

Health Professionals and Pharmacist's Awareness and Attitude Towards Counterfeit Medicine

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ABSTRACT

Background: Counterfeit medicine is not only illegal, but it is also an insidious threat and poses serious public health and safety concern. Health professionals can play an important role in campaign against counterfeit drugs by staying vigilant, reporting suspicious products and preventing the distribution of counterfeit medicine. The present study aims to assess the awareness and attitude towards counterfeit medicine among health professionals and pharmacists in Nepal.

Methods: It was a cross-sectional study conducted among 264 health professionals and pharmacists of Saptari, Nepal. Samples were recruited by quota sampling technique and pretested, self-administered questionnaire were used for collecting data regarding socio-demographic, knowledge and attitude on counterfeit medicine. Descriptive & inferential statistics were used to analyze the data generated.

Results: This study found that mean knowledge score of respondent was 12.11 ± 4.3 and only 31.7% (n=39) of the respondents had good knowledge on counterfeit medicine while 44.7% (n=55) showed moderate and 23.6% (n=29) had poor knowledge levels. Nurses, paramedics and pharmacists scored statistically lower than doctors, however there was no significant difference in knowledge between nurses and pharmacists ($p < 0.001$). Mean attitude score was 3.82 (± 0.68) and majority of respondents (85.3%) showed favorable attitude towards counterfeit medicine. Respondents having poor knowledge level had statistically significant unfavorable attitude towards counterfeit medicine

Conclusions: The study highlighted the need for counterfeit medicine awareness campaigns and training to enhance the role of health professionals and pharmacists to recognize and report suspicious medicine and prevent counterfeit medicines-associated harms.

Keywords: Attitude; counterfeit medicine; health professionals; knowledge; pharmacists

INTRODUCTION

Counterfeit medicine trafficking is one of the world's fastest growing criminal business and have raise enormous global health challenge. WHO has estimated that 10% of global pharmaceutical commerce i.e. \$21 billion worth is involved in trading of counterfeit drug and nearly one-half (48.7%) of the documented cases were reported in developing countries of the Western Pacific, followed by developing countries of Africa, with 18.7%.^{1,2} Counterfeit medicines are those products that contain no active pharmaceutical ingredients, an incorrect amount of active ingredient, a wrong active ingredients, contaminants, a substandard drug or repackaged expired products.³ Awareness among health

professionals and pharmacists can play a pivotal role in mitigating the circulation of counterfeit medicine and protect patients from its harmful effect. As there is paucity of evidence based information regarding healthcare professionals and pharmacists' awareness and attitude towards counterfeit medicine, this study aimed to assess the awareness and attitude towards counterfeit medicine among health professionals and pharmacists in Nepal.

METHODS

This was a cross sectional study conducted using self-administered close ended questionnaires aimed at assessing knowledge and attitude on counterfeit

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medicines among health professionals and pharmacists working in Saptari district. An ethical approval by Nepal health research council (Reg no. 259/2022) was obtained prior to the study and individual informed consent were secured prior to data collection to respect sovereignty of the subjects. Samples were recruited in the study using non probability quota sampling technique considering work place setting for assigning quota i.e. health professionals working at government hospital and at private hospital and pharmacy professionals with diploma or bachelor or above in pharmacy working at medical stores and community pharmacies. 264 samples were selected disproportionately from three quotas i.e. 88 samples from each quotas. Sample size was calculated using single population proportion formula considering 95% confidence interval, 5% margin of error and 22% prevalence of awareness on counterfeit medicine among doctors and medicine wholesale distributors in western India.⁽⁴⁾ Health professionals and pharmacists without professional license and having work experience less than one year were excluded from the study.

A self-administered structured questionnaire was developed by reviewing similar studies with some modification. A pilot study was conducted among 25 health professionals and pharmacists and reliability of the tool was determined using Cronbach α test and appropriate amendments were carried out prior to main study. Cronbach α value for knowledge domain was 0.72 and attitude domain was 0.70 indicating reliability of the questionnaire.

Two pharmacy students were trained to collect data and principal investigator double checked the accuracy and consistency of the data collected. Questions of knowledge, attitude and factors responsible for counterfeiting of medicines were asked to only those respondents who have heard or knew about counterfeit medicine. Each correct answer to knowledge questionnaire was given a score of one and each incorrect answer and don't know both were given a score of zero. The cumulative and mean scores were calculated. Respondents who scored between 16 to 22 were defined as having good knowledge, score between 8-15 were assigned moderate knowledge and those who scored below 7 were defined as poor knowledge. The attitude of respondents was calculated using structured five-point Likert scale ranging from; 'strongly agree' i.e. 5 to 'strongly disagree' i.e. 1 and reverse scoring system was used to negatively framed questions. All individual answers to attitudinal questions were computed to obtain total scores and calculated for means. Based on the cumulative scores, the respondents who scored above the mean score were termed as having

a "favorable attitude", and those who scored below the mean score were defined as a "unfavorable attitude".

Data was cleaned, arranged, classified and analyzed using SPSS version 21. Frequencies, percentages, means and standard deviations (SD) were used to describe numerical variables and chi-square, independent t-test & ANOVA test was used to test the statistical significance of relationship between selected socio-demographic variables of respondents and their knowledge related to counterfeit medicines considering p value significant at less than 0.05.

RESULTS

Among 264 respondent, 56.1% (n=149) were male and 43.9% (n=115) were female with the mean age 31.37±8.12 years (29-38 years). Around 60.0% of respondents were of proficiency certificate level and majority (53.8%) had about 0-5 years of professional working experience. None of the respondents had previous training on counterfeit medicine and only 46.6% (n=123) were aware of counterfeit medicine (Table 1).

Table 1. Socio-demographic profile of the study subjects categorised by awareness status.

Variables	Aware (N=123) n (%)	Not Aware (N=141) n(%)	Total (N=264) n(%)
Age Group			
18-28	49 (39.8%)	56 (39.7%)	105 (39.8%)
29-38	56 (45.5%)	57(40.4%)	113 (42.8%)
39-48	17 (13.8%)	21 (14.9%)	38 (14.4%)
49-58	1 (0.8%)	7 (5.0%)	8 (3.0%)
Gender			
Male	76 (61.8%)	73 (51.7%)	149 (56.4%)
Female	47 (38.2%)	68 (48.2%)	115 (43.6%)
Qualification			
Proficiency certificate level	51 (41.4%)	109 (77.3%)	160 (60.6%)
Bachelor	48 (39.0%)	32 (22.7%)	80 (30.3%)
Masters	24 (19.5%)	0 (0.0%)	24 (9.1%)
Profession			
Doctor	28 (22.7%)	20 (14.2%)	48 (18.2%)
Nurse	26 (21.1%)	38 (27.0%)	64 (24.2%)
Paramedics	28 (22.7%)	36 (25.5%)	64 (24.2%)
Pharmacist	41 (33.3%)	47 (33.3%)	88 (33.3%)
Professional work experience			

0-5 years	64 (52.0%)	73 (51.8%)	142 (53.8%)
6-10 years	40 (32.5%)	49 (34.7%)	89 (33.7%)
11-15 years	10 (8.1%)	14 (10.0%)	24 (9.1%)
16-20 years	4 (3.3%)	5 (3.5%)	9 (3.4%)
Place of practice			
Government hospital	30 (24.4%)	58 (41.1%)	88 (33.33%)
Private hospital	52 (42.2%)	36 (25.5%)	88 (33.33%)
Community Pharmacy	41 (33.3%)	47(33.3%)	88 (33.33%)
Previous training on counterfeit medicine			
Yes	0	0	0 (0%)
No	123 (100%)	141 (100%)	264 (100%)

This study found that mean knowledge score of respondent was 12.11±4.3 and only 31.7% (n=39) of the respondents had good knowledge on counterfeit medicine while 44.7% (n=55) showed moderate and 23.6% (n=29) had poor knowledge levels. There is no significant difference in knowledge mean score between male and female respondents (12.34 vs 11.72;P=0.446) and those who had proficiency certificate level of qualification scored statistically lower than others (p <0.001). Nurses, paramedics and pharmacists scored statistically lower than doctors, however there was no significant difference in knowledge on counterfeit medicine between nurses and pharmacists (p<0.001). There is no statistically significant difference in knowledge score with the duration of professional experience and place of professional practice of respondents (Table 2).

Table 2. Knowledge on counterfeit medicine among respondents (N=123).

Knowledge classification	Knowledge Score	Frequency (%)	Mean knowledge score (SD)
Good	16-22	39 (31.7%)	12.11 (±4.3)
Moderate	8-15	55 (44.7%)	
Poor	≤ 7	29 (23.6%)	
Socio-demographic Variables	N	Mean knowledge score (SD)	P Value*
Gender			
Male	76	12.34 (± 4.32)	0.446 ^a
Female	47	11.72 (±4.41)	
Qualification			
PCL Level	51	9.75 (±3.74)	<0.001 ^b
Bachelor	48	12.83 (±4.16)	
Masters	24	15.67 (±2.82)	

Profession			
Doctor	28	15.11 (±3.06)	<0.001 ^b
Nurse	26	11.46 (±4.58)	
Paramedics	28	10.64 (±3.63)	
Pharmacist	41	11.46 (±4.57)	
Professional work experience			
0-5 years	64	11.57 (±4.34)	0.133 ^b
6-10 years	40	12.73 (±4.05)	
11-15 years	10	14.30 (±4.83)	
16-20 years	4	9.75 (±4.85)	
Place of practice			
Government hospital	30	12.57 (±4.53)	0.503 ^b
Private hospital	52	12.35 (±4.08)	
Community Pharmacy	41	11.46 (±4.57)	

^aIndependent Sample T-test, ^b One-way ANOVA with post-hoc analysis, *P< 0.05 shows statistical significance

In a series of questions with multiple responses allowed, out of 123 respondents, 45.5% perceived counterfeit medicine as products with inadequate quantities of active ingredients, 48% considered it as medicine with incorrect active ingredients, 39% pointed it as products having potentially unsafe ingredients that are not on the label, 55.3% indicated it as products with expired ingredients that have been relabeled, 57.7% thought it to be made up of herbs and 56.9% presumed it to be usually low priced medicine. When asked about the dispense of counterfeit medicine, majority (92%) believed it to be dispensed from unregistered pharmacy, whereas 46.3% indicated it to be sold at registered pharmacy too and only 45.5% identified online pharmacy as a source of counterfeit medicine. Only 26% respondents stated that they could visually distinguish a counterfeit medicine from genuine one. Out of 123 respondents, more than half indicated that they should check medicine effect, packaging and information on package to distinguish counterfeit medicine. Furthermore, 44.7% mentioned cost and only 22% specify about hologram embossing and very minimal (6.5%) pointed that suppliers should also be checked for authenticity of medicine. The descriptive analysis of the knowledge on counterfeit medicine found that doctors scored significantly higher than other profession and paramedics scored lowest (Table 3).

Table 3. Knowledge on counterfeit medicine between respondents from different profession.

Knowledge aspects	Max score	Doctor (n=28) Mean(SD)	Nurse (n=26) Mean(SD)	Paramedic (n=28) Mean(SD)	Pharmacist (n=41) Mean(SD)	Total (N=123) Mean(SD)	P-value
Characteristics of counterfeit medicines.	9	6.39(±1.96)	4.96(±2.42)	4.21(±2.28)	4.12(±2.84)	4.84(±2.58)	0.001 ^b
Locations where counterfeit medicines can be found.	4	2.29(±0.85)	1.69(±0.78)	1.68(±0.72)	2.10(±0.83)	1.96(±0.83)	0.009 ^b
Reason to avoid counterfeit medicines.	3	2.82(±0.39)	2.12(±1.03)	1.96(±0.92)	2.07(±0.98)	2.23(±0.93)	0.001 ^b
Ways to distinguish between genuine and fake medicine.	6	3.61(±1.19)	2.69(±1.61)	2.79(±0.91)	3.17(±1.26)	3.08(±1.29)	0.033 ^b

^b One-way ANOVA with post-hoc analysis, * P< 0.05 shows statistical significance

Majority of respondents who are aware of counterfeit medicine shared their view that inadequate awareness among health professionals and consumers followed by inadequate legislation and inspection of medicine production and supply chain by concerned authority are major factors for medicine counterfeiting (Figure 1).

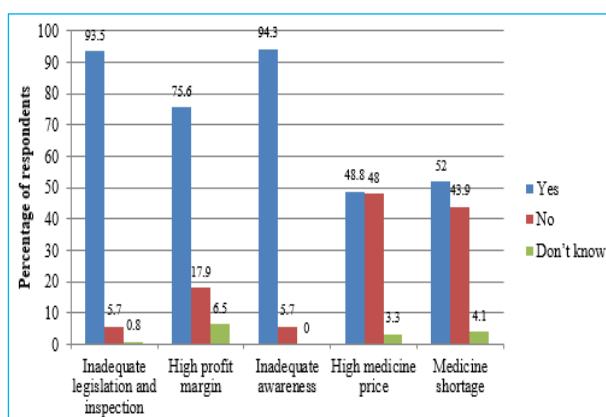


Figure 1. Opinion on factors responsible for medicine counterfeiting.

In the present study the mean attitude score was 3.82 (±0.68) and majority of respondents (85.3%) showed favorable attitude towards counterfeit medicine. Majority of health professionals and pharmacists agreed that we should be suspicious of heavily discounted medicines and it's illegal to dispense counterfeit medicine. They also believe that educational programs can provide health professionals enough knowledge to prevent dispensing of counterfeit medicines. Respondents having poor knowledge level had statistically significant unfavorable attitude towards counterfeit medicine (Table 4).

Table 4. Attitude towards counterfeit medicine among health professionals and pharmacists.

Attitude variable	Mean (±SD)
There is no harm in purchasing medicines whose shape and size are not uniform.	3.76 (±1.18)
In exceptional cases it is fine to use drugs which is packed different from original ones.	3.75 (±1.18)
Over-the-counter (OTC) medicines does not have the risk to be counterfeited.	3.82 (±0.97)
In the case of any adverse reaction caused by a counterfeit drug, the dispensing pharmacist is the major responsible.	3.19 (±0.85)
In the case of medication shortage, it's fine to provide it from unofficial (not registered) supplying source like online pharmacies.	3.72 (±0.92)
It is fine to dispense some counterfeit drugs which are not vital to treat diseases.	3.90 (±0.88)
Individual health professionals' intervention can prevent dispensing of counterfeit drugs.	3.46 (±0.87)
We should be suspicious of heavily discounted medicines.	4.06 (±0.71)
Educational programs can provide health professionals enough knowledge to prevent dispensing of counterfeit drugs.	4.13 (±0.81)
There is no legal problem in dispensing counterfeit medicines.	4.41 (±0.60)

Summary

Level of knowledge (score)	Level of attitude (Mean score)		Total	P-value
	Unfavorable (≤ 3)	Favorable (> 3)		
Poor (<7)	14	15	29	<0.001 ^c
Moderate (8-15)	4	51	55	
Good (16-22)	0	39	39	
Total	18	105	123	

^c Chi square test, * P< 0.05 shows statistical significance

DISCUSSION

Medicine plays a crucial role in saving lives, restoring health, promoting wellbeing, preventing diseases and epidemics. However, to produce the desired effect, they should be safe, effective, of good quality and have to be used rationally. But when it is counterfeit or substandard, it poses threat to the health and wellbeing of the individual patient, ranging from deleterious effect, treatment failure, toxicity, drug resistance and even death in extreme cases in addition to economic and social burden.^{1,3,5} It has been reported that both generic and innovator medicines are falsified, ranging from high-demand, very expensive medications such as various chemotherapeutic drugs, vaccines, erectile dysfunction drugs, antibiotics, weight loss aids, hormones, steroids, antihistamines, antivirals, antianxiety drugs to very inexpensive analgesics for treatment of pain.^{1-3,5} World Health Organization (WHO) has estimated that 1 in 10 medicines circulating in low and middle income countries are counterfeit.⁶ Southeast Asia is considered to be the Centre for counterfeit healthcare products.^{7,8}

Nepal is at higher risk when it comes to counterfeit medicine as two of its major trade partner countries, India and China are leading producers of counterfeit pharmaceutical products. A surveillance of quality of drugs available in Nepalese market within Kathmandu valley in 2015 showed that out of 40 drug samples, 90% did not comply with the regulatory requirement on labelling, 42.5% brands did not meet pharmacopoeial standard and among them 40% were from domestic companies and 28% were imported.⁹ Likewise a review of drug recalls issued by Department of Drug Administration (DDA), Nepal between 2010 to 2020 revealed that the number of recalled pharmaceutical products has increased significantly over past decade and most frequently recalled drugs were antimicrobials followed by gastrointestinal medicines, vitamins and supplements, analgesics and palliative medicines. Out of those recalled drugs 11% were counterfeit and number of imported recalled drugs were slightly higher (42.2%) than domestic recalled drugs (40.7%).¹⁰ This means that people are taking medicines that fails to treat or prevent disease and have threat to develop drug resistance.

Literature review has highlighted the problem of counterfeit medicine as an emerging health menace in current situation. It may pose an even greater threat in the future if prevention measures are not taken now. It may be controlled if concerned authority, health professionals and public together identify and disrupt the counterfeit drug distribution chain. Despite of health and safety risks of counterfeit medicines, public

awareness of the prevalence and consequences of taking such medicines is lacking. It's a role of the vigilant authorities as well as pharmacists, physicians, nurses and all health professionals to introduce and explain the issues related to counterfeit medicine to patient and general public.

The present study reveals that one half of the study participants were aware of counterfeit medicine and majority (44.7%) of them showed moderate level of knowledge on counterfeit medicine which is higher than study result by Nagaraj et al. from western India.⁴ Contrary to this study, awareness on counterfeit medicine in similar study done in south west Ethiopia by Siraj J et al is found high (84.2%) among healthcare providers.¹¹ It was also observed in the study that pharmacists were more aware of counterfeit medicine than health professionals as they are key person in dispensing medicines. This finding is supported by the study done by Abu Taleb and Al Madadha in Jordan and from Sudan done by Wagiealla WW et al. which indicated that the majority of the community pharmacists were aware of counterfeit medicine.^{12,13} Meanwhile, the data obtained also showed that doctors had more knowledge level followed by pharmacist and nurses with same knowledge level and paramedics with lowest knowledge. This could be due to the fact that paramedics are less exposed to medicine in their daily practice compared to doctors, nurses and pharmacists which reduces their knowledge on counterfeit medicine.

Study showed significant association between knowledge and participants' educational status and profession. This finding is contradicted by the study from Iran and Sudan where no significant association was identified between awareness and participants' demographics.^{13,14}

WHO defines counterfeit medicines as "medicines with the wrong ingredients, without active ingredients, with insufficient active ingredients, or with fake packaging".^{15,16} These characteristics of counterfeit medicine were pointed out by less than fifty percent of the study participants. A low awareness and unclear perception of counterfeit medicine has been reported by studies from elsewhere too.^{4,11,14,17-19} Online availability of pharmaceutical products is the most common source of counterfeit medicines, but more than half of the respondents in the present study had no information about purchasing of these medicines online. This finding is in line with the studies conducted in western India and Poland.^{4,17} A large percentage of study participants believed that unregistered pharmacies sell counterfeit medicines, however a significant proportion of the products recalled by the DDA contained essential

medicines supplied by the government of Nepal.^{10,20} This demonstrates that even legitimate retailers and pharmacies sell counterfeit medicines, triggering the need for further research. According to a study on medicine procurement practice in Nepal, most of the hospital pharmacies procured only registered medicines, nevertheless, a small percentage claimed to have bought unregistered medications through unauthorized supply chains.²¹ To fully accept regulation of national and international policies for expanding accessibility to high-quality medicines, such pharmacies may need education and training.

Another important finding of this study is that only one out of four respondents stated that they could distinguish between genuine and counterfeit medicine. It is unacceptable that majority of them lack knowledge and sufficient skill to detect counterfeit medicine, which predisposes patient's health at risk. Other studies from both developed and developing countries demonstrated the difficulty in distinguishing counterfeit medicine from genuine through visual examination.^{4,17-19} Counterfeit medicines are "look-alike" products that may create uncertainty, confusion and doubts on the value of genuine drugs which could lead patients in poor underdeveloped and developing countries to seek a cheaper alternative to the genuine brands, simply because of the high cost of medicines relative to their income.⁸ The only way to confirm whether drug is genuine or counterfeit is by performing a chemical analysis in a laboratory. However, signs such as different doses of medicine inside the packs from those stated on the outside, the pack containing capsules when the box states tablets, no active ingredients or incorrect ingredients, expiry dates and batch numbers on the box not matching those of the drugs inside, and patient's information leaflets being in the wrong language and not providing sufficient information of manufacturer indicates whether a drug is counterfeited.²² Awareness on these signs is important for suspicion of counterfeit drugs and avoidance of buying such drugs which will help in protecting patients from its harmful consequences. However, if this lack of awareness continues in the future, it will contribute towards an increase threat of counterfeit medicine trade in Nepal. Therefore this insufficient awareness towards counterfeit medicine among health professionals and pharmacists need to be improved through proper training.

Furthermore, participants stated that inadequate awareness followed by inadequate legislation and regulatory control by concerned authority are the major contributing factor for distribution of counterfeit

medicine, which is consistent with global views. There may be several factors responsible for the circulation of such counterfeit drugs in market varying from country to country. The problem is more pronounced in countries where the manufacture, importation, distribution, supply and sale of drugs are less regulated and enforcement is weak.^{2,8} According to WHO, the most common factors considered for the existence of counterfeiting drugs are lack of legislation prohibiting counterfeiting of drugs; weak penal sanctions; weak or absent national drug regulatory authorities; weak enforcement of drug laws; shortage/erratic supply of drugs; lack of control of drugs for export; trade involving several intermediaries and free trade zones; corruption and conflict of interest.^{23,24} In affirmation with the study done in Iran, the present study showed that the study participants had favorable attitude though majority had low knowledge level.

Limitations of the present study include its reliance on a self-reported information, which provided very subjective results and might have been affected by reporting error and recall biases of the participants, thereby limiting the reliability of the data.

CONCLUSIONS

The study revealed moderate level of awareness with majority having favorable attitude towards counterfeit medicine among health professionals and pharmacist. Therefore, a regular educational program or continuing professional development activities through capacity building regarding counterfeit medicine is necessary for health professionals and pharmacist, emphasizing their role in detection of fake medicine and educating/protecting patients. In addition, future research to further explore the knowledge, experience, views and belief of the public, pharmacists, health professionals and regulatory bodies regarding counterfeit medicine and how they believe it can be controlled can identify the appropriate measures required for control of counterfeit medicine.

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CONFLICT OF INTEREST

The authors declare no conflict of interest.

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