KNOWLEDGE, ATTITUDE AND PRACTICE OF UNREGISTERED MEDICINES AMONG PATIENTS WITH CHRONIC DISEASE AT URBAN HEALTH CLINIC, KELANTAN, MALAYSIA

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ABSTRACT

Introduction: Products registered with the National Pharmaceutical Regulatory Agency (NPRA) have two main features: MAL Registration Number and Meditag[™] Hologram sticker. Both of these features need to be displayed on each pack of drug sales. Missing either one or both above features consider as unregistered medicines. This study aims to determine the prevalence and factors associated with knowledge, attitude and practice of unregistered medicines usage among patients with chronic disease attending Klinik Kesihatan Bandar Kota Bharu, Kelantan. Methods: A cross-sectional study involving 108 respondents using convenient sampling was conducted at the outpatient unit of Klinik Kesihatan Bandar Kota Bharu, Kelantan, Malaysia, from June 2019 to July 2019. Results: The prevalence of unregistered medicines usage was 15.7%. Although the respondents had good knowledge about unregistered medicines. More than half (64.8%) of respondents have good knowledge of unregistered knowledge and 91.7% of respondents have negative attitude towards unregistered medicines. Factors associated with practice of unregistered medicines use is found to be level of education and perceived of health believe. Lower education and perceived benefit of unregistered medicines 4 times and 12 times more likely to take unregistered medicines respectively compare to higher education level and perceived no health benefit. Conclusion: In conclusion, prevalence of unregistered medicines usage was 15.7%. More than half (64.8%) of the respondents were categorized as having good knowledge. We need to strengthen our education program to modify patient's belief on the non-benefit using unregistered medicines.

Keywords: Unregistered medicines, chronic diseases, KAP, Malaysia

Introduction:

According to Know Your Medicine booklet (Ministry of Health 2016a) chemical substances that are used to prevent, control and treat diseases are medicines. At best, a fake medicine will do nothing to relieve a patient's condition: at worst, a fake medicine contain toxins such as arsenic or anti-freeze can kill (Liu & Lundin 2016). Yet fake medicines are a booming global trade. The growth in counterfeit medications is a significant public health issue. These products were produced and marketed as equivalents to the regulated versions of the medications they represent. However, it can cause an inadequate therapeutic response or contribute to mortality and morbidity among those who use these medications.

In protecting and preserving the people's health, all medications either pharmaceuticals or traditional medicines can be imported, manufactured or sold in Malaysia, provided it must first be registered with the Drug Control Authority (DCA), Ministry of Health Malaysia. The objective of product registration is to ensure safety, efficacy and guality, while the traditional products have been evaluated and tested for safety and quality (Ismail 2017). A definition of registered and unregistered medicines is quite confusing and interchangeable at the beginning. World Health Organization (WHO) provided 60 countries (including Malaysia) to give feedback regarding their use of the term "counterfeit drugs" and majority of these countries use "counterfeit" (34) in their national legislation. Others used "falsified". "illicit "illegal", "unregistered", "unauthorized" and "adulterated" (Sabine 2009).

In Malaysia, there is no precise definition of counterfeit drugs in Malaysian Law, but in The Sale of Drug Act (SODA) 1952 there are specific provision under regulation 7(1) (a), 7(1A) (a-g) Control of Drugs and Cosmetics Regulations (CDCR) 1984 which requires all medicinal products to be registered with National Pharmaceutical Control Bureau (NPCB) of the Ministry of Health (MOH) before entering the market and follow a process which requires stringent evaluation and final approval by the Drug Control Authorities (DCA). After the medicinal products have gone through all the requirements it is known as registered medicines or registered products.

According to Ismail (2017) a registered medicine is a medicine which has been evaluated, tested and proven to be of quality, effective and safe and approved by the DCA and can be sold or used by consumers in Malaysia.

In this study the term unregistered medicines were used. In Malaysia, unregistered medicines are illegal to be in the market. According to Annual Report 2012 by Enforcement Pharmacy, there is an increasing trend in the number of raids since 2010 till 2012. Raid amount of seized unregistered medicine has achieved up to RM27 million per year was reported (Ministry of Health 2012). Zulkifli et al. (2015) stated that there is a high possibility of increasing trend in the seized value year by year and the Pharmacy Programme Annual Report 2016 proved it (Ministry of Health 2016b). Unregistered medicines are dangerous and considered threat to public health and safety around the world (Furman-Assaf et al. 2010).

With the growing unregistered medicines in the market and the lack of stringent enforcement (Zulkifli et al. 2016b), more patients with chronic diseases are susceptible to unregistered medicines. This study is designed to determine the prevalence and factors associated with knowledge, attitude and practice of unregistered medicines use among patients with chronic disease attending Klinik Kesihatan Bandar Kota Bharu, Kelantan and provide the suggestions for the current policy and what needs to be done in combating unregistered medicines in Malaysia.

Methods:

Study design and population

A cross-sectional study using validated questionnaire involving patients with chronic disease receiving treatment in the outpatient clinic Klinik Kesihatan Bandar Kota Bharu was conducted for 60 days from June 2019 to July 2019. The study was approved Ministry of Health NMMR (NMRR-19-1570-48485 IIR) and Review Board and Ethics Committee of UKM (FF-2019-328).

Kish L (1965) formula was used to calculate the sample size. The prevalence used in the calculation was set at 0.052, obtained from the report by Steven and Mydin (2013) where fake medicine use is prevalent in 5.2% of the study population. Using this formula, the sample size is calculated to be 73. An additional 20% was added as buffer for rejection and/or incomplete data. The final sample size needed to conduct this study was determined as 100.

The sampling population was all registered patients who have an appointment at the date of the study and the sampling frame was generated from the patient's appointment list the day before. Convenient sampling was employed in this study. The inclusion criteria was any Malaysian aged 18 years old and above and diagnosed of chronic diseases attending outpatient clinic Klinik Kesihatan Bandar Kota.

Patients who could not understand Malay or English were excluded from the study as well as patients who did not consent to be interviewed. Also excluded were patients who were diagnosed with active psychiatric conditions and unable to give informed consent. Those who did not meet any of those criteria were excluded from the study.

Development of questionnaire

The questionnaire was adapted from previous studies. Patients were interviewed face-to-face using this questionnaire by the investigator. Other than that, details regarding patient's medical conditions and treatments were obtained from their medical records.

The questionnaire comprised of four parts. Part A obtained the demographic characteristics of the respondents. Patient's medical conditions were also collected, and patients were asked to rate their health status based on these categories (Very Poor, Poor, Fair, Good, Very Good). Part B was designed to evaluate knowledge of unregistered medicines by answering seven questions relating to medicines and unregistered medicines in Malaysia. Three options are provided for answer based on 'Yes', 'No' and 'Not Sure'. Part C of the questionnaire consisted of 10 statements to evaluate their attitude towards unregistered medicines. Based on a 5-point Likert Scale, with 1 denoting extremely disagree and 5 denoting extremely agree, patients were required to select the option that most represent their thoughts on the statements in the section. The maximum score a patient can get was 50 whereas the minimum score was 10. Part D was designed to evaluate the practice of unregistered medicines by answering 11 questions. Patient's use of unregistered medicine was measured in the first two questions and the remaining 9 questions were designed to explore how unregistered medicines were used and the environmental factors that influence patients' unregistered use.

The questionnaire was solely designed in Malay (the national language of Malaysia). Face content validation and of the questionnaire was done by is Senior Principal Assistant Director and Principal Assistant Director in Enforcement Division, Kelantan State Health Department. A pre-test was conducted to ensure construct validity of the questionnaire after experts have ensured its content validity. The questionnaire was pretested among 53 patients with chronic diseases attending the outpatient unit at Klinik Kesihatan Wakaf Che Yeh which was still within Kota Bharu district approximately 7km from the actual study site. Eligible respondents were approached and face-to-face interviews using the questionnaire were conducted after consent were obtained. Apart from answering the questions, respondents were also asked regarding their opinion on the questionnaire.

Consequently, the same interviewer conducted the interview of main study in Klinik Kesihatan Bandar Kota Bharu. The respondents who participated in the pre-test were excluded in the main study. Cronbach's alpha for section C that measure attitude was 0.825. Reliability testing was conducted for the attitude's responses from the pilot test. The results showed internal consistency of the items tested with the Cronbach's α value of 0.76.

Data Analysis

Upon return of the completed questionnaires, raw data were processed and uploaded into Statistical Package for Social Sciences (SPSS) software version 23.0 for data analysis until the end of the study period or the number of samples required was achieved. At the end of the study, computer assisted analysis was carried out. Descriptive analysis is used to summarize the data accordingly (frequency and percentage, mean and standard deviation). Bivariate analysis was conducted (chi-square) to determine the association between the independent variables and the use of unregistered medicines. Multivariate analysis was also conducted to detect and control any confounders.

Results:

A total of 108 respondents from the Outpatient Unit of Klinik Kesihatan Bandar Kota Bharu, Kelantan completed the questionnaire given throughout the study. A summary of the demography of respondents is seen in Table 1. All respondents recruited were almost equal balance between male and female. There is wide range of age among the respondents, with the youngest being 24 years old and the oldest being 80 years old. According to DOSM, our study includes 79.6% of respondents that is within the age of working group (\leq 64 years old). A total of 86.1% (n= 93) respondents were Malay, making up majority of the respondents in the study. Non-Malay races includes 9.3% **Table 1 Respondent profile** (n= 10) Chinese respondents, 4.6% (n= 5) Indian. More than half of the respondents were married (80.6%), 4.6% single, 3.7% divorced and 11.1% widowed.

| Variable | N (%) |
|--|-----------------|
| Gender | |
| Male | 52(48.1) |
| Female | 56(51.9) |
| Age (in years) (mean ±sd) | 55.99 ±9.996 |
| Age | |
| ≤64 | 86(79.6) |
| 65 and above | 22(20.4) |
| Race | |
| Malay | 93(86.1) |
| Chinese | 10(9.3) |
| Indian | 5(4.6) |
| Others | 0(0) |
| Marital status | |
| Married | 87(80.6) |
| Single | 5(4.6) |
| Divorced | 4(3.7) |
| Widow | 12(11.1) |
| Education | |
| No formal education | 1(0.9) |
| Primary | 5(4.6) |
| Secondary | 58(53.7) |
| Diploma/certificate | 27(25.0) |
| Degree | 15(13.9) |
| Postgraduate degree | 2(1.9) |
| Work sector | |
| Government | 36(33.3) |
| Private | 11(10.2) |
| Self-employed | 21(19.4) |
| Pensioner | 26(24.1) |
| Not working | 2(1.9) |
| Housewife | 12(11.1) |
| Student | 0(0) |
| Household income per month (RM) (mean ±sd) | 3774.07±4165.17 |
| Household income per month | |
| ≤RM3079 | 69(63.9) |
| RM3080 and above | 39(36.1) |
| Diseases | |
| Diabetes mellitus | 64(59.3) |
| Hypertension | 87(80.6) |

| Dyslipidemia | 25(23.1) | | |
|--|------------|--|--|
| Renal disease | 3(2.8) | | |
| Ischaemic heart disease | 0(0) | | |
| Osteoarthritis/Osteoporosis | 4(3.7) | | |
| Stroke | 1(0.9) | | |
| COPD | 0(0) | | |
| Heart failure | 1(0.9) | | |
| Gout | 2(1.9) | | |
| Cancer | 0(0) | | |
| Others | 5(4.6) | | |
| Morbidity | | | |
| Single morbidity | 46(42.6) | | |
| Multiple morbidity | 62(57.4) | | |
| Duration of disease (years) (mean ±sd) | 7.08±5.898 | | |
| Duration of disease (years) | | | |
| <15 | 99(91.7) | | |
| ≥15 | 9(8.3) | | |
| Self-perceived health status | | | |
| Good | 97(89.8) | | |
| Poor | 11(10.2) | | |
| | | | |

Table 2 Association between sociodemographic / socioeconomic and practice of unregistered medicines use among chronic patients

| Variable | Unregistered Medicines User, n (%) | Unregistered Medicines Non-User, n (%) | X ² | p- value |
|----------------------------|--|---|----------------|----------|
| | | | | |
| Gender | | | | |
| Male | 10(19.2) | 42(80.8) | 0.921 | 0.337 |
| Female | 7(12.5) | 49(87.5) | | |
| Age | | | | |
| ≤ 64 | 13(15.1) | 73(84.9) | 0.001ª | 0.981ª |
| 64 and above | 4(18.2) | 18(81.8) | | |
| Race | | | | |
| Malay | 16(17.2) | 77(82.8) | 0.433ª | 0.511ª |
| Non-Malay | 1(6.7) | 14(93.3) | | |
| Marital status | | | | |
| Married | 12(13.8) | 75(86.2) | 0.636ª | 0.425ª |
| Unmarried | 5(23.8) | 16(76.2) | | |
| Education | | | | |
| Higher Education | 4(9.1) | 40(90.9) | 2.476 | 0.116 |
| Lower Education | 13(20.3) | 51(79.7) | | |
| Work sector | | | | |
| Employed | 10(14.7) | 58(85.3) | 0.148 | 0.700 |
| Unemployed | 7(17.5) | 33(82.5) | | |
| Household income per month | | | | |
| Group B40 | 13(18.8) | 56(81.2) | 1.384 | 0.239 |
| Non Group B40 | 4(10.3) | 35(89.7) | | |

| Morbidity | | | | |
|--|----------|----------|--------------------|---------------------|
| Single morbidity | 5(10.9) | 41(89.1) | 1.434 | 0.231 |
| Multiple morbidity | 12(19.4 | 50(80.6) | | |
| Duration of disease (years) | | | | |
| <15 | 3(27.3) | 8(72.7) | 0.451ª | 0.502 ^a |
| ≥15 | 14(14.4) | 83(85.6) | | |
| Self-perceived health status | | | | |
| Good | 16(16.5) | 81(83.5) | 0.041 ^a | 0.840 ^a |
| Poor | 1(9.1) | 10(90.9) | | |
| Knowledge toward unregistered medicine | | | | |
| Good ≥4 | 8(11.4) | 62(88.6) | 2.789 | 0.095 |
| Poor <3 | 9(23.7) | 29(76.3) | | |
| Attitude toward unregistered medicine | | | | |
| Good attitude ≥30 | 15(15.2) | 84(84.8) | 0.006 ^a | 0.937ª |
| Poor Attitude <30 | 2(22.7) | 7(77.8) | | |
| Perceived benefit of unregistered medicine | | | | |
| No Benefit | 11(11.5) | 85(88.5) | 9.217ª | 0.002 ^{a*} |
| Benefit | 6(50.0) | 6(50.0) | | |
| Perceived safety of unregistered medicine | | | | |
| Safe | 3(50.0) | 3(50.0) | 3.220ª | 0.073 ^a |
| Not Safe | 14(13.7) | 88(86.3) | | |

In terms of education, majority of the respondents in this study completed (53.7%) their mandatory education and only 5.5% (n= 6) did not. Among those who pursued their tertiary education, certificate/diploma holders comprised the most numbers (25.0%). In with high participation accordance of respondents among the younger age group, most of them were employed (62.9%), with 33.3% (n= 36) working in the public sector and 10.2% working in the private sector. Respondent's monthly household income median were RM 3774.07±4165.17. There is notable wide range of monthly household income. The lowest income is RM300.00 while the highest is RM26,000.00.

More than half (57.4%) of respondents suffer from at least two chronic diseases whereas 42.6% (n= 46) of respondents are diagnosed with only single morbidity. The most diagnosed diseases obtained were Hypertension (80.6%) and Diabetes Mellitus Type-2 (59.3%). The duration of disease is calculated from the date of diagnosis, giving a median of 7.08 years \pm 5.898. Almost all (89.8%) of respondents perceive their health to be good and their diseases were well-managed.

Table 2 shows summary of bivariate analysis regarding association between sociodemographic / socioeconomic and practice of unregistered medicines among chronic patients. Among the many sociodemographic / socioeconomic factors measured, perceived benefit only of unregistered medicine is significant.

Bivariate analysis is conducted to identify factors associated with practice of unregistered medicines use. Bivariate analysis reveals only perceived benefit of unregistered medicine and perceived safety of unregistered medicine be statistically significant between user and nonuser. Prior to conducting multiple logistic regression, all variables are run through simple logistic regression with 'Enter' method. Multiple logistic regression is then conducted using 'Forward LR' and 'Backward LR' method.

Factors associated with unregistered medicines use

Simple Logistic Regression reveals only perceived benefit of unregistered medicine (p=0.003), and perceived safety of unregistered medicine (p= 0.042) to be statistically significant. Table 3 show summary of factors associated with unregistered medicine use using Multiple Logistic Regression.

Table 3 Factors influencing unregistered medicines use among chronic patients based onmultivariate analysis

| Variable | Crude OR | (95% CI) | Adjusted OR | (95% CI) | X 2(df) | p- value |
|---|-------------|---------------|----------------|---------------|-----------|-------------|
| Education Level (1) | 0.392 | (0.119,1.296) | 0.226 | (0.054,0.948) | 4.131(1) | 0.042 |
| Perceived benefit of unregistered medicine (1) | 0.129 | (0.035,0.472) | 0.079 | (0.018,0.360) | 10.798(1) | 0.001 |

Lower education [Wald: $X^2(df=1,N=1080=4.131,p<0.05;OR=0.226]$ and perceived health benefit of unregistered medicines [Wald: X^2 (df=1,N=108)=10.798, p<0.05;OR=0.079] increased the risk of using unregistered medicines by 77.4% and 92.1%, respectively.

Gender, age, race, marital status, employment status, income, morbidities, duration of disease, self-perceived health status, knowledge on unregistered medicines and perceived safety of unregistered medicine all result in p- value of more than 0.05, thus no association can be proven between these variables and unregistered medicine use.

DISCUSSION:

The prevalence of unregistered medicines use among patients with chronic disease attending outpatient clinic at Klinik Kesihatan Bandar Kota Bharu was found to be 15.7%. Compared to the prevalence of unregistered medicines in Malaysia, our finding was considerably larger. Steven and Mydin (2013) found that the prevalence of unregistered medicine in Malaysia is 5.2%. The state prevalence is higher that than the national because Kelantan is more prone to medicine trafficking due to the nearby border of Malaysia and Thailand. Carolyn Nordstrom (2007) in her book discusses various forms of border crossings between legal and illegal space, including smuggling of medicines. This article may availability suggest that, the easy of unregistered medicines may increase the prevalence. However, more specific study should be done to dig in more accurate reason for this prevalence.

The Declaration of the Regulation of Drugs and Cosmetics in June 1984 marked the beginning of a regulatory era in Malaysia. This sets the necessary benchmarks for the development of a more systematic system of pharmaceutical regimes in Malaysia. In January 1985, the Drug Control Authority (NPRA) was established chaired by the Director General of Health Malaysia with the aim of ensuring the quality, safety and effectiveness of pharmaceutical products before being marketed in Malaysia. To achieve this goal, the Drug Control Authority (UN) through a National Pharmaceutical Control Agency (NPRA) secretariat carries out regulatory functions such as product registration, sample analysis, inspection and licensing, post-marketing monitoring and monitoring of drug side effects.

Control over the sales of pharmaceutical products was started in 1985 with the first phase of registration for product containing poison listed in the Poisons Act 1952. The enforcement of registrations was then continued with non-poison products (OTC) in 1988, traditional medicinal products in 1992 and followed by veterinary products which was enforced in 2014.

After almost 35 years of the regulation, unregistered medicines still exist. According to a study by Narsai et al. (2012), some of the reason of the availability of unregistered medicines were registration costs; commercial; retention costs, GMP inspection fees and GMP inspection requirements. Without registration, manufacturers just have bear minimal cost for production and will generate wider profit without needing to pay other costs. This is the reason why unregistered medicines still are available in market with cheaper price.

In this study, almost all the respondents who used unregistered medicines (94.1%, n=16) did not inform their healthcare providers about their usage of unregistered medicines. This finding is common among patients in Malaysia and Thailand (Hasan et al. 2009; Putthapiban et al. 2017). They did not see the need to disclose the information on their use of unregistered medicines. The statements "doctor never asked" and "afraid of doctors disagree and get scolded " were the main reasons provided by the respondents for their non-disclosure of unregistered medicine use. Thus. this information is important for healthcare professionals in order to assess patient needs, and more importantly to know whether there are any potential drug interactions and adverse drug reactions due to the use of unregistered medicines. Similarly, conventional health practitioners should acquire and develop essential skills in the area of unregistered medicines practice and its education should be incorporated into medical and health sciences curriculum.

Most of the patients (80%) knew that they need to take prescribed medications and unregistered medicines at different times to avoid any possible interactions. This study was comparable to a study by Fadzil et al. (2018) in which patients take supplement and prescribed medicines at different times to avoid interactions.

Section B of the questionnaire aims to measure respondents' knowledge of registered medicines. It consists of seven questions that gave 1 mark for each correct answer, the questions were based on the basic information on registered medicines. Twenty-two of the respondents managed to achieve full mark, and 64.8% (n=70) of respondents were found to have good knowledge of registered medicines. Compared to the National Survey Use of Medicines (NSUM) 2015 (Division 2016), which found that 53.2% of patients have a good knowledge of medicines, this finding was a bit higher, probably because of the NSUM 2015 was done throughout Malaysia, and the locality effect was a significantly associated factor in that study.

In term of attitude towards unregistered medicines use, The Theory of Reasoned Action that was developed by Martin Fishbein and Icek Ajzen, explicitly note that respondent's attitude influences behavior on the use of unregistered medicines. However, this theory also recognized that there were situations (or factors) that limit the influence of attitude on behavior. For example, if our attitude leads us to want to go to buy something but at the same time, we have no money, it will prevent our attitude from causing us to buy it. The same goes to the usage of unregistered medicine, associated with a few factors. The perceived benefit of unregistered medicines influences the patient to take medicines. This is also supported by Health Belief model (Janz & Becker 1984).

Various sociodemographic parameters were examined in this study, but not all parameters were statistically significant in the bivariate and multivariate analysis. For example, the race of respondents was not significantly associated with unregistered medicines use, even though in the study on cosmetics showed that attitudes toward cosmetic products among the participants were influenced by race and religion (Ayob et al. 2016). Another study by Albarrán and Zapata (2008) about selfmedication showed that women were selfmedicated compared to men. However, the usage of unregistered medicine in this study does not show similar finding with the above studies.

Kotler and Keller (2012) stated that monthly of income was one the economic circumstances that fall into the personal factors category which influences consumers' buying behavior. However, this study found that the monthly household income did not influence them to buy unregistered medicines. This finding was different compared other study where household income was a factor affecting this behavior which give a significant impact on their attitudes related to cosmetic products (Ayob et al. 2016).

Among the most obvious explanations for the association between education and health is that education itself produces benefits that later predispose the recipient to better health outcomes (Zimmerman et al. 2015). The human capital theory of learned effectiveness states that educated, instrumental people merge otherwise unrelated habits and ways into a healthy lifestyle that consequently behaves as a coherent trait. In theory, education makes individuals more effective users of information. Education encourages individuals to acquire information with the intent to use it. Thus, person with higher education may assemble a set of habits and ways that are not necessarily related except as effective means toward health (Mirowsky 2017).

The Health Belief Model (HBM) is a social psychological health behavior change model developed to explain and predict health-related behaviors, particularly regarding the uptake of health services. The HBM was developed in the 1950s by social psychologists at the U.S. Public Health Service (Janz & Becker 1984). The HBM suggests that people's beliefs about health problems, perceived benefits of action and barriers to action, and self-efficacy explain engagement (or lack of engagement) in healthpromoting behavior. A stimulus, or cue to action, must also be present in order to trigger the health-promoting behavior. The theory also supported by other theory of Reasoned Action. This theory was developed by Martin Fishbein and Icek Ajzen, in which it is explicitly concerned with behavior. However, this theory also recognizes that there are situations (or factors) that limit the influence of attitude on behavior. This will lead the chronic disease patients to practice unregistered medicines because of their perceived benefit towards unregistered medicines.

This study found that perceived benefit of unregistered medicines was a factor associated with the practice. It was also demonstrated in another study by Killelea et al. (2019) in which multivariate analyses demonstrated that participants who reported a large perceived benefit were significantly more likely to undergo radiotherapy treatment (odds ratio 10.34; 95% confidence interval: 1.66-66.35). Furthermore, advertisements nowadays may influence the perception towards use of unregistered medicines.

Patients will use unregistered medicines for the sake of benefit, and its use was not affected by income in this study. The high perception of benefit led them to buy the unregistered medicines. Ismail et al. (2016) found that the attitude and the actual purchase is more compelling for buyers who have a high perception of benefit compared to buyers with low perceived benefits. In addition to our study, patients probably use unregistered medicines due to cheaper price. This statement is supported by a study by Rao (2017) which found that smuggled medicine is cheaper.

The results of this study were impeded by several limitations. Firstly, the sampling method employed was convenience sampling, thus the results obtained cannot be inferenced to the whole population. Another limitation of the study was although we try to include patients of differing demography, voluntary participation indicates a certain pattern of respondents. Younger patients for instance, were less likely to be included in the study. The prevalence of unregistered medicines use in this study might also not represent the whole population of Malaysia as the composition of respondents of in this study is focused on patients attending Klinik Kesihatan Bandar Kota Bharu which was located in a semi-urban area. Extending this study to several other areas in urban and rural areas might result in a different result. Moreover, the location of Kelantan has a neighboring border of Thailand, whereas the medication may be easily accessed from the neighbor country by smuggling.

The prevalence of unregistered medicines use in this study was larger than the prevalence of unregistered medicines in Malaysia, it is undeniable that unregistered medicines still hold a place among these patients. Some findings from this study further consolidates the finding of previous studies, and many others were unable to be ascertained as no statistically significant difference was detected.

CONCLUSION:

The prevalence of unregistered medicines usage was 15.7%. More than half (64.8%) of the respondents were categorised as having good knowledge of unregistered medicines. In attitude towards term of unregistered medicines, the proportion of respondents with a negative (91.7%) views of unregistered medicines was comparable to those with positive (8.3%) attitude towards unregistered medicines. Various parameters were investigated in the study to determine the factors associated with the practice of unregistered medicines use. After adjusting for confounders, respondents with lower education and perceived benefit of unregistered medicines were more likely to take unregistered medicines. It is therefore suggested that we should strengthen our education programme to modify patient's belief on benefit unregistered medicines. Heavier fine or penalty should be administered to manufacturers who did not register their medicines

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Conflicts of Interest:

The author declare no conflicts of interest.

References:

Albarrán, K. F. & L. V. Zapata 2008. Analysis and quantification of self-medication patterns of customers in community pharmacies in southern Chile. Pharmacy world & science 30(6): 863-868.

Alghanim, S. 2011. Self-medication practice among patients in a public health care system. Eastern Mediterranean Health Journal 17(5).

Aris, N. A. 2019. Ministry tracks thousands of online ads for illicit medicines. Free Malaysia Today,

Ayob, A., A. I. Awadh, H. Hadi, J. Jaffri, S. Jamshed & H. M. A. Ahmad 2016. Malaysian consumers' awareness, perception, and attitude toward cosmetic products: Questionnaire development and pilot testing. Journal of pharmacy & bioallied sciences 8(3): 203.

Balbuena, F. R., A. B. Aranda & A. Figueras 2009. Self-medication in older urban mexicans. Drugs & aging 26(1): 51-60.

Carolyn Nordstrom. 2007. Crime, money, and power in the contemporary world. R. Borofsky. Ed. Berkeley: University of California Press, 2007.

Division, P. S. 2016. A National Survey on the Use of Medicines (NSUM) by Malaysian Consumers 2015.

Eisend, M. & P. Schuchert-Güler 2006. Explaining counterfeit purchases: A review and preview. Academy of Marketing Science Review 2006: 1.

El Nimr, N., I. Wahdan, A. Wahdan & R. Kotb 2015. Self-medication with drugs and complementary and alternative medicines in Alexandria, Egypt: prevalence, patterns and determinants. EMHJ-Eastern Mediterranean Health Journal 21(4): 256-265. Fadzil, S. K., M. Omar & N. M. J. I. J. o. P. H. R. Tohit 2018. Practice of Dietary Supplements and its Influence towards Treatment Adherence among Chronic Disease Patients. 8(2): 998-1005.

Furman-Assaf, S., O. Tamir, E. Marom, M. Arieli & J. Shemer 2010. [Counterfeit drugs in Israel and worldwide. Part II: distribution profile and anti-counterfeiting strategies and actions]. Harefuah 149(7): 470-5, 479.

Haque, A., A. Khatibi & S. Rahman 2009. Factors influencing buying behavior of piracy products and its impact to Malaysian market. International Review of Business Research Papers 5(2): 383-401.

Hasan, S. S., S. I. Ahmed, N. I. Bukhari & W. C. W. J. C. T. i. C. P. Loon 2009. Use of complementary and alternative medicine among patients with chronic diseases at outpatient clinics. 15(3): 152-157.

Isles, M. 2017. What's in a Word? Falsified/Counterfeit/Fake Medicines-The Definitions Debate. Medicine Access@ Point of Care 1: maapoc. 0000008.

Ismail, A. b. 2017. Why should you use registered medicines? Kementerian Kesihatan Malaysia, MyHealth Portal. <u>http://www.myhealth.gov.my/en/why-shouldyou-use-registered-medicines/</u> (Accessed).

Ismail, S., S. S. M. J. I. R. o. M. Mokhtar & Marketing 2016. Moderating role of perceived benefit on the relationship between attitude and actual purchase. 6(7S): 22-28.

Janz, N. K. & M. H. J. H. e. q. Becker 1984. The health belief model: A decade later. 11(1): 1-47.

Jr., W. C. S. 2018. Medical Definition of Chronic disease. Medicinenet. <u>http://www.medicinenet.com/script/main/art.as</u> <u>p?articlekey=33490</u> (Accessed 9 September).

Kamran, A., G. Sharifirad, Y. Shafaeei & S. Mohebi 2015. Associations between self-medication, health literacy, and self-perceived health status: A community-based study. International Journal of Preventive Medicine 6(1): 66-66.

Killelea, B. K., S. B. Evans, S. S. Mougalian, C. P. Gross, L. Fraenkel & S. Y. J. T. b. j. Wang 2019. Association between perceived benefits

and receipt of radiotherapy among older breast cancer patients.

Kotler, P. & K. L. Keller. 2012. Marketing Management Ed. 14th Edition. Prentice Hall; 2012.

Liu, R. & S. Lundin 2016. Falsified medicines: Literature review. Working Papers in Medical Humanities 2(1).

Mhando, L., M. B. Jande, A. Liwa, S. Mwita & K. J. Marwa 2016. Public awareness and identification of counterfeit drugs in Tanzania: A view on antimalarial drugs. Advances in Public Health 2016.

Ministry of Health, P. S. D. 2012. Pharmacy Programme Annual Report 2012.

Ministry of Health, P. S. D. 2016a. Know Your Medicine Ed.

Ministry of Health, P. S. D. 2016b. Pharmacy Programme Annual Report 2016. Laporan.

Mirowsky, J. 2017. Education, social status, and health Ed.: Routledge.

Narsai, K., A. Williams & A. K. Mantel-Teeuwisse 2012. Impact of regulatory requirements on medicine registration in African countries - perceptions and experiences of pharmaceutical companies in South Africa. Southern med review 5(1): 31-37.

OECD/EUIPA. 2016. Trade in Counterfeit and Pirated Goods: Mapping the Economic Impact Ed.: OECD.

Petersen, A., N. Held & L. Heide 2017. Surveillance for falsified and substandard medicines in Africa and Asia by local organizations using the low-cost GPHF Minilab. PloS one 12(9): e0184165.

Pharmaceutical Security Institute, P. 2018. Counterfeit Situation. <u>http://www.psi-inc.org/counterfeitSituation.cfm</u> (Accessed).

Putthapiban, P., W. Sukhumthammarat & C. Sriphrapradang 2017. Concealed use of herbal and dietary supplements among Thai patients with type 2 diabetes mellitus. Journal of diabetes and metabolic disorders 16: 36-36.

Rao, M. J. M. J. o. P. S. 2017. Medicine Tourism. 3(2): 2-3.

Republic of Kenya Ministry of Health, P. a. P. B. a. D. o. M. C. 2007. Antimalarial medicines in Kenya: Availability, quality and registration status. 2007. Laporan.

Ritson, M. 2007. Fakes can genuinely aid luxury brands. Marketing 25: 21.

Sabine, K. 2009. WHO Survey On Terminology On "Counterfeit" Medicines Or Equivalent. Quality Assurance and Safety: Medicines Essential Medicines and Pharmaceutical Policies. . Laporan.

Salim, M. R. b. 2014. Counterfeit medicines. My Health Portal, Ministry of Health Malaysia, <u>http://www.myhealth.gov.my/en/counterfeit-</u> <u>medicines-2/</u> (Accessed 16 December 2018).

Services, I. L. B. 2017. Malaysian Laws on Poisons and Sale of Drugs Ed. Selangor, Malaysia: International Law Book Services.

Steven, P. & D. H. H. Mydin. 2013. Fake Medicine in Asia. Emerging Market Health Network World Health Organization. 1992. Counterfeit drugs—Report of a WHO/IFPMA Workshop. Laporan.

World Health Organization. 2018. Substandard and falsified medical products. <u>http://www.who.int/en/news-room/fact-</u>

sheets/detail/substandard-and-falsified-

<u>medical-products</u> (Accessed 16 December 2018).

Zimmerman, E. B., S. H. Woolf, A. J. P. h. b. Haley & s. s. i. A. publication 2015. Understanding the relationship between education and health: a review of the evidence and an examination of community perspectives. (15-0002): 347-84.

Zulkifli, N. W., N. A. Aziz, Y. Hassan, M. A. Hassali & N. L. Z. Bahrin 2015. Development of Validated Questionnaire to Access Public Knowledge on Registered Drugs. Procedia - Social and Behavioral Sciences 172: 749-753.