

Knowledge, Attitude and Practice of Community Pharmacy Professionals' towards Substandard and Falsified Medicines in Addis Ababa, Ethiopia: A Cross-sectional Survey

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Research Article

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ABSTRACT

Introduction: The availability of substandard and falsified medicines in the market grants a serious public health problem and a significant impact on the national economy. The current estimate suggests that 10% of prescription drugs sold worldwide are substandard, fake or contaminated, and in parts of Africa and Asia, the figures exceed 50%. Professionals awareness of falsified medicines is a major problem that could lead to a public health crisis. This study aimed to assess the community pharmacy professionals' knowledge, attitude and practice towards SFMs in Addis Ababa, Ethiopia.

Methods: An institutional-based cross-sectional study design with a systematic random sampling technique was employed on community pharmacy professionals. Data were collected using a structured questionnaire and the collected data was analyzed using a Statistical Package for Social Sciences (SPSS) version 25. Simple descriptive statistics were used to describe the variables.

Results: Among the total 323 community pharmacists, 264 (81.7%) were aware of SFM and only 98 (37.1%) of them correctly define SFMs. Among those having awareness, 196 (74.2%) respondents claimed that the main country of origin for SFM was India followed by China 103 (39%) and Ethiopia 43 (16.3%). Antibiotics 128 (48.5%), chronic disease medicines 94 (35.6%) and expensive and unavailable medicines 79 (29.9%) were the most frequently mentioned class of medicines with the highest risk of falsification. Whereas, Mebendazole suspension 46 (45%), Metronidazole 32 (31.4%) and Muscle builders 31 (30.4%) were among the most frequently mentioned

SFMs they encountered. The participants' mean level of agreement for attitude questions was between 2.02 and 4.19 whereas SFMs use and practice was very low.

Conclusion: This study indicated community pharmacy professionals' knowledge and practice were found to be moderate and a large proportion of them had a positive attitude, although there appeared to be differences across attitude questions. Designing and implementing continuing education programs on SFMs and enforcement of vigilant laws were identified as means of tackling SFM.

INTRODUCTION

Substandard and Falsified Medicines (SFMs) may be of poor quality, unsafe or ineffective medicines than standards and also might cause damage by a lack of active or the presence of a harmful ingredient [1]. Falsified medicines are a global problem; it has been reported in developing countries as well as in developed countries [2]. SFMs potentially make up more than 50% of the global drug market with a significant proportion in developing countries [3]. Among the total reported incidents involving health damage due to falsified medicines, 27 (56.3%) occurred in developing countries and 21 (43.7%) in developed countries [4].

Antibiotic resistance caused by sub-standardization or falsification might have contributed significantly to the inability to eradicate or control serious infections such as malaria and tuberculosis in developing countries [5]. The recent emergence of falsified Artemisinin derivatives and antiretroviral drugs in some countries is potentially disastrous [6, 7].

The problem of poor quality of drugs is likely to cause more damage shortly. Tackling corruption at various levels of the pharmaceutical systems, increasing public awareness of SFMs, establishing a pharmacovigilance system, more stringent regulation and legal action and quality education are the major strategies to combat SFMs [8, 9].

Pharmacists are healthcare professionals who are mostly involved in compounding, pharmaceutical marketing, distribution and dispensing of medicines [10]. By raising awareness and implementing recommendations to ensure the integrity of supply chain, pharmacists can help to address the threat and play a critical role in preventing the distribution of SFMs [11].

Research done in Iran showed that pharmacists had low knowledge and practice level about SFMs [2]. Even though literature showed low awareness of the problem of SFMs which could lead to public health crisis, knowledge, attitude and practice of pharmacists regarding SFMs are often undermined and given less concern in the area [12].

Ethiopia is not an exception to this worldwide phenomenon, as SFMs make up more than 50% of the global drug market, with a significant proportion in developing countries [3]. But information on the knowledge, attitude and

practice of SFMs is scanty. This study aimed to assess community pharmacy professionals' knowledge, attitude and practice towards SFMs in Addis Ababa, Ethiopia.

METHODS AND METHODOLOGY

Study setting and period

The study was conducted in Addis Ababa, Ethiopia. Addis Ababa is located at the geographic center of the nation and covers about 540 Km² [13]. It is divided administratively into 10 sub-cities and has a total population of 3.43 million [14]. According to Addis Ababa Regional Health Bureau data in 2017, it had around 731 community pharmacies and drug stores [15]. The research was conducted from February to May, 2018.

Study design

An institutional-based cross-sectional survey was conducted to assess the knowledge, attitude and practice of community pharmacy professionals regarding substandard and falsified medicine.

Source and study population

The source population for this research was all community pharmacy professionals working in Addis Ababa and the study population was selected pharmacy professionals practicing in the selected community pharmacies of Addis Ababa. All pharmacy professionals working in the selected community pharmacies were included in the study.

Sample size determination

The number of participants to be involved in the study was determined by using a single population proportion formula [16].

The source population for the study was estimated 2000 pharmacy professionals according to Addis Ababa regional health bureau data in 2017 [15] and the sample was adjusted using the formula;

$n = \frac{(z_{\alpha/2})^2 * P(1-P)}{d^2}$ Where,

n=the required sample size, P=the prevalence (0.5), Z= Z score at 95% confidence interval=1.96, d=the margin of error=0.05

Accordingly, the sample size was estimated as: $n = \frac{(1.96)^2 * 0.5(1-0.5)}{(0.05)^2}$ n=384

Using sample correction formula; Where; n= sample size, N= the size of source population

Corrected Sample size (Nc) = $\frac{n * N}{n + N}$

$\frac{(384 * 2000)}{(384 + 2000)} = 323$

Adding 10% non-respondent rate 323+33=356 subjects

Sampling procedure

First, six out of ten sub-cities were selected randomly using a lottery method. The total number of pharmacy professionals in six sub-cities was 547. Then, the sample size was divided proportionally for six randomly selected

sub-cities depending on the number of pharmacy professionals in each sub-city. Community pharmacies were identified randomly and recruitment of the respondents was achieved through a consecutive sampling approach until the quota for the sub-city was fulfilled.

Data collection methods and instruments

Closed and open-ended self-administered questionnaires were prepared in English. And they were designed to collect demographic data, professional characteristics; knowledge, attitude and practice of pharmacists regarding SFMs. Knowledge and practice questions were designed as multiple choices and written questions. Attitude questions were prepared based on a five-level Likert scale (Strongly agree,5; Strongly disagree,1). The questionnaires were pre-tested on a sample of 20 (other than the study population) community pharmacy professionals to evaluate the reliability and clarity of the questions. After a week, the final questionnaires were used to collect data from the main study population.

Data processing and analysis

In analyzing the results, for knowledge and practice questions, scores of 1 and 2 were assigned to Yes and No answers, respectively. For the attitude questions, score from 1 to 5 was assigned, 1 represented the lowest and 5 represented the highest attitude. The numerical variables were described numerically and entered into the computer using SPSS Version 25. Descriptive statistics were used to explain the study participant's relation to study variables.

Ethical consideration

An ethical clearance letter was obtained from the Ethical Review Committee of school of pharmacy, Addis Ababa University. To enhance cooperation, the local authorities were informed about the study objectives through a letter written from the Department of Pharmaceutics and Social Pharmacy, School of Pharmacy. Privacy and confidentiality were strictly maintained throughout the whole process. All the study subjects were kept anonymous and the files did not bear any name or identification number.

RESULTS

A total of 356 community pharmacy professionals were enrolled in the study and 323 participants returned completed questionnaires with a response rate of 90.7%.

Of the total 323 participants, the majority were male 165 (51.1%) and 167 (51.7%) were married. The mean age of the participants was 31.37 years and the highest proportion of 185 (57.3%) was found in the age group of 18-30 years. The participants have a qualification of diploma, degree and masters as claimed by 76 (23.5%), 220 (68.1%) and 27 (8.4%) of them, respectively. The mean number of total years of experience was 6 years (Table 1).

Knowledge, attitude and practice about substandard and falsified medicines

Knowledge towards substandard and falsified medicines: Among the total participants in the study, 264 (81.7%) were aware of SFMs. Of the participants who were aware of SFM, 98 (37.1%) of the community pharmacy professionals correctly define SFM. Regarding their source, 160 (60.6%) of respondents claimed school, 102

(38.6%) mentioned mass media, 81 (30.7%) claimed colleagues and 75 (28.4%) of them mentioned health facilities as the source of awareness about SFM.

Almost 212 (80.3%) of respondents thought that SFMs were available in Ethiopian pharmaceutical market. They also believed that the main origins of SFMs were India 196 (74.2%), China 103 (39%) and Ethiopia 43 (16.3%).

The study revealed that participants believed that importers 144 (54.5%), community pharmacies 138 (52.3%), medicine wholesales 118 (44.7%) and drug stores 110 (41.7%) were the main institutions involved in the chain of SFMs transactions.

In this study, the class of medicines with the highest risk of counterfeiting were antibiotics 128 (48.5%), chronic disease medicines 94 (35.6%) and expensive and unavailable medicines 79 (29.9%). Respondents believed that Ethiopian Food and Drug Authority (EFDA) 237 (89.8%), Ministry of Health (MOH) 183 (69.3%) and pharmacy professionals 142 (53.8%) would take the blame for negative health impact due to SFMs (Table 2).

Table 1: Socio-demographics characteristic of community pharmacy professionals in Addis.

Variable		Frequency (%)
Gender	Male	165 (51.1%)
	Female	158 (48.9%)
Age Group	18-30	185 (57.3%)
	31-40	109 (33.7%)
	>40	29 (9.0%)
Marital Status	Single	148 (45.8%)
	Married	167 (51.7%)
	Divorced	8 (2.7%)
Educational Status	Diploma	76 (23.5%)
	Bachelor	220 (68.1%)
	Master degree and above	27 (8.4%)
Years of Experience	0-5 years	190 (58.8%)
	6-10 years	97 (30.0%)
	11-15 years	25 (7.7%)
	>15 years	11 (3.4%)
Role in the Pharmacy*	Management	82 (25.4%)
	Dispensing	290 (89.8%)
	Procurement	43 (13.3%)
*Note : Multiple responses were possible		

Table 2: Community pharmacy professionals knowledge towards substandard and falsified.

Variable	Frequency (%)
Aware of SFMs	Yes 264 (81.7%)
	No 59 (18.3%)
Correctly defining SFMs	Yes 98 (37.1%)
	No 166 (62.9%)
Source of information for SFMs *	School/College 160 (60.6%)
	Mass media 102 (38.6%)
	Colleagues 81 (30.7%)
	Health facilities 75 (28.4%)
Belief on availability of SFMs in Ethiopia	Yes 212 (80.3%)
	No 52 (19.7%)
Country of origin for SFMs *	India 196 (74.2%)
	China 103 (39%)
	Ethiopia 43 (16.3%)
	Germany 37 (14%)
Type of medicine mostly falsified*	Antibiotics 128 (48.5%)
	Chronic disease medicines 94 (35.6%)
	Expensive and unavailable 79 (29.9%)
	Eye drops 37 (14%)
Institutions involved SFMs chain*	Importers 144 (54.5%)
	Wholesales 118 (44.7%)
	Community pharmacy 138 (52.3%)
	Drug store 110 (41.7%)
	Hospital pharmacy 57 (21.6%)
	Shops 84 (31.8%)
Who was involved in SFMs transactions*	Pharmacists 201 (76.1%)
	Other health professionals 136 (51.5%)
	Non-health professionals 175 (66.3%)
Responsible for combating SFMs *	Ministry of Health 183 (69.3%)
	Food and Drug Administration 237 (89.8%)
	Pharmaceutical Supply Agency 90 (34.1%)
	Business owners 103 (39%)
	Pharmacists 142 (53.8%)
*Note : Multiple responses were possible	

Table 3: Community pharmacy professionals attitude towards substandard and falsified medicines in Addis Ababa, June 2018 (N=264).

Attitude questions	Strongly Disagree, N(%)	Disagree, N(%)	Neutral, N(%)	Agree, N(%)	Strongly Agree, N(%)	Mean ± SD
All community pharmacy professionals are aware about SFMs	22 (8.3)	65 (24.6)	41 (15.5)	95 (36.0)	41 (15.0)	3.26 ± 1.225
All non-registered medications are falsified	26 (9.8)	43 (16.3)	89 (33.7)	55 (20.8)	51 (19.3)	3.23 ± 1.220
SFMs are always low in quality	22 (8.3)	36 (13.6)	40 (15.2)	61 (23.1)	105 (39.8)	3.72 ± 1.1.332
SFMs are more affordable (less costly) than the registered original medicines	14 (5.3)	56 (21.2)	48 (18.2)	68 (25.8)	78 (29.5)	3.53 ± 1.260
It is easy to identify falsified medicines by their quality and price	53 (20.1)	97 (36.3)	51 (19.3)	43 (16.3)	20 (7.6)	2.55 ± 1.198
Falsified medicines can be very dangerous	20 (7.6)	18 (6.8)	39 (14.8)	52 (19.7)	135 (51.1)	4.00 ± 1.273
Most counterfeit medicines are as effective as the originals	97 (36.7)	59 (22.3)	49 (18.6)	34 (12.9)	25 (9.5)	2.36 ± 1.341
In exceptional all cases it is fine to use SFMs	118 (44.7)	66 (25.0)	34 (12.9)	24 (9.1)	22 (8.3)	2.11 ± 1.297
In the case of original medication shortage, its fine to dispense SFMs for customers	125 (47.3)	53 (20.1)	42 (15.9)	30 (11.4)	14 (5.3)	2.07 ± 1.251
It is fine to dispense some SFMs which are not vital to treat disease	118 (44.7)	71 (26.9)	42 (15.9)	17 (6.4)	16 (6.1)	2.02 ± 1.189
In the case of any harm caused by SFMs, the pharmacy professional is highly responsible	20 (7.6)	24 (3.1)	57 (21.6)	74 (28.0)	89 (33.7)	3.71 ± 1.233
SFMs are available in most of community pharmacies	38 (14.4)	-3814.4	83 (31.4)	67 (25.4)	38 (14.4)	3.11 ± 1.242
Most community pharmacies knowingly dispense falsified medicines	45 (17.0)	39 (14.8)	81 (30.7)	81 (30.7)	18 (6.8)	2.95 ± 1.188
I have knowingly bought SFMs in the past	106 (40.2)	46 (17.4)	57 (21.6)	37 (14.0)	18 (6.8)	2.30 ± 1.307

Most likely I have a chance to purchase and use SFMs	62 (23.5)	54 (20.5)	69 (26.1)	67 (25.4)	12 (4.5)	2.67 ± 1.215
Most likely my family members have a chance to purchase and use SFMs	44 (16.7)	48 (18.2)	49 (18.6)	89 (33.7)	34 (12.9)	3.08 ± 1.304
Most likely the community has a chance to purchase and use SFMs	30 (11.4)	24 (9.1)	52 (19.7)	96 (36.4)	62 (23.5)	3.52 ± 1.261
Dispensing falsified medicines is against the professional code of ethics	19 (7.2)	13 (4.9)	24 (9.1)	53 (20.1)	155 (58.7)	4.18 ± 1.223
Community pharmacists gave high priority for the profit instead of the customer safety	49 (18.6)	42 (15.9)	67 (25.4)	66 (25.0)	40 (15.2)	3.02 ± 1.328
Individual pharmacists' intervention can prevent dispensing of SFMs	15 (5.7)	28 (10.6)	43 (16.3)	85 (32.2)	93 (35.2)	3.81 ± 1.191
Educational strategies can help to prevent dispensing of SFMs	8 (3.0)	20 (7.6)	38 (14.4)	80 (30.3)	118 (44.7)	4.06 ± 1.080
Regulatory strategies can help to prevent dispensing of SFMs	11 (4.2)	8 (3.0)	42 (15.9)	62 (23.5)	141 (53.4)	4.19 ± 1.076

Attitude towards substandard and falsified medicines: The participants' mean level of agreement for attitude questions ranged from 2.02 to 4.19. The lowest mean (mean=2.02) was recorded for the question “It is fine to dispense some SFMs which are not vital to treat diseases”. Relatively, the participants had a better mean attitude for the questions “Dispensing counterfeited medicines is against the professional code of ethics” and “Educational strategies can help to prevent dispensing of SFMs” with a mean (mean=4.18) and (mean=4.06), respectively. Moreover, the highest mean satisfaction was taken for the question that says “Regulatory strategies can help to prevent dispensing of SFMs” (Mean= 4.19) (Table 3).

Practice towards substandard and falsified medicines: Of those having awareness about SFMs, 141(53.4%) of community pharmacy professionals encountered with SFMs and the majority 209 (79.2%) of them never dispensed SFMs. Of those who encountered SFM, 102(72.3%) of the respondents remembered the name and 49(48%) of them remembered the country of origin for the SFMs. Mebendazole suspension 46(45%), Metronidazole 32(31.4%), muscle builders 31(30.4%) and Paracetamol 27(26.5%) were the most frequently mentioned drugs the study participants encountered. Regarding SFMs origin, India 37(75.5%), Ethiopia 25(51%), Egypt 23(46.9%) and Jordan 13(26.5%) were frequently mentioned countries for SFMs.

The community pharmacy professionals differentiated SFMs from their originals through packaging material 05(39.8%), ISO/regulatory certification 98(37.1%) and labeling 75(28.4%). The study also revealed that of respondents who were familiar with SFMs, 146(45.2%) of respondents reported knowing other pharmacists that dispensed SFMs, and 57(38.1%) believed that the pharmacists were aware that they were dispensing SFMs (Table 4).

Table 4: Community pharmacy professionals practice towards substandard and falsified.

	Variable	Frequency (%)
Experienced with SFMs	Yes	141 (53.4%)
	No	123 (46.6%)
Remember the name of SFMs	Yes	102 (72.3%)
	No	39 (27.7%)
Name of SFMs *	Mebendazole suspension	46 (45%)
	Metronidazole	32 (31.4%)
	Muscle Builders	31 (30.4%)
	Paracetamol	27 (26.5%)
	Tetracycline	13 (12.7%)
	Trifluoperazine	12 (11.8%)
	Amitriptyline	8 (7.8%)
Remember country of origin for SFMs	Yes	49 (48%)
	No	53 (52%)
Country of origin for SFMs *	India	37 (75.5%)
	Ethiopia	25 (51%)
	Egypt	23 (46.9%)
	Jordan	13 (26.5%)
	UAE	8 (16.3%)
	Cyprus	2 (4%)
Experience of Dispensing SFMs	Yes	49 (18.5%)
	No	209 (79.2%)
	Not Sure	6 (2.3%)
Knowing others dispensing SFM	Yes	146 (45.2%)
	No	177 (54.8%)
Aware of dispensing SFMs	Yes	57 (38.1%)
	No	61 (41.8%)
	Not sure	28 (19.1%)
Method of differentiating SFMs *	Packaging	105 (39.8%)
	ISO/Regulatory Certificate	98 (37.1%)
	labeling	75 (28.4%)
	Expiry date	64 (24.2%)
	Brand Name	61 (23.1%)
	Color	61 (23.1%)
	Country of origin	44 (16.7%)
Attending training on SFMs	Yes	52 (19.7%)
	No	212 (80.3%)
*Note : Multiple responses were possible		

DISCUSSION

This study has been carried out to assess the community pharmacy professionals' knowledge, attitude and practice towards SFMs in Addis Ababa, Ethiopia. Two hundred sixty-four (81.7%) of community pharmacy professionals were aware of SFMs and 98 (37.1%) of them correctly define SFM. Similar studies in Alexandria, Egypt among pharmacists and Nuh, Haryana, India among medical doctors indicated a relatively lower finding, 98 (56.0%) and 57.77%, respectively [16,17]. This study also revealed that the main source of awareness about SFM were school 160 (60.7%) and colleagues 81(69.3%) but a similar study in Lebanon showed TV 88 (39.5%) and MoH 81(36.3%) were the main sources of awareness about SFM [18].

Among community pharmacy professionals who were aware of SFMs, 212 (80.3%) of respondents believed SFMs were available in Ethiopian pharmaceutical market and more than half of them reported that they have encountered SFMs. Similarly, a study in Egypt showed 175 (96%) of the respondents believed that the problem of medicines falsified existed with 50% of them [16]. A study in Italy also showed falsified medicines are widespread (23.0%) in their country and 51 (7.6%) participants reported previous experience with falsified drugs [19].

This study also indicated 196 (74.2%) of respondents believed the main country of origin for SFM was India followed by China 103 (39.0%) and Ethiopia 43(16.3%). Whereas, India 37 (75.5%), Ethiopia 25 (51%) and Egypt 23 (46.9%) were the countries of origin for SFMs they encountered. A study in Lebanon indicated 82 (38.7%) of respondents believed the main source of SFMs to be China, India, Arab countries and Lebanon by 50 (23.6%), 38 (17.9%), 19 (9%) and 51 (24.1%), respectively [19]. These studies were strengthened by another study in developing countries indicating Indian medicines were often substandard [20].

In our study, more than half of respondents believed that importers and many other medicine supply chain parties were involved in the chain of SFMs transactions. A similar study in Nigeria showed chaotic open market medicine distribution networks were a major source of medicine purchase to hospital pharmacy stores, wholesalers, retailers, medicine stores and pharmaceutical manufacturers [21]. Medicine counterfeiters targeted markets in countries where the capacity to detect defective products and the penalty for engaging in them were low [22]. Therefore, creating a medicine supply chain that is flexible enough to respond to the actions of sub-standardization and falsification reduces leakage [22].

The study also identified that the mean attitude rate of the community pharmacists related to the SFMs use in the community was a moderately positive attitude which was lower than a completely positive attitude of Iranian community pharmacists [2].

The majority 209 (79.2%) of community pharmacy professionals reported that they had never dispensed SFMs. Similarly, a study conducted in Egypt indicated 77.7% of respondents returned the suspect medicine to the supplier and 23.4% of respondents reported the incident to the Egyptian Drug Authority [16].

Participants perceived that antibiotics 128 (48.5%), chronic disease medicines 94 (35.6%) and expensive and unavailable 79 (29.9%) were medicines with the highest risk of falsification but Mebendazole suspension 46 (45%), Metronidazole 32 (31.4%), Muscle builders 31(30.4%) and Paracetamol 27(26.5%) were among the SFMs. A study to investigate the diffusion of SFMs in developing countries identified the main target for agents to falsify are highly-priced, lifesaving medicines like amoxicillin which is widely subject to be falsified [20].

The respondents' main methods of differentiating SFMs from their originals were through packaging material 105 (39.8%), followed by ISO/regulatory certification 98 (37.1%) and labeling 75 (28.4%). A similar study in Lagos state, Nigeria, also indicated community pharmacists commonly used visual security techniques; seals/embossments (83%), the character of print (77%) and hologram (68%) [23].

There is no single technique that can eliminate the public health threat posed by SFMs due to the complexity of the drug production and distribution system. Stringent regulation and improved vigilance [24] transaction records as drug products move and verification of drug products [25,26] increasing awareness of SFMs to the public [21] and active involvement and ethical practice of pharmacists might contribute a lot in preventing SFMs catastrophe.

CONCLUSION

This study estimated that community pharmacy professionals' knowledge and practice were found to be moderate and their attitude was also moderate regarding SFMs. Due to the complexity of the drug production, pharmaceutical marketing, distribution system and pharmaceutical care and as a key players of pharmacists in these activities, they are properly positioned to stem the tide of SFMs. Interventions have to be designed and implemented to improve the community pharmacy professionals' knowledge, attitude and practice.

DECLARATION

Availability of data

All relevant raw data, is freely available to any scientist wishing to use them.

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Competing interests

The authors declare that they have no competing interests.

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