ECONOMIC EVALUATION AND FACTORS AFFECTING SMOKING CESSATION USING iSTOP PROGRAM IN A LOCAL MANUFACTURING COMPANY

by

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LIST OF ABBREVIATIONS

CA	Continuous Abstinence
CDC	Centers for Disease Control and Prevention, US
CO	Carbon Monoxide
COHb	Carboxy-haemoglobin
ETS	Environmental Tobacco Smoke
FCTC	Framework Convention on Tobacco Control
FTND	Fagerström Test for Nicotine Dependence
GPs	General Practitioners
HRD	Human Resource Department
ITT	Intention-To-Treat
IRR	Internal Rate of Return
LC-MS/MS	Liquid Chromatography-Tandem Mass Spectrometry
NICE	The National Institute for Health and Care Excellence
NHMS	National Health and Morbidity Survey
NHIS	National Health Interview Survey conducted by CDC, US
NRT	Nicotine Replacement Therapy
PP	Per Protocol
PPA	Point of Prevalence Abstinence
RCTs	Randomised Controlled Trials
ROI	Return on Investment

SHS	Second-Hand Smoke
SMS	Short Message Service
SR	Self-Reported
TTM	Transtheoretical Model
UMCAS	University Malaya Centre of Addiction Science
UMMC	University Malaya Medical Centre
VAR	Varenicline
WHO	World Health Organisation

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PENILAIAN EKONOMI DAN FAKTOR MEMPENGARUHI BERHENTI ROKOK MENGGUNAKAN PROGRAM iSTOP DI SYARIKAT PEMBUATAN TEMPATAN

ABSTRAK

Produk tembakau umpama serampang dua mata. Produk tembakau bukan sahaja menyumbang kepada ekonomi negara malah, ia juga merupakan faktor risiko kepada kesihatan manusia dan pencuri senyap kekayaan penggunanya, masyarakat dan negara. Selain daripada kos penjagaan kesihatan, prestasi kerja perokok turut terjejas mengakibatkan penurunan produktiviti. Banyak kajian menunjukkan bahawa program berhenti merokok di tempat kerja adalah berkesan dan menjana simpanan positif kepada majikan. Oleh itu, pemberhentian merokok di tempat kerja dilihat sebagai satu strategi yang berpotensi untuk memerangi penggunaan produk tembakau. Banyak kajian telah dijalankan di luar negara tetapi kajian tempatan adalah kurang, terutamanya dalam sektor pembuatan swasta. Ini adalah satu kajian kohort prospektif keratan rentas tunggal pemberhentian merokok di tempat kerja yang dijalankan di sebuah syarikat pembuatan tempatan. Kajian ini mengkaji program intervensi berhenti merokok yang inovatif dengan multi-komponen selama 12 minggu untuk menyokong pekerja yang merokok berhenti merokok. Program ini dikenali sebagai program "iSTOP". Objektif kajian adalah untuk menilai keberkesanan program inovatif ini dan tingkah laku perokok serta mengenal pasti faktor yang mempengaruhi berhenti merokok dan kembali merokok. Di samping itu, kualiti program ini juga dinilai dengan mengunakan kaedah analisis kualitatif, menjadikannya lebih berkesan dalam membantu perokok berhenti merokok. Oleh kerana program ini ditaja sepenuhnya oleh Syarikat, bahagian terakhir adalah mengira pulangan ekonomi kepada majikan dengan

menggunakan penunjuk komersil biasa (ROI dan IRR) yang biasa digunakan oleh pihak Pengurusan. Kajian ini juga merupakan kajian pertama yang memberi ubat Varenicline dan kombinasi Varenicline dengan terapi gentian nikotin (NRT) di tempat kerja. Hasil kajian ini amat menggalakkan. Sejumlah 155 orang perserta mengambil bahagian dan mereka dibahagikan kepada dua kumpulan untuk mengikuti program iSTOP. Secara keseluruhan kadar berhenti merokok untuk jangka pendek dan jangka panjang masing-masing 45.8% dan 37.4%. Analysis multivariate menyimpulkan bahawa faktor-faktor yang mempengaruhi perberhentian merokok jangka panjang selama satu tahun adalah tahap kepatuhan kepada program intervensi klinikal dan mempunyai persepsi yang kuat terhadap kesan merokok ke atas kesihatan. Faktor-faktor yang berkaitan dengan mereka kembali merokok adalah tinggal di kawasan bandar, percubaan berhenti merokok kurang daripada 1 minggu dan tidak menerima nasihat GP pada tahun semasa. Semua peserta yang ditemuramah menghargai usaha yang dilakukan oleh Syarikat untuk menganjur program ini secara percuma. Penggunaan varenicline dan gabungannya dengan NRT telah diterima baik oleh peserta. Kesanggupan diri, efikasi kendiri dan motivasi diri dengan sokongan dan motivasi yang berterusan dari persekitaran adalah faktor kritikal kejayaan berhenti merokok. Ini membawa kepada penciptaan model “CARE” untuk program pemberhentian merokok di tempat kerja. ROI dalam 5 tahun dan IRR setahun program in masing-masing 156% and 20.7%, mengesahkan bahawa program “iSTOP” adalah satu projek pelaburan yang menarik bagi pihak Pengurusan. Kesimpulannya, tesis ini menesahkan bahawa program pemberhentian merokok di tempat kerja berkesan dan memberi manfaat kepada majikan. Tindakan masa depan termasuklah memasukkan model “CARE” dalam program berhenti merokok di tempat kerja supaya keberkesanan program dapat ditingkatkan lagi.

ECONOMIC EVALUATION AND FACTORS AFFECTING SMOKING CESSATION USING iSTOP PROGRAM IN A LOCAL MANUFACTURING COMPANY

ABSTRACT

Tobacco products are a double-edged sword. While tobacco products contribute to a country's economic significantly, it is also a notable risk factor for human health and a silent thief of the wealth of its users, society and nation. Apart from the healthcare cost, the work performance of smokers is also being affected leading to lower productivity. Many studies have also shown that workplace smoking cessation programs are effective and have generated positive savings for the employers. Therefore, workplace smoking cessation has been viewed as a potential strategy to combat the usage of tobacco products. Abundant studies have been carried out abroad, but local studies are scares; especially in the private manufacturing sector. This study was a cross-sectional single prospective cohort workplace smoking cessation study conducted in a local manufacturing company. This study reviewed a 12-week innovative multi-component smoking cessation intervention program to support smoking employees to quit smoking, called "iSTOP" program. The objectives of this study were to evaluate the effectiveness of this innovative program and the smokers' behaviours as well as to identify factors affecting smoking cessation and relapse. On top of these, the quality of this program was also evaluated using qualitative analysis method, making it more effective in assisting smokers to quit smoking. As this was the Company fully sponsored program, the last section was to calculate the economic return this program to the employer using the common commercial indicators (ROI and IRR), which are familiar by the Management team. This study was also the first

study prescribing varenicline and the combination of varenicline with nicotine replacement therapy (NRT) in a workplace setting. The results of this study were very encouraging. A total of 155 participants took part, and they were divided into two batches to go through the iSTOP program. The overall short-term and long-term abstinent rates were 45.8% and 37.4% respectively. The multivariate analysis concluded that the factors affecting abstinence for one year were the level of adherence to the clinical intervention program and having a strong perception of the effect of smoking on health. Factors related to relapse were staying in the urban area, previous quit attempt of less than 1 week and not receiving GP's advice in the current year. All the interviewed participants valued the effort put on by the Company for this free-of-charge program. Use of varenicline and its combination with NRT were well-accepted by the participants. Self-willingness, self-efficacy and self-motivation with continuous support and motivation from the surroundings were critical factors in successful smoking cessation. This lead to the development of "CARE" model for workplace smoking cessation program. The ROI over 5 years and IRR per year of this program were 156% and 20.7% respectively, confirming that iSTOP program was a promising investment project for the Management. In conclusion, this thesis confirmed that iSTOP program was effective and benefited the employers. Future actions were to apply the "CARE" model in a workplace smoking cessation program to further enhance its effectiveness.

CHAPTER ONE

GENERAL INTRODUCTION

1.1 Background

Cigarette is a highly engineered, pleasure, addictive and deadly tobacco product. It contains nicotine and releases more than 7,000 toxic chemical compounds when burning (U.S. Department of Health and Human Services, 2014). Nicotine is an addictive active pharmaceutical compound. It contains in cigarette, which the only legal drug that delivers nicotine to the brain immediately after inhaling, as effective as intravenous injection, but is not regulated as controlled medicine (World Health Organization, 2008, 2015).

Smoking gives "carrots and sticks" to smokers. In the early group of smoking, its users gain sensory gratification (calming, relaxation, reward, alertness and confidence), social crutch and weight lost. Over the time, smokers not only develop addiction and dependence on nicotine but also habit. Unfortunately, apart from the dependence, smoking is a gradual killer. Tobacco contained in the cigarettes kills half of its users when it is used as per the manufacturers instruction and on average 15 years prematurely (Institute for Public Health (IPH), 2012; World Health Organization, 2008, 2015) It effects nearly all organs of the body will be seen only after a lag of several years, which ultimately, threaten the health and reducing the wealth of the smokers (U.S. Department of Health and Human Services, 2014; World Health Organization, 2008).

Since the landmark 1964 Surgeon General's report published, the evidence on smoking and health has expanded greatly (U.S. Department of Health and Human Services, 2014). Nowadays, tobacco smoking including second-hand smoke is known to be the leading preventable causes of premature morbidity and mortality in the world today (U.S. Department of Health and Human Services, 2014; World Health Organization, 2011). Tobacco kills a third to half of its users 15 years prematurely and one person is

killed every 6 seconds (U.S. Department of Health and Human Services, 2014) If current trend continues, tobacco will kill one person every 4 seconds and up to 1 billion of smokers could be killed in 21st century (World Health Organization, 2012). More importantly, the premature death of smokers raises the cost of healthcare, deprives household income of smoking families and hinders economic development of a country (Institute for Public Health (IPH), 2012).

Unfortunately, the impact of smoking has been screened by smokers and hence only the pleasure of smoking is acknowledged. Currently, there are about 1.3 billion smokers globally and is expected to increase to 1.6 billion by 2025 (Clive & Andy, 2004; Elgoni, 2010). Developing countries comprise 73% of the world smoker's population (Elgoni, 2010; H. K. Lim et al., 2013; Peto, 1994).

In 2015, Malaysia has about 5 million smokers, comprising 22.8% of the Malaysian population aged 15 years and above. 43.0% of Malaysia men smoke while only 1.4% of women smoke. Prevalence of smoking in the rural areas (24.3%) was slightly higher than the urban areas (22.7%). About 60% of them smoke 15 or more cigarettes per day with average daily consumption 12 cigarettes per day (Institute for Public Health (IPH), 2015a; Wee, Shahab, Bulgiba, & West, 2011).

In Malaysia, at least 15% of the total hospitalisations are due to smoking (K. H. Lim et al., 2009; Yong et al., 2013). Smoking-related diseases have been the primary cause of mortality since 1980 (H. K. Lim et al., 2013). It is estimated that annually 10,000 deaths and 35% of hospital deaths are attributed to smoking (K. H. Lim et al., 2009; Yong et al., 2013). A study on the burden of disease estimated that one-fifth of disability adjusted life years (DALYs) and one-third of years of life lost (YLL) for Malaysians were due to smoking-related diseases (Institute for Public Health (IPH), 2015a; H. K. Lim et al., 2013). 2.92 billion Ringgit Malaysia was spent on treating

three major smoking-related diseases, namely lung cancer, ischemic heart disease and chronic obstructive pulmonary disease (COPD) (Al-Naggar, Jawad, & Bobryshev, 2012; Cheah & Naidu, 2012; H. K. Lim et al., 2013). If the current trend continues, it is estimated that by 2020, 30,000 smokers will die due to smoking-related diseases yearly (K. H. Lim et al., 2009). In order to achieve the World Health Organisation Non Communicable Diseases Global target, there is a need to reduce current smoking prevalence to 15% by the year 2025 (Institute for Public Health (IPH), 2015b).

Many activities have been carried out by the Malaysia Government to reduce the smoking prevalence. “Tak Nak Merokok” (Don’t want Smoking) was launched in 2004 to increase the public awareness on the harmfulness of smoking to the smokers and second-hand smoke. In Jan 2007, “Infoline” for smoking cessation was established to help smokers and family of a smoker to quit smoking (Kassim & Mohd Zain, 2015). To promote smoking cessation, Melaka became first state in the country to gazette five areas as no-smoking zones in 2011(Murali, 2011). This was followed by Penang, which announced the heritage enclave and Penang Hill to be smoke-free area in 2016 and 2017 respectively (Arnold, 2016; Edmund, 2017). Meanwhile, Penang aimed to be smoke-free state by 2023 (The Star/Asia News Network, 2018). KUALA Lumpur City Hall (DBKL) aimed to be fully smoke-free city in the future to reduce the prevalence of smoking in the city (The Star, 2018).

About 70% of Malaysian adult smokers are working, spending minimally 9 hours in their working places. As the nicotine withdrawal symptoms usually start within a few hours after the last cigarette, these smokers need to smoke during working hours. Approximately 40% of those who work indoors had been exposed to second-hand smoke in their workplace (Institute for Public Health (IPH), 2015b). There are enough evidences showing that smoking has harmful effects to health not only to smokers but

also second-hand smokers (Mattias Öberg, 2010). Therefore, smoking in the workplace has detrimental effect not only on the employees' health, but also imperil the safety and healthy as well as productivity of the workplace (Institute for Public Health (IPH), 2012; Robert C. Klesges, Cigrang, & Glasgow, 1987; S. P. Tsai, Wen, Hu, Cheng, & Huang, 2005).

Smoking is a remarkably refractory and sticky behaviour. Therefore, quitting smoking is not easy. In fact, very few tobacco users can successfully quit the habit easily. Therefore, many studies have been conducted to understand the factors affecting successful smoking cessation. Many predictors have been identified as predictors for smoking cessation; including older age, being male, married, having higher education, higher social economic status, no smoking or smoking partner at home, has been smoking for more than 15 years, low addiction to nicotine, previous quit attempts, smoke-free policy at workplace, self-motivated and self-confidence (Biener, Hamilton, Siegel, & Sullivan, 2010; Bravin et al., 2015; Caponnetto & Polosa, 2008; Ezat, Selahuddeen, & Aljunid, 2008; Fai, Yen, & Malik, 2016; Ghani et al., 2012; Kim, 2014; Lee & Kahende, 2007; Li et al., 2010). In general, these factors are found in the both abroad and local studies.

Smoking is such an irresistible and inviting behaviour or habit. Those smokers who have stopped smoking easily lapse and hence relapse. About 65& to 75% of the ex-smokers would relapse from abstinent in the first year (Lee & Kahende, 2007). Therefore, studies have also been conducted abroad and local to understand the predictors for relapse from smoking cessation. Some factors related to relapse are younger age, high level of nicotine dependence, experiencing nicotine withdrawal symptoms, smoking environment in both home and workplace, depression, poor social support in workplace and prior quit attempt that last for less than six months (Batra,

Collins, Torchalla, Schroter, & Buchkremer, 2008; Buczkowski, Marcinowicz, Czachowski, & Piszczek, 2014; Caponnetto & Polosa, 2008; Li et al., 2010; Wee et al., 2011).

Therefore, the essential in quitting journey is to address both addictive and behavioural aspects. There are two types of smoking cessation interventions: behavioural and pharmacological, which could be administered as monotherapy or in combination. These different smoking cessation interventions have been studied extensively in many controlled or uncontrolled studies and reviewed by many researchers and positioned in smoking cessation guidelines (Anderson & Wetter, 1997; Ebbert, Elrashidi, & Stead, 2015; Glynn, Cryan, Kent, Flynn, & Kennedy, 2009; Dorothy K. Hatsukami & Mooney, 1999; J. Hughes, 2008; Jiloha, 2014; Lancaster, Stead, Silagy, & Sowden, 2000; Schmelzle, Rosser, & Birtwhistle, 2008). Apart from these two mainstay treatments, other quitting methods are also available, including hypnotherapy, acupuncture, electronic cigarettes, and aversion therapy (Maseeh & Kwatra, 2005; Niaura et al., 2008; White, Rampes, Liu, Stead, & Campbell, 2014).

There are nine validated pharmacotherapy, four validated behavioural interventions for smoking cessation (J. Hughes, 2008). The pharmacotherapy is divided into first-line medications, consisting of all 5 types of nicotine replacement therapy formulations (gum, lozenges, patch, inhaler, and nasal spray), bupropion and varenicline. The second-line medications are Clonidine and Nortriptyline. The behavioural interventions are psychosocial treatment, which could be divided into first line, which consists of Group discussion, individual discussion and telephone help line. The second line behavioural interventions are rapid smoking and internet program. All these intervention have been validated and proven to be effective in assisting smokers during their quitting process and listed in the algorithm for choosing among smoking

cessation treatments (J. Hughes, 2008). These interventions also have been reviewed to be effective with sufficient evidences in Malaysia Clinical Practice Guideline of Tobacco Use and Disorder 2016 (Disease Control Division, 2016; J. Hughes, 2008).

Quitting smoking is difficult because it is a cluster of behavioural, cognitive and physiological phenomena (Piasecki, 2006). Therefore, pharmaco-behavioural therapy, which is the combination of Pharmacotherapy and behavioural intervention, is developed (J. Hughes, 2008). Review study concluded that combined pharmacotherapy and non-pharmacotherapy increased quitting rate 82% compared to usual non-pharmacotherapy cessation method (Patnode et al., 2015). Hence smoking cessation support is crucial to help the smokers to quit successfully (Glynn et al., 2009).

With the anti-smoking campaigns and restricting or banning tobacco advertisement, awareness on the harmfulness of smoking has been increased making many smokers want to quit smoking. However, only a few get the support they need. Currently, in Malaysia smoking cessation service is available as health services in selected government hospitals and government clinics. The smokers have to make an effort to visit the smoking cessation clinics which operate during working hours only. Therefore, workplace becomes an ideal setting for implementing smoking cessation intervention to support smoking working adults to quit smoking.

The smoking cessation program implemented in the workplace were varied significantly, from a simple and low-intensity program; such as telephone counselling or self-help program to a comprehensive and high-intensity multicomponent program, such as self-help manuals, group counselling, mass media campaign, and smoking policy (Cahill & Lancaster, 2014). Therefore, the outcome of the studies on the effectives of a workplace smoking cessation program varies.

Workplace smoking cessation program is very feasible as majority of the smokers are adults. In Malaysia, about 70% of them were working (Institute for Public Health (IPH), 2012, 2015b). About half of the current smokers made a quit attempt in the past 12 months. Therefore, implementing smoking cessation intervention at workplace would provide much support to smokers who intend to quit smoking but they could not visit the smoking cessation clinic due to their job responsibilities.

Therefore, smoking cessation program will be a main source of information and support for the smoking employees to assist them to quit smoking effectively. It gives them convenience, particularity if the program is held during working hours and at the workplace. The program will also help them to reduce their expense in quitting smoking and increase their savings if their employers subsidize all or part of the program fee. They will not only regain their health but also their wealth. Initially, the smokers will spend to purchase tobacco products and enjoy the pleasure from smoking. Later years, they will have to spend purchase tobacco products to maintain their addiction and also spend to treat illnesses related to smoking, such as respiratory diseases, cardiovascular diseases, cancer and other disease.

The losses and expenditure which the employers suffer from their smoking employees are significant. They have not only increased healthcare cost but also productivity lost, due to poor health, absenteeism, presenteeism, accidents and injuries (Berman, Crane, Seiber, & Munur, 2014; Halpern, Dirani, & Schmier, 2007b; Halpern, Shikiar, Rentz, & Khan, 2001; Robbins et al., 2000; Sindelar, Duchovny, Falba, & Busch, 2005; Weng, Ali, & Leonardi-Bee, 2013). In US, the healthcare cost of smokers was about 35% per year higher than non-smokers (Berman et al., 2014). The smokers were also 35%-43% more being absence than never smoking employees (Sindelar et al., 2005). In UK, smoking employees were absent at an average of 2.74 more days per year or 19%

increased risk of absenteeism compared with abstainers (Weng et al., 2013).

Therefore, workplace smoking cessation program indeed, over a long-term period of 4 years, will reduce the healthcare cost and increase their smoking employees' productivity as well as reduce absenteeism (Cahill & Lancaster, 2014; Javitz et al., 2004; Javitz, Zbikowski, Swan, & Jack, 2006; Robert C. Klesges et al., 1987). It will eventually generated benefit-cost ration of 8.75 (Warner, Smith, Smith, & Fries, 1996).

The workplace smoking cessation program has many advantages. It has access to many smokers who would make a relatively stable population for the quit smoking program. This population is unique to the community or clinical setting as they know each other and hence will encourage sustained per-group support among them. Moreover, they could also get support from their non-smoking colleagues. Some may feel positive peer pressure too if their peers have stopped smoking successfully. Another significant benefit is that the participants do not need to travel if the program is held at the workplace during office hours. It also gives an opportunity to target the young population which are relatively healthy and do not seek doctors' consultations frequently. Moreover, the company occupational health staffs could be hand on to give professional support. Therefore, workplace smoking cessation program has a higher participation rate, which leads to higher smoking cessation rates compared with non-workplace environment(Cahill & Lancaster, 2014).

1.2 Problem statement

Workplace smoking cessation program have been evaluated and reviewed since 1970s (Cahill & Lancaster, 2014; Danaher, 1980; Robert C. Klesges et al., 1987). Many studies evaluating efficacy of workplace smoking cessation programs and have unanimously concluded that workplace is an appropriate and convenient setting for

implementing smoking cessation program due to its stable smoking population and ease of access to the smoking cessation program (Danaher, 1980; Robert C. Klesges et al., 1987; Smedslund, Fisher, Boles, & Lichtenstein, 2004; Stachnik & Stoffelmayr, 1983).

Systemic review on these intervention studies have reported diverged outcomes and the overall evaluation of its effectiveness is held back by a large heterogeneity in intervention. A meta-analysis conducted in 1990 on the long-term (average=l2 months) abstinence rates of smoking cessation programs held in the workplace in North America concluded that one year quit rates ranged from 3% to 28%, with 13% as a reasonable benchmark for assessing the effectiveness of future smoking cessation efforts (K. J. Fisher, Glasgow, & Terborg, 1990). About 10 years later, another meta-analysis on newer studies revealed that the quit rates were higher with 1 year quit rate of 20.8%; but the effect seemed to diminish over time and was not present beyond 12 months (Smedslund et al., 2004).

All the available studies explored effectiveness of the workplace smoking cessation program were conducted abroad; except a study conducted by Noor et al 2011, which evaluated efficacy of an herbal compound (Viva QS®) (Noor, Aris, Mohamed, Draman, & Bux, 2011). Other local studies were conducted among students and staffs of local universities (Yasin, Retneswari, Moy, Taib, & Ismail, 2013).

All the workplace smoking cessation studies by different researches have been using different interventions in their program. Therefore, till to-date, there is no standard approach being recommended for workplace smoking cessation program. Moreover, the lack of local workplace smoking cessation studies using different interventions in the manufacturing industry has also caused the local employers not convincing of the feasibility of implementing workplace smoking cessation program in the workplaces.

There have been many studies reviewing the factors affecting smoking cessation and relapse from smoking. Some studies had different findings. For example, female in Korean was concluded to be more likely to quit smoking than males (Kim, 2014). At the same time, some workplace studies had different findings from other community studies, which being married did not associated with smoking cessation (Yasin et al., 2013). In Malaysia, studies reviewing these factors were mainly based on population from smoking cessation clinics and university. There has been no study to review these factors based on the population from manufacturing industry.

Generally, interventions which are effective in non-workplace settings are effective in workplace settings. A recent 2014 review showed strong evidences that group therapy, individual counselling, pharmacotherapies and multi-components smoking cessation intervention program increased cessation rate in comparison to no treatment or minimal intervention controls. (Cahill & Lancaster, 2014) Most of the workplace smoking studies applied these interventions studied in non-workplace settings in workplace settings using similar implementation strategies and standardized intervention components. For example, workplace smoking cessation studies involved pharmacological therapy applying a standard nicotine replacement therapy (NRT) regimen to the all participants (Cahill & Lancaster, 2014; Smedslund et al., 2004). Study evaluating effectiveness of flexible and individualized treatment program is lacking (Aubin, Karila, & Reynaud, 2011; Bell, McCullough, et al., 2007b).

Varenicline tartrate, a partial cholinergic nicotinic agonist, assisting the smokers to manage their addiction to nicotine and nicotine withdrawal symptoms during quitting is the latest anti-smoking medicine introduced to the market since 2006 (Antonopoulos & Bercume, 2007; Ebbert, Hays, & Hurt, 2010). It appears to generate highest long-term quit rates. Large clinical trials have also demonstrated the superiority of

varenicline over bupropion SR and NRT for increasing quit rate among cigarette smokers (Aubin, 2009; Cahill, Stead, & Lancaster, 2012; Ebbert et al., 2010). Despite its high initial cost, it is recommended as the first-line option and also has been proven to be cost-effective for smoking cessation (Faulkner, 2009; Garrison & Dugan, 2009). However, post-marketing surveillance and case reports related Varenicline with high incidence of nausea occurring in 16% to 42% of varenicline-treated subjects and potential neuropsychiatric adverse effects events, such as depressed mood, agitation, and suicidal ideation (Oncken et al., 2006). This creates worries among the practitioner while prescribing it to working adults and hence till to-date, it has not been studied in any of the workplace smoking cessation study (McClure et al., 2009).

Smoking has been seen as individual habit where smokers have to make their own effort and be responsible to correct it. Therefore, worrying increased cost of administration and reported low quit rate, Malaysia's employers generally have low interest in conducting the workplace smoking cessation program. Moreover, anti-smoking medicine is not covered by the insurance companies. Even if the employers would like to support, internal and external resources to implement the workplace smoking cessation program are also lacking and local guidance is not available.

Studies conducted to evaluate the benefits of workplace smoking cessation using financial indicator, such as ROI (return on investment) and IRR (internal rate of return) are limited and only available in the abroad studies. These studies were mainly related to the pharmacotherapy (Javitz et al., 2004; Javitz et al., 2011). Only one study has been known to calculate the economic return from the employers perspective using ROI (Mulligan, 2010). It was estimated that the ROI of workplace smoking cessation ranged from minimal of 300% to a maximum of 1400% (Mulligan, 2010).

1.3 Rational of study

In Malaysia, community smoking cessation programs have been available from quit smoking clinic for more than 2 decades in Malaysia (NoorZurani & Mohammad Hussain, 2012). The quit rates reported were 17.3% and 31.8% respectively (Ezat et al., 2008; Wee et al., 2011). The pharmacist-led integrated quit smoking program achieved higher quit rate of 42.6% (Fai et al., 2016). Unfortunately, its reach to the smokers is very limited because it is not known widely by smokers and the service is only available during working hours. Hence, workplace smoking cessation program becomes plausible to support smoking employees to stop smoking so as to curb the increasing trend of smoking.

The currently available studies evaluating the effectiveness of the workplace smoking cessation programs using different interventions were mainly studied abroad, such as United States, United, Austria, Finland, Japan and other countries. Due to the differences in social and culture, there is a need to evaluate applicability and effectiveness of these interventions locally and the acceptance of the smoking workers. Meanwhile, most of these interventions were carried out in the general community without leveraging the unique characteristic of a workplace. Moreover, no study is evaluating the use of Varenicline in the workplace. The local research on the factors affecting smoking cessation and relapse among the workers from the manufacturing industry is scared as well.

Workplace smoking cessation program is new to Malaysia. Only limited resources and knowledge are available to support companies to provide workplace smoking cessation program to the smoking employees. Limited studies have been conducted in local workplace environment, which reported quit rate of 30.7% in a manufacturing company and 13% in local university (Noor et al., 2011; Yasin et al., 2013).

Meanwhile, evidences are available showing that workplace smoking cessation programs are not only benefit smoking employees but also have direct benefits to the employers. It can yield positive cost savings for employers by increasing productivity and reducing the risk of fire hazards due to cigarette butts. Ultimately, a company's image is improved (Halpern et al., 2007b; Halpern et al., 2001; Lundborg, 2007).

Unfortunately, majority of the employers in Malaysia view that smokers would not stop smoking successful after attending the smoking cessation program and for those who had stop smoking, they will relapse after a period. Moreover, they viewed that the smoking cessation success rate is low and the running cost is high, especially when pharmacotherapy is provided, which is not covered by the local insurance companies. Therefore, many companies are reluctant to implement workplace smoking cessation programs.

There are many studies concluded workplace smoking cessation program did bring positive economic impact to the employers (Ekpu & Brown, 2015; Halpern et al., 2007b; Halpern et al., 2001; Igarashi et al., 2016; Parrott & Godfrey, 2004). Hence, this study is timely in encouraging other local employers to consider implementing smoking cessation program in their workplaces. The outcome of this study could be the beginning for future study or reference for developing guidance for any local company which intend to implement workplace smoking cessation program. The findings of the economic return could also be shared with the local employers to convince them the benefits of the workplace smoking cessation program and to encourage them to implement workplace smoking cessation programs.

1.4 Study objectives

Based on the previous workplace smoking cessation studies in other countries program, a local multi-component workplace smoking cessation program was planned to be conducted in a large manufacturing company. This study focused on workplace smoking cessation program. It evaluated the effectiveness of an innovative workplace multi-component smoking cessation intervention program in reducing smoking prevalence in a large manufacturing company as well as the cost and benefits of this workplace smoking cessation program.

The objectives of this research are as follows:

i) To evaluate the profile of the participants from the workplace, including their social-demographic and smoking behaviours

ii) To evaluate the 12-week multicomponent workplace smoking cessation program on its effectiveness in helping smokers to quit smoking

iii) To determine factors affecting smoking cessation and relapse from abstinent

iv) To evaluate the quality of this 12-week multi-component workplace smoking cessation program from qualitative perspective, making it more effective by incorporating the inner voices of the participants

v) To calculate the economic return of this 12-week multi-component workplace smoking cessation program to the Management

1.5 Significance of study

Findings from this study will benefits to various stakeholders; including smokers, smoking cessation providers, employer, researchers, and the Country.

For smokers, especially those working in the studied company, they will experience a guided, structure, systematic and medicated quitting process; instead of quitting themselves without any support. Those who have stopped successfully will then sharing their experiences with other smokers who are motivated to quit smoking. They also could be the ambassador for quitting smoking to encourage smokers who are in the pre-contemplating and contemplating stages to quit smoking.

Due to difference of culture and healthcare system between foreign countries and Malaysia, smoking cessation programs studied in other countries may not be suitable in the local context. Hence, findings from this study will help the smoking cessation providers to structure a more effective workplace smoking cessation program for local companies. Researcher will also have this initial data to plan for the future study.

Having positive findings will encourage the employer to continue implementing this workplace smoking cessation program for the smokers. Moreover, these local positive findings will also encourage other employers to conduct workplace smoking cessation program for their smoking employees to reduce smoking prevalence in their companies.

It is hoped that the findings from this study will help the Ministry of Health to develop a guideline on the smoking control in the workplace and how the employer could implement smoking cessation program in their workplace.

1.6 Thesis overview

This research was conducted in all major cities of Malaysia. It utilised both quantitative and qualitative research techniques. This thesis reported the outcome of the objectives discussed in Chapter 1 as shown in Table 1.1.

Table 1.1: Thesis outline

Chapter	Objectives
Chapter 2	Review literatures about methods in quitting smoking, especially used in workplace, efficacy of workplace smoking cessation program, verification of the outcome of smoking cessation program, factors affecting smoking cessation and relapse as well as general profiles of smokers in Malaysia
Chapter 3	Described the qualitative and quantitative methodologies which are relevant to the research work of this thesis.
Chapter 4	Understand social-demographic and smoking behaviours of the participants in this study
Chapter 5	Evaluate short-term efficacy of iSTOP program by assessing 7-day point prevalence abstinence
Chapter 6	Evaluate long-term efficacy of iSTOP program by assessing 52 weeks continuous abstinence
Chapter 7	Quantitative evaluation on the variables affecting smoking cessation and relapse
Chapter 8	Perform qualitative assessment on the effectiveness of iSTOP program and insights of success in quitting smoking
Chapter 9	Perform economic analysis of iSTOP program
Chapter 10	Thesis conclusion. Recommendation for workplace smoking cessation studies and future research activities are discussed.

CHAPTER TWO

LITERATURE REVIEW

2.1 Literature review

2.1.1 Background

Tobacco use is a social malady. Decades of scientific research have concluded that tobacco use is the leading cause of premature morbidity and mortality in the world (U.S. Department of Health and Human Services, 2014). Nevertheless, use of tobacco has never been stopped, discontinued or even regulated. If the trend of tobacco consumption continues, billions of people worldwide will be killed by tobacco over the 21st century (Warner & Mackay, 2008). In response to globalisation of tobacco epidemic, WHO developed Framework Convention on Tobacco Control (FCTC) and entered into force in 2005 with the objective to protect present and future generations from the devastating health, social, environmental and economic consequence of tobacco consumption as well as exposure to tobacco smoke. It sets out the minimum actions that government must take pertaining to tobacco related matters; including provisions for supply and demand reduction as well as protection of environment. (Warner & Mackay, 2008).

Apart from the public-health approaches, medical interventions in smoking cessation is also important. Medical intervention, both behavioural and pharmacological and therapy are effective evidence-based methods to improve health and also being proven as the most cost-effective remedies in medicine (Cromwell, Bartosch, Fiore, Hasselblad, & Baker, 1997; D. K. Hatsukami, Stead, & Gupta, 2008). Therefore, review will be begun by evaluating all the available smoking cessation interventions methods followed by methods of validating smoking status of the abstainers. Validating smoking status is a crucial step to assure the quality of a study as it affects the outcome of the study (Jarvis, Tunstall-Pedoe, Feyerabend, Vesey, & Saloojee, 1987; SRNT Subcommittee on Biochemical Verification, 2002).

Apart from clinic-based intervention, a subset is application of the smoking cessation interventions in workplace settings; which has also been researched considerably since 1960s. It is noted that generally smoking interventions applied in non-workplace settings were studied in workplace settings. Workplace is a rather stable and small community. Therefore, review will be focused on smoking cessation programs held in workplaces. It evaluates the current literatures that evaluates effectiveness of workplace smoking cessation programs and its economic impacts to employers. Hence, review on the available literatures will present an overview of this topic and helps in planning for further research to fill the gaps identified from the current literatures.

Smoking is a pleasure and sticky behaviour (Piasecki, 2006). Therefore, relapse is common and quitting smoking successfully in first quit attempt is rare. In general, smokers will make a 7 - 8 attempts before quitting smoking successfully (Disease Control Division, 2016). Hence, it is crucial to understand smoking behaviour and factors affecting quitting attempt taken by the smokers. Considering work environment and the triggering factors among working adults, will further enhance the quality of the workplace smoking cessation program.

2.1.2 Search Strategy

Published literatures were identified by a systemic search strategy via computer. Search was focus on English literatures and was performed from databases available at the university library; including Medline, Pubmed, Ebsco host, Science Direct, Wiley Interscience, Cochrane Database of Systematic Reviews, Springerlink, Blackwell Synergy, Sage, Ovid, and Scopus as well as internet search engine such as google and google scholar.

A series of keywords were used to identify the topic of interest using text word search for all fields; such as ‘smoking’, ‘smoking cessation’, ‘quit smoking’, ‘stop smoking’, ‘smoking factor’, ‘smokers’, ‘workplace’, ‘worksite’, ‘intervention’, ‘cigarette’, ‘tobacco’, ‘nicotine’, ‘nicotine dependence’, ‘addiction’, ‘health impact’, ‘economic evaluation’. Some of these keywords were used in combination. On top of the database search, the literature search was also supplemented by examining the reference list of literatures identified. Eligibility of the literatures for this review were published studies, published workplace smoking cessation guidelines or review articles or report prepared by trustworthy organization, such as Ministry of Health of Malaysia, World Health Organisation (WHO) National Institute for Health and Care Excellence (NICE), U.S. Department of Health and Human Services, quit smoking organization and peer-reviewed articles. These literatures were written in English. Due to available of the vast literatures, aligned with the topic of discussion in this study, the search focused on the healthy population only. Thereafter, a database of references was compiled.

2.1.3 Interventions for Smoking Cessation

Since the release of the first report of the Surgeon General's Advisory Committee on Smoking and Health, the smoking society has evolved towards quit smoking milieu and the number of people giving up smoking has increased yearly. New quitting smoking method and programs have also been developed and studied to help the smokers to quit effectively.

Nicotine contained in the cigarettes, has made its users addicted to smoking and crave for cigarette if smoking is discontinued. This smoking behaviour repeats consistently over a period, at last making smoking becomes a habit. This explains the difficulty in quitting smoking whereby nearly half of the smokers who have stopped smoking without any support, could only stop for less than a week and less than 5% remain

abstinent for a year (Hughes, Keely, & Naud, 2004; McRobbie, Bullen, Hartmann-Boyce, & Hajek, 2014). There are two approaches in quitting smoking, "cold turkey" and "cutting down". "Cold turkey" is the most common used approach. Please refer to Appendix A for details of these two approaches.

Therefore, during the quitting journey, it is crucial to support the quitters physiologically to overcome the nicotine withdrawal symptoms and psychologically to overcome their smoking habit as well as enhance their motivation to quit (Aubin et al., 2011). Study had shown that support given during smoking cessation will generate quit rate up to 20% (Zhu, Melcer, Sun, Rosbrook, & Pierce, 2000).

2.1.3(a) Behavioural intervention

Behavioural intervention is a non-pharmacological approach and is also known as advice, coaching, counselling, psychotherapy or psychosocial treatments (J. Hughes, 2008). It improves smoking cessation outcomes via three components of therapies: behavioural (change habit to anticipate and avoid smoking cues), motivation (list down the reasons of why not smoking) and cognitive (learn to reduce and cope with nicotine withdrawal symptoms as well as urge to smoke). It could be delivered in different format by a trained counsellor, via telephone, face-to-face (individual and groups) or by a medium, via printed materials, video, televisions or internet (self-help programs). The content could be standard or tailored to individual at various frequency and duration. Moreover, these interventions could be implemented alone or in combination; such as group therapy plus telephone counselling. It could also be delivered in clinical setting or broad dissemination to a geographic community or workplaces. Appendix B described these interventions in detail.

Overall, all these interventions were effective compared to no intervention. How this intervention is delivered to the quitters affects the intensity and efficacy of the treatment, from minimal intervention to intensive intervention with different content and frequency; determined by the content, frequency and its medium. Meanwhile, there is a strong relationship between intensity and the efficacy of the treatment. The intervention duration and number of sessions also will affect the quit rates. For example, counselling could be delivered minimally which is normally 3 minutes of less ("minimal contact") or delivered briefly between 3 and 10 minutes ("brief counselling") or counselled for more than 10 minutes ("counselling"). The quit rate for these 3 types of counselling were 11%, 12% and 19% respectively, compared to no counselling of 9% (Anderson & Wetter, 1997). It is noted that the longer is the intervention duration, the higher is the efficacy. Intervention duration of 2 weeks, 2-4 weeks, 4-8 weeks, longer than 8 weeks recorded quit rates of 10%, 16%, 16% and 24% respectively (Anderson & Wetter, 1997).

Meanwhile, it is also noted that increasing the number of contact will increase the quit rate due to due to additional contact and assessments (Anderson & Wetter, 1997; Hartmann-Boyce, Lancaster, & Stead, 2014; Lancaster et al., 2000). Nevertheless, the optimal number of session is between four and seven for counselling. Increasing the number of treatment session to more than seven had shown no significant increase in the quit rate (Anderson & Wetter, 1997; Dorothy K. Hatsukami & Mooney, 1999).

It is also noted that those interventions having tailored content to the quitters and more interactive are more effective that standard content and not interactive. This was seen in tailored self-help, telephone calls and internet-based intervention. For internet-based and telephone interventions, it was noticed that effectiveness was increased when it was interactive (Gilbert, Nazareth, Sutton, Morris, & Godfrey, 2008; Hartmann-Boyce

et al., 2014; Stead, Hartmann-Boyce, Perera, & Lancaster, 2013). Nevertheless, self-help materials targeted solely to group characteristics (for example age, gender, or race) were no superior than standard materials (Lancaster et al., 2000).

The content of the counselling will also increase the quit rates. The content could be general problem-solving skills, such as recognition of danger situations which may increase the likelihood of smoking, coping skills under danger situations (example stress, drinking alcohol) and information about smoking and quitting. Clinical support during counselling, such as encourage the smokers to make quit attempt as well as care and concern about the smokers well-being during quitting will also affect the success of quit attempts (Anderson & Wetter, 1997; Dorothy K. Hatsukami & Mooney, 1999).

Having the flexibility of tailoring messages and interactive sessions with the quitters as well as the number of counselling sessions, explains that of all the behavioural intervention, individual counselling and group counselling are most effective (Miller & Wood, 2003). This, of course, had to be delivered by trained service provider, especially physician (Miller & Wood, 2003; Rice, Hartmann-Boyce, & Stead, 2013; Sinclair, Bond, & Stead, 2004; Stead et al., 2013). This was because physician and other healthcare professionals could integrate the various aspects of an effective counselling to advise smokers to quit (Cornuz, 2007).

Meanwhile, it is also noted that combination of different type of behavioural interventions would increase the cessation rate. Three or more self-help interventions would increase quit rates to 15% compared to no treatment of 8%. (Anderson & Wetter, 1997). There is a small effect when individual counselling is more intensive counselling and added to pharmacotherapy (Niaura, 2008; Stead et al., 2013).

Not only trained counsellor could support the smokers to quit smoking, the smokers' family members and their peers are also play important roles. Environment (smoking

restriction, culture, advertising) of the quitters is undoubtedly affecting the ability of smokers to quit in some degree. Many ex-smokers have received some social support during their quitting journey. Social support is believed to provide high levels of emotional, informational, and instrumental support to the quitters (Westmaas, Bontemps-Jones, & Bauer, 2010). A meta-analysis concluded that enhancing partner support would improve smoking cessation quit rate at twelve or more months (Park, Schultz, Tudiver, Campbell, & Becker, 2002). In another review by Westmaas et al. (2010), it was concluded that quit rates among socially supported quitters was not different from the control group (Westmaas et al., 2010). Despite these controversial findings, social support has been regarded as one of the main components in quitting smoking in smoking cessation guidelines (Disease Control Division, 2016; Foll, Melihan-Cheinin, Rostoker, Largue, & AFSSAPS, 1005; The Clinical Practice Guideline Treating Tobacco Use and Dependence 2008 Update Panel, 2008)

Apart from giving education to the quitters, the quitters could also be further motivated by via competition and incentives, which was normally applied in workplace smoking cessation programs to encourage the smoking employees to participate or to quit at the predefined stage. A variety of incentives or rewards have been used, including cash payments, promotional items (such as T-shirt, pens, bags etc.), salary bonuses, lottery tickets, holidays and luxury goods (such as cars or boats). These rewards were paid for their attendance, were scaled relative to the quitters' success or were guaranteed paid out irrespective of the outcome. Most of the rewards program are positive reinforcement but there are some programs implemented negative reinforcement where penalties will be imposed for non-compliance (Cahill & Perera, 2011). Competition is arranged where the participants were divided into groups to compete among the groups to encourage competitions to quit smoking among groups.