ABSTRACT
Introduction: Annually, especially in poor resourced countries, significant amount of money is spent to treat chronic diseases. The money instead could be saved by spending on health promotion programs for preventing chronic diseases.

Aim: To conduct cost-effectiveness analysis of various intervention modules in the “Smoking Cessation” program conducted in Universiti Sains Malaysia (USM).

Materials and Methods: This was an observational study design. Cost-effectiveness analysis was used to assess the costs and outcomes of the intervention. Data were collected retrospectively from medical records of all clients (n = 129) and then all the participants were followed-up for at least 6 months from the date of participation. Data were analysed descriptively using frequency (%) and mean (sd). Kolmogorov-Smirnov test was carried out to test for normality. Chi-square and Kruskal-Wallis tests were used at alpha level of 0.05. All analyses were done using SPSS version 19.

RESULTS: The findings of the study showed that the majority of participants were Malays (n= 108; 83.7%), males (n= 128; 99.2%), USM’s staff (n= 71; 55.0%) and within an age group of 23 years or less (n= 38; 29.5%). Among those who successfully quit were male (n= 30; 100%), Malays (n= 29; 96.7%), staff (n= 19; 63.3%), moreover, their age ranged from 35 to 56-year-old (n= 15; 50.0%). Further analysis of data showed that there were significant associations between success rate and modules of intervention, occupation, motivation factors, and frequency of counselling. Total cost of the Smoking Cessation Program was MYR 38,634.66 (during a period of 34.5 months), with a success rate equal to 29.1%. The most cost-effective module of intervention was counselling alone (CE ratio equal to MYR360.00 per 1% of success rate). The study found counselling with patch was ineffective during the study period.

Conclusion: Counselling alone module was the most cost-effective in Smoking Cessation program conducted in USM, Malaysia.

INTRODUCTION
About 15 billion of cigarettes sold daily (10 million every minute) all over the world [1]. The economic burden on health-service resources in the treatment of smoking-related diseases is about £1.7 billion (MYR11.9 billion) every year in UK and more than US$150 billion (MYR570 billion) a year in USA [1,2].

Malaysian Global Adult Tobacco survey (GATS) indicated that more than 40% of Malaysian men smoke, or a total of 4.7 million adult smokers. Almost no women i.e. less than 1% smoke in Malaysia [3]. The figure might be underestimated due to strong social stigma among women. The study further illustrated that four out of 10 adults were found to be exposed to second-hand smoke at home (7.6 million adults), and four out of 10 were found to be exposed to second-hand smoke indoors at their workplace (2.3 million adults). Among those adults who visited a restaurant in the past 30 days, seven out of 10 were exposed to second-hand smoke (8.6 million adults).

In 2000, Universiti Sains Malaysia (USM) initiated the intensive smoking cessation clinic, which provides services to staff and students in the university with the main objective to help all smokers to quit. This was one of the activities under the Healthy Campus Program of the university which aimed to promote health and wellbeing of the university community. The smoking cessation clinic was run by a multidisciplinary team of providers consists of a physician, clinical pharmacist and a nurse. The main activities of the program were provided through two broad goals, firstly, counselling by the physician or the pharmacist, including the use of pharmacological intervention, i.e. nicotine replacement products (NRP) to targeted individual when necessary. Secondly, the program designed awareness campaigns targeting at USM’s community, in general. The awareness campaigns consisted of road show, printing materials, organizing general health promotion lectures and talks on smoking cessation, and annual celebration of “World No Tobacco Day”. The whole programs were carried out since the establishment of the USM Healthy Campus Program.

The smoking cessation clinic was located in a medical clinic (also called as USM Wellness Center). This initiative comes under the USM Healthy Campus Program which promote wellness as one of its main objective. USM is a public university located in the northern part of Peninsula Malaysia. USM has approximately 1660 academic staff and 30,799 fulltime students [4]. Healthcare expenditure for students for a period from 2000-2009 was between MYR418,342.50 – MYR1,451,641.23, while it was between MYR254,677.43 – MYR796,189.83 for staff (exchange rate of USD1=MYR3.20). Generally, the expenditure for both groups showed an increasing trend. The amount spent showed dramatic annual increase with a percentage equal to about 32.2%. In contrast, the annual increase of budget for the same period was only about 4.1%.

The cause of high healthcare expenditure and increasing trend is partly due to the burden of chronic diseases suffered by staff and students. Tobacco use is the single most preventable cause of disease, disability and death. Smoking is linked with serious illness and can cause people die prematurely [5]. Quitting smoking greatly reduces the risk of developing smoking-related diseases, hence could reduce the institution long-term health care expenditure.

AIM
The primary objectives of the study were: (1) to describe the smoking cessation program in terms of demographic data, health
status, and smoking habit of participants; (2) to calculate the cost and success rate of the program; and (3) to estimate the cost-effectiveness of the program.

The results of the study could provide justification for the university management to allocate budget for health preventive programs under the University Healthy Campus Program.

MATERIALS AND METHODS

Study Design

This research used observational and pharmacoeconomics (i.e. cost-effectiveness) analysis methods. Data for clients who participated in the program since the year 2000 were retrieved retrospectively, and the clients were followed-up for at least 6 months from the quitting date. This study calculated the direct costs of the program, estimated outcomes, and applied cost-effectiveness analysis. Outcome was expressed as total of money (MYR) spent per 1 percent of success rates (USD1=MYR3.2). In addition, the study conducted sensitivity test. The study was conducted from the payer’s (organization; USM) perspective. The Lam Wah Ee Hospital-School of Pharmaceutical Sciences, USM Ethics Committee, approved the study.

Program's intervention

The intervention i.e. Quit Smoking, was conducted in the Quit Smoking Clinic at the University Medical Clinic, called as Wellness Center. There were four modules of intervention: (1) Counselling with gum; (2) Counselling with patch; (3) Counselling with combination of gum and patch; and (4) Counselling alone. According to the Malaysian Clinical Practice Guidelines Treatment of Tobacco Use and Dependence [6], the program runs two types of interventions, i.e. brief intervention through the general clinic and intensive intervention via the Quit Smoking Clinic. The first step of the brief intervention was to identify tobacco users. Therefore, all patients who visited the general clinic in USM’s Wellness Centre were asked if they smoke or not. Evidence demonstrated that interventions as brief as 3 minutes can significantly improve cessation rates [6,7].

In brief intervention, physicians screen for current or past tobacco use in every patient who visits the Wellness Centre. This screening results in four possible responses [7]:

(i) The patient used tobacco and is now willing to make an attempt to quit.
(ii) The patient used tobacco but is not willing to make an attempt to quit.
(iii) The patient used tobacco once, but has quitted since then.
(iv) The patient never regularly used tobacco.

The second step is the assessment of tobacco use, determining level of addiction and willingness for quitting. The assessment of nicotine dependence (i.e. low= 10 or less cigarettes per day, moderate=11-20 cigarettes per day, high=21-30 cigarettes per day, and very high=31 or more cigarettes per day) was done using a questionnaire designed by Fagerstrom [6]. The questionnaire was modified and used in the program as Fagerstrom Modified Questionnaire. On the other hand, smokers in USM were already motivated by the campaigns of smoking cessation done by the university, these campaigns assisted in smoking relapse prevention, which is complementary to smoking cessation efforts. Therefore, with additional brief counselling and advice from doctors, they enjoyed the program. Based on the Fagerstrom Modified Questionnaire, patients who were willing to quit were referred to the Quit Smoking Clinic where the multidisciplinary team was ready to deliver the third step.

The physician and the pharmacist counselled clients on the benefits of smoking cessation, the health risks related to smoking, and gave the clients behavioural and social support. The clinic’s nurse arranged the appointments for each client, prepared a file for him and did the necessary measurements such as blood pressure, level of carbon monoxide, peak expiratory flow rate (PEFR), waist circumference, and weight.

Each client was given follow-up counselling schedule, which required one visit every week after quitting date for the first month (4 visits in 1 month), one visit every two weeks for the following two months (4 visits in 2 months) and one visit every month for the next three months (3 visits in 3 months). Ideally, the total visits for each patient should be 11 during a period of six months, but no restriction to this schedule if goals were not achieved. The smoker participating in the program was considered abstinent if he or she remained smoking-free at follow-up for at least six months from the quitting date [6].

Population and sampling

The program was opened to all staff and students. The selection was a non-random method. Patients (both staff and students) who are willing to quit were referred to the Quit Smoking Clinic.

Application of pharmacoeconomic techniques

This study calculated the direct costs of the program and estimated outcomes. It applied cost-effectiveness analysis and expressed as total of cost (RM) spent per 1 percent of success rates. The study estimated the average cost for the client in each module of intervention. The total cost of the program consisted of human resources, NRT, educational materials, disposables, space and assets. Total cost of human resources includes overall costs of professionals’ time spent in the program (i.e. physician, pharmacist and nurse). This was calculated as average salary of each personnel per minute) x (average time (in minute) spent with a client per visit) x (number of visits). The cost of the nicotine replacement product was calculated based on the (acquisition price x number of item used). Education materials cost includes cost to produce pamphlets, posters for campaign and stationary. Space was measured based on a cost of (RM35/square foot x 200 square feet). Assets include furniture, BP set, stethoscope, and micro (CO) monitor, and peak expiratory flow meter.

STATISTICAL ANALYSIS

Data collected was input into SPSS version 19. Descriptive statistics i.e. frequency (percentages) and averages (mean±sd or median (IQR)) were used to describe the data. Data was tested for normality. Based on the characteristics of the data, Chi-Square and success rate of the program; and (3) to estimate the cost-effectiveness of the program.

RESULTS

Outcomes of the program

The program achieved a moderate rate of success (23.26%), with 30 quitters out of 129 clients participated in the “Smoking Cessation” program (i.e. 11 clients (8.5%) who maintained abstinent for less than 6 months, 8 clients (6.2%) between 6 months to one year, 1 client (0.8%) for one year and 10 clients (7.8%) for more than one year). There were 73 clients (58.59%) who failed to quit, and 26 (20.16%) who were still continuing in the program.

Total of visits by the clients in each module of treatment (types of intervention) showed that the clients in the counselling with gum module (n=62) visited the clinic 296 times [Table/Fig-1]. On the other hand, the clients in the counselling with patch module (n=10) visited the clinic 19 times, clients in gum with patch module (n=28) visited 188 times, while the clients in counselling alone module (n=29) went to the clinic 104 times. Kruskal-Wallis test showed a highly significant difference (p = 0.001) when tested the total number of visits between the different modules of intervention. Among the clients who succeeded in quitting (n= 30), there were 22 (73.3%) attempted to quit, while there were only 8 successors
(26.7%) who did not have any attempt before. Cross-tabulation for outcomes of the programs and previous attempt to quit showed a relation between these variables. Chi-Square test conducted to measure this relationship was significant (p = 0.017).

[Table/Fig-2] below describes the association between modules of intervention and their outcomes. There were 13 (24.1%) successful clients when counselled with gum, 6 (30.0%) were successful when counselled with gum and patch, and 11 (45.8%) were successful when counselled alone without any NRT. In contrast, there was no successful client when counselled with patch.

In terms of nicotine dependency, the study found that the majority of the clients (n= 90; 69.7%) were either low (n= 53; 41.2%) or medium nicotine dependency (n= 37; 28.7%).

**Pharmacoeconomic analysis**

Cost of inputs
Pharmacoeconomic data collected in the program estimated the direct cost only i.e., the direct medical and non-medical costs and it found that the total cost of the program is equal to MYR 38,634.66 (34.5 months), with monthly cost equal to MYR1,119.85 and annual cost of MYR 13,438.20 [Table/Fig-3].

**Outcomes**
The program achieved a moderate success rate in each module of intervention. The highest rate found in counselling alone module (45.8%), followed by counselling with gum and patch module (30.0%), and lastly, counselling with gum module (24.1%). In contrast, in this research during the study period, counselling with patch module was not effective at all (0.0%).

**Cost-effectiveness analysis**
Cost-effectiveness ratio (C/E ratio) for each module was calculated by dividing the total cost of the module by its success rate (outcomes). These calculations estimated the counselling alone module as the lowest per success rate (MYR 360.00). Therefore, it was considered as the most cost-effectiveness module. The cost-effectiveness ratios for counselling with gum and counselling with gum and patch modules are MYR 1066.99 and MYR 841.19, respectively. This study found that the counselling with patch module was not effective at all during the study period [Table/Fig-4].

**DISCUSSION**
The Malay clients were predominant because they represent the majority of USM’s staff. In line with these findings, the annual report of World Health Organization stated that the majority of smokers in Malaysia were Malays [1,3].

In terms of gender, the findings were similar as reported by Southeast Asian Tobacco Control Alliance (SATCA) country’s profile that indicated that male’s smoking prevalence in Malaysia was 49.2%, while 3.5% for females [8]. Nevertheless, smoking among females is rising to 8% according to the fact sheet [1]. Therefore, the program should also consider this fact in targeting female smokers in USM.

This research showed a significant correlation between outcomes and total number of cigarettes smoked. This finding is consistent with the previous Malaysian study conducted in 1996 that reported smokers consumed an average of 13.3 cigarettes per day, with over 60% reported to smoke over 10 cigarettes per day [9]. Low and moderate smokers (20 or less cigarettes per day) consisted 78.3% of the clients in the program, and this in line with the clinical fact that low and moderate nicotine dependants are more liable to quit than high dependants.

The most reported factors that motivate the clients to quit were doctor’s advice and family encouragement. Many studies reported that doctor’s advice on quit smoking is more effective and it increases the quit rates effectively [10-12].

Majority of the clients attempted to quit before, but they failed to do so. The study found a strong correlation between success rate and previous attempts to quit. This may be because higher nicotine dependants seek assistance more than those with lower dependant do. Results obtained from one study conducted in USA showed that the previous attempts to quit with assistance are associated with a greater success rate [13]. Moreover, the study found that there was no two smokers are alike regarding smoking habit.

Total number of visits to the “Quit Smoking Clinic” by the clients varied from one to 50 visits, whereas, the ideal visits should be 11 [14]. The research showed a significant statistical difference between success rate and total number of visits to the clinic. In addition, there was a significant difference between outcomes and continuation of the clients with the program. The more
the clients visited the clinic, the more they are exposed to counselling intervention. These results showed that counselling as an intervention supports and plays an important role in quit smoking [7].

The study found that the majority of the clients were either in low or medium nicotine dependency level. The success to quit smoking was easily achieved due to the low and medium levels of nicotine dependency.

According to the modules of treatment, results showed that fewer clients were in counselling with patch module, whereas this module achieved a zero success rate i.e. no client was successful in this module during the study period (34.5 months). Therefore, more consideration should be given when choosing this type of intervention. In addition, Chi-Square test showed a significant association between modules of intervention and outcomes, and this results statistically proved that outcomes (success rate) which achieved by the program was a direct result of this intervention.

The program achieved a moderate rate of success with 30 quitters out of 129 clients who participated in the program. In contrast, more than half of the clients failed, and there were one-fifth of clients who continued on treatment. One previous study concluded that group counselling was better than self-help and other less intensive interventions, but there was enough evidence on their effectiveness on cost-effectiveness compared to intensive individual counselling [13].

It was so difficult to compare outcomes of this research with other results from previous studies, because every study has its own criteria and they are affected by the variation such as methods used, the perspective taken, and the way of calculating outcomes. Nevertheless, most of the previous studies were consistent with this study i.e. the reported outcomes of such program varied according to modules of intervention [14-16].

The success rate of this study was not much difference from the “Swedish Quit Line” program in which the number of smokers who quitted and reported abstinence after 1 year was 354 (31%) [17]. This finding was consistent with a study done in 1997, in which the success rate found was 22.2% [15].

The most cost-effectiveness module of intervention is counselling alone followed by counselling with gum and patch, and then lastly counselling with gum. The study found that counselling with patch was not effective at all during the study period. The same descending order was found in a previous study, which concluded that the most cost-effective treatments were bupropion and patch, then the spray, and lastly the gum [18]. One study conducted in the United States evaluated the cost-effectiveness of three smoking cessation programs and concluded that the most cost-effectiveness program was smoking cessation class, the incentive-based smoking contest, and lastly self-help quit smoking kit [19].

In another study conducted in the United States, concluded that nicotine transdermal patch was cost-effective and less costly per year of life saved than other widely accepted medical practices [16]. In addition, a comparison of cost-effectiveness analysis across previous studies was not easy and it may demonstrate like the comparison of “apples with oranges”, and referral to each modality should be based on smokers’ characteristics and the societal value placed on health as well [20]. This study found that the highest cost in the program was associated with NRT cost. In contrast, counselling alone module had no cost of NRT; so it is better to start with this approach for all smokers, and switch to another module only in case of failure to achieved the goals.

Sensitivity test showed that counselling alone module was the most cost-effective, and the alternative module can achieved the same cost/effectiveness ratio as the first choice in case its success rate increased to 70.09%. Therefore, counselling alone was insensitive to changes in all scenarios done or rather to be robust.

LIMITATIONS

Even though the study was successful to carry out the pharmacoeconomics analysis, it has several limitations. The study used retrospective data partially in the program that limited the study design and not allowing the researchers to study other variables needed in the study, such as details of the health status of the clients, and opinions of clients before and after the intervention. In addition, researchers also faced with missing data and inconsistency of data. In the cost analysis, cost of utilities i.e. electricity and telephone bills, that are difficult to estimate were not included. The study also could not estimate how much influence the regular national antismoking campaigns have on this program.

CONCLUSION

The finding of the study showed that the majority of the successful quitters were male, Malays, staff, and their age ranged from 35 to 56-year-old. The study found significant correlation between success rate and modules of intervention, and total of visits to the Quit Smoking Clinic. The most cost-effectiveness module of intervention is counselling alone followed by counselling with gum and patch, then lastly counselling with gum. The study found that counselling with patch was not effective at all during the study period.

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REFERENCES

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