

Identification of Preventable Adverse Drug Reaction in Vietnamese Pharmacovigilance Database: A Retrospective Analysis

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INTRODUCTION

The **pharmacovigilance (PV) databases** is a potential source for identifying preventable adverse drug reactions (ADRs) and the associate medication errors (ME) ⁽¹⁾.

There is no gold-standard methods for assessing preventability of ADRs from ADR spontaneous reports. To date, the **P-method** is the only validated tool that designed for this purpose. Despite the limited quality information, spontaneous ADR reports in Vietnamese PV database still can be used to detecting PV signals and MEs ⁽²⁾. **Thus, the aims of this study were:**

1. To detect preventable ADRs (pADRs) from ADR reports in Vietnamese PV database.
2. To describe the preventable ADRs (pADRs) detected.

MATERIALS

Spontaneous ADR reports of a two-month period from 16/12/2013 to 15/2/2014 from healthcare facilities national wide sent to Vietnamese PV database except ones with no ADRs, no exact ingredients, no references to evaluate the reported drug use or the ones reporting test of allergy.

METHOD

The assessment consists of two phases as described below:

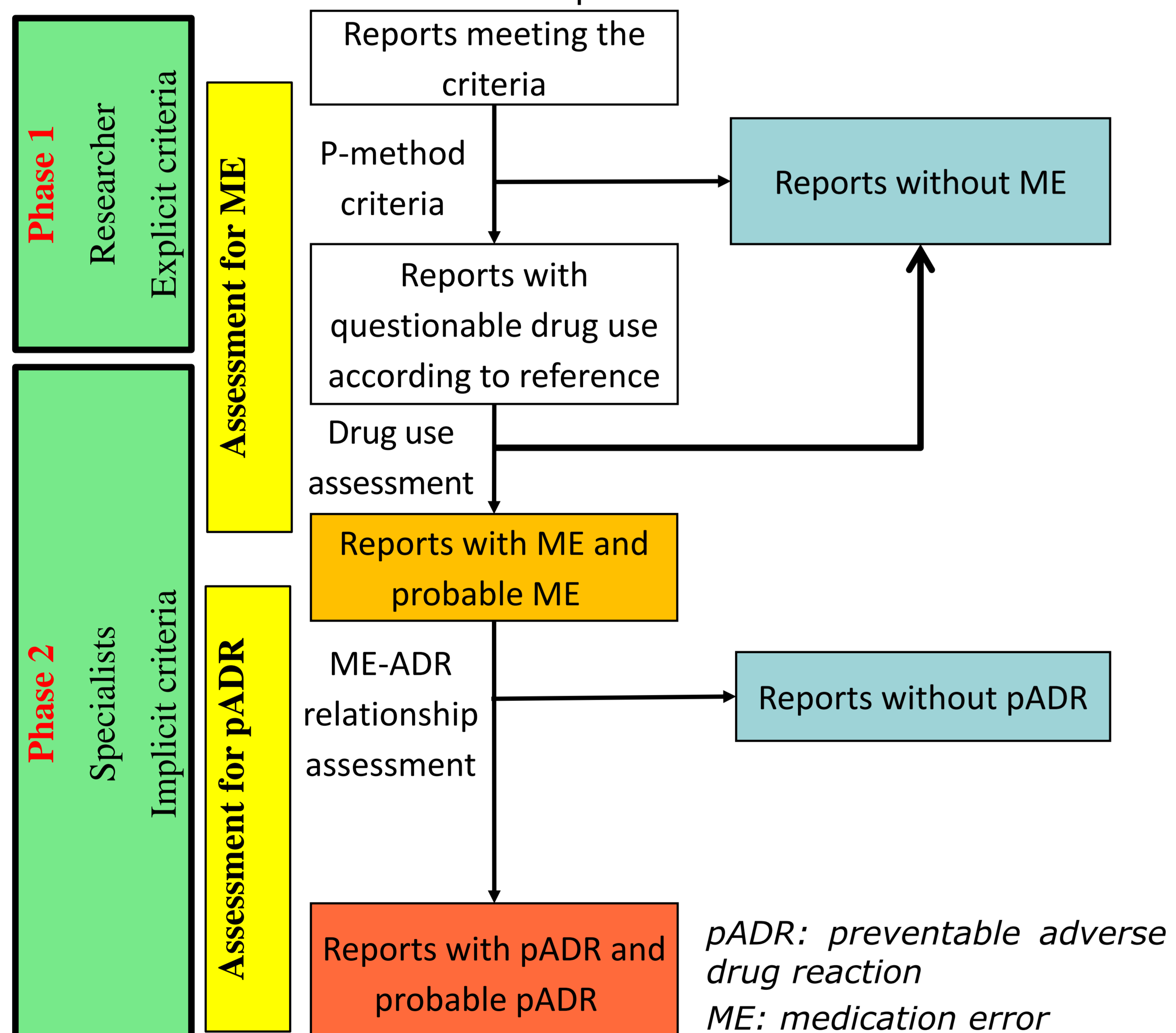


Figure 1. Report assessment procedure

Table 1. Drug use problems mentioned in P-method's criteria ⁽²⁾

Healthcare professionals' practices ('Pr')

1-Dose; 2- Adm. route; 3-Adm. duration; 4-Dosage form; 5-Expired drug; 6-Storage; 7- Adm. technique; 8-Indication; 9-Inappropriate for patient's characteristics; 10- Inappropriate for medical condition/pathology; 11- Known hypersensitivity; 12-Interaction; 13-Therapeutic duplication; 14- Lack of necessary medication; 15-Withdrawal syndrome; 16-Monitoring.

Product/drug ('Pd')

17. Poor-quality drug; 18. Counterfeit drug

Patient ('Pa')

19. Non-compliance; 20. Self-medication with non-OTC drug.

Adm. : administration. OTC: over-the-counter

RESULTS

152/763 reports evaluated were classified as having medication error (127) or probable medication error (25).

85/763 reports showed preventable ADR (60) or probable preventable ADR (25).

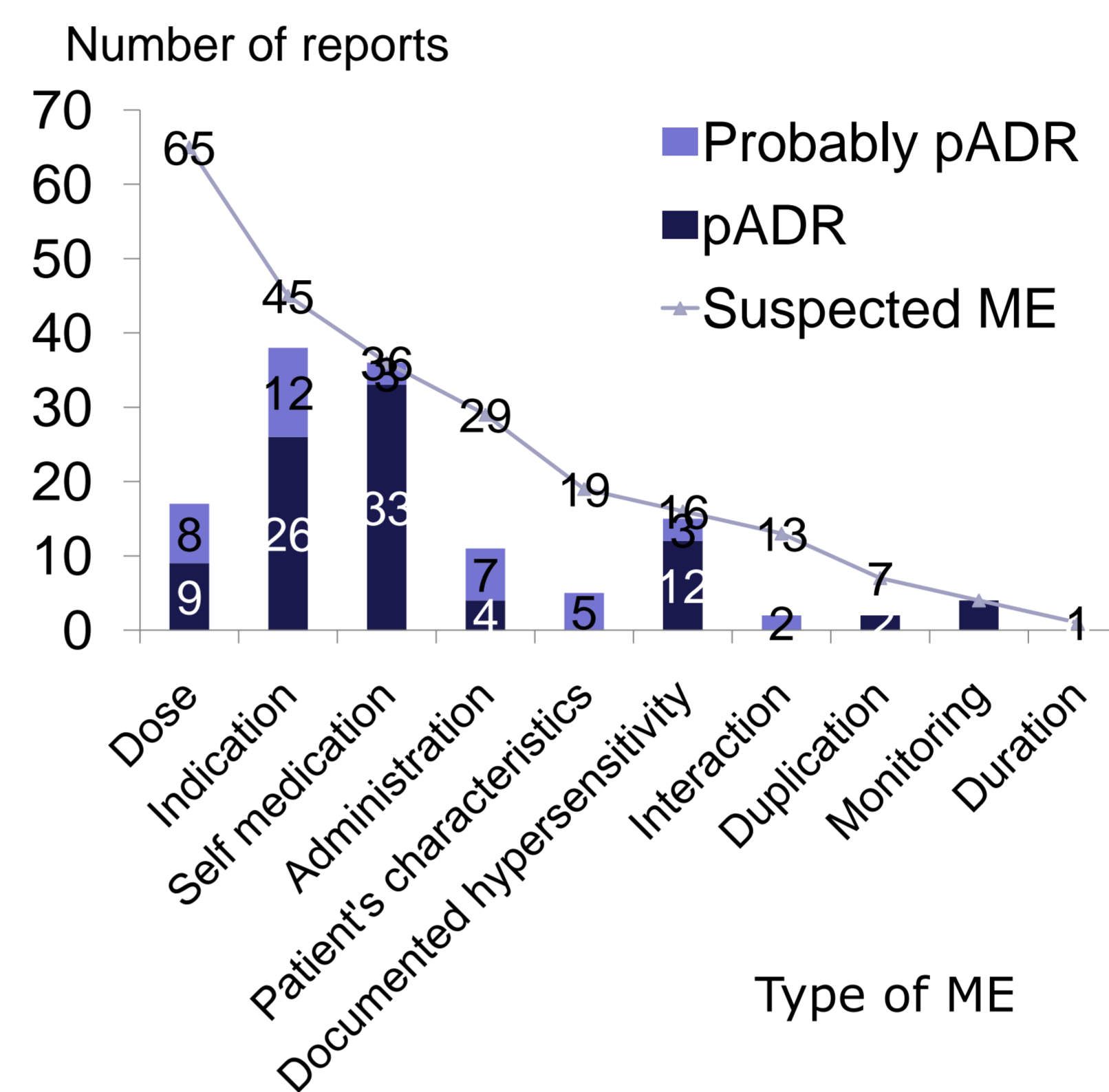


Figure 2. Type of medication errors

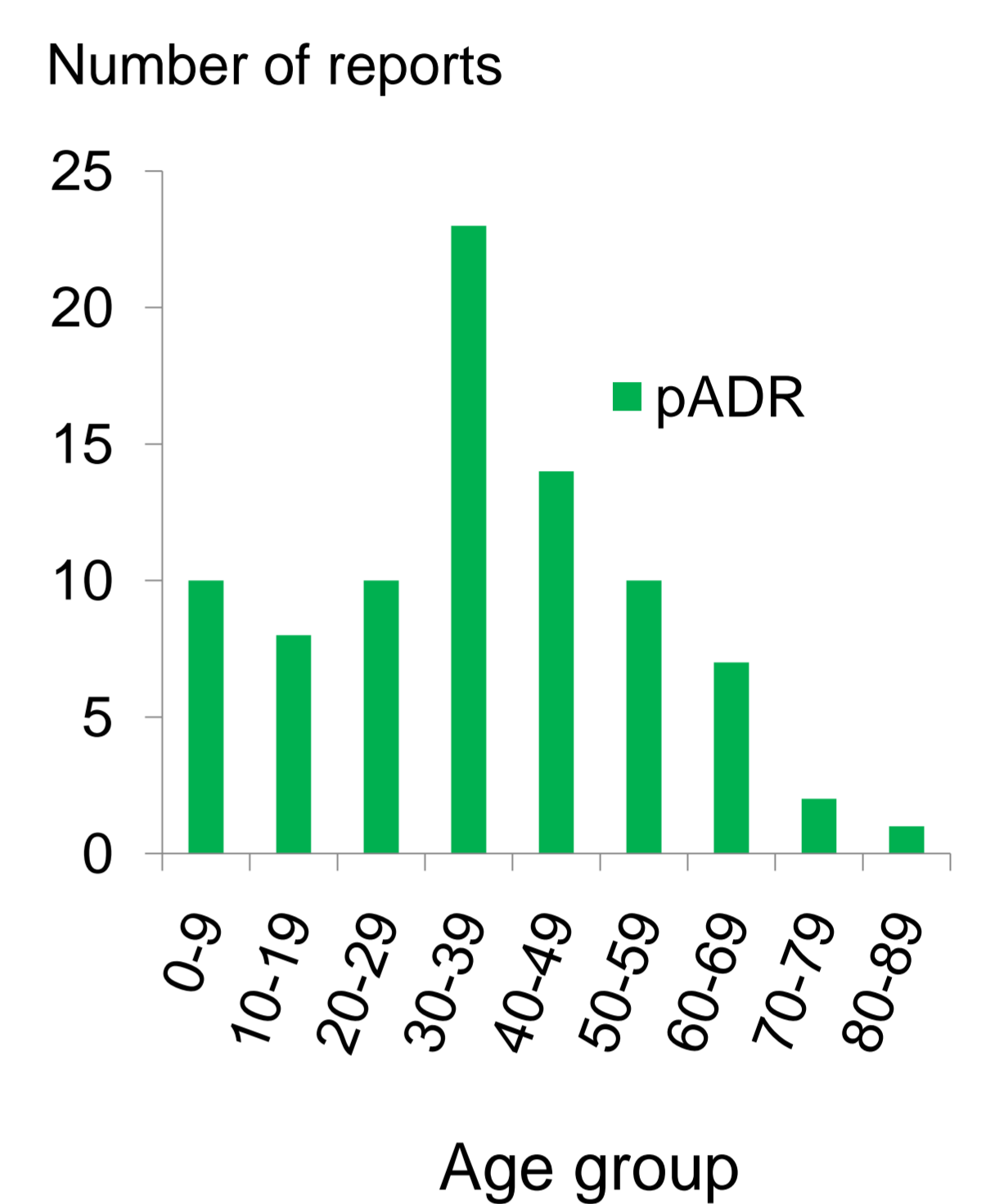


Figure 3. Age group of patients involved in pADR

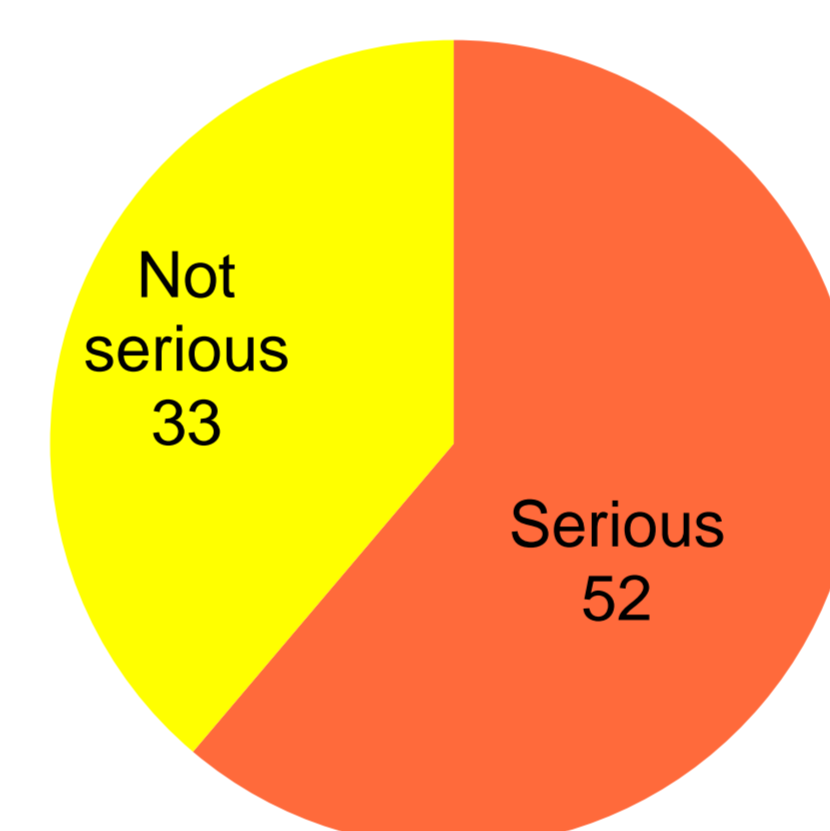


Figure 3. Seriousness of pADR (number of reports)

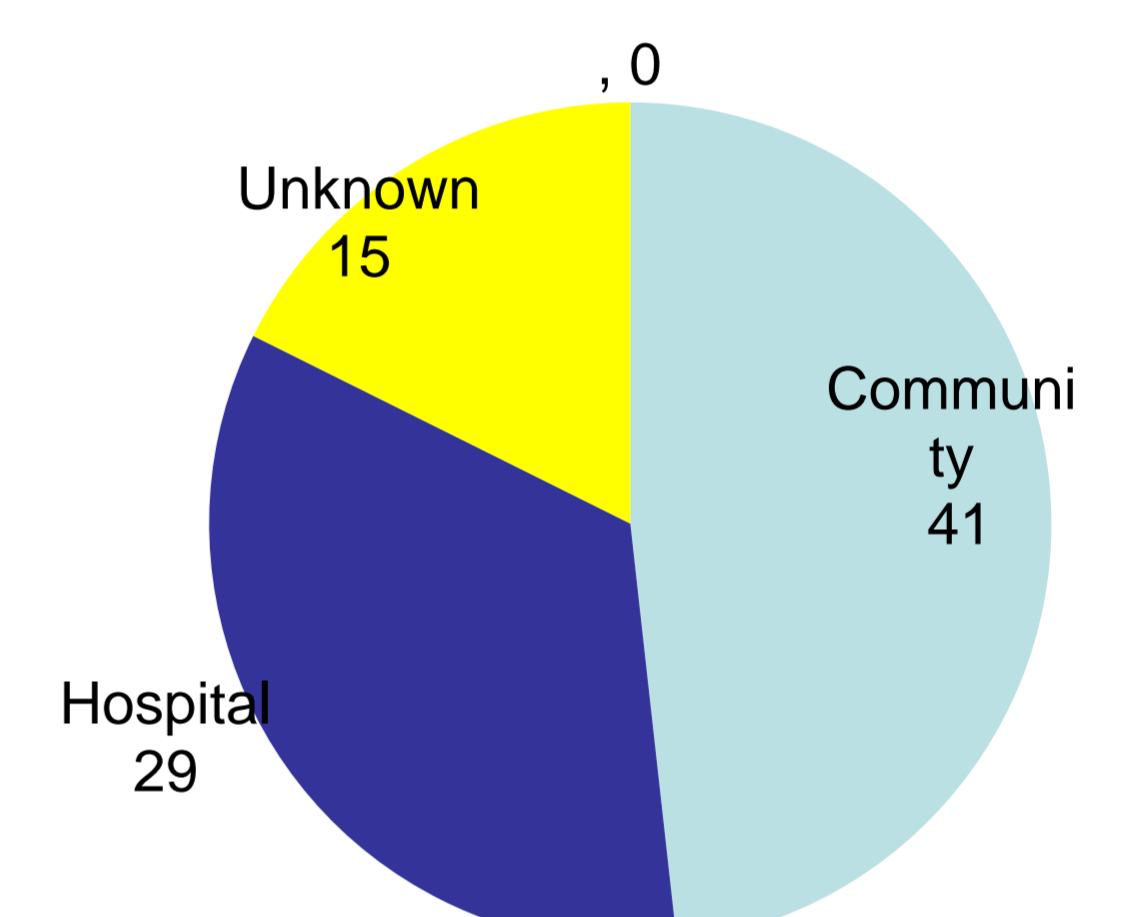


Figure 4. Setting where pADR occurred (number of reports)

Table 2. Top system-organ classes effected (N, %)

System-organ class	N	%
Skin and appendages disorders	57	67,1
Gastro-intestinal disorders	16	18,8
Psychiatric disorders	16	18,8
Body as a whole – general disorders	13	15,3
Central & peripheral nervous system disorders	12	14,1

Table 3. Top medication classes involved (N, %)

Medication class	N	%
J01D- Other beta-lactam antibacterials	21	24,7
J01C- Beta-lactam antibacterials, penicillins	12	14,1
J01F- Macrolides, lincosamides and streptogramins	8	9,4
M01A- Antiinflammatory and antirheumatic products, non-steroids	8	9,4
J01E- Sulfonamides and trimethoprim	6	7,1
J01G- Aminoglycoside antibacterials	6	7,1

Conclusion

Vietnamese pharmacovigilance database is potential resource that can be used to detect preventable adverse drug reactions and the characteristics of involving medication errors

Reference: 1. WHO (2014), Reporting and learning systems for medication errors: the role of Pharmacovigilance centres, p.9-10
2. R. Benkiran, 2015. **38**(4): p. 383-393.