A Community Based Observational Study on Cosmetics Use and Allied Adverse Events

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Abstract: **Cosmetics are widely used, with millions of people around the world including these products in their everyday routines. The study includes a 21 item semi structured questionnaire designed to obtain information on the participants knowledge about safe and effective use of cosmetics and ADR reporting. The objective of the study is to determine the awareness and knowledge of community members about safe and responsible cosmetics use practice and to identify the need for public health interventions. The questionnaire consisted of 2 parts, the first included the questions on the demographic variables such as age, gender, occupation and education level. The second part consisted of 20 questions which tested the participant's knowledge, attitude and practice towards the cosmetics usage. The aim of the study is to investigate cosmetics use and associated adverse events among community members and to inform public health strategies for safe and responsible cosmetics use. The questionnaire was distributed through google form and 304 responses were obtained, out of which 300 responses were selected as per the inclusion and exclusion criteria. The study underscores the widespread use of cosmetics and the significant occurrence of adverse events linked to their use. These findings stress the importance of increasing public awareness about cosmetic safety, advocating for stricter regulations on cosmetic products, and encouraging individuals to be more cautious when choosing and using these products to minimize potential risks. Encouraging the reporting of adverse reactions can help identify harmful ingredients and lead to quicker regulatory actions.**

Keywords: **Cosmetovigilance, Adverse events, Cosmetics, Questionnaire, Knowledge, Attitude, ADR monitoring, Public awareness**

INTRODUCTION

The Federal Food, Drug, and Cosmetic Act (FD&C Act) defines cosmetics as "articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body for cleansing, beautifying, promoting attractiveness, or altering the appearance". Cosmetics and personal care products (PCPs) are widely used by consumers of all ages around the globe, driven primarily by concerns about personal hygiene, appearance, and well-being. These products are categorized into skincare, haircare, makeup, nail care, fragrances, oral care, and body care. Among them, skincare products have seen a significant surge in popularity, transforming the beauty industry with innovations like serums, oils, and masks. However, improper or excessive use of these products, often due to lack of knowledge, can lead to various skin issues. Therefore, monitoring and reporting adverse reactions is essential for consumer safety, aiding manufacturers in refining formulations and educating users about potential risks. Post-marketing surveillance of cosmetics plays a key role in tracking the safety and effectiveness of products after their market release. By continuously monitoring the impact of these products, post-marketing surveillance ensures public confidence and supports future product development and regulation.

PHARMACOVIGILANCE

According to World Health Organization (WHO) Pharmacovigilance(PV) is defined as the "Science and activities relating to the detection, assessment, understanding and prevention of adverse effects (AE)", particularly long term and short term side effects of medicines or any other drug related problems. The Ministry of Health and Family Welfare (MoHFW) of the Government of India launched the Pharmacovigilance Programme of India (PvPI) in 2010 at AIIMS, New Delhi, which initially served as the National Coordinating Centre (NCC). In April 2011, the program was transferred to the Indian Pharmacopoeia Commission (IPC), which became the new NCC. In July 2015, the name of the program was changed to the National Coordinating Centre for the Materiovigilance Programme of India (MVPI). Since July 2017, IPC-NCC-PvPI has been recognized by the World Health Organization (WHO) as a collaborating center for pharmacovigilance in public health programs and regulatory services. Growing emphasis on drug

safety has highlighted the importance of pharmacovigilance in the pharmaceutical sector. The WHO initiated the International Drug Monitoring Program, which involves 134 countries sharing country-level data to assess and evaluate the risk-benefit profiles of drugs.

Importance of pharmacovigilance

Pharmacovigilance (PV) plays a crucial role in healthcare by evaluating, monitoring, and identifying interactions between drugs and their effects on humans. While pharmaceutical and biotechnological medicines are developed to treat, prevent, or cure diseases, they also carry risks, particularly adverse drug reactions (ADRs), which can be harmful to patients. Therefore, ongoing monitoring of ADRs is essential for ensuring medication safety throughout a drug's life cycle. This includes monitoring during the drug's development phase (such as pre-marketing and clinical trials) and continuing through post-marketing surveillance. PV focuses on detecting, assessing, understanding, and preventing ADRs to enhance patient safety.

Scope of pharmacovigilance

Pharmacovigilance aims to protect public health by identifying, assessing, and reducing health risks to ensure that the benefits of available treatments outweigh their potential harms. However, the growing trend of withdrawing certain medications from global markets has drawn more attention to pharmacovigilance practices. This has sparked discussions on improving the current pharmacovigilance system and emphasized the importance of standardizing international guidelines for reporting side effects.It has become crucial to address the challenges posed by the expanding variety and potency of pharmaceutical and biological medicines, including vaccines, as these products inherently carry a potential for harm that is often unpredictable and inevitable.

Cosmetovigilance

The term "Cosmetovigilance" was introduced to describe the surveillance conducted by the industry to ensure the safety of cosmetic products. Cosmetovigilance refers to the activities involved in collecting, assessing, and monitoring spontaneous reports of adverse events that occur during or after the normal or expected use of a cosmetic product. It was introduced by the French health products safety agency as a component of the pharmacovigilance system specifically for cosmetics. It was first coined by Vigan in 1997 to refer to the monitoring of cosmetic product safety. Today, it is widely recognized as an important concept in public health.

Need of Cosmetovigilance

India has a large population, and similarly, its cosmetic market is vast. Conditions like contact dermatitis and other skin disorders are common in the country, with cosmetics often being a contributing factor. As per Section 135B of the Drugs and Cosmetics Act, the import of cosmetics tested on animals is prohibited in India. Just like other health issues, cosmetic-related disorders also result in pharmacoeconomic losses. Therefore, alongside the proper regulation of these products, an effective vigilance system is essential to safeguard public health. The primary goal is to identify and evaluate any adverse reactions, side effects, or other safety concerns associated with the use of cosmetics. This system is essential to detect and reduce the danger related to the use of cosmetics.

ADVERSE DRUG REACTION

An ADR, according to the World Health Organization, is “a response to a drug which is noxious and unintended and occurs at doses normally used in man for prophylaxis, diagnosis or therapy of disease, or for the modification of physiological function. Any medication, including those derived from natural sources, has the potential to cause an adverse drug reaction (ADR). ADRs can vary from mild, uncomfortable side effects to severe, life-threatening reactions. The more general term, adverse drug event (ADE), encompasses any harm caused by a medication. This includes not only ADRs but also medication errors, overdoses, and other issues that may not be directly caused by the medicine itself. While some ADRs are mild side effects, others can significantly raise the risk of morbidity or mortality. To minimize the chances of a patient experiencing an ADR, it is essential to ensure thorough documentation, close monitoring, and effective communication during the processes of prescribing, dispensing, and administering medications.

METHODOLOGY

Study design

The study was conducted among the public with the age group between 18-45 years of age over the period

of 3 months from October 2024 - December 2024.The questionnaire was prepared in such a way that all subjects could answer it with relative ease. It was validated by the research guide and experts from the department of pharmacy practice. The questionnaire was first distributed to 15 individuals to run a trial response. Later the questionnaire was distributed through google form and 304 responses were obtained, out of which 300 responses were selected as per the inclusion and exclusion criteria.

2.1.2 Study Instrument and Administration

The study instrument was a 21 item semi structured questionnaire designed to obtain information on the participants knowledge about safe and effective use of cosmetics and ADR reporting. The questionnaire consisted of 2 parts, the first included the questions on the demographic variables such as age, gender, occupation and education level. The second part consisted of 21 questions which tested the participant's knowledge, attitude and practice towards the cosmetics usage.

To create the questionnaire, we began with an extensive literature review, which informed the adaptation of the study instrument and we further modified it to suit our context. Questionnaire was distributed through google forms to the public and asked to submit the responses in their free time. Responses recorded later than December 31,2024 were not considered for the study. Data collected were analyzed statistically.

Inclusion/Exclusion Criteria

2.1.3 Inclusion:

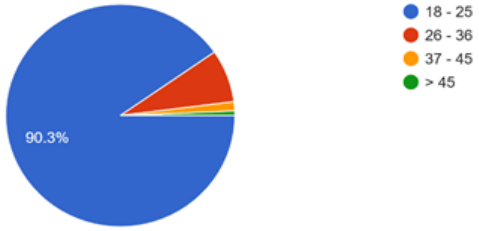
- Selected persons from the age of 18-45 years.
- All the answers should be filled in the questionnaire.

2.1.4 Exclusion:

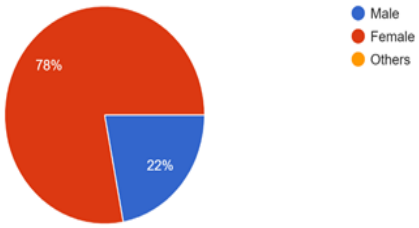
- Selected person below 18 and above 45 years of age.
- Incomplete questionnaires were also excluded.

RESULTS AND DISCUSSION

AGE GROUP OF INDIVIDUALS UNDER THIS SURVEY



GENDER DISTRIBUTION OF INDIVIDUALS UNDER THIS SURVEY



EDUCATIONAL QUALIFICATION OF INDIVIDUALS UNDER THIS SURVEY

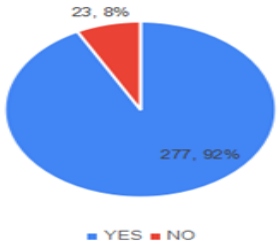


Fig 1: Usage of cosmetic products

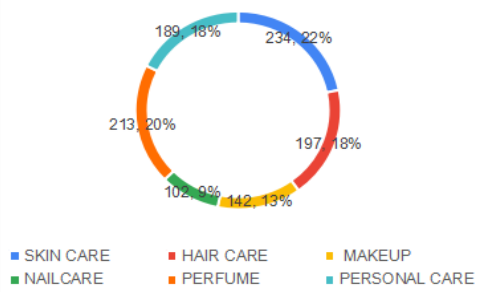


Fig 2: Types of cosmetics used

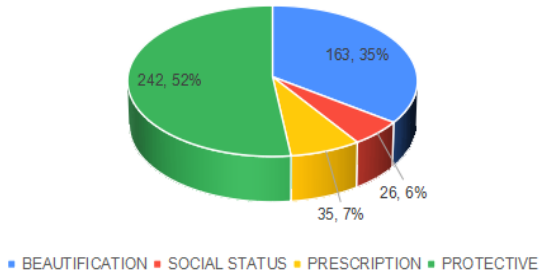


Fig 10: Reason for using cosmetics

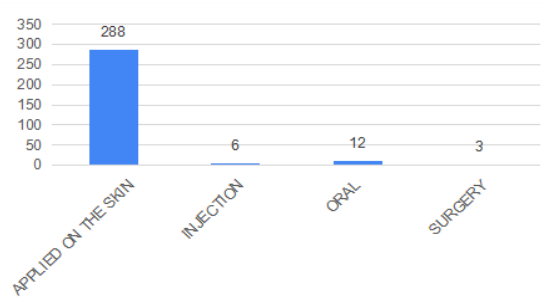


Fig 11: Way of application

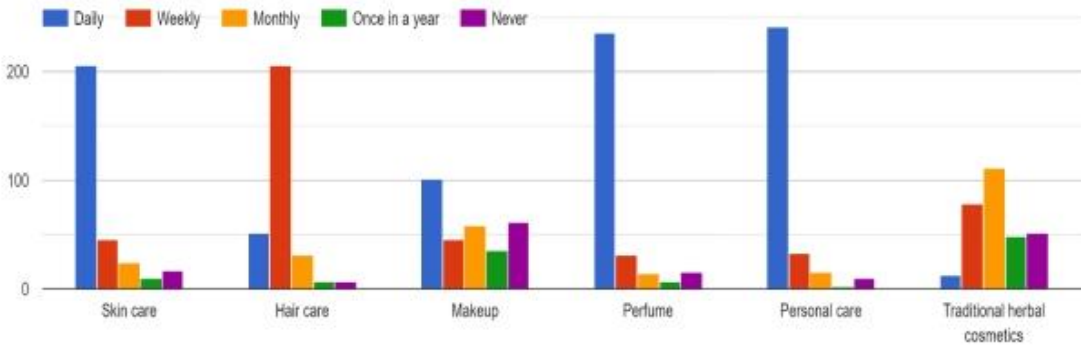


Fig 12: Frequency of usage of product

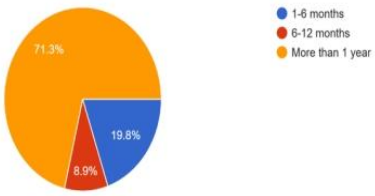


Fig 13: Duration of using the cosmetic products

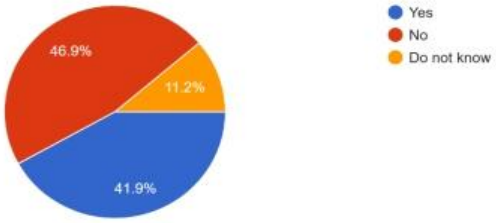


Fig 16: Do allergic tests before using the products

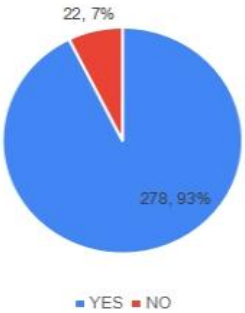


Fig 14: Expiry date checking

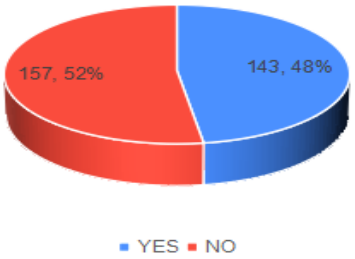


Fig 17: Using more than one product simultaneously

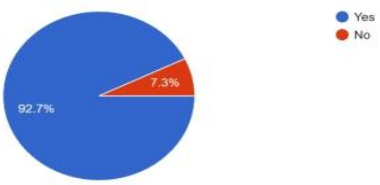


Fig 15: Information before purchasing the product

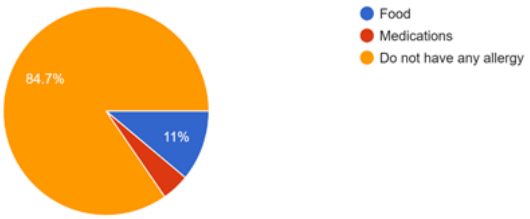


Fig 18: allergic to any food/medication

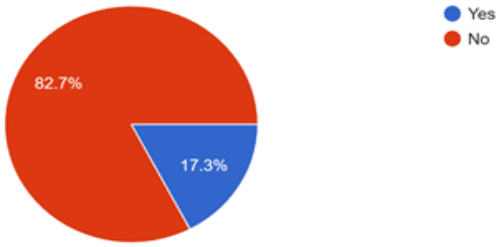


Fig 19: Family history of allergy

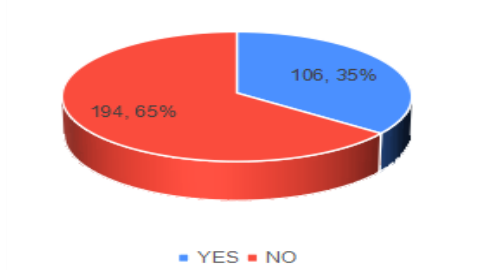


Fig 20: Noticing any kind of reactions while using cosmetics

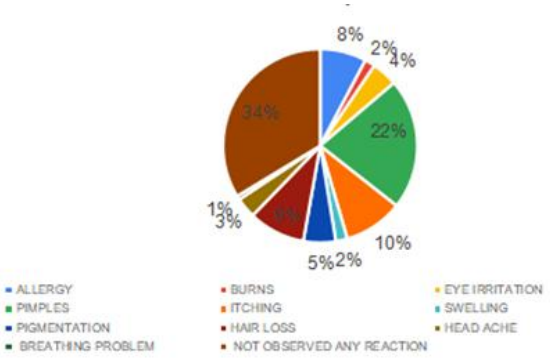


Fig 21: Type of reaction observed while/after using the cosmetic product

Fig 22: Observed reaction after using cosmetics

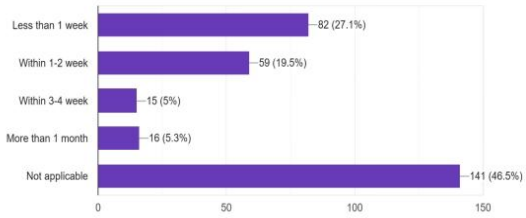


Fig 23: Time taken for the recovery of reaction

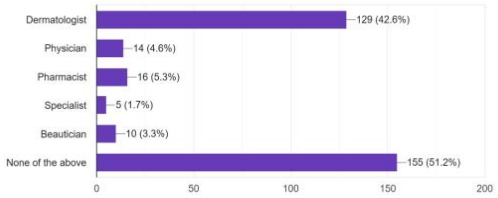


Fig 24: Consultation adopted

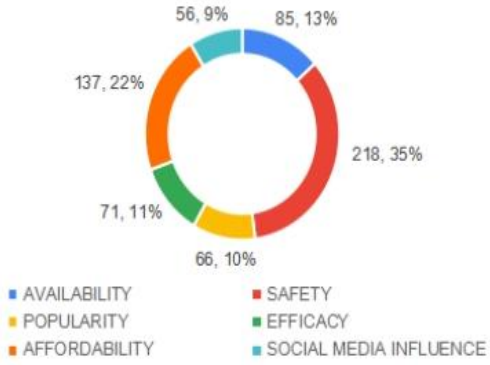


Fig 25: Criteria for choosing cosmetics

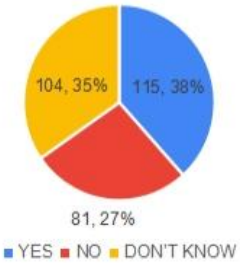


Fig 26: Proper system for reporting

DISCUSSION

This observational study was conducted to assess the knowledge, attitude and practice regarding the cosmetics usage, related adverse events within the community and to guide public health initiatives aimed at promoting safe and responsible cosmetics use. The study highlights the importance of increasing consumer awareness regarding the potential risks of cosmetic products. Further research is warranted to explore the long-term effects of cosmetic product use and the development of new guidelines for consumer safety. Cosmetovigilance is a growing branch of pharmacovigilance. Through a self-reported survey, this study explores patterns of cosmetic use and associated adverse reactions (ARs). The study concluded by highlighting the importance of monitoring cosmetic-related adverse events and the need for a structured approach to Cosmetovigilance.

Cosmetics have been linked to a variety of adverse reactions, such as pigment abnormalities, irritation, contact urticaria, photosensitivity, damage to hair and nails, and acne-like breakouts. In our study a total of 92% of respondents of the community are using the cosmetic products whereas 8% are not. Approximately 22% reported using skincare products regularly, followed by 20% perfume, 18% personal care and hair care, 13% makeup and 9% nail care. A majority 82.2% of participants used face wash, followed by 61.3% cream, 30.9% scrub, 29.4% serum, 26.8% face mask and 14.9% toner. The 97.8% of participants claimed that they used shampoo as hair care product followed by 64.9% conditioner, 10.1% hair gel, 9.4% hair spray and 6.9% hair color. The majority of 77.6% of participants used lipstick followed by 71.9% kajal, 36.4% eyebrow pencil, 36% mascara, 32% loose powder and 20.6% foundation.86.8% of participants used nail polish, followed by 52.3% nail polish remover and only 13.2% used nail cone.52% of participants used cosmetics as protective followed by 35% for beautification, 7% for prescription and 6% for social status.96% of participants applied cosmetics on the skin followed by 4% oral, 2% injection and 1% surgery.97% of participants check the expiry date of the product before use, whereas 3% do not check. 46.9% of participants have not done any allergic tests before using cosmetics, 41.9% of participants have done and only 11.2% of participants are not aware. Typically around 52%, may report that they are not using multiple cosmetic products simultaneously.65% didn't found any reactions while using the cosmetics product while remaining 35% of the participants may encounter various kinds of reactions.22% of people confronted with skin problems like pimples,10% of the respondents faced itching as an adverse reaction,9% of study population reported hair loss as the reaction due to the use of cosmetics followed by 8% allergy, 5% pigmentation, 4% eye irritation, 3% head ache, 2% burns and swelling finally 1% of people suffered from breathing problem.

The data obtained from the survey,58.4% of participants stopped using the products when they observed a reaction after using the cosmetics, 23.4% participants changed the product, 21.8% of participants opted self-medication, 5.3% participants chose drug treatment and 24.4% of participants preferred other measures.42.6% of community adopted consultation by dermatologist followed by 5.3% pharmacist, 4.6% physician, 3.3% beautician and 1.7% specialist. From the data obtained,72.9% of participants have chosen safety as the criteria for choosing cosmetics, 45.5% affordability, 28.1% availability,23.1% efficacy, 21.5% popularity and 18.5% social media influence. About 38.3% of participants in the survey questionnaire believed that there is a proper system for reporting if a reaction had occurred as a result of usage of any cosmetics whereas 26.4% think that there is no proper reporting systems and 35.3% are not aware about the reporting systems.

CONCLUSION

The study underscores the widespread use of cosmetics and the significant occurrence of adverse events linked to their use. These findings stress the importance of increasing public awareness about cosmetic safety, advocating for stricter regulations on cosmetic products, and encouraging individuals to be more cautious when choosing and using these products to minimize potential risks. Encouraging the reporting of adverse reactions can help identify harmful ingredients and lead to quicker regulatory actions.

REFERENCE

[1] Assessing the safety of cosmetic chemicals: Consideration of a flux decision tree to predict dermally delivered systemic dose for comparison with oral TTC (Threshold of Toxicological Concern). Regulatory Toxicology and Pharmacology [Internet]. 2016 Apr 1 [cited 2021 Feb 9];76:174–86. Available from: https://www.sciencedirect.com/science/article/pii/S0273230016300058

[2] Praveen J, Thirumalai Velu Swaminathan. Cosmetovigilance: Emerging safety trends. Indian journal of pharmacy and pharmacology. 2023 Oct 15;10(3):132–41.

[3] Suke SG, Kosta P, Negi H. Role of Pharmacovigilance in India: An overview. Online Journal of Public Health Informatics [Internet]. 2015 Jun 22;7(2). Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4576445/

[4] Khalid Abbood M, Alaa Aldeen Khalaf H, H. Abudlqader E, Sagban Taghi H, Alaa Al-Temimi A. Scope of Pharmacovigilance:

Comprehensive Review. Chemical Science International Journal. 2022 Dec 31;29–39.

[5] Toklu HZ, Antigua A, Lewis V, Reynolds M, Jones J. Cosmetovigilance: A review of the current literature. Journal of Family Medicine and Primary Care [Internet]. 2019 May 1;8(5):1540–5. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6559068/

[6] Sarma P, Kumar H, Medhi B. Cosmetovigilance in India: Need of the day. Indian Journal of Pharmacology [Internet]. 2017 [cited 2021 Nov 30];49(5):341–3. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5830843/

[7] Yadav S, Sinha M, Kanishka Taradia, Sharma AK, Mayank Kulshreshtha. Pharmacovigilance, Cosmetovigilance, Hemovigilance, and Materiovigilance in Healthcare domains. Journal of Medicine Surgery and Public Health. 2024 Dec 1;100175–5.

[8] Ausmed. Adverse Drug Reactions: An Overview [Internet]. Ausmed.com. Ausmed Education Pty Ltd; 2024 [cited 2024 Dec 30]. Available from: https://www.ausmed.com/learn/articles/adverse-drug-reactions?utm_source=link&utm_medium=resource_share

[9] REMYA GAYATHRI, RAJ D, ABDULLA, MARY A, JOY A, NOUSHAD S, SAJI S. A Comprehensive Study on Skin Whitening Products. International Journal of Innovative Research in Technology [Internet]. 2024 Nov 28 [cited 2024 Dec 13];11(7):200–8. Available from: https://ijirt.org/Article?manuscript=170343

[10] Hermans AM, Decates T, Boerman SC. Understanding cosmetic consumers: exploring consumption patterns and predictors through a cross-sectional survey. European journal of plastic surgery. 2024 Jun 22;47(1).

[11] Siddiqui A, Ali N, Pandey A, Mohammad Daud Ali, Haider N, Mohammed Zaafar Khan, et al. A Cross-sectional Survey-based Study of Knowledge, Attitude, and Practice Towards Uses of Cosmetics and Cosmetovigilance in India. Journal of Pharmacy And Bioallied Sciences [Internet]. 2024 Jan 1 [cited 2024 Aug 30];16(1):31–7. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC11060625/

[12] Lahiru Udayanga, Nirma Subashini, Menuka Udugama, Silva P, Tharaka Ranathunge. Knowledge, perceptions, and consumption behaviour of cosmetics among undergraduates of Sri Lanka: a descriptive cross-sectional study. Frontiers in Public Health. 2024 Jan 5;11.

[13] G AM, Hiremath P, Divya K, Abhiram P. A survey study on adverse effects of synthetic cosmetics. International journal of community medicine and public health/International journall of community medicine and public health. 2023 Oct 31;10(11):4147–52.

[14] Kumari S, Pal B, Tiwari D, Sushanta Kumar Sahu. Cosmetics utilization and associated adverse events: A community based cross-sectional study. Clinical Epidemiology and Global Health. 2023 Sep 1;23:101382–2.

[15] Juraimi SA, O'Brien J, Hirsh J, Tan A, Teo J, Khaiat A, et al. Consumer habits and practices for cosmetics and personal care products in Singapore: An online survey. Food and Chemical Toxicology [Internet]. 2023 Apr 1 [cited 2023 Apr 9];174:113659. Available from: https://www.sciencedirect.com/science/article/pii/S0278691523000613

[16] Mohd Aqil, Kumar K, Tabassum N, Ashima. Survey on Cosmetic Consumption in Delhi and NCR. International Journal of Research in Clinical and Hospital Pharmacy [Internet]. 2021 [cited 2024 Dec 31];3(1). Available from: https://rubatosis.org/journals/index.php/ijrhcp/article/view/181

[17] Nayak M, Sreedhar D, Prabhu SS, Ligade VS. Global Trends in Cosmetics Use-Related Adverse Effects: A Bibliometric Analysis of Literature Published during 1957–2021. Cosmetics. 2021 Aug 24;8(3):75.

[18] Lucca JM, Joseph R, Hussain Al Kubaish Z, Mohammad Al-Maskeen S, Ali Alokaili Z. An observational study on adverse reactions of cosmetics: The need of practice the Cosmetovigilance system. Saudi Pharmaceutical Journal : SPJ [Internet]. 2020 Jun 1 [cited 2022 Feb 8];28(6):746–53. Available from: https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7292860/#:~:text=Previous%20literature%20shows%20the%20prevalence

[19] Husain K. A survey on usage of personal care products especially cosmetics among university students in Saudi Arabia. Journal of Cosmetic Dermatology. 2018 Sep 10;18(1):271–7.

[20] Infante VH, Calixto LS, Campos PM. Cosmetic consumption behaviour among men and women and the importance in products indication and treatment adherence. Surg Cosmet Dermatol. 2016;8(2):134-41.

[21] Nisar F, Ali A, Shahid H, Iqbal MM, Khan H, Khan Q, et al. Questionnaire-Based Study of 392 Women in Abbottabad, Pakistan, to Evaluate the Types of Cosmetic Products Purchased Between December 2018 and March 2019 and Their Associated Adverse Events. Medical science monitor basic research/Medical science monitor Basic research [Internet]. 2024 Mar 29 [cited 2024 Dec 31];30. Available from: https://pmc.ncbi.nlm.nih.gov/articles/PMC10986314/

[22] Olcer Z, Cal A, Unal N, Oztas B, Oge G. Examining the use of cosmetic products and the awareness of healthy life among university students. Turkish Journal of Dermatology [Internet]. 2023 Jul 1 [cited 2024 Jan 10];17(3):79. Available from: https://journals.lww.com/tjod/fulltext/2023/17030/examining_the_use_of_cosmetic_products_and_the.1.aspx

[23] Mahabaleshwarkar S, Patil H, Pathak A, Joshi P, Mukane S. A Survey on Chemicals in Cosmetic Products. International Journal for Research in Applied Science and Engineering Technology. 2022 Mar 31;10(3):1531–3.

[24] Šniepienė G, Jonuševičienė J. COSMETICS USAGE HABITS AND RELATED SIDE EFFECTS AMONG FEMALES: LITHUANIAN CASE. CBU International Conference Proceedings. 2019 Sep 30;7:824–32.

[25] Ray M, Mangal S, Saha S, Paul S, Maji H. Perception regarding Selection and Use of Skincare Products and the Impact of advertisement: a questionnaire-based Randomized Survey. Egyptian Pharmaceutical Journal. 2021;20(3):173–9.

[26] Alani JI, Davis MD, Yiannias JA. Allergy to cosmetics: a literature review. Dermatitis. 2013 Dec 1;24(6):283-90.

[27] Bilal AI, Tilahun Z, Osman ED, Mulugeta A, Shekabdulahi M, Berhe DF. Cosmetics use-related adverse events and determinants among Jigjiga town residents, Eastern Ethiopia. Dermatology and therapy. 2017 Mar;7:143-53.

[28] Di Giovanni C, Arcoraci V, Gambardella L, Sautebin L. Cosmetovigilance survey: are cosmetics considered safe by consumers?. Pharmacological Research. 2006 Jan 1;53(1):16-21.

[29] Huf G, Rito P da N, Presgrave R de F, Bôas MHSV. Reações adversas aos produtos cosméticos e o Sistema de Notificação em Vigilância Sanitária: um inquérito. Revista Brasileira de Epidemiologia [Internet]. 2013 Dec 1;16:1017–20. Available from: https://www.scielo.br/j/rbepid/a/Mwz4854XxnQNSCXpxBqJrzj/abstract/?lang=pt

[30] Pereira JX, Pereira TC. Cosmetics and its health risks. Glob. J. Med. Res. 2018;18:63-70.

[31] https://www.who.int/

[32] Joseph M, Karishma Shaji, M MT, B NP, Das K. Cosmetic use related adverse events and need for cosmetovigilance. Journal of Innovations in Applied Pharmaceutical Science (JIAPS). 2023 Nov 30;64–71.