



Original Research Article

HEALTH CARE PROVIDERS' KNOWLEDGE, ATTITUDE AND PRACTICE TOWARD COUNTERFEIT MEDICINES ACROSS CHENNAI

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ABSTRACT

Background: Counterfeit medicines are a growing public health concern especially in south asian countries like India. They not only compromise patient safety but also break down trust among public in healthcare systems. This study assessed the knowledge, attitude, and practice of healthcare providers regarding counterfeit medicines across Chennai, Tamil Nadu, India.

Materials and Methods: A cross-sectional study was conducted among 140 healthcare providers using a pretested semi-structured questionnaire. Data were analyzed using SPSS v22. Descriptive statistics and multivariable logistic regression were used to evaluate the knowledge, attitude and practice as well as associated factors.

Results: Most participants (83.6%) were aware of counterfeit medicines, yet only 20.7% had received formal training. More than half (57.1%) correctly identified counterfeit medicines, and 92.9% reported they would report suspected cases. 57.9% of the respondents demonstrated a good attitude toward counterfeit medicines. Lack of training was significantly associated with poor attitude (AOR=3.78, p=0.007), while awareness of counterfeit medicines (AOR=0.18, p=0.002) and being a physician (AOR=0.27, p=0.011) were associated with more positive attitudes.

Conclusion: Healthcare providers demonstrated satisfactory knowledge and generally positive attitudes and practices regarding counterfeit medicines. The introduction of training programs and strengthening reporting systems can help in the fight against eradication of counterfeit medicines.

Keywords: Counterfeit medicines, Healthcare providers, Knowledge, Attitude and Practice (KAP), Patient safety, Drug regulation, Chennai.

INTRODUCTION

A substandard and falsified [SF] medical product (counterfeit medicine) is deliberately and fraudulently mislabeled with respect to identity and/or source.

Counterfeiting can apply to both branded and generic products, and counterfeit products may include those with the correct ingredients, the wrong ingredients, no active ingredients, insufficient active ingredients, or fake packaging.^[1]

According to the WHO, counterfeit medicines are further classified as:

Substandard: Also called "out of specification", these are authorized medical products that fail to meet either their quality standards or specifications, or both.

Unregistered/Unlicensed: Medical products that have not undergone evaluation and/or approval by the National or Regional Regulatory Authority for the market in which they are marketed/distributed or used are subject to permitted conditions under national or regional regulation and legislation.

Falsified: Medical products that deliberately/fraudulently misrepresent their identity, composition or source.^[2]

In India, the production and distribution of counterfeit medicines has increased by almost 47% from 2020 to 2021 during the pandemic and is posing an important threat to the healthcare industry as a whole.^[3]

In a 2017 report, the WHO claimed 10.5 percent of medicines sold in low and middle-income countries, including India, were substandard and falsified, which is a serious threat to patient safety.^[4]

Tamil Nadu is also currently dealing with a drug crime where crores of rupees worth of medicines, which were past their sell-by date, were repackaged with new expiry dates and resold in the market.^[5]

The World Health Organization (WHO) also estimates that there are over one million deaths per annum from counterfeit and substandard drugs, causing around \$21 Billion of global financial impact.^[6]

Counterfeit medicines are a threat to public health because patients may not receive the intended therapeutic effect, that leads to disease progression, complications, disability, or even death.

Low quality medicines often contain substandard concentrations of active pharmaceutical ingredients. This exposes microorganisms to inadequate drug levels, promoting the development of antimicrobial resistance. In a country like India that is increasingly facing the gigantic obstacle of drug resistant infections like tuberculosis and malaria, counterfeit medicines add fuel to the fire.

Counterfeit medicines not only adversely affect patient health but they also increase healthcare expenditure by prolonging illness and increasing the need for expensive second line treatments.

All of these issues erode the trust that the public place on healthcare systems and providers.

India is one of the largest producer of medicines and pharmaceutical products. The majority of the population depend on affordable medicines, weighed down by the burden of infectious diseases. Thus, this issue is particularly important in India.

The general lack of knowledge about these drugs and their effects is aiding their distribution. Due to a lack of data about awareness of counterfeit medicines, we aim to analyze the knowledge, attitude and practice about substandard and falsified medicines among healthcare professionals.

Objectives:

In this study, we aim

1. To assess the knowledge, attitude and practice about counterfeit drugs among health care providers.
2. To identify factors associated with adequate knowledge, attitude and practice regarding counterfeit drugs.

MATERIALS AND METHODS

Site of Study: Chennai, Tamil Nadu
Type of Study: Cross-Sectional Study
Period of Study: 2 Months

Sample Size: 140

Sample Size Formula:^[7]

Formula: $\frac{4pq}{d^2}$

Taking, prevalence p of 22%, q (1-p) as 78%, allowable.

error d: 7

The sample size comes to 140.

Methodology: Pretested Semi structured Questionnaire assessing the knowledge, attitude and practice regarding counterfeit medicines.

Analysis: Data entry was entered in Excel. The data were statistically analyzed using SPSS software (IBM SPSS Statistics v22). Categorical variables are expressed in frequency and percentages. Continuous variables are expressed in mean and SD. The health care providers' attitude was assessed using a 5-point Likert scale: "Strongly agree" was given a score of 5, "Agree" a score of 4, "Neutral" a score of 3, "Disagree" a score of 2, and "Strongly Disagree" a score of 1 for positive questions. Negative questions were scored in the opposite way. The overall level of attitude was analyzed by using the mean score. Participants who scored above or equal to the mean score were said to have a good attitude regarding counterfeit medicines, and vice versa for a bad attitude. Supervisors consistently double-checked the consistency and reliability of the data collected.

Inclusion Criteria

Healthcare providers across Chennai, Tamil Nadu.

Exclusion Criteria

Healthcare providers who were not willing to participate in the study.

Sampling Procedure:

Convenience Sampling.

Ethics Approval: Ethical clearance was obtained from Government Medical College, Omandurar Government Estate, Chennai-600002 (IEC No: 90/IEC/GOMC/2023).

RESULTS

Demographic Characteristics (Table 1.0)

A total of 140 health care providers participated in our study conducted across the city of Chennai, Tamil Nadu. Among the participants, the majority were female (55.7%), while males accounted for 43.6% of the study population. Most of the participants had >4 years of professional experience (71.4%), thus providing us with an insight into the outlook on counterfeit medicines among long-term healthcare providers. Regarding professional distribution, physicians/doctors formed the largest group (43.6%), followed by nurses (25.0%) and pharmacy professionals (17.9%).

Table 1.0: Demographic Profile of the Participating Health Care Providers Across Chennai

Demographic variable	Category	Frequency (%)
Sex	Male	61(43.6)
	Female	78(55.7)
	Prefer not to say	1(0.7)
Professional distribution	Physician/doctor	80(57.1)
	Nurse	35(25.0)
	Pharmacy professional	25(17.9)
Years of service	<1 year	14(10.0)
	1-2 years	12(8.6)
	2-3 years	14(10.0)
	>= 4 years	100(71.4)

Health Care Providers' Knowledge Towards Counterfeit Medicines [Table 2.0, 2.1, 2.2]

The majority of the participants (83.6%) reported that they were aware of counterfeit medicines, whereas 16.4% reported that they did not know about counterfeit medicines. Regardless of this fact, the majority of study participants (79.3%) reported not having undergone any training or educational exercise regarding counterfeit medicines.

Most participants (57.1%) mentioned that counterfeit medicines can be all of the above, with

the incorrect ingredient identity and quantity, with toxic impurities or with fake packaging. 34.3% participants mentioned educational sources as their reference for information regarding counterfeit medicines, while 31.4% reported it to be the media. 25.7% of study participants reported their workplace to be the data source on counterfeit medicines. The vast majority of study participants reported that counterfeit medicines pose risks in all 3 areas- efficacy, safety and economy.

Table 2.0

Which of these are counterfeit medicines?	n	%
All of the above	80	57.1
Correct packaging but incorrect identity/quantity + toxic impurities + fake packaging/fake active ingredients	18	12.9
Correct packaging but incorrect identity/quantity	15	10.7
Fake packaging but correct identity and quantity	10	7.1
Correct packaging but incorrect identity/quantity + toxic impurities	5	3.6
Fake packaging and fake active ingredient	4	2.9
None of the above	4	2.9
Products with toxic impurities	3	2.1
Other combined response	1	0.7
Total	140	100.0

Table 2.1

What is your source of information on counterfeit medicines?	n	%
Education	48	34.3
Media	44	31.4
Working area	36	25.7
Friends	9	6.4
No response	2	1.4
Other	1	0.7
Total	140	100.0

Table 2.2

What are the problems associated with counterfeit medicines in the market?	n	%
All	42	30.0
Efficacy, Safety and Economic problem	40	28.6
Safety problem	27	19.3
Efficacy problem and Safety problem	22	15.7
Efficacy problem	4	2.9
Economic problem	3	2.1
No problem	1	0.7
Safety problem and Economic problem	1	0.7
Total	140	100.0

Practices of Health Care Providers Towards Counterfeit Medicines [Table 3.0]

The majority of respondents (59.3%) reported that they were able to distinguish counterfeit medicines from genuine products, with nearly half (49.3%) selecting a combination of all available methods. 38.6% of the study participants reported not

following any preventive measures to curb the distribution of counterfeit medicines, while 26.4% relied on raising public awareness. A large majority of the group (92.9%) responded that they would report counterfeit medicines if they encountered them.

Table 3.0

	Response	Frequency (n)	Percentage (%)
Ability to distinguish counterfeit medicines	Yes	83	59.3
	No	57	40.7
Methods used to identify counterfeit medicines	All of the above	69	49.3
	By physical observation	21	15.0
	By physical observation and lack of effectiveness	19	13.6
	By its unexpected side effects	12	8.6
	By lack of effectiveness	10	7.1
Methods taken to prevent distribution of counterfeit medicines	Not able to identify	9	6.4
	No response	54	38.6
	Creating public awareness	37	26.4
	All of the above	27	19.3
Would report counterfeit medicines if encountered	Informing drug regulatory bodies	18	12.9
	Technological tools	4	2.9
	Yes	130	92.9
	No	10	7.1

Health Care Providers Attitude Towards Counterfeit Medicines [Table 4.0]

Attitude toward counterfeit medicines was assessed using six Likert-scale statements with the previously described method of scoring positive statements and reverse-scoring negative statements. A minimum possible score of 6 and a maximum possible score of

30 was established, and total attitude scores ranged from 12 to 30. The mean attitude score was 24.86 ± 3.64 . Using the mean score as the cutoff point, 81 (57.9%) study participants were classified as having a good attitude, whereas 59 (42.1%) respondents were classified as having a poor attitude toward counterfeit medicines.

Table 4.0

Statement	Strongly Agree n (%)	Agree n (%)	Neutral n (%)	Disagree n (%)	Strongly Disagree n (%)
Dispensing and prescribing counterfeit medicine is unethical	113 (80.7)	16 (11.4)	0	5 (3.6)	6 (4.3)
Dispensing and prescribing counterfeit medicine is illegal	105 (75.0)	26 (18.6)	3 (2.1)	3 (2.1)	3 (2.1)
There is no difference in efficacy between counterfeit and genuine medicines*	8 (5.7)	11 (7.9)	15 (10.7)	36 (25.7)	70 (50.0)
Using counterfeit medicines is cost-effective*	18 (12.9)	37 (26.4)	29 (20.7)	25 (17.9)	31 (22.1)
Counterfeit medicines are as safe as genuine medicines*	2 (1.4)	9 (6.4)	7 (5.0)	30 (21.4)	92 (65.7)
Counterfeit medicines may not work	57 (40.7)	48 (34.3)	21 (15.0)	11 (7.9)	3 (2.1)

*The starred statements are reverse-scored on the Likert scale.

Factors Associated with Attitude of Health Care Providers' Toward Counterfeit Medicines [Table 5.0]

Multivariable logistic regression analysis of factors associated with poor attitude toward counterfeit medicines among healthcare providers revealed the following statistically significant findings:

1) Healthcare providers who had not attended CME or training programs on counterfeit medicines were more likely to have poor attitudes toward counterfeit medicines. (AOR = 3.78, 95% CI: 1.44–9.98, $p = 0.007$).

- 2) Study participants who reported to be aware of counterfeit medicines were less likely to have poor attitude about them. (AOR = 0.18, 95% CI: 0.06–0.54, $p = 0.002$).
- 3) In terms of professional category, physicians/doctors demonstrated lower odds of poor attitude compared with nurses (AOR = 0.27, 95% CI: 0.10–0.74, $p = 0.011$).
- 4) Sex and years of professional experience did not significantly affect attitudes toward counterfeit medicines.

Table 5.0

Variables	Category	Poor Attitude n (%)	Good Attitude n (%)	AOR (95% CI)	P-value
Sex	Female	31 (39.7)	47 (60.3)	1.00	
	Male	28 (45.9)	33 (54.1)	0.81 (0.32–2.05)	0.653
Profession	Nurse	18 (51.4)	17 (48.6)	1.00	
	Pharmacy Professional	12 (48.0)	13 (52.0)	1.62 (0.41–6.39)	0.493
	Physician/Doctor	29 (36.3)	51 (63.7)	0.27 (0.10–0.74)	0.011*
Years of Service	1–2 years	5 (41.7)	7 (58.3)	1.00	
	<1 year	6 (42.9)	8 (57.1)	0.92 (0.14–6.15)	0.932
	2–3 years	6 (42.9)	8 (57.1)	1.16 (0.18–7.61)	0.876
	≥4 years	42 (42.0)	58 (58.0)	0.77 (0.16–3.60)	0.736

Attended CME/Training on Counterfeit Medicines	Yes	6 (20.7)	23 (79.3)	1.00	
	No	53 (47.7)	58 (52.3)	3.78 (1.44–9.98)	0.007*
Knowledge of Counterfeit Medicines	No	17 (73.9)	6 (26.1)	1.00	
	Yes	42 (35.9)	75 (64.1)	0.18 (0.06–0.54)	0.002*

Abbreviations: AOR = Adjusted Odds Ratio; CI = Confidence Interval.

*Statistically significant at $p < 0.05$.

DISCUSSION

Counterfeit medicines act like a three-headed demon: not only do they compromise patient safety, but they also raise healthcare costs and reduce the public's confidence in healthcare systems. This study assessed healthcare providers' knowledge, attitude, and practices regarding counterfeit medicines in Chennai, Tamil Nadu, India and also identified factors linked to negative attitudes toward these medicines.

The findings showed that most of the participants (83.6%) reported being aware of counterfeit medicines. This self-reported awareness level is similar to that found in a previous study,^[8] where 84.2% of healthcare professionals said they had prior knowledge of counterfeit medicines. This high awareness can be due to a cocktail of factors: higher media coverage, especially in the background of COVID-19, increasing professional education and an overall increasing focus on patient care and pharmacological safety. An important point to note is that despite this awareness, only 20.7% of respondents had attended formal continuing medical education (CME) or training programs on counterfeit medicines. This shows us that knowledge regarding counterfeit medicines comes mainly from informal sources rather than structured professional education. This vacuum of absence of training programs/lack of access to such programs presents a significant opportunity for healthcare institutions and regulatory bodies to boost continuing medical education regarding this subject. The study participants showed mainly positive feelings toward fighting the battle against counterfeit medicines. Most participants strongly agreed that dispensing counterfeit medicines is both unethical and illegal. Additionally, most disagreed with statements that claim that counterfeit medicines are as safe or effective as genuine medicines. The cost-effectiveness of counterfeit medicines was a highly debated statement, with 17.9% of the professionals disagreeing and 22.1% strongly disagreeing. In the big picture, 57.9% of respondents had a good attitude toward counterfeit medicines. This shows us that the winds are blowing towards a world with vigilant healthcare professionals, eager to curb the distribution of counterfeit medicines.

In terms of practice, almost all of the study participants indicated they would report counterfeit medicines if they encountered them in their professional practice, which signals a strong sense

of professional responsibility. In other surveys, results have been mirrored, showing that awareness of the risks associated with counterfeit medicines increases reporting chances.^[9] On the other hand, most respondents did not follow any way of curbing the distribution of such medicines, which points toward a lacuna in education.

Multivariable logistic regression analysis showed several factors significantly linked to poor attitudes toward counterfeit medicines.

- 1) Healthcare providers who had not attended CME or training programs on counterfeit medicines were more likely to have poor attitudes toward counterfeit medicines. This shows us that educating healthcare professionals about the risks of counterfeit medicines is of prime importance.
- 2) Study participants who reported being aware of counterfeit medicines were less likely to have a poor attitude about them.
- 3) In terms of professional category, physicians/doctors had lower odds of poor attitude compared with nurses. This difference might reflect variations in training and exposure to information about counterfeit medicines. It could also be clouded by the lower sampling size among nurses and pharmacy professionals.

Limitations

- 1) A cross-sectional study design limits the ability to establish strong causal relationships
- 2) Limited sampling among other healthcare professionals and in other geographical areas
- 3) Self-reported responses create more room for bias.

CONCLUSION

Overall, this study indicates that healthcare providers have satisfactory knowledge and generally positive attitudes and practices regarding counterfeit medicines. Vital gaps to address are formal training among healthcare professionals and ensuring reporting mechanisms are in place to halt the distribution of counterfeit medicines. These actions are crucial for ensuring patient safety and supporting the global efforts to tackle the ever-growing challenge of counterfeit medicines.

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