Original Article

Retrospective Assessment of the Reporting of Adverse Drug Reactions in a Malaysian Clinical Training Center: A Short Communication

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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 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.

KEYWORDS: *Adverse drug reaction reporting, completeness assessment, Malaysia, pharmacovigilance, quality assessment*

INTRODUCTION

Globally, most countries started to establish pharmacovigilance systems that concern with medication safety, particularly after the global catastrophe associated with the use of thalidomide in pregnant mothers. These efforts culminated in the establishment of the World Health Organization (WHO) Collaborating Center for International Drug Monitoring in cooperation with the University of Uppsala, known as the Uppsala Monitoring Center (UMC) in 1968. The center is working by collecting, assessing, and communicating information from member countries' national pharmacovigilance centers concerning the benefits, harm, effectiveness, and risks of drugs. Currently, 156 countries are full members of the WHO Program for International Drug Monitoring; 26 of them are associate members.[1]

Moreover, the program has received more than 20 million anonymous reports on the suspected adverse effects of medications suffered by patients.[2] In Malaysia, any adverse drug reactions (ADRs) experienced or suspected by patients or health-care providers were advised to be reported to the Malaysian Adverse Drug Reactions Advisory Committee (MADRAC) by filling in the ADR reporting form.[3] This committee was established in 1987 under the Drug Control Authority (DCA) at the Malaysian

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Ministry of Health. DCA is responsible for performing the function of pharmacovigilance for drugs registered for use in Malaysia.[4] It is worth noting here that in 1990, Malaysia obtained the full membership of the WHO-UMC program.

Although the spontaneous reporting of ADRs system is the backbone of postmarketing drug safety surveillance (pharmacovigilance) systems, underreporting and incomplete data are two main weaknesses that limit the desired conclusions from such systems to assess the causality relationship between the suspected drug and the event.[5,6] Consequently, these limitations constrain the capacity of spontaneous ADRs reporting systems in signal detecting. The quality and completeness of the information filled in the ADR reporting form will facilitate and hasten the process of signal generation. According to the WHO, ADR reports, which suggested an adverse reaction that cannot be judged because the information is insufficient or contradictory, and cannot be supplemented or well verified, are classified as un-assessable/Unclassifiable (WHO report). In Malaysia, four "4" mandatory fields should be filled at least for the report to be accepted by MADRAC.[7] The minimum four "4" mandatory fields are identifiable patient, a named suspected drug, suspected reaction, and identifiable reporter. Therefore, if the ADR report is classified as insufficiently documented or fails to fulfill the approved and specific criteria, it will be excluded from further pharmacovigilance assessment.[8] The quality of ADRs reported problem was the focus of attention and concern of the relevant authorities involved in the pharmacovigilance activities. Therefore, it is essential to encourage health-care providers as well as the patients to submit a complete ADR report form and check the quality of the form in its initial preparation stages. This can help to maintain the value of the reported information that could be further utilized at local and international levels.

Moreover, it is worthy of highlighting that having a large amount of poor-documented and low-quality ADRs reports might contribute to erroneous signal associations and affect the accuracy of the causality data. However, there is scarce research on the quality of ADR reports in Malaysia. Therefore, this study has been conducted to review and assess the completeness and the quality of the ADR reports submitted to the Pharmacovigilance Unit (PVU) in the clinical training center (CTC), Faculty of Medicine, UiTM Sungai Buloh Campus.

Materials and Methods

Study design

It was a cross-sectional, retrospective study that included all 31 ADR reports that were submitted to the PVU in the Pharmacy Department in CTC, Faculty of Medicine, Sungai Buloh Campus, UiTM, from its inception in the year 2000 to December 31, 2018.

Study instrument

Referring to the Malaysian ADR report form, a data collection sheet was developed for the process of data extraction and data analysis. The sheet included patient information, ADR information, suspected drug information, and reporter's information fields: the patient's information, such as age, gender, and ethnic group; the ADR information such as the ADR description, onset of reaction, duration of reaction, seriousness of the ADR, the action taken after the occurrence of ADR, management of the ADR, and the outcome of the management; also the suspected drug's information, such as the name of the suspected drug, drug registration number, duration of drug usage, and concomitant drugs, and the reporter's information, such as the occupation of the reporter and their contact details.

Study procedure

The study was carried out by reviewing and examining the components of the ADR reporting form that were retrieved from the PVU in CTC, Faculty of Medicine, UiTM Sungai Buloh Campus. The completeness assessment was done by reviewing all the elements and assessing how many of the data were completed. The data were then computed in percentage. The quality of the report was evaluated as "good" if it mentions at least one of these three criteria:[9] first, the specific adverse event, second, the sign and symptoms and including the laboratory data with other information such as concomitant diseases and medications, and third, the sign and symptoms and including full details on the events and the patient.

Ethical approval

The study protocol was approved by the Research Ethics Committee of Universiti Teknologi Mara (Reference no: 600-IRMI (5/1/6) REC/19/241). All the ethical requirements were considered, fulfilled, and sought before the commencement of the study.

Statistical analysis

Descriptive statistics in the form of frequencies and percentages were employed to represent the patients' demographic information, ADR-related information, suspected drug information, and the reporter's information data. The data were analyzed using SPSS software (version 24; SPSS, Inc., Chicago, IL, USA).

Results

A total number of ADR reports that were received by the PVU in CTC, Faculty of Medicine, Sungai Buloh Campus, from its inception in December 2000 to December 31, 2018, were 35 reports. Only in 2014, the PVU began receiving ADR reports. The reports that were received by PVU in 2014 were 6.5% (n = 2), in 2015 were 16.1% (n = 5), in 2016 were 16.1% (n = 5), in 2017 were 22.6% (n = 7), and in 2018 were 38.7% (n = 16), as depicted in Figure 1.

However, only 31 (88.5%) reports have been included and subjected to analysis in this study. Four reports were excluded because they did not contain two or more of the required information necessary to submit ADR reports.

Completeness assessment of the adverse drug reaction report fields

In a total of 31 reports that were subjected to analysis, 96.8% (n = 30) of the patient's information and 100% (n = 31) of ADR descriptions were completed, while for the suspected drug's information and the reporter's details, they were completed by 51.6% (n = 16) and 80.6% (n = 25), respectively [Figure 2]. Of the 31 reports, 38 events of suspected ADR were detected and reported. The average was 1.2 ADR events per report. The date when the event started was completed in about half (n = 14, 44.8%) of the reports; meanwhile, the date when the reaction disappeared was recorded in about one-third (n = 11, 35.2%) of the reports. For action taken for the ADR event section, it was completed in about half of the reports (n = 17, 54.8%). In almost half (n = 16, 53.3%) of the analyzed reports, the section of the outcome of the action taken to tackle the ADR event was completed.

Furthermore, the study findings indicated that the majority (n = 15, 93.8%) of the patients were fully recovered, and only one of them (n = 1, 6.3%) was in recovering status. The section of the time onset of the event was recorded in about half (n = 16, 51.6%) of the analyzed reports. The "de-challenge" field and the "re-challenge" field were completed in substantially more than half of the reports (n = 18, 58.0%: n = 17, 54.8%), respectively, as shown in Table 1. Regarding the seriousness of the event and examining the causal relationship between the culprit drug and the event, data analysis shows that the information about the seriousness of the event and the information on the causal relationship were recorded with almost equal proportions in the reports (n = 18, 58.0%: n = 17, 54.8%, 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 [Figure 3]. Meanwhile, for the drug-event causality relationship, both certain and probable were reported with the same proportion (n = 6, 35.3%). However, about one-third of the recorded events were described as possible (n = 5. 29.4%), as illustrated in Figure 4. Information about a "doubtful" and/or "definite" drug-event causal relationship was not recorded in the reviewed reports.

The suspected drug field was completed in 16 reports (52.2%). This completeness includes the drug's name, the drug's batch number, the drug's dose, and frequency and the date when the therapy started and ended. The drug name and the batch number were completed in 96.8% (n = 30) and 19.4% (n = 6) of the reports, respectively. Moreover, the dose and frequency section was filled in 58.1% (n = 18) of the reports, therapy started and therapy ended sections were filled in 48% (n = 15) and 38.4% (n = 12) of the reports, respectively. As for the concurrent drugs section, it was only filled in in 9.6% (n = 3) of the reports. For laboratory data and medical history, 6.5% (n = 2) and 35.5% (n = 11) of the reports were filled in, respectively. The reporter's information section was provided in almost all (n = 25, 80.6%) of the reports. This section includes information related to the reporter's name, reporter's institution, and their contact details. Both the name of the reporter and his or her affiliated institution were provided in all (n = 31, 100%) of the reports. Whereas, for the contact details, only 38.7% (n = 12) of the field was completed. Whereas, for the contact details field, it was only completed in 12 (38.7%) reports.

Of the 31 reports, the study findings indicated that slightly more than half (n = 17, 54.8%) of the patients were female. Moreover, study findings indicate that the majority (n = 17, 56.7%) of the suspected ADRs have occurred among adults (age 18–60 years old), followed by (n = 12, 40%) incidences among the elderly (age above than 60 years old), while only one (n = 1, 3.3%) report was among adolescents aged between 13 and 18 years old. As

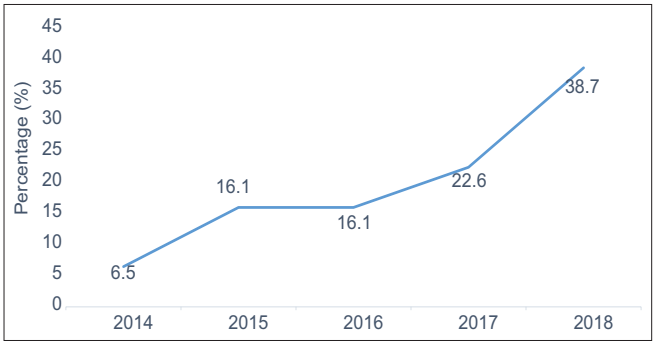

Figure 1: Percentage of ADR reports received by Pharmacovigilance Unit per year

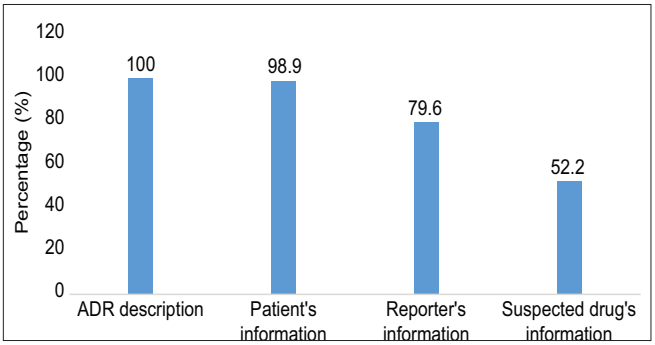

Figure 2: Percentage of the completeness of the ADR reporting section

expected, the analyzed reports showed that most (n = 29, 93.5%) of those who had suspected ADRs were Malays. Meanwhile, both Chinese and Indians have a similar percentage, which is 3.2% (n = 1). Among all reported suspected ADR events, skin and subcutaneous disorders were the most reported events with 65.8% (n = 25) followed by respiratory, thoracic, and mediastinal disorder and eye disorder with 7.9% (n = 3) each [Figure 5].

Of the suspected drugs that were reported, 86% (n = 37) of these drugs were suspected of causing the ADR(s), while 14% (n = 6) of these drugs were concomitant. Among the suspected drugs, 29.7% (n = 11) were not known to be either suspected drug or concomitant drugs as the reporter listed all the medications taken by the patient in the suspected drug's field. The most frequent suspected drugs reported to the pharmacovigilance center were aspirin, amoxicillin, and sulbactam (Augmentin), and cefuroxime, with a percentage of 8.1% (n = 3) each, followed by clopidogrel, insulin, and pethidine with a percentage of 5.4% (n = 2) each. Among all the suspected medicines, drug class of antibiotics (32.4%, n = 12) is the most reported suspected drugs that caused ADR followed by drug class of opioid analgesic (8.1%, n = 3) and nonsteroidal anti-inflammatory drugs (NSAID) (8.1%, n = 3). Of 31 reports, all the reporters were found to be medical officers (100%, n = 31). However, only 38.7% (n = 12) of the reporters filled in their contact details, while 61.3% (n = 19) did not fill in their contact details.

During the data extraction, 64.5% (n = 20) of the data were extracted from the ADR reporting form, while other 35.5% (n = 11) of the data were obtained from allergic card application form instead of from ADR reporting form. Besides that, all the ADR reporting forms in CTC were found attached to the allergic card application form. However, the data retrieved from the allergic card application form are still valid to be used as it includes the patient's information, ADR description, suspected drug's information, and reporter's information. This information is mandatory to be filled in the ADR reporting form.

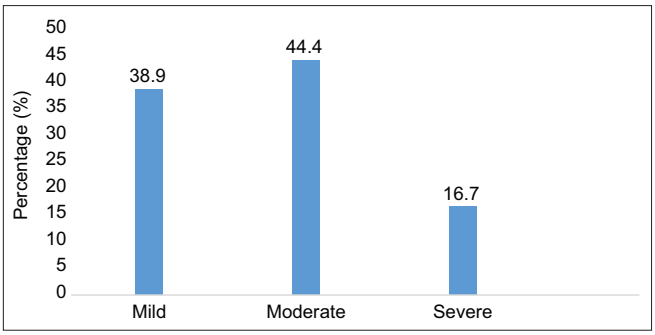

Figure 3: The severity of reported ADRs

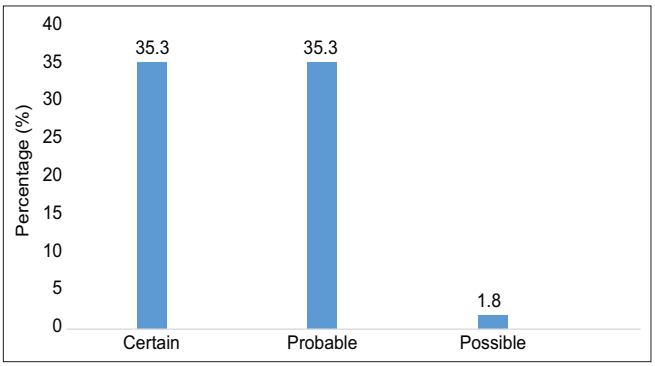

Figure 4: The ADR-Drug causality relationship analysis

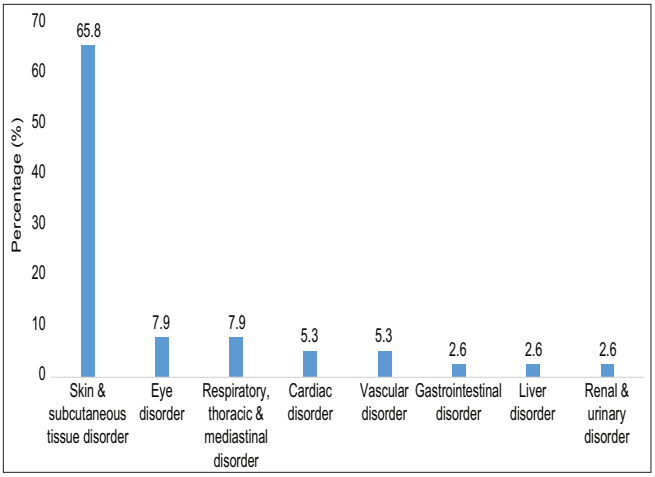

Figure 5: Organ Systems Classification affected by the ADRs

Discussion

This retrospective, single-center study has been conducted to examine the quality and completeness of ADR reports submitted to the PVU through the pharmacy department in Sungai Hulu Hospital in Malaysia. To the best of our knowledge, this is the first exploratory study to assess the quality and completeness of adverse event reporting systems in the country. Despite the small number of the sample of the reports submitted to this center, the study findings showed an improvement in the rate of ADR reporting this center over time. However, the total number of ADR reports submitted by the health-care professionals as well as the patients was 45 reports. No reports have been submitted to the PVU from the pharmaceutical companies, although they have obliged MADRAC guidelines. The pharmacist in charge of the PV unit in the pharmacy department has followed these reports. Most of these reports have been submitted by physicians, followed by a pharmacist where the number of reports submitted by patients was negligible. The study findings are in concordance with previous studies in the developed counties where most of the reports were submitted by physicians

Table 1: Completeness of the outcome of the ADR after de-challenge and re-challenge of the suspected drug

ADR	Number of reports completed	Completeness of the section (%)
De-challenge	18	58.1
ADR subsided	10	55.6
ADR not subsided	3	16.7
Unknown	5	27.8
Re-challenge	16	54.8
ADR reappeared	3	17.6
ADR not reappeared	1	5.9
Not applicable	12	70.6

and other health-care professionals. These findings might be attributed to that physicians have more access to patient's records, possess more awareness, and received well training and education concerning reporting ADRs. As per the results of this study (low of ADR reports), it is vital to increase the awareness of the health-care professional and general public about the pharmacovigilance importance and activities in this particular region.

Our findings showed that females had reported ADR more frequently compared to males in a pattern that tends to be consistent with previous studies that highlighted the increased frequency of ADR reports among females compared to males.[10-12] In a systematic review of the factors affecting the development of ADR, it has been highlighted that the drug pharmacokinetics and pharmacodynamics might be altered by differences in anatomical and physiological function in both genders.[13] Moreover, the relative increase of ADR reporting among females might be attributed to their increased attentiveness to discomfort symptoms that might increase their perception of the symptom as the symptom of illness.[14,15]

Concerning the age group that was more frequently existed in the reported ADR, our findings highlighted that the adult age group (18–60 years old) was associated with the highest frequency among the reported ADRs. Similarly, a Korean study has reported that 64% (n = 6209) of the patients who experienced the ADR were in the adult age group but with an age range from 19 years old to 64 years old.[12,16] In addition, our findings showed that 40% of the reported ADRs were related to individuals aged higher than 60 years that might occur because of the aging that is potentially associated with alteration to drug metabolism and clearance.[17] Thus, it may lead to an increase in ADR incidence and disease susceptibility among elderly individuals.[18] Furthermore, polypharmacy and multiple drug combinations that were frequently reported to be more prevalent among the elderly may increase the potential medication safety concerns and contribute to the occurrence of the ADR.[19]

In this study, antibiotics were the most drug classes that cause the ADR, followed by opioid analgesic and NSAID. A Korean study has found a similar result in which antibiotics were the most reported drug class that cause the ADR.[20] Even though this study found Augmentin and cefuroxime, second-generation cephalosporins, as the most frequent antibiotics that cause the ADR in CTC patients, other studies found that ceftriaxone, third-generation cephalosporins,[21-24] as the most frequent antibiotics that cause the ADR. Opioid analgesics and NSAID obtain the same result, which is 8.1% (n = 3). The opioid analgesics were found to be meperidine and morphine, while the NSAIDs were found to be diclofenac and etoricoxib. A study has found similar results in which diclofenac was found as the most frequent NSAID to cause the ADR.[25]

In our findings, skin and subcutaneous tissue disorders were the most reported events followed by eye disorder and respiratory, thoracic, and mediastinal disorders. Similarly, a cross-sectional study in Northeast India also reported that skin was the most common organ system affected by the ADR.[11] Moreover, a Swedish study has also found that skin and subcutaneous disorders were the most reported events in adults followed by neurological disorders, gastrointestinal disorders, psychiatry disorders, and cardiac disorders.[26] In contrast, an observational study in India reported that gastrointestinal disorders were the most frequent organ affected by the ADR, followed by skin and subcutaneous tissue disorder.[10]

Our work reported that the majority of the occurred skin and subcutaneous tissue disorders were associated with the administration of the antibiotics. This finding seemed to be consistent with previous local and international data that showed the antibiotics as most frequently associated with skin and subcutaneous tissue disorders.[27,28] This could be rationally explained by the undesired skin reactions mediated by immunological and nonimmunological mechanisms induced by the use of commonly used antibiotics such as penicillin and cephalosporins.[28,29]

Overall, in our study setting, the allergic card application has captured only the basic information such as the name and age of the patient, name of the drug, and the suspected ADR and the applicator's information. Unlikely, the standard ADR reporting form required more detailed information to be filled. The information deficiency in the ADR reports might be influenced by the knowledge and attitude of the reporters.[30] Lacking time[31] and lacking knowledge and confidence in ADR reporting methods[32,33] may contribute to the incomplete information in the ADR reporting form.

Conclusion

The process of ADR reporting in our study setting is still

can be improved. Further efforts and relevant interventions should be considered to increase the reporting frequency and to enhance the completeness and the quality of the ADR report. Better completeness of the ADR report will provide more accurate information and will help to promote better assessment for drug safety monitoring.

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Nil.

Conflicts of interest

There are no conflicts of interest.

References

1. UMC. Uppsala Monitoring Centre (UMC) Members of the WHO programme Uppsala, Sweden: Uppsala Monitoring Centre (UMC); 2020. Available from: https://www.who-umc.org/global-pharmacovigilance/who-programme-for-international-drug-monitoring/. [Last cited on 2020 Jul 14].
2. UMC. Uppsala Monitoring Centre (UMC): What is VigiBase? Uppsala, Sweden: Uppsala Monitoring Centre (UMC); 2020. Available from: https://www.who-umc.org/vigibase/vigibase/. [Last cited on 2020 Jul 13].
3. NPRA. National Pharmaceutical Regulatory Agency (NPRA): Reporting Adverse Drug Reactions and Adverse Events Following Immunisation KL, Malaysia: National Pharmaceutical Regulatory Agency (NPRA); 2020. Available from: https://www.npra.gov.my/index.php/en/health-professionals/reporting-adr. [Last updated on 2020 Jul 14].
4. Vargesson N. Thalidomide-induced teratogenesis: History and mechanisms. Birth Defects Res C Embryo Today 2015;105:140-56.
5. Elkalmi RM, Al-Lela OQ, Jamshed SQ. Motivations and obstacles for adverse drug reactions reporting among healthcare professionals from the perspective of lewinâ s force field analysis theory: Analytic approach. J Pharmacovigil 2014;2:3.
6. Gahr M, Eller J, Connemann BJ, Schönfeldt-Lecuona C. Underreporting of adverse drug reactions: Results from a survey among physicians. Eur Psychiatry 2017;41:S369-S.
7. MADRAC. Malaysian Guidelines for the Reporting and Monitoring of ADR. Kuala Lumpur, Malaysia: National Pharmaceutical Control Bureau, Ministry of Health; 2002.
8. Rejani PP, Sumesh TP, Shaji KS. Cost of care: A study of patients hospitalized for treatment of psychotic illness. Indian J Psychol Med 2015;37:71-4.
9. Ali S, Egunsola O, Al Dossari DS, Al Zaagi IA. Adverse drug reaction reporting in a large tertiary hospital in Saudi Arabia: results of an incentive strategy. Therapeutic advances in drug safety. 2018;9(10):585 90. Alsaleh F, Lemay J, Al Dhafeeri R, AlAjmi S, Abahussain E, Bayoud T. Adverse drug reaction reporting among physicians working in private and government hospitals in Kuwait. Saudi pharmaceutical journal. 2017;25(8):1184 93.)
10. Härmark L, van Grootheest AC. Pharmacovigilance: Methods, recent developments and future perspectives. Eur J Clin Pharmacol 2008;64:743-52.
11. Jeetu G, Anusha G. Pharmacovigilance: A worldwide master key for drug safety monitoring. J Young Pharm 2010;2:315-20.
12. Jones JK. Why Should I Report an Adverse Drug Event? Medscape Pharmacists © 2008 Medscape, LLC; 2008. Available from: https://www.medscape.org/viewarticle/578160#:~:text=In%20fact%2C%20individual%20ADE%20reports, possible%20new%20and%20serious%20ADEs. [Last accessed on 2020 Jul 23; Last updated on 2008 Aug 18].
13. Alshammari TM, Al-Kathiri WH, Le Louet H, Aljadhey HS. Completeness of adverse drug reactions reports of the Saudi adverse event reporting system. Saudi Med J 2015;36:821-8.
14. Yu YM, Shin WG, Lee JY, Choi SA, Jo YH, Youn SJ, *et al*. Patterns of adverse drug reactions in different age groups: Analysis of spontaneous reports by community pharmacists. PLoS One 2015;10:e0132916.
15. Venkatasubbaiah M, Reddy PD, Satyanarayana SV. Analysis and reporting of adverse drug reactions at a tertiary care teaching hospital. Alex J Med 2018;54:597-603.
16. Leape LL. Why should we report adverse incidents? J Eval Clin Pract 1999;5:1-4.
17. Lihite RJ, Lahkar M, Das S, Hazarika D, Kotni M, Maqbool M, *et al.* Study on adverse drug reactions in a tertiary care hospital of Northeast India. Alex J Med 2017;53:151-6.
18. Alomar MJ. Factors affecting the development of adverse drug reactions (review article). Saudi Pharm J 2014;22:83-94.
19. Verbrugge LM. Gender and health: An update on hypotheses and evidence. J Health Soc Behav 1985;26:156-82.
20. Klotz U. Pharmacokinetics and drug metabolism in the elderly. Drug Metab Rev 2009;41:67-76.
21. Brahma DK, Wahlang JB, Marak MD, Ch Sangma M. Adverse drug reactions in the elderly. J Pharmacol Pharmacother 2013;4:91-4.
22. Hilmer SN, McLachlan AJ, Le Couteur DG. Clinical pharmacology in the geriatric patient. Fundam Clin Pharmacol 2007;21:217-30.
23. Le Couteur DG, McLachlan AJ, de Cabo R. Aging, drugs, and drug metabolism. J Gerontol A Biol Sci Med Sci 2012;67:137-9.
24. WHO. The Safety of Medicines in Public Health Programmes: Pharmacovigilance an Essential Tool. Geneva, Switzerland: World Health Organization; 2006. Available from: https://www.who.int/medicines/areas/quality_safety/safety_efficacy/Pharmacovigilance_B.pdf?ua=1. [Last accessed on 2020 Jul 23].
25. Jung IY, Kim JJ, Lee SJ, Kim J, Seong H, Jeong W, *et al*. Antibiotic-Related Adverse Drug Reactions at a Tertiary Care Hospital in South Korea. Biomed Res Int 2017;2017:1-7.
26. Kiguba R, Karamagi C, Bird SM. Antibiotic-associated suspected adverse drug reactions among hospitalized patients in Uganda: A prospective cohort study. Pharmacol Res Perspect 2017;5:e00298.
27. Akalu SD, Belavadi NG. Pattern of adverse drug reactions due to antibiotics in a tertiary care hospital. Int J Basic Clin Pharmacol 2017;6:2027-31.
28. Shamna M, Dilip C, Ajmal M, Linu Mohan P, Shinu C, Jafer CP, *et al*. A prospective study on Adverse Drug Reactions of antibiotics in a tertiary care hospital. Saudi Pharm J 2014;22:303-8.
29. Dhar K, Sinha A, Gaur P, Goel R, Chopra VS, Bajaj U. Pattern of adverse drug reactions to antibiotics commonly prescribed in department of medicine and pediatrics in a tertiary care teaching hospital, Ghaziabad. J Appl Pharm Sci 2015;5:078-82.
30. Kelly M, Kaye KI, Davis SR, Shenfield GM. Factors influencing adverse drug reaction reporting in New South Wales Teaching Hospitals. J Pharm Pract Res 2004;34:32-5.
31. Gor AP, Saksena M. Adverse drug reactions of nonsteroidal anti-inflammatory drugs in orthopedic patients. J Pharmacol Pharmacother 2011;2:26-9.
32. Farshchian M, Ansar A, Zamanian A, Rahmatpour-Rokni G, Kimyai-Asadi A, Farshchian M. Drug-induced skin reactions: A 2-year study. Clin Cosmet Investig Dermatol 2015;8:53-6.
33. Wallerstedt SM, 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. Drug Saf 2011;34:669-82.