A QUALITATIVE EXPLORATION OF PERCEPTIONS AMONG PATIENTS AND HEALTH CARE PROFESSIONALS TOWARDS SMOKING CESSATION TREATMENT FAILURE AND PROCESS AND ECONOMIC OUTCOME ASSESSMENT OF PHARMACIST MANAGED QUIT SMOKING CLINIC IN THE STATE OF MALACCA, MALAYSIA

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By

LEE MEI LIN

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Dedication

This dissertation is dedicated to:

The memory of my late father, for his simple humility and his steadfast principles, ñFor your faith in me, Papa.ò

My dearest mother and my darling daughter, ó*my* Little Womenô, for their patience, ñAt last.ò

My *wicked*, spirited sisters, ñSisters in need, sisters indeed. *Gracias, senoritas*. *Menendez* again?ò

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List of Abbreviations

GBP	British Pound
CA	Continuous Abstinence
CPG	Clinical Practice Guidelines
FTND	Fagerstrom Test for Nicotine Dependence
HCP	Health Care Professional
MOH	Ministry of Health, Malaysia
MYR	Malaysian Ringgit
NHS	National Health Service
NRT	Nicotine Replacement Therapy
PA	Prolonged Abstinence
PP	Point Prevalence
QSC	Quit Smoking Clinic
SCA	Smoking Cessation Aid
UK	United Kingdom
US	United States
USD	US Dollars
WHO	World Health Organization

Publications

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1. Lee, M.L., Hassali, M.A., Shafie, A.A., & Abdol Aziz, A.M. (2011). Challenges of Pharmacist-Managed Smoking Cessation Services-A Viewpoint [Letter-to-Editor]. *Nicotine & Tobacco Research*, 13(6), 504-505.

Conference Presentations

1. Lee, M.L., Hassali, M.A., & Shafie, A.A. Exploring the reasons smokers dropped out after enrolling at the Quit Smoking Clinic (QSC) in Malaysia. 14th International Society for Pharmacoeconomics Or Research (ISPOR) Annual European Congress. 5-8 November 2011, Madrid, Spain.
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PENEROKAAN PANDANGAN SECARA KUALITATIF DI KALANGAN PESAKIT DAN KAKITANGAN KESIHATAN TERHADAP KEGAGALAN RAWATAN BERHENTI MEROKOK DAN PENILAIAN PROSES DAN HASILAN EKONOMIK PENGENDALIAN KLINIK BERHENTI MEROKOK OLEH PEGAWAI FARMASI DI MELAKA, MALAYSIA

ABSTRAK

Kegagalan untuk penyambungan rawatan di kalangan perokok menghalang keberkesanan rawatan berhenti merokok. Walaupun terdapat banyak kajian yang meramalkan sifat-sifat perokok yang sedemikian, namun sebab-sebab mereka tidak menyambung rawatan dan kekal merokok jarang diterokai. Oleh itu, komponen kualitatif kajian ini bertujuan untuk menerokai sebab-sebab demikian dengan mengkaji halangan-halangan yang ditempohi oleh perokok-perokok sedemikian dan kakitangan kesihatan (Health Care Professionals, HCPs) mereka. Teori Kognitif Sosial telah digunakan sebagai rangka konsep kajian kualitatif fenomenologi ini. Dari bulan Mei 2010 sehingga Mac 2011, 15 perokok dan sembilan HCPs daripada dua Klinik Berhenti Merokok (Quit Smoking Clinics, QSCs) di daerah Melaka Tengah, Melaka telah ditemuduga. Temuduga mereka telah dirakam secara audio dan ditranskrib. Transkrip Melayu dan Mandarin diterjemahkan ke Bahasa Inggeris. Kesemua transkrip dianalisa melalui analisa kandungan tema. Halangan yang ditempohi dikenalpasti sebagai peringkat individu dan klinik. Kedua-dua pihak perokok dan HCPs mengakui kerendahan tahap motivasi dalaman merupakan peringkat halangan individu. Peringkat halangan klinik berkenaan peranan, kemahiran dan sikap HCPs serta kerberkesanan dan kehadiran bantuan berhenti merokok (Smoking Cessation Aids, SCAs). Walaupun perokok beranggapan bahawa program ini kurang membantu, namun HCPs menyatakan kekurangan sokongan organisasi sebagai halangan utama. Sebab utama kegagalan penyambungan rawatan berorientasikan

ketidakpuasan terhadap rawatan (program dan faktor HCPs serta SCAs) bersama-sama dengan kelemahan motivasi dalaman perokok.

Kebanyakan kajian menunjukkan kerberkesanan peranan doktor dalam pengurusan berhenti merokok walaupun mereka kurang berbuat demikian. Sebaliknya, kajian mengenai keberkesanan pegawai farmasi dalam konteks tempatan serba kekurangan. Oleh itu, komponen kuantitatif bertujuan menilai keberkesanan khidmat berhenti merokok oleh pegawai farmasi dari segi kadar berhenti merokok, kadar tidaksambungan rawatan, kos dibelanjakan untuk setiap perokok dan bekas perokok serta purata hari bekas perokok kekal dalam rawatan. Rekod kad perokok berdaftar di QSC diperiksa secara retrospektif dari tempoh Januari 2009 sehingga Disember 2010. Purata hari bekas perokok kekal dalam rawatan ialah 298 hari. Kadar berhenti merokok ialah 5.8% sementara kadar ketidaksambungan rawatan ialah 71.8%. Dari sudut sistem kesihatan, kos dibelanjakan bagi setiap perokok dan bekas perokok masing-masing ialah RM55.71 dan RM953.28. Manakala, kos dibelanjakan untuk setiap cubaan berhenti merokok ialah RM34.74.

A QUALITATIVE EXPLORATION OF PERCEPTIONS AMONG PATIENTS AND HEALTH CARE PROFESSIONALS TOWARDS SMOKING CESSATION TREATMENT FAILURE AND PROCESS AND ECONOMIC OUTCOME ASSESSMENT OF PHARMACIST MANAGED QUIT SMOKING CLINIC IN THE STATE OF MALACCA, MALAYSIA

ABSTRACT

Treatment default among smokers hinders the effectiveness of cessation service delivery. While most studies predicted the defaultersô characteristics, the reasons these smokers dropped out and remain smoking are seldom explored. Thus, this qualitative component of this study aimed to explore these reasons by examining the barriers encountered by such smokers and their respective healthcare providers (HCPs). Social Cognitive Theory was used as the conceptual framework for the phenomenological qualitative study. From May 2010 to March 2011, 15 current adult smokers and nine HCPs from two Quit Smoking Clinics (QSCs) in Melaka Tengah District, Malacca were interviewed. The interviews were audio-recorded and transcribed verbatim. The non-English transcripts were subsequently translated to English and analyzed using thematic content analysis framework. The barriers encountered were categorized as individual- and clinic-level. Both smokers and HCPs acknowledged that the smokersô low intrinsic motivation was the individual-level barrier. The clinic-level barriers were the smokersô and HCPsô mismatched perceptions regarding the HCPsô roles, skills and attitudes as well as the availability and efficacy of smoking cessation aids (SCAs). While the smokers viewed the programme as not helpful, the HCPs cited the lack of organizational support as their main barrier**.** The reasons for treatment default centred on the overall treatment dissatisfaction (the programme, HCP and SCA factors) intertwined with the smokersô low intrinsic motivation.

Many studies demonstrated the efficacy of the physicianôs role in cessation management despite of the lack of such service provision. The studies examining the effectiveness of pharmacist-managed cessation services, however, were largely ignored in the local context. Thus, for the quantitative component of this research, it aimed to evaluate the effectiveness of pharmacist-managed QSC, in terms of the quit and default rate achieved, the cost per quitter and cost per patient incurred and the median number of days of the quitters remained in the managed care of the pharmacist. The patientsô medical records at the pharmacist-managed QSC were examined retrospectively from January 2009 to December 2010. The quit rate between January 2009 and December 2010 were 5.8% while the default rate was 71.8%. The average quit period for all smokers enrolled was 298 days. From the health system perspective, the average costs per quitter, per patient and per quit attempt were MYR953.28, MYR55.71 and MYR34.74, respectively.

CHAPTER 1 INTRODUCTION

1.1 Overview of Smoking-related Ill Health

Cigarette smoking is the most important primary cause of preventable morbidity and mortality in both developed and developing countries (Nakamura, et al., 2009; Woodward et al., 2005). The detrimental effects that cigarette smoking impacted on the burgeoning healthcare-related costs, economic burdens and loss of productivity in smokers are well-documented (Bartechhi, Mackenzie & Schrier, 1994; Centers for Disease Control and Prevention, 2008; Leistikow, 2000).

In Malaysia, the smoking prevalence rate is 21.5%, with 27.0% had smoked (Ministry of Health, 2008). Cigarette smoking is significantly linked with 90% cases of lung cancer, 75% cases of chronic obstructive airway disease and 25% cases of cardiovascular diseases (Lim, 1986). Smoking-related diseases were accounted for at least 15% of hospitalization admissions and 35% of hospital deaths (Ministry of Health, 2008). In addition, slightly more than a quarter (26.4%) of Ministry of Health, MOH, financial yearly budget, RM 2925 million, was used to treat three smoking-related diseases (Ministry of Health, 2008).

Interestingly, Peto and colleagues (2000) estimated that tobacco-related mortality would not be affected by smoking prevention until 2050. Hence, they argued that the only current available option to reduce tobacco-related mortality rates in a medium term outlook was to reach out to the current smokers and induce them to quit. To this point, many studies have demonstrated that health risks associated with cigarette smoking is reversible after a sufficient period of abstinence (Daly, Mulcahy, Graham & Hickey, 1983; Davies, Latto, Jones, Veale & Wardrop, 1979). Thus, maintaining this life-long abstinence is an important public health goal for developed and developing countries, especially in Malaysia. Consequently, assisting tobacco cessation is an important component of comprehensive tobacco-control policies and evidence-based recommendations implied that smokers

benefitted from it (Pound, Coleman, Adams, Bauld & Ferguson, 2005; World Health Organization, 2008). Recognizing this, the Malaysiaôs MOH had included tobacco cessation as one of the key areas in preventing and reducing disease burden in the Ministry Strategic Plan of 2006-2010 (Ministry of Health, 2008).

1.2 Rationale of Establishment of Quit Smoking Clinics (QSCs)

In terms of addressing tobacco cessation, the prospect of establishing cessation clinics in primary care settings is seen to be an opportunistic intervention to reach out to the vast population of smokers (Lichenstein et al., 1996). This is on the account of taking advantage of the four salient points of smokersô attributes (strong intention to quit, attempt(s) made to quit, contact with a health care professional (HCP) and difficulty to quit unaided).

Firstly, in relation to the intention to quit, slightly more than two third (70.1%) of current Malaysian adult smokers were reported to harbour intention to quit within six months (Ministry of Health, 2008). Secondly, the nationwide survey in 2006 revealed that 70.5% of adult Malaysian smokers attempted to quit smoking; averaging about two quit attempts yearly (Ministry of Health, 2008). In Malacca itself, three in every four adult smokers (77.1%) made an attempt to quit, initiating almost two attempts (1.8 times) yearly (Ministry of Health, 2008). Thirdly, more than 70% of the smokers initiated contact with a physician at least once yearly and each smoker averages over three office visits annually (Centers for Disease Control and Prevention, 1993). Finally, many current smokers cited that willpower alone is insufficient in order to quit (Zhu, Melcer, Sun, Rosbrook & Pierce, 2000). Studies have shown that a mere 3-7% of the smokers who attempted to quit via sheer willpower managed to remain abstinent after six months (Hughes et al., 1992; Viswesveran & Schmidt, 1992). This point was further substantiated by Hughes and colleagues (2009) who pointed that 68%

of smokers who expressed their intention to quit within a month would utilize a treatment in order to quit.

In Malaysia, the establishment of public-funded Quit Smoking Clinics (QSCs) serves to encourage and facilitate access to cost-free resources made available to smokers who want to quit. Currently, there are 336 QSCs established in Malaysia (Ministry of Health, 2008). The smokers attend these clinics by referral or walk-in encounters. The heavily subsidized services comprised of counselling and provision of formal smoking cessation aids (SCAs) such as nicotine replacement therapy(s) (NRTs) and varenicline (Ministry of Health, 2003).

Considering the recognized smoking hazards and cessation benefits, it is expected that smokersô intention to quit and their access to public-funded cessation programmes should lead to a high participation rate and thus culminate in successful cessation intervention. However, it was found that there was no correlation between the initial enrolment rate for smoking cessation programmes and the eventual quit rate due to the significant default rate (Bauld, Chesterman, Judge, Pound & Coleman, 2003; Challenger, Coleman & Lewis, 2007; Ferguson, Bauld, Chesterman & Judge, 2005). For the National Health Service (NHS) Stop-Smoking Clinics in the UK, both Bauld et al. (2003) and Ferguson et al. (2005) revealed varying degrees of default rate (20%-40%) at 4- and 52-week follow-up. Similarly, Challenger et al. (2007) calculated a 21.7% default rate at 4-week follow-up and further predicted these defaultersô characteristics. In Malaysia, the average default rate of five urban public-funded QSCs was 51.8% at 24-week follow-up (Wee, Shahab, Bulgiba & West, 2011a). This default rate, interpreted as negative treatment outcome, affects the cessation servicesô design and delivery since substantial resources are spent on engaging this subgroup of smokers.

1.3 Overview of Healthcare Professionals (HCPs) Significance in Smoking Cessation

Most smokers are in contact with many different parts of the healthcare system, such as hospitals, health clinics, dental offices and pharmacies at any one point of their lives (An et al., 2008; West et al., 2006). Pertaining to tobacco cessation, having access to both formal SCAs and commanding a certain degree of respect from their patients, the HCPsô role are increasingly recognized as pivotal in engaging smokers to quit during the opportunistic window of contact between them (World Health Organization, 2005).

1.3.1 The Physicians

To date, the physicians were invariably singled out among the categories of HCPs as *the* cessation service provider. A large body of research sought to demonstrate the efficacy of the physicianôs role in cessation management (Slama, Redman, Perkins, Reid & Sanson-Fisher, 1990; Stead, Bergson & Lancaster, 2008; Wilson et al., 1988). In particular, the physicianôs advice to quit was cited by the smokers as an important motivator to attempt cessation (Kottke, Brekke, Solberd & Hughes, 1989). Slama et al. (1990) further found that 35% of smokers tried to stop smoking in response to this advice. Finally, substantial claims demonstrated that minimal contact by the physician, which is defined as less than three minutes, increased the cessation rates by 3% (Fiore et al., 2008; Stead, Bergson & Lancaster, 2008).

Despite the overwhelming aforementioned studies demonstrating the significance of the physiciansô interventions in improved treatment outcomes, however, it was also found that physicians lack in assessing tobacco use and providing smoking cessation service to their patients (Ferketich et al., 2008; Gunes, Karaoglu, Genc, Pehlivan & Egri, 2005; Schiffman, Ferguson & Hellebusch, 2007; Solberg, Asche, Boyle, Boucher & Pronk, 2005). For example, at any given office visits, up to 80% of smokers do not receive cessation advice

from their physician (Ceraso et al., 2009) and only one third of smokers are referred to a cessation programme (Anda, Remington, Sienko & Davis, 1987; Sherman, Yano, Lanto, Simon & Rubenstein, 2005; Thorndike, Rigotti, Stafford & Singer, 1998). Moreover, Denny and colleagues (2003) revealed that approximately two million smokers were not subjected to any cessation advice or intervention during their routine health check-up in the past one year in the US.

It also been reported that only 3.6% ex-smokers credited their physician in assisting them to quit (Frank, Winkleby, Altman, Rockhill & Fortmann, 1991) while smokers who did not receive any support from their physicians were more likely to remain abstinent than those who did (Schiffman, Ferguson & Hellebusch, 2007). Similiarly, in Hong Kong, the over-whelmed physicians only spent an average of three to five minutes with each patient as a result of heavy patient-load in public-funded health clinics (Yu et al., 2004).

Likewise, a randomized controlled trial involving physicians revealed that the total time spent counselling smokers was only 8.7 minutes while simple advice only took about 1.4 minutes, 0.12 minutes longer than the average consultation (Slama et al., 1990). Lastly, in a systematic review by Vogt and colleagues (2005), they noted the prominent negative beliefs and attitudes displayed in the significant minority of medical practitioners during the interaction with their patients who were smokers.

1.3.2 The Pharmacists

On the contrary, less attention is being paid to the other categories of HCPs, such as the pharmacist. Yet, among all the HCPs, the pharmacists are the most accessible by the public and deemed trustworthy for the provision of health advice (West, Wilkin & Bentley, 2003). In Poland, Polish smokers ranked pharmacist as the top healthcare professional that they would approach in smoking cessation (Goniewicz et al., 2009). Thus, it is argued that the pharmacists are ideally situated to initiate behaviour change among patients or complement the effort of other providers.

The notion of having pharmacist engaging patients to quit smoking is not new. A large body of research have exemplified the value-added impact of pharmacist delivery in smoking cessation services (Dent, Harris & Noonan, 2007; Dent, Harris & Noonan, 2009; Dent, Scott & Lewis, 2004; Kennedy, Giles, Chang, Small & Howards, 2002; Maguire, McElnay & Drummond, 2001; Philbrick, Newkirk, Farris, McDanel & Homer, 2009; Ragucci & Shrader, 2009; Roth & Westman, 2001; Zillich, Ryan, Adams, Yeager & Farris, 2002). While most pharmacists currently are not being utilized as a resource for smoking cessation, patients perceive that receiving advice or assistance from a pharmacist would either probably (46%) or definitely (17%) increase the probability of them to stop smoking (Hudmon, Hemberger, Corelli, Kroon & Prokhorov, 2003).

1.4 Purpose of the Study

The qualitative component of this study was undertaken to examine the reasons of such default in the smokers. In addition, to look at this issue from a different viewpoint, this study also engaged the perspectives of their corresponding HCPs (primary care physicians, pharmacists, trained medical assistants and registered nurses) who were responsible for the provision of the cessation services. Meanwhile, the quantitative component of this study aimed to assess the effectiveness of pharmacist-delivered cessation services in public QSC in Malacca.

1.4.1 Research Questions

This study sought to address two central questions.

1. Why the current smokers who were motivated enough in attempt to quit, and thus initiated contact at the QSC but to eventually drop out, leading to high default treatment rate? A qualitative semi-structured interview approach was used to address this aim.
2. How effective was the pharmacist-managed QSC, in terms of cessation rate, cost analysis and survival analysis? A retrospective observational approach was used to address this aim.

1.4.2 Research Objectives

Accordingly, the methods employed in this study were guided by five objectives. The first two objectives aimed to answer the first central question in relation to treatment attrition. Thus, the first objective was to explore the barriers encountered by this subgroup of smokers, taking into account of their perceptions of their smoking, cessation, and the QSC. Secondly, this study intended to explore the barriers encountered by the corresponding HCPs who were

responsible for the provision of the cessation services at the QSCs, taking into account of their perception of smoking and cessation, their role undertaken at the QSC and the QSC.

As for the treatment outcomes evaluation, the second half of this study attempted to ascertain the rates of quit and default in the pharmacist-managed QSC between the year 2009 and 2010. In the context of abstinence, this study set out to estimate the time-to-quit (days) and relationship between socio-demographic variables and abstinence, for patients enrolled at the pharmacist-managed QSC within the period of January 2009 to December 2010. For the cost analysis, this study determined to calculate the average cost(s) per quitter, per quit attempt and per patient enrolled in the pharmacist-managed QSC within the period of January 2009 to December 2010.

1.5 Overview of Thesis

This research constituted of two independent components; qualitative and quantitative components. The qualitative component examined the reasons of treatment default while the quantitative component evaluated the effectiveness of the pharmacist-managed QSC. As such, the thesis comprises of eight chapters, inclusive of this chapter. A brief summary of the each chapter are described subsequently.

Chapter 2 represents the critical appraisal of the relevant literatures in the context of this study. Firstly, the terminologies of treatment attrition used in various tobacco-related studies are thoroughly explored and correspondingly, this is followed suit with the studies indicating the heterogeneity of dropouts and defaulters. In addition, the predictors of dropouts and defaulters in various cessation trials and programmes in the context of smokersô characteristics are examined. In line with the incorporation of the HCPsô perspectives, the barriers encountered by them are duly examined. The second half of this chapter deals with literatures pertaining to the effectiveness of the pharmacist-managed QSCs in terms of the

quit rate and costs analysis. Prior to appraise the effectiveness literatures fairly, the measurements of various cessation treatment outcomes are discussed at great length.

The next chapter, Chapter 3 deals with the general methods employed in carrying out the research. It encompasses the rationale of qualitative research in examining the reasons of treatment attrition and correspondingly, the approaches adopted. This chapter also considers the theoretical frameworks utilized in both components of the study for the processes of data collection and data analysis.

The ensuing chapters, Chapter 4, 5 and 6, respectively are independent chapters, addressing the qualitative and quantitative components of this study. Both Chapter 4 and Chapter 5 contain the qualitative findings of the first half of this research. The former, Chapter 4 introduces the perspectives of the smokers in their qualitative interviews about their perception towards treatment default. Meanwhile, the latter, Chapter 5 summarizes the findings from the corresponding HCPs on the same subject matter. The subsequent chapter, Chapter 6 describes the effectiveness of the pharmacist-managed QSC, in particular, the evaluation of the quit and default rate. In addition, cost analyses were also performed to calculate the costs incurred per smoker, per quitter and per quit attempt.

Finally, the findings of the preceding chapters (Chapter 4, 5 and 6) are concluded in Chapter 7 (general conclusion). In addition to the conclusions presented, the final chapter also briefly outlines the apt recommendations based on the results of this research study and suggests the directions of the future researches.

CHAPTER 2 LITERATURE REVIEW

2.1 Introduction

This study aimed to investigate the phenomenon of treatment failure, in particular the treatment attrition in the MOH-funded QSCs and the effectiveness of the pharmacist-managed QSC. Given the focal point of interest was the subgroup of defaulters from the cessation clinics, the literature reviews considered the varied terminologies employed to define treatment attrition, the heterogeneity of these defaulters, their predictors from cessation trials and subsequently from the cessation clinics/ programmes. On the other hand, since the perspectives of the HCPs managing the QSCs was necessary to address the reliability of the qualitative approach, the review also took into account the studies enumerating the barriers encountered by the HCPs in the rest of the population. Aside from reviewing the literatures on the smokers and the HCPs, the studies on the cessation clinics characteristics in relation to dropouts, were collectively examined in order for a fairer representation of the treatment attrition phenomenon. Meanwhile, the second half of the literature review dealt with the studies evaluating the effectiveness of the pharmacist-managed QSCs. Apart from treatment attrition, the review also adopted a broader perspective in the measurement of treatment outcomes of smoking cessation interventions. Thus, in-depth analyses of studies that evaluated the quit rate achieved, the relevant cost analysis that entailed and the survival analysis in terms of treatment retention, pertaining to the pharmacist-led cessation interventions, were conducted in this second half of the literature review.

2.2 Reasons of Treatment Attrition

2.2.1 Definition of Treatment Attrition

Among the indicators of a ñgoodò epidemiological study is the high study participation rate (Galea & Tracy, 2007). Since the studies reporting low participation rates were deemed to be inferior, subsequently this raised doubts in the validity and reliability of their findings (Galea & Tracy, 2007; Ribisl et al., 1996). Hence, for this exact reason, both Gnich et al. (2008) and Gray et al. (2011) whose studies had significantly low participation rates, cautioned their readers to exercise restraints in interpreting the smoking cessation rate outcomes in their evaluation of the said intervention.

Typically, the definition of ñnon-participation ratesò is employed to represent non-response rates in the simplest sense, in the context of surveys and interviews (Galea & Tracy, 2007; Siddiqui, Flay & Hu, 1996). Similarly, this term has been utilized in other studies as the implication of ñnon-availabilityò or ñmissingò data (Barnes, Larsen, Schroeder, Hanson & Decker, 2010; Siddiqui et al., 1996).

However, in the framework of intervention studies, in addition to the conventional non-response rates obtained in the studiesô participants, the ñnon-participation ratesò also assumed a broader significance, that is the ñtreatment attrition ratesò. This is especially so given that treatment attrition alongside with treatment retention are considered as part of the evaluation of treatment outcomes (Epstein & McCoy, 1975).

On the whole, in many tobacco-related studies, ñtreatment attritionò has been loosely applied as a function of ñtreatment failureò (Khara & Okoli, 2010; Mayer, Hawkins & Todd, 1990), conforming to Hughes and colleagues (2003) suggested definition of ñtreatment failureò; a distinctive attribute of treatment outcome rather than the treatment objective itself. In tobacco-related studies, the term ñtreatment attritionò were addressed in various expressions, such as ñtreatment non-participationò (Pohl, Martinelli & Antonakos, 1998,

Sussman, Dent, Wang, Cruz, Sanford & Johnson, 1994), ñtreatment non-engagementò (Khara & Okoli, 2010; Okoli, Greaves, Bottorff & Marcellus, 2010), ñtreatment non-respondersò (Schumann et al., 2008), ñtreatment non-completersò (Britt, Knisely, Dawson & Schnoll, 1995; Costello et al., 2011; Kealey et al., 2007), ñtreatment lossò (Ferguson, Bauld, Chesterman & Judge, 2005), ñtreatment drop-outò (Britt, Knisely, Dawson & Schnoll, 1995; Epstein & McCoy, 1975; Oshima, Ito & Nomura, 2009; Stark, 1992), ñtreatment defaultò (Challenger et al., 2007; Wee et al., 2011a) and ñlost due to follow-upsò (Snow, Connett, Sharma & Murray, 2007). In longitudinal tobacco studies, however, the term ñstudy attritionò is assumed to adopt the meaning of study participants lost as a result of follow-up time intervals (Ribisl et al., 1996; Li et al., 2010; Siddiqui, Flay & Hu, 1996).

On the other hand, in a smaller proportion of the cessation intervention studies, the nomenclature ñtreatment attritionò was adopted to define ñprogramme complianceò in which the endpoint measurement is the goal of the intervention treatment, namely, cessation (adherence) and smoking/relapse (attrition) (Vermeire, Hearnshaw, Van Royen & Denekens, 2001). For instance, Hays et al. (2010) included those who failed to adhere to their smoking cessation medications as well as those who dropped out from their cessation trials as ñtreatment noncompletersò. While Hays and colleagues (2010) did not specifically state their adherence to the suggestion of an older Russell Standard (RS) that stipulated ñtrial protocol violatersò as those who fail to adhere to their cessation medications or fail to attend treatment session, nonetheless, the similarities in both the methodology employed by Hays et al. (2010) and the proposed standard of cessation trials outcome criteria by West et al. (2005) were palpable.

Amidst this diverse use of terminologies to indicate treatment attrition, there also remained the temporal classifications of the treatment attrition. More broadly, the term ñtreatment attritionò is differentiated into preinclusion attrition and postinclusion attrition,

taking into account of the timeframe of the treatment attrition occurrences (Howard, Cox, & Saunders, 1990). Howard et al. (1990) interpreted that the preinclusion attrition occurred prior to participantsô recruitment such as during screening or recruitment evaluations while the postinclusion attrition is said to have occurred anytime during the treatment sessions or postreatment follow-ups. In the context of cessation treatment, however, many time-related designations were identified in the treatment attrition studies. Firstly, there are varying definitions of the number of treatment session(s) in attendance that were considered as attrition (Khara & Okoli, 2010; King & Canada, 2004; Patterson et al., 2003; Schmitz & Tate, 1994) or the duration of the treatment programme (Borrelli et al., 2002; Sussman et al., 1994) or the continuous as opposed to intermittent treatment sessionsô attendance (Curtin, Brown & Sales, 2000). In addition, both Leeman et al. (2006) and Curtin et al. (2000) distinguished the establishment of quit date as the timeframe point of references in relation to their study dropouts, early dropout (prior to quit date) and late dropout (after quit date), with Curtin et al (2000) further specifically emphasized the distribution of the attended treatment sessions to differentiate these early and late dropouts. Finally, there were studies examining the variables associated with the said treatment attrition, relative to timeframe of the intervention; during treatment (Borrelli et al., 2002; Leeman et al., 2006; Patterson et al., 2003; Woods et al., 2002) as opposed to a defined follow-up period after the said intervention had ended (Smith, Reilly, Miller, DeBusk & Taylor, 2002; Snow et al., 2007) or even both (Backinger et al., 2008).

As such, there is a lack of consistency in defining the terms of cessation treatment attrition. Therefore, for the purpose of this study and subsequently the relevant review of its literature, the generic term of ñnon-participation ratesò is established so as to comprised solely of postinclusion, during-treatment attrition rates and the term ñdropoutsò and ñdefaultersò is utilized to imply study participants who dropped out after initial enrolment,

prior to treatment completion (Epstein & McCoy, 1975), without any discrimination to the number, duration or the nature of their attendance (whether continuous or discrete) of the treatment session(s), at the cessation trials and programmes, respectively. Accordingly, this excluded the literature that examined participants (smokers) lost to follow-ups despite completed the cessation programmes (Smith et al., 2002; Snow et al., 2007).

2.2.2 Heterogeneity of Dropouts and Defaulters

Conceptualizing the conservative ñintention-to-treatò analyses in tobacco treatment-outcome studies, this led to most cessation studies to adopt the dichotomous dependent variable (abstinence or using tobacco-related products) in the outcome measurement. As a result, these studies assumed that the dropouts in cessation programme and trials to be smokers (Boyd & Briggs, 2009; Hughes & Carpenter, 2005; Lando, McGovern, Barrios & Etringer, 1990). Thus, it masked important information about the intricacy of smoking and quitting process. In addition, taking into account of the technical aspect of data analysis, this assumption gave rise a certain degree of bias reporting in cessation studies (Barnes, Larsen, Schroeder, Hanson & Decker, 2010).

Borellli and colleagues (2002) postulated that characteristics of smokers who dropped out were different from those who remained smoking despite completing the cessation trials. These cessation trials (Borrelli et al., 2002; Leeman et al., 2006; Patterson et al., 2003; Woods et al., 2002) demonstrated that this distinctive group of smokers were heterogeneous and behaved in a different manner than those who were unable to quit despite completing the programme. This further reaffirmed what was initially proposed by Klesges and colleagues in 1988 who predicted a different set of factors associated with participation, attrition and outcome in a smoking cessation programme at the workplace. According to Klesges et al. (1988), the defaulters (45%) of the workplace cessation programme would likely recorded a

lower level of pre-test carbon monoxide reading and adopted a more negative attitude towards the workplace adoption of smoke-free policies.

2.2.3 Predictors of Dropouts in Cessation Trials-Smokers' Characteristics

A large number of studies sought to identify the predictors of attendance and dropout in cessation trials. They centred on the socio-demographics characteristics of the dropouts such as comprising of the younger age group of smokers (Leeman et al., 2006; Audrain-McGovern et al., 2009), female smokers (Patterson et al., 2003), Non-white smokers (Audrain-McGovern et al., 2009; Leeman et al., 2006), lower education level (Audrain-McGovern et al., 2009; Borrelli et al., 2002; Leeman et al., 2006; Patterson et al., 2003) and lower income level (Nevid, Javier & Moulton III, 1996). The studies also predicted that living with a smoker (Audrain-McGovern et al., 2009), possessing higher nicotine dependence (Borrelli et al., 2002) and registering a lower body mass index (Patterson et al., 2003) would result in treatment attrition. Balanced against the overwhelming number of quantitative researches, Woods and colleagues (2002), however, adopted mixed methods of quantitative and qualitative approaches to analyze participation of African Americans in a smoking cessation trial. Subsequently, their findings revealed that lack of readiness to quit, inadequate reminders and employment conflicts as the participation barriers (Woods et al., 2002).

The most recent trial is, by far, the only study that attempted to evaluate the effectiveness of community pharmacistsô intervention in relation to treatment retention (Costello et al., 2011). In their trial of 6987 smokers in Canada, the number of cessation treatment attendance has been operationalized as the intervention variables to the quit rate (outcome variable) (Costello et al., 2011). Similar to the findings of Challenger et al. (2005), and Leeman et al. (2006), Costello et al. (2011) also discovered that non-completers were

younger smokers. Apart from revealing the smoker-characteristics (younger) in the non-completers, two other new predictors emerged from Costello et al. (2011) study; an initial shorter treatment session and being provided NRT inhalers, of which they were study-specific indicators.

2.2.4 Predictors of Defaulters in Cessation Programmes/Clinics-Smokers' Characteristics

Amidst all the previous studies that were conducted in cessation trials, the study whose findings were more relevant to the delivery of smoking cessation treatment in routine healthcare settings is the retrospective, observational study carried out by Challenger and colleagues (2007). They attempted to predict variables associated with high default rate in the NHS Stop-Smoking Clinics in England (Challenger, Coleman & Lewis, 2007). Consistent with the previous findings of the cessation trials studies, they too found that the defaulters were more likely to be younger and heavier smokers, living alone or in a house with a smoker, and possessed lower motivation to quit as compared to the programme completers.

While Challenger et al. (2007) study solely intent upon predicting the defaulters, on the other hand, there were three other pertinent studies whose treatment default findings were incidental to their primary aim of cessation treatment outcome evaluations. Firstly, it was a general evaluation of the English cessation services outcome study that was conducted by Ferguson and colleagues (2005). Since the loss rates was regarded as part of the treatment outcome, their findings indicated that the servicesô users lost to follow-ups were generally younger and displayed a shorter time delay of the first cigarette upon waking up (less than five minutes) (Ferguson, Bauld, Chesterman & Judge, 2005). Likewise, Dorner and colleagues (2011) recently attempted to predict variables associated with cessation in the context of treatment sessions attendance and observed that participants who attended fewer

sessions were younger. Finally, in their study, Schnoz et al. (2011) analyzed their participant dropouts, whom they defined as cancelling prior to the last intervention session. They subsequently found that barriers to the study logistics location and to cessation were essentially the reasons for five participants to default in their targeted Turkish-based cessation programme in Switzerland (Schnoz, Schaub, Schwappach & Gross, 2011).

On the whole, both Challenger et al. (2007) and Akkaya et al. (2006) generalized that the patients who failed to turn up for the subsequent treatment sessions as possessing low motivation to quit. Echoing the same sentiment, Costello et al. (2011) suggested ñlow motivationò on the account of an alarming 50% drop-out rate in the 3-session treatment arm group in spite of the provision of free NRTs. Even so, the reasons underlying the ñlow motivationò among the dropouts and defaulters remain largely ignored.

2.2.5 Barriers Encountered By the HCPs

Incorporating the perspectives of the HCPs in addition to the current smokers conceptualized the idea of data triangulation (Barbour, 2001; Berg, 2009). By probing their views on smoking behaviour and cessation in their patients and their individual role on smoking cessation provision and programme, this approach attempted to offset the particular weakness and challenged the biases that arise from considering only the perspectives of the smokers. This alternative viewing angle was not meant to validate and justify the current smokersô perspective but to reveal slightly different information, seeking to paint a clearer picture of the focus of this study.

There is an interesting mix of both qualitative and quantitative researches that identified the barriers encountered in the provision of cessation service in the different categories of HCPs; the physicians (Kottke, Willms, Solberg & Brekke, 1999), the general practitioners (Awad & OôLoughlin, 2007; Helgason & Lund, 2002; Twardella & Brenner,

2005; Ulbricht et al., 2006; Vogt, Hall & Marteau, 2005), the pharmacists (Aquilino, Farris, Zilich & Lowe, 2003; Hudmon, Prokhorov & Corelli, 2006; Williams, Newsom & Brock, 2000), the nurses (Studts et al., 2010) and the multi-team providers such as physicians, nurses, pharmacists and others (Blumenthal, 2007; Dozier et al., 2009; White, Bush, Kai, Bhopal & Rankin, 2006).

Almost all studies found that time constraints (Aquilino et al., 2003; Awad & OõLoughlin, 2007; Blumenthal, 2007; Dozier et al., 2009; Helgason & Lund, 2002; Hudmon et al., 2006; Kottke et al., 1999; Studts et al., 2010; Twardella & Brenner, 2005; Ulbricht et al., 2006; Vogt, Hall & Marteau, 2005; White et al., 2006) was the principal barrier for the HCPs in assisting the smokers to quit. The rest comprised of the HCPsô low self-efficacy (Blumenthal, 2007; Dozier et al., 2009; Kottke et al., 1999; Vogt et al., 2005; Williams et al., 2000) lack of training (Hudmon et al., 2006; Twardella & Brenner, 2005), lack of financial remuneration (Aquilino et al., 2003; Hudmon et al., 2006; Kottke et al., 1999; Williams et al., 2000), lack of patient education materials (Awad & OõLoughlin, 2007; Blumenthal, 2007) and lack of organizational support (Blumenthal, 2007; Helgason & Lund, 2002; Hudmon et al., 2006; Kottke et al., 1999). Lastly, the language barrier was acknowledged by the HCPs who counselled smokers from the ethnic minority groups (White et al., 2006).

In relation to the smokers themselves, the HCPs disclosed that the characteristics of the smokers (Studts et al., 2010; Williams et al., 2000) such as not ready to quit (Blumenthal, 2007), lack of interest (Kottke et al., 1999) and lack of motivation (Ulbricht et al., 2006; White et al., 2006) presented a formidable barrier in the cessation service provision.

An interesting point to note is the mention of the perceived advocacy of commercial propagation of tobacco (Kottke et al., 1999), which appeared to further established the acceptability of smoking and thus, a barrier to cessation service provision.

2.2.6 Attributes of Cessation Clinics Associated with High Default Rates

Bauld and colleagues (2003) acknowledged that several traits of the cessation services in the NHS Stop-Smoking Clinics that was strongly associated with higher default rates. In terms of the HCPs managing the cessation clinics, Bauld and colleagues (2003) found that those whose service coordinators had other concurrent work responsibilities and were paid less compared to their corresponding counterparts in other locations were most likely to lose their enrolled smokers. Moreover, the services who failed to obtain good training courses for their coordinators and who did not train skilled multi-team cessation specialists also tend to yield high loss rates (Bauld et al., 2003). Lastly, in relation to the formal SCAs prescribed, the services whose advisors recommended the usage of bupropion were most likely to retain their clients as compared to those who did not (Bauld et al., 2003).

Secondly, Ferguson and colleagues (2005) reported that the clients of the cessation services located in primary care settings were more likely to default compared to other settings (hospital, workplace or community) in their retrospective evaluation of treatment outcomes study.

In relation to the frequency of contact made with the cessation programme, Schmitz and Tate (1994) claimed that less frequent contact by the participants led to more dropouts, in their comparison of low- (2-weekly), medium- (3-weekly) and high-frequency (6-weekly) intervention groups in a clinic-based pharmacological-behavioural cessation programme.

2.2.7 Smoking Cessation Aids

As outlined by Kotz, Fidler and West (2009), there are several approaches to assist the smokers to quit; pharmacotherapy (Waring, 2003; Frishman, 2009) and behavioural interventions (Spring, et al., 2009; West, Walia, Hyder, Shahab, & Michie, 2010). The former refers to formal smoking cessation aids (SCAs). Meanwhile, the latter, comprising of

telephone (Stead, Lancaster, & Perera, 2003), individual behavioural (Lanacaster, & Stead, 2003) and group support (Stead & Lancaster, 2003), while receiving tremendous attention of late, would not be appraised here.

Among, the most widely used SCAs is the nicotine replacement therapy (NRTs) in six varied formulations; gums, patches, sprays, inhalers, sublingual tablets and lozenges (Stead, et al., 2008). The rationale in utilizing an NRT is to replace the nicotine from the cigarettes and thus reduce the withdrawal symptoms associated with nicotine addiction when the smokers are trying to quit (Stead, et al., 2008). A large body of research has substantiated the effectiveness of NRTs in improving cessation rates in smokers in both trials (Hughes, Peters, & Naud, 2011; Silagy, Mant, Fowler, & Lodge, 1994) and cessation programmes settings (Brose, et al., 2011; Molyneux, et al., 2003; West, & Zhou, 2007).

Other formal SCAs comprised of non-nicotine preparations such as bupropion, clonidine and varenicline (Waring, 2003; Frishman, 2009; Siu, & Tyndale, 2007). Only the latter would be discussed here as it is currently being prescribed in the QSCs in Malaysia. Varenicline is a relative newly-developed partial agonist of the nicotinic receptor that encourages cessation in two ways (Cahill, Stead, & Lancaster, 2012; Siu & Tindale, 2007). As a weak nicotinic agonist, varenicline firstly, reduces craving and withdrawal symptoms (Rollema, et al., 2007). Secondly, it also partially blocks the nicotine receptor stimulation, thus reduces nicotine-mediated reinforcing effects of smoking satisfaction (Rollema, et al., 2007). Despite recent studies claiming the efficacy of varenicline in improving cessation rates however, caution must be exercised in light of the recent psychiatric events occurred in the smokers being prescribed varenicline (Cahill, Stead, & Lancaster, 2012).

As a result of seemed inconsistencies in the actual prescribing practices by the HCPs, Bader, McDonald and Selby (2009) has included a thorough and extensive algorithm for

appropriate use and prescribing of formal SCAs in different contexts of smoking cessation treatments.

2.3 Effectiveness of Pharmacist-Managed QSCs

2.3.1 Overview of Pharmacist-Managed QSCs

Current published literatures on pharmacist-managed cessation services were limited to several established subject matters, albeit undertaken in different study populations and health settings. Of these studies, they comprised of the review of pharmacistsô knowledge, attitude and beliefs in relation to the cessation services (Hudmon et al., 2006, Williams et al., 2000), the evaluation of their current practices in the context of ñAsk, Assess, Advise, Assist and Arrangeò (Aquilino et al., 2003; Hudmon et al., 2003; Meshack, Moultry, Hu, & McAlister, 2009), their encountered barriers (Aquilino et al., 2003; Hudmon et al., 2003; Williams et al., 2000) and the related factors of exposed training (Aquilino et al., 2003; Meshack et al., 2009) and smoking cessation in academic curriculum (Hudmon, Bardel, Kroon, Fenlon & Corelli, 2005; Williams, 2009). In addition, there were also studies evaluated the customers and patients satisfaction towards the pharmacists in cessation provision (Goniewicz et al., 2009; Hudmon et al., 2003). On the whole, many of these studies concluded that the pharmacists shared many similarities in relation to the provision, barriers encountered and academic curriculum exposure to smoking and cessation with other categories of HCPs such as the medical practitioners. As such, the relevant review of literatures pertaining to the specifics of cessation treatment outcome measurement that comprised of the quit rate, the cost analysis and survival analysis are discussed below.

2.3.2 Measurement of Cessation Treatment Outcomes

Notwithstanding treatment attrition, the widely accepted evaluation of a tobacco cessation treatmentôs efficacy is the abstinence rate achieved. Alternatively, there were several studies that utilized cigarettes reduction as their primary treatment outcome but these would not be discussed here. Briefly, the primary treatment outcome that utilized sustained cigarettes reduction in clinical trial is defined as reported cigarettes reduction of at least 50% as compared to the baseline cigarettes consumption from the week 6 to week 16 (Chan, et al, 2011; Lindson, Aveyard, & Hughes, 2010; Moore, et al., 2009; Wennike, et al., 2003). However, as Veliver et al. (1992) cautioned, the cigarettes reduction strategy is argumentative, attributed to the patterns of the cigarettes smoked (compensatory mechanisms). Similarly, the evidence-based recommendations from both British (National Institute for Health and Clinical Excellence, 2008) and American (Fiore, et al., 2008) do not seem to favour cigarettes reduction strategy in cessation.

The primary measures that were essentially employed in the abstinence rate assessment are self-reported (by the smokers) and biochemical verification to ascertain tobacco use (Velicer, Prochaska, Rossi & Snow, 1992). Biochemical validations comprised of exhaled carbon monoxide measurement, salivary thiocynate measurement and urinary cotinine measurement (SRNT Subcommittee on Biochemical Verification, 2002). While they were recommended for the evaluation in the MOH settings, unfortunately, they were not performed at any one point of the smokersô assessment of their treatment follow-up in this setting of pharmacist-managed QSC. Hence, it would not be reviewed here.

According to Velicer et al. (1992), the smokersô self-reported measures comprised of point prevalence, continuous abstinence and prolonged abstinence. In an individual, point prevalence (PP) is generally defined as the abstinence reported during a pre-defined time window [24 hours, seven days (the most common) or even 30 days] prior to the follow-up

assessment (Hughes et al., 2003; Velicer et al., 1992). While the earlier studies (Hughes et al., 2003; Velicer et al., 1992) allowed a small degree of generalization in the brief time window, the more recent meta-analytical study (Hughes, Carpenter & Naud, 2010) adopted a more rigid and specific approach in which they re-assigned the older definition of PP as Period Prevalence while defined Point Prevalence as abstinence from tobacco use on the day of the follow-up assessment itself. On the other hand, all agreed that Continuous Abstinence (CA) is regarded as complete abstinence from the time period of the quit date until the day of the follow up assessment (Hughes et al., 2010; Hughes et al., 2003; Velicer et al., 1992). As in the case of PP, similarly, the timeframe to follow-up in CA measurement varies according to the study design specifications; from three to six months (clinical trials) (Hughes et al., 2003; West, Hajek, Stead & Stapleton, 2005) and one to several years (population study) (Velicer et al., 1992).

Lastly, the term Prolonged Abstinence, PA is similar to CA in the sense that it refers to sustained abstinence but with the inclusion clause of ñafter an initial grace periodò, and thus affords a greater degree of flexibility and dismisses the exclusivity of an immediate cut-off time interval post-quit date (Hughes et al., 2003; Velicer et al., 1992). Although the older studies (Hughes et al., 2003; Velicer et al., 1992) specified PA as continuous abstinence after the grace period, so as to distinguish it from CA, the newer ones (Hughes, Carpenter & Naud, 2010; West et al., 2005) adopted a less stringent approach by using both terms interchangeably to indicate the grace period inclusion; CA (West et al., 2005) and PA/CA (Hughes et al., 2010).

CA is considered to be far more superior as compared to PP in the treatment outcome measure. According to Hughes et al. (2003) and Velicer et al. (1992), firstly, since CA commands a longer abstinence period as compared to PP, therefore it provides a more just and stable representation of the abstinence, particularly of the relapse episodes. Secondly,

since CA is measured from the time lapsed since the quit date, therefore it is more aptly employed as the measurement of treatment efficacy in the intent-to-treat analyses (Hughes et al., 2003; Velicer et al., 1992). As a result of its conservative and rigorous definition, both Hughes et al. (2003) and Velicer et al. (1992) concluded that CA represents an objective evaluation of a cessation treatment efficacy.

Therefore, for the purpose of this study, the CA measurement is established as the primary measurement of cessation treatment outcome and it is designated as the continuous abstinence from the targeted quit date excluding the grace period such as the cigarettes reduction phase.

2.3.3 Quit Rate

In their favourable systematic review of pharmacist-delivered interventions in smoking cessation studies, Dent and colleagues (2007) indicated the capability of pharmacist delivering tobacco cessation intervention in the aspect of comparable quit rates, to the rest of the categories of HCPs. Both Poulsen et al. (2010) and Dent et al. (2007) challenged the numerical manifestation of the quit rates in their systematic reviews with the former, in their broad review of all cessation programmes across three European countries (Poulsen, Dollerup, & Møller, 2010) and the latter, in their specific context of pharmacist-led cessation programmes (Dent et al., 2007). Both concluded that the wide disparities in the number of programmes and trials that were examined, however, gave rise to the inability to formally compare the treatment outcomes of these studies (Dent et al., 2007; Poulsen et al., 2010). Firstly, in the context of the pharmacist-led intervention, many cessation studies failed to include a control group in order for a robust conclusion to be drawn upon the said pharmacist intervention. Secondly, in the aspect of the duration of the interventions, the studies displayed varied timeframes, with some studies measured the quit rate at 3-month, 6-month or 12-