Abstract of the Thesis Entitled

Evidence-based protocol on smoking cessation intervention for tuberculosis patients

Submitted by

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Pulmonary tuberculosis caused by Mycobacterium tuberculosis is a highly infectious airborne disease. In Hong Kong, there is nearly 5000 people are infected with tuberculosis every year. An active tuberculosis patient can infect about 10 to 15 closely contact people, and without prompt treatment, the mortality rate can be high as one-third. Studies have shown that tobacco smoking, another epidemic health problem, is a risk factor which significantly increase the chance of getting tuberculosis, relapsed tuberculosis, and corresponding mortality rate. It is believed that the integration of smoking cessation program into directly observed treatment (DOT) of tuberculosis will lead to smoking abstinence, a better treatment outcome and a lower rate of relapse and secondary infection among the smoking tuberculosis patients.

Currently, there is still no introduction of evidence smoking cessation program specifically for tuberculosis patients in Hong Kong. This dissertation provides a critical appraisal, summary and synthesis of existing research studies about the implementation of brief smoking cessation
intervention in DOT of tuberculosis which significantly increase the smoking abstinence in tuberculosis patients. In this thesis, electronic databases PubMed and Cumulative Index to Nursing and Allied Health Literature (CINAHL) Plus were used to select the most relevant studies about smoking cessation intervention of pulmonary TB patients. 161 relevant articles were searched. Eight studies rated as from 1++ to 2+ level of evidence were selected finally, and they were critically appraised according to the Scottish Intercollegiate Guidelines Network (SIGN) checklist. After the critical appraisal, there will be a discussion about the transferability and feasibility of these studies in the Hong Kong target setting, as well as the potential risks and benefits during the implementation. Finally, an evidence-based protocol of brief smoking cessation intervention for tuberculosis patients and the corresponding implementation plan, including the communication plan between chief stakeholders, pilot study plan and evaluation plan with sample size calculation will be developed.
Evidence-based protocol on smoking cessation intervention for tuberculosis patients

By

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BNurs (Hons) H. K. U., R. N.

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Declaration

I declare this dissertation represents my own work, except where due acknowledgment is made, and that it has not been previously included in a thesis, dissertation or report submitted to this University or to any other institution for a degree, diploma or other qualification.

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Lam Wai Ying
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<td>Ask, Brief Advice, Cessation</td>
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<td>CINAHL</td>
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Chapter 1: Introduction

1.1 Background

Tuberculosis, also known as TB, is an airborne infectious disease chiefly caused by Mycobacterium tuberculosis. TB is also a top infectious disease killer globally which causes deaths mainly in low and middle-income countries. Currently, about one-third of people around the globe have latent TB, which means they are infected but have no symptoms and are not able to transmit the disease. Once infected, they have about a 10% chance that TB will become active in their lifetime, especially if they are immunocompromised, malnourished, suffer chronic diseases like diabetes mellitus, or smoke. Patients with active TB can infect up to 10 to 15 close contacts every year, and without imminent treatment, the mortality rate can be high as one-third. Nonetheless, the disease is totally curable in 6 to 9 months if antibiotics treatment is started promptly (World Health Organization, 2016).

According to the World Health Organization (WHO) (2009), smoking is a risk factor which greatly increases the chance of TB and corresponding death, and is believed to lead to more than 20% of TB cases globally. Systematic reviews conducted by WHO and the International Union Against Tuberculosis And Lung Diseases (The Union) have jointly shown that both active and passive tobacco smoking are significantly associated with TB, and active smoking is significantly linked to relapsed TB and corresponding mortality, regardless of other risk factors and confounders. Therefore, the WHO and The Union have made joint efforts to control these two worldwide epidemics, including developing a guide to integrate tobacco control programs with current TB treatment services, involving the use of pharmaceutical support, counselling and intensive support (WHO, 2007).
Since the 1970s, the use of short course anti-TB drug treatment has greatly decreased both the incidence and mortality rate of TB. However, multidrug-resistant TB emerged in the 1980s and the WHO declared TB a global emergency in 1993. In 2014, there were 4705 new TB notifications with a death rate of 3.97% among these cases in Hong Kong (Center for Health Protection, 2015). A study by Leung et al. (2015) pointed out that tobacco smoke seriously influences the baseline severity, treatment outcome and disease relapse in TB patients, and tobacco cessation probably lowers the relapse rate and secondary infection.

1.2 Affirming the need in the target setting

In Hong Kong, the Tuberculosis and Chest Service in the Department of Health plays a very important role in providing primary care, prevention and surveillance in the TB epidemic in the city. There are 17 chest clinics under the service which provide holistic work to control TB. Their duties include monitoring disease statistics, for the government, providing Bacilli Calmette-Guerin vaccination to all newborns and children under 15, finding contact cases and tracing defaulters, providing health education and promotion to the public, providing Directly Observed Treatment (DOT), consultation counselling and diagnostic tests to TB patients, and conducting relevant research studies. The target patients in the TB and Chest Service mainly have active TB, but patients with other chest diseases such as chronic obstructive pulmonary disease and asthma are also included. TB patients who live in Hong Kong can receive the service free of charge. In 2013, the total attendance at all chest clinics was 722,504. Patients with active, inactive and other forms of TB accounted for about 19.3% of all new patients with various chest diseases (Department of Health, 2015).
The target setting where the proposal in this dissertation would be implemented is five of the 17 chest clinics located in a crowded district in Hong Kong. The target population is all newly diagnosed active TB patients who are current smokers. About 150 TB patients come to the clinics for DOT every day. The typical duration of DOT is about 6-9 months, with regular follow-up to see the medical officer in charge for treatment monitoring and modification and to receive health education by nurses once each month on average. There are around 20 to 40 newly diagnosed cases of TB every month. These new patients are mainly referred or transferred in from general practitioners, and public and private hospitals in Hong Kong. However, there are no official figures about the smoking status of these newly diagnosed TB patients.

In the current setting, health talks on the topic of quitting smoking are held regularly 1 to 2 times every month for patients at follow-up appointments. There are also regular support sessions for groups of 2-3 TB patients who are active smokers. These health talks and support group sessions, which last around 20 to 30 minutes, obviously stress the importance of smoking cessation on the outcome of the disease. Nonetheless, these patients are recruited by referral from doctors or from nurse observations such as the appearance or smell of tobacco on their clothing. These patients are then invited to attend the talks and support groups. Many patients find these sessions boring and time consuming. The target patients for these sessions are not limited to newly diagnosed cases. Patients in any phase of the treatment can be recruited by nurses and they may just attend one session, with no follow up or evaluation of their smoking status afterwards.

There is no systematic way to assess every newly diagnosed TB patient’s smoking status and intention to quit in the current setting. The recruitment of patients is mainly by chance and it is dependent on the nurses’ judgment and personal preference in advising patients to quit smoking. In order to increase the awareness of currently smoking patients, a more holistic approach to assess,
educate, support and follow-up is suggested. Integrating non-pharmacological smoking cessation interventions based on suggestions from the WHO and The Union into the existing TB DOT service is believed to be simple and cost-effective. An increasing number of randomized controlled trials and cohort studies in countries such as China, Indonesia, Sudan, India, and Bangladesh have investigated the introduction of smoking cessation interventions into TB treatment. The results are mostly promising and show that a brief smoking cessation intervention can effectively and significantly improve smoking cessation and abstinence among target patients. According to Leung et al. (2015), the sputum smears and cultures of both smokers and ex-smokers are significantly more prone to remain positive after receiving TB treatment for 2 months, and among patients who finished treatment successfully, 19.4% of relapses were due to smoking. The study also showed that it is more difficult for both current smokers and ex-smokers to complete treatment in 2 years, much longer than the typical treatment duration of 6 to 9 months, because of the higher default rate in current smokers and mortality rate in ex-smokers. We can see that the current practice of advising smoking patients is good, but inadequate to promote smoking cessation among TB patients. There is currently no published systematic review of these foreign studies, and there is need to integrate the results to determine a good evidence-based guideline appropriate for a Hong Kong chest clinic setting.

1.3 Objectives and Significance

1.3.1 The objectives of this thesis are as follows:

1. To provide a literature review of current research studies on the implementation of a brief tobacco cessation intervention in TB treatment and to compare these study interventions.
2. To analyze the feasibility of transferring these foreign studies into a Hong Kong chest clinic setting.

3. To propose a cost-effective and efficient smoking cessation intervention that will not cause extra burden or inconvenience for nurses or patients and to develop an evidence-based guideline.

4. To develop an evaluation plan for the new guideline.

1.3.2 Significance of the innovation:

Based on the results of research showing a strong association between smoking and the prognosis of TB, it is believed that promoting smoking cessation in TB patients will bring positive outcomes such as shortening the course of treatment, reducing the relapse rate in recovered patients, and improving both the physical and mental health of patients, as anti-TB treatment might cause various side effects and thus affect patients’ daily life and put them under psychological stress. In the long run, smoking cessation can reduce the costs to the health care system and ease the heavy workload of medical staff, as well as help smoking patients establish a more healthy lifestyle.
Chapter 2: Critical Appraisal

2.1 Search and Appraisal Strategies

The research question proposed in this thesis in PICO format is: In patients with newly diagnosed TB (Patients), how does a brief smoking cessation intervention incorporated in usual DOT (Intervention) compared with only directly observed treatment (Comparison) affect the smoking abstinence rate (Outcome)?

In the process of searching for relevant articles, keywords including “Tuberculosis”, “Smoking”, “Tobacco smoking”, “Cigarette smoking”, “Smoking cessation”, “Tobacco cessation”, “Intervention”, “Education”, “Nurse-led”. “Smoking” AND “Tuberculosis” were used in the beginning of the search to get a general picture of relevant studies. The combination of “Tuberculosis” AND “Smoking OR Tobacco smoking OR Cigarette smoking” AND “Tobacco cessation OR Intervention OR Education” AND “Nurse-led” was subsequently used in order to yield more specific results. Titles of the articles in the search results were screened to eliminate irrelevant studies. Then the abstracts of the remaining studies were read to further exclude articles that were not suitable for the guideline.

2.1.1 Inclusion criteria

The inclusion criteria for the selection of studies were all kinds of study designs, preferably randomized controlled trials (RCTs), non-randomized controlled trials or quasi-experiments, and cohort studies. Target participants included patients with newly diagnosed active TB who had just started anti-TB therapy or DOT and were current cigarette smokers. The patients included both men and women and were all 18 years old or older. The target setting was outpatient clinics where treatment for TB patients is provided.
2.1.2 Exclusion criteria

Exclusion criteria in the search were articles published more than 20 years ago, articles with no full text available, and topics related to smoking substances other than cigarettes, such as hookahs and water pipes, inpatient settings, underage smokers, and relapsed TB patients.

2.1.3 Search Strategy

The search was conducted from the mid-October, 2015 to mid-December, 2015. Electronic databases used included PubMed and CINAHL Plus which could be accessed through The University of Hong Kong Libraries electronic resources website.

The reference lists of the articles identified above were checked to find other relevant studies and supporting journals.

The critical appraisal strategy used in this thesis was that of the Scottish Intercollegiate Guidelines Network (SIGN) which was adopted as an appraisal tool in 1993. It aims to enhance health care quality in Scotland by standardizing clinical practice and outcome. SIGN has developed a series of evidence-based clinical guidelines in the form of checklists for various critically appraised types of study designs. The studies selected in this thesis were critically appraised by choosing the methodology checklists for controlled trials and cohort studies based on SIGN’s “Algorithm for classifying study design for questions of effectiveness”. Both checklists include the internal validity and overall assessment of the study. SIGN checklists for the 8 articles analyzed in this thesis are shown in Appendix B.
2.2 Results

2.2.1 Search results

A total of 157 articles were retrieved from Pubmed (from 1977 to the end of November, 2015) and 16 articles were retrieved from CINAHL Plus (from 2006 to the end of November, 2015), for a total of 173 articles. All of the articles were in English. After removal of duplications with the help of Endnote version X7.4, and after manual removal of duplications not recognized by Endnote, 161 articles remained. After skimming through the topics, reading the abstract and context, and following the inclusion and exclusion criteria, 48 full-text articles with relevant keywords in the topics and abstract were identified. Finally, 8 eligible articles were selected for this thesis after elimination of outdated articles.

2.2.2 Preferred Reporting Items for Systematic Reviews and Meta- Analyses (PRISMA) flowchart

The process of selecting articles with reasons for exclusion are shown in the PRISMA flowchart in Appendix A.

2.2.3 Table of Evidence description and summary of the appraisal results

Two of the 8 eligible studies were RCTs, 3 were non-randomized controlled trials using convenience sampling and a quasi-experimental design, and 3 were prospective cohort studies. According to the SIGN Grading System 1999-2012 (Appendix D), the levels of evidence of the 2 RCTs were rated 1++ (Siddiqi et al., 2013; Louwagie et al., 2014) and the remaining studies were all rated 2+ (Sony et al., 2006; Awaisu et al., 2011; Siddiquea et al., 2013; Campbell et al., 2014; Lin et al., 2015; Bam et al., 2015).

All studies selected had a quantitative research design, using prospective, longitudinal data collection in a naturalistic real world setting. Suitable and clear-focused research questions, target group characteristics, details of interventions and potential outcomes were well-addressed.
in all 8 studies. The full table of evidence which gives a general picture of bibliographic citations, study types, patient characteristics, interventions, comparisons, length of follow-up, outcome measures and effect sizes in all 8 studies is included in Appendix C.

I. Randomized Controlled Trials

The first cluster RCT which was conducted in Pakistan (Siddiqi et al., 2013) clearly addressed the use of behavioral support sessions with or without 7 weeks of bupropion therapy in adult patients with suspected TB who were regular tobacco smokers compared with patients in the control group who received only usual care and self-help leaflets. The primary outcome was abstinence at month 6 and the secondary outcome was point abstinence at months 1 and 6. Both primary and secondary outcomes yielded statistically significant results in relative risks.

In the second RCT conducted in South Africa (Louwagie et al., 2014), the target patients were adults with newly diagnosed TB who were initiating anti-TB treatment. The intervention, brief motivational interviewing in addition to brief smoking cessation advice from a TB nurse, was compared with only the latter advice in the control group. The primary outcome was self-reported sustained abstinence in 6 months, and the secondary outcomes were sustained abstinence at 3 months and the 7-day point prevalence abstinence (PPA) at months 1, 3 and 6, as well as quit attempts. The primary outcome more than doubled in the intervention group.

For internal validity, the Pakistan study used simple stratified randomization with adequate concealment by blinded researchers in the allocation. The overall drop-out rate was 9.97% which was acceptable. In the South Africa study, allocation of patients
to both groups was also randomized and concealed adequately by sequentially numbered and sealed opaque envelopes. Lay health care workers who gave the intervention could not be blinded but TB nurses who provided brief advice in the control group were blinded to the allocation. The overall drop-out rate was 23.47 and intention to treat (ITT) analysis was used. In both studies, the baseline characteristics of both groups were similar, and the only difference between groups was the intervention. All the outcomes were measured by valid and reliable biochemical tests. Both studies were rated as having high quality as almost all of the criteria were met.

II. Non-randomized Controlled Trials (Quasi-Experiments)

All three non-randomized controlled trials, conducted in Sudan (Sony et al., 2006), Malaysia (Awaisu et al., 2011) and Nepal (Campbell et al., 2014), targeted newly diagnosed TB patients who were current smokers. The Sudan study addressed the feasibility of a simple smoking cessation intervention of asking open questions to reinforce patients’ decisions to quit smoking throughout standard TB treatment. The secondary outcome of abstinence at month 12 in the intervention group was about triple that in the control group who had usual treatment only. The Malaysia study addressed the integration of smoking cessation intervention into directly observed therapy short-course (DOTS) compared with the control group who had DOTS only. The results showed that the intervention group was had a significantly higher 7-day PPA and continuous prevalence abstinence at months 3 and 6 than the control group. The Nepal study addressed an intervention of repeated brief advice regarding smoking cessation on the primary outcome of continuous abstinence for more than 6 months.
Results showed that 39% in the intervention group and no patients in the control group achieved the primary outcome.

Regarding the internal validity, the sample sizes in both the intervention and control groups were not similar but most of the patient characteristics were similar with an overall drop-out rate of 16.76% in the Sudan study. In the Malaysia study, similar baseline characteristics were noted in both groups, however, the overall drop-out rate was as high as 28.33%. The patient number was not balanced between groups in Nepal because of political and organizational issues and the overall drop-out rate was 6.1%. Measurement was done by self-report in the Sudan study and by valid, reliable biochemical verification tests in the other two studies. The quality of all three studies was rated acceptable, as they were relevant to the key questions but did not meet some of the criteria in the SIGN checklist.

III. Cohort Studies

New registered TB patients who were active smokers were targeted in the three cohort studies, conducted in Bangladesh (Siddiquea et al., 2013), Indonesia (Bam et al., 2015) and China (Lin et al., 2015). All three studies addressed smoking cessation interventions based on the guide developed by The Union involving the “ABC” approach (Ask, Brief advice & Cessation support). Results showed high cessation rates at months 2, 5 and 6 in the Bangladesh study, high cessation rates at month 6 in the Indonesia study and China study, as well as high attempt rates plus low relapse rates for smoking cessation at months 2, 3, and 6 in the China study.

Regarding the internal validity, in both Bangladesh and Indonesia studies, the smoking pattern was assessed at baseline to minimize the chance that the patients would have
the outcome at the time of enrollment but there was no mention of this possibility in the China study. In the Bangladesh study, the drop-out rate was 9% and there was no information about follow-up in the attrition group. In the Indonesia study, the drop-out rate was 20.1%. In the China study, the drop-out rate was 12.2%.

The quality of all three cohort studies was rated acceptable, with clearly defined outcomes, exposure levels to the intervention assessed more than once and confidence intervals provided. There was no ITT in the three studies. Assessment of exposure used in the three studies was done according to the guidelines of The Union and WHO which were evidence-based and reliable. Moreover, confounders such as the possibility of desirable responses in self-report and the influence by external health promotion programs and doctor’s advice were mentioned.

2.3 Summary and Synthesis

In this section, the summary of results, limitations and conclusions, study design and setting, sample size, patient characteristics and smoking status, interventions and controls, and outcome measurements, as well as attrition rates will be covered.

2.3.1 Summary of results and conclusions

Statistically significant results from the studies were presented in the form of relative risk ratios, crude relative risks or adjusted relative risks in the RCTs in 95% confidence intervals with P-values < 0.001, which assumed that the true results were found with 95% certainty and the results would be significantly different with a small enough possibility to ensure validity (McGough & Faraone, 2009). Relative risk, which is the ratio of the probability of improvement in the intervention group to the probability of improvement in the control group ranging from 0 to infinity, is an easy-to-implement method to show the effect size relating to the magnitude, direction and
relevance. Results in all three non-RCTs were shown with percentages. The intervention group showed successful results 3 times more often than the control group, at a significant P-value given in 1 study. All cohort studies showed successful results of more than 60% post intervention among participants.

The conclusions from all 8 studies showed significant results in that the majority of TB patients would benefit from simple, time-efficient, and cost-effective ways to incorporate smoking cessation intervention into traditional TB treatment regimens including education, cognitive behavioural modification, motivational interviewing or counselling. In the Pakistan and South Africa studies, the authors suggested extending the measurement of smoking abstinence to month 12 instead of month 6 in order to get a more accurate approximation of lifelong effect. Louwaige et al. (2014) pointed out that the results were better than in other studies with intensive intervention times longer than 30 minutes, and a non-judgmental method was better than the usual “paternalistic” counselling from health care professionals. The authors of the study from Sudan pointed out that a systematic smoking cessation intervention could be delivered to a large population of patients in routine TB treatment. This would not cause a higher burden on manpower and resources. The authors of the SCIDOTS Project (quasi experiment) from Malaysia pointed out the benefit of non-randomization in that the intervention could be provided based on patient readiness, while the authors of other cohort studies like the Nepal and the China studies suggested using randomization in future designs to ensure higher quality. Campbell et al. (2014) pointed out that smoking TB patients with a low intensity of dependence were more likely to accept advice to quit smoking while those with a higher level of dependence or patients with TB with a non-pulmonary origin were less likely to quit. Authors of the Malaysia and China studies suggested that anti-TB treatment and DOTS provided teachable moments for cessation
intervention. In the Nepal and China studies, it was suggested that more objective tests to be used to verify subjective self-reported data. In conclusion, all studies under review showed significant results for abstinence in patients who had repetitive smoking cessation intervention from the start of TB treatment. Siddique et al. (2013) pointed out that similar studies in Romania and the United Kingdom did not yield significant results, probably due to cultural differences. All in all, the results in the reviewed studies were promising, and the interventions and setting were similar. The integration of smoking cessation intervention into traditional TB treatment would be suitable for low-resource settings, which means that it would not cause too much extra burden on financial and manpower resources.

2.3.2 Synthesis of the study results

2.3.2.1 Study design and setting

One of the two RCTs was a cluster randomized trial with 3 groups (2 intervention groups and 1 control group), and the other was a multicentre, two-group, parallel, individual randomized trial. All non-randomized controlled trials had a non-equivalent comparison group design because of ethical considerations. In one trial, convenience sampling was used to select 24 health care centres. A prospective quasi-experiment was used in another trial and patients were assigned based on their readiness to quit smoking according to the transtheoretical model approach. In the third trial, two interventions and two control centres were used initially but this was reduced to one intervention and one control centre by the end, as the study was delayed because of political factors. In one of the three cohort studies, routinely collected data from a non-governmental organisation information system was used, the second was a prospective pilot study at two tuberculosis clinics, and in the remaining study, a field based intervention was assessed. All the studies were conducted in outpatient settings which provided anti-TB treatment to TB patients, including health centres
primary care TB clinics, chest (respiratory) clinics, TB treatment centres, peri-urban TB service facilities, and TB dispensaries.

2.3.2.2 Sample size, patient characteristics and smoking status

The sample size in the studies ranged from the 86 to 1955 patients. In 3 studies only male patients were included as few females smoke in low and middle-income countries. In the remaining studies male patients were dominant. Of a total of 4328 participants in all studies, 4215 were male (97.39%) and 113 were female (2.61%). Their ages ranged from 14 to 92 years and all were current cigarette smokers. Only 1 study included hookah smoking participants (< 20% in both groups). To document the smokers’ dependence intensity, one study included a heaviiness of smoking index, one study provided patient details and two studies provided detailed definitions of smoking patterns.

2.3.2.3 Interventions and controls

All smoking cessation interventions used in the studies were conducted in settings providing anti-TB treatment to patients with active TB, and lasted for 5-30 minutes. Most of the studies were based on guidelines from The Union and WHO suggestions. In two studies, behavioural support interventions involving patient-centred behavioural change techniques based on the WHO’s “5 A’s” approach with the use of an educational flipbook were compared with usual care with a self-help leaflet. In one study, motivation was briefly assessed by an interview. Patients were helped to identify problems and solutions and provided with health education and a booklet about the risks of smoking compared with just a brief sentence by nurses. One intervention aimed to reinforce patients’ decisions to quit smoking by repeatedly asking questions 3 times in the treatment course. In 4 studies, the intervention consisted of giving brief advice on smoking cessation repeatedly at each visit or more than 2 times in the treatment course. The interventions in 2 studies were based
on The Union’s “ABC” guideline. The interventions in 2 studies included an additional group providing pharmaceutical help with nicotine replacement therapy or a 7-week course of bupropion. All control groups in the 8 studies received either usual treatment care with no intervention (n=2) or an education booklet or leaflet (n=2).

2.3.2.4 Outcome measures and methodological qualities

The outcome measures in all 8 studies were specifically about cigarette smoking abstinence at various points of time and after different durations. In 7 studies, the primary outcome was continuous smoking abstinence at month 6 after the start of the intervention. In the remaining study, continuous abstinence at month 12 was the secondary outcome. In 3 studies, the point abstinence or the 7-day PPA was reported at different months up to month 6 during TB treatment. In 2 studies, attempts to quit were secondary outcomes. In 1 study, the rate of creating a smoke-free environment was a secondary outcome. Outcomes were evaluated by self-report from the participants in all 8 studies. In 3 studies, including the 2 RCTs and 1 non-RCT, biochemical tests such as the carbon monoxide breath test, cotinine test or saliva test were used to validate self-reported smoking abstinence. In 1 study the self-report results were verified by participants’ family members if possible.

2.3.2.5 Attrition rates

The overall attrition rates in all the selected studies ranged from 6.1% to 28.33%. Five of the studies had acceptable attrition rates less than 20%, and the other three studies had attrition rates of 20.1%, 23.47% and 28.33%. Only 1 RCT included ITT analysis.

2.3.2.6 Evidence supporting the proposed innovation

According to Flore et al. (2008) & Rigotti (2002), smoking cessation rates in the general population were significantly lower than the corresponding rates reported in the studies reviewed in this thesis,
which were generally higher than 60% in TB patients. This is largely because patients with diseases are more willing to listen to health messages and follow health advice delivered by health care professionals (Slama, Chiang, & Enarson, 2007). This is consistent with the studies by Shin et al. (2012) and Novotny (2008) who showed that when patients have TB, they tend to listen to their doctor’s suggestion to quit smoking. The start of DOT is an educable moment for newly diagnosed TB patients. If they understand the tremendous benefits of smoking cessation on disease progress and treatment outcome and stop smoking, it will increase the chance of treatment success.

The widely used 5 A’s mode developed by the WHO for primary care settings was suggested to assess the smoking status of patients. 5A’s consists of Ask, Advise, Assess, Assist and Arrange. Using this guide, a nurse can quickly assess a patient’s readiness to quit smoking and provide advice on the implementation plan in only 3-5 minutes (World Health Organization, 2014).

Another smoking cessation intervention, the ABC for TB intervention developed by The Union (International Union Against Tuberculosis and Lung Disease, 2010) involves 3 steps, A= ask, B= brief advice, C= cessation) and was adopted in most of the reviewed studies. The ABC for TB intervention specifically targets smoking TB patients, while WHO’s 5A’s approach is aimed at all smokers.

The use of brief motivational interviewing (MI) in the South Africa study was also recommended in the proposal. MI is a patient-centric counselling method to assist patients in recognizing their problems and establishing behavioural changes. It is more specific and focused on a health problem compared with direct counselling and was developed for behavioural changes such as medication dependence, dietary modification and smoking cessation. Studies show nurses can provide psychological interventions like MI to improve patient health outcomes (Droppa & Lee, 2014).
According to a systematic review by Heckman, Egleston & Hofmann, (2010), MI for tobacco cessation is effective in both adolescents and adults.

All in all, there is enough evidence to support the interventions adopted in the proposal, which are targeted at newly diagnosed TB patients who are current smokers.
Chapter 3: Implementation Potential and Clinical Guidelines

3.1 Transferability

3.1.1 Target Setting

The proposed evidence-based protocol for smoking cessation will be implemented in 5 tuberculosis and chest (TB & Chest) clinics located in the most crowded geographic district in Hong Kong. There is an average of about 30 newly diagnosed TB cases in each TB & Chest clinic every month. About seven to ten registered nurses and enrolled nurses work in these clinics every day. Two to four nurses provide DOT, in which TB patients are observed taking anti-TB medications and monitored for side effects. Other nurses assist doctors in patient consultation and work in the public health unit to provide health education and interview patients.

3.1.2 Target Audience

According to the 8 studies reviewed previously, the target audience of the proposed protocol will have the following patient characteristics:

1. Newly diagnosed with pulmonary TB, both direct smear positive and negative
2. Both women and men 18 years old and older.
3. Current smokers
4. Mentally capable of communicating effectively with others
5. No diagnosis of multi-drug or extensive drug resistant TB, which may require a longer treatment duration
6. Any ethnicity and can communicate in Chinese or English
3.1.3 Transferability of the findings in the target setting

The studies reviewed were conducted at health centers, primary care TB clinics, chest clinics and TB treatment centers. These settings are similar to the TB & Chest clinics in Hong Kong, which are primary care settings providing DOT for TB patients. In the reviewed studies, the patients were mainly adults older than 16 years, with pulmonary TB, and both sexes were included. All patients were smokers. As the studies were conducted in southeast Asian countries, the ethnicities were similar to those of patients in the Hong Kong setting. As DOT is a standardized TB treatment under WHO guidelines, the treatment duration and follow-up patterns are similar across countries in the world. The studies reviewed should be highly transferable to the proposed TB & Chest clinic setting in Hong Kong.

3.1.4 Philosophy of care

The selected studies for the translational nursing research in the target setting were in accordance with the WHO and The Union (The Union, 2010), which have developed an approach to smoking cessation intervention for TB patients. The ABC approach of Ask, Brief Advice, Cessation Support has been shown to increase the chance of quit smoking attempts among smoking TB patients and to have a positive influence on treatment outcomes and prognosis. Since DOT ensures that smoking TB patients have regular contact with nurses at a chest clinic for at least 6 months, and their disease state can also motivate them to realize the importance of modifying unhealthy behaviors, this is a good opportunity to educate and help these patients quit smoking. Moreover, in our target setting, family members of patients are always welcome to attend the interviews and follow-up consultations. Family support is important in treatment outcome and adherence to the smoking cessation intervention.
One of the main objectives in the target setting is to provide health education and promotion relevant to the control of TB, pulmonary illnesses and general health (Department of Health, 2010). Therefore, apart from the anti-TB treatment itself, it is also necessary to help patients to modify unhealthy behaviors that can jeopardize their disease prognosis and improve their quality of life.

3.1.5 Number of clients who can benefit

There will be about 180 newly diagnosed TB patients in a 6-month period in each TB & Chest clinic. With a conservative estimate that 20% of these new patients are current smokers, about 36 patients at each TB & chest clinic and 180 patients at all 5 target clinics could benefit from the proposed evidence-based protocol within a 6-month period. If the translational research is implemented in all the TB & Chest clinics in Hong Kong in the future, more than 800 smoking TB patients could benefit from the study protocol every year. The physical, psychological and social health of these patients will improve and people around them such as their family members and friends may also benefit.

3.1.6 Duration for implementation and evaluation of the innovation

Prior to implementation of the proposed evidence-based protocol, one-month of preparation is required for circulation of the protocol between the 5 TB & Chest clinics, communication and multidisciplinary meetings between various departments including Tuberculosis and Chest Services, the tobacco control office and the Central Health Education unit, as well as training sessions and workshops for the nurses. Afterwards, the 6-month evidence-based program will be started for any newly diagnosed TB patients who are current smokers and fulfill the target patient characteristics. In the 6-month period, the targeted clients’ progress will be summarized every month. After implementation of the program, one month will be required to evaluate the outcome.
All in all, 8 months will be reserved to conduct the whole proposed evidence-based study. The timeline of the study is shown in Appendix E.

### 3.2 Feasibility

#### 3.2.1 Freedom for nurses to conduct the innovation

Both registered nurses and enrolled nurses who work at the targeted TB & Chest Clinics have the freedom and autonomy to conduct the proposed study and to attend the associated training sessions and workshops. In current practice, all nurses in the target clinics interview patients during follow-up consultation to monitor disease progress, handle questions, and provide health education and counselling about TB treatment. It is believed that these nurses have the ability to communicate well with the patients and have the fundamental skills for educating and counselling patients. Moreover, as every nurse in the target clinic interacts with the patients, they become increasingly familiar with their condition. Therefore, during implementation of the innovation, nurses also have the autonomy to provide client-oriented counselling based on their professional assessment of patients’ smoking status. Nurses at the target setting should have the responsibility and commitment to carry out the full protocol in the 6-month period. As it is not certain that the target patients will cease smoking by the end of the period, if nurses cannot complete the whole study without a reasonable cause such as leaving the job or illness, they should hand over their cases to other available nurses.

The innovation will not interfere with the normal function of staff or add extra burden to the daily operation in the target setting. The proposed innovation will be incorporated into the existing interviews provided in the public health unit in the TB & Chest clinics. It will undoubtedly increase the duration of the interview of newly diagnosed TB patients who smoke. However, the increase will be less than 30 minutes for the first interview and 5 to 10 minutes for follow-up
interviews. In existing practice, nurses in the public health unit of the target clinics provide health education to smoking patients with a freestyle approach and there is no systematic approach for them to handle these patients. With the aid of the proposed protocol, they will have more precise direction in assessing and counseling smoking patients, enabling them to conduct interviews more smoothly. There is no need for extra manpower for the innovation.

3.2.2 Administration Support and Organizational Climate

One of the main objectives of the services provided in the target setting is to carry out research on TB and other chest diseases, to find better measures to treat these diseases. The administrative staff is always supportive of any evidence-based studies that are beneficial to the treatment outcome of the patients. The DOT provided in the TB & Chest clinics is in strict adherence with the evidenced-base guidelines developed by the WHO. The organization of the target setting is also supportive of continuous education and training for staff. They offer a subsidy for staff to enroll in postgraduate degrees in public health and regularly provide health seminars and training sessions during working hours. It is believed that the organizational climate will be conducive to carry out the proposed innovation.

3.2.3 Nurses’ support and acceptance

Nurses in the target setting will shoulder an important role for successful implementation of the evidence-based protocol. Generally speaking, they are supportive of innovation as long as it benefits the patients and themselves, and does not cause extra burden to their daily workload. The simple yet effective evidence-based practice has been carried out in other countries and the results were mostly promising. The great autonomy offered to the nurses to carry out the study and the positive outcome for smokers with TB will give them great satisfaction. The counselling skills and knowledge about smoking cessation they acquire will enhance the image of both the nurses’
and the organization, as well. All these factors are essential to gain nurses’ acceptance of the innovation.

Nonetheless, the nurses may feel more stressed and have mental reservations about the study. Smoking cessation intervention requires that they have a considerate attitude and good observation skills of target patients, and they also need to provide accurate information to patients when they have enquiries. Therefore, training sessions and practical workshops are necessary to build their confidence. Details about training for nurses before implementation of the study will be discussed in the next chapter.

3.2.4 Multidisciplinary cooperation

In the preparation phase of the study, those in the target setting need to cooperate with professionals in other disciplines including the tobacco control office for expertise on counselling skills for smoking cessation, and the central health education unit to design and print tailor-made pamphlets on smoking cessation for TB patients. In addition, during the implementation phase, if nurses encounter any difficulties, they can get assistance and suggestions from the tobacco control office. TB patients with a serious addiction to tobacco who require further assistance, such as pharmacological intervention, can be referred to smoking cessation clinics run by the Department of Health, the Tung Wah Group of Hospitals, Pok Oi Hospital or the Hospital Authority in Hong Kong.

3.2.5 Resources for implementation

The simple evidence-based protocol requires minimal resources and equipment for implementation. The resources include the existing public health unit room for interviews, computers and telephones for communication with other disciplines and patients, and printers,
paper and folders for proper documentation of the protocol. Also, a financial allowance from the organization is required for designing and printing information pamphlets.

3.2.6 Tools for evaluation

Evaluation of the study outcome is mainly based on self-report by the target patients. Self-reported data about smoking abstinence will be collected at every follow-up visit and will be summarized by nurses at the end of the 6-month implementation period. Each TB & Chest clinic already has one carbon-monoxide analyzer in place which can be used for verification of smoking status. The detailed evaluation plan will be discussed in the next chapter.

3.3 Cost-Benefit Ratio

3.3.1 Risks and benefits of the innovation

The evidence-based protocol will be beneficial for smoking TB patients, nurses, and the organization. First, the organization can fulfill its mission of conducting research for better practices to fight TB and hence will have a better image and reputation for providing evidence-based practice. Second, the innovation has been developed according to significant studies conducted in low-income countries, so it will be inexpensive (Siddiqi et al., 2013) and it does not require extra manpower, so there will not be much financial burden on the organization. Various studies have pointed out that this is an ideal opportunity for patients to quit smoking as they will understand that both smoking and TB badly affect the lungs. So, smoking patients will be more motivated to quit smoking than general smoking populations (Siddiqi et al., 2013; Louwagie et al., 2014). Moreover, behavioral modification interviews incorporated in smoking cessation interventions can reduce long-term smoking-related complications and lead to better TB treatment outcomes. The study from Awaisu et al., showed the potential effects of tobacco cessation on sputum smear conversion (2011). The risks of TB patients not trying to stop smoking include
increased infectivity, high TB relapse rates and mortality rates, recurrent TB, poor treatment adherence, and increased risks of suffering permanent damage (Siddiquea et al., 2013; Campbell et al., 2014).

One potential risk of the innovation is that TB patients at clinics other than the target setting will not have a chance to receive the potential benefits from the smoking cessation intervention proposed in the protocol, such as faster sputum conversion rates, resulting in an ethical dilemma (Awaisu et al., 2011). As smoking cessation may depend on the seriousness of tobacco dependence, some highly addicted clients will be referred to smoking cessation clinics. These patients need to deal with long-time treatment and smoking cessation intervention at the same time. They may have increased stress over the implementation period. Moreover, patients may want to exaggerate their progress to fulfill the desired outcome, and thus the study might be at risk of yielding false-positive results. Therefore, nurses should reinforce that maintaining a healthy mental status and being relaxed are also key factors for successful treatment and smoking cessation. There may also be risks of non-compliance from the patients and a heavy workload among staff.

3.3.2 Cost Calculation

Setup and running costs

Setup up costs for training sessions for nurses in the preparation phase include a total of 5 manuals printed for the 5 target clinics to provide information and procedures on the proposed evidence-based protocol. Each manual will cost less than $10 HKD and for a total of less than $50. The two-day training session includes one day for briefing, lectures and discussion of the manual, and one day for practical workshops, which will allow nurses to simulate conducting behavioral modification interviews and giving brief advice. Each two-day session can accommodate 10 nurses from the 5 clinics, so there will be 5 sessions (10 days) in total for the 50 nurses working in the 5
target clinics. Assuming the ratio of registered nurses to enrolled nurses will be 1:1, there will be 25 registered nurses and 25 enrolled nurses participating in the study. The cost for each enrolled nurse for a training session ranges from $1027.33 to $2184 HKD, and for each registered nurse, $1785.67 to $2873.67 HKD. Health education pamphlets and booklets on smoking cessation intervention will cost around $1000.

The implementation phase of the innovation can make good use of the existing resources available in the target setting. The study will be incorporated into the current practice of individual interviews provided by nurses after each follow-up consultation. Assuming enrolled nurses and registered nurses will each handle half of the target patients, the maximum budget for the implementation and evaluation of the protocol for 180 target patients will be $52111.8. The detailed cost for the study is described in Appendix F.

The material cost of not implementing the innovation will mainly be the cost of the extra length of treatment for each target patient, which depends on the medication selected and extra diagnostic tests.

**3.4 Evidence-Based Practice Protocol**

3.4.1 Background

A pulmonary TB patient who is also a smoker has a higher chance of relapse, and the death rate is higher in smokers than non-smokers. Smoking TB patients have a higher chance infecting a family member. A smoker with a productive cough is more likely to spread the disease than a non-smoker. As a result, smoking cessation can benefit smoking TB patients in both treatment outcome and disease progress, offer better protection for their families, and ultimately decrease the disease prevalence in society.
3.4.2 Objectives

- To provide an evidence-based clinical pathway for patients with pulmonary TB who are current smokers.
- To increase nurses’ awareness of the importance of smoking cessation among patients with pulmonary TB.
- To improve the smoking cessation success rate among patients with pulmonary TB.

3.4.3 Target users

Nurses working in chest clinics in Hong Kong

3.4.4 Target patient population

(Refer to Chapter 3.1.2)

3.4.5 Rating scheme for the strength of the recommendations

The smoking cessation protocol was developed according to the graded research and grading guide from of SIGN methodology in SIGN 50: A guideline developer’s handbook (SIGN, 2012). Details of the grading system utilized are attached in Appendix D.

3.4.6 Recommendations & Protocol

The recommendations about properties of the target population, assessment, planning and evaluation, with corresponding evidence from the selected studies are shown in Appendix G.

Chapter 4: Implementation Plan

4.1 Communication Plan

Prior to developing an effective communication plan, the major stakeholders of the innovation must be identified at the administrative, clinical and recipient levels in order to ensure smooth
and consistent delivery of the innovation to the target patients, and also to minimize misunderstandings about the plan.

4.1.1 Stakeholders at the administrative and management levels

To obtain approval for the proposed innovation, nursing officers in the target settings will first be asked for permission. Each of the targeted chest clinics has one nursing officer who monitors the overall operation of the clinic, arranges work schedules for all nurses and staff, and also attends regular administrative meetings with other nursing officers, supporting nursing officers and senior nursing officers in the Tuberculosis and Chest Service headquarters. After the nursing officer gives preliminary approval for the proposed study in my chest clinic, she will discuss it in the regular nursing officers meeting. The four nursing officers at the other four target chest clinics will be involved in the discussion and they need to ensure the possibility of running the innovation. When a consensus on running the innovation is achieved, and after approval from the senior nursing officer, details will be presented to the senior nursing officer, including cost calculations and the evidence-based guideline to obtain funding support from the Center for Health Promotion and Department of Health. Ongoing evaluation and refinement after the pilot study will be presented periodically to the nursing officers and senior officer.

4.1.2 Stakeholders at the clinical level

After getting approval from the nursing officers and senior nursing officer, registered nurses and enrolled nurses in the target chest clinics will be informed, as they are also important stakeholders in the implementation of the study. As nurses are the users of the proposed protocol, their suggestions and feedback are valuable for implementation, refinement and data analysis during the study period and improvements in the future. They will have two-day training sessions on the
innovation and the success of the innovation is dependent on them. Therefore, the design and implementation of the evidence-based protocol should focus on acceptance and suggestions from the nurses, as how they use the protocol and their compliance with the implementation will affect the clinical outcome of the study. Their feedback and suggestions for improvement will be collected through electronic mail and regular staff meetings in the clinics.

Other stakeholders at the clinical level are the medical officers and senior medical officers. In the initial assessment of TB treatment, they will advise patients who are smokers to stop smoking. Therefore, during the design and implementation phases, informal meetings between nurses and medical officers will be held if necessary. Suggestions and information will be obtained from them to increase the confidence of the nurses and patients. Moreover, through telephone inquiry from nurses and nursing officers, expert opinions about relevant practice and information on smoking cessation will also be provided from the Tobacco Control Service such as their smoking cessation hotline and other smoking cessation clinics under the Department of Health, Tung Wah Groups of Hospitals, Pok Oi Hospital, and United Christian Nethersole Community Health Service.

4.1.3 Stakeholders at the recipient level

The target smoking TB patients who fulfill the patient characteristics mentioned in Chapter 3.1.2 are the recipients of the proposed innovation. After selection of the target population for the study by participating nurses, informed consent in paper format will be obtained, and details of the study and pamphlets will be provided to these patients to ensure their willingness to participate in and comfort with the study. During their first visit at the diagnosis of TB and each follow-up visit, motivational interviews and brief advice will be given and self-report on smoking abstinence will be obtained from them and their family members. It is important to build good rapport with the target patients and their family members and nurses have the responsibility to ensure that they
clearly understand the proposed study by providing a detailed introduction and answering any questions promptly. Feedback from the target patients and their family members or caregivers and their level of satisfaction will be obtained through face to face interviews and a designated questionnaire distributed at the end of the study for future revision and improvement. (Appendix H)

4.1.4 Other stakeholders

Other stakeholders include the clerical staff working in the general office of each target clinic. They obtain basic patient details from newly diagnosed patients at their first visit and they provide assistance in computer skills and data collection to nurses if necessary. Lastly, the Central Health Education Unit will be contacted to print the nursing manuals and pamphlets stated in the previous chapter.
4.2 Pilot Study Plan

After implementation of the communication plan with the various stakeholders mentioned above, a pilot study with a small sample size of fewer than 20 subjects will be conducted to test the running feasibility of the proposed evidence-based protocol. The trial will allow all stakeholders to have a general picture of the implementation, such as obstacles in real practice, flaws in the methodology, problems in logistics, and feedback from the nurses who conduct the study and the target recipient patients. The pilot study is essential for modifications and improvement of the innovation.

4.2.1 Study design of the pilot study

The target setting will be one of the five target TB & Chest clinics. The target sample population in the pilot study will have the same target characteristics mentioned in Chapter 3.1.2., that is newly diagnosed TB patients who are current smokers. The pilot study period will be three months, including the first motivational interview with the target patient at their first visit to the public health unit in the chest clinic, and one subsequent follow-up interview with a brief advice session provided by participating nurses after one month. The pilot study will be in a quasi-experimental cohort design adopting the convenience sampling method for patient recruitment. In 2015, there were 4498 new TB notifications in the 12 full-time chest clinics and 5 mobile chest clinics. It is estimated that there is about one new TB notification every day in the target clinic. With the assumption that 20% of TB patients are smokers, approximately 6 eligible patients will be recruited monthly. Therefore, three months are required to recruit about 13 patients and to interview each patient at their first and second visits after treatment starts, assuming no loss to follow-up.

4.2.2 Objectives of the pilot study

- To assess the feasibility of full-scale implementation of the new evidence-based protocol
- To identify possible difficulties during the implementation and evaluation phases

- To assess the compliance of both nurses and target patients with the innovation

- To assess the actual proposed running budget and extra expenditures in the implementation

- To assess manpower logistics and the effectiveness of the proposed communication plan

- To preview the effectiveness of smoking cessation among TB patients through the innovation

4.2.3 Ethical approval

Ethical approval should be obtained from the Ethics Committee of the Department of Health. The purpose of the study, potential risks and benefits, data collection methods and privacy issues will be covered in the consent form and verbally explained by nurses before target patients sign the consent.

4.2.4 Plan for refinement of the proposed protocol based on pilot results

Ongoing evaluation of the pilot study will be performed from the start of the study until the first follow-up visit. Data on smoking status, and intention to stop smoking at the beginning and at the first visit after one month will be collected by nurses through patients’ self-report and family member feedback when possible. Continuous smoking abstinence will be assessed at the first follow-up visit by self-report and verified by carbon monoxide analyzer. Changes in attitude regarding smoking and adherence to the proposed protocol will then be evaluated and summarized by nurses at the end of the study.

Possible difficulties, logistics and manpower problems will be explored in the regular monthly staff meeting. At the end of the study, both compliance and satisfaction levels will be assessed
through author-designed questionnaires for participating nurses and target patients, respectively. (Appendix H & I)

The evaluation and summary report by nurses and results of the questionnaires will be presented in the nursing officers meeting to obtain final approval from the senior nursing officer. These reports will also be printed and circulated in other TB and Chest clinics. Opinions are welcome through electronic mail for further refinement.

4.3 Evaluation Plan

An ongoing evaluation plan is necessary to ensure the analysis and summary of the data collected is accurate and to facilitate improvement and implementation of the evidence-based protocol. Evaluation of various outcome measures, the data collection method, the timeline for the study, the budget and sample size calculation will be covered in this section.

4.3.1 Outcome measures

Outcome measures are evaluated by the main stakeholders in the innovation, including patients, nurses, and system outcomes.

4.3.1.1. Patient outcomes

Patient outcomes will be the most important outcomes in the evaluation, as the aim of the proposed evidence-based protocol is to encourage smoking cessation in newly diagnosed TB patients who are current smokers, which will be beneficial to their treatment outcome. According to the selected studies, the effectiveness of the proposed smoking cessation intervention protocol will be measured by continuous 3-month abstinence as the primary outcome at the 6 month follow-up. The secondary outcome, the 7-day PPA will also be measured. Both continuous abstinence and the 7-day PPA will be measured through self-report and family members’ report if possible, and
verified biochemically by a carbon monoxide testing analyzer, which is already available in the target settings. There will be an author-designed progress sheet (Appendix J) for patients or family members/caregivers to record the number of cigarettes smoked every day.

Other secondary outcomes including the target patients’ satisfaction with the innovation will be analyzed by an author-designed 6-point Likert scale questionnaire (Appendix H). Other outcomes including increased knowledge about smoking cessation, treatment compliance and duration will be evaluated by nurses’ written records in the traditional public health unit as usual practice.

4.3.1.2 Nurses outcomes

Participating nurses will need to fill out an author-designed questionnaire about their compliance to conduct the study and their satisfaction level using a 6-point Likert scale (Appendix I). Opinions and suggestions are welcome and will be collected in written or electronic format and in the regular staff meeting held in the target clinics. A nurse will be assigned as the study nurse in each target clinic and will be responsible for collecting and recording feedback in the meetings.

4.3.1.3 System outcomes

The total cost in the preparation phase, and any extra operational expenditures will be evaluated at the end of the study for better estimation in future budgetary plans. Issues of manpower allocation and overtime work which may affect daily operations in the target settings will be discussed in regular staff meetings. The treatment duration of target patients in both the patient case records and public health unit records will be evaluated and discussed with senior and medical officers if necessary.
4.3.2 Timeline for the study

The proposed total duration for implementation of the evidenced-based protocol will be around eight months. The actual dates and periods of different phases of the study will be recorded and evaluated continuously. The initial phase will last one month, including writing study manuals, requesting approval from the senior nursing officer and the Ethics Committee of the Department of Health, circulating the proposed protocol in the target settings, and organizing the two-day training and workshop sessions for nurses. The implementation phase of the innovation will be started from the second month to the seventh month, and will last for about six months in total. At the end of the second month in the timeline, ongoing summarization of the progress and evaluation of patient outcomes, nurse outcomes and system outcomes will be done monthly until the end of the eight-month study. The timeline for the study is shown in Appendix E.

4.3.3 Nature of the clients and sample size calculation

The target patient characteristics mentioned in Chapter 3.1.2 were determined by the general characteristics in the reviewed literature. Patient statistics including mean age, age group proportion, male to female ratio, mean duration of smoking in years, and median number of cigarettes smoked per day will be calculated by SPSS 22. Russ Lenth’s Java Applets for Power and Sample Size (Lenth, 2006) will be used to calculate the sample size in the evaluation plan. In the randomized controlled trial study by Louwagie et al. (2014) reviewed and rated as 1++ in the SIGN Checklist, the biochemically verified sustained 3-month abstinence was 4.9% in the control group and 10.2% in the brief motivational interviewing intervention group. Using the test of one proportion with a power of 0.8048 and a significance level of 0.95, a sample size of 166 was generated by the software. With a conservative estimate of a 20% drop out rate, the sample size will be 208.
4.4 Basis for Implementation

According to the literature reviewed previously, the proposed evidence-based protocol will be considered effective when the following criteria for outcome measures are achieved.

I. Primary outcome: Continuous smoking abstinence at month 6
Abstinence means a person stops smoking, not even a puff. Abstinence can be temporary or permanent. (Bissell, K., Fraser, T., Chiang, C., & Enarson, 2010). In the RCTs reviewed, the minimum difference in the proportion of continuous smoking abstinence between the intervention group and control group was 25.4% - 12.8% = 12.6%. Therefore, a minimum 12.6% continuous smoking abstinence at the end of the proposed study will be regarded as effective.

II. Secondary outcome: 7-day PPA at month 6
The 7-day PPA is commonly used in research to indicate smoking abstinence in the past 7 days, and the result can be verified biochemically (Hughes et al., 2003). The minimum difference in the proportion of 7-day PPA between the intervention group and control group was 44.9% - 40.2% = 4.7%. Therefore, a minimum 4.7%. 7-day PPA at the end of the study is expected.

In biochemical verification of smoking, a person's carbon monoxide level is measured via a breathing test. If the result is greater than 9 parts per million, he/she is considered to be smoking even if stated otherwise. (West, Hajek, Stead and Stapleton, 2005)

III. Other patient outcomes: satisfaction level
The “Patient Satisfaction Survey” (Appendix H) will be used to collect the patient’s level of satisfaction with the study. There will be six questions, ranging from “Strongly disagree” to “Strongly agree”, and a mean value of 24 total points or above for each patient will be regarded as an effective outcome. The patient drop-out rate should be less than 20%.
IV. Nurse outcomes: compliance and satisfaction level

In the “Nurse Satisfaction and Compliance Survey” (Appendix I), an answer of “Yes” to all five questions on nurse compliance is targeted for quality control in the study. As with the patient satisfaction level, a mean value of 24 total points or more for each involved nurse will be regarded as effective.

V. System outcomes: Total cost

The total cost for the 2-day training session for all nurses in the target setting should be maintained under $126,417, and the total cost for each patient should be maintained between $117.7 and $329.45. The costs are estimated according to the monthly salary range of nurses. (Appendix F)
Chapter 5: Conclusion

TB is highly contagious epidemic disease, and has been considered a global emergency since 1993. Thanks to the development of anti-TB antibiotic regimens and DOT in the 1970s, the disease gradually become curable and under control. Nonetheless, Hong Kong has had more than 4500 TB notifications every year in the last decade. More effort is needed to stem this threatening epidemic, such as controlling the associated risk factors of the disease. There is increasing evidence of a strong association between smoking and TB, such as the baseline severity, prognosis, treatment outcome and relapse rate after completion of treatment. Incorporating smoking cessation intervention into DOT for TB is a convenient and cost-effective method to help smoking patients quit. The six-month treatment period is a teachable moment for patients to realize that smoking has bad consequences on their health, and smoking abstinence has a positive impact on the disease outcome. Moreover, studies have shown that the innovation will not cause a burden on manpower, resources and finances, so it can be applied to a large population.

In this dissertation, an evidence-based guideline was developed based on several high-quality studies in southeast Asian countries after critical analysis of transferability and feasibility. The primary outcome of the guideline is sustained smoking abstinence at the end of the standard six-month DOT. It is believed that the patient-centered innovation will be more direct, specific and focused on individual patients, and thus more effective than traditional health talks and support groups. To enhance the effectiveness of the innovation, more high-quality studies such as RCTs are needed for improvement of the guidelines in the future.

References

Awaisu, A., Nik Mohamed, M. H., Mohamad Noordin, N., Abd Aziz, N., Syed Sulaiman, S. A.,


### Selected articles

<table>
<thead>
<tr>
<th>Studies</th>
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Appendix I: Nurse Satisfaction and Compliance Survey for Evidence-based Smoking Cessation Intervention Protocol for Tuberculosis Patients

Appendix J: Cigarette consumption record for TB patient
Appendix B PRISMA 2009 Flow Diagram

Records identified through database searching (PubMed) (n=157)

Additional records identified through other sources (Cinahl Plus) (n=16)

Records after duplicates removed (n=161)

Records screened (n=48)

Records excluded (n=114)
Reasons: Topics are not related; target setting and patients not related; use of pharmacological interventions

Full-text articles assessed for eligibility (n=48)

Full-text articles excluded (n=40)
Reasons: Published more than 20 years; only selected RCTs, cohort, controlled trials, observational studies

Studies included in qualitative synthesis (n=8)

Studies included in quantitative synthesis (meta-analysis) (n=0)
### Appendix C Table of Evidence

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<th>Bibliographic Citation</th>
<th>Study Type</th>
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<th>Interventions</th>
<th>Comparison</th>
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<td>Siddiqi, Khan, Ahmad, Dogar, Kanaan, Newell &amp; Thomson, 2013</td>
<td>RCT (1++)</td>
<td>Sex (M): 1955 Age: &gt;= 18 Patient with suspected pTB (cough for &gt;= 3 weeks without any other cause) Regular tobacco smokers (&gt;= 1 cigarette/day) Outpatient Mean age: 40.91 Smoking type: Cigarette and Hookah- only</td>
<td>-BSS Group: 2 structured sessions delivered by DOT facilitators using an educational flipbook -30- minute session at 1st visit to envision patients as nonsmokers and plan for a quit day 1 week later -2nd session: 10-minute to review progress</td>
<td>-Control group: usual care and self-help leaflet on smoking cessation</td>
<td>-BSS and BSS+ groups at 1, 5 and 25 weeks after 1st contact and control participants at 5 and 25 weeks</td>
<td>1) Primary outcome: continuous smoking abstinence at 6 months (BSS) 2) Secondary outcome: point abstinence at 1 month 3) Secondary outcome: point abstinence at 6 months</td>
<td>1) RRR: (1-8.2)/1 = -7.2 P&lt;0.001 95%CI in BSS: (3.4-16.4) 2) RRR: (1-9.9)/1 = -8.9 P&lt;0.001 95%CI in BSS: (4.7-20.9) 3) RRR: (1-3.2)/1 = -2.2 P&lt;0.001 95%CI in BSS: (1.7-6.3)</td>
</tr>
<tr>
<td>Louwagie, Okuyemi &amp; Ayo-Yusuf, 2014</td>
<td>RCT (1++)</td>
<td>Sex (M/F): 368/41</td>
<td>Age: &gt;=18</td>
<td>Current smokers</td>
<td>Newly diagnosed patients initiating TB treatment</td>
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<tr>
<td></td>
<td></td>
<td>Brief MI: brief MI session (15-20) minutes from the LHCW: simple one-page approach of a quick assessment, the patient identifying problems and solutions and the setting of targets, message about risks tailored to relationship between smoking and TB - LHCWs helped highly motivated and highly confident to quit patients to quit with a quit plan</td>
<td>Short standardized smoking cessation message from TB nurse - Smoking cessation booklet supplied by the NCSSA</td>
<td>Intervention group: Follow-up questionaires by LHCWs at 1, 3, 6-month TB treatment visits (by telephone if unable to attend)</td>
<td>1) Primary outcomes: Self-reported 6 month sustained abstinence Secondary outcomes: 2) Self-reported 7-day PPA 1-month follow-up 3) Sustained 3-month abstinence 3-month follow-up 4) Sustained 7-day PPA 3-month follow-up 5) Success quit attempts</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

1) Crude RR: 2.29 95%CI: (1.34, 3.92) 2) Crude RR: 1.44 95%CI: (1.02, 2.03) 3) Crude RR: 1.98 95%CI: (1.24, 3.18) 4) Crude RR: 1.12 95%CI: (0.83, 1.50) 5) Crude RR: 1.11 95%CI: (0.87, 1.41)
<table>
<thead>
<tr>
<th>Study Authors</th>
<th>Study Design</th>
<th>Sample Size/Description</th>
<th>Intervention Details</th>
<th>Control Group Details</th>
<th>Follow-up Survey</th>
<th>Secondary Outcome</th>
<th>Intervention vs Control</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sony, Slama, Salieh, Elhaj, Adam, Hassan &amp; Enarson</td>
<td>Level III Non-RCT</td>
<td>Sex (M): 308 All new cases of TB patients Current smoker</td>
<td>- Open questions about quitting to reinforce the decision making at the beginning of TB treatment and during the course of treatment at 2, 5 and 8 months</td>
<td>- No intervention</td>
<td>Follow-up survey at 12 months</td>
<td>Secondary outcome: 1) Quit smoking at month 12</td>
<td>1) 53.6% in intervention group reported quitting vs. 14.3% in control group</td>
</tr>
<tr>
<td>Awaisu, Mohamed, Noordin, Aziz, Sulaiman, Muttalif &amp; Mahayiddin, 2011</td>
<td>Level III Non- RCT using quasi-experimental design Non-equivalent comparison</td>
<td>Sex (M/F): 85/1 All current manufactured cigarette smokers newly diagnosed with active TB</td>
<td>- An overview of the integrated DOTS plus SCI program (CBT) +/- NRT - asked to establish a</td>
<td>- Overview of DOTS plus conventional TB counseling - Patient-centered intervention</td>
<td>- Control group: follow-up schedules for TB on 2-monthly basis (baseline, end of second, 3) CPA (for 2 weeks at end of 3rd months)</td>
<td>1) 7-day PPA (3 months) 2) 7-day PPA (6 months) 3) CPA (for 2 weeks at end of 3rd months)</td>
<td>Intervention vs Control: 1) 75% vs 13% 2) 82.5% vs 10.9% 3) 70% vs 10.9%</td>
</tr>
</tbody>
</table>
| Siddiquea, Islam, Bam, Satyanarayana, Enarson, Reid, Husain, Ahmed, Ferdous & Ishikawa | Cohort study of routinely collected data (2+) | Sex (M/F): 559/3 All TB patients registered for treatment from May 2011 to April 2012 (Including new and previous treated) Current smokers | target quit date
- Personalized behavioral counseling, educational materials and refills of drug prescription related to smoking cessation
- Patient-centered intervention techniques using 5As strategy
- Receive DOTS on daily-basis | techniques using 5As strategy
- Receive DOTS on daily-basis | fourth and sixth month
- Intervention group: Weekly for 1st month, fortnightly for the 2nd and 3rd month, monthly from the fourth to sixth month (total 11 follow-up visits) | CPA (for 4 weeks at end of 6th months) 4) 77.5% vs 8.7% P < 0.001 | 1) Smoking cessation at month 2 in anti-TB treatment
2) Smoking cessation at month 5 in anti-TB treatment
3) Smoking cessation at month 6 in anti-TB treatment
4) 77.5% vs 8.7% P < 0.001 |
improve their health and the effectiveness of their anti-TB treatment at healthy facility level

Evaluated by health workers at the end of months 2 and 5 and at the end of anti-TB treatment (usually at month 6 or 8) to assess whether they had quit smoking

month 6 or more in anti-TB treatment

<p>| Campbell, Chaudhary, Holdsworth &amp; Lyne, 2014 | Level III Non-RCT (2+) | Sex(M/F): 197/49 Age: &gt;=16 Patients started treatment for smear positive pTB Smokers(Tobacco users other than cigarette smokers were excluded Capable for informed consent | -At two treatment centers: simple information about the harm from smoking with its negative association with TB and its effect on children's health and education -Followed by brief advice about stopping (about 10 minutes) at the -No intervention -Assessed for smoking status only | At the end of the 6-month course of anti-TB treatment, patients were asked about whether they had stopped smoking | 1)Primary outcome: claimed CPA for &gt;=6 months (biologically verified at 6th month) | Intervention vs Control 1)39% vs 0% |</p>
<table>
<thead>
<tr>
<th>Study</th>
<th>Cohort Study</th>
<th>Sex (M/F): 569/19</th>
<th>ABC smoking cessation intervention( 5-10 minutes every session)</th>
<th>No control</th>
<th>Smoking status and smoke free environment at home were assessed at the 1st visit, each monthly follow-up to month six</th>
<th>1)quit smoking at month six 2)created a smokefree home at six month follow-up</th>
<th>1)66.8% 2)86.1%</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bam, Aditama, Chiang, Rubaeah &amp; Suhaemi, 2015</td>
<td>Level IV Cohort study assessing a field based intervention (2+)</td>
<td>All consecutive new diagnosed and registered sputum smear-positive TB cases in the 17 health centres Age &gt;=15 Recruited &lt;7 days of commencement of anti-TB treatment Current smokers</td>
<td></td>
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<tr>
<td>Lin, Wang, Qiu, Huang, Shu, Lin, Meng, Zeng, Xiao, Bam &amp; Chiang, 2015</td>
<td>Level IV Prospective study of a pilot project Cohort Study(2+)</td>
<td>Sex(M/F): 234/0 Age: 14-92 years All consecutive TB patients registered in rural China TB patients who were willing to quit smoking</td>
<td>SCI: General information on the harmful effects of tobacco smoking on health, specific information on smoking and</td>
<td>No control</td>
<td>Smoking status re-assessed at the follow-up visits carried at 2, 3 and 6 of anti-TB treatment</td>
<td>1)Attempt to quit and relapse rate at month 2 2)Attempt to quit and relapse rate at month 3</td>
<td>1)Attempt to quit: 82.5% Relapse:9.8% 2)Attempt to quit: 80.4% Relapse:8.5% 3)Attempt to quit: 66.6% Relapse:12%</td>
</tr>
<tr>
<td>Denotes:</td>
<td>M: Male</td>
<td></td>
<td></td>
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<tr>
<td>----------------------------------------</td>
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</tr>
<tr>
<td>5As: ask, brief advice, cessation support</td>
<td>MI: motivational interviewing</td>
<td></td>
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<td></td>
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<td></td>
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</tr>
<tr>
<td>ABC: ask, brief advice, cessation support</td>
<td>NCSSA: National Council against Smoking of South Africa</td>
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</tr>
<tr>
<td>BSS: behavioural support sessions</td>
<td>NRT: nicotine replacement therapy</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>BRAC: Bangladesh Rural Advancement Committee</td>
<td>PPA: point prevalence abstinence</td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>CBT: cognitive behavioural therapy</td>
<td>pTB: pulmonary tuberculosis</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>CI: confidence interval</td>
<td>RCT: randomized controlled trial</td>
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<td></td>
</tr>
<tr>
<td>CPA= Continuous Prevalence Abstinence</td>
<td>RRR: relative risk ratio</td>
<td></td>
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<td></td>
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</tr>
<tr>
<td>DOTS: Directly Observed Therapy- Short course</td>
<td>SCI: smoking cessation intervention</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>F: Female</td>
<td>TB: Tuberculosis</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>LHCW: Lay health care workers</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>TB, and brief advice to quit Reinforced during each visit to the TB dispensary</th>
<th>3) Attempt to quit and relapse rate at month 6</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>4) Smoking cessation for &gt;= 3 months at month six of anti-TB treatment</td>
</tr>
<tr>
<td></td>
<td>4) 64.9%</td>
</tr>
</tbody>
</table>
Appendix D SIGN Grading System 1999-2012

SIGN GRADING SYSTEM 1999 – 2012

LEVELS OF EVIDENCE

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>1++</td>
<td>High quality meta-analyses, systematic reviews of RCTs, or RCTs with a very low risk of bias</td>
</tr>
<tr>
<td>1+</td>
<td>Well-conducted meta-analyses, systematic reviews, or RCTs with a low risk of bias</td>
</tr>
<tr>
<td>1-</td>
<td>Meta-analyses, systematic reviews, or RCTs with a high risk of bias</td>
</tr>
<tr>
<td>2++</td>
<td>High quality systematic reviews of case control or cohort or studies</td>
</tr>
<tr>
<td>2+</td>
<td>Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal</td>
</tr>
<tr>
<td>2-</td>
<td>Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal</td>
</tr>
<tr>
<td>3</td>
<td>Non-analytic studies, e.g. case reports, case series</td>
</tr>
<tr>
<td>4</td>
<td>Expert opinion</td>
</tr>
</tbody>
</table>

GRADES OF RECOMMENDATIONS

- **A**
  At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or
  - A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results

- **B**
  A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or
  - Extrapolated evidence from studies rated as 1++ or 1+

- **C**
  A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or
  - Extrapolated evidence from studies rated as 2++

- **D**
  Evidence level 3 or 4; or
  - Extrapolated evidence from studies rated as 2+
Appendix E

Timeline for the implementation of Evidence-based protocol on smoking cessation intervention for tuberculosis patients

Initial phase: Month 1

Implementation phase: Month 2-7

Evaluation phase: Month 8

<table>
<thead>
<tr>
<th>Tasks</th>
<th>Months</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>1 2 3 4 5 6 7 8</td>
</tr>
<tr>
<td>Request approval from the authority</td>
<td></td>
</tr>
<tr>
<td>Circulation of protocol &amp; multidisciplinary meeting</td>
<td></td>
</tr>
<tr>
<td>Training &amp; workshop sessions for nurses</td>
<td></td>
</tr>
<tr>
<td>Implementation of the intervention</td>
<td></td>
</tr>
<tr>
<td>Summarization of the progress</td>
<td></td>
</tr>
<tr>
<td>Outcome Evaluation</td>
<td></td>
</tr>
</tbody>
</table>
### Appendix F Cost calculation for the innovation

<table>
<thead>
<tr>
<th>Items</th>
<th>Calculation</th>
<th>Cost (HKD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>5 Manuals of the Innovation</td>
<td>$10/manual x 5 manuals</td>
<td>$50</td>
</tr>
<tr>
<td>2-day training session</td>
<td>5 sessions (10 days in total)</td>
<td>Each EN: From $1027.33 to $2183</td>
</tr>
<tr>
<td></td>
<td>For 25 RNs and 25 ENs:</td>
<td>Each RN: From $1785.67 to $2873.67</td>
</tr>
<tr>
<td></td>
<td>EN Monthly salary/30days x 2days : ($15410 to $32760)/30x2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>RN Monthly salary/30days x 2 days : ($26785 to $43105)/30x2</td>
<td></td>
</tr>
<tr>
<td></td>
<td>(per 2-day training session)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total cost for 25 ENs: From $25683.25 to $54575</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Total cost for 25 RNs: From $44641.75 to $71841.75</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Maximum budget=</td>
<td></td>
</tr>
<tr>
<td></td>
<td>$54575+$71841.75</td>
<td></td>
</tr>
<tr>
<td></td>
<td>=$126416.75</td>
<td></td>
</tr>
<tr>
<td>Health Education pamphlets and booklets</td>
<td>$5x 200 (for &gt;=180 patients and spare copies)</td>
<td>$1000</td>
</tr>
<tr>
<td>Implementation and evaluation of the protocol in each target patient</td>
<td>Month 0 (30mins): EN: From $15410/30/8/60x30 = $32.10</td>
<td>Total cost for each patient By EN: From $117.7 to $249.57</td>
</tr>
<tr>
<td>To</td>
<td>$32760/30/8/60x30=$68.06</td>
<td></td>
</tr>
<tr>
<td>----</td>
<td>-------------------------</td>
<td></td>
</tr>
<tr>
<td>RN: From</td>
<td>$26785/30/8/60x30=$55.80</td>
<td></td>
</tr>
<tr>
<td>To</td>
<td>$43105/30/8/60x30=$89.80</td>
<td></td>
</tr>
<tr>
<td>Month 6 (30mins): same as above</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Month 1/2/3/4/5 (10mins at each follow-up):</td>
<td></td>
<td></td>
</tr>
<tr>
<td>EN: From</td>
<td>$15410/30/8/60x10=$10.70</td>
<td></td>
</tr>
<tr>
<td>To</td>
<td>$32760/30/8/60x10=$22.69</td>
<td></td>
</tr>
<tr>
<td>RN: From</td>
<td>$26785/30/8/60x10=$18.60</td>
<td></td>
</tr>
<tr>
<td>To:</td>
<td>$43105/30/8/60x10=$29.93</td>
<td></td>
</tr>
</tbody>
</table>

By RN: From $204.6 to $329.45

Assume EN & RN handle 90 patients respectively:

Total cost for 90 patients by EN:

From $10593 to $22461.3

Total cost for 90 patients by RN:

From $18414 to $29650.5

Maximum budget:

$22461.3+$29650.5=$52111.8
Appendix G Recommendations

Target population:

Recommendation 1: prolonged smoking cessation support is recommended to high-intensity nicotine dependence.

Evidence:

- High-intensity nicotine dependence is less likely to quit when comparing to low-intensity dependence. (Siddique, Islam, Bam, Satyanarayana, Enarson, Reid, … Ishikawa, 2013)  
  C  
  2+

Recommendation 2: Assess the patient’s educational level to predict their readiness to cease smoking.

Evidence:

- Low educational level related to low smoking cessation rate. Campbell, Chaudhary, Holdsworth & Lyne, 2014  
  C  
  2+

Assessment:

Recommendation 1: smoking status should be assessed at least 4 times for 6 months during DOT visit.

Evidence:

- Patient’s smoking status determines the smoking cessation support provided. (Louwagie, Okuyemi & Ayo-Yusuf, 2014; Siddiqi, Khan, Ahmad, Dogar, Kanaan, Newell & Thomson, 2013)  
  A  
  1++
Planning:

Recommendation 1: brief advice for 15 to 30 minutes on smoking cessation should be provided to newly diagnosed TB patients who are current smokers during the first attendance at public health unit, and 5 to 10 minutes during each monthly follow-up visit.

Evidence:

- General and personalized brief advice provide to smokers during DOT have a significant effect on quit smoking rate. (Lin, Wang, Qiu, Huang, Shu, Lin, Meng, Zeng, Xiao, Bam & Chiang, 2015; Bam, Aditama, Chiang, Rubaeah & Suhaemi, 2015; Siddiquea, Islam, Bam, Satyanarayana, Enarson, Reid, … Ishikawa, 2013)

- Smoking cessation rate improved after the intervention, if it is in conjunction with bupropion, the combined intervention is not superior to the intervention alone. (Siddiquea, Islam, Bam, Satyanarayana, Enarson, Reid, … Ishikawa, 2013)

Recommendation 2: Element of motivation should be included in the intervention, including brief motivational interview (brief MI), and Ask, Brief advice and Cessation support

Evidence:

- High motivation is correlated to high treatment completion rate and low default rate. (Louwagie, Okuyemi & Ayo-Yusuf, 2014; Sony, Slama, Salieh, Elhaj, Adam, Hassan & Enarson, 2007)
Evaluation

Recommendation 1: using a self-report questionnaire or analyze patient’s breath by smokerlyzer to evaluate their smoking status have the same level of accuracy.

Evidence:

- No discrepancy noted in the self-report questionnaire and CO level measured by smokerlyzer throughout the whole intervention. (Awaisu, Mohamed, Noordin, Aziz, Sulaiman, Mutalif & Mahayiddin, 2011)
Appendix H: Patient Satisfaction Survey for Evidence-based Smoking Cessation

Intervention Protocol for Tuberculosis Patients

Date: ____________________  Surname: ____________________

*Please grade the following items according to your satisfaction towards the new protocol.

<table>
<thead>
<tr>
<th>Item No.</th>
<th>Description</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Slightly disagree</th>
<th>Slightly agree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The new protocol is beneficial to you</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>You feel good during the implementation of the new protocol.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Workload is acceptable throughout the implementation.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>The effect of cigarette withdrawal is manageable.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>You are confident that you can remain smoke-free after the new protocol.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>You are satisfied with the new protocol as a whole.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>
Appendix I: Nurse Satisfaction and Compliance Survey for Evidence-based Smoking Cessation Intervention Protocol for Tuberculosis Patients

Date:_________________ Name & Rank:_________________

*Please grade the following items according to your satisfaction and compliance towards the new protocol

<table>
<thead>
<tr>
<th>Item No.</th>
<th>The new protocol achieved its intended purposes.</th>
<th>Strongly disagree</th>
<th>Disagree</th>
<th>Slightly disagree</th>
<th>Slightly agree</th>
<th>Agree</th>
<th>Strongly agree</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td></td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>2</td>
<td>Training is adequate and clear; training material is easy to understand.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>3</td>
<td>Smoking cessation assessment form is understandable and easy to use</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>4</td>
<td>The daily routine is not severely impaired by the new protocol.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>5</td>
<td>The new protocol decrease workload among nurses consequently.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
<tr>
<td>6</td>
<td>You are satisfied with the new protocol as a whole.</td>
<td>1</td>
<td>2</td>
<td>3</td>
<td>4</td>
<td>5</td>
<td>6</td>
</tr>
</tbody>
</table>

Compliance
<table>
<thead>
<tr>
<th>Item No.</th>
<th></th>
<th>Yes</th>
<th>No</th>
<th>N/A</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Identify and recruit patient into new protocol according to inclusion criteria</td>
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<td>2</td>
<td>Obtain informed consent from eligible patient</td>
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<td>3</td>
<td>Explain to patient the benefit of smoking cessation during DOT</td>
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<td>4</td>
<td>Obtain patient’s smoking status at each visit</td>
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<td>5</td>
<td>Reinforce smoking cessation at the end of DOT</td>
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</tbody>
</table>

6. Did you encounter any difficulty during the implementation of new protocol? If, yes, please specify.

_____________________________________________________________________________
_____________________________________________________________________________
_____________________________________________________________________________

7. Any information you would like to add to the new protocol?

_____________________________________________________________________________
_____________________________________________________________________________

8. Please provide comment to improve the new protocol.

_____________________________________________________________________________
_____________________________________________________________________________
Appendix J: Cigarette consumption record for TB patient

Name:__________________________

Date:___________________________

If you have consumed cigarette, please record the amount for each day; please calculate the total amount and return this card to a nurse at the end of each month.

<table>
<thead>
<tr>
<th>Date</th>
<th>Cigarettes</th>
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Total:__________________________