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Extent of Filipinos' Awareness in Identifying Counterfeit Medicines: A Quantitative Cross-Sectional Study

Jennie Vave D. Isuga [1, *], Cathlyanna May D. Dela Cruz [1], Jacob T. Urriza [1], Luigi G. Abas [1], Eireen Mean D. Dela Cruz [1], Del Celestine B. Jardinero [1], Maria Elisha A. Flores [1], Shaira Mae D. Sevilla [1], Mary D. Catapang [1], Cecilia D. Santiago [1, 2] and Mylene S. Andal [1]

[1] School of Pharmacy, Centro Escolar University-Manila, 9 Mendiola St., San Miguel, Manila 1008, Metro Manila, Philippines.
[2] The Graduate School, Centro Escolar University-Manila, 9 Mendiola St., San Miguel, Manila 1008, Metro Manila, Philippines.

Abstract

Counterfeit drugs have been purposefully and falsely mislabeled in terms of their identity and/or source of both branded and generic products. The use of these drugs can lead to reduced safety and efficacy that may result in adverse events. This study aimed to assess the extent of Filipinos' awareness in identifying counterfeit medicines, and its association with the sociodemographic characteristics of the respondents. A quantitative cross-sectional survey was conducted on 267 Filipino consumers residing in the Philippines with the use of convenience sampling, where a pre-validated online questionnaire was utilized to gather data about the respondents' sociodemographic characteristics, sources of information, knowledge of counterfeit medicines, and ability to identify counterfeit medicines. The study utilized frequencies, percentages, mean, standard deviation, Chi-square, and t-test for independence. Among the six demographic characteristics, only the respondents' marital status (p-value = 0.000) had a significant association with the sources of information regarding counterfeit medicines while both age (p-value = 0.010) and marital status (p-value = 0.000) were found to be associated with their knowledge of counterfeit medicines. The results of the Chi-square test showed that a high level of knowledge was significantly associated only with a moderate level of ability to identify counterfeit medicines (p-value=0.000) since 73.03% of the sample had a high level of knowledge while 61.80% had a moderate level of ability to identify counterfeit medicines. Therefore, the need for public education and raising awareness is essential, which necessitates the involvement of healthcare professionals.

Keywords: Counterfeit medicines; Awareness; Identification; Cross-sectional

1. Introduction

Counterfeit drugs are defined as drugs that have been purposefully and falsely mislabeled in terms of their identity and/or source of both branded and generic products. In addition to that, counterfeit medicines may also be products that have specified ingredients but are deficient in terms of their quantities, such as inadequacy or absence of active pharmaceutical ingredients, as well as those products that have erroneous ingredients. Moreover, counterfeit medicines have fraudulent parts, and containers, or branded without the approved trademark, brand names, or other recognition label or imprint that indicates registration or property to the Bureau of Patent, Trademark, and Technology Transfer (BPTTT) in the title of another human or non-human legal entity. Furthermore, unregistered foreign-made products that are not acknowledged or merited by associated health information, and drugs that contain counterfeit active substances or below 80% of the active material it claims to acquire are also considered counterfeit medicines. In which

[*] Corresponding author: Jennie Vave D. Isuga; Email: isuga1902085@ceu.edu.ph
School of Pharmacy, Centro Escolar University-Manila, 9 Mendiola St., San Miguel, Manila 1008, Metro Manila, Philippines.

all of these may result in reduced safety, efficacy, quality, strength, and/or purity of the drugs leading to adverse events [1, 2]. These products do not undergo various processes and validation upon marketing resulting in reduced safety, efficacy, quality, strength, and/or purity of the drugs leading to adverse events such as unexpected side effects, allergic reactions, worsened pre-existing conditions, or even death [3].

This major public hazard is observed in many underdeveloped countries such as Asia, Latin America, and Africa where the number of counterfeit pharmaceuticals on the market is more than 30%. Meanwhile, less than 10% of all pharmaceuticals available in other developing markets are counterfeit [4]. Despite the rampancy of counterfeit pharmaceuticals, studies have shown that these countries often focus on efforts that measures and quantify the incidences of counterfeit medicines and neglect to address the variables that contribute to their prevalence. For instance, the demand from the consumers contributes to the continuous supply of counterfeit drugs but there has been surprisingly little research aimed at investigating the counterfeit drug problem in these countries, particularly from the standpoint of consumers. In fact, the Philippines is still named as the leading source of counterfeit drugs by the United States Trade Representative (USTR) despite the presence of RA 8203 or the Special Law on Counterfeit Drugs. This is due to the fact that this law is more focused on the supply side, but the problem applies to both supply and demand. Therefore, there is a dire need in assessing the situation from the Filipino consumers' point of view.

Lack of awareness and identification limits consumer involvement or readiness to report counterfeit products, as a consequence, scattered and insufficient reporting of occurrences is obtained, making it difficult to quantify the effect on patient's health and the implications of counterfeit drugs [5, 6].With that, this study aims to determine the extent of Filipinos' awareness in identifying counterfeit medicines to help raise public knowledge against counterfeit drugs, and public awareness about the growing counterfeit drug trade as well as the dangers they pose to public health.

2. Material and methods

This quantitative cross-sectional study was conducted in the Philippines between February 2022 and March 2022 and was approved by the Centro Escolar University Institutional Ethics Review Board prior to the data collection. A sample size of 267 respondents was determined using Cochran's formula, wherein a non-probability convenience sampling was utilized. The respondents were Filipino consumers 18 years old and above with English and/or Filipino literacy who tend to use and purchase their medicines in either drug stores or online platforms. People below 18 years old who lack access to the Internet were not included in the study. The questionnaire was validated (Cronbach's α = 0.928) by three BS Pharmacy lecturers from CEU-Manila, and one faculty from the Psychology Department of CEU-Makati.

The research instrument used in this study was in the form of an online survey questionnaire through Google Forms, which was inspired by previously conducted similar studies. It was composed of forty-nine items, which were divided into four sections namely respondent's socio-demographic profile, sources of information, knowledge of counterfeit medicines (CFMs), and ability to identify CFMs. All the questions on knowledge of CFMs and ability to identify CFMs were prepared on a four-point Likert scale, ranging from strongly disagree to strongly agree, corresponding to 1 point to 4 points, respectively. A scale based on a study by Alfadl et al. [7]. was modified and used to assess the extent of respondents' knowledge regarding CFMs and their ability to identify CFMs. The total scores for the 14 questions on the knowledge of CFMs were classified as low-level (14-27), moderate level (28-44), and high-level (45-56). On the other hand, the total scores for the 24 questions on the ability to identify CFMs were also categorized as low-level (24-47), moderate level (48-76), and high-level (77-96).

Data were analyzed using the Statistical Package for Social Sciences (SPSS) version 21. Frequencies and percentages were used to determine the socio-demographic profile of the respondents. Means and standard deviations were utilized in determining the respondents' main source of information regarding CFMs, knowledge of CFMs, and ability to identify CFMs. Chi-square was performed to determine the association between independent variables and the extent of Filipinos' awareness in identifying CFMs. Lastly, t-test for independence was utilized to determine if there was a difference between the respondents' ability to identify counterfeit over-the-counter medicines and counterfeit prescription medicines.

3. Results and discussion

In this study, the majority of the respondents were 18-25 years old (47.57%) belonging to Gen Z. Most of the respondents were female (76.03%), single (71.16%), college graduates (50.56%), and had a healthcare-related occupation (41.95%). Also, most of the respondents have a monthly income of P24,001 to P47,000 (36.70%), categorized as a lower-middle-income class (Table 1).

Table 1 Respondents' Sociodemographic Characteristics

Sociodemographic Characteristic	Parameter	Frequency (n)	Percentage (%)
Age	18 – 25	127	47.57
	26 – 41	101	37.83
	42 – 57	37	13.85
	58 – 67	2	0.75
	68 – 76	0	0.00
Sex	Male	64	23.97
	Female	203	76.03
Marital Status	Single	190	71.16
	Married	73	27.34
	Separated or Divorced	1	0.37
	Widowed	3	1.12
Educational Attainment	Elementary Undergraduate	0	0.00
	Elementary Graduate	1	0.37
	High School Undergraduate	2	0.75
	High School Graduate	21	7.87
	Vocational	9	3.37
	College Undergraduate	83	31.09
	College Graduate	135	50.56
	Post-Baccalaureate	16	5.99
Occupation	Healthcare Related	112	41.95
	Non-healthcare Related	66	24.72
	Unemployed	89	33.33
Household's Average Monthly Income	Below P12,000	36	13.48
	P12,001 to P24,000	67	25.09
	P24,001 to P47,000	98	36.70
	P47,001 to P82,000	49	18.35
	P82,001 to P140,000	7	2.62
	P140,001 to P234,000	6	2.25
	P234,000 and above	4	1.50

The majority of the respondents mentioned healthcare facilities as a source of information (mean = 3.195), which was then followed by various social media platforms (mean = 3.127) (Figure 1). This finding opposed the results of a study by Wagiella et al. [8], which suggested that social media platforms are the main source of information about CFMs, followed by pharmacies.
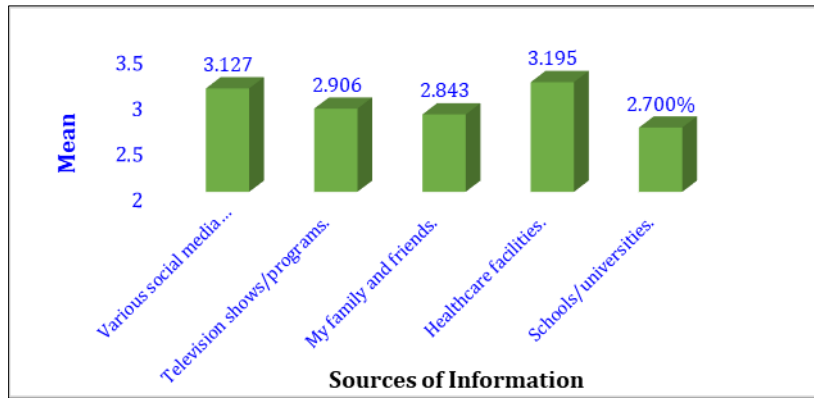
Figure 1 Respondents' Sources of Information Regarding CFMs

The respondents defined CFMs as products with insufficient amounts of correct ingredients, wrong ingredients, without active ingredients, and with sufficient quantity of active ingredients, which might all result in the reduction of the drug's safety, efficacy, quality, and strength, or purity (mean = 3.386); and as a drug that is deliberately and intentionally mislabeled with respect to identity and/or source or with fake packaging (mean = 3.386) (Table 2). The second definition coincides with that of the World Health Organization, which defines it as deliberately and fraudulently produced and/or mislabeled with respect to identity and/or source to make it appear to be a genuine product [9]. On the other hand, the respondents recognized checking if the security seal is intact or has been tampered with as the main method of checking the authenticity of medicines (mean = 3.618) (Table 3). This result corresponds with the finding of a survey in Hong Kong, which revealed that the top method for verifying the authenticity of medicines was also checking the intactness of the security seal [10]. Meanwhile, treatment failure was the most identified health consequence of CFMs (mean = 3.573) (Table 4). This finding is higher than that of the study conducted in India wherein more than half of the respondents had the knowledge that counterfeit drugs are associated with treatment failure [11].

Table 2 Respondents' Knowledge of CFMs Based on their Definition on RA 8203

Sr. no.	Definition of CFMs	Mean	Verbal Interpretation
	I am aware that CFMs refer to:		
1.	Medicinal products with insufficient amount of correct ingredients, wrong ingredients, without active ingredients, with sufficient quantity of active ingredient; which might all result in the reduction of the drug's safety, efficacy, quality, strength or purity.	3.386	Strongly Agree
2.	A drug which is deliberately and intentionally mislabelled with respect to identity and/or source or with fake packaging.	3.386	Strongly Agree
3.	Products that can be both branded and generic.	2.996	Agree
4.	A drug product refilled in containers by unauthorized persons if the legitimate labels or marks are used.	3.273	Strongly Agree
5.	An unregistered imported drug product that is not confirmed and justified by accompanying medical records.	3.292	Strongly Agree
	Overall Mean	**3.267**	**Strongly Agree**

*Verbal Interpretation: Strongly disagree = 1.00-1.74; Disagree = 1.75-2.49; Agree = 2.50-3.24; Strongly Agree = 3.25-4.00

Table 3 Respondents' Knowledge of CFMs Based on the Methods of Checking the Authenticity of Medicines

Sr. no	Method of Checking the Authenticity of Medicines	Mean	Verbal Interpretation
	I am aware that methods of checking the authenticity of medicines include:		
1	Checking if the security seal is intact or has been tampered with.	3.618	Strongly Agree
2	Looking out for unusual fonts, font sizes, print color, and spelling errors.	3.446	Strongly Agree
3	Asking a doctor about the authenticity of the medicine.	3.386	Strongly Agree
4	Asking a pharmacist about the authenticity of the medicine.	3.543	Strongly Agree
	Overall Mean	**3.498**	**Strongly Agree**

*Verbal Interpretation: Strongly disagree = 1.00-1.74; Disagree = 1.75-2.49; Agree = 2.50-3.24; Strongly Agree = 3.25-4.00

Table 4 Respondents' Knowledge of CFMs Based on their Health Consequences

Sr. no.	Health Consequence of CFMs	Mean	Verbal Interpretation
	I am aware that counterfeit medicine/s is/are associated with:		
1	Treatment failure.	3.573	Strongly Agree
2	Increased number of unexpected side effects.	3.569	Strongly Agree
3	Unexpected allergic reactions.	3.566	Strongly Agree
4	Overdosing, which in some cases may lead to poisoning.	3.509	Strongly Agree
5	Increase in the cost of treatment.	3.431	Strongly Agree
	Overall Mean	**3.530**	**Strongly Agree**

*Verbal Interpretation: Strongly disagree = 1.00-1.74; Disagree = 1.75-2.49; Agree = 2.50-3.24; Strongly Agree = 3.25-4.00

In terms of the ability to identify CFMs, the most identified physical attribute was the pattern on the packaging and placement of the printed details (mean = 3.378) (Table 5). This finding did not coincide with the studies conducted by El-Dahiyat et al. [12], wherein the most identified label of information was found to be the manufacturing and expiration date. On the other hand, Phenylephrine HCl + Chlorpheniramine Maleate + Paracetamol was the most identified counterfeit over-the-counter (OTC) medicine (mean = 3.191) (Table 6), while Sildenafil citrate (mean = 3.195) was established as the most identified counterfeit prescription medicine (Table 7). The sophisticated skills of counterfeit manufacturers led to the production of drugs where the packaging looks almost exactly the same as the authentic medicines, coming to the point where the only method to distinguish them is through chemical tests and analytical techniques [10]. It justifies the result that regardless of the category of the medicine, counterfeiting skills are applied to maximize fraudulent activities. Meanwhile, the result in the t-test of independence showed that there was no significant difference between the respondents' ability to identify counterfeit OTC medicines and counterfeit prescription medicines (p-value = 0.697) (Table 8).

Table 5 Respondents' Ability to Identify CFMs Based on Label, Packaging, and Appearance
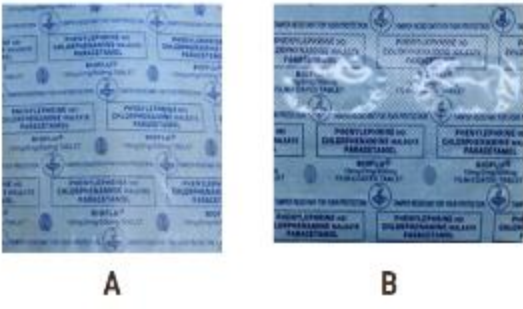
Sr. no	Ability to Identify CFMs Based on Label, Packaging, and Appearance	Mean	Verbal Interpretation
	I am aware that the presented image is a/an:		
1	Counterfeit medicine based on its generic name.	2.813	Agree
2	Counterfeit medicine based on its batch number/lot number.	3.060	Agree
3	Counterfeit medicine based on its pack size.	2.753	Agree
4	Counterfeit medicine based on its dosage strength & dosage form.	2.914	Agree

5	Counterfeit medicine based on its manufacturing & expiration date.		2.850	Agree
6	Authentic medicine based on its brand name.		3.337	Strongly Agree
7	Authentic medicine based on the pattern on the packaging and the placement of the printed details.		3.378	Strongly Agree
8	Authentic medicine based on its net volume.		3.011	Agree
9	Authentic medicine based on the tablet markings.		2.929	Agree

10	Authentic medicine based on the tablet's color.		3.165	Agree
	Overall Mean		**3.021**	**Agree**

*Verbal Interpretation: Strongly disagree = 1.00-1.74; Disagree = 1.75-2.49; Agree = 2.50-3.24; Strongly Agree = 3.25-4.00
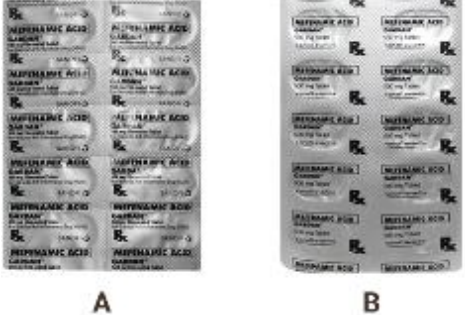
Table 6 Respondents' Ability to Identify Counterfeit OTC Medicines

Sr. no	Ability to Identify Counterfeit OTC Medicines	Mean	Verbal Interpretation
	I am aware that:		
1	Figure A is an authentic medicine compared to Figure B.	2.891	Agree
2	Figure B is an authentic medicine compared to Figure A.	3.180	Agree
3	Figure B is an authentic medicine compared to Figure A.	3.191	Agree

4	Figure A is an authentic medicine compared to Figure B.		2.528	Agree
5	Figure A is an authentic medicine compared to Figure B.		2.798	Agree
6	Figure B is an authentic medicine compared to Figure A.		2.865	Agree
7	Figure A is an authentic medicine compared to Figure B.		2.805	Agree
	Overall Mean		**2.894**	**Agree**

*Verbal Interpretation: Strongly disagree = 1.00-1.74; Disagree = 1.75-2.49; Agree = 2.50-3.24; Strongly Agree = 3.25-4.00

Table 7 Respondents' Ability to Identify Counterfeit Prescription Medicines

Sr. no	Ability to Identify Counterfeit Prescription Medicines	Mean	Verbal Interpretation
	I am aware that the presented image is a/an:		
1.	Figure A is an authentic medicine compared to Figure B.	3.064	Agree
2.	Figure A is an authentic medicine compared to Figure B.	2.708	Agree
3.	Figure A is an authentic medicine compared to Figure B.	2.955	Agree
4.	Figure B is an authentic medicine compared to Figure A.	2.603	Agree

5.	Figure A is an authentic medicine compared to Figure B.		2.801	Agree
6.	Figure A is an authentic medicine compared to Figure B.		3.105	Agree
7.	Figure B is an authentic medicine compared to Figure A.		3.195	Agree
	Overall Mean		**2.919**	**Agree**

*Verbal Interpretation: Strongly disagree = 1.00-1.74; Disagree = 1.75-2.49; Agree = 2.50-3.24; Strongly Agree = 3.25-4.00

Table 8 Difference Between the Respondents' Ability to Identify Counterfeit OTC Medicines and Counterfeit Prescription Medicines

Differentiated Variables	p-value	Interpretation
Counterfeit OTC Medicines and Counterfeit Prescription Medicines	0.697	No Significant Difference

*Significant at .05 level (p<.05)

Among the six sociodemographic characteristics of the respondents, only the marital status was found to be significantly associated with sources of information regarding CFMs (p-value = 0.000), which opposed the findings of Włodarczak et al. [13] that linked higher education to increased access to information (Table 9).

Both the respondents' age (p-value = 0.010) and marital status (p-value = 0.000) had a significant association with the knowledge of CFMs (Table 10). These findings did coincide with the results of a study by Mhando et al. [14], which suggested that the respondents with healthcare- related occupations had a higher level of knowledge of CFMs compared to those who had non-healthcare-related occupations. All the respondents' sociodemographic characteristics were not significantly associated with the ability to identify CFMs. These findings coincide with the result of a study by Mhando et al. [14], wherein age, sex, education level, and marital status were not determinants for the identification of counterfeit drugs. Moreover, this finding corresponded with the results in a study conducted by Por et al. [15] where both educational attainment and monthly income did not have a significant relationship with the respondents' ability to identify whether medicines are authentic (Table 11).

Table 9 Association Between the Respondents' Sociodemographic Characteristics and Sources of Information Regarding Counterfeit Medicines

Sociodemographic Characteristic	Sources of Information Regarding CFMs	Verbal Interpretation
	p-value	
Age	0.423	No Significant Association
Sex	0.490	No Significant Association
Marital Status	0.000	Significant Association
Educational Attainment	0.143	No Significant Association
Occupation	0.274	No Significant Association
Household's Average Monthly Income	0.298	No Significant Association

*Significant at .05 level (p<.05)

Table 10 Association Between the Respondents' Sociodemographic Characteristics and Knowledge in Counterfeit Medicines

Sociodemographic Characteristic	Knowledge of CFMs	Verbal Interpretation
	p-value	
Age	0.010	Significant Association
Sex	0.124	No Significant Association
Marital Status	0.000	Significant Association
Educational Attainment	0.339	No Significant Association
Occupation	0.060	No Significant Association
Household's Average Monthly Income	0.785	No Significant Association

*Significant at .05 level (p<.05)

Table 11 Association Between the Respondents' Sociodemographic Characteristics and Ability to Identify Counterfeit Medicines

Sociodemographic Characteristic	Ability to Identify CFMs	Verbal Interpretation
	p-value	
Age	0.946	No Significant Association
Sex	0.190	No Significant Association
Marital Status	0.822	No Significant Association
Educational Attainment	0.624	No Significant Association
Occupation	0.122	No Significant Association
Household's Average Monthly Income	0.611	No Significant Association

*Significant at .05 level (p<.05)

The results indicated that 73.03% of the sample had a high level of knowledge (Table 12) while 61.80% had a moderate level of ability in identifying CFMs (Table 13). Based on the Chi-square test, a significant association was found between the respondents' knowledge of CFMs and their ability to identify CFMs (p-value=0.000), showing that a high level of knowledge of CFMs was associated with only a moderate level of ability to identify CFMs (Table 14).

Table 12 Respondents' Level of Knowledge of Counterfeit Medicines

Respondents' Level of Knowledge of CFMs		
Level of Knowledge	Frequency	Percentage (%)
Low	11	4.12
Moderate	61	22.85
High	195	73.03

*Legend: Low-level = 14-27, Moderate level =28-44, and High-level = 45-56

Table 13 Respondents' Level of Ability in Identifying Counterfeit Medicines

Respondents' Level of Ability in Identifying CFMs		
Level of Ability	Frequency	Percentage (%)
Low	13	4.87
Moderate	165	61.80
High	89	33.33

*Legend: Low-level = 24-47, Moderate level =48-76, and High-level = 77-96

Table 14 Association Between the Respondents' Knowledge of CFMs and their Ability to Identify CFMs

Variables	p-value	Verbal Interpretation
Respondents' Knowledge Regarding CFMs and Ability to Identify CFMs	0.000	Significant Association

*Significant at .05 level (p<.05)

4. Conclusion

Among the sociodemographic characteristics of the respondents, only marital status was associated with the sources of information regarding counterfeit medicines, while both age and marital status were significantly associated with the knowledge of counterfeit medicines. On the other hand, all of the demographic characteristics of the respondents were not significantly associated with their ability to identify CFMs. It was also found that there was no significant difference between the respondents' ability to identify counterfeit over-the-counter medicines and counterfeit prescription medicines. Moreover, a high level of knowledge of the respondents regarding counterfeit medicines was significantly associated only with a moderate level of ability to identify counterfeit medicines. Overall, the majority of the respondents showed a moderate extent of awareness in identifying counterfeit medicines, which is concerning. Hence, there is still a need to raise awareness and educate the public to decrease their vulnerability to counterfeit medicines, which necessitates the involvement of healthcare professionals.

Compliance with ethical standards

Disclosure of conflict of interest

The authors declare no conflict of interest.

Statement of ethical approval

The authors hereby confirm that the study protocol and informed consent underwent review, and were approved by the Centro Escolar University - Institutional Ethics Review Board (CEU-IERB) last March 20, 2022.

Statement of informed consent

Informed consent was obtained from all individual participants included in the study.

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