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## Abstract

**Background:** Adverse drug reactions (ADRs) are the leading cause of morbidity, mortality and increased healthcare cost. A new scientific tool has been developed to monitor and report ADRs. Trigger tool is one of the active data collection process which triggers to identify the ADR in a quicker fashion. The objective of our research was to study and assess the trigger tools for detection and analysis of ADRs.

**Method:** This prospective study was conducted in internal medicine department of a tertiary care hospital for duration of 3 months. Patients aged 18 years of either gender admitted were included. Subjects treated on OPD basis, emergency cases, and ICU cases were excluded. Patients and their medical records were reviewed for trigger tools (if any) to monitor and further report ADRs.

**Result:** A total of 220 subjects were enrolled into the study. Out of them, 40 subjects experienced 93 ADRs. Eighty three trigger tools were identified in 40 subjects. Out of which, 63 trigger tools were utilized to report 80 (86.02%) ADRs. The incidence of ADRs was found to be 18.1%. Male 132 (62.85%) preponderance was observed over females 88 (41.90%). Polypharmacy (67.74%) was one of the most prominent predisposing factors reported. Majority of ADRs were found to be of probable 64 (68.8%) in nature. On severity analysis, 21 (22.5%) ADRs were of moderate (Level 3) severity and 75 (80.6%) were probably preventable.

**Conclusion:** Our results showed incidence of 18.1%. Trigger tools proved to be one of the best scientific tool in identification and reporting of ADRs in our study. Scientific validation of trigger tools is required to further utilize in large scale studies.



Trigger tool; Adverse drug reactions



ADR: Adverse Drug Reaction; NCCMERP: National Coordinating Council for Medication error Reporting and Prevention; IOM: Institute of Medicine; ADE: Adverse Drug Event; AE: Adverse Event; WHO: World Health Organization; IEC: Institutional Ethics Committee



Adverse drug reactions (ADRs) are the leading cause of morbidity, mortality and increased healthcare cost [1-4]. Despite of drastic improvement in healthcare practices, ADRs are contributing towards poor clinical outcome, hospitalization, prolongation of hospital stay, and enhanced economic burden [5-8].

Medication error occurs frequently and portrays a real image of adverse effects at a rate comparative to the growing population of India [9,10]. Along with multiple uses of drugs or multiple complications; inappropriateness in the dosage or dose interval makes patient care contraindicated in all way around. The National Coordinating Council for Medication error Reporting and Prevention (NCCMERP) defines medication error as "any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professionals, patient or consumer" [11-14].

Americans are injured every year by medication error in hospitals, nursing homes and doctor's offices (IOM 2006) which puts impairment of trust from the Health care professionals. It should be preventable by definition through education and effective system controls involving pharmacists, prescribers, nurses, administrators, regulators and patients [15,16].

Corresponding author: Atul Aggarwal, 24, Rajendra Nagar, Saharanpu- 247001r, Saharanpur, India, Tel: 9456018555, 7353262628; E-mail: [atul1507@gmail.com](mailto:atul1507@gmail.com)

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30.1%) and 13 (13.9%) were unknown due to lots of follow-up discharge (Table 1).



Subjects who are enrolled during the study for the suspected ADRs are treated for the better outcome in terms of health, medication related burden to give the disease free environment. The specific treatment provided to the suspected ADRs was (38, 40.8%), maximum are given No treatment (48, 51.6%) and lastly symptomatically treated subjects are 7 (7.5%).



The incidence of ADRs calculated over the study period of time was 18.1% and that was a good number to overcome the traditional reporting system of ADRs which was greatly compared to the other studies done by the Vora et al. (5.42%), Arulmani et al. (9.8%) and Sinha et al. (3.31%) [37-40].

The reason for increase in the incidence of ADR was due to the use of Trigger tool reporting system that was largely supported by the authors all over wide across the world like Classen et al., Rozich et al., Sarkar et al., Takata et al., and one of the study by Pinney et al., in Surgery stated that the trigger tool uncovered AEs in 14.6% of patients [30,31,35,41,42].



Vora et al., showed that in internal medicine males and females incidence rate were 3.37% and 2.05% respectively and a similar type of study showed reason of admission due to ADR is higher in female (57%) than male (43%) [37]. Arulmani et al., showed higher incidence of rate in females (78, 64.5%) than males (43, 35.5%) [38]. An Indian study by Gor et al., stated that sex of the patient does not affect the incidence of ADR [39]. In state of the above data our study resulted in Male 132 (62.85%) preponderance over females 88 (41.90%).



Poly-pharmacy (67.74%) was one of the most prominent predisposing factor reported in the study that was similar to the other study done by the Fattinger et al., [43]. The other predisposing factors which are contributed in the study are Inter current disease (51, 31.48%), Age (23, 14.1%), Gender (7, 4.3%) and others (6, 3.7%).



In one the study by the by Vora et al., showed that the Anti-microbial agents cause maximum of ADR (40.43%) which equally proved by the other author Arulmani et al., Anti-microbial agents (44, 17.0%) followed by Anti-hypertensive agents (25,14.3%) [37,38].

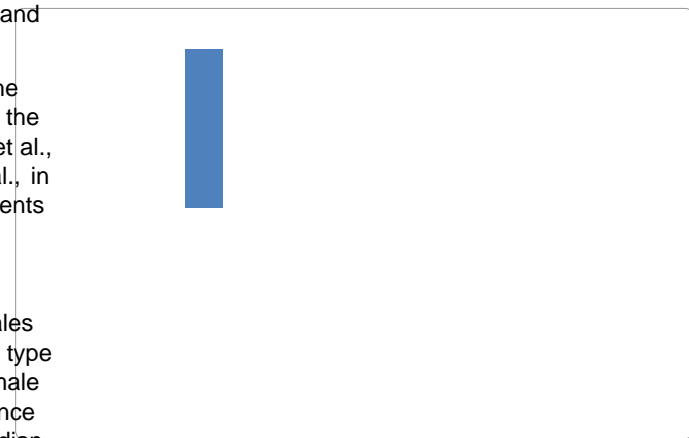
Sinha et al., showed that the most common drugs associated in the ADR are Anti-hyperglycemias agents, anti-hypertensive, chemotherapeutic agents and insulin [40]. Major of the cardiovascular agents are related to the increase in the liver enzymes (28) showed by the Dormann et al. [44]. In view of above data, our drug class study maximum related to the Anti-hypertensive (35, 37.6%) followed by the Anti-hyperglycaemias (12, 12.9%), 10 each of Steroids, NSAIDs (10.7%) and others (26, 27.9%) (Figure 2).



Maximum of the drugs affecting the organ system was

cardiovascular system (CVS, 32.2%), followed by the Endocrine (30.1%), Neurological (8.6%), Gastrointestinal (7.5%), Dermatological (5.3%) and Mucosekeletal, Respiratory, Haematological, Ophthalmic (1 each, 1.07%) in comparison to other studies Plessen CV et al., and Fattinger et al., showed Gastrointestinal was the major affecting organ system [43,45]. Arulmani et al., showed that the most affected organ system was skin (56, 34.1%) followed by the CNS (31, 18.9%) [38] (Figure 3).

Depending upon the WHO causality scale the highest ADR falls in the category of probable (64, 68.8%) followed by the certain (21, 22.5%), Possible (7, 7.5%) and unlikely (1, 1.0%) that is similar to the results of Arulmani et al., classified two third of the reactions as probable (102, 62.2%) [38]. Another study by Vora et al., stated that maximum of ADRs occurred as certain (28, 59.57%) [37] (Figure 4).





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