Abstract of thesis entitled

An evidence-based nursing education and counselling program for Chronic Obstructive Pulmonary Disease patients to improve medication compliance and quality of life

Submitted by

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Chronic Obstructive Pulmonary Disease (COPD) is a worldwide health issue nowadays and it affects many people all over the world. According to World Health Organization (WHO), it predicts that COPD will become the third leading cause of death by 2030 (WHO, 2012). Also, COPD imposes negative impacts on healthcare system in Hong Kong. Owing to the aging population, the number of elderly suffering from COPD is increasing in Hong Kong. As a result, it brings substantial social and economic burdens to the community.

On the other hand, one of the common problems of COPD patients is inadequate inhalation compliance of medication. This results in poor health status and
Quality of Life (QoL). Furthermore, there are some studies have shown that good medication compliance can reduce hospital admission and improve QoL. Also, some researches proved that nursing education and counselling could effectively improve medication compliance and QoL of COPD patients. Therefore, nursing education and counselling program is supposed to be an effective innovation for improving medication compliance and QoL of COPD patients. The aims of this dissertation are to evaluate the current evidences on the effect of implementing education program into clinical setting, to develop an evidence-based practice (EBP) protocol, to assess the implementation potential and to formulate the implementation plan.

Six eligible research studies were extracted from two electronic searching databases. Critical appraisal was performed to ensure the validity and quality of the eligible studies. It was examined by using checklists developed by The Scottish Intercollegiate Guidelines Network (SIGN). Then, research findings were summarized and synthesized.

Implementation potential was evaluated in terms of transferability and feasibility. For transferability, it assessed the availability of implementing evidenced-based suggestions into real-life settings. Then, feasibility analyzed the capability of evidenced-based recommendations being accomplished by healthcare professionals in clinical settings. Afterwards, cost-benefit ratio was manipulated and it discussed the risks and benefits of new innovation. Furthermore, EBP protocol was developed for clinical uses.
Then, implementation plan was described and sorted into communication plan, pilot study plan and evaluation plan respectively. In communication plan, stakeholders were identified and communication process was explained. Then, pilot study plan was used to evaluate the feasibility of new innovation. At the same time, evaluation plan was prepared for monitoring program effectiveness and outcomes achievements. Last but not least, a set of basis was formulated to consider as the criteria of program effectiveness.

The implementation of the nursing education and counselling program is suggested to be deserved and worthy of adaption into clinical settings in order to safeguard benefits of patients, healthcare providers and healthcare system in Hong Kong.
An evidence-based nursing education and counselling program for Chronic Obstructive Pulmonary Disease patients to improve medication compliance and quality of life

By

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(B.Nurs. H.K.U.)

A thesis submitted in partial fulfillment of the requirements for

the Degree of Master of Nursing

at The University of Hong Kong

In July 2016
Declaration

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

Signed: ________________________________

Ho Ling Kit
Acknowledgements

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## Abbreviations

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<th>Full Text</th>
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<tr>
<td>AECOPD</td>
<td>acute exacerbation of COPD</td>
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<td>APN</td>
<td>Advanced Practice Nurse</td>
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<tr>
<td>COPD</td>
<td>Chronic Obstructive Pulmonary Disease</td>
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<tr>
<td>COS</td>
<td>Chief of Service</td>
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<tr>
<td>DOM</td>
<td>Departmental Operation Manager</td>
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<tr>
<td>EBP</td>
<td>evidence-based practice</td>
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<tr>
<td>FEV1</td>
<td>forced expiratory volume in one second</td>
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<tr>
<td>FVC</td>
<td>forced vital capacity</td>
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<td>GOLD</td>
<td>Global Initiative for Chronic Obstructive Lung Disease</td>
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<td>HAHO</td>
<td>Hospital Authority Head Office</td>
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<tr>
<td>HRQoL</td>
<td>Health Related Quality of Life</td>
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<td>ITT</td>
<td>Intention-to-treat</td>
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<tr>
<td>MO</td>
<td>Medical Officer</td>
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<tr>
<td>MDI</td>
<td>metered dose inhaler</td>
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<tr>
<td>NHP</td>
<td>Nottingham Health Profile</td>
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<tr>
<td>NO</td>
<td>Nursing Officer</td>
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<tr>
<td>NS</td>
<td>Nursing Specialist</td>
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<tr>
<td>p-value</td>
<td>level of significance</td>
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<td>Abbreviation</td>
<td>Full Form</td>
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<tr>
<td>PRISMA</td>
<td>Preferred Reporting Items for Systematic Reviews and Meta-Analyses</td>
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<tr>
<td>QoL</td>
<td>Quality of Life</td>
</tr>
<tr>
<td>RCT</td>
<td>randomized controlled trial</td>
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<td>SIGN</td>
<td>Scottish Intercollegiate Guidelines Network</td>
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<tr>
<td>SGRQ</td>
<td>St. George’s Respiratory Questionnaire</td>
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<tr>
<td>SPSS</td>
<td>Statistical Package for the Social Science</td>
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<td>TOE</td>
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<td>WHO</td>
<td>World Health Organization</td>
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<td>WM</td>
<td>Ward Manager</td>
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Chapter 1: Introduction

This chapter of the dissertation introduces the background information of Chronic Obstructive Pulmonary Disease (COPD), including its definition, management, global and local situations. Also, the affirming needs and significance of nursing education and counselling program towards COPD patients to improve their medication compliance and quality of life (QoL) are explained. Moreover, the objectives and research question are shown in order to enable the public to know more about this dissertation.

1.1 Background

1.1.1 Definition

According to the Global Initiative for Chronic Obstructive Lung Disease (GOLD), COPD is characterized by persistent airflow limitation that is usually progressive and associated with an enhanced chronic inflammatory response in the airways and the lung to noxious particles or gases. Although COPD is an incurable disease, it is preventable by controlling its signs and symptoms. Exacerbations and comorbidities contribute to the overall severity in individual patients (GOLD, 2013).

1.1.2 Signs, Symptoms and Diagnosis Measurement

A diagnosed COPD patient usually has signs and symptoms of dyspnea, chronic cough or sputum production, shortness of breath and different respiratory infections. Moreover, having history of exposure to risk factors such as tobacco smoke and
occupational dusts and family history of COPD are also the main reasons for developing COPD clinically. Furthermore, COPD can be diagnosed by spirometry as below: the presence of a post-bronchodilator FEV1 /FVC < 0.70. Also, according to the GOLD, the severity of airflow limitation in COPD can be categorized into mild, moderate, severe and very severe. Details will be shown in Appendix A.

1.1.3 Management of COPD

In usual circumstances, COPD managements can be divided into 2 categories: pharmacological and non-pharmacological treatments. For pharmacological methods, it aims at reducing symptoms, frequencies and severity of exacerbation. For example, bronchodilators and corticosteroids are two types of pharmacological medications used to managing COPD.

For non-pharmacological measures, it focuses on smoking cessation, physical activity training, rehabilitation and vaccination. In a research study, it indicates that smoking cessation intervention programs can have a substantial positive effect on subsequent mortality (Anthonisen NR et al., 2005). Therefore, early smoking cessation enables better prognosis and improved health status.

1.2 Affirming the Need

1.2.1 Global Trend

According to a survey, it suggests that nearly one-quarter of adults aged 40 years and above have mild airflow obstruction (Buist AS et al., 2007). Moreover, a
study has showed that COPD is the fourth leading cause of death worldwide, accounting for approximately 2.75 million deaths every year (Decramer M et al., 2012). This causes great burdens to the society and affects many people all around the world. According to World Health Organization (WHO), it predicts that COPD will become the third leading cause of death by 2030 (WHO, 2012), as mortality resulting from cardiac diseases and stroke decreased over the last 30 years, while that of COPD doubled over the same period (Jemal A et al., 2005). This causes substantial social and economic burdens to the society such as huge medical expenditures.

Between 1991 and 2000, the hospital admission rate of COPD in the UK doubled and it accounted for 1% of all hospital admissions in the year 2000 (Lung and Asthma Information Agency, 2003). Moreover, COPD has great economic drawbacks to healthcare systems in different parts of the world. In the European Union, the total direct costs of respiratory disease are estimated to be about 6% of the total health care budget, with COPD accounting for 56% (38.6 billion Euros) of the cost spent on respiratory disease (European Respiratory Society, 2003). Therefore, it shows that COPD really has negative impacts on people in many aspects worldwide, resulting in poor QoL, higher mortality and admission rate and greater social and economic burdens.

1.2.2 Local Context

Apart from global situations, COPD also has great negative impacts on healthcare system in Hong Kong. A local study, included 1008 people aged 60 and above, showed that 14% of total sample had moderate to very severe severity of COPD
(Ko FWS et al., 2008). Through estimation, owing to the aging population, this figure shows that many elderly in Hong Kong suffer from the problem of COPD. Furthermore, acute exacerbation of COPD (AECOPD) also worsens the hospital admissions in Hong Kong. In 2009, there were over 29,600 episodes of in-patient discharges and deaths attributed to COPD in public and private hospitals (Hospital Authority, 2009). Moreover, COPD accounted for 1,628 registered deaths in 2009, representing 4% of all registered deaths in that year (Department of Health and Census and Statistics Department, 2009).

1.2.3 Target Setting

The education and counseling program is conducted in respiratory wards of a local hospital as a study has showed that education program results in better medication compliance in target group (Farber HJ, Oliveria L, 2004). Moreover, as this kind of ward mainly has patients diagnosed of different respiratory problems such as AECOPD and asthmatic attack, comparatively, it is easier for me to choose suitable subjects as target population in order to have larger sample sizes for higher generalizability.

1.2.4 Description of Target Setting

Being a registered nurse in a respiratory medical ward of a local hospital, I always need to handle patients with respiratory diseases such as AECOPD. Usually, physicians prescribe antibiotics, steroids and puffs as medical treatments towards this
kind of patients. Based on my personal observation, most of the patients do not show proper and correct inhalation techniques. Usually, they do not follow the step “breathe in slowly through mouth over 4-5 seconds, until lungs are full of air” and the step “hold breath for 10 seconds after inhale a puff”.

Even though there are nurse clinics focusing on inhalation techniques provided by respiratory nurses in the hospital, the result is not satisfactory. Also, the respiratory follow-up of COPD patients usually requires 3-4 months interval, it is difficult for respiratory nurses to offer intense training to COPD patients. Thus poor inhalation technique results in poor QoL and disease management. Therefore, it is important to think of effective methods in order to ensure good medication compliance among COPD patients.

1.2.5 Introduction of New Innovation to Improve Current Practice

According to a research study, the biggest problems of COPD patients with inhalers is using them too much, not using them enough, or using them incorrectly (Hahn K, 1987). As a result, incorrect use and underuse of medications not only cannot relieve the breathing difficulties, but also even worsen the conditions. The knowledge deficit of COPD patients towards the use of inhalers prevents them from getting an adequate dose and eventually misleads the physicians for the effectiveness of medications prescribed. The medical conditions of COPD patients will not be improved under this circumstance. Also, most of the patients usually follow the education instructions and listen to the counselling provided by medical staffs (both physicians
and nurses) due to their professionalism. Therefore, patient education is able to greatly improve compliance and adherence in patients with COPD. Most importantly, nursing counselling only takes few resources and times, compared with the one used to struggling with COPD. As a result, nursing counselling is one of the good method enabling COPD patients to have a better medication adherence and QoL.

In fact, there are many literatures reviewed to assess the relationship between pharmacological medications and severity of COPD. For example, inhaled bronchodilators, like salbutamol and terbutaline, are the primary medications used in treating COPD (Decramer M et al., 2012). However, very few existing data concerns the medication adherence in COPD patients. It was previously reported that only about 37% of patients with chronic lung illness are fully adherent with medical treatments (Shumaker S et al., 2008).

It is important for patients to have good drug compliance. Regrettably, the existing literatures reviewed seldom study the effect of nursing education and counselling on drug compliance of COPD patients. This leaves a research area for us in order to know more about the relationship between counselling and medication compliance of COPD patients. Also, no published systematic reviews can be found on studying the effectiveness of nursing education and counselling program towards medication compliance and QoL among COPD patients. Therefore, there is a need for us to develop an evidence-based protocol of nursing education and counselling program in improving COPD patients’ medication compliance and QoL.
1.3 Significance and Objectives

1.3.1 Significance

Although there is a decreasing number of deaths for chronic respiratory illnesses in Hong Kong from 2005 to 2012, this does not indicate that the problem of COPD has been solved. In fact, according to the service statistics and review conducted by Hospital Authority Head Office (HAHO) in 2013, weekly average of inpatient admission to medical ward during winter surge period has been increasing from 338 in 2012 to 394 in 2013 (HAHO, 2013).

In a study of elderly subjects including patients with asthma and COPD, good compliance to medication reduced both hospital admissions and physician visits (Balkrishnan R et al., 2000). However, medication adherence by patients with COPD is generally poor, with reports citing adherence rates to different treatment regimens of approximately 50% only (Make BJ., 2003) which is low compliance rate. Poor compliance of COPD patients become a significant concern nowadays. As a result, it is very important for COPD patients to adhere to drug so as to lower the hospital admission and thus improve the QoL.

Also, adherence to medical therapies is a growing issue; even the WHO defined it as ‘a new pharmacological problem’. The medical role of drug compliance is getting more and more important. Furthermore, strong relationship derived from a randomized controlled trial (RCT) on the impact of interventions would have the greatest potential and best outcomes in order to make sure that the interventions would be implemented.
in hospital and community settings. Many COPD patients will get benefit from this study.

1.3.2 Objectives

1. To describe the background, affirming needs and significance of COPD in global and local situations.
2. To search for suitable evidence-based studies and reviews of education program towards COPD patients according to research question.
3. To appraise the relevant studies and reviews of education program in improving COPD patients’ medication compliance and QoL.
4. To summarize and synthesize the relevant studies and reviews of related topics.
5. To assess the implementation potential and clinical protocol involving transferability, feasibility and cost-benefit ratio of relevant topics.
6. To develop an implementation plan including feasibility issues, innovation evaluation and implementation basis.

1.3.3 Research Question

The research question is based on PICO process. In fact, PICO process is a technique used in evidence-based practice to frame and answer a clinical question (Huang X, Lin J, Demner-Fushman D, 2006). By identifying P (population), I (intervention), C (comparison) and O (outcome), a research question can be formulated. In this dissertation, P is patients with COPD, I is nursing education and counselling
program, C is routine care, O is medication compliance and QoL. So the research question is “In patients with chronic obstructive pulmonary disease, how does nursing education and counselling program compare to routine care affect medication compliance and quality of life?”.
Chapter 2: Critical Appraisal

2.1 Search and Appraisal Strategies

2.1.1 Identification of Studies


2.1.2 Inclusion Criteria

1. The study population includes people, clinically diagnosed of COPD, aged 40 years old or above of both sex.

2. The primary intervention is education and counselling program compared with
patients receiving routine cares provided by medical or nursing sectors in control group.

3. The study outcomes are medication compliance and QoL and using validated assessment tools for measurement.

4. The study design is randomized controlled trial (RCT) and is from 2000 – 2015.

5. The research study is in English version and in full-text available.

2.1.3 Exclusion Criteria

1. Population with poor cognitive state or mental instability.

2. Population with an exacerbation during the run-in period.

3. Studies including population diagnosed with asthma and low level of evidence such as editorials and case studies.

2.1.4 Appraisal Strategies

All the research studies included will be critically appraised by the checklists developed by The Scottish Intercollegiate Guidelines Network (SIGN). In fact, SIGN is a national healthcare improvement organization in Scotland and it was formed in 1993. It aims at developing and disseminating evidence-based practice guidelines in order to improve the quality of health care (SIGN, 2014). The level of evidence of eligible studies will be graded by SIGN grading system 1999 – 2002. Details of SIGN grading system and checklists will be shown in Appendix B.
2.2 Results

2.2.1 Search Results

All the eligible studies were searched by PubMed and Cochrane Library. During the searching process, 4 sets of searching keywords were included separately by Boolean “OR”. Then, the respective searching results were combined by Boolean “AND”. At this stage, no additional filters were applied so as to obtain maximum number of eligible studies. Finally, there were totally 778 suitable journals searched in both databases: 306 for PudMed and 472 for Cochrane Library respectively.

Also, manual searching was incorporated as other sources and Google Scholar was applied in this searching process. There were 512 suitable journals identified from Google Scholar. Afterwards, 27 duplicates were found and removed. Then, additional filters were applied according to inclusion and exclusion criteria and then 117 RCTs were screened. Afterwards, after assessing all full-text articles, only 6 suitable quantitative journals were left. They were M. R. Khdour et al. (2009), E.O. Efraimsson et al. (2008), G. Ninot et al. (2011), Press, V. G.et al. (2012), Leiva-Fernández et al. (2014) and Wei, L. et al. (2014). Searching details will be shown in Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2009 flow diagram as Appendix C.

In fact, PRISMA is an evidence-based minimum set of items in systematic reviews and meta-analyses and it is a useful tool in reporting of reviews evaluating randomized trials (PRISMA statement, 2015).
2.2.2 Description of Table of Evidence (TOE)

A TOE is a chart summarizing the content of an interventional study. It provides us the information of bibliographic citation, study design, sample characteristics, intervention, comparison, length of follow up, outcome measures, effect size and evidence level. The appraisal strategies of internal validity will be discussed in the following paragraph and the TOE of each eligible study will be shown in Appendix D.

2.2.3 Appraisal Strategies of Internal Validity

2.2.3.1 Research Titles

In these 6 eligible journals, all of them address an appropriate and clearly focused title respectively. Aim and objective of each study states clearly and specifically in the abstract and introduction. As a result, research titles can be easily identified and this enables us to clearly understand the major goal of the interventional studies.

2.2.3.2 Study Design

All of the journals selected were RCTs and they were conducted in different parts of the world including Ireland, Sweden, France, the United States, Spain and China. All of them clearly state the intervention and control group which are the crucial element of a RCT. Moreover, M. R. Khdour et al. (2009) and Wei, L. et al. (2014) offered education and counselling program by pharmacists while E.O. Efraimsson et al. (2008) provided interventional program by nurses. Also, most of the control group of all studies received routine cares provided by medical, pharmacological or nursing
sectors. Moreover, Press, V. G. et al. (2012) gave brief instruction as control group while intervention group composed of brief instruction and demonstration of inhaler uses.

### 2.2.3.3 Randomization Method and Allocation Concealment

Randomization of the study sample allocated into intervention and control group was maintained. Different methods of randomization were provided including minimization method, block randomization technique, biostatistician-generated random allocation sequence and computer-generated coding. However, E.O. Efraimsson et al. (2008) and G. Ninot et al. (2011) did not provided information of randomization methods. For allocation concealment, Wei, L. et al. (2014) used sealed envelope labeled with consecutive numbers while E.O. Efraimsson et al. (2008) appointed an independent person to draw lots for allocation. The rest of 4 studies did not mentioned about the concealment method so that we cannot make conclusion of achieving method of concealment.

### 2.2.3.4 Blinding

Blinding was only achieved by Wei, L. et al. (2014) because computer-generated and sealed in envelopes labeled with consecutive numbers minimized the chance being noted by educators. On the contrary, rest of 5 studies did not provide details of blinding method because counselling interventions required educators to
involve actively. Therefore, it is quite difficult to maintain a complete blinding to both educators and participants and thus results in study bias.

2.2.3.5 Baseline Characteristics

The baseline characteristics of participants in both intervention and control group were reported and shown in charts in all studies. Within these journals, the baseline characteristics were similar and no significant difference was noted. Also, P values were mentioned by M. R. Khdour et al. (2009), Press, V. G.et al. (2012) and Leiva-Fernández et al. (2014). In fact, p value is the observed chance to committing a false positive error. Taking level of significance is 5%, If p>0.05, it means that similar baseline characteristics are resulted in intervention and control group. The p-value in these studies is greater than 0.05.

2.2.3.6 Measurement Tools

Totally, there were 5 eligible studies used St. George’s Respiratory Questionnaire (SGRQ) and Press, V. G.et al. (2012) applied symptom questionnaires as their measurement tools respectively. No validation detail of symptom questionnaires was provided. In fact, SGRQ is a scientific questionnaire in measuring the health related quality of life (HRQoL) of COPD patients. Moreover, the SGRQ has been shown to be a valid measure of health impairment in patients with chronic airflow limitation and to be responsive to change as a result of therapy (Jones PW., 1992).
Furthermore, it totally consists of 76 items and includes three major parts: symptoms, activity and impact. A comprehensive review of the patient’s respiratory status can be obtained by calculating the total scores from all components. The scoring range for each component is from 0 to 100, with the highest scores indicating the poorest health level.

2.2.3.7 Attrition Rate and Intention-to-treat Analysis

Attrition rate is the measurement of the number of subjects moving out from the study population over a research period. The sample size of each study ranged from 45 to 173 and all of them had different drop-out rates ranged from 16% to 30%. Within the 6 eligible studies, only Leiva-Fernández et al. (2014) and Wei, L. et al. (2014) mentioned about the application of Intention-to-treat (ITT) analysis while the rest of 4 journals did not have any information provided. In fact, ITT analysis helps to minimize the misleading artifacts deduced from interventional studies. Therefore, increased attrition bias will be resulted if ITT analysis does not apply.

2.2.3.8 Study Quality

According to the notes of methodology checklist, the study quality can be classified as high (++), acceptable (+) and low (-). When all or most of the checklist criteria have been fulfilled, journal will be graded as high (++); when some of the items are met, acceptable (+) grading will be given and when few or no criteria are fulfilled,
low quality (-) of the study will be resulted. In fact, all of the journals selected were graded as acceptable (+) because both studies had advantages and limitations. For example, M. R. Khdour et al. (2009) showed good randomization process by using minimization method while lack of blinding procedure increased the risk of bias. The overall study quality was satisfactory and they were adopted in developing evidenced-based protocol in this dissertation topic.

2.2.3.9 Levels of Evidence

The level of evidence of all eligible studies will be graded by SIGN grading system 1999 – 2002 (SIGN, 2014) and they were reported in TOE. According to the system hierarchy, it ranges from 1++ to 4 depending on the study designs and risks of bias. E.O. Efraimsson et al. (2008) and Wei, L. et al. (2014) were ranked as 1+ as they were well-conducted RCTs with a low risk of bias such as application of ITT analysis and blinding strategy. Then, the rest of 4 journals were rated as 1- due to their high risks of bias such as small sample size and low generalizability. The overall evidence level was good and the results of the studies gave us useful framework in designing the evidenced-based protocol.
2.3 Summary and Synthesis

2.3.1 Summary of Findings

2.3.1.1 Patient Characteristics

There were totally 593 patients were recruited as eligible participants in all 8 research studies. Their age range was 18 years old or above and both sex of patients were included. Inclusion criteria were clearly listed and this gave us the details of patient characteristics. For example, the presence of a post-bronchodilator FEV1/FVC < 0.70 was one of the inclusion criteria and this was the COPD diagnosis guideline suggested by GOLD. Also, some studies required stable COPD patients which indicated that there were no AECOPD during the research period. On the contrary, subjects with congested heart failure, moderate to severe learning difficulties and attended pulmonary habilitation programs before were excluded in these studies. Moreover, patients having other respiratory problems except COPD were also being excluded.

2.3.1.2 Intervention, Duration and Frequency

All 8 studies selected examined the relationship between education and counselling programs towards the medication compliance and QoL of COPD patients respectively. For example, E.O. Efraimsson et al. (2008) offered nursing education program to intervention group and its content including self-care training and coping ability towards AECOPD. Each session lasted for 1 hour and 3-5 months interval follow-up were provided in order to monitor the effectiveness of intervention towards
COPD patients. Also, G. Ninot et al. (2011) provided 2 hours self-management program for 4 weeks as intervention to examine the effects towards QoL.

2.3.1.3 Length of Follow-up

The length of follow-up of each study varied and it ranged from 30 days to 12 months. Most of the studies provided 2 follow-up sessions except Press, V. G.et al. (2012) offered a 10 minute telephone interview and Leiva-Fernández et al. (2014) provided 3, 6, and 12 months follow-up to both intervention and control group.

2.3.1.4 Outcomes and Measurement Tools

The outcomes of the research topic were adherence of medication and QoL. Medication adherence was measured by Morisky scale and dose counter while QoL was measured by SGRQ and Nottingham Health Profile (NHP). In fact, all of these measurement tools were validated in studying one’s QoL and drug compliance. Higher score in SGRQ and NHP indicated poorer health status. Fewer number of dose counter represented better compliance while higher score of Morisky scale indicated lower compliance.
2.3.1.5 Study Results

For the study results, almost all journals agreed that there was positive relationship between education programs towards medication compliance and QoL. Only Leiva-Fernández et al. (2014) showed that there were no differences in SGRQ score between intervention and control group. Moreover, almost all studies provided statistically significant results in SGRQ, NHP, Morisky scale and dose counter. For example, Wei, L. et al. (2014) showed statistically significantly results in components of symptoms and impacts in SGRQ and at 6 months and 1 year follow-up in dose counter.

2.3.2 Synthesis of Findings

2.3.2.1 Study Design

From the studies above, all are RCTs and this gives us the idea of using its advantages to develop evidenced-based protocol. In fact, RCT is a good study design in measuring the effectiveness of medical intervention in clinical trial. Also, RCT is regarded as the most reliable form of scientific evidence in evidence hierarchy, advantages of RCT can be clearly shown. Furthermore, random allocation, blinding and allocation concealment help to minimize the study bias and thus increase the objectivity and study quality. Wei, L. et al. (2014) is a good example of RCT as it matches most of the categories in SIGN checklists, therefore, its study design can give us a good framework for thinking of study protocol.
2.3.2.2 Patients Characteristics

From the previous paragraph, we know that there were totally 593 patients were recruited in 8 research studies. M. R. Khdour et al. (2009) included patients with an FEV1 between 30% - 80% while that for Wei, L. et al. (2014) ranged between 25% - 79%. Both studies recruited 173 and 117 eligible participants respectively. According to the Classification of Severity of Airflow Limitation in COPD suggested by GOLD, they belonged to GOLD 2 (moderate), GOLD 3 (severe) and GOLD 4 (very severe). Due to the relatively larger sample size in these studies, it suggests us to choose patients with these categories so as to get higher generalizability. Also, Wei, L. et al. (2014) excluded patients with major diseases such as severe heart, liver and kidney diseases because these types of illnesses usually affect breathing ability of subjects and thus severity of COPD may be affected too. This is one of the good exclusion criteria and need to be considered when we set our protocol.

2.3.2.3 Intervention

In our 8 studies selected, all of them examine the relationship between education and counselling programs towards the medication compliance and QoL of COPD patients respectively. This matches our research topic. Also, all studies show positive impact towards outcomes measure by implementing different interventions. E.O. Efraimsson et al. (2008) provided education program by teaching COPD patients the self-care skills and coping strategies in nurse-led clinics. Each session lasted for 1 hour and 3-5 months interval follow-up were provided in order to monitor the
effectiveness of intervention towards COPD patients. Its advantage is the convincing effects of nurse-led clinic towards COPD patients which had been shown to be effective. However, the research nurse of the study performed the intervention and this induced confronting factors to the study. In my opinion, I think that the professional effect of nurse helps us to convince patients to remember the content of education program and this facilitates the progress of interventions. However, researchers should avoid performing interventions in order to maintain objectivity of the study.

2.3.2.4 Control

In fact, 7 out of 8 studies’ control groups received usual care provided by medical, pharmacological and nursing professionals. On the contrary, Press, V. G.et al. (2012) gave brief instruction as control group while intervention group composed of brief instruction and demonstration of inhaler uses. In my opinion, I think that the control setting of Press, V. G.et al. (2012) should be avoided owing to comparison of two interventional effects. Confusion will be resulted and it is quite difficult to measure the effect of 2 interventions in a single study.

2.3.2.5 Outcome Measures

The primary and secondary outcomes of the research topic are medication compliance and QoL respectively. Moreover, I think that outcome should be measured by some validated measuring tools so as to increase the trustworthiness and quality of
the study. In fact, dose counter and SGRQ are two validated measuring tools to investigate the medication compliance and QoL of an individual. Therefore, these two measuring tools can be applied due to their advantages shown.

2.3.2.6 Methodological Quality

For the methodological quality, good randomization procedure, blinding technique and allocation concealment should be adopted in order to maintain good quality of a study. For example, minimization method and block randomization technique are applied by M. R. Khdour et al. (2009) and Leiva-Fernández et al. (2014) respectively. Also, randomization codes generated by computer and sealing in envelop was applied by Wei, L. et al. (2014) to maintain allocation concealment. These techniques are good measures adopted in formulating the study protocol.

2.3.3 Conclusion

In conclusion, COPD is a worldwide and local health issue nowadays and it causes great economic and health burdens to the societies. Also, 6 eligible studies were adopted through the searching process and criteria. All of them suggest that education and counselling programs are effective towards the medication adherence and QoL of COPD patients. Also, the qualities of the journals are critically appraised by SIGN grading system and checklists and the results are summarized and synthesized. Furthermore, details of each research are concluded in the form of TOE.
From the above studies, education program applied by Wei, L. et al. (2014) includes many aspects such as the use of respiratory devices and medication management. They are important factors in maintaining good medication compliance and QoL. In fact, COPD patients usually are elderly and it is difficult for them to adopt and maintain new techniques taught by others. Therefore, the interventions suggested by Wei, L. et al. (2014) can be applied in my clinical setting due to the advantageous content of education program. Furthermore, dose counter and SGRQ are two validated tools in measuring the medication adherence and QoL of an individual. Being a nursing staff in a respiratory ward, it is easy for me to observe the poor medication compliance and QoL among COPD patients. As a medical professional, it is important for me to develop an evidenced-based protocol of education program improving the drug compliance and QoL among COPD patients in order to prevent the situation from worsening.

As a result, an evidence-based education and counselling protocol can be established based on the evidence proved by studies above and it can be applied to patients who meet the requirement of the target population in the appropriate setting.
Chapter 3: Implementation Potential and Clinical Guideline

Before we can develop our evidence-based practice (EBP) protocol, implementation potential should be evaluated in order to lower the chance of failure and get a more realistic approach. It is a criteria developed for generating and assessing evidence for nursing practice (Polit & Beck, 2008). In fact, implementation potential includes 3 components and they are transferability, feasibility and cost-benefit ratio.

Furthermore, transferability assesses the availability of implementing the EBP suggestions, which are recommended by research studies and journals, into real-life situations. Then, feasibility analyzes the capability of EBP recommendations being accomplished by healthcare professionals in clinical settings. Finally, cost-benefit ratio discusses the risks and benefits of new innovation.

3.1 Target Setting and Audience

3.1.1 Target Setting

The education and counselling program will be conducted in respiratory wards (both male and female ward) of a local hospital. In fact, they are medical admission wards and have totally 100 beds for admitted patients. Usually, these respiratory wards handle patients with different respiratory illnesses such as acute exacerbation of COPD, pleural effusion, asthmatic attack etc. According to the admission rate of the Department of Medicine in 2015, there were approximately one-third (33%) of the total patients admitted for COPD exacerbation.
Moreover, the program will be organized as an in-patient basis and mainly focuses on improving medication compliance and Quality of Life (QoL) of COPD patients. In current situation, there is no relevant education program targeting medication adherence and QoL. Also, the health education provided is not standardized and not all COPD patients receive such counselling by healthcare professionals.

3.1.2 Target Audience

According to admission record of respiratory wards in 2015, the target audiences have some common characteristics. They are patients aged 40 years old or above of both sex. Also, they are diagnosed of COPD, from GOLD 1 to 4 according to the classification of severity of airflow limitation in COPD (GOLD, 2013). Then, they are able to communicate with English, Cantonese or Mandarin.

Furthermore, patients without terminal diseases such as end stage malignant illnesses, lacking an exacerbation during the run-in period and not participated in respiratory rehabilitation programs in the past year are included. However, patients with poor cognitive state or mental instability are excluded. Also, patients with unstable cardiac diseases such as congestive heart disease and ischemic heart disease are not included. This is to ensure similar characteristics between participated patients.
3.2 Transferability of the Findings

Before we transfer the EBP protocol into real-life situations, it is necessary for us to assess whether the findings suggested from eligible studies are transferable into the target setting. In fact, it includes 4 categories and they are similarity between target setting and audience and those in literatures reviewed, philosophy of care, clients benefit from the innovation and duration of implementation and evaluation. Details will be shown as below.

3.2.1 Similarity of Target Setting and Audience and those in Literatures Reviewed

3.2.1.1 Basic Characteristics of Target Audience

Details of similarity between target setting and audience and those in literatures reviewed are summarized and shown in Appendix E. From the table, we can see that the age range of population in proposed setting and literature reviewed is similar. Also, both of them diagnosed with mild to very severe COPD (GOLD, 2013). As a result, they share similar basic characteristics between target audiences in terms of population and severity of disease.

3.2.1.2 Similarity of Setting

According to the selected journals, they carried out their interventions in out-patient COPD clinics, in-patient care settings and university-based centers. For my proposed setting, the education and counselling program will be implemented in in-
patient respiratory wards. Also, nurses and pharmacists are the main educators in literatures reviewed while nursing is the major discipline for organizing intervention in my proposed setting. Therefore, they share similarities in terms of setting and educator.

3.2.1.3 Country/ Region of Intervention

The eligible studies implemented their interventions in both Western and Asian countries while my proposed innovation will be carried out in Hong Kong. Cultural difference maybe a minor problem but it is not expected to affect the innovation in a great extent. As a result, they share similar characteristics in country/ region of intervention.

3.2.2 Philosophy of Care

Philosophy of care is another aspect required to consider in transferability. The aim of innovation is to improve medication compliance and QoL of COPD patients by implementing education program in clinical settings. Also, it focuses on promoting EBP protocol in real-life situations. These are similar with the objectives of literatures reviewed. Moreover, we need to provide holistic cares and practice benefits to our patients. This is the objective of our education program and it coincides with aims of eligible studies. Therefore, both proposed setting and those in literatures reviewed have similar philosophy of care.
3.2.3 Clients benefit from the innovation

As we have mentioned before, there are totally 100 admission beds in both male and female respiratory wards. According to the 2015 admission record of the Department of Medicine, around 33% of patients admitted for COPD exacerbation. As a result, around 33 COPD patients will be benefited from the education program. They will be offered education and counselling program to improve their medication compliance and QoL.

3.2.4 Duration of Implementation and Evaluation

According to the research journals discussed in chapter 2, the duration of implementation varied in different studies and it usually ranged from 3-5 months interval. Also, the evaluation period ranged from 30 days to 12 months in follow-up session. For the education program, it is estimated that the implementation and evaluation will last for 3 months period and at the end of education program respectively as suggested by most of the journals selected. As a result, the time frame between proposed setting and literatures reviewed is similar.

3.3 Feasibility

After assessing the transferability of new innovation, we need to evaluate the feasibility of the program. There are 7 categories in feasibility and they are freedom of nurses to implement or terminate the program, interference with current staff functions,
administration support and organizational climate, consensus, nursing staff training and skills, equipment and facilities and measurement tools for evaluation respectively.

3.3.1 Freedom of Nurses to Implement or Terminate the Program

The education program will be initiated and operated independently and solely by nurses. As healthcare professionals, nurses require to utilize their own nursing knowledges and skills to make appropriate clinical decisions and judgements in order to safeguard patients’ benefits. During education program, the nurses’ in-charge is responsible for monitoring the medical conditions and progresses of participants. Furthermore, the case nurses of each ward have the duty to introduce and refer suitable patients to join the program. Moreover, all nurses involved are welcomed to give any comments towards the program. Pre-intervention education session will be offered to nurses so as to strengthen their confidences for clinical changes. As a result, nurses have the freedom to implement or terminate the program with reasons specified.

3.3.2 Interference with Current Staff Functions

Gaining the cooperation from current staff is an important factor to run a new innovation smoothly in clinical settings. However, reluctant to change of nursing staff may bother and hinder the progress of program. Therefore, we need to think out related solutions to maintain good operation of the program. For example, we can offer meetings and briefing sessions to existing staff so as to enable them to know more
about the aims and objectives of the program. Moreover, mainly nursing staff are responsible for conducting the program and therefore the intervention will not interfere with daily operation of the department.

3.3.3 Administration Support and Organizational Climate

Good administration support is crucial to operate the program successfully. Therefore, a detailed proposal of the education program should be presented to the Chief of Service (COS), the Departmental Operation Manager (DOM) and Ward Managers (WM) in order to enable them to assess the budget planning and manpower support of the program. In the past 5 years, there were several new projects implemented in different settings such as patient’s diary and patients’ satisfaction survey. As a result, they always welcome for new innovations and so the proposed program can gain the supports from administrators.

3.3.4 Consensus

Consensus should be made among administrators, nurses and patients of the hospital. Firstly, the program coordinator should acknowledge the administrators about the benefits and importance of organizing an education program to COPD patients. After getting the approval from administrators, WMs of respiratory wards will inform the frontline nursing staff for the implementation of new intervention. On the other hand, patients should also be acknowledged as they are the target population of the
program. In view of promoting medication compliance and QoL, it is believed that they will join the program.

3.3.5 Nursing Staff Training and Skills

As nurses will be the educators of our participants, they are required to attend a 2-hours training session for the introduction and details of the program. Nurses who have joined the training workshop will be eligible professional for educating COPD patients. During the training workshop, they will learn to use dose counter and St. George’s Respiratory Questionnaire (SGRQ) to evaluate medication compliance and QoL respectively. In view of training period, it is feasible for the department to arrange the session and manpower for joining the education and counselling program.

3.3.6 Equipment and Facilities

As the education program will be held as an in-patient basis, equipments such as education room, stationary, projector and computers are already available in current settings. Also, puffs and aero-chambers are ward-stock items and no extra preparation is needed. However, education pamphlets and evaluation forms are required to prepare before the implementation of the program.
3.3.7 Measurement Tools for Evaluation

Dose counter is used to evaluate medication compliance while SGRQ is chosen to monitor QoL of participants respectively. In fact, dose counter is one of the most commonly used and is a relatively objective method for evaluating medication compliance. Moreover, SGRQ is a validated measuring tool with good reliability and is a disease-specific instrument designed to measure impact of respiratory symptoms on overall health, daily life and perceived well-being.

3.4 Cost-Benefit Ratio of the Innovation

Cost-benefit ratio is required to be reviewed after evaluating the transferability and feasibility of the innovation. These mainly include potential benefits and potential costs of the innovation.

3.4.1 Potential Benefits

3.4.1.1 Potential Benefits of Patients

Education and counselling program might provide clinically significant improvements in QoL (G. Ninot et al., 2011); (E.O. Efraimsson et al., 2008). Also, studies suggested that the use of education intervention could contribute to adherence in COPD patients and could allow them to better understand the concept of adherence (Leiva-Fernández et al., 2014). Furthermore, an individualized education program could promote medication compliance in patients with COPD (M. R. Khdour et al.,
2009); (Wei, L. et al., 2014) (1+). As a result, benefits of innovation can be easily shown as suggested by literatures reviewed.

### 3.4.1.2 Potential Benefits of Nurses

Through developing an EBP protocol, this provides nurses with standardized and unique recommendations towards improving medication compliance and QoL of COPD patients. Also, the protocol offers nursing staff with updated and comprehensive medical knowledge and information and this matches the concept of whole-person development. Furthermore, better nurse-clients relationship could be established as suggested by research journal (E.O. Efraimsson et al., 2008). Moreover, the workloads and burdens of nurses might be decreased when handling patients with more stabilized medical conditions after education.

### 3.4.1.3 Potential Benefits of Healthcare System

World Health Organization (WHO) predicts that COPD will become the third leading cause of death by 2030 (WHO, 2012). As a result, it brings great social and economic burdens to healthcare systems worldwide. A study suggested that education program was associated with a statistically significance in costs of COPD medication compared to usual care (G. Ninot et al., 2011). Also, reduction in healthcare service utilization relieves the pressure of acute hospitals and shortens the consultation time of patients admitted.
3.4.2 Potential Costs

3.4.2.1 Potential Risks to Patients

There were no obvious risks to patients as mentioned by all research studies. The participants continue their physicians’ expert managements in addition to the nursing education program. Moreover, the innovation is free of charge and education time is the only cost to patients. Considering the improved health outcomes of patients, it is worthy to spend their time on the program.

3.4.2.2 Potential Risks of Maintaining Current Practices

Due to the problem of aging population, greater COPD prevalence in Hong Kong can be anticipated. Education program is an effective method for improving medication compliance and QoL as discussed before. Therefore, more patients with COPD will get suffered if maintaining current practice. Also, this results in huge burdens on healthcare system and giant medical expenditures will be expected. On the other hand, this also increases the workload of medical experts when taking care of more COPD patients in the future. As a result, patients, healthcare professionals and system will be affected if continuing current practice.

3.4.2.3 Potential Material and Non-Material Costs

For material cost, it can be divided into set-up and running costs. A table of estimated annual set-up and running cost with detailed calculations are summarized
and shown in Appendix F. The estimated set-up cost consists of a staff training session and an education session respectively. The total estimated set-up cost is $522.

The estimated running cost of education program mainly includes a 10-pages education pamphlet and a 6-pages evaluation form. With each photocopy costs $0.3, the printing cost is $960. Also, 4 registered nurses are appointed as training staff and it costs $1,312 for entire education session. Therefore, the total estimated running cost is $45,568 with additional costs for individualized action plans. As the program requires 4-months period including preparation and evaluation time, it can operate 3 times per year. Therefore, the annual estimated costs of the program would be $137,226 ($522+$45,568x3).

For non-material costs, transition period should be allowed for nurses to get familiar with the program so as to enable them to provide effective education to COPD patients. On the contrary, since the intervention results in nurses’ extra working hours, it may become the burden to the frontline staff. In long term, it may lead to low staff morale, high staff turnover and absence rate.

3.5 Evidence-Based Practice Protocol

After assessing the implementation potential, including transferability, feasibility and cost-benefit ratio, an EBP protocol is formulated in order to implement the proposed intervention into real clinical settings. From the selected research journals and studies, there are totally 10 EBP recommendations proposed. The level of evidence of eligible studies and the grade of recommendations will be assessed by SIGN grading
system 1999 – 2002 (SIGN, 2014). Details of the EBP protocol and the grade of recommendations are summarized in Appendix G and H respectively.

### 3.6 Conclusion

After evaluating the implementation potential of innovation, the education program is highly transferable and feasible. Also, the intervention is cost-effective as potential benefits outweigh potential costs. As a result, it is worthy to implement new innovation to the target population.
Chapter 4: Implementation Plan

After assessing the implementation potential and formulating the clinical protocol, it is crucial to develop an implementation plan in order to promote successful operation of the proposed program. In fact, an implementation plan includes a communication plan, a pilot study plan and an evaluation plan.

4.1 Communication Plan

Good communication between each stakeholder is important for smooth implementation of new innovation and it mainly depends on a good communication plan.

4.1.1 Identification of Stakeholders

In fact, a stakeholder is someone who is affected by or may affect the proposed changes or anticipated results of the proposed innovation. In the education program, stakeholders can be divided into 2 categories: managerial and frontline level.

For managerial level, Chief of Service (COS) of the hospital, Departmental Operation Manager (DOM) of the Department of Medicine and Ward Managers (WM) of respiratory wards are the stakeholders in the program. As they are responsible for decision-making and clinical development, it is important to get their approvals and supports before we can initiate the innovation. Letters and meetings will be formally presented and organized for notification and agreement seeking.
For frontline level, nursing staffs are the stakeholders as they are the target users of the evidence-based practice (EBP) protocol. As nurses are the major health educators in the program, it is important to equip them with updated and standardized clinical knowledge in order to provide a high-quality education. Training session will be offered to nurses before the initiation of the innovation.

4.1.2 Process of Communication Plan

A good communication plan enables different stakeholders having a better understanding of the program and less conflict will be aroused throughout the implementation. The communication plan lasts for 2 months and details will be explained as below.

4.1.2.1 Communication with Managerial Level of the Hospital

Managerial colleagues of the hospital, for example, COS, DOM and WM of respiratory wards, are the first target group we need to communicate and approach before program initiation. As they usually are the policy and decision makers, getting their approvals and supports is vital towards the innovation.

First of all, formal letters will be presented to the managerial staffs of the hospital in order to draw their attentions and give them a brief concept of the education program. Afterwards, formal meetings will be organized so as to provide them with a comprehensive and detailed proposal of the innovation. This will be carried out in the
form of PowerPoint presentation. Then, the contents of the presentation are clearly shown and include the significances of initiating the clinical changes, the supporting literatures reviewed, the transferability and feasibility into clinical settings etc. Also, the whole implementation plan will be provided for better understanding.

4.1.2.2 Forming a Communication Team

For effective program initiation and sustainment, a communication team should be organized. There are totally 8 team members and each of them has different roles. First of all, a Respiratory Nursing Specialist (NS), who is mainly responsible for monitoring the progress and supervising the quality of education, will be appointed as team leader. Then, 4 link nurses in respiratory wards will act as team members and they will organize regular team meetings and update the latest information to ward staffs. Afterwards, a respiratory medical consultant and a medical officer will be invited as members of the communication team. Their main duty is to review the education contents and refer eligible patients as target participants of the program. Finally, a trainer (me) will be responsible for program promotion and education training to different healthcare professionals in clinical settings.
4.1.2.3 Communication with Nursing Officers (NO) and Advanced Practice Nurses (APN) of respiratory wards

Formal E-mails will be sent to NO and APN by the communication team leader in order to inform them the program initiation and seek for their cooperation. Also, they will be invited to attend the regular team meetings for monitoring the progress of the program. Furthermore, they are encouraged to update the latest program information to clinical colleagues in daily handover session.

4.1.2.4 Communication with Nurses in Respiratory Wards

Then, we need to communicate with the EBP protocol users, nurses in each respiratory ward, for the program implementation. Firstly, a 30-minutes briefing session will be offered by link nurses. The first session mainly introduces ward colleagues about the education program and the EBP protocol. Furthermore, any updated information from communication team will be shared and disseminated by link nurses during sharing sessions. Also, nurses are welcomed to make any enquiries towards the program by either sending E-mails or approaching the related link nurses. Also, they are encouraged to provide any feedbacks and suggestions for program improvement. Then, the WM will give a briefing session to nursing staffs so as to gain their supports. Furthermore, an education pamphlet and EBP protocol will be given to each respiratory ward for references.
4.1.2.5 Communication with Respiratory Medical Officers (MO) in the Department

Formal E-mails will be sent to each respiratory MO for the program implementation. The contents include comprehensive details of the program which enables them to understand the new clinical changes. Also, the respiratory medical consultant will brief his colleagues about the innovation to gain their supports and cooperation.

4.2 Pilot Study Plan

Before the initiation of a full scale study, a pilot study plan is essential to evaluate the feasibility of the new changes. As there are no such clinical protocols in my clinical setting, it is important to have a pilot testing for feasibility monitoring and program evaluation.

4.2.1 Objectives

1. To assess the feasibility of implementing education program in clinical setting.
2. To identify potential barriers during pilot testing and make relevant modifications.
3. To assess staffs’ compliance towards the program.
4. To assess satisfaction level of staffs and patients towards the program.
4.2.2 Pilot Study Setting and Recruitment

The inclusion criteria of the target settings and participants are identical to the EBP protocol mentioned in chapter 3. The pilot test will be implemented in both respiratory wards (male and female) of the hospital. Also, the target participants are hospitalized patients aged 40 years old or above and are diagnosed of COPD according to the classification of severity of airflow limitation in COPD (GOLD, 2013). Also, they are mentally stable and able to communicate with English, Cantonese or Mandarin. All eligible participants are recruited by convenience sampling. From the statistics record of the Department of Medicine, the average monthly admission rates for acute exacerbation of COPD are approximately 10 patients in a ward. As a result, there are totally 20 COPD patients recruited for the pilot testing in order to fulfil data saturation.

4.2.3 Time Frame

The pilot study and evaluation will last for 3 months. Details of communication plan and pilot study plan will be shown in Appendix J. Firstly, 6-weeks period will be used for communicating with managerial and frontline staffs. Then, forming a communication team will last for 2 weeks. Afterwards, training period and material preparation will require 1 month respectively. Then it comes to recruitment stage which will last for 2 weeks. Furthermore, pilot testing, which will require 2-months period, will be followed. Finally, we use 1-month period for evaluating study’s feasibility and revising protocol.
4.2.4 Pilot Review

After the completion of pilot study, the communication team will evaluate the program before full scale implementation. Afterwards, related modifications towards EBP protocol will be made.

For satisfaction level of patients, a questionnaire will be distributed to each patient who has participated in the education program. Details of the questionnaire will be shown in Appendix K.

For staffs’ compliance and satisfaction level, it is a vital element towards program evaluation. Therefore, it is important to investigate their difficulties encountered, for example heavy workload, lacking support from colleagues etc., towards the program. Each staff will be allocated a set of 5-point scale questionnaire and details will be shown in Appendix L.

After the pilot study analysis and program refinement, the amended EBP protocol and education program will be sent to managerial staffs. Then, full scale intervention will be implemented after their approvals.

4.3 Evaluation Plan

After discussing the communication plan and pilot study plan, we need to consider the evaluation plan in order to determine the program effectiveness and outcomes achievements.
4.3.1 Identifying Outcomes to be Achieved

Throughout the education program, 3 major outcomes can be identified and they are patient outcomes, healthcare provider outcomes and system outcomes.

4.3.1.1 Patient Outcomes

For patient outcomes, it is used to assess the clinical benefits of the innovation, which mainly focuses on improving medication (puff) compliance (primary outcome) and quality of life (QoL) (secondary outcome) of COPD patients.

For medication compliance, dose counter will be used as a measuring tool for evaluation. In fact, it is a counter attached to each metered dose inhaler (MDI) to show how many puffs of medication the patients left. The counter will count down by one after the MDI is pressed each time. Therefore, the fewer numbers shown in the dose counter indicate the better medication compliance of the patients.

For QoL, St. George’s Respiratory Questionnaire (SGRQ), which also used in the research studies, will be used to monitor patients’ health status and living standard. In fact, SGRQ is a validated and scientific questionnaire in measuring QoL of COPD patients. Furthermore, it totally consists of 76 items and includes symptoms, activity and impact three major parts. The scoring range is from 0 to 100, with the highest scores indicating the poorest health level.

In addition, patients’ satisfaction level towards the program will also be assessed by patients’ satisfaction questionnaire. Patients’ views towards the program
will be rated by using ‘5- strongly agree’, ‘4- agree’, ‘3- neutral’, ‘2- disagree’ and ‘1- strongly disagree’ respectively. Higher score indicates better satisfaction.

4.3.1.2 Healthcare Provider Outcomes (secondary outcome)

Nurses are the major concerns in healthcare provider outcomes as they are the target protocol users. In order to make sure smooth and effective evaluation of the program, nurses’ compliance and satisfaction level towards the innovation are required to be assessed. Furthermore, a staffs’ satisfaction questionnaire will be distributed to each nurse to seek for their suggestions and feedbacks. Staffs’ views towards the program will be rated by using ‘5- strongly agree’, ‘4- agree’, ‘3- neutral’, ‘2- disagree’ and ‘1- strongly disagree’ respectively. Higher score indicates better compliance and satisfaction.

4.3.1.3 System Outcomes (secondary outcome)

Re-admission rates of COPD patients will be treated as system outcomes of the education program. It is used to measure the system effectiveness and can be traced according to the admission record of the Department of Medicine. A decline in re-admission rates indicates better system outcomes.
4.3.2 Nature and Number of Clients to be Involved

For nature of clients to be involved, it is the same as the inclusion criteria of target participants in clinical protocol. Firstly, they are hospitalized patients who aged 40 years old or above of both sex. Also, they are diagnosed of COPD, from GOLD 1 to 4 according to the classification of severity of airflow limitation in COPD (GOLD, 2013). Furthermore, they are mentally stable and lack of unstable cardiac and terminal diseases. In addition, they are able to communicate with English, Cantonese or Mandarin.

For number of clients to be involved, sample size is needed to calculate in order to recruit adequate eligible participants. Then, Lenth’s Java Applets (2009) will be chosen as online resources in manipulating the sample size. One sample (paired) t test will be used for the analysis. Provided that power and significance level will be set as 80% and 0.05 respectively, 51 patients will be recruited. If it is anticipated that 5% of clients will be lost to follow-up, a total of 54 participants will be required. According to the statistic admission record of the Department of Medicine, the average monthly admission of COPD patients is around 20 in 2 respiratory wards. As a result, sufficient number of eligible patients can be selected by using 3-months period.
4.3.3 Data Collection

4.3.3.1 Patient Outcomes

For medication compliance and QoL, dose counter and SGRQ will be used as assessment tools respectively. From the eligible studies (Wei, L. et al., 2014); (M. R. Khdour et al., 2009), data collection should be measured at the beginning, at 6- and 12-months follow up. Therefore, baseline and clinical data can be collected for comparison by pre-test and post-test methods.

For patient’s satisfaction level, a 5-point scale questionnaire will be distributed at 6- and 12-months after the program.

4.3.3.2 Healthcare Provider Outcomes

For staffs’ compliance and satisfaction level, a 5-point scale questionnaire will be distributed and collected at 6- and 12-months after the program.

4.3.3.3 System Outcomes

For re-admission rates from January to December, 2016, clinical records should be traced and collected at the beginning and 12-months after the intervention.
4.3.4 Data Analysis

All eligible patients will receive education and data will be collected at the beginning, at 6- and 12-months follow up. Also, it is a hypothesis testing with medication (puff) compliance and QoL as the primary and secondary outcome respectively. As same group of patients will be involved in the program, paired t test will be used for significance testing.

Statistical Package for the Social Science (SPSS), Version 21.0, will be utilized for statistical analysis, provided that p-value <0.05 to be considered as statistically significant. All study variables will be shown as descriptive data, including mean, median and mode of quantitative variables.

4.3.5 Basis for an Effective Change of Practice

It is necessary to determine whether the new innovation is effective for program adoption. From the eligible studies, the criteria to consider as effective changes as below.

For medication compliance, patient inhaled more than 80% of prescribed puff as shown in dose counter will be regarded as effective change, compared those at the beginning and 12-months after. It is the number of doses taken divided by the number of doses prescribed and presented as a percentage (Wei, L. et al., 2014); (Leiva-Fernández et al., 2014).
For SGRQ, a decrease in 10 units in total mean score will be treated as effective change, compared with those at the beginning and 12-months after (Wei, L. et al., 2014); (M. R. Khdour et al., 2009). Also, this standard has been validated as a clinically significant threshold (Jones PW, 2002).

For staffs’ compliance, patients’ and nurses’ satisfaction level, more than 60% (at least 5 out of 8 questions) of items belongs to neutral or above (neutral, agree and strongly agree) will be regarded as effective change (Jenkinson et al., 2002).

For re-admission rates, a decrease in the value will be regarded as effective change, compared with those at the beginning and 12-months after. As participants are expected to have an improved medication compliance and QoL, a decrease in re-admission rates will be resulted.

4.3.6 Conclusion

In order to ensure smooth implementation, communication plan and pilot study plan are essential to perform. Also, evaluation plan is important for monitoring program effectiveness. Under the implementation plan, it is believed that more and more COPD patients will be benefited from the education program.
Chapter 5: Conclusion

Nowadays, COPD is a worldwide and global health issue and it affects people in physical, psychological and spiritual aspects. Due to the problem of aging population, COPD prevalence becomes more and more common in Hong Kong. Acute exacerbation of COPD not only causes medical and economic burdens to the society, but also results in poor health status and QoL of COPD patients.

In order to prevent the situation from worsening, there is an urgent need to think of related methods and solutions. In fact, some research studies showed that good medication compliance could reduce hospital admission and improve QoL of COPD patients. Also, nursing education had been proved as an effective way to promote medication compliance and QoL of patients with COPD. However, there are no current evidenced-based practice (EBP) protocols in my clinical setting. Therefore, it is essential to develop an EBP protocol for improving medication compliance and QoL of COPD patients.

There are totally six eligible research studies were extracted and critically appraised. Evidences from these literature journals suggest that nursing education and counselling program is positively associated with better medication compliance and QoL of patients diagnosed of COPD. After assessing the implementation potential, the new innovation is highly transferable and feasible into my local setting.

Afterwards, an EBP protocol is developed for improving medication compliance and QoL of COPD patients. Totally, there are ten recommendations
established by summarizing and synthesizing data from eligible studies. This can be regarded as a standardized hospital reference for healthcare professionals to follow.

Then, a communication team is formed in order to monitor and evaluate the progress of education program after communication with relevant stakeholders. Furthermore, a pilot study is performed to explore the feasibility of implementing the new innovation. At the same time, evaluation plan and related modifications on EBP protocol and education program are done after the pilot testing.

To conclude, the nursing education and counselling program is worth to be implemented into respiratory wards in Hong Kong. It is believed that more and more COPD patients can be benefitted from the program.
Appendix A: Classification of Severity of Airflow Limitation in COPD

According to Global Initiative for Chronic Obstructive Lung Disease, spirometry is the most reproducible and objective measurement of airflow limitation available. Spirometry should measure the volume of air forcibly exhaled from the point of maximal inspiration (forced vital capacity, FVC) and the volume of air exhaled during the first second of this maneuver (forced expiratory volume in one second, FEV1), and the ratio of these two measurements (FEV1 /FVC) should be calculated.

<table>
<thead>
<tr>
<th>Classification of Severity of Airflow Limitation in COPD</th>
</tr>
</thead>
<tbody>
<tr>
<td>(Based on Post-Bronchodilator FEV1)</td>
</tr>
<tr>
<td>In patients with FEV1 /FVC &lt; 0.70</td>
</tr>
<tr>
<td>GOLD 1</td>
</tr>
<tr>
<td>GOLD 2</td>
</tr>
<tr>
<td>GOLD 3</td>
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<tr>
<td>GOLD 4</td>
</tr>
<tr>
<td>Level of Evidence</td>
</tr>
<tr>
<td>-------------------</td>
</tr>
<tr>
<td>1++</td>
</tr>
<tr>
<td>1+</td>
</tr>
<tr>
<td>1-</td>
</tr>
</tbody>
</table>
| 2++               | High quality systematic reviews of case control or cohort or studies  
|                   | 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 |
| 2+                | Well-conducted case control or cohort studies with a low risk of confounding or bias and a moderate probability that the relationship is causal |
| 2-                | Case control or cohort studies with a high risk of confounding or bias and a significant risk that the relationship is not causal |
| 3                 | Non-analytic studies, e.g. case reports, case series |
| 4                 | Expert opinion |
### Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification (Include author, title, year of publication, journal title, pages)</th>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
</table>

Guideline topic: To investigate the impact of a disease and medicine management programme, focusing on self-management in patients with chronic obstructive pulmonary disease (COPD).

Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question □ 2. Other reason □ (please specify):

### SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes √ No □ Can't say □</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised. (minimization method described by Gore)</td>
<td>Yes √ No □ Can't say □</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used.</td>
<td>Yes □ No □ Can't say √</td>
</tr>
<tr>
<td>1.4 The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
<td>Yes □ No □ Can't say √</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes √ No □ Can't say □</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes √ No □ Can't say □</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes √ No □ Can't say □</td>
</tr>
</tbody>
</table>
What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?

17% drop out rate:
1 - (143/173) x100%

All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).

Yes ☑ No ☐
Can’t say ☑ Does not apply ☐

Where the study is carried out at more than one site, results are comparable for all sites.

Yes ☑ No ☐
Can’t say ☑ Does not apply ☐

SECTION 2: OVERALL ASSESSMENT OF THE STUDY

2.1 How well was the study done to minimise bias?

*Code as follows:*
High quality (++)[☑]
Acceptable (+)[✓]
Low quality (-)[☐]
Unacceptable – reject 0 [☐]

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 study intervention?

I certain that there is a direct relationship between overall effect and the intervention. Reasons are as below: a) statistically significant (p < 0.05), b) match most of the items on this checklist.

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

As this study only has a relatively small sample size (n = 173), in my opinion, I think more researches with larger sample sizes should be conducted in order to assess the generalizability and accountability of this research topic before we implement this intervention to other healthcare systems.

2.4 Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

In the study, the authors suggested that the clinical pharmacy-led management programme could improve adherence, reduce the need for hospital care in patients with COPD and improve aspects of their quality of life (QoL). However, in my opinion, I think that the limited sample size (N=173) bothers the generalizability of the intervention to treatment and control group. Larger sample sizes should be recruited in order to have a higher generalizability.
Methodology Checklist 2: Controlled Trials

Study identification: (Include author, title, year of publication, journal title, pages)

Key Question No:  Reviewer:

Guideline topic: To examine the effects of a structured educational intervention programme at a nurse led primary health care clinic (PHCC) on quality of life (QoL), knowledge about COPD and smoking cessation in-patients with COPD

Before completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

**SECTION 1: INTERNAL VALIDITY**

In a well conducted RCT study…

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<td><strong>Yes √</strong></td>
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<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
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<td>1.2 The assignment of subjects to treatment groups is randomised.</td>
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<td>1.6 The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
</tr>
<tr>
<td>1.8 What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
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</table>

16% drop out rate: 1 - (52/62) x100%
| 1.9  | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes □  | No □  |
|      |                                                                 | Can't say □  | Does not apply √ |

| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Yes □  | No □  |
|      |                                                                 | Can't say □  | Does not apply √ |

### SECTION 2: OVERALL ASSESSMENT OF THE STUDY

**2.1** How well was the study done to minimise bias? *Code as follows:*
- High quality (++)[□]
- Acceptable (+)[√]
- Low quality (-)[□]
- Unacceptable – reject 0 □

**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 study intervention?
- I certain that there is a direct relationship between overall effect and the intervention. Reasons are as below: a) statistically significant between intervention and control (p <0.05), b) match most of the items on this checklist.

**2.3** Are the results of this study directly applicable to the patient group targeted by this guideline?
- As this study only recruited 62 patients, a larger sample size should be recruited in order to have a higher generalizability. Also, a confounding factor may have been that one of the researchers (Eva Österlund Efraimsson), as a nurse in the PHCC, performed the intervention. This implies that patients are in a dependent relationship which may have affected the responses in a favorable direction.

**2.4** **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.
- In the study, the authors suggested that a structured programme with self-care education was needed to motivate patients for life-style changes. However, in my opinion, I think that the limited sample size (N=62) bothers the generalizability of the study. Larger sample sizes should be recruited in order to have a higher generalizability. Also, a confounding factor may have been that one of the researchers (Eva Österlund Efraimsson), as a nurse in the PHCC, performed the intervention. This implies that patients are in a dependent relationship which may have affected the responses in a favorable direction.
**Methodology Checklist 2: Controlled Trials**

**Study identification** (Include author, title, year of publication, journal title, pages)

**Guideline topic:** To determine the 1-year beneficial effect of a self-management education program which included supervised exercise sessions.

**Before** completing this checklist, consider:

1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

### SECTION 1: INTERNAL VALIDITY

**In a well conducted RCT study…**

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<th>Does this study do it?</th>
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<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised. (using block of 4)</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
<td>Yes ☐ No ☐ Can't say √</td>
</tr>
<tr>
<td><strong>1.4</strong> The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
<td>Yes ☐ No ☐ Can't say √</td>
</tr>
<tr>
<td><strong>1.5</strong> The treatment and control groups are similar at the start of the trial.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td><strong>1.6</strong> The only difference between groups is the treatment under investigation.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td><strong>1.7</strong> All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td><strong>1.8</strong> What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>16% drop-out rate: 1-(38/45) x100%</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis).</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
</tr>
</tbody>
</table>

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

| 2.1 | How well was the study done to minimise bias?  
*Code as follows:*  
High quality (++)[ ]  
Acceptable (+)[✓]  
Low quality (-)[ ]  
Unacceptable – reject 0 [ ] | I certain that there is a direct relationship between overall effect and the intervention. Reasons are as below: a) statistically significant (p < 0.05), b) match most of the items on this checklist. |
| 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 study intervention? | Small sample size (n=45) of this study limits the generalizability of the effectiveness of the intervention. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | |
| 2.4 | **Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | In the study, the authors suggested that the present hospital-based intervention combining supervised exercise with self-management education provided significant improvements in patient’s exercise tolerance and HRQoL, and significant decreased of COPD medication costs, compared to usual care. However, in my opinion, I think that the high drop-out rate of this study limits the effect and generalizability of the intervention. Also, none of the information is given for the concealment method and blinding between subjects and investigators. |
Methodology Checklist 2: Controlled Trials

### Study Identification
(Include author, title, year of publication, journal title, pages)

### Guideline topic:
To compare two strategies (BI and TTG) for teaching inhaler use to hospitalized patients with asthma or chronic obstructive pulmonary disease (COPD).

### Key Question No:

### Before completing this checklist, consider:
1. Is the paper a **randomised controlled trial** or a **controlled clinical trial**? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a **controlled clinical trial** questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+
2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

### Reason for rejection: 1. Paper not relevant to key question 2. Other reason (please specify):

### SECTION 1: INTERNAL VALIDITY

#### In a well conducted RCT study...

<table>
<thead>
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<th>Does this study do it?</th>
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<tbody>
<tr>
<td>1.1</td>
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<td>1.2</td>
<td>The assignment of subjects to treatment groups is randomised.</td>
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</tr>
<tr>
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<td>The treatment and control groups are similar at the start of the trial.</td>
</tr>
<tr>
<td>1.6</td>
<td>The only difference between groups is the treatment under investigation.</td>
</tr>
<tr>
<td>1.7</td>
<td>All relevant outcomes are measured in a standard, valid and reliable way. (By Symptom questionnaires)</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
</tbody>
</table>

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**61**
| 1.9 | All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). | Yes ☐ | No ☐ | Can't say ☐ | Does not apply √ |
| 1.10 | Where the study is carried out at more than one site, results are comparable for all sites. | Yes ☐ | No ☐ | Can't say ☐ | Does not apply √ |

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

| 2.1 | How well was the study done to minimise bias? *Code as follows:*  
High quality (++): ☐  
Acceptable (+): √  
Low quality (-): ☐  
Unacceptable – reject: 0 ☐ | |
| 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 study intervention? | I certain that there is a direct relationship between overall effect and the intervention. Reasons are as below: a) statistically significant (p < 0.05), b) match most of the items on this checklist. | |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | As this study only have a relatively small sample size (n = 50), in my opinion, I think more researches with larger sample sizes should be conducted in order to assess the generalizability and accountability of this research topic before we implement this intervention to other healthcare systems. | |
| 2.4 | Notes. Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above. | In the study, the authors suggested that TTG (Teach To Goal) was generally more effective than BI (Brief Intervention) in reducing misuse of MDI and Diskus® devices and participants in the TTG group had significantly fewer acute health-related events at 30 days than those in the BI group. However, in my opinion, I think that the limited sample size (N=50) bothers the generalizability of the intervention to treatment and control group. Larger sample sizes should be recruited in order to have a higher generalizability. | |
Methodology Checklist 2: Controlled Trials

Study identification (Include author, title, year of publication, journal title, pages)

Guideline topic: To evaluate the effectiveness of a multifactorial intervention on improving the therapeutic adherence in chronic obstructive pulmonary disease (COPD) patients with scheduled inhalation therapy.

Key Question No: 
Reviewer:

Before completing this checklist, consider:
1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+
2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question ☐ 2. Other reason ☐ (please specify):

<table>
<thead>
<tr>
<th>SECTION 1: INTERNAL VALIDITY</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>In a well conducted RCT study...</strong></td>
<td></td>
</tr>
<tr>
<td>1.1 The study addresses an appropriate and clearly focused question.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.2 The assignment of subjects to treatment groups is randomised. Block randomisation technique (blocks of four patients)</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.3 An adequate concealment method is used. (not mentioned)</td>
<td>Yes ☐ No ☐ Can't say √</td>
</tr>
<tr>
<td>1.4 The design keeps subjects and investigators 'blind' about treatment allocation.</td>
<td>Yes ☐ No ☐ Can't say √</td>
</tr>
<tr>
<td>1.5 The treatment and control groups are similar at the start of the trial.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.6 The only difference between groups is the treatment under investigation.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.7 All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes √ No ☐ Can't say ☐</td>
</tr>
<tr>
<td>1.8</td>
<td>What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
</tr>
<tr>
<td>1.9</td>
<td>All the subjects are analysed in the groups to which they were randomly allocated (often referred to as intention to treat analysis). (Just mentioned and no elaboration offered)</td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites. (mentioned multicenter only)</td>
</tr>
</tbody>
</table>

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

| 2.1 | How well was the study done to minimise bias? *Code as follows:* | High quality (++)elude{☐} Acceptable (+)✓ Low quality (-)☐ Unacceptable – reject 0 ☐ |
| 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 study intervention? | I certain that there is a direct relationship (no relationship) between overall effect and the intervention. Reasons are as below: a) statistically significant between intervention and control (p <0.05), b) match most of the items on this checklist. |
| 2.3 | Are the results of this study directly applicable to the patient group targeted by this guideline? | This study has high drop-out rate (30%) and this limits the effect and generalizability of the intervention. |

**Notes.** Summarise the authors' conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

In the study, the authors suggested that multifactorial intervention (COPD information, dose reminders, audio-visual material, motivational aspects and training in inhalation techniques) in COPD patients was associated with an increased benefit of 48% in the adherence to prescribed treatment. However, in my opinion, I think that the high drop-out rate of this study limits the effect and generalizability of the intervention. Also, none of the information is given for the concealment method and blinding between subjects and investigators.
Methodology Checklist 2: Controlled Trials

<table>
<thead>
<tr>
<th>Study identification (Include author, title, year of publication, journal title, pages)</th>
<th>Key Question No:</th>
<th>Reviewer:</th>
</tr>
</thead>
</table>

Guideline topic: To investigated whether pharmaceutical care by clinical pharmacists could reinforce medication adherence to reduce exacerbation and improve HRQoL.

Before completing this checklist, consider:

1. Is the paper a randomised controlled trial or a controlled clinical trial? If in doubt, check the study design algorithm available from SIGN and make sure you have the correct checklist. If it is a controlled clinical trial questions 1.2, 1.3, and 1.4 are not relevant, and the study cannot be rated higher than 1+.

2. Is the paper relevant to key question? Analyse using PICO (Patient or Population Intervention Comparison Outcome). IF NO REJECT (give reason below). IF YES complete the checklist.

Reason for rejection: 1. Paper not relevant to key question  □  2. Other reason □ (please specify):

SECTION 1: INTERNAL VALIDITY

<table>
<thead>
<tr>
<th>In a well conducted RCT study…</th>
<th>Does this study do it?</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>1.1</strong> The study addresses an appropriate and clearly focused question.</td>
<td>Yes √  No □  Can't say □</td>
</tr>
<tr>
<td><strong>1.2</strong> The assignment of subjects to treatment groups is randomised.</td>
<td>Yes √  No □  Can't say □</td>
</tr>
<tr>
<td><strong>1.3</strong> An adequate concealment method is used.</td>
<td>Yes √  No □  Can't say □</td>
</tr>
<tr>
<td><strong>1.4</strong> The design keeps subjects and investigators ‘blind’ about treatment allocation.</td>
<td>Yes √  No □  Can't say □</td>
</tr>
<tr>
<td><strong>1.5</strong> The treatment and control groups are similar at the start of the trial.</td>
<td>Yes √  No □  Can't say □</td>
</tr>
<tr>
<td><strong>1.6</strong> The only difference between groups is the treatment under investigation.</td>
<td>Yes √  No □  Can't say □</td>
</tr>
<tr>
<td><strong>1.7</strong> All relevant outcomes are measured in a standard, valid and reliable way.</td>
<td>Yes √  No □  Can't say □</td>
</tr>
<tr>
<td><strong>1.8</strong> What percentage of the individuals or clusters recruited into each treatment arm of the study dropped out before the study was completed?</td>
<td>25% drop out rate: 1 - (87/117) x100%</td>
</tr>
</tbody>
</table>

65
<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Yes</th>
<th>No</th>
<th>Can't say</th>
<th>Does not apply</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.9</td>
<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></td>
<td></td>
<td>√</td>
<td></td>
</tr>
<tr>
<td>1.10</td>
<td>Where the study is carried out at more than one site, results are comparable for all sites.</td>
<td></td>
<td></td>
<td>√</td>
<td></td>
</tr>
</tbody>
</table>

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

<table>
<thead>
<tr>
<th></th>
<th>Question</th>
<th>Code as follows:</th>
</tr>
</thead>
</table>
| 2.1| How well was the study done to minimise bias?                           | High quality (++)
Acceptable (+)
Low quality (-)
Unacceptable – reject 0 |
| 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 study intervention? | Certain that there is a direct relationship between overall effect and the intervention. Reasons are as below: a) statistically significant (p < 0.05), b) match most of the items on this checklist. |
| 2.3| Are the results of this study directly applicable to the patient group targeted by this guideline? | As this study only has a relatively small sample size (n = 117), in my opinion, I think more researches with larger sample sizes should be conducted in order to assess the generalizability and accountability of this research topic before we implement this intervention to other healthcare systems. Also, high drop-out rate of this study inhibits the evidence level. |

**Notes.** Summarise the authors’ conclusions. Add any comments on your own assessment of the study, and the extent to which it answers your question and mention any areas of uncertainty raised above.

In the study, the authors suggested that the pharmaceutical care provided by clinical pharmacists could reinforce medication adherence to reduce exacerbation and improve HRQoL. However, in my opinion, I think that the limited sample size (N=117) bothers the generalizability of the intervention to treatment and control group. Larger sample sizes should be recruited in order to have a higher generalizability. Also, high drop-out rate of this study inhibits the evidence level.
Records identified through database searching  
(n = 778)  

Additional records identified through other sources  
(n = 512)  

Records after duplicates removed (27)  
(n = 1263)  

Records excluded (n = 1164)  
Non – English: n = 48  
Non – RCT: n = 562  
Non- full text: n = 554  

Records screened (RCT)  
(n = 117)  

Full-text articles assessed for eligibility  
(n = 6)  

Full-text articles excluded, with reasons  
(n = 111)  
Population includes asthma: n = 65  
Studies not include searching period: n = 46  

Studies included in qualitative synthesis  
(n = NA)  

Studies included in quantitative synthesis  
(meta-analysis)  
(n = 6)  

- Searching databases: PubMud & Cochrane Library  
- Other sources: manual searching: Google scholar  
- All studies are RCT and in English version  
- All studies are from 2000 - 2015
### Appendix D: Table of Evidence

**Table of Evidence**

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures (no. of subject)</th>
<th>Effect size (Intervention- Control)</th>
<th>Evidence Level</th>
</tr>
</thead>
<tbody>
<tr>
<td>Khdour, M. R., Kidney, J. C., Smyth, B. M., &amp; McElnay, J. C. (2009). Clinical pharmacy-led disease and medicine management programme for patients with COPD. <em>British Journal Of Clinical Pharmacology</em>, 68(4), 588-598.</td>
<td>Randomized controlled, longitudinal prospective clinical trial</td>
<td>1. Mean age: 65.63 years, SD: 10.1, P= 0.20 2. Female: 55.8%</td>
<td>1. received education on disease state, medications and breathing techniques 2. given booklets and a customized action plan (antibiotic and oral steroid to be initiated promptly by patients for exacerbations) (N=86)</td>
<td>usual care (control) group -received usual hospital outpatient care from medical and nursing staff, but did not receive the structured intervention by the clinical pharmacist (n=87)</td>
<td>followed up at 6 and 12 months during a scheduled visit</td>
<td>1. Health-related quality of life-disease specific - St George Respiratory Questionnaire (<em>SGRQ</em>) 2. Adherence to prescribed medication-Self-reported adherence (Morisky scale)</td>
<td>1. Baseline: -0.7 (-6.9 to 5.5) ; p= 0.81 6 months: -7.8 (-14.3 to 1.0) ; p= 0.01 12 months: -7.5 (-14.1 to 0.1) ; p= 0.04 2. 6 months: 81% vs. 63%; p=0.019 12 months: 77.8% vs. 60%; p= 0.019</td>
<td>1-</td>
</tr>
</tbody>
</table>

SD: Standard Deviation
### Table of Evidence

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures (no. of subject)</th>
<th>Effect size</th>
<th>Evidence Level</th>
</tr>
</thead>
</table>
| Efraimsson, E. O., Hillervik, C., & Ehrenberg, A. (2008). Effects of COPD self-care management education at a nurse-led primary health care clinic. *Scandinavian Journal Of Caring Sciences*, 22(2), 178. | An experimental design in which 52 patients with COPD from a Swedish primary care setting were randomized into two groups (intervention or control). | 1. Mean age: 68 years, SD: 9.7 2. Female: 26 | Education program: Intervention group received education with an emphasis on self-care ability and how to support the individual based on his or her unique requirements and abilities to cope with disease and treatment (n = 26) | Continue to receive standard care (n = 26) | two visits with a 3–5-months interval in between | Quality of life: (a) reduction in symptoms of cough, phlegm, dyspnoea and wheezing  
Smoking: (b) smokers had stopped smoking during the intervention phase  
Knowledge about COPD: (c) an increase in knowledge about COPD | (a)53.4/100 > 25.2/100 (I) vs unchanged (C), (higher score= poor health)  
(b) 6/16(I) vs 0/14(C) (No/Total)  
(c) 15/26(I) vs 2/26(C) (No/Total) | 1+ |

SD: Standard Deviation
<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures (no. of subject)</th>
<th>Effect size (Intervention- Control)</th>
<th>Evidence Level</th>
</tr>
</thead>
</table>
| Ninot, G., Moullec, G., Picot, M. C., Jaussent, A., Hayot, M., Desplan, M., & ... Prefaut, C. (2011). Cost-saving effect of supervised exercise associated to COPD self-management education program. *Respiratory Medicine, 105*(3), 377-385. | Randomized controlled trial | 1. Mean age: 65 years CI: (59, 75) 2. Female: 6 | The program emphasized on the acquisition of self-management skills: to promote smoking cessation, encourage prompt management of acute exacerbation, ensure correct inhaler techniques, ensure right secretion removal techniques, optimize nutrition and promote active lifestyle (n=23) | visited by their own physicians without additional support (n=22) | follow up at the beginning (initial) and at 12 months | **Primary outcome:** (a) 6-min walking distance (6MWD)  
**Secondary outcomes:** (b) health-related quality of life (HRQoL) -the St. George’s Respiratory Questionnaire (SGRQ)  
-Nottingham Health Profile (NHP)  
-healthcare utilization. | (a) 50.5 (2 to 99); p= 0.04  
(b) SGRQ:-14.0 (-23 to -5); p <0.01  
NHP: energy 19.8 (-38 to -1); p= 0.04  
NHP: emotional reaction -10.4 (-20 to 0); p= 0.04  
Cost of COPD medication: -480.7 (-891 to -70); p= 0.02 | 1- |

CI: Confidence Interval
### Table of Evidence

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures (no. of subject)</th>
<th>Effect size (Pre and post result)</th>
<th>Evidence Level</th>
</tr>
</thead>
</table>
| Press, V. G., Arora, V. M., Shah, L. M., Lewis, S. L., Charbeneau, J., Naureckas, E. T., & Krishnan, J. A. (2012). Teaching the use of respiratory inhalers to hospitalized patients with asthma or COPD: a randomized trial. *Journal Of General Internal Medicine*, 27(10), 1317-1325. | Randomized controlled trial | Mean age: 56.4 years; SD: 19.0  Female: 16 (67%) | TTG (Teach To Goal)  Intervention: BI plus repeated demonstrations of inhaler use and participant comprehension assessments (teach-back) (n= 24) | Brief intervention [BI]: single-set of verbal and written step-by-step instructions (n= 26) | Symptom questionnaires and utilization of health care services was collected at 30-days post-hospital discharge using a 10-minute phone interview | **Primary outcome:** Metered dose inhaler (MDI) misuse post-intervention (<75% steps correct).  **Secondary outcomes:** Diskus® misuse | TTG:65% vs 13%, p=0.01  BI: 78% vs 46%, p=0.008  **Secondary outcomes:**  TTG: non-significant decrease  BI:46% vs 13%, p=0.01 | 1-  

SD: Standard Deviation
<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures (no. of subject)</th>
<th>Effect size</th>
<th>Evidence Level</th>
</tr>
</thead>
</table>
| Leiva-Fernández et al. | Randomized controlled trial | 1. Mean age: 69.57 years, CI: (67.74,1.4); p= 0.509 | 1. Motivational aspects used to improve adherence 2. Cognitive aspects related to treatment adherence 3. Skills development involving training in inhalation techniques (n= 72) | attend usual follow up session without intervention (n= 74) | 3, 6 and 12 months | Primary outcome: adherence to a medication regimen  
Secondary outcomes: 1. functional status - *forced spirometry* 2. health-related quality of life - *the St. George respiratory questionnaire (SGRQ)* | (dose/pill count)  
Intervention: 48.6%  
Control: 32.4%  
P= 0.046  
1. Intervention increase of 23.7%  
P= 0.006  
2. similar in both groups, | 1- |
| CI: Confidence Interval |
### Table of Evidence

<table>
<thead>
<tr>
<th>Bibliographic citation</th>
<th>Study type</th>
<th>Patient characteristics</th>
<th>Intervention(s)</th>
<th>Comparison</th>
<th>Length of follow up</th>
<th>Outcome measures (no. of subject)</th>
<th>Effect size (intervention-Control)</th>
<th>Evidence Level</th>
</tr>
</thead>
</table>
2. Female = 20 (34.5%)  
3. P > 0.10 | Comprehensive pharmaceutical care program:  
1. Provision of individualized education and a series of telephone counselling (n = 58) | Received general counselling, but no individualized education and follow-up telephone counselling (n = 59) | 6-months pharmaceutical care and one-year follow-up | Primary outcome:  
1. Medication adherence  
- Pill counts plus direct interview  
- 6-months & 1 year  
Secondary outcome:  
2. HRQoL  
- SGRQ  
- Before assessment at 6 months | 6 months:  
1. Mean: 20.7,  
p = 0.016  
1 year:  
1. Mean: 12.1,  
p = 0.039  
Before assessment:  
2. Mean: 0.91,  
p = 0.562  
6 months:  
2. Mean: -9.17,  
p = 0.018 | 1+ |

HRQoL: Health Related Quality of Life; SGRQ: St George’s Respiratory Questionnaire; SD: Standard Deviation
## Appendix E: Similarity of Target Setting and Audience and those in Literatures Reviewed

<table>
<thead>
<tr>
<th>Characteristics</th>
<th>Target Setting and Audience</th>
<th>Literature Reviewed</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Target Population</td>
<td>COPD patients aged 40 or above</td>
<td>COPD patients aged 45 or above</td>
</tr>
<tr>
<td>2. Setting</td>
<td>In-patient respiratory wards</td>
<td>Out-patient COPD clinics, In-patient care settings and university-based centers</td>
</tr>
<tr>
<td>3. Severity of COPD</td>
<td>Mild to very severe</td>
<td>Mild to very severe</td>
</tr>
<tr>
<td>4. Country/ Region</td>
<td>Hong Kong</td>
<td>Ireland, Sweden, France, the United States, Spain and China</td>
</tr>
<tr>
<td>5. Intervention</td>
<td>Education and counselling program</td>
<td>Education and counselling program</td>
</tr>
<tr>
<td>6. Educator</td>
<td>Nurses</td>
<td>Nurses and Pharmacists</td>
</tr>
</tbody>
</table>
Appendix F: Table of Estimated Set-Up Cost and Running Cost of the Program

<table>
<thead>
<tr>
<th>Set-Up Items</th>
<th>Costs ($)</th>
<th>Operational Items</th>
<th>Costs ($)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Staff Training Workshop (1 session x 2 hours)</td>
<td>Stationary</td>
<td>Free</td>
<td>/</td>
</tr>
<tr>
<td>Teaching Staff (Respiratory Nurse x 1)</td>
<td></td>
<td>$522</td>
<td>/</td>
</tr>
<tr>
<td>Puffs (Demonstration)</td>
<td></td>
<td>Free</td>
<td>/</td>
</tr>
<tr>
<td>Aero-chambers</td>
<td></td>
<td>Free</td>
<td>/</td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>$522</td>
<td><strong>Subtotal</strong></td>
<td>$0</td>
</tr>
<tr>
<td>Education Session (2 sessions x 1 hour)</td>
<td>Venue (Education Room)</td>
<td>Free</td>
<td>Education Pamphlets $0.3x10pgsx2x100</td>
</tr>
<tr>
<td>Computer and Software</td>
<td>Free</td>
<td>Evaluation Form</td>
<td>$0.3x6pgsx2x100</td>
</tr>
<tr>
<td>Projector</td>
<td>Free</td>
<td>Training Staff (4 RNs) $164x1x2x4RNs</td>
<td>$1,312</td>
</tr>
<tr>
<td>Projector Screen</td>
<td>Free</td>
<td>Individualized Action Plan (4 RNs) $164x2x33x4RNs</td>
<td>$43,296</td>
</tr>
<tr>
<td>Puff (Demonstration)</td>
<td>Free</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Audio-Visual Equipment</td>
<td>Free</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Aero-chambers</td>
<td>Free</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Subtotal</strong></td>
<td>$522</td>
<td><strong>Subtotal</strong></td>
<td>$45,568</td>
</tr>
<tr>
<td><strong>Total Set-Up Cost</strong></td>
<td>$522</td>
<td><strong>Total Running Cost</strong></td>
<td>$45,568</td>
</tr>
<tr>
<td><strong>Total</strong></td>
<td></td>
<td></td>
<td>$46,090</td>
</tr>
<tr>
<td>**Total(Annual) ($522+$45,568x3)</td>
<td></td>
<td></td>
<td>$137,226</td>
</tr>
</tbody>
</table>
Remarks:

1. All costs are calculated in HKD.
2. Hourly rate of healthcare staff is calculated according to the median monthly salary of their relevant rankings with weekly working hours of 44 hours and with reference to the master scale pay of 2013 (Civil Service Bureau, 2013).
3. The education program will compose 2 intervention sessions and each part contains 1 hour.
4. The education program requires 4-months’ time including preparation and evaluation time, it can operate 3 times per year.
5. RN: Registered Nurse
Appendix G: Evidence-Based Practice Protocol

3.4.1 Background

Nowadays, COPD is a global health issue and it affects a wide variety of people all around the world. Moreover, according to World Health Organization (WHO), it predicts that COPD will become the third leading cause of death by 2030 (WHO, 2012). Furthermore, COPD mainly causes negative impacts to elderly and Hong Kong may get suffered due to the problem of aging population.

According to a randomized controlled study, it has stated that patient education is an important element in clinical guidelines for COPD care (Gallefoss F, 2001). It includes better medication compliance, quality of life (QoL) and lower emergency care visits of patients with COPD. Therefore, it is crucial for us to develop an evidence-based practice (EBP) protocol based on the element of patient education in order to improve medication compliance and QoL. However, there is no existing nursing education and counselling program in Hong Kong. Therefore, it is important for us to develop such innovation to take care of the needs of COPD patients in Hong Kong.

3.4.2 Title of the EBP protocol

An evidence-based nursing education and counselling program for Chronic Obstructive Pulmonary Disease patients
3.4.3 Aim of EBP protocol

To provide evidence-based recommendations for healthcare professionals in improving COPD patients’ medication compliance and QoL

3.4.4 Objectives of EBP protocol

1. To develop an evidenced-based protocol of nursing education and counselling to COPD patients.
2. To summarize and synthesize the evidence-based protocol for COPD patients to improve medication compliance and QoL.
3. To promote educational program to COPD patients about disease managements so as to lower their needs for utilizing healthcare services.
4. To unify and standardize the evidence-based protocol in promoting health status of COPD patients.
5. To reinforce the concept of good medication compliance of COPD patients in order to improve their QoL.

3.4.5 Target Users

The target users are all nurses with all rankings who directly taking care of patients with respiratory problems and working in respiratory wards of a local hospital
3.4.6 Target Population

The target populations are hospitalized patients of respiratory wards (both male and female ward) with the following criteria:

1. aged 40 years old or above of both sex
2. diagnosed of COPD, from GOLD 1 to 4 according to the classification of severity of airflow limitation in COPD (GOLD, 2013)
3. without poor cognitive state or mental instability
4. without an exacerbation during the run-in period
5. not participated in respiratory rehabilitation programs in the past year
6. without unstable cardiac diseases such as congestive heart failure and ischemic heart disease
7. without terminal diseases such as end stage malignant illnesses
8. able to communicate with English, Cantonese or Mandarin

3.4.7 Evidence-Based Recommendations

Recommendation 1: New Innovation

Recommendation 1.1: An education and counselling program can help COPD patients to improve their medication compliance and Quality of Life (Grade A).

An education and counselling program is found to be an effective and efficient method for COPD patients in order to improve their medication adherence (Wei, L. et al., 2014) (1+); (Leiva-Fernández et al., 2014) (1-); (M. R. Khdour et al., 2009)
(1-) and QoL (Wei, L. et al., 2014) (1+); (E.O. Efraimsson et al., 2008) (1+); (G. Ninot et al., 2011) (1-). These are the evidences to support that this innovation can have positive impacts in these two aspects of outcomes.

**Recommendation 2: Mode of Education**

**Recommendation 2.1: Nurses are responsible for teaching COPD patients about the contents of education program (Grade A).**

Nurses are found to be an important element for improved QoL and better medication compliance of COPD patients. This may be owing to the trusting relationships that have been established between nurses and patients. In contrast to visits to nurse, physician visits are often time-limited and mainly focus on pharmacological treatments. As a result, nurses may have more time in educating COPD patients about inhalation skills, relaxation techniques etc (E.O. Efraimsson et al., 2008) (1+).

**Recommendation 2.2: The duration of education program should be held around 1 hour for 2 sessions (Grade A).**

The duration of education session is about 1 hour for 2 sessions (E.O. Efraimsson et al., 2008) (1+); (M. R. Khdour et al., 2009) (1-). It is not feasible to hold a longer period of education session in real clinical setting. On the contrary,
nurses may not have enough time to gather details and provide education to patients if the time is too short.

**Recommendation 2.3: The education program should be conducted as an individual session (Grade A).**

Through individual counselling session, nurses are capable to know more information and enquiries of each patient. As a result, we can help our patients in a great extent according to their unique needs (Wei, L. et al., 2014) (1+); (Leiva-Fernández et al., 2014) (1-).

**Recommendation 3: Contents of Education Program**

**Recommendation 3.1: Action plan should be tailor-made with each patient (Grade A).**

Since each COPD patient has different problems such as poor medication compliance and exacerbation management, therefore, we need to customize and discuss the action plan with each individual. As a result, this is a method for patients to follow and memorize the education contents in an easier way (E.O. Efraimsson et al., 2008) (1+); (M. R. Khdour et al., 2009) (1-); (G. Ninot et al., 2011) (1-).
Recommendation 3.2: The contents of education program should include inhalation techniques, exacerbation management skills and information of COPD (Grade A).

Correct inhalation technique ensures COPD patients to get adequate medication dosage and it is crucial to maintain their illness at a stable condition (E.O. Efraimsson et al., 2008) (1+); (M. R. Khdour et al., 2009) (1-); (Press, V. G.et al., 2012) (1-).

Teaching patients about the management of acute exacerbation of COPD aims at stabilizing their conditions and maintaining a good QoL (E.O. Efraimsson et al., 2008) (1+); (M. R. Khdour et al., 2009) (1-); (G. Ninot et al., 2011) (1-).

Educating patients about the knowledge of COPD emphasizes the rationales that they need to take their medication in a proper manner. As a result, better medication compliance and good QoL will be resulted (E.O. Efraimsson et al., 2008) (1+); (Wei, L. et al., 2014) (1+); (Press, V. G.et al., 2012) (1-).

Recommendation 4: Written Materials

Recommendation 4.1: Written materials such as education pamphlets and booklets should be given to patients (Grade A).

In order to strengthen and reinforce the memories of COPD patients, pamphlets and booklets should be prepared to assist in education session and they
are given a copy to take home with them (M. R. Khdour et al., 2009) (1-); (Press, V. G.et al., 2012) (1-).

Recommendation 4.2: Written information should be presented in a simple and clear way, with audio-visual graphics as instruction guide (Grade A).

Simple and clear sentences enable COPD patients to have a better understanding to the educational contents. Also, with audio-visual graphics as support helps them to elaborate the skills into real situations. Moreover, as most of COPD patients are elderly, these strategies enable them to learn the techniques in an easy way (Leiva-Fernández et al., 2014) (1-); (M. R. Khdour et al., 2009) (1-); (Press, V. G.et al., 2012) (1-).

Recommendation 5: Evaluation

Recommendation 5.1: Medication compliance (primary outcome) can be evaluated by dose counter (Grade A).

Dose counter is one of the most commonly used and is a relatively objective method for evaluating medication compliance. Also, it has been used in outpatient practices as the reference standard to define the diagnostic validity of medication compliance. It is the number of doses taken divided by the number of doses prescribed and presented as a percentage. Usually, it is considered as good
compliance when the counting result is between 80% (20% of doses missed) and 110% (the patient inhales 10% more doses) of the dose prescribed (Wei, L. et al., 2014) (1+); (Leiva-Fernández et al., 2014) (1-).

Recommendation 5.2: Quality of Life (secondary outcome) can be evaluated by St. George’s Respiratory Questionnaire (SGRQ) (Grade A).

SGRQ is a disease-specific instrument designed to measure impact of respiratory symptoms on overall health, daily life and perceived well-being (St. George’s University of London, 2000). It is a validated measuring tool with good reliability and scores are calculated for three aspects including symptoms, activity and impacts (psycho-social). The scoring range is from 0 to 100 and higher score indicates poorer level of health (E.O. Efraimsson et al., 2008) (1+); (Wei, L. et al., 2014) (1+); (M. R. Khdour et al., 2009) (1-); (G. Ninot et al., 2011) (1-).

Details of SGRQ will be shown in Appendix I.

Remarks:

If COPD patients still have the problem of poor medication compliance after completed the education program such as improper inhalation techniques, nurses should refer the cases back to physicians and respiratory nurses for further managements in order to prevent their medical conditions from worsening.
References:


<table>
<thead>
<tr>
<th>Recommendation</th>
<th>Grade</th>
<th>Evidence (Level of Evidence)</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Recommendation 1: New Innovation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.1: An education and counselling program can help COPD patients to improve their medication compliance and Quality of Life</td>
<td>A</td>
<td>(Wei, L. et al., 2014) (1+); (Leiva-Fernández et al., 2014) (1-); (M. R. Khdour et al., 2009) (1-); (E.O. Efraimsson et al., 2008) (1+); (G. Ninot et al., 2011) (1-)</td>
</tr>
<tr>
<td><strong>Recommendation 2: Mode of Education</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.1: Nurses are responsible for teaching COPD patients about the contents of education program</td>
<td>A</td>
<td>(E.O. Efraimsson et al., 2008) (1+)</td>
</tr>
<tr>
<td>2.2: The duration of education program should be held around 1 hour for 2 sessions</td>
<td>A</td>
<td>(E.O. Efraimsson et al., 2008) (1+); (M. R. Khdour et al., 2009) (1-)</td>
</tr>
<tr>
<td>2.3: The education program should be conducted as an individual session</td>
<td>A</td>
<td>(Wei, L. et al., 2014) (1+); (Leiva-Fernández et al., 2014) (1-)</td>
</tr>
<tr>
<td><strong>Recommendation 3: Contents of Education Program</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3.1: Action plan should be tailor-made with each patient</td>
<td>A</td>
<td>(E.O. Efraimsson et al., 2008) (1+); (M. R. Khdour et al., 2009) (1-); (G. Ninot et al., 2011) (1-)</td>
</tr>
<tr>
<td>3.2: The contents of education program should include inhalation techniques, exacerbation management skills and information of COPD</td>
<td>A</td>
<td>(E.O. Efraimsson et al., 2008) (1+); (M. R. Khdour et al., 2009) (1-); (Press, V. G.et al., 2012) (1-). (G. Ninot et al., 2011) (1-). (Wei, L. et al., 2014) (1+)</td>
</tr>
<tr>
<td><strong>Recommendation 4: Written Materials</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4.1: Written materials such as education pamphlets and booklets should be given to patients</td>
<td>A</td>
<td>(M. R. Khdour et al., 2009) (1-); (Press, V. G.et al., 2012) (1-)</td>
</tr>
<tr>
<td>4.2: Written information should be presented in a simple and clear way, with audio-visual graphics as instruction guide</td>
<td>A</td>
<td>(Leiva-Fernández et al., 2014) (1-); (M. R. Khdour et al., 2009) (1-); (Press, V. G.et al., 2012) (1-)</td>
</tr>
<tr>
<td><strong>Recommendation 5: Evaluation</strong></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.1: Medication compliance (primary outcome) can be evaluated by dose counter</td>
<td>A</td>
<td>(Wei, L. et al., 2014) (1+); (Leiva-Fernández et al., 2014) (1-)</td>
</tr>
<tr>
<td>5.2: Quality of Life (secondary outcome) can be evaluated by St. George’s Respiratory Questionnaire (SGRQ)</td>
<td>A</td>
<td>(E.O. Efraimsson et al., 2008) (1+); (Wei, L. et al., 2014) (1+); (M. R. Khdour et al., 2009) (1-); (G. Ninot et al., 2011) (1-)</td>
</tr>
</tbody>
</table>
## Appendix H: SIGN Grading System 1999 – 2012

### Grade of Recommendations

<table>
<thead>
<tr>
<th>Grade</th>
<th>Statements</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>A</strong></td>
<td>At least one meta-analysis, systematic review, or RCT rated as 1++, and directly applicable to the target population; or A body of evidence consisting principally of studies rated as 1+, directly applicable to the target population, and demonstrating overall consistency of results.</td>
</tr>
<tr>
<td><strong>B</strong></td>
<td>A body of evidence including studies rated as 2++, directly applicable to the target population, and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 1++ or 1+</td>
</tr>
<tr>
<td><strong>C</strong></td>
<td>A body of evidence including studies rated as 2+, directly applicable to the target population and demonstrating overall consistency of results; or Extrapolated evidence from studies rated as 2++</td>
</tr>
<tr>
<td><strong>D</strong></td>
<td>Evidence level 3 or 4; or Extrapolated evidence from studies rated as 2+</td>
</tr>
</tbody>
</table>
Appendix I: St. George’s Respiratory Questionnaire (SGRQ)

ST. GEORGE’S RESPIRATORY QUESTIONNAIRE
ORIGINAL ENGLISH VERSION

This questionnaire is designed to help us learn much more about how your breathing is troubling you and how it affects your life. We are using it to find out which aspects of your illness cause you most problems, rather than what the doctors and nurses think your problems are.

Please read the instructions carefully and ask if you do not understand anything. Do not spend too long deciding about your answers.

Before completing the rest of the questionnaire:

Please tick in one box to show how you describe your current health:

Very good  Good  Fair  Poor  Very poor

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Fax +44 (0) 20 8725 5955

UK/ English (original) version

continued...
### St. George’s Respiratory Questionnaire

**PART 1**

*Questions about how much chest trouble you have had over the past 3 months.*

Please tick (✓) one box for each question:

<table>
<thead>
<tr>
<th>Question</th>
<th>most days a week</th>
<th>several days a week</th>
<th>a few only with chest infections</th>
<th>not at all</th>
</tr>
</thead>
<tbody>
<tr>
<td>1  Over the past 3 months, I have coughed:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2  Over the past 3 months, I have brought up phlegm (sputum):</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>3  Over the past 3 months, I have had shortness of breath:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>4  Over the past 3 months, I have had attacks of wheezing:</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5  During the past 3 months how many severe or very unpleasant attacks of chest trouble have you had?</td>
<td></td>
<td></td>
<td></td>
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</tr>
<tr>
<td>6  How long did the worst attack of chest trouble last?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>(Go to question 7 if you had no severe attacks)</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>7  Over the past 3 months, in an average week, how many good days (with little chest trouble) have you had?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>8  If you have a wheeze, is it worse in the morning?</td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

Please tick (✓) one:

- more than 3 attacks
- 3 attacks
- 2 attacks
- 1 attack
- no attacks

Please tick (✓) one:

- a week or more
- 3 or more days
- 1 or 2 days
- less than a day

Please tick (✓) one:

- No good days
- 1 or 2 good days
- 3 or 4 good days
- nearly every day is good
- every day is good

Please tick (✓) one:

- No
- Yes
St. George’s Respiratory Questionnaire

PART 2

Section 1

How would you describe your chest condition?

Please tick (✓) one:

- The most important problem I have
- Causes me quite a lot of problems
- Causes me a few problems
- Causes no problem

If you have ever had paid employment.

Please tick (✓) one:

- My chest trouble made me stop work altogether
- My chest trouble interferes with my work or made me change my work
- My chest trouble does not affect my work

Section 2

Questions about what activities usually make you feel breathless these days.

Please tick (✓) in each box that applies to you these days:

<table>
<thead>
<tr>
<th>Activity</th>
<th>True</th>
<th>False</th>
</tr>
</thead>
<tbody>
<tr>
<td>Sitting or lying still</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Getting washed or dressed</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking around the home</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking outside on the level</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking up a flight of stairs</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Walking up hills</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Playing sports or games</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
St. George’s Respiratory Questionnaire
PART 2

Section 3

Some more questions about your cough and breathlessness these days. Please tick (✓) in each box that applies to you these days:

- My cough hurts
- My cough makes me tired
- I am breathless when I talk
- I am breathless when I bend over
- My cough or breathing disturbs my sleep
- I get exhausted easily

Section 4

Questions about other effects that your chest trouble may have on you these days. Please tick (✓) in each box that applies to you these days:

- My cough or breathing is embarrassing in public
- My chest trouble is a nuisance to my family, friends or neighbours
- I get afraid or panic when I cannot get my breath
- I feel that I am not in control of my chest problem
- I do not expect my chest to get any better
- I have become frail or an invalid because of my chest
- Exercise is not safe for me
- Everything seems too much of an effort

Section 5

Questions about your medication, if you are receiving no medication go straight to section 6. Please tick (✓) in each box that applies to you these days:

- My medication does not help me very much
- I get embarrassed using my medication in public
- I have unpleasant side effects from my medication
- My medication interferes with my life a lot
St. George’s Respiratory Questionnaire  
PART 2

Section 6

These are questions about how your activities might be affected by your breathing.

Please tick (✓) in each box that applies to you because of your breathing:

- I take a long time to get washed or dressed
- I cannot take a bath or shower, or I take a long time
- I walk slower than other people, or I stop for rests
- Jobs such as housework take a long time, or I have to stop for rests
- If I walk up one flight of stairs, I have to go slowly or stop
- If I hurry or walk fast, I have to stop or slow down

My breathing makes it difficult to do things such as walk up hills, carrying things up stairs, light gardening such as weeding, dance, play bowls or play golf

My breathing makes it difficult to do things such as carry heavy loads, dig the garden or shovel snow, jog or walk at 5 miles per hour, play tennis or swim

My breathing makes it difficult to do things such as very heavy manual work, run, cycle, swim fast or play competitive sports

Section 7

We would like to know how your chest usually affects your daily life.

Please tick (✓) in each box that applies to you because of your chest trouble:

- I cannot play sports or games
- I cannot go out for entertainment or recreation
- I cannot go out of the house to do the shopping
- I cannot do housework
- I cannot move far from my bed or chair
St. George’s Respiratory Questionnaire

Here is a list of other activities that your chest trouble may prevent you doing. (You do not have to tick these, they are just to remind you of ways in which your breathlessness may affect you):

- Going for walks or walking the dog
- Doing things at home or in the garden
- Sexual intercourse
- Going out to church, pub, club or place of entertainment
- Going out in bad weather or into smoky rooms
- Visiting family or friends or playing with children

Please write in any other important activities that your chest trouble may stop you doing:

..............................................................................................
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Now would you tick in the box (one only) which you think best describes how your chest affects you:

- It does not stop me doing anything I would like to do
- It stops me doing one or two things I would like to do
- It stops me doing most of the things I would like to do
- It stops me doing everything I would like to do

Thank you for filling in this questionnaire. Before you finish would you please check to see that you have answered all the questions.
### Appendix J: Time Frame of Communication Plan and Pilot Study Plan

<table>
<thead>
<tr>
<th>Time</th>
<th>Staff and Activities</th>
<th>Contents</th>
</tr>
</thead>
<tbody>
<tr>
<td>Week 1-2</td>
<td>COS, DOM, WM (Gain approvals and supports)</td>
<td>Formal letters and meetings:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Aims and objectives of education program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Significances of education program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Potential benefits</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Literatures Reviewed supported</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Cost-Benefit Ratio</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Transferability and Feasibility</td>
</tr>
<tr>
<td>Week 3-4</td>
<td>NO, APN (Gain supports and cooperation)</td>
<td>Formal E-mails and meetings:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Aims and objectives of education program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Significances of education program</td>
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<tr>
<td></td>
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<td>- Potential benefits</td>
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<td></td>
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<td>- Literatures Reviewed supported</td>
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<td></td>
<td></td>
<td>- Cost-Benefit Ratio</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Transferability and Feasibility</td>
</tr>
<tr>
<td>Week 4-5</td>
<td>Respiratory Consultant, MO (Gain supports</td>
<td>Formal E-mails and meetings:</td>
</tr>
<tr>
<td></td>
<td>and cooperation)</td>
<td>- Aims and objectives of education program</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Significances of education program</td>
</tr>
<tr>
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<td>- Potential benefits</td>
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<td>- Literatures Reviewed supported</td>
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<tr>
<td></td>
<td></td>
<td>- Cost-Benefit Ratio</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Transferability and Feasibility</td>
</tr>
<tr>
<td>Week 5-6</td>
<td>Nursing staffs (Gain supports and cooperation)</td>
<td>Briefing and sharing sessions:</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Update information and progress from meetings</td>
</tr>
<tr>
<td>Week 7-8</td>
<td>Formation of Communication Team</td>
<td>- Arrange formal meetings</td>
</tr>
<tr>
<td></td>
<td>1 Respiratory NS (Team Leader)</td>
<td>- Prepare training session and education materials</td>
</tr>
<tr>
<td></td>
<td>4 Link Nurses</td>
<td>- Monitor program effectiveness</td>
</tr>
<tr>
<td></td>
<td>1 Respiratory Consultant</td>
<td>- Evaluate pilot study</td>
</tr>
<tr>
<td></td>
<td>1 Respiratory MO</td>
<td></td>
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<tr>
<td></td>
<td>1 Trainer</td>
<td></td>
</tr>
<tr>
<td>Week 8-11</td>
<td>Training Period</td>
<td>- Update and standardize the COPD managements and cares</td>
</tr>
<tr>
<td>Week 12-15</td>
<td>Preparation Period</td>
<td>- Prepare education pamphlets, related tools such as aero-chamber, puff</td>
</tr>
<tr>
<td></td>
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<tr>
<td>Week 16-17</td>
<td>Recruitment Period</td>
<td>- Recruit eligible patients</td>
</tr>
<tr>
<td>Week 18-25</td>
<td>Pilot Study</td>
<td>- Pilot Study Trial</td>
</tr>
<tr>
<td>Week 26-29</td>
<td>Evaluation of Pilot Study</td>
<td>- Assess staffs’ compliance, nurses’ and patients’ satisfaction level</td>
</tr>
<tr>
<td></td>
<td></td>
<td>- Related program modifications</td>
</tr>
</tbody>
</table>

Remarks: COS: Chief of Service; DOM: Departmental Operation Manager; WM: Ward Managers; NO: Nursing Officers; APN: Advanced Practice Nurses; MO: Medical Officers; NS: Nursing Specialist
Appendix K: Patients’ Satisfaction Questionnaire

內科部門 - 慢性阻塞性肺病教育計劃
病人滿意度問卷調查

請在適當空間上填上”✓”

<table>
<thead>
<tr>
<th>教育計劃</th>
<th>非常同意</th>
<th>同意</th>
<th>無意見</th>
<th>不同意</th>
<th>非常不同意</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.你能夠清楚了解計劃的內容</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>2.你覺得計劃的指引易於跟隨</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>3.你認為計劃的資料易於得到</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>4.你覺得醫護人員的協助是足夠</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>5.你滿意醫護人員的教導</td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>6.你認為本計劃對你有好處</td>
<td></td>
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<td></td>
</tr>
<tr>
<td>7.你認為本計劃對整體生活沒有影響</td>
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<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>8.你滿意整個教育計劃</td>
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</tr>
<tr>
<td>9.你對本教育計劃最為滿意的地方</td>
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</tr>
<tr>
<td>10.你對本教育計劃最為不滿的地方</td>
<td></td>
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<tr>
<td>11.請問您對本教育計劃有哪些建議?</td>
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</tbody>
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病人標籤
### Appendix L: Staffs’ Satisfaction Questionnaire

內科部門-慢性阻塞性肺病教育計劃
員工滿意度問卷調查

請在適當空間上填上”✓”

<table>
<thead>
<tr>
<th>教育計劃</th>
<th>非常同意</th>
<th>同意</th>
<th>無意見</th>
<th>不同意</th>
<th>非常不同意</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.你能夠清楚了解計劃的目的</td>
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<tr>
<td>2.你覺得計劃的指引易於明白</td>
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<tr>
<td>3.你能夠清楚了解計劃的內容</td>
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<td>4.你有足夠時間去作準備</td>
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<td>5.你認為計劃對病人有幫助</td>
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<td>6.你有信心去教育病人</td>
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<tr>
<td>7.你認為本計劃對整體工作量沒有影響</td>
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<td>8.你滿意整個教育計劃</td>
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</tr>
</tbody>
</table>

9.你對本教育計劃最為滿意的地方
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

10.你對本教育計劃最為不滿的地方
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________

11.請問您對本教育計劃有哪些建議?
_____________________________________________________________________
_____________________________________________________________________
_____________________________________________________________________
References:


15. In-patient Statistics. Hong Kong SAR: Hospital Authority, Department of Health and Census and Statistics Department


