

Patients' Beliefs about Generic Medicines in the Outpatient Setting, Sibu Hospital

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Abstract

Introduction: Malaysia implemented National Generic Medicines policy since 2006 to encourage generic medicines prescribing. After ten years of implementation, patients' belief about generic medicines is yet to be assessed.

Objective: The objectives were to assess patients' beliefs about the similarity and efficacy of generic medicines, and to determine the association between demographic characteristics with patients' beliefs about the generic medicines in Sibu Hospital.

Methods: This is a cross-sectional study conducted at the outpatient pharmacy of Sibu Hospital between January and May 2017 using convenience sampling method. The Generic Medicine Scale (GMS), a validated self-administered questionnaire was used. Data was analysed using SPSS software.

Results: A total of 150 respondents were included in the analysis. Majority of the respondents knew about generic medicines (60.7%). The mean scores of the efficacy and similarity domains were 2.97 (95% CI 2.89, 3.04) and 3.18 (95% CI 3.08, 3.28) respectively. In terms of efficacy, 41.3% of the respondents believed that generic medicines were as efficacious as branded medicines and could be used to treat the same illnesses (54.0%), but 44.7% of respondents believed that generic medicines took longer time to be efficacious and longer treatment duration was required (43.3%). With regard to similarity, majority of respondents were neutral about generic medicines being similar to branded medicines, but 60% of the respondents agreed that generics had different box (packaging). Respondents' beliefs on generic medicines was significantly affected by age ($p=0.001$), gender ($p=0.007$), ethnicity ($p=0.014$), education level ($p=0.028$) and knowledge on generic medicines ($p=0.036$).

Conclusion: Patients attending the outpatient pharmacy in Sibu Hospital had mixed belief on the efficacy of generic medicines, and were relatively neutral on the similarities of generic drugs compared to branded product. Age, gender, ethnicity and education level were shown to be affecting respondents' perception on generic medicines.

Keywords: generic medicines, Sibu Hospital

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Introduction

Generic medicine is medicine that is similar to the innovator medicine in terms of its dosage form, safety, strength, route of administration, quality, performance characteristics and intended use. It is proven to be bioequivalent to innovator medicine. In order for a generic medicine to be marketed, pharmaceutical companies must get approval from the national authority by submitting an abbreviated new drug application (ANDA). In Malaysia, the National Pharmaceutical Regulatory Agency is the regulatory body that issues approval for generic medications. The criteria for generic medicines to gain approval are the generic medicines must contain the same active ingredients, strength, dosage form and route of administration as the innovator medicine. The indications of the generic medicine must be identical and proven to be bioequivalent to the innovator medicine. The manufacturing of generic medicines must meet the same batch requirements for the formulation in terms of its identity, strength, purity and quality. By meeting the requirements, health professional and consumers can be assured that generic medicines are as effective as innovator medicines¹.

Healthcare expenditure is increasing globally over the years. Pharmaceutical cost has been shown to be the second driver for healthcare cost escalation, after healthcare professional wages. A similar trend is observed in the Malaysian healthcare system. In Malaysia, the public sector caters for approximately 65% of the Malaysian population². Public healthcare services are comprehensively subsidised by the Malaysian government. National surveys have demonstrated the progressive cost escalation in pharmaceutical industry². A report by the World Health Organization (WHO) stated that healthcare expenditure in Malaysia is significantly higher than the average value of other upper-middle income countries. One of the approaches to reduce healthcare expenditure is encouraging the use of generic medicines instead of expensive innovator medicines. In Malaysia, generic medicines substitution is reported to potentially save up to 60% of the pharmaceutical cost^{1,3}. Due to the cost saving benefits of generic medicines substitution, Malaysian government has formulated policies to encourage the use of generic medicines. Generic Medicines Policy formulated under the third component of Malaysian National Medicines Policy (2007) encourages generic prescribing and substitution to reduce the pharmaceutical expenditure².

Despite continuous effort by the Malaysian government to increase generic substitution rate in Malaysia, generic medicines only contributes to about 40% of the total prescription market³. Factors that contribute to low generic medicines market are misconception and insufficient knowledge of consumers or patients about generic medicines³. Generic medicines are cheaper compared to innovator medicines, ideally. Yet consumers always have the perception that cheaper in price means lower in quality. It was found that one-third of patients assumed that generic drugs are cheaper because they are less efficacious^{1,3}. However, this perception is not entirely true. Generic medicines are cheaper because pharmaceutical companies do not have to repeat the costly clinical trials of new drugs and do not pay for the costly advertising, marketing and promotion. Moreover, market competition among multiple generic companies that market the same generic products usually result in lower prices¹.

A national wide study conducted in the United States by Shrank *et al.* found that Americans generally agreed that generic medicine was less expensive and had better value than innovator medicine. Although patients believed that generic medicine was just as good as innovator drug, only one-third of Americans agreed to use generic medicine. The study also indicated that wealthier patient preferred generic medications while healthier patients were more concerned with the safety and efficacy of generic drugs⁶. On the other hand, the perception of Jordanian patients towards generic drug substitution was excellent. According to Farris *et al.*, 92% of Jordanian patients preferred to be prescribed the cheapest medicine. They believed that cost should be considered before medication was prescribed. Besides that, 78% of the patients agreed that generic substitution could provide significant cost saving. The study also showed that 83% of Jordanian believed that cost of medicines in Jordan was the main driver to choose generic medicines⁷.

Another review conducted by Hakonsen *et al.* in Norway was aimed to summarise the patient's perspectives on generic substitution in the western world between 2000 and 2011. The outcomes of the review showed that one third of all patients still preferred to use brand named medicines. Some patients reported to experience more adverse effects with generic medicines and claimed that generic medicines were less efficacious compared to innovator medicines. The authors concluded that poor awareness on generic substitution caused confusion and reduced patient acceptability to generic medicines. Also, patient's acceptance of generic substitution was influenced by age, level of education, diseases' perception, generic drug information and prescribers' advice⁸.

In Malaysia, two studies were conducted to explore the perception of generic medicines substitution after the implementation of generic medicines policy in year 2006. The first study conducted by Thomas *et al.* showed that more than half (67.5%) of the consumers in community pharmacies did not know what generic medicines were¹⁰. Among the consumers who never use generic medicines, they perceived that generic medicines were not as effective or as safe as brand medicines. Price was one of the reasons why consumers chose to use generic medicines, in 31 out of 86 respondents. A lack of knowledge about generic medicines was also the factor that led to negative perception amongst the consumers in community pharmacy setting in Malaysia. The second study conducted by Wong *et al.* in a government hospital showed that only 49% of patients involved knew the term 'generic medicine'⁹. Almost half of the patients had negative belief in generic medicines. Few demographic characteristics were found to significantly affect patient's belief on generic medicines. Patient with higher level of education and income status tended to have positive belief on generic medicines³.

As part of the implementation of National Generic Medicines Policy, Sibul Hospital had been supplying more and more generic medicines to patients since year 2006. After more than 10 years of utilising generic medicines, we would like to explore the patients' beliefs and views about generic medicines. To the best of our knowledge, there is no similar study conducted regarding perception of using generic medicines among the Sarawak population. Therefore, this study aimed to assess the current beliefs and views of patients on generic medicines in Sibul Hospital. The objectives of our study were (1) to assess patients' beliefs about the similarity and efficacy of generic medicines, and (2) to determine the association between demographic characteristics with patients' beliefs about the generic medicines in Sibul Hospital.

Methods

This was a cross-sectional study conducted at the outpatient pharmacy, Sibul Hospital, from 1 January to 31 March 2017. A validated self-administered Generic Medicines Scale (GMS) questionnaire in both Malay and English language was used as the data collection tool. The inclusion criteria were any adult patients aged more than 18 years old, who were able to speak, read and write in Malay or English language. Meanwhile, paediatric patients, caregivers, psychiatric patients and patients with cognitive impairment were excluded. Convenient sampling method was applied in the study. Every patient that fulfilled the eligibility criteria was approached by the investigators. Patients agreed to participate in the research were given a letter explaining the background, purpose and procedure of the study. A brief explanation on definition of generic and original medicine was given to the respondents. Patients who consented to participate were given the questionnaire to be filled in.

Sibul Hospital is the major specialist referral hospital for the central region of Sarawak. The average number of patients attending outpatient pharmacy in Sibul Hospital per day was 650. Over the three-month data collection period, total estimated number of patients was 58,500. Sample size was calculated using Sample Size Calculator for Estimations Version 1.0.03 developed by Lin Naing *et al.*¹¹. By using the estimated population of 58,500 patients in the outpatient pharmacy, with confidence level of 95% and acceptable margin error (precision) of 5% and standard deviation of 0.3³, the

calculated sample size was 139. However, to allow for potentially high non-response rate, the final sample size was increased by 20% to 170.

Generic Medicine Scale (GMS) questionnaire developed by Figueirras *et al.*¹² was used to assess patients' beliefs about generic medicines. The English version of the GMS was validated by Figueirras *et al.* while the Malay version of the GMS was validated by Wong *et al.* in 2014¹³. Both versions of the questionnaire were used in this study. The GMS consisted of two parts: Part A was collecting respondents' social demographic information (age, gender, ethnic, education level and monthly income), while Part B was questions relating to respondents' knowledge and perceptions on generic medicines. Part B consisted of a combination of 16 positive and negative statements using five points Likert scale (1=strongly disagree, 2=disagree, 3=neutral, 4=agree and 5=strongly agree). Respondents were expected to spend approximately 15 to 20 minutes to complete the questionnaire.

The data was analysed using Statistical Package for Social Sciences (SPSS). Descriptive statistics were used to describe the demographic data of the participants. The GMS questionnaire was presented as descriptive data in numbers and percentage as well as mean score and 95% confidence interval (CI) for the efficacy and similarity domains. Negative statements in the efficacy domain was re-coded during analysis so that the score can reflect same direction in respondents' beliefs. The mean score calculated ranged from one (negative beliefs) to five (positive beliefs) with three as the neutral point. Independent t-test was used to detect the significant difference in participants' response between genders and knowledge about generic medicines. One-way Anova was used to detect the significant differences in participants' response for other demographic factors, namely ethnic, age, education level, income and occupation of respondents. Post-hoc analysis was applied to determine significant differences between groups for factor with more than two levels, by using Scheffé method. All these tests were performed with significance level set at 0.05.

Results

A total of 332 patients were approached during the study period and 158 patients were consented to participate in this study, which led to the low response rate of 47.6%. Eight out of the 158 patients were excluded from the analysis due to more than 70% missing data in the questionnaire. This resulted the final number of respondents at 150. The respondents' demographic characteristics were shown in Table 1. The mean age of the final respondents was 42.7 years old (standard deviation 15.86). Majority of the respondents were female (56.7%), Chinese (52.0%), had at least secondary education (48.7%) and from lower income group earning less than RM1,000 a month (44.7%). More than half (60.7%) of the respondents knew about generic medicines.

Table 2 and Table 3 showed the responses for the efficacy and similarity domains. The mean score of efficacy domain was 2.97 (95% CI 2.89, 3.04) while the mean score for similarity domain was 3.18 (95% CI 3.08, 3.28). Almost half (41.3%) of the respondents believed that efficacy of generic medicines were the same as branded medicines and it could be used to treat the same illnesses (54.0%). However, almost half of the patients believed that generic medicines took longer time to be effective (44.7%), required longer treatment duration (43.3%), should be used for less serious illnesses (53.3%) and cheaper because of reduced efficacy (34.0%). In terms of quality, 41.4% of the respondents disagreed that generic medicines were made with lower quality substances but 36.6% respondents disagreed that the quality control of generic medicine was better. In terms of patients' beliefs on the similarities of generic medicines, majority of the respondents were neutral on the similarities of tablet (36.0%), taste (44.0%) and side effects profile (42.7%) of generic medicines compared to branded medicines. However, more than half of the respondents knew generic medicines had different box (60.0%) and usage is similar to branded medicines (50.7%).

Table 4 showed the factors influencing patients' beliefs about the generic medicines. The respondents' beliefs on generic medicines was significantly affected by age ($p=0.001$), gender ($p=0.007$), ethnic ($p=0.014$), education level ($p=0.028$) and knowledge on generic medicines

($p=0.036$). Male agreed treatment with generic antibiotics were less efficacious compared to branded antibiotics ($p=0.021$). Those who knew about generic medicines agreed that generic medicines were used for the same illnesses ($p=0.036$). Compared to Malays, Chinese were more prone to believe that generic medicines took longer treatment duration ($p=0.021$), have better quality control ($p=0.001$) and generic medicines had a different box compared to branded medicines ($p=0.038$). Malays were more prone to believe that generic medicines were the same as branded medicines compared to Sarawak Bumiputeras ($p=0.023$). Age was found to affect respondents' belief in generic medicines too. Results showed only respondents between 31 and 40 years old had higher level of agreement that generic medicines had similar taste as branded medicines compared to respondents more than 50 years old. In terms of education level, degree holders ($p=0.027$) believed that generic medicines had the same effect as brand medicine compared to respondents with primary education only.

Table 1: Patients' demographic characteristics (N= 150)

Characteristics	n (%)
Gender	
Male	65 (43.3)
Female	85 (56.7)
Ethnic	
Chinese	78 (52.0)
Sarawak Bumiputera	54 (36.0)
Malay	18 (12.0)
Age group	
≤ 30	40 (26.7)
31-40	31 (20.7)
41-50	29 (19.3)
51-60	26 (17.3)
> 60	24 (16.0)
Education	
No formal education	6 (4.0)
Primary education	17 (11.3)
Secondary education	73 (48.7)
Form 6 and diploma	31 (20.7)
Degree and above	23 (15.3)
Income	
< RM1,000	67 (44.7)
RM1,000 - RM2,000	32 (21.3)
RM2,001 - RM3,000	22 (14.7)
RM3,001 - RM4,000	14 (9.3)
> RM4,000	11 (7.3)
Missing data	4 (2.7)
Occupation	
Professional	28 (18.7)
Non-professional	50 (33.3)
Self-employed	17 (11.3)
Unemployed	50 (33.3)
Missing data	5 (3.3)
Ask doctor about medications	
Yes	100 (66.7)
No	50 (33.3)
Having medical cards for health insurance	
Yes	69 (46.0)
No	81 (54.0)
Know about generic medicine	
Yes	91 (60.7)
No	59 (39.3)

Table 2: Patients' beliefs about the efficacy of generic medicines (n=150)

Items in questionnaire	Number of responses, n (%)				
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
1. The efficacy of generic medicines is same as that of the brand medicines.	6 (4.0)	45 (30.0)	37 (24.7)	57 (38.0)	5 (3.3)
2. Generic medicines take longer time to be efficacious.	4 (2.7)	31 (20.7)	48 (32.0)	63 (42.0)	4 (2.7)
3. Generic medicines are good for less serious diseases.	5 (3.3)	27 (18.0)	38 (25.3)	75 (50.0)	5 (3.3)
4. Treatments with generic medicines take longer time.	4 (2.7)	33 (22.0)	48 (32.0)	60 (40.0)	5 (3.3)
5. Generic medicines are made with lower quality substances.	4 (2.7)	58 (38.7)	43 (28.7)	39 (26.0)	6 (4.0)
6. Generic antibiotics are less efficacious than brand antibiotics.	4 (2.7)	33 (22.0)	60 (40.0)	45 (30.0)	8 (5.3)
7. Generic medicines have a better quality control than brand medicines.	2 (1.3)	53 (35.3)	52 (34.7)	39 (26.0)	4 (2.7)
8. Generic medicines are cheaper because they are less efficacious.	0 (0.0)	62 (41.3)	37 (24.7)	46 (30.7)	5 (3.3)
9. Generic medicines have the same effect than brand ones.	2 (1.3)	45 (30.0)	48 (32.0)	52 (34.7)	3 (2.0)
10. Generic medicines are used for the same illnesses.	2 (1.3)	20 (13.3)	47 (31.3)	76 (50.7)	5 (3.3)

Table 3: Patients' beliefs about the similarities of generic medicines (n=150)

Items in questionnaire	Number of responses, n (%)				
	Strongly disagree	Disagree	Neutral	Agree	Strongly agree
11. Generic tablets are the same as brand ones.	1 (0.7)	44 (29.3)	54 (36.0)	48 (32.0)	3 (2.0)
12. Generic medicines have a similar taste as brand medicines.	2 (1.3)	38 (25.3)	66 (44.0)	42 (28.0)	2 (1.3)
13. Generic medicines have the same side effects as brand medicines.	2 (1.3)	36 (24.0)	64 (42.7)	46 (30.7)	2 (1.3)
14. Generic medicines have a different box from brand medicines.	2 (1.3)	16 (10.7)	42 (28.0)	81 (54.0)	9 (6.0)
15. The use of generic medicines is similar to brand ones.	5 (3.3)	25 (16.7)	44 (29.3)	66 (44.0)	10 (6.7)
16. Generic medicines are exactly the same as brand medicines.	6 (4.0)	40 (26.7)	47 (31.3)	49 (32.7)	8 (5.3)

Table 4: Factors affecting patients' beliefs about the generic medicine in Sibuh Hospital and significant level (*p*-value)

Items in questionnaire	Gender*	Ethnic**	Age**	Education level**	Income**	Job**	Know generic*
1. The efficacy of generic medicines is same as that of the brand medicines.	0.524	0.685	0.032^p	0.363	0.526	0.262	0.451
2. Generic medicines take longer time to be efficacious.	0.310	0.349	0.178	0.063	0.456	0.727	0.437
3. Generic medicines are good for less serious diseases.	0.952	0.836	0.452	0.156	0.194	0.922	0.805
4. Treatments with generic medicines take longer time.	0.211	0.011^p	0.301	0.837	0.744	0.451	0.190
5. Generic medicines are made with lower quality substances.	0.125	0.268	0.669	0.184	0.335	0.574	0.149
6. Generic antibiotics are less efficacious than brand antibiotics.	0.021	0.887	0.278	0.266	0.411	0.934	0.231
7. Generic medicines have a better quality control than brand medicines.	0.231	0.001^p	0.133	0.108	0.074	0.959	0.124
8. Generic medicines are cheaper because they are less efficacious.	0.706	0.084	0.428	0.648	0.292	0.496	0.599
9. Generic medicines have the same effect than brand ones.	0.892	0.040^p	0.027^p	0.004^p	0.696	0.328	0.726
10. Generic medicines are used for the same illnesses.	0.602	0.284	0.195	0.024^p	0.788	0.780	0.036
11. Generic tablets are the same as brand ones.	0.562	0.011^p	0.052^p	0.174	0.437	0.476	0.739
12. Generic medicines have a similar taste as brand medicines.	0.200	0.099	<0.0001^p	0.040^p	0.521	0.140	0.285
13. Generic medicines have the same side effects as brand medicines.	0.342	0.303	0.088	0.024^p	0.500	0.703	0.797
14. Generic medicines have a different box from brand medicines.	0.129	0.034^p	0.140	0.115	0.591	0.915	0.632
15. The use of generic medicines is similar to brand ones.	0.524	0.372	0.006^p	0.011^p	0.804	0.906	0.681
16. Generic medicines are exactly the same as brand medicines.	0.927	0.231	0.171	0.355	0.806	0.461	0.500

All data were normally distributed, tested with Kolmogorov-Smirnov test.

* Independent t-test, ** One-way Anova, ^p Post-Hoc using Scheffe method

Discussion

The implementation of generic medicines policy is necessary to reduce the government's financial burden in the heavily subsidised healthcare system in Malaysia. Year 2017 marked the first decade Malaysia implemented generic medicines policy. The findings from this study could serve as a review of general public's acceptance and confidence in generic medicines policy. Our study showed 60.7% of the respondents knew about generic medicines, which was higher compared to the findings of 28.3% by Al-Gegadi *et al.*¹⁵ in Penang, 32.5% by Thomas and Vitry⁴ in Kuala Lumpur and 49% by Wong *et al.*³ in Alor Setar. This finding reflects the steadily increasing trend of awareness towards generic medicines over the years compared to study^{3,4,15} done during the early implementation of generic medicines policy.

Despite the knowledge on generic medicines, our respondents showed mixed beliefs in generic medicines. This finding was similar to study done by Wong *et al.*⁵ Almost half of our respondents showed negative perception on efficacy of generic medicines, for example it took longer time to be effective (44.4%), required longer treatment duration (43.3%), should be used for less serious illnesses (53.3%) and generic medicines were cheaper because of reduced efficacy (41.3%). This could imply that respondents may not have the confidence to use generic medicines for serious or life threatening disease. We would also like to highlight that almost one third of the respondents were neutral in their belief on the efficacy of generic drugs. This could reflect that the respondents were unsure whether there is a difference between generic and branded drugs.

In terms of quality control, respondents were also showing conflicting opinions. Almost half (41.4%) of the respondents disagreed that generic medicines were of lower quality but 36.6% respondents disagreed that the quality control of generic medicine was better. General public might be rarely exposed to the quality assurance process and strict compliance to Good Manufacturing Practice required in any pharmaceutical manufacturing plant. The national generic drug recall notification on atenolol tablet in January 2017 that coincided with data collection period, could have affected the general public's confidence in quality control. Therefore, it is important to empower patient with information about regulatory approval and registration system for medicines in the country to boost their confidence in the quality of generic medicines.

Majority of the respondents were neutral on the similarities of tablets (36.0%), taste (44.0%), side effects profile (42.7%) of generic medicines compared to branded medicines. This may be due to lack of knowledge about the similarity and difference between generic and original medicines. However, more than half of respondents knew generic medicines had different box (60%) and usage is similar to branded medicines (50.7%). This could be related to their experience with brand switching during medication supply in the pharmacy. Whenever there is any brand switching, changes in the packaging would first catch the eyes of the patients while staff at dispensing counter would explain to the patients about the brand switching and the similarity in the drug efficacy. However, patients may not routinely compare the differences in the taste and side effects profiles between generic medicines and branded medications. We also found out that majority of respondents in the less than 30 years old group were neutral on most of the statements in similarities domain compared to the older age group. This could be possibly due to the younger respondents had relatively shorter history of medical illnesses and they were only started their follow up in hospital after the implementation of generic medicines policy, thus they were unsure about the differences between generic drugs and branded drugs.

In terms of gender, this study showed that male participants believed that treatment with generic antibiotics were less efficacious compared to branded antibiotics. This might be related to personal experience. On the other hand, degree holders agreed that generic medicines had the same effect as branded medicines due to their greater acceptance in the information they were given

regarding generic or branded medicines. Greater acceptance means that they were less bias in supporting generic medicines or branded medicines alone.

There were few limitations in our study. Firstly, convenient sampling was used in the study due to the busy setting in the outpatient pharmacy of Sibul Hospital. Also, the study team was unable to recruit the expected sample size of 170 subjects due to the poor response rate. However, this may not affect the outcome of the study as the minimum sample size of 139 was still achieved. In view of the above limitations, our results may not be generalised to the general population of Sibul.

Conclusion

This study suggested that the knowledge about generic medicines among the patients who attended Sibul Hospital outpatient pharmacy was high. These patients had mixed perception on the efficacy of generic medicines but were neutral on the similarities of generic medicines. Age, gender, ethnicity, education level and knowledge about generic medicines were shown to be affecting the respondents' perception on generic medicines.

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Conflict of Interest Statement

No external funding was received and the authors declared no conflict of interest.

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