



# Article Cosmetic Use-Related Adverse Events: Findings from Lay Public in Malaysia

Hazrina Hadi <sup>1</sup>, Nur'ain Ai <sup>2</sup>, Mazlina Zamli <sup>3</sup>, Ammar Ihsan Awadh <sup>4</sup>, Muhammad Zeeshan Zafar <sup>5</sup> and Shazia Jamshed <sup>6,7,\*</sup>

- <sup>1</sup> Pharmaceutical Technology, Kulliyyah of Pharmacy International Islamic University Malaysia, Bandar Indera Mahkota, Kuantan 25200, Pahang, Malaysia; hazrina@iium.edu.my
- <sup>2</sup> Department of Pharmacy, Hospital Wanita dan Kanak-kanak Sabah, Kota Kinabalu 88996, Sabah, Malaysia; mna.nurain@gmail.com
- <sup>3</sup> Department of Pharmacy, Hospital Sultanah Nur Zahirah, Jalan Sultan Mahmud, Kuala Terengganu 20400, Terengganu, Malaysia; amir.amira92@yahoo.com
- <sup>4</sup> Department of Pharmacy, Al-Esraa University College Baghdad, Baghdad 999048, Iraq; ammar.ehsan@esra.edu.iq
- <sup>5</sup> Department of Pharmacy, University of Sargodha, Sargodha, Punjab 40100, Pakistan; shanmughal11@gmail.com
- <sup>6</sup> Pharmacy Practice, Kulliyyah of Pharmacy, International Islamic University Malaysia, Bandar Indera Mahkota, Kuantan 25200, Pahang, Malaysia
- <sup>7</sup> Qualitative Research-Methodological Application in Health Sciences, Kulliyyah of Pharmacy, International Islamic University Malaysia, Jalan Gombak 53100, Selangor, Malaysia
- \* Correspondence: shazia\_jamshed@iium.edu.my

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**Abstract: Objectives:** Although the occurrence of adverse cosmetic reactions is often underestimated by the consumers, the documentation of the incident might be helpful for the authority in regulating the cosmetic products. The objectives of this study were to assess the prevalence and type of adverse cosmetic event (ACE), as well as the measures adopted by those experiencing the ACE. **Methods:** A cross-sectional descriptive study was conducted using a structured questionnaire comprised of 11 questions. The questionnaire was divided into two sections: demographic profile and adverse cosmetic reaction. A total of 552 cosmetic users in Malaysia participated in this study. Data were entered into Statistical Package for Social Sciences (SPSS) version 20 and descriptive statistics was applied. **Findings:** A total of 29% respondents have experienced ACEs. Eczema was found to be the most frequent type of ACE. Facial area (n = 178) was reported to be the most frequent body site affected by ACEs. A mere 41% attempted to consult health professionals. **Conclusions:** Few respondents consulted health professionals for recommendations, indicating that they misjudge occurrences related to adverse outcomes. The high diversity and non-specificity of cosmetic adverse reactions reported in the current research highlighted the need for a vigorous cosmetovigilance system.

Keywords: cosmetic; cosmetovigilance; eczema; skin; adverse event

# 1. Introduction

According to the World Health Organization (WHO), adverse drug reaction is defined as an unintended and noxious response to a cosmetic that normally occurs after a correct application of a cosmetic, whereas an adverse cosmetic event (ACE) is an anticipated noxious injury hypothetically related to a cosmetic use [1–3].

It is a known fact that the use of cosmetics can sometimes evoke adverse reactions. A large body of research evidence reported severe cosmetic reactions such as hair loss, blistering, breathing problems,

loss of consciousness, dizziness, skin burns, and nausea [4]. Søsted (2007) found 17 respondents (1.4%) had edema and suppuration/ulceration and 67 respondents (5.3%) had either eczema with or without edema and/or suppuration/ulceration after hair coloring. It should be noted that the occurrence of an allergic reaction to cosmetics is found to be caused more frequently by preservatives [5–9]. Lindberg et al. (2004) discovered a significant difference between DMDM hydantoin (formaldehyde releaser, a preservative that was commonly used) with females who reported previous or present adverse reactions that had positive patch tests in the study [10].

To date, the number of reported adverse cosmetic reactions that are known is relatively low because of self-diagnosis (due to the absence of medical consultation) and self-medication, which are common in the presence of mild to moderate skin reactions. However, the adverse cosmetic reactions are still underestimated even in the presence of medical consultation. The most common symptoms of adverse effects are erythema, itching, scaling, and a burning sensation, as the reactions are usually localized on the skin (cutaneous reactions). The most common effects are irritant contact dermatitis and allergic contact dermatitis [2,6-8].

Cosmetic safety regulations are designed to prevent hazardous products entering the market or reaching the consumers and as well as to inform the user on the safe use of cosmetics. A few distinct examples include the Food and Drug Administration in the United States, the Europe Union (EU) Regulation 1223/2009 in Europe, the Pharmaceutical Affairs Law (Law No. 145) applied by Japan's Ministry of Health, Labor and Welfare, and the Food and Drug Act and the Cosmetic Regulations applied by Health Canada. In harmony to the ASEAN Cosmetic Directive, the Guidelines for the Control of Cosmetic Products in Malaysia is prepared and created [11].

Despite the regulations, consumers still may encounter undesirable effects after using cosmetic products. Adverse reactions from the use of cosmetic products were commonly experienced by the participants. However, ACEs are still under reported [12–14].

Hence, the aim of this study was to assess the prevalence and characteristic of ACEs reported by the respondents in Malaysia and to determine the type of measures adopted by them.

#### 2. Materials and Methods

This study was carried out in September 2016 after obtaining approval from the International Islamic University Malaysia Research Ethics Committee IREC (IREC\_registration number IREC 587).

The developed questionnaire consisted of two parts: (1) demographic profile and (2) adverse cosmetic reaction. The demographic profile section consisted of 11 questions, and the respondents were required to declare their gender, age, marital status, race, location, education background, occupation, income range, monthly expenditure on cosmetic products, the place where they often buy their cosmetic products, and the experienced of adverse cosmetic reaction by choosing one of the options provided in the questionnaire [15] For the adverse cosmetic reaction part, the respondents were allowed to choose more than one answer if they thought they were appropriate to their condition. The type of ACEs that occur, the body parts that are affected, the type of cosmetic products that cause the reaction, the type of consultation adopted, and the type of measures taken can be extracted.

The English version of the developed questionnaire was translated into the local language: Bahasa Malaysia (the official language in Malaysia) by direct translation (one-way) without using the back-translation technique. This method was employed as it saves time and cost [16,17]. The translation was carried out by two qualified and experienced people whose mother tongue was Bahasa Malaysia and were fluent in English reading and writing. The final draft of the translated questionnaire was handed to three pharmacists who had prior experience in the field of cosmetology. The instrument was subjected to face and content validity, and minor modifications were suggested. Then, the final instrument was decided on the basis of their suggestions.

The Survey Monkey web link collector was chosen to be the medium for the distribution of the questionnaire. The developed questionnaire was encrypted in the web page before it can be distributed to most of the social networks, mainly Facebook and WhatsApp. The link to the online survey was also

forwarded to the respondents who agreed to participate through e-mail. The sample was assumed to represent the whole population of Malaysia as the survey was widely distributed. The questions' summaries, data trends, and the individual response from the respondents can be obtained from the Survey Monkey web link collector. All the researchers had access to the data.

The total number of participants was estimated based on Population and Housing Census of Malaysia. According to the 2010 census, the total population in Malaysia was 30,261,700. However, the number of people within the population who were 20 years old and above in Malaysia was estimated to be 19,701,100 people. According to the sample size formula as mentioned below, the sample size needed is 383. The desired margin of error for this study is 5%, and the Z score was set to 1.96, as this is the Z score value that is appropriate for a 95% confidence interval. There might be a dropout rate of about 20% of the participants in the study. Therefore, the final number of participants in this study was about 500 participants. The formula for the sample size estimation used is as follows:

$$ss = Z^2 \times (p) \times (1 - p) c^2.$$
 (1)

Equation of sample size formula: ss = sample size; Z = standard value of 1.96 (for 95% confidence level); p = percentage picking a choice (in decimal, 0.5); c = confidence interval (in decimal, 0.05 = 5%)

A cross-sectional study design was applied to assess the incident of the ACEs among cosmetic users in Malaysia. The study took place across Malaysia, which is a federal constitutional monarchy located in Southeast Asia that is comprised of two regions: Peninsular and East Malaysia. Peninsular Malaysia was formerly known as Malaya [18], and it covers all 13 states and two federal territories, which are Kuala Lumpur and Putrajaya. Meanwhile, East Malaysia consists of two states and a federal territory, which is Labuan. The total population in Malaysia is around 30,261,700 and Malay, Chinese, and Indian are the three largest ethnic divisions, which cover 78.61% of the total population in Malaysia, and the remaining was divided into Others Bumiputera, Others, and Non-Malaysian Citizens [17].

Generally, the survey was addressed to all cosmetic users in Malaysia. The snowball sampling method was used in this study by selecting the sample using networks [19]. In this study, friends were asked to share or spread the questionnaire to their friends using virtual networks such as Facebook and WhatsApp messenger. This sampling method was able to reduce the time and cost required to collect enough respondents and expand the geographical scope [20–22].

To be eligible to participate in this study, certain criteria must be fulfilled by the participants which are (1) consumers who are using cosmetic products, (2) aged 20 years old and above, (3) able to understand and write in Malay or English, and (4) a resident in Malaysia.

The questionnaire was distributed by using the SurveyMonkey web link collector. Data from 552 respondents were collected for this study. On average, the respondents were able to complete the questionnaire within 5 min.

The data collected in this study were tabulated and analyzed using Statistical Package for Social Sciences (SPSS) version 20.

All respondents were required to answer the demographic section. The respondents were expected to proceed with the second part if they declared that they had experienced any adverse cosmetic reaction in the demographic section. Descriptive statistics was done to find the frequency and percentage of both sections, which are the demographic data and the adverse cosmetic reaction.

#### 3. Results

The demographic characteristics of respondents are listed in Table 1. The majority were Malay females within the age range of 20–29 years. Most reported a monthly income of less than RM 2000 (68.5%) and spent less than RM100 on cosmetic products (75.9%). Around 73.6% of the respondents reported having a higher educational qualification.

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Characteristics	Frequency (%)
Gender	
Male	107 (19.4)
Female	445 (80.6)
Age	× ,
20–29	468 (84.8)
30–39	62 (11.2)
40–49	14 (2.5)
50-59	8 (1.4)
Marital Status	
Single	436 (79.0)
Married	116 (21.0)
Race	
Malay	528 (95.7)
Chinese	13 (2.4)
Others	11 (2.0)
Location	
Urban	447 (81.0)
Rural	105 (19.0)
Education	
SPM and below	53 (9.6)
STPM/STAM/Diploma	78 (14.1)
Degree/Master	406 (73.6)
PhD	15 (2.7)
Occupation	
Not working	16 (2.9)
Student	363 (65.8)
Private Sector	58 (10.5)
Government Sector	115 (20.8)
Income range	
Less than RM2000	378 (68.5)
RM2000-RM3000	72 (13.0)
RM3001-RM6000	71 (12.9)
RM6001-RM9000	21 (3.8)
RM9001 and above	10 (1.8)
Monthly Expenditure	
Less than RM100	419 (75.9)
RM100-RM200	102 (18.5)
RM201-RM300	18 (3.3)
RM301-RM400	8 (1.4)
RM401 and above	5 (0.9)

 Table 1. Sociodemographic characteristics.

Slightly more than one-quarter of the respondents (n = 160; 29%) have experienced ACEs,19.4% (n = 107) reported to have experienced at least one ACE (Table 2), and 9.6% (n = 53) reported more than one event. No statistically significant difference was observed between gender and the number of ACE as well as age.

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 Table 2. Characteristics of the affected sample. ACE: adverse cosmetic event.

	Females (%)	Males (%)	Total (%)
Total respondents	445 (80.6)	107 (19.4)	552(100)
ACE affected people	135 (30.3)	25 (23.4)	160(29.0)

Regarding the nature of the reported ACE, 211 (91.3%) events were cutaneous, and 20 (8.7%) events were systemic. Among cutaneous events, eczema was the most frequent and accounted for 43.7% of total cutaneous events. For detailed results, please refer to Table 3.

Type of Adverse Cosmetic Event	No of Events	Percentage (Total Events)
Cutaneous		
Burning	50	21.6
Itching	24	10.4
Eczema	101	43.7
Others	36	15.6
Total cutaneous	211	91.3
Systemic		
Headache	6	2.5
Nausea	3	1.3
Dizziness	4	1.7
Dyspnea	3	1.3
Others	4	1.7
Vomiting	-	-
Total systemic	20	8.7
Total ACE	231	100.0

Table 3. Type and number of adverse cosmetic events.

Generally, there are 21 choices of body sites that are expected to be affected by ACEs and are therefore included in the questionnaire. As a result, a total number of 256 cases of body sites affected by ACEs were reported by the respondents. A total of 178 events (69.5%) involved the facial area pertaining to the ocular mucous membrane, periorbital area, forehead, lips, and perioral area and thus were reported to be the most frequent site affected by ACEs. The second most frequent body site affected by ACEs was axilla with 18 (7.0%) events followed by the entire scalp area with 15 (5.9%) events and neck with 11 (4.3%) events. For details, please refer to Table 4.

Body Site	No of Cases	Percentage of Total Cases
Axilla	18	7.0
Body diffuse	4	1.6
Decollete	1	0.4
Eye (ocular mucous membrane)	5	2.0
Eye (periorbital)	14	5.5
Face diffuse	117	45.7
Forearm	6	2.3
Fore head	22	8.6
Glans	1	0.4
Groin	-	-
Hand	10	3.9
Heart	1	0.4
Leg	5	2.0
Lips	15	5.9
Mammary gland	-	-
Neck	11	4.3
Perioral area	5	2.0
Scalp diffuse	15	5.9
Thigh	1	0.4
Thorax	2	0.8
Upper arm	1	0.4
Upper limb	2	0.8
Total no of cases	256	100.0

Table 4. Affected body sites.

A total of 13 different cosmetic classes has been offered to the respondents. There are five classes of cosmetics that were reported to cause the highest number of ACEs. Of the 290 episodes of ACEs, the majority of the episodes were caused by products that were meant to be applied to the face area.

The most frequently reported cosmetic class was facial care products, which cover 37.9% (n = 110) of the events (Table 5). The rank was then followed by deodorants with 32 (11.0%) events, facial make up with 27 (9.3%) events, body care products with 24 (8.3%) events, and cleanliness products with 21 (7.2%) events.

<b>Class of Cosmetic Utilized</b>	* No. of ACE Episodes	Percentage (%)
After sun products	10	3.4
Body care products	24	8.3
Cleanliness products	21	7.2
Deodorants	32	11.0
Depilatory products	2	0.7
Eye care products (eye contour cream)	5	1.7
Eye make-up	10	3.4
Facial care products	110	37.9
Facial make-up	27	9.3
Hair care products	15	5.2
Perfume and fragrances	12	4.1
Sunscreens	19	6.6
Toothpastes	3	1.0
Total episodes	290	100.0

Table 5. Cosmetic adverse events stratified for cosmetic class.

\* More than 160 episodes as each respondent can answer more than 1 choices.

Table 6 illustrates the type of consultations adopted by all of the respondents. Unfortunately, by referring to the table above, 58.9% (n = 96) of the respondents reported that they did not go for any consultation with medical specialists, general practitioners, pharmacists, or beauticians. A total of 67 (41.1%) respondents chose to get consultations from professionals. Of 67 (41.1%) respondents, 9.8% (n = 16) of them sought consultations from a combination of a pharmacist and medical specialist, followed by 7.4% (n = 12) of respondents who consulted with a combination of general practitioners and medical specialists. Alternatively, an equal number of respondents referred their problem only to a general practitioner, pharmacist, or beautician with the total of 11 (6.7%) events for each option.

Table 6.	Type of	consultation	adopted.
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Type of Consultation	No of Events	Percentage (%)
Medical specialist	6	3.7
General practitioner	11	6.7
Pharmacist	11	6.7
General practitioner and medical specialist	12	7.4
Pharmacist and medical specialist	16	9.8
Beautician	11	6.7
None	96	58.9
Total no of event	163	100.0

In general, the respondents who declared that they experienced ACEs would be asked about the measures that they have adopted, whether in the presence or absence of a consultation with a health professional. Product change, which accounts for 51.8% (n = 88), was the most frequent measure adopted by the respondents who experienced ACEs, which was followed by product suspension with 62 (36.5%) cases. Medications or drugs were used in 17 (10.0%) of the cases of the remaining respondents.

Only 4 (2.4%) out of 170 respondents reported taking other measures, which are not included in the questionnaire.

#### 4. Discussion

The data obtained in this study represented the general population in Malaysia, as the respondents were comprised of a multiracial population. The data showed that skin was the most affected part in ACEs, which is in concordance with the previously published studies [2,3] In this study, eczema was reported to be the most frequent reaction reported by the consumers. Similarly, a study done by Lindberg et al. (2007) in Sweden also found eczema to be the most reported adverse reactions to cosmetics [10] Hence, differences in climatic background did not play a role in regard to this matter, as the manifestations of eczema in Malaysia were pretty much the same as in Western countries.

The facial area has been reported to be the most frequent affected body site documented in this study. The result was found to be in line with previous studies as the researchers also mentioned that the most frequently reported body site was the face area [7,22]. Although the result obtained is in line with previous studies, Sportiello et al. (2009) opinionated that underreporting may render this less valuable in resembling the general situation [17].

In addition, the result of this study also revealed that the affected body sites were associated with the intended application site of the most frequently reported class of cosmetics. The majority of ACEs were reported to occur on the facial area of the respondents, and the results show that most of the events occur due to the products that are intended to be applied to the face area such as facial care products, facial make-up, eye make-up, and eye care products. Moreover, the second most common area was axilla, which is in line with the site of application of deodorants. Interestingly, the result is in line with previous research which mentioned that the application site of the suspected products was correlated with the affected sites, and the adjacent site might also be affected due to the type of the cosmetic products [16]

The number of respondents who made an attempt to consult health professionals is 41.1%, which is 17.8% lower than those who did not go for any consultation. In the current research, the low number of people seeking consultation highlighted that they are underestimating the occurrence of ACEs. Studies show that underreporting of the ACEs occurs among the consumers, although in some of the cases, the consumers were severely harmed [3,7,15] Extensive usage of cosmetics among the population has made consumers underestimate the occurrences of ACEs; although in some cases, the consumers were severely harmed [17].

A few previous researchers suggested identifying the cosmetics' ingredients that can cause harm to the consumers [13,22,23]. Previous studies also highlighted the occurrence of more severe reactions related to the internal body system, such as cancer [13,24,25] Litner suggested that every cosmetic product is made up of at least one but frequently many chemical substances [26]. Therefore, many believed that it is the responsibility of the manufacturer to do a safety evaluation of their products before they are marketed to the public [27–30].

Although there is a lack of awareness surrounding consulting health professionals, the measures adopted by the respondents are equitable regarding when they chose to change their cosmetic products as well as to suspend the usage of the products. Initiation of the usage of drug in cases where they need to continue the usage of the cosmetic is also wisely selected, and this option is also most probably recommended by the consultant [2].

In the current research, half of the ACE-affected respondents bought their cosmetic products at an appointed store in malls. This is possible, since the total number of respondents who bought their cosmetic products at appointed stores in malls is a large proportion compared to the other places. Interestingly, although only 19 respondents who bought their cosmetic products online had reported ACEs, it should be noted that this number exceeds the number of respondents who had no ACEs that bought their cosmetic products from the same source. Although at present, the number of respondents affected is small (11.9%; n = 19), it is believed that this number will grow substantially in the near future, as a few scholars also believed that online business has great potential that can gain much more profit as the Internet and social media were perceived as easy to use and convenient by the consumers [31–33], which may attract more consumers to buy cosmetic products online.

Moreover, a study by the International Data Corporation (IDC) Asia-Pacific showed that the online shopping in Malaysia in the future has great potential [34,35].

## 5. Conclusions

The current research is a baseline insight about cosmetic adverse reactions in Malaysia. The results reported that the facial area was the mostly affected region and eczema was identified as the most frequent adverse cosmetic reaction among Malaysian consumers. The number of consumers who consulted the health professional for advice is lower than those who refused any consultation, indicating their underestimation toward any adverse incidents related to cosmetic use. Therefore, a formal and reliable cosmetovigilance system is needed to be in place that apprises the population about the identification and reporting of adverse events related to cosmetic use.

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