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Internship report

**Safety signal detection from Vietnamese spontaneous
adverse drug reaction reporting system for
several high-cost drugs covered by
Vietnam health insurance fund**

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List of Abbreviations

ADR	Adverse Drug Reaction
AGEP	Acute Generalized Exanthematous Pustulosis
ART	Adverse Reaction Terminology
BCPNN	Bayesian Confidence Propagation Neural Network
DRESS	Drug Reaction with Eosinophilia and Systemic Symptoms
IC	Information Component
MGPS	Multi-item Gamma Poisson Shrinker
NDIADRC	National Drug Information & Adverse Drug Reaction Monitoring Center
NPDV	National Pharmacovigilance Database of Vietnam
PRR	Proportional Reporting Ratio
PT	Preferred Term
ROR	Reporting Odds Ratio
SCAR	Serious Cutaneous Adverse Reaction
SJS	Stevens-Johnson syndrome
SOC	System Organ Class
SPC	Summary of Product Characteristics
TEN	Toxic Epidermal necrolysis
UMC	Uppsala Monitoring Center
WHO	World Health Organization

Abstract

Background Irrational drug use causes many significant problems such as waste of money, ineffective treatment, an increase in the number of patients with ADRs. In the specific sociological context of Vietnam, the study aims to describe and quantify the noticeable ADRs relating to 41 high-cost drugs in the list of drugs of Vietnam health insurance fund using the National Pharmacovigilance Database of Vietnam.

Methods Spontaneous reporting of adverse drug reactions (ADRs) recorded in the period of 2010 – 2016 were retrospectively analysed to identify reports of 41 high-cost drugs. Characteristics of ADR reports relating to these drugs were described. Disproportionality analysis was used for signals generation.

Results Of the 38,521 ADR reports from healthcare units in the period of 2010 – 2016, 36,792 reports had ADR causality for suspected drugs. ADR reports of 40/41 drugs in the list were recorded except for glycyrrhizin/glycine/L-cysteine combination. Reports relating to antibiotics, especially cephalosporins were predominant. In addition to high-risk agents which were widely known causing anaphylaxis such as β -lactams and anti-cancer agents (paclitaxel, oxaliplatin), there were some important signals relating to methylprednisolone (ROR= 1.98 [1.03-3.78]), piracetam (ROR= 2.26 [1.34-3.82]), chymotrypsin (ROR= 1.70 [1.25-2.31]), glutathione (ROR= 4.02 [1.82-8.85]) and L-ornithine L-aspartate (ROR= 1.80 [1.11-2.92]). Ciprofloxacin and levofloxacin had significantly high incidence rates of application site reactions, which were 23.4%, ROR= 14.77 [12.78-17.08] and 23.8%, ROR= 12.83 [10.73-15.34] respectively. SCAR signals relating to cefixime (ROR= 7.58 [4.08-14.07]) and paracetamol (ROR= 3.46 [2.31-5.17]), and arthralgia, hepatitis signals relating to levofloxacin (ROR= 3.89 [2.09-7.22] and 2.72 [1.19-6.22] respectively) were also generated.

Conclusion In spite of some limitations of spontaneous ADR reporting system, the finding released necessary results for drug safety in specific context of Vietnam. This study also confirmed that routine analysis of database plays an essential role in timely identifying potential risks as well as providing proper management and enhancing effective communication.

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