

## Research Article

# Public Awareness and Identification of Counterfeit Drugs in Tanzania: A View on Antimalarial Drugs

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**Background.** The illicit trade in counterfeit antimalarial drugs is a major setback to the fight against malaria. Information on public awareness and ability to identify counterfeit drugs is scanty. **Aim.** Therefore, the present study aimed at assessing public awareness and the ability to identify counterfeit antimalarial drugs based on simple observations such as appearance of the drugs, packaging, labelling, and leaflets. **Methodology.** A cross-sectional study was conducted using interviewer administered structured questionnaire and a checklist. Respondents were required to spot the difference between genuine and counterfeit antimalarial drugs given to them. Data was analysed using SPSS version 20. **Results.** The majority of respondents, 163 (55.6%), were able to distinguish between genuine and counterfeit antimalarial drugs. Respondents with knowledge on health effects of counterfeit drugs were more likely to identify genuine and counterfeit drugs than their counterparts ( $P = 0.003$ ; OR = 2.95; 95% CI: 1.47–5.65). The majority of respondents, 190 (64.8%), perceived the presence of counterfeit drugs to be a big problem to the community. **Conclusions.** A substantial proportion of respondents were able to distinguish between genuine and counterfeit antimalarial drugs. Public empowerment in identifying counterfeit drugs by simple observations is a major step towards discouraging the market of counterfeit drugs.

## 1. Introduction

There is a wide variation on how various nations define counterfeit drugs [1]. The WHO defines counterfeit pharmaceutical product as a product which is deliberately and fraudulently mislabelled with respect to identity and/or source [2]. Counterfeiting can apply to both branded and generic products and counterfeit drugs may include products with the correct ingredients but fake packaging, incorrect ingredients, no active ingredients, or insufficient active ingredients and toxins [2, 3].

Counterfeiting is regarded as one of the oldest crimes in history [4]. The history of counterfeit/fake drugs goes back to several millennia ago with references to a supply of fake antimalarials: cinchona in the early 1600s and quinine in the 1800s [3]. Currently, it is estimated that 10–15% of the global drugs supplied are counterfeit [3, 5]. The prevalence is higher in developing countries in Africa and in parts of Asia and Latin America where up to 30–60% of drugs on the

market are counterfeit [3, 5–9]. India is a major supplier of poor quality drugs whereby 35–75% of fake/counterfeit drugs globally originate from India [10, 11].

The most affected people with counterfeit drugs are the poor living in developing countries [8, 12–15] where self-medication is common and in a few of these countries in Africa drugs are sold through the informal economy in open-air markets together with vegetables and fruits or by hawkers alongside newspaper vendors [16, 17]. Counterfeit drugs are a major cause of therapeutic failure, serious adverse events, deaths, economic burden, drug resistance, and loss of public confidence in drugs and health services [7, 8, 12, 14, 18–23].

The economic effects resulting from counterfeiting drugs are of great significance in developing countries in terms of lost sales revenues, lost tax revenues, lost jobs, costs incurred in combating these counterfeit drugs, and wasted money by poor people to purchase these drugs plus frequency hospitalization due to therapeutic failure [24–26].

Drug counterfeiting is nowadays regarded as murder or terrorism and the greatest evil against human health and economy [27–29]. Statistics support this as it is estimated that, out of one million deaths reported due to malaria, 200,000–450,000 are contributed by the use of counterfeit or fake drugs [24, 29]. The World Health Organization estimates that counterfeit drugs potentially make up more than 50% of the global drug market with a significant proportion of these fake products coming from developing countries [8].

Antimalarials like other anti-infectives are among the most counterfeited drugs globally [3, 14, 28, 30] and there is a diversity of counterfeit packaging types [12]. Studies done in South East Asia indicate that a high proportion of antimalarials in the market are counterfeit where 38–53% of artesunate tablets do not contain active ingredient [20, 31] and the problem is increasing significantly globally [20, 23]. The illicit trade in counterfeit antimalarial drugs is a great threat to lives of patients and the fight against malaria [31–33] due to the fact that such patients treated with counterfeit drugs are at a high risk of developing severe malaria and occurrence of death [23].

Antimalarials are among the most targeted drugs in counterfeit black trade in Africa. The continent accounts for approximately 90% of the 300 million global cases of malaria [34, 35]. Consequently, antimalarials are the most used drugs in African tropical countries like Tanzania which have a high burden of malaria and other infections/infestations [36, 37].

In Uganda, which is a neighboring country to Tanzania, 37% of artemisinin based combination therapies (ACTs) sold in private drug shops are fake/counterfeit [38]. Tanzania, being a developing country, is not an exception as far as counterfeit drugs are concerned. Counterfeit anti-malarial drugs have been identified in Tanzania, a good example being sulphadoxine-pyrimethamine (Metakelfin, 500 mg/25 mg) and dihydroartemisinin (60 mg per tablet, Cotecxin in 200) [23, 39, 40]. These products use identical batch numbers, identical expiry dates, and identical packaging with the purpose of ensuring that they look like the genuine product [23, 39].

The rapid increase in black market in counterfeit drugs in Africa and other parts of the world is attributed to the widespread use of the Internet to market counterfeit drugs, advanced computer technologies which allow forging labels, weakness in regulatory systems, neglect of good manufacturing practice, lack of awareness among health workers and the public, corruption, and a large profit potential from the black counterfeit market [28, 39, 41–43]. The Internet has a significant impact especially in developed countries as it is estimated that 50% of drugs purchased through the Internet are fake [44].

Unfortunately, the illegal trade in counterfeits has now extended to herbal drugs which are mostly used in developing countries [37]. Counterfeiting is also conceded as a major threat to pharmaceutical firms and these firms are now employing various strategies to combat counterfeiting including partnership with governments and health advocates [25, 45].

The WHO and studies recommend the need for public awareness on the growing trade in counterfeit drugs and

the public health risks associated with it [16, 21]. However, information on public awareness on counterfeit drugs and the ability to identify or suspect counterfeited drugs is scanty.

The WHO established guidelines for combating counterfeit drugs in 1999 [46] and launched the International Medical Products Anti-Counterfeiting Taskforce (IMPACT) which included national drug regulatory authorities and law enforcement agencies in 2006 aiming at putting an end to the illicit trade in fake/counterfeit drugs [16]. Many strategies for eliminating counterfeit drugs in the market have therefore been established. These include establishment of strict laws, enforcement/legal actions on illicit traders, application of fast and reliable detection/analysis of the suspect products to distinguish genuine from counterfeit drugs, education and information to the public who are the consumers, improvement on the management of supply chain, and improvement on controls of secondary markets [41, 47, 48].

Despite much efforts put to implement the proposed strategies, the trade in counterfeit drugs has increased significantly. Only few countries have succeeded in this war against illicit traders in counterfeit drugs, Nigeria being an example where a decrease has been recorded significantly from 41% (2002) to 10% (2011) and the country is seeking to eradicate counterfeits in the market [15, 49, 50]. There is a strong need of understanding the mechanisms and structure of the illicit market of counterfeit drugs, consumer's behavior, and maneuvers used by counterfeiters of drugs.

A counterfeit drug may look like the genuine version of the drug. Unfortunately, the only way to confirm whether it is 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, 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 or out of date may indicate whether a drug/product is counterfeited.

Awareness of respondents on these signs is important towards suspicion of counterfeit drugs and avoidance of buying such drugs consequently reducing the market and profit of these illicit drugs.

Therefore, the present study was carried out to assess public awareness and the ability to identify antimalarial drugs which are commonly used in Tanzania.

## 2. Methods

**2.1. Study Population.** This cross-sectional study was conducted between January and November 2014 in Mwanza city, Tanzania. Mwanza is a malaria endemic area.

**2.1.1. Sampling Procedure.** Multistage sampling technique was used to select wards and streets. Then, random sampling was employed to select respondents from the selected streets.

**2.1.2. Questionnaire and Data Collection.** The questionnaire was developed in English and translated into the



FIGURE 1



Sulfametopyrazine-pyrimethamine 500/25 mg (counterfeit)



FIGURE 2

local language (Swahili) and then administered through face-to-face interviews. Pretesting of the questionnaire was done at Mkuyuni Ward in Mwanza to assess practicability and respondent's understanding of the questionnaire. Each respondent was given four antimalarial drug samples to distinguish between genuine and counterfeit drugs based on observations while giving specific reason(s)/justifications for his/her choice. Respondents were not informed of the issues to look for before in order to avoid bias as the study aimed at respondent's experience. A checklist was then used to evaluate respondent's ability to distinguish between genuine and counterfeit drugs. The questionnaire captured the information on the sociodemographic characteristics, public perception on counterfeit drugs, source(s) of information on counterfeit drugs, and recommendations on measures to be taken to control the illicit trade in counterfeit drugs.

The four antimalarial drugs samples used were sulphadoxine-pyrimethamine 500/25 mg (Orodar®) made by Elys Chemical Industries Ltd. and its counterfeit and sulfametopyrazine-pyrimethamine (Laefin®) and its counterfeit (Figures 1 and 2). These drug samples were obtained from the Tanzania Food and Drugs Authority (TFDA), Mwanza branch. The above SP drugs have now been replaced by artemisinin based combination therapies (ACTs) as first lines of treatment of uncomplicated malaria and are only reserved for intermittent preventive treatment (IPT) for malaria during pregnancy. However, these drugs were picked because most patients still use them widely for treatment of uncomplicated malaria and they are the most reported to be counterfeited among antimalarial drugs in Tanzania.

**2.2. Data Processing and Analysis.** Data was analysed using the Statistical Package for Social Sciences (SPSS) version 20. Chi-square and Fischer's exact tests were performed for determining association between independent variables and public ability to distinguish counterfeit antimalarial drugs. Strength of association of public ability to distinguish counterfeit drugs with independent variables was analysed by using bivariate logistic regression analysis. Odds ratios (OR) and 95% confidence intervals (95% CI) were reported as a measure of effect. A *P* value of  $\leq 0.05$  was considered statistically significant.

**2.3. Ethical Consideration.** Ethical and study approval was granted by the joint Catholic University of Health and Allied Sciences/Bugando Medical Centre institutional review board. Further permission was sought from the regional medical officer, ward executive officers, and village executive leaders. All respondents signed written informed consent and were guaranteed privacy and confidentiality.

### 3. Results

**3.1. Sociodemographic Characteristics of the Interviewed Respondents.** In this study, a total of 293 respondents were enrolled; the mean age was 28 years (SD = 6.12). About 187 (63.8%) of the respondents were males and 106 (36.2%) were females. A total of 128 (43.7%) respondents had primary education and 3 (1%) had never been to school. The majority of respondents were married 206 (70.3%), whereas 87 (29.7%) were single. Among the respondents, 184 (62.8%) were unemployed (Table 1).

**3.2. Factors Enabling Respondents to Distinguish Counterfeit and Genuine Drugs.** Among the interviewed respondents, 163 (55.6%) were able to distinguish between a genuine and a counterfeit drug while 130 (44.4%) failed. The majority of the respondents with health profession (84%) were able to distinguish a genuine drug from a counterfeit antimalarial drug (*P* value 0.003) (Table 2).

**3.3. Information on Counterfeit Drugs.** The majority of respondents, 202 (68.9%), mentioned media to be a source of information on counterfeit drugs and only 12 (4.1%) mentioned health facilities as a source of information.

**3.4. Factors Affecting Ability to Distinguish between Genuine and Counterfeit Antimalarial Drugs.** Table 4 shows the association of factors enabling distinguishing between genuine and counterfeit drugs. There was a significant association between knowledge on health effects of counterfeit drugs

TABLE 1: Sociodemographic characteristics of the respondents.

Characteristics	Frequency	Percent
<i>Age group</i>		
18–28	76	25.90
29–39	137	46.80
40–50	60	20.50
51–61	13	4.40
Above 62	7	2.40
<i>Sex</i>		
Male	187	63.80
Female	106	36.20
<i>Respondents education</i>		
Primary	128	43.70
Secondary	72	24.60
College or above	90	30.70
None	3	1.00
<i>Marital status</i>		
Married	206	70.30
Single	87	29.70
<i>Respondent occupation</i>		
Health workers	25	8.50
Non-health workers	84	28.70
Unemployed	184	62.80

and knowledge of distinguishing features with distinction of genuine and counterfeit drugs ( $P$  value: 0.015 and 0.005), respectively.

Respondents who had knowledge on health effects of counterfeit drugs were nearly 3 times more likely to distinguish genuine and counterfeit drugs than their counterparts (OR = 2.95; 95% CI = 1.47–5.65). Those with health profession were 2.1 times more likely to distinguish between genuine and counterfeit drugs (OR = 2.16; 95% CI = 1.248–3.733) than non-health workers (Table 5).

**3.5. Distinguishing Features between Genuine and Counterfeit Drugs.** Respondents with knowledge on packaging material as a distinguishing feature were 5.7 times more likely to distinguish the drugs compared to those with knowledge on expiry date; similarly, those with knowledge on label/legitimacy were 7.4 times more likely to distinguish the drugs compared to those with knowledge on expiry date, both being of highly statistical significance with  $P < 0.0001$  (Table 6).

**3.6. Magnitude on the Concerns on Counterfeit Drugs.** In this study, most of the interviewed respondents, 190 (64.8%), reported the magnitude of counterfeit drugs to be a big problem, 99 (33.8) did not know the extent of counterfeit drugs, and a few, 4 (1.4%), reported that counterfeit drugs do not exist.

**3.7. Public Advice on Measures to Reduce Counterfeit Drugs Proliferation.** Most respondents, 134 (45.7%), reported that counterfeit drugs will be successfully reduced through sensitizing people's awareness against counterfeit drugs. Adherence to ethics, 87 (29.7%), strictness of entry points (borders), 41 (14%), and the necessity of authorizing pharmacy dealers, 17 (5.8%), were also suggested. Only a few respondents, 14 (4.8%), emphasized the need for TFDA to adhere to/carry on surveillance several times.

## 4. Discussion

The WHO and studies recommend the need for public awareness on the growing trade in counterfeit drugs and the public health risks associated with it [16, 21]. This study has explored public awareness and identification of counterfeit antimalarial drugs. Antimalarial drugs were chosen because they are the most counterfeited and are commonly used in developing countries such as Tanzania where malaria is endemic, the market of counterfeit antimalarial drugs is high, and self-medication is common [36, 37]. Therefore, it is expected that respondents frequently use antimalarial drugs and are mostly likely to recognize these drugs based on the past experience and frequency of use. Respondent's awareness and ability to identify counterfeit drugs qualitatively based on packaging, labelling, and appearance/colour are an important step towards creating suspicion and discouraging the illicit trade in counterfeit drugs for malaria and other conditions.

A substantial number of respondents were able to distinguish between genuine and counterfeit antimalarial drugs. This finding is encouraging with regard to the fight against illicit trade in counterfeit antimalarial drugs in developing countries where 200,000–450,000 deaths out of one million reported due to malaria result from the use of counterfeit or fake drugs [24, 29]. Recognition of counterfeit/fake drugs by the public is expected to decrease the purchase of such drugs in the market.

With regard to the correlation between knowledge on distinguishing features and ability to identify counterfeit drugs, the majority of those who had knowledge on labelling as a way of identifying a counterfeit drug were able to identify counterfeit antimalarial drugs (Table 4). A similar observation is recorded with those who knew packaging material is used in identifying counterfeit drugs (Table 4). A significant proportion of those with knowledge on expiry date and country of origin as distinguishing features used were also able to identify counterfeit drugs compared to those aware of brand name.

The majority of the respondents (84%) with health profession background were able to distinguish genuine against counterfeit antimalarial drugs compared to their counterparts who did not have health profession background (Tables 2 and 4). This finding is encouraging since health care workers are supposed to be in a front line in the fight against counterfeit drugs as per WHO recommendation [2]. However, when logistic regression was performed, health profession background was not a strong predictor for identification of counterfeit antimalarial drugs (Table 5).

TABLE 2: Sociodemographic characteristics of the respondents and the ability to distinguish between genuine and counterfeit drugs.

Characteristics	Ability to distinguish between genuine and counterfeit drugs		Chi-square	P value
	Yes	No		
	N = 163 n (%)	N = 130 n (%)		
<i>Age group</i>				
18–28	45 (59.2)	31 (40.8)	1.121	0.891
29–39	72 (52.6)	65 (47.4)		
40–50	35 (58.3)	25 (41.7)		
51–61	7 (53.8)	6 (46.2)		
Above 62	4 (57.1)	3 (42.9)		
<i>Sex</i>				
Male	104 (55.6)	83 (44.4)	0.000	0.994
Female	59 (55.7)	47 (44.3)		
<i>Education level</i>				
Primary	68 (53.1)	60 (46.9)	2.088	0.554
Secondary	39 (54.2)	33 (45.8)		
College or above	55 (61.1)	35 (38.9)		
None	1 (33.3)	2 (66.7)		
<i>Marital status</i>				
Married	113 (54.9)	93 (45.1)	0.170	0.680
Single	50 (57.5)	37 (42.5)		
<i>Respondent's occupation</i>				
Health workers	21 (84.0)	4 (16.0)	8.912	0.003
Non-health workers	142 (53.0)	126 (47.0)		

TABLE 3: Distribution of respondents according to source of information on counterfeit drugs.

Source of information on counterfeit drugs	Frequency	Percent
Media	202	68.90
Relatives and friends	49	16.70
Schools	16	5.50
Advertising materials	14	4.80
Health facilities	12	4.10
<i>Total</i>	293	100.00

The only strong predictor for identification of counterfeit drugs recorded was knowledge on health effects of counterfeit drugs (Table 5).

Conversely, age, sex, education level, and marital status were not borne out to be determinants for identification of counterfeit drugs (Table 2).

The media were established as the main source of information on counterfeit drugs to the community (Table 3). Respondents perceived the presence of counterfeit drugs in the community to be a big problem. Respondent's views on how to reduce the magnitude of counterfeit drugs include sensitizing people awareness against counterfeit drugs, adherence to ethics, strictness of entry points, and the

necessity of authorized pharmacy dealers and adherence to surveillance several times by the FDA.

Community involvement is a neglected issue in the fight against the illicit trade in counterfeit drugs. The present study establishes a need for further empowering the community to enable consumers to identify/suspect counterfeit or fake drugs for common diseases/conditions such as malaria based on physical observation, thus acting as a primary source of information to FDA which will further confirm the suspicion of counterfeit drugs by employing laboratory techniques.

## 5. Conclusion

A substantial proportion of respondents were able to distinguish between genuine and counterfeit drugs. The main source of information on counterfeit drugs was the media. There is a need of empowering the public in identifying counterfeit drugs for common diseases like malaria by simple observations as a major step towards discouraging the market of counterfeit drugs and part of postmarketing surveillance.

## Abbreviations

TFDA: Tanzania Food and Drug Authority  
 FDA: Food and Drug Authority  
 WHO: World Health Organization.

TABLE 4: Association of factors affecting ability to distinguish between genuine and counterfeit drugs.

Factors	Ability to distinguish between genuine and counterfeit drugs		Chi-square	P value
	Yes	No		
	N = 163 n (%)	N = 130 n (%)		
<i>Knowledge on health effects of counterfeit drugs</i>				
Yes	138 (58.2)	99 (41.8)	3.387	0.015
No	25 (44.6)	31 (55.4)		
<i>Knowledge on economic effects of counterfeit drugs</i>				
Yes	30 (47.6)	33 (52.4)	2.087	0.149
No	133 (57.8)	97 (42.2)		
<i>Knowledge of distinguishing features</i>				
Label/legitimacy	68 (54.4)	57 (45.6)	8.736	0.005
Packaging material	50 (55.6)	40 (44.4)		
Expiry date	23 (57.5)	17 (42.5)		
Country of origin	7 (63.6)	4 (36.4)		
Brand name	9 (47.4)	10 (52.6)		
ISO certification	6 (75.0)	2 (25.0)		
<i>Source of information on counterfeit drugs</i>				
Media	108 (53.5)	94 (46.5)	4.977	0.290
Relatives and friends	26 (53.1)	23 (46.9)		
Schools	10 (62.5)	6 (37.5)		
Advertising materials	9 (64.3)	5 (35.7)		
Health facilities	10 (83.3)	2 (16.7)		

TABLE 5: Logistic regression on factors associated with identification of genuine and counterfeit drugs.

Factors	Ability to distinguish between genuine and counterfeit drugs		OR (95% CI)	P value
	Yes	No		
	N = 163 n (%)	N = 130 n (%)		
<i>Knowledge on health effects of counterfeit drugs</i>				
Yes	138 (58.2)	99 (41.8)	2.954 [1.47–5.65]	0.003
No	25 (44.6)	31 (55.4)	1	
<i>Respondent's occupation</i>				
Health workers	21 (84.0)	4 (16.0)	2.158 [1.248–3.733]	0.006
Non-health workers	142 (53.0)	126 (47.0)	1	

TABLE 6: Association of distinguishing features and identification of genuine and counterfeit drugs.

Distinguishing features	N	(%)	OR	P value (95% CI)
Expiry date	40	13.7	1	
Packaging material	101	34.5	5.7	P < 0.0001 (3.7–12.7)
Label/legitimacy	152	51.9	7.4	P < 0.0001 (4.1–15.6)

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## Competing Interests

The authors declare that they have no competing interests. The financial support offered by the university to the main author as part of his studies does not lead to any conflict of interests.

## Authors' Contributions

Karol J. Marwa participated in proposal development, sample collection, data analysis, and paper drafting and submitting. Linus Mhando participated in proposal development, sample collection, data analysis, and paper drafting. Mary B. Jande,

Stanley Mwita, and Anthony Liwa participated in proposal development, paper revising, and approval for publication.

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