

# Counterfeit Medicine: Knowledge and Experience among Indigenous People in Remote and Urbanised Settlements in Malaysia

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## Abstract

Under-recognition of counterfeit medicines is worrisome in the face of their growing span. Universal existing low levels of knowledge on health and accessibility of health information in indigenous populations may lead to inadvertent use of these counterfeits. Face-to-face interview using a structured questionnaire was carried out on indigenous adults residing in urbanised and remote settlements in Malaysia to assess their knowledge and experience with counterfeit medicines. Male gender, being in employment, having a secondary level of education and being from a urbanised settlement is significantly associated with having better knowledge on counterfeit medicines. However, despite better knowledge found in the urbanised settlers, majority of respondents were not able to discern the characteristics of counterfeit and genuine registered medicines. Improved manner of education and communication pertaining to counterfeit medicines are urgently needed to reach as well as attract individual subsets of the indigenous communities.

**Keywords:** *counterfeit medicines, indigenous populations, knowledge, Malaysia*

## 1. Introduction

Counterfeit medicines are a serious threat to public safety and continue to be a major problem in both industrialised and developing countries.<sup>1,2,3,4</sup> To date, there is no universal definition for counterfeit

medicines and its definition varies from one country to another. WHO has previously defined counterfeit medicines as those which are deliberately and fraudulently mislabeled with respect to identity and/or source and may include products with correct or wrong ingredients, without active ingredients, with insufficient or inadequate quantities of ingredient(s) or with fake packaging.<sup>5</sup>

The exact prevalence of medicine counterfeiting in Malaysia, an upper middle-income country is unknown. However, the implementation of Meditag<sup>TM</sup> hologram for authentication of registered products, enhanced enforcement and awareness programmes have been reported to successfully reduce its number. From 10,478 unregistered products seized by the government enforcement officers in 2002, 2.23% were found to be counterfeit products while out of 27,836 unregistered items seized in 2013, only 0.42% were counterfeits.<sup>6</sup>

A number of factors have been reported to contribute to the usage of counterfeit medicines around the world, namely, demand of affordable products, ineffective enforcement of the existing laws, distance from healthcare providers and inadequate awareness and knowledge.<sup>7,8</sup> For example, a multi-centred survey carried out throughout Malaysia in 2008 to determine the awareness and perception among public towards the use of Meditag<sup>TM</sup> hologram as a form of product authentication found that only 36.7% of the 3000 public respondents were aware of the use of Meditag<sup>TM</sup> hologram.<sup>9</sup>

The indigenous minority of the Peninsular Malaysia

or better known as the Orang Asli mainly reside on reserved lands called Asli Reserve Land.<sup>10</sup> The land reserves can be divided into suburban settlements; which are within the vicinity or outskirts of existing rural villages; and remote settlements located distant from the main road or town and can only be reached by using multipurpose vehicles due to inconvenient geographical area and rocky trails access. In addition, remote settlements may not have 24 hours supply of electricity, continuous water and other basic facilities.<sup>10,11,12</sup>

Health status and health-related knowledge disparities among indigenous people globally and in Malaysia have been previously reported.<sup>10,13,14,15</sup> In view of lower accessibility to source of genuine medicines subsequently risk of exposure to counterfeits, the need to evaluate their knowledge and experience towards counterfeit medicines arises.

## 2. Materials and Methods

This was a cross-sectional study conducted using face-to-face interview of close-ended questionnaires aimed at assessing knowledge of and experience with counterfeit medicines among study populations residing in urbanised and remote settlements. Urbanised study population comprised of indigenous people residing in Bukit Tadam, a suburban settlement within 20 kilometers to the national administrative capital, Putrajaya. The indigenous people in Pos Piah village, located in a hilly region 60 km from Sungai Siput, a small town in the state of Perak constitutes the remote study population.

Approval by the Department of Orang Asli Development, Malaysia (JKOA) was obtained prior to research. Consent from the heads of the indigenous settlements and individual informed consent were obtained prior to data collection period to respect the sovereignty of these communities. Subjects of this study were recruited purposively through the village heads who acted as middlemen in helping to identify potential respondents that meet the inclusion criteria. Individuals  $\geq 18$  years old were invited to participate in this study and are excluded if they could not understand any of the following languages: Bahasa Melayu, English, Mandarin or Tamil, or had cognitive or hearing impairment.

Sample size was calculated according to  $Z^2 \times (p) \times [(1-p) / C^2]$  where  $Z$  is the standard normal distribution = 1.96 at 95% confidence interval;  $p$  is the hypothesised proportion of outcome of interest and  $C$  is the acceptable allowable error of 0.05. Sample sizes were then corrected according to the

estimated population of both the urbanised and rural settlements.

A structured questionnaire comprises of 3 sections to determine demographic information, knowledge and experience with counterfeit medicines of the studied subjects. The study tool was developed by adaptation of a tool for visual inspection of medicines provided by World Health Professions Alliance (WHPA).<sup>16</sup> Additional questions and features were adopted and adapted from books, published articles and Malaysia's Ministry of Health (MOH) website on counterfeit medicines.<sup>17,18,19</sup> Translation into Malay language was prepared once the questionnaire had been reviewed by 2 experts in the public health and pharmacy fields. Two independent translators were appointed to facilitate in the translation process.

A pilot study was carried out on 20 respondents to determine face validity of the study tool and appropriate amendments were carried out prior to final data collection. Reliability was determined by calculating the Cronbach  $\alpha$  coefficients in which the values for knowledge domain was 0.70 and experience domain was 0.78.

The final questionnaire had multiple choice questions encompassing definition and characteristics of counterfeit and registered (genuine) medicines. Each correct response was given a score of 1 point for a total of 10 points. Subsequently, those who scored 7-10 points were classified as having good knowledge, 4-6 points were classified as moderate knowledge while a score of 0-3 points was classified as having poor knowledge. Six questions encompassing physical appearance of the medicine and its packaging, presence of surface holographic authenticity marker and labelling, were utilised to assess the experience of respondents on the use of potential counterfeit medicines.

Data was arranged, classified and analysed using Statistical Package for Social Sciences (SPSS) software version 22.0. Descriptive and inferential statistics were utilised as appropriate to analyse the data.

## 3. Results

The mean age (SD) of the 244 respondents were 34.93 (12.71) and 38.87 (13.53) years for remote and urbanised settlements respectively and majority of the respondents were female (Table 1). All remote respondents were from the Temiar tribe while

majority of the urbanised population was from the Temuan tribe. There were statistically significant association between types of settlements with highest education qualification, nature of employment and monthly income ( $P < 0.05$ ).

This study found that only 33.2% ( $n = 81$ ) of the respondents from both the remote and urbanised settlements have good knowledge on counterfeit medicine while the remaining showed moderate and poor knowledge levels (Table 2). However, male respondents found to have better knowledge compared to female respondents (5.68 vs 4.54;  $P < 0.001$ ), those who did not obtain formal education scored statistically lower than others ( $P < 0.001$ ) and unemployed and housewives scored statistically lower than those in employment ( $P < 0.001$ ). Respondents without regular income also scored lower than those who earn  $> RM 1000$  per month (4.40 vs 6.36;  $P < 0.001$ ).

**Table 1. Socio-demographic background of the study respondents**

Characteristic	Mean (SD)		P Value*
	Remote n = 141	Urbanised n = 103	
<b>Age</b>	34.93 (12.71)	38.87 (13.53)	0.021 <sup>a</sup>
	Frequency (%)		
	Remote	Urbanised	
<b>Gender</b>			0.998 <sup>b</sup>
Male	52 (36.9)	38 (36.9)	
Female	89 (63.1)	65 (63.1)	
<b>Tribe</b>			
Temiar	141 (100.0)	0 (0)	
Temuan	0 (0)	101 (98.1)	
Semelai	0 (0)	2 (1.9)	
<b>Highest education qualification</b>			$<0.001^b$
No formal education	64 (45.4)	7 (6.8)	
Primary school	62 (44.0)	51 (49.5)	
Lower secondary school	9 (6.4)	28 (27.2)	
Upper secondary school & above	6 (4.3)	17 (16.5)	
<b>Employment status</b>			0.006 <sup>b</sup>
Working			
outside village	6 (4.3)	18 (17.5)	
inside village	58 (41.1)	32 (31.1)	
Unemployed	20 (14.2)	8 (7.8)	
Housewife	55 (39.0)	43 (41.7)	
Student	2 (1.4)	2 (1.7)	
<b>Monthly income</b>			0.002 <sup>b</sup>
Less than RM500	46 (32.6)	20 (19.4)	
RM500 – RM999	8 (5.7)	15 (14.6)	
RM1000 & above	7 (5.0)	15 (14.6)	
No regular income	80 (56.7)	53 (51.4)	

<sup>a</sup>Independent Sample T-test

<sup>b</sup>Pearson's Chi-squared test

\*  $P < 0.05$  shows statistical significance

**Table 2. Knowledge on counterfeit medicine among the respondents**

Knowledge classification		Frequency (%)	
		N = 244	
Good (7-10)		81 (33.2)	
Moderate (4-6)		85 (34.8)	
Poor (0-3)		78 (32.0)	
Socio-demographic background		Mean knowledge score (SD)	P value*
		N	
<b>Gender</b>			
Male	90	5.68 (2.36)	$<0.001^a$
Female	154	4.54 (2.45)	
<b>Highest education qualification</b>			
No formal education	71	3.11 (2.06)	$<0.001^c$
Primary school	113	5.31 (2.28)	
Lower secondary school	37	6.35 (1.87)	
Upper secondary school and above	23	6.7 (1.94)	
<b>Employment Status</b>			
Working	114	5.56 (2.28)	0.001 <sup>c</sup>
Unemployed	28	4.25 (2.56)	
Housewife	98	4.40 (2.50)	
Student	4	6.50 (2.52)	
<b>Monthly income</b>			
Less than RM500	66	5.32 (2.34)	$<0.001^c$
RM500 to RM999	23	5.83 (2.04)	
RM1000 and above	22	6.36 (2.13)	
No regular income	133	4.40 (2.52)	

<sup>a</sup>Independent Sample T-test

<sup>c</sup>One-way ANOVA with post-hoc analysis

\*  $P < 0.05$  shows statistical significance

Respondents from the remote settlement were found to have statistically lower knowledge than those from the urbanised settlement (4.55 (2.58) vs 5.52 (2.20);  $P = 0.002$ )(Table 3). The descriptive analysis of the knowledge on counterfeit medicines found that although more respondents from the urbanised settlement answered most knowledge questions correctly, majority of respondents from both settlements were unable to discern the characteristics of counterfeit and genuine medicines.

**Table 3: Comparison of knowledge between respondents from remote and urbanised settlements**

Knowledge score	N	Mean (SD)	P value*
Remote settlement	141	4.55 (2.58)	0.002 <sup>a</sup>
Urbanised settlement	103	5.52 (2.20)	
Knowledge on counterfeit medicines among studied subjects		Frequency (%)	
		Remote settlement N = 141	Urbanised settlement N = 103
1. Characteristic of counterfeit medicines		53 (38)	43 (42)
2. Example of counterfeit medicines		64 (45)	61 (59)
3. Negative impact of counterfeit medicines		81 (57)	81 (79)
4. Ways to reduce sale of counterfeit medicines		46 (33)	42 (41)

5. Locations counterfeit medicines can be found	85 (60)	92 (89)
6. Governing bodies responsible in approving genuine medicines	78 (55)	80 (78)
7. Characteristic of registered medicines	69 (49)	62 (60)
8. Properties of registered medicines	61 (43)	46 (45)
9. Benefit of using genuine antibiotics	51 (36)	37 (36)
10. Characteristic of genuine registered traditional medicines	53 (38)	25 (24)

<sup>a</sup>Independent Sample T-test

\* P <0.05 shows statistical significance

Table 4 depicts the frequency of using potential counterfeit medicine in the past among the respondents, based on characteristics of counterfeit medicine adopted from WHPA's checklist.<sup>16</sup> Respondents from the remote settlements reported to have experienced using medicines without or with false holograms as the most frequent (n= 21, 14.9%) while respondents in the urbanised settlement reported experiencing using medicine with presence of embedded surface spots or visible contaminations on the tablets/capsules as the most common (n= 24, 23.3%). Interestingly, the urbanised respondents was found to be statistically more frequent in encountering medicines with visible contaminations than those from the remote area (24 vs 16; P = 0.011).

**Table 4: Experience of using potential counterfeit medicine based on the defined characteristics**

Characteristics of potential counterfeit medicine encountered by studied subjects	Frequency (%)		P value <sup>b</sup>
	Remote settlement N = 141	Urbanised settlement N = 103	
1. Without proper seal and closure of the container	17 (12.1)	11 (10.7)	0.739
2. Absence of hologram and no change colour of hologram (if presence) when viewed from different angle	21 (14.9)	14 (13.6)	0.775
3. Absence of drug strength	9 (6.4)	9 (8.7)	0.487
4. Absence of date of manufacture and the expiry date	9 (6.4)	9 (8.7)	0.487
5. Presence of embedded surface spots or contamination on the tablets/ capsules	16 (11.3)	24 (23.3)	0.011
6. Presence of empty capsules in the capsule blister packaging	9 (6.4)	9 (8.7)	0.487

<sup>b</sup> Pearson's Chi-squared test

\* P <0.05 shows statistical significance

## 4. Discussion

The mean age of respondents in both settlements were relatively young since most of the elderly had to be excluded from the study due to language barrier. However, majority do not have any formal education or only completed primary school as their highest academic qualification and these characteristics were more pronounced in the remote settlement. Similarly, those from the remote settlement were also statistically associated with no or lower monthly income. This corresponds with previous publications which stated that almost half (49.2%) of local indigenous people were illiterate, while the main remainder have primary education.<sup>20</sup> A study among indigenous people in Perak also reported relatively low quality of education due to limited accessibility to an educational institution.<sup>21</sup>

Only 33.2% of the respondents in this study have good knowledge regarding counterfeit medicines and statistically significant lower knowledge was also measured in females, those without formal education and those without regular monthly income. The gender difference is mirrored by previous studies which have also demonstrated gender disparities in health-seeking behaviours of rural and indigenous communities.<sup>22</sup> This observation is attributed to lesser work-related mobility thus lower exposure to outside source of health-related information for females of the communities in whom majority are housewives, which are expected of their culture. Good education is needed to ensure future occupational opportunities and earning potential, hence providing knowledge and life skills that allow ready access to health information. High educational attainment also improves health directly and indirectly through work and economic conditions, social-psychological resources, and healthy lifestyles.<sup>23</sup>

Higher level of knowledge on counterfeit medicine were seen among respondents living in the urbanised settlement compared to those in the remote settlements. Although still unsatisfactory, more urbanised settlers were able to identify the characteristics of genuine and fake medicines since access to health information is possible due to being near to the town area and healthcare facilities and better accessibility to mass media.<sup>24,25,26</sup> Regular contact with other communities as a source of health information is another possible attribute to higher knowledge among the urbanised Orang Asli settlers since a higher fraction of them are working outside of their village as security guards, laborers, factory workers, and vegetable sellers.<sup>15</sup> Of the 10 items asked, item 5 which asked on the possible locations



of where counterfeit medicines can be bought was answered correctly the most by both groups of respondents. This translates to respondents being able to identify that counterfeit medicines have been seen being sold at night and at street markets. This worrying trend has also been previously reported where street vendors were found to be the highest marketplace for counterfeit medicines in developing countries and should warrant appropriate immediate measures to eradicate such activities.<sup>27</sup>

This study also found that a disturbing number of potential counterfeit medicines have been encountered by respondents from both settlements. Although the medicines reported in this study may be of substandard rather than counterfeit, the data gathered should be able to provide some clues on the current trends as prevalence of counterfeit medicine usage among Malaysian indigenous population has never been reported previously. Current national awareness programmes have correctly emphasised on the ways to identify genuinely registered medicines which are the identification of product registrations numbers and presence of Meditag™ holograms.<sup>28</sup> However, we also found that it is also beneficial to highlight the characteristics of substandard and counterfeit medicines as clearly outlined by the visual tool provided by WHPA to ensure better knowledge. This will also assist the public in differentiating genuine and fake medicines better.

This study recorded a predominance of female respondents who were housewives. Majority of the male respondents were not available during the data collection period due to working obligation as most of them are self-employed. Elderly respondents had difficulties in understanding interview questions due to limited Malay language vocabulary and had to be excluded from this study. Potential encounter with counterfeit medicine were recorded based on respondents' recall on their experience with counterfeits. As a result, the respondents may not fully depict their true experience, which is a recognised limitation in this study.

## 5. Conclusion

Majority of respondents in this study were not able to discern the characteristics of counterfeit and genuine registered medicines despite much efforts put in by both the government and non-governmental organizations (NGOs) in educating the public on medicine counterfeiting in Malaysia. Therefore, a slightly different approach might be needed to ensure the knowledge is appreciated by indigenous

populations especially those living in the remote area where language barrier is evident. Organising comprehensive community-based programmes in the remote settlement that are customised to the local language, belief and social culture should be highly encouraged to increase their understanding. Such programmes should avoid the use of complex medical terminologies, use simple yet practical visual aids and conducted in an informal and interesting manner. Negative prejudicial attitudes of the healthcare workers against ethnic minority groups should also be addressed and removed to attract and obtain their trust in modern practice and genuine medicines.<sup>29</sup> Free medical check-ups followed by dispensing free medicines should be incorporated in the community-based programmes which will help in reducing their financial burden, eliminating their reliance on traditional herbs and counterfeit medicines.<sup>30</sup>

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