

#### ORIGINAL RESEARCH

# Concern on Skin Lightening Product Safety: Level of Awareness and Associated Factors Among Female Users in Bahir Dar City, Ethiopia

Ashagrachew Tewabe Yayehrad 101, Abel Lule 102, Adugna Tasew Tebabal 102, Muhammed Esmael 3, Nuralhuda Risqey<sup>3</sup>, Samrawit Temesgen<sup>3</sup>, Selam Negash<sup>3</sup>, Selama Hamid<sup>3</sup>, Silenat Tasew<sup>3</sup>, Sosina Mekonen<sup>3</sup>, Ebrahim Abdela Siraj 101

Department of Pharmacy, School of Health Sciences, College of Medicine and Health Sciences, Bahir Dar University, Bahir Dar, Ethiopia; Dean Office, GAMBY Medical and Business College, Bahir Dar, Ethiopia; 3Department of Pharmacy, School of Medicine, GAMBY Medical and Business College, Bahir Dar, Ethiopia

Correspondence: Ashagrachew Tewabe Yayehrad, Department of Pharmacy, School of Health Sciences, College of Medicine and Health Sciences, Bahir Dar University, PO BOX: 79, Bahir Dar, Ethiopia, Tel +251 912 960 525, Email ashutewabe@gmail.com

Background: Most skin lightening products are composed of some toxic chemicals such as mercury and hydroquinone which are classified under critical ingredients which need evaluation. Consumption without sufficient awareness may lead to toxicities endangering skin health.

**Objective:** The aim of this study was to assess the level of awareness towards the side effects of skin lightening products and associated factors among females in Bahir Dar city, Ethiopia.

Methods: An institutional-based cross-sectional study design was conducted in Bahir Dar city from June 28 to August 28, 2022 among females that had been using skin whitening. Samples of 362 females were selected by using multistage sampling technique from selected drug retail outlets. The data was coded, cleaned, and analyzed by using SPSS version 26. The variables were analyzed through multiple regression in order to identify the associated factors towards the level of awareness on the side effects of skin lightening products.

**Results:** Only 42.7% of the respondents had a favorable level of awareness. The highly influencing factors for using skin lightening products were peer pressure (39.9%) and social media (37.4%). Nearly half of the users experienced side effects. Only 8.9% of the respondents know the active ingredients of the products. Level of education was found to have significant association with level of awareness (AOR = 7.66, 95% CI: (1.23, 47.59); P = 0.029).

Conclusion: Only less than half of women have favorable awareness towards skin lightening products they use. The significant association between educational level and level of awareness should be considered as an alternative intervention in addition to regulatory restrictions.

Keywords: skin lightening product, awareness, safety, side effects, Ethiopia

### Introduction

Skin lightening is a skin de-pigmenting cosmetic practice with the purpose of making the skin tone bright or enhancing the complexion. This can be achieved by lessening the melanin concentration attempting to reduce its physiological skin-coloring effect. Skin lightening products (SLPs) contain elements such as arbutin, kojic acid, mercury, ascorbic acid, and hydroquinone that cause skin safety problems such as rash, melasma and irreversible darkening.<sup>2</sup> A systematic review on SLPs and their ingredients for safety, and health risk categorized the sources of ingredients with safety into three broad categories: Halal-Safe, Haram-Prohibited, and Critical-Need for Evaluation. Based on this categorization, mercury, zinc oxide, titanium oxide, arsenic, and hydroquinone are classified as critical ingredients which need evaluation.<sup>3</sup> Females use these products to treat skin problems such as dark spots, acne scars, or hormone-related discolorations, and to enhance bleaching. SLPs act on the skin

through different mechanisms such as inhibition of tyrosinase transcription, hastening of epidermal turnover, inhibition of melanosome transfer, and countering inflammatory and free radical activities.<sup>5</sup> As the rate limiting step in melanin production is arbitrated by tyrosinase enzyme, acting on this enzyme will have a determinant effect on skin patterns.<sup>6</sup>

Reports indicated that skin-lightening practice is being habituated among ladies, even without a medical consultation. The products are also being available in drug retail outlets as over-the-counter (OTC) agents. These destitute health practices, allied with the obsession with and wish for fair skin particularly in dark-skinned cultures, may aggravate and complicate safety concerns regarding such products. Up to 10% of previously studied populations reported some types of skin side effects including irritant contact dermatitis and skin sensitiveness to foreign substances. Skin lightening is more popular cosmetic practice among women living in many African countries like Nigeria (75%), Senegal (60%), Mali (50%), and Ghana (30%). South Africa rated lower prevalence after banning hydroquinone-based cosmetics and OTC dispensing. Rwanda, Côte d'Ivoire, Tanzania, Kenya, and Ghana have also put some restrictions on cosmetic consumption. Studies reported that female's age, level of education, employment status, occupation, and marital status are the determinant factors towards the awareness on the safety of SLPs. Females may sometimes know that those products can cause some adverse effects but their awareness on the nature and severity of these complications may be non-favorable. Lack of formal health education and counseling, ignorance, lack of regulatory restrictions, and women's hobbies on beautifulness and attraction should be well addressed in order to restore cosmetics safety in females.

Cosmetics use and beauty care is a common practice in Ethiopia with a considerable increase in terms of number of users and variety of products. The consumption is even more prevalent in urbanized regions. On the bad side, cosmetics do not need marketing authorization in Ethiopia unlike other medicinal products. A study in southwestern Ethiopia revealed that dermatological products consumed by the people contain prohibited ingredients. Bahir Dar is the capital city of Amhara Regional State located in northwest Ethiopia. It is the first of the most beautiful, multi-cultural, and tourism-centered cities in the country. Evaluating the extent of SLP consumption from various aspects should lead to the development of targeted interventions aimed at changing perceptions and educating consumers of the potential consequences of their use. Hence, the aim of this study was to assess the level of awareness towards the side effect of SLPs and associated factors among females who are living in Bahir Dar city.

#### **Methods**

The study was conducted in Amhara Regional State, Bahir Dar City, Ethiopia. The study setting was all community pharmacies which are found in the city. There are six sub-cities, and in these sub-cities, there are 140 drug retail outlets (75 pharmacies and 65 drug stores). The city has an estimated projection population of 455,901 people from which 227,712 are females. An institutional-based cross-sectional study was conducted from June 28 to August 28, 2022 among females purchasing SLPs from drug retailers. All females below 18 years old, those who did not use SLPs or those who did not come to drug retails at the time of study were excluded from this study. Level of awareness of females towards SLP safety was considered as a dependent variable, while demographic characteristics were taken as predictor variables. The research was aimed to answer the questions that arise regarding the level of awareness of females towards SLP safety and the determinant factors for favorable awareness level.

A two-step stratified random sampling was used to collect the data in a way that makes it representative of the geography and population density of the city as illustrated by Figure 1. Sample size was determined by using population formula.

$$n=\frac{\left(Z_{a/2}\right)^2P(1-P)}{d^2}$$

Z = standard deviation of the normal distribution is 1.96 at CI = 95%; P = 75% (observed as common p value in most similar studies); d = 5% (margin of error to be tolerated); n = Minimum sample size.

From the population formula, sample size (n) was determined to be 288. Then, considering the non-respondent rate (5%) and a design effect (1.2) for a multi-stage sampling design, the total sample size became 362. A pre-tested, structured, self-administered questionnaire adapted from previous studies<sup>14–16</sup> was distributed to the selected retailers, and data was collected by the attending research group members who had been sufficiently trained about the objectives

Dovepress Yayehrad et al

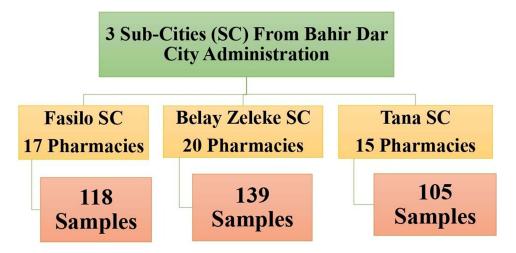


Figure 1 Schematic presentation of sampling procedure.

and the methods of the survey. The questionnaire included the demographic information (Age, Education level, Job, and Income) and questions to assess participant's level of awareness about their SLPs. Numbers of respondents range in 6–10 per pharmacy or drug store.<sup>17</sup> For respondents who could not write and read, the data collection team used an interviewer administered questionnaire. Ethical approval was obtained from the Ethical Review Committee of GAMBY Medical and Business College. The data collection was done in accordance with the Declaration of 110 Helsinki and all participants provided informed consent.

SPSS 26 was used to analyze the descriptive statistics. Bivariate and multivariable logistic regression analyses were used in order to identify truly associated factors and control confounding effects. Independent variables with a p-value of <0.25 were selected for multi-variable logistic regression analysis. Odds ratio (OR) with 95% CI was then computed for each variable for the corresponding P-value. The value of P < 0.05 was considered statistically significant. Knowledge score above the median score was considered as "favorable awareness", while a score below the median was considered as "non-favorable awareness". 18

#### Results

# Sociodemographic Characteristics of the Respondents

The study sample size was 362 respondents; thus, the response rate becomes 98.8%. Among the participants, 34.1% (n = 122) were above 45 years. Majority (98.6%) of the respondents are urban residents from which 42.2% had good awareness. Table 1 depicts the socio-demographic background of respondents.

# Skin Whitening Product Usage Pattern of Females

About two-thirds of the respondents expedite about 200–500 birr monthly for SLPs. The highly influencing factor for using the products was peer pressure from friends (39.9%). The reason for nearly one-third of the respondents to use SLPs is to bleach their skin. Nearly half of the users experienced SLP-related side effects. The detail of SLP consumption pattern of females in Bahir Dar is presented in Table 2.

### Awareness of Women Towards SLPs

The mean and median scores from awareness evaluating questions are 3.5 and 3, respectively. The overall skin lightening awareness among female users is only 42.7%. About 99.7% (n = 357) of the users know the name of consumed products of which 42.8% had favorable awareness. Only 8.9% of the respondents know the active ingredients of the products. Table 3 summarizes the results on awareness-related data.

Table I Socio-Demographic Background of Respondents (n = 358)

Variables		Level of Aw	Level of Awareness		Chi-Square
		Non-Favorable Awareness	Favorable Awareness		(P-value)
Age	18–30 31–45	68(33.2) 57(27.8)	48(31.4) 63(41.2)	116(32.4) 120(33.5)	0.017
	>45	80(39.0)	42(27.5)	122(34.1)	
Residence	Rural Urban	I (0.5) 204(99.5)	4(2.6) 149(97.4)	5(1.4) 353(98.6)	0.090
Education Level	Cannot read and write Can read and write Primary school Secondary & above	8(3.9) 49(23.9) 49(23.9) 99(48.3)	2(1.3) 14(9.2) 27(17.6) 110(71.9)	10(2.8) 63(17.6) 76(21.2) 209(58.4)	0.000
Marital Status	Married Not married	110(53.7) 95(46.3)	80(52.3) 73(47.7)	190(53.1) 168(46.9)	0.797
Occupation	Governmental Private work House wife Others	49(23.9) 46(22.4) 41(20.0) 69(33.7)	34(22.2) 50(32.7) 23(15.0) 46(30.1)	83(23.2) 96(26.8) 64(17.9) 115(32.1)	0.165
Monthly Income in Ethiopian Birr	1000–3000 3001–5000 5001–7000 >7000	63(30.7) 31(15.1) 63(30.7) 48(23.4)	41(26.8) 30(19.6) 48(31.4) 34(22.2)	104(29.1) 61(17.0) 111(31.0) 82(22.9)	0.667

 $\textbf{Note} \hbox{: Statistically significant values are shown in bold (P-value < 0.05)}.$ 

**Table 2** Skin Whitening Product Usage Pattern of Females (n = 358)

Variables	Level of A	Level of Awareness		Chi-Square	
		Non- Favorable Awareness	Favorable Awareness		(P-value)
Monthly expenditure (Ethiopian Birr) on SLPs	200-500 501-800 801-1100 >1100	133(64.9) 43(21.0) 21(10.2) 8(3.9)	95(62.1) 29(19.0) 16(10.5) 13(8.5)	228(63.7) 72(20.1) 37(10.3) 21(5.9)	0.328
How often you purchase SLPs	Weekly Monthly Annually Occasionally	10(4.9) 150(73.2) 1(0.5) 44(21.5)	10(6.5) 100(65.4) 3(2.0) 40(26.1)	20(5.6) 250(69.8) 4(1.1) 84(23.5)	0.294
What influence you to use SLPs	Media (TV, radio) Social media Family Friends	19(9.3) 70(34.1) 27(13.2) 89(43.4)	10(6.5) 64(41.8) 25(16.3) 54(35.3)	29(8.1) 134(37.4) 52(14.5) 143(39.9)	0.237
SLPs make you look more beautiful?	Yes No	189(92.2) 16(7.8)	144(94.1) 9(5.9)	333(93.0) 25(7.0)	0.480

(Continued)

Table 2 (Continued).

Variables	Level of A	Level of Awareness		Chi-Square	
		Non- Favorable Awareness	Favorable Awareness		(P-value)
Your main reason to use SLPs?	To remove melisma To remove acne and acne dark spot To whiten my skin	58(28.3) 46(22.4) 68(33.2)	24(15.7) 33(21.6) 61(39.9)	82(22.9) 79(22.1) 129(36.0)	
	To be more beautiful and gain confidence	33(16.1)	35(22.9)	68(19.0)	
The most preferred body part you apply SLPs	Face only Upper part Lower part	174(84.9) 28(13.7) 3(1.5)	115(75.2) 36(23.5) 2(1.3)	289(80.7) 64(17.9) 5(1.4)	0.055
Satisfied with the outcome of SLPs	Yes No	191(93.2) 14(6.8)	141(92.2) 12(7.8)	332(92.7) 26(7.3)	0.715
Experienced side effects of SLPs such as: Inching on application area, Redness on cheeks and nose, Skin rash, Acne, Recurrent inflammation, Swelling around your eyes, Melasma, Irreversible darkening	No Yes	106(51.7) 99(48.3)	74(48.4) 79(51.6)	180(50.3) 178(49.7)	0.532

Note: Statistically significant values are shown in bold (P-value <0.05).

Abbreviation: SLPs, Skin Lightening Products.

**Table 3** Awareness Evaluating Questions for Women Towards SLPs (n = 358)

Awareness Evaluating Questions	Level of Awareness		Total		
		Non-Favorable Awareness	Favorable Awareness		
Have you ever heard about skin whitening products before use?	No	0	0	0	
	Yes	205(100)	153(100)	358(100)	
Do you know the name of the skin whitening products you use?		1(0.5)	0(0.0)	1(0.3)	
		204(99.5)	153(100)	357(99.7)	
Is a medical prescription and supervision necessary for SLPs?	No	203(99.0)	101(66.0)	304(84.9)	
		2(1.0)	52(34.0)	54(15.1)	
Do you know one or more of these SLP: Beta carotene, Kojic acid, Faiza,	No	9(4.4)	1 (0.7)	10(2.8)	
Hydroquinone, Hydrocortisone?	Yes	196(95.6)	152(99.3)	348(97.2)	
Do you know the active ingredients in skin whitening agents you use?	No	203(99.0)	123(80.4)	326(91.1)	
		2(1.0)	30(19.6)	32(8.9)	
Do you know that some skin lightening agents can harm your health?		202(98.5)	37(24.2)	239(66.8)	
		3(1.5)	116(75.8)	119(33.2)	

Abbreviation: SLPs, Skin Lightening Products.

Table 4 Factors Associated with Level of Awareness of Females Towards Skin Whitening Product

Variables	Level of Awareness (N = 358)		COR (95% CI)	AOR (95% CI)	P-value
	Favorable	Not Favorable			
Age	48(31.4)	68(33.2)			
18–30			1	1	0.017
31–44	63(41.2)	57(27.8)	1.57(0.94, 2.62)	1.39(0.66, 2.93)	0.381
≥45	42(27.5)	80(39.0)	0.74(0.44, 1.26)	0.88(0.39, 2.01)	0.764
Level of Education	2(1.3)	8(3.9)			
Cannot read and write			1	1	0.000
Can read and write	14(9.2)	49(23.9)	1.14(0.22, 6.01)	1.63(0.25, 10.40)	0.608
Primary school	27(17.6)	49(23.9)	2.20(0.44, 11.13)	3.57(0.57, 22.32)	0.174
Secondary & above	110(71.9)	99(48.3)	4.44(0.92, 21.43)	7.66(1.23, 47.59)	0.029*

Notes: I, reference group; \*Statistically significant (P<0.05).

Abbreviations: AOR, Adjusted odds ratio; COR, crude odds ratio; CI, Confidence interval; SLP, Skin lightning product.

# Associated Factors with Awareness of Females Towards SLPs

As presented in Table 4, the only independent variable that is significantly associated with the level of awareness was the level of education of females. Females with secondary and above educational status have 7.66 times more favorable knowledge than those who cannot read and write (AOR = 7.66, 95% CI: (1.23, 47.59); P = 0.029).

# **Discussion**

Beauty care products should be nontoxic, nonirritating, and safe for the clients. Consumers may use them through their life with or without being aware of the side effects. This may even be complicated specifically in countries like Ethiopia where the literacy rate is very low. <sup>12</sup> Skin lightening is perceived as a significant global health concern in developing countries. This further becomes more intricate under circumstances of non-favorable public awareness and scarce evidence on the safety and risks of the ingredients used in the manufacturing of SLPs. Our current study assessed the comprehensive awareness of women towards the SLPs they use. The study also tried to demonstrate correlations and associations of factors that predict the awareness level. The study revealed that the overall skin lightening awareness among female users is only 42.7%. This result is nearly similar with awareness of immigrant women in Rome, Italy, <sup>19</sup> better than women in Ghana, <sup>10</sup> but lower than those in Sudan South Africa where the awareness levels were 41.5%, 17.6%, 89.1%, and 85%, respectively. Consuming SLPs with lower level of community awareness may aggravate the possibility of risks from those products. Hence, the advancement of targeted interventions intended to optimize perceptions, educate the community, and change the practice is necessary.

The highly influencing factors for using SLPs were peer pressure from friends (39.9%) and social media (37.4%). This is in line with the habit of women in Sudan<sup>15</sup> and Zimbabwe,<sup>21</sup> where societal influences, whether in peer or media forms, have enumerable impact on using SLPs. Hence, educating some possible group of the society by any means will have a direct impact on the larger population. The result has also a great implication on using the social media for awareness creation about skin health risks and skin product safety. Beauty is an important factor as 93% of the respondents believed that the SLPs make them look more beautiful. Similarly, majority of women living in Jordan (62.3%) believed that lighter skin tone which is achieved by applying SLPs is considered more beautiful.<sup>17</sup>

Bleaching their skin was the most scored reason of using SLPs. The aspiration for white and fair skin is a common habit especially in non-white Asian, African, South American, and Middle-Eastern community who have their own traditions of skin lightening.<sup>22</sup> Yesuf et al<sup>23</sup> also confirmed that about 38.7% of East African women prefer a lighter skin color which is in line with the current result. A review on skin lightening safety underlined that the motivational factor for most African women towards seeking SLPs is cosmetic skin lightening than treating skin pigmentary disorders.<sup>8</sup> The study result explores the growup of that lightening culture into using modern products. Majority of women use SLPs for their faces only. This may be due to

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the desire and the common practice of using SLPs for aesthetic values as it is nowadays becoming common in both developed and developing nations such as some British, American, Caribbean, African, and Asian communities.<sup>5,24</sup>

Almost half of the respondents experienced at least some tolerable side effects from SLPs. Similar results are reported from other studies on the potential harmful effects of SLPs.<sup>19,25</sup> This is really expected as the chemical groups applied in SLP manufacturing are associated with particular undesirable effects. Exhaustive use of SLPs can also lead to severe pathological disorders including burns, acne, stretch marks, hypopigmentation, and even cancer. Furthermore, as most SLPs are often applied for very long-term durations, it is important to consider some unpredictable adverse effects.<sup>26</sup> Underestimated cutaneous and systemic side effects may occur from non-disclosed product components.<sup>27</sup> SLPs formulated with highly toxic ingredients are straightforwardly accessible from the market; i.e, their consumption can lead to diverse adverse events, with severe and even fatal complications. Hence, SLPs become an evolving health alarm in many countries.<sup>28</sup> Hence, regulatory restriction should be applied on such products in addition to enhancing public awareness. South Africa, Rwanda, Cote d'Ivoire, Tanzania, Kenya, and Ghana were some of the African countries which pose regulatory restrictions and bans on cosmetic marketing.<sup>29</sup> Lower consumption rate of SLPs is reported from countries which set banning and restrictions.<sup>28</sup>

Almost all of the respondents knew the name of the SLPs they use. However, only 8.9% knew the active ingredients in the product they use. The same was reported from Jordan where three-fourth of women did not know the ingredients of their SLPs. This results calls for emphasis on consumer counseling by dispensers and other health professionals about the nature of ingredients in SLPs and their potential side effects. Not more than half of them believed a medical prescription and supervision is necessary for the use of SLPs, while only one-third of them are aware of the harmful effects of SLPs. This is in line with a study report from Sudan where almost half of the women did not believe the skin harming effects of SLPs. This is an important result that should not be over-looked. These assumptions may be derived from their lucky safety experiences, the loose regulatory conditions, the free accessibility and the uncontrolled marketing practice of the products.

Level of education was found to be a significant factor for level of awareness towards health safety and risks associated with SLPs. About 71.9% of women with favorable knowledge are educated at least at a secondary level which also indicates the role of education in awareness of health risk and safety. This is similar to a study report from South Africa where women with more than ten years of education were favorably aware of SLPs and were less likely to involve in skin lightening habits.<sup>7</sup> Other study reports also showed that women with low educational level most often consume SLPs mainly because of their preference than based on scientific or medical evidences.<sup>17</sup>

There are certain limitations to this study. First, the cross-sectional-based study method may hinder the exact causation of factors. Second, the study population cannot denote all Ethiopian women. In addition, the psychological, political, and environmental factors are not assessed. Hence, population-based survey may be applied to maximize the results and recommendations at large. Nevertheless, the implication of this research for the policymakers, researchers, and the society may not be ignored.

### Conclusion

Cosmetics and personal care products should be nontoxic and should pose no risk under normal use. For this, not only appropriate manufacturing system, but also a favorable awareness towards their health risk during use is mandatory. It is observed from this study that only less than a half of the women have favorable awareness towards the SLPs they use. They consume those products due to peer and social media pressures mean the same influence can be used to limit the rate of SLP use without medical consultation. Women are using the products without knowing the type of ingredients they are manufactured from and they are experiencing some type of side effects from their products. Hence, consumers have to be aware about the side effects related to cosmetic products, and they should be alerted to seek information on their products from the labels, the dispensers, or other information sources. The significant association between educational level and level of awareness is another view which should be considered as an alternative intervention approach. Similarly, all stakeholders in cosmetic manufacturing, cosmetic marketing, dermatological research, regulatory authority, and in health care providing should consider the public health concerns related to cosmetics use. Auxiliary investigations are recommended to discern the acute and chronic effects of those cosmetics in this study as well as laboratory analysis of the ingredients to identify their toxic content and toxicity level.

# **Abbreviations**

OTC, Over the Counter; SLP, Skin Lighting Product.

#### **Author Contributions**

All authors made a significant contribution to the work reported, whether that is in the conception, study design, execution, acquisition of data, analysis and interpretation, or in all these areas; took part in drafting, revising or critically reviewing the article; gave final approval of the version to be published; have agreed on the journal to which the article has been submitted; and agree to be accountable for all aspects of the work.

# **Disclosure**

The authors report no conflicts of interest in this work.

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