Abstract of dissertation entitled

“A Health Education Program for Tuberculosis Patients”

Submitted by

TSE CHI YING

For the degree of Master of Nursing

The University of Hong Kong

August, 2012

ABSTRACT

Although effective anti-tuberculosis agents have been available for over thirty years, tuberculosis (TB) is still a global health concern and the incident rate in Hong Kong remains high. Directly Observed Therapy, Short-course (DOTS) strategy, in combination with patient education are proved to be more effective in reducing TB incidence than the DOTS strategy alone. However, there is a lack of evidence based protocol to guide nurses through the implementation of health education for TB patients.

This dissertation is a translational nursing research aims at developing an evidence-based health education guideline for nurses to deliver health education to TB patients to improve treatment adherence. The objectives are to gather evidence on the effectiveness of nursing health education in promoting treatment adherence among TB patients, conduct quality assessment of the reviewed articles, develop evidence-based health education protocol for TB patients, assess the implementation potential of the innovation and discuss its implementation and evaluation plan.
In this dissertation, a systematic review of 8 relevant and up-to-date research papers was performed and a guideline was then generated based on the extracted data. The guideline consists of 3 components: effective individual health education, essential elements for health education booklet and training for nurses. The implementation potential of the guideline is considered to be high while the implementation and evaluation plan of the guideline are also discussed.

With the implementation of the evidence-based protocol on TB health education, the treatment adherence of the TB patients is expected to be increased.
“A Health Education Program for Tuberculosis Patients”

By

TSE CHI YING

BNurs (CUHK)

A dissertation submitted in partial fulfillment of the requirements for

The Degree of Master of Nursing

at the University of Hong Kong

August 2012
DECLARATION

I declare that this dissertation represents my own works, except where due acknowledgement 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 qualifications.

Signed: ____________________

TSE CHI YING
ACKNOWLEDGEMENTS

I would like to acknowledge my supervisor, Dr Catherine Lo, from the School of Nursing at the University of Hong Kong, for her guidance and support in this dissertation.

May I also show my deepest gratitude to my family, friends and colleagues for their continuous and warm support during the completion of this paper. Sincere thanks should be specially given to my best friend, Vivien Wong Wan Chee, Trainee Clinical Psychologist (DClinPsy) at University College London, for her precious comments, support and encouragement during my writing process.
# TABLE OF CONTENTS

<table>
<thead>
<tr>
<th>Section</th>
<th>Page</th>
</tr>
</thead>
<tbody>
<tr>
<td>ABSTRACT</td>
<td>i</td>
</tr>
<tr>
<td>DECLARATION</td>
<td>iv</td>
</tr>
<tr>
<td>ACKNOWLEDGEMENTS</td>
<td>v</td>
</tr>
<tr>
<td>TABLE OF CONTENTS</td>
<td>vi</td>
</tr>
<tr>
<td>Chapter 1 INTRODUCTION</td>
<td></td>
</tr>
<tr>
<td>1.1 Background</td>
<td>1</td>
</tr>
<tr>
<td>1.2 Affirming the needs and significance</td>
<td>3</td>
</tr>
<tr>
<td>1.3 Research question, hypothesis and objective of the dissertation</td>
<td>5</td>
</tr>
<tr>
<td>1.4 Conclusion</td>
<td>6</td>
</tr>
<tr>
<td>Chapter 2 CRITICAL APPRIASAL</td>
<td></td>
</tr>
<tr>
<td>2.1 Search strategies</td>
<td>7</td>
</tr>
<tr>
<td>2.2 Appraisal strategies</td>
<td>10</td>
</tr>
<tr>
<td>2.3 Result</td>
<td>10</td>
</tr>
<tr>
<td>2.4 Data analysis</td>
<td>16</td>
</tr>
<tr>
<td>2.5 Conclusion</td>
<td>20</td>
</tr>
<tr>
<td>Chapter 3 IMPLEMENTATION POTENTIAL</td>
<td></td>
</tr>
<tr>
<td>3.1 Target setting and audience</td>
<td>21</td>
</tr>
<tr>
<td>3.2 Transferability of findings</td>
<td>22</td>
</tr>
<tr>
<td>3.3 Feasibility</td>
<td>25</td>
</tr>
<tr>
<td>3.4 Cost-benefit ratio of the innovation</td>
<td>29</td>
</tr>
<tr>
<td>3.5 Conclusion</td>
<td>31</td>
</tr>
</tbody>
</table>
Chapter 4  EVIDENCE-BASED PRACTICE GUIDELINE

4.1 Background é é é é é é é é é é é é é é é é é é é é é é . 32

4.2 Rating system for the strength of the recommendation é é é é é é é .......... 33

4.3 Recommendations é é é é é é é é é é é é é é é é é é é é é é ... 33

4.4 Conclusion é é é é é é é é é é é é é é é é é é é é é é ... 39

Chapter 5  IMPLEMENTATION PLAN

5.1 Communication plan é é é é é é é é é é é é é é é é é é é é é é 40

5.2 Pilot testing é é é é é é é é é é é é é é é é é é é é é é ............... 44

5.3 Conclusion é é é é é é é é é é é é é é é é é é é é é é 47

Chapter 6  EVALUATION PLAN

6.1 Outcomes to be achieved é é é é é é é é é é é é é é é é é é é é é é .......... 48

6.2 Demographics and number of clients to be involved é é é é é é é é é é é é 49

6.3 Data collection and analysis é é é é é é é é é é é é é é é é é é .......... 50

6.4 Basis for an effect change of practice é é é é é é é é é é é é é é é é 54

6.5 Conclusion é é é é é é é é é é é é é é é é é é é é é é .... 56

Chapter 7  CONCLUSION é é é é é é é é é é é é é é é é é é é é é é ......... 57

REFERENCES é é é é é é é é é é é é é é é é é é é é é é é é é é ......... 58

APPENDICES é é é é é é é é é é é é é é é é é é é é é é é é é é é é ... 65

TABLES é é é é é é é é é é é é é é é é é é é é é é é é é é é é . 81
CHAPTER 1
INTRODUCTION

Although effective anti-tuberculosis agents have been available for over thirty years, the incident rate of the disease is still increasing (Corbett et al., 2003). Directly Observed Therapy, Short-course (DOTS) strategy, the central pillar of global tuberculosis (TB) control (Raviglione & Pio, 2002), in combination with patient education are proved to be more effective in reducing TB incidence than the DOTS strategy alone (Vlomink & Garner, 1997).

This chapter will cover background information about TB disease control, the significance and need of practice change in TB patient health education, and the aim and objectives of this dissertation.

1.1 BACKGROUND

1.11 Epidemiology of TB in the world

Tuberculosis is a global health concern and the incident rate of the disease is still increasing over the years. According to the recent report from the World Health Organization (WHO), there are 9.4 million incident case worldwide in 2009 (WHO, 2010), which is higher than the 8.9 million incident case in 2004 (Dye, 2006). Because of the long duration of standard TB treatment, which generally lasts for at least six months, there is a risk of treatment default (Jakubowiah, Bogorodskaya, Borisov, Danilova & Kourbatova, 2009). Such problem of low treatment adherence may result in the emergence of resistant strains of mycobacterium tuberculosis, increasing mortality and prolonging the treatment duration.
According to a systematic review of qualitative research, there are four main structural factors affecting the adherence of TB patients. They are poverty and gender discrimination, social factors, health service factors and personal factors, including one's knowledge, attitude and beliefs of the treatment and its side effects, as well as the interpretation of illness and wellness (Munro, Lewin, Smith, Engel, Fretheim, & Volmink, 2007).

Directly Observed Therapy, Short-course (DOTS), a strategy that require patient to visit health workers and to be observed to take a dose of medication everyday or every alternate day is recommended and considered to be the most effective method for increasing treatment adherence (WHO, 2001). However, researchers indicate that the DOTS strategy alone is not adequate. A systematic review suggested that the effect of the DOTS strategy can be strengthened by combination with other interventions, such as provision of health education and incentives (Vlomink et al., 1997).

1.12 Epidemiology TB in Hong Kong

According to the report from the World Health Organization (WHO, 2010), the Hong Kong Government has granted US$ 23 millions to the TB and chest service in 2010. Despite the large sum of money being put to control the disease, the incident rate and the treatment success rate of the disease do not meet with the target set by WHO. According to the WHO (2010) report, incident rate of TB is considered to be high when there are more than 20 cases
per 100,000 population per annum while the incident rate in Hong Kong in 2009 was four times the figure (WHO, 2010), at 82 cases per 100,000 population. Moreover, the treatment success rate in Hong Kong of 68% in 2008, is considered as low when compared to the WHO’s expected standard of treatment completion rate of 85% (WHO, 2010). This phenomenon is in line with Chang, Leung, Yew, Ho and Tam’s (2004) study where the data obtained from the computer registry of TB patients in Hong Kong during period of 1998 to 2000, indicated that the treatment completion rate of only 70%.

1.2 AFFIRMING THE NEED AND SIGNIFICANCE

1.21 Affirming Needs - Tuberculosis Control in Hong Kong

In Hong Kong, DOTS strategy has been employed on a government service basis since the late 1970s. TB patients have the option of attending any chest clinic of the Department of Health and intake the TB medication under supervision of nurses everyday or every alternative day free of charge (Tam, 2006). Although this strategy has been implemented for over thirty years, the treatment completion rate and incident rate fail to meet the WHO standard as discuss previously.

Over the years, DOTS programme has evolved to adopt a multipronged approach which includes the provision of patient health education, incentives, client-focused regimens, defaulter tracing and referral of social support (Tam, 2006). Health education in particular, there is still a lack of evidence based protocol to guide nurses through the implementation of
health education. This is evident in the researcher’s own clinical experience, the chest clinic has not developed tools and guidelines to aid nurses’ implementation of health education to patients who are newly diagnosed with or proved to be infected by TB.

1.22 Significance of the Study

In order to improve treatment adherence of TB patients, a systematic review indicates the need for the service providers to tailor a localized patient-centred program which is specifically suitable for a unique cultural and social belief of the community as opposed to a single world-wide intervention (Noyes & Popay, 2006). This study also suggested that one of the causes of TB patients disengaging from treatment is healthcare professionals’ failure to listen and response to patients’ misconceptions of the TB treatment and the disease (Steyn, van der Merwe, Dick, Borcherds & Wilding, 1997). Intervention should be designed to change the professional practice and organization of care so that good relationship and communication between professional and clients can be achieved (Dick, Lewin, Rose, Zwarenstein & van Der Walt, 2004). In order to ensure the most effective and up-to-date nursing health education for TB patient to improve treatment adherence, a review of recent and related studies is essential to the Hong Kong health care system.

To conclude this section, an integrated review of nursing health education to tuberculosis patient to increase treatment adherence and success should be conducted, so that an evidence based guideline can be developed.
1.3 RESEARCH QUESTION, HYPOTHESIS AND OBJECTIVES OF THE DISSERTATION

The research question, aim and objective of this dissertation formed basis the literature search. Using the PICO framework (Sackett, Richardson, Rosenberg & Haynes, 1997), the current literature search focuses on four areas, population, intervention, comparison and outcome.

1.31 Research Question

Does an evidence-based nursing health education program increase the treatment adherence among TB patients?

1.32 Hypothesis

Subjects who receive the proposed education intervention will be more adhered to the TB treatment than subjects who do not receive it.

1.33 Objectives

1. To gather evidence on the effectiveness of nursing health education in promoting treatment adherence among TB patients.

2. To conduct quality assessment of the reviewed studies.

3. To develop evidence-based nursing education programme for TB patients using the evidence obtained.

4. To assess the implementation potential of the protocol.
1.4 CONCLUSION

An evidence based protocol to guide nurses' deliverance of health education to promote patients' TB treatment adherence in Hong Kong is essential for the disease control. A systematic and integrative review of recent high quality evidence should be conducted in order to achieve the proposed objective.
CHAPTER 2
CRITICAL APPRAISAL

Having affirmed the need to develop an evidence-based nursing health education to tuberculosis (TB) patients to promote treatment adherence, database searching strategy for relevant literature and criteria for critically appraising the studies will be described in this chapter. This will be followed by the quality assessment, summary and synthesis of data.

2.1 SEARCH STRATEGIES

2.1.1 Database Search

The primary search was carried out in the electronic database from October, 2010 to 24th August, 2011. A search for clinical guidelines was conducted in the National Guidelines Clearinghouse, CMA infobase, Guidelines advisory guidelines, Health service/technology assessment text, National Institute for Clinical Excellence (NICE), Scottish Intercollegiate Guidelines Network (SIGN), New Zealand Guideline Group and Cochrane Library. Despite the vast number of sources, no relevant guideline was yielded.

The systematic search continued with four electronic engines, PubMed (1950-2011), Cumulative Index of Nursing and Allied Health Literature (CINAHL) (Ovid SP) (1975-2011), British Nursing Index (1994-2011) and Medline (Ovid SP) (1948-2011). Detailed database and keyword searches were illustrated in Appendix A.
2.12 Selection Criteria

Inclusion and Exclusion Criteria

The systematic search of the empirical evidence is confined to studies that involve adult TB patients who were treated in outpatient setting. Two groups of pulmonary TB patients were included: those receiving first time standard treatment and those receiving treatment for latent infections. Both groups share identical treatment duration and frequency yet difference is found in the dosage of medication administered, where latent TB patients tend to receive a smaller dosage of medication than typical TB patients. Munor et al. (2007) systematic review, however, indicated that side effects do not influence one’s decision to abandon treatment but the lack of knowledge and attention about the side effects given by health care workers. Thus both groups of patients are included since the dosage of medication does not affect the treatment adherence of patients.

TB patients who were hospitalized or institutionalized throughout the course of treatment would be excluded as higher their treatment adherence is anticipated under supervision of the institution. Patients with other or multiple site of TB infection, recurrent or multiple drug resistant TB who receive second-line TB treatment would also be excluded as the treatment duration is usually longer than typical TB patients. Moreover, patients with mental and psychiatric problems, cognitive dysfunction or infected with human immunodeficiency virus (HIV) were also excluded since there could be confounder that
would affect the results.

**Intervention**

Health education to tuberculosis patients.

**Outcome measures**

1) The difference in treatment adherence rate of the TB patients.

2) The difference in treatment success rate of the TB patients.

3) The change in patient’s knowledge on TB.

**2.13 Keywords used**

Database search was done using the keywords “pulmonary tuberculosis”, “health education”, “treatment adherence” and “treatment compliance”. Further keywords were identified from the abstracts or keywords of the identified studies including “treatment outcome”, “treatment success”, “patient knowledge” and “education booklet”. Different combination of keywords was used to yield relevant studies and searching was stopped when no additional publication appeared in the reference list.

**2.14 Retrieval of References and Handling**

The number of studies searched ranged between 25 to 1734 results from the four engines. The topics and abstract were checked according to the inclusion and exclusion criteria as mentioned above. After integrated the studies yielded without overlapping and the reference lists of the selected studies were also followed up. Finally, eight articles were selected and
will be discussed in details in the chapter 2.3.

2.15 Extraction of Evidence

Data extracted from the selected studies were presented in the form of tables of evidence with reference to the table of intervention studies of the Scottish Intercollegiate Guidelines Network (SIGN) (Scottish Intercollegiate Guidelines Network, 2008). The details of the tables of evidence of each study were illustrated in Table 1.

2.2 APPRAISAL STRATEGIES

Critical Appraisal and Rating Scheme for quality assessment of studies

The methodological qualities of the eight studies were critically appraised using sections 1 and 2 of the appraisal checklist of SIGN (2008), which were illustrated in Table 2. The appraisal checklists 1, 2, 3 and 4 were used in this dissertation. However there was no checklist for cross-sectional per-experimental study, the methodology checklist 4, which was the most suitable, was used instead. The notes concerning the 4 appraisal checklists were shown in Appendix B. After the critical appraisal, the levels of evidence of the eight studies were assigned according to SIGN (2008). The key for grading was presented in Appendix C.

2.3 RESULTS

2.31 Overview of study characteristics

The eight selected studies consisted of one systematic review (Volmink et al., 1997), three randomized control trials (RCTs) (Leifooghe, Suetens, Meulemans, Moran & De
Muynck, 1999; Nyamathi, Christiani, Nahid, Gregerson & Leake, 2006; White, Tulsky, Goldenson, Portillo, Kawamura & Menendez, 2002), one descriptive cohort study of one of the selected RCT done by White et al. (2002) to evaluate the translation of the result into practice (White, Tulsky, Menendez, Arai, Goldenson & Kawamura, 2005), two case control studies (Clark, Karagoz, Apikoglu-Rabus & Izzettin, 2007; Dick & Lombard, 1997) and one pre-experimental cross-sectional study (Ailinger, Martyn, Lasus & Garcia, 2010). The studies were conducted in the United States of America, South Africa, Turkey and Pakistan.

2.32 Summary of quality assessment and data obtained

2.32.1 One Systematic review of RCTs

Systematic review of RCTs is being considered as the most powerful in the hierarchy of evidence (Craig & Smyth, 2007). Volmink et al.’s (1997) systematic review was chosen as it remains the only systematic review of RCTs that look at strategies for increasing TB treatment adherence. The review was at the evidence level of 1+, where the focused question, usage of keywords and methodology for literature review of the study were well covered. The searching strategy and quality assessment of the selected studies of the review were however inadequately addressed. The review article indicated that education in combination with other strategies such as direct observe therapy and incentives could significantly improve treatment adherence in TB patients. However the effect of education as a stand-alone treatment on treatment adherence was unclear.
2.322 Three Randomized Controlled Trials

The three RCTs were at the level of evidence from 1++ to 1+. All of the three studies had provided clear background information and well covered the research question of the studies. Two studies (Leifooghe et al., 1999; White et al., 2002) clearly stated the randomization sampling procedure yet only one study adopted allocation concealment. Due to nature of the treatment, it was infeasible to blind the nurses and counsellors who provided intervention to the participants. It is however possible to blind the participants as demonstrated by Leifooghe et al. (1999) study in spite of debatable ethical concerns. All of the studies detailed the result measurement and all outcome variables were well defined. The sample sizes of the three studies were large, ranged from 520 to 1078, but only one study (White et al., 2002) presented the sample size calculation using statistical power analysis with sufficient power of 0.8. All three studies reduced selection bias by ensuring equivalent groups. Tests of homogeneity (Levene Test, where p-value >0.05) that compared the intervention and control groups baseline demographic data indicated no pre-existing significant difference between the intervention group and the control group. Any post hoc differences detected were thus likely to be the effect of the intervention.

One of the studies focused on TB patients (Leifooghe et al, 1999) while two of the studies focused on latent TB patients (Nyamathi et al, 2006; White et al, 2002). The study conducted by Leifooghe et al. (1999) with evidence level of 1++, found significantly lower
drop out rate among patients who received individual counselling and education during follow up than those who did not. The impact of education was also found to be stronger in women; those who were not the main provider of the family; with poor knowledge of the disease and with shorter delay of treatment.

White et al.â€™s study (2002) with the evidence level of 1++ indicated significantly higher rate of community follow up attendance and treatment completion rate among latent TB infected jail inmates who received education intervention before released from jail than those in the incentive group and the control group.

Nyamathi et al.â€™s study (2006) with the evidence level of 1+ found higher rate of treatment completion and the improvement in TB knowledge in homeless latent TB patients who received nurse case-managed education with defaulter tracking over a six months treatment programme when compared to those who received only one lecture on TB knowledge at the time of diagnosis. However, results should be interpreted cautiously with consideration to potential treats to internal validity. This may include the use of defaulter tracking in the intervention group as a possible confounding factor and bias (e.g. attribution and social desirability) among self-report measurement.

**2.323 Descriptive cohort study of the RCT by White et al. (2002)**

The descriptive cohort study by White et al. (2005) with the level of evidence of 2+ was the study to evaluate the translation of the results from one of the selected RCT by White et al.
(2002) into practice. The focus question and the background information were well covered. The outcome variable and the assessment method were also well defined.

The rates of treatment completion of the two cohort were compatible but the rate of first visit to the TB clinic after released from jail was significantly less in the cohort of the study conducted in 2005 than the one conducted in 2002. The study indicated that the result of the RCT by White et al. (2002) could be translated into practice. However, the authors suggested that differences in personnel administering the protocol and training, high turnover rate of staffs and lack of time to provide health education as possible factors affecting accounting for the change in results. The authors also suggested that researcher should collaborate with clinicians to develop a protocol so the results from tightly controlled randomized trial can be replicated in the real setting.

2.324 Two case-control studies

The levels of evidence of the two case-control studies ranged from 2+ to 2++. Both studies had well defined the focus question with TB patients represented in both case and control groups. Participants of case and control groups of both of the studies are comparable, however only study conducted by Dick et al (1997) had presented with demographic data of the two groups.

Clark et al. study (2007) with level of evidence of 2+ found significantly higher rate of attendance at follow up and general treatment adherence among patients receiving oral and
written health education by pharmacists as well as routine nursing and medical care when compared with patients receiving only routine nursing and medical care. The article also indicated essential information that should be included in education booklet issued to participants during the interventions.

Study conducted by Dick et al. (1997) was at the level of evidence 2++ indicated that the treatment adherence rate of patients receiving health education counselling and booklet was significantly higher than those patients receiving no intervention.

2.325 One cross-sectional study

The cross-sectional study conducted by Ailinger et al. (2010) was at the level of evidence 2+. The study had presented the focused question with adequate background information of the issue. The intervention and control groups were comparable since the control was the cohort of patients who were treated in the same clinic and with the same ethnicity as the intervention group. The demographic data of the two cohorts were also presented. However, the outcome measure was by self-report from the participants where potential bias could not be ruled out. No confounders was identified or discussed by the author.

The study indicated significantly higher adherence to treatment would be found in intervention group who had received culture-specific health education and culturally relevant education material when compared to those who had received no intervention.
2.4 DATA SYNTHESIS

After extracting, summarizing and performing quality assessment of the eight selected studies, important data were synthesis according to the objectives, hypothesis and aim of this integrative review.

2.41 Individual health education

All of the selected studies recommended education intervention to be delivered in the form of individual counselling with variation in the frequency of the educational intervention across the eight studies. Four studies (Ailinger et al., 2010; Leifooghe et al., 1999; Nyamathi et al., 2006; Volmink et al., 1997) recommended education intervention to be conducted during patients’ monthly follow up appointments in outpatient clinics, with additional interview provided by Leifooghe et al. (2007) and Nyamathi et al. (2006). Whereas White et al (2002; 2005) held education sessions fortnightly before the patients were released as an outpatients and Clark et al. (2007) and Dick et al. (1997) suggested an one-off education intervention after the diagnosis of the disease. With the highest number of studies recommendation, education intervention delivered each time of follow up visit was recommended since it was the most feasible and effective intervention which was supported by high level of evidence.

Most of the studies did not indicate the duration of each education session. For those that indicated, Nyamathi et al. (2006) suggested each session to last for an hour while White et al.
(2002) suggested that each session to last for only 10 to 15 minutes. This variation suggested that health education might be more helpful to tailor-made and the standardization of treatment duration may not be necessary as the interaction between patients and nurses varies in different situations.

Moreover, as recommended by Ailinger et al. (2010) and Nyamathi et al. (2006), culturally-specific education intervention would increase treatment adherence and would develop rapport between nurses and patients.

2.42 Component of the health education session

After integrating all the data obtained from the eight studies, five main components were extrapolated to be incorporated into health education intervention to TB patients.

The first component is to provide essential facts about the disease. Study conducted by Leifooghe et al. (1999) suggested that important information about the diagnosis of the disease and the treatment regimen should be provided to patients so that misconception about the disease can be minimized.

The second component is to provide information addressing the importance of and potential barriers to treatment adherence as recommended by Dick et al. (1997) and Leifooghe et al. (1999). This is essential for patients to understand that adhering to treatment regimen would help control the spreading of the disease and to prevent the emergence of resistant strains of tuberculosis.
The third component is to provide information concerning possible adverse effect of the medication as suggested by Clark et al. (2007) and White et al. (2002). Adverse effects such as drug-induced skin itchiness and symptoms of nausea and vomiting should be discussed and suitable intervention to deal with such side effects should be presented to patients so that when they encountered the adverse effect during treatment, they would seek medical help instead of defaulted from treatment.

The fourth component is to provide emotional support to patient during health education intervention as recommended by Dick et al. (1997) and Nyamathi et al. (2006). Emotional support should be delivered to patients by means of reinforcement through counselling. This is based on the principles of the theory of social learning so that the treatment adherence would be promoted.

The last component is to encourage social support from family and friends as recommended by Leifooghe et al. (1999) and Nyamathi et al. (2006). With positive social networks and relationships, patient could maintain behavior change to adhere to the treatment regimen.

2.43 Health education booklet

Four of the selected studies recommended the issuing of health education booklet to patients in combination with verbal health education. After integrating all the data from the studies, four main characteristics of the health education booklet were identified.
First, information such as essential information concerning the disease, the nature of transmission and treatment available should be provided to patients as recommended by Ailinger et al. (2010), Dick et al. (1997) and White et al. (2002) so that misconception concerning about the disease can be clarified. Possible adverse effects of the medication and action to be taken if adverse reaction emerged should also be included as recommended by Clark et al. (2007) so that patients encountering adverse reaction after the medication can adopt appropriate action including seeking medical help could be taken instead of defaulting from treatment.

Secondly, the booklet should be written in simple and clear manner. According to the studies conducted by Ailinger et al. (2010) and Clark et al. (2007), the booklet should be written in low literacy and could be illustrated in question and answer format, so that information could be delivered effectively to patients of all education background.

Thirdly, information could be delivered in the form of pictures or photographs as recommended by Ailinger et al. (2010) and Dick et al. (1997) so that information about the disease could be more easily adopted by patients through cognitive stimulation. This can also aid patient’s understanding in spite of minimal educational level.

Lastly, the design of the booklet should provide motivational support to patients as recommended by Ailinger et al. (2010) and Dick et al. (1997) with aid of a positive proverb or slogan, so that patients could be motivated to adhere to treatment and follow up.
consultation.

2.44 Staff training

Three of the selected studies had incorporated staff training into the study design. Such staff training were intensive and focus on facilitating the staff’s knowledge on the disease and treatment (Leifooghe et al., 1999; White et al., 2005), strengthening the communication skills of staffs (Dick et al., 1997), introducing intervention to promote motivation and social support of patients (Leifooghe et al., 1999) and practising the skills through role playing (White et al., 2005).

2.5 CONCLUSION

After the systematic review and quality appraising the current studies concerning about health education to TB patients to promote treatment adherence, it was concluded that an evidence based guideline on a one-to-one verbal and written health education to patients which consist of providing essential information about the disease, promoting emotional and social support should be developed.
CHAPTER 3

IMPLEMENTATION POTENTIAL

The previous chapters have shown the urgency to develop an evidence-based health education for tuberculosis (TB) out-patients to promote their treatment adherence.

In this chapter, the implementation potential of the guideline would be discussed in terms of target setting, target audience, transferability of the findings, feasibility and the cost-benefit ratio of the innovation (Polit & Beck, 2008).

3.1 TARGET SETTING AND AUDIENCE

3.11 Target setting

The guideline is suggested to be held in the TB and chest clinics of the Department of Health in Hong Kong, with a chest clinic selected as the pilot clinic. The TB and chest clinics in Hong Kong provide medical services to about two thousand TB patients every year and there are more than one hundred patients receiving direct observed treatment (DOT) in each clinic daily (Department of Health, 2009). These services also provide contact checking to TB patients’ relatives to identify latent TB infection as an epidemiological measure and provides care to patients with other respiratory diseases.

In the pilot clinic, there are 10 nursing staff who are working, including one nursing officer, five registered nurses and four enrolled nurses.
3.12 Target audience

The target audience of the proposed innovation includes all out-patients who are:

- aged 18 or above
- diagnosed with active pulmonary TB or latent TB infection
- receiving standard or prophylactic treatment
- not diagnosed with multiple drug resistant TB
- not diagnosed with HIV infection

3.2 TRANSFERABILITY OF FINDINGS

The transferability of findings from the reviewed articles will be discussed in terms of setting, philosophy of care, number of patients who will benefit from the innovation and the time required to implement and evaluate the innovation as suggested by Polit and Beck (2008). The criteria to evaluate the transferability of findings are shown in Appendix D.

3.21 Setting and audience

All of the eight reviewed studies were conducted in outpatient clinics, which is similar to the target setting. The participants of the reviewed studies were also compatible to the target audience. The population of all of the review studies was adult except the systematic review conducted by Volmink and Gamer (1997), which include patients of all age. The ethnicity of all of the review articles was mixed, which include Asian, Black, White and Latino except two studies which only focused on one ethnic group (Ailinger et al., 2010;
Leifooghe et al., 1999). Gender criteria were not involved in the review papers and all of the studies recruited male and female patients, which were similar to Hong Kong setting as it provided services to patients of both gender with different ethnicity. Patients in the reviewed studies were also similar to the target audience in terms of diagnosis and treatment of the disease. Three of the review articles studied patients with active pulmonary TB (Clark et al., 2007; Dick et al., 1997; Leifooghe et al., 1999) while four of them studied patients with latent TB infection (Ailinger et al., 2010; Nyamathi et al., 2006; White et al., 2002; White et al., 2005). In the systematic review conducted by Volmink and Garner (1997), the authors analyzed articles which were conducted on patients with active or latent TB infection. All of the patients in the review articles received standard or prophylactic treatment for six months which is the same as the target audience. Therefore, the characteristics of setting and populations in the review articles were similar to the target group and the findings were highly transferable to the patients in the proposed setting.

3.22 Philosophy of care

One of the components of the “stop TB strategy” which is established by the World Health Organization (2006), is to encourage patients to engage and adhere to the direct observed treatment. To act accordingly, Hong Kong tuberculosis control program of the Department of Health aims to provide effective treatment to active and latent TB patients as well as promote knowledge about the disease through health education (Department of Health,
2006). Based on the above principles, the primary goals of nursing care in the target setting are to promote drug compliance of patients, control the spread of the disease, promote evidence-based practice, build a good nurse-patients relationship and to promote patients' knowledge of the disease.

The philosophy of care of the proposed innovation is coherent with that of the target setting, this is in congruent to the objective of all of the reviewed articles that promote drug compliance of active or latent TB patients through the provision of health education. Previous studies have also shown a significantly increase in attendance of follow up of patients after health education which will help control the spread of the disease (Clark et al., 2007; White et al., 2002; White et al., 2005). Moreover, study conducted by Nyamathi et al. (2006) also found that patients who received case-managed health education improved significantly in TB knowledge than those who did not. Thus, evidence to date suggests that with an increase in treatment adherence, follow-up attendance and knowledge of the disease, the spread of the disease can be controlled. The objective to control the spread of the disease can possibly be achieved in this current study through the implementation of the innovation.

3.23 Number of patients who would be benefit

Every year there is around two thousand TB patients received care from the TB and chest clinics (Department of Health, 2009). Since every active or latent TB patient under the care of the TB and chest clinic would receive health education as suggested by the innovation,
a significant number of patients could benefit from the proposed implementation in this study. Transferring the findings of the review studies to the target setting is therefore highly recommended.

3.24 Duration of implementation and evaluation

The implementation of the innovation is estimated not to require any extra manpower and it will utilize from the day when the patient was diagnosed with the disease until the end of finished the whole course of standard treatment. Hence the length of implementation and evaluation would be six months which is consistent with the duration of implementation and evaluation of all of the review studies.

3.3 FEASIBILITY

The feasibility of the innovation will be discussed in terms of organizational climate, administrative support, the availability of nursing staff, resources and the degree of collaboration among different departments of the target setting as suggested by Polit and Beck (2008). The criteria to evaluate the feasibility of the utilization are shown in Appendix D.

3.31 Organizational climate

The target setting provides a positive organizational climate which encourages evidence-based practices and research. Its academic excellence is evident by robust number (at least 10) of articles being published and co-authored by medical officers of the TB and
cheast clinic and public chest hospitals. Academic works are frequently accepted for
publication in renowned international journals which include the *American Journal of
Respiratory and Critical Care Medicine* and the *International Journal of Tuberculosis and
Lung Disease*. The service has also produced tuberculosis manual and guidelines to guide
medical staffs’ practice which indicates the organization’s commitment to evidence-based
practice. The department also sponsors and encourages nurses to undertake various nursing
care projects and to pursue master level of education. This results in the development of
numerous evidence-based nursing guidelines which has huge contribution to the continuous
development of the nursing profession.

### 3.32 Administrative support

The target setting is run by nursing officers, public health nurse specialists and nursing
staff who initial various evidence-based nursing innovations under the leadership of senior
nursing officer. For instance, the service has successfully incorporated an infection control
checklist to ensure nurses’ adherence to infection control principles. Also, the senior nursing
officer has recently invited the nursing staff to review the nursing manual of the service,
dated from 2004 and encouraged all to incorporate evidence-based practice guidelines into
the manual in order to ensure high quality of nursing practice.

With administrative support and a relatively straight-forward innovation implementation
which does not requires additional materials and manpower, it appears feasible to obtain the
approval for the proposed guidelines. However, consensus should be obtained from all the stakeholders and administration, and a comprehensive presentation of the evidence, framework of the guideline, budget and schedule plan should be produced. The details of the communication plan will be discussed in chapter 5.

3.33 Availability of nursing staff

The availability of nursing manpower is an important element when considering the implementation potential of the innovation. The proposed guideline does not require additional workload as it is already within the protocol of current practice, where nurses regularly deliver health education when they interview patients during follow up consultation. There are also adequate numbers of experienced nurses practising in the service. According to the annual report of the tuberculosis and chest service (Department of Health, 2009), there are a total of 166 nurses working for the service, including 1 senior nursing officer, 12 nursing officers, 70 register nurses and 83 enrolled nurses. Among the 10 nursing staffs working in the pilot clinic, 7 of them have serviced the department for more than 10 years, and 3 of them are public health nurse specialists, hence they are well experienced to deliver health education to patients.

3.34 Availability of resources

Resources are readily available in the service including interviewing room, computers, projector, printers and microphone. The outcome measuring tools are available as a computer
registry system to accurately record the treatment attendance of patients during their daily attendance to the clinic for medication. The rate of treatment adherence can then be calculated using the formula of dividing the number of doses of medication taken by patient over the number of doses of medication being prescribed by medical officers (Clark et al., 2007; Dick et al., 1997). With the resources available in the service, the innovation is highly feasible to be translated into the target setting.

3.35 Collaboration among departments

It is highly feasible as patients regularly attend the chest clinic for follow-up appointments as part of the current established treatment, no additional arrangement is required.

The medical officers of the service are unlikely to be a potential resistance since the innovation does not involve any change of their practices. Moreover the implementation of evidence-based practice and research is supported by the medical officers as discussed previously. A high degree of consensus can be obtained among the medical colleagues is thus anticipated.

However, a review of the existing booklets is required, where reprinting of the material is expected. Thus, actions is needed to collaborate with the Government Logistics Department which is responsible for the printing all materials within the Hong Kong Government. This can be done with the executive support from the senior nursing officer and
the executive officer of the service.

3.4 COST-BENEFIT RATIO OF THE INNOVATION

The cost and benefit ratio of the innovation will be discussed in reference to potential risk of the patients, potential benefit of the innovation, risk of maintaining current practice, the material and non-material cost of the innovation as suggested by Polit and Beck (2008). The criteria to evaluate the cost and benefit ratio are shown in Appendix D.

3.4.1 Potential risk of patients and potential benefit of the innovation

Cost-benefit analysis is required to weight up the potential risk of patient and the potential benefit of the innovation.

The potential risks of patients are minimal as the innovation does not involve any change of the medical procedure. However, the length of time required for the interviews between patients and nurses may increase when compare to the current practice.

As evidenced by all the review articles, patients are likely to benefit from the innovation as health education is found to increase treatment adherence and treatment completion. The knowledge about the disease of the patients will be improved (Nyamathi et al., 2006) as well as better social and emotional support from family, friends and nurses (Ailinger et al., 2010). Hence the implementation of the innovation is anticipated to improve treatment outcome, social and emotional wellbeing of the patients.

Nursing staff can also benefit from the innovation. Better treatment adherence of
patients implies lesser number of patients defaulting from treatment. This will in turn reduce the amount of time spends on tracing patients. Nurses will also acquire further specialist knowledge on the disease upon completion of staff training and their job satisfaction is likely to increase as the implementation of evidence-based innovation allows nurses with greater autonomy in independent decision making (Cullum, Ciliska, Haynes & Marks, 2008).

3.42 Risk of maintaining current practice

According to the report from the World Health Organization (WHO, 2011), the Hong Kong Government granted US$ 25 million to the TB and chest service in 2011 as compare to US$ 23 million in 2010. Despite of an increase in budget, the incident rate of TB in 2011 only slightly decreased to 80 cases per 100,000 population as compare to 82 cases per 100,000 population in 2010. The report also indicates that the Hong Kong Government has spent more than US$ 4000 on each TB patients for the free medication and consultation (WHO, 2011). Without changes to the current practice, low treatment adherence with high incident rate will remain and will continue to cause huge financial burden to the health care system.

3.43 Material and non-material cost

Material and non-material costs for the innovation are minimal when compare to the huge health care expenses. Its potential benefits such as improvement in treatment outcome and patients emotional wellbeing is invaluable. As discussed, equipments are readily available in the service. The cost of reprinting and design of the review booklet is estimated
to be around $1000. The training cost of the nursing staff is estimated to be around $5000.

One nurse from each clinic would receive a two-hours training session and would then act as the trainer of their clinics to provide in-house training sessions to their colleagues during working hours.

Potential nonmaterial costs of the innovation may include frictions among nurses and an increase in stress and anxiety due the change of current practice. Possible remedies include prioritising communications among nursing staff to help relieve stress and anxiety and adopting appropriate timing and pace to promote acceptance and compliance of the change in practice. The implementation plan would be discussed in details in chapter 5.

3.5 CONCLUSION

To conclude this chapter, the proposed utilization appears to be highly transferable and feasible, with potential benefits outweighing the potential risk of the innovation. Implementation is thus recommended.
CHAPTER 4

EVIDENCE-BASED PRACTICE GUIDELINE

After the presentation of the significant evidence and the discussion of the implementation potential of the proposed innovation, an evidence-based clinical guideline on health education for tuberculosis (TB) patients to promote treatment adherence was developed.

4.1 BACKGROUND

In response to the high incident rate of TB and low treatment adherence rate of TB patients, an evidence based guideline on health education to promote treatment compliance is suggested.

Purpose of the guideline:

Provide evidence-based health education to TB patients to promote treatment adherence.

The objectives of the protocol are:

1. To promote treatment adherence of TB patients through evidence-based health education

2. To increase the nurses’ awareness of the importance of health education on treatment adherence of patients

3. To assist nurses to integrate the best available evidence into clinical practice

Target user of the protocol: Nurses working in the TB and chest clinic
Target population of the protocol:

- Aged 18 or above
- Diagnosed with active pulmonary TB or latent TB infection
- Currently receiving standard or prophylactic treatment

Name of the protocol:

Evidence based guideline on health education for TB patients to promote treatment adherence

4.2 RATING SYSTEM FOR THE STRENGTH OF THE RECOMMENDATIONS

The recommendations are generated and synthesized from the reviewed evidence, hence the grades of recommendations are determined by the level of evidence of the reviewed studies. The grade of each recommendation is assigned according to SIGN (2008) and the key for grading is presented in Appendix E.

4.3 RECOMMENDATIONS

The recommended practice consists of an illustration of all essential elements of the three components of the programme: the provision of individual health education, designing of the booklet and staff training programme for nurses.
Component 1: Individual health education

Recommendation 1.1

To present facts about the etiology of disease (Grade A)

Evidence:

Provide knowledge concerning the transmission and curability of the disease is an essential component of counseling as suggested by the principle of social-cognitive learning theory. (Ailinger et al., 2010; Leifooghe et al., 1999) (2++; 1++)

Recommendation 1.2

To address the importance of and potential barriers to treatment adherence (Grade A)

Evidence:

Provide information concerning the potential barriers to completing treatment and the correct understanding of drug intake is another important component of counselling, which is based on the principle of social learning theory. (Dick et al., 1997; Leifooghe et al., 1999) (2++; 1++)

Recommendation 1.3

To provide information concerning possible side effects of the medication (Grade A)

Evidence:

Adverse effects including drug-induced skin itchiness, nausea and vomiting should be addressed and recommended actions should be discussed. This will prepare patients for any
potential encounters with side effects and to encourage seeking medical advice instead of defaulting from treatment. (Clark et al., 2007; White et al., 2002) (2+; 1++)

Recommendation 1.4

To encourage social support from patients’ families and friends (Grade A)

Evidence:

Positive relationships and social network can help patients maintain behaviour change (Nynamthi et al., 2006) (1+); Families and friends could act as source of motivation and to monitor patients’ drug intake. (Leifooghe et al., 1999) (1++)

Recommendation 1.5

To provide emotional support to patients (Grade B)

Evidence:

Based on Social Learning Theory, nurses can provide emotional support to patients by sharing expectations of treatment and offering reinforcement. (Dick et al., 1997; Nyamathi et al., 2006) (2++, 1+)

Recommendation 1.6

To deliver the educational session in a culturally specific manner (Grade C)

Evidence:

Culturally appropriate care and approaches are essential to increase treatment adherence in TB patients. (Ailinger et al., 2010; Nyamathi et al., 2006) (2+; 1+)
Component 2: Booklets

Recommendation 2.1

To illustrate essential facts concerning the disease, including the etiology of the disease and possible adverse reaction of the medications (Grade A)

Evidence:

Information concerning the nature of transmission and available treatment should be provided to avoid misconception (Ailinger et al., 2010; Dick et al., 1997; White et al., 2002) (2+; 2++; 1++)

Possible adverse effects of treatment and appropriate action to take when reaction emerged should be included in the booklet so that patients could seek medical advice when encountering discomfort after medication. (Clark et al., 2007) (2+)

Recommendation 2.2

To illustrate information in the form of pictures or photographs (Grade B)

Evidence:

Illustrating information concerning the disease in the form of pictures or photographs can facilitate patients’ understanding of the information through cognitive stimulations. (Ailinger et al, 2010; Dick et al., 1997) (2+; 2++)
Recommendation 2.3

To design the booklet to provide motivational support to patients (Grade B)

Evidence:

The motivation to adhere to treatment can be promoted by creating a booklet consists of a positive proverb, slogan or logo, which would create a strong cognitive impact on patients.

(Ailinger et al., 2010) (2+)

Booklet should be design to reinforce and motivate patients to adhere to treatment (Dick et al., 1997) (2++)

Recommendation 2.4

To present information in a simple and clear manner (Grade C)

Evidence:

Information should be written in simple language without medical jargons so that facts concerning the disease can be delivered to patients of all education background. (Ailinger et al., 2010) (2+)

Information could be illustrated in question-and-answer or points-to-note formats which would enhance the readability of the booklet. (Clark et al., 2007) (2+)
Component 3: Staff training

Recommendation 3.1

To equip staffs with the essential facts about the disease (Grade A)

Evidence:

Providing essential facts to staffs can reinforce their knowledge concerning the disease.

(Leifooghe et al., 1999; White et al., 2005) (1++; 2+)

Recommendation 3.2

To provide strategies that strengthen the communication skills (Grade B)

Evidence:

Training in communication skills in nurses can result in a more patient-centered care and enhance mutual satisfaction of nurses and patients. (Dick et al., 1997) (2++)

Recommendation 3.3

To introduce interventions that promote motivation and social support of patients (Grade A)

Evidence:

Interventions that promote motivational and social support in patients would encourage patients’ adherence to treatment through positive social reassurance. (Leifooghe et al., 1999) (1++)

Recommendation 3.4

To practice the skills acquired in the training session through role playing (Grade C)
Evidence:

The skills acquired can be reinforced through practice and observations (White et al., 2005) (2+)

4.4 CONCLUSION

After critically appraising all up-to-date studies on health education to TB patients to promote treatment adherence, significant evidences were extracted. The components for effective individual health education, essential elements for health education booklet and training for nurses were illustrated in the guidelines. With reference to relevant studies in its development and high implementation potentials, utilization of the guideline is thus recommended to promote cost effectiveness in nursing practice.
CHAPTER 5

IMPLEMENTATION PLAN

The previous chapter has illustrated the details of an evidence-based health education guideline for adult tuberculosis (TB) patients. However, new research findings will not be beneficial to patient unless the health care system, organization and professionals apply and implement them in clinical setting (Cullum et. al., 2008). In this chapter, the implementation plan will be developed from communication plan and pilot test of the guidelines.

5.1 COMMUNICATION PLAN

5.11 Identifying stakeholders

It is essential that the stakeholders, who have the vest interest in the proposed change, would be identified since they are the most affected populations (Craig & Smyth, 2007). They are:

1. Decision makers in the TB and Chest service, including the Chief of Service, Senior Nursing Officer and Nursing Officer

2. Public health nurse specialists

3. Clinic nurses

4. Clinic medical officer

5.12 Communication plan with stakeholders

5.121 Nursing Officer, Senior Nursing Officer and Chief of Service
It is important to gain approval and support from the managerial level of the service. Initially, a discussion about the need for practice change, the elements generated from literature review, the effectiveness of the evidence-based protocol, the feasibility and potential barriers of the proposed innovation can be carried out with the nursing officer of the pilot clinic. Through this communication process, support and approval can be obtained.

The need to gain the approval from the senior management of the service for the implementation and evaluation of the protocol is also essential. A proposal should be prepared and submitted to the senior nursing officer and chief of service for review in advance. The proposal should present evidence in a clear and persuasive manner in order to show the current innovation is worth supporting (Streubert-Speziale & Carpenter, 2003). For instance, this would include the need for practice change, the summary of the utilization of the up-to-date and high level of evidence, the proposed protocol, as well as the implementation potentials, barriers, feasibility, the cost effectiveness, the budget plan and timetable of the proposed innovation. A summary of the proposal will then be presented during the senior staff meeting of our service if permission is granted.

5.122 Public health nurse specialists

After gaining the permission to carry out the innovation from senior management, an innovation team can be set up which comprises of the guideline proposer and the two public health nurse specialists of the pilot clinic. This team will be responsible to carry out the pilot
testing and evaluation plan of the innovation. A two-hour workshop will be attended by two team members who are well experienced in delivering health education, training of nursing staff and carrying out clinical auditing, so that they can become trainers and auditors of the proposed innovation. The workshop includes:

- Details of the affirming needs and need for practice change
- Critical appraisal of recent literature
- The proposed evidence-based guideline
- Feasibility, potential benefit and barriers of the innovation
- Implementation plan and pilot test
- Evaluation plan
- Audit plan and audit tool
- Budget plan
- Timeframe

The background information of the proposed innovation would be presented in the form of oral presentation, while the skill to disseminate the proposed guideline and evaluation plan would be in the form of role playing, simulation exercise and discussion. A written training kit which include all the above information would be given to the team, so that a readily access set of information and material can be retrieved for future reference (Tappen, 2011).

As a gesture of appreciation for the contribution by the innovation team, the nursing officer
of the pilot clinic would record staff’s effort in the annual appraisal records as suggested by Pilot and Beck (2008).

5.123 Clinic nurses

Since the clinic nurses working in the pilot clinic were well experienced in the delivery of health education as mentioned in chapter 3, a one-hour training session conducted by the innovation team would be provided during working hour. The content of training session will focus on the proposed innovation which is similar to the workshop for the innovation team, but without the discussion of audit planning. Written material would also be provided for future reference. The nursing staff are encouraged to raise any issue concerning the proposed innovation. Similar to the innovation team, their effort would also be recognized in their annual appraisal records.

5.124 Clinic medical officer (clinic-in-charge)

Although the proposed guideline does not involve any change of practice of the medical officer, it is the guideline proposer’s responsibility to inform the clinic-in-charge of the implementation of the proposed innovation. An oral presentation that include the rationale for practice change, proposed evidence-based guideline, the potential benefits and barriers, the cost effectiveness, implementation and evaluation plan would be given during working hours so as to gain support from the medical officer for the implementation of the innovation.
5.2 PILOT TEST

After communicating with the decision makers and stakeholders, a pilot test would be carried out to explore the strengths and weaknesses of the proposed innovation (Streubert-Speziale & Carpenter, 2003). Through the process of data collection and analysis of the pilot test, the feasibility of the innovation could be assessed in an objective manner. Potential problems of the guideline could also be identified so that appropriate modification could be made.

5.21 Ethical consideration

The fundamental ethical principles in conducting medical research are to protect the rights, dignity and welfare of research participants. Researchers are obliged to explore and actively seek advice and judgments about the specific ethical issues involved in their study (Barker, Pistrang and Elliott, 2002). This includes consideration of a study’s beneficence while actively avoid violation of justice (Johnson, 2004). Hence, it is important to seek ethic approval from the hospital research ethics committee before proceeding the pilot test.

Information concerning the pilot test should be explained fully and informed consent should also be obtained from all participants. Consent forms and the information sheets should be in Chinese and English which illustrate the purpose, procedure, risks, benefits and the way to collect data of the pilot test. The consent form should also be made clear that participation is in the participants’ voluntary decision without coercion and the right to
withdraw is well respected.

5.22 Design, setting and sampling plan

A one group pretest-posttest quasi-experimental design will be used for the pilot testing as an open clinical trial. In this design, the primary outcome is to compare the treatment adherence rate from past data with the rate of the participants who have received intervention of the new guideline. The test will be carried out in the target setting which is one of the tuberculosis and chest clinics of the Department of Health. Convenience sampling technique will be used. After consideration of time and cost constraints (Hulley, Cummings, Browner, Cummings, Hulley & Hearst, 2001), an estimated sample size of 65 participants is required to obtain a power of 0.8 and significance level ($\alpha$) of 0.05, which is calculated using statistical power analysis via an online programme (Lenth, 2009). The sampling procedure is estimated to take 4 to 6 months.

5.23 Objectives

The objectives of the pilot testing are:

1. To observe if the treatment adherence of TB patients after the implementation of the guideline cohere with the research findings from literature

2. To determine the feasibility of the guideline

3. To assess the compliance and satisfaction towards the innovation among frontline staff
4. To estimate the budget of implementation

5. To identify potential problems of the major study

5.24 Outcome measures

Outcomes to be measured in the pilot test are:

1. Anti-tuberculosis treatment adherence of participants

2. Patients satisfaction level

3. Compliance and satisfaction of nurses

4. Implementation cost

5. Unanticipated problems associated with the guideline

The treatment adherence of the participants is the primary outcome of the pilot test. Since there are documented treatment adherence of patients in Hong Kong in the WHO report (WHO, 2010), the data would be used as the pretest component of the test. The posttest treatment adherence would be calculated from the treatment attendance record by the computer registry system of the service after the participants had completed the six months treatment regimen.

The patients’ satisfaction level would be assessed using the Chinese or English versions of Client Satisfaction Questionnaire developed by Larsen, Attkisson, Hargreaves and Nguyen (1979) (See Appendix F). This standardized questionnaire is used because of its high reliability and validity (Attkisson & Greenfield, 2004). Participants would be asked to fill in
the questionnaire at the beginning and at the end of treatment, which is after 6 months. This would be done anonymously to minimize response bias.

The satisfaction level of nurses towards the innovation will be assessed by a self-complete questionnaire designed by the guideline proposer. Open-end questions in the questionnaire would also encourage fuller comments from respondents. Nursing compliance and performance would also be assessed via an audit plan prepared by the innovation team.

The cost of the pilot test will be calculated in terms of material and non-material cost, an estimated budget for the actual implementation of the proposed innovation is helpful. Problems encountered during the pilot test will be reviewed and analyzed, so that the guideline can be modified accordingly.

The details of data measurement, collection and analysis, which are similar to the evaluation plan, will be presented in the next chapter.

5.3 CONCLUSION

To ensure an effective implementation of the innovation in long term, executions of the communication plan with stakeholders and pilot test are essential.
CHAPTER 6
EVALUATION PLAN

Following the implementation, evaluation is essential to assess the feasibility and expected outcomes of the innovation. During the evaluation process, the appropriate use of instruments for data collection and analysis is crucial (Streubert-Speziale & Carpenter, 2003). In this chapter, the evaluation plan will be discussed with reference to the anticipated outcomes, as well as a presentation of data measurement, collection and analysis plan of the innovation.

6.1 OUTCOMES TO BE ACHieved

6.11 Patient outcomes

Improvement of patient outcomes, measured by anti-tuberculosis (TB) treatment adherence is anticipated following the implementation of the innovation (provision of health education), drawing from papers previously discussed in chapter 2, the change in patients’ treatment adherence is regarded as the major factor to determine the effectiveness of the innovation.

The second patient outcome to be achieved is the increase in knowledge concerning TB after the implementation of the guideline. One out of eight paper reviewed (Nyamathi et al., 2006) has indicated that significantly increase in patients’ knowledge on TB can be facilitated via health education. Hence the change in patient’s knowledge can be regarded as an
indication of effectiveness of the proposed innovation.

Patients’ satisfaction is considered to be one of the major determinants of the quality of care (Johansson, Oléni & Fridlund, 2002) and is thus evaluated to assess the effectiveness of the guideline.

6.12 Health care provider outcomes

The quality of care can be reflected on the level of satisfaction of the nursing staff (Fletcher, 2001). In other words, the higher the quality of care, the higher the job satisfaction level of the staff. Hence, the satisfaction level of the nursing staff would be assessed to determine the effectiveness of the innovation.

Clinical audit has also been shown to be an essential tool to assess the quality and effectiveness of patient care delivered by nurses (Burnett & Winyard, 1998). Nurses’ compliance and performance would thus be assessed.

6.13 System outcomes

The cost of the innovation would be evaluated, which include the reprinting and design of the reviewed booklet, the purchase of Client Satisfaction Questionnaire (Larsen et al., 1979) from copyright holder for evaluating patients’ satisfaction level, staff training and manpower allocation.

6.2 DEMOGRAPHICS AND NUMBER OF CLIENTS TO BE INVOLVED

Adult, non-relapse pulmonary TB patients who are treated with standard regimen in the
pilot clinic would be evaluated.

The number of clients to be evaluated is based on the primary outcome, the study design and the method of analysis. The primary evaluation objective is to compare treatment adherence of the clients after the intervention to the known treatment adherence data in Hong Kong from the WHO (2010) report. Although the profile of the clients from the pilot clinic is expected to be similar to the Hong Kong TB population described in the WHO (2010) report, they are of two different populations. The two set of data can be standardized by using z-test, which then allow direct comparison using within-group t-test. Using statistical power analysis via an online programme (Lenth, 2009), an estimated sample size of 65 participants is required to obtain a power of 0.8, phi-prime ($\Phi'$) of 0.35 (which produce a moderate to large effect) and significance level ($\alpha$) of 0.05. The sampling procedure is estimated to take 4 to 6 months.

6.3 DATA COLLECTION AND ANALYSIS

6.3.1 Patient outcomes

6.3.1.1 Treatment adherence of patients

The anti-TB treatment adherence rate can be calculated using the treatment attendance of the sample population retrieved from the computer registry of the TB and Chest service. The evaluation objective is to determine whether there is an increase in treatment adherence after the intervention of the innovation or otherwise as compared to the known treatment
adherence data in Hong Kong (WHO, 2010). The treatment adherence rate from WHO (2010) would be first standardized using the z-test, which will serve as the pre-test data. The data collection from the evaluation sample would be performed after completion of 6-months standard treatment. Again, the post-test data would be standardized. Both the pre and post-test data will be analyzed using the Statistical Package for the Social Sciences (SPSS) version 19 (2010). The change in treatment adherence would then be tested by performing mean comparison, using one-sample t-test.

A medication record chart designed by the service (see Appendix G) would be provided for a minority of patients who are not under direct observe therapy-short course (DOTS). For example, those who are less ambulatory and are thus supervised by community nurses or latent TB patients who are supervised by family members at home. The treatment adherence will be obtained from the chart upon completion of the 6-month treatment. This post-treatment data together with the pre-test data, which is the treatment adherence rate from WHO (2010) would also be standardized using the z-test as mentioned above. The change in treatment adherence would then be tested by performing a one-sample pre-post t-test.

As a way to ensure internal reliability of the data obtained from the medication chart, patients will be asked to fill in the Morisky 8-item Medication Adherence Questionnaire (Morisky, Ang, Krousel-Wood, & Ward, 2008) (see Appendix H) every time they had their follow-up visit, so that their treatment adherence rate can be assessed by a reliable and valid
tool. The score can be collected and analyzed by descriptive statistical method.

6.312 TB knowledge of patients

The second outcome variable to be evaluated is the change in knowledge concerning the disease after the implementation of the guideline. The knowledge level would be assessed using the 13-item instrument from Morisky et al. (1990). The instrument consists of 13 questions about TB and correct responses were summed for a score of 0 to 13. Patients will be asked to fill in the questionnaire before they receive the evidence-based intervention. Patients will then be asked to fill in the questionnaire again upon the completion of the 6-month standard treatment. The difference between the pre-test and post-test score would then be analyzed using the one-sample t-test using with aid of the SPSS program.

6.313 Patient’s satisfaction level

The third outcome variable to be evaluated is the patient’s satisfaction level towards the innovation. It is assessed using the Chinese or English versions of Client Satisfaction Questionnaire (Larsen, et al., 1979) (See Appendix F). The questionnaire is consisted of 8 questions and scores are ranged from 8 to 32, with higher values indicating higher satisfaction. The expectation of the patients towards the intervention would be assessed before the treatment, their satisfaction level will then be assessed again upon the completion of the 6-month standard treatment. The change in the pre-test and post-test scores would then be analyzed by performing a one-sample t-test using the SPSS program.
6.32 Health care provider outcomes

6.321 Satisfaction level of staff

The nursing staff satisfaction level will be evaluated half yearly during the first year of implementation using a self-administrated questionnaire designed by the guideline proposer. The first part of the questionnaire will consist of a set of questions concerning about the implementation of the guideline for the nurses to rate using a five-point Likert Scale. The second part of the questionnaire will consist of open-ended questions for staff to comment on the innovation and problems that they encountered during the implementation.

Data obtained from the first part of the questionnaire will be analyzed using descriptive statistical method to indicate the satisfaction level of the frontline staff, while the data obtained from the second part of the questionnaire will be analyzed qualitatively until data saturation occurred.

6.322 Nursing compliance

The second nursing outcome variable to be evaluated is the staff’s compliance to the protocol. It can be assessed using an audit tool developed by the innovation team, which involves systematically reviewing all relevant evidences and guidance from expert opinion (Infection Control Nurses Association, 2004). The nursing audit will perform yearly by the innovation team and the level of compliance would be analyzed using descriptive statistic method.
6.33 System outcomes

The material cost for the implementation of the innovation is recorded to evaluate the cost effectiveness of the guideline. The material costs include the cost of paper of the audit chart, the copyright fee of the Client Satisfaction Questionnaire (Larsen et al., 1979), the reprint of the health education booklet, the printing of the material in the training kit and the cost of training time of staff. Those material costs will be calculated in a half-yearly basis.

The cost-benefit of the innovation would also be assessed in a half-yearly basis by evaluating how much manpower and medical cost could be saved with the increase in treatment success and adherence rate after the implementation of the guideline. The cost effectiveness of the innovation could then be evaluated by comparing the cost and benefit of the implementation.

6.4 BASIS FOR AN EFFECTIVE CHANGE OF PRACTICE

The major objective of the new guideline is to increase the anti-TB treatment adherence of patients upon receiving evidence-based health education intervention. The outcome is optimistic according to literature review, where patient’s treatment adherence was shown to increase significantly from 7% to 23% (Aillinger et al., 2010; Clark et al., 2007; Dick et al., 1997; Leifooghe et al., 1999; White et al., 2002; White et al., 2005; Volmink et al., 1997). The new guideline will therefore be deemed effective if the treatment adherence rate of patients who have received the evidence-based health education is significantly increased by
over 15% as compared to the historic treatment adherence in Hong Kong as reported by WHO (2010). It is also targeted that at least 80% of the patients who were asked to fill in the Morisky 8-item Medication Adherence Questionnaire (Morisky, Ang, Krousel-Wood, & Ward, 2008) would have a score of 0, which indicated high adherence with the treatment regimen.

The second outcome variable, which is the knowledge concerning about TB of patients is also an important measure to indicate the effectiveness of the protocol. According to the literature review, patients' knowledge on the disease was found to have significantly increased by 32% following evidence-based health education intervention (Nyamath et al., 2006). Therefore, the current innovation can be considered to be effective when the knowledge level of patient is significantly increased by 30% following the evidence-based intervention.

The satisfaction levels of patients and frontline nursing staffs are also essential indicators of an effective change of practice, with a target of over 80% for a favourable outcome. The nursing compliance of the innovation, which is assessed by nursing audit, is also an important justification of the effectiveness of the innovation. The compliance rate is considered to be high when the score obtained by the staff is 85% or above (Infection Control Nurses Association, 2004). Moreover, the innovation is also considered to be effective if the resources saved due to the increase in treatment adherence outweigh the costs of implementation.
6.5 CONCLUSION

By assessing the cost and benefit of the proposed innovation to our patients, frontline staffs and the TB and Chest service, the effectiveness of the guideline could be evaluated in a systematic manner.
CHAPTER 7

CONCLUSION

Tuberculosis (TB) is a global health concern and the incident rate in Hong Kong remains high. Directly Observed Therapy, Short-course (DOTS) strategy, in combination with patient education are proved to be more effective in reducing TB incidence than the DOTS strategy alone (Vlomink & Garner, 1997). However, there is a lack of evidence based protocol to guide nurses through the implementation of health education for TB patients.

In this translational research, an evidence-based health education guideline for TB patients was developed after systematic reviewing and critically appraising 8 up-to-date high quality research papers. The guideline consists of 3 components: effective individual health education, essential elements for health education booklet and training for nurses.

The guideline is going to be disseminated in the target clinic, which is one of the TB and chest clinics in Hong Kong. The implementation potential of the guideline is considered to be high while the implementation and evaluation plan of the guideline are also discussed. With the implementation of the evidence-based protocol on TB health education, the treatment adherence of the TB patients is expected to be increased.
REFERENCES


Noyes, J., & Popay, J. (2006). Directly observed therapy and tuberculosis: how can a


Tam, C.M. (2006). The DOTS strategy in Hong Kong. *The Hong Kong Medical Diary, 2*(1), 3-4.


APPENDIX A: SEARCHING ENGINES

CLINICAL GUIDELINE SEARCH (till 24th Aug, 2011)

National guidelines clearinghouse

- by keywords: pulmonary tuberculosis: 0 out of 150; tuberculosis and health education (72); tuberculosis and health education (34)
  \[\rightarrow\] all are irrelevant

CMA infobase

- by keywords: pulmonary tuberculosis (20); tuberculosis and health education (0); tuberculosis and health education (0)
  \[\rightarrow\] all are irrelevant

Guidelines advisory guidelines:

- by topic: pulmonary tuberculosis (no relevant topic)

Health service/technology assessment text (HSTAT)

- pulmonary tuberculosis (218); tuberculosis and health education (20); tuberculosis and health education (9)
  \[\rightarrow\] all are irrelevant

National Institute for Clinical Excellence (NICE):

- by topic: pulmonary tuberculosis (no relevant topic)

Scottish Intercollegiate Guidelines Network (SIGN)

- by topic: pulmonary tuberculosis (no relevant topic)

New Zealand Guideline Group:

- by topic: pulmonary tuberculosis (no relevant topic)

Cochrane library

- by topic: pulmonary tuberculosis (no relevant topic)
APPENDIX A: SEARCHING ENGINES (CONT’D)

PubMed (1950-2011): 11 relevant studies were found on 24/8/2011

<table>
<thead>
<tr>
<th>Search Term</th>
<th>Time</th>
<th>Count</th>
</tr>
</thead>
<tbody>
<tr>
<td>#1 search Pulmonary Tuberculosis</td>
<td>18:18:13</td>
<td>192387</td>
</tr>
<tr>
<td>#2 search Health education</td>
<td>18:35:21</td>
<td>317649</td>
</tr>
<tr>
<td>#3 search Treatment adherence</td>
<td>18:35:43</td>
<td>39748</td>
</tr>
<tr>
<td>#4 search Treatment outcome</td>
<td>18:36:05</td>
<td>629095</td>
</tr>
<tr>
<td>#5 search Treatment success</td>
<td>18:36:20</td>
<td>93345</td>
</tr>
<tr>
<td>#6 search Patient knowledge</td>
<td>18:36:42</td>
<td>114594</td>
</tr>
<tr>
<td>#7 search Education booklet</td>
<td>18:37:42</td>
<td>2914</td>
</tr>
<tr>
<td>#8 search #1 AND #2</td>
<td>18:37:43</td>
<td>1734</td>
</tr>
<tr>
<td>#9 search #1 AND #3</td>
<td>18:37:59</td>
<td>870</td>
</tr>
<tr>
<td>#10 search #1 AND #4</td>
<td>18:38:20</td>
<td>5616</td>
</tr>
<tr>
<td>#11 search #1 AND #5</td>
<td>18:38:42</td>
<td>963</td>
</tr>
<tr>
<td>#12 search #1 AND #6</td>
<td>18:39:10</td>
<td>1048</td>
</tr>
<tr>
<td>#13 search #1 AND #7</td>
<td>18:39:27</td>
<td>0</td>
</tr>
<tr>
<td>#14 search #8 AND #9 AND #10 AND #11 AND #12</td>
<td>18:40:09</td>
<td>0</td>
</tr>
<tr>
<td>#15 search #8 AND #9</td>
<td>18:40:34</td>
<td>101(7)</td>
</tr>
<tr>
<td>#16 search #8 AND #9 AND #10</td>
<td>18:45:41</td>
<td>21(4)</td>
</tr>
<tr>
<td>#17 search #8 AND #9 AND #10 AND #11</td>
<td>18:46:41</td>
<td>2(0)</td>
</tr>
</tbody>
</table>
APPENDIX A: SEARCHING ENGINES (CONT’D)

CINAHL (Ovid SP) 1975-2011: 4 relevant studies were found on 24/8/2011

<table>
<thead>
<tr>
<th>Search</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Pulmonary Tuberculosis</td>
<td>2191</td>
</tr>
<tr>
<td>2) Health education</td>
<td>6367</td>
</tr>
<tr>
<td>3) Patient adherence</td>
<td>252</td>
</tr>
<tr>
<td>4) Education booklet</td>
<td>8</td>
</tr>
<tr>
<td>5) 1 AND 2</td>
<td>25(3)</td>
</tr>
<tr>
<td>6) 1 AND 2 AND 3</td>
<td>0</td>
</tr>
<tr>
<td>7) 1 AND 3</td>
<td>4(1)</td>
</tr>
<tr>
<td>8) 1 AND 3 AND 4</td>
<td>0</td>
</tr>
<tr>
<td>9) 1 AND 2 AND 3 AND 4</td>
<td>0</td>
</tr>
</tbody>
</table>
APPENDIX A: SEARCHING ENGINES (CONT’D)

British Nursing Index 1994-2011: 5 relevant studies were found on 24/8/2011

<table>
<thead>
<tr>
<th>Search</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Pulmonary Tuberculosis</td>
<td>251</td>
</tr>
<tr>
<td>2) Patient: Education</td>
<td>4750</td>
</tr>
<tr>
<td>3) Patient: Compliance</td>
<td>1302</td>
</tr>
<tr>
<td>4) Education booklet</td>
<td>5</td>
</tr>
<tr>
<td>5) 1 AND 2</td>
<td>3(1)</td>
</tr>
<tr>
<td>6) 1 AND 3</td>
<td>20(3)</td>
</tr>
<tr>
<td>7) 1 AND 4</td>
<td>0</td>
</tr>
<tr>
<td>8) 1 AND 2 AND 3</td>
<td>1(1)</td>
</tr>
</tbody>
</table>
APPENDIX A: SEARCHING ENGINES (CONT’D)

Medline (Ovid SP) 1948-2011: 6 relevant studies were found on 24/8/2011

<table>
<thead>
<tr>
<th>Search</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>1) Pulmonary Tuberculosis</td>
<td>45889</td>
</tr>
<tr>
<td>2) Health Education</td>
<td>48344</td>
</tr>
<tr>
<td>3) Patient Compliance</td>
<td>41266</td>
</tr>
<tr>
<td>4) Pamphlets</td>
<td>2786</td>
</tr>
<tr>
<td>5) 1 AND 2</td>
<td>253</td>
</tr>
<tr>
<td>6) 1 AND 3</td>
<td>614</td>
</tr>
<tr>
<td>7) 1 AND 2 AND 3</td>
<td>13(4)</td>
</tr>
<tr>
<td>8) 1 AND 4</td>
<td>2(1)</td>
</tr>
<tr>
<td>9) 1 AND 2 AND 3 AND 4</td>
<td>1(1)</td>
</tr>
</tbody>
</table>
APPENDIX B: NOTES ON THE USE OF METHODOLOGY CHECKLISTS FROM SIGN (2008)

Section 1: For each question in this section you should use one of the following to indicate how well it has been addressed in the study:

- Well covered
- Adequately addressed
- Poorly addressed
- Not addressed (i.e. not mentioned, or indicates that this aspect of study design was ignored)
- Not reported (i.e. mentioned, but insufficient detail to allow assessment to be made)
- Not applicable.

Section 2: Based on the responses in section 1, the methodological quality was assessed using the following coding system:

<table>
<thead>
<tr>
<th>Symbol</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>++</td>
<td>All or most of the criteria have been fulfilled. Where they have not been fulfilled the conclusions of the study or review are thought very unlikely to alter.</td>
</tr>
<tr>
<td>+</td>
<td>Some of the criteria have been fulfilled. Those criteria that have not been fulfilled or not adequately described are thought unlikely to alter the conclusions.</td>
</tr>
<tr>
<td>-</td>
<td>Few or no criteria fulfilled. The conclusions of the study are thought likely or very likely to alter</td>
</tr>
</tbody>
</table>
APPENDIX C: Key to Evidence Statement and Grades of Recommendations from Scottish Intercollegiate Guidelines Network (SIGN) (2008)

**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&lt;br&gt;High quality case control or cohort studies with a very low risk of confounding or bias and a high probability that the relationship is causal</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>
APPENDIX D: CRITERIA FOR EVALUATING THE IMPLEMENTATION POTENTIAL OF AN INNOVATION UNDER SCRUTINY

TRANSFERABILITY OF THE FINDINGS

1. Will the innovation fit in the proposed setting?

2. How similar are the target population in the research and that in the new setting?

3. Is the philosophy of care underlying the innovation fundamentally different from the philosophy prevailing in the practice setting? How entrenched is the prevailing philosophy?

4. Is there a sufficiently large number of clients in the practice setting who could benefit from the innovation?

5. Will the innovation take too long to implement and evaluate?

(Polit & Beck, 2008)
APPENDIX D: CRITERIA FOR EVALUATING THE IMPLEMENTATION PORTENTIAL OF AN INNOVATION UNDER SCRUTINY (CONT’D)

FEASIBILITY

1. Will nurses have the freedom to carry out the innovation? Will they have the freedom to terminate the innovation if it is considered undesirable?

2. Will the implementation of the innovation interfere inordinately with current staff functions?

3. Does the administration support the innovation? Is the organizational climate conducive to research utilization?

4. Is there a fair degree of consensus among the staff and among the administrators that the innovation could be beneficial and should be tested? Are there major pockets of resistance or uncooperativeness that could undermine efforts to implement and evaluate the innovation?

5. To what extent will the implementation of the innovation cause friction within the organization? Does the utilization project have the support and co-operation of department outside the nursing department?

6. Are the skills needed to carry out the utilization project (both the implementation and the clinical evaluation) available in the nursing staff? If not, how difficult will it be to collaborate with or to secure the assistance of others with the necessary skills?

7. Does the organization have the equipment and facilities necessary for the innovation? If not, is there a way to obtain the needed resources?

8. If nursing staff need to be released from other practice activities to learn about and implement the innovation, what is the likelihood that this will happen?

9. Are appropriate measuring tools available for a clinical evaluation of the innovation?

(Polit & Beck, 2008)
APPENDIX D: CRITERIA FOR EVALUATING THE IMPLEMENTATION PORTENTIAL OF AN INNOVATION UNDER SCRUTINY (CONT’D)

COST/BENEFIT RATIO OF THE INNOVATION

1. What are the risk to which clients would be exposed during the implementation of the innovation?

2. What are the potential benefits that could result from the implementation of the innovation?

3. What are the risks of maintaining current practices (i.e. the risks of not trying the innovation)?

4. What are the material costs of implementing the innovation? What are the costs in the short term during utilization, and what are the costs in the long run, if the change to be institutionalized?

5. What are the material cost of not implementing the innovation (i.e. could the new procedure result in some efficiencies that could lower the cot of providing service)?

6. What are the potential non-material costs if implementing the innovation to the organization (e.g. lower staff morale, staff turnover, and absenteeism)?

7. What are the potential non-material benefits of implementing the innovation (e.g. improved staff morale, improve staff recruitment)?

(Polit & Beck, 2008)
APPENDIX E: KEY TO EVIDENCE STATEMENT AND GRADES OF RECOMMENDATIONS FROM SCOTTISH INTERCOLLEGIATE GUIDELINES NETWORK (SIGN) (2004)

GRADES OF RECOMMENDATION

<table>
<thead>
<tr>
<th>Grade</th>
<th>Description</th>
</tr>
</thead>
<tbody>
<tr>
<td>A</td>
<td>At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; <em>or</em>&lt;br&gt;A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results</td>
</tr>
<tr>
<td>B</td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; <em>or</em>&lt;br&gt;Extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td>C</td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; <em>or</em>&lt;br&gt;Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td>D</td>
<td>Evidence level 3 or 4; <em>or</em>&lt;br&gt;Extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>

GOOD PRACTICE POINTS

- Recommended best practice based on the clinical experience of the guideline development group
# APPENDIX F: CLIENT SATISFACTION QUESTIONNAIRE (SCQ-8) AT PRETREATMENT

Please circle your answers

1. How would you rate the quality of service you have received thus far?
   - 4 Excellent
   - 3 Good
   - 2 Fair
   - 1 Poor

2. Did you expect that you will get the kind of service you want in our program?
   - 1 No, definitely not
   - 2 No, not really
   - 3 Yes, generally
   - 4 Yes, definitely

3. To what extent do you feel that our program will meet your needs?
   - 4 Almost all of my needs
   - 3 Most of my needs
   - 2 Only a few of my needs
   - 1 None of my needs

4. If a friend were in need of similar help, would you recommend our program to him/her?
   - 1 No, definitely not
   - 2 No, I don't think so
   - 3 Yes, I think so
   - 4 Yes, definitely

5. How satisfied do you think you will be with the amount of help you receive here?
   - 1 Quite satisfied
   - 2 Indifferent or mildly satisfied
   - 3 Mostly satisfied
   - 4 Very satisfied

6. Do you think the services you receive here will help you to deal more effectively with your problem?
   - 4 Yes, they will help a great deal
   - 3 Yes, they will help somewhat
   - 2 No, they really will not help
   - 1 No, they will make things worst

7. In an overall, general sense, how satisfied do you think you will be with the service you receive here?
   - 4 Very satisfied
   - 3 Mostly satisfied
   - 2 Indifferent or mildly dissatisfied
   - 1 Quite dissatisfied

8. If you were to seek help again, would you come back to our program?
   - 1 No, definitely not
   - 2 No, I don't think so
   - 3 Yes, I think so
   - 4 Yes, definitely

Source:

APPENDIX F: CLIENT SATISFACTION QUESTIONNAIRE (SCQ-8) AT POSTTREATMENT (CONT’D)

Please circle your answers

1. How would you rate the quality of service you received?
   4 Excellent  3 Good  2 Fair  1 Poor

2. Did you get the kind of service you wanted in our program?
   1 No, definitely not  2 No, not really  3 Yes, generally  4 Yes, definitely

3. To what extent has our program met your needs?
   4 Almost all of my needs  3 Most of my needs  2 Only a few of my needs  1 None of my needs

4. If a friend were in need of similar help, would you recommend our program to him/her?
   1 No, definitely not  2 No, I don’t think so  3 Yes, I think so  4 Yes, definitely

5. How satisfied are you with the amount of help you received here?
   1 Quite satisfied  2 Indifferent or mildly satisfied  3 Mostly satisfied  4 Very satisfied

6. Have the services you received here helped you to deal more effectively with your problem?
   4 Yes, they helped a great deal  3 Yes, they helped somewhat  2 No, they really didn’t help  1 No, they seemed to make things worst

7. In an overall, general sense, how satisfied are you with the service you receive here?
   4 Very satisfied  3 Mostly satisfied  2 Indifferent or mildly dissatisfied  1 Quite dissatisfied

8. If you were to seek help again, would you come back to our program?
   1 No, Definitely not  2 No, I don’t think so  3 Yes, I think so  4 Yes, definitely

Source:

APPENDIX G MEDICATION RECORD CHART FOR PATIENTS

Treatment regimen

<table>
<thead>
<tr>
<th>Medication</th>
<th>Dose</th>
<th>Administration</th>
</tr>
</thead>
<tbody>
<tr>
<td>Rifampicin</td>
<td>mg x</td>
<td>/7</td>
</tr>
<tr>
<td>Isoniazid</td>
<td>mg x</td>
<td>/7</td>
</tr>
<tr>
<td>Ethambutol</td>
<td>mg x</td>
<td>/7</td>
</tr>
<tr>
<td>Pyrazinamide</td>
<td>mg x</td>
<td>/7</td>
</tr>
<tr>
<td>Streptomycin</td>
<td>mg x</td>
<td>/7</td>
</tr>
</tbody>
</table>

Name: __________________________

Treatment no.: __________________

Clinic no.: __________________________

Remarks:

1. Please sign and indicate the date on the space provided after each administration

2. Please bring along this record upon each follow-up visit

Month: __________, 2012

<table>
<thead>
<tr>
<th></th>
<th>SUN</th>
<th>MON</th>
<th>TUE</th>
<th>WED</th>
<th>THR</th>
<th>FRI</th>
<th>SAT</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
APPENDIX H: MORISKY 8-ITEM MEDICATION ADHERENCE QUESTIONNAIRE

<table>
<thead>
<tr>
<th>Question</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Do you sometimes forget to take your medicine?</td>
<td>Yes / NO</td>
</tr>
<tr>
<td>2. People sometimes miss taking their medicines for reasons other than forgetting. Thinking over the past 2 weeks, were there any days when you did not take your medicine?</td>
<td>Yes / NO</td>
</tr>
<tr>
<td>3. Have you ever cut back or stopped taking medicine without telling your doctor because you felt worse when you took it?</td>
<td>Yes / NO</td>
</tr>
<tr>
<td>4. When you travel or leave home, do you sometimes forget to bring along your medicine?</td>
<td>Yes / NO</td>
</tr>
<tr>
<td>5. Did you take all your medicine yesterday?</td>
<td>Yes / NO</td>
</tr>
<tr>
<td>6. When you feel like your systems are under control, do you sometimes stop taking your medicine?</td>
<td>Yes / NO</td>
</tr>
<tr>
<td>7. Taking medicine everyday is a real inconvenience for some people. DO you ever feel hassled about sticking to your treatment plan?</td>
<td>Yes / NO</td>
</tr>
<tr>
<td>8. How often do you have difficulty remembering to take all your medicine?</td>
<td></td>
</tr>
<tr>
<td>A. Never / rarely</td>
<td></td>
</tr>
<tr>
<td>B. Once in a while</td>
<td></td>
</tr>
<tr>
<td>C. Sometimes</td>
<td></td>
</tr>
<tr>
<td>D. Usually</td>
<td></td>
</tr>
<tr>
<td>E. All the time</td>
<td></td>
</tr>
</tbody>
</table>

(Morisky, Ang, Krousel-Wood, & Ward, 2008)
APPENDIX H: MORISKY 8-ITEM MEDICATION ADHERENCE QUESTIONNAIRE (CONT’D)

Interpretation Key

Question Values:

- Question 1 to 7 (except question 5): Each answered yes = 1 point
- For question 5, the answer no= 1 point
- For question 8:
  - The answer ‘Never / Rarely’= 0 points
  - The answer ‘Once in a while, sometimes, Usually, and All the time’= 1 point

Scores:

If the patient’s total score is:

- >2 = low adherence
- 1,2 = medium adherence
- 0 = high adherence
<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Types of studies</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Volmink, J., &amp; Garner, P. (1997).</td>
<td>Systematic review</td>
<td>1+</td>
<td>5 RCTs</td>
<td>Active or latent TB patients</td>
<td>RCTs 1) Reminder cards to treatment defaulter (Paramasivan et al., 1993) 2a) Money; 2b) peer health adviser (Pilote et al., 1996) 3) health education (Sanmarti et al., 1993) 4) incentive and health education counseling (Morisky et al., 1990) 5) Intensive supervision and motivation in clinic by senior doctor (Jin et al., 1993)</td>
<td>RCTs 1) no action 2) usual care 3) leaflet alone 4) usual care with defaulter tracing 5) Routine supervision of staff</td>
<td>6 months</td>
<td>Treatment adherence</td>
<td>Relative risk to adhere to treatment: RCT1: 1.2 (95% CI: 1.1-1.4) RCT2a:1.6 (95% CI: 1.3-2.0) RCT2b:1.4 (95% CI: 1.1-1.8) RCT3: 1.3 (95% CI: 1.1-1.5) RCT4: 2.4 (95% CI: 1.5-3.7) RCT5: 1.2 (95% CI: 1.1-1.3)</td>
</tr>
</tbody>
</table>

**Remarks:** The only systemic review of RCT that can be found concerning intervention to promote adherence to TB treatment
Table 1: Table of Evidence (Cont’d)

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>2. Leifooghe, R., Suetens, C., Meulemans, H., Moran, M.B. &amp; De Muynck, A. (1999).</td>
<td>RCT</td>
<td>1++</td>
<td>1) TB patients 2) Adult 3) not critically ill 4) receiving standard treatment</td>
<td>Receive individual counseling and education by counselor each time they attend for follow up</td>
<td>No intervention</td>
<td>6 months</td>
<td>1) Rate of default from TB treatment</td>
<td>1) 46.6% in intervention group vs 53.6% in control group (risk ratios: 0.87; 95%CI: 0.77-0.98; p=0.03)</td>
</tr>
</tbody>
</table>

**Conclusion:**

1) Patients received individual counseling and education each time they attended for follow up would have a significantly lower default rate from TB treatment than those who did not

2) The impact of education was stronger in women; who were not the main provider of the family; with poor knowledge of TB and with shorter delay of treatment
<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>3. Clark, P.M., Karagoz, T., Apikoglu-Rabus, S., &amp; Izzettin, F. V. (2007).</td>
<td>Prospective, randomized, case-control study</td>
<td>2+</td>
<td>First time TB patients excluding those with recurrent multiple drug resistant TB, mental or psychiatric disease, cognitive dysfunction or literacy problems</td>
<td>Oral and written education by pharmacist (n=56)</td>
<td>No intervention (n=58)</td>
<td>6 months</td>
<td>Compare the adherence to TB treatment by comparing: 1) Attendance of follow up all the scheduled visits 2) Percentage of patient with 100% positive urine test with isoniazid metabolites 3) Percentage of tablets being consumed by patients</td>
<td>1) 53.6% in intervention group vs 29.3% in study group (p&lt;0.001) 2) 80.4% vs 42.3% (p=0.049) 3) 88.7% ±10.7% vs 85.8% ± 9.4%, but it is statistically insignificant (p-value is not provided)</td>
</tr>
</tbody>
</table>

**Conclusion:** Patients received oral and written health education would have significantly higher attendance of follow up and treatment adherence than those who did not.
Table 1: Table of Evidence (Cont’d)

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>4. Dick, J., &amp; Lombard, C. (1997).</td>
<td>Case control</td>
<td>2++</td>
<td>Adult TB patients and exclude those with extra-pulmonary disease, multidrug resistant TB and on preventive treatment</td>
<td>Patient-centred health education counseling and issuing of education booklet</td>
<td>No intervention</td>
<td>6 months</td>
<td>Treatment adherence rate</td>
<td>1) The relative risk of non-adherence in control group to intervention group: 4.3 (95%CI: 1.3-14.5, P=0.014) 2) The mean treatment adherence rate of intervention group increased from 72.4% to 95% (p&lt;0.0001) 3) The mean treatment adherence rate of control group increased from 77% to 83%. But was statistically insignificant (p=0.0902)</td>
</tr>
</tbody>
</table>

**Conclusion:** Patients receiving health education counseling and booklet would have a significantly higher treatment adherence rate than those who do not
<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>5. White, M.C., Tulsky, J.P., Goldenson, J., Portillo, C.J., Kawamura, M., &amp; Menendez, E. (2002).</td>
<td>RCT</td>
<td>1++</td>
<td>1) Jail inmates began latent TB treatment in jail and released into the community while still undergoing therapy 2) Spanish or English speaking 3) without psychiatric problem 4) HIV -ve</td>
<td>Receiving usual care in combination of: 1) education provided every 2 weeks in jail (education group, n=107) 2) the promise of an incentive (US$25) provided at the first visit to the TB clinic (incentive group, n=114)</td>
<td>No intervention (control group, n=104)</td>
<td>6 months</td>
<td>1) Rate of first visit to the TB clinic within 1 month after release from the jail 2) Rate of completion of a full course of therapy of latent TB jail inmate</td>
<td>1) 37% in education group vs 37% in incentive group vs 24% in control group (Odd ratios: 1.85; 95%CI: 1.04-3.28; p=0.02) 2) 65% in education group vs 33% in incentive group vs 48% in control group (p=0.02)</td>
</tr>
</tbody>
</table>

**Conclusion:** Patients who receive education intervention have a significantly higher rate of follow up in outpatient TB clinic and rate of treatment completion than those in the incentive group and treatment group.
<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>6. White, M.C., Tulsky, J.P., Menendez, E., Arai, S., Goldenson, J., &amp; Kawamura, L.M. (2005).</td>
<td>Descriptive cohort study of article 6</td>
<td>2+</td>
<td>1) Jail inmates began latent TB treatment in jail and released into the community while still undergoing therapy 2) Spanish or English speaking 3) without psychiatric problem 4) HIV -ve</td>
<td>Counseling and education (the education group in article 1) by research assistance under randomized trial in article 1 done in 1998-99 (study group, n=104)</td>
<td>Counseling and education by jail health workers done in 2002-03 (usual care group, n=164)</td>
<td>6 months</td>
<td>1) Rate of first visit to the TB clinic within 1 month after release from the jail 2) Rate of completion of a full course of therapy of latent TB jail inmate</td>
<td>1) 15% in usual care group vs 33% in study group (relative risk: 0.79; 95%CI: 0.68-0.92; p=0.001) 2) 52% in usual care group vs 50% in study group (p=0.049)</td>
</tr>
</tbody>
</table>

**Conclusion:** 1) Result of the RCT in article 6 was partially translated into practice 2) Personnel administering the protocol and training, high turnover rate of staffs and lack of time are obstacles of translational research
Table 1: Table of Evidence (Cont’d)

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>7. Nyamathi, A.M., Christiani, A., Nahid, P., Gregerson, P., &amp; Leake, B. (2006).</td>
<td>RCT</td>
<td>1+</td>
<td>Homeless latent TB patients who slept in one of the study shelters</td>
<td>Receive nurse case-managed with incentive program in which participants will receive: 1) 8 one-hour TB education sessions which emphasizes effective coping and communication skills, feelings of self-worth and self esteem, and promotion of health-seeking behavior over the 6 months treatment 2) incentive: $5 US for each DOT dose 3) tracked by outreach worker when default from treatment</td>
<td>Receive 1) a 20-minutes basic lecture on TB and the importance of treatment adherence 2) had a 10-minutes period to discuss questions with nurses during each DOT dose 3) incentive: $5 US for each DOT dose</td>
<td>6 months</td>
<td>1) Treatment completion rate 2) Scores of TB knowledge improvement</td>
<td>1) 62% in intervention group vs 39% in control group(p&lt;0.01; Odd ration: 3.08; 95% CI: 1.28-7.42) 2) improved 3.8 points in intervention group vs 2 points in control group (p&lt;0.01)</td>
</tr>
</tbody>
</table>

**Conclusion:** 1) The rate of treatment completion and the improvement in TB knowledge and TB patients who received a one hour nurse case-managed education session each time they attend for follow up with defaulter tracing was significantly higher than those who only receive one lecture on TB knowledge 2) Defaulter tracking is a potential confounder of the study
### Table 1: Table of Evidence (Cont’d)

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Level of evidence</th>
<th>Patient characteristics</th>
<th>Intervention</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures</th>
<th>Effect size</th>
</tr>
</thead>
<tbody>
<tr>
<td>8. Ailinger, R. L., Martyn, D., Lasus, H., &amp; Garcia, N.L. (2010).</td>
<td>Pre-Experimental (cross-sectional design)</td>
<td>2+</td>
<td>Latino latent TB patients</td>
<td>Culture specific health education and issuing culturally relevant education materials</td>
<td>Historical data from the clients’ records randomly selected in previous year</td>
<td>9 months</td>
<td>Adherence to treatment by means of counting the number of doses taken by patient</td>
<td>157 doses in intervention group vs 129 doses in historical group (p=0.028)</td>
</tr>
</tbody>
</table>

**Conclusion:** Patients received culture specific health education and culturally relevant education materials would have significantly higher adherence to treatment than those who did not.
Table 2: Methodology Checklist

**SIGN Methodology Checklist 1: Systematic Reviews and Meta-analyses**


**SECTION 1: INTERNAL VALIDITY**

**IN A WELL CONDUCTED SYSTEMATIC REVIEW**

<table>
<thead>
<tr>
<th></th>
<th>The study addresses an appropriate and clearly focused question.</th>
<th>Well covered</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1</td>
<td>A description of the methodology used is included.</td>
<td>Well covered</td>
</tr>
<tr>
<td>1.2</td>
<td>The literature search is sufficiently rigorous to identify all the relevant studies.</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.3</td>
<td>Study quality is assessed and taken into account.</td>
<td>Adequately addressed</td>
</tr>
<tr>
<td>1.4</td>
<td>There are enough similarities between the studies selected to make combining them reasonable.</td>
<td>Adequately addressed</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
<thead>
<tr>
<th></th>
<th>How well was the study done to minimise bias? <em>Code ++, +, or –</em></th>
<th>+</th>
</tr>
</thead>
<tbody>
<tr>
<td>2.1</td>
<td>If coded as +, or – what is the likely direction in which bias might affect the study results?</td>
<td>- Only five studies were included without explanation - Detailed searching procedure were not presented</td>
</tr>
</tbody>
</table>
Table 2: Methodology Checklist (Cont’d)

**S I G N Methodology Checklist 2: Controlled Trials**


<table>
<thead>
<tr>
<th><strong>SECTION 1: INTERNAL VALIDITY</strong></th>
<th><strong>The criteria are:</strong></th>
<th><strong>Remarks:</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td>In a well conducted RCT study…</td>
<td></td>
<td></td>
</tr>
<tr>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>The assignment of subjects to treatment groups is randomised</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>An adequate concealment method is used</td>
<td>Not addressed</td>
<td></td>
</tr>
<tr>
<td>Subjects and investigators are kept blind about treatment allocation</td>
<td>Not applicable</td>
<td>The participants and interviewers did not know which group they belonged to. However it is impossible to blind the counselors who carried out intervention</td>
</tr>
<tr>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>The only difference between groups is the treatment under investigation</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>6.3% in intervention group vs 5.8% in control group</td>
<td></td>
</tr>
<tr>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>Where the study is carried out at more than one site, results are comparable for all sites</td>
<td>Not addressed</td>
<td>The sample was recruited from 1 hospital</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<p>| How well was the study done to minimise bias? <em>Code ++, +, or –</em> | ++ |
| If coded as +, or – what is the likely direction in which bias might affect the study results? | |
| Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? | Yes |
| Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes, the target population, intervention and outcome are corresponding to my objective |</p>
<table>
<thead>
<tr>
<th>SIGN</th>
<th>Methodology Checklist 4: Case-control studies</th>
</tr>
</thead>
</table>

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In an well conducted case control study:</th>
<th>In this study:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question</td>
<td>Well covered</td>
<td></td>
</tr>
</tbody>
</table>

#### SELECTION OF SUBJECTS

| 1.2 The cases and controls are taken from comparable populations | Adequately covered | |
| 1.3 The same exclusion criteria are used for both cases and controls | Well covered | |
| 1.4 What percentage of each group (cases and controls) participated in the study? | Cases: 56% Controls: 58% | |
| 1.5 Comparison is made between participants and non-participants to establish their similarities or differences | Adequately addressed | |
| 1.6 Cases are clearly defined and differentiated from controls | Adequately addressed | |
| 1.7 It is clearly established that controls are non-cases | Not addressed | Both case and control were TB patients |

#### ASSESSMENT

| 1.8 Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment | Not applicable | |
| 1.9 Exposure status is measured in a standard, valid and reliable way | Not applicable | |

#### CONFOUNDING

<p>| 1.10 The main potential confounders are identified and taken into account in the design and analysis | Not applicable | |</p>
<table>
<thead>
<tr>
<th>STATISTICAL ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.11</td>
</tr>
</tbody>
</table>

<table>
<thead>
<tr>
<th>SECTION 2: OVERALL ASSESSMENT OF THE STUDY</th>
</tr>
</thead>
</table>
| **2.1** | *How well was the study done to minimise the risk of bias or confounding?*  
*Code ++, +, or –* | + |
| **2.2** | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated? | Yes |
| **2.3** | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
Table 2: Methodology Checklist (Cont’d)

Methodology Checklist 4: Case-control studies


### SECTION 1: INTERNAL VALIDITY

**In an well conducted case control study:**

<table>
<thead>
<tr>
<th>In this study the criterion is:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question</td>
<td>Well covered</td>
</tr>
</tbody>
</table>

**SELECTION OF SUBJECTS**

<table>
<thead>
<tr>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.2</strong> The cases and controls are taken from comparable populations</td>
</tr>
<tr>
<td><strong>1.3</strong> The same exclusion criteria are used for both cases and controls</td>
</tr>
<tr>
<td><strong>1.4</strong> What percentage of each group (cases and controls) participated in the study?</td>
</tr>
<tr>
<td><strong>1.5</strong> Comparison is made between participants and non-participants to establish their similarities or differences</td>
</tr>
<tr>
<td><strong>1.6</strong> Cases are clearly defined and differentiated from controls</td>
</tr>
<tr>
<td><strong>1.7</strong> <em>It is clearly established that controls are non-cases</em></td>
</tr>
</tbody>
</table>

**ASSESSMENT**

<table>
<thead>
<tr>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.8</strong> Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment</td>
</tr>
<tr>
<td><strong>1.9</strong> Exposure status is measured in a standard, valid and reliable way</td>
</tr>
</tbody>
</table>

**CONFOUNDING**

<table>
<thead>
<tr>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.10</strong> The main potential confounders are identified and</td>
</tr>
<tr>
<td>taken into account in the design and analysis</td>
</tr>
<tr>
<td>---</td>
</tr>
</tbody>
</table>

**STATISTICAL ANALYSIS**

| 1.11 | Confidence intervals are provided | Yes |

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1  | *How well was the study done to minimise the risk of bias or confounding?*  
*Code ++, +, or –* | ++ |
| 2.2  | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated? | Yes |
| 2.3  | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |
Table 2: Methodology Checklist (Cont’d)

### SIGN Methodology Checklist 2: Controlled Trials

5. White, M.C., Tulsky, J.P., Goldenson, J., Portillo, C.J., Kawamura, M., & Menendez, E. (2002). Randomized controlled trial of interventions to improve follow-up for latent tuberculosis infection after release from jail. *Archives of Internal Medicine, 162*, 1004-1050

## SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>The criteria are:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>The assignment of subjects to treatment groups is randomised</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>An adequate concealment method is used</td>
<td>Well covered</td>
<td>Using ordered sealed envelopes containing allocation determined by random number table</td>
</tr>
<tr>
<td>Subjects and investigators are kept blind about treatment allocation</td>
<td>Not applicable</td>
<td>It is impossible to blind the incentive group</td>
</tr>
<tr>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>The only difference between groups is the treatment under investigation</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>42% in education group vs 38% in incentive group vs 44% in control group. The high drop out rate is due to the completion of treatment before the study completed and participants were sent to other facility</td>
<td></td>
</tr>
<tr>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis)</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>Where the study is carried out at more than one site, results are comparable for all sites</td>
<td>Not applicable</td>
<td>The sample was recruited from 1 place</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| How well was the study done to minimise bias? |
| Code ++, +, or – |
| ++ |

| If coded as +, or – what is the likely direction in which bias might affect the study results? |

| Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention? |
| Yes |

| Are the results of this study directly applicable to the patient group targeted by this guideline? |
| Yes, the target population is the same and the intervention is corresponding to my objective |
Table 2: Methodology Checklist (Cont’d)

<table>
<thead>
<tr>
<th>Methodology Checklist 2: Cohort studies</th>
</tr>
</thead>
</table>

**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In a well conducted cohort study:</th>
<th>The criteria are:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
<td></td>
</tr>
</tbody>
</table>

**SELECTION OF SUBJECTS**

| 1.2 The two groups being studied are selected from source populations that are comparable in all respects other than the factor under investigation. | Well covered | |
| 1.3 The study indicates how many of the people asked to take part did so, in each of the groups being studied. | Well covered | |
| 1.4 The likelihood that some eligible subjects might have the outcome at the time of enrolment is assessed and taken into account in the analysis. | Well covered | |
| 1.5 What percentage of individuals or clusters recruited into each arm of the study dropped out before the study was completed. | 38% in study group vs 44% in usual care group | |
| 1.6 *Comparison is made between full participants and those lost to follow up, by exposure status.* | Not addressed | |

**ASSESSMENT**

| 1.7 The outcomes are clearly defined. | Well covered | |
| 1.8 The assessment of outcome is made blind to exposure status. | Not applicable | Blinding is not possible |
| 1.9 Where blinding was not possible, there is some recognition that knowledge of exposure status could have influenced the assessment of outcome. | Not applicable | |
| 1.10 | The measure of assessment of exposure is reliable. | Adequately addressed |
| 1.11 | Evidence from other sources is used to demonstrate that the method of outcome assessment is valid and reliable. | Adequately addressed |
| 1.12 | Exposure level or prognostic factor is assessed more than once. | Adequately addressed |

**CONFounding**

| 1.13 | The main potential confounders are identified and taken into account in the design and analysis. | Not addressed |

**statistical analysis**

| 1.14 | Have confidence intervals been provided? | Yes |

## section 2: overall assessment of the study

| 2.1 | How well was the study done to minimise the risk of bias or confounding, and to establish a causal relationship between exposure and effect?  
*Code ++, +, or –* | + |
| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated? | Yes |
| 2.3 | Are the results of this study directly applicable to the patient group targeted in this guideline? | Yes |
Table 2: Methodology Checklist (Cont’d)

**SIGN Methodology Checklist 2: Controlled Trials**


### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>The criteria are:</th>
<th>Remarks:</th>
</tr>
</thead>
<tbody>
<tr>
<td>The study addresses an appropriate and clearly focused question.</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>The assignment of subjects to treatment groups is randomised</td>
<td>Not addressed</td>
<td></td>
</tr>
<tr>
<td>An adequate concealment method is used</td>
<td>Not addressed</td>
<td></td>
</tr>
<tr>
<td>Subjects and investigators are kept blind about treatment allocation</td>
<td>Not applicable</td>
<td>It is impossible to blind the nurse in the intervention group</td>
</tr>
<tr>
<td>The treatment and control groups are similar at the start of the trial</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>The only difference between groups is the treatment under investigation</td>
<td>Well covered</td>
<td></td>
</tr>
<tr>
<td>All relevant outcomes are measured in a standard, valid and reliable way</td>
<td>Adequately covered</td>
<td>The rate of treatment completion is based on self report which may lead to bias.</td>
</tr>
<tr>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>Not addressed</td>
<td></td>
</tr>
</tbody>
</table>
All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis) | Well covered
---|---
Where the study is carried out at more than one site, results are comparable for all sites | Adequately covered

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

<table>
<thead>
<tr>
<th>How well was the study done to minimise bias?</th>
<th>+</th>
</tr>
</thead>
<tbody>
<tr>
<td>If coded as +, or – what is the likely direction in which bias might affect the study results?</td>
<td>The method of randomization and blinding were not addressed which may lead to possible bias. The confounder of defaulter tracking may also influence the outcome. The rate of treatment completion was based on self-reported number of doses taken, which may lead to bias.</td>
</tr>
<tr>
<td>Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the study intervention?</td>
<td>Yes</td>
</tr>
<tr>
<td>Are the results of this study directly applicable to the patient group targeted by this guideline?</td>
<td>Yes, the intervention and outcome are corresponding to my objective</td>
</tr>
</tbody>
</table>
Table 2: Methodology Checklist (Cont’d)

Methodology Checklist 4: Case-control studies


**SECTION 1: INTERNAL VALIDITY**

<table>
<thead>
<tr>
<th>In an well conducted case control study:</th>
<th>In this study the criterion is:</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question</td>
<td>Well covered</td>
</tr>
</tbody>
</table>

**SELECTION OF SUBJECTS**

| 1.2 The cases and controls are taken from comparable populations | Well covered |
| 1.3 The same exclusion criteria are used for both cases and controls | Well covered |
| 1.4 What percentage of each group (cases and controls) participated in the study? | Cases: 40%  Controls: 60% |
| 1.5 Comparison is made between participants and non-participants to establish their similarities or differences | Well covered |
| 1.6 Cases are clearly defined and differentiated from controls | Not applicable  Both case and control were TB patients |
| 1.7 *It is clearly established that controls are non-cases* | Not applicable  Both case and control were TB patients |

**ASSESSMENT**

| 1.8 Measures will have been taken to prevent knowledge of primary exposure influencing case ascertainment | Not applicable |
| 1.9 Exposure status is measured in a standard, valid and reliable way | Not applicable |

**CONFOUNDING**

<p>| 1.10 The main potential confounders are identified and taken into account in the design and analysis | Not applicable |</p>
<table>
<thead>
<tr>
<th>STATISTICAL ANALYSIS</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.11</td>
</tr>
</tbody>
</table>

**SECTION 2: OVERALL ASSESSMENT OF THE STUDY**

| 2.1 | How well was the study done to minimise the risk of bias or confounding? **Code ++, +, or −** | + |

| 2.2 | Taking into account clinical considerations, your evaluation of the methodology used, and the statistical power of the study, are you certain that the overall effect is due to the exposure being investigated? | Yes |

| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | Yes |