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Retrospective assessment of the reporting of adverse drug reactions in a Malaysian clinical training center: A short communication

Elkalmi R.^{a,f} ✉, Elnaem M.^{b,c}, Sapar N.^d, Blebil A.^e[📁 Save all to author list](#)^a Department of Pharmacology, Faculty of Medicine, Sebha University, Sabha, Libyan Arab Jamahiriya^b Department of Pharmacy Practice, Kulliyah of Pharmacy, Malaysia^c Quality Use of Medicines Research Group, Kulliyah of Pharmacy, International Islamic University Malaysia, Kuantan, Pahang, Malaysia^d Department of Pharmacy Practice, Faculty of Pharmacy, Universiti Teknologi Mara, Selangor, Malaysia[View additional affiliations](#) ✓[Full text options](#) ✓[Abstract](#)[Author keywords](#)[Metrics](#)**Abstract**

Objectives: This study aimed to assess the completeness and quality of adverse drug reaction (ADR) reports that were submitted to the Pharmacovigilance Unit (PVU) in clinical training center (CTC), Faculty of Medicine, UiTM Sungai Buloh Campus. **Materials and Methods:** A retrospective study was conducted using all ADR reports that were submitted to the PVU in CTC from December 31, 2000, to December 31, 2018. The completeness was assessed by reviewing all the required elements to be filled in the ADR reports. The quality was assessed by investigating the required information in the ADR reporting form. Descriptive statistics have been used to present the findings. **Key Findings:** In a total of 31 reports that were submitted to the PVU in CTC, 98.9% of patient's information and 100% of ADR descriptions were completed. Suspected drug information and the reporter's details were completed by 52.2% and 79.6%, respectively. Of 58.0% of the information about seriousness recorded, 38.9% (n = 7) is mild, 44.4% (n = 8) is moderate, and 16.7% (n = 3) is severe. Among all the suspected medicines, drug class of antibiotics (32.4%, n = 12) is the most reported suspected drugs that caused ADR, followed by

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opioid analgesic (8.1%, n = 3) and nonsteroidal anti-inflammatory drugs (8.1%, n = 3). Conclusion: Further efforts and relevant interventions should be considered to increase the reporting frequency and to enhance the completeness and the quality of the ADR reports in the study setting. © 2021 Wolters Kluwer Medknow Publications. All rights reserved.

Author keywords

Adverse drug reaction reporting ; completeness assessment ; Malaysia; pharmacovigilance; quality assessment

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References (33)

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1 (2020) *Uppsala Monitoring Centre (UMC) Members of the WHO programme Uppsala*
UMC. Sweden: Uppsala Monitoring Centre (UMC); [Last cited on 2020 Jul 14]
<https://www.who-umc.org/global-pharmacovigilance/who-programme-for-international-drug-monitoring/>

2 (2020) *Uppsala Monitoring Centre (UMC): What is VigiBase Uppsala*
UMC. Sweden: Uppsala Monitoring Centre (UMC); [Last cited on 2020 Jul 13]
<https://www.who-umc.org/vigibase/vigibase/>

3 (2020) *National Pharmaceutical Regulatory Agency (NPRA): Reporting Adverse Drug Reactions and Adverse Events Following Immunisation KL*
Malaysia: National Pharmaceutical Regulatory Agency (NPRA); [Last updated on 2020 Jul 14]
<https://www.npra.gov.my/index.php/en/health-professionals/reporting-adr>

4 Vargesson, N.
Thalidomide-induced teratogenesis: History and mechanisms
([Open Access](#))
(2015) *Birth Defects Research Part C - Embryo Today: Reviews*, 105 (2), pp. 140-156. Cited 344 times.
[http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)1542-9768](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)1542-9768)
doi: 10.1002/bdrc.21096
[View at Publisher](#)

5 Elkalmi, RM, Al-Lela, OQ, Jamshed, SQ.
Motivations and obstacles for adverse drug reactions reporting among healthcare professionals from the perspective of Lewin's force field analysis theory: Analytic approach
(2014) *J Pharmacovigil*, 2, p. 3. Cited 3 times.

6 Gahr, M, Eller, J, Connemann, BJ, Schönfeldt-Lecuona, C.
Underreporting of adverse drug reactions: Results from a survey among physicians
(2017) *Eur Psychiatry*, 41, pp. S369-S. Cited 2 times.

- 7 (2002) *Malaysian Guidelines for the Reporting and Monitoring of ADR*. Cited 3 times.
Kuala Lumpur, Malaysia: National Pharmaceutical Control Bureau, Ministry of Health
-
- 8 Rejani, P., Sumesh, T., Shaji, K.
Cost of care: A study of patients hospitalized for treatment of psychotic illness ([Open Access](#))

(2015) *Indian Journal of Psychological Medicine*, 37 (1), pp. 71-74. Cited 6 times.
<http://www.ijpm.info/>
doi: 10.4103/0253-7176.150823

View at Publisher
-
- 9 Ali, S., Egunsola, O., Al-Dossari, D.S., Al-Zaagi, I.A.
Adverse drug reaction reporting in a large tertiary hospital in Saudi Arabia: results of an incentive strategy ([Open Access](#))

(2018) *Therapeutic Advances in Drug Safety*, 9 (10), pp. 585-590. Cited 9 times.
<http://www.uk.sagepub.com/journals/Journal201944>
doi: 10.1177/2042098618790209

View at Publisher
-
- 10 Härmark, L., Van Grootheest, A.C.
Pharmacovigilance: Methods, recent developments and future perspectives

(2008) *European Journal of Clinical Pharmacology*, 64 (8), pp. 743-752. Cited 163 times.
doi: 10.1007/s00228-008-0475-9

View at Publisher
-
- 11 Jeetu, G., Anusha, G.
Pharmacovigilance: A worldwide master key for drug safety monitoring ([Open Access](#))

(2010) *Journal of Young Pharmacists*, 2 (3), pp. 315-320. Cited 33 times.
<http://www.jyoungpharm.in>
doi: 10.4103/0975-1483.66802

View at Publisher
-
- 12 Jones, JK.
(2008) *Why Should I Report an Adverse Drug Event Medscape Pharmacists © 2008 Medscape, LLC*
[Last accessed on 2020 Jul 23; Last updated on 2008 Aug 18]
<https://www.medscape.org/viewarticle/578160#:~:text=In%20fact%2C%20individual%20ADE%20reports,possible%20new%20and%20serious%20ADEs>
-
- 13 Alshammari, T.M., Al-Kathiri, W.H., Le Louet, H., Aljadhey, H.S.
Completeness of adverse drug reactions reports of the Saudi adverse event reporting system ([Open Access](#))

(2015) *Saudi Medical Journal*, 36 (7), pp. 821-828. Cited 13 times.
<http://smj.psmmc.med.sa/index.php/smj/article/download/smj.2015.7.11751/7429>
doi: 10.15537/smj.2015.7.11751

View at Publisher
-

- 14 Yu, Y.M., Shin, W.G., Lee, J.-Y., Choi, S.A., Jo, Y.H., Youn, S.J., Lee, M.S., (...), Choi, K.H.
Patterns of adverse drug reactions in different age groups: Analysis of spontaneous reports by community pharmacists (Open Access)

(2015) *PLoS ONE*, 10 (7), art. no. e0132916. Cited 26 times.
<http://www.plosone.org/article/fetchObject.action?uri=info:doi/10.1371/journal.pone.0132916&representation=PDF>
doi: 10.1371/journal.pone.0132916

[View at Publisher](#)

- 15 Venkatasubbaiah, M, Reddy, PD, Satyanarayana, SV.
Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital
(2018) *Alex J Med*, 54, pp. 597-603. Cited 2 times.

- 16 Leape, L.L.
Why should we report adverse incidents? Editorial
(1999) *Journal of Evaluation in Clinical Practice*, 5 (1), pp. 1-4. Cited 59 times.
doi: 10.1046/j.1365-2753.1999.00162.x

[View at Publisher](#)

- 17 Lihite, RJ, Lahkar, M, Das, S, Hazarika, D, Kotni, M, Maqbool, M
Study on adverse drug reactions in a tertiary care hospital of Northeast India
(2017) *Alex J Med*, 53, pp. 151-156. Cited 6 times.

- 18 Alomar, M.J.
Factors affecting the development of adverse drug reactions (Review article) (Open Access)

(2014) *Saudi Pharmaceutical Journal*, 22 (2), pp. 83-94. Cited 183 times.
<http://www.sciencedirect.com/science/journal/13190164>
doi: 10.1016/j.jsps.2013.02.003

[View at Publisher](#)

- 19 Verbrugge, L.M.
Gender and health: an update on hypotheses and evidence.

(1985) *Journal of health and social behavior*, 26 (3), pp. 156-182. Cited 907 times.
doi: 10.2307/2136750

[View at Publisher](#)

- 20 Klotz, U.
Pharmacokinetics and drug metabolism in the elderly

(2009) *Drug Metabolism Reviews*, 41 (2), pp. 67-76. Cited 448 times.
doi: 10.1080/03602530902722679

[View at Publisher](#)

- 21 Brahma, D.K., Wahlang, J.B., Marak, M.D., Sangma, M.C.
Adverse drug reactions in the elderly (Open Access)

(2013) *Journal of Pharmacology and Pharmacotherapeutics*, 4 (2), pp. 91-94. Cited 51 times.
doi: 10.4103/0976-500X.110872

[View at Publisher](#)

- 22 Hilmer, S.N., McLachlan, A.J., Le Couteur, D.G.
Clinical pharmacology in the geriatric patient (Open Access)

(2007) *Fundamental and Clinical Pharmacology*, 21 (3), pp. 217-230. Cited 208 times.
doi: 10.1111/j.1472-8206.2007.00473.x

View at Publisher
-
- 23 Le Couteur, D.G., McLachlan, A.J., De Cabo, R.
Aging, drugs, and drug metabolism (Open Access)

(2012) *Journals of Gerontology - Series A Biological Sciences and Medical Sciences*, 67 A (2), pp. 137-139. Cited 16 times.
doi: 10.1093/gerona/glr084

View at Publisher
-
- 24 (2006) *The Safety of Medicines in Public Health Programmes: Pharmacovigilance an Essential Tool*. Cited 115 times.
Geneva, Switzerland: World Health Organization; [Last accessed on 2020 Jul 23]
https://www.who.int/medicines/areas/quality_safety/safety_efficacy/Pharmacovigilance_B.pdfua=1
-
- 25 Jung, I.Y., Kim, J.J., Lee, S.J., Kim, J., Seong, H., Jeong, W., Choi, H., (...), Kim, J.M.
Antibiotic-related adverse drug reactions at a tertiary care hospital in South Korea (Open Access)

(2017) *BioMed Research International*, 2017, art. no. 4304973. Cited 7 times.
<http://www.hindawi.com/journals/biomed/>
doi: 10.1155/2017/4304973

View at Publisher
-
- 26 Kiguba, R., Karamagi, C., Bird, S.M.
Antibiotic-associated suspected adverse drug reactions among hospitalized patients in Uganda: a prospective cohort study (Open Access)

(2017) *Pharmacology Research and Perspectives*, 5 (2), art. no. e00298. Cited 6 times.
[http://onlinelibrary.wiley.com/journal/10.1002/\(ISSN\)2052-1707](http://onlinelibrary.wiley.com/journal/10.1002/(ISSN)2052-1707)
doi: 10.1002/prp2.298

View at Publisher
-
- 27 Akalu, SD, Belavadi, NG.
Pattern of adverse drug reactions due to antibiotics in a tertiary care hospital (2017) *Int J Basic Clin Pharmacol*, 6, pp. 2027-2031.
-
- 28 Shamna, M., Dilip, C., Ajmal, M., Linu Mohan, P., Shinu, C., Jafer, C.P., Mohammed, Y.
A prospective study on Adverse Drug Reactions of antibiotics in a tertiary care hospital (Open Access)

(2014) *Saudi Pharmaceutical Journal*, 22 (4), pp. 303-308. Cited 30 times.
<http://www.sciencedirect.com/science/journal/13190164>
doi: 10.1016/j.jsps.2013.06.004

View at Publisher
-

- 29 Dhar, K., Sinha, A., Gaur, P., Goel, R., Chopra, V.S., Bajaj, U.
Pattern of adverse drug reactions to antibiotics commonly prescribed in department of medicine and pediatrics in a tertiary care teaching hospital, Ghaziabad ([Open Access](#))

(2015) *Journal of Applied Pharmaceutical Science*, 5 (4), pp. 78-82. Cited 8 times.

http://www.japsonline.com/admin/php/uploads/1479_pdf.pdf
doi: 10.7324/JAPS.2015.50413

[View at Publisher](#)

- 30 Kelly, M., Kaye, K.I., Davis, S.R., Shenfield, G.M.
Factors Influencing Adverse Drug Reaction Reporting in New South Wales Teaching Hospitals

(2004) *Journal of Pharmacy Practice and Research*, 34 (1), pp. 32-35. Cited 13 times.

<http://jppr.shpa.org.au/>
doi: 10.1002/jppr200434132

[View at Publisher](#)

- 31 Gor, A.P., Saksena, M.
Adverse drug reactions of nonsteroidal anti-inflammatory drugs in orthopedic patients ([Open Access](#))

(2011) *Journal of Pharmacology and Pharmacotherapeutics*, 2 (1), pp. 26-29. Cited 21 times.

doi: 10.4103/0976-500X.77104

[View at Publisher](#)

- 32 Farshchian, M., Ansar, A., Zamanian, A., Rahmatpour-Rokni, G., Kimyai-Asadi, A., Farshchian, M.
Drug-induced skin reactions: A 2-year study ([Open Access](#))

(2015) *Clinical, Cosmetic and Investigational Dermatology*, 8, pp. 53-56. Cited 6 times.

<http://www.dovepress.com/getfile.php?fileID=23617>
doi: 10.2147/CCID.S75849

[View at Publisher](#)

- 33 Wallerstedt, S.M., Brunlöf, G., Sundström, A.
Rates of spontaneous reports of adverse drug reactions for drugs reported in children: A cross-sectional study with data from the swedish adverse drug reaction database and the swedish prescribed drug register

(2011) *Drug Safety*, 34 (8), pp. 669-682. Cited 21 times.

doi: 10.2165/11591730-000000000-00000

[View at Publisher](#)

👤 Elkalmi, R.; Department of Pharmacology, Faculty of Medicine, Sebha University, Sabha, Libyan Arab Jamahiriya; email:Edriph@gmail.com

👤 Elkalmi, R.; Department of Clinical Pharmacy and Pharmacotherapeutics, Dubai Pharmacy College for Girls, Dubai, United Arab Emirates; email:Edriph@gmail.com

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