

A Survey on Knowledge of Registered Drugs amongst Patients from the Specialist Clinic, Malaysia

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Abstract

Introduction: One of the solutions to reduce unregistered drugs usage is via awareness and educational programmes. The aim of this study is to determine the significance difference of patients' level of knowledge between control and intervention groups towards registered drugs.

Method: The study used a pre- and post-test by answering the validated survey during October-November 2018 at a tertiary hospital in Malaysia. It has two groups as an intervention group (IG) receiving counseling and control group (CG) which did not receive any counseling. This study used systematic random sampling. The data analysis was performed using SPSS version 23. Descriptive data was reported, including the answers each question, score, level of knowledge based on the percentages and the socio-demographic data. The pre and post differences of the score between control and intervention groups were assessed using ANCOVA.

Result: A total of 657 respondents were obtained which overall response rate of 93%. Majority of the participants are aged between 18-28 years old (47%), female (58.3), Malay (47.4%), Degree holder (69.1%) and in the government sector (38.3%). However, the majority of participants are in the category of the acceptable level of knowledge towards registered drugs (40.8%) and only 3.5% of the participants are in the category of excellent. However, about 66.1% of the participants have scored above 50%. It can be considered that the majority of the participants have knowledge about registered drugs. IG group displayed significantly higher post-test results compared with CG group ($p < 0.001$).

Conclusion: The used of the validated survey during the awareness programmes might give benefit to the public who attends the awareness and educational programmes and finally can improve the effectiveness of the programmes in the future. In the future, the improvement of the design of the campaign might include the use of a survey in order to give more understanding to the public towards registered drugs. [DOI: [10.22401/ANJS.22.3.04](https://doi.org/10.22401/ANJS.22.3.04)]

Keywords: registered drugs, knowledge survey, educational campaign, counterfeit drugs.

Introduction/Background

There are many solutions to reduce unregistered drugs usage. One of the solutions is the awareness and educational program [1]. Food Drug Administration (FDA) is one of the organizations which provides information on educating the public on counterfeit drugs via a website [2]. Meanwhile, in Malaysia, Pharmaceutical Services Division (PSD) is one of the agencies that provide awareness programs throughout the country as well as in its website. One of the campaigns was "Know Your Medicines". This campaign was held to ensure that, the public is aware and responsible for types of medications they consumed and purchased [3]. It visualised that the

government has placed its effort to educate and provide vital information to the public regarding health and drug-related issues. Despite the awareness program, there is still a lack of specific research to ascertain the level of public understanding regarding general knowledge towards registered drugs.

As mentioned earlier, MOH already has the campaign known as 'Know Your Medicine'. 'Know Your Medicine' is a programme introduced as part of Quality Use Medicines activities which, aim to ensure that patients or consumers take their medications rationally. The programmes promoted on the 5R (Right) concept, which is: patient; medicines; dose; the route of administration

and the time of administration. There is another campaign which is the subset of the 'Know Your Medicine' programme which is known as 'Choose Registered Drugs'.

Choose Registered Drugs campaign is mainly conducted by the Enforcement Pharmacy Unit. The campaign is primarily about registered and unregistered drugs information. All of the information in the campaign is more focused about the characteristic of registered drugs, cosmetic, advertisement, online shopping, the harmful effect of unregistered drugs and the danger of food and drink that contaminated with poison [4].

The information of unregistered drugs characteristic is valuable information that every consumer in Malaysia need to know before they buy any pharmaceutical products whether in the market or online. The registered drugs aspect is every pharmaceutical product must have MAL number as registration and Hologram label on the packaging. Consumers need to be aware of the pharmaceutical products that they bought. They need to check the registration number via the website and to confirm that the label is authentic. The consumers also need to go to any registered pharmacy store to use the hologram Meditag® to identify the originality of the sticker. It is the fundamental requirement that every consumer need to be aware and understands [4].

There are several types of research in 'Konvensyen Inovasi Kebangsaan Farmasi' (KIKF), and Quality Assurance (QA) which investigated this matter. One study in KIKF, which was conducted by Enforcement Pharmacy Kelantan, assessed the understanding of registered drugs amongst healthcare provider in Kelantan throughout 2013. The findings found that only 19.5% of the respondents understand the registered drugs. Rasyimah et al., 2013, claimed that after the counselling session to all of the participants, the assessment of understanding result increased to 80.1 % [5].

There is a National Survey on the Use of Medicines (NSUM) by Malaysian Consumers conducted by PSD to evaluate the performance of the "Know Your Medicines" campaign in 2012. The primary purpose of this study was

to help to establish the QUM nationwide and directly embark the initiatives done in the 10th Malaysia Health Plan [6]. NSUM is the pioneer in the field of study that used as a foundation for this study. According to the result from NSUM, up to 76.4% of the participants were aware of the requirement to register with MOH for all modern and traditional medicines before marketing them [6]. Furthermore, only 38.7% of the participants were aware of Meditag® availability [6]. These results showed that the majority of Malaysian consumers did not know about Meditag® and its functions. The result of the awareness is high, which showed that participants were aware of the requirement for registration but at the same time, they did not know what Meditag® is. Knowledge about Meditag® is one of the crucial pieces of information that consumers need to know to prevent them from buying unregistered drugs.

Furthermore, the statistics of unregistered drug confiscated is increasing in trend since 2010 and the value has amounted to RM 27 million per year [7]. Surprisingly, the possibility that the statistics might increase every year might be possible [8]. There are also reports on the increasing trend of adverse drug reaction had been indicated that experienced by consumers after they consumed the unregistered drugs [9]. This report gives a reflection that there are still demands from the consumers towards unregistered drugs. Both of these issues showed that consumers need to be more knowledgeable and alert about these issues. It is to prevent any harm to them whether in short term or long term of adverse drug reactions.

Rationale of the study

The used of a validated tool to assess public knowledge on the registered drugs might help the public and pharmacists to identify the knowledge that the public is lacking and straight away give education on the topic that they less understand. Moreover, in this study, it would be beneficial to assess the efficacy of the current awareness and educational programmes in order to fill in the gaps of the previous study.

1- Justification of the study

The Ministry of Health (MOH) administrates the Malaysian National Medicines Policy (MNMP) that acts to promote equitable access and rational use of safe, effective, and affordable essential medicines of good quality to improve health outcomes. In the policy have five strategies have been reorganized. One of these strategies addresses counterfeit drugs Table (1).

The main concern is to ensure all products in the market (online and shops) are registered [10]. Many solutions may be considered. One such solution is to educate and give awareness to the public concerning registered drugs [11]. According to the policy, public awareness and roadshow on counterfeit issues is one of the activities that need to be implemented. Therefore, the aim of this study is to add-on the use of the validated survey during the campaign might possibly increase the benefits to the public that attend the campaign.

2- The Validated Survey

The survey is already validated and conducted in the Malaysia setting [12]. The final version of the questionnaire had 12 questions which are divided into five areas of information that needed for educating the consumer on registered drugs. This questionnaire had a clarity index of 8.78 ± 0.51 . The intraclass correlation coefficient was 0.96, and Cronbach's alpha, 0.866. The information in the survey is the combination some of the result from the qualitative study and the extraction of the information from the 'Choose Registered Drugs' campaign. The survey is multiple choices and if they do not know the answer they can answer E (I do not know).

Table (1)
Quality, Safety and Efficacy of Medicines Strategy: Counterfeit Drugs.

No	Activities	Implementation Timeline	Indicators	Targets	Stakeholder
1	Monitoring of retailers and wholesaler through inspection	2016-2017 (upon the effective date of New Pharmacy Act)	Percentage of counterfeit drugs confiscated	TBD (to get baseline data)	Local Authorities PSD
2	Public Awareness and roadshow on counterfeit/ SSFFC issues	On-going	Number of activities conducted	Not less than 50 per year	PSD
3	Comprehensive monitoring of the illegal online sale of medicine by Pharmacy Digital Forensic Unit	2015	Percentage of websites selling medicine illegally for which action is taken	Not less than 50% TBD	PSD, MCMC

Source: Malaysian National Medicines Policy (MNMP) 2014

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patient 2 (skip) → patient 3(skip) → patient 4 intervention group).

METHODOLOGY

This prospective cohort study used a pre- and post-test by answering the validated survey Fig.(1). It has two groups as an intervention group (IG) receiving counseling and control group (CG) which did not receive any counseling. This study used systematic random sampling (patient 1(control group) →

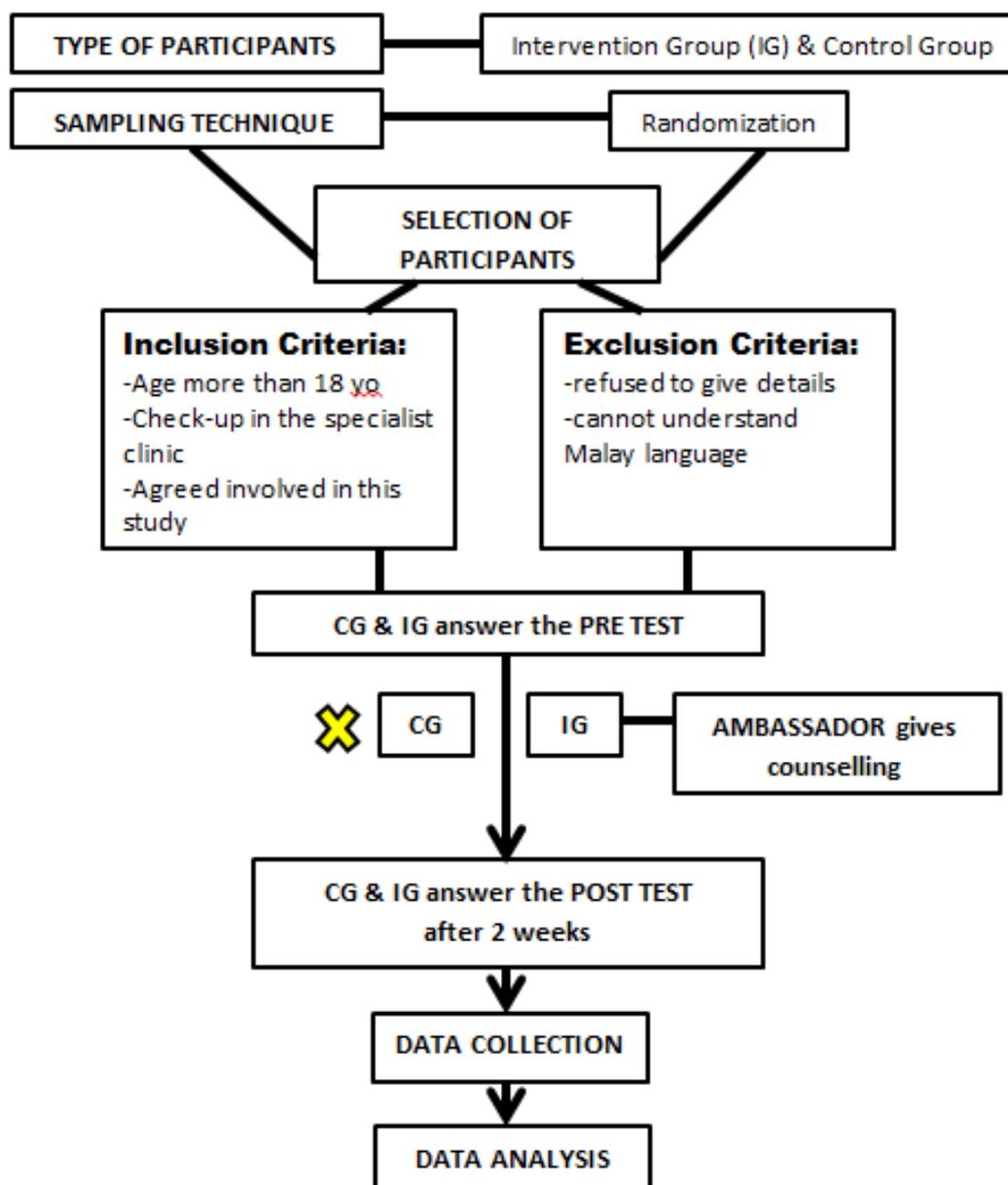


Fig.(1): Study Flowchart.

The intervention is the counseling session when the researcher gave to the IG. The researcher gave marks to the survey and then explained all of the questions to the participants. In addition, all of the researchers have a checklist of the information that they need to counsel the participants. The reason is to reduce biased in this study. Before the study begins, all of the researchers (4 people), have trained to use the tool and the checklist. Then, they had the assessment by the main researcher before they are certified to use the checklist.

Then, the participant had been approached and explained the procedure along with the study and they need to sign the consent letter. The post-test will be repeated after 2 weeks.

The survey was already validated [12]. The survey consists of topics that need to be answered by the participants which are; registered drugs' characteristic, cosmetics identification, advertisement and internet, adulterated food products and information references. The survey is in Malay version only.

After the participants answered the survey, the marking depends on the marks that already stated Table (2). Every question will have different marks because it depends on the weightage of the questions. The classifications of knowledge are excellent, good, acceptable, little and insufficient knowledge Table (3). The public that classified in the rate below 50% is considered to have limited knowledge

of registered drugs. All the questions have multiple choices. If the public does not know the answer they can choose D which is, I do not know, and they will have 0% because it is considered that they did not have knowledge towards this objective.

Table (2)
Marking percentages of every question.

Objective	Portion of test (%)
Registered drugs' characteristic	N:4 (40)
Cosmetics identification	N:2 (20)
Advertisement food products	N:2 (15)
Adulterated food products	N:2 (15)
Information references	N:2 (10)

Then, after the pre-test survey, the IG received counselling session for about 10-15minutes about the registered drugs. Finally, after 2 weeks both of the group which is IG and CG need to answer the survey again. They had contacted by the researcher by email, call or face to face meeting.

Table (3)
Classification the Marks of the level of knowledge amongst public.

%	Classification of knowledge
90-100	Excellent
70-89	Good
50-69	Acceptable
30-49	Little
<30	Insufficient

Patients were contacted after 2 weeks as mentioned in the study design. If the patient cannot be contacted after 2 weeks, the sample was withdrawn without replacing with other patients. The criteria of the withdrawn sample:

- During the post-test patients disagree to continue the study (patients don't want to answer the survey)
- The researcher cannot contact the patients after 2 weeks.
- Patients contact us to answer the survey after 2 weeks.

In this research used two formula of sample size. Before began the research, the

calculation of the sample size used the Raosoft calculation as below.

Population estimated 100000, based on Raosoft the sample size is 383. The participants divided into two groups which are control and intervention. The potential dropout value is considered at 4-5%. The final sample size is 400 samples which are the control group and intervention group 200 each.

After we began to start to collect the data, we used the formula compare two group means sample size formula to estimate the sample size [13]. About 25 sample each group to calculate the sample by using the formula as below.

The result of the sample size is 429. Based on these two results, the estimation for the sample size is 500. Both groups are 250 of samples.

The data was analyzed using the SPSS version 23. Descriptive data is the answers of each questions, score, level of knowledge based on the percentages and the socio-demographic data.

The pre and post differences of the score between control and intervention groups were assessed using ANCOVA.

The study was conducted in compliance with ethical principles outlined in the Declaration of Helsinki and Malaysian Good Clinical Practice Guideline. The registration number for this research is NMRR-18-1492-41496. Ethical approval for this study was obtained from the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

1. Informed Consent/Assent Process

Patients were informed of the study during their usual clinic visits. They were requested to contact investigators if they are interested. An appointment was made where the patient information sheet will be provided and explained to them. The consent forms were signed and dated if they expressed willingness to participate. If they need to, they were allowed to take the information sheet home to consult with their family member and another day for getting consent arranged.

Results

A total of 657 respondents were obtained during study period (October-November 2018) with overall response rate of 93%) Figure (2). Of these responses, 78% were obtained during face to face meeting and others via call and email. Majority of the reason for the dropout is they cannot be contacted and they contacted the researcher after the time frame which is 2 weeks after the post-test.

The demographic characteristics of the study population are reported in Table (4).

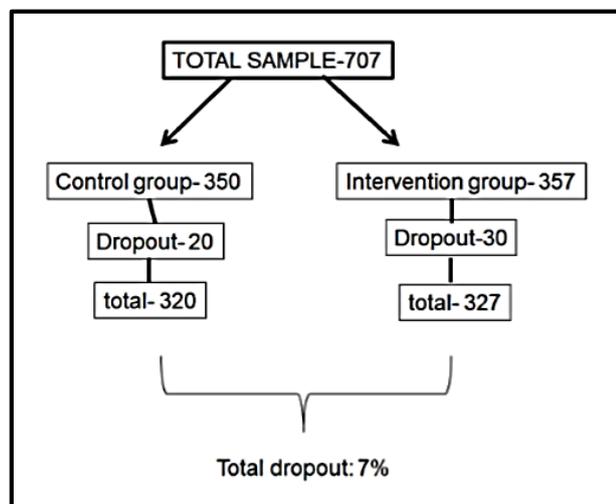


Fig. (2): Data Collection.

*Table (4)
Demographic characteristics of the participants.*

		Control n (%)	Intervention n (%)	Total
AGE	18-28	142 (43)	167 (51)	309
	29-39	82 (25)	82 (25)	164
	40-50	63 (19)	66 (20)	129
	51-61	37 (11)	8 (3)	45
	>62	6 (2)	4 (1)	10
GENDER	Male	156 (47)	118 (36)	274
	Female	174 (53)	209 (64)	383
RACE	Malay	133 (40)	179 (55)	312
	Chinese	156 (47)	112 (34)	268
	Indian	31 (9)	29 (9)	60
	Others	10 (4)	7 (2)	17
LEVEL OF EDUCATION	Primary	6 (2)	0 (0)	6
	Secondary	79 (24)	26 (8)	105
	Diploma	46 (14)	43 (13)	89
	Degree	196 (59)	258 (79)	454
	Others	3 (1)	0 (0)	3
OCCUPATION	Government	115 (35)	137 (42)	252
	Private	136 (41)	88 (27)	224
	Self employed	26 (8)	32 (10)	58
	Pensionner	9 (3)	18 (6)	27
	Unemployed	7 (2)	12 (3)	19
	Student	37 (11)	40 (12)	77

Based on Table (5), the majority of the participants are age between 18-28 years old (47%), female (58.3), Malay (47.4%), Degree holder (69.1%) and in the government sector (38.3%).

Table (5)
The majority of participants' answers.

Questions (Q)	Answer	N (%)
Q1 What is the registered drug in Malaysia?	Medicines that have been approved by the Drug Control Authority (DCA) and have tested efficacy, quality and safety.	288 (43.8)
Q2 Below is a fact about the product registration category. Please choose the TRUE statement?	Traditional medicine is marked "T" at the end of the registration number	335 (50.9)
Q3 Registered drug has	I do not know	260 (39.5)
Q4 The tool used to detect the authentic of the Meditag holographic sticker is	Infrared Device.	293 (44.6)
Q5 Please select the TRUE statement about cosmetic products below.	Having a notification number for example is NOT98727124K.	287 (43.7)
Q6 To ensure your cosmetic products do not have any hazardous materials such as	Hidrokuinon, Merkuri, Tretinoin.	443 (67.4)
Q7 Please select TRUE statement about drug advertising or purchase of medicines via the internet below.	All products with medical claims have a KKLIU registration number in the ads.	430 (65.4)
Q8 Please select a reliable ad statement below	This product can increase our body's resistance.	447 (68.0)
Q9 From which sources do you get information on health care, disease and product health?	Doctors and pharmacists at nearby hospitals, clinics or pharmacies.	534 (81.3)
Q10 Please select the TRUE statement below	If the general public is exposed to dubious drug sales, they need to complain to the authorities immediately.	417 (63.5)
Q11 Please select the TRUE statement below	Sildenafil and steroids cannot be mixed into health products as it can damage your health.	377 (57.4)
Q12 Please select a FALSE pre-mixed pair for violation of the law.	Tea and Sildenafil drinks	367 (55.6)

Based on Table 6, question number 3, majority of the participants did not know the answer (39.5%) and question number 4,

majority of the participants answered wrongly (44.6%). However, majority of the participants answered correctly for other questions.

Table (6)
The score of the Pre-test.

Level of knowledge (%)	N (%)
Excellent (90-100)	23 (3.5)
Good (70-89)	143 (21.8)
Acceptable (50-69)	268 (40.8)
Little (30-49)	126 (19.2)
Insufficient (<30)	97 (14.8)

Based on Table (6), the majority of participants are in the category of the acceptable level of knowledge towards registered drugs (40.8%) and only 3.5% of the participants are in the category of excellent. However, about 66.1% of the participants scored above 50% and it can be considered that the majority of the participants have knowledge about registered drugs.

The pre and post differences of the score between control and intervention groups were assessed using ANCOVA. The result after analysis using ANCOVA showed that it is statistically significant approved ($p < 0.001$) between the group for the post test.

Discussion

According to the descriptive data, the majority of the patients that follow up in the specialist clinic are in the government sector. Moreover, most of the patients that easily been approached during the selection of the sample are female, educated (degree holder) and age between 18-28 years old. Others sample do not have the inclusion and exclusion criteria and had to be excluded from this study. The reason to choose the specialist clinic as the main setting of this research is to have a population that has a regular check up with any clinic.

Meanwhile, the majority of the respondent answered the test correctly. However, there have two questions in which the majority of the respondent answered wrongly and answered they did not know the answer. Both questions are under category characteristic of registered drugs which is one of the important questions that public need to know [12]. Based on this result, in the future can focus more to assess public about the characteristics of the registered drugs and have the hands-on session to make it more interactive.

For this study, the result is more than 50% of respondents have marks above 50%

compared to other research that conducted awareness survey [5] [12]. But again, the answer of every question needs to check to ensure that the public really understands about the registered drugs and can identify what topic that they are still lacking and focus to give education towards that topic.

The result after analysis using ANCOVA showed that it is statistically significant approved ($p < 0.00$) between the group for the post test. The previous study also get the same result but she has the descriptive data. In this research used ANCOVA which showed that the tool gave a significantly positive impact to the public.

Implications/Conclusion

The implementation of the validated survey during the awareness programmes reflects potential benefit to the public who attends the campaign and can improve the effectiveness of the programmes in the future.

Furthermore, the usefulness of this finding not only limited to pharmacists and public but also for other health care professionals. The authorised body should take action such as making it compulsory for health care provider learning to use the tool and act as an ambassador for the public in giving awareness towards the registered drugs. Therefore, the burden not only for the pharmacists to give the knowledge to the public but also can be shared with other health care providers. The cooperation amongst health care provider regarding these issues might help to improve the understanding of the public towards registered drugs.

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Conflicts of Interest

None declared.

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