pharmacoepidemiology

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Pharmacovigilance from the Patient's Perspective: Self-Reported Adverse Drug Reactions in Kosovo's Elderly Population

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Abstract

Background: Pharmacovigilance is a critical component of patient safety, particularly among older adults with chronic diseases who are frequently exposed to polypharmacy. In Kosovo, adverse drug reactions (ADRs) reported by patients remain insufficiently recognized within the healthcare system. Polypharmacy, limited access to pharmaceutical counseling, and self-medication practices may contribute to increased medication-related harm. Capturing ADRs directly from patients provides valuable insight into medication safety challenges and communication gaps in clinical care. Objective: To assess the frequency, characteristics, and reporting behavior of adverse drug reactions among adults aged 60–75 years with chronic diseases in Kosovo, and to identify factors associated with awareness and reporting practices. Methods: A multicenter cross-sectional study was conducted between January and September 2025 in four major cities in Kosovo (Prishtina, Prizren, Peja, and Gjilan). A total of 1024 patients receiving continuous therapy for at least one chronic condition were surveyed using a structured questionnaire covering demographic characteristics, drug exposure, ADR experience, and reporting behavior. Statistical analyses included descriptive statistics, chi-square testing, and multivariable logistic regression to identify predictors of ADR reporting. Results: Overall, 47.3% of participants reported experiencing at least one ADR in the preceding 12 months. Among those, 39.5% reported the event to a healthcare professional, whereas 60.5% did not seek professional advice. The most frequently implicated drug classes were antihypertensives (32.8%), analgesics and non-steroidal anti-inflammatory drugs (27.4%), and antirheumatic agents (14.6%), with mainly gastrointestinal (24.1%) and cardiovascular (18.9%) manifestations. Approximately 19.8% of participants reported discontinuing medication due to adverse effects. Female patients were more likely to report ADRs compared to males ($p < 0.01$). Lack of prior counseling about potential side effects was independently associated with lower reporting (OR = 2.17; 95% CI: 1.41–3.33). Patients using more than six medications had a higher prevalence of ADRs (61.2%). Conclusion: Adverse drug reactions were frequently reported by older patients, while formal reporting to healthcare professionals remained limited. Strengthening patient education, improving patient–provider communication, and integrating clinical pharmacists into primary care may enhance pharmacovigilance practices and medication safety.

Keywords: pharmacovigilance; adverse drug reactions; older adults; reporting behavior; polypharmacy

Academic Editor: Carlotta Franchi

Received: 5 November 2025
Revised: 16 January 2026
Accepted: 26 January 2026
Published: 30 January 2026

1. Introduction

The global ageing of populations represents one of the most significant public health challenges of the 21st century. Along with increased life expectancy, the prevalence of chronic diseases has risen substantially, resulting in a marked escalation in long-term medication use among older adults [1]. As individuals age, pharmacotherapy becomes increasingly complex due to physiological changes affecting drug metabolism and elimination, which contributes to a heightened vulnerability to adverse drug reactions (ADRs).

Polypharmacy, commonly defined as the concurrent use of five or more medications, has become highly prevalent among older populations. While often clinically necessary, polypharmacy substantially increases the risk of drug–drug interactions and ADRs [2]. Recent European data indicate that the prevalence of polypharmacy has increased from approximately 27% in 2000 to over 45% in 2020, placing a considerable burden on healthcare systems [3]. ADRs associated with polypharmacy are a leading cause of avoidable hospital admissions and contribute significantly to morbidity and mortality among patients aged over 60 years [4,5]. It is estimated that 10–20% of older adults experience at least one clinically relevant ADR annually [6].

Pharmacovigilance plays a central role in the detection, assessment, understanding, and prevention of drug-related adverse outcomes [7]. However, traditional pharmacovigilance systems have relied primarily on reports submitted by healthcare professionals, which has contributed to substantial underreporting [8]. In response, patient-reported outcomes have increasingly been recognized as an essential component of modern drug safety monitoring. Basch (2010) [9] highlighted that the "missing voice" in pharmacovigilance is frequently the patient, whose experiences may better capture the subjective burden and early manifestations of ADRs. Moreover, systematic reviews have demonstrated that adverse events remain underreported in both industry-sponsored trials and published literature, underscoring the importance of strengthening post-marketing surveillance through patient engagement [10].

Over the past decade, patient-centered pharmacovigilance has emerged as a paradigm shift in healthcare safety practices. Direct patient reporting has been shown to improve the detection of safety signals and enrich clinical understanding of drug tolerability [11]. Bahri and Pariente (2021) [12] further proposed a structured framework for engaging patients, healthcare professionals, and regulators in collaborative risk governance. Additionally, the integration of patient-reported outcome measures into routine practice has been increasingly adopted to enhance drug safety monitoring in real-world settings [13]. The growing availability of digital health tools and mobile reporting applications also presents new opportunities to improve accessibility and reporting rates, particularly among older adults with adequate digital literacy.

In Southeastern Europe, including Kosovo, pharmacovigilance systems remain underdeveloped, and patient involvement is limited. Evidence from the region suggests that a significant proportion of patients experiencing ADRs either fail to inform healthcare professionals or discontinue their medication independently [14]. This communication gap between patients, physicians, and pharmacists presents an additional challenge to effective chronic disease management and jeopardizes treatment adherence and safety. Economic constraints, limited access to pharmaceutical counseling, and cultural beliefs may further influence reporting practices and self-management behaviors.

Several determinants influence ADR reporting behavior, including educational level, number of medications, previous experiences with ADRs, trust in healthcare professionals, and awareness of pharmacovigilance systems [15–17]. Many patients remain unaware of their role in reporting safety concerns or underestimate the clinical significance of mild or transient symptoms. Consequently, understanding patients' perceptions and

experiences is essential for strengthening pharmacovigilance infrastructure, particularly in aging populations.

Against this background, the present study aimed to evaluate the prevalence and characteristics of self-reported adverse drug reactions among adults aged 60–75 years with chronic diseases in Kosovo, to assess patterns of reporting behavior, and to identify key factors influencing awareness and communication regarding ADRs. The findings are intended to inform national policy development, reinforce the role of clinical pharmacists in primary healthcare, and support targeted interventions to improve medication safety and patient engagement in pharmacovigilance.

2. Results and Analysis

A total of 1024 participants were included in the analysis. The age of participants ranged from 60 to 75 years, with a mean of 67.4 ± 4.2 years; females accounted for 52.7% of the sample. Most participants (63.5%) resided in urban areas. Polypharmacy, defined as the concurrent use of more than five medications, was observed in 61.2% of respondents.

Overall, 47.3% of participants reported experiencing at least one adverse drug reaction (ADR) during the previous 12 months. Reporting rates were higher among females (44.8%) than males (33.2%) ($p < 0.01$). The most frequently affected systems were gastrointestinal (24.1%), cardiovascular (18.9%), and central nervous system (13.7%). Among participants who experienced ADRs, 39.5% reported the event to a healthcare professional, whereas others either continued treatment without consultation, discontinued therapy, or took no action.

Table 1 summarizes the demographic and clinical characteristics of the study population. Table 2 presents the distribution of ADRs by organ system. Table 3 shows drug classes associated with ADRs, including a description of the "Other" category. Table 4 presents reporting behavior by gender and education with the "Not Reported" column removed as requested. Table 5 summarizes sources of pharmacovigilance information. Table 6 presents multivariable logistic regression analysis. Table 7 details patient behavior following ADRs, with an additional entry to indicate the proportion who discontinued therapy after consultation with a physician (to be completed, as requested by reviewers).

Table 1. Demographic and clinical characteristics of participants (N = 1024).

Variable	N (%)	Mean ± SD	*p*-Value
Age (years)	–	67.4 ± 4.2	–
Age range (years)	60–75	–	–
Gender (Female/Male)	540 (52.7%)/484 (47.3%)	–	–
Residence (Urban/Rural)	650 (63.5%)/374 (36.5%)	–	0.128
Education (High/Medium/Low)	268/512/244	–	<0.01
Number of medications			
1–2 medications	118 (11.5%)	–	–
3–4 medications	279 (27.3%)	–	–
5–6 medications	342 (33.4%)	–	–
≥7 medications	285 (27.8%)	–	–
Average number of drugs	–	5.7 ± 2.1	–
Polypharmacy (>5 drugs)	627 (61.2%)	–	<0.001

Table 2. Frequency of reported adverse drug reactions by affected system.

Affected System	N (%)	95% CI
Gastrointestinal	247 (24.1%)	21.4–26.8
Cardiovascular	194 (18.9%)	16.4–21.3
Central nervous system	141 (13.7%)	11.5–15.8
Musculoskeletal	118 (11.5%)	9.6–13.5
Renal/Urinary	65 (6.3%)	4.8–7.8
Others	83 (8.1%)	6.5–9.8

Table 3. Drug classes associated with reported adverse reactions.

Drug Class (ATC)	N (%)	Notes
Antihypertensives (C02–C09)	336 (32.8%)	
Analgesics/NSAIDs (N02, M01)	281 (27.4%)	
Antirheumatic drugs (M01, L04)	149 (14.6%)	
Hypoglycemics/Insulins (A10)	102 (10.0%)	
Statins/Lipid-lowering agents (C10)	74 (7.2%)	
Hypnotics and sedatives (N05C)	48 (4.7%)	Insomnia-related drugs
Others	32 (3.1%)	

Table 4. Reporting of adverse reactions by gender and education level.

Variable	Reported N (%)	*p*-Value
Female	242 (44.8%)	<0.01
Male	161 (33.2%)	<0.01
Higher education	141 (52.6%)	<0.001
Secondary education	189 (36.9%)	–
Primary education	73 (29.9%)	–

Table 5. Sources of information on pharmacovigilance.

Source of Information	N (%)	95% CI	*p*-Value
Pharmacist	312 (30.5%)	27.8–33.3	<0.01
Family doctor	229 (22.4%)	20.0–24.9	<0.01
Media/Internet	198 (19.3%)	17.0–21.6	0.043
Family/Friends	143 (14.0%)	11.9–16.1	–
No information received	142 (13.8%)	11.7–15.9	–

Table 6. Logistic regression analysis of predictors of active ADR reporting.

Variable	OR	95% CI	*p*-Value
Age (60–65 years)	1.41	1.09–1.83	0.012
Gender (Female)	1.36	1.05–1.77	0.021
Higher education	1.68	1.23–2.29	<0.001
Regular pharmacist counseling	1.94	1.39–2.72	<0.001
Previous ADR experience	1.53	1.11–2.11	0.008
Polypharmacy (>5 drugs)	1.27	0.94–1.71	0.112

Table 7. Patient behavior following the experience of adverse reactions.

Action Taken	N (%)	95% CI	*p*-Value
Reported to healthcare professional	192 (39.5%)	36.1–42.9	<0.001
Self-discontinued medication	96 (19.8%)	17.1–22.4	<0.001
Continued therapy without consultation	144 (29.2%)	26.1–32.3	–
Took no action	55 (11.3%)	9.0–13.5	–

3. Discussion

This study provides a comprehensive evaluation of patient-reported adverse drug reactions (ADRs) and associated reporting behavior among older adults with chronic diseases in Kosovo. The observed prevalence of ADRs (47.3%) corresponds with findings from European studies reporting rates between 42% and 52% among elderly populations [3,6], confirming that medication-related harm represents a global challenge in geriatric pharmacotherapy.

Despite the high frequency of ADRs, only 39.5% of affected patients reported their experience to healthcare professionals. This level of underreporting is comparable to data from Spain, Italy, and Poland [16,18], but remains considerably lower than that reported in Nordic countries where patient-centered digital pharmacovigilance systems have facilitated reporting rates exceeding 60% [17]. These discrepancies likely reflect differences in healthcare infrastructure, patient education, and accessibility of reporting mechanisms. The findings support the argument that Kosovo is at an early stage of implementing patient-centered pharmacovigilance, where awareness and patient engagement remain limited.

The importance of patient reporting has been highlighted in the literature. Basch (2010) [9] emphasized that the "missing voice" in pharmacovigilance is often that of the patient, whose perspective enables earlier detection of subjective and subtle adverse effects. Furthermore, evidence indicates that underreporting of ADRs is also prevalent within pharmaceutical research and development, reinforcing the need for stronger post-marketing surveillance mechanisms [10]. The integration of patient-reported outcome measures into routine healthcare practice has increasingly been recognized as a paradigm shift toward safer medication use [13].

Gender differences were evident in ADR reporting, with women being significantly more likely to report reactions than men. This observation is consistent with studies linking female sex to increased pharmacovigilance engagement and higher health literacy [5,19]. In contrast, men may be less inclined to recognize or disclose symptoms, suggesting the need for targeted educational strategies addressing gender-related communication barriers.

Higher educational attainment and pharmacist counseling were strong independent predictors of ADR reporting. Patients who received regular pharmaceutical counseling exhibited greater awareness and engagement with safety reporting mechanisms. Pharmacist-led interventions have been associated with reductions in serious ADR-related hospital admissions across Europe, highlighting the importance of integrating clinical pharmacists into primary healthcare teams [18,19]. These findings support recent frameworks advocating systematic engagement of patients, healthcare professionals, and regulators in pharmacovigilance processes [12].

Antihypertensive agents and non-steroidal anti-inflammatory drugs (NSAIDs) constituted the most frequently implicated drug classes in this study. This finding mirrors European trends, where these medications remain among the leading contributors to ADR-related hospitalizations in adults over 65 years of age [20]. These drug classes are commonly associated with gastrointestinal, cardiovascular, and renal complications, underscoring

the importance of careful medication review and individualized therapy in older patients, particularly in the presence of polypharmacy.

Nearly one in five participants discontinued treatment following an ADR without consulting a healthcare provider. Almost one in five patients (19.8%) reported discontinuing their medication following an ADR. However, the study did not systematically distinguish whether discontinuation occurred after consulting a physician or was entirely self-directed, which limits a more detailed interpretation of patient behaviour. Similar behaviors have been documented in Southern European countries, where self-management is associated with limited patient–provider communication and diminished trust in healthcare systems [20]. In Kosovo, discontinuation of prescribed therapy without supervision may increase the risk of disease exacerbation, drug resistance, or harmful self-medication practices.

The study's strengths include its multicenter design, large sample size, and robust analytical approach using multivariable regression modeling. Nevertheless, several limitations should be acknowledged. First, the cross-sectional design precludes causal inference. Second, ADRs were self-reported, introducing potential recall bias and misclassification. Second, information regarding whether treatment discontinuation occurred before or after medical consultation was not collected. Future studies should explicitly capture this variable in order to better understand patient decision-making following adverse drug reactions. Third, the lack of clinical verification limits differentiation between perceived reactions and objectively confirmed ADRs. Importantly, information regarding alternative therapeutic recommendations (e.g., lifestyle interventions, first-line analgesic choices, deprescription strategies) was not collected. Future studies should examine whether patients were offered non-pharmacological alternatives, deprescribing, or medication substitutions prior to treatment initiation.

The possible influence of historical and social factors, including the long-term impact of conflict in Kosovo, warrants consideration as a contextual determinant of healthcare-seeking behavior and trust in medical institutions.

In conclusion, the findings highlight an urgent need to strengthen national pharmacovigilance efforts through patient education, pharmacist integration into primary care, and the development of accessible digital reporting platforms. Encouraging patient participation in medication safety represents a strategic investment in safer healthcare and improved treatment outcomes.

4. Materials and Methods

Study Design and Setting: A multicenter cross-sectional study was conducted to assess the prevalence, characteristics, and reporting behavior of adverse drug reactions (ADRs) among elderly patients aged 60–75 years with chronic diseases in Kosovo. The study followed internationally accepted methodological standards for observational pharmacovigilance research and was reported in accordance with the Strengthening the Reporting of Observational Studies in Epidemiology (STROBE) guidelines.

Data was collected between January and September 2025 in four major cities of Kosovo (Prishtina, Prizren, Peja, and Gjilan) to ensure representation of diverse socioeconomic and healthcare settings. Participants were recruited from primary healthcare centers, secondary care institutions, and community pharmacies.

Study Population and Eligibility Criteria: The study included patients aged 60–75 years with at least one physician-diagnosed chronic disease (such as hypertension, diabetes mellitus, cardiovascular disease, or rheumatoid arthritis) who were receiving continuous pharmacological treatment for a minimum duration of six months.

Inclusion criteria:

- Age between 60 and 75 years
- Prescription of at least one medication for a chronic condition
- Ability to understand and independently complete the questionnaire

Exclusion criteria:

- Cognitive impairment or neurodegenerative conditions affecting comprehension or recall
- Current hospitalization or residency in long-term care facilities
- Refusal to participate

Sampling and Sample Size: Participants were selected using a systematic random sampling approach. Every third eligible patient attending a healthcare facility or pharmacy for consultation or prescription refill was invited to participate. Of the 1086 patients approached, 1024 agreed and completed the questionnaire, yielding a response rate of 94.3%.

Data Collection Instrument: Data was obtained using a structured questionnaire, adapted from previously validated instruments used in pharmacovigilance research and adjusted for cultural relevance. Specifically, the questionnaire was informed by tools used in large European pharmacovigilance surveys and prior patient-reporting studies [11,16,19].

The questionnaire comprised four sections:

- Section A: Demographic and socioeconomic characteristics (age, sex, education, residence, income status).
- Section B: Clinical and pharmacological data (chronic conditions, therapy duration, number of medications, comorbidities).
- Section C: Patient-reported ADRs (type, severity, affected system, duration, and functional impact).
- Section D: Awareness and reporting behavior (reporting channels, knowledge of pharmacovigilance systems, and perceived barriers). A pilot study was conducted with 40 participants to assess clarity and feasibility. Internal consistency demonstrated good reliability (Cronbach's $\alpha = 0.84$).

4.1. Classification and Causality Assessment of ADRs

Adverse drug reactions were coded using the World Health Organization Adverse Reaction Terminology (WHO-ART) and categorized by therapeutic class according to the Anatomical Therapeutic Chemical (ATC) classification system.

Causality was assessed using the WHO–Uppsala Monitoring Centre (WHO-UMC) system, classifying reactions as certain, probable/likely, possible, unlikely, or unassessable. Only cases categorized as certain, probable, or possible were included in the final analysis.

Severity of ADRs was classified as:

- Mild: transient symptoms not requiring intervention
- Moderate: reactions requiring dosage modification or drug withdrawal
- Severe: reactions resulting in hospitalization or urgent medical care

4.2. Ethical Considerations

This study was conducted in accordance with the principles of the Declaration of Helsinki for research involving human participants. The study was non-interventional in nature and did not involve any medical treatment, clinical intervention, or alteration of standard patient care. Data were collected exclusively through an anonymous, questionnaire-based survey, and participation was entirely voluntary. According to national regulations and institutional policies, formal ethical committee or Institutional Review Board (IRB) approval was not required for this type of study, as it involved anonymous self-reported data collection without any risk or intervention involving human subjects. All participants

were fully informed about the purpose and procedures of the study and provided written informed consent prior to participation. Confidentiality and anonymity were strictly maintained throughout the research process, and no personally identifiable information was collected. The study was conducted with the administrative and institutional support of the local health authorities, including the Directorate of Health in Ferizaj, which facilitated access to the study setting without influencing data collection, analysis, or interpretation.

4.3. Statistical Analysis

Data were analyzed using IBM SPSS Statistics version 26 (IBM Corp., Armonk, NY, USA). Continuous variables were reported as mean ± standard deviation (SD) or median (interquartile range, IQR), whereas categorical variables were described as frequencies and percentages.

Associations were evaluated using the Chi-square (χ^2) test, independent *t*-test, or one-way ANOVA as appropriate. Multivariate binary logistic regression was applied to identify predictors of ADR reporting behavior. Independent variables included age, gender, education, number of medications, previous ADR experience, and receipt of counseling.

Adjusted odds ratios (ORs) with 95% confidence intervals (CIs) were reported. Model adequacy was confirmed using the Hosmer–Lemeshow goodness-of-fit test. All tests were two-tailed, and statistical significance was set at $p < 0.05$.

5. Conclusions

This study demonstrated a high prevalence of self-reported adverse drug reactions among older adults with chronic diseases in Kosovo, while formal reporting to healthcare professionals remained limited. Almost half of participants experienced at least one ADR, yet fewer than 40% reported these events through official channels.

Educational level, gender, and regular pharmacist counseling were identified as significant predictors of ADR reporting. Female patients and those with higher educational attainment were more likely to report reactions, and patients who received counseling from pharmacists showed the strongest likelihood of proactive reporting.

Antihypertensives and non-steroidal anti-inflammatory drugs were the most frequently implicated medication groups, supporting the need for careful monitoring of commonly prescribed therapies and systematic medication review in elderly populations exposed to polypharmacy.

These findings indicate that strengthening patient education, expanding the role of clinical pharmacists in primary care, and promoting accessible reporting mechanisms may improve patient engagement in pharmacovigilance. The results provide a foundation for developing structured national strategies aimed at improving medication safety and reporting practices in Kosovo.

Further longitudinal research is required to assess the long-term outcomes of patient-centered pharmacovigilance and to evaluate the effectiveness of targeted interventions aimed at reducing adverse drug reactions.

Author Contributions: Conceptualization, F.A. and A.H.A.; methodology, F.A. and A.H.A.; data collection, F.A. and A.H.A.; formal analysis, F.A.; writing—original draft preparation, F.A.; writing—review and editing, A.H.A.; supervision, A.H.A. All authors have read and agreed to the published version of the manuscript.

Funding: This study received no financial support from any governmental, commercial, or non-profit funding agency. The research was conducted independently by the authors without any external sponsorship.

Institutional Review Board Statement: Institutional Review Board approval was waived, based on compliance with the Declaration of Helsinki for non-interventional research using anonymized data, the CIOMS International Ethical Guidelines (2016), which allow exemption for minimal-risk observational studies under institutional oversight, and the applicable national and institutional research ethics framework in Kosovo.

Informed Consent Statement: Informed consent was obtained from all subjects involved in the study.

Data Availability Statement: The data supporting the findings of this study are not publicly available due to ethical and privacy restrictions related to anonymous patient-reported data but are available from the corresponding author upon reasonable request.

Conflicts of Interest: The authors declare that they have no conflict of interest regarding the publication of this paper. There were no financial, personal, or professional relationships that could have influenced the study results or their interpretation.

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https://doi.org/10.3390/pharma5010006