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DETECTING MEDICATION ERRORS FROM ADVERSE DRUG REACTION MONITORING CENTRE DATABASE - A RETROSPECTIVE ANALYSIS

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ABSTRACT: Introduction: Despite the traditional focus on adverse drug reactions, pharmacovigilance centres have recently been identified as a potentially rich and important source of medication error (ME) data. The aim of this study is to identify ME from adverse drug reaction (ADRs) reports. **Materials and methods:** A retrospective analysis of ADR reports notified to adverse drug reaction monitoring centre of tertiary care teaching hospital and medical college during January 2014 to December 2016 was done. Those reports which had inappropriate information were excluded. **Result:** A total of 651 reports met the inclusion criteria and were reviewed, The mean age and weight of patients experienced ADRs due to ME was 32.6 ± 16.1 years and 51.9 ± 17.3 kg respectively, among which 35 men and 39 women. Regarding type of medication errors, most of them were related to monitoring errors (56.2%) followed by prescribing errors (37.5%). Considering categories of ME, 73.4% was into category E which was related to temporary harm to the patient. Majority of ADR reports were mild in nature and produce mild temporary harm to the patients. **Conclusion:** Explore new role of pharmacovigilance centre to identify medication error which is preventable and indirectly improve quality of health care system and ensuring patient safety.

INTRODUCTION: The goal of drug therapy is the achievement of defined therapeutic outcomes that improve a patient's quality of life while minimizing patient risk. There are inherent risks, both known and unknown, associated with the therapeutic use of drugs (prescription and non prescription) and drug administration devices. The incidents or hazards that result from such risk have been defined as drug misadventuring, which includes both adverse drug reactions (ADRs) and medication errors [1].

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According to National Coordinating Council for Medication Error and Prevention (NCC MERP), a medication error is defined 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 professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems, including prescribing; order communication; product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use" [2].

Medication errors are broadly classified into 3 groups: Prescribing error, dispensing error and administering error. Medication errors are much more frequent than ADRs but only a small minority actually causes ADRs [3].

The problems and sources of medication errors are multifactorial. Errors occur from lack of knowledge, substandard performance and mental lapses, or defects or failures in systems. Medication errors may be committed by any staff of hospital premises including physicians, nurses, pharmacy technicians, students, administrators, patients themselves and their caregivers or outside the hospital premises including pharmacists, pharmaceutical manufacturers and medical devices manufacturers [1]. A medication error can occur at any step of the medication use process. Some ADRs are associated with medication errors which are preventable in nature **Fig. 1**. Minor errors that have little or no potential for harm are not considered potential ADRs but some medication errors result in serious patient morbidity or mortality. Thus, medication errors must not be taken lightly. Furthermore, WHO has highlighted the importance of identifying medication errors and is now working toward expansion of existing roles of pharmacovigilance centres to include monitoring of medication errors [4].

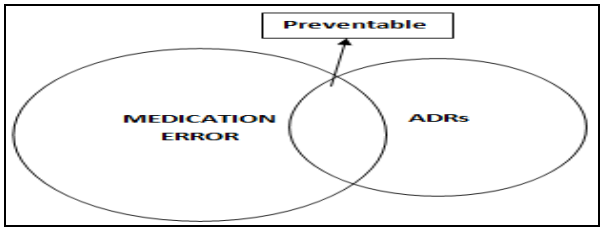

FIG. 1: ADRs ARE ASSOCIATED WITH MEDICATION ERRORS WHICH ARE PREVENTABLE IN NATURE

Pharmacovigilance centres are beginning to work collaboratively to prospectively or retrospectively identify medication errors [5]. The major methods for detecting medication errors and associated adverse drug-related events are chart review, computerized monitoring, administrative databases, and claims data, using direct observation, incident reporting, and patient monitoring [6, 7, 8, 9].The aim of this study is to identify medication errors from ADRs reported to pharmacovigilance centre of tertiary care teaching hospital and medical college, and to describe the characteristics of these medication errors: incidence, types, categories, harm and severity.

MATERIAL AND METHODS:

Study Design: A retrospective analysis of pharmacovigilance database was undertaken from the year January 2014 to December 2016.

Selection Criteria: All ADR reports notified to Rajkot pharmacovigilance centre during January 2014 to December 2016 were considered for inclusion. Those reports which did not have Worldwide unique number or did not upload in Vigiflow database were considered for exclusion for better analysis.

Method:

Detection of Medication Error: In order to identify medication error by assessing ADR reports.

Type of Medication Errors: Detected medication errors were organized in various types on basis of American Society of Hospital Pharmacists ASHP guidelines [1].

Type of Error:

Prescribing Error: Incorrect drug selection (based on indications, contraindications, known allergies, existing drug therapy, and other factors), dose, dosage form, quantity, route, concentration, rate of administration, or instructions for use of a drug product ordered or authorized by physician (or other legitimate prescriber); illegible prescriptions or medication orders that lead to errors that reach the patient.

Omission Error: The failure to administer an ordered dose to a patient before the next scheduled dose, if any.

Wrong Time Error: Administration of medication outside a predefined time interval from its scheduled administration time (this interval should be established by each individual health care facility).

Unauthorized Drug Error: Administration to the patient of medication not authorized by a legitimate prescriber for the patient.

Improper Dose Error: Administration to the patient of a dose that is greater than or less than the amount ordered by the prescriber or administration of duplicate doses to the patient, *i.e.*, one or more dosage units in addition to those that were ordered.

Wrong Dosage-form Error: Administration to the patient of a drug product in a different dosage form than ordered by the prescriber.

Wrong Drug-preparation Error: Drug product incorrectly formulated or manipulated before administration.

Wrong Administration-technique Error: In-appropriate procedure or improper technique in the administration of a drug.

Deteriorated Drug Error: Administration of a drug that has expired or for which the physical or chemical dosage-form integrity has been compromised.

Monitoring Error: Failure to review a prescribed regimen for appropriateness and detection of problems, or failure to use appropriate clinical or laboratory data for adequate assessment of patient response to prescribed therapy.

Compliance Error: Inappropriate patient behavior regarding adherence to a prescribed medication regimen.

Other Medication Error: Any medication error that does not fall into one of above predefined categories.

Categorization of Medication Errors: For further evaluation of detected medication errors, they were categorized on basis of NCC MERP Index [10].

Category A: Circumstances or events that have the capacity to cause error.

Category B: An error occurred but the error did not reach the patient (An "error of omission" does reach the patient).

Category C: An error occurred that reached the patient but did not cause patient harm.

Category D: An error occurred that reached the patient and required monitoring to confirm that it resulted in no harm to the patient and/or required intervention to preclude harm.

Category E: An error occurred that may have contributed to or resulted in temporary harm to the patient and required intervention.

Category F: An error occurred that may have contributed to or resulted in temporary harm to the patient and required initial or prolonged hospitalization.

Category G: An error occurred that may have contributed to or resulted in permanent patient harm.

Category H: An error occurred that required intervention necessary to sustain life.

Category I: An error occurred that may have contributed to or resulted in the patient's death.

Severity Criteria: The severity of the reaction as mild, moderate and severe was determined according to Hartwig Scale [11]. Mild ADRs (Level 1, 2) were self limiting and able to resolve over time without treatment and do not contribute to prolongation of length of stay.

Moderate ADRs (Level 3, 4, 5) were required therapeutic intervention and hospitalization prolonged by one day but resolved in 24 h or change in drug therapy or specific treatment to prevent a further outcome. Severe ADRs (Level 6, 7) were life threatening, producing disability and those that prolonged hospital stay or lead to hospitalization, required intensive medical care, or lead to the death of the patient.

Assessment of Harm: On basis of 2014 American Society for Healthcare Risk Management [12], all ADRs occurred due to medication errors were assessed for their harm and classified in 7 different classes (A to F) according to severity of harm. Furthermore assessment of duration of harm due to ADRs also had been evaluated.

Statistical Analysis: By Microsoft Excel software 2007 in numbers and percentages.

RESULT: Over a period of 3 year, 665 reports of ADRs were reported to AMC of tertiary care teaching hospital and medical college.

TABLE 1: AGE, SEX AND WEIGHT WISE DISTRIBUTION OF MEDICATION ERRORS

Socio-demographic profile		Number of ME (%)
Age (n=64)	0-14	11
	15-20	03
	21-49	37
	50-64	13
	>= 65	00
Sex (n=64)	Male	35 (55%)
	Female	29 (45%)
Weight (n=40)	<16	01 (2.5%)
	16-25	03 (7.5%)
	26-45	05 (12.5%)
	46-70	26 (65%)
	> 70	05 (12.5%)

14 ADR reports were incomplete so they were excluded. Out of 651 reports, there were 64(9.8%) medication errors associated with ADRs. The mean age of patients experienced ME was 32.6 ± 16.1 years. Regarding sex distribution, 35 ADRs reported in men and 29 ADRs were reported in women. Information regarding weight was mentioned in 40(63.5%) ADR reports, among these the mean weight of patients was 51.9 ± 17.3 kg **Table 1**. Regarding type of medication errors, most of them were related to monitoring errors (56.2%) followed by prescribing errors (37.5%). Considering categories of ME, 73.4% was into category E which was related to temporary harm to the patient **Table 2**. Regarding severity of ADR reports, 33 reports were mild, followed by 29 reports were moderate and 2 reports were severe which produced mortality of the patient **Table 3**.

TABLE 2: EVALUATION OF MEDICATION ERROR-TYPES AND CATEGORY

		Number of ME n=64 (%)
Type	Prescribing error	24 (37.5%)
	Omission error	-
	Wrong time error	-
	Unauthorized drug error	-
	Improper dose error	-
	Wrong dosage-form error	-
	Wrong drug-preparation error	-
	Wrong administration-technique error	03 (4.6%)
	Deteriorated drug error	-
	Monitoring error	36 (56.2%)
	Compliance error	01 (1.7%)
	Other medication error	-
Category	A	-
	B	01 (1.8%)
	C	02 (3.1%)
	D	03 (4.6%)
	E	47 (73.4%)
	F	07 (10.9%)
	G	-
	H	02 (3.1%)
	I	02 (3.1%)

TABLE 3: SEVERITY OF pADRs OCCURRED DUE TO ME

Category of severity	Number of pADRs n=64 (%)
Mild (level 1; 2)	33
Moderate (level 3;4;5)	29
Severe (level 6;7)	02

Among the ADRs occurred due to ME, 76.6% ADR reports produced mild harm followed by 17.2% produced moderate and 3.1% produced severe harm to the patients. However 3.1% reports were fatal. Considering duration of harm, 3.1% produced permanent harm, 50% produced temporary harm and 46.9% produce unknown harm **Table 4**.

TABLE 4: EVALUATION OF PATIENT HARM TYPE AND DURATION DUE TO MEDICATION ERROR

		Number of pADRs n=64 (%)
Type	A:-death	02 (3.1%)
	B:-severe harm	02 (3.1%)
	C:-moderate	11 (17.2%)
	D:-mild	49 (76.6%)
	E:-no harm	-
	F:-unknown	-
Duration	Permanent	02 (3.1%)
	Temporary	32 (50%)
	Unknown	30 (46.9%)

DISCUSSION: Medication errors have important implications for patient safety. A medication error can occur at any step of the medication use process which can be capable to do adverse drug reactions (ADRs). Medication errors are much more frequent than ADRs. Minor errors that have little or no potential for harm are not considered potential ADRs- *e.g*. a dose of non-critical medication such as docusate is given several h later which does not produce any harm but it is considered to be medication error. If the incident has potential to harm a patient- *e.g*. a dose of critical medication such as intravenous antibiotic is not given which is considered both a medication error and a potential ADR which is preventable in nature.

However, some medication error produces serious morbidity and mortality to the patients, so detection of medication error is more important from various sources. In a study of ADRs spontaneously reported to regional drug monitoring centre of Tours, France, over a one year period, approximately 17% of patients were adjudged to have experienced a preventable ADR [pADR] secondary to inappropriate prescribing which was medication error [13]. The WHO has highlighted the importance of identifying MEs and now working towards expansion of existing roles of pharmacovigilance centres which are beginning to work collaboratively to identify MEs by either prospective or retrospective manner [14, 15]. In our study, we revealed 9.8% ADRs (n=64) are preventable resulting due to medication errors, while Aji *et al*., study revealed that 14.4% were considered preventable and Desiree *et al*., study revealed that 4.3% were considered preventable ADRs which occurred due to MEs [16, 17].

According to literature [18], pADRs due to ME were more common in elderly population (65 years and over) with female predominance, but in our study, pADRs are more common in adult population (21-49 years) with male predominance. Most of pADRs fall in mild category of severity in which the suspected drug was put on hold, discontinued or otherwise changed. Some patient also required antidote or other treatment to overcome to the reaction which produced temporary harm but that does not increase patient hospital stay.

According to Koppe *et al*., study [19], pADRs occurred in the prescribing and administration stages, while in our study, prescribing and monitoring stages were identified as most common stages of medication use at which ME occurred. However, our study had some limits; retrospective analysis meant that events could not be easily followed up to obtain further information about patient recovery from that event. In addition, possible causal factors were not captured using the ADR form, limiting the ability to undertake root cause analyses and form conclusions about why the event occurred. Despite these limitations, our study illustrates that even such databases have value in identifying medication errors, when the primary reason of reporting is not medication error.

CONCLUSION: In order to evaluate capacities and limits of pharmacovigilance centre in detecting medication error, it is advisable to conduct retrospective analysis by each pharmacovigilance centre, so to have a comprehensive knowledge on medication error issue.

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CONFLICT OF INTEREST: There are no conflicts of interest.

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