

Chapter One

1. Introduction

1.1 Introduction:

Tuberculosis (TB) is a chronic infectious disease caused by *M. tuberculosis*. The main source of infection is untreated smear-positive pulmonary tuberculosis patients discharging *M. tuberculosis* (Manalebh, *et al.*, 2015). Tuberculosis, reported as the second most common infectious cause of death worldwide, is key mortality contributor in developing countries and globally. Control of the disease has been highlighted as a priority for the World Health Organization (WHO) and as such is a key component of the millennium development goal. For this reason, it is necessary to conduct assessments of the knowledge and attitudes about TB amongst healthcare providers in laboratory sample handling, in order to identify potential problems, limitations and areas for improvement (Minnery, *et al.*, 2013). Clinicians should therefore have basic knowledge about the types of specimens collected be able to provide clear instructions to their patients on how to provide such specimens at the lab or in the clinic; a good diagnostic approach for TB requires collection of the right clinical specimen of adequate quality and quantity. Microbiology specimens are to be received in uncontaminated containers that are intact and are consistent with laboratory specimen collection policy. Submit specimens to the laboratory in transport bags that isolate the patient requisition from specimens, always limit bags to one patient to prevent misidentification and cross -contamination (Michael , *et al.*, 2012). International and national procedures have been established for the safe transport of biological materials by all modes of transportation (air, sea and land). Different packaging and transport arrangement applied depending on

whether materials are infectious substances, biological products, cultures, genetically modified organism (GMO) or exempt substances. The requirements of various regulatory bodies are based on the United Nations recommendations on the transport of dangerous goods model regulations which are adopted by International Air Transportation Association (IATA) and Malaysian Standard (MS 1513). It is the responsibility of sender to ensure compliance with all packaging and transport regulations (Shahnaz, *et al.*, 2012). The preparation and packaging of the specimens complied with (IATA) regulations no decontamination procedure was performed prior to storage or transportation, specimens were transported in one batch after the data collection period. Ice packs were added to the package of the specimens during transport, and specimens were stored at -80°C after arrival at the mycobacteriology laboratory (Tessema, *et al.*, 2011).

1.2 Objective:

The aim of this study was to assess the knowledge, attitude and practice toward tuberculosis laboratory samples handling and transportation among the TB healthcare providers.

Chapter Two

2. Literature Review

2.1 Definition of quality:

The standard of something as measured against other things of a similar kind, the degree of excellence of something (Elizabeth, *et al.*, 2015).

2.1.1 Concept of quality:

The concept of quality management is applied to the provision of services as well as the production of goods. Since these are not tangible in the same way as goods, the idea of customer satisfaction has been introduced and quality has been equated with this slogans such as “quality means meeting customer expectations” or “quality means exceeding customer expectations” have been used. In the provision of services the contract between the provider and the consumer of services is a relational one and the quality of the service is often defined through the keeping of promises which are expressed in the form of “customer charters” or service guarantees. An essential element of quality in services is to establish a clear description of what is offered - “say what you do what you say you do”. The idea of quality as an important feature of the production of goods and the provision of services has led to its being an important factor in the management of companies and other organizations. The procedures are divided into “quality assurance”, the steps which need to be taken to produce goods or provide services of high quality; and “quality control”, the procedures devised to check that the aimed for or promised quality is achieved. The idea of quality has been introduced into the public domain, with governments promising specific standards in the provision of health services or education (Frank, 2000).

There have also been attempts to define all working relationships as being influenced by client satisfaction, with every person in an organization having clients, either internal or external, whose needs must satisfy, and providers, who provide services which enable people to carry out their tasks efficiently. Various organizations have been set up to establish standards, either general or for a particular activity, and to validate that the standards are being kept. The International Standards Organization (ISO) has a series of norms. The ISO certification checks that there are proper procedures for ensuring quality standards and these are consistently applied, but makes no judgment of the quality of the product or service itself (Frank, 2000).

2.2 Tuberculosis disease:

Tuberculosis is a chronic granulomatous disease affecting man and many other mammals. It is an infection, which most commonly affects the lung where it is called pulmonary tuberculosis, but it can also affect the central nervous system (meningitis), circulating system and gastrointestinal tract (miliary tuberculosis), genitourinary system, bones and joint where it is called extra pulmonary tuberculosis (Grange, 2002).

2.2.1 Historical background:

Tuberculosis is a disease of great antiquity, having been found in the mummies of ancient Egypt. *M. tuberculosis* was probably first seen in tissues by Baumgartner and Koch in 1882. Koch cultivated *M. tuberculosis* and reproduced the disease in the period from 1882 to 1884 (Carter, *et al.*, 1986).

The bacterium first infected animals possibly by inhalation or ingestion from the soil, and passed to humans through the animals flesh and milk. It affects many kinds of animals including cows, birds, fish and reptiles. The earliest evidence of tuberculosis in humans is from a Neolithic grave near Heidelberg, Germany, dating back to 5000 BC, examination of the spines of mummies and of tomb paintings from 4000 BC confirms tuberculosis was a common disease in ancient Egypt. And skeletal remains in Italy from the same date also show tuberculosis in the spine by the mid 17th century, one in five a death in London as recorded in the bills of mortality was due to tuberculosis consumption. TB soon became an epidemic in Britain and major cities in the USA and Europe, commonly known as the white plaque (Betty, *et al.*, 1998).

2.3 Epidemiology of tuberculosis in Sudan:

Tuberculosis (TB) remains a major health problem in countries with low income. It is considered as one of the most serious diseases and a considerable public health problem due to its high risk of person-to-person transmission, morbidity, and mortality. It was reported that 8.9-9.9 million reported TB cases worldwide, most of them in Africa and Asia. Sudan is currently suffering from many factors which may predispose for the occurrence and increase of TB infection rates, among which are the civil war in some areas and displacement of people in a search of a better life. This may enhance the occurrence and spread of many health hazardous diseases, among them is TB. The other factors include poverty and lack of well-equipped medical centers that enable identification and treatment of TB in its earlier stage. Hence, identification of epidemiological factors affecting the prevalence rates of TB is fundamental and crucial for decision-makers enabling them

having the appropriate strategy to minimize the incidence of the disease and identifying the risk factors helping in its distribution (Mohammed, 2016).

2.4 Definition of some terminology:

The following definitions align with the UN model regulations.

2.4.1 Patients' specimens:

Those collected directly from humans, including, but not limited to, excreta (feces & urine), secreta (body fluids), blood and its components, tissue (including fresh tissue, , preserved tissue paraffin blocks and glass slides) and swabs, and body parts being transported for purposes such as diagnosis, research, investigational activities, disease treatment and prevention (Shahnaz, *et al.*, 2012).

2.4.2 Referring laboratory:

Laboratory that sends biological substance or environmental sample to a referral laboratory for further investigations (Shahnaz, *et al.*, 2012).

2.4.3 Referral laboratory:

Laboratory which receives specimens from another facility for investigation (Shahnaz, *et al.*, 2012).

2.4.4 Shipper:

Individual or agency that has the licence to transport specimen (Shahnaz, *et al.*, 2012).

2.4.5 Primary container or receptacle:

Container or receptacle in contact with the biological or environmental material to be transported (Shahnaz, *et al.*, 2012).

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2.4.6 Secondary packaging:

Provides additional protection for the primary container is leak-proof and may include absorbent material (Shahnaz, *et al.*, 2012).

2.4.7 Outer container:

A sturdy, leak-proof container, for example, a box, flask, Styrofoam box, chiller box that is used to contain the secondary container (Shahnaz, *et al.*, 2012).

2.4.8 Over pack:

A large box that is used to transport multiple triple packages (Shahnaz, *et al.*, 2012).

2.5 Procedure for air, land and water transport:

This procedure used for packing and transporting of patients specimens, infectious substances, cultures, clinical wastes and genetically modified organisms to the designated referral laboratory (Shahnaz, *et al.*, 2012).

2.5.1 General requirements:

Determine the specimens to be transported, identify the UN class applicable to the specimen category (Appendix I), pack all patients' specimens according to categories specified in IATA packaging instructions different categories have slightly different packaging needs specified in IATA packaging instructions but all follow the basic triple packaging requirement (Appendix II), ensure that packages will arrive at their destination in good condition and present no hazard to persons or animals during transport, pack category B biological materials for air transport following requirements in IATA packaging instructions 650: PI) use the package with the appropriate UN number and proper shipping name (UN 3373 for biological substance for category B).

(WHO, 2008) (Appendix III), Pack, mark and label all infectious substances' using a triple packaging system the system comprises a primary receptacle, secondary packaging and an outer packaging (Appendix IV) (Shahnaz, *et al.*, 2012).

2.5.1.1 A leak-proof primary receptacle container:

Label the primary container with the name of patient identification card or hospital registration number specimen type (if necessary) and test request. secure the primary receptacle with a water proof, leak-proof seal and secure the screw cap with a stretch wrapping e.g. parafilm or masking tape (Shahnaz, *et al.*, 2012).

2.5.1.2 A leak-proof secondary packaging:

For liquids place absorbent material e.g. gauze, cotton, paper towel or super absorbent pad between the primary container and the secondary packaging to absorb the entire contents so that during transport any release or leak of liquid substance will not reach the outer packaging and will not compromise the integrity of the cushioning material, individually wrap the primary containers and place them in a single secondary packaging to prevent cross contamination, use a rigid outer container of adequate strength for its capacity mass and intended use and with at least one surface having a minimum dimension of 100 mm x 100 mm, specimen data and/or request forms, letters and other types of information that identify or describe the specimens should be taped to the outside of the secondary container, for infectious substances belonging to category B the maximum net quantity permitted in a single package is 4 L or 4 kg on both passenger or cargo aircraft, if shipping using dry ice use leak-proof container and an outer packaging that allow for the release of carbon dioxide gas when the solid evaporates ,place the dry ice

outside the secondary packaging Provide interior support to secure the secondary container as the refrigerant evaporates dry ice is considered a miscellaneous hazard (Class 9) by IATA . Use an over pack to combine several triple packages into one large package mark and label each triple package inside the over pack the outside of the over pack must bear the same markings and labels as the triple packages within including hazard labels proper shipping names and net quantities mark the outer container of the over pack with the word “over pack used” the over pack marking is an indication that packages contained within comply with prescribed specification (Shahnaz, *et al.*, 2012).

2.6 Marking and labeling:

Label the outer packaging in print or clear writing in capital letters:

Shipper: Enter the full name, address and contact number of the person packing the shipment this person must be trained on packaging biological substances for transport. Consignee: Enter the full name address and contact number of recipient. Transport Details: Enter the category, proper shipping name, UN number and hazard Class. Quantity and type of packaging: Enter the quantity (weight or volume) of the specimen and type of packaging if using an over pack state. Enter emergency contact number of the referring laboratory (must be contactable 24 hours). All the information above must also be entered on the over pack container (Shahnaz, *et al.*, 2012).

2.7 Documentation:

Complete a shipper’s declaration for dangerous goods form in triplicates when infectious substance belonging to category B is being transported retain one copy for your record for a minimum of 3 months or until the results are received, documents identifying the contents of the primary receptacle or

request forms should be outside the secondary package. Any documents required by a transporter shall be accessible without opening the package (Shahnaz, *et al.*, 2012).

2.8 Types of laboratory samples shipping:

Infectious substances are transported for a variety of different reasons, within countries and across international borders. It is incumbent upon shippers to ensure packaging and shipping conditions meet regulatory requirements to preserve the integrity of materials, and facilitate their timely arrival at destination. (WHO, 2012)

The international regulations for transport of infectious substances, including diagnostic specimens, are based on the United Nations model regulations and the standard for transport by all means of transportation including air transport; the (IATA) regulation specifically addresses air shipment. In 2005 and 2006 there were major improvements in the procedures for shipping infectious substances. These substances are divided into category A, which includes primarily cultures of the more pathogenic agents and category B, all the other substances. Category A shipments must have a dangerous goods certificate and meet other requirements. Category B shipments, which include most diagnostic tissue specimens, do not. These regulations specifically exempt certain substances, including those that have been neutralized or inactivated to destroy pathogens and samples from "normal" animals. The packaging's requirements help insure that biocontainment is maintained during shipment to protect the shipper and the environment. The packaging requirements and the shipping procedures provide a chain of custody and assist in supporting biosecurity. The more stringent category A requirements

provide increased biocontainment and biosecurity safeguards for these potentially more dangerous (Pearson, 2007).

2.8.1 Regulations for packaging and shipping laboratory specimens:

Laboratories must maintain the integrity of patient specimens before the specimens are analyzed. Maintaining specimen integrity in the laboratory is not simple, and it becomes even more complex when specimens are transported by public conveyance. Specimens must be kept from leaking and from being crushed in unexpected accidents. They must be packed to protect both the specimens and those who handle them. The regulations need to be applied depend on how the specimen is sent. Each model of transportation has its own rules. For specimens sent by mail, the US postal service regulations regarding dangerous goods should be followed. For specimens sent by ground courier, department of transportation regulations should be followed regulations governing specimen transport are incorporated in a document referred to as “49 CFR”. If specimens are sent by air, the dangerous goods regulations of the (IATA) and international civil aviation organization must be followed (Barth, 2001).

2.9 Shipping of tuberculosis samples:

Recommendations of international regulations on the transport of infectious substances are included in the model regulations on the transport of dangerous goods, developed by the United Nations Economic and social council's committee of experts on the transport of dangerous goods and updated every two years. These recommendations form the basis of national and international transport regulations. Packing requirements, labeling and documentation are subject to regulation for the national (where applicable)

and international transport of infectious substances. For the international transport of TB samples, cultures of *M. tuberculosis* should be shipped according to United Nations packaging instruction P620 and accompanied by the appropriate dangerous goods documentation (shipping declaration UN2814). Other TB-containing specimens should be shipped according to United Nations packaging instruction P650. No accompanying dangerous goods documentation is required in these cases (shipping declaration UN3373). Laboratories that send TB samples should be aware of all applicable regulations and have the necessary materials available. It is advisable to identify locally available services and have supplies and local arrangements in place in advance (WHO, 2008).

2.10 Challenges of laboratory samples shipping:

Many clinical trial protocols require specimens to be shipped to central laboratories outside the country, often to perform specialized testing not performed by the laboratory, or when consistency of having a single laboratory perform the test is desirable in order to minimize laboratory-to-laboratory variation in the results. Shipping of samples can be a major obstacle for some laboratories. Prior to shipping, material transfer agreements and export/import permits need to be obtained, which can result in long delays to shipments. Some countries will not allow shipping of certain samples as the country would like to see capacity developed in-country, and sometimes due to concerns over how the samples will be used. Some countries allow samples to be shipped only to a specialty laboratory within the region and not to a central laboratory in the United States or Europe. This can result in additional costs and delays in testing. The expense of shipping is usually covered by the clinical trial budget; however, laboratories need to have personnel trained in

the international shipping of clinical samples, some of which must be shipped under the IATA designation of “dangerous goods” (Joseph and Fitzgibbon. 2014).

2.11 Challenges of tuberculosis samples shipping:

The successful isolation of *M. tuberculosis* from remote settings requires proper collection, storage, and transportation of sputum specimens to TB laboratories. The WHO recommends that two sputum specimens be collected from remote areas and transported to reference laboratories without delay. There may be a substantial cost associated with the handling, transportation, and processing of two sputum specimens from each patient without delay. In addition, sputum specimen preservatives, such as 0.6% cetylpyridinium bromide (cpb) or 1% cetylpyridinium chloride (cpc), are recommended when a delay is unavoidable, cpc is known to effectively liquefy and decontaminate sputum samples and keep tubercle bacilli viable for up to 8 days; it is still the most commonly used preservative for the storage and transport of sputum specimens. Previous studies have also shown the negative effects of cpc on microscopic examination and culture, including (i) a significant reduction in the positivity of acid-fast bacilli with ziehl-neelsen staining and (ii) the inhibition of mycobacterium growth, especially when inoculated into culture media, also recommended that sputum samples should be transported rapidly to the reference laboratory to avoid overgrowth by other microorganisms: when the transport or processing of the sputa is delayed, specimens should be stored for no more than 5 days at 4°C until they are transported or processed for culture (Belay, 2011).

2.12 Quality of laboratory samples shipping:

The total testing process entails three essential and sequential parts that are the preanalytical phase, the analytical phase and the post analytical phase (Giuseppe and Camilla . 2016).

Ensuring quality has become a daily requirement in laboratories. Quality is determined by a pre-analytical step that encompasses all procedures, starting with the formulation of the medical question, and includes patient preparation, sample collection, handling, transportation, processing, and storage until time of analysis. This step, based on a variety of manual activities, is the most vulnerable part of the total testing process and is a major component of the reliability and validity of results (Magnette, *et al.*, 2016).

Indeed, the more critical phases of shipment should be accurately optimized and standardized to ensure that the quality of the specimens is preserved upon reaching the testing sites, so that they can be used for producing reliable test results. Hand transportation for close distance, along with transportation by “wheels” (thus including motorcycles, cars, tracks and other motor vehicles) and even planes or helicopters for longer routes. Many problems still emerging from the shipment of biological specimens highlight the need to place more efforts for improvement and standardization. At the dawn of the third millennium, the progress in healthcare cannot be disjointed from the use of emerging technology, and many healthcare organizations have already deployed industrial technology to improve their efficiency. Notably, transportation of biological samples is a unique healthcare activity. And subjected to strict control by national or international regulatory bodies (Giuseppe and Camilla.2016).

2.13 Quality of tuberculosis samples shipping:

The quality test results require quality specimens; the accurate, rapid microbiological diagnosis of TB and other mycobacterial infections begins with proper specimen collection and rapid transport to the laboratory. To ensure the collection of the best possible specimen, the health care worker must be properly trained; the detection of *M. tuberculosis* through the growth of viable cells is highly dependent on the quality of specimen collection, storage, and transportation. In addition, shipments of specimens containing viable TB require special packaging and handling according to national and international biosafety standards (Linda, *et al.*, 2011).

2.14 Training of health cader in laboratory samples shipping:

Effective employee training and appropriate emergency response procedures are required to significantly minimize the risk of exposure and subsequent transmission of infection or disease. Shipping of infectious substances should be performed or supervised by a person who has received training in the shipping of such materials. It is the shipper's responsibility to ensure that packages being shipped meet current regulations .appropriate regulations for the shipment of infectious materials must be followed when sending specimens to the PHL. In conjunction with appropriate training (Romesh, *et al.*, 2016).

2.15 Training of health cader in laboratory tuberculosis samples shipping:

A reliable and efficient system for transporting TB specimens is essential for effective TB patient care, allowing for more rapid diagnosis, initiation of treatment, and patient follow up. The dangerous goods regulations require all personnel involved in transport to undergo appropriate training. For the

transport of category A infectious substances, personnel must undergo training in accordance with the modal requirements. For the transport of category B infectious substances there is a requirement that clear instructions on the use of the packaging are supplied to the user; this is regarded as sufficient “training” for the shipping of these substances (WHO, 2007).

To achieve the national public health laboratory networking organizational objectives and deliver quality service, laboratories require a workforce equipped with the necessary technical and managerial skills. Therefore, training and development of laboratory personnel is indispensable in improving the quality of laboratory services. There is a risk of laboratory-acquired infections for those working with infectious microbiological agents. It is, therefore, essential that laboratory personnel are aware of potential hazards. They must be trained and proficient in the practices and techniques of handling such materials safely and that specifies practices and procedures designed to minimize or eliminate exposures must be adopted and made available. Further details are also available in the guidelines for transport of Infectious substances and knowledge. This will enable them to perform their duties optimally and remain motivated as valuable members of the public health workforce (Jean, *et al.*, 2008).

2.16 Survey on the knowledge, attitudes and practices on tuberculosis (TB) among health care workers:

The World Health Organization (WHO) has deemed tuberculosis (TB) a global public health emergency since 1993. TB ranks as the leading cause of death from infectious disease. In 2014, there were 9.6 million new cases and 1.5 million deaths due to TB. TB control is more likely to be achieved if the level of knowledge regarding TB is increased among health care workers

(HCWs) managing high-risk groups. HCWs need to be adequately educated and trained in order to effectively treat TB. In particular, front-line staff members are intrinsically linked to the success of TB control programs through their involvement in treatment services and supervision, and patient support .As such, assessing the Knowledge, Attitudes and Practices (KAP) about TB in front-line TB HCWs is essential in order to optimize difficulties, limitations and capacities for enhancement. KAP-style surveys can be used to establish a baseline or measure intervention-related changing a person's understanding, related thoughts and skills. Some studies have found that TB knowledge among HCWs was in general poor, especially in terms of diagnosis and treatment (Andrés, *et al.*, 2017).

2.17 Survey on the knowledge, attitudes and practices on tuberculosis (TB) sample handling and transportation among health care workers in Sudan:

No KAP-style TB assessments among HCWs in samples handling and transportation have been published in Sudan, a country facing challenges in the fight against TB, with fragile of health system and considerable work overload of health personnel therefore we aimed to assess the level of knowledge, attitudes and practices regarding TB among HCWs in challenge of sample handling and transportation in Sudan.

Chapter Three

3. Materials and Methods

3.1 Study design:

Descriptive case study.

3.2 Study population:

All Khartoum resident TB health care providers who agreed to participate in this study were included while who refused was excluded.

3.3 Sample size:

Purposive sample size technique were used to select study participants
sample size = 100 participants.

3.4 Data collection:

Primary data were collected using a questionnaire, questionnaire included information about general and demographic data, TB-related attitudes and practice, request form, packaging, transportation and regulations; labeling marking and documentation.

3.5 Data analysis:

Data was entered and analyzed by SPSS statistical program version 16.0 frequencies were calculated.

3.6 Ethical consideration:

The study protocols were ethically and scientifically passed by the scientific and ethics committees of the ministry of health, khartoum state.

Chapter Four

4. Results

In the current study includes 100 participant, the frequency of the participants regarding to the education levels, (56%) of participants were post graduated, followed by (39%) was graduated and the rest of other levels were illustrated in table (4.1).

The participants who received training in handling of infectious material were distributed as follow lab specialist (15/34) nurses (14/33) physician (5/33), majority (66%) of study participant have never been receiving training as illustrated in table (4.2).

The participants who received training in transportation of specimens were distributed as follow lab specialist (10/34) nurses (4/33) physician (3/33), majority(83%) of study participant have never been receiving training as illustrated in table (4.3).

The current study showed availability of request forms was as follow, (54%) of participants had request forms, while (46%) of participants hadn't request forms in their facilities as illustrated in table (4.4).

(64%) of data on the request form was clearly stated, while (36%) of study participant found to be not clearly stated data on request form as illustrated in table (4.5).

There is no available sampling time to handle to the laboratory and no available time releasing result for patient in request form.

Feedback mechanism between the lab and health facility, about (25%) of study participant had feedback mechanism, majority (75%) of study participant hadn't feedback mechanism as illustrated in table (4.6).

Availability of transport box in different health facility, about (18%) of study participant had transport box, majority (82%) of study participant hadn't transport box in facility as illustrated in table (4.7).

Availability of responsible person for transportation, about (27%) of study participant who had responsible person, majority (73%) of study participant hadn't responsible person in facility as illustrated in table (4.8).

Procedures for transportation of specimens which met international regulation requirement, about (5%) of study participant met requirement, majority (95%) of study participant hadn't met international regulation requirement as illustrated in table (4.9).

Packing of category B (biological material) for air transport following requirement in IATA packaging instruction, about (5%) of study participant following requirement instruction, majority(95%) of study participant hadn't following requirement instruction as illustrated in table(4.10).

Specimens arrived within time frame appropriate to the nature of requested examination and protect the specimens from deterioration, majority (70%) of study participants were found specimens arrived in time frame, while (30%) of study participant found specimens not arrived within time frame as illustrated in table (4.11).

Availability of incident reporting during transportation that may affect the quality of specimens and safety of personnel, about(16%) of study participant had incident report ,majority(84%) of study participant hadn't incident report during transportation as illustrated in table (4.12).

Outer packaging label clear, shipper, consignee, transport details, quantity and type of packaging, packaging instruction, refrigerant were used, about (7%) of study participant label, majority(93%) of study participant hadn't package as illustrated in table (4.13).

Document identifies the content of the primary receptacle or request form outside the secondary packaged, about (19%) of study participant had found request form outside secondary packaged, majority (81%) of study participant hadn't found package as illustrated in table (4.14).

Table (4.1): Distribution of education level among the study population

Education level	Physicians		Nurses		Labs specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
General education	0	0	2	2.0	0	0	2(2%)
Graduate	3	3.0	27	27.0	9	9.0	39(39%)
Post graduate	27	27.0	4	4.0	25	25.0	56(56%)
Others	3	3.0	0	0	0	0	3(3%)
Total	33		33		34		100

Table (4.2): Result of handling of infectious materials of study participants regarding to health cadre

Training	Physicians		Nurses		Labs specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Trained	5	5	14	14	15	15	34(34%)
Not trained	28	28	19	19	19	19	66(66%)
Total	33		33		34		100

Table (4.3): Result of transportation of specimens of study participants regarding to health cadre

Training on transportation	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Trained	3	3	4	4	10	10	17(17%)
Not trained	30	30	29	29	24	24	83(83%)
Total	33		33		34		100

Table (4.4): Result of availability of request form in facility

Request form available	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Available	6	6	20	20	28	28	54(54%)
Not available	27	27	13	13	6	6	46(46%)
Total	33		33		34		100

Table (4.5): Result of clearly stated data on the request form regarding to Health cadre

Data stated on request form	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Yes	15	15	24	24	25	25	64(64%)
No	18	18	9	9	9	9	36(36%)
Total	33		33		34		100

Table (4.6): Result of feedback mechanism between the lab and health facility

Feedback mechanism	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Yes	3	3	7	7	15	15	25(25%)
No	30	30	26	26	19	19	75(75%)
Total	33		33		34		100

Table (4.7): Result of availability of transport box in different health facilities

Transport box available	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Available	3	3	7	7	8	8	18(18%)
Not available	30	30	26	26	26	26	82(82%)
Total	33		33		34		100

Table (4.8): Result of availability of responsible person for transportation

Responsible person for transportation	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Available	4	4	8	8	15	15	27(27%)
Not available	29	29	25	25	19	19	73(73%)
Total	33		33		34		100

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Table (4.9): Result of transportation procedure of specimens

Transportation procedure meet regulatory requirement	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Yes	2	2	0	0	3	3	5(5%)
No	31	31	33	33	31	31	95(95%)
Total	33		33		34		100

Table (4.10): Result of packing instruction of category B (biological material) for air transport

Packing category (B) requirement instruction	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Yes	2	2	0	0	3	3	5(5%)
No	31	31	33	33	31	31	95(95%)
Total	33		33		34		100

Table (4.11): Result of specimens arrives within time frame

Arrival time frame	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Yes	15	15	29	29	26	26	70(70%)
No	18	18	4	4	8	8	30(30%)
Total	33		33		34		100

Table (4.12): Result of availability of incident report

Incident report Available	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Available	0	0	8	8	8	8	16(16%)
Not available	33	33	25	25	26	26	84(84%)
Total	33		33		34		100

Table (4.13): Result of outer packaging label clear

Outer packaging label	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Yes	2	2	0	0	5	5	7(7%)
No	31	31	33	33	29	29	93(93%)
Total	33		33		34		100

Table (4.14): Result of document identifies the content of the primary receptacle or request form

Request form outside secondary package	Physicians		Nurses		Lab specialist		Total
	Frequency	%	Frequency	%	Frequency	%	
Yes	3	3	7	7	9	9	19(19%)
No	30	30	26	26	25	25	81(81%)
Total	33		33		34		100

Chapter Five

5. Discussion

This study includes 100 participants. In this study found that the knowledge and awareness related to TB on handling of infectious materials only a few of participants had attended training session the highest frequency among the lab specialist (15/34), nurses (14/33) and physician(5/33) were receive training. majority of study participant had never been training and few participants of lab specialist (10/34), nurses (4/33) and physician (3/33) were trained on transportation of specimens while the majority of study participants had never been training, this result is similar with study survey in India, which reported that nurses lacked knowledge in a variety of aspects concerning TB (Single, *et al.* 1998). Other studies had found physicians demonstrating inadequate TB knowledge (Single, *et al.* 1998; van, *et al.* 2011); a study in Russia showed overall TB knowledge scores were low among healthcare workers, especially lab specialist and support staff (Woith, *et al.* 2010).

The request form was available in 54% of facility while not available in 46% of facilities. Majority (64%) of the participants found the data on the request form were clearly stated while 36% of participants found data not stated clearly on the request form. The result of the current study was similar to other study which reported that the most (66.98%) of providers had positive attitudes towards providing TB services (Sumanee, *et al.* 2012).

This study found that the practice related to TB, five percentages of the study participants met international regulation requirement procedures for transportation of specimens while 95% didn't meet the international requirement. Five percentage of the study participants following requirement instruction in IATA for packing category B, while 95% didn't following

requirement instruction. Seven percentages of study participants were found to be label outer packaging clear, shipper, consignee, transport details, quantity and type of packaging, packaging instruction, refrigerant are used, while 93% of study participant didn't found package. (19%) of study participants were found to be the document identifies the content of the primary receptacle or request form outside secondary packaged, majority (81%)of study participant didn't found package .there are no studies related to this practice.

Chapter six

6. Conclusion and Recommendation

6.1 Conclusions:

On the basis of this study we conclude that:

- Few of healthcare providers had attended training session on handling of infectious materials and transportation.
- Majority of healthcare providers had positive attitude in clearly stated data on request form and availability of request form in facility.
- Majority of healthcare providers had lack practice in packaging, transportation, regulation, labeling, and marking, documentation instruction.

6.2 Recommendations:

On the basis of this study we recommended that:

- The results of this study can be used to plan for better healthcare provision in terms of strengthening providers capabilities, improving patient care, and delivering higher quality services
- All TB-care team members should be need attending comprehensive training in TB to increase and update their knowledge.
- All healthcare providers must be following the guidelines for handling of infectious material, transportation to improve practice. Additionally guidelines need to cover all professions involved with the TB care team.

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Appendices

Appendix I:

Classes of dangerous goods:

Dangerous goods are articles or substances, which are capable of posing a risk to health, safety, property or the environment and which are shown in the list of dangerous goods in the regulations or which are classified according to the regulations (IATA DGR).

Dangerous goods are also defined as those goods which meet the criteria of one or more of the nine UN hazard classes and, where applicable, to one of three UN packing groups. The nine classes relate to the type of hazard, whereas the packing groups relate to the applicable degree of danger within the class.

The nine classes of dangerous goods:

- Class 1: Explosives
- Class 2: Gases
- Class 3: Flammable liquids
- Class 4: Flammable solids
- Class 5: Oxidizing substances and organic peroxides
- Class 6: Toxic and infectious substances
- Class 7: Radioactive material
- Class 8: Corrosives
- Class 9: Miscellaneous dangerous goods

Appendix II:

Classification of biological materials for transport:

The classifications of biological materials are based on the level of the infectivity of the biological material and the model (s) of the transportation used while acknowledging the regulatory requirements where applicable. Infectious substances shall be classified as dangerous goods and assigned the appropriate UN number: UN 3373 and classified as category B. There is no direct relationship between risk groups of microorganisms and categories A and B.

Category B, UN 3373:

An infectious substance which does not meet the criteria for inclusion in Category A. Infectious substances in category B shall be assigned to UN 3373. The proper shipping name of UN 3373 is biological substance, category B. (The shipping name diagnostic specimens, clinical)

Appendix III:

Packing instruction P650:

This packing instruction applies to UN 3373 on passenger and cargo aircraft (CAO).

(1) The packaging shall be of good quality, strong enough to withstand the shocks and loadings normally encountered during transport. Packaging's shall be constructed and closed to prevent any loss of contents that might be caused under normal conditions of transport by vibration or by changes in temperature, humidity or pressure.

(2) The packaging shall consist of three components:

- (a) A primary receptacle
- (b) A secondary packaging
- (c) An outer packaging

Of which either the secondary or the outer packaging shall be rigid.

(3) Primary receptacles shall be packed in secondary packagings in such a way that, under normal conditions of transport, they cannot break, be punctured or leak their contents into the secondary packaging. Secondary packagings shall be secured in outer packagings with suitable cushioning material.

(4) For transport, the mark illustrated below shall be displayed on the external surface of the outer packaging and shall be clearly visible and legible. Shipping name "biological substance, category B" must be marked on the outer package.

(5) At least one surface of the outer packaging must have a minimum dimension of 100 mm × 100 mm.

(6) The completed package shall be capable of successfully passing the drop test in 6.3.5.3 as specified in

6.3.5.2 of these regulations at a height of 1.2 m. Following the appropriate drop sequence, in the secondary packaging.

(7) For liquid substances

(a) The primary receptacle(s) shall be leak proof, and must not contain more than 1 litre.

(b) The secondary packaging shall be leak proof.

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

(d) Absorbent material shall be placed between the primary receptacle(s) and the secondary packaging.

(e) The primary receptacle or the secondary packaging shall be capable of withstanding, without leakage.

(f) The outer package must not contain more than 4 litres. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

(8) For solid substances

(a) The primary receptacle(s) shall be sift proof

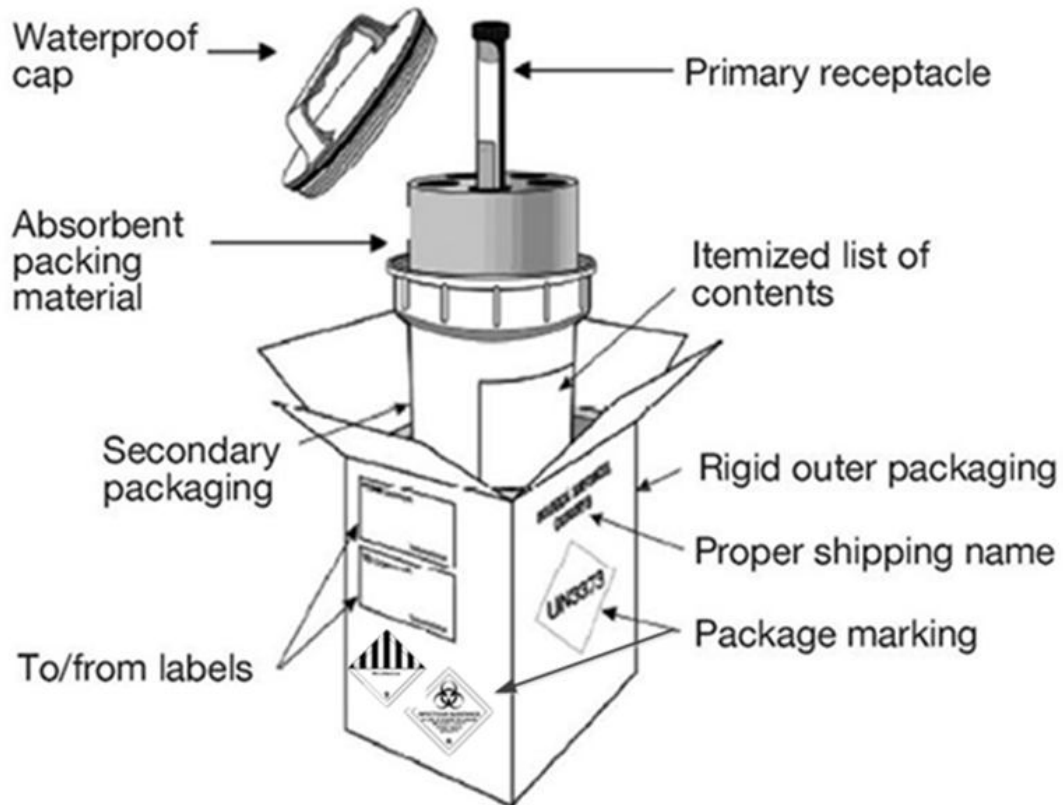
(b) The secondary packaging shall be sift proof

(c) If multiple fragile primary receptacles are placed in a single secondary packaging, they shall be either individually wrapped or separated to prevent contact between them.

(d) The outer package must not contain more than 4 kg. This quantity excludes ice, dry ice or liquid nitrogen when used to keep specimens cold.

Appendix IV:

Examples of triple layer packaging:



Packing and labeling of category B infectious substances

Appendix V:

Questionnaire

Sudan University of Science and Technology

College of Graduate Studies

Master of Total Quality Management and Excellence

Questionnaire for scientific research

Assessment of Knowledge, Attitude and Practice in Handling and
Transportation of Samples among Tuberculosis Healthcare Providers
in Khartoum State

Consent Form

Researcher:

**Please
Initial box:**

1. I confirm that I have read and have understood the information sheet dated 0/ 0/ 2017 for the above study. I have the opportunity to consider the Information, ask questions and have these answered satisfactorily.
2. I understand that my participation is voluntary and that I am free to withdraw at any time without giving any reason and without my rights being affected.
3. I understand that, under the data protection act, I can at any time ask for Access to the information I provide and I can also request the destruction of that information if I wish.
4. I agree to take part in the above study.

Participant Name
Signature.....

Date.....

Researcher.....
Signature.....

Date

Questionnaire

Data Collector: _____

questionnaire No:

Date Collected: _____

Health Facility: _____

All questionnaires are completed anonymously. We would appreciate you if you answer all the questions and answer as honestly as possible.

Please put a check mark (✓) in the box that best answers the question. **Kindly make only one**

GENERAL AND DEMOGRAPHIC QUESTIONS

1. Education level?

General education

Graduate

Post graduate

Other (Please specify) _____

TB-RELATED ATTITUDES AND PRACTICE

2. Did you receive any training in handling of infectious materials?

Yes

No

REQUEST FORM

3. Is the request form available in your facility?

Yes

No

4. Are all the necessary data (comprising the patients name, date of birth, department, physicians name, sample type, ordered test) clearly stated on the request form?

Yes

No

5. Is the sampling time to handle to the laboratory available on the request form?

- Yes
 No

6. Is the time of release result for patient available on the request form (TAT)?

- Yes
 No

7. Is any feedback mechanism between the lab and health facility?

- Yes
 No

PACKAGING, TRANSPORTATION AND REGULATION

8. Are you receive training on transportation of specimens ?

- Yes
 No

9. Is the transport box available or not in your facility?

- Yes No

If yes:

- | | | |
|--|------------------------------|-----------------------------|
| A-Is it local made (not according to standard) | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| B-Is it local made (according to standard)? | <input type="checkbox"/> Yes | <input type="checkbox"/> No |
| C- Have you International standard box | <input type="checkbox"/> yes | <input type="checkbox"/> No |

10. Is there available responsible personnel for transportation?

- Yes No

11. Is the procedure for transportation of specimens meeting regulatory requirement?

- Yes No

12. Is packing category B (biological material) for air transport following requirement in IATA packaging instruction?

- Yes
 No

13. Is specimens arrive within time frame appropriate to the nature of requested examinations and protects the specimens from deterioration?

Yes

No

14. Are an incident reporting during transportation that may affect the quality of specimens and safety of personnel is available?

Yes

No

LABELLING, MARKING AND DOCUMENTATION

15. Is the outer packaging label clear, shipper, consignee, transport details, quantity and type of packaging, packaging instructions, refrigerant are used?

Yes

No

16. Is the document identifies the content of the primary receptacle or request form outside the secondary packaged?

Yes

No

