

Antibiotics Dispensing for URTIs by Community Pharmacists (CPs) and General Medical Practitioners in Penang, Malaysia: A Comparative Study using Simulated Patients (SPs)

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ABSTRACT

Background: In Malaysia, doctors in private clinics (often called dispensing doctors) are permitted to dispense medicines. This potentially may compromise rational dispensing of medicines in general and antibiotics in particular.

Aim: This study explored, assessed and compared dispensing of antibiotics between Community Pharmacist (CP) and General Practitioners (GPs) regarding symptomatic diagnosis, antibiotic categories, adherence to therapeutic doses and promotion of generic antibiotics.

Method: The study used trained Simulated Patients (SPs), who used a scenario of common cold symptoms at GP private clinics and community pharmacies to observe and explore the practice of antibiotics dispensing. The study was conducted within the period of May to September 2011 in Penang, Malaysia. The data was analysed using descriptive statistics, Chi-square and Fisher's Exact Tests at alpha level of 0.05.

Results: GPs dispensed more antibiotics than CPs ($p=0.001$) for

common cold symptoms. They dispensed more Amoxicillin ($n=14, 35%$) than CPs ($n=11, 11%$) ($p<0.001$) and more Tetracycline ($n=3, 7.5%$) while no CP dispensed this category ($p=0.022$). On the other hand, CPs ($n=11, 11%$) suggested brand antibiotics where as GPs dispensed only generic antibiotics ($p<0.001$). Generally GPs comply better with the symptomatic diagnosis standard e.g. when asking SPs about the symptoms they had, all GPs ($n=40, 100%$) complied better with this standard. Despite that, they dispensed more antibiotics ($n=26, 65%$) than CPs ($n=29, 29%$) ($p=0.001$). GPs ($n=22, 55%$) also are better than CPs ($n=16, 16%$) in adherence to therapeutic doses ($p<0.001$).

Conclusion: Findings showed poor adherence to rational dispensing of antibiotics by both providers. Although, GPs adhere better to symptomatic diagnosis and therapeutic dosing of antibiotics than CPs, they unnecessarily prescribe and dispense more antibiotics for Upper respiratory tract infection (URTI) symptoms. Establishing prescription guidance and regulatory actions, especially for URTIs treatment, and separating of medication dispensing are seemed to be crucial steps for the reform.

Keywords: Community pharmacists, Dispensing doctors, Dispensing separation, General practitioners, Simulated patients

IMPACT OF FINDINGS ON PRACTICE

The study highlighted antibiotic dispensing practices undertaken by GPs and CPs in the current situation of the lack of dispensing separation and absence of check-and-balance in Malaysia.

Findings can assist in exploring the roles of practice regulations for antibiotic utilization by both providers and implementing a suitable reform to separate between them and encourage further collaboration and cooperation in various medication concerns.

New strategies can be established to reduce antibiotic prescribing and dispensing for upper respiratory tract infections (URTIs) and other viral ailments.

INTRODUCTION

In Malaysia, where separation of dispensing from prescribing has not yet taken place, dispensing doctors in general practice clinics were found to prescribe 7 times more antibiotics than non-dispensing doctors in public primary care clinics and 1.6 times higher than university-based primary care clinics [1]. A study from Zimbabwe suggested that doctors when allowed to dispense medicines, compared to non-dispensing ones, were found to prescribe more medicines, more injections, more antibiotics and show less clinically and economically rational prescribing, leading to a lower quality of health care with them [2].

The policy of dispensing separation was implemented in many Asian countries such as Korea and Taiwan. The impact of separating prescribing and dispensing on provider behavior was studied in both countries some years after the implementation of the policy. Results showed that policy of reform in Korea benefitted in reducing prescribing of all medicines and antibiotics particularly for viral infections. In Taiwan it could be useful in reducing drug expenditure and prescribing habits of dispensing doctors but has no impact on total health expenditure [3,4]. To prepare a platform for the policy of separation, all health professionals, policy makers and the public should be involved and the current status should also be broadly evaluated [5].

Study Objectives

- To explore antibiotic dispensing for (upper respiratory tract infections) URTIs undertaken by CP and GPs.
- To evaluate and compare the rationality of antibiotic dispensing practices by both providers in relation to symptomatic diagnosis, antibiotic categories, adherence to therapeutic doses and promotion of generic antibiotics.

To fulfill these objectives and evaluate healthcare providers' behaviours it is most suitable to adapt SP methodology [6].

MATERIAL AND METHODS

Study design: A cross-sectional exploratory design was chosen for this study using SPs as a tool for collecting data. Trained SPs were instructed to play their roles according to a repeated scenario by exhibiting a scenario of having symptoms of common cold at GP clinics and an over-the-counter (OTC) self-medication scenario at private community pharmacies. SPs observed and explored rationality of dispensing of antibiotics for URTIs by both providers.

Ethical consideration: Ethical approval was obtained from the Joint Ethics Committee of School of Pharmaceutical Sciences, USM-Lam Wah Ee Hospital.

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

Study area and population: The study was restricted only to Penang state, in northwest part of Peninsula Malaysia. All medical doctors in private clinics (n = 436) and 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: Two convenient samples of 20 clinics and 50 community pharmacies were selected according to the ease of access by the SPs and financial ability since study was not funded by any organization. Number of clinics was less than the number of pharmacies because when visiting a clinic we needed to pay twice for consultation fees and purchasing of medicines.

Validation of method: To eliminate the psychological barriers when acting as a SP and prepare a training session for a comprehensive study including both CPs and GPs, we conducted a small pilot SP case study which involved the first author of this article. The SP visited two randomly chosen community pharmacies (Pharmacy A and Pharmacy B) in the state of Penang. During the visit, SP requested medications for himself (53-year-old) and his son (8-year-old) to treat common cold symptoms. All details and observations were documented by the SP. The findings of this case study suggested poor professional practices in both pharmacies and paved the way for the comprehensive study to evaluate dispensing practices in general and compare between CPs and GPs in the rationality of these practices [7].

Simulated patients training module: Based on the literature review, the pilot case study, and training session, a comprehensive SP interview method was conducted to observe, explore, evaluate, and compare dispensing of antibiotics for URTIs undertaken by GPs and CPs in Penang, Malaysia. Twenty students sat for a one-week training session on how to act as SPs who were complaining of common cold symptoms. They were also trained on how to act and exhibit a scenario of these symptoms in front of a doctor or a pharmacist. Common cold was chosen for avoiding providers' drawing notice to the involvement of the SP in a study [8].

SPs were trained to interact with practitioners and record their observations after the visit and away from the premise area. For more standardization and validation of results, the 20 SPs were grouped in 10 pairs. Each two SPs were assigned to visit 5 pharmacies and two clinics. In each visit 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. So, each pharmacist and GP dealt with 2 encounters with 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: 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). After every visit and away from the pharmacy or clinic, each SP recorded what was observed in the pharmacies and clinics visited. The data collected from GPs and CPs was based on the following components:

Categories of antibiotics dispensed and promotion of generics: The study indicated categories of antibiotics dispensed besides promotion of generic ones by GPs and CPs for the common cold symptoms.

Antibiotic dispensing and adherence to symptomatic diagnosis: 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. The two providers who adhered to symptomatic diagnosis questions were compared further according to antibiotic dispensing in relation to these questions.

Antibiotics dispensing and adherence to recommended therapeutic dosages and duration:

All antibiotics dispensed were orally administered with doses of 250 milligram to 1 gram, frequencies between 2 to 4 times a day and duration of 7 days or more [9,10]. GPs and CPs were compared according to their commitment to these criteria whether they stick to the recommended therapeutic doses of the antibiotics they dispensed or deviated to the sub-therapeutic ones.

DATA ANALYSIS

Descriptive analysis was run to describe the basic features of dispensing antibiotics by CPs and GPs. These descriptive statistics include frequencies, percentages of antibiotics dispensed and therapeutic and sub-therapeutic doses adhered to by both providers. Since all variables are categorical, Chi-Square and Fisher's exact tests are used for inferential analysis. p-value of less than 0.05 was set as significant for all statistical procedures undertaken.

RESULTS

All results from data analysis are shown in [Table/Fig-1-4]. Comparison between different variables of antibiotic dispensing is based on numbers of visits of SPs to GPs (n=20, visits= 40) and CPs (n=50, visits=100) but not on number of premises.

Categories of Medicines Dispensed by GPs and CPs for Common Cold

A wide range of medicines was dispensed by both types of professionals, from simple analgesics and vitamins to prescription-only items such as antibiotics, and encompassing antihistamines, anti-inflammatory drugs and cough remedies. GPs and CPs differed significantly in dispensing antibiotics ($p < 0.001$) and suggesting brand medicines for SPs ($p = 0.014$). A greater number of GPs (n=26, 65%) prescribed and dispensed antibiotics than did CPs (n=32, 32%) for the symptoms of the common cold exhibited by SPs. On the contrary, some CPs suggested brand medicines (n=11, 11%) whereas all GPs prescribed and dispensed generic medicines and none prescribed a brand version.

Antibiotics Dispensed for Common Cold

This section presents the comparison between different categories of antibiotic dispensed [Table/Fig-1], adherence to symptomatic diagnosis in relation to dispensing of antibiotics, and adherence to therapeutic dosage of antibiotics. The antibiotics dispensed were oral penicillin (Amoxicillin and Amoxiclav), macrolide (Erythromycin), cephalosporin (Cefalexin) and tetracycline. GPs and CPs differed significantly in dispensing oral penicillin ($p = 0.001$). GPs (n=14, 35%) dispensed more Amoxicillin and Amoxiclav than CPs (n=11, 11%) for common cold symptoms. Only three GPs (7.5%) dispensed

tetracycline while no CP dispensed such an item for SPs ($p=0.022$). On the other hand, eleven CPs (11%) suggested brand antibiotics for SPs but they did not dispense them, while no GP suggested or dispensed such versions ($p<0.001$).

Antibiotic dispensed	CP (n = 50) (visits =100) no. (%)	GP (n = 20) (visits = 40) no. (%)	p-value*
Penicillin (Amoxil and Amoxiclav)	11 (11.0)	14 (35.0)	<0.001
Macrolide (erythromycin)	9 (9.0)	3 (7.5)	1.000
Cephalosporin (Cefalexin)	4 (4.0)	0 (0.0)	0.578
Tetracycline	0 (0.0)	3 (7.5)	0.022
Unlabeled antibiotic (No name)	8 (8.0)	6 (15.0)	0.160
Provider suggested brand antibiotic	11 (11.0)	0 (0.0)	<0.001

[Table/Fig-1]: Antibiotic categories prescribed/dispensed by GPs and CPs for common cold
*Fisher's Exact Test (Significance: $p<0.05$)

Comparison of Antibiotics Dispensing between GPs and CPs Who Adhered to Symptomatic Diagnosis

Although GPs adhered to the standards for symptomatic diagnosis of the common cold better than CPs, they prescribed more antibiotics in relation to these diagnostic parameters, despite the fact that they indicated that the case was only a viral infection and no medication was needed. [Table/Fig-2] shows that those respondents who asked about the patient's age differed significantly in dispensing antibiotics ($p=0.001$). In more detail, of twelve CPs who asked about the patient's age only one (8.3%) gave antibiotics, while all GPs who adhered to this management standard ($n=5$, 100%), prescribed antibiotics to treat this minor ailment. With regard to asking about symptoms, of 87 CPs who adhered to this standard 29 (33.4%) agreed to dispense antibiotics for common cold symptoms. In contrast, 26 (65%) of the 40 GPs who adhered to this standard also prescribed antibiotics ($p=0.001$). Regarding the question about the duration of symptoms, of 53 CPs who adhered to this standard 21 (39.6%) agreed to dispense antibiotics for common cold symptoms. In contrast 21 (65.6%) of the 32 GPs who adhered to this standard consequently dispensed antibiotics ($p=0.026$). Concerning soliciting information about the colour of sputum, of 46 CPs who adhered to this question 11 (23.9%) agreed to dispense antibiotics for common cold symptoms compared with 17 (65.4%) of the 26 GPs who adhered to this standard and who nevertheless prescribed antibiotics ($p=0.001$). Those respondents who asked about the frequency of the same complaints occurring per year differed significantly from each other in dispensing antibiotics

($p=0.015$). Of six CPs who asked about this diagnostic standard only one (16.7%) gave antibiotics, whereas all GPs who adhered to this standard ($n=5$, 100%) proceeded to prescribe antibiotics. Concerning soliciting information about allergies to medicines, of 37 CPs who adhered to this question 14 (37.8%) agreed to dispense antibiotics for common cold symptoms. In contrast, 14 (82.4%) of the 17 GPs who adhered to this standard still dispensed antibiotics ($p=0.003$).

Adherence to Antibiotic Therapeutic Doses

[Table/Fig-3] shows the recommended daily dosage and duration of antibiotics dispensed, while [Table/Fig-4] compare GPs and CPs in their response in dispensing antibiotics and their adherence to the recommended therapeutic dose and duration, respectively. The numbers and categories of medicines dispensed show that GPs were more likely than CPs to dispense antibiotics for the SPs' minor complaints ($p=0.001$). Despite the inappropriate dispensing of antibiotics, GPs appeared to adhere to therapeutic dosages ($n=22$, 55%) and were less inclined to sub-therapeutic dosages ($n=4$, 10%) than the 16 CPs (16%) for both therapeutic and sub-therapeutic adherences ($p<0.001$).

DISCUSSION

Results of this study showed clear irrationality of antibiotics dispensing by both CPs and GPs with respect to disregarding patients' safety. In discussing these results according to the objectives of the study and research questions, findings are classified and argued under the following components.

Irrational Use of Antibiotics

The concept of rational use of drugs (RUD) was defined by the WHO as "Patients receive medications appropriate to their clinical needs, in doses that meet their own individual requirements for an adequate period of times and at the lowest cost to them and their community" [11]. Our respondents (CPs and GPs) in this study are not complying with the concept of RUD by inappropriate prescribing and dispensing of antibiotics for a non-bacterial infection. This inappropriateness is included in common types of irrational use of medicines i.e. utilizing of too many medicines per patient (poly pharmacy), use of injection and inappropriate use of antibiotics. These irrationalities will lead to wasting of resources, jeopardizing patients' safety by enhancing bacterial resistance to antibiotics [12]. GPs and CPs responding to this study dispensed more unnecessary antibiotics. This malpractice if not justified, patient safety, their affordability and care quality all will be put at risk [13]. Our study added to the finding of the study

HCPs suggested question "SP's suggested answer"	CP response (n=50) (visits =100) Antibiotic dispensing			GP responses (n=20) (visits =40) Antibiotic dispensing			p-values*
	Refused (%)	Agreed (%)	Total adherence (%)	Refused (%)	Agreed (%)	Total adherence (%)	
1. How old are you? "20 years old"	11 (11.0)	1 (1.0)	12 (12.0)	0 (0.0)	5 (12.5)	5 (12.5)	0.001
2. What symptoms have you got? "Cough with phlegm, running nose, sneezing, headache, low grade fever and fatigue"	58 (58.0)	29 (29.0)	87 (87.0)	14 (35.0)	26 (65.0)	40 (100)	0.001
3. How long have you had the symptoms? "For three days and still complaining"	32 (32.0)	21 (21.0)	53 (53.0)	11 (27.5)	21 (52.5)	32 (80)	0.026
4. What is the color of sputum? "White to green, i.e. yellowy"	35 (35.0)	11 (11.0)	46 (46.0)	9 (22.5)	17 (42.5)	26 (65.0)	0.001
5. Is there any blood in sputum? "No"	4 (4.0)	2 (2.0)	6 (6.0)	0 (0.0)	5 (12.5)	5 (12.5)	0.061
6. How many times/year you presented the same complaint? "2 or 3 times a year"	5 (5.0)	1 (1.0)	6 (6.0)	0 (0.0)	5 (12.5)	5 (12.5)	0.015
7. What medicines have you used before for? "Many with an antibiotic"	6 (6.0)	4 (4.0)	10 (10.0)	5 (12.5)	11 (27.5)	16 (40.0)	0.228
8. Are you allergic to any medicine? "No"	23 (23.0)	14 (14.0)	37 (37.0)	3 (7.5)	14 (35.0)	17 (42.5)	0.003
9. Are you smoking? "No"	0 (0.0)	0 (0.0)	0 (0.0)	3 (7.5)	0 (0.0)	3 (7.5)	**

[Table/Fig-2]: Comparison of antibiotic dispensing between community pharmacists and general practitioners who adhered to symptomatic diagnosis of common cold
*Fisher's Exact Test (Significance: $p<0.05$)

** No statistics are computed because GPs and CPs responses and antibiotic dispensing are constants

No.	Antibiotic dispensed	Recommended daily dosage	Duration
1.	Penicillin (Amoxil and Amoxiclav)	250-500 mg 3 times/day	For 7 to 10 days
2.	Macrolide (Erythromycin)	1g/day (2,3 or 4 times a day)	For at least 10 days
3.	Cephalosporin (Cefalexin)	250-500 mg 4 times/day	For 7 to 10 days
4.	Tetracycline	250-500 mg 4 times/day	For 7 to 10 days

[Table/Fig-3]: Therapeutic dosage and duration of antibiotics dispensed by GPs and CPs

Antibiotics dispensed	CPs (n=50) (visits=100) Frequency (%)	GPs (n=20) (visits=40) Frequency (%)	Total (n= 70) (visits= 140)	p-value
Refused to dispense	68 (68.0)	14 (35.0)	82 (58.6)	0.001*
Agreed to dispense	32 (32.0)	26 (65.0)	58 (41.4)	
Total	100 (100)	40 (100)	140 (100)	
Adherence to therapeutic doses				
Therapeutic doses for 7 days or more	16 (16.0)	22 (55.0)	38 (21.4)	<0.001**
Sub-therapeutic doses < 7 days	16 (16.0)	4 (10.0)	20 (20.0)	
Total	32 (32)	26 (65)	58 (41.4)	

[Table/Fig-4]: Antibiotics dispensed and adherence to therapeutic doses by general practitioners and community pharmacists

*Fisher's Exact Test (Significance: $p < 0.05$)

**Chi-Square Test

from Zimbabwe [2] that dispensing doctors, besides exceeding non-dispensing doctors, they are also dispensing more antibiotics than CPs for common cold symptoms.

Antibiotics for Viral Infections (common cold)

The symptoms shown by our SPs were symptoms standing for common cold which mainly caused by viral pathogens such as rhinovirus, parainfluenza, adenovirus, RSV and influenza and resolves without the use of antibiotics [14]. Some of the GPs and CPs in this study both prescribed/dispensed antibiotics for these symptoms. We find no justification for this behaviour except the suspect of providers' fear of dissatisfying their patients when refusing to prescribe antibiotics for them [15]. They might also put in mind the probability of the emergence of bacterial rhino sinusitis complicates which was about only 2% of the cases to happen [16]. Those CPs and GP are not relying to the guidelines in diagnosing and treating non specific URTIs of viral entity in which antimicrobial therapy and antibiotics are not indicated.

Categories of Antibiotics Dispensed and Promotion of Generics by CPs and GPs

These categories are penicillin (Amoxicillin), macrolides (Erythromycin), Cephalosporin (Cefalexin) and Tetracycline. Some responding CPs suggested the use of innovated brand antibiotics for the sake of increasing their income by selling high-priced medicines. They may be forced to do so because they seldom receive prescriptions from GPs [17]. Contrary to that, all GPs prescribed and dispensed low-priced generic antibiotics (Amoxicillin and Tetracycline) to collect high mark-ups from the high margin of profit obtained from generic medicines. In addition, GPs do make large profit margin from the extra bonuses of medicines they received from medical representatives compared to CPs who usually receive none or less. These finding are found to be consistent with previous studies in Malaysia and Korea where doctors are marking up the low-priced generics to make profit or purchase drugs that have much lower cost than the insurance price to put high margins for profit [18, 19].

Adherence to Therapeutic Doses and Duration of Antibiotics Dispensed

When dispensed for other purposes than bacterial infections, antibiotics were characterized to be inappropriately prescribed or misused [12,14]. Appropriate use of antibiotics might not be achieved by focusing on their efficacy but also on the prescriber's adhering to more rational prescribing [20]. As the definition of RUD implies, the first important factor of prescribing medicines to patient is to be appropriate for their clinical needs [11]. Although GPs in this study adhered better to therapeutic doses and duration of antibiotics, they prescribed and dispensed these antibiotics inappropriately regardless to actual clinical needs of their patients. By doing so, unfortunately they masked their adherence to better dosing. In conformity with the Malaysian poisons act, it is prohibited for pharmacists to dispense antibiotics without legal prescriptions from doctors.

Recommendations: Concerning inappropriate prescribing and dispensing, it is necessary to adopt a strong and explicit line of actions, especially towards misuse of antibiotics, otherwise the stream of antibiotics in Malaysia will dry up due to the aggravated resistance. 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 medicines.

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, encourage use of generic medicines, maximize therapeutic outcomes of medication use and improve their safety and quality of care. More studies about appropriate use of medicines and stringent legislation and guidelines are urgently needed to promote safe use of medicines in the Malaysian community.

It is also important to study the perspectives, and experiences of health care providers and consumers towards CP's role in the provision of health care to establish a strong basis for the implementation of pharmaceutical care strategies after highlighting gaps and weak areas in real practice, which may prohibit the pharmacist from realizing his real mission and communicating with other parties.

LIMITATION

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, when SPs are taken there is an element of biasness due to the acting and communication skills of the SPs. URTI also exhibit certain sign which a doctor cannot find in a SP; hence diagnosis and prescription for the ailment can differ. A common cold may seem to providers as a redundant condition, although some of them prescribed and dispensed antibiotics for it.

CONCLUSION

The findings in this study revealed unnecessary dispensing of antibiotics in both community pharmacies and private clinics. GP dispense more antibiotics than CPs. Although, GPs adhere better to symptomatic diagnosis and therapeutic dosing of antibiotics than CPs, they unnecessarily prescribe and dispense more antibiotics for URTI symptoms. Promotion of brand version of antibiotics by CPs and generic version by GPs is mainly for increasing their incomes from profit margins. Separation will definitely contribute to more concentration of both professionals on their roles as healthcare providers and improve their experiences and skills towards behaving rationally and being more patient oriented. After separation of roles every professional will definitely feel the urgent need for collaboration and communication in medication use problem and availability, the thing that is missing in the current situation.

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