# The Pharmacovigilance Practices by Healthcare Providers in Oncology: A Cross Sectional Study.

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## INTRODUCTION

- Pharmacovigilance is one of the most important components of patient care, especially when it comes to identifying adverse drug reactions (ADRs).
- ADRs studies in the Oncology setting are vital to the safe use of drugs.
- Cancer treatment involves highly complex regimens, which makes patients highly susceptible to ADRs.
- ADRs are generally under-reported.
- Practitioners commonly undervalue ADRs related to oncological medications, as they believe they are common and unavoidable[1 2].
- The reporting practices of ADRs in oncology settings have not been investigated previously.

## OBJECTIVES

**Primary objective:**

- To assess the knowledge and awareness of ADRs reporting and pharmacovigilance systems among healthcare providers (HCPs) in oncology settings.

**Secondary objectives:**

- To explore the gaps and inconsistencies in the reporting process.
- Identify reasons for under-reporting of ADRs in oncology settings.
- Determine the type of ADRs most likely to be reported.

## METHODS

- **Study design and participants:** Cross-sectional study involving healthcare professionals, including pharmacists, physicians, and nurses, working in the field of oncology.
- **Tool:** A validated online survey [3] was distributed across the Kingdom of Saudi Arabia, which consists of questions related to demographics, ADRs knowledge and practices.
- **Statistical analysis:** descriptive statistics using numbers and frequencies.
- Ethical approval for the study was obtained (no. E-21-6279) [4].

## RESULTS

- Until March 2022, we received 119 responses, 65 responders were eligible to enter the study.

**Table 1.** Characteristics of participants.

| Characteristics | n (%) | Characteristics | n (%) |
|---|---|---|---|
| **Age:** | | **Setting:** | |
| 25-35 | 56.9% | Ministry of Health Facilities | 21.9% |
| 36-45 | 26.2% | Military Hospitals | 17.2% |
| 46-55 | 12.3% | Ministry of the Interior | 1.6% |
| 56-65 | 4.6% | Referral Hospitals | 9.4% |
| 66+ | 0% | University Hospitals | 39.1% |
| **Gender:** | | Private Facilities | 10.9% |
| Female | 49.2% | **Role:** | |
| Male | 50.8% | Physician | 10.2% |
| **Years in practice:** | | Nurse | 25.4% |
| Less than 1 year | 6.2% | Pharmacist | 50.8% |
| 1-4 years | 24.6% | Pharmacy technician | 11 % |
| 5-9 years | 23.1% | Other | 2.5% |
| 10-19 years | 36.9% | | |
| 20 years or more | 9.2% | | |

**Figure 1.** The average number of Adverse Drug Reaction incidents HCPs reported, (on a monthly basis).

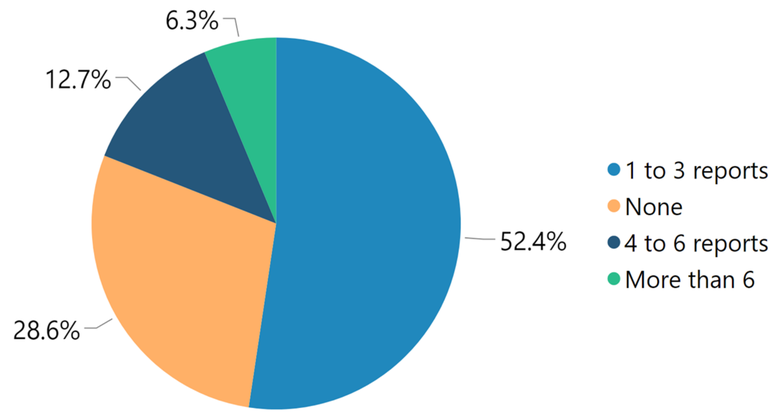



**Figure 2.** Reasons that may prevent health care providers from reporting ADRs.

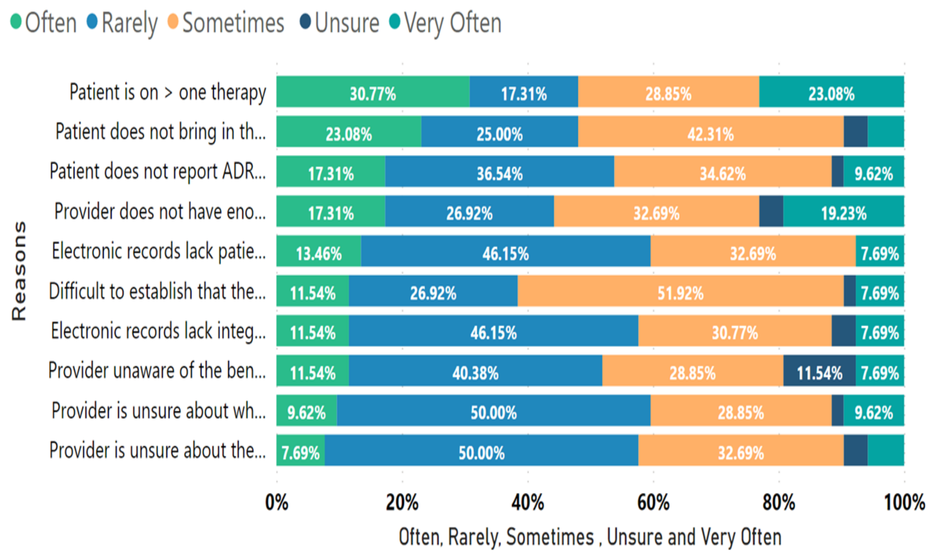


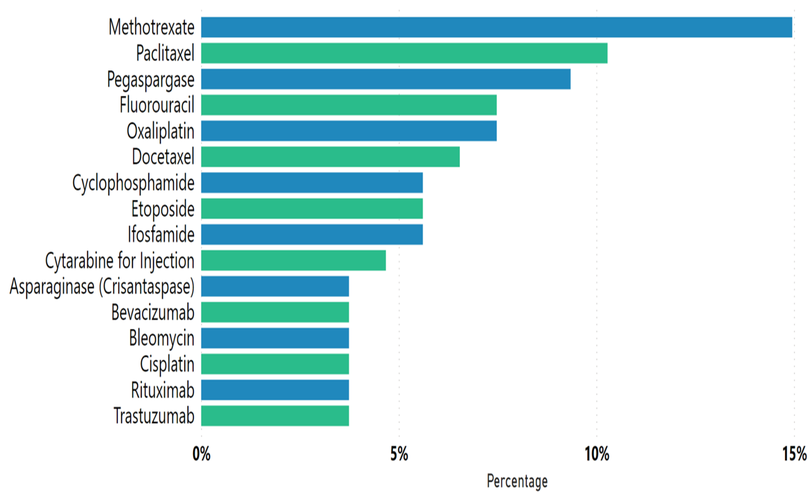

**Table 2.** Reporting practices.

| Characteristics | n (%) |
|---|---|
| **Which organizations HCPs reported an ADR for** | |
| The healthcare organization where HCPs work | 58.9% |
| Ministry of Health | 9.6% |
| Drug manufacturer | 5.5% |
| SFDA pharmacovigilance Program | 12.3% |
| Never reported | 13.7% |
| **Did HCPs received education related to ADR** | |
| Yes | 76.9% |
| No | 23.1% |
| **Are HCPs familiar with a formal procedure for reviewing reports submitted to the Incident Reporting System** | |
| Yes | 38.5% |
| No | 6.2% |
| Unsure | 53.8% |
| Not Applicable | 1.5% |
| **How HCPs identify ADRs** | |
| Temporal relationship between the onset of drug therapy and the adverse reaction | 31.7% |
| There was a dechallenge or rechallenge | 27% |
| Signs and symptoms of ADRs | 12.7% |
| Laboratory tests | 4.8% |
| Patient complaint | 23.8% |

**Table 3.** Characteristics of reporting in oncology.

| Characteristics | n (%) | Characteristics | n (%) |
|---|---|---|---|
| **Most encountered type of ADRs** | | **Most observed reaction type** | |
| Nausea and vomiting | 14.5% | Unprovoked/Unexpected reaction | 56.1% |
| Dermatological toxicity (skin, hair, and nail modifications) | 11.4% | Exaggerated pharmacological action | 43.9% |
| Febrile neutropenia | 10.4% | **The most observed level of ADR severity** | |
| Cardiovascular toxicity | 9.3% | Category 1 | 30% |
| Diarrhea or constipation | 7.8% | Category 2 | 23.3% |
| Other | 6.7% | Category 3 | 21.1% |
| Fatigue | 6.2% | Category 4 | 18.9% |
| Mucositis | 6.2% | Category 5 | 4.4% |
| Thrombosis | 5.2% | Category 6 | 2.2% |
| Infusion reactions | 4.7% | Category 7 | 0% |
| Neuropathic pain | 4.7% | **Most often action taken once an ADR is detected** | |
| Central Venous Catheters -related complications (infections, thrombosis, extravasation) | 3.6% | Discontinue suspect medication(s) | 26.9% |
| Infections | 3.6% | Treatment with medications | 20.7% |
| Palmar-plantar erythrodysesthesia (hand-foot skin reactions) | 3.1% | Adjust dose, route, frequency | 20% |
| Cognitive dysfunctionality | 2.1% | Therapy held | 16.6% |
| Hormonal impairment, Infertility | 0.5% | Switch to alternative agent | 11.7% |
| | | Other medical treatment | 4.1% |

**Figure 3.** Medication for which healthcare providers have reported ADRs.




## DISCUSSION AND CONCLUSION

- The findings from this study reveal that practitioners received a good education about ADRs reporting; however, there is a lack of a standardized ADRs reporting processes.
- Practitioners in oncology settings mostly report ADRs related to nausea and vomiting, followed by dermatological toxicities. Furthermore, these are frequently reported in adult's patients.
- Clear practice guidelines on ADRs reporting, and further training to reach a satisfaction with ADRs reporting practices are highly warranted.

## REFERENCES

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