Compliance Towards Dispensed Medication Labelling Standards: A Cross-Sectional Study in the State of Penang, Malaysia

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Abstract: Good medicine labelling practice is vital to ensure safe use of medicines. Non-compliance to labelling standards is a potential source of medication errors. This study was intended to evaluate and compare compliance towards labelling standard for dispensed medications between community pharmacists and general practitioners in Penang, Malaysia. A total of 128 community pharmacies and 26 general practitioners’ clinics were visited. Using ‘Simulated Client Method’ (SCM), data were collected on the medications dispensed upon presentation of hypothetical common cold symptoms. The medications dispensed were evaluated for labelling adequacy. Result revealed that majority of the dispensed medications obtained were not labelled according to regulatory requirements. However, general practitioners complied better than community pharmacists in terms of labelling for: name of patient (p<0.001), details of supplier (p<0.001), dosage of medication (p=0.023), frequency to take medication (p=0.023), patient’s reference number (p<0.001), date of supply (p<0.001), special instructions for medication (p=0.008), storage requirements (p=0.002), and indication for medication (p<0.001). Conversely, community pharmacists labelled dispensed medications with the words “Controlled Medicine” more often than did general practitioners (p<0.001). Although laws for labelling dispensed medicines are in place, most community pharmacists and general practitioners did not comply accordingly, thereby putting patients’ safety at risks of medication errors.

Keywords: Labelling, dispensed medicines, community pharmacists, general practitioners, safety, medication errors.

INTRODUCTION

The dispensing of a prescription by a healthcare professional involves labelling and supply of medicines in appropriate containers according to legal and regulatory requirements. The labelling encompasses the provision of information and instructions to ensure the safe and effective use of the products by the patient. Such dispensed medicine’s label is one of the most important sources of information available to patients. The label should contain correct information about the name of the medicine, how, when and why to use it. This information should be presented in a way that can be understood and acted on by the patients [1]. Yet this written information is almost always inconsistent, incomplete or difficult for patients to understand. Poor labelling of medication has been cited as a potential cause of medication errors [2, 3]. Furthermore, the recent Institute of Medicine’s report estimated that 1.5 million medication errors occur annually in the United States and that poorly designed prescription drug labels were an important source of such errors [4]. Hence, proper labelling of medications plays a vital role in ensuring that the medications are administered safely. In addition, difficulties in understanding and using health information among the patients have also led to higher rates of hospitalization [5]. Therefore, good medicine labelling practices by health professionals who dispense medications could prevent the occurrence of medication errors and perhaps minimize hospitalization rates among patients.

Regulation 12(1) of the Malaysian Poison Regulation 1952 stated that “where any poison is sold or supplied as a dispensed medicine, or as an ingredient in a dispensed medicine, the container of such medicine shall be labelled in a conspicuous and distinct manner” [6]. The label must include the name and address of the supplier or seller; the name of the patient or purchaser; the name of the medicine; adequate directions for the use of such medicine; the date of delivery of such medicine; and where such medicine is sold or supplied and entered in a prescription book detailing reference to the serial number of the entry in such book relating to such sale or supply. Regulation 12(2) further makes it mandatory to label any poison or medicine containing any poison that is sold or supplied as a dispensed medicine, or any medicine in any container ready for sale as a dispensed medicine, with the words “Controlled Medicine” [6]. Under this regulation, if any person committed an offence for improper labelling of medicines he or she shall be liable on conviction to a fine not exceeding RM25000 (US$6700), or to imprisonment for a term not exceeding 3 years or both, and for a second or subsequent offence shall be liable to a fine not exceeding RM50000 (US$13400) or imprisonment not exceeding 5 years or both [6]. This
regulation has been imposed since 1st January 2004 by the Malaysian drug regulatory agency (Fig. 1).

Furthermore, in Malaysia, the laws in place have granted the rights for registered medical practitioners to exercise the responsibility of dispensing medications and general medical practitioners in private clinics (GPs) are legally allowed to dispense medications. One study has evaluated the compliance of community pharmacies towards labelling standards for dispensed medications in Malaysia [7]. However, compliance to labelling standards for medications dispensed by GPs’ clinics have not been evaluated or compared with that of community pharmacies. In addition, there is inadequate data on the impact of current labelling practices by health professionals towards patients’ safety. In an effort to expand our current knowledge on how community pharmacists and GPs comply with the current labelling standards for dispensed medications, we conducted a pilot study using ‘simulated client’ method in the State of Penang, Malaysia.

METHODS

We utilized the ‘simulated client’ method (SCM) to study community pharmacists’ and GPs’ attitudes toward labelling dispensed medications. The SCM has been used for over two decades to study healthcare providers’ behaviours while minimizing observation bias at the same time [8]. In developing countries, SCM has proven to be useful in the study of drug retailer practices as it can help to assess and improve the quality of pharmacy practice in community pharmacies [8, 9]. We therefore utilized this established method to explore the extent to which pharmacists and GPs comply with professional and legal requirements related to prescription drug labels.

Currently ethics approval is not required for non-institutionalised and non-human contact observational based study in Malaysia. However, for the present study, the ethical approval was sought and granted by a panel of health service research experts at USM. No pharmacists or general practitioners were informed about the study as this might cause the service providers to modify their behaviours, which could cause observational bias.

In Malaysia, cough and cold preparations such as decongestants, antihistamines, and anti-tussive are classified as Group C Poisons [10]. According to section 22 of Poison Act 1952 [11], Group C Poisons can be sold or supplied by retail as a dispensed medicine or as an ingredient in a dispensed medicine without the prescription from doctors. Thus, patients normally can either buy common cold medications from the community pharmacies or obtain from general practitioners by attending to the clinics.

Visit to Community Pharmacies: For the purpose of this study, an updated list of all retail pharmacies within the State of Penang, comprising their addresses and names of pharmacist in-charge was obtained through the State Health Department. Of the 200 retail pharmacies in the list, eight were excluded as the researcher had acquaintance with the pharmacist in-charge of the eight premises. A sample size of 128 was estimated using an online calculator (80% power and 95% confidence interval) [12]. From October to December 2007, one of the researchers acted as a simulated client and visited 128 conveniently selected pharmacies within the State of Penang.

Common cold was chosen as a common ailment to avoid drawing attention to the study [7]. Besides that, prescriptions for this ailment comprise of common medicines which would have public health significance than with less commonly used medicines [13]. Previous studies have used formal scenarios for the simulated patients in order to standardize the visits [8]. In this study, the case scenario used was that of a 26-year-old woman (the researcher) who presented with early symptoms of common cold (running nose, sneezing, no coughing or sore throat) for the past one day, requesting for a sedative medication. Upon purchase of the recommended medication(s), all the relevant data shown in the labels were recorded into a standardized data collection form.

Visit to General Practitioners’ Clinics: There were 388 clinics run by GPs in the State of Penang. Due to financial constraints, only 35 University Science Malaysia’s (USM) panel clinics within the 388, where students and staff of the university receive free medical care, were chosen as the sample. However, the sample size was reduced to 26 clinics, since nine clinics from the initial sample were meant for USM staff only.

Thirteen first year pharmacy students were recruited and trained as ‘simulated clients’ to portray patients with

![Fig. (1). A sample label meeting all Malaysian legal requirements.](image-url)
common cold symptoms. The training comprised of role-playing for possible interactions with the GPs and practice of recording information after the visits. Each of the “standardized simulated patients” visited two clinics. At the clinics, the patients presented a scenario of common cold symptoms, in order to receive medications. Standardized instructions for the simulated patients included a script of behaviour, questions to ask, complaints to make and measures to record. The simulated patients played a relatively passive role, answering questions only if they were asked, but not volunteering information. After each visit, a simulated patient filled the information obtained into a standardized data collection form, as it was done in the case of community pharmacies.

**Data Collection:** Under the Malaysian Poison Regulation 1952, seven main elements have been identified as the standard for labelling dispensed medications [6]. Therefore, all the medications obtained from the visits in this study were evaluated for their adequacy in labelling by using a standardized data collection form with a dichotomous checklist, developed based on the seven elements. Pictures of the labels on the dispensed medication were taken.

The data collected for the community pharmacies and clinics were based on the following aspects of labelling: name of patient, details of supplier (address and name of pharmacy or clinic), name and the strength of medication, information of medication (indication, duration, dosage, frequency, before or after food, storage of medication, date of supply, date of expiry), patient’s reference number, auxiliary label (special instructions, controlled medicine), label presentation (handwritten, computer-generated writing), language used, and medication packaging (blister packaging, loose packaging).

**Statistical Analysis:** The relevant data were stored and analyzed using Microsoft Excel 2003 and SPSS version 13.0. Descriptive statistics (mainly frequencies and percentages) were used to analyze the data. Chi-square test was used to compare the rate of community pharmacies’ vs clinics’ compliance with each of the labelling standards. A p-value of less than 0.05 was considered statistically significant.

**RESULTS**

Of the 128 community pharmacies and the 26 GPs’ clinics visited, 129 and 48 labels were obtained, respectively. Findings from the study revealed that most of the community pharmacists and GPs did not comply with the labelling standards required by the law.

The study showed that an overwhelming proportion (97.9%; n=47) of the medications dispensed at the clinics was labelled with the name of the patient, whereas none of the medications dispensed at community pharmacies was labelled with this information.

Only 19.4% of the dispensed medications (n=25) given by community pharmacies were labelled with the name of the medication (2.3% with generic names and 17.1% with brand names). Similarly, only 18.8% (n=9) of the medications obtained from GPs were labelled with the name of the medications (6.3% with the generic names and 12.5% with the brand name). In addition, less than 10.0% of community pharmacies and GPs’ clinics complied with the requirement of including the strength of the dispensed medications on the labels.

None of the dispensed medications from both the community pharmacies and clinics was labelled with the information about the duration that the medications should be taken.

Only 5.4% of dispensed medications purchased from community pharmacies (n=7) were labelled with the date of supply and 3.9% of the labels (n=5) were labelled with the expiry date. On the other hand, 85.4% of dispensed medications obtained from GPs (n=41) were labelled with the date of supply, but only 2.1% of (n=1) were labelled with the expiry date.

Other pertinent data about the survey are presented in Table 1. In comparing the two groups of healthcare providers, the results revealed that GPs did significantly better than community pharmacists in terms of labelling for: the name of patient, details of supplier, dosage of medication, frequency to take medication, patient’s reference number, date of supply, special instructions for medication, storage, and indication of medication. On the other hand, community pharmacists labelled dispensed medications with the phrase “Controlled Medicine” as required under Regulation 12(2) more often than did GPs (p<0.001).

In terms of label presentation for the dispensed medication, 124 labels (96.1%) that we obtained from community pharmacies were handwritten. Only one label (0.8%) was computer-generated. However, 3.1% (n=4) of the dispensed medications from community pharmacies were not labelled at all. Out of 48 dispensed medications obtained from GPs’ clinics, 75% of the labels (n=36) were also handwritten and the rest were computer-generated.

**DISCUSSION**

Medication labelling has been identified as an issue of significant importance in medication safety [14] and one of the factors contributing to safe use of medications among consumers is the ability to read the medication label and act upon the information presented accordingly. Ideally, all the therapeutic information which is for patient references should be printed on the dispensed medication. However, from this pilot study, up to 92.2% (n=119) and 81.3% (n=39) of the common cold medications that we obtained from community pharmacies and general practitioners respectively, were dispensed in loose packaging (which is not the original packaging from the manufacturers). As dispensing medications in the form of loose packaging is a common practice among the healthcare practitioners in Penang, the adequacy in labelling of these loose packaging dispensed medications is of particular concern and interest.

In order to ensure that a medication is taken by the right patient, the patient’s name should be written on the label. However, this study revealed that none of the dispensed medications by community pharmacies was labelled with the name of the patient. This can be a potential source of fatal medication error.

It is worthwhile that medications are labelled with information on how and when to take them [1]. The present study found that there were statistically significant differences between community pharmacies and GPs’ clinics
in terms of labelling for dose and frequency of the dispensed medications ($P = 0.023$), where clinics complied better than community pharmacies. Although patients might have been informed about the dose, frequency and duration during dispensing on the counter, they might have forgotten this information after reaching home. Therefore, such vital information should not be neglected as part and parcel of medication label.

Furthermore, auxiliary labels play an important role in informing patients about the side-effects of the medications and stress on other vital information not contained on the main label. This information is vital to prevent patients from taking their medications inappropriately. For instance, in this study, a sedative medication, which may cause drowsiness, was requested by the simulated client. The simulated client should be instructed not to drive while taking the medicine. However, these type of specific medication instructions or warnings that are of importance to the safety of the patients were apparently neglected by most of the practitioners.

It must be stressed that labelling of the name and strength of the medication are vital in providing identification information and education to the patients. Even though patients may not be very knowledgeable on this, yet they will be able to name and identify the medicine that they are taking when asked. This may also prevent patients from receiving therapeutic duplications when visiting other healthcare facilities. Surprisingly, one of the labels obtained from a community pharmacy was labelled with two brand names, “Piriton®” and “Kotamin ®” which can create confusion. Besides this, we found it very difficult to identify the common cold medications given by the community pharmacies and general practitioners in this study as most of the medications were dispensed in loose packaging.

Similarly, the rate of including indication of the medication in the label was significantly higher among GPs’ clinics compared to community pharmacies. A study by Shrank and colleagues reported that a drug’s indication is one of the information requested by patients besides the expected benefits, duration of therapy, and a thorough list of potential adverse effects [15].

Overall, doses of medications and the frequencies with which they should to be taken were the most frequently stated information on the labels, whereas the inclusion of the duration of therapy and expiry date in the medication labels was not a common practice among the healthcare providers.

As labels contain the most precious information about the dispensed medication, it is vital to ensure that this information is presented in a way that can be understood and acted on by the patients. Consequently, a proper presentation of the label can aid in reducing medication errors and further

### Table 1. Practitioners’ Compliance to Standard Labelling Requirements

<table>
<thead>
<tr>
<th>Labelling Element</th>
<th>Community Pharmacies (n = 129)</th>
<th>GPs Clinics (n = 48)</th>
<th>$P$-Value</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. Name of patient</td>
<td>0 (0.0)</td>
<td>47 (97.9)</td>
<td>&lt;0.001</td>
</tr>
<tr>
<td>2. Details of supplier:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Name of pharmacy/clinic</td>
<td>42 (32.6)</td>
<td>48 (100.0)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Address of pharmacy/clinic</td>
<td>38 (29.5)</td>
<td>45 (93.8)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>3. Directions to take:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Dose</td>
<td>116 (89.9)</td>
<td>48 (100.0)</td>
<td>0.023</td>
</tr>
<tr>
<td>Frequency</td>
<td>116 (89.9)</td>
<td>48 (100.0)</td>
<td>0.023</td>
</tr>
<tr>
<td>Duration</td>
<td>0 (0.0)</td>
<td>0 (0.0)</td>
<td>1.000</td>
</tr>
<tr>
<td>Before or after food</td>
<td>76 (58.9)</td>
<td>30 (62.5)</td>
<td>0.666</td>
</tr>
<tr>
<td>Special instructions</td>
<td>9 (7.0)</td>
<td>10 (20.8)</td>
<td>0.008</td>
</tr>
<tr>
<td>4. Name of medicine:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Generic name</td>
<td>3 (2.3)</td>
<td>3 (6.3)</td>
<td>0.201</td>
</tr>
<tr>
<td>Brand name</td>
<td>22 (17.1)</td>
<td>6 (12.5)</td>
<td>0.462</td>
</tr>
<tr>
<td>Strength of medicine</td>
<td>9 (7.0)</td>
<td>3 (6.3)</td>
<td>0.865</td>
</tr>
<tr>
<td>5. Patient’s reference no</td>
<td>0 (0.0)</td>
<td>8 (16.7)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>6. Date:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Date of supply</td>
<td>7 (5.4)</td>
<td>41 (85.4)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>Date of expiry</td>
<td>5 (3.9)</td>
<td>1 (2.1)</td>
<td>0.559</td>
</tr>
<tr>
<td>7. Label of ‘Controlled Medicine’</td>
<td>96 (74.4)</td>
<td>6 (12.5)</td>
<td>&lt; 0.001</td>
</tr>
<tr>
<td>8. Others:</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Indication</td>
<td>69 (53.5)</td>
<td>38 (79.2)</td>
<td>0.002</td>
</tr>
<tr>
<td>Storage of medications</td>
<td>3 (2.3)</td>
<td>10 (20.8)</td>
<td>&lt; 0.001</td>
</tr>
</tbody>
</table>

* $P < 0.05$ (significant).
ensuring medication safety among patients. In our study, the adequacy of labelling information is extremely important as most of the dispensed medications that we obtained were in loose packaging. However, there was no label found on dispensed medications purchased from 4 community pharmacies (3.1%).

According to FIP Guidelines, pharmacy labels should be printed or typewritten [16]. From our study, 2 types of label presentation: handwritten, and computer-generated were observed. We believe that computer-generated label is better way to present the information of medication as it is clearly printed, standardized and also diminish the risk of illegible handwriting. The use of computer programs that would not print the label unless all the required information was inputted may also help in generating a proper label with adequate information for patient references. From the findings in this study, majority of the labels on dispensed medications obtained from community pharmacies and general practitioners were not computer-generated. This may be due to the absence of computerized system in their practicing pharmacies or clinics.

This exploratory study only involved samples from Penang State since it was a pilot. Hence, the results obtained cannot be generalized to the whole population of healthcare practitioners in the country. Secondly, due to financial and administrative constraints, the simulated patients visited only USM panel clinics, where they could obtain free treatment since they were students of the university. Third, there is a possibility that the inadequacy in labelling for the dispensed medications as observed in our study was limited to only common cold preparations. Perhaps the healthcare practitioners do not perceive this information as essential if compared to other medications such as antihypertensive, oral hypoglycaemic agents or anticoagulants. However, in Malaysia most of the medications used for common cold are categorized as the Group C poisons, which can only be dispensed by a registered pharmacist or medical practitioner.

Despite the above limitations, this study indicates that the rate at which practitioners in Malaysia comply with dispensed medications labeling standards is dismally low and it paves the way for a more comprehensive study in this important area.

CONCLUSION

The findings from this survey revealed that most of the community pharmacists and GPs visited by the simulated patients provided insufficient and confusing information on the dispensed medications labels and did not adhere to the current laws and regulations. However, when both groups of healthcare providers were compared, the results revealed that GPs clinics complied with standards better than community pharmacies in most aspects of labelling. The findings from this pilot survey are serious pointers for urgent changes in labelling practices in order to safeguard the health of patients and consumers. The study has important implication on reformation of dispensing policies and enforcement of laws.

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REFERENCES