB registers ultimately help in planning, procurement, distribution and maintenance of adequate anti TB drugs nationwide.

The NTP can get benefit from engaging private retail pharmacies for; screening of individuals with symptoms suggestive of TB and referring them to the TB control programme (case detection), supervised treatment, education, counselling and awareness. In order to attain these goals a baseline assessment of the TB knowledge, attitude and practices of the

staff at the pharmacies is an essential pre-requisite. A cross sectional survey of the knowledge, attitude and practices of the retail pharmacy staff has been conducted in four cities; Rawalpindi, Peshawar, Islamabad and Lahore, (unpublished data). The various regions of Pakistan differ greatly with respect to the distribution of resources, population, the availability of health services and literacy rates, warranting the need of the baseline surveys in a number of areas to make sure that the different interventions programmes based on these surveys for engaging pharmacies in the TB control would be successful.

CHAPTER TWO: RESEARCH OBJECTIVES

2.1 General objective:

To engage retail pharmacy staff (private pharmacies) in TB control in the Dera Ismail Khan (DI Khan) city, Pakistan.

2.2 Specific Objectives:

1. To determine the level of knowledge on various aspects of TB disease and its treatment, and national TB control programme and the DOTS centres among providers from private pharmacies/ chemist shops.
2. To determine practices related to the TB suspects identification, and their referrals
3. To determine practices related to the sale of anti-TB drugs.

CHAPTER THREE: METHODS AND MATERIALS

3.1 Study design:

The study was a cross-sectional survey, which employed a questionnaire to collect the data through interviewing the private retail pharmacy staff by the principal investigator within DI Khan city, Pakistan. The pharmacy staff includes pharmacists, pharmacy assistants and sales persons who have the responsibility of dispensing drugs to the customers.

3.2 Study setting:

DI Khan is one of the south most district of Khyber Pukthoon Khwa province, Pakistan. The area of district is 7,326 km². District has population of about 1,167,317. There is one district headquarter hospital (DHQ), 1 tehsil headquarter hospital (THQ), 4 Rural Health Centres, 29 Basic Health Units, 26 Civil Dispensaries and 5 Mother and Child Health Care Centres, 4 Civil hospitals, 3 Reproductive health centres in the whole District (58). DI Khan city has 93 pharmacies in total. Each pharmacy staff vary in number depending on the size of the pharmacy and customers. The staff may include pharmacists, pharmacy assistants and sales persons. The drugs are dispensed by any of the above mentioned persons.



Figure 3: Map of Pakistan (also showing the study district DI Khan)

source: Google maps

3.3 Data collection:

All the data was collected by the principal investigator (PI) during the working hours of the pharmacies by personal visits to the pharmacies. The questionnaire was also pretested 4 times before data collection was started. At each pharmacy permission was taken from the owner of the pharmacy and the main seller (if they were different) by administering the information sheet containing the necessary information about the study, voluntary participation,

confidentiality and anonymity. Further elaboration by the PI was done if required. After this elaboration the participants were asked to sign the consent form. After informed consent, PI started collection of data by using the structured questionnaire. All the collected data in paper form and the signed consent forms was brought back to the University of Bergen.

The data was collected from one retail pharmacy staff which had the longest experience from each pharmacy within DI Khan city during October - December 2014.

3.4 Inclusion and exclusion criteria:

Inclusion criteria was one of the member of retail pharmacy staff, which had the longest experience from each pharmacy and had given consent to participate in the study were included.

Exclusion criteria were those who refused to participate in the study, those who participated in the pre-testing of the questionnaire and homeopathic pharmacies.

3.5 Data management and analysis:

Data were checked immediately after collection by the principal investigator for accuracy and completeness. Data and tools used during the data collection were kept under lock and key at the residence of the principal investigator and thereafter carried to Norway. Data was entered, cleaned and analysed in Statistical Package for the Social Sciences (SPSS) version 22.

The information obtained from the observations was used to define different variables used in statistical presentations and analyses of this study. The definitions of privacy, cleanliness, siting, water and requirements for toilets and wash hand basins are given in Table 1.

Table 1: Classification of selected variables

Variables	Classification of knowledge	
	Good knowledge If person HAVE the knowledge of:	Poor Knowledge If person DO NOT HAVE the knowledge of:
TB transmission	Breathing in the air containing TB causing micro-organisms	Breathing in the air containing micro-organisms
TB spread factors	<ol style="list-style-type: none"> 1. Poor ventilation 2. Overcrowding, 3. Presence of untreated TB patients in the house/community 	<ol style="list-style-type: none"> 1. Poor ventilation 2. Overcrowding 3. Presence of untreated TB patients in the house/community
TB symptoms	<ol style="list-style-type: none"> 1. Persistant cough 2. Fever at night time 3. Sweat at night time 	<ol style="list-style-type: none"> 1. Persistant cough, 2. Fever at night time. 3. Sweat at night time
TB prevention	<ol style="list-style-type: none"> 1. Covering mouth and nose when patient cough or sneez 2. By curing TB patients 	<ol style="list-style-type: none"> 1. Covering mouth and nose when patient cough or sneez 2. By curing TB patients
TB diagnosis	Sputum smear microscopy	Sputum smear microscopy
Duration of TB treatment	6-9 months	6-9 months

Consequences of TB treatment non-compliance	If the person have the knowledge of 3 consequences out of the following 1. TB resistance 2. Disease gets worse/deteriorates 3. Disease spread to others 4. Disease comes back/Recurrence	If the person do not have the knowledge of 3 consequences out of the following 1. TB resistance 2. Disease gets worse/deteriorates 3. Disease spread to others 4. Disease comes back/Recurrence
Multi drug resistance TB factors	If the person have the knowledge of 2 factors out of the following Improper treatment, failure to complete treatment, Presence of patients with MDR-TB in household/community	If the person do not have the knowledge of 2 factors out of the following Improper treatment, failure to complete treatment, Presence of patients with MDR-TB in household/community

3.6 Ethical considerations:

The protocol was exempted from the requirement of ethical clearance from the Regional Ethical Committee of Norway, and was approved by the National Bioethical Committee (NBC) Pakistan, (Ref: No. 4-87/14/NBC-156/RDC/477). Informed consent was obtained from every participant for voluntary participation in the study. Confidentiality was also ensured by not revealing the identity of any study participants to other than the principal investigator.

CHAPTER FOUR: RESULTS

Results: There are 93 private retail pharmacies within the DI Khan city, and 82 (88%) were included in the study. The owners of 7 retail pharmacies did not agree to be interviewed while 4 pharmacies were included in pre-test but not included in the results. The interviews were conducted by primary investigator from one of the member of retail pharmacy staff, which had the longest experience from each pharmacy.

4.1 Private retail pharmacies staff characteristics:

Private retail pharmacies staff characteristics are summarised in Table 2. The median age was 33.5 years. Only 4 (4.8%) pharmacies had a person with five year professional degree in pharmacy, 27 (33 %) had received 2 years formal training as a pharmacy assistant, while 51 (62 %) had not received any formal training in pharmacy and were hired as a sales person. The median experience of staff in retail pharmacy was 7 years. About half of the members had > 5 years of experience.

Table 2: Characteristics of the staff members working in the private retail pharmacies

Characteristics of the staff members working in the retail pharmacies	Number (%)
Total participants	82 (100)
Sex	
Male	82 (100)
Female	0 (0)
Age (years)	
≤ 20	1 (1.2)
21-30	22 (26.8)

31-40	35 (42.7)
41-50	14 (17.03)
> 50	10 (12.2)
Professional background	
Pharmacists	4 (4.8)
Pharmacy assistants	27 (33)
Sales person	51 (62.2)
Experience in retail pharmacy (years)	
≤ 5	34 (41.5)
6-15	30 (36.6)
16-25	10 (12.2)
> 25	8 (9.7)

4.2 Private retail Pharmacies characteristics:

Private retail pharmacies characteristics are summarised in Table 3. Most of the pharmacies were quite close to the health facility within a walking distance of 10 minutes, TB DOTS centre were also located in close proximity of DHQ hospital. In about 38% of pharmacies, daily customers were ≤ 50 customers while 22% had more than 100 customers per day. The majority of the pharmacies lacked records of the medicines sold to the patients.

Table 3: Characteristics of the private retail pharmacies

Characteristics of the private retail pharmacies	Number (%)
Total participants	82 (100)
Distance of health facility from pharmacy by walking	
Less than 10 minutes	62 (75.6)
Less than 30 minutes	20 (24.4)
Years of pharmacies established	
0-5	24 (29.3)
6-15	29 (35.4)
16-25	18 (21.9)
> 25	11 (13.4)
Number of customers per day	
≤ 50	31 (37.8)
51-100	33 (40.2)
> 100	18 (22)
Records for customers	
Sales/drug register	11 (13.4)
No record	71 (86.6)
Informational materials present in pharmacies relevant to TB	
Brochures/pamphlet	10 (12.2)
Posters	11 (13.4)
Pharma companies TB medicines Sale advertisement	10 (12.2)
No Information material	51 (62.2)
Number of staff working in pharmacies	

2.00	23 (28)
3.00	24 (29.3)
4.00	16 (19.5)
5.00	13 (15.9)
6.00	4 (4.9)
7.00	2 (2.4)

4.3 Knowledge of private retail pharmacy staff about tuberculosis and the national tuberculosis control programme:

Knowledge of private retail pharmacy staff about TB and the NTP are summarised in table 4. The Majority of the pharmacy staff knew that TB spreads through presence of untreated TB patients in community and poverty but limited number of pharmacy staff knew that TB spreads through poor ventilation and overcrowding. Eighty five percent knew that TB could be prevented by covering mouth and nose when TB patient cough or sneeze and by curing TB patients. The majority of pharmacy staff had knowledge about TB diagnosis through sputum microscopy and almost 66% of pharmacy staff lacked knowledge about MDR-TB and the factors leading to development of resistance. Only 57% of pharmacy staff were aware of NTP while only 30% had heard of the TB DOTS. Nearly 66% of the pharmacy staff wanted to know more about NTP and 83% of pharmacy staff were willing to be involved in TB control efforts by getting training and referring patients to the DOTS delivery facility.

Table 4: Knowledge of private retail pharmacy staff about tuberculosis and the national tuberculosis control programme

	Number (%)
Total participants	82 (100)
Spread of TB in community	
Through poor ventilation	41 (50)
Through overcrowding	23 (28)
Through presence of untreated TB patients	76 (92.7)
Through poverty	59 (72)
TB Symptoms	
Persistent cough	75 (91.5)
Fever at night time,	26 (31.7)
Excessive night sweat	21 (25.6)
Loss of weight	49 (59.8)
Fatigue, body malaise	28 (34.1)
Haemoptysis	46 (56.1)
Shortness of breath	38 (46.3)
Chest pain	50 (61)
TB prevention	
By covering mouth and nose when you cough	64 (78)
By curing TB patients	76 (92.7)
TB Diagnosis	
Through Chest X-ray	64 (78)
Through sputum exam	67 (81.7)

Through physical examination	26 (31.7)
Through history of TB in the family	20 (24.4)
Through skin test	8 (9.8)
Patient who does not complete treatment	
Disease gets worse	66 (80.5)
Disease come back	29 (35.4)
Disease spread to others	62 (75.6)
TB become resistant	22 (26.8)
Dies	39 (47.6)
MDR-TB factors	
Improper treatment regimens	24 (29.3)
Failure to complete treatment	26 (31.7)
Presence of patients with MDR-TB in community	15 (18.3)
Do not know about MDR-TB factors	54 (65.8)
Anti-TB drugs administration	
Empty stomach	75 (91.5)
Full stomach	4 (4.9)
I do not know	3 (3.7)
Knowledge about NTP	47 (57.3)
Heard of TB DOTS	25 (30.5)
Want to know more about NTP	54 (65.9)
Want to be involve in TB controls efforts by getting training and referring patients to the DOTS delivery facility	68 (82.9)

4.4 Practices related to identification and referral of the tuberculosis patients:

Practices related to identification and referral of tuberculosis patients are summarised in Table 5. The frequency of TB suspects identification varied. The majority of pharmacy staff answered that they (67%) saw none or one suspect during one week, , while only 2 pharmacy staff answered that they saw 5 suspected TB patients per week. The majority of the staff (80%) referred the suspected TB patients to chest physicians, and none referred patients to the national TB control programme`s DOTS centres. Informational materials relevant to TB for pharmacies staff and patients were present in almost 38% of retail pharmacies. No one had received training relevant to TB in last two years.

Table 5: Frequency of tuberculosis suspects, referral practices, socio-economic class of tuberculosis patients

	Number (%)
Total participants	82 (100)
Suspected TB patients per week	
0	28 (34.1)
1.00	27 (32.9)
2.00	20 (24.4)
3.00	5 (6.1)
5.00	2 (2.4)
Referral of suspected TB patients	
Refer to nearby laboratory	22 (26.8)
Refer to nearby GP	19 (23.2)
Refer to specialized chest physician	65 (79.3)
Refer to TB DOTS centre	0 (0)

No referral	
Dispense broad spectrum antibiotics	11 (13.4)
Dispense cough syrup	28 (34.1)
Dispense anti-TB drugs	1 (1.2)
Socio-economic class of TB patients	
Middle class	14 (17.1)
Low class	68 (82.9)

4.5 Practices related to the sale of anti-TB drugs:

Practices related to the sale of anti-TB drugs are summarised in Table 6. All the interviewed pharmacy staff informed that the TB patients presented anti-TB drugs prescriptions and in more than 75% prescriptions the duration of anti-TB drugs were 6 months. All the interviewed staff answered that frequently sold anti-TB drugs were combination preparation of 4 drugs (4-FDC-RHZE) or 2 drugs (2-FDC-RH) combinations. Almost 83% retail pharmacy staff answered that TB patients belong to a low socioeconomic class.

Table 6: Practices related to the sale of anti-tuberculosis drugs

	Number (%)
Total participants	82 (100)
TB patients who come with a doctor's prescription	82 (100)
Duration of anti-TB drugs in prescription	
6 months	62 (75.6)
9 months	16 (19.5)
Do not know	4 (4.9)
Drugs present in TB patient prescription	

2 medicines	25 (30.5)
3 medicines	39 (47.6)
4 medicines	18 (22)
Vitamin B6 supplement Present in prescription	73 (89)
Frequently sold TB medicines	
4-FDC-RHZE combination	82 (100)
3-FDC-RHE combination	7 (8.5)
2-FDC-RH combination	79 (96.3)
Isoniazid	1 (1.2)
Pyrazinamide	0 (0)
Ethambutol	0 (0)
Streptomycin	28 (34.1)
Kanamycin	4 (4.9)
Patients buy anti-TB medicines	
1 month	7 (8.5)
2 months	11 (13.4)
3 months	22 (26.8)
4 months	3 (3.7)
6 months	35 (42.7)
9 months	4 (4.9)

4.6 Associations between tuberculosis knowledge and the professional background of the retail pharmacy staff:

Associations between TB knowledge and the professional background of the retail pharmacy staff are summarised in Table 7. This study revealed that there was a positive association between knowledge of TB and the formal training in pharmacy except TB transmission factors, TB spread factors, TB prevention, TB diagnosis and duration of TB treatment. Pharmacists had better knowledge about TB as compare to Pharmacy assistants and sales person, while pharmacy assistants had better knowledge as compared to the sales person.

Table 7: Associations between tuberculosis knowledge and the professional background of the retail pharmacy staff

Professional background	TB transmission			Fisher's Exact test P-value
	Poor knowledge n (%)	Good knowledge n (%)	Total	
Pharmacists	0 (0)	4 (100)	4	0.071
Pharmacy assistants	2 (7.4)	25 (92.6)	27	
Sales person	14 (27.4)	37 (72.5)	51	
	TB spread factors			
Pharmacists	0 (0)	4 (100)	4	0.451
Pharmacy assistants	5 (18.5)	22 (81.5)	27	
Sales person	15 (29.4)	36 (70.6)	51	
	TB symptoms			
Pharmacists	0 (0)	4 (100)	4	0.000
Pharmacy assistants	12 (44.4)	15 (55.6)	27	
Sales person	42 (82.4)	9 (17.6)	51	

TB prevention				
Pharmacists	0 (0)	4 (100)	4	
Pharmacy assistants	6 (22.2)	21 (77.8)	27	0.213
Sales person	19 (37.3)	32 (62.7)	51	
TB diagnosis				
Pharmacists	0 (0)	4 (100)	4	
Pharmacy assistants	2 (7.4)	25 (92.6)	27	0.103
Sales person	13 (25.5)	38 (74.5)	51	
Consequences of treatment non-compliance				
Pharmacists	0 (0)	4 (100)	4	
Pharmacy assistants	15 (55.6)	12 (44.4)	27	0.002
Sales person	40 (78.4)	11 (21.6)	51	
MDR-TB factors				
Pharmacists	0 (0)	4 (100)	4	
Pharmacy assistants	18 (66.7)	9 (33.3)	27	0.003
Sales person	41 (80.4)	10 (19.6)	51	
Duration of TB treatment				
Pharmacists	0 (0)	4 (100)	4	
Pharmacy assistants	1 (3.7)	26 (96.3)	27	1.00
Sales person	3 (5.9)	48 (94.1)	51	

4.7 Associations between duration of working experience of the staff in retail pharmacy and tuberculosis knowledge:

Associations between duration of working experience of the staff in retail pharmacy and tuberculosis knowledge are summarised in table 8. This study revealed that there was a significant positive association between knowledge of TB, and the duration of working experience of pharmacy staff with the exception of MDR-TB related factors and duration of TB treatment. TB knowledge of pharmacy staff with > 15 years experience was better as compared to pharmacies staff with 6 to 15 years experience and ≤ 5 years experience and TB knowledge of pharmacy staff with 6-15 years was better as compared to pharmacies staff with ≤ 5 years experience.

Table 8: Associations between duration of working experience of the staff in retail pharmacy and tuberculosis knowledge

Experience in years	TB transmission			Fisher's Exact test P-value
	Poor knowledge n (%)	Good knowledge n (%)	Total	
	≤ 5 years	15 (44.1)	19 (55.9)	
6-15 years	1 (3.3)	29 (96.7)	30	0.000
> 15 years	0 (0)	18 (100)	18	
TB spread factors				
≤ 5 years	14 (41.2)	20 (58.8)	34	0.008
6-15 years	5 (16.7)	25 (83.3)	30	
> 15 years	1 (5.5)	17 (94.4)	18	
TB symptoms				

≤ 5 years	29 (85.3)	5 (14.7)	34	
6-15 years	19 (63.3)	11 (36.7)	30	0.001
> 15 years	6 (33.3)	12 (66.7)	18	
TB prevention				
≤ 5 years	18 (52.9)	16 (47.1)	34	
6-15 years	7 (23.3)	23 (76.7)	30	0.000
> 15 years	0 (0)	18 (100)	18	
TB diagnosis				
≤ 5 years	10 (29.4)	24 (75.6)	34	
6-15 years	5 (16.7)	25 (83.3)	30	0.032
> 15 years	0 (0)	18 (100)	18	
Consequences of treatment non-compliance				
≤ 5 years	29 (85.3)	5 (14.7)	34	
6-15 years	20 (66.7)	10 (33.3)	30	0.001
> 15 years	6 (33.3)	12 (67.7)	18	
MDR-TB factors				
≤ 5 years	27 (79.4)	7 (20.6)	34	
6-15 years	21 (70)	9 (30)	30	0.360
> 15 years	11 (61.1)	7 (38.9)	18	
Duration of TB treatment				
≤ 5 years	3 (8.8)	31 (91.2)	34	
6-15 years	1 (3.3)	29 (96.7)	30	0.535
> 15 years	0 (0)	18 (100)	18	

4.8 Associations between the customer load and suspected tuberculosis patients, pharmacy staff and their work experience:

Associations between the customer load and suspected tuberculosis patients, pharmacy staff and their work experience are summarised in table 9. Pharmacies with higher number of staff and staff with longer duration of work experience had higher customer load. The pharmacies with higher customer load had higher percentage of suspected TB patients per week as expected.

Table 9: Associations between customer load and the number of suspected tuberculosis patients, number of staff and their length of experience

Number of customers per day	Suspected TB patients per week			Fisher's exact test P-value
	0-1 suspected TB patient n (%)	2 suspected TB patients n (%)	3-5 suspected TB patients n (%)	
≤ 50 customers	27 (87.1)	4 (12.9)	0 (0)	31
51-100 customers	24 (72.7)	7 (21.2)	2 (6.1)	33
> 100 customers	4 (22.2)	9 (50)	5 (27.8)	18
	Experience in years			Total
	≤ 5 years n (%)	6-15 years n (%)	> 15 years n (%)	

≤ 50 customers	22 (71)	5 (16.1)	4 (12.9)	31	
51-100 customers	7 (21.2)	17 (51.5)	9 (27.3)	33	0.001
> 100 customers	5 (27.8)	8 (44.4)	5 (27.8)	18	
Number of staff in pharmacy					
	2-3 staff n (%)	4-5 staff n (%)	6-7 staff n (%)	Total	
≤ 50 customers	30 (96.8)	1 (3.2)	0 (00)	31	
51-100 customers	15 (45.5)	17 (51.5)	1 (3)	33	0.000
> 100 customers	2 (11.1)	11 (61.1)	5 (27.8)	18	

CHAPTER FIVE: DISCUSSION

Discussion:

Numerous findings of our research study point to the necessity and the possibility of involving private retail pharmacies in TB control in Pakistan. The pharmacy staff had insufficient knowledge about the DOTS facility and they referred the suspected TB patients to specialized chest physician instead of TB-DOTS centre. Interestingly a considerable number of TB patients purchased anti-TB drugs from the private retail pharmacies despite the presence of free of cost good quality drugs at the DOTS centres. This seems to be due to the insufficient information about NTP's DOTS programme and pharmacies have a great potential to contribute towards this by imparting this information to the public. The majority of the retail pharmacy staff wanted to be involved in NTP efforts and were willing to receive relevant training for this purpose involving patient education and counselling, achieving better adherence to recommended therapy, developing a private-public sector collaboration and referring patients to the DOTS delivery facility.

By involving pharmacy staff there is a potential to reduce the practices of dispensing broad spectrum antibiotics or cough syrup to suspected TB patients, thereby reducing the emergence of resistance to antibiotics and delay in TB diagnosis.

This research study also revealed that all of the retail pharmacy staff working at different private retail pharmacies were males and this can be correlated to social and cultural factors in this region of Pakistan where gender roles define that females do not generally participate in sales and marketing professions. This could have some implications in the interaction of the staff with the female patients/ TB suspects and it would be an advantage to have some balance in the gender distribution of the pharmacy staff.

An important finding of our study was shortage of qualified personnel in private retail pharmacies. In Pakistan, working in the retail pharmacy is not preferred by the professional pharmacists and only 10% of the them work in private retail pharmacy while 55% are involved in the economically attractive pharmaceutical manufacturing, 15% in sales and marketing, 15% in hospital pharmacy and provincial and federal drug control authority, and 5% in research and teaching (59). One of the reason behind a lesser number of pharmacists working in community pharmacies is lack of recognition of pharmacists as health care professionals in Pakistan, an attitude that should be changed.

The study also revealed that there was no clear difference between the tasks performed by the pharmacist, pharmacy assistants and sales persons. Patients were mainly handled by unqualified salesmen leading to unsatisfactory consultation. Similar findings has also been reported by some earlier studies carried out in other cities of Pakistan (60-62). Thus, there is a need of implementation of law that to guarantee presence of educated and qualified people in private retail pharmacies which will result in better patient care oriented services.

The research study showed that private retail pharmacies operating had varied distribution in the DI Khan city and majority of pharmacies were situated near hospitals or private clinics because the majority of patients prefers to buy medicines from nearby pharmacies. Patient counselling were also more frequent at retail pharmacies situated near hospitals which could be due to the extra competitive environment among these close situated pharmacies near hospitals, which ultimately leads to improved patient care services. The study also revealed 11 pharmacies were established 25 years ago, this is important because pharmacies established for a longer duration have better contact with people, win the trust of people and people use them more often as consultation sites as compared to newly established pharmacies.

The study revealed that informational material relevant to TB were present in very limited numbers of retail pharmacies. So further educational efforts are also vital to keep private retail pharmacy staff updated on national TB treatment guidelines. According to pharmacies staff the majority of TB patients visiting private retail pharmacies were of low socioeconomic class, but they still bought anti-TB drugs from private pharmacies instead of free medicines available at NTP DOTS centres. Possible explanations could be the lack of information about DOTS, lack of trust on quality of medicine and easy access to a private sector as compared to government treatment centre. In the last 2 years, none of the pharmacy staff received any training relevant to TB, which shows null activities of NTP in private retail pharmacies in this area.

This research study did not permit us for an evaluation of the frequency of sales of anti-TB drugs without prescription. But our study findings suggest, that anti-TB drugs are more commonly sold with a prescription of the doctors. The majority of anti-TB drugs present in the pharmacies were fixed dose combinations of either four or two first line anti-TB drugs, thereby reducing the probability of over-the-counter delivery of anti-TB drugs as broad spectrum antibiotics for other purposes. Furthermore personal observation of the investigator provided no clue of drugs from the NTP being present in the private pharmacies for sale. However, the results of a previous study showed that more than 1/3rd of the pharmacy staff dispensed medicines without a doctor's prescription without specifying the sale of anti-TB drugs (63). The study also showed that less than 50% TB patients bought full treatment course. Possible explanations could be poverty, lack of knowledge about the importance of complete treatment.

Our study also revealed that only about 57% of the retail pharmacy staff knew that TB treatment given by the NTP was free of charge, only a few knew about TB DOTS strategy and almost 83% wanted to be involved in TB control efforts by getting training and referring

patients to the DOTS delivery facility. A study of Mumbai city, India, showed that by giving training to retail pharmacy staff through collaborative NTP or professional association workshops can give easy access to TB education and information for primary health care suppliers (64).

Our study findings show that there is significant scope for involving private retail pharmacies in TB control programme as DOTS motivators and providers and for completion of treatment, and for endorsing awareness about TB and DOTS in the society. The government and management of NTP should keenly seek the involvement of private retail pharmacies through proper training, promotion and imparting a common sense of ownership in the NTP. Collaboration between the private and public sector is very important in the effort to provide good quality of care for the patients and prevent drug resistance in the society (65). In DI Khan city the private retail pharmacy staff could play a vital role in the control of TB. It is obvious that private retail pharmacies have to run their medicines selling's, but still the majority of retail pharmacy staff indicated that they would inform people about public services when it is clear that they could not afford to buy medicines. It is the accountability of the NTP to persuade private retail pharmacy staff to take part in the combined efforts for TB control in Pakistan.

Study implications

This research study has shown up the deficiencies of qualified staff, educational materials, TB training, knowledge about TB, NTP, DOTS strategy and lack of involvement of private retail pharmacies in TB control in DI Khan city. The results of this research study can provide a baseline data for stakeholders, researchers and policy makers to design potential interventions for involving the private retail pharmacies in TB control programmes countrywide.

Study strengths:

All the data collected by the primary investigator on a pre-designed questionnaire. Urdu and Pashto language were used, which allowed easy communication between primary investigator and study participants and this also diminished the misunderstandings between the interviewees and interview. Data was collected from all the pharmacies in the region which has reduced the sampling error.

Study limitations:

The research study was conducted in only DI Khan city limiting the generalisation of results. Recall bias was also a limitation of this type of study. The interviewees were selected based on the longest period of experience to improve the quality of data, but this could affect the representability of data for all the staff members in a pharmacy.

Conclusion:

This research study shows that private retail pharmacies can play a potential role in TB control by referring suspected TB patients to TB DOTS centres, emphasizing the value of taking the complete course of treatment, proper counselling regarding administration of anti-TB drugs and their side effects and it is feasible to involve these pharmacies in TB control to provide patient oriented services and quality of care to TB patients in Pakistan after proper training.

Recommendations:

The following recommendations are suggested for involvement of private retail pharmacies in TB control:

- Provision of training about NTP- DOTS programme facilities, identification of TB suspects, development of easy-to-use system for referral of TB suspects to the DOTS facilities.
- Recording of referrals in the DOTS register.
- Continuous support of private retail pharmacies by NTP staff.
- Implementation of laws and regulations regarding presence of at least one qualified pharmacist in each pharmacy.
- Encouragement through incentives shall also be commenced for the pharmacists to enter into private retail pharmacy by the government.
- Recognition of private retail pharmacy staff as essential health care providers.
- Stricter laws to prevent sales of medicines without prescription.
- Public information to give confidence to people to request proper counselling from private retail pharmacy staff about TB, anti-TB drugs use.

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APPENDICES

Information sheet in English

Researcher: Yasir Shahzad, Centre for International Health , University of Bergen

I am a Pharmacist from University of Peshawar and currently undertaking Master in International Health at the University of Bergen, Norway. As part of international health degree I am doing a research project leading to a thesis. The project is on the assessment of the knowledge of the retail pharmacy staff about tuberculosis and public tuberculosis Control Programme and sale practices of anti-tuberculosis drugs and the purpose is to involve private retail pharmacies in TB control. This research project has received approval from Ethical Committees of Pakistan.

I would collect information by taking interview from the main sellers of pharmacy by using a short questionnaire. The questionnaire will take about half an hour to complete. If any participant wants to pull out from the project, he may do so without giving any reason at any time.

Responses will make the foundation of my research project and will be put into a written report on an anonymous and confidential basis. All data collected will be reserved anonymous and confidential. No other person except me and my supervisor will see the questionnaires. The copy of thesis will be submitted to university of Bergen and will be deposited in the University Library. It is planned that the data will also be used to write research article for publication in public health journal. Questionnaires will be destroyed three years after the end of this research project.

If you have any additional questions or would like to receive further detail information about the research project, please feel free to contact me on my email address yasirshahzad203@yahoo.com.

Consent form

Assessment of the knowledge of the retail pharmacy staff about tuberculosis and public tuberculosis Control Programme, and sale practices of anti-tuberculosis drugs in DI Khan city, Khyber Pukthoon Khwa Province, Pakistan

I have been given all the relevant information regarding this research project and have understood an explanation of this research project. I have had chance to enquire questions and have them answered to my fulfilment. I have the knowledge that I may pull out myself from this research project at any time depending on my wish without giving any reasons.

I understand that any information I give will be kept anonymous and confidential. I understand that no opinion will be connected to me in any means that will recognize me and the published results will not use my pharmacy name or my name. I understand that the data I provide will not be used for any other purpose or released to others without my written consent. I voluntarily choose to take part in this research project.

Name of principal investigator: Yasir Shahzad

Signature of principal investigator:

Name of participant:

Signature of Participant:

Date:

Information sheet in Urdu:

معلوماتی شیٹ

ایک ریسرچ پروجیکٹ کے لئے معلوماتی شیٹ

ریسرچر: یاسر شہزاد، انٹرنیشنل ہیلتھ یونیورسٹی آف بگرن

میں یونیورسٹی آف پشاور سے ایک فارمسٹ ہوں جو کہ بین الاقوامی صحت کی ڈگری حاصل کرنے کے ناطے سے میں ایک ریسرچ پروجیکٹ کر رہا ہوں جو کہ Thesis کی طرف جاتا ہے۔ یہ پروجیکٹ پب ڈق اور پبلک ہیڈ ڈق کنٹرول پروگرام اور نپ ڈق کنٹرول ادویات کی سیل پریکٹس کے متعلق فارمیسی سٹاف کے علم کا تعین کرتا ہے اس ریسرچ پروجیکٹ کی منظوری پاکستان اور ناروے کی Ehtical کمیٹی سے لی گئی ہے۔

میں فارمیسی کے بڑے سیکر سے اتروویو اور مختصر سوالات کے ذریعے معلومات اکٹھی کی ہیں سوالات تقریباً آدھے گھنٹے میں مکمل کیے جائیں گے اگر کوئی نمائندہ خود کو اس پروجیکٹ سے علیحدہ کرنا چاہتا ہو تو وہ بغیر کسی وجہ کے کسی بھی وقت وہ علیحدہ ہو جائے۔ ردعمل میری ریسرچ پروجیکٹ کی بنیاد پر ہوں گے اور اس کی تحریری رپورٹ پوشیدہ اور مخفی بنیادوں پر رکھی جائے گی اس کے تمام دینا و جو جمع کیا گیا ہے وہ مخفی طور پر محفوظ رکھا جائے گا میرے سپروائزر کے علاوہ کسی شخص کو میرے سوالنامے کو دیکھنے کی اجازت نہیں ہوگی۔ اس ریسرچ کی کاپی یونیورسٹی آف بگرن کی لائبریری میں جمع کروائی جائے گی یہ بھی پلان کیا گیا ہے کہ ڈیٹا ریسرچ آرکیوئل کے طور پر پبلک صحت کے جرنل میں بھی شائع کیا جائے گا اس ریسرچ پروجیکٹ کے ختم ہونے کے تین سال بعد سوالنامہ ضائع کر دیا جائے گا۔ اگر کوئی اضافی سوالات اور مزید تفصیلی معلومات اس ریسرچ کے متعلق حاصل کرنا چاہے تو بلا تکلف میری ای میل آئی ڈی

yasirshahzad203@yahoo.com

پر رابطہ کر سکتا ہے۔

Consent form in Urdu

تحقیق میں شمولیت کے لئے منظوری

ڈیرہ اسماعیل خان (KPK) میں (ٹی بی) تپ دق اور پبلک دپ دق کنٹرول پروگرام اور دپ دق کی روک تھام کے لیے سیل پریکٹس کے متعلق فارمیسی سٹاف کے علم کا تعین کرنا ہے۔

میں نے اس ریسرچ پروجیکٹ کے متعلق تمام معلومات اور ایک قابل فہم وضاحت فراہم کر دی ہے مجھے ایک موقع ملا ہے کہ میں اپنی تسکین کے لئے ان سوالوں کا حصول جن کے جواب دیے جائیں میں اس بات کا علم رکھتا ہوں کہ شاید بغیر کسی وجہ کے میں خود کو کسی بھی وقت اس ریسرچ پروجیکٹ سے علیحدہ کر سکتا ہوں یہ میری اپنی مرضی پہ منحصر ہے۔

میں سمجھتا ہوں کہ جو انفارمیشن میں دیتا ہوں وہ پوشیدہ اور مخفی اور گمنام رکھی جائیں گی میں کہتا ہوں کہ جو بھی رائے کسی بھی سے زریعے سے مجھ سے جوڑی جائے گی وہ میری وجہ سے جانی جائے گی اور میری فارمیسی کے پہلے شدہ نتائج فارمیسی کا نام یا میرا نام استعمال نہیں کیا جائے گا اور میں یہ بھی کہتا ہوں میرا ڈیٹا میری تحریری مرضی کے بغیر کسی بھی مقصد کے لئے استعمال یا ریلیز نہیں کیا جائے گا اس ریسرچ پروجیکٹ میں میں نے اپنی خوشی سے حصہ لیا ہے میں مزید سمجھتا ہوں کہ اس کو فیڈرل یا صوبائی قانون میں شامل کرنا کوئی مشکل کام نہیں ہے۔

TUBERCULOSIS QUESTIONNAIRE

General information & Retail Pharmacy Profile

Date of the interview:

1a. Are you the:

Owner

Pharmacist

Sales person

1b. Gender:

Male

Female

2. Age (in years):.....

3. How long has this chemist been in operation?.....years (Please observe the license/registration certificate)

4. Is this chemist part of the chain?

Yes

No [*move to Q6*]

5. If yes, what is the name of the chemist's chain?.....

6. How many branches do you have?.....

7. What is your professional background?

Pharmacist

Pharmacy Assistant

Sales person

8. How long have you worked in this chemist?year(s) orMonth.....

9. What are the working hours of operation of this pharmacy?

Openam. Close.....pm

10. How many days in a week are you open?.....

11. How many sales person working in this pharmacy?

12. Is there any health facility (private or public or both) around this pharmacy?

Yes

No

13. If yes, how far by walking

less than 10 minutes

less than 30mins

less than 1 hour

14. Where are the majority of your clients coming from? (Tick only one)

Private clinics/GP clinic

Patients from both private and public health facilities

Self-referral/medication/Home

Informal providers (hakims, homeopathic]

Others (specify)

15. On average, how many clients/customer do you serve/see per day?.....

16. Do you keep records for your clients? (Please observe those records before ticking)

Yes

No

17. If yes (please tick)

Sales/drug register

Prescriptions file

Others (Please specify).....

Knowledge about tuberculosis and TB DOTS

18. Do you know how TB is transmitted?

Through breathing in the air containing TB causing microorganisms

Through sharing of utensil

Through sex

- Use an already used syringe
- Smoking cigarette
- Using narcotics
- I don't know
- Others. Specify.....

19. What factors contribute to the spread of TB from patients to other people in the community? (Please tick all that apply do not read but probe by asking “any other factor”)

- Poor ventilation in the house
- Overcrowding
- Presence of untreated TB patients in the house/community
- Poverty
- I don't know
- Others (Please specify).....

20. What are the symptoms of a person who is sick with TB disease (Do not read the list, please tick all that apply and probe by asking “any other symptoms?”)

- Persistent cough (two weeks or more)
- Fever at night time
- Excessive night sweat
- Loss of weight
- Fatigue, body malaise
- Haemoptysis
- Shortness of breath
- Chest pains

- I don't know
- Others (please specify).....

21. How did you learn about these symptoms? (Please tick)

- When I was at school/ college/university
- During World TB commemoration day
- During community sensitization meetings
- Reading brochures
- Billboards
- Fellow health care providers
- Radio
- Television
- Newspapers
- At the mosque
- Others (please specify).....

22. How TB can be prevented?

- By covering mouth and nose when you cough
- By curing TB patients
- Any other

23. Do you know which parts of the body that can be affected by tuberculosis?

- Lungs
- Other organs as well
- Only lungs

24. How is TB Diagnosed?

- Chest x-ray
- Sputum exam
- Physical examination
- History of TB in the family
- Skin test
- I don't know
- Others, specify.....

25. How long does it take to treat TB?

- Less than 6 months
- 6 months
- I don't know
- Other. Specify.....

26. What happens to a patient who does not complete TB treatment?

- Dies
- Disease gets worse/deteriorates
- Disease comes back/Recurrence
- Disease spread to others
- TB becomes resistant
- I don't know

27. Have you heard of TB DOTS (Directly Observed Treatment Short Course?)

Yes

No [*skip to Q28*]

28. If yes, where did you hear it from?

When I was at college/university

During World TB commemoration day

During community sensitization meetings

Reading brochures and newspapers

Billboards

Fellow health care providers

Others (please specify).....

29. Are you aware of multidrug resistant (MDR) TB?

Yes

No

30. What factors contribute to the spread of MDR TB? (Tick all that apply)

Improper treatment regimens

Failure to complete treatment

Presence of patients with MDR-TB in household/community

I don't know

Other

31. How anti-TB drugs should be taken?

Empty stomach

Full stomach

I don't know

32. Which first line anti-TB medicine causes discolouration of urine?

Isoniazid

Rifampicin

Ethambutol

pyrazinamide

Streptomycin

I don't know

Action and practices in TB case detection

33. Based on your experiences, do you see clients come to this pharmacy with TB symptoms?

Yes

No

34. How many suspected TB patients do you see on average per week?

35. What do you do when you suspected a TB patient? (Please tick more than one)

Refer to a nearby laboratory

Refer to a nearby GP

Refer to a nearby specialized chest physician

Refer to a TB DOTS center

Dispense broad spectrum antibiotics [e.g. Flouroquinolones]

- Dispense cough syrup
- Dispenses Anti- TB drugs
- Others (please specify).....

36. Do you see TB patients who come with a doctor's prescription of anti TB medicines?

- Yes
- No

37. If yes, on average how many patients do you dispense TB medicines per week?.....

38. On average, what is the duration of anti-TB drugs in prescription?

- 1 month
- 2 month
- 3 month
- 4 month
- 5 month
- 6 month
- Other (please specify).....

39. On average, for how much long time patient buy anti-TB medicines?

- less than 1 month
- 1 month
- 2 months
- 3 months
- 4 months

- 5 months
- 6 months
- Other (please specify).....

40. Majority of TB patients belongs to which socio-economic class?

- High class
- Middle class
- Low class

41. On average, how many anti-TB drugs are present in prescription?

- 1
- 2
- 3
- 4
- 5
- 6
- Other (please specify).....

42. Vitamin B6 supplement is present in TB patient prescription?

- Yes
- No

43. Are there any Informational Education and Communication materials on TB available in the chemist shop? Please observe

- Yes
- No

44. If yes, what are they?

- Brochure/pamphlet

- Posters
- Pharma companies TB medicines sales advertisement
- Others specify.....

45. Have you received any training on TB in last two years?

- Yes
- No [*skip to Q47*]

46. Which organization/institution conducted the training?.....

47. What did the TB training cover?

- TB General
- MDR TB
- Direct Observed Therapy (DOTs)
- I don't remember
- Others. Specify.....

48. Which are most frequently sold TB medicines? (Please tick the top 3 frequently sold)

- 4-FDC-RHZE (Rifampicin/Isoniazid/Pyrazinamide/Ethambutol) combination
- 3-FDC- RHE combination
- 2-FDC-RH combination
- Isoniazid
- Rifampicin
- Pyrazinamide
- Ethambutol
- Kanamycin
- Streptomycin
- Others. Specify.....

49. Do you know about the National TB Program (NTP)?

Yes

No

50. If no, would you like to know more about the National TB Program (NTP)?

Yes

No

51. Would you like to be involved in the TB control efforts by getting training and thereby referring patients to the DOTS delivery facilities?

Yes

No

Ethical approval Pakistan:

 **National Bioethics Committee (NBC) Pakistan** 

Ref: No.4-87/14/NBC-156/RDC/477 **Date: September 11, 2014**

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University of Bergen,
Norway

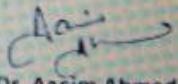
Subject: Involvement of retail pharmacies in Pakistan TB control (NBC-156)

Dear Dr Yasir Shahzad,

I am pleased to inform you that the above mentioned project has been cleared by "Research Ethics Committee of National Bioethics Committee".

Kindly keep the National Bioethics Committee Secretariat updated with the progress of the project and submit the formal final report on completion

Yours sincerely


(Prof Dr. Aasim Ahmad)
Chairman
NBC-Research Ethics Committee

NBC Secretariat
Pakistan Medical Research Council, M.A. Jinnah Stadium, 6th Cross, 4th Avenue, Sector D-9, Islamabad-75200
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