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Assessment of Potentially Inappropriate Medication Use Among Elderly Patients in Bulgarian Pharmacies: A Preliminary Study Based on the EU(7)-PIM List

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ABSTRACT

This pilot study set out to examine, for the first time in Bulgaria, how effectively the EU(7)-PIM List can identify potentially inappropriate medications (PIMs) prescribed to older adults. Drug-related complications are well-documented contributors to increased rates of illness, death, and healthcare use. Although earlier Bulgarian research has discussed methods for detecting such medications, the application of the EU(7)-PIM List has not been thoroughly explored and requires further evaluation. A prospective prescription assessment was undertaken for patients aged 65 years and older in a community pharmacy located in Veliko Turnovo, Bulgaria. The investigation, conducted between November 2022 and April 2023, reviewed prescriptions reimbursed by the National Health and Insurance Fund. Data, anonymized by the pharmacy manager, included patients' ages, prescribed drugs, and corresponding ICD codes. Data from 255 patients, covering 2,623 prescribed medicines, were analyzed. Polypharmacy—defined as the daily use of more than five medications—was recorded in 61.96% of participants, of whom 67% were prescribed at least one PIM according to the EU(7)-PIM List. Overall, 173 PIMs were found, distributed across four main therapeutic categories: alimentary tract and metabolism, blood and hematopoietic system, cardiovascular system (CVS), and nervous system. Most PIMs (75.72%) belonged to the CVS class. Within this group, digoxin and several antiarrhythmics (propafenone, flecainide, amiodarone) were each responsible for 11 PIMs. Trimetazidine accounted for nine cases, centrally acting antiadrenergic drugs for 22 (mostly moxonidine, n=16), and peripherally acting agents like doxazosin for another 22. Diuretics, especially spironolactone, were implicated in 24 PIMs, while calcium channel blockers such as verapamil accounted for 18. Antithrombotic agents represented the largest share (n=30), including acenocoumarol, dabigatran, rivaroxaban, and apixaban. Analysis of ICD data indicated that most PIMs were linked to cardiovascular diagnoses, particularly ICD I11.0 and I11.9, which corresponded to 40 and 47 PIMs, respectively. The study underscores the widespread presence of potentially inappropriate prescribing, especially among older patients with cardiovascular diseases. The results support the EU(7)-PIM List as an effective reference for identifying high-risk medications in the elderly. Considering the growing prevalence of polypharmacy and the ageing population, it is essential that healthcare professionals, policymakers, and educators adopt stronger measures to monitor, regulate, and reduce PIM use as part of comprehensive deprescribing strategies in geriatric care.

Keywords: Polypharmacy, Elderly patients, Cardiovascular diseases, Inappropriate prescribing, EU-7 PIM List

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Introduction

The World Health Organization (WHO) defines polypharmacy as the simultaneous use of several medications, though no universal standard exists. It is most often described as the regular use of five or more different drugs, including prescription, over-the-counter, and traditional or complementary medicines [1]. In some clinical contexts, polypharmacy may be justified—termed appropriate polypharmacy—when multiple medications are necessary to achieve specific therapeutic goals agreed upon with the patient, when those goals are either currently met or expected to be met in the future, when the treatment plan minimizes the likelihood of adverse drug

reactions, and when the patient adheres to therapy as prescribed [1]. However, when multiple drugs are used without a clear clinical justification or continue to be taken despite no longer being needed, the situation is referred to as inappropriate polypharmacy. This form has been associated with a variety of negative outcomes, particularly among older adults with multiple chronic illnesses, including increased mortality, falls, medication non-adherence, hospital admissions, and drug–drug interactions. Consequently, polypharmacy has become a growing public health burden and a defining issue among ageing populations [2].

Europe has experienced a steady demographic shift toward an ageing population for several decades. As of January 1, 2022, the total EU population reached approximately 446.7 million, with individuals aged 65 years and older representing 21.1% of this total. Moreover, the subgroup of those aged 80 years and above is projected to grow significantly—from 6.1% in 2022 to 14.6% by 2100 [3]. Bulgaria mirrors this trend; national data indicate that 22% of its citizens are aged 65 and above [4]. As populations continue to age, the prevalence of polypharmacy is expected to rise, necessitating the establishment of effective frameworks and strategies to prevent, monitor, and mitigate its inappropriate use. Healthcare systems are thus increasingly emphasizing structured interventions and evidence-based methodologies to identify and manage polypharmacy.

One key approach in mitigating inappropriate medication use involves pharmacist-led medication reviews, designed to detect, resolve, and prevent drug-related problems while optimizing treatment outcomes. A Europe-wide online survey conducted in 2011 across 28 EU member states and four additional European countries (n=32) explored how medication reviews were integrated into healthcare practice. Findings revealed that 64% of these countries had implemented medication review procedures; however, Bulgaria lacked a formal process for evaluating medication adherence [5]. Another essential intervention is deprescribing—a structured process involving the safe withdrawal of medications that may no longer be beneficial or could be causing harm. Deprescribing is increasingly recognized as a vital component in addressing the global issue of inappropriate polypharmacy [6]. Several international and regional collaborations now promote deprescribing initiatives. In Europe, examples include the English Deprescribing Network (EDeN) and the Network of European Researchers in Deprescribing (NERD), both of which encourage knowledge exchange, research, and clinical innovation. Despite these advances, uniform agreement on optimal deprescribing practices tailored to different healthcare environments and cultural settings remains limited.

Potentially inappropriate prescribing (PIP) represents one of the main consequences of polypharmacy. It encompasses prescribing practices that are suboptimal—such as incorrect dosing or duration, prescribing medications with significant drug–drug or drug–disease interactions, or the use of drugs associated with a high risk of adverse events [7]. Numerous assessment tools have been developed internationally to detect PIP and assist in deprescribing, particularly for elderly patients. These tools have been refined to align with the healthcare structures and clinical priorities of various European nations, promoting safer prescribing, facilitating deprescribing decisions, and ultimately enhancing patient safety.

Among these tools, the EU(7)-PIM List was created by experts from seven European countries representing northern, southern, central, and eastern regions. It serves as a unified reference for identifying and comparing potentially inappropriate medications (PIMs) across Europe. The list comprises 275 chemical entities, including two drug combinations and seven broader drug classes, grouped into 55 therapeutic classes and 34 therapeutic categories [8]. The list has proven useful in multiple European studies, demonstrating its reliability for assessing inappropriate prescribing patterns across diverse healthcare systems [9, 10]. Given its broad European validation, this pilot study seeks to explore the practicality and relevance of applying the EU(7)-PIM List to evaluate prescribing trends among older adults in Bulgaria.

Materials and Methods

Study design

This pilot investigation employed a prospective review design to evaluate prescription patterns among elderly patients aged 65 years and above in Veliko Turnovo, Bulgaria. The study period spanned from November 2022 to April 2023. Only prescriptions reimbursed by the National Health and Insurance Fund were examined. To maintain confidentiality, the pharmacy manager supplied the data in an anonymized and coded format, which contained information on patients' ages, the medications dispensed, and the corresponding ICD diagnostic codes.

Inclusion and exclusion criteria

Participants included all individuals aged 65 years or older who obtained medications from the selected community pharmacy during the study timeframe. The only inclusion requirement was age, with no additional restrictions applied. Because direct access to patient medical records was not available, diagnoses were identified through the ICD codes listed on the prescriptions, which served as indicators of each patient's underlying health conditions.

Ethical considerations

All personal identifiers were removed before data transfer to ensure strict privacy protection. The pharmacy manager, acting as the data privacy officer, provided coded datasets that contained no identifiable patient information. Informed consent was obtained from the pharmacy manager prior to the sharing of prescription data, confirming awareness of the study's purpose and voluntary participation. Only prescription records from patients who had provided consent were included in the analysis.

Results and Discussion

Medication profile and identification of PIMs

The study evaluated a total of 255 elderly patients. Within this group, the largest proportion (54%) were between 70 and 79 years old, reflecting the dominant age range in the sample, while 11% of participants were aged 85 years and above **(Table 1)**.

Table 1. Age groups of the study population.

Age (years)	Nr of patients
65–69	44 (17.25%)
70–74	70 (27.45%)
75–79	68 (26.67%)
80–84	44 (17.25%)
>85	29 (11.37%)

During the study period, a total of 2,623 individual medications were dispensed, corresponding to 1,328 separate prescriptions **(Table 2)**.

Table 2. Medications and prescriptions among the study population.

Characteristics:	Nr
Total nr of patients with PIM	170
Total Nr of medications	2623
Total Nr of prescriptions	1328
Total Nr of PIM	173

The analysis showed that 61.96% of participants experienced polypharmacy, characterized by the daily use of more than 5 reimbursed medications, whereas 38.13% of patients consumed fewer than 5 medications per day **(Table 3)**.

Table 3. Distribution of patients based on medication intake.

Number of medications	Nr (%)
1–2	27 (10.59%)
3–4	70 (27.45%)
5–6	67 (26.28%)
7–8	48 (18.82%)
9–10	25 (9.80%)

>10	18 (7.06%)

Using the EU(7)-PIM List criteria, a total of 173 potentially inappropriate medications (PIMs) were detected among 170 patients experiencing polypharmacy, indicating that 67 percent of the study population had at least one PIM. According to the ATC first-level classification, the majority of PIMs were distributed across four main categories: alimentary tract and metabolism, blood and blood-forming organs, cardiovascular system (CVS), and nervous system **(Table 4)**.

Table 4. Number of PIMs based on ATC classification.

	ATC-1st level	**Nr of PIMs identified (%)**
A	Alimentary tract and metabolism	10 (5.78%)
B	Blood and blood-forming organs	30 (17.34%)
C	Cardiovascular system	131 (75.72%)
N	Nervous system	2 (1.16%)

The largest proportion of PIMs (75.72%) was found within the ATC cardiovascular system category. Among these CVS-related PIMs, 11 were linked to digoxin use, and another 11 were associated with antiarrhythmics, including propafenone (n=7), flecainide (n=2), and amiodarone (n=2). Trimetazidine accounted for 9 PIMs. Antiadrenergic agents were also notable contributors, with centrally acting agents responsible for 22 PIMs, predominantly moxonidine (n=16), while peripherally acting agents were associated with 22 PIMs, mainly doxazosin. Diuretics, particularly spironolactone, accounted for 24 PIMs, and selective calcium channel blockers, specifically verapamil, were linked to 18 PIMs, highlighting important considerations regarding their safety and use. Within other ATC categories, antithrombotic agents represented the highest number of PIMs (n=30), including acenocoumarol (n=11), dabigatran (n=1), rivaroxaban (n=8), and apixaban (n=10), emphasizing the need for careful evaluation of their appropriateness in clinical practice **(Table 5)**.

Table 5. Identified PIMs based on EU (7)-PIM List.

ATC-Code	**Potentially inappropriate drugs**	**Nr of PIMs identified**
A	**Alimentary tract and metabolism**	
A10B	***Blood glucose lowering drugs, excl. insulins***	
A10BB12	Glimepiride	5
A10BF01	Acarbose	5
B	**Blood and blood-forming organs**	
B01A	***Antithrombotic agents***	
B01AA07	Acenocoumarol	11
B01AE07	Dabigatran	1
B01AF01	Rivaroxaban	8
B01AF02[i]	Apixaban	10
C	**Cardiovascular system**	
C01A	***Cardiac glycosides***	
C01AA05	Digoxin	11
C01B	***Antiarrhythmics, Class I and III***	
C01BC03	Propafenone	7
C01BC04	Flecainide	2
C01BD01	Amiodarone	2
C01E	***Other cardiac preparations***	

C01EB15	Trimetazidine	9
C02A	***Antiadrenergic agents, centrally acting***	
C02AC01	Clonidine	3
C02AC05	Moxonidine	16
C02AC06	Rilmenidine	3
C02C	***Antiadrenergic agents, peripherally acting***	
C02CA04	Doxazosin	22
C03D	***Potassium-sparing agent***	
C03DA01	Spironolactone (>25 mg/d)	24
C04A	***Peripheral vasodilators***	
C04AD03	Pentoxifylline	2
C04AE02	Nicergoline	9
C08C	***Selective calcium channel blockers with mainly vascular effects***	
C08CA05	Nifedipine (non- sustained-release)	3
C08D	***Selective calcium channel blockers with direct cardiac effects***	
C08DA01	Verapamil	18
N	**Nervous system**	
N06B	***Psychostimulants, agents used for ADHD and nootropics.***	
N06BX03	Piracetam	2

Analysis of the ICD codes confirmed that the majority of PIMs were associated with the cardiovascular system. In particular, patients diagnosed with ICD I11.0 (Hypertensive heart disease with congestive heart failure) and ICD I11.9 (Hypertensive heart disease without congestive heart failure) had 40 and 47 PIMs identified, respectively. Overall, a total of 161 PIMs were detected within the cardiovascular disease-related ICD codes **(Table 6)**.

Table 6. ICD Codes Associated with PIMs

ICD Code	Condition	Number of PIMs Identified
E11.4	Type 2 diabetes mellitus with neurological complications	9
E11.5	Type 2 diabetes mellitus with peripheral vascular complications	1
G63.2	Diabetic polyneuropathy	2
I10	Essential (primary) hypertension	2
I11.0	Hypertensive heart disease with congestive heart failure	40
I11.9	Hypertensive heart disease without congestive heart failure	37
I12.9	Hypertensive kidney disease without renal failure	3
I20.8	Other forms of angina pectoris	17
I48	Atrial fibrillation and flutter	24
I50.0	Congestive heart failure	23
I50.1	Left ventricular failure	3
I69.3	Sequelae of subarachnoid hemorrhage	11
I80.2	Phlebitis and thrombophlebitis of other deep veins of lower limbs	1

This study represents the first assessment of potentially inappropriate prescribing (PIP) in elderly patients in Bulgaria using the EU(7)-PIM List within a secondary healthcare setting, aiming to examine medication patterns among older adults receiving prescriptions under the national health insurance system.

The findings partially corroborate previous research in Bulgaria that applied the STOPP/START criteria among patients with cardiovascular diseases [11]. For instance, digoxin is commonly prescribed in Bulgaria for heart failure and atrial fibrillation, yet geriatric patients are at higher risk of toxicity due to age-related pharmacokinetic changes [12]. Similarly, centrally acting antihypertensives such as clonidine and moxonidine, as well as aldosterone antagonists like spironolactone, are frequently flagged by inappropriate prescribing tools because of their potential for drug interactions, orthostatic hypotension, bradycardia, and electrolyte disturbances, including hyperkalemia and hyponatremia [8].

The current results clearly indicate that PIMs were predominantly associated with cardiovascular conditions. This is consistent with the high prevalence of cardiovascular disease (CVD) among older adults, attributable to long-term exposure to risk factors and age-related comorbidities. Managing CVD in this population requires a multifactorial approach due to the complexity of age-associated cardiovascular conditions. U.S. data suggest that nearly 70% of individuals over 70 years are expected to develop CVD, with over two-thirds also having non-cardiovascular comorbidities [13]. In Europe, CVD remains the leading cause of death, responsible for over 3.9 million deaths annually, representing 45% of total mortality. The burden varies by country, ranging from 23% of deaths in France to 60% among Bulgarian men and 25% to 70% among women [14].

The risk of cardiovascular conditions—including heart failure, atrial fibrillation-related stroke, valvular disease, and coronary heart disease—increases with age. European projections estimate that the population over 65 will reach 155 million by 2040 [3], suggesting a corresponding rise in CVD incidence.

Several studies have examined PIMs in patients with cardiovascular conditions. In a U.S. tertiary care retrospective review, PIMs constituted 20% of all medications, with an average of 2.4 PIMs per patient; 87.4% of patients were prescribed at least one PIM, and usage was associated with higher numbers of home medications, female sex, and multiple comorbidities [15]. In Portugal, a study using the PIM-MACCE list identified 682 PIMs, over half (n=378) linked to major adverse cardiac and cerebrovascular events (MACCE). The prevalence of PIMs posing a risk for cardiac/cerebrovascular complications was 59.4% (n=404), with 47.4% of patients having a prior CVD history [16]. Similarly, a Turkish study using the Beers Criteria evaluated 65 million prescriptions and found an 11.56% rate of PIMs, including drugs to be used with caution; the most frequently prescribed PIMs were doxazosin for hypertension and methyldopa [17].

Beyond cardiovascular disease, PIM assessments have extended to other patient populations. In Denmark, elderly patients with dementia were evaluated using the Red-Yellow-Green list and the German PRISCUS list, revealing higher polypharmacy exposure and elevated PIM rates, highlighting the need for interventions to improve medication safety in this vulnerable group [18]. In Northern Sweden, a comparison of PIM prevalence among 93 hospitalized elderly patients using the EU(7)-PIM List and Swedish quality indicators found that 18.3% had at least one PIM per Swedish criteria, mainly non-steroidal anti-inflammatory drugs like diclofenac. Using the EU(7)-PIM List, 45.2% of patients were prescribed one or more PIMs, with hypnotics and sedatives being the most common and apixaban as the most frequently prescribed specific PIM [19].

These findings collectively underscore the value of systematic PIM assessment tools for identifying inappropriate prescribing patterns in elderly patients. They highlight the need for targeted interventions to optimize pharmacotherapy and enhance medication safety in older adults, particularly in populations at high risk due to polypharmacy and comorbidities.

In today's digital age, there is an increasing focus on creating technological solutions that help identify patients at risk and prevent inappropriate medication prescribing. One such innovation is a machine learning-based risk warning platform for potentially inappropriate prescriptions (PIP) in elderly patients with cardiovascular disease in China, which can effectively alert clinicians to PIP risks and support the development of tailored treatment strategies [20].

Another technological advancement is a mobile application based on the 2023 Updated AGS Beers Criteria for Potentially Inappropriate Medication Use in Older Adults. This app aids clinicians in following prescribing guidelines by offering a comprehensive list of medications that should either be avoided or used cautiously in older patients [21].

Ongoing monitoring of prescribed medications is essential to improve medication management and minimize adverse drug reactions in elderly patients. Using validated tools and criteria to evaluate prescription

appropriateness is particularly crucial for identifying potentially inappropriate medications (PIMs). Nevertheless, reliance on PIM lists does not replace the importance of personalized clinical judgment, as these tools have inherent limitations.

The current study illustrates the applicability of the EU(7)-PIM List in Bulgarian prescribing practices and its effectiveness in detecting PIMs. Detected PIMs are categorized according to ATC and ICD codes, enabling clinicians to pinpoint areas of concern regarding inappropriate prescribing. This structured approach provides valuable insights into prescription patterns and identifies domains requiring attention.

However, the study has limitations. Firstly, it only considered medications covered by health insurance, excluding non-prescription drugs such as aspirin or NSAIDs. This may have led to conservative estimates, with a larger number of patients potentially exposed to PIMs than reported. Secondly, as a pilot study with a relatively small sample, the findings may not fully reflect broader trends, highlighting the need for further research with larger patient populations.

Additional limitations include the narrow geographic scope, focusing exclusively on patients visiting a single pharmacy in Veliko Tarnovo. In 2022, the municipality had 34,331 residents aged 65 and above [4]. While the sample size calculation suggests that broader coverage is needed for representativeness, the study aimed specifically to test the EU(7)-PIM List in local practice rather than analyze all prescriptions. Furthermore, only reimbursable prescriptions were included, excluding OTC medications and dietary supplements, which could underestimate polypharmacy prevalence.

Conclusion

The study highlights a substantial prevalence of PIMs among patients with cardiovascular conditions. As a pilot application of the EU(7)-PIM List, it demonstrates the tool's utility in optimizing medication management for adult patients. In Bulgaria, no official guidelines exist for assessing PIMs, and these findings underscore the necessity for medical consensus on implementing standardized prescription assessment tools. This is increasingly important in light of demographic aging trends and the growing focus on elderly patient care. Given the critical role of PIMs in deprescribing strategies for older patients with polypharmacy, prescribers, educators, and regulatory authorities should prioritize developing measures and guidance to address PIM usage effectively.

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