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Do Professional Practices among Malaysian Private Healthcare Providers Differ? A Comparative Study using Simulated Patients

Health Management & Policy Section

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ABSTRACT

Background: Malaysia, a South East Asian country, legally permits general medical practitioners in private clinics to dispense medicines. This possibly can dilute the pharmacist role in the provision of healthcare and pharmaceutical care and deprive patients to benefit from these services.

Objective: This study explored, assessed and compared the current status of medicines labeling, patient's counseling, and symptomatic diagnosis by general practitioners and community pharmacists.

Material and Methods: This study used trained Simulated Patients (SP), who participated in a scenario of common cold symptoms at private clinics and community pharmacies. SPs explored medication labeling, patients counseling and symptomatic diagnosis undertaken by general practitioners and community pharmacists. Later, study authors assessed and compared these practices. The study was conducted during June 2011 in Penang, Malaysia.

Results: The study used descriptive statistics and Fisher-exact test to analyze data. Regarding patients counseling standard, among 100 visits by simulated patients, 64 (64%) from community pharmacists provided information about the medicine name, its indication, dosage and route of administration versus 17 (42.5%) general practitioners during 40 visits (p=0.024). Concerning adherence to labeling standard, for instance, only in one pharmacy visit, (1%) the pharmacist wrote the name of the patient on the medication label versus in 32 (80%) of doctors' visits, the doctors adhered to this labeling standard (p<0.001). In all doctors' visits (n=40, 100%), SPs were asked about symptoms, whereas in 87 (87%) CPs' visits, pharmacists fulfilled this counseling standard (p=0.02).

Conclusion: Although pharmacists showed less compliance to medicine labeling and symptomatic diagnosis compared to doctors, their counseling of patients was better. Separation will definitely contribute to more concentration of each provider on his/her roles and improve and direct the experiences and skills towards being more patient oriented.

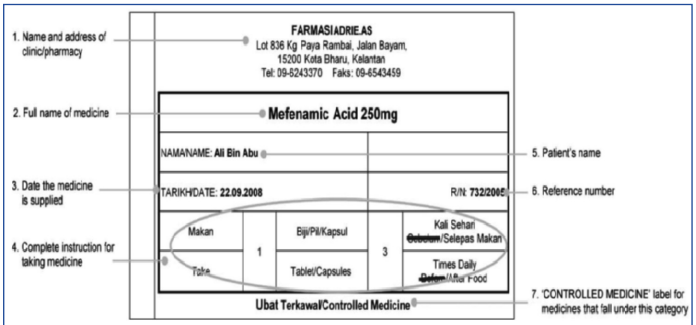
Keywords: Common cold, Community pharmacists, Dispensing doctors, Dispensing separation, General medical practitioners, Malaysia, Medicine labelling, Patient's counselling, Simulated patients

INTRODUCTION

Pharmacy is expected by the public as the place where they find reliable health and medicines information and the pharmacist as the most qualified provider of such services [1]. Over a number of decades, training of pharmacists have taken a more clinically oriented trend and researchers have recognized that patient counseling by pharmacist is important to improve medicines rational use and realize the desired therapeutic results. Consequently, pharmaceutical care has been held as a mission of pharmacy and pharmacists have been required legally to counsel patients about the use of their medicines [2]. Information through counseling is essential for patients to assist in adhering to their medication regimens [3]. The second professional practice of the pharmacist is the adequate labeling of medicines which contains certain characteristics to improve reading and understanding of patients [4]. Malaysian Poisons Regulation stated that "where any poison is sold or supplied as a dispensed medicine, or as an ingredient of a dispensed medicine, the container shall be labeled in a conspicuous and distinct manner" [5]. Doctors and pharmacists may assume that their patient can read, understand or act on short directions found in the label of medicines, but this possibly will not be true [6]. Good labeling is very important to guarantee safe use of medicines and inappropriate labeling of medicines will lead to medication errors [7]. The third practice is the responsibility of patient assessment through symptomatic diagnosis. Pharmacists are now becoming capable enough to carry this responsibility. Unlike other healthcare experts, community pharmacists have no access to patient records and hence they don't know the patient's problem unless a communication between the two parts is initiated. So, pharmacists need to improve their knowledge and understanding of commonly occurring medical conditions for correctly and differentially diagnose the patient [8]. Regarding these backgrounds, the International Pharmaceutical Federation (FIP) and WHO introduced the notion of "The seven stars pharmacist" which characterizes the role of the pharmacist to be a care giver, decision maker, communicator, manager, lifelong learner, teacher and leader [9]. Although pharmacy profession is documented to be important in healthcare provision in many developed countries, in the majority of developing countries is remaining underutilized [10]. This underutilization is very clear in some Asian countries by allowing doctors to prescribe and dispense medicines [11]. Many of these countries (Japan, South Korea, Taiwan, Indonesia, Philippines and India) have separated dispensing and prescribing roles between doctors and pharmacists [12]. This movement for health system restructuring has facilitated for the improvement to allow pharmacists playing their roles in dispensing medicines [13]. Many other countries allow doctors to dispense medicines for certain justifications including scarcity in pharmacists, high patient accessibility and the existence of abundant amounts of

medicines besides the rationale for doctors to increase income [14]. In Malaysia, the 1952 law and other regulatory legislations approved the right for registered general medical practitioners (GPs) in private clinics to legally dispense medicines [15] leaving the sector of private pharmacies to operate in a very harsh and critical environment and not receive even a single prescription a day [16]. The doctor dispensing practice has been allowed since the era of colonization when Malaysia went through a sensitive paucity of experts. That is not the case now and change through separation must be achieved soon [16].

This study was mainly conducted to highlight and evaluate the problems emerging from this dual situation. This method showed a useful and adaptable evaluating style with a coherent cost-effectiveness [17]. Using simulated patients and common cold symptoms, the findings from a similar pilot survey conducted in Penang by Neoh et al. 2009, to study labeling standards revealed that CPs and GPs provided deficient and confusing information of the dispensed medication labels and did not comply with the current regulatory legislations [Table/Fig-1]. The survey finding also showed that GPs adhered to labeling standards better than CPs, reflecting a serious need for a vital reform in labeling practices to comply with the health requirements of patients and consumers. The study also paved the way for a more comprehensive study in this essential field [7].



[Table/Fig-1]: An ideal Malaysian label of a medicine (from Neoh et al. 2009)
*Fisher's Exact Test (Significance: $p<0.05$).

Study Objective

To assess and compare the professional practices accompanying dispensing of medicines such as medicines labeling standard, patient's counseling standard and symptomatic diagnosis between general practitioners and community pharmacists.

MATERIAL AND METHODS

Study design: A cross-sectional exploratory design was chosen for this study using Simulated Patients (SP) as a tool for collecting data. Trained SPs were instructed to play their roles according to a repeated scenario by exhibiting an Over-The-Counter (OTC) self-medication scenario at private community pharmacies and go over the same scenario at GP clinics. SPs observed and explored adherence of GPs and CPs to medicine labeling standards patient's counseling standards, and symptomatic diagnosis of treated ailment (common cold).

Study duration: The duration was suggested to take place within the period of May 2011 to September 2011 without appointing a specific date before conducting the study to avoid practitioners' awareness and then violation of the study.

Study area and population: The study was restricted only to Penang state, in northwest part of Peninsula Malaysia. Penang occupies an area of 1,048 km^2 with a population of 1.5 million and a population density of 1,500/km^2. All medical doctors in private clinics (n= 436) and community pharmacists in private community pharmacies (n= 300) in Penang State were taken as the study population and informed in a mailed consent about the aim and objectives of the study.

Sampling procedure: Non-random samples of 20 clinics and 50 community pharmacies were selected according to the ease of access by the SPs and our financial ability since we need to pay for consultations and medicines considering that the study was not funded by any organization.

Validation of methods and tools: We conducted a small pilot SP case study to eliminate the psychological barriers when acting as a Simulated Patient (SP), validate tools, and prepare a training session for a comprehensive study including both CPs and GPs. All details were documented on an observation form developed by the first author from literature [3,7,8]. This form was developed before the pilot case study and amended later after the case study by deleting some items from the counseling standard sections given that it was too long. The findings of this case study suggested poor professional practices in both pharmacies and paved the way for the comprehensive study [18].

Simulated clients training module: A comprehensive simulated patient interview method was conducted to observe, explore, assess, and compare professional services relating to dispensing provided to patients by General Practitioners (GPs) and Community Pharmacists (CPs) in the State of Penang, Malaysia. Twenty students sat for a one-week training session on how to act as simulated patients (SPs) who were complaining of common cold symptoms. They were trained on how to exhibit a scenario of these symptoms in front of a doctor or a pharmacist. The symptoms exhibited by them are common cold symptoms usually caused by a viral infection. Common cold usually starts, following an incubation period between 1 and 3 days, with sore throat and sneezing, then profuse nasal discharge and congestion. Cough and post-nasal drip and headache may come after, mild to moderate fever and general malaise might also occur. Because it is a self-limiting ailment within a period of one week in most cases (in some cases 2 weeks) considered to be an insignificant condition and can easily be neglected [8]. A common cold symptom was chosen for avoiding providers' drawing notice to the involvement of the SP in a study [19].

SPs were trained to interact with practitioners and record information in the checklist after the visit and away from the premise area. For more standardization of tools and validation of results, the 20 SPs were grouped in 10 groups. Each two SPs were assigned to visit 5 pharmacies and two clinics. In each round and in an interchangeable manner, each two SPs visited four premises (two pharmacies and two clinics). If SP X visited pharmacy A and clinic A' and SP Y visited Pharmacy B and clinic B' in the first round, after two hours the two SPs interchanged their positions to visit the same two pharmacies and clinics. Therefore, each pharmacist and general practitioner dealt with 2 encounters by two different SPs leading to a total of 100 encounters in pharmacies and 40 encounters in clinics. SPs were given instructions to enquire only about the symptoms of common cold they pretended to have and not to give information or try to answer critical questions from providers to avoid revealing themselves and violating the study.

Data Collection: As mentioned, each premise was visited twice by two alternating SPs leading to a total of 140 visits (100 visits to 50 pharmacies and 40 visits to 20 clinics). All details were documented in the designed observation form to explore professional practices standards. After every visit and away from the pharmacy or clinic, each SP filled in two forms with what was observed in the pharmacies and clinics visited. All sections in the form used dichotomous answers (YES or NO). The data collected from GPs and CPs was based on the following standards:

Labeling Standard: This included writing the patient's name, strength of medicine, dose frequency, quantity of medicine, manufacturer's name, date of dispensing, expiry date, dose, course duration, potential danger to children, and writing "Controlled

Medicine" [15, 20].

Counseling Standards: Providing information about name, indication, dosage, and route of administration of the medication, asking patient if he/she will have a problem taking the medication as prescribed, tailoring the medication regimen to patient's daily routine, cautioning about possible side effects, ADRs, and medication use barriers before emphasizing benefits of medications, advising about other treatments, asking about allergies, discussing precautions, contra-indications and storage recommendations besides ancillary instructions (e.g., shelf-well, refrigeration), checking for understanding by asking the patient to repeat back key information (drug name, side effects, etc), advising for checking the medicines before leaving the premises and suggesting a follow-up visit. The counseling part of the checklist was developed by Bergeret et al. to determine how information is exchanged between the dispenser and the patient in a way that increases the patient's compliance with the treatment regimen [3].

Symptomatic diagnosis scenario: These included GPs' and CPs' asking SPs about age, symptoms, the duration of these symptoms, the nature and color of sputum, the presence of blood in sputum, history of using medicines, history of allergy to certain medicines, history of smoking and history of presenting the same complaint per year with the suggested answers for every provider's questions [8].

Ethics

Before conducting this study ethical approval was obtained from the Joint Ethics Committee of School of Pharmaceutical Sciences, USM-Lam Wah Ee Hospital on Clinical studies starting from April 2011.

Statistics

Data were managed and analyzed by using SPSS version 16.Descriptive analysis was run to describe the basic features of professional practices such as medicine labeling, patient counseling and symptomatic diagnosis provided by CPs and GPs. Fisher's Exact test to substitute Chi-square test was used for categorical data of both dependent and independent variables. *P-value* of less than 0.05 was set as statistically significant.

RESULTS

Comparison between different variables of professional practices is based on numbers of visits of SPs to GPs (visits=40) and CPs (visits=100) but not number of premises.

Results concerning adherence of GPs and CPs to labeling standards are indicated in [Table/Fig-2]. GPs (n=32, 80%) were found to adhere to writing down the patient's name on the label more than CPs (n=1, 1%). A very high significant difference between the two types of professionals was indicated in this regard (p< 0.001). There was also a very high significant difference between GPs and CPs regarding writing the date of dispensing on the label (p< 0.001). GPs (n=30, 75%) showed more adherence than CPs (n=23, 23%) to write the date of dispensing on the label. Course duration was found to be adhered to by a greater number of GPs (n= 6, 15%) than CPs (n= 4, 4%), with a clear significant difference between them in this respect (p= 0.032). When they labeled medicines (especially loose packs) GPs differed significantly from CPs in naming the medicine (whether generic or brand) on the label (p< 0.001). Less than half of GPs' visits (n=16, 40%), they adhered to the requirement to write the medicine's name, a much higher rate of omission than among the CPs (n=7, 7%).

[Table/Fig-3] shows that the majority of CPs' visits (n=68, 68%), they refused to give antibiotics to SPs for common cold symptoms, a higher rate of refusal than among the GPs (n=14, 35%), with a high significant difference between the two (*p*= 0.001).Information about the name, indication, dosage, and route of administration of the medication differed significantly between GPs and CPs (p= 0.024). A larger number of CPs (n=64, 64%) were found to counsel patients in telling them this information than GPs (n=17, 42.5%). Asking the patient if he/she will have problems with the medicine/s differed significantly between the two professions (p=0.005). In a number of CPs' visits (n=21, 21%), they were found to counsel patients by asking about these problems, more than among the GPs (n=1, 2.5%). The CPs also had a higher rate (n=38, 38%) than GPs (n=6, 15%) of tailoring medication regimens to the patient's daily routine, with a clear significant difference between the two professions (p=0.009). CPs counseled SPs about side effects and barriers to medication use (n=27, 27%) more than did GPs (n=1, 2.5%), with a significant difference between them in this regard (p=0.001).

Scenario of common cold symptoms between providers and

Labeling Variables	CP (n= 50) (100 visits) No. (%)	GP (n= 20) (40 visits) No. (%)	p-values*
Writing patient's name	1 (1.0)	32 (80.0)	<0.001
Strength of medicine	40 (40.0)	16 (40.0)	1.000
Dose frequency	98 (98.0)	38 (95.0)	0.624
Quantity of medicine	52 (52.0)	17 (42.5)	0.352
Manufacturer's name	50 (50.0)	15 (37.5)	0.195
Date of dispensing	23 (23.0)	30 (75.0)	<0.001
Expiry date	33 (33.0)	9 (22.5)	0.307
Dose	71 (71.0)	27 (67.5)	0.688
Course duration	4 (4.0)	6 (15.0)	0.032
Warning about potential danger to children "Keep away from children"	17 (17.0)	5 (12.2)	0.613
Writing "Controlled Medicines"	0 (0.00)	2 (5.0)	0.080
Unnamed medicines	7 (7.0)	16 (40)	<0.001

[Table/Fig-2]: Comparison of adherence to medicines labeling standard between CPs and GPs

Counseling Variables	CP (n=50) (100 visits) No. (%)	GP (n= 20) (40 visits) No. (%)	p-values*
Refusing to dispense antibiotics	68 (68)	14 (35)	0.001
Informing about name, indication, dosage, and route of administration of the medication	64 (64)	17 (42.5)	0.024
Explaining how long it will take for a medication to show an effect	10 (10)	1 (2.5)	0.178
Explaining how long the patient might be in the medication regimen	14 (14)	5 (7.5)	1.000
Asking patient if he/she will have a problem taking the medication	21 (21.0)	1 (2.5)	0.005
Asking about other treatments	10 (10.0)	1 (2.5)	0.178
Asking about allergies	36 (36.0)	15 (37.5)	1.000
Tailoring the medication regimen to patient's daily routine	38 (38.0)	6 (15.0)	0.009
Discussing precautions and contra indications	4 (4.0)	2 (5.0)	1.000
Explaining side effects(ADRs) and barriers before emphasizing benefits of medications	27 (27.0)	1 (2.5)	0.001
Discussing storage recommendations and ancillary instructions (e.g., well refrigerate)	0 (0.0)	1 (2.5)	0.286
Checking for understanding by asking the patient to repeat back key information (drug name, side effects, etc)	1 (1.0)	0 (0.0)	1.000
Advising the patient to check the medicines before leaving the premises	1 (1.0)	1 (2.5)	0.491
Suggesting a follow-up visit	1 (1)	1 (2.5)	0.491

[Table/Fig-3]: Comparison of adherence to patients' counseling standard between CPs and GPs
*Fisher's Exact test (Significance: p<0.05)

HCPs Questions	SP's answer	CP (n= 50) (visits=100) No. (%)	GP (n= 20) (visits=40) No. (%)	p-values*
How old are you?	20^{+} years old	12 (12)	5 (12.5)	1.000
What symptoms have you got?	Cough with phlegm, running nose, sneezing, headache, low grade fever and fatigue	87 (87)	40 (100)	0.020
How long have you had the symptoms?	For three days and still getting worse	52 (52)	32 (80)	0.004
What is the color of sputum?	White to green, i.e. yellow	46 (46)	26 (65)	0.061
Is there any blood in sputum?	No	6 (6)	5 (12.5)	0.294
History of presenting same complaint	Two or three times a year	6 (6)	5 (12.5)	0.295
What medicines have you used before for these symptoms?	Many medicines with an antibiotic, but I don't remember their names	10 (10)	16 (40)	<0.001
Are you allergic to any medicine?	No	37 (37)	17 (42.5)	0.569
Are you smoking?	No	0 (0)	3 (7.5)	0.022

[Table/Fig-4]: Symptomatic diagnosis: scenario of common cold between health-care providers (HCPs) and simulated patients (SPs)
*Fisher's Exact test (Significance: $p<0.05$)

simulated patients are shown in [Table/Fig-4]. All GPs (n= 40, 100%) asked the SPs about the common cold symptoms, a higher rate than among CPs (n=87, 87%) with a clear significant difference between the two professions in this respect (p=0.020).A high significant difference (p=0.004) was indicated between GPs and CPs in asking SPs about the duration of their symptoms. GPs (n=32, 80%) adhered to this counseling standard more than did CPs (n=52, 52%).Soliciting information about the history of using medicines for the same symptoms in the past was found to differ significantly between both providers (p<0.001). In all the GPs' visits (n=40, 100%), the GPs adhered to this diagnostic standard whereas few CPs did (n=10, 10%).The question 'Do you smoke?' was asked by only three GPs (7.5%) while no CP seems to have asked this important counseling question (p=0.022).

DISCUSSION

Results of this study showed poor compliance to professional practices standards accompanying dispensing by both CPs and GPs such as medicines labeling standard, patients counseling standard and symptomatic diagnosis. In discussing these results according to the objectives of the study and research questions, finding are classified and argued under the following components:

Adherence to labeling standard: Instructions are usually given to patients to ensure correct and safe use of medicines to the optimal benefits in line with medication objectives. These instructions include warning (if applicable), discussing storage recommendations in a secured isolated container, and the protection from light and heat and refrigeration if needed [20]. The safe use of all medicines depends on the patient's ability to read carefully the label on a medication package and to understand and proceed on the information presented. The primary purpose of labeling is to clarify the identification of the medicine, the condition for its rational use, and to help minimize the incidence of medication errors [21]. As stated by FIP, the minimum requirements for a label are: generic name of medicine, strength, dose frequency, duration of course, name of patient, date of dispensing, name and address of supplier, and child safety warning. In order to ensure that the right medication has been used by the right patient, the patient's name should be written on the label. This will protect practitioners from making fatal mistakes and medication errors [7]. According to regulations 12 (1) and 12 (2) of the Malaysian Poisons Law, the container of any dispensed medicines shall be clearly labeled by writing the name and address of the supplier, patient's or customer's name, date of dispensing and writing the word "Controlled Medicine". Anyone not following these regulations will be convicted to pay a penalty not exceeding RM 25000 (US$ 8333) or be imprisoned for not less than 3 years or both penalties. If the supplier repeated the same wrong doing then the penalty will be doubled [5]. In our study, clinics show better adherence to labeling standard than community pharmacies. This finding is consistent with the study conducted by Neoh et al., which evaluated and compared adherence to labeling standard regarding medicines dispensed between GPs and CPs in Penang [7]. GPs in our study are very keen to write the patient's name, medicine name, the date of dispensing and the duration of the medication course. Most providers in private GP clinics and community pharmacies are not giving full consideration to writing the word "controlled medicine" or potential danger of medicines to be taken by children when stored at their reach by writing "Keep medicines away from children". This warning phrase should be added to the ideal label shown in [Table/Fig-2].

Adhering to counseling standard: Over the past four decades, the pharmacist has changed the role from that of a compounder and dispenser to one of 'drug therapy manager'. This encompasses responsibilities of selecting quality products, procurement, appropriate storage, distribution and contribution to patients' health improvement, and not harming them when dispensing medicines. Pharmacy practice now involves patient counseling with cognitive functions in the provision of pharmaceutical care services [22]. Although pharmacists in this study showed low adherence to counseling standard in general, they differed significantly from doctors in private clinics (GPs) in some counseling elements. They refused to dispense antibiotics, provided better information about the name, indication, dosage, and route of administration of the medication and in asking SP if he/she will have a problem taking the medication dispensed. Pharmacists also did well in explaining side effects and possible Adverse Drug Reaction (ADRs) and barriers to the continuation of medicine use to be avoided. Patient counseling standard enables the pharmacist to organize information about the use of medicine he provides to his patients and also information obtained from them. The advent of consumerism in healthcare should make healthcare providers, in particular pharmacists, aware of what services patients demand from them [22]. Pharmacists in this study gave much more comprehensive information related to medicines used by patients compared to clinics. They were tailoring the medication regimen to patient's daily routine, like advising patients not to drive during the medication period and the necessity to stay in bed till convalesce when taking the medicines. These pharmaceutical care interventions are considered to be crucial responsibilities of the pharmacists in developing communicative relationships of an educational nature with the patient and optimizing the outcomes of medication use [23]. Pharmaceutical care is the mission to be provided by a pharmacist. It is the direct, responsible provision of medication-related care for the purpose of achieving definite outcomes that improve a patient's quality of life [24]. Other criteria like informing about name and indication, asking about other treatments and allergies, etc, are not fully adhered to by most of CPs and GPs.

Symptomatic diagnosis: GPs in private clinics tended to comply better with asking questions that explore typical symptoms of common cold. They showed high competence to solicit patients' identities, complaints, symptoms, and diagnoses than community pharmacists. They often asked about the patient's symptoms and how long he/she had had these symptoms. GPs approached their

real roles by following the correct guidelines in disease diagnosis. It is quite clear that the symptoms presented by our simulated patients to either GPs or CPs are only signs simulating viral infections, which do not require any medication other than simple advice for bed rest and drinking warm fluids. Our study respondents deviated far from their real roles when they prescribed and dispense antibiotics for such a minor and self-limiting ailment, reflecting the impact of the lack of separating these roles and lack of collaboration on the services provided.

Recommendations: Malaysian pharmacists and the Malaysian Pharmaceutical Society (MPS) should understand carefully and undertake their ethical responsibilities toward their patients and their profession especially at the community level. To achieve their objective of medication dispensing separation, pharmacists must comply with the regulations and ethics and follow every guideline of the rational dispensing of medicines. On the other hand, policy makers are required to pay attention to the problem of irrational medicines dispensing. Working coherently for an urgent and potent intervention is needed to correct this problem and avoid unwanted consequences, which may afflict the whole healthcare system. This means that pharmacists should fully change their business-oriented behaviors and adopt patient-oriented approaches as healthcare providers and medicine use advisers and counselors.

It is better for doctors to concentrate on their main roles and leave the dispensing of medicines to pharmacists, in order to avoid any possibility of conflict of interest, following their persistence in prescribing and dispensing of medicines.

LIMITATIONS OF THE STUDY

The study sample was taken only from the state of Penang. Hence, the results cannot be generalized to all GPs and CPs in Malaysia. Also, due to financial constraints, SPs visited only a limited number of premises. In addition, a common cold may seem to providers a redundant condition, although some of them prescribed and dispensed antibiotics for it. There is also possible an element of biasness due to the inconsistency of acting and communication skills of the simulated patients. URTI also exhibit certain sign which a doctor cannot find in a simulated patient; hence diagnosis and prescription for the ailment can differ.

CONCLUSION

It became evident that CPs showed better adherence to patients counseling standards while GPs did extremely well with labeling standards and following the correct guidelines in symptomatic diagnosis. Dispensing separation should be considered as a policy of the short near future, since it will lead to reductions in prescribing/dispensing of medicines and medical expenditures, maximizes therapeutic outcomes of medication use and improve their safety and quality of care in the country. More studies about appropriate use of medicines and stringent legislation and guidelines are urgent needs to promote safe use of medicines in the Malaysian community.

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