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Role of the Clinical Pharmacist in Monitoring and Reporting of Outside Adverse Drug Reactions (ADR's) to Ensure Patient Safety while Hospitalization in Apollo Hospitals Bilaspur

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Abstract
Medicines, whether synthetic or derived from natural sources, are widely used to treat diseases but may cause side effects or adverse drug reactions (ADRs), especially when multiple medications are combined. ADRs can result in significant patient harm, leading to hospitalization, surgery, or loss of productivity, often exceeding the cost of the medications themselves. According to the World Health Organization (WHO), pharmacovigilance (PV) involves the detection, assessment, understanding, and prevention of adverse effects related to medicines. Pharmacovigilance practices began over 169 years ago, evolving into an essential activity for ensuring drug safety. Serious adverse drug events have led to the withdrawal of drugs such as Thalidomide (phocomelia), Bicalutamide (fetal harm), and Rosiglitazone (fractures). In India, despite accounting for 20% of the global disease burden and 16% of the world's population, less than 1.4% of global clinical trials are conducted in the country, highlighting the importance of robust ADR reporting systems like PvPI (Pharmacovigilance Programme of India). PvPI publishes monthly safety alerts, aiding in early ADR detection and patient safety improvement. From March 2016 to September 2020, 106 ADRs were reported by PvPI. This study conducted at Apollo Hospitals Bilaspur monitored ADRs between January 2021 and September 2022 among 28,847 admitted patients, identifying 14 ADR-related admissions (0.99%). No new ADRs developed during hospitalization, and all patients were successfully discharged after treatment. Clinical pharmacists conducted patient counseling and ensured reporting to PvPI. Promoting ADR reporting among healthcare professionals, alongside patient awareness, is crucial for minimizing risks. Continuous monitoring, evaluation, and education are essential to enhance patient safety and public health.

Keywords: *Adverse drug reaction (ADR), Pharmacovigilance (PV), World health Organization (WHO), Pharmacovigilance Program of India (PvPI).*

INTRODUCTION

Medicines become one of the amongst the foremost important of health care systems worldwide. Medicine saves our lives. This unquestionable reality makes rational prescription, procurement, distribution and ration use of initial and foremost superiority in health care. Medicines are the common intervention, use to treat the diseases however Medicines themselves can show fatal and can result in Adverse drug reactions (ADRs); because the language justly goes "Medicines are two edged sword" [(1)] Health care professionals plays an important performance in free reportage of ADRs. [(2)] Unfortunately, there are typically shortcomings in prescribing and taking medicines. One vital concern is that of safety. Medicines are produced synthetically or from natural substances, and most can show some form of side effect or adverse reaction. There is a big interest in treating this community with future medicines and vaccines, particularly given the massive burden of disease here. India accounts for 20% of the world's unwellness overburden and 16% factor questionnaire of the world's population, however but less than 1.4% of global clinical trials are finished in India.[(3)]It is forecasted to grow at a compound annual rate of growth of 30 %. [(4, 5)].The ADRs are the fourth to sixth leading reason for death. [(2)] Generally, ADR-related costs, like hospitalization, surgery, and lost productivity, exceed the value of the medications. [(6)]

Adverse drug reaction (ADR) is developed once consolidation of two or more medicines occurs. Once injury affects and administration of a medication, it causes a one dose or continued dose of a medication. It causes side effects. [(7)]

According to the world Health Organization "any response to a drug that is pestilent and unintentional, and happened at doses commonly used in man for prophylaxis, diagnosis or medical care of disease, or for the modification of physiologic function". [(8)] ADRs are an important reason of mortality and

morbidity and represent a massive burden on the society. There is a desire to analyse the ADRs and its reporting to minimize the risk of medicines. As per the ADR observations in our country, very little attention has been given thus few original studies have been given during this regard. We have very few ADR monitoring centers right away and much of effort is needed so to bring together, ADR information which can generate safety surveillance of billions of therapeutically active substances either alone or in combinations. A recent study showed that ADRs accounted for approximately 3.5% of hospital admission. [9, 10] Furthermore, ADRs were the cause of ~ 197000 deaths in Europe annually. [11]

Initial detection, evaluation, observation and reporting of ADRs are essential to make drug treatment safe and cost effective. [8] The incidence and severity of ADRs is influenced by patient connected factors like age, gender, concerted diseases, genetic factors, and drug related factors like type of drug, Route of administration, duration of therapy, and dosage. The other essential possible factors connected with ADRs are gender, enlarged range of drug exposures, advanced age, length of hospital stay and function of excreting organs. [12]

There are lots of ways of ADR detection and reporting. Among all the ways, the spontaneous reporting system (SRS) played an important role in detecting alarm from post marketing surveillance of medicines. Moreover, this SRS is may be a helpful and frequently used tool to confirm newly developed post-marketing ADRs. [12] Post-marketing phase detects those ADRs that were not detected in phase 2 or 3 clinical trial. Information from SRS will also found the risk factors for incident of significant ADRs. [13] ADRs from SRS can provide feedback to health care professionals regarding safety of patients. [14]

India's contribution to Uppsala Monitoring Database is incredibly little though India has participated in pharmacovigilance programme.[15] The history routes of the word "Pharmacovigilance" are: Pharmakon (Greek word of 'drug') and vigilare (Latin word for 'to keep watch') [16] WHO defines ADR as, "Pharmacovigilance (PV) is outline because the science and activities belonging with the detection, assessment, understanding and prevention of adverse reactions to medicines (i.e. adverse drug reactions or ADRs). The furthermost aim of this activity is to reinforce the safe and rational use of medicines, thereby improving patient care and public health."[17]

Materials and Methods:-

Study Design - Hospital based prospective observational and non-interventional studies.

Time Frame - Jan'21 to Sep'22 (1.8year)

Who can report ADRs – Medical Team, Nurses and Pharmac` ist.

Responsibility - Clinical Pharmacists

Audit schedule – Regular

Study approvals - Formal permission from Assistant Medical Superintendent (AMS) of Apollo hospitals bilaspur. Were obtained prior to initiation of the study.

Planning-

All new patients are being audited by clinical pharmacists, when patient admitted with the complaint of any ADR from outside hospital or at home. After admission check thoroughly patient file for patient medication history and adverse drug reaction, to ensure medication reconciliation. While daily round differentiate patient came from where like other hospital, discharge from our hospital or patient using home medication. If we found the patient had admitted due to complain of ADR, We were used ADRs reporting form for data collation. Suspected drug details should be updated on patient case sheet for prevention of further ADR Update the ADR form and submit to clinical pharmacology dept for further analysis and reporting. ADRs were replied to the clinicians/reporting persons and discussed regarding the causality, management of the particular reaction. Finally the data obtained is analyzed and results are formulated. The data collection ADRs of a suspected adverse drug reaction reporting forms are collected from the clinicians/reporting persons either during ward rounds by clinical pharmacist.

This data was documented after receiving the ADR forms, only those cases which fulfilled the criteria were included in the study. The details of cases were documented in "Adverse drug reaction reporting and documentation form". Complete history of the patient is taken from case reports, medication charts, and personal interviews with patient and patients' attendants. Disease states of the patients and other conditions are properly enquired and noted down. Medication history of the patient is obtained from the patient medication slips, prescriptions and also from in-depth patient interview regarding medication use. Sometimes the screening of the remaining medication of the patients that he had used prior to the reaction, which helps in disclosing the facts of medication use and details of the drug products like brand name, manufacturer, Lot no, Exp dates, and other information. Efforts were made to collect as much information as possible. The causality of the reported ADRs was carried out using "Naranjo causality

assessment scale" [18], assessment of causality based on WHO. Assessment of severity [19] is based on the Hartwig scale [20]-. The documented cases are followed up daily. Patients/patient's attendants are interviewed daily so as to excavate any unnoticed and unseen details of history of the patients and events prior to the reaction. Discussion with reporters/clinicians to give feedback on the reaction and management of the patient condition by providing reports and drug information service.

Inclusion criteria –

- The patient who are admitted in hospitals with the complain of ADRs.

Exclusion criteria -

- Patient with drug reaction due to intentionally or unintentionally use over dose of medicine.
- ADR due to medicine related Homeopathy, Ayurvedic preparation and Unani medicine.
- Drug-Drug interaction, Drug-food interaction, Drug
- interaction with a use of alternative system of medicine
- Drug-Drug interaction, Drug-food interaction, Drug
- interaction with a use of alternative system of medicine
- Drug-Drug interaction, Drug-food interaction, Drug interaction with a use of alternative system of medicine
- Any reaction due to implants or blood components.
- ADR due to prescription error or dispensing error.
- Psychiatric patients ADRs.

Plan of work

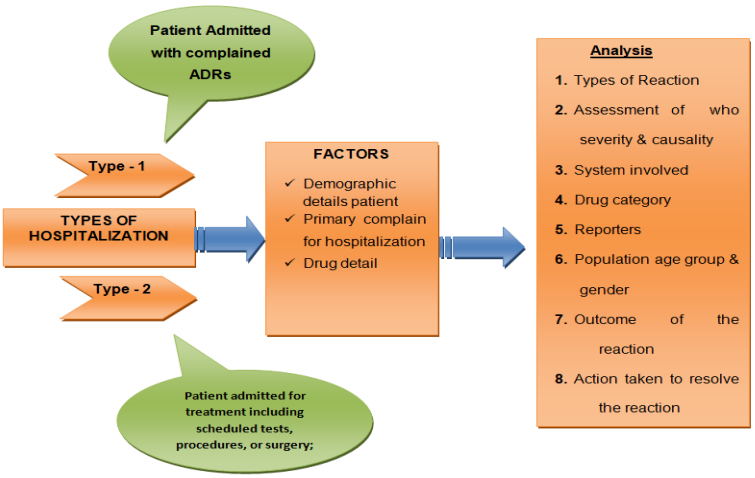

Figure 1: Hospitalization and Analysis of ADR Cases

Discussion and Analysis

As per analysis since Jan'21 to Sep'22, total 28847 patient got admitted in our hospital, out of these 14 patient got admitted with the complain of ADR. Which 0.99%. Graph no. 1 Total 14 patient got admitted due to ADR complains. During medication reconciliation we found that following process was overlooked which led to ADRs and Intervention of clinical pharmacist for management of ADRs.

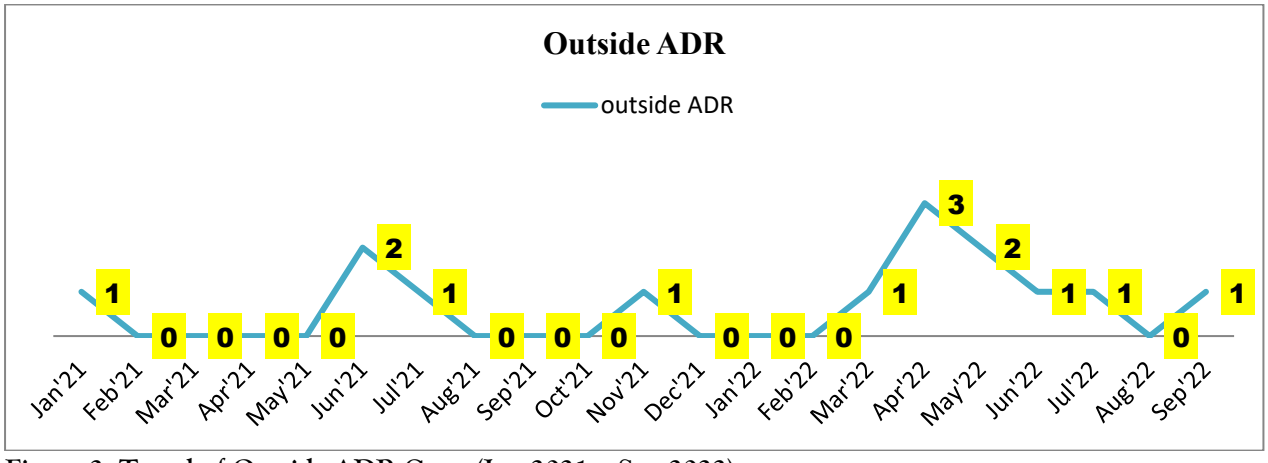

Figure 2: Trend of Outside ADR Cases (Jan 2021 – Sep 2022)

Analysis of overlooks which led to ADR

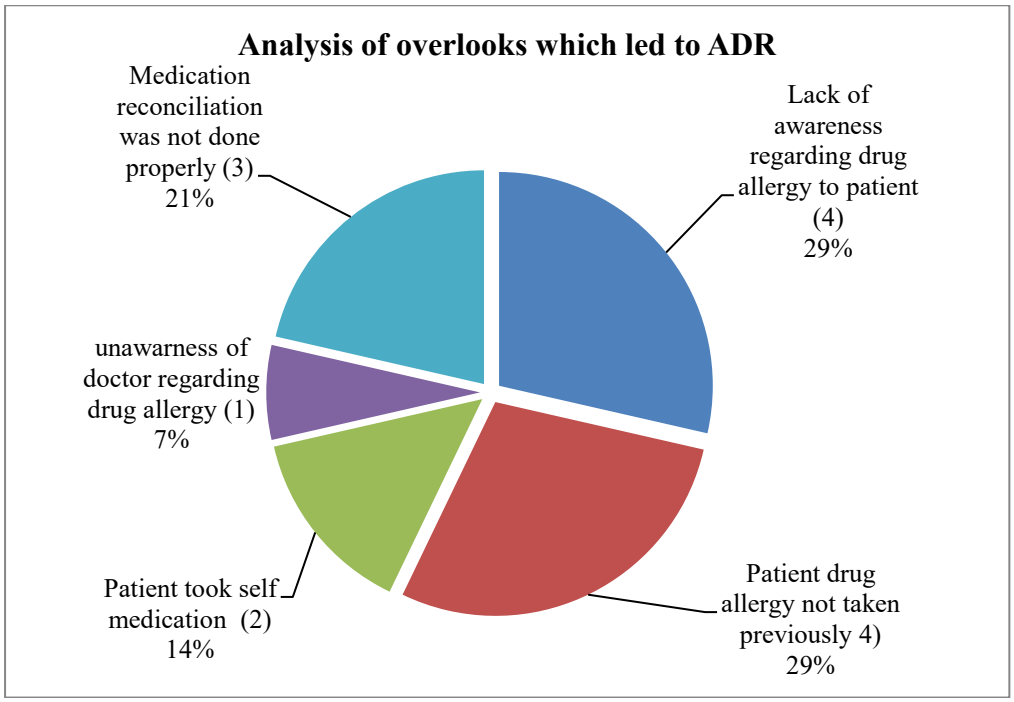

Figure 3: Analysis of Overlooks Leading to ADR

Type of reaction find below

Table 1: Type of reaction

Type of reaction	Numbers
Abdominal distension, Abdominal pain and fever, rashes on skin	1
Blood in stool , rashes and itching all over face and body , hematuria	1
Itching all over body , abdomen pain, vomiting	1
Pain in abdomen, Loose motion, episodes Rashes and itching, Facial puffiness, swelling on eye lids	1
Rashes all over the body, Fever , Generalized body pain Nausea	1
Rashes and blisters over trunk, upper limb and thigh. Ulcerative lesion over lips buccal mucosa Vomiting	1
Rashes with itching, Facial Puffiness , Swelling Around Eye	1
shortness of breath, bilateral pedal edema, anorexia and generalized weakness, abdominal pain and insomnia	1
skin rashes all over the body	1
Uticaria & itching	1
vomiting Fever Body ache	1

itchy eruptions with redness all over body, and fever	1
Oral ulcers Odynophysia dizziness with Generalized weakness loose motion nasal bleeding	1
Oral ulcers, Bleeding from blister, Odynophysia	1

Naranjo Algorithm Analysis [18]
10 ADRs were Possible +4, 5 ADRs were Probable +5 and 2 were severe +6. [Reference - Scoring - ≥ 9 = definite ADR, 5-8 = probable ADR, 1-4 = possible ADR, 0 = doubtful ADR]

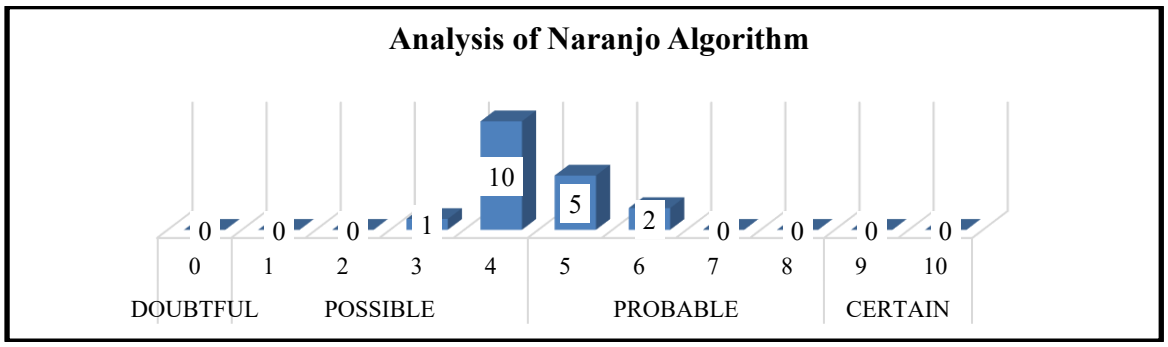

Figure 4: Analysis of ADR Cases Using the Naranjo Algorithm

According to WHO probable scale [19] – 12 ADRs were possible and 2 were probable/ likely.

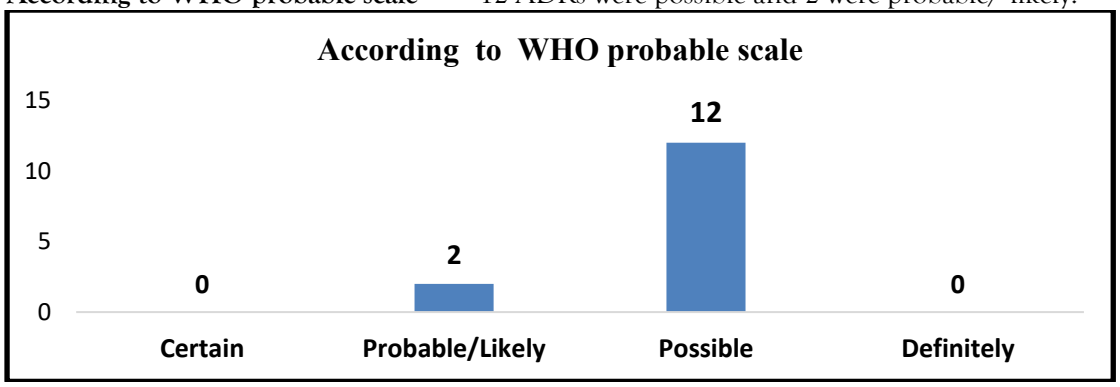

Figure 5: ADR Assessment According to WHO Probability Scale
Severity Assessment Scale: Hartwig's Severity Assessment Scale [20]-12 ADRs were analysis level -4 and 2 ADRs were level 4 severe. (Level 4 mean - Any Level 3 ADR which increases length of stay by at least 1 day. OR The ADR was the reason for the admission) Hartwig's Severity Assessment Scale.

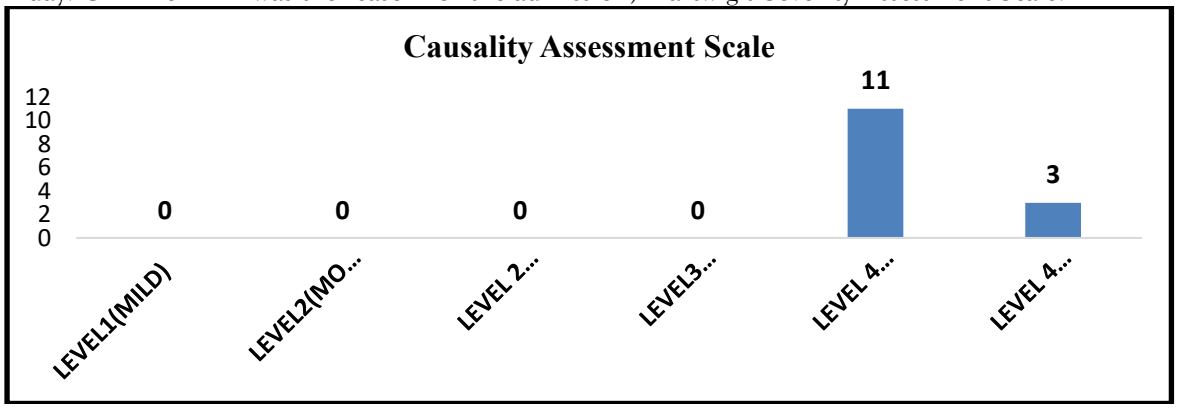

Figure 6: Causality Assessment Scale for ADR Severity

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Category wise analysis of ADR - Antibiotics and NSAIDs were common drug as per analysis.

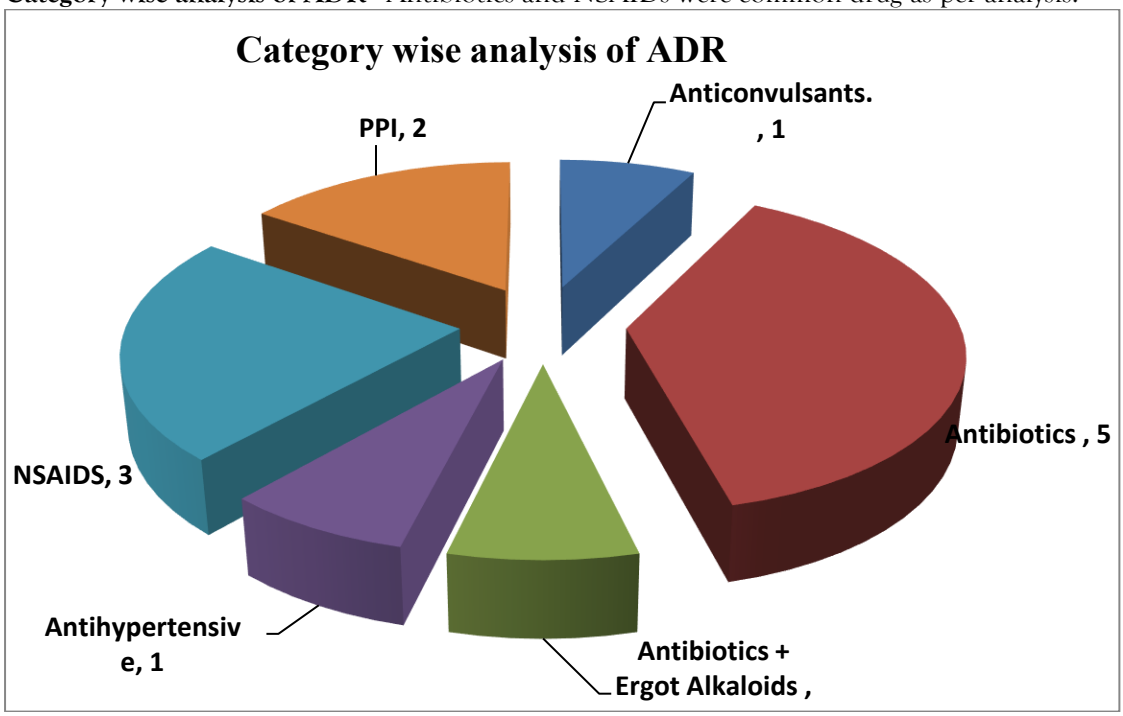

Figure 7: Category-Wise Analysis of ADR Cases by Drug Class

Reporter – All outside ADR were reported by Pharmacist during new patient medication reconciliation audit.

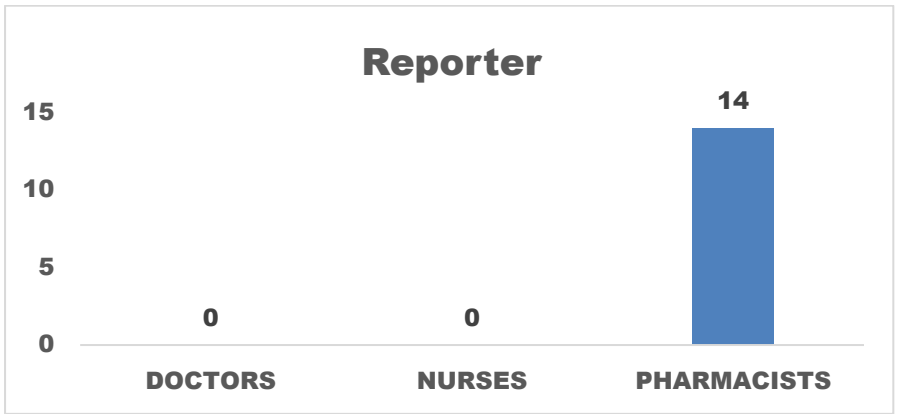

Figure 8: Distribution of ADR Reports by Reporter Category

Population (Age) – Elderly (45 years and above) having 80% ADR and 20% adult (19yrs to 45yrs)

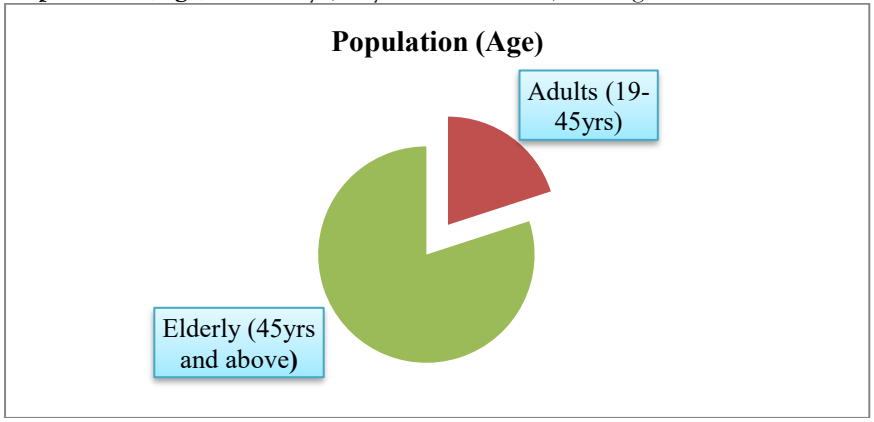

Figure 9: Population Distribution by Age Group in ADR Cases

Gender Distribution - As per analysis we found that 64% were female and 36% were male.

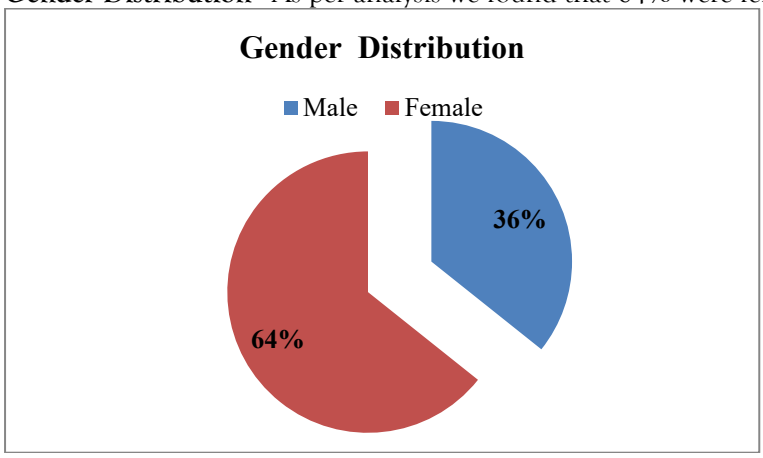

Figure 10: Gender Distribution of ADR Cases

Training Activity – During these study periods we have conducted 58 training classes and covered 661 health care providers, which 28hrs.

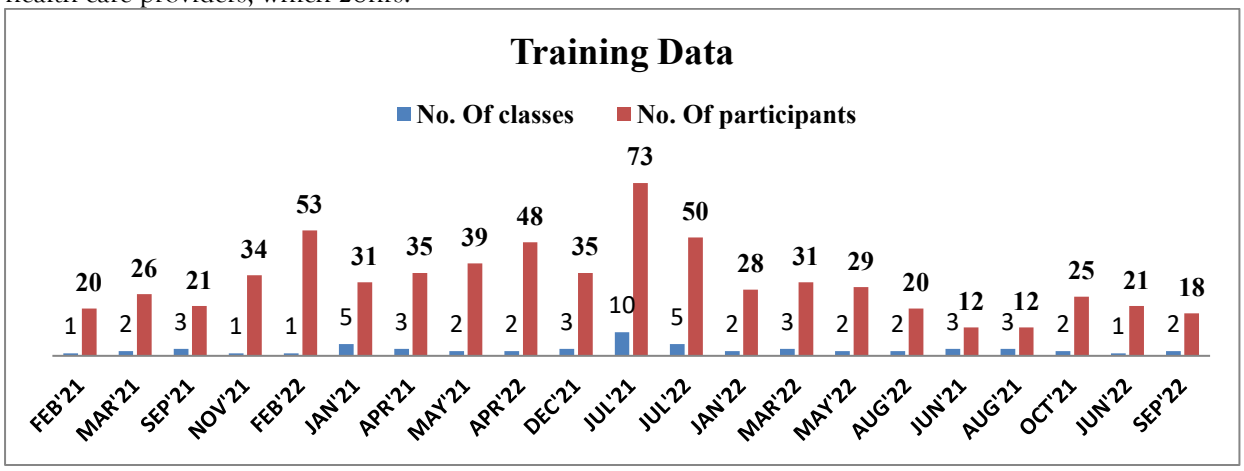

Figure 11: Training Data – Number of Classes and Participants Over Time

Difficulties & Challenges-

1. When the patient gets discharged/ expired within 24 hours of admission it is difficult to monitor properly
2. Improper medication reconciliation
3. Suspicious diagnosis but not confirmed that it is due to any ADR.
4. Lack of clinical and ADR awareness
5. Hesitation of reporting

Impacts or benefits of the projects

An ADR monitoring and reporting programme can furnish following benefits:

1. It caters information about quality and safety of pharmaceutical products.
2. It initiates risk-management plans.
3. It prevents the predictable adverse effects and helps in measuring ADR incidence.
4. It instructs health care team, patients, pharmacists and nurses about adverse drug effects and creates awareness regarding ADRs.

CONCLUSION

We monitor all outside Adverse Drug Reactions (ADR's) As per monitoring and root Cause analysis we found that since Jan'21 to Sep'22, total 28847 patient got admitted in our hospital; Total 14 patient got admitted due to ADR complains which is 0.99%.

Clinical Pharmacist Intervention – Daily new admission follow up done by clinical pharmacist. If we observe any discrepancies or any kind of undesirable effects or any suspected reactions, we record complete information of suspected medication history, concomitant medications and description of the

events. Clinical Pharmacist ensures updation of patient's drug allergy in their medical records including discharge summary. A clinical pharmacist always monitors drug-drug interactions and Drug food interactions during hospitalization. Patient as well as patient attender were educated regarding the drug allergy, at the time of admission, during hospitalization as well as at the time of discharge. We also provided contact number of clinical pharmacology department (Bilaspur) for any queries and unwanted reactions (if occur). We have discussed intervention of clinical pharmacist in management of ADRs as per discussion above mention Table-2. All ADRs are reported to concerned departments, morning hurdles meetings and also shared in every Drug and Therapeutic committee meetings.

As per analysis of recorded outside ADRs, we found that common reason of admissions were Itching all over body , abdomen pain, vomiting , Fever , nausea, blisters, Oral ulcers, Odynophysia, dizziness with generalized weakness, loose motion, nasal bleeding, and hematuria. This affects the Integumentary (Skin), CNS, GIT and Respiratory system. As per Naranjo Algorithm analysis – 10 ADRs were Possible +4, 5 ADRs were Probable +5 and 2 were sever +6. Reference - Scoring - ≥ 9 = definite ADR, 5-8 = probable ADR, 1-4 = possible ADR, 0 = doubtful ADR] According to WHO probable scale – Most of the ADR were possible (12) and 2 were probable/ likely. Causality Assessment Scale – 12 ADRs were analysis level -4 and 2 ADR were level 4 sever. (Any Level 3 ADR which increases length of stay by at least 1 day. OR The ADR was the reason for the admission). Category wise analysis of ADR - Antibiotics and NSAIDs were common drug as per analysis. Reporter – All outside ADR were reported by Pharmacist during new patient medication reconciliation audit. Population (Age) – Elderly (45 year and above) having 80% ADR and 20% adult (19yrs to 45yrs). Gender Distribution - As per analysis we found that 64% were female and 36% were male. To ensure patient safety while treatment in our hospitals we have also taken lots of Class room (CRT) and on job training (OJT). Training has been conducted for the Doctors, Nurses and Pharmacist by the prescription audit team. Total 58 training has been conducted 661 staff has been benefitted and total 28hrs cover for training on ADR monitoring and Reporting. We found that 14 patient got admitted with complain of ADR with different kind of drugs. While hospitalization we monitor the patient and found that no any ADR were developed during treatment, patient got Discharge after getting treatment. 14 admissions were due to ADR complaints but while hospitalization no any ADR developed. Patient counseling has been done on ADR and patient record has been updated to prevent further ADRs.

All ADRs information were shared (PPT) in clinical audit committee as we have taken the project on same for awareness of healthcare providers to monitor the ADRs on early detection of unwanted reaction or undesirable effects. Clinical excellence or Service excellence which led to Patient Satisfaction – With the supervision, mentorship, case study preparation, discussion, and clinicians group work we ensure patient safety. The clinicians working in the hospitals usually do the spontaneous monitoring, Reports sent by the clinicians are evaluated in a wider perspective, i.e., with the causality assessment criteria and the detailed assessment is done. To create awareness about ADRs among patients and families to motivate our all the healthcare professionals like the Doctors, Nurses, Pharmacist working in hospitals to report the ADRs and minimize the risk. Early detection, evaluation and monitoring of ADR are essential to reduce patient harm and improve public health.

Take Home Message for Health Care Providers-

Health care providers and pharmacovigilance constrain being more conscious of perceive the ADRs in the patient. Without a doubt, hospital Pharmacists has been defining roles for themselves in the clinical environment. These roles include taking drug histories, on newly admitted patients, reviewing drug orders for drug incompatibilities, including patient record and participating in evaluation of drug therapy. These activities coupled with the traditional function of control and distribution of medications makes the pharmacists ideally suitable to monitor and report ADRs. Medication errors and ADRs must be reported immediately to the practitioner who ordered the medication. Records of the episodes should become part of the patient's chart and of the pharmacy records. To prevent drug induced illness, several principles should be followed.

- One should be knowledgeable about the patient's medications (e.g allergy to drugs, duplication of drug with similar pharmacologic activity)
- When poly pharmacy medication is prescribed, it is important to have a thorough understanding of its pharmacology
- One should be knowledgeable concerning characteristics of the patient himself
- Patient should be given fewest medications

- Patients must be educated to avoid self-medications such as PPIs, NSAIDs, laxatives, purgatives, antacids etc. and reactions which can occur due to these medications.
- During patient counseling we should educate to strictly avoid concomitant medication of different systems such as Ayurveda, Siddha, Unani, Homoeopathy, and allopathy
- Always educate to the patient regarding Drug-Drug interaction as well as drug food interactions, because local vegetables are also considered for causing drug food interaction and Drug-Drug interaction which may result as ADR sometime.

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