WORLD JOURNAL OF PHARMACEUTICAL RESEARCH
SJIF Impact Factor 6.805
Volume 5, Issue 4, 388-409. Research Article ISSN 2277– 7105

ASSESSMENT OF THE KNOWLEDGE, ATTITUDE, AND PERCEPTION OF SUDANESE COMMUNITY PHARMACISTS TOWARDS GENERIC MEDICINES.

Maysoon Mohamed Elfateh Mousa[1], Kamal Addin Mohammad Ahmad Idris[2*]

[1]University of Gezira, Faculty of Pharmacy, Department of Pharmaceutics, P.O. Box 20, Medani, Sudan.

[2]UMST University of Medical Sciences & Technology, P.O. Box 12810, Khartoum, Sudan,

Article Received on
16 Feb 2016,
Revised on 07 March 2016,
Accepted on 27 March 2016
DOI: 10.20959/wjpr20164-6014

***Correspondence for Author**
Kamal–Addin Mohammad Ahmad Idris
University of Gezira, Faculty of pharmacy, Department of Pharmaceutics, P.O.Box 20, Medani, Sudan.

ABSTRACT

Introduction: Community pharmacists are important members of the health care team. They procure, stock, store, recommend, dispense and monitor drugs therapeutic outcomes for patients. **Objective:** Main objective of this study is: to assess the knowledge, attitude and perception of community pharmacists towards generic medicines; which secure availability and affordability of patients. **Methods:** A structured open to answer questionnaire of (30) close -ended questions, was handed over to all community pharmacists (116) in Khartoum North, Town center, Sudan. Results: were expressed in frequencies and percentages. Data were analyzed using IBM-SPSS version 20. Results showed majority (74.1%) of participantswere young, average age (28.4) years, females (69.8%). Majority (88.8%) had undergraduate studies in Sudan. Majority (88.9%) had fair practical experience (1-10 years). Majority (95.7%) differentiated genericsfrom brands. Majority (71.6%) believed thatgenericsmust prove bioequivalent to theirbranded counterparts. Majority (60.3%) doubted thatgenerics licensedin Sudan, passed bioequivalence tests. Majority (69%) reported poor patients' satisfaction with generics. Majority (74.1%) practiced generics substitution upon prescribers' (67.2%) and patients' (65.5%) endorsement. Majority (81.9%) appreciated affordability benefits of generics. Majority (71.6%) wereskeptical about substitution ofnarrow therapeutics index products. Associations between participants' demographics (age, gender, marital status, place of undergraduate studies, employment status, post graduate studies, community pharmacy practice) and respondents' knowledge,

attitude, and perception of genericsproved significant, (P< 0.05). **Conclusion:** Results suggest that participants had good knowledge and perception about generics. Recommendation: Pharmacists shall continuously educate themselves to improve their knowledge, attitude and perceptions about generic medicines.

KEYWORDS: Sudanese, community, pharmacists, knowledge, attitude, perception, generics.

INTRODUCTION

Though access of patients to health care is a fundamental human right, enshrined in international treaties and recognized by governments throughout the world, yet, the World Health Organization (WHO) estimates that more than two billion people in low- and middle-income countries (LMIC) lack adequate access to essential medicines.[1]

The factors influencing that poor access to essential medicines are the:

1. Irrational prescribing,
2. High costs of medications (brands),
3. Non- sustainable financing
4. Poor health supply system.

In Sudan, according to The Federal Ministry of Health, Pharmaceutical Country Profile, 2010; the expenditureon pharmaceuticals in 2010, whichare mainly imported, accounted for 36% of the total expenditure on health.[2]

When the other factors affecting access are under control, the use of generic medicines represents the solution for improving access to essential medicines.[3]

Inadequate knowledge, negative attitude, and perception of pharmacists, prescribers and patients stand as real barriers to the promotion of generic medicines use.[4]

The low cost generic pharmaceuticals (200-90%), which are only licensed after proving bioequivalent to their branded counterparts, provides availability, affordability, and accessibility of patients to equally effective and safe medications at a greater low cost. Patients are known to be more familiar with branded medications.[5-8]

Patients' acceptance, which is very pivotal for the promotion of generics use, is reported to be rather inconsistent. [9]

Patients' requests are reported to change the physician prescription in their favor.[10-12]

Some researchers, also, reported negative community pharmacists attitudes towards generics.[13]

Communitypharmacistshaving positive attitude, perception and knowledgeabout generics, arein position to educate, convince and assure both the prescribers and patients of generics, and ultimately increase their needed use.[14]

The knowledge attitude and perception of physicians greatly affects their prescribing preference.[15]

Endeavors to promote more use of generics in Sudan, should accordingly strongly consider the assessment of the knowledge, attitude and perception of community pharmacists towards generic pharmaceuticals and then, study or define the factors that can positively, or negatively impact the community pharmacists' knowledge, attitudes and perception towards generic, before looking into the proper intervention. Based on above, this study is mainly conducted to: Assess the knowledge, attitude and perception of community pharmacists in Khartoum North, town center, Sudan, towards genericdrugs.

Main study objective: This studyaim toassessthe knowledge, attitude andperception of community pharmacists toward genericdrugs in Khartoum North, Towncenter, Sudan.

2. METHODOLOGY

A descriptive cross sectional questionnaire based surveywas carried out at community pharmacies in Khartoum North, town center, Sudan. The total number of community pharmacies in Khartoum North, town center, Sudan who wascovered was one hundred and sixteen(116). The main variablesof the potential participants were the participants' gender, age, education, years of practice, marital status, place of undergraduate studies, post graduate studies, years of practice, specialties and the employment status. Data werecollected using a specifically pre-tested designedstructured, pre-piloted and open to answer questionnaireconsisting of thirty(n=30) questions. The questionnaire was composed oftwoparts: part one to determine the socio - demographic characteristics of the pharmacists,

And part two to find out community pharmacists knowledge, attitude and perception toward generic medicine. The study was conducted during the period from June to Augustus 2014.

Data were analyzed using Statistical Package for Social Sciences (SPSS) version20 for windows. Values were compared by independent samplet-test and P<0.05 was considered as significant.

Ethical Considerations

The entire communitypharmacists included in the study wasinformed of the objectives and the nature of the research, and was strongly requested to participate. They were also informed that participation is absolutely free. Verbal consent wasobtained from all potential participants pharmacists, included in the study.

RESULTS

Response rate was 116 (100%).

Table 1: Participant pharmacists' socio-demographic characteristics

Demographic characteristic.	**Number and (%).**
1-Age in years.	
20-29.	86(74.1%)
30-39.	22(18.9%)
40-49.	2(1.7%)
50-59.	6(5.1%)
Total	116
2-Gender.	
Male.	35(30.2%)
Female.	81(69.8%)
Total	116
3-Marital status.	
Single.	78(67.2%)
Married.	38(32.8%)
Total	116
4-Place of undergraduate studies.	
Sudan.	103(88.8%)
Abroad.	11(9.5%)
Missing.	2(1.7%)
Total.	116
5-Employment status:	
Owner of the community pharmacy.	19(16.4%)
Employee.	96(82.8%)
Missing.	1(0.9%)
Total.	116
6-Post graduate studies in pharmacy	

Yes.	33(30%)
No.	77(70%)
Total.	116
7- Years of practice.	
1-10	103(88.9%)
11-20	7(6%)
21-30	0(0%)
31-40	3(2.6%)
Missing.	3(2.6%)
Total.	116

8. In your judgment, what is the financial status of the majority of the patients who attend your pharmacy?

Poor 10(8.6%), average 103(88.8%), rich 3(2.6%).

Table 2 (A): Participants pharmacists' responses to questions exploring their knowledge, attitude and perception about generic medicines:

Question No	**Frequency (%)**		
	Yes	**No**	**Missing**
9. Do you clearly differentiate between the generic pharmaceutical products, and the original branded ones?	111(95.7%)	5(4.3%)	
10. Do you know the exact WHO definition of the generic medicine?	51(44%)	50(43.1%)	15(12.9%)
11. Do you know that for a generic pharmaceutical product to be registered, it must first prove to be Bioequivalent, to its original branded counterpart?	83(71.6%)	28(24.1%)	5(4.3%)
12. Are you sure that all the generic products currently available in your pharmacy, passed bioequivalent test, before being registered in Sudan?	42(36.2%)	70(60.3%)	4(3.4%)
13. If you know that the majority of the registered generics in Sudan are registered without proven bioequivalence, would you still hand them over to your patients?	33(28.4%)	79(68.1%)	4(3.4%)
14. In general, if the generic products are tested and proven bioequivalent to the original brand, do you consider them equally effective and safe same to the branded versions?	64(55.2%)	48(41.4%)	4(3.4%)
15. Have your patients, ever reported to you that they are not satisfied with the effectiveness or safety of the generics you dispensed to them?	80(69%)	32(27.6%)	4(3.4%)
16. Do you know that the generic represent around 65% of prescribed products in the USA, Europe and Japan (By volume)?	21(18.1%)	91(78.4%)	4(3.44%)
17. Do you frequently substitute branded product with generic one, when the original brand is prescribed?	86(74.1%)	24(20.7%)	6(5.2%)

18. When you make a generic substitution, do you always do that in response to the patient or his/her payer requests?	38(32.8%)	73(62.9%)	5(4.3%)
19. Do you always contact the prescriber before making a generic substitution?	78(67.2%)	33(28.4%)	5(4.3%)

Table 2 (B): Participants pharmacists' responses to questions exploring their knowledge, attitude and perception about generic medicines:

Question No	Frequency (%)		
	Yes	No	Missing
20. If the prescribed original brand is not available in your pharmacy, do you first convince the patient that the generic equivalent is equally effective and safe before substitution?	76(65.5%)	35(30.2%)	5(4.3%)
21. In your own experience, do your patients know the difference between a generic and the original brands?	47(40.5%)	65(56%)	4(3.4%)
22. Do you know that the excipients (inactive ingredients) in the generics are usually different from those in the original branded counterparts?	93(80.2%)	19(16.4%)	4(3.4%)
23. Do you know that those differences in excipients (inactive ingredients) can cause harm to some patients (hypersensitivity)?	95(81.9%)	16(13.8%)	5(4.3%)
24. Do you agree that the low prices are of generic are of great benefit to patients of low income (poor) countries?	95(81.9%)	14(12.1%)	7(6%)
26. Do you recommend generics to patients in your Over The Counter (O.T.C) practices?	88(75.9%)	21(18.1%)	7(6%)
27. When an original brand product of narrow therapeutic index e.g. (Carbamazepine, Phenytoin, Warfarin, digoxin, theophylline) is prescribed, would you trustfully substitute it with a generic, if both are available?	29(25%)	83(71.6%)	4(3.4%)
28. There are Generic from Europe, Japan and the USA, and there are other comings from India, the Middle East etc. Do you consider all of them of the same quality, safety?	18(15.5%)	94(81%)	4(3.4%)

25. If you personally, or a member of you family, is ill, would you use generics, or you would prefer the original brand?

I prefer the generics. 19(16.4%)

I prefer the original brand. 52(44.8%)

Both are same to me. 40(34.5%)

Missing 5(4.3%)

29. Are you sure that substitution is legalized in Sudan?

Yes N

30. Is the bioequivalence test for generics only limited to solid dosage forms (Tablets, capsules) or it also is valid for suspensions, eye drops and other medication's dosage forms?

Only for solid dosage form 11(9.5%)

For all dosage form 99(85.3%)

Missing 06(5.2%)

Bivariate analysis

Table 3 (A): Association between respondents' demographic criteria and their knowledge and beliefs on generic using a prior significance level of p<.05.

Age, Gender, MS Marital status, POUS Place Of Undergraduate Studies, ES, Employment Status, PGS, Post Graduate Studies, CPP, Community Pharmacy Practice.

Question	AGE	Gender	MS	POUS	ES	PGS	CPP
Q 8. In your judgment, what is the financial status of the majority of the patients who attend your pharmacy?	.000	.000	.015	.494	.000	.042	.000
Q9. Do you clearly differentiate between generic pharmaceutical products, and the original branded ones?	.057	.133	.118	.478	.309	.558	.843
Q10. Do you know the exact WHO definition of the generic medicine?	.000	.778	.680	.087	.000	.177	.003
Q11. Do you know that for a generic pharmaceutical product to be registered, it must be Bioequivalent to the original brand?	.000	.091	.747	.200	.660	.158	.051
Q12. Are you sure that all the generic products currently available in your pharmacy, passed bioequivalent test, before being registered in Sudan?	.000	.114	.261	.113	.337	.021	.000
Q13. If you know that the majority of the registered generics in Sudan are registered without proven bioequivalence, would you still hand them over to your patients?	.001	.184	.016	.519	.000	.052	.011
Q14. In general, if the generic products are tested and proven bioequivalent to the original brand, do you consider them equally effective and safe to the branded versions?	.000	.000	.106	.034	.002	.437	.000

Table 3 (B): Association between respondents' demographic criteria and their knowledge and beliefs on generic using a prior significance level of p<.05.

Question No.	AGE	Gender	MS	POUS	ES	PGS	CPP
Q15. Have your patient, ever reported to you that they are not satisfied with the effectiveness or safety of the generics you dispensed to them?	.000	.000	.471	.491	.042	.116	.001
Q16. Do you know that the generic represent around 65% of prescribed products in the USA, Europe and Japan (By volume)?	.000	.023	.135	.361	.125	.245	.005
Q17. Do you frequently substitute branded product with generic one, when the original brand is prescribed?	.000	.305	.320	.867	.762	.411	.004
Q18. When you make substitution, do you always do that in response to the patient or his/her payer requests?	.021	.777	.130	.736	.245	.920	.179
Q19. Do you always contact the prescriber before making a substitution?	.000	.785	.105	.936	.082	.060	.000
Q20. If the prescribed original brand is not available in your pharmacy, do you first convince the patient that the generic equivalent is equally effective and safe before substitution?	.000	.000	.012	.006	.184	.049	.004
Q21. In your own experience, do your patients know the difference between a generic and the original brands?	.001	.394	.000	.641	.315	.186	.005
Q22. Do you know that the excipients (inactive ingredients) in the generics are usually different than those in the original brands?	.000	.479	.151	.968	.058	.060	.002
Q23. Do you know that those differences in excipients (inactive ingredients) can cause harm to some patients (hypersensitivity)?	.030	.127	**.**655	.342	.352	.026	.111

Table 3 (B): Association between respondents' demographic criteria and their knowledge and beliefs on generic using a prior significance level of p<.05.

Question	AGE	Gender	MS	POUS	ES	PGS	CPP
Q24. Do you agree that the generic low prices are of great benefit for patients of low income (poor) countries?	.000	.925	.014	.006	.240	.011	.007
Q25. If you personally, or a member of you family is ill, would you use generics, or you prefer the original	.000	.203	.000	.422	.002	.663	.000

brand?							
Q26. Do you recommend generics to patients in your over the counter (O.T.C) practices?	.052	.333	.131	.384	.601	.534	.006
Q27. When an original brand product of narrow therapeutic index e.g. (Carbamazepine, Phenytoin, and Warfarin) is prescribed, would you trustfully substitute it with a generic, if both are available?	.017	.052	.093	.579	.225	.102	.000
28. There are Generic from Europe, Japan and the USA and there are other comings from India. The Middle East, do you consider all of them of the same in quality, safety?	.063	.572	.062	.248	.745	.194	.238
29. Are you sure that free generic substitution is legalized in Sudan?	.003	.128	.925	.044	.677	.304	.018
30.Is the bioequivalence test for generics only limited to solid dosage forms (Tablets, capsules) or it ,also ,is valid for suspensions, eye drops and other dosage forms?	.000	.032	.576	.396	.165	.022	.546

DISCUSSION

Table 1, showsa veryhigh response rate 116 (100%) of respondents. The majority (74.1%) of participants were young in the age group 20-29 years. That might be because experienced pharmacists prefer to work in pharmaceutical companies' promotion sector, or migrate abroad for better payment. That might be because a clear majority (55%) of the registered pharmacists in Sudan are females.[16]

In general Sudanese female pharmacistsmostly prefer to work in the community pharmacy sector of employment, which is the biggest employer, and the employee community pharmacist can fit him/her self with the suitable number ofdaily work hours. The majority 81 (69.8%) of participants were females The female community pharmacists may not feel inclined to migrating abroad as they succumb to the dominant Islamic and oriental cultures. The majority 103(88.8%) of participants had their undergraduate pharmacy studies in Sudan. The big number (15) of the recently established schools of pharmacy, with their big intake capacitiescaused a big increase in the pharmacy graduates.

As per Table 3, A & B, the study results showed that there were varying rates and magnitudes of significant correlations between the study participants' socio demographic characteristics e.g., age, gender, marital status, place of under graduate studies, employment

status, post graduate studies, and length of pharmacy practice periods, with twenty three variables(23) related to their knowledge, attitudes, perception and believes about the generic pharmaceuticals and their use,(p ranges 0.000- 0.049)in tapering order. Thus, participants' age (20), duration of pharmacy practice (16) gender (6), employment status (6), post graduatestudies (6), marital status (5) and place of under graduate studies (4).

Other researchers reported that the socio-demographics of their studied participants showed varying positive or negative significant correlations to their knowledge, attitudes and perception towards generics medications use.[17,18]

Unlike the findings of Basak, and Sathyanarayana, 2012, the majority111 (95.5%) of the participants reported that they can easily differentiate between generics pharmaceuticals, and the original branded ones.[17]

As pharmacy schools graduates, the differentiation between branded and generic pharmaceuticals is a basic knowledge. An even simpler way that might have helped them is the manufacturers' name, where the originators are known to them. Moreover, almost 80% of the registered pharmaceuticals in Sudan are either generics or branded generics mainly belonging to companies from the Middle East, and South East Asia, where generic manufacturers are dominant.

Astonishingly enough, only fifty one 51 (44%) of the participant pharmacists reported that they know the exact WHOdefinition of the generic medicine. This poor result is matching to findings of other researchers.[19]

However, it shows that the participants were poorly educated, since such information should be one of the very basics for a qualified pharmacist.

Ninety five 95(81.9%) of respondent pharmacists agreed that the generics' low prices (affordability) are of great benefit to patients, especially those in low income (poor) developing countries**.** This reflects the participants' concern for the availability, affordability and accessibility of generics forboth the individual patients and their communities. As**,** in Sudan the Pharmaceutical expenditure accounts for 2.2% of thetotal GDP which makes up to 36% of the total health expenditure. The budget for pharmaceuticalsrepresents aneconomic burden to both individual patients and their communities.[20]

Eightyeight (75.9%) of the participant reported theyprefer torecommend generics to patients in their Overthe Counter (O.T.C) practices. Thisparticipants' opinion ismatching to the findings of other researchers.[21]

Affordability of generics might explain the root cause for that recommendation, as the majority of self medicationsseeker, are either pushed by time constraints or the private sectors doctors'exorbitant visits fees.[22]

There was a significant association between the participant pharmacists' age, marital status, and place of undergraduate studies, post undergraduate studies and the participants' tendency to recommend generics in their O.T.C practice, (P0.000,0.014,0.006,0.011,0.007) respectively.

Pharmacists' positive attitude, knowledge and perceptions are crucial for acceptanceand use of generic medicines, but evidence had shown that a positive attitude towards generic medicines, alone, may not necessarily result in the actual prescribing or dispensing (behavior) of generic medicines. Attitudesdifferentfrom behavior, though it isimportant for it.[23]

Therefore, demand-sidepoliciesaimed at improving the knowledge and perceptions of generic medicines,should be combined with policies to facilitate the substitution of generics, and help creating a positive attitude, knowledge and perceptions into the actual dispensing(behavior)of, or asking for generic medicines, in the case of self medication seekers.[24,25]

Many Studies had shown that some of their participant patientsbelieved thatgenerics were less effective than branded products, as they were cheaper than the branded drugs.[26,27]

Forty two (36.2%), of this study participant community pharmacists, were not sure that all the generic products, currently available in their pharmacies, had passed the bioequivalent test, before being registered in Sudan.[28]

Moreover, 79 (68.1%) of the participants reported that they will not dispense generic products, if their bioequivalence to their branded counterparts is not already proven before licensing. This opinion reflects apositive opinion, but a rather cautious stance from the participant community pharmacists towards generic substitution, as they quite frequently substitute generics for their branded counterparts.[29]

Accordingly, it is evident that that the participantswere keen to dispense or recommend products of proven effectiveness and safety, to patients. But, it also reflects that they are rather skeptical about the safety and effectiveness of generics.

There was a significant associationbetween the participant pharmacists' age, marital status, employment status, community pharmacy practice and their concerns about bioequivalence and standard of quality of the generic medicines in their pharmacies, (P0.001,0.016,0.000,0.011), respectively. Concerns and doubts of the participants about the bioequivalence and interchangeability (Substitution) of generic medicines compared to originator medicines, were important signals of the negative attitudes of pharmacists, prescribers and patients, towards generic medicines.[30]

According to astudy in Istanbul, Turkey, half oftheir participant pharmacistsasserted that they were unsure about the bioequivalence of the generics.[31]

Eighty six of theparticipant pharmacists 86(74.1%), reported that they frequently substitute branded products with genericsones when the original brand is prescribed and 78(67.2%) of them reported that they usually contact the prescriber before making that substitution.

Sudanese community pharmacistsmight be in real confusion about the legality of generic substitution. According to National Drug Policy of Sudan (2005-2009).

‘’The dispensing pharmacist in the public and private pharmacy should inform the purchaser before dispensing the medicine, of the available generic alternatives and their prices to choose from, but the replacement of the branded medicine is not allowed, if the prescribing doctor indicated that in writing’’.[32]

This clearlygives the patient and the prescriber the casting word. The role of the pharmacists, here, is only to suggest and is not casting!

In contrast, The Pharmacy & Poisons Act, and Regulation & Orders, July 2008, in its provisions(In Arabic) states in article 35, 1 and 2 p: 83., that(**Translation),**‘’1- No licensed person shall, knowingly, dispense or sell any drug, as a substitute to the prescribed one and this provision does not apply to the dispensing and selling of another pharmaceutical product same to the needed one.

2- Medicines and pharmaceutical preparations appearing in the table2, annexed to this act are exempted and are allowed to be sold without a medical prescription''[33]

It well documented thatthe defined policies for the promotion of generics prescribing and use are of casting importance for their increased use.[34,35]

This is a very confusing statement! Sudanese doctors in one study expressed positive attitude towards pharmacists' practices such as detecting medication errors, therapeutic monitoring and suggesting use of prescription medicines. However, they werenot happy with pharmacists' suggestions of prescription medicines use to patients (Substitution ad/or OTC) practices.[36]

The participant community pharmacists are under pressure from the prescribers who may refuseany substitution of their prescribed medications. Moreover, a majority of the Sudanese prescribers, quite frequently ask their patients to come back after visiting the pharmacy, to check any substitutions made by the pharmacists. This might shake the patients'; trust in the pharmacy profession, at large. In contrast, other researcher, in other countries, reported that doctors hold high regard tothe pharmacists.

According to Bacchetta, 2005; ''Physicians also assume that pharmacists will monitor potential drug-drug interactions and recommend appropriate drug substitution".[37]

Almost the same positive opinion was expressed by doctors in Kuwait.[36]

It shall be well strongly emphasized thatcollaboration between doctors and pharmacists is very important and crucial for the patient's ultimate benefits. The relationship between doctors and pharmacist had historically been a tenuous one. However, the patients' health needs in a safe and effective use of medication leading to the targeted health outcomes necessitate their collaboration.

Historically doctors consider the patient care to be their own prime responsibility. They look at the pharmacist as a drugs' professional whom they just instruct to dispense their prescriptions without any interference (instructions).[38]

Some authors tried to elucidate the expectation of doctors from or about the practicing pharmacists. They reported that doctors, broadly, expect that the pharmacist be

knowledgeable drug experts, takes personal responsibility about discovering drug related problems such as prescription medication errors related to doses, length of treatment, missed dose, over dose management, drug-interactions, advise doctors about cost of treatment, and cost effectiveness, help them in designing drug therapy, educate patients about the appropriate use of their medications and advice them to adhere to their prescribed medications regimens. However, they are uncomfortable with pharmacists recommending changes on therapy (substitution).[38-41]

Experience from The UK, Australia, New Zealand and Canada proved that collaboration of doctors and pharmacist, after clear definition of their respective role and the joint patients' medication reviews, greatly improve patients' care and health outcomes.[42-44]

There was no significant association between the respondent pharmacists' gender, marital status, place of undergraduate studies, employment status, post graduate studies and their tendency for substitution of generic medicines (P0.305,0.320,0.867,0.762,0.411) respectively. Toimplementgeneric substitution and successfully improve generic prescribing, it is important to have clear policies to promote generic use and guidelines on therapeutically interchangeable drug products to help healthcare professionals to perform generic substitution appropriately, and to avoid any pitfalls or errors that may arise from any possible inappropriate generic substitution, but not rule it out altogether.[35]

Quality use of generic medicines, thesuccessful implementation of generic substitution policies, and generic prescribing require communication and co-operation of all the involved parties in this process. There should be co-operation between healthcare professionals (pharmacists, physicians, nursing staff, and other prescribers and dispensers). For example, when prescribers oppose generic substitution made by community pharmacists, it is an obstacle to the successful implementation of generic substitution, and all its well recognized benefits to patients and their communities, alike.[45]

Transparent communication between the national regulatory authorities, healthcare professionals and consumers by providing them with information on the requirements to register medicines in general and generic medicines, is particularly important.

Kobayashiet al; 2011, conducted a study that involved1, 253 pharmacists and observed that the majority were in favor of dispensing generics.[13]

Eighty 80(69%) of participants in this study, reportedthat many of their patients werenot satisfied with the effectiveness and/or safety of the generics.[46]

However, 76(65.5%) of the them, reported that they usually try to convince (educate) the patients that the generics are equivalent, equally effective and safesame to their branded counterparts, but have far low cost to them.[47]

According to Heikkilä et al., 2007; Finnish consumers accept substitution for two main reasons, desire to save money and recommendation by pharmacists.[48-49]

There was a significant association between the participantpharmacists' age, gender, marital status, place of undergraduate studies, post graduate studies and the participant community pharmacistsefforts to educate and convince patients about the safety and effectiveness of generics(P0.000,0.000,0.012,0.006,0.049,), respectively. Eighty three 83(71.6%) of the participant pharmacists reported that they would not substitute narrow therapeutic index (NTI) medicines with generics. Substitution of narrow therapeutic index medicine is a rather controversial issue. It is hypothesized that small differences in bioavailability between NTI medicines, even those within the regulatory limits which define bioequivalence, can lead to changes in clinical outcomes when patients are switched between originator and generic medicines.[50]

InaMalaysian study, (76%) of respondents pharmacists indicated that generic substitution of medicines with a narrow therapeutic index is inappropriate.[51-53]

There was no significant association between the respondent pharmacists,' gender, marital status, place of undergraduate studies, employment status,post graduate studies and their substitution of narrowtherapeutic index (NTI)generic medicines where (P= 0.052,0.093,0.,0.579,0.225,0.102) respectively.

It ispertaining, here, to mention that many safety experts felt that the current bioequivalence standards are inadequate for NTI products, as case reports and some observational studies did not rule out their skepticism.

However, well- controlled studies have contradicted that, as no evidence was found that proves that bioequivalent substitution of NTI medications was associated with exacerbation of disease condition.[54-55]

The American Medical Association Council on Science and Public Health stated that: there is no strong evidence of difference in clinical performance between narrow therapeutic index (NTI drugs and their branded counterparts. Difference, ‘’either does not exist or is extremely weak’’.[56]

A majority 93 (80.2%) of the participant community pharmacists reported that theexcipients in the generics’ formulations are usually different from those in the original brands, and ninety five 95 (81.9%) of participants asserted that these different excipients (inactive ingredients) can cause harm to some patients (hypersensitivity). This is a clear indication that the participant community pharmacists are knowledgeable about the differences between generic and branded pharmaceuticals.

According to Haywood and Glass, 2011, from James Cook University, Queensland, excipients in average make up toabout 90 % of the weight of each pharmaceutical product. Excipients were formerly considered as "Inactive ingredients", but were proven, by many authors to be active!, and might even , possibly, elicit hypersensitivity and adverse effects reactions in patients ranging from mild rashes to potentially life threatening reactionsof varying natures and magnitudes same as the active ingredients of the medications used. Pharmacists are accordingly in position to provide important information to patients about drug allergens, which in extreme cases can provoke fatal reactions. Potential allergens include glutens, alcohol, shellfish, cornstarch, lactose, and some dyes. Even trace amounts of these substances (e.g. one millionth of a percent of alcohol wash) can be a problem, if a patient is highly sensitive to them.[57-63]

There was asignificant association between the respondent pharmacists’ age, post graduate studies and their knowledge about the harm of some inactive ingredients where the (P 0.030, 0.026) respectively. Pharmacists can provide important information to patients about generic drugspotential allergens and educate them to increase their use of generics.[64]

CONCLUSION

The current study showed good knowledgeand perception towards generic medicinesamong participant community pharmacists inKhartoum North, town center, Sudan. It also highlighted a mixed attitudetowards generic medicine dispensing, and substitution, by patients, pharmacists and the prescribing doctors.

4.3 RECOMMENDATIONS

Continuous education for pharmacists seems to be needed to improve their knowledge and perceptions about generic medicines, with special focus on the concepts of quality control criteria and bioequivalence of medicines. In this way, pharmacists can take up their informative role for patients and facilitate the safe and appropriate use of generic medicines by Sudanese patients, who are mostly of low income status and this majority, pay out – of – pockets.

CONFLICT OF INTERESTS

The researchers have no conflict of interest to declare.

REFERENCES

1. Access to Essential Medicines. The World Medicines Situation 2004. Geneva: World Health Organization (WHO); 2004.http://apps.who.int/medicinedocs/en/d/Js6160e/9.html.
2. The Ministry of Health. Pharmaceutical Country Profile, 2010. Available at:http://www.who.int/medicines/areas/coordination/sudan_pharmaceuticalprofileDecember2010.pdf.
3. Nguyen TA, HassaliMAA,McLachlanA.Report from the field: Generic medicines policies in the Asia Pacific region: ways forward. WHO South-East Asia Journal of Public Health, 2013; 2(1): 72-74. DOI: 10.4103/2224-3151.115849.
4. Siam MKS, Khan A, Khan TM. Medical and pharmacy students' knowledge and perception about generic medicines in Bangladesh .J Pharm Health Ser Res., 2008; 4(1): 57-61. http://dx.doi.org/10.1111/jphs.12008.
5. Albadr Y, Khan TM. Factors influencing community pharmacis decision to dispense generic or branded medicines; Eastern Province, Alahsa, Saudi Arabia. Saudi Pharm J., 2015; 23: 143-146.
6. Shafie AA, Hassali MA. Price comparison between innovator and generic medicines sold in community pharmacies in the state of Penang, Malaysia. J Generic Med., 2008; 6: 35-42.
7. Simoens S, De Coster S. Sustaining Generic Medicines Markets in Europe. Catholoic University of Leuven, Leuven, Belgium, 2006.
8. Jamshed SQ, Hassali MAA, Ibrahim MIM, Shafie A A, Barber Z. Knowledge, Perception and Attitude of Community Pharmacists towards Generic Medicines in Karachi, Pakistan : A Qualitative Insight. Trop. J. Pharm. Res., 2010; 9(4): 409-4015.

9. Alrasheedy AA, Hassali MA, Stewart K, Kong DCM, Aljadhey H, Mohamed Ibrahim MI, Al-Tamimi SK. Patient knowledge, perceptions, and acceptance of generic medicines: a comprehensive review of the current literature. Patient.Intell, 2014: 6: 1—29. DOI:http://dx.doi.org/10.2147/PI.S46737.
10. McKinlay JB[1], Trachtenberg F, Marceau LD, Katz JN, Fischer MA. Effects of patient medication requests on physician prescribing behavior: results of a factorial experiment. Med Care, Apr, 2014; 52(4): 294-9. doi: 10.1097/MLR.0000000000000096.
11. McKinlay JB, Felicia L. Trachtenberg FL, Marceau LD, Fischer MA. Do patient medication requests affect primarycare physician prescribing? Results from a factorial experiment. Conference: 141st APHA Annual Meeting and Exposition 2013 (Conference Paper).
12. Science Daily major impact on prescribing, reports study. Wolters Kluwer Health: Lippincott Williams & Wilkins, March 14, 2014. https://www.sciencedaily.com/releases/2014/03/140314111348.htm.
13. Kobayashi E, Satoh N, Uedain S. Community pharmacists' perspectives on generic substitution in Japan. J. Public. Health, 2011; 19: 249–256.
14. Toverud EL, Røise AK, Hogstad G, Wabø I. Norwegian patients on generic antihypertensive drugs: a qualitative study of their own experiences. Eu. J. Clin. Pharmacol., 2011; 67(1): 33-8. doi: 10.1007/s00228-010-0935-x.
15. Gonzalez-Gonzalez C, López-Vázquez P, Vázquez-Lago JM, Piñeiro-Lamas M, Herdeiro MT, Arzamendi PC, et al. (2015) Effect of Physicians' Attitudes and Knowledge on the Quality of Antibiotic Prescription: A Cohort Study. PLoS ONE 10(10): e0141820. doi:10.1371/journal.pone.0141820.
16. Federal Ministry of Health, General federal Pharmacy Directorate. Annual Pharmaceutical statistical report, 2014: 51.
17. BasakSC and Sathyanarayana D. Exploring Knowledge and Perceptions of Generic Medicines among Drug Retailers and Community Pharmacists. Indian. J. Pharm. Sci., Nov-Dec, 2012; 74(6): 571–575. doi: 10.4103/0250-474X.110611.
18. Toklu HZ, Akici A, Oktay S, Cali S, Sezen SF, Keyer Uysal M. The pharmacy practice of community pharmacists in Turkey. Marmara. Pharm. J., 2010; 14: 53–60.
19. BasakSC and Sathyanarayana D. Exploring Knowledge and Perceptions of Generic Medicines among Drug Retailers and Community Pharmacists. Indian. J. Pharm. Sci., Nov-Dec, 2012; 74(6): 571–575. doi: 10.4103/0250-474X.110611.

20. Drozdowwska A, Hermanowski T. Exploring factors underlying the attitude of community pharmacists to generic substitution: a nationwide study from Poland, Int J Cli Pharm., 2016; 38: 162-170.
21. Annual Pharmaceutical Statistical Report. Sudan: MOH, 2006-2007.
22. Kohli E, Buller A. Factors Influencing Consumer Purchasing Patterns of Generic versus Brand Name Over-the-Counter Drugs. Southern Medical Journal, 2013; 106(2): 155-160.
23. Vilako P, Volmer D, Ral A. Factor influencing purchase of and counseling about prescription and OTC medicines at community pharmacies in Tallinn, Estonia. Acta Pol Pharm, 2012; 69(2): 335-340.
24. Ashby P. The difference between attitude and behavior. Professional Development People. September 8, 2014. Available at: http://professionaldevelopmentpeople.co.uk/understanding-difference-between-attitude-and-behavior.
25. DutiM, Alili- Idrizi EA, Ahmeti- Lika S, Malaj L. Overview on generic policies and pharmaceutical pricing in the Europen countries and the republic of Macedonia. Scientific Journal, 2015; 11(3): ISSN: 1857–7881
26. Kaplan WA, Ritz LS, Vitello M, Wirtz VJ. Policies to promote use of generic medicines in low and middle income countries: A review of published literature, 2000-2010. Health Policy, 2012. http:dx.doi.org/10.1016/j.healthpol.2012.04.015.
27. Shrank WH, Cox ER, Fischer MA, Mehta J, Coudhry NK. Patients' Perceptions of Generic Medications. Health Aff (Millwood), 2009; 2892: 546-556. Doi: 10.1377/hlthaff.28.2.546.
28. Dunne S, Dunne CP. What do people really think of generic medicines? A systematic review and critical appraisal of literature on stakeholder perception of generic drugs. BMC Medicine, 2015; 13: 173. DOI:10.1186/s12916-015-0415-3.
29. Republic of Sudan, Federal Ministry of health, Directorate General of Pharmacy, National Drug Policy, (2005-2009) 2005: 3.6, 3: 15.
30. Birkett D J. Generics-equal or not? Aust Prescr, 2003; 26: 85-87.
31. Meredith PA. Potential concerns about generic substitution: bioequivalence versus therapeutic equivalence of different amlodipine salt forms. Curr Med Res OPIN, 2009; 25(9): 2179-2189.
32. Toklu HZ, Akici A, Oktay S, Cali S, Sezen SF, Keyer Uysal M. The pharmacy practice of community pharmacists in Turkey. Marmara. Pharm. J., 2010; 14: 53–60.

33. Republic of Sudan, Federal Ministry of health, Directorate General of Pharmacy, National Drug Policy, 2005-2009; 2005: 3,6,3: 15.
34. National Medicines and poisons Board. Medicines and Poisons Act 2009 and Provisions issued according to it : Sudan currency printing press, Khartoum, 2009; 83.
35. Kaplan WA, Ritz LS, Vitello M, Wirtz VJ. Policies to promote use of generic medicines in low and middle income countries: A review of published literature, 2000-201, Health Policy, 2012; .http://dx.doi.org/10.1016/jhealthpol.2012.04.015.
36. Hassali AM, Alrasheedyaa, McLachlan A, Nguyen TA, Al-Tamimi SK, Ibrahim MIM, Aljadhey H. The experiences of implementing generic medicine policy in eight countries: A review and recommendations for a successful promotion of generic medicine use. Saudi Pharm J, 2014; 22(6): 491-503. Doi:10.1016/j.jsps.2013.12.017.
37. Matowe L, et al. Physcians' perception and expectations of pharmacists' professional duties in government hospitals in Kuwait. Med. Princ. Pract., 2006; 15: 185-189.
38. Bacchetta S. Attention: Pharmaceutical products and brand managers. Another Member of the team. Pharmaceutical Representative October 1, 2005. Almost the same positive opinion was expressed by doctors in Kuwait. [38].

    Matowe L, et al. Phscians' perception and expectations of pharmacists' professional duties in government hospitals in Kuwait. Med. Princ. Pract., 2006; 15: 185-189.
39. Wilburg K, Beniles A, Hammuda A. Physician perception of pharmacists role in a primary care setting in Qatar. Globalization and Health, 2012; 8: 12. Available at:http://www.globalizationhealth.com/contents/8/1/12.
40. Wilburg K, Beniles A, Hammuda A. Physician perception of pharmacists role in a primary care setting in Qatar. Globalization and Health, 2012; 8: 12. Available at: http://www.globalizationhealth.com/contents/8/1/12.
41. Berhane A, Ali E, Odegard P, Suleman S. Physicians' Expectations of Clinical Pharmacists in Jimma University Specialized Hospital, South West Ethiopia. IJPTP, 2013; 4(2): 571-574.
42. Khan N, Abbas AA, McGarry K, Shahid S. Perception and experience of physicians regarding integration of clinical pharmacists in health practices; a survey of hospitals of Karachi, Pakistan. IJAMSCR, 2014; 2(3): 222-234.
43. Azhar S, Et al. Qualitative Assessment of the Pharmacist's Role in Punjab, Pakistan; Medical Practitioners' Views. Tropical Journal of Research, 2015; 14(2): 323-327. Availabl at:http://www.tjpr.org.

44. Bradley F, Wagner AC, Elvey R, Noyce PR, Ashcoft DM. Determinants of the uptake of medicines use reviews (MURs) by community pharmacists in England: a multi-method study. Health Policy, 2008; 88: 258-68.
45. Lee E, Braund R, Tordoff J. Examining the first year of Medicine use review services provided by pharmacists in New Zealand: 2008. NA Med J., 2009; 122: 3566.
46. Pottie K, et al. integrating pharmacists into family practice teams. Can Fm Physician, 2008; 54: 1714-7.
47. Kobayashi E, Satoh N, Uedain S. Community pharmacists' perspectives on generic substitution in Japan. J. Public. Health, 2011; 19: 249–256.
48. Himmel W, Simmennorth – Nayda A, Niebling W, Ledig T, Jansen RD, Kochen MM, Gleiter CH, Hummers –Pradier E. What do patients think about generic drugs? Int J Clin Pharmacol Ther, 2005; 43(10): 472-9.
49. Allenet B, Barry H. Opinion and behavior of pharmacists towards the substitution of branded drugs by generic drugs: survey of 1,000 French communitypharmacists. Pan World Sci., 2003; 25: 197-202.
50. Heikkilä R, Mäntyselkä P, Hartikainen-Herranen K, Ahonen R. Customers' and physicians' opinions of and experiences with generic substitution during the first year in Finland. Health Policy, 2007; 82: 366-74.
49. Babar ZU, Stewart J, Reddy S. An evaluation of consumers' knowledge, perceptions and attitudes regarding generic medicines in Auckland. Pharm. World. Sci., 2010; 32(4): 440–448.
50. Heikkilä R, Mäntyselkä P, Hartikainen-Herranen K, Ahonen R. Customers' and physicians' opinions of and experiences with generic substitution during the first year in Finland. Health Policy, 2007; 82: 366-74.
51. Babar ZU, Stewart J, Reddy S. An evaluation of consumers' knowledge, perceptions and attitudes regarding generic medicines in Auckland. Pharm. World. Sci., 2010; 32(4): 440–448.
52. Chong CP, Hassali MA, Bahari MB, Shafie AA. Exploring community pharmacists' views on generic medicines: a nationwide study from Malaysia. Int J Clin Pharm, 2011; 33: 124–131.
53. Paveliu MS, Paviliu FS. Generic substitution issues: Generic –generic substitution andgerneric substitution of narrow therapeutic index (NTI). Medica- a Journal of Clinical Medicine, 2011: 6(1): 52-58.

54. Haknosen H, Toverud E-L. A review of patient perspective on generics substitution: what are the challenges for optimal drug use. GaBI, 2012; 1(1): 28-32. DOI:10.5639/gabij.2012.0101.008.
55. Kesselheim AS[1], Misono AS, Lee JL, Stedman MR, Brookhart MA, Choudhry NK, Shrank WH. Clinical equivalence of generic and brand-name drugs used in cardiovascular disease: a systematic review and meta-analysis. JAMA, 2008; 300: 251-2526. doi:10.1001/jama.2008.758PMID:19050195.
56. Kesselheim A S, Stedman MR, Bubrick E J, Gagne JJ, Misono AS, Lee JL, M. Alan Brookhar MA, Avorn J, Shrank WJ. Seziure outcomes following the use of generic versus brand-name antiepileptic drug; a systematic review and meta- analysis. Drug, 2010; 70: 605-621. Doi: 10.2165/10898530-000000000-oooooPMID: 20329806.
57. American Medical Association Council on Science and Public Health. Generic substitution of narrow therapeutic index drugs. 2007. Available at:http://www.ama-assn.org/resources/doc/csaph/x-pub/csaph2a07.
58. Shangraw RF and Demarest DA, A Survey of Current Industrial Practices in the Formulation and Manufacture of Tablets and Capsules. Pharm Technol, 1993; 17(1): 32–44.
59. Napke E. Exceptions, adverse drug reactions and patients rights. CMAJ, 1994; 151(5): 529–533.
60. Pifferi G, Restani, P. The safety of pharmaceuticalexciptients. IL Framaco, 2003; 58: 541–550.
61. Osterberg R E, See NA. Toxicity of excipients--a Food and Drug Administration perspective. Int J Toxicol, 2003; 22(5): 377-80.
62. Balbani AP, StelzerLB, Montovani J C. Pharmaceutical excipients and the information on drug labels. BrazOtorhinolaryngol, 2006; 72(3). http://dx.doi.org/10.1590/S0034-72992006000300018.
63. Noiles K, Vander Stichele R. Are exceptients really inert ingredients? A review of adverse reactions to excepients in oral dermatological medicine in Canada. J Cutan Med Surg, 2010; 14(3): 105–114.
64. Haywood A, Glass DB. Pharmaceutical excipients – where do we begin? Aust Prescr, 2011; 34: 112–4.