Pharmaceuticals Safety Practices-A Comparative Pilot Study

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Abstract

Introduction: The safety of medicine is essential for the safety of patients. Inappropriate drug storage, expiration dates, sharing prescription drugs, self medication habits and misuse of some drugs are contributing factors affecting medication safety. One or more of these factors may lead to serious health complications and even death.

Objectives: The purpose of this study was to highlight the common errors and pharmaceutical malpractices that people usually engage in on a daily basis and to correlate these to culture, gender and educational levels. This may spread awareness in an easy and understandable manner and provide certain guidelines to drug consumers ensuring that pharmaceutical preparations are used correctly and safely.

Methods: Two hundred questionnaires were randomly distributed in two countries; Saudi Arabia and India. The collected data were statistically analyzed.

Outcomes and conclusion: Results showed that alarming percentages of various participants were using pharmaceuticals inappropriately due to carelessness, unawareness or intentional mistakes. Therefore, active participation by health care professionals is essential for the prevention of drug misuse. Increasing population awareness about self medication, products expiration, pharmaceuticals labels and optimum storage conditions would minimize the adverse effects and may even be life saving.

Key words: Pharmaceuticals, medication safety, patient safety, errors, storage, misuse, self medication, adverse effects

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Introduction

Medication and patient safety measures are indispensable in any health care system. Medication safety is the design of medication administration strategy to ensure the five rights; right patient, right medication, right dose, right route and right time. [1] While patient safety refers to the sustained, proactive process of identifying, avoiding and rapidly resolving errors, omissions, mishaps and miscommunications that could affect a patient's healing, health or well-being at any point, at any time, in any care setting. [1]

Adverse drug events are common, costly and serious problems. These include adverse drug reactions and medication errors. [2] The latter means any preventable actions that may lead to patient harm. These errors may include sharing prescription drugs, self medication habits, medication misuse, administration of drugs after expiration date, carelessness of reading the labels and misplacement of the products.

Whether it is prescription or Over-the-Counter (OTC), no medicine is without risk. [3] Up to half of people who use medicines, do not use them as prescribed. [4] Home medicine chests, which are often kept in inappropriate locations and containers, promote opportunities for irrational consumption, exchanging of medicines, irresponsible self-medication, unintentional toxic exposure and intentional intoxication (drug misuse among the adolescents). [5] Proper methods of storage and preservation of drugs are of great importance for maintenance of their potency. [6] Depending on the product's composition, it may expire long before its expiration date if it has not been stored and handled properly. [7] Some of the environmental factors such as air, chemicals, insects and bacterial and fungal growth increase the risk of contamination. [8, 9] Others like moisture, light and temperature variations may adversely affect the different dosage forms of drugs and may lower their original potency. [8, 9] Summer heat can potentially degrade the drug which is often unnoticed especially in hot countries. [4] Reading the label before purchasing any sort of cosmetic product or medicine is less practiced by the consumers. [6] Most people find it difficult to understand the terminology and instructions given in the leaflet due to lack of its simple explanation especially for those with low literacy level. [10] A high incidence of inappropriate medication use has been documented in the older non-institutionalized population [11-13] and in long-term care. [14] Therefore, the risk of medication errors may be high in older home healthcare patients. Such patients are frequent medication users, and advanced age and frailty may increase their susceptibility to adverse medication effects. [15]

This goes not only for medicines but also for cosmetics as well. Many people use makeup on a daily basis which is a major factor of concern since a considerable amount of cosmetics can actually be absorbed into the skin or breathed into the lungs. [16]

Global drug safety depends on strong national systems that monitor the development and quality of medicines, report their harmful effects, and provide accurate information for their safe use. [3, 7] Saudi Food and Drug Authority (SFDA) and Central Drugs Standard Control Organization (CDSCO) are the two regional regulatory authorities that assure the safety, quality and efficacy of medications in Saudi Arabia (SA) and India (IN), respectively. [17, 18] Research has shown that medical errors and the associated injuries are a significant problem as these errors occur frequently and have significant clinical and financial consequences. [19, 20] Hence, preventing medication errors is a blueprint for change in medication safety. [21] Recent research reports have raised concern about the protocols of administration of various pharmaceuticals that are used in health care systems and their effects on medication and patient safety in order to minimize the index of errors to the lowest. [22-26]

Literature data from survey studies on the prevalence of common medication errors at home is lacking. Medication-related safety incidents are a source of concern not only to patients but also to policy makers and clinicians. [22] To promote adherence to medication and patient safety measures there is an urgent need to highlight the common errors that individuals make during their daily life when using pharmaceutical preparations either due to unawareness or carelessness. Comparing such practices between people of different genders, education levels or from different communities would help in

determining their predisposing factors. Therefore, this snapshot study was carried out to determine how individuals use pharmaceuticals and highlight their daily home malpractices in order to focus on ways to minimize the index of errors and improve the patients' health, recovery and well-being.

Materials and Methods:

Materials:

- Individuals from Saudi Arabia and India.
- Questionnaire made of 23 questions.

Inclusion Criteria:

- Individuals of both genders
- Individuals aged above 18 years

Exclusion Criteria:

- Uneducated people who could not read or write
- Individuals aged less than 18 years

Methods:

This research design was cross sectional and used a questionnaire survey distributed randomly among selected populations in Saudi Arabia and India. The questionnaire had multiple questions pertaining to pharmaceutical preparations used and kept at home and self medication habits. Some of these questions were about the placement of drugs stored at home whether they are prescription or OTC, keeping the leftover drugs for future use (standby drugs), checking the labels and expiration dates of pharmaceuticals, understanding instructions given, sharing medications and completion of the recommended dose.

A questionnaire comprising of 38 questions was designed after referring to previous studies and interviews with five senior pharmacists who had over ten years of experience in the academic field. [٢٧] Pretesting was done by distributing the questionnaire to a sample of 10 participants selected randomly from both countries. The responses from those individuals were subjected to a factor analysis. As a result, a minor change to certain terminology was made to some questions and the total number of questions was reduced to 23 questions. The content validity was finally assessed by discussion and rating by academics and students.

A pilot questionnaire was given to 10 participants and then re-given to them after 45 days to test reliability and reproducibility. The Cronbach's alpha was used to test the reliability, the values for the questions ranged from 0.82 to 0.95 with an overall Cronbach's alpha of ٠.92 showing excellent reliability.

Two hundred hard copies (paper forms) were randomly distributed among populations. In addition, soft copies of the questionnaire using my easy survey website (www.myeasysurvey.com) were available. A systematic random sampling technique was used when questionnaires were distributed. The participants were selected from Riyadh Colleges of Dentistry and Pharmacy directory list that included all students' names and every fourth name (aged 18 years and above) was chosen. Every third customer entering some pharmacy stores in both countries was selected to fill in a questionnaire. A total of 200 questionnaires were distributed, participants were requested to fill in the questionnaires after reading and signing an informed consent statement. After three months, 166 filled questionnaires were returned. In Saudi Arabia; all hundred distributed questionnaires were filled and returned while only 61 were returned in India. Five additional questionnaires (late reporting) from Saudi Arabia were also included in the study. Collected data was analyzed using Statistical Product and Service Solutions (SPSS) software analysis tool (version 18). Chi square test with $p < 0.05$ was used to check for significance of differences in responses.

Results

Total of 166 questionnaires from paper and online versions were filled and returned with a response rate of 83%. From those, 105 came from Saudi populations and 61 from Indian populations. There were 48 females and 117 males with an indeterminate case. Of these, 84 were students, 62 had bachelor degrees, 11 had postgraduate degrees, and 9 were indeterminate (Figure 1).

Significant variations between participants of different cultures, genders and educational levels have been found upon comparison of their daily practices when using pharmaceutical preparations (Tables 1-3).

Pharmaceutical malpractices have been noticed from populations in both countries with significant differences in certain responses from each one (Table 1). On gender basis; females were found to be notably more curious than males when dealing with pharmaceuticals (Table 2). Remarkable variations between participants of different educational levels were found when using pharmaceutical products (Table 3).

Figure 1: Study populations divided into different categories

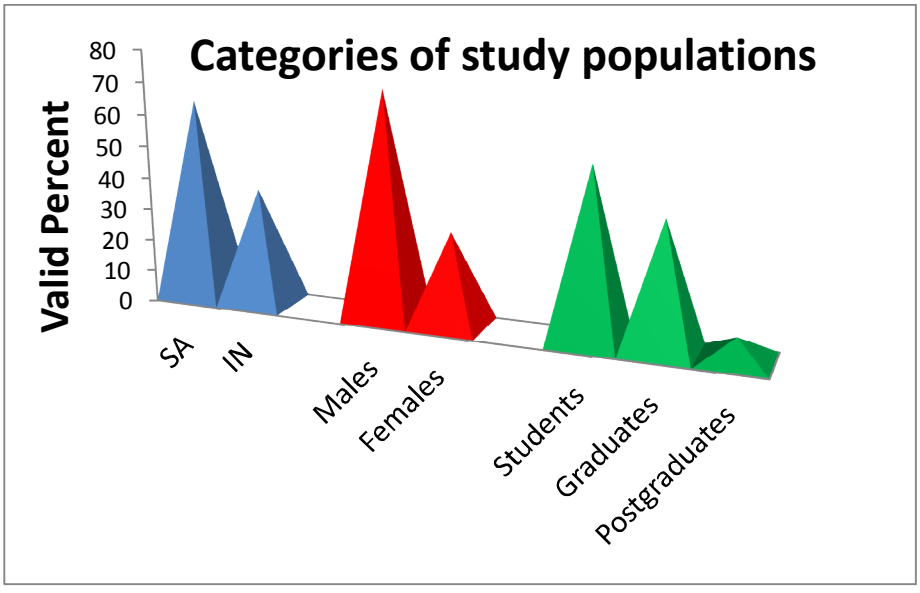

Table 1: Saudi and Indian populations' safety measures when using pharmaceuticals

*Practice of pharmaceuticals safety measures	Place		p
	SA (%)	India (%)	
Careful to ask pharmacist about drug action	57 (54.3)	20 (33.3)	0.009
Never repeated prescribed medications without physician consultation	15 (14.3)	1 (1.6)	0.017
Used to clean drug cabinets and discard expired items in front of children	25 (24.0)	45 (73.8)	0.000
store their medications in front of adolescents most of the time	33 (31.4)	34 (55.7)	0.012
Store cosmetic products: -in moist places -according to their state of requirements	 6 (5.7) 41 (39.0)	 9 (15.0) 13 (21.7)	 0.028 0.028
Use dining tables for drug storage	19 (18.1)	2 (3.3)	0.018
Prefer using unfavorable places for drug storages such as kitchens, bathrooms or dining tables due to unknown reasons	29 (27.6)	29 (47.5)	0.030
Repack medications and put them all in one container for future use	28 (26.7)	2 (3.3)	0.002
Not keeping self updated about medicines and cosmetics	22 (21.0)	26 (42.6)	0.001
Mostly did not check RAFDS approval: - there is no need for that as the product is on the market, -due to difficulty to understand the product labels	 41 (40.2) 40 (39.2)	 43 (70.5) 10 (16.4)	 0.001 0.001

*Responses with significant differences

Table 2: Differences in responses about pharmaceuticals safety practices based on gender basis

*Practice of pharmaceuticals safety measures	Gender		p
	Female (%)	Male (%)	
Careful to ask pharmacist about contraindications of their medication and its interactions with other drugs	26 (57.8)	40 (34.5)	0.007
Careful to ask pharmacist about what to do with drug leftover	15 (31.3)	13 (11.2)	0.002
Read the leaflet of a prescribed medication	26 (54.2)	33 (28.7)	0.002
Do not understand the leaflet when trying to read	18 (37.5)	84 (72.4)	0.000
Never check drug cabinet for expired item	7 (14.6)	44 (37.6)	0.009
Store their medications in front of adolescents sometimes	25 (52.1)	36 (30.8)	0.022
Do not check RAFDS approval	31 (64.6)	93 (80.2)	0.034
Fully updated about medicines and cosmetics	17 (35.4)	14 (12.0)	0.002

*Responses with significant differences

Table 3. Level of education in relation to participants' responses of pharmaceuticals safety

*Practice of pharmaceuticals safety measures	Education			
	Students (%)	Graduates (%)	Postgraduates (%)	p
Careful to ask pharmacist about the dose of their medication	67 (81.7)	39 (62.9)	6 (54.5)	0.018
Throw the drug leftover immediately after the prescribed period elapsed	5 (6)	6 (9.7)	3 (27.3)	0.049
Do not understand the leaflets of pharmaceuticals when trying to read	52 (62.7)	47 (75.8)	3 (27.3)	0.006
Share prescribed medications with others	61 (73.5)	38 (61.3)	4 (36.4)	0.030
Never repeated prescribed medications without physician consultation	7 (8.3)	3 (4.8)	5 (45.5)	0.001
Used to clean drug cabinets and discard expired items in front of children	43 (51.2)	22 (36.1)	0 (0)	0.003
Never use medications for purposes other than those labeled on the package without consultation	18 (21.4)	17 (27.9)	7 (63.6)	0.026
Store their medications in front of adolescents: - Sometimes - Most of the time	 24 (28.6) 45 (53.6)	 26 (41.9) 17 (27.4)	 8 (72.7) 0 (0)	 0.004 0.004
Store cosmetic products: - in kitchens - in moist places	 1 (1.2) 6.(7.1)	 4 (6.6) 8 (13.1)	 2 (18.2) 0 (0)	 0.049 0.049

*Responses with significant differences

Discussion

Comparison of the safety measures practiced by the study participants when using pharmaceuticals has been done on the basis of culture, gender and education. The study asked about all pharmaceutical preparations that people were using on their daily life including prescription and OTC medications, cosmetic and various health care products. Selecting people from different communities would significantly help in understanding some of the leading factors to pharmaceuticals safety practices. Especially within Saudi and Indian communities where there are many challenges to health care services although their governments have given high priority to the development of health care systems (2٨-٣٠). On the other hand, comparing participants of both genders and different educational levels for their attitudes when using pharmaceuticals had determined how those factors would affect their safety measures when using pharmaceuticals and hence their health and well being.

Analysis of the data revealed that most of the involved populations did not usually obtain full information from pharmacists about the pharmaceutical product they purchase in pharmacy stores (Tables 1-3). This could be due to self dependence on reading the products' labels. However, the results showed that more than 60% of the respondents did not try to read the leaflets of their medications. Females and postgraduates were more curious to read such leaflets. This could be explained as the majority (> 70%) of the males and graduates could not understand the terminology found in the leaflets (Tables 2 and 3).

A few (17%) of the participants were careful enough to ask the pharmacist what to do with their medications leftover. This explains why more than half of them (> 50%) stored the leftover until further needed. Females and postgraduates were significantly the best in dealing with their medications leftover (Tables 2 and 3). More than half of the total participants shared their prescribed medications with others while about three quarters of them use some medications for purposes other than those labeled on the package without consultation. With respect to educational levels, it was found that, the higher the educational degree, the lesser the percentage of such malpractices (Table 3). Sharing and repeating prescription medications is a common habit in developing countries where the strict laws for dispensing prescription drugs are lacking. Although 40% of the study participants repeated their prescribed medications whenever they felt sick, Saudi and postgraduate populations significantly avoided such habit when compared to Indian and graduate ones, respectively (Tables 1 and 3).

Saudi, female and postgraduate participants were found to be remarkably more aware about the suitable instructions to be followed to ensure the safe storage of pharmaceutical preparations at home (Tables 1-3). About two third of the total population thought that humid places (kitchens and bathrooms) or dining tables were the best places to keep pharmaceuticals. There were no significant differences between either genders or people with different education levels or from different cultures regarding this matter. This might be due to ease of accessibility and/or avoidance of forgetting taking the medicaments on their respective timing. Participants were used to practice such despite the damage occurred to certain products if kept in those places. More than three quarters of participants stored their medications in the presence of adolescents noting that Indian-, female- and student-participants were found to engage more in such behavioral mistakes (Tables 1-3). The latter might lead to some intentional drug intoxications by those teenagers and increased rates of suicides.

Although all of the populations involved in the study were educated, most of them did not care to keep a list of emergency numbers or contacts of the closest drug poison centers in case of accidents or drug poisoning. About three quarters of the participants did not keep standard measurement tool for accurate drug dosage or check the approval of regulation authorities for food and drug safety (RAFDS) of the pharmaceuticals upon purchasing from pharmacies or retail markets. Some participants stated that if the product was available in the market, they thought no need to check this as it should have been approved already while others believed that it was hard to go through the product's label and understand it. More than three quarters of the

participants were found not to bother to update themselves about medications. Saudi-and female- participants were particularly more interested for being updated to be the first to know about harmful and useless products so they could avoid any complications before they occur (Tables 1 and 2).

Indicating all precautions about pharmaceuticals would be extremely difficult. The prudent alternative is to make reasonable judgments based on the best available evidences combined with successful experiences in health care. [3١] One of the limitations of the study is the difficulty to access different families in order to ask them about their attitudes when using pharmaceutical products. From each house, only one questionnaire is to be filled and represents what they usually do. The responses from Saudi Arabia were higher than that from India as the study was mainly done in Saudi Arabia and the distance played a factor on that. Accordingly, this is considered a snapshot study in order to achieve its main goal to capture an insight into the different individuals practice towards pharmaceuticals that they are using and keeping at home in two developing countries.

Conclusion:

Increased vulnerabilities of drug consumers might be due to increased errors, most of which might be unintentional or due to the consumer's carelessness. Although the limited number of samples, this pilot study focused on the common mistakes that the consumers of pharmaceuticals usually make and highlighted their increased percentages between those consumers. In addition, the study discussed the predisposing factors and reasons of such practices. A detailed study with a greater sample size is still necessary to elaborate on the factors unreached by this study.

Neglecting such malpractices can have a serious negative impact not only on individuals and community but also on the national economy. Hence, increasing population awareness about self medication, drug expiration, medications labels and optimum storage conditions would minimize the drug adverse events and even be life saving. The former would be achieved by the participation of health care professionals and researchers that should underline those mistakes and the reasons for their occurrence. People work in pharmaceutical industry also have a great responsibility to improve medication safety by supplying the market with products that are stable in most conditions, easily identified from each others with labels which are easy to be read and understood. The role of policy makers comes afterwards to set the rules which aim to minimize the index of errors to minimum, hence, improving the medication and patient safety practices.

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