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TWELVE YEARS OF CLINICAL PHARMACIST-LED ADVERSE DRUG REACTION REPORTING IN ONCOLOGY PATIENTS AT A UNIVERSITY HOSPITAL

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BACKGROUND AND IMPORTANCE

- Pharmacovigilance is a key component of good clinical practice, particularly in the post-marketing phase.
- Systematic adverse drug reactions (ADR) reporting is crucial - polypharmacy and novel therapies the increase the risk.
- Clinical pharmacists are uniquely positioned to detect and report suspected ADRs, supporting early identification of safety signals, high-risk drugs, and vulnerable patient populations.

AIM AND OBJECTIVES

- To describe and analyse the spectrum, frequency, and clinical impact of suspected ADRs reported by a clinical pharmacist in oncology patients over twelve years at a tertiary care hospital.

MATERIALS AND METHODS

- Retrospective analysis of all suspected ADRs in oncology patients reported by a clinical pharmacist to the Czech State Institute for Drug Control between **November 2013 and April 2025**.
- Data collected: patient demographics, cancer type, drug and therapy category, ADR type and severity, clinical outcomes, and annual reporting trends.
- Descriptive statistics were applied for the analysis.

RESULTS

- **Total ADRs reported:** 217 (82 (38%) males, 134 (62%) females).
- **Most affected age group:** 60–79 years (62% reports), no reports in 10–19 years group.
- **Annual reporting trends:** *see Fig.1 (2013 and 2025 cover only 4/12 months; reports in 2020–2022 influenced by acute SARS-CoV-2 response)*
- **Most frequent diagnoses** (ICD-based (International Classification of Diseases) were C64 (38%), C50 (33%), C43 (27%), C18 (19%), C56 (18%), other less than 10%.
- **Main treatment types associated with reported ADRs:** *Fig.2.*
- **Most frequently reported drugs:** *Fig.3.*
- **Common ADRs:** allergic reactions/drug intolerance, diarrhoea/colitis, exanthema, nephrotoxicity, hematotoxicity, hepatotoxicity, pneumonitis, and neuro/myotoxicity *Fig.4.*
- **Severity:** ~ 40% of ADRs were serious (hospitalisation, life-threatening events, death); most patients fully recovered.
- **Trends:** increasing proportion of immunotherapy-related ADRs in recent years.

CONCLUSION AND RELEVANCE

- Twelve years of clinical pharmacist-led ADR reporting provided valuable real-world pharmacovigilance data in oncology.
- Allergic and immune-related reactions were the most frequent and clinically significant.
- Persistent underreporting remains, mainly due to limited access to patient data, time constraints, and insufficient awareness of post-marketing safety monitoring.

PRACTICE IMPLICATIONS

- **Routine pharmacist involvement in ADR reporting can further improve oncology patient safety.**

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Fig. 1: Annual reporting trends

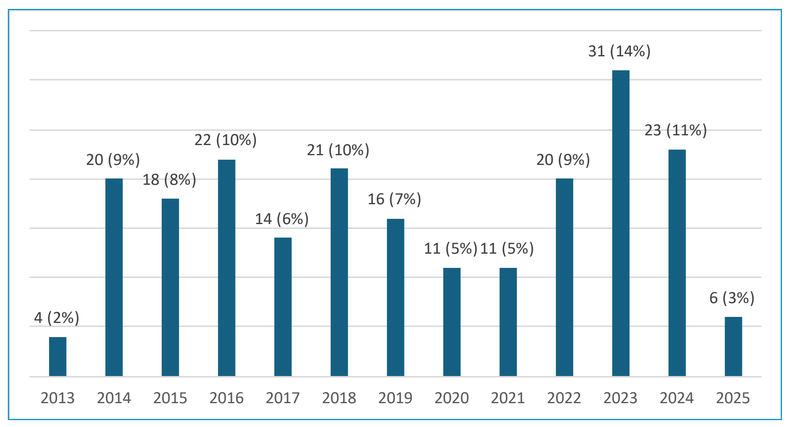
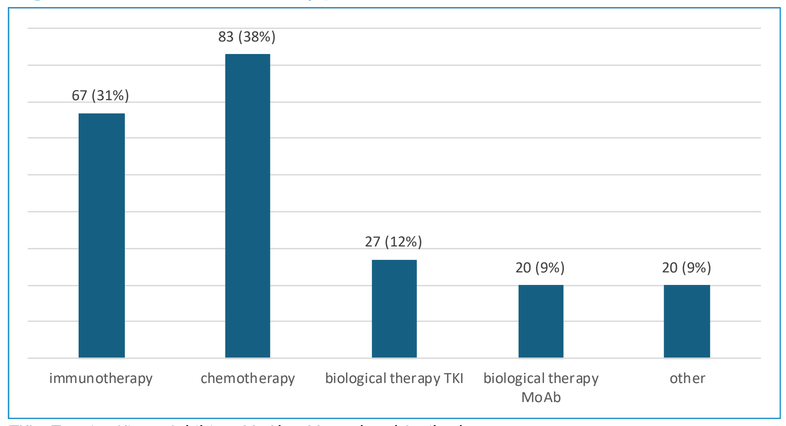


Fig. 2: Main treatment types



TKI = Tyrosine Kinase Inhibitor, MoAb = Monoclonal Antibody

Fig. 3: Most frequently reported drugs

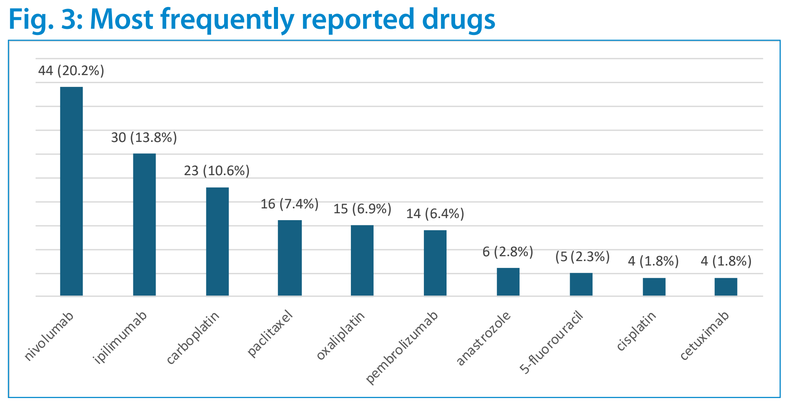


Fig. 4: Main reported ADRs (Adverse Drug Reactions)