

Knowledge, Perception, and Practice of Generic Medicine and Associated Factors among Community Pharmacists in Jaffna, Sri Lanka

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ABSTRACT

Good knowledge of Generic medicines (GM) among healthcare professionals including pharmacists improves the effective usage of generic medicine among patients and thus reduces their healthcare costs. The objective of this study is to assess knowledge of GM among community pharmacists in the Jaffna district of Sri Lanka. An analytical cross-sectional study was conducted among all community pharmacists in the Jaffna district using a self-administered questionnaire. SPSS version 26 was used to analyze data. Independent sample t-test and one-way ANOVA were used to assess the relationship between sociodemographic and work-related factors and knowledge of GM among community pharmacists at the 95% confidence interval and a p-value less than 0.05 was considered significant. Fifty nine pharmacists (88%) were responded to the study. The median age of pharmacists was 42 years (IQR=23) and 59.32% of them were males. The total score for knowledge of generic medicine was 55. The mean score of knowledge on generic medicine was 33.27±13.1. Age (p=0.04), professional qualification (p=0.033), and participation in the workshop (p=0.020) had significant differences with knowledge of GM. Most of the pharmacists selected generic substitutes based on the customer's request (94.9%), followed by the quality of the generic medicine (67.8%) and familiarity of generic brands (61%). Community pharmacists lack knowledge and negatively inclined perception of GM. However, most pharmacists practice generic substitutions during dispensing. Conducting continuous professional development programs and workshops regularly and upgrading their professional qualifications to diploma or degree from certificate level could improve not only their knowledge of generic medicines but also good dispensing practice.

Keywords: *Generic medicine, knowledge, perception, practice, community pharmacists, Sri Lanka.*

INTRODUCTION

A generic medicine is “a medication created to be the same as an already marketed brand-name drug in dosage form, safety, strength, route of administration, quality, performance characteristics, and intended use” [1]. These similarities help to illustrate bioequivalence, which means a generic medicine acts the same way as an innovative brand medicine and offers the same clinical advantage.

The cost of generic medicines is usually less than innovator brands because they do not necessarily conduct animal and human clinical studies [1]. Generic substitution is defined as the act of substituting an innovator brand medicine and/or equivalent generic brand medicine [2].

In Sri Lanka, the cost of generic medicines is 80 to 85 percent lower than innovator brands on average, so generic medicines can reduce healthcare costs significantly [2]. The cost of the innovator brand is more than the one-day wage of the lowest-paid government worker; meanwhile, the affordability of generic substitutes is less than one wage [3]. However, innovator brands

are not available for most of the drugs in Sri Lanka and only limited drugs have innovator brands. Generic substitutes were available with wide price differences in Sri Lanka. Therefore, community pharmacists in Sri Lanka practice generic medicine substitution. They provide drug information to patients as pharmaceutical experts, switch to a generic substitute with the lowest price from originally prescribed higher-cost generic medicine on the request of the customer, and thus play a role in reducing healthcare cost spending by patients.

In Sri Lanka, the National Medicines Regulatory Authority (NMRA) is responsible for the regulation and control of, licensing, registration, manufacture, importation, and all other aspects related to medicines. The NMRA Act 2015 defines generic medicine in the guidelines for registration of medicine as “(a) having the same quantitative composition of therapeutically active substances, consisting of substances of similar quality to those used in a registered medicine; (b) having the same pharmaceutical form; (c) are bioequivalent; and (d) have the same safety and efficacy characteristics” [4].

Patients lack adequate knowledge and have a negative perception of generic substitutes in many countries [5]. It could result in failing to get benefits from cost-effective generic substitutes by patients. Healthcare professionals such as pharmacists could play an important role in educating patients regarding generic substitutes. Good

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knowledge of generic medicines among pharmacists is crucial in educating patients. Several studies on the knowledge and practice of generic medicine have been conducted in countries like India [6], Saudi Arabia [2], Nigeria [7], Vietnam [8] and Malaysia [9]. However, no such published studies were among pharmacists in Sri Lanka. Therefore, this study assesses community pharmacists' knowledge of generic medicine and perception, and practice of generic medicine in the Jaffna district of Sri Lanka.

METHODS

This cross-sectional study was conducted among community pharmacists at the pharmacies in the district of Jaffna, Sri Lanka. This study was conducted from November 2020 to November 2021.

According to the National Medicines Regulatory Authority (NMRA) of Sri Lanka, around 5,000 community pharmacists are working in Sri Lanka, which has 25 districts. Jaffna district is situated in the northern part of Sri Lanka. Only sixty-seven community pharmacists worked in the district of Jaffna during the study period. All community pharmacies in the Jaffna district were included in this study.

A self-administered questionnaire was used to collect data. The questionnaire was developed by adapting previous studies with modifications. [2, 6, 10, 11] Face and Content validities of the questionnaire were done by the experts which included community physicians, pharmacologists, and pharmacists. According to their suggestions, the questionnaire was revised.

The questionnaire included information about the socio-demographic and work-related factors of community pharmacists. 11-item questions regarding knowledge of generic medicine, which contained one open-ended question and 10 closed-ended statements, 07 statements regarding the perception of generic substitution, and 02 questions related to the practice of generic substitution.

In the 11-item knowledge questionnaire, one open-ended question on the definition of generic medicine carried a maximum of 5 scores. If the response was fully corrected, then five marks were given and if partially corrected then three marks were given. If there was a wrong or do not know response, then a zero mark was given. For the next 10 knowledge items statements, each statement carried five scores for the correct response, and zero scores for an incorrect response or do not know. The maximum score given for knowledge of GM was 55.

The responses to the 7-item perception questionnaire were given as agree, disagree, and uncertain. The responses were presented as frequency and percentage. Practice questions also were presented as frequency and percentage.

Continuous variables such as age and experience in years were categorized as follows. The age of the participants in years was categorized according to adult age categorization as young adulthood (18-35 years), middle-age adulthood (36-55 years), and older adulthood (above 55 years). The experience in years was categorized based on medium.

Consent forms were obtained before the data collection from pharmacists. Data were collected during their free time without interfering with their routine activities. Ethical clearance was obtained from the Ethical Review committee, Faculty of Medicine, University of Jaffna, Sri Lanka.

The collected data were entered into SPSS 26 (Statistical Product and Service Solutions). The mean knowledge of pharmacists under different categories was compared by independent t-test and one-way ANOVA at the 95% confidence interval and a P-value less than 0.05 was considered significant.

RESULTS

The response rate of this study was 88% (n=59). Table 1 displays knowledge of generic medicine among pharmacists. Table 2 illustrates the distribution of socio-demographic and work-related factors. Among the total (n = 59) participants, most of them (40.67%) were in the age group of 36 - 55 years. The age range of the pharmacists was between 26 and 65 with a median age of 42 years (IQR= 23). The majority of the participants (59.32%) were males. Most of the participants (62.71%) completed certificate courses in pharmacy.

Among the total study participants, 44% participated in workshops regarding generic medicines. More than half of them (54.23%) worked at pharmacies in rural areas. Two-thirds (67.79%) of the participants worked as an employee. Only 55.93% of participants have less than 08 years of experience.

Fig. (1) depicts the knowledge score of pharmacists. Older pharmacists, pharmacists having diploma/degree qualifications, and pharmacists who participated in the

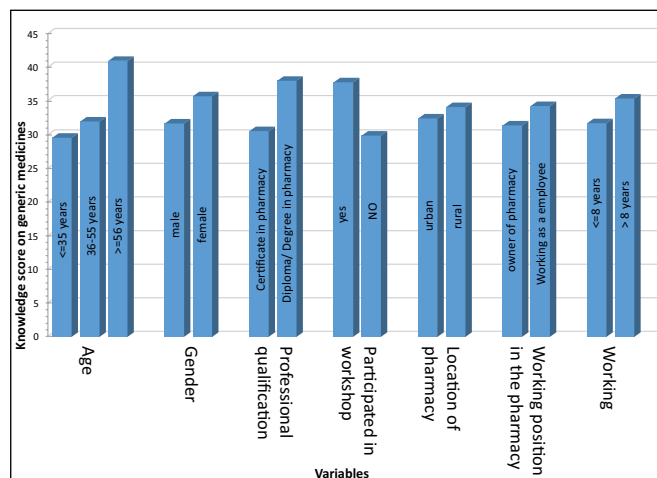


Fig. (1): Knowledge of generic medicines among pharmacists.

Table 1: Knowledge of generic medicine among pharmacists.

| Items | Correct Response | Partially Correct Response | Incorrect Answer / Do not Know |
|---|------------------|----------------------------|--------------------------------|
| | f (n) [P (%)] | | f (n) [P (%)] |
| 1. Definition of generic medicine | 41 [69.50%] | 06 [10.17%] | 12 [20.33%] |
| 2. A generic drug is bioequivalent to the innovator brand. (Correct) | 38 [64.4%] | - | 21 [35.6%] |
| 3. A generic drug should be in the same dosage form (capsule or tablet) as the innovator brand. (Correct) | 52 [88.14%] | - | 07 [11.86%] |
| 4. A generic drug must contain the same strength as an innovator brand. (Correct) | 52 [88.14%] | - | 07 [11.86%] |
| 5. Generic drugs demonstrate less efficacy compared to innovator brands. (Incorrect) | 20 [33.9%] | - | 39 [66.10%] |
| 6. A generic drug has the same route of administration as the innovator brand. (Correct) | 46 [77.96%] | - | 13 [22.04%] |
| 7. A generic drug should have the same appearance (size, shape, and color) as the innovator brand. (Incorrect) | 47 [79.67%] | - | 12 [20.33%] |
| 8. A generic drug should have the same excipients (bulking agents, fillers, and diluents) as the innovator brand. (Incorrect) | 47 [79.67%] | - | 12 [20.33%] |
| 9. Innovator brand is required to meet higher safety standards than generic drugs. (Incorrect) | 14 [23.73%] | - | 45 [76.27%] |
| 10. Generic drugs produce more side effects compared to innovator brands. (Incorrect) | 21 [35.6%] | - | 38 [64.4%] |
| 11. Generic drugs can be registered without submitting product quality data. (Incorrect) | 35 [59.33%] | - | 24 [40.67%] |

Table 2: Factors associated with knowledge of generic medicines among pharmacists.

| Factors | Categories | n (%) | Knowledge of Generic Medicine | | |
|----------------------------------|-----------------------------|-------------|-------------------------------|------------|-------|
| | | | mean \pm SD | t or F | P |
| Age | ≤ 35 | 20 (33.89%) | 29.25 \pm 11.31 | F = 3.966 | 0.024 |
| | 36 – 55 | 24 (40.67%) | 31.87 \pm 13.73 | | |
| | ≥ 56 | 15 (25.42%) | 40.86 \pm 11.79 | | |
| Gender | Male | 35 (59.32%) | 31.62 \pm 13.61 | t = -1.166 | 0.248 |
| | Female | 24 (40.67%) | 35.66 \pm 12.20 | | |
| Professional qualification | Certificate in Pharmacy | 37 (62.71%) | 30.48 \pm 12.36 | t = -2.185 | 0.033 |
| | Diploma/ Degree in pharmacy | 22 (37.28%) | 37.95 \pm 13.24 | | |
| Participated in workshops | Yes | 26 (44.06%) | 37.69 \pm 12.34 | t = 2.392 | 0.020 |
| | No | 33 (55.93%) | 29.78 \pm 12.79 | | |
| Location of pharmacy | Urban | 27 (45.76%) | 32.37 \pm 9.92 | t = -0.499 | 0.620 |
| | Rural | 32 (54.23%) | 34.03 \pm 15.40 | | |
| Working position in the pharmacy | Owner of the pharmacy | 19 (32.20%) | 31.31 \pm 14.51 | t = -0.787 | 0.434 |
| | Working as an employee | 40 (67.79%) | 34.2 \pm 12.46 | - | - |
| Working experience (Years) | ≤ 8 | 33 (55.93%) | 31.66 \pm 10.61 | t = -1.014 | 0.316 |
| | > 8 | 26 (44.06%) | 35.30 \pm 15.69 | | |

workshop had comparatively higher knowledge than their counterparts.

Table 1 describes the knowledge of GM among pharmacists. More than two-thirds of pharmacists were able to define generic medicine. Most of the pharmacists wrongly reported that innovator brands need higher safety standards compared to generic medicines. Most of the pharmacists correctly reported that generic medicines should have the same dosage forms and the same strength as innovator brands.

The mean score of knowledge on generic medicine among pharmacists was 33.27 \pm 13.1. The maximum and minimum scores obtained by pharmacists were 55 and 10 respectively with the range of 45.

According to Table 2, age, professional qualification and participation in the workshop showed statistically significant differences with the mean score of knowledge of generic medicine. However, gender, working position

in the pharmacy, location of pharmacy, and working experience did not show significant differences with the mean score of knowledge of GM.

Table 3 shows the perception of generic substitutes among community pharmacists. According to Table 4, most pharmacists practice generic substitutes while dispensing. Most pharmacists reported reasons for substitutes were customer request, quality, familiarity with the generic brand, and the manufacturing country.

DISCUSSION

Good knowledge and positive perception of generic medicines among pharmacists promote the practice of generic substitution and educate patients regarding the usage of generic medicines. The usage of generic substitutes reduces healthcare costs of patients [12].

Knowledge of Generic Medicine

In this study, knowledge of GM is substantial among pharmacists. A study done in Palestine also reported

Table 3: Perception of generic substitution among pharmacists.

| Items | Agree | Uncertain | Disagree |
|---|---------------|---------------|---------------|
| | f (n) [P (%)] | f (n) [P (%)] | f (n) [P (%)] |
| 1. Patients have less awareness of generic substitution in Sri Lanka. | 38 [64.4%] | 17 [28.8%] | 4 [6.8%] |
| 2. Patients should be educated well about the generic substitution. | 33 [55.9%] | 16 [27.1%] | 10 [17.0%] |
| 3. All generic substitutes available in Sri Lanka have the same quality. | 18 [30.50%] | 20 [33.9%] | 21 [35.6%] |
| 4. The quality of generic substitutes depends on their price. | 36 [61.0%] | 11 [18.7%] | 12 [20.3%] |
| 5. Branded or expensive generics are preferred in life-threatening conditions. | 24 [40.7%] | 20 [33.9%] | 15 [25.4%] |
| 6. Locally manufactured generics have the same quality as imported generics. | 18 [30.5%] | 33 [55.9%] | 08 [13.6%] |
| 7. Patients tend to trust doctors more than pharmacists on matters related to prescription, including generic substitution. | 40 [67.8%] | 17 [28.8%] | 02 [3.4%] |

Table 4: Practice of generic substitution among pharmacists.

| Question | Responses | Frequency (n) | Percentage (%) |
|---|--|---------------|----------------|
| Do you dispense generic substitutes for prescribed brand medicines in your pharmacy? (n=59) | Yes | 56 | 94.9% |
| | No | 3 | 5.1% |
| What basis, you will substitute generics?* | Familiarity with generic brands | 36 | 61.0% |
| | Based on the manufacturer's company | 20 | 33.9% |
| | Based on the manufacturing country | 32 | 54.2% |
| | Customer's request | 56 | 94.9% |
| | Availability of generic brands | 28 | 47.5% |
| | Quality of generic brands | 40 | 67.8% |
| | Promotion by a marketed representative | 13 | 22.0% |
| | Depends on profit | 11 | 18.6% |

*Multiple responses

a low level of knowledge of GM [13]. Our result is further supported by studies done in Kuwait which reported a lack of knowledge on GM among community pharmacists [14]. Ethiopian study also reported that there is a gap in knowledge on GM among pharmacists [15]. A study done in India also found limited knowledge of GM among pharmacists [6]. However, a study done in China revealed that pharmacists have good knowledge of GM [16].

In this study, two-third of pharmacists were able to define the generic medicine completely. In the studies done in other countries such as Palestine [13] and Ethiopia [17], more than half of the study participants answered correctly the definition of generic medicine.

Our study demonstrated a low level knowledge of GM among study participants. In Sri Lanka, the minimum qualification needed to work as a pharmacist is a certificate-level course conducted by the government. However, diploma and degree pharmacy courses also were available in Sri Lanka. Even though pharmacists in Sri Lanka have different qualifications such as certificate, diploma, and degree levels, most of the community pharmacists have certificate-level qualifications only. Further, they are less likely to follow professional development programs and/or workshops regularly to improve their knowledge. This results in inadequate knowledge of GM among them.

Association of Factors on Knowledge of Generic Medicine

In this study, the relationship between socio-demographic and work-related characteristics with the knowledge

of generic medicine revealed that age, professional qualification and participation in the workshop showed significant differences.

Participants who were in the age group above 56 years, participated in workshops, and had diploma or degree qualifications comparatively have good knowledge of generic medicine than their counterparts. Similarly, Indian study reported that higher level of education had an association with having good knowledge of generic medicines [6]. In this study, most of the pharmacists had certificate-level qualifications in the pharmacy profession and they had less knowledge compared to those having diploma/degree qualifications.

However, females and experienced pharmacists had more knowledge on generic medicines than their counterparts, they did not show significant differences. A similar study conducted in Qatar, reported that gender only influenced on the knowledge of GM [18]. In contrast, study in the Saudi Arabia reported that no statistically significant difference with knowledge of GM was observed with sociodemographic factors of participants [2].

Perception of Generic Medicine Substitution

More than half of the pharmacists reported that the patients had less awareness of generic substitution in Sri Lanka and reported that patients should be educated well about the generic substitution. In a similar study in Qatar, more pharmacists reported that patients should be explained enough to choose generic medicines for them [18].

Only less than one-third of participants believed that all generic substitutes available in Sri Lanka have the same quality. This result is in line with the finding of systemic review which reported that healthcare professionals of the countries having less mature healthcare system believed that generic medicine have inferior quality [19]. The public in Sri Lanka also are less likely to purchase cheaper generic medicines due to their quality concern [20]. Quality problems of generic substitutes in Sri Lanka is further confirmed by the studies in which quality analysis of some of the generic substitutes of metformin [21] and amoxycillin [22] available in Sri Lanka failed to demonstrate their quality. Only one-third of participants believed that the locally manufactured generic substitutes have the same quality as imported generic substitutes. However, in the Ethiopian study, more than half of the study participants reported that local and imported generics have the same quality [17].

Most of the participants accepted that patients tend to trust doctors more than pharmacists on generic substitution. A study conducted in Kuwait disclosed that nearly two-thirds of the participants agreed that patients trust doctors more than pharmacists in the choice between brand and generic medicines [14].

In our study, most of the pharmacists have a negatively inclined perception of generic substitutes. This result was supported by studies done in India [6, 23] and Kuwait [14]. However, a study done in Qatar [15] reported a positive perception of generic substitution among pharmacists. Negative perception of generic substitutes among pharmacists in Sri Lanka could be due to concern about the quality of generic substitutes.

Practice of Generic Medicine Substitution

In this study, most of the participants (94.9%) were dispensed generic substitutes for prescribed brands this result is consistent with the Malaysian study in which 97.9% of pharmacists practiced generic substitution [9]. In this present study, most of the participants select generic substitutes based on the customer's request, followed by the quality of the generic medicine and familiarity of generic brands. This is similar to the study conducted in Saudi Arabia, which disclosed that nearly two-thirds of the participants (65.3%) said that the quality of the generic medicine, followed by cost saving and availability of generic medicines [2]. Cost, consumer preference, and stock availability were the reasons for the selection of generic substitution in the study done in Qatar [18].

Our study demonstrated that community pharmacists need to encourage updating their knowledge of GM. Competent pharmacists with regular updating of their knowledge could be formed by conducting professional developmental programs and/or series of workshops, which can be initiated by government and pharmacy professional bodies of the country. More attention should be given to pharmacists who have certificate-

level qualifications. Bridge courses could be introduced to pharmacists who have certificate-level qualifications to upgrade their qualifications to degree or diploma levels. This will make them competent professionals and will provide efficient services to the patients. Meanwhile, quality of locally manufactured and imported generic medicines should be strictly monitored by regulatory bodies to ensure their required quality. This will increase the confidence among healthcare professionals about generic substitutes available in Sri Lanka.

The strength of the study was that it was conducted first time among community pharmacists in Sri Lanka. The limitation of the study was less sample size. To generalize the results obtained in our study, it should be conducted by including more community pharmacists from other parts of Sri Lanka.

CONCLUSION

Community pharmacists who worked in the Jaffna district of Sri Lanka lacked knowledge of generic medicine. Further, they have a negatively inclined perception of generic substitutes. However, they are practicing generic medicine substitution. Pharmacists should have enough knowledge to educate patients about generic medicines. Continuous professional educational programs and workshops should be conducted regularly among pharmacists. Further professional qualifications of pharmacists should be upgraded to diploma or degree levels from certificate level by giving opportunities for high education to the community pharmacists. It could improve pharmacists' knowledge of generic medicines. Further, the quality of generic substitutes should be strictly monitored and ensured. It will increase the trust in generics among pharmacists and other healthcare professionals.

CONSENT FOR PUBLICATION

Written informed consent was taken from the participants.

CONFLICT OF INTEREST

The authors declare no conflict of interest.

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AUTHORS' CONTRIBUTION

Among the three authors, Nizad Mohamed was involved in the design, data collection, data analysis, report writing, and manuscript writing. Thuvaragan S and Coonghe PAD were involved in the data analysis, manuscript revising, and proof reading of the final manuscript.

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