

Compliance of Malaysian healthcare workers towards tuberculosis prevention programmes in workplace: An exploratory sequential mixed method study protocol

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ABSTRACT

Introduction: The World Health Organization (WHO) stated that the incidence of tuberculosis among healthcare workers is increasing yearly and exceeds the incidence of tuberculosis in the community in almost all the countries that report to the WHO. The problem is greater in countries with high burden of tuberculosis disease in the community. The cause of this problem may be contributed by the attitudes of the healthcare workers themselves, such as non-compliance of the procedures at their work tasks meant to prevent them from contracting the disease. Therefore, this study aims to assess the perceptions and the behaviours of healthcare workers in relation to compliance towards prevention activities on tuberculosis at their workplace.

Materials and Methods: We plan to conduct a two-phase exploratory sequential mixed method study to determine the factors affecting compliance of Malaysian healthcare workers towards tuberculosis prevention programmes in their workplace based on the guidelines of the Ministry of Health, Malaysia. Phase one is a qualitative study with a focus group discussion and questionnaire development and phase two is a quantitative study where data will be collected among healthcare workers in government clinics and hospitals in Selangor. The data from phase one will be analysed using Atlas.Ti software for thematic analysis and data from phase two will be analysed using SEM AMOS software for structural equation modelling.

KEYWORDS:

Compliance, adherence, health personnel, tuberculosis, prevention and control

INTRODUCTION

Tuberculosis (TB) is a chronic infectious disease that has existed for centuries throughout the world. This disease is caused by the rod-shaped non-spore forming aerobic bacterium, namely *Mycobacterium tuberculosis* which can infect all human organs, especially the lungs. Tuberculosis germs measuring between 0.5 to 3.0 micrometres and classified as acid-fast bacilli which has a unique cell wall structure and is spread through airborne particles by untreated individuals and is contracted when in contact with

them for a period of time.¹ Tuberculosis infection is almost exclusively an airborne transmitting disease as it was initially an infection of the alveolar macrophage.² The World Health Organization (WHO) had estimated that in 2019, 1.2 million people died from tuberculosis worldwide including 208,000 deaths reported among people with HIV due to tuberculosis, whereas 10 million people fell ill with tuberculosis in 2019 worldwide.³ Malaysia is categorised as an intermediate country of tuberculosis burden. In 2019, WHO had estimated the burden of tuberculosis in Malaysia was 29,000 cases with tuberculosis incidence rate between 79 to 106 cases per 100,000 population.⁴ The exact number of tuberculosis cases being reported to the Ministry of Health Malaysia in 2020 were 23, 644 cases with the incidence rate of 72 cases per 100,000 population.⁵

The incidence of tuberculosis among healthcare workers is increasing since many years but are being minimally highlighted and it has exceeded the incidence of tuberculosis in the community in almost all of the countries that report to the WHO.⁶ Tuberculosis began to be recognized as an occupational hazard in early 1950s.^{7,8} A systematic review conducted by Rajnish J et al., in 2006 stated that tuberculosis was a significant occupational problem among healthcare workers in low-middle income countries and there was a need to design and implement several recommended tuberculosis infection control strategies in healthcare facilities.⁹ Control strategies and prevention measures are very important to be implemented, especially in a high-risk workplace, to prevent and reduce the risk of healthcare workers contracting tuberculosis disease from their workplace. The WHO has outlined measures for the control and prevention of tuberculosis in congregate spaces and health facilities comprising management or administrative control, engineering control and respiratory protection control.⁶ Ministry of Health (MOH), Malaysia has published a guideline to prevent healthcare workers from contracting tuberculosis disease from the workplace based on the WHO guidelines in 2010 and was fully implemented in all their government health facilities in 2012.¹⁰ The guidelines and standard operational procedures of the activities pertaining to prevention of tuberculosis transmission in the workplace were created and established in order to prevent Malaysian healthcare workers who are at risk of contracting the disease, where it is in line with the Occupational Safety and Health

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Act 1994, which states “It is the duty of every employer and every self-employed person to ensure, as far as practicable, safety, health and welfare while working of all its employees”.¹¹

Tuberculosis among healthcare workers is a long-standing global health problem. The risk of transmission of tuberculosis between an infected individual to a healthcare worker and vice versa has been identified from the previous studies, especially in high-risk areas or places such as health facilities or health institutions.^{9,12-15} The healthcare workers are at higher risk for developing tuberculosis due to their association with patients from a variety of health backgrounds. Several studies stated that even in a controlled environment for airborne infection transmissions, such as hospitals or health clinics, the risk of a healthcare worker to contract tuberculosis infection is similar to the community where they live.^{14,15} Tuberculosis among healthcare workers is a health issue that is given less attention than tuberculosis in the community. Tuberculosis among healthcare workers is a serious and persistent threat worldwide.^{9,12} Many studies focus on the prevention and control for tuberculosis in the community, while the issue of tuberculosis among healthcare workers has received less attention in terms of implementation methods and effectiveness by most countries, especially low-income countries.⁹

Several studies have stated that the incidence rate of tuberculosis among healthcare workers is higher compared to the incidence rate of tuberculosis among the community which is between 25 to 5,361 per 100,000 health workers per year.^{9,12} A higher burden of tuberculosis in a country can also lead to a higher incidence rate of tuberculosis among their healthcare workers, for example, in China which is one of the countries with a high burden of tuberculosis, Wang et al., stated that the prevalence rate of tuberculosis among healthcare workers in China was 760 per 100,000 healthcare workers.¹⁴ Jones et al. also noted that in 2013, four percent of new tuberculosis cases reported yearly in the United States of America (USA) were among health workers.¹⁶ In Thailand, a total of 109 health workers were diagnosed with tuberculosis in a five-year period between 2011 to 2014 with an incidence rate ranging from 1.35 to 2.53 per 1,000 healthcare workers.¹³

Various behavioural theories are used to study the relationship between human behaviour and the tendency of a person to perform that behaviour, especially in health-related studies.¹⁷ Human factors such as attitudes or compliance of healthcare workers are major factors that contribute to or are associated with occupational risk to healthcare workers. Several studies stated that poor adherence or compliance of healthcare workers towards standard operating procedures to prevent them from contracting occupational tuberculosis disease was significant.¹⁸⁻²¹ Taking this into consideration, limited studies were conducted to examine the relationship between the behaviour of healthcare workers who are responsible for delivering health services to the community with occupational tuberculosis. Hence, these situations require research and further analysis related to the factors that influence the compliance of healthcare workers to the control

and prevention activities, specifically on tuberculosis transmission in the workplace.

However, studies conducted in several countries proved that poor and incomplete implementation as well as non-compliance with the guidelines were among the main causes of the increase in tuberculosis cases among healthcare workers.^{13,22,23} Although healthcare workers do know and are aware of the risks of contracting tuberculosis infection in their workplace, the absence of policies and guidelines as well as the lack of training given to them made it difficult for them to implement and adhere to preventive measures. Studies conducted in several countries pertaining to the implementation of tuberculosis prevention activities among healthcare workers also proved that the increase in the incidence of tuberculosis among healthcare workers are in line with the failure to comply to preventive measures as outlined.^{14,22,24} Studies conducted in countries with high burden of tuberculosis, such as South Africa and Lagos, Nigeria, found that although tuberculosis prevention guidelines are available and the knowledge of the disease are high among the healthcare workers, the infection control practices among them are still low.^{25,26}

The latest guidelines on preventing tuberculosis among healthcare workers in the workplace by WHO was published in 2009,⁶ in which the management of controlling and preventing the spread of tuberculosis disease can be divided into three main controls, namely administrative controls, environmental controls and respiratory protective control. Administrative controls are defined as managerial or administrative measures in managing the tuberculosis program as a whole, including early identification of tuberculosis cases, and early separation and treatment of tuberculosis patients to reduce the risk of transmission to healthcare workers.^{6,10} Environmental factors as defined by the WHO and MOH are the activities or methods to reduce the concentration of infectious aerosols (example: droplet nuclei) in the air and methods to control the direction of infectious air in the workplace.^{6,10} Respiratory protective control or personal protective equipment are methods that should be used together with administrative controls and environmental controls to ensure complete protection and prevention to healthcare workers who are exposed.

Issues on tuberculosis among healthcare workers were identified in the early 1950s,^{7,8} and various guidelines were published by the WHO as early as the 1990s but only focusing on management of tuberculosis in the community with establishment of tuberculosis treatment and high-risk group management. Guidelines on tuberculosis in the workplace and occupational tuberculosis were initially introduced by the WHO in 2003,²⁷ focusing more on managing the workplace if there were tuberculosis cases identified. The guidelines focusing on preventing healthcare workers in the workplace were initially published in year 2009 by WHO,⁶ and in 2012 by MOH.¹⁰ Although tuberculosis prevention and control policies and guidelines have been strengthened since 1997 in Malaysia, the burden of tuberculosis in this country is still high with a case notification rate of between 65 to 81 cases per 100,000 population over the past 10 years, as shown in Figure 1.²⁸ For

tuberculosis cases among healthcare workers, it shows a very significant increment over the past 10 years with the notification rate of tuberculosis cases among healthcare workers between 100 to 126 cases per 100, 000 health workers from 2010 to 2018, as shown in Figure 2.²⁸ The WHO stated that up to 80 per cent of tuberculosis cases among healthcare workers were contracted from the workplace. Close contact activities among healthcare workers with tuberculosis patients during their work task is a major factor that places healthcare workers at a high risk of getting occupational tuberculosis.²⁹ The risks get higher when healthcare workers do not comply to the prevention and activity guidelines.

In Malaysia, the initial guideline for preventing tuberculosis among healthcare workers were introduced in 2012, but despite that, the incidence and numbers of tuberculosis cases among healthcare workers increased significantly, as shown in Figure 2. The MOH had stated that the incidents of tuberculosis among healthcare workers in this country is likely to be work-related, since their investigation showed that the source of infection was found to be more from healthcare facilities than the community.¹⁰

OBJECTIVES

This study aims to explore and identify factors that influence and contribute to the compliance of healthcare workers in implementing tuberculosis prevention programs or activities in their workplace. This study will also determine the level of compliance of healthcare workers towards tuberculosis prevention programmes and the factors associated with it based on the theory of planned behaviour and self-protective behaviour in the workplace.

Research Questions

- i. Why is the incidence of tuberculosis cases among healthcare workers increasing even though various guidelines and programmes related to tuberculosis prevention activities in the workplace have been issued?

Phase 1: Qualitative study

- ii. What are the behavioural factors that influence the compliance of healthcare workers in implementing tuberculosis prevention programs in the workplace?

Phase 2: Quantitative study

- iii. What are the occupational factors that influence the compliance of healthcare workers in implementing tuberculosis prevention programs in the workplace?
- iv. What are the environmental factors that influence the compliance of healthcare workers in implementing tuberculosis prevention programs in the workplace?

MATERIALS AND METHODS

We will conduct an exploratory sequential mixed method study design comprising a qualitative study as the phase one, followed by a quantitative study as the phase two. We plan to conduct the study in Selangor since this state have the highest cases of tuberculosis among healthcare workers in Malaysia, as shown in Table I.²⁸

Variables

In this study, we plan to explore and analyse several variables according to the three main factors, namely individual factor (based on the theory of planned behaviour such as intention, perceived control behaviour, attitude and subjective norm), knowledge related to the disease (tuberculosis and tuberculosis prevention measures in the workplace), environmental factors and organizational factors. Healthcare workers in this study is defined as those workers in the health institution who are doing clinical and administrative tasks pertaining to managing tuberculosis patients.

Individual factors will be defined as attitudes and perceptions of the healthcare workers in complying to the guidelines based on the Theory of Planned Behaviour (TPB). Intentions according to TPB is defined as the desire or willingness to perform a behaviour including a person's positive or negative beliefs and the individual's assessment of the behaviour outcome.^{17,30} Intentions may be influenced by attitudes, perception-controlled behaviour and subjective norms of an individual. Attitudes will be defined as a behaviour or practice that will be implemented against a certain behaviour. Attitudes can be influenced by beliefs and outcome evaluation of the behaviour. The attitude in this study indicates the degree of inclination of an individual to perform and comply to the activities in the guidelines. Perceived control behaviour will be defined as the response of an individual to that particular behaviour whether the response is positive or otherwise. Subjective norms will be defined as social responses and pressures experienced by an individual in initiating the behaviour.

Organisational factors that will be anticipated in this study are the activities provided by management of the facilities as in the guidelines to reduce and halt the transmission of tuberculosis in the workplace, such as initiating a tuberculosis control committee, monitoring the implementation of the activities, designating a liaison officer or person in charge of the programmes for a better implementation as well as providing training to the healthcare workers and conducting surveillance programmes for tuberculosis among healthcare workers in the workplace.

Environmental factors that will be anticipated in this study are the activities conducted to reduce the concentration of the tuberculosis bacteria in the air, such as controlling the source of the infection by providing and using local exhaust ventilation and diluting and removing contaminated air by proper ventilation. Other measures in these environmental factors are controlling the airflow to prevent contamination of air areas adjacent to the source and cleaning the air using "high efficiency particulate air" (HEPA), filtration or "ultraviolet germicidal irradiation" (UVGI). All the variables that will be studied in this research are based on the Ministry of Health Malaysia's guidelines.¹⁰

Patient and Public Involvement

Patients and/or public are not involved in this study. We will recruit the healthcare workers as the participatory subjects in this study.

Study Design

Phase 1

This study will be conducted based on the Theory of Planned Behaviour by Ajzen,^{17,31} and Self-Protection Behaviour in Workplace by DeJoy.³² We will identify factors related to the compliance of healthcare workers towards the tuberculosis prevention program in their workplace. In the phase one of this study, a qualitative approach will be conducted to explore and determine the factors that influence healthcare workers' adherence towards tuberculosis prevention programs in the workplace according to the theory of planned behaviour and the "Self-Protective Behaviour at Workplace" model.

A focus group discussion (FGD) will be conducted involving a group of health experts selected via purposive sampling methods to produce a set of survey questions. A total of 11 informants or experts involved in the development and implementation of the tuberculosis prevention program in the Disease Control Division, MOH and Occupational Health Unit and Tuberculosis Unit, Selangor State Health Department will be included. The discussion will be conducted in two sessions involving 4 and 7 informants. Each of the session will be conducted in a suitable selected private meeting room with around two and half hours or more time provided. All the sessions will be conducted using a semi-structured questionnaire which will involve two of the research officers as interviewer and co interviewer for note taking. The information and data gathered in this phase will then be analysed using Atlas.Ti to generate thematic analysis. Subsequently, a set of questionnaires will be developed from the thematic analysis and will be validated before being used in phase two.

Phase 2

Phase two of this study will be conducted in selected government hospitals and primary health clinics in the state of Selangor. A total of five government district hospitals and eight primary health clinics in the Selangor Health State Department were purposively selected in this study based on the burden of tuberculosis among healthcare workers at their facilities. This phase will be conducted using a self-administrated questionnaire that is given to the respondents.

Sampling Size and Sample Population

Phase 1

A total of 11 informants will be selected through purposive sampling based on their expertise and involvement in the tuberculosis prevention program of healthcare workers to undergo this FGD session. The informants that will be considered to participate in this session are Medical Officers, Supervisors/Head Nurses, Assistant Medical Officers, Environmental Health Officers or Assistant Environmental Health Officers from the Tuberculosis/Leprosy Unit or Occupational Health Unit in the Disease Control Division, Ministry of Health and Selangor Health State Department.

Phase 2

For quantitative studies, there will be several sample size calculations that will be proposed according to several guidelines in order to find out the best and the most accurate way of determining the sample size required for this study

and to reduce the error of the parameter estimate. The first calculation is using the Sample Size Calculation Software Epi Info 7 Statcalc and based on the formula of Kish. L (1965) as follows:

$$n = (Z)^2 \times [P(1-P) / D^2]$$

n = Sample size

Z = 1.96 (For CI of 95%, Z = 1.96; normal distribution)

P = prevalence of tuberculosis of health members

D = precision of study

From the data obtained from the MOH, the prevalence of tuberculosis among health workers in 2018 was 126 per 100,000 health workers. Therefore, according to the above calculation, the estimated sample size is 169 respondents, in which the minimum sample size required is 202 samples (additional 20% for dropout of respondents). The second calculation is based on the number of sample size required from previous literature searches and according to the factors to be studied, the highest sample size reported was 236 respondents as reported in the study by Engelbrecht,³³ and the smallest sample size was 20 respondents as reported by Barker.³⁴ The third calculation to be considered is by the Structural Equation Modelling method. In this study, there will be five constructs to be studied, therefore the sample size required based on the structural equation modelling method is 100 samples.³⁵

From the three ways of calculations proposed, the sample size that was selected for this study is 236 respondents based on the previous literature searches as this calculation gave the highest numbers of sample size required, thus bringing the total number of respondents required to 283 respondents including an additional 20% dropout of respondents.

The respondents to be selected are those healthcare workers that work in the tuberculosis unit or involved in managing tuberculosis patients directly or indirectly at their respective facilities. The respondents will be selected through the simple random sampling technique. A list of respondents will be requested from the Human Resource Unit, Selangor State Health Department.

The inclusion criteria for this study are all healthcare workers involved in the management of tuberculosis cases in selected health facilities during the study period and are Malaysian citizens. While the exclusion criteria decided for this study are all healthcare workers who are on leave or do not agree to participate in the study during the study period as well as healthcare workers who are former tuberculosis patients or close contact of tuberculosis patients.²⁶

Data Analysis

Phase 1

The entire interview session will be recorded using an audio recorder and will be analysed to produce a thematic analysis. Each response from the informant will be rewritten in the form of notes along with responses from the researcher's initial observations and research assistants. All answers will be typed into Microsoft Word for analysis and will be transcribed using ATLAS.ti TM software (ATLAS. Ti Inc. Berlin, Germany).

Table I: Table showing the number of tuberculosis cases among healthcare workers reported to the Ministry of Health Malaysia 2016 to 2018

STATE/YEAR	2016	2017	2018
Johor	24	33	35
Kedah	16	14	21
Kelantan	21	12	19
Melaka	7	7	3
Negeri Sembilan	18	10	11
Pahang	11	19	15
Perak	23	20	25
Perlis	1	2	2
Pulau Pinang	11	11	15
Sabah	58	34	48
Sarawak	20	24	22
Selangor	47	50	60
Terengganu	10	17	14
WPKL	24	27	32
WP Labuan	2	1	1
TOTAL	293	281	323

Source: Ministry of Health Malaysia, 2019

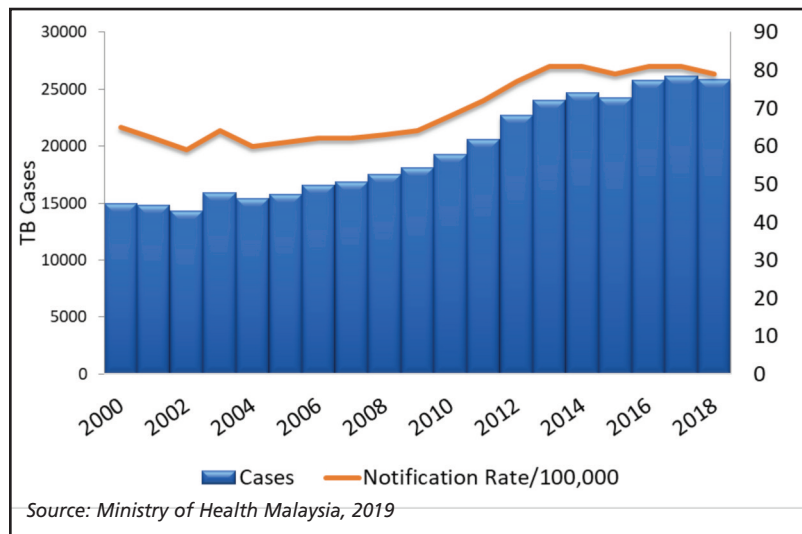


Fig. 1: Graph showing the total cases reported and notification rate of tuberculosis cases 2000–2018.

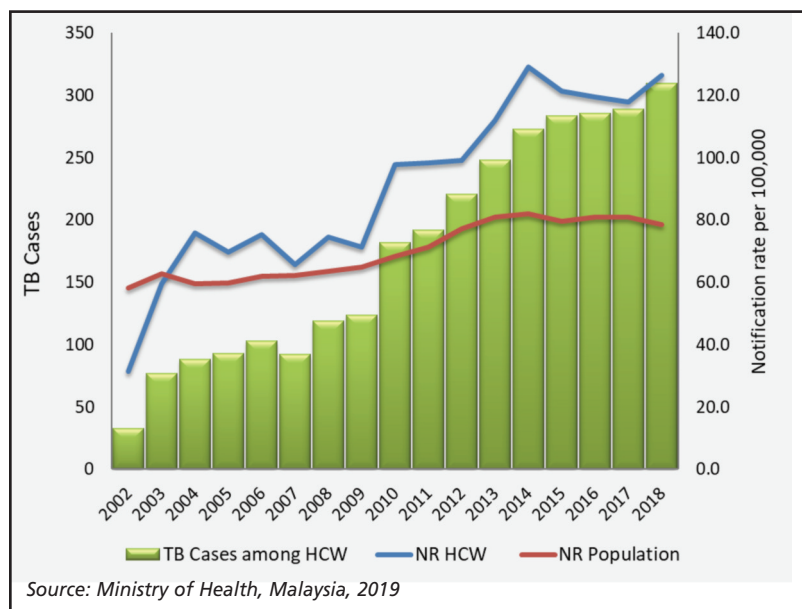


Fig. 2: Graph showing the total cases reported and notification rate of tuberculosis among healthcare workers 2000–2018.

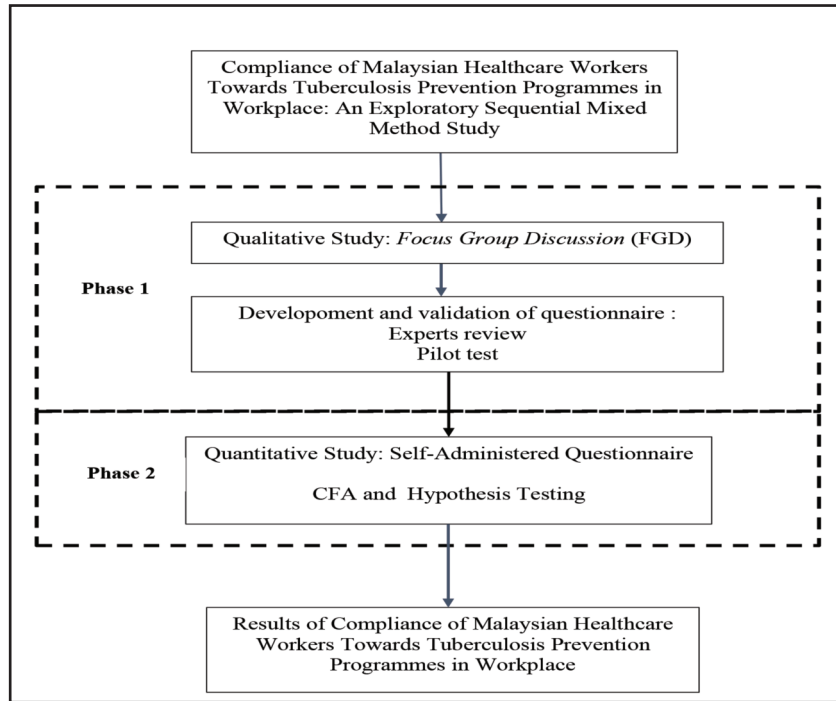


Fig. 3: The study flow chart.

At the early stage, the researcher and research assistants will give a code to each of the significant answer recorded in a text conferring to the objectives of the study. Then, the codes will be analysed, given a meaning and combined as appropriately as possible to form the basic theme. Subsequently, these basic themes will then be formed according to the appropriate clusters to produce the main theme. The main themes that have been formed will be analysed, coordinated and discussed again together with the research assistants in order to reduce bias. A total of 20 main themes will be needed to be agreed upon and will be used to design and develop the questionnaire.

The questionnaire that has been developed will be sent for evaluation by experts for the triangulation process. The Content Validation Index (CVI) will be calculated after all the experts completed their reviews and the questionnaire will be edited accordingly to ensure that the questions produced are truly inclusive and relevant to the objectives of this study. The number of experts proposed in this study are minimum of six experts with acceptable CVI values of at least 0.83.³⁶ Then the questionnaire edited will be used in pilot study using 150 respondents from another group of healthcare workers. The questionnaire will then be analysed using Cronbach’s Alpha analysis in determine the internal consistency reliability. The cut-off points of Cronbach’s Alpha more than 0.7 is opted. The feedback received in this validation and reliability process will be used to improve and strengthen this questionnaire.

Phase 2

The second phase is a field study via a quantitative cross-sectional method where the data will be collected via a self-administered questionnaire based on the model of Self-

Protection Behaviour at Workplace in determining the compliance of healthcare workers towards tuberculosis prevention activities in their workplace. Factors that will be studied are individual, organisational and work environment factors. This phase will be using a Confirmatory Factor Analysis (CFA) test to proof the model via Structural Equation Modelling (Structural Equation Modelling).

DISCUSSION AND CONCLUSIONS

This study aims to determine the compliance of Malaysian healthcare workers towards tuberculosis prevention activities in their workplace based on the guideline provided by the WHO and MOH, Malaysia. This is the first study that explores Malaysian Healthcare workers’ compliance towards tuberculosis prevention programs based on a behavioural theory (Theory of Planned Behaviour). The contribution of this study may improve the current tuberculosis prevention program in government health facilities. However, this study is limited to Selangor and the generalizability may not be applicable.

In summary, this study will be conducted in the following steps, qualitative data collection and analysis, then based on the findings in the qualitative data analysis, the questionnaire will be prepared for quantitative data collection, pilot testing followed with data collection in the field. The collected data in quantitative study finally will be analysed for reliability, confirmatory factors analysis (CFA) with hypothesis testing and interpretation. We will reach our conclusions based on findings after the interpretation and connect the qualitative and quantitative results to evaluate the compliance of Malaysian healthcare workers towards tuberculosis prevention activities in their workplace. The flow

chart of the study process is shown in figure 3. The conclusions can be used as measurement or key performance of current tuberculosis prevention programmes in Malaysia, especially focusing on the healthcare worker group. This conclusion can be used as a guideline for improvement or restructuring of the current programmes. Our implications for the research will suggest priorities for future research and outline the remaining uncertainties in the area of occupational hazards or occupational diseases among the group of healthcare of workers.

Ethics and Dissemination

Ethical approval from National Medical Research Register, Ministry of Health Malaysia and ethical community board of National University of Malaysia was obtained in August 2020 (NMRR-20-1270-55199, PPUKM-FR 20-084). Currently, this study is in phase one, in which data collection have just been completed and currently in designing and validating the questionnaire. We plan to use the findings of this study to update the Tuberculosis Prevention Sector and Occupational Health Sectors, Disease Control Division in Ministry of Health Malaysia for further improvement of the programmes. All findings will be shared and disseminated at any local or international conferences, including preliminary findings to the Disease Control Division of Ministry of Health Malaysia.

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