RESEARH ARTICLE   **OPEN ACCESS**

Perception and attitude of General Practitioners toward local generic medicines in Sudan: A hospital-based study

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Published by: OZZIE Publishers

Abstract

Background: Use of generic medicines significantly reduces the cost of medicines to both governments and patients. The adoption of generic drugs in medical practices is a complex phenomenon and many determinants can affect it. Physicians and general practitioners play a key role in controlling this phenomenon and their decision in prescribing generic drugs is likely to be affected by many factors. Understanding general practitioners' perception of the quality and efficacy of generic medicines may help identify potential barriers to greater generic medication use. *Objective*: To assess the perception, attitude and practice of general practitioners towards prescribing generic medicines in the emergency room of public hospitals in Khartoum, Sudan. *Methods*: A hospital-based descriptive cross-sectional study was implemented. All of the Emergency rooms in public hospitals of Khartoum Sudan were assessed. The data was collected through a standardized questionnaire (Annex). The data were analysed through the Statistical Package for Social Sciences (SPSS) version 21.0 (IBM SPSS Inc., Chicago, IL) was used. *Results*: The predominant gender was females who account for 53% per cent of the sample, while males were 47%. According to the distribution of general practitioners understanding, 72% had a good understanding of generic medicines while 28% had a poor understanding of generic medicine. According to the distribution of general practitioners perception, 64% of had, good perceptions towards generic medicines while 36% had poor perceptions towards generic medicine. According to the distribution of general practitioners attitude, 68% had a good attitude towards prescribing generic medicines while 32% had poor perceptions of generic medicine. *Conclusion*: Good understanding, perceptions and attitudes among general practitioners towards prescribing generic medicines in the emergency room of public hospitals was observed in Khartoum, Sudan. Majority of the GPs think that generic medicines locally manufactured in Sudan are not following Good Manufacturing Practices (GMP) guidelines as multinationals.

KEYWORDS: General Practitioners, Generic Medicine, Emergency Hospital, Perception, Attitude Practice, Sudan

INTRODUCTION

One of the biggest challenges facing the global political agenda is access to medicines in developing countries. Un-affordability is the major cause of inadequate access to medicines. In many countries, health authorities strongly support the practice of generic medicines prescribing and substitution. This proved to have a clear effect on cost reduction for essential medicines, regulation of medicines promotion, and increase adherence to Essential Medicines List (EML) and Standard Treatment Guidelines (STG) by healthcare providers i.e. improving equity, affordability and access to medicines [1]

The term "generic drug" or "generic medicine" can have varying definitions in different markets. However, the World Health Organization (WHO) defines it as ''a pharmaceutical

product which: is usually intended to be interchangeable with an innovator product, is manufactured without a license from the innovator company, and is marketed after the expiry date of the patent or other exclusive rights'' [2]. While the United States Food and Drug Administration [US FDA], which regulates the pharmaceutical market in the United States, defines generic medicines as ''A drug product that is comparable to brand/reference listed drug product in dosage form, strength, route of administration, quality and performance characteristics, and intended use. Copies of brand-name drugs and are the same as those brand name drugs in dosage form, safety, strength, route of administration, quality, performance characteristics and intended use''. The European Medicines Agency (EMA) defines a generic medicine as "a medicine that is developed

to be the same as a medicine that has already been authorized (the 'reference medicine')". Generic medicine contains the same active substances as the reference medicine, and it is used at the same dose to treat the same disease as the reference medicine. However, the name of the medicine, its appearance (such as shape or colour or its packaging can be different from those of the reference medicine [3].

Sudan practices a "free market economy" and pay-per-fee system, whereby the population pays for medicines prescribed in public hospitals (except for the first 24 hours emergency inpatients, renal dialysis and transplantation, blood transfusion services, and much anticancer therapy). However, medicines prices are still under government control, in which the manufacturer, distributor and retailers have to set their prices according to the National Medicine and Poison Board (NMPB) medicines price legislation 2009. Generic drugs' prescribing is an important tool for reducing overall health expenditure. Indeed, generic drugs are more affordable than branded. The medicines prices, availability,

affordability, and price components survey in Sudan 2012 revealed that originators branded medicines are generally sold at 3.47 times their international reference prices compared to 2.22 times for the lowest price of generic medicines in the public sector [4].

Use of generic medicines significantly reduces the cost of medicines to both governments and patients. Approval of generic medicine is based on the demonstration of interchangeability or therapeutic equivalence to the innovator through bioequivalence studies. Bioequivalence is the absence of a significant difference in the rate and extent to which the active ingredient or active moiety in pharmaceutical equivalents or pharmaceutical alternatives becomes available at the site of drug action when administered at the same dose [5,6].

This study generally aims to assess the perception, attitude and practice of general practitioners towards prescribing generic medicines at the emergency room of public hospitals in Khartoum, Sudan.

MATERIALS AND METHODS

Study design

A hospital-based descriptive cross-sectional study was implemented. The study was conducted in the three localities of Khartoum state: Omdurman, Bahri and Khartoum. All public hospitals in the three localities were concerned. The total number of public hospitals with fully functioning emergency rooms in these three localities was 13. The study population was all the general practitioners working in the emergency rooms of these hospitals in October 2017.

Sampling technique and sample size

All of the Emergency rooms in public hospitals of Khartoum Sudan were assessed. The 13 public hospitals are distributed as follows: 5 hospitals in Khartoum (Altamayoz, Ibrahim Malik, Jabel awleya, Turkish, Bashaer Teaching hospital), 4 hospitals in Omdurman (Alnaw, Ombada, Rajehi and Omdurman Teaching hospital) and 4 hospitals in Bahri (Haj Alsafi, Ban jaded, Ali Abdelfatah and Bahri Teaching Hospital).

Data collection, management and analysis

The data was collected through a standardized questionnaire. The data were analysed through the Statistical Package for Social Sciences (SPSS) version 21.0 (IBM SPSS Inc., Chicago, IL) was used. Initially, all information gathered via a questionnaire was coded into variables. Descriptive statistics were carried to summarize the data graphically and numerically (mean, standard deviation and median). Statistical analysis was performed to assess the association among variables for the chi-square test. A *p*-value of less than 0.05 was considered statistically significant.

Although the questionnaire used for assessing understanding, in order to have a better assessment of overall understanding, each correct answer carried 1 mark while the wrong answer carried 0 marks, this makes a total score of 7 when all the 7 questions are correctly answered and 0 when none of them

was addressed correctly. The scores in knowledge domains were not normally distributed. The scores were expressed as median then were categorized as poor (less than the median) and good (median and above). For the perception section, each correct answer carried 1 mark while the wrong answer carried 0 marks, this makes a total score of 9 when all the 9 questions are correctly answered and 0 when none of them was addressed correctly. The scores in perception domains were not normally distributed. The scores were expressed as median then were categorized as poor (less than the median) and good (median and above). For the attitude section, each correct answer carried 1 mark while the wrong answer carried 0 marks, this makes a total score of 11 when all the 11 questions are correctly answered and 0 when none of them was addressed correctly. The scores in attitude domains were not normally distributed. The scores were expressed as median then were categorized as poor (less than the median) and good (median and above).

Ethical consideration

It was sought from Sumasri Institutional Review Board (SIRB) from UMST (University of Medical Science and Technology). Approval from university, Khartoum state ministry of the health research department, and from hospitals. All required ethical consideration steps were followed according to the Khartoum state ministry of the health research department guidelines.

RESULTS

Demographic characteristics of general practitioners of the 72 participants, the majority (52.8%, n=38) were females. median of their age was 25 years ranging from 23 to 33 years (Refer to Table 1).

Table 1: Demographic characteristics of general practitioners

Variables (n=72)	Number (%)
Gender	
Male	34(47.2)
Female	38(5)
Age in years	
Median age	25
Min-Max	23-33
Less than 25 years	18(25)
25 years and more	54(75)

Information on Practice

Table 2 gives information about Information on practitioners Practice. The practitioners were exercising from 12 months to 24 months with a median of 18 months. Their daily workload (number of patients daily received) ranged from 0 to 80 with an average of 40 patients ±16. They met representatives from multinational companies once a month (median=1, range: (0-12). While they met representatives from local companies once a month (median=1, range: (0- 10).

Table 2: General practitioners Information on Practice

Variables (n=72)	Number (%)
Practising as a general practitioner	
Less than 18 months	33(45.8)
18 months and more	39(54.2)
The daily average number of patients	
Less than 40	33(45.8)
40 and more	39(54.2)
Monthly meeting representatives from multinational companies	
No	35(48.6)
Yes	37(51.4)
Monthly meeting medical representatives from local companies	
No	28(38.9)
Yes	44(61.1)

Understanding of general practitioners towards generic medicines

Table 3 revealed the answers of the participants while **table 4** indicates the understanding of general practitioners towards generic medicines. **Table 5** shows the distribution of understanding of general practitioners towards generic medicines score by demographic characteristics and information on practice.

Table 3: Distribution according to the understanding of general practitioners towards generic medicines

Understanding variables (n=72)	Yes Number (%)	No Number (%)	Don't know Number (%)
Generic medicines are interchangeable with brand name medicines	42 (58.3)	23(31.9)	7(9.7)
Generic medicines are therapeutically equivalent to brand name medicines	42(58.3)	23(31.9)	7(9.7)
Generic medicines must be in the same dosage form (such as a tablet, capsule) as brand name medicines	51(70.8)	15(20.8)	6(8.3)
Generic medicines are less safe than brand name medicines	16(22.2)	43(59.7)	13(18.1)
Generic medicines are available in Sudan market (pharmacies)	55(76.4)	6(8.3)	11(15.3)
Generic medicines are manufactured after the patent expiry of originator	43(59.7)	3(4.2)	26(36.1)
Brand name medicines are required to meet higher safety standards than generic medicine	20(27.8)	25(34.7)	27(37.5)

Table 4: Understanding of general practitioners towards generic medicines scored as good and poor variables

Variable (n=72)	Number (%)
Poor	26(36.1)
Good	46(63.9)

Table 5: Distribution of understanding of general practitioners towards generic medicines score by demographic characteristics and information on practice

Understanding of general practitioners towards generic medicines score				
Variables		Poor	Good	Chi-square P-value
Gender (n=72)	Male	9(26.5%)	25(73.5%)	
	Female	11(28.9%)	27(71.1%)	0.815*
Age groups (n=72)	Less than 25 years	6(33.3%)	12(66.7%)	
	25 years and more	14(25.9%)	40(74.1%)	0.543*
Practicing as general Practitioner (n=72)	Less than 18 months	5(15.2%)	28(84.8%)	
	18 months and more	15(38.5%)	24(61.5%)	0.028**
Daily average number of Patients (n=72)	Less than 40	10(30.3%)	23(69.7%)	
	40 and more	10(25.6%)	29(74.4%)	0.660*
Monthly meeting representatives from multinational companies	No	13(37.1%)	22(62.9%)	
	Yes	7(18.9%)	30(81.1%)	0.084*
Monthly meeting medical representatives from local companies	No	11(39.3%)	17(60.7%)	
	Yes	9(20.5%)	35(79.5%)	0.082*

- Pearson's chi-squared test.
- **.P value < 0.05 that's considered as statistically significant.
- *.P value >0.05 that's considered as statistically insignificant.

Perception of general practitioners towards generic medicines

Table 6 revealed the answers of the participants while table 7 indicates the perception of general practitioners towards generic medicines. **Table 8** shows the distribution of perception of general practitioners towards generic medicines score by demographic characteristics and information on practice. The perception of general practitioners towards generic medicine was evaluated through 7 variables (table 8), out of which only understanding of general practitioners towards generic medicines was statistically significant (p=0.039)

Table 6: Distribution according to the perception of general practitioners towards generic medicines

Perception Variables (n=72)	Agree	Neutral	Disagree
I believe that locally manufactured medicines are more affordable than brand name medicines	59(81.9%)	7(9.7%)	6(8.3%)
I believe that locally manufactured medicines are of the same effectiveness as brand name medicines	27(37.5%)	20(27.8%)	25(34.7%)
I view generic medicines of a low quality than brand name Medicines	14(19.4%)	19(26.4%)	39(54.2%)
I think generic medicines produce more side effects than brand name medicines	8(11.1%)	22(30.6%)	42(58.3%)
I believe that multinational products are of good quality than local company products	47(65.3%)	17(23.6%)	8(11.1%)
I believe that my prescribing decision is influenced by medical Representatives	28(38.9%)	13(18.1%)	31(43.1%)
I believe that all the local companies in Sudan are not following Good Manufacturing Practices (GMP) guidelines as Multinationals	16(22.2%)	42(58.3%)	14(19.4%)
I believe that there should be a training program to increase the awareness regarding generic drugs among doctors and patients	64(88.9%)	8(11.1%)	0(0%)
I believe that it is easier to remember a brand name medicine	35(48.6%)	16(22.2%)	21(29.2%)

Table 7: Perception of general practitioners towards generic medicines scored as good and poor variables

Variable	Number
Poor	26(36.1%)
Good	46(63.9%)

Table 8: Distribution of perception of general practitioners towards generic medicines score by demographic characteristics and information on practice

Perception of general practitioners towards generic medicines score				Chi-square P-value
Variables (n=72)		Poor	Good	
Gender	Male	13(38.2%)	21(61.8%)	
	Female	13(34.2%)	25(65.8%)	0.723*
Age groups	Less than 25 years	7(38.9%)	11(61.1%)	
	25 years and more	19(35.2%)	35(64.8%)	0.777*
Practicing as general practitioner	Less than 18 months	9(27.3%)	24(72.7%)	
	18 months and more	17(43.6%)	22(56.4%)	0.151*
Daily average number of patients	Less than 40	11(33.3%)	22(66.7%)	
	40 and more	15(38.5%)	24(61.5%)	0.652*
Monthly meeting representatives from multinational companies	No	11(21.4%)	24(68.6%)	
	Yes	15(40.5%)	22(59.5%)	0.421*
Monthly meeting medical representatives from local companies	No	11(39.3%)	17(60.7%)	
	Yes	15(34.1%)	29(65.9%)	0.655*
Understanding of general practitioners towards generic medicines score	Poor	11(55.0%)	9(45.0%)	
	Good	15(28.8%)	37(71.2%)	0.039**

- Pearson's chi-squared test.
- **.P value < 0.05 that's considered as statistically significant.
- *.P value >0.05 that's considered as statistically insignificant

The attitude of general practitioners towards generic medicines

Table 9 revealed the answers of the participants while table 10 indicates the attitude of general practitioners towards generic medicines. Table 11shows the distribution of attitude of general practitioners towards generic medicines score by demographic characteristics and information on practice.

Table 9: Distribution according to the attitude of general practitioners towards generic medicines

Attitude variables (n=72)	Agree	Neutral	Disagree
I am concerned about the therapeutic failures that are serious problems with some locally manufactured medicines	45(62.5%)	12(16.7%)	15(20.8%)
I am hesitant to prescribe low-cost brands in some specific therapeutic classes in my practice	27(37.5%)	19(26.4%)	26(36.1%)
I feel that the socio-economic condition of my patient influences the prescription	67(93.1%)	2(2.8%)	3(4.2%)
I am comfortable to prescribe products from all-local manufacturers	37(51.4%)	19(26.4%)	16(22.2%)
I feel that my personal experience with medicines influences my prescribing decisions	42(58.3%)	14(19.4%)	16(22.2%)
I feel that patients' demands of medicine influence my prescription	36(50%)	15(20.8%)	21(29.2%)
I feel that medical representatives are a good source of information	51(70.8%)	10(13.9%)	11(15.3%)
I feel that pharmaceutical companies premium offers (gifts) influence my prescribing behaviour	13(18.1%)	13(18.1%)	46(63.9%)
I feel that there is a lack of quality check in locally manufactured products	30(41.7%)	27(37.5%)	15(20.8%)
I am comfortable if the brand name medicine in prescription is changed by drug seller or pharmacist	44(61.1%)	10(13.9%)	18(25%)
I offer my patients generic medicines	47(65.3%)	20(27.8%)	5(6.9%)

Table 10: Attitude of general practitioners towards generic medicines scored as good and poor variables

Variables	Number
Poor	23(31.9%)
Good	49(68.1%)

Table 11: Distribution of attitude of general practitioners towards generic medicines score by demographic characteristics and information on practice

The attitude of general practitioners towards generic medicines score				
Variables (n=72)		Poor Number (%)	Good Number (%)	P- value
Gender	Male	12(35.3)	22(64.7)	0.564*
	Female	11(28.9)	27(71.1)	
Age groups	Less than 25 years	5(27.8)	13(72.2)	0.662*
	25 years and more	18(33.3)	36(66.7)	
Practicing as general practitioner	Less than 18 months	8(24.2)	25(75.8)	0.197*
	18 months and more	15(38.5)	24(61.5)	
Daily average number of patients	Less than 40	13(39.4)	20(60.6)	0.212*
	40 and more	10(25.6)	29(74.4)	
Monthly meeting representatives from multinational companies	No	9(25.7)	26(74.3)	0.270*
	Yes	14(37.8)	23(62.2)	
Monthly meeting medical representatives from local companies	No	8(28.6)	20(71.4)	0.624*
	Yes	15(34.1)	29(65.9)	
Understanding of general practitioners towards generic medicines score	Poor	7(35)	13(65)	0.730*
	Good	7(35)	13(65)	
Perception of general practitioners towards generic medicines score	Poor	11(42.3)	15(57.7)	0.156*
	Good	12(26.1)	34(73.9)	

- Pearson's chi-squared test.
- *.P value >0.05 that's considered as statistically insignificant.

DISCUSSION

Our study on generic medicines was conducted on a sample of 72 participants aged from 23 to 33 years old, out of which 53% were females. 45.8% of the study participants were practising for < 18 months while 54.2% had ≥ 18 months working experience.

Our findings revealed that 58.3% of GPs knew that generic medicines are interchangeable with brand name medicines. This finding was within the range of 47.1% to 71.8% revealed elsewhere in the literature [7,8,9, 10].Regarding the understanding of general practitioners towards generic medicines, our findings were higher than some published studies but lower than others [8,11]. Our findings showed that 70.8% of GPs had the knowledge that generic medicines should be in the same dosage form (such as a tablet, capsule) as brand name medicines. In studies published elsewhere in the literature, the findings were within the range of 64.9% to 76.7% [9,8].Regarding the perception of general practitioners towards generic medicines our study revealed that 81.9% of GPs believed that locally manufactured medicines are more affordable than brand name medicines. While, in another study, the findings were 94% [7].

Most of the concerns regarding generic medicines revolve around their safety and efficacy versus originators (brand name medicines). In our study, 65.3% of general practitioners believed that multinational products are of good quality than local company products. Whereas in other studies it was within the range of 35.6% to 59.7% [8,11]. In our research, 38.9% of GPs believed that their prescribing decision is influenced by medical representatives, elsewhere the findings were within the range 20.9% to 56.8% [8,11].

Whenever a generic drug product is granted approval, it has fulfilled strict regulations required by the regulatory body with respect to identity, strength, quality, purity, and potency. The regulatory body appraises the manufacturer's compliance to the GMP guidelines before the drug is marketed, and the manufacturer needs to give detailed information about the facilities it uses for production, packaging, labelling, among others, of the generic drug [9]. Our study revealed that 58.3% of GPs were neutral that generic drugs manufactured in local companies in Sudan are not following Good Manufacturing Practices (GMP) guidelines as multinationals. Most of the doctors were found to have a greater doubt in generic drugs as pointed out in a study which revealed a proportion of 28.6% [11].

Our research revealed that 88.9% of GPs believed that there should be a training program to increase the awareness of generic drugs among doctors and patients. In studies, conducted elsewhere, the findings were within the range of 88.5% to 88.8% [8,11]. Regarding the attitude of general practitioners towards generic medicines, 62.5% of GPs are concerned about the therapeutic failures with some locally manufactured medicines, elsewhere the findings were within the range of 63.1% to 82.7% [8,11].

Our study findings indicated that 51.4% of GPs were comfortable to prescribe products from all local manufacturers while in other published studies the findings were within the range of 33.3% to 41.4% [8,11].

In our study, 70.8% of GPs feel that medical representatives are a good source of information. In studies conducted elsewhere, the findings were within the range of 44.5% to 76.6% [8,11]. Our results pointed out that 41.7% of GPs felt that there was a lack of quality check in locally manufactured products while other studies reported 52.9% [11]. Our study concluded that 65.3% of the GPs offered their patients generic medicines, whereas in studies conducted elsewhere the findings were within the range of 61.3% to 63% [8,9,11].

CONCLUSION

Good understanding, perceptions and attitudes among general practitioners towards prescribing generic medicines in the emergency room of public hospitals in Khartoum, Sudan, were observed. Most of the GPs thought that generic medicines locally manufactured in Sudan were not complying with Good Manufacturing Practices (GMP) guidelines as multinationals. Furthermore, the majority of the GPs felt that they need to be continuously educated on the efficacy, safety, and quality criteria of generic medicines to enable them to be confident while prescribing generic drugs.

Policy implications

- ✓ The Government needs to sensitize and educate prescribers of generic medicines to reduce the financial burden on both patients and health services.
- ✓ Official regulators should advocate prescription of generic medicines at least in all public health facilities.
- ✓ The Government needs to establish a database of brand name medicines and their generic equivalents to be disseminated to hospitals, pharmacies and other health services.
- ✓ On- job- training of the general practitioners on the efficacy, safety, and quality criteria of generic medicines will promote their prescription and use.

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