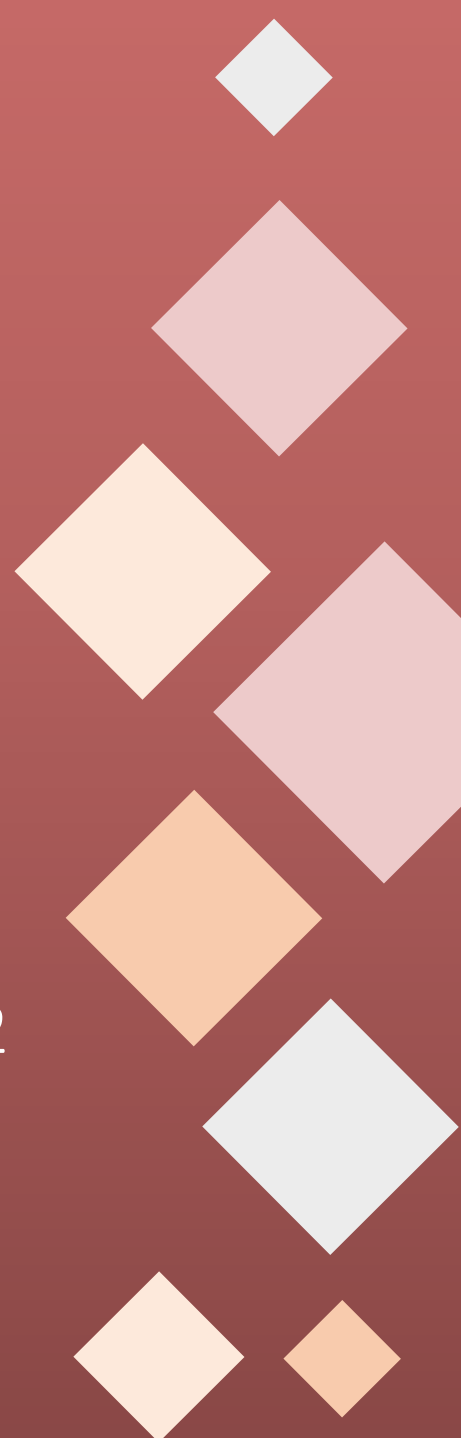MINISTRY OF HEALTH MALAYSIA
PHARMACEUTICAL SERVICES PROGRAMME

# PHARMACY RESEARCH REPORTS

Volume 5 • Issue 1 • April 2022
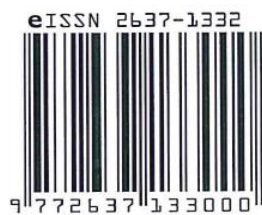
# PHARMACY  RESEARCH  REPORTS

## Volume 5 • Issue 1 • April 2022

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# ACKNOWLEDGEMENT

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# Using Pharmacy Value Added Services (VAS) to Collect Repeat Medications: Awareness and Perception of Patients Toward Two Newly Introduced Variants

Kho Boon Phiaw[1], Yeo Bi Qi[1], Debra Tan Yuin Yuin[1], Lavinia Kong Jin Qi[1]

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**Abstract**

**Introduction:** Pharmacy Value Added Services (VAS) facilitate the collection of repeat medications at outpatient pharmacy departments (OPD) of Malaysian government facilities. Two new VAS variants, namely Scan and Collect, and WhatsApp and Collect were introduced in Sarawak General Hospital (SGH) in April 2019 to increase the uptake of VAS, which had plateaued.

**Objective:** The objective of this study was to determine the awareness and perception regarding these two new VAS variants among eligible patients who were not using the services six months post-implementation.

**Methods:** This cross-sectional study entailed distribution of self-administered questionnaires to patients collecting their repeat medications at OPD, SGH between October and December 2019. The VAS studied were (1) Scan (QR) code and Collect, and (2) WhatsApp and Collect, both introduced in April 2019. Included patients had partial medication supply, literate, and not using both services. Respondents' demographic data, experience in collecting medication, awareness towards current and new VAS, as well as perception and likelihood to adopt new VAS were collected.

**Results:** A total of 167 usable responses were analysed. Demographic characteristics were balanced. Lack of parking space was the main problem faced in collecting medications (n=126). One-third were current VAS users, and 46% (n=76) had heard about the new VAS variants, mainly from pharmacy staff (n=63). Service uptake was mainly hampered by the lack of understanding on how to use the service (n=52). Respondents largely perceived novel VAS as time-saving and convenient but remained neutral on the ease of use of these services. High likelihood (60%) to adopt both services were demonstrated. Diversifying avenues of service promotion and increasing ease of use may improve service uptake.

**Conclusion:** Pharmacy users mostly have positive perceptions of new VAS introduced but awareness of the service can be improved. Thus, efforts should be concentrated on ratification of identified barriers to improve service uptake.

**Keywords:** pharmacy service, repeat medication supply, outpatient pharmacy, awareness, Malaysia

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**Introduction**

Patients with chronic illnesses requiring long term medical therapy are often provided with repeat prescriptions by outpatient clinics, to be dispensed on a monthly basis at pharmacies (1). This practice reduces the frequency of clinic visits and is thus highly convenient for both doctors and patients alike, besides enabling treatment monitoring by pharmacists (2). However, an increase in the number of repeat prescriptions needing to be dispensed compelled pharmacies to provide alternative medication delivery options that are faster and more convenient, to better manage patient waiting time and experience (3). Various options are successfully introduced in countries around the world, including drive-through pharmacy services, pick-ups, home delivery services, mail order and robotised dispensing hubs (4).

In Malaysia, public healthcare facilities are the first port of call for the majority of the population when they have health problems (5). The popularity of these heavily subsidised government institutions, which provide both outpatient and inpatient services, resulted in high volumes of patients and prescriptions.

Based on latest published data, a total of 50.7 million outpatient prescriptions were dispensed by pharmacies in Malaysian public healthcare facilities in 2015, with 19.3 million (38%) in hospital outpatient pharmacies. Comparatively, only 42.4 million prescriptions were dispensed in 2011 (6). For patients on chronic medications, it is the policy of the Ministry of Health Malaysia (MOH) that medications are to be supplied on a monthly basis. Partial drug supply is purported to enhance the quality use of medicine, reduce medications wastage and improve patients' adherence to medications besides allowing monitoring of any side effects experienced by patients (7).

Unfortunately, the need for monthly supply and increase in prescription load resulted in long waiting time for patients collecting their medications at the outpatient pharmacies, as well as contributing to workplace stress and medication errors for pharmacy staff (4). In response, the Pharmaceutical Services Programme (PSP), MOH introduced innovative means for patients to refill their repeat prescriptions. These alternatives, collectively known as pharmacy value added services (VAS), include Integrated Drug Dispensing System (SPUB), Medicines by Post (UMP), Drive-Thru Pharmacy, Appointment Cards, as well as Fax/Email/SMS and Take (F.E.S.T) service (4,7). For these services, medications are prepared beforehand, and there is no need for patients to queue, endure a long wait or even go to the pharmacy for their refill prescriptions, depending on the variants chosen. Studies had found that patients were more satisfied collecting their medications via VAS compared to traditional pharmacy counters in Malaysia, with the main perceived benefit being the shorter waiting time needed (8,9). More importantly, VAS also reduced the overall waiting time in the outpatient pharmacy (10).

In line with this nationwide strategy, the outpatient pharmacy department (OPD) in Sarawak General Hospital (SGH) has offered all these VAS since 2011. However, despite being heavily advertised by pharmacy staff, patients' uptake was only moderate, with around 20% of repeat prescriptions being dispensed via the VAS platform in 2018. Several studies have highlighted various barriers that impede the uptake of these services in Malaysia. Patients using the Integrated Drug Dispensing System, which enable them to have repeat prescriptions dispensed at facilities nearest to their home instead of the de facto treating facilities, complained that they still had to spend time going through traditional counters at the appointed facility (8). Those using drive-through pharmacy services aired grouses regarding the impractical and unclear location of the drive-through counter, as well as traffic congestion at the drive through lane (10,11). They are also concerned that interaction with pharmacy staff will be reduced (12). Delayed postal delivery, concern of medication errors and additional fees imposed were issues leading to patient hesitation in utilising the postal delivery service (10). Besides these service specific complaints, patient's general lack of awareness and knowledge of VAS also contributed to the low uptake (10,11).

In order to improve the uptake of VAS and refresh the services offered, OPD in SGH introduced two new variants in April 2019, namely "Scan and Collect" and "WhatsApp and Collect". For Scan and Collect, a QR code is added onto repeat prescriptions for patients to scan and subsequently schedule the date of collecting their medicines online. For WhatsApp and Collect, patients just need to capture a picture of their repeat prescription and WhatsApp to a designated number to make the appointment. Both services aim to exploit the popularity of mobile phone-based services, increasing convenience and ease of use for patients, especially for the younger generations.

With the introduction of any new service, it is essential to determine patients' awareness and perceptions toward the service, as their acceptance and adoption can affect its long-term sustainability. High reuptake rate of VAS is also found to significantly minimise waiting time at OPD, and it is important that the newly introduced service will be able to contribute to this goal (11). To the best of our knowledge, these two variants are yet to be introduced in other government healthcare facilities, thus their receptiveness by patients is unknown. Therefore, this study aimed to determine the perceptions and awareness of patients yet to use these services, in order to identify the barriers faced in adoption and make recommendations for improvement.

## Methods

### Study design and setting

This cross-sectional study utilised self-administered questionnaires to ascertain patients' awareness and perceptions towards the Scan and Collect and WhatsApp and Collect VAS provided by the outpatient pharmacy department of Sarawak General Hospital (OPD, SGH). It was carried out from October to December 2019, six months after both services were introduced. Various promotional activities were carried out during these six months, including distribution of promotional leaflets, posters and videos, as well as verbally advertising to doctors and patients.

*Recruitment and sampling*
The population of the study were literate adult patients or their carers who had a prescription that was partially supplied by the OPD, SGH, and had yet to use the two novel VAS variants. Individuals who were illiterate, had psychiatric disorders, aged below 18 years old, not having prescriptions requiring partial supply of medications or have medications not suitable to be dispensed using VAS were excluded.  Based on the figure of 26,947 unique patients in OPD, SGH with repeat prescriptions in 2019, and the proportion of patients who were aware of VAS being 0.4 as per Liana *et al.* (2015), the required sample size to achieve a representative sample with a precision of 0.075 was 164 as calculated using the PS Power and Sample Size Calculations software by Dupont and Plummer (12).

*Development and validation of survey instrument*
Previous studies evaluating customers' perception of drive-thru pharmacy service by Liana et al. (2015) and Hammour et al. (2019) served as references for the development of this questionnaire. Items that were not relevant to our setting were dropped, for example items specific to drive-thru pharmacy and promotional activities that were not carried out in our facility. The final questionnaire  comprised items on patients' socio-demographics (six multiple choice questions), current experience collecting medications at OPD, SGH (three multiple choice questions), awareness about VAS in general (three multiple choice questions), awareness about Scan and Collect and WhatsApp and Collect (three multiple choice questions), perceived advantages and disadvantages of the service (eight three-point Likert scale questions), as well as willingness to take up the service (two five-point Likert scale questions).

The questionnaire which was originally in English was translated into Chinese and Malay by study authors, before being backtranslated to English by another pharmacist proficient in all three languages. The similarity in meaning for both original and back-translated English versions was adjudicated by two experienced pharmacists with research backgrounds. Differences in opinions were resolved via consensus to finalise the questionnaire. Content validity was performed by having ten patients completing each set of the questionnaire and commenting on the clarity and comprehension of the questions included. Minor changes were made before the questionnaire was finalised.

*Data Collection*
Data collection was carried out at the waiting area of OPD, SGH. Patients or their carers with repeat prescriptions were approached by study investigators while waiting to collect their medications. They were recruited if they fit the inclusion and exclusion criteria and provided informed consent after the study protocol was explained to them. Study investigators were in attendance to answer any questions throughout. For those not aware of the new VAS, the services were explained to them using a prepared pamphlet before they answer the section on perceptions toward the service.

*Data analysis*
Collected data were tabulated into Microsoft Excel, with descriptive data subsequently being presented as frequencies (n) and percentages (%). The significance of association between selected variables were then determined using Chi-square test or ANOVA based on the nature of the data. All data were analysed using IBM Statistical Package for the Social Sciences (SPSS) version 20.0.

*Ethical consideration*
The research was registered with the National Medical Research Register with the registration number NMRR-19-1239-48096, and ethical approval was granted by the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia [Ref:KKM/NIHSEC/P19-1265(5) dated July 11, 2019].

**Results**
A total of 172 subjects recruited. Respondents need to answer at least one item in each of the sections of the questionnaire for it to be included in the analysis. Five responses were discarded as they contained whole sections that were left empty. The other 167 responses were analysed.  Respondents' demographic characteristics were summarised in Table 1. The age and gender of respondents were well distributed. Lack of parking space was the biggest problem faced in collecting repeat prescriptions at OPD, SGH (75.4%). The majority received their medicines within 30 minutes (72.2%) and were satisfied with the level of service provided (80.9%).

In terms of experience and knowledge on legacy VAS services, including Integrated Drug Dispensing System (SPUB), Fax/Email/SMS and Take (FEST), Medicines by Post (UMP) and Appointment card system, around half of total respondents were aware of at least one service, whereas one-third were using one of the services offered. Regarding the new variants, slightly less than half (46.1%) were aware of at least one service offered, predominantly via promotion by pharmacy staff (82.9%). Lack of service uptake was mainly contributed by the lack of understanding on how to use the service. This was summarised in Table 2.

Perception wise, the majority of respondents agreed that the new VAS services will save time, increase convenience and improve their compliance. Nearly half opined the new VAS will reduce interaction with pharmacists. However, most are confident that correct medications will be dispensed to them. This was summarised in Table 3.

Based on a five-point Likert scale (very unlikely to very likely), the likelihood of respondents to adopt both variants of VAS were encouraging, with 59.8% and 64.6% indicating that they are very likely or likely to use Scan and Collect and WhatsApp and Collect respectively in the future. The rest of the respondents were mostly neutral in their intention to adopt VAS. Likelihood to adopt was not predicted by respondents' demographics, but those who were current legacy VAS user were more likely to use the Scan and Collect in the future (p=0.03), whereas those aware of new VAS were more likely to use Whatsapp and Collect (p=0.01) (Table 4). Respondents who agreed that novel VAS saves time and reduces frequency of visits to the hospital are significantly likely to adopt both VAS (p<0.01 and p=0.01). Furthermore, those who disagreed that VAS had a complicated registration process nor had too many rules and regulations were significantly more likely to use WhatsApp and Collect (both p<0.01). This was summarised in Table 5.

Table 1: Demographic characteristics of respondents (n=167)

| Characteristics | Frequency (n) | Percentage (%) |
|---|---|---|
| Gender | | |
|    Male | 75 | 44.9% |
|    Female | 92 | 55.1% |
| Age [#] | | |
|    18-29 years old | 53 | 32.3% |
|    30-39 years old | 42 | 25.6% |
|    40-49 years old | 39 | 23.8% |
|    50 years old and above | 30 | 18.3% |
| Collect for | | |
|    Yourself | 73 | 43.7% |
|    Family member | 81 | 48.5% |
|    Both | 6 | 3.6% |
|    Others (friends/colleagues/as carer) | 7 | 4.2% |
| Difficulty faced in collecting medications * | | |
|    No parking | 126 | 75.4% |
|    Long waiting time | 59 | 35.3% |
|    Traffic congestion | 47 | 28.1% |
|    Distance | 33 | 19.8% |
|    No staff | 20 | 12.0% |
|    Travel cost | 6 | 3.6% |
| Average waiting time for prescription refill ^ | | |
|    Less than 15 minutes | 19 | 11.4% |
|    15-30 minutes | 101 | 60.8% |
|    30-60 minutes | 40 | 24.1% |
|    More than 60 minutes | 6 | 3.6% |
| Satisfaction level with OPD service | | |
|    Satisfied | 135 | 80.9% |
|    Neutral | 27 | 16.2% |
|    Not satisfied | 5 | 3.0% |

[#] There were three missing data points
* Respondents can choose more than one answer
^ There was one missing data point

Table 2: Experience and knowledge on VAS (n=167)

| Characteristics | Frequency (n) | Percentage (%) |
|---|---|---|
| Awareness of current VAS services | | |
| Integrated Drug Dispensing System (SPUB) | 50 | 29.9% |
| Fax/Email/SMS and Take (FEST) | 46 | 27.5% |
| Medicines by Post (UMP) | 42 | 25.1% |
| Appointment card system | 99 | 59.3% |
| Current VAS user # | | |
| Yes | 58 | 34.7% |
| No | 104 | 62.3% |
| Awareness of new VAS variants (Scan & Collect, WhatsApp & Collect) ^ | | |
| Not aware | 90 | 53.9% |
| Aware of WhatsApp & Collect | 23 | 13.8% |
| Aware of Scan & Collect | 7 | 4.2% |
| Aware of both | 46 | 27.5% |
| Made aware via (n=76) * | | |
| Promoted by pharmacy staff | 63 | 82.9% |
| Family and friends | 8 | 10.5% |
| Promotional leaflet | 5 | 6.6% |
| Others | 5 | 6.6% |
| Promoted by doctors | 2 | 2.6% |
| Rationale of not enrolling in new VAS (n=76) * | | |
| Don't understand how to use | 52 | 68.4% |
| Lack of time | 9 | 11.8% |
| Happy with current VAS | 7 | 9.2% |
| Not interested | 5 | 6.6% |
| Complicated | 4 | 5.3% |
| No smartphone | 2 | 2.6% |

# There were five missing data points
^ There was one missing data point
* Respondent can choose more than one answer

Table 3: Perceptions on new VAS

| Statement | No. of responses # | Disagree n, (%) | Neutral n, (%) | Agree n, (%) |
|---|---|---|---|---|
| 1. This service saves my time in queueing up to collect repeat medications. | 165 | 1 (0.6) | 34 (20.6) | 130 (78.8) |
| 2. This service reduces the frequency of visits to hospital to drop off prescription and collect medicines. | 164 | 4 (2.4) | 33 (19.8) | 127 (76.0) |
| 3. This service has complicated registration procedures. | 157 | 39 (24.8) | 89 (56.7) | 29 (18.5) |
| 4. There are too many rules and regulations regarding the use of this service. | 153 | 41 (26.8) | 86 (56.2) | 26 (17.0) |
| 5. I would prefer if the pharmacy gives me full supply rather than partial supply of my medications. | 157 | 16 (10.2) | 53 (33.8) | 88 (56.1) |
| 6. I'm confident that correct medications will be dispensed to me as all medicines are checked by pharmacists beforehand. | 164 | 4 (2.4) | 45 (27.4) | 115 (70.1) |
| 7. This service reduces my interaction with pharmacists when collecting medications. | 156 | 15 (9.6) | 68 (43.6) | 73 (46.8) |
| 8. This service helps to improve compliance as I am more likely to collect medications on time. | 161 | 3 (1.9) | 54 (33.5) | 104 (64.6) |

# Number of responses varied for each item due to missing data

Table 4: Association between demographic characteristics and experience using VAS on likelihood to adopt the service

| Demographic characteristics | Likelihood to adopt Scan & Collect | | | | Likelihood to adopt Whatsapp & Collect | | | |
|---|---|---|---|---|---|---|---|---|
| | n | mean (SD) | t/F statistics | p-value | n | mean (SD) | t/F statistics | p-value |
| Gender[α] | | | | | | | | |
| Male | 73 | 3.79 (1.105) | 0.06 | 0.95 | 73 | 3.85 (1.139) | 0.53 | 0.60 |
| Female | 88 | 3.78 (1.077) | | | 87 | 3.94 (1.093) | | |
| Age group[β] | | | | | | | | |
| 18-29 years old | 51 | 3.73 (0.981) | | | 50 | 3.86 (0.990) | | |
| 30-39 years old | 41 | 3.93 (1.127) | 0.54 | 0.66 | 41 | 3.95 (1.139) | 0.56 | 0.98 |
| 40-49 years old | 38 | 3.92 (0.882) | | | 38 | 3.92 (1.100) | | |
| 50 years old and above | 28 | 3.68 (1.362) | | | 28 | 3.93 (1.303) | | |
| Current legacy VAS user[α] | | | | | | | | |
| Yes | 56 | 3.93 (0.871) | 4.70 | 0.03 | 56 | 4.04 (0.934) | 2.21 | 0.14 |
| No | 100 | 3.70 (1.193) | | | 99 | 3.82 (1.207) | | |
| Awareness of new VAS[α] | | | | | | | | |
| Yes | 75 | 3.88 (1.078) | 0.26 | 0.61 | 75 | 4.07 (0.949) | 6.19 | 0.01 |
| No | 85 | 3.71 (1.231) | | | 84 | 3.75 (1.231) | | |

[α] Independent t-test
[β] One-way ANOVA

Table 5: Association between perceptions of new VAS on likelihood to adopt the service

| Perceptions on new VAS | Likelihood to adopt Scan & Collect | | | | Likelihood to adopt Whatsapp & Collect | | | |
|---|---|---|---|---|---|---|---|---|
| | n | mean (SD) | t/F statistics | p-value | n | mean (SD) | t/F statistics | p-value |
| Service saves queuing time [α] | | | | | | | | |
| Neutral/disagree | 34 | 3.38 (0.922) | 2.79 | 0.01 | 34 | 3.26 (1.136) | 4.31 | < 0.01 |
| Agree | 125 | 3.94 (1.053) | | | 124 | 4.11 (0.981) | | |
| Service reduces number of visits to hospital [α] | | | | | | | | |
| Neutral/disagree | 35 | 3.31 (1.105) | 2.96 | 0.01 | 34 | 3.41 (1.131) | 2.94 | < 0.01 |
| Agree | 123 | 3.92 (1.053) | | | 123 | 4.03 (1.078) | | |
| Service has complicated registration steps [β] | | | | | | | | |
| Disagree | 37 | 3.97 (1.040) | 2.22 | 0.11 | 37 | 4.27 (0.838) | 7.31 | < 0.01 |
| Neutral | 88 | 3.84 (0.958) | | | 88 | 3.98 (0.971) | | |
| Agree | 26 | 3.42 (1.361) | | | 26 | 3.27 (1.457) | | |
| Service has too many rules & regulations [β] | | | | | | | | |
| Disagree | 40 | 4.05 (1.154) | | 0.07 | 40 | 4.40 (0.810) | 7.15 | < 0.01 |
| Neutral | 83 | 3.78 (0.884) | 2.72 | | 83 | 3.79 (1.068) | | |
| Agree | 24 | 3.42 (1.381) | | | 24 | 3.46 (1.285) | | |
| Prefer pharmacy give full supply [α] | | | | | | | | |
| Neutral/disagree | 65 | 3.83 (0.961) | 0.16 | 0.87 | 65 | 3.91 (1.011) | 0.13 | 0.90 |
| Agree | 86 | 3.80 (1.136) | | | 86 | 3.93 (1.135) | | |
| Confident correct medicines dispensed [α] | | | | | | | | |
| Neutral/disagree | 47 | 3.49 (1.231) | 2.59 | 0.01 | 47 | 3.77 (1.108) | 1.25 | 0.21 |
| Agree | 111 | 3.96 (0.937) | | | | 4.00 (1.057) | | |
| Service reduces interaction with pharmacist [α] | | | | | | | | |
| Neutral/disagree | 80 | 3.74 (1.016) | 1.03 | 0.31 | 80 | 3.89 (1.019) | 0.48 | 0.63 |
| Agree | 71 | 3.92 (1.118) | | | 71 | 3.97 (1.146) | | |
| Service helps improve my compliance [α] | | | | | | | | |
| Neutral/disagree | 54 | 3.69 (0.865) | 1.22 | 0.22 | 54 | 3.72 (1.017) | 1.76 | 0.08 |
| Agree | 102 | 3.90 (1.139) | | | 101 | 4.04 (1.094) | | |

[α] Independent t-test. Respondents who answered neutral/disagree were combined so that normality assumption was satisfied.
[β] One-way ANOVA

**Discussion**

This study elucidates the awareness and perception regarding two new VAS variants, namely Scan and Collect and WhatsApp and Collect, which were recently implemented in Sarawak General Hospital to facilitate the collection of repeat medications among eligible patients not using the services. To the best of our knowledge, there was no known evaluation, or even description of these services in the literature.

The results showed that slightly less than half of the respondents surveyed were aware of either one or both services, which was not unexpected as the services were still at an early implementation phase. Nearly all patients gained awareness of the service from the pharmacy staff. Having a varied set of promotional methods is likely to improve the awareness level, such as via word of mouth by family members, friends and doctors, promotional banners and social media (10-11,13). In particular, modern telecommunication and electronic media, which enabled the creation of these VAS, should be exploited to facilitate their adoption (14). As the utilization of these VAS was found to be affected by the lack of understanding on how to use the services, this aspect should be emphasised. Simplifying the registration process as well as related regulations may improve the uptake of this service. Easy to understand diagrams or flow-charts on how to use both VAS should also be made available, as well as active demonstration or guidance for uninitiated patients. Once acquainted with the proper knowledge and know-hows to utilise the services, they are more likely to continue using them (15).

Findings of this study revealed that most respondents perceived the new VAS as time-saving and convenient. This was consistent with the intention of introducing VAS in Malaysia government facilities, and in concordance with other studies which reported positive customer satisfaction as the service reduced waiting time (4,8,13,16). Despite this, concerns on the perceived lack of interaction with pharmacy staff need to be addressed, as personalised services cannot be sacrificed for convenience in healthcare provision (17). For these two novel VAS, this concern is misplaced, as both services preserve the nature of the dispensing process with the added benefit of skipping queues and saving time. Collection of medicines is carried out at a dedicated counter, with the dispensing pharmacist available to provide patient-oriented care and counselling to patients or their carers, as well as answering queries. Besides, the intended patients for VAS are those who are already counselled and well-versed with their long-term medications (14). This needs to be clarified while promoting the services to avoid future misconceptions. Most respondents also agreed that these VAS help to improve compliance as they are more likely to refill prescriptions on time, suggesting that facilitation of repeat medication collection does encourage compliance towards medications (18).

Respondents who perceived the new VAS as time saving, convenient and easy to use were more likely to adopt them. This further consolidated the assertion that positive attitudes toward perceived advantages of VAS enticed patients to use them (14). Understanding customers' perspectives and behaviour is essential as it provides a clearer picture of their individual inclinations, which is vital to ensure the success of new pharmaceutical service implementation (15,17). This research is thus timely, providing data to advise further improvements on the design and promotion of both VAS to enhance their relevance to the intended population. Furthermore, at the time of writing, VAS are ideal means to ensure seamless supply of medications for patients during the Covid-19 pandemic, thus expansion of these services should be considered (19).

There were several limitations in the study. The questionnaires depended on customers' self-assessment of their perceptions, which could be subjected to recall bias, and filling the questionnaire in the presence of government pharmacists may result in acquiescence and social desirability biases. Based on the responses, the lack of parking spaces was the major barrier complicating medication collection, suggesting that drive-thru pharmacy, which had yet to be introduced in SGH during data collection, may be a more suitably tailored VAS option. Nevertheless, most of the issues identified in this study are fundamental information which can serve as references for future VAS implementation.

**Conclusion**

This study showed that nearly half of the respondents were aware of the new VAS implemented. Perceptions towards the service were mainly positive. Practically, the study will serve as reference for other outpatient or ambulatory pharmacy departments interested in implementing similar services, providing insights on patients' level of awareness, perception, receptiveness, likelihood to adopt as well as potential barriers faced. These findings will ideally provide help and support for future decision-making regarding improvements on service uptake, allowing for a more targeted approach to be taken towards optimising pharmacy service delivery.

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# Evaluation of Knowledge on Pharmaceutical Regulatory among Pharmacists in Kedah

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## Abstract

**Introduction:** One of public service pharmacists' routine job is to educate the public by disseminating accurate information under the QUMC programme. However, their level of understanding in pharmaceutical regulatory aspect remains limited to ensure only quality, safe and efficacious products been consumed, access to approved medicinal advertisements and increase consumers awareness on the usage of registered products/cosmetics.

**Objectives:** This study aimed to assess pharmacist's knowledge on medicine registration, cosmetic notification and medicinal advertisement, and also to compare their knowledge based on demographic background.

**Method:** A cross-sectional study that recruited all pharmacists from 21 facilities in Kedah from December 2018 to February 2019 was conducted using a validated self-administered questionnaire. The questionnaire consisted three parts, with eleven questions on medicine registration, eight questions on cosmetic notification and eight questions on medicinal advertisement, respectively. One score was given for each correct answer. The level of knowledge was categorised as Good (>22 scores), Moderate (17-21 scores) and Low (<16 scores).

**Results:** This study was participated by all 476 pharmacists in Kedah and recorded 100% response rate. Majority of the respondents were female (80.7%), without experience in pharmacy enforcement (95.4%), working in hospital (56.7%) and had averagely serviced for 6.8 years. On average, their mean knowledge score was 17.8 (±2.4), with mean score 7.6 (±1.3) for medicine registration, 4.6 (±1.2) for cosmetic notification and 5.6 (±1.1) for medicinal advertisement. There were significant associations between knowledge score with their gender (p=0.014), enforcement experience (p=<0.001), workplace (p=0.005) and years of services (p=0.02).

**Conclusion:** The study revealed that pharmacists' pharmaceutical regulatory knowledge was moderate. Current study suggested that there was a necessity to strengthen the existing trainings and implement continuous education on pharmaceutical regulatory periodically for every pharmacist.

**Keywords:** pharmacist's knowledge, medicine registration, cosmetic notification, medicinal advertisement

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## Introduction

The roles of pharmacists have expanded beyond dispensing and packaging. Nowadays, pharmacists are often referred to ensure the rational use of drugs, improve clinical outcomes and promoting health status by working with the public and other healthcare professionals. In the Ministry of Health Malaysia (MOH), pharmacy services have been expanded from the conventional inpatient and outpatient pharmacy to Clinical Pharmacy Service, Medication Therapy Adherence Clinic (MTAC), Home Care Pharmacy Services (HCPS) which was formerly known as Home Medication Review (HMR), Nonsterile Pharmacy, Clinical Pharmacokinetic Services, Oncology Pharmacy Service, Parenteral Nutrition Service, Methadone Replacement Therapy, Drug Information Enquiry Service, Nuclear Pharmacy Service, and Procurement and

Supply Services (1-3). In addition, pharmacists in the major hospitals provide drug and poison information to healthcare professionals and the public (4).

In Malaysia, the Malaysian National Medicines Policy (MNMP) was implemented to promote equitable access to, and rational use of safe, effective and affordable essential drugs of good quality to improve health outcomes of the people. The MNMP emphasized that the compliance with the standards shall be supported by legislation where appropriate. Relevant legislations or regulations shall be developed and reviewed regularly to ensure an efficient supply chain network and integrated medicines management to safeguard the public. Independent, high quality, evidence-based information shall be made readily available to healthcare providers via continuing education programmes, unbiased promotion of medicines and linkages to the National Drug Information Centre and other relevant health portals (5).

One of the MNMP strategies was to include principles of safe, appropriate and quality use of medicines in the curricula for the education and training of all healthcare providers involved in medication management (5). In 2007, the MOH Pharmaceutical Services Programme launched the Know Your Medicines Campaign to increase consumers' understanding, awareness on medication and educate the public on rational use of medicines. The MOH pharmacists-led training and educational activities of the campaign include training of trainers for *Duta Kenali Ubat Anda* (Know Your Medicines Ambassadors), exhibitions and talks, continuous promotion through mass media, and home visit (*Duta Prihatin Masyarakat*). The programme was built not only for healthcare providers, but also for the community to play their roles in promoting equitable access and rational use of medicine (6).

In health education curricula and activities, pharmacists are often involved as trainers, speakers and researchers. Pharmacists are responsible to advise patients about medicines, including how to take them, what reactions may occur and answering patients' questions. Pharmacists also advise other healthcare professionals about safe and effective medicines use while ensuring safe and secure supply of medicines (7). Pharmacists are regarded as the platform in providing the legitimate source of medicine information. Therefore, pharmacist's must be knowledgeable about the regulatory control of medicines, cosmetics and medical advertisement to ensure that they are providing and disseminating accurate, unbiased and relevant information to public. To date, nevertheless, limited studies were conducted in Malaysia to evaluate the pharmacists' knowledge on the laws and regulations of medicines, cosmetics and medicinal advertisements. Therefore, this study aimed to assess the knowledge of pharmacists who were working in the government setting in the state of Kedah about medicine registration, cosmetic notification and medicinal advertisement, and to compare their knowledge based on their demographic characteristics.

**Method**

*Study type and design*

This study was a cross-sectional study using a self-administered questionnaire among fully-registered pharmacists who were working in government health facilities in Kedah. There were 81 health facilities in Kedah, which included the state health department (abbreviated as JKN), nine hospitals, eleven district health offices (abbreviated as PKD) and sixty health clinics (abbreviated as KK) from eleven districts in the state.

All the 81 health facilities in Kedah were divided among one principal investigator and four co-investigators. All the government sector pharmacists were distributed with the information sheet of the study after the written permission of the chief pharmacist in each health facility was obtained. They were requested to contact the investigators within seven days of being informed by their Chief Pharmacists if they were interested to participate in the study. An appointment was made where the study information sheet (or written consent form) in both English and Malay languages were provided and explained to them by the investigators at the study site. The written consent forms were signed and personally dated by the respondents before participating in this study. The Chief Pharmacists from every study sites were responsible to schedule the date and time for the respondents based on their availability and informed to investigators verbally in order to conduct the data collection in several sessions. The pharmacists were required to self-answer the questionnaire without any references within 30 minutes after the informed consent process during the data collection sessions.

Ethics approval and permission to collect data were acquired from the Medical Research & Ethics Committee (MREC), Ministry of Health Malaysia before data collection was initiated (NMRR-18-2696-43394 (IIR)).

*Sample size*

Based on a population of 476 public sector fully-registered pharmacists in Kedah (information provided by the Pharmacy Management Branch, Kedah State Health Department), the sample size was calculated using Raosoft® sample size calculator (margin of error 5%, confidence level 95%, response distribution 50%) which yielded the minimum sample size of 213 participants (9). Non-probabilistic quota sampling was conducted since all fully-registered pharmacists were included in this study. The inclusion criteria included all fully registered pharmacists under the Pharmaceutical Service Programme, MOH in Kedah during the period from 1 December 2018 to 28 February 2019. Pharmacists who worked in the Kedah Pharmacy Enforcement Branch, and pharmacists who were on any leave (e.g. maternity leave, study leave, sick leave, or unrecorded leave) for more than three months consecutively were excluded.

*Study instrument*

This was a validated, self-administered 27-item questionnaire to measure the level of knowledge on pharmaceutical regulatory among the pharmacists. The knowledge domain were divided into three parts. There were 11 questions measuring the knowledge on medicine registration (Part A), 8 questions focusing on cosmetic notification (Part B) and 8 questions addressing information regarding medicinal-related advertisement (Part C). Demographic characteristics questions were also included in this questionnaire. Each correct answer in the knowledge domain carried 1 score while incorrect or blank answer carried 0 score. This gave a score range from 0 to 27 for the overall knowledge domain. The knowledge were categorised as Low (score 16 and less), Moderate (score between 17 to 21) and Good (score 22 and more). The questions of medicine registration were adapted from two Malaysian studies (8, 9), while the questions on cosmetic notification and medicinal-related advertisement were adopted from relevant Acts including the Control of Drugs and Cosmetics Regulations 1984 and Medicines (Advertisement & Sale) Act 1956 (10) and guidelines issued by National Pharmaceutical Regulatory Agency (NPRA) and Medicine Advertisements Board (MAB) (11-13). The content of questionnaire was thoroughly validated by an expert review panel which consisted of the Kedah Deputy Director of Health (Pharmacy), Head of Pharmacy Enforcement Branch and Head of Pharmacy Practice and Development Branch. Then, five pharmacists from the Kedah State Health Department were invited to conduct face validation to ensure that the questions were not ambiguous. To test the reliability, a pilot study was conducted among 33 randomly selected pharmacists from Sultan Abdul Halim Hospital, Sungai Petani, Kedah before data collection was initiated (14).

*Statistical analysis*

Data were analysed using Statistical Package for Social Sciences software (SPSS) version 16 and Excel spreadsheet. Initially, all information collected was coded into variables and the normality of data was tested using histogram. The knowledge scores were descriptively expressed as mean and standard deviation (SD). Inferential statistics involving independent t-test and one-way ANOVA test were used for analysis of normally distributed demographic characteristics. Simple Logistic Regression was also used to determine the magnitude of association between independent and outcome variables in term of odds ratio (OR). A p-value of less than 0.05 was considered statistically significant.

**Results**

The internal consistency (reliability) of the questionnaire was 0.601 (Cronbach's alpha) and was deemed acceptable by the investigators (15). A total of 476 questionnaires were distributed to all pharmacists from the 81 government health facilities in Kedah and all 476 were returned, giving a response rate of 100%. Majority of the respondents were female (80.7%), Malay (62.2%), and most of them did not have pharmacy enforcement (95.4%) and regulatory experience (99.6%) (Table 1).

Table 2 showed that the mean knowledge score was 17.8 (SD 2.4). Majority of the respondents (67.0%) had moderate knowledge on pharmaceutical regulatory and only 5.3% had good knowledge level. The mean scores for Medicine Registration (Part A), Cosmetic Notification (Part B) and Medicinal Advertisement (Part C) were 7.6 (SD 1.3) out of 11 questions, 4.6 (SD 1.2) out of 8 questions and 5.6 (SD 1.1) out of 8 questions respectively (Table 3).

Most respondents (99.4%) knew the two main features that needed to be displayed on the package of a registered medicine and 469 respondents (98.5%) knew that *Meditag*[TM] *decoder* was a tool to check the authenticity of the hologram label and thus indicates the respondents knew well how to identify the

regulatory features on registered pharmaceutical product in Malaysia. Nevertheless, only 239 respondents (50.2%) had knowledge on regulatory control of veterinary product in Malaysia and only 128 respondents (26.9%) knew that Drug Control Authority (DCA) was responsible for product registration in Malaysia.

In terms of cosmetic notifications, 433 respondents (91.0%) knew that cosmetics should not contain claims with medicinal purposes and 370 respondents (77.7%) could recognise cosmetic notification number as a proof of notification in Malaysia. Only 34 respondents (7.1%), however, knew that the Senior Director of Pharmaceutical Services was the correct Competent Authority that is responsible for the cosmetic notification. For medicinal advertisement, the result shows that 453 respondents (95.2%) were aware of the requirement to display advertisement's approval number on medicine's advertisement, but only 93 respondents (19.5%) answered correctly for the validity period for an approved advertisement, which is 3 calendar years in accordance to Medicine Advertisement Board, Ministry of Health Malaysia.

This study had further compared knowledge of pharmacists by their demographic characteristics (Table 4). Male respondents (mean score 18.4 with SD 2.5) had higher knowledge score than female respondents (mean score 17.7 with SD 2.3) ($p=0.014$). Pharmacists with previous pharmacy enforcement experience (mean score 20.0 with SD 2.3) had better knowledge comparing to pharmacists that never worked in pharmacy enforcement (mean score 17.7 with SD 2.3) ($p<0.001$). The simple logistic regression showed that pharmacists who worked in pharmacy enforcement previously had higher odds to be knowledgeable in pharmaceutical regulatory compared others without pharmacy enforcement experience (OR 8.52, 95% CI 1.13-63.97, $p=0.037$) (Table 5).

The one way ANOVA test showed statistical significance that pharmacists who worked at state health department (mean score 20.1 with SD 2.6) had higher knowledge score as compared to three other facilities ($p=0.005$) (Table 4). The Scheffé post-hoc test further showed that the knowledge score in pharmacists who worked at state health department were statistical significantly higher than pharmacists who worked in hospital, district health offices and health clinics ($p<0.05$) (Table 6).

Majority of the respondents (83.6%) have working experience of less than 11 years. One way ANOVA test showed statistically significant difference in knowledge score by the years of services ($p=0.02$). Furthermore, inspection of scatter plots between duration of service and mean scores showed homoscedasticity. Therefore, a Pearson's correlation was run on the data. The result, however, showed only a weak positive correlation between the two variables ($r=0.167$, $p=<0.001$) (Table 8).

Table 1: Demographic characteristics of pharmacists in government sector in Kedah (n=476)

| Variable | n (%) | Mean (SD) |
|---|---|---|
| Age, years | | 31.3 (4.7) |
| Gender | | |
| Female | 384 (80.7) | |
| Male | 92 (19.3) | |
| Ethnicity | | |
| Malay | 296 (62.2) | |
| Chinese | 155 (32.6) | |
| Indian | 25 (5.3) | |
| Workplace | | |
| JKN | 12 (2.5) | |
| Hospital | 270 (56.7) | |
| PKD | 46 (9.7) | |
| KK | 148 (31.1) | |
| Service duration, years | | 6.8 (4.7) |
| Pharmacy enforcement experience | | |
| Yes | 22 (4.6) | |
| No | 454 (95.4) | |
| NPRA experience | | |
| Yes | 2 (0.4) | |
| No | 474 (99.6) | |

Abbreviation: SD – standard deviation; JKN – state health department; PKD – district health office; KK – health clinic; NPRA – National Pharmaceutical Regulatory Agency.

Table 2: Pharmacist's overall level of knowledge on pharmaceutical regulatory (n=476)

| Level of knowledge | n (%) | Score, mean (SD) |
|---|---|---|
| | | 17.8 (2.4) |
| Low (score ≤ 16) | 132 (27.7) | |
| Moderate (score 17 to 21) | 319 (67.0) | |
| Good (score ≥ 22) | 25 (5.3) | |

Abbreviation: SD – standard deviation.

Table 3: Pharmacist's knowledge on medicine registration, cosmetic notification and medicinal advertisement (n=476)

| Domain | Correct answer, n (%) | Incorrect / blank answer, n (%) | Score, mean (SD) |
|---|---|---|---|
| Part A: Medicine Registration | | | 7.6 (1.3) |
| 1) Features of Registration | 473 (99.4) | 3 (0.6) | |
| 2) Hologram's Version | 129 (27.1) | 347 (72.9) | |
| 3) Hologram Label | 218 (45.8) | 258 (54.2) | |
| 4) OTC Medicine | 385 (80.9) | 91 (19.1) | |
| 5) Fake Registration | 260 (54.6) | 216 (45.4) | |
| 6) Controlled Medicine | 446 (93.7) | 30 (6.3) | |
| 7) Traditional Medicine | 464 (97.5) | 12 (2.5) | |
| 8) Veterinary Medicine | 239 (50.2) | 237 (49.8) | |
| 9) Hologram Authenticity | 469 (98.5) | 7 (1.5) | |
| 10) Competent Authority | 128 (26.9) | 348 (73.1) | |
| 11) Vitamin C Injection | 418 (87.8) | 58 (12.2) | |
| Part B: Cosmetic Notification | | | 4.6 (1.2) |
| 1) Function | 433 (91.0) | 43 (9.0) | |
| 2) Notification Number | 370 (77.7) | 106 (22.3) | |
| 3) Packaging Label | 118 (24.8) | 358 (75.2) | |
| 4) Website | 463 (97.3) | 13 (2.7) | |
| 5) Competent Authority | 34 (7.1) | 442 (92.9) | |
| 6) Prohibition | 221 (46.4) | 255 (53.6) | |
| 7) Safety & Quality | 122 (25.6) | 354 (74.4) | |
| 8) Manufacturing | 445 (93.5) | 31 (6.5) | |
| Part C: Medicinal Advertisement | | | 5.6 (1.1) |
| 1) Approval | 453 (95.2) | 23 (4.8) | |
| 2) Competent Authority | 404 (84.9) | 72 (15.1) | |
| 3) Approval Number | 351 (73.7) | 125 (26.3) | |
| 4) Validity Period | 93 (19.5) | 383 (80.5) | |
| 5) 20 Prohibited Diseases I | 469 (98.5) | 7 (1.5) | |
| 6) 20 Prohibited Diseases II | 294 (61.8) | 182 (38.2) | |
| 7) Example of Advertisement I | 152 (31.9) | 324 (68.1) | |
| 8) Example of Advertisement II | 426 (89.5) | 50 (10.5) | |

Abbreviation: SD – standard deviation.

Table 4: Pharmacist's knowledge score on pharmaceutical regulatory based demographic characteristics (n=476)

| Demographic Characteristics | n (%) | Score, mean (SD) | t * / F # statistics (df) | p-value |
|---|---|---|---|---|
| Gender | | | 2.5 (474) | 0.014 * |
| Male | 92 (19.3) | 18.4 (2.5) | | |
| Female | 384 (80.7) | 17.7 (2.3) | | |
| Pharmacy enforcement experience | | | 4.6 (474) | <0.001 * |
| Yes | 22 (4.6) | 20.0 (2.3) | | |
| No | 454 (95.4) | 17.7 (2.3) | | |
| Workplace | | | 4.3 (3, 472) | 0.005 # |
| JKN | 12 (2.5) | 20.1 (2.6) | | |
| Hospital | 270 (56.7) | 17.7 (2.4) | | |
| PKD | 46 (9.7) | 17.7 (2.3) | | |
| KK | 148 (31.1) | 17.9 (2.3) | | |
| Service duration | | | 3.0 (4, 471) | 0.02 # |
| 0.00 – 2.99 years | 102 (21.4) | 17.5 (2.3) | | |
| 3.00 – 6.99 years | 148 (31.1) | 17.4 (2.3) | | |
| 7.00 – 10.99 years | 148 (31.1) | 18.1 (2.3) | | |
| 11.00 – 13.99 years | 41 (8.6) | 18.2 (2.8) | | |
| 14.00 – 34.99 years | 37 (7.8) | 18.6 (2.2) | | |

Abbreviation: SD – standard deviation; df – degrees of freedom;  JKN – state health department; PKD – district health office; KK – health clinic
* independent t-test; # One way ANOVA test

Table 5: Association between knowledge score on pharmaceutical regulatory and pharmacy enforcement experience (n=476)

| Pharmacy enforcement experience | n (%) | Score, mean (SD) | OR | 95% CI | p-value $ |
|---|---|---|---|---|---|
| Yes | 22 (4.6) | 20.0 (2.3) | 8.52 | 1.13-63.97 | 0.037 |
| No | 454 (95.4) | 17.7 (2.3) | 1.00 | | |

Abbreviation: OR – odds ratio; CI – confidence interval; SD – standard deviation.
$ Simple logistic regression

Table 6: Pairwise comparisons of knowledge score on pharmaceutical regulatory by workplace (n=476)

| Workplace | Mean difference (x) in score | p-value π |
|---|---|---|
| JKN vs Hospital | 2.5 | 0.006 |
| JKN vs PKD | 2.5 | 0.016 |
| JKN vs KK | 2.3 | 0.016 |
| Hospital vs PKD | | 1.000 |
| Hospital vs KK | | 0.887 |
| PKD vs KK | | 0.976 |

Abbreviation: SD – standard deviation; JKN – state health department; PKD – district health office; KK – health clinic; vs – versus.
π Post-hoc test using Scheffé procedure

Table 7: Correlation between service duration and knowledge score on pharmaceutical regulatory (n= 476)

| Variable | Mean (SD) | r | p-value [ø] |
|---|---|---|---|
| Service duration, year | 6.8 (4.7) | 0.167 | <0.001 |
| Score | 17.8 (2.4) | | |

Abbreviation: SD – standard deviation
[ø] Pearson Product-Moment Correlation

## Discussion

In this study, pharmacfists' knowledge on pharmaceutical regulatory were measured using a questionnaire that was adapted from previous studies and the relevant laws and guidelines. The Chronbach's alpha value of the questionnaire was 0.601 based on a pilot sample of 33 pharmacists. The investigators considered the questionnaire as having sufficient internal consistency as according to Saeed and Kassim (2017), composite reliability values of 0.60 to 0.70 are acceptable for exploratory research (15). The response rate of this study was 100%, with all the 476 distributed questionnaires answered. The very high response rate might be due to the commitment by the chief pharmacists in all study sites to facilitate the survey sessions. In addition, face-to-face personnel meeting of researchers with the respondents and limiting the survey response time to 30 minutes may have helped to ensure the response rate.

In this study, the pharmacist's knowledge score was divided into three categories which is good (above 80% - score 22 and more), moderate (between 60 to 79.9% - score between 17 to 21) and low (less than 59.9% - score 16 and less) in accordance to the category of performance in the appraisal system for public service officers that suggested by Public Service Department (16). Besides, Pharmacy Board, Ministry of Health Malaysia also set that every Provisionally Registered Pharmacist (PRP) shall obtain at least 60% for all sections and average of overall score of at least 60% for the purpose of full registration in accordance with the Registration of Pharmacists Act 1951 (1,10). The results of this study indicated that Kedah public service pharmacist's overall knowledge on pharmaceutical regulatory were in moderate level. Specifically, the knowledge of pharmacist in Kedah on medicine registration and medicinal advertisement was at moderate level (69.1% and 70% respectively) while their knowledge on cosmetic notification was at low level (57.5%).

Pharmacists in the government sector should have good knowledge on medicine registration, cosmetic notification and medicinal advertisement because pharmacists are always the first point of contact for public enquiries regarding the rational use of medicines. Better knowledge will help them in providing timely and accurate information to the public to choose safe, quality and efficacious medication, hence decrease the demand of adulterated and counterfeit drugs. Hanafi *et al.* (2013) had concluded that good knowledge is a prerequisite for good pharmacy practice. Enhancing our pharmacists' knowledge and attitude is parallel with the increase in the quality of their practice. It provides important clues for national pharmaceutical organisations to organise educational programmes for the community pharmacists to equip them for their important role in community practice which is promoting rational drug use (17).

Woodcock (2004) from Food and Drug Administration (FDA) explained the acceptable quality of pharmaceutical products, which is also known as drug quality, as one that meets its established quality attributes and standards and has been manufactured in accordance with Current Good Manufacturing Practices (CGMPs) as stated in the Federal Food, Drug, and Cosmetic Act (18). Based on our results, 99.4% of the pharmacists were able to identify the two features to differentiate a registered pharmaceutical product from an unregistered pharmaceutical product or counterfeit pharmaceutical product. These two features are registration number MAL and Meditag[TM] Hologram, which are compulsorily imprinted on the outer packaging of every pharmaceutical product. The ability to identify the features of registered pharmaceutical products has enabled the public and relevant authorities to identify those registered pharmaceutical products (19).

To ensure the integrity of the pharmaceutical products, all advertisements of registered pharmaceutical products need to be approved by Medicine Advertisement Board (MAB) to ensure that all the medicinal information presented to the public are accurate and not misleading and also increase the consumers' awareness on the usage of the registered products (1). The World Health Organization (2002)

also agreed that monitoring and regulating medicine promotion is one of the regulatory measures to support rational use of medicines to ensure that it is ethical and unbiased and thus all promotional claims should be reliable, accurate, truthful, informative, balanced, up-to-date, capable of substantiation and in good taste (20). According to the Pharmacy Programme Statistics Report 2019, a total of 9,248 medicinal related advertisements been approved by the Medicine Advertisement Board (MAB) from year 2017 to 2019 (21).

The cosmetic industry in Malaysia is growing rapidly. Chemical substances were commonly used to replace the natural ingredients in this new era to increase its production through the use of technology and innovation. Therefore, the abundance of cosmetic products in market could pose some safety risks to the consumers (22). Thus, pharmaceutical regulatory plays an important role to ensure that pharmaceutical products and cosmetics in the market are genuine in terms of registration and notification to reduce the demands for unsafe or hazardous products (1). Based on the Pharmacy Programme Statistics Report 2019, a total of 1,859 registered pharmaceutical products were rejected, cancelled, recalled and withdrawn by Drug Control Authority (DCA) from a total of 4,237 registered products from year 2017 to 2019. There was also a total of 214,128 notified cosmetics in 2019. Out of 230,505 applications, 9,854 cosmetics were rejected and cancelled by the Senior Director of Pharmaceutical Services from years 2018 and 2019. Based on the samples taken in Post Marketing Surveillance Programme, 54 cosmetic products were found to be adulterated with scheduled poisons listed in the Poisons Act 1952, such as hydroquinone, mercury, tretinoin, chloramphenicol, betamethasone, triamcinolone and diphenhydramine, which can endanger the public's health upon consumption. Their notifications were cancelled by Senior Director of Pharmaceutical Services (21). Thus, pharmacists should be equipped with adequate knowledge regarding medicine registration, cosmetic notification and medicinal advertisement as an awareness and to educate public timely regarding pharmaceutical and cosmetics safety.

This study also aimed to compare the pharmacist's knowledge on the medicine registration, cosmetic notification and medicinal advertisement based on their demographic characteristics. There were four main findings that were highlighted in this study. Firstly, we found that male pharmacists scored significantly higher than female pharmacists. A similar behaviour was observed in several previous studies in which men tend to have better general knowledge than females (23-25).

The second characteristics that with statistically significant difference in the knowledge of pharmacists was previous working experience as Pharmacy Enforcement Officer.  Those experienced in pharmacy enforcement had better knowledge than those who never worked in pharmacy enforcement field. The simple logistic regression further confirmed the observation. This result was in line with a study conducted by Schmidt *et al.* (1986) that the impact of job experience on job knowledge is stronger than its impact on work sample performance (26).

Thirdly, there was a statistically significant difference that pharmacists working in the Kedah State Health Department obtained higher knowledge scores than pharmacists working in hospitals, district health offices and health clinics. The pharmacists working in the state health department often collaborated with the Pharmacy Enforcement Branch (PEB) in organising various public education and awareness activities as the PEB is also a branch under the state health department and located in the same building. Exposure to this collaboration to some extent may have contributed to the better knowledge of pharmacists who worked in state health department. The collaboration among members in the team is important and the performance of the team tends to improve when the members of the team emphasize to work together (27). Ting *et al.* (2017) also revealed that the awareness of Royal Malaysian Customs (RMC) officers towards counterfeit pharmaceutical products were sufficient through the collaboration with PEB officers (19).

Finally, this study also was observed that the knowledge of pharmacists on pharmaceutical regulatory increased by the duration of service. A study by Kotur *et al.* (2014) indicated that the performance of the employees gradually improved with their experience but after 20 years the performance might deteriorate (28). Ting *et al.* also concluded that RMC officers who have worked for more than 10 years had significantly greater awareness towards counterfeit pharmaceutical products compared to those with less experience (19).

The results of this study may be influenced by some limitations. The smaller number of male respondents, respondents who worked in state health department and respondents with pharmacy enforcement experience may be the limiting factors. Since the study participants were only from Kedah's public sector, the sample population did not fully represent all pharmacists in Malaysia. Therefore, this study could be expanded nationwide in the future by using online questionnaire, and also to include the community pharmacists.

According to our findings, pharmacists' knowledge on pharmaceutical regulatory needs to be improved and to optimise the quality of services to the public. The delivery of accurate, unbiased and relevant information will guide the public or patients to use safe, quality and effective medicines and cosmetics, thus protecting public's health and ensure better treatment outcome. Continuous training on regulatory updates of medicines, cosmetics and medicinal advertisements' modules can be conducted periodically for every pharmacists especially who were involved in the QUMC activities through organizing Training of Trainers (TOT) workshop more frequently. Satisfaction surveys can also be suggested to understand and explore the needs from public in terms of information requirement regarding medicines, cosmetics and medicinal advertisements after the each conducted QUMC activities. Ongoing training for fresh graduate pharmacists needs to be conducted as pharmacists are always the symbolic icon of medicine. These recommendations were in line with Hallit *et al.* (2019) who recommended trainings and workshops for all pharmacists to increase the pharmacists' awareness to good practices and improve the quality of care (29).

**Conclusion**

Pharmacists' knowledge on pharmaceutical regulatory was moderate and were particularly low with regards to regulation of cosmetics. Their average knowledge score was 17.8 out of 27, which was equivalent to 65.9%. There were statistically significant associations between pharmacists' pharmaceutical regulatory knowledge with gender, pharmacy enforcement experience, workplace and duration of service. This study suggested the necessity to strengthen existing trainings techniques and implement continuous educations for the pharmacists to improve their knowledge on pharmaceutical regulatory and thus optimise the quality of QUMC services to the public.

**Conflict of Interest Statement**

This study did not receive any funding from public, commercial or non-profit organisations. The authors declared no conflict of interest.

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# A Cross Sectional Study: Prevalence of Repeated Offences by Licensed Premises under the Purview of Pharmaceutical Services Division, Kedah

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**Abstract**

**Introduction**: The Ministry of Health Malaysia pharmacy enforcement services are responsible in ensuring that all licensed premises within their purview adhere to all rules and regulations. Warning letters issued after unsatisfactory inspection serve as an official notification to the licensed premises on the violation of the Malaysian laws on poisons and sale of drugs and related regulations.

**Objective**: This study aimed to describe the offences committed by licensed premises under the purview of Kedah Pharmaceutical Services Division and to evaluate the association between repeated offences and the characteristics of the licence holders.

**Method**: Warning letters issued to the licensed premises over a two-year period from 2017 to 2018 was retrieved and reviewed. Information about the premises, characteristics of the licence holders, and repeated offences were recorded.

**Result**: Out of 409 licensed premises, a total of 71 premises were issued with regulatory letters with 83 offences recorded. The most common offences in 2017 were the violations of Poisons (Psychotropic Substances) Regulations 1989 (n=22, 26.50%), specifically on Regulation 15 (n=16, 19.3%) that involved the non-compliance to the terms and conditions specified in to the Permit to Purchase and Use Psychotropic Substances (Methadone and Buprenorphine). A total of 15 (21.1%) premises were found to commit repeated offences (15 offences) in 2018 despite the issuance of warning letter in the previous year. In terms of licence type, holders of Permit to Purchase and Use Psychotropic Substances (Methadone and Buprenorphine) recorded the highest percentage (80.0%) of repeated offences. Age (p=0.001) and years of holding licence (p=0.001) had significant associations with the prevalence of repeated offence.

**Conclusion:** The prevalence of repeated offences in Kedah is considered low with most of the license premises being able to comply with the law during inspection the following year after receiving regulatory letters.

**Keywords**: prevalence, poisons, warning letters, offences, enforcement

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## Introduction

The World Health Organization (WHO) defined drug regulation as a process that encompasses various activities aimed at promoting and protecting public health by ensuring the safety, efficacy and quality of drugs, as well as the accuracy of information. Medicines regulation is a key instrument employed by many governments to ensure that all these objectives can be achieved. Stringent drug regulation was introduced in many countries in the 1960s following the thalidomide disaster and had since been embraced by the industry as a commercial essential seal of safety and quality (1). Regulations are the basic devices employed by most governments to protect the public against substandard, counterfeit and low quality medicines. In Malaysia, there are five acts related to the control of pharmaceuticals that are being enforced by the Ministry

of Health Malaysia (MOH). They are the Poisons Act 1952 (PA 1952), Sale of Drugs Act 1952 (SODA 1952), Registration of Pharmacists Act 1951 (ROPA 1951), Medicines (Advertisement and Sale) Act 1956 (MASA 1956), and Dangerous Drugs Act 1952 (DDA 1952), and the related regulations (2).

The Pharmacy Enforcement Division (PED) in the MOH headquarters is responsible for the protection of the public's health by ensuring that pharmaceuticals, traditional and cosmetics that are available in the market are genuine in terms of registration and notification. It ensures that the supply, marketing, advertising and usage of the pharmaceutical products (including the medical services) comply with the provisions of legislations (3). The PED is supported by Pharmacy Enforcement Branches (PEB) under the Pharmaceutical Services Divisions in every state. The PEBs carry out intelligence activities, raids, audits on controlled medicines, licensing and inspections, prosecutions in the court, monitoring medical advertisements and conducting investigation in cases involving violation of acts in force.

Licensing is one of the main activities conducted by PEBs in every state. Licences are usually granted for a period of one year and may be renewed at the end of December every year. There are seven types of licences and permits being issued by PEBs under the Poisons Act 1952, namely Licence A, Licence B, Licence E, Permit to Purchase Store and Use of Sodium Hydroxide (abbreviated as Permit NaOH), Permit to Purchase and Use Psychotropic Substances (Methadone and Buprenorphine) (abbreviated as Permit Methadone & Buprenorphine), Permit to Purchase and Use Psychotropic Substances for Industry), and Permit to Purchase and Use Psychotropic Substances (Management of wildlife / animal). Type A Licence is issued to a pharmacist to import, store, and sale or supply registered medicines (Poisons) by wholesale and retail. Type B License is issued to a person or company to import, store and sell by wholesale specific poisons, while Licence E holders can only import, store and use Sodium Hydroxide. The Permit Methadone & Buprenorphine are specifically issued for registered medical practitioners for opioid replacement therapy (2).

Licensed premises such as pharmacies, clinics, and factories are inspected at least once per year before the licences are granted or renewed. Inspections are carried out by pharmacy enforcement officers from the PEB in every state. During the inspections, they will observe for any non-compliance to the guidelines or policies, violation of acts and regulations in terms of recording, labelling, and storage of poisons, advertisements, and non-compliance to the specific requirements of the licences or permits. The acts and regulations observed in this inspection are PA 1952, Poisons Regulations 1952 (PR 1952), MASA 1956, and Control of Drugs and Cosmetics Regulations 1984 (CDCR 1984). The results of inspections should be satisfactory before the premises can proceed with licence renewal in the following year.

When the pharmacy enforcement officers found any activity or product that is suspected to be in violation of law, regulatory letters will be issued to the licence or permit holders to inform them regarding the acts or regulations that is violated and the penalties. The licence or permit holders are required to reply to the regulatory letter stating all remedial actions that were taken to address the issue. Licence renewal will be allowed for this premise when all the remedial actions had been carried out and deemed satisfactory. Overall, regulatory letter represents the PEB's first official notification to the licensed premises upon discovering a product or activity in violation of the Malaysian laws and related regulations on the regulation of pharmaceuticals (4).

Since year 2014, the number of licensed premises that has been taken legal action by the PEB, Pharmaceutical Services Division, Kedah State Health Department increased from six premises to eight premises in 2015 and 13 premises in 2016, even though inspections were carried out routinely. Most of the offences were related to inappropriate poison storage, incomplete recording of dispensed medicines or psychotropic substances, cancellation of an entry in the register and advertisements related to certain diseases, skill or services.

To date, there is limited analysis on pharmacy enforcement offences and repeated offences. Data reported routinely was limited to the number of regulatory letters issued per year while the details of offences were not analysed. Therefore, this study aimed to describe the offences committed by licensed premises that warranted the issuance of regulatory letters and to evaluate the association between repeated offences and the characteristics of the licence holders. In this study, those receiving regulatory letter will be considered as committing an offence and if they receive another regulatory letter the following year with the same offence, it will be considered as a repeated offence. The findings of this study will be useful in designing more specific approaches to create awareness or education about the regulatory requirements to licence and permit holders. Hopefully, it can also help the MOH to determine further actions and measures to reduce repeated offences.

**Method**

This is a cross sectional study that analysed the frequency and types of offences recorded in the regulatory letters issued in 2017 by the Kedah PEB to the licence or permit holders under PA 1952 which included Licence A, Licence B, Licence E, Permit NaOH, Permit Methadone & Buprenorphine, Permit to Purchase and Use Psychotropic Substances (for Industry), and Permit to Purchase and Use Psychotropic Substances (Management of wildlife / animal).

All records of regulatory letters which included Warning Letters, Reminder Letters and Notices of Violation that were issued in the period from 1 January 2017 to 31 December 2017 were reviewed. All premises that received any of these regulatory letters issued by the Kedah PEB in 2017 were included in this study. Premises that cancelled their licence or permit without any replacement, and premises that ceased operation in 2017 and 2018 were excluded from this study.

A pre-designed three-page data collection form was used in this study. The first page recorded all the information regarding the premise and licence holder. Data collected include type of license, district, number of licence holders in the premise (specifically for Licence A), ownership as well as the demographic data of the licence holder (age, gender and education background). The second page recorded the date and results of the inspection, either satisfactory or unsatisfactory. The type of offences stated in the regulatory letters and the feedback stated in explanation letters from the licence holder were also recorded. Finally, the third page consists of an attachment on coding for types of licences. All these data were then transferred to Excel sheet for analysis.

The 2018 the inspection records of the included premises were reviewed and any regulatory letters issued were recorded. If they receive another regulatory letter in 2018 with the same offence, it will be considered as a repeated offence.

Data were analysed using the Statistical Package for Social Sciences software (SPSS) version 16 and Excel spreadsheet. All information gathered was coded into variables and normality of data was tested. The frequencies of offences were expressed as numbers (n) and percentage (%). Inferential statistics including independent t-test, Fischer's Exact test and Mann-Whitney U test were used to analyse the association between repeated offences and characteristics of the licence holders, with the level of significance set at $p < 0.05$.

**Results**

There were 409 licensed premises under the purview of PEB, Pharmaceutical Services Division, Kedah in 2017. Out of these, 71 premises were issued with regulatory letters and four types of licences or permits were involved, which were Licence A, Licence B, Permit NaOH and Permit Methadone & Buprenorphine. Regulatory letters had been issued the most to Licence A holder with 30 letters and the least to Licence B holder with only 9 letters. The number of male licence holder (86.7%) as repeat offenders was higher compared to female (13.3%). This is in sync with the higher number of male licence holders (69.0%), involved in this study compared to the number of female licence holder (31.0%). Holders of Permit Methadone & Buprenorphine (80.0%) was more prone to repeating the same offence in the following year and there was no repeated offence by Permit NaOH holders despite contributing to 18.3% of offences in 2017.

From the 71 regulatory letters issued in 2017, 83 offences were recorded. Apart from the violations of acts and regulations, there were also non-compliance to guidelines or policies and terms and conditions specified in the permits (Table 2). The most frequent offences in 2017 were the violations of Poisons (Psychotropic Substances) Regulations 1989 (26.50%), specifically on Regulation 15 (n=16) that involved the non-compliance to the terms and conditions specified in Permit Methadone & Buprenorphine. Among these, condition No. 2 which specified that permit holder have to inform and send the invoices of all Methadone and Buprenorphine purchases to the Pharmacy Enforcement Branch within 14 days upon receiving the stock was the most common (n=15). In terms of repeated offences in 2018 (15 offences), non-compliance to the condition No. 2 contributed to 10 out of 11 offences under Regulation 15. The lowest offences were under CDCR 1984 with only three offences recorded and these were related to the possession of unregistered product.

Table 3 showed the associations between repeated offences and characteristics of licence holders. There were no significant association between repeated offence and gender as well as ownership. On the other hand, the mean age of licence holders with (53.9, SD 11.77) and without repeated offence (42.4, SD 11.1) was significantly different (p=0.001). Also, the duration of holding licence was significantly different

between licence holders with (median 6 years, IQR 2) and without repeated offence (median 3 years, IQR=4, *p*=0.001).

Table 1: Demographic data of licence or permit holders issued with regulatory letters in Kedah in 2017 (n=71)

| Variables | Licence holders with offence in 2017 (n=71) | | Licence holders with repeated offence in 2018 (n=15) | |
|---|---|---|---|---|
| Age, year, mean (SD) | 44.5 | (12.3) | 53.9 | (11.8) |
| Years as licence holder, median (IQR) | 4.0 | (4.0) | 6.0 | (2.0) |
| Gender, n (%) | | | | |
| Male | 49 | (69.0) | 13 | (86.7) |
| Female | 22 | (31.0) | 2 | (13.3) |
| Type of Licence, n (%) | | | | |
| Licence A | 30 | (42.3) | 2 | (13.3) |
| Licence B | 9 | (12.7) | 1 | (6.7) |
| Permit NaOH | 13 | (18.3) | 0 | |
| Permit Methadone & Buprenorphine | 19 | (26.8) | 12 | (80.0) |
| Ownership, n (%) | | | | |
| Owner | 39 | (54.9) | 12 | (80.0) |
| Employee | 31 | (43.7) | 3 | (20.0) |
| Shareholder | 1 | (1.4) | 0 | |
| Race, n (%) | | | | |
| Malay | 33 | (46.5) | 3 | (20.0) |
| Chinese | 23 | (32.4) | 4 | (26.7) |
| Indian | 12 | (16.9) | 7 | (46.7) |
| Others | 3 | (4.2) | 1 | (6.7) |

Abbreviation: Permit NaOH – Permit to Purchase Store and Use of Sodium Hydroxide; Permit Methadone & Buprenorphine – Permit to Purchase and Use Psychotropic Substances (Methadone and Buprenorphine); SD – standard deviation; IQR – interquartile range.

Table 2: Type of offences recorded in the regulatory letters issued in 2017 (n=83)

| Acts / Regulations | Offence in 2017, n (%) | Repeated Offence in 2018, n (%) |
|---|---|---|
| **Poison Act 1952** | **18  (21.68)** | **3  (20.00)** |
| S 15: Sale of poisons by wholesale | 12 | 1 |
| S 21: Group B Poisons | 1 | 1 |
| S 24: Prescription book | 3 | 1 |
| S 16: Sale of poison by retail | 1 | |
| S 26: Licenses | 1 | |
| **Poison Regulations 1952** | **14  (16.86)** | **-** |
| Reg 6: Manner in which poisons are to be stored | 11 | |
| Reg 12: Labelling of dispensed medicine | 1 | |
| Reg 9: All poisons to be labelled "Poison" | 1 | |
| Reg 11: Labelling of Part II Poisons on sale | 1 | |
| **Poison (Psychotropic Substances) Regulations 1989** | **22  (26.50)** | **12  (80.00)** |
| Reg 28: Labelling requirement for purposes of medical, dental or animal treatment | 3 | |
| Reg 19: Records for purposes of medical, dental or animal treatment | 1 | |
| Reg 22: Keeping and maintenance of register | 2 | 1 |
| Reg 15: Application for a permit to purchase and use psychotropic substances * | 16 | 11 |
| **Medicines (Advertisement and Sale) Act 1956** | **8  (9.63)** | **-** |
| S 4B: Advertisement of medicines to be approved | 6 | |
| S 4A: Prohibition of advertisements relating to skill and service | 2 | |
| **Control of Drugs and Cosmetics Regulations 1984** | **3  (3.61)** | **-** |
| Reg 7: Prohibition against manufacture, sale, supply, importation, possession and administration | 3 | |
| **Terms and conditions in Permit NaOH** | **13  (15.66)** | **-** |
| Permit and detail of purchase submitted to supplier | 6 | |
| Purchase should not exceed maximum quantity allowed | 2 | |
| Format for recording of purchase and use of sodium hydroxide | 4 | |
| Other | 1 | |
| **Guideline / Policy** | **5  (6.02)** | **-** |
| Signboard | 5 | |
| **Total** | **83** | **15** |

Abbreviation: S – Section; Reg – Regulation.

* Under the provision of Regulation 15(3) of Poisons (Psychotropic Substances) Regulations 1989, terms and conditions specified for Permit Methadone & Buprenorphine must be complied by the permit holder.


Table 3: Association between repeated offence and characteristics of licence or permit holders

| Variable | All licence holders (n=71) | Repeated offence (n=15) | No repeated offence (n=56) | p-value |
|---|---|---|---|---|
| Age, year, mean (SD) | 44.5 (12.3) | 53.9  (11.8) | 42.4  (11.1) | 0.001 [a] |
| Years as licence holder, median (IQR) | 4.0 (4.0) | 6.0  (2.0) | 3.0  (4.0) | 0.001 [b] |
| Gender, n (%) | | | | 0.123 [c] |
| Male | 49 (69.0) | 13  (26.5) | 36  (73.5) | |
| Female | 22 (31.0) | 2  (9.1) | 20  (90.9) | |
| Ownership, n (%) | | | | 0.061 [c] |
| Owner | 39 (54.9) | 12  (30.8) | 27  (69.2) | |
| Employee | 31 (43.7) | 3  (9.7) | 28  (90.3) | |
| Shareholder | 1 (1.4) | 0  (0.0) | 1  (100.0) | |

[a] Independent t-test; [b] Mann-Whitney test; [c] Fisher's exact test.

Abbreviation: SD – standard deviation; IQR – interquartile range.

**Discussion**

In this study, the types and frequency of offences are described by characterising them according to the acts and regulations under the purview of MOH Pharmacy Enforcement Services. Regulatory letters in this study included Warning Letters, Reminder Letters and Notices of Violation that were issued to the licence or permit holders upon detection of any activity or product that violate the law. There are a number of regulatory letters being practiced by regulatory agencies around the globe. For example, the United States Food and Drug Administration (FDA) have a few types of letters when it comes to regulatory actions, depending on the significance of the offence (5). One of it is warning letter. It is issued to achieve voluntary compliance and to establish prior notice. This will give an individuals and firms an opportunity to take voluntary and prompt corrective action before enforcement action is initiated. The FDA position is that warning letters are issued only for violations of regulatory significance that may lead to enforcement action if not promptly and adequately corrected (6). The Kedah Pharmacy Enforcement Branch also issued notices of violation, reminder letters and warning letters, all referred as regulatory letters in this study. All these letters are included in this study and those receiving these letters were asked to take remedial action. A warning letter case study showed that a medical device company sought a consultant company to guide and create a response and remediation strategy (7). It showed that warning letters had a very big impact to those receiving it and actions were taken as not to repeat the same offence. Nevertheless, in this study, the same offences were still being repeated despite the issuance of regulatory letters.

From all the offences found in this study, most of them were related to Licence A and Licence B holders as they deal with various poisons and therefore were more bound to these acts and regulations. Licence A applicants are registered pharmacists who must pass the Qualifying Examination to Practice Pharmacy which is the prerequisite for registration with the Pharmacy Board of Malaysia (PBM) (8). Only those registered with PBM can apply for Licence A and practice pharmacy in Malaysia. This ensure that they are well versed with the Malaysian laws on poisons and sale of drugs. As for Licence B holders, they may not have the exposure to the act and regulations, but they have to go through an interview related to the law, with a passing mark of 50% before they can become a Licence B holder (9). For Permit (NaOH) holders, there is no exam or interview related to law, because they only deal with Sodium Hydroxide and all terms and conditions are printed out on the permit. This is also the same scenario with Permit (Methadone and Buprenorphine) that all the terms and conditions are printed on the permit. However, they are also bound to specific regulations such as Poisons (Psychotropic Substance) Regulations 1989. All the Permit (Methadone and Buprenorphine) holders are registered general practitioners who are familiar with psychotropic substances. Therefore, all the license or permit holders have basic knowledge about the related laws, thus ignorance of the law should not be the excuse for any non-compliance or violations.

Our study found that fifteen premises were still being issued with warning letters in 2018, for the same offences they have conducted in 2017. The highest frequency repeated offence was the non-compliance to condition No. 2 in Permit (Methadone and Buprenorphine). This requirement requires the permit holders to inform and send the invoices of all Methadone and Buprenorphine purchases to the Pharmacy Enforcement Branch within 14 days upon receiving the stock (2). Regulatory letters are issued if the invoices were received after more than 14 days or were not received at all. As mentioned previously, all the terms and conditions are printed clearly on the permit and it should be followed by the permit holders. Feedbacks by the permit holders stated that the required documents have been sent but were not received by the Pharmacy Enforcement Branch, or they missed out to send in the documents. A dialogue session will be a good platform to discuss this issue and create awareness in this targeted population to increase the compliance to the law. Further study is needed to figure out the reason of these repeated offences despite receiving the regulatory letters.

As we proceed to see the associations between repeated offences and the characteristics of the licence holders, statistical tests showed that there were no significant association between repeated offence with gender and ownership. However, the age and years of having licence did have a significant association with repeated offence. One notable theory of the age-crime curve is Moffitt's group-based typology introduced in 1993. The relationship showed that crime increases in early adolescence, around the age of 14, peaks in the early to mid-20's, and then declines thereafter (10). However, our findings did not fit this 'age-curve' crime, as our mean age of repeated offenders are 54 years old. Nearly all the work put forth to explain the age-crime curve has focused on traditional street crimes and according to Kanazawa & Still, (2000) crimes require physical strength and energy, both of which recede with age (11). This does not apply to the situation in this study as the offences recorded in this study did not fall under street crimes, nor did it

require physical strength and energy. Most of the offences were closer to 'white-collar' crimes which could be engaged by those considerably older than the typical street criminal (12).

The duration of holding a licence were also significantly associated with repeated offences, with the median duration of 6 years having license. This was in sync with our findings on significant association between age and repeated offence. An older age reflected a longer duration of having license. The highest repeat offenders were Permit Methadone holders, and they were general practitioners that had been in practice for years.

Even though warning letter had been issued, the same offences were still being repeated by 22.72% of the premises. Repeated offences by the license or permit holders showed that either the license or permit holders did not take the warning letter seriously or they were comfortable knowing that no legal action will be taken. Nevertheless, to ensure regulatory compliance, more serious enforcement actions can be taken by the Pharmacy Enforcement Branch such as licence revocations or suspensions, audit or prosecution. On the other hand, our sub-analysis found that 19 premises did not commit repeated offences but they were issued regulatory letters for different offences in the following years. The Pharmacy Enforcement Officers conducting the inspection will go through the same inspection elements every year. Further studies were needed to analyse whether this was due to lack of knowledge or plain ignorance.

With the results of this study, hopefully it can give a clear picture to which acts or regulations most violated and help PED to draft a measure as when to start taking legal action to these licensed premises with repeated offence. The results of this study, however, may be influenced by a number of limitations. Our main limitation is short period of time for data collection as we only include warning letter issued in 2017. Since the study sample only involved licensed premises in Kedah, Malaysia, it does not fully represent all licensed premises across Malaysia. Future studies could improve by having a longer period of observation with more data related to the licence holder collected, and to identify factors of repeated offences. It is believed that certain offence is intentionally done due to demand-supply concept. Future studies could also look into the environmental factors, location and socioeconomic of the local population, beyond the licence or permit holders.

## Conclusion

In summary, this study described the types and frequency of offences committed by licensed premises under the purview of Pharmaceutical Services Division, Kedah. The highest offences were related to the Poisons (Psychotropic Substances) Regulations 1989 and the least offence committed falls under Control of Drugs and Cosmetics Regulations 1984. Overall, the prevalence of repeated offences in Kedah was considered low with most premises being able to rectify and comply with the law during inspection the following year. The results of our study, however, demonstrated a need to formulate a more strategic approach to create awareness and educate the licence holders about the regulatory requirements.

## Acknowledgement

## Conflict of Interest Statement

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# The Number of Pharmacy Enforcement Inspections Conducted on Premises without Pharmacists that Sell Over-The-Counter Medicines and Cosmetics (PWPOTC) in Labuan

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## Abstract

**Introduction:** The pharmacy enforcement officers under the Ministry of Health Malaysia routinely inspect the premises without pharmacists that sell over-the-counter medicines and cosmetics (PWPOTC) to ensure the quality, efficacy and safety of the products in the market.

**Objective:** This study analysed the number and characteristics of PWPOTC inspected for the first time by the Labuan Pharmacy Enforcement Branch from January 2016 to December 2018, within the Federal Territory of Labuan, Malaysia.

**Methods:** This was a retrospective study that analysed secondary data gathered from the inspection reports of PWPOTC from 2016 to 2018. The list of 435 PWPOTC licensed in 2017 was obtained from the local authority. The PWPOTC were categorised into 24 areas based on their locations in Labuan.

**Result:** Overall, 300 and 135 PWPOTC were located in the town and outskirt areas, respectively. Of these, 249 (57.2%) of the PWPOTC were inspected, with most (n=181, 72.7%) located in the town areas. Most of the areas with less than half of the PWPOTC being inspected were from the outskirts (8 out of 13 areas), compared to town areas (5 out of 11 areas). Notably, three areas that had none of the PWPOTC being inspected were all from the outskirts. The most common category of PWPOTC being inspected were grocery shops, medicine shops and supermarkets.

**Conclusion:** The findings reflect the unequal proportion of PWPOTC being inspected in different areas in Labuan. A strategic plan for exhaustive coverage of inspections towards PWPOTC by the authority is urged. Similar studies may also be useful for other pharmacy enforcement branches in Malaysia.

**Keywords:** inspection, over-the-counter medicines and cosmetics, Pharmacy Enforcement, unregistered

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## Introduction

The pharmacy enforcement officers under the Ministry of Health Malaysia (MOH) routinely inspect licensed premises that sell or manage medicines such as pharmacies and clinics. Inspections can also be carried out on premises without pharmacists that sell over-the-counter medicines and cosmetics (PWPOTC). Inspection is the act of examining or looking closely at all drugs attributes and the condition of all facilities that deal with drugs (1). In Malaysia, pharmacy enforcement officers have jurisdictions under the Sale of Drugs Act (SODA) 1952 to inspect all premises that sell drugs, cosmetics and over-the-counter medicines (OTC) (2). This includes PWPOTC such as traditional medicine shops, grocery stores, mini markets, supermarkets, hair salons, beauty salons, direct sales businesses and cosmetic shops.

Inspection activities are part of the MOH's efforts to ensure that all drugs and cosmetics on the market comply with the standard of quality, efficacy, and safety set by the authority. The aim of inspection is to ensure the health and safety of the public and to see if there are any breaches to the guidelines and legislation enforced by the pharmacy enforcement services under MOH (3). Unregistered medicines are often associated with tens of thousands of deaths, mainly in young children in poor countries. Poor-quality

drugs cause economic losses of up to US$200 billion annually and contribute to the increasing of antimicrobial resistance (4) .

Unregistered medicines and unnotified cosmetics can still be found in the Federal Territory of Labuan after decades of implementation of SODA 1952. Every year, raids were carried out on PWPOTC in Labuan. There were 17 raids on PWPOTC with confiscation of unregistered medicines and unnotified cosmetics worth RM23,178 in 2016, 16 raids with confiscation value of RM23,866 in 2017 and 15 raids with confiscation value of RM21,589 in 2018 (5).This observation is a concern to the Labuan Pharmacy Enforcement Branch as unregistered medicines are a real threat to public health. Therefore, there is a need for the pharmacy enforcement officers to carry out routine inspection on all PWPOTC. This could help to reduce premises that sell unregistered medicines and cosmetics, so that enforcement officers can then concentrate to take action on illegal online sales of medicines.

Activities carried out by pharmacy enforcement officers during PWPOTC inspection include checking the security label and registration number on medicines' outer packaging to ensure that the products are registered with MOH (6). The status of notified cosmetics and registered medicines are verified through the QUEST3+ database in the National Pharmaceutical Regulatory Agency (NPRA) website. The pharmacy enforcement officers will seize any illegal products such as unregistered medicines and unnotified cosmetics if found. Education will also be given to the owners and staffs of PWPOTC using leaflets and pamphlets during inspections (3).

In view of the importance of inspection activities, the Labuan Pharmacy Enforcement Branch aimed to inspect all the PWPOTC in Labuan within five years period, from 2016 to 2020. Hence, the objective of this study was to analyse the proportion and characteristics of first-time inspection among PWPOTC in Labuan from 2016 to 2018. By knowing the progress of inspection, the Pharmacy Enforcement Branch can plan and strategise their manpower for the remaining years (i.e. 2019 and 2020) to ensure that all PWPOTC in Labuan were inspected.

## Methods

This was a retrospective study that analysed the secondary data gathered from routine inspection reports of PWPOTC, from 2016 to 2018. This study included PWPOTC licensed by the local authority (Labuan Corporation) in year 2017. Any new PWPOTC licensed after year 2017 and PWPOTC that were inspected before year 2016 are excluded in this study.

The list of PWPOTC licensed in year 2017 was obtained from Labuan Corporation as a baseline to know the number of PWPOTC existed in Labuan at the mid-term of this study. The locations of the premises were also provided by Labuan Corporation. PWPOTC included in this study were categorised into five groups. Group 1 consisted of medicine shops, grocery shops, mini markets and supermarkets, group 2 consisted of hair salons, beauty salons, spa and aromatherapy, group 3 consisted of kiosks, group 4 consisted of direct sales premises, and group 5 consisted of traditional and complementary medicine (TCM) practitioners. The PWPOTC were further categorised into 24 areas based on their geographical locations in Labuan.

A Microsoft Excel workbook was created to record all the PWPOTC information obtained from Labuan Corporation. The inspected premises were analysed according to the year and location of premises. The percentage of PWPOTC that were inspected for the first time during 2016-2018 were calculated. The findings were presented using descriptive statistics which was frequency (n) and percentage (%). Microsoft Excel was used to collect information, analyse data and generate descriptive results. This study was registered with the National Medical Research Register (NMRR) and exemption for ethics approval was granted by the Medical Research and Ethics Committee (MREC), Ministry of Health Malaysia.

## Results

In total, 435 PWPOTC were included in this study. Three hundred premises were located in the town area and 135 premises were in the outskirt area (Table 1). Most of the owners of the business were Malay (54.7%, n=238) and Chinese (25.5%, n=111).

Of the included premises, 249 (57.2%) of PWPOTC were inspected for the first time during 2016-2018, with most of them (n=181, 72.7%) located in the town areas (Table 2 and Table 3). Most of the areas with less than half of the PWPOTC being inspected were from the outskirt areas (8 out of 13 areas), compared to town areas (5 out of 11 areas). Notably, three areas that had none of the PWPOTC being inspected were all from the outskirts. The number of inspections done in 2016 was 114, 2017 was 103 and

2018 was 128. Out of all these 345 premises inspected, only 249 were first-time inspections. Others were repeated inspections of the same premises or inspection on premises that were not in the list of local authority. This study also found that 18 PWPOTC at the outskirt areas were not in operation in 2018.

The most common group of PWPOTC being inspected was group 1 premises (grocery shops / medicine shops / mini market / supermarket) (70.3%, n=175), followed by the group 2 premises (beauty salon / spa / aromatherapy / hair salon) (16.1%, n=40). Among the first-time inspected PWPOTC, all direct sales premises (n=5) and TCM practitioners (n=2) were inspected.

Table 1: Characteristics of PWPOTC included in this study (n=435)

| Race of owner | Location | | Total, n (%) | |
|---|---|---|---|---|
| | Town area, n (%) | Outskirt area, n (%) | | |
| Malay | 145 (60.9%) | 93 (39.1%) | 238 | (54.7%) |
| Chinese | 77 (69.4%) | 34 (30.6%) | 111 | (25.5%) |
| Indian | 6 (100%) | 0 | 6 | (1.4%) |
| Others | 37 (82.2%) | 8 (17.8%) | 45 | (10.3%) |
| Company | 35 (100%) | 0 | 35 | (8.0%) |
| | 300 (69.0%) | 135 (31.0%) | 435 | (100%) |

Table 2: First-time inspected PWPOTC in Labuan town area in 2016-2018 (n=300)

| Town Area | Total premises | Inspected, n (%) |
|---|---|---|
| 1. Town area (Financial Park) | 90 | 65 (72.2%) |
| 2. Town area (Others) | 50 | 34 (63%) |
| 3. Market Central | 25 | 20 (80%) |
| 4. Patau-Patau | 32 | 12 (37.5%) |
| 5. Town area (Jalan Kemajuan) | 23 | 10 (43.5%) |
| 6. Lazenda (Town area) | 22 | 10(45.5%) |
| 7. Rancha-rancha | 12 | 8 (66.7%) |
| 8. Town area (Jati) | 17 | 7 (41.2%) |
| 9. Town area (Jalan Merdeka) | 7 | 6 (85.7%) |
| 10. Times Square | 8 | 5 (62.5%) |
| 11. Town area (Jalan OKK Awang Besar ) | 10 | 4 (40%) |
| Total Premises | 300 | 181 (60.3%) |

Table 3: First-time Inspected PWPOTC in Labuan outskirt area in 2016-2018 (n=135)

| Outskirt Area | Total premises | Inspected, n (%) |
|---|---|---|
| 1. Tanjung Kubong/Lubok Temiang/Tanjung Aru | 17 | 13 (76.5%) |
| 2. Bebuloh/Sg. Lada/Buton | 19 | 13 (68.4%) |
| 3. Pohon Batu/Batu Manikar | 12 | 11 (91.7%) |
| 4. Ganggarak/Merinding/Lajau | 8 | 8 (100%) |
| 5. Sungai Keling | 12 | 7 (58.3%) |
| 6. Gersik/Batu Arang/Kerupang | 16 | 6 (37.5%) |
| 7. Sg Bedaun/Sg Labu/ Bukit Kallam | 16 | 4 (25%) |
| 8. Sg Bangat | 7 | 3 (42.9%) |
| 9. Kilan/ Bukit Kuda/Layang-layangan | 8 | 2 (25%) |
| 10. Sungai Miri | 5 | 1 (20%) |
| 11. Durian Tunjong/Kg Pantai | 6 | 0 (0%) |
| 12. Belukut | 3 | 0 (0%) |
| 13. Taman Mutiara | 6 | 0 (0%) |
| Total Premises | 135 | 68 (50.4%) |

Table 4: Categories of first-time inspected PWPOTC in 2016-2018 (n=435)

| Category | Total premises, n (%) | Inspected premises, n (%) | Percentage (n=249) |
|---|---|---|---|
| 1. Grocery shops / medicine shops / mini market / supermarket | 321 (73.8%) | 175 (54.5%) | 70.3% |
| 2. Beauty salon / spa / aromatherapy / hair salon | 47 (10.8%) | 40 (85.1%) | 16.1% |
| 3. Kiosk | 60 (13.8%) | 27 (45.0%) | 10.8% |
| 4. Direct sales premise | 5 (1.1%) | 5 (100%) | 2.0% |
| 5. TCM practitioner | 2 (0.5%) | 2 (100%) | 0.8% |
| Total | 435 | 249 (57.2%) | 100% |

Abbreviation: TCM – traditional and complementary medicines

**Discussion**

This study analysed the proportion and characteristics of first-time inspection among PWPOTC in Labuan from 2016 to 2018. Similar activities of inspection of drug store were carried out by the inspectors in Tanzania, which includes looking for prohibited products, checking of drug expiry dates and storage of the products (7). According to a study in Tanzania, most shops which sell unregistered medicines or noncompliance to the law are likely due to lack of inspections, poor knowledge of regulations, a failure of authority to charge and silent consent of enforcement officers (7). Therefore, inspection is one of the way to increase compliance rate.

Overall, the owners of the PWPOTC in Labuan were similar to the percentage of races of the population in Labuan where Malays are the majority race in Labuan and then followed by Chinese (8). Only slightly more than half (57.2%) of the PWPOTC in Labuan were inspected for the first time during the three-year period, from 2016 until 2018. Since we have identified the 186 premises that have not been inspected yet with their location, we will ensure that all these premises will be inspected within the next two years by closely monitoring the inspection progress. We hope to first reduce the sale of unregistered medicine and unnotified cosmetics in the physical market so that we can then have more time to target the illegal sale of unregistered medicines and unnotified cosmetics online.

Majority of the PWPOTC were in the town areas. This observation was expected because town areas can attract crowds easier as a lot of shops were at town areas. This study found that inspections from 2016 to 2018 were mainly concentrated in town areas. Hence, in order to achieve 100% of PWPOTC inspection by year 2020, future inspections should focus more on the uninspected premises which are located further from the town or the pharmacy enforcement office. Priority to uninspected premises must also be given by the pharmacy enforcement officers.

The common contributing factors of difficulty implementation of inspections are due to insufficient resources. The availability of transport was reported as one of the limiting factors in a study in Tanzania (7). In terms of manpower, at least two enforcement officers are required to conduct an inspection on one premise. Referring to the MOH Inspection Guideline, at least two pharmacy enforcement officers are needed during an inspection as enforcement officers will inspect status of registration of medicines and cosmetics, advertisement and educate the public using leaflets. The presence of two officers will reduce the chance of bribery or improve the safety if the premise owner become abusive (3).

Although public campaigns such as "Know Your Medicines" had been carried out widely to raise consumers' awareness to safe and effective use of medicines, pharmacy enforcement officers also play an educational role during inspection. Improving consumer awareness are part of the objectives of inspection activities. It is necessary to educate the public on the importance to consume genuine and registered medicines. The awareness activities were also aimed to business owners as poor knowledge of regulations was identified as potential causes for infringements of pharmaceutical regulations(9).

This study found that 18 PWPOTC at the outskirt areas were not in operation in the year 2018. This was based on no notice at the door of the closed premises, and there was no sign that the premises were still in operation. It is advisable that enforcement officers contact the owners first before they inspect premises at outskirts areas, or an updated list needs to be requested from the local authority yearly. Strengthening and co-ordination of information between stakeholders would ensure that premise inspection can be conducted smoothly in the future.

After identifying the PWPOTC and their location which have not been inspected within 2016-2018 from this study, the percentage of first-time inspected PWPOTC has successfully increased from 57.2% to 80% in 2019 and 100% in 2020. We hope to use this technique of more effective monitoring of inspected premises with Microsoft Excel inspection workbook and avoid repeated inspection of the same premises unless necessary, to ensure that all PWPOTC can be inspected within the next three years instead of five years for the new cycle (year 2021-2023).

## Conclusion
The findings reflected the unequal proportion of PWPOTC being inspected in different areas in Labuan. The findings also provided insights to the Labuan Pharmacy Enforcement Branch to improve the coverage of inspections in the future. A similar study could also be useful for other pharmacy enforcement branches in Malaysia.

## Acknowledgement

## Conflict of Interest statement
The study was not funded by any source and the authors had no conflict of interest in this study.

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