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Adverse drug reactions (ADRs): Managing and Monitoring at 199 Hospital

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ABSTRACT

On time detection of Adverse Drug Reactions (ADRs) helps avoid the harmful effects to patients, and promptly prevent mishaps or disasters to our health care. To assist in monitoring the safety in the use of drugs for patients, and providing maximum data to the National Center for DI&ADR on the drug safety of Phase 4 (the drugs are widely used in the community), clinical pharmacists have monitored ADRs actively instead of waiting for clinical reports. A cross-sectional description study was done by interview, review profiles, examine inpatients randomly at any time of the treatment (priority to choose patients with complex pharmacotherapy or high-risk drugs causing adverse reactions). A total of 455 interviews, examinations, and follow-ups of 15 ADRs cases were actively exploited by pharmacists (3.3%). Harmful reactions are also recorded in most specialties. The first rate was acute reaction (47%, 7 cases), the second rate was sub -acute reaction (33%, 5 cases), and the delayed reaction accounted for at least (20%, 3 cases). There are 14 drugs that are suspect or certainly related to adverse reactions, 8 of these are high-risk drugs on A-PINCH list (accounting for 57%). Proactive ADRs monitoring is necessary to minimize the risks for patients. Clinical pharmacists should get involved in the process and follow through. Aside from providing health care providers with frequent trainings to keep them with the up-to-date information needed, an improvement of prescription software to minimize ADRs should be applied.

Keyword: *ACCP, ADR, Monitoring, Clinical Pharmacy , Adverse, Reactions , 199 Hospital*

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INTRODUCTION

Drug is a substance or mixture of substances used for the purpose of treatment, prevention, diagnosis of disease or to regulate and restore physiological functions of the body. In modern life, drugs have become familiar to everyone. However, the safe and rational use of drugs is an issue that needs to be considered in order to ensure their safe, rational, and effective use.

The 199 Hospital has been doing a commendable job in reporting Adverse Drug Reactions (ADRs) since clinical pharmacology spread awareness about the importance of reporting ADRs. On time

detection of drug safety helps prevent harmful effects that drugs can cause to the community, even averting disasters for mankind. However, the question arises: could there be unreported ADRs that have gone unnoticed by clinicians due to their inability to recognize ADRs, lack of understanding about the importance of reporting, shortage of personnel responsible, or fear of troublesome procedures?

With the aim to support clinical monitoring of drug safety for patients and provide maximum data to the National Pharmacovigilance Center regarding drug safety of phase 4 (when the drug is widely used in the community), clinical pharmacists have shifted from passively waiting for clinical reports to actively visiting clinics to explore and monitor the safety of patients' drug use.

This presents an opportunity for pharmacists to acquire in-depth knowledge of drug side effects, identify clinical manifestations in patients, and establish stronger connections with patients and clinicians. It can also be an effort to integrately care for the patients, ultimately enhancing patient satisfaction..

MATERIALS AND METHODS

Research subjects

Inpatients at 199 Hospital from April 2022 to June 2022.

Research methods

Cross-sectional descriptive study.

ADR assessment based on:

Temporal Relationship: There should be a clear temporal relationship between drug administration and the occurrence of the adverse event. The event should occur after drug exposure, and the reaction should resolve or improve after discontinuation or dose reduction.

Previous Reports: Look for previous reports or literature evidence linking the suspected drug to similar adverse reactions. This helps establish a known association.

Dose-Response Relationship: Assess whether the adverse event's severity or frequency correlates with the drug dose. A higher dose should lead to a greater likelihood or increased severity of the reaction.

Dechallenge/Rechallenge: Evaluate if the adverse event improves or resolves when the drug is discontinued (dechallenge) and reappears upon re-administration (rechallenge). These steps provide additional evidence of a causal relationship.

Alternative Explanations: Rule out other potential causes or factors that could explain the adverse event. Consider other medications, underlying diseases, concurrent illnesses, or patient characteristics.

Consistency: Determine if the adverse event has been reported in other patients or in the literature, indicating consistency in the association between the drug and the reaction.

Biological Plausibility: Assess whether there is a plausible biological mechanism that could explain the occurrence of the adverse reaction based on the drug's pharmacology or known effects.

Issues of assessment were referenced on Decision 29/QĐ-BYT 2022 Guidelines for Monitoring Adverse Drug Reactions at Medical Examination and Treatment Facilities [1].

Selection criteria: Inpatients were selected for interviews, record mining, and examinations throughout their treatment course. Preference was given to patients with

complex treatment regimens or those receiving drugs with a high risk of causing adverse reactions. Assessments were primarily conducted on the 3rd, 7th, 14th, 21st, and subsequent days of the treatment course.

Data processing: The data were processed using the Microsoft Excel application.

RESULTS

General results: From a total of 455 checks, 15 drug interactions, side effects or adverse drug reactions were identified, representing 3.3% of the total. In 14 of these, the pharmacist intervened to change or discontinue the medication regimen, with the prescriber's consent.

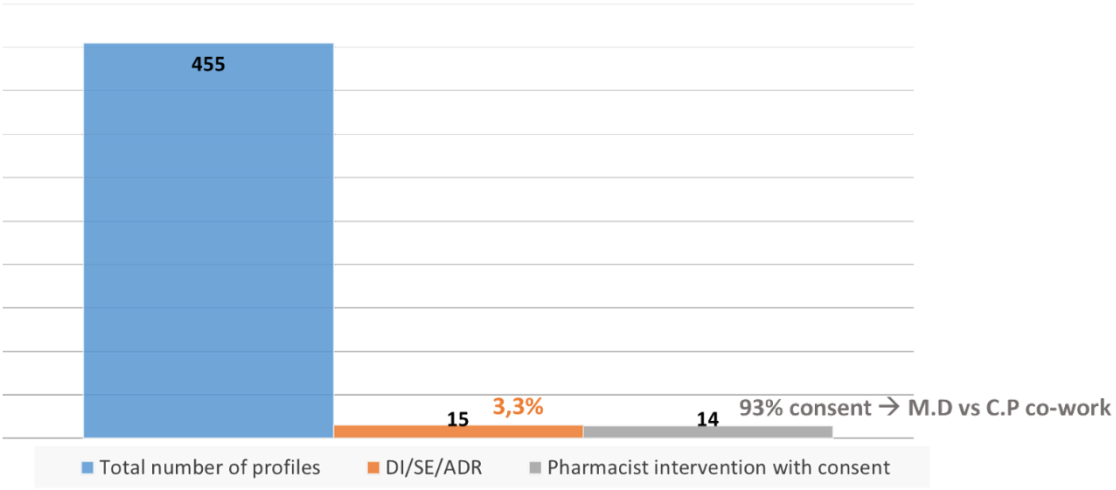

Figure 1: Summary of Adverse Drug Reactions and Interventions

Data of departments: Harmful reactions were observed in multiple medical specialties: 2 cases were documented in the Neurology Department, 1 case in the Gastroenterology Department, 1 case in the Cardiology Department, 2 cases in the Pulmonology Department, 4 cases in the Endocrinology and Diabetology Department, and 5 cases in the Orthopaedics Department. However, no cases were reported in the ICU and General Surgery Departments.

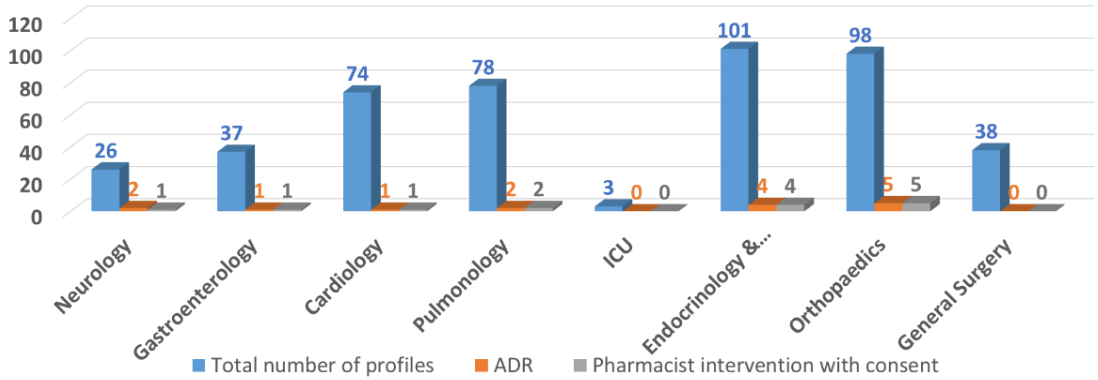

Figure 2: Adverse Reactions by Specialty

Onset of events: The most common type of reaction was acute, comprising 47% (7 cases), followed by sub-acute reactions at 33% (5 cases), while delayed reactions accounted for at

least 20% (3 cases).

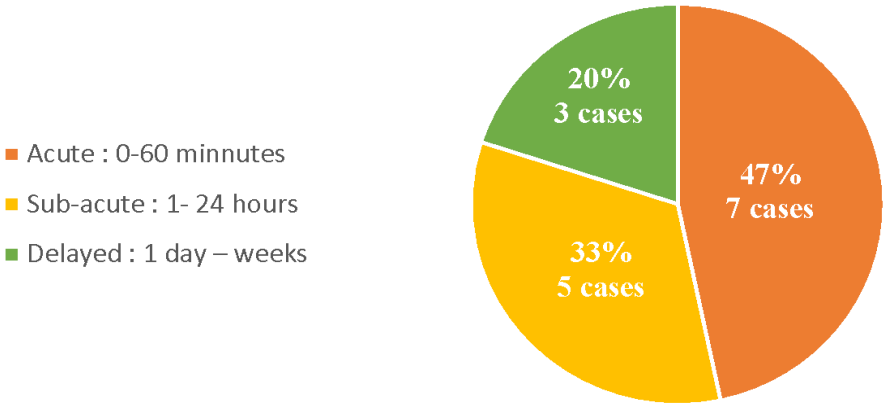

Figure 3: Onset of Drug-Related Event

List of suspected medications relating to ADRs: Among the suspected or confirmed drugs associated with these adverse reactions, 14 were identified, with 8 of them being high-risk drugs listed on the A-PINCH list, making up 57% of the cases.

Table 1: Drugs suspected/certainly associated with adverse reactions

Suspected medications	Active ingredients	Number of ADRs	Number of concurrent medications	Type of reactions
Metoclopramid	**Metoclopramid**	**1**	4	Arrhythmia
Rotundin	**Rotundin**	**1**	6	Arrhythmia
Levofloxacin	**Levofloxacin**	**1**	3	Arrhythmia, Urticaria
Levofloxacin	**Levofloxacin**	**1**	4	
Diclofenac	**Diclofenac**	**1**	1	Urticaria
MARCAINE	**Bupivacaine**	**1**	0	Urticaria
Metronidazon	**Metronidazol**	**1**	1	Skin redness
Meloxicam	**Meloxicam**	**1**	0	Skin redness, Adominal pain
Meloxicam	**Meloxicam**	**1**	1	
Clarithromycin Amoxilin/ acid clavulanic	**Clarithromycin Amoxicilin/ acid clavulanic**	**1**	1	Skin redness
Colchicin	**Colchicin**	**1**	2	Diarrhea
Aclasta	**Acid Zoledronic**	**1**	0	Fever
Terpin codein / Ultracet	**Terpin codein / Tramadol/ Paracetamol**	**1**	2	Constipation

Suspected medications	Active ingredients	Number of ADRs	Number of concurrent medications	Type of reactions
Uniferon	**Fe ++**	**1**	2	Constipation
Syndopa	**Levodopa/ Carbidopa**	**1**	4	Nausea, Dizziness

DISCUSSIONS

General results

In addition to the number of ADR cases reported by clinicians to the pharmacy department, the proactive efforts of the pharmacists resulted in the identification and recording of 15 additional cases of adverse drug reactions (DI – Drugs Interaction, SE – Side Effect, ADR/AE - Adverse Reactions), accompanied by 14 interventions where there was consensus. This initial data suggests a clear effectiveness of proactive monitoring, compared to passive information reception. Moreover, 14 interventions with consensus, representing a-positive outcomes that highlight a strong partnership between clinicians and pharmacists.

Data of departments

Adverse reactions have been reported in the majority of 199 Hospital departments. Every medical specialty has potential risk for adverse drug reactions. However, in certain specialties, the number of collected samples is relatively low due to various factors. These include a smaller number of patients, shorter treatment duration, and the severity of the disease preventing patient participation in interviews which play the significant role in the survey process.

For departments in which no adverse reactions were reported, several potential causes can be considered. It is possible that the clinical conditions of patients in those departments are generally mild, the patients' conditions are not complicated, the drugs used are not complex, or that fewer high risk drugs are employed. These factors can contribute to the absence of reported adverse reactions.

On the contrary, some departments primarily manage more severe diseases, which may result in fewer patients participating in interviews. Given the importance of interviews in the survey process, this can result in under reported cases. Additionally, differences in investigative skills among individual pharmacists, and varying abilities to assess and capture the depth of reactions may also contribute to these variations.

Onset of events

The first rate was acute reaction (47%, 7 cases), the second rate was sub-acute reaction (33%, 5 cases), and the delayed reaction accounted for at least (20%, 3 cases). This can be attributed to the fact that acute reactions are typically more evident and easily identifiable compared to delayed reactions. Furthermore, determining the cause of acute reactions is often more straightforward.

It is important to note that reactions can also occur either early or late in the treatment process and their occurrence is unpredictable. Therefore, it is crucial to maintain continuous monitoring of drug safety throughout the entire treatment duration.

List of suspected medications relating to ADRs

The majority of the suspected medications identified were found on the A-PINCH list (A-PINCH include Anti-infective agents, anti-psychotics, Potassium, Insulin, Narcotics and sedative agents, Chemotherapy and Heparin and other anticoagulants)[2], which consists of high-risk medications. This further supports our recommendation to prioritize the monitoring of patients with complex/high-risk pharmacotherapy.

Furthermore, it is worth noting that antibiotics accounted for 27% (4 of 15) of the reported adverse drug reactions (ADRs). This highlights the importance of reducing the unnecessary use of antibiotics, not only to mitigate the risk of ADRs but also to combat antibiotic resistance.

CONCLUSIONS

Generally, proactive adverse drug reactions monitoring has a noticeable impact.

Adverse reactions were reported in most departments. Any medical specialty has a potential risk for adverse drug reactions. Acute reactions are predominant. This aligns with the observation that acute reactions are often more apparent and recognizable than delayed reactions.

Adverse reactions are frequently associated with drugs that are known to carry a high risk of causing ADRs.

RECOMMENDATIONS

ADRs are unintended and required the promoted monitoring and management.

ADRs monitoring should be practiced during the treatment phase of the clinical process.

Patients with complexed or high risk pharmacotherapy should have prioritized monitoring.

Education on drug safety, prescription, administration, and using should be updated continuously, especially for high risk medications.

Drugs interaction alerts for prescriber should be integrated to hospital management software to aid the reduction of ADRs.

REFERENCES

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