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Role of a Clinical Pharmacist in Monitoring, Reporting and Management of Adverse Drug Reactions in Psychiatric Department

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Abstract

Background:
Various psychiatric disorders are treated with psychotropic agents. A high incidence of adverse drug reactions is associated with the majority of these drugs, which result in substantial morbidity and mortality. In addition to raising awareness and promoting pharmacovigilance, clinical pharmacists assist patients and healthcare professionals in identifying possible adverse reactions.

Method:
The inpatient and outpatient psychiatry departments of RIMS Government General Hospital, Kadapa, were subjected to a prospective observational study. This study is done by obtaining informed consent forms from the patients or caretakers. The primary purpose of this study is to monitor, report, manage and measure the incidence rate of ADRs.

Results:
Among 200 patients, 39 ADRs were reported; 26 males and 13 females. The most common age group reporting ADRs was 30 - 39 years old, mostly outpatients. As in other studies, 19.5% of ADRs occurred in this study. The neurological system accounted for 43.58% of ADRs, followed by the metabolic system at 20.53% and the behavioral system at 17.94%. Common ADRs were weight gain, insomnia, and tremors. Antipsychotics account for most ADRs. According to the WHO scale, 66.66% of reports were possible. A Hartwig scale found 30.76% mild and 69.24% moderate reactions. According to the Schumock-Thornton scale, most ADRs were preventable. Depending on risk-benefit ratios and physician presence, a clinical pharmacist had done interventions on ADRs.

Conclusion:
Based on the results of this study, it is concluded that the involvement of clinical pharmacists in patient care has a significant impact on the identification, resolution, and prevention of adverse drug reactions in hospitals, thus improving patient safety.

Keywords:
Adverse drug reactions [ADRs], Psychotropic agents, Incidence rate, Clinical Pharmacist, Pharmacovigilance, Risk-benefit ratio.

I. Introduction

Psychiatry is the medical speciality dedicated to preventing, diagnosing, treating and studying "mental disorders." [1] These include various abnormalities related to behaviour, mood, perceptions, and cognition.
Some common mental disorders seen in the psychiatric department are:

- Schizophrenia: A condition that affects an individual's ability to judge, feel and behave distinctly.
- Bipolar disorder: A condition associated with Cyclothymia ranging from manic highs to depressive lows.
- Clinical depression: A cognitive health disorder described by prolonged depression or lethargy affecting daily functioning.
- Anxiety disorder: A Condition described by feelings Anxiety, worry, or fear that interferes with daily activities.
- Obsessive-compulsive disorders (OCD): Extreme thoughts that lead to recurrent behaviours.

- Attention-deficit/hyperactivity disorder: A chronic concern including concentration difficulty, hyperactivity, and capriciousness.[2]

Psychiatric Medications

Majorly psychiatric medications are divided into six groups.

- **Antidepressants:** These drugs treat anxiety disorders, borderline personality disorders, clinical depression, dysthymia and eating disorders. **E.g.,** Amitriptyline, Escitalopram, Fluoxetine, Sertraline.
- **Antipsychotics:** Typically used to treat schizophrenia and other psychotic disorders such as mood disorders, these drugs prevent psychotic symptoms from occurring. **E.g.,** Clozapine, Haloperidol, Risperidone, Olanzapine and Quetiapine.
- **Anxiolytics:** These drugs treat anxiety disorders, also called depressants. **E.g.,** Diazepam, Clonazepam and Alprazolam
- **Mood stabilizers:** They are used to treat bipolar disorders and schizoaffective disorders. **E.g.,** Lithium, Carbamazepine, Lamotrigine and Valproate.[3]

Drugs are utilised for a person's wellness, but other than their significance, multiple adverse effects are seen. Psychotropic agents are the backbone of therapy for psychiatric disorders.
Discontinuation of therapy or noncompliance due to Adverse drug reactions (ADRs) are generally seen in psychotropic agents.

Need for ADR monitoring in Psychiatry

Chronic psychiatric illnesses necessitate long-term therapy with anti-psychotics, which address the need for ADR monitoring which results in favourable outcomes of pharmacovigilance in the department of psychiatry; they are

- Benefits to the patient: Early recognition of issues can improve quality of life and patient adherence.
- Physician benefits: A psychiatrist's regular pharmacovigilance practice can enhance identifying and managing potential ADRs.
- Benefits to the pharmaceutical industry: The Central Drugs Standard Control Organisation (CDSCO) has made it mandatory for the pharmaceutical industry to report adverse reactions, known as "periodic safety update reporting."
- Benefits to regulatory authorities: Authorities can withdraw or limit the use of Drugs when ADRs are detected earlier. [4]

Epidemiology

An adverse drug reaction (ADR) is the leading cause of mortality and morbidity. Five to thirty-five percent of all Inpatients encountered an ADR, about three to six percent of hospital admissions were directly related to ADRs, and between 24 and 30 percent of these patients had a second reaction. [5]

It has been estimated that between 1964 and 2001, the prevalence of mental health morbidity in India increased from 9.5 to 102.8 cases per 1000 population. This is because there were over 16 cases per 1000 people. According to a study, there is an estimated 5% lifetime prevalence of mental disorders. [6]

2–3 times more women than men suffer from depression, anxiety, and unspecified psychological distress. Poor women have a high prevalence of mental disorders, which may be caused by hormonal factors (reproductive cycles may make them more susceptible to depression). Furthermore, excessive partner behavior, alcohol consumption, and physical and sexual violence by the spouse are other factors that contribute to marital breakdown.[7]

Predisposing factors

Following are the predisposing factors that can develop a risk towards ADRs in patients.

Age

There is a strong correlation between age and the occurrence of ADRs. It is common for drugs to cause ADRs in paediatric and older patients because these age groups are less likely to be studied for drug interactions. In relation to drug absorption and metabolism, aging results in less predictable changes (pharmacokinetics and pharmacodynamics), resulting in more adverse drug reactions.
E.g., Postural hypotension caused by an angiotensin-converting enzyme inhibitor.

Gender

As a result of ADRs, gender plays a significant role. It is possible for some drugs to have different effects on males and females due to biological differences. In terms of anatomy and physiology, there are differences in body weight, composition, liver metabolism, and renal function. Women have a smaller body weight and size than men. This is because their fat content is considerably higher, their gastric motility is significantly higher, and

their glomerular filtration rate is lower than that of men. The pharmacokinetics and pharmacodynamics of drugs in women are altered because of these differences. So, women are more susceptible to ADRs compared to men. E.g., chloramphenicol-induced aplastic anemia is twice as common in women as in men.

Polypharmacy

Patients with polypharmacy, especially those over 65, take multiple medications simultaneously. A disproportional increase in adverse drug reactions occurs as the number and severity increase. There may be a variety of causes, including additive effects, synergistic effects, drug interactions, duplication, and discontinuation.

Multiple diseases

Because multiple diseases involve the consumption of multiple medications, a patient is more susceptible to adverse drug reactions (ADRs). In renal and hepatic diseases, there are more chances of developing ADRs because these organs eliminate drugs.

Race and genetic factors

Drug response varies from person to person. Genetics plays a crucial role in developing ADR for specific drugs over others. Individuals differ based on polymorphisms in genes encoding drug-metabolizing enzymes, drug transporters, and receptors.

E.g., the Caucasian race has more chances of hypersensitivity towards Abacavir.

Drug characteristics

When a patient is treated with certain drugs which are highly toxic, they have a chance of developing ADRs. E.g., nausea and vomiting are common adverse reactions following treatment with cytotoxic anticancer drugs. [8]

Detection of ADRs

Only trained professionals can detect an ADR. An essential tool for observational research is case reports. Patients exposed to novel drugs are potential candidates for developing ADRs. ADRs are often confused with symptoms of an underlying disorder or disease condition. Thus it is essential to have a thorough knowledge of the pharmacology of drugs.

The first step to diagnose an ADR is to find out which kind of products are taken by the patient, along with OTC medications knowing the patient's thorough history of medications and The second step is to ascertain whether the observed effect, i.e., ADR, could be due to any of these medications or a drug-drug interaction. Multiple factors should also be considered during the causality assessment. Correlation should be made between adverse events and suspected drugs regarding timing and pattern recognition for class effects. Drug interactions and timing are inextricably linked. Whenever a reaction occurs minutes or hours after drug administration, there is a fair chance that it is drug-related.[9]

Methods of ADR Monitoring

1. Anecdotal reporting:

Doctors usually report adverse reactions anecdotally when they observe a patient having an unusual reaction. Further research is necessary to validate such anecdotal reports, which sometimes fail to provide a definitive answer.

2. Intensive monitoring studies:

In these studies, data are collected from well-defined groups of inpatients systematically and in detail. All the drugs administered, as well as any events that might be associated with the use of drugs, were monitored by specially trained medical personnel.

3. Spontaneous reporting:

Monitoring the safety of marketed drugs is primarily accomplished through this method. ADRs are monitored in India by a spontaneous reporting system. Drug adverse reactions will be reported by clinicians as part of this system. This system has identified rare ADRs and evaluated the safety of newly marketed drugs for those reactions.

4. Cohort studies (Prospective studies):

A record of events is kept for each patient taking a particular drug. This method has the disadvantage of likely only involving a small number of patients. A suitable control group is also necessary to assess the background incidence. It would be difficult and expensive to justify such a study for every new drug.

5. Case-control studies (Retrospective studies):

These studies aim to determine whether patients with symptoms or illnesses related to a drug reaction have taken the drug. Using this population as a reference, the prevalence of drug use is compared with the prevalence in a population without symptoms or illness. Identifying whether a drug causes an adverse event can be achieved by conducting a case-control study once there is some initial indication that the drug may do so. A method such as this cannot, however, be used to detect completely new ADRs.

6. Case cohort studies:
This study combines prospective case-control with retrospective case control. The presence of symptoms or illnesses that an adverse drug reaction may cause is checked for in patients with such symptoms or illnesses. In order to assess the incidence of symptoms and illness, results are compared with a prospective cohort.
7. Record linkage:
A variety of patient records will be gathered, including general practice records relating to illness events and presentations. As a result, medication prescriptions may be linked to illness events. For instance, the prescription event monitoring scheme is a specific use of record linkage. This is because the prescription pricing authority obtains all the prescriptions written for a specific drug by selected parishioners. Any adverse events occurring in patients taking the drugs should be reported to the scheme by the prescribers. Other surveillance methods are more expensive and time-consuming.
8. Meta-analysis
This is a quantitative method for determining a general effect and pinpointing the reasons for variation in study results based on the results of two or more independent studies. ADRs can be identified, and drug safety can be assessed using this method. [10]
9. Use of population statistics:
In cases of highly remarkable or frequent drug-induced events, cancer and congenital disabilities registers can be utilized. Observational cohort studies and case-control studies may be initiated if suspicion is raised.
10. Assessing causality:
There may be a benefit to assessing whether an ADR is definitely, probably, or possibly the result of a drug. This process is known as causality assessment. An assessment of causality of adverse reactions has been rationalized by various systematic approaches.
It includes the WHO probability scale, Naranjo's ADR probability scale, Karch & Lasagna causality assessment scale, ADR severity assessment scale (Modified Hartwig and Siegel), Criteria for determining the predictability of an ADR (Modified Shumock and Thornton).

Objectives of ADR Monitoring
ADRs are to be detected in terms of their nature and frequency.
- To minimize adverse events by assisting the Drug Regulatory Authority, Public Health Programs, Scientists, and Consumer Society.
- Health Care Professionals are provided with updated drug safety information.
- It will be necessary to upgrade the package, design appropriate package inserts information, and disseminate marketing information.
- Developing effective consumer education programs for the dissemination of information.
- In order to identify risk factors that could contribute to the development, severity, or incidence of adverse drug reactions.

Role of Clinical Pharmacist in Monitoring and Reporting of ADRs
- Provide education and training to other healthcare professionals on the prevention, detection, and reporting of ADRs.
- Reporting and Monitoring of ADRs should be developed in accordance with policies and procedures.
- An overview of nursing, pharmacy, risk management, and other health care professionals' roles and responsibilities.
- Identification of drugs and patients at high risk for ADRs.
- To report serious ADRs to the FDA.
- To provide patient counseling on ADRs. [11]

II. Materials and Methods

Study Design and Population
A six-month prospective observational study was conducted in the psychiatry department of RIMS Government General Hospital Kadapa. For the sake of protecting the confidentiality of individuals, all patients were codified and anonymized. To further protect participants' privacy, all data records were deleted after data coding and analysis.

Data Collection
The Rawlins and Thomson classification of ADRs, the CDSCO suspected ADR report form, the Modified Hartwig-Siegel severity scale and the Shomuck and Thornton preventability scale were used to collect data from the treatment charts and medication history interviews of the subjects included in the study at the

outpatient and inpatient departments. Patients presenting to the psychiatric department who meet any of the following criteria will be included in the study. In a psychiatric department or referred from another department, a patient treated with psychopharmacological agents. The study excluded patients treated without psychopharmacological agents and cases with incomplete data and a preliminary diagnosis.

Data Processing and Statistical Analysis

Using a Microsoft Excel spreadsheet, data were captured on a computer. An Excel Spreadsheet was used to edit the data during and after it had been entered. Microsoft Excel spreadsheets were used for descriptive analysis of the data. Percentages were used to present the results.

III. Results

Table 1: The distribution of ADRs based on gender, age, and hospitalizations.

Demographical Details	**Patients without ADRs (n=161)**	**Patients with ADRs (n=39)**	**Total (n=200)**
Gender			
Male	98 (60.86%)	26 (66.66%)	124 (62.0%)
Female	63 (39.14%)	13 (33.33%)	76 (38.0%)
Age (years)			
≤19	18(11.18%)	4(10.25%)	22(11.0%)
19-29	32(19.87%)	7(17.94%)	39(19.5%)
30-39	41(25.46%)	10(25.64%)	51(25.5%)
40-49	39(24.22%)	10(25.64%)	49(24.5%)
50-59	20(12.42%)	5(12.82%)	25(12.5%)
≥60	11(5.5%)	3(7.69%)	14(7.0%)
Hospitalization			
Inpatient	42(26.08%)	12(30.76%)	54(27.0%)
Outpatient	119(73.91%)	27(69.23%)	146(73.0%)

Observing the above table 1, we note that a significant number of ADRs occur among males, in outpatient settings, and between 30 to 49 years old.

Table 2: System-wise Distribution of ADR's.

Sl. No.	Adverse drug reactions	No. of occurrences	Percentage %
1.	**Neurological ADR**	**17**	43.58%
	Tremors	6	
	Insomnia	6	
	Sedation	2	
	Somnolence	2	
	Giddiness	1	
2.	**Gastro-intestinal**	**2**	5.13%
	Constipation	2	
3.	Metabolic	**8**	20.53%
	Weight gain	8	
4.	**Psychiatric/behavioural**	**7**	17.94%
	Mood Swings	1	
	Anxiety	2	
	Hallucination	2	
	Night Mares	1	
	Depression	1	
5.	**Sexual function**	**1**	2.56%
	Impotency	1	
6.	**Others**	**4**	10.26%
	Slurred speech	1	
	Increased salivation	3	
	Total	39	100%

ADRs are most commonly associated with neurological effects such as tremors, insomnia, etc., followed by metabolic changes, psychiatric/behavioral changes, and gastrointestinal effects.

Out of 200 patients, schizophrenia was the most prevalent disease and accounted for 63 of them. Bipolar disorder accounted for 29, depression accounted for 29, and psychosis accounted for 17.

Table 3: The types of ADRs associated with drugs.

Type of ADR	Total number of ADRs	Drugs responsible for ADRs	Number of Occurrences
Weight gain	8	Quetiapine Risperidone Olanzapine Risperidone+Clozapine Diazepam+Olanzapine Quetiapine+Olanzapine	1 2 2 1 1 1
Insomnia	6	Fluoxetine Clozapine Alprazolam Sertraline Lithium	2 1 1 1 1
Tremors	6	Sodium valproate Lithium Olanzapine Risperidone	2 1 1 1
Anxiety	2	Fluvoxamine Sertraline	1 1
Somnolence	2	THP Diazepam	1 1
Constipation	2	Lorazepam Fluvoxamine	1 1
Sedation	2	Haloperidol Clozapine	1 1
Hallucination	2	Sodium Valproate THP	1 1
Mood swings	1	Bupropion	1
Depression	1	Clonazepam	1
Impotency	1	Lithium	1
Night mares	1	Propranolol	1
Slurred speech	1	Olanzapine	1
Giddiness	1	Alprazolam	1
Increased salivation	3	Risperidone Clozapine	1 2

The table details the types and numbers of adverse drug reactions and the drugs responsible for those reactions. Eight Weight gain cases are seen, which are caused by risperidone, olanzapine, Quetiapine etc. Six insomnia cases were caused by fluoxetine, clozapine, alprazolam etc., six tremor cases were caused by sodium valproate, lithium etc. two Anxiety cases caused by fluvoxamine and sertraline, two somnolence cases caused by THP and diazepam, two Constipation cases caused by lorazepam and fluvoxamine, two sedation cases caused by haloperidol and clozapine, two hallucination cases caused by sodium valproate and THP, one case of mood swings caused by bupropion, one case of depression caused by clonazepam, one case of impotence caused by lithium, one case of nightmares caused by propranolol, one case of slurred speech caused by olanzapine, one case of giddiness caused by alprazolam.

Table 4: Class of Drug causing ADRs

Assessment	Category	Number of ADRs
Casuality (WHO scale)	Certain	0
	Probable	9(23.07%)
	Possible	26(66.66%)
	Unlikely	4(10.25%)
Severity (Hart wig & Siegel severity scale)	Severe	0(0%)
	Moderate	12(30.76%)
	Mild	27(69.24%)
Preventability scale (Shomuck & Thronton preventability scale)	Definitely preventable	23(58.97%)
	Probably preventable	9(23.07%)
	Not preventable	7(17.94%)

The above table shows that the majority of the ADRs were suspected to be possible cases 66.66%, followed by probable cases 23.77%. According to the severity scale, most adverse events were mild 69.24%, followed by moderate 30.76%, and no severe effects were detected. A significant number of ADRs 58.97% were preventable.

The majority of ADRs are observed in the Anti-psychotic class of drugs 44%, followed by Anti-depressants 20%, Benzodiazepines 13%, Mood stabilizers 8% etc.

In 51% of cases, clinical pharmacist interventions are accepted. There are 28% of cases accepted with some modifications. In 41% of cases, they are treated, 10% have their dose altered, and 5% have their suspected drugs withdrawn. It shows that 62% of cases are recovered, and 36% are recovering. Interventions are not accepted in 16% of cases, and no changes are made to the treatment in 44% of cases. In 5% of cases, interventions are ineffective.

IV. Discussion

The study builds up a representative profile of suspected ADRs in the psychiatric department in a tertiary care hospital. 200 patients reported 39 adverse events, 26 males, 13 females, during the study period.

In the gender-wise distribution of data (table 1), the total sample of participants was divided into males (62.08%), and females (38%), wherein males outweighed females, as males predominated in the study. More males suffer from ADRs, indicating that male predominance was observed in both cases of disease and ADR occurrence. In accordance with previous studies, the results suggest that male predominance might be a function of differences in pharmacokinetics, pharmacodynamics, genetics, immunological factors and hormonal factors, which may produce a difference in results between sexes. [12 - 13]

Age-wise distribution of data (table 1) was observed, with patients categorized into different age groups. Based on these data, the 19-49 year age group has a very high percentage of patients with disease and ADR. According to previous studies, the opposite was true; psychiatrists should consider and monitor elderly patients and children who are suffering from mental health issues. There should be an effort made to prescribe low doses, or avoid high-risk drugs and combinations that are vulnerable to adverse events, thus reducing the risk of ADRs in these groups.

According to the distribution of inpatient and outpatient data (table 1), outpatient visits are more significant than inpatient visits. So ADR occurrence was most commonly seen in outpatients than inpatients. It was similar to other studies, ranging from 3.6% to 91%, that 19.5% of patients had adverse events. [14 - 16]

There were 39 ADRs identified, and the number of ADRs was distributed according to their systems, with the majority of ADRs being found in the neurological system (43.58%), metabolic systems (20.53%), and behavioral systems (17.94%). The use of antipsychotic drugs has been associated with metabolic and motor symptoms in many studies. [17 - 18]

Weight gain, insomnia, and tremors have been documented as significant adverse drug reactions associated with their respective drugs. The results of this study are similar to those of previous studies. This study found that antipsychotic medications (44%) were the Involved drugs most frequently, which is consistent with previous studies. [19]

Patients with schizophrenia and other psychotic disorders reported the highest number of adverse drug reactions, in accordance with studies conducted in a tertiary care hospital's psychiatry department. [20]

Patients with psychiatric disorders are particularly at risk for adverse drug reactions due to their sedentary lifestyles and the involvement of another organ system during disease progression.

As a result of the causality assessment of the study, there were no "certain" cases since the suspected adverse events were primarily mild to moderate in intensity. The offending drug was not rechallenged in the Brazilian study, in which 24 cases were determined to be "definite" after a rechallenge.

Based on our study's results, it may be possible to identify medications that should be targeted for quality improvement projects and patient education based on the frequency, severity, and preventability of adverse drug reactions. Considering that the majority of the adverse events in the study were predictable and, therefore, preventable, reducing the risk of preventable adverse events by identifying targets in high-risk medications will significantly impact reducing them.

A clinical pharmacist conducted an intervention on ADRs based on the risk-benefit ratio and the presence of a physician. 39 ADRs have been accepted, 11 have been accepted with some modifications, six have been rejected, and two have not been applied.

It was determined that 10% of ADRs were successfully managed by the withdrawal of the suspected drug and 41% by dosage alteration. In comparison, 44% were managed by providing specific or symptomatic treatment, and 5% were left unchanged. Regarding the ADRs' outcome, no fatal ADRs were reported, 62% of the ADRs were recovered, and 32% were still present at the assessment time.

In addition to providing information on clinical pharmacist intervention, this study also includes information on interviewing patients regarding their medications and noting down adverse reactions and implementing strategies as implemented by psychiatrists, prescribing appropriate recommendations for preventable adverse reactions, ultimately reducing the occurrence of adverse reactions and maintaining compliance with these recommendations.

Pharmacist involvement in clinical activities has also been confirmed by the number of interventions performed.

In addition, CDSCO documented that the suspected ADRs were reported to the nearest pharmacovigilance center, and 31 ADRs have been assigned AMC report numbers.

V. Conclusion

In order to maintain patient compliance, clinical pharmacists may significantly influence the prevention, early detection, and resolution of adverse drug reactions (ADRs). In the course of the study period, one breakthrough was achieved in our institution when clinical pharmacists were involved in daily clinical activities in inpatient & outpatient units. This complements their everyday activities.

The present study concludes that monitoring and reporting adverse events in the psychiatric department of Government General Hospital Kadapa. This is because a clinical pharmacist is integral to the health management system following physicians' interventions. The evidenced ADRs were reported, and the same were processed for further evaluation. Although necessary events were altered with different therapy, it still requires further investigation to monitor such classes of drugs.

A clinical pharmacist's interventions can enhance the outcomes of the medication use process, thus ensuring improved safety, effectiveness, and cost-effectiveness of pharmacotherapy.

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