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## Role of Public in Counteract Substandard Drugs and Poor Medicine's Handling in Low and Middle Income Countries: Cross Sectional Study from Malaysia and Sudan

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#### ABSTRACT

**Background:** Two of the main problems concerning accessibility of quality medicines in low and middle income countries are availability of substandard drugs and poor medicine's handling.

**Objectives:** This study is aimed at measuring the level of awareness of the Malaysian and Sudanese public towards medicines handling, their proposed role against substandard medicines and their possible contribution in pharmaceutical regulatory system.

**Methods:** A cross-sectional study was conducted in three major cities in Malaysia and other five big cities in Sudan. A total of 844 respondents from Malaysia and Sudan included in this study.

**Results:** 25% in Malaysia and 12% in Sudan did not understand the information on the medicine package, and 29% in Malaysia and 6.3% in Sudan did not read the recommended storage conditions. Most of the respondents in Malaysia (94%) and Sudan (88.6%) kept medicines at home, and 23% in Malaysia and 10.7% in Sudan kept it for more than six months. Majority of respondents (66.9%) in Malaysia and 16.7% of participants in Sudan ignored problems related to the use of medicines.

**Conclusion:** This study found that there was lack of awareness in information about medicine handling. Policy makers should be concerned about enhancing public role in counteracting substandard medicines and promoting appropriate medicine handling.

## INTRODUCTION

WHO definition for substandard drugs are genuine medicines produced by the manufacturers authorized by the National Regulatory Authority which do not meet specifications set for them by national standards<sup>[1,2]</sup>. The production or availability of such medicines is a result of inadequate implementation of the good manufacturing practices (GMP) requirements and weak legislation to ascertain the quality, safety and efficacy of medicines. Based on WHO definition, GMP is a part of quality assurance to ensure and control consistency, production, quality, efficacy and safety according to the quality standards specified by the local regulatory body as well as required by the marketing authorization, and appropriate for their intended use<sup>[3]</sup>. In addition, it minimizes production errors such as cross-contamination and mix-up, so the GMP concept is an efficient system which encompasses three main issues- quality, efficacy and safety-that need to be fulfilled to the required level throughout the process starting from the manufacturer until the medicines reach the patients' hands. Pharmaceutical regulations and legislations can work and cover all medicine supply chain points, except the stage when medicines are given to patients by pharmacists or doctors, and this is where awareness can play a role as an additional protective measure.

Substandard drugs can result in manifestation of adverse drug reactions, development of microbial resistance or drug toxicity<sup>[4]</sup>, all of these reactions ultimately exacerbate illness and increase a patient's expenses to recover. Numerous studies have proven the availability of substandard drugs, especially in the developing countries such as found in studies done in Thailand (as an Asian country example) and Nigeria (as an African country example). In this study, 96 samples for various medicines were assessed, from which 36.5% were substandard<sup>[5]</sup>. The shortage of capacity in the regulatory authorities of developing countries results in difficulty in detection of substandard drugs because of the lack of compliance to the GMP standards<sup>[2]</sup>. WHO conducts a prequalification programme to report substandard drug. The general public can contribute in reporting their experiences in dealing with medicines through a certain mechanism based on a certain level of awareness of Pharmaceutical GMP; therefore pharmaceutical regulators should support the people and health systems by refining imperative information resources and educating them through specific programmes.

Consumer health information is important to help consumers share the decision with their health providers. Realizing this USA is pioneer in making provision for health information<sup>[6]</sup>. Access to high quality information about medicines is a step towards accessing high quality medicines. Many studies have proven that health information enhances the compliance to medical treatment and help people to share their knowledge in choosing their medicines.

Incidents concerning medicine quality problems are common and the general public should know what and how to report upon facing such problems. The public needs to know the appropriate storage conditions of medicines. They should also have the capability to read the expiration dates and precautions on medicine labels. People should be able to discern any changes in the characteristics of the medicines or their packaging. Improving the level of awareness towards all of these good manufacturing practice issues will provide an additional defence barrier to the consumers and strengthen the health care and pharmaceutical regulatory system.

This is the first study of its kind to assess public awareness on checking of medicines upon receiving them from the pharmacists, dealing with medicine problems and evaluate the significance of keeping medicines at home. The aim of the study was achieved by statistically analyzing the results and identifying knowledge gaps. Furthermore, this article highlights some of the people's key concerns in the build-up of robust regulatory system as an issue of crucial importance. The interaction between policy makers, health practitioners and the general public activates the dynamic process of progress in improving health care and to work out a win- win formula for health service providers and users. One of the tools to hear the people's voice and concerns is by conducting surveys<sup>[7]</sup>.

## METHODS

This study has been approved by the University of Malaya Medical Ethics Committee, Faculty of Medicine, Kuala Lumpur, Malaysia and regulatory authority in Sudan. The questionnaires were designed according to the Likert scale method<sup>[8]</sup>. The questionnaires were arranged into parts to simplify understanding and enhance the concentration of the respondents. The questions cover the quality elements that the public needs to know. The questionnaires were distributed in Malay and English in Malaysia and in Arabic language in Sudan. Content and face validity was conducted by sending the questionnaires to the National Pharmaceutical Control Bureau (NPCB) in Malaysia and National Medicines and Poisons Board (NMPB) in Sudan to obtain feedback<sup>[9,10]</sup>. The pilot study was done in two stages: first, the copies were distributed personally to three people to ascertain their thoughts on the questions and their capability of understanding the questions and answering them; then, it was distributed personally to a larger group of twenty people to do the pilot test, and this excluded the workers in the medical field<sup>[11]</sup>.

The questionnaires were distributed to three cities in Malaysia:Kuala Lumpur, Penang and Kota Baru. In Sudan it was distributed in Khartoum, Khartoum Bahri, Omdurman, Atbara and Berber. They were distributed and collected mostly through personal administration and also by email and post. Medical staffs, as well as people below eighteen and above sixty years old, were excluded from this study. Data analyses were performed using the SPSS 20 software.

## RESULTS

**Table 1** shows the demographic characteristics of the respondents in Malaysia, the age group of 20-29 years old represents the highest number of respondents, with a percentage of 66.5%. In Sudan the majority of respondents were from age group 20-29 (41%) and 30-39 (42.7%) years old. In Malaysia the majority of respondents were university graduates (54.8%) followed by secondary school leavers (35.8%). The group of people working as professionals, such as engineers, had the highest number of representatives (22.8%) while the retired people had the least (0.7%).

**Table 1.** Demographic characteristics

Characteristics		Malaysia N (%)	Sudan N (%)
Gender	Male	291 (53.5)	176 (58.7)
	Female	253 (46.5)	124 (41.3)
Age	20-29	362 (66.5)	123 (41.0)
	30-39	98 (18.0)	128 (42.7)
	40-49	60 (11.0)	42 (14.0)
	50-59	24 (4.0)	7 (2.3)
Education level	Post graduated	34 (6.3)	15 (5.0)
	University Graduated	298 (54.8)	258 (86.0)
	Secondary school graduated	195 (35.8)	27 (9.0)
	Primary school graduated	2 (0.4)	17 (5.7)
	Non educated	15 (2.8)	63 (21.0)
Current position	Un employed	93 (17.1)	114 (37.9)
	Student	112 (20.6)	124 (34.0)
	Professional	124 (22.8)	4 (1.3)
	Support staff	106 (19.5)	176 (58.7)
	Business	105 (19.3)	124 (41.3)
	Retired	4 (0.7)	123 (41.0)

**Table 2** shows that 25% of respondents in Malaysia did not understand what are written on the medicines package. On the other hand 12% of respondents in Sudan were not aware of that. The majority of respondents in Malaysia (94.3%) and Sudan (95.7%) checked the expiration dates before use.

**Table 2.** Awareness on medicines checking

Scale items	Malaysia N (%)				Sudan N (%)			
	Yes	No	Don't know	Not applicable	Yes	No	Don't know	Not applicable
Do you understand what is written on the medicine package?	369 (67.8)	136 (25.0)	38 (7.0)	1 (0.2)	243 (81.0)	36 (12.0)	19 (6.3)	2 (0.7)
Do you check the production date of the medicine before use?	380 (69.9)	151 (27.8)	13 (2.4)	-	285 (95.0)	10 (3.3)	4 (1.3)	1 (0.3)
Do you check the expiration date of the medicine before use?	513 (94.3)	25 (4.6)	6 (1.1)		287 (95.7)	7 (2.3)	5 (1.7)	1 (0.3)
Do you check the manufacturer name of the medicine before use?	251 (46.1)	280 (51.5)	6 (1.1)	7 (1.3)	145 (48.3)	141 (47.0)	13 (4.3)	1 (0.3)
Do you check the precautions of the medicine before use?	506 (93.0)	33 (6.1)	5 (0.9)		268 (89.3)	20 (6.7)	11 (3.7)	1 (0.3)
Do you check storage conditions of the medicine?	402 (73.9)	135 (24.8)	7 (1.3)		275 (91.7)	19 (6.3)	5 (1.7)	1 (0.3)
Do you check the dosage of the medicine before use?	522 (96.0)	18 (3.3)	4 (0.7)		289 (96.3)	6 (2.0)	5 (1.7)	0
Do you check the packaging quality?	299 (56.4)	227 (41.7)	15 (2.8)	3 (0.6)	162 (54.0)	114 (38.0)	24 (8.0)	0

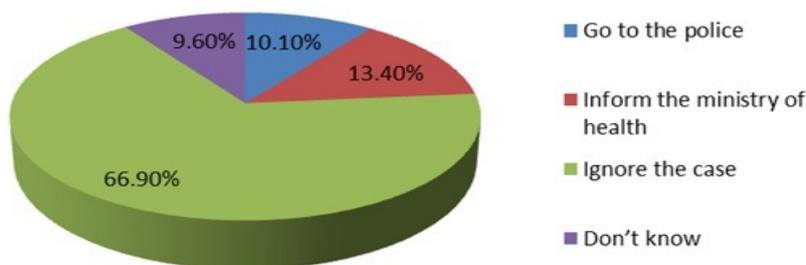
In Malaysia 51.5% of respondents did not care about the name of the manufacturer while 47% of respondents in Sudan did not give attention to manufacturers names. In Malaysia 24.8% used to neglect checking storage conditions of medicines while in Sudan only 6.3% were not caring about ensuring of storage conditions (**Tables 3**). Malaysian respondents show nearly half of the public did not have any concern about the quality of packaging. In Sudan 38% have the same manner.

**Table 3.** Medicines at homes.

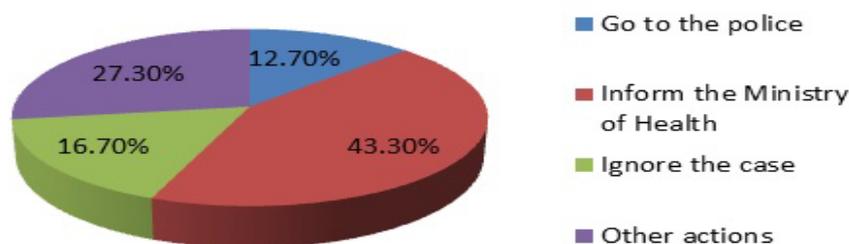
Scale items	Result	Malaysia N (%)	Sudan N (%)
Do you keep medicines at your home?	Yes	512(94.1)	266(88.6)
	No	30(5.5)	23(7.8)
	Don't know	1(0.2)	10(3.3)
	Not applicable	1(0.2)	1(0.3)
Usually how long do you keep the medicines?	Less than one month	121(22.2)	107(35.7)
	From one to three months	163(30.0)	106(35.3)
	From three to six months	108(19.9)	21(7.0)
	More than six months	127(23.3)	32(10.7)
What is the reason of keeping medicine at home?	Medicine of a chronic disease	72(13.2)	175(58.3)
	Due to long term treatment	195(35.8)	47(15.7)
	Sometimes there is a difficulty to find the medicine	89(16.4)	31(10.3)
	Other reasons	185(34.0)	47(15.7)

**Table 3** shows that the majority of respondents in Malaysia (94.1%) and Sudan (88.6%) keep medicines at home. In Malaysia (23.3%) and Sudan (10.7%) public used to keep them more than six months for various reasons.

Regarding the actions of people upon encountering medicine problems, **Figure 1** shows that most of Malaysian respondents (66.9%) ignored the cases and only 13.4% would inform the Ministry of Health. Among Sudanese respondents as presented in **Figure 2**, 16.7% did not care about such cases while 43.3% would report to ministry of health.



**Figure 1.** Malaysian public actions upon facing medical problems



**Figure 2.** Sudanese public actions upon facing medicines problems

## DISCUSSION

The manner of distributing the questionnaires randomly gave equal chances for both gender groups to participate in the study, therefore the number of males and females in Malaysia and Sudan are close to each other. The majority of study participants in Malaysia were from the age group of 20-29 years old and were university graduates. On the other hand most of participants in Sudan were from age group (20-29) and (30-39) years old. Normally in developing countries these age groups were expected to be educated and active, thus being more aware of health care matters. In both countries most levels of education were involved in the study, ranging from post graduates to non-official educated people with different positions. This is because of the random distribution of the questionnaires and no respondent was excluded based on his or her academic qualification or position; however those aged below 20 and above 60 years old as well as those working in the medical field were excluded.

This study in Malaysia found that 25% of the participants did not understand what is written on medicine labels as shown in **Table 2**. In Sudan only 12% of respondents didn't understand. The Australian guide to labelling drugs and poisons defines label as a written, printed or graphic matter on or attached to a container to identify its contents and inform the consumer about its

qualities, uses and hazards<sup>[12]</sup>. Therefore, it is essential for the medicines users to read label, understand and follow instructions within labels especially if pharmacist did not give full information.

The results showed a high level of awareness in terms of checking the expiration date is due to the fact that it is a general issue in product safety including food and pharmaceutical products. 94.3% of the Malaysian, respondents have checked their medicines expiry date before use. A close percentage (95.7%) displayed by the respondents in Sudan. This result is a positive indication of the people's concern towards expiration dates.

In particular degree of quality is different for the same products produced by different manufacturers. Hence, Checking of manufacturers name is an indicator of perception on quality of items produced by certain manufacturers as well as consumer awareness on such issue. In Malaysia 64.1% of respondents, also in Sudan 48.3% were looking for the manufacturers name but 51.5% in Malaysia and 47% were not bothered about manufacturer name.

Awareness on precautions of medicines use accelerates degree of safety upon medicines handling. The study shows that 93% in Malaysia and 89.3% in Sudan have checked precautions before use. This high percentage of people indicates an improved awareness regarding precautions.

The storage conditions of medicines should be checked by the patients in order to keep medicines at required conditions. Hence, enable keeping of drug quality, efficacy and safety. The results displayed that 73.9% of the respondents in Malaysia have checked storage conditions but 24.8% have not checked. In Sudan a lower percentage (6.3%) did not concern about storage conditions. In fact ignorance of such information enhances the risk of losing some quality parameters. External factors like in appropriate temperature may affect the stability of drug and consequently affect quality and shorten expiration. Furthermore, lack of public awareness on storage conditions would defeat the purpose of GMP.

Appropriate packaging is one of the GMP requirements. Public can contribute in counteracting substandard package and this may lead to identification of substandard drugs. In Malaysia, **Table 2** shows that 56.4% of respondents have checked packaging quality while 54% in Sudan were caring about quality of packaging. In contrast 41.7% in Malaysia and 38% in Sudan had no interest to check packaging. Low quality of packaging could be one of the factors of loosing of medicines quality. In some cases packaging is not consistent in terms of quality and cannot easily detect through authority testing. Therefore, authorities should encourage people to check packaging to enhance their contribution in combatting substandard drugs.

The study shows that most of the Malaysian respondents (94%) as well as Sudanese people (88.6%) keep medicines at home for various reasons as shown in **Table 3**; these medicines include antihypertensive, inhalers, antibiotics and painkillers. The majority of respondents use the drugs for chronic diseases, while some like to keep them for emergency cases or to preserve them as stockpile. As shown in the study, (23.3%) of participants in Malaysia and (10.7%) in Sudan keep in their homes more than a six months. This will negatively affect some of the medicines quality parameters unless they know the storage conditions and have the capability of determining any alteration in the characteristics of the drug. Therefore they need to know the storage conditions and how to read the expiration dates and precautions on the labels as well as be able to discern any changes in the characteristics of the medicines. In addition, the packaging also needs to be durable. A study conducted in Australia in 2002 had proven that unnecessary storage of medicines in patients' homes expose these medicines to expiration, misuse as well as increasing the risk of these medicines on the children and patients<sup>[13]</sup>. This part of the study demonstrates the need for people to have some knowledge about some quality parameters<sup>[14]</sup>. This is particularly true since the medicines kept at home may be affected by various factors and partially loss their efficacy or quality, or even expire. Policy makers should concern about the sustainability of medicine supply to diminish preserving medicines at home.

Regulatory bodies control the medicine quality and are responsible to take actions when problems with medicines arise. With respect to the problems related to medicines, the majority of the people in Malaysia ignored the case (66.9%) as displayed in **Figure 1**, whereas in Sudan (16.7%) of respondents don't care about this case as shown in **Figure 2** and this indicates the lack of awareness on reporting medicine consequence. Most probably ignorance of such cases is related to totally dependence on the government regulatory system, personal attitude towards problems or feeling that these problems are not public responsibilities.

To enhance safety, people need to notice if there is any alteration in the characteristics of medicines or any unexpected side effects, and then report them as soon as possible to the authorities in order for them to take appropriate actions. Around the world, many tragic events have happened despite the positive clinical trials; these include the catastrophe in Pakistan in late January 2012, in which 125 people died in Punjab as a result of taking isosorbide dinitrate contaminated with pyrimethamine<sup>[15]</sup>. This indicates that although it has been 52 years since the thalidomide disaster, we are still not protected against these unwanted consequences and therefore one early report may save a life or maintain the health of hundreds of people. People's awareness about some issues in GMP will help in combating counterfeit medicines which constitute 10% of the world's medicines<sup>[16,17]</sup>. Moreover, elevated awareness will contribute in counteracting substandard drugs which make up 25% of medicine supply in the developing countries<sup>[18]</sup>.

The study displayed deficiency on awareness of Malaysian respondents compared to Sudanese in spite of the fact that living standards and personal income were higher in Malaysia. Further, the participants from Malaysia had higher level of education. This may be due to shortage of information given to the patients by pharmacists, doctors or regulatory bodies. Moreover, another possible factor is the practicing of medicines dispensing by doctors in Malaysia.

Interaction and communication between regulatory bodies and the public are good means to enrich information on the reality of medicine effectiveness and safety alongside laboratory test results. People could be source of information to the authority regarding behaviour of medicines. Therefore, awareness of public towards their role in counteract substandard medicines enhances efficiency of such information flow and built effective relation between people and authority. Furthermore, authority should encourage public participation in the regulatory system and conducting programmes to improve their attitude towards positive contribution in protection of their communities from substandard drugs.

The findings of the study suggest crucial role of public in GMP regulatory system and the entire health system. In particular physical checking role upon medicines receive; other roles showed were appropriate storage and properly usage of medicines. Further, people could contribute in assessing health system by reporting of medicines problems before or after use.

## **CONCLUSION**

This study displayed a deficiency in the level of public awareness on appropriate medicines handling and consequently their role in counteract substandard medicines. Enhancing the level of awareness could improve the level of understanding importance of public contribution in regulatory system and enhance reporting of medicines effects. Further, it is recommended for the manufacturers to make the labels understandable not only for the use of medical practitioners but also for the consumers in order to provide them with the possible tools of increased safety and quality. Furthermore, there is need to educate people about importance and understanding of labels. Moreover, doctors and pharmacists should enhance information accessibility for the patients. A sustainable supply of medicines in public pharmacies is essential, since some people find difficulties in acquiring the medicines on time, and hence try to stockpile. In addition, the results extend the issue of the pharmaceutical supply chain to ensure the quality until the time such as when the patient takes the medicine. Surprisingly economic and education growth in Malaysia could not improve level of awareness. Hence, further studies were needed to search for the reasons correlated to the lack of awareness.

Finally, awareness could be improved through the involvement of the media and by making it a part of the health promotion programme by the Ministry of Health.

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