

The role of the State Drug Formulary of Ukraine in providing rational pharmacotherapy for elderly patients

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Abstract

Applying the Classification for Drug-Related Problems (DRPs) of the Pharmaceutical Care Network Europe (V 9.00, 2019) allowed to systematize the information on the use of drugs in elderly patients given in the Annex of the State Drug Formulary of Ukraine. As a result of this work, special warnings and recommendations of the State Drug Formulary were presented together with the possible causes for potential DRPs, which they allow to prevent. The lists of potentially inappropriate medications (PIMs) for the elderly (n = 98), drugs the dosage of which in patients of this age group should be adjusted (n = 127), and drugs that need monitoring (n = 108) were formed. The obtained results can serve as a basis for the development of a specialized geriatric tool to ensure rational pharmacotherapy, in particular in the provision of pharmaceutical care.

Keywords

elderly, potentially inappropriate medication, pharmaceutical care, State Drug Formulary

Introduction

The prevalence of comorbidity, polypharmacy, and physiological changes increase the susceptibility of the elderly (≥ 65 years) to adverse drug reactions and complications of pharmacotherapy (Masnoon et al. 2018; Motter et al. 2018; Yena et al. 2018; Curtin et al. 2019; Pazan et al. 2019a). To increase the safety of drug consumption and provide proper prescribing practice, a number of specific geriatric tools have been developed (Motter et al. 2018; Yena et al. 2018; Curtin et al. 2019; Pazan et al. 2019a). Mostly, geriatric tools are based on the concept of potentially inappropriate medications (PIMs) that have an unfavorable balance of benefits and harms compared to alternative treatment options (Renom-Guiteras et al. 2015;

Motter et al. 2018; American Geriatrics Society Beers Criteria Update Expert Panel 2019).

The first list of PIMs for patients aged ≥ 65 was the Beers criteria (Beers et al. 1991), most recently revised by the American Geriatric Society (American Geriatrics Society Beers Criteria Update Expert Panel 2019). However, Beers' criteria were primarily developed based on drugs available in the USA (Steinman et al. 2015). In other countries, PIMs that are not included in this list may be used (Onder et al. 2013; Steinman et al. 2015).

Considering this, following the publication of the Beers criteria, national lists of PIMs were developed in Canada (McLeod et al. 1997), France (Laroche et al. 2007), Germany – PRISCUS (Holt et al. 2010). Subsequently, these tools became the basis for the development of the

List of PIMs of the European Union (EU(7)-PIM list, 2015) (Renom-Guiteras et al. 2015). The developed tool turned to be closer to the clinical practice in the countries of the European Union, compared to the Beers criteria, but there still exist the limitations for its use, particularly in the countries of Central and Eastern Europe (Fialova et al. 2019).

Based on the work of Irish and British experts (Gallagher et al. 2008), the European specialists also developed the STOPP / START criteria (version 2) (O'Mahony et al. 2015). In addition to the list of PIMs (STOPP - Screening Tool of Older People's Prescriptions), these criteria include reminders of potentially necessary prescriptions for the patients in this age group (START - Screening Tool to Alert to Right Treatment) (O'Mahony et al. 2015). They belong to the tools with the patient-in-focus listing approach (PILA) (Carvalho et al. 2019; Pazan et al. 2019a). The results of the researches show the advantages of their use in hospitals compared to the standard pharmaceutical care (O'Mahony et al. 2015).

The FORTA (Fit FOR The Aged) tool is also used to identify PIMs for elderly patients. This classification system was introduced in 2008 (Wehling 2008). Initially, it was used to help doctors in Germany (Wehling 2008, 2009), and later, in the other participating countries (Austria, Switzerland) (Kuhn-Thiel et al. 2014; Pazan et al. 2016, 2019b). Today it is represented by the lists of EURO-FORTA, 2018 (Pazan et al. 2018), and U.S.-FORTA, 2019 (Pazan et al. 2020). These lists determine the belonging of drugs to the classes as follows: A (A-bsolutely: indispensable), B (B-eneficial), C (C-areful: questionable), and D (D-on't: avoid) depending on the level of evidence of their effectiveness, safety, and appropriateness of use because of age (Wehling 2009; Pazan et al. 2018, 2019b). The separate lists of drugs have also been developed for the long-term pharmacotherapy of lower urinary tract symptoms (LUTS-FORTA, 2014) (Oelke et al. 2015), and the treatment of atrial fibrillation with oral anticoagulants (OAC-FORTA, 2016) (Wehling et al. 2017).

The distinctive feature of the STOPP / START and FORTA tools that appeared almost simultaneously is the combination of over- and undertreatment issues (Pazan et al. 2019a). Drugs from the STOPP list correspond to the classes C and D defined by the FORTA system, and drugs recommended by the START criteria predominantly belong to the FORTA classes A or B (Kuhn-Thiel et al. 2014).

However, despite developments towards "internationalization", the potential obstacles to this process should not be ignored. Most PIMs lists and clinical tools do remain country-specific (Kuhn-Thiel et al. 2014). There are country-specific differences and divergence in drug availability, prescribing trends, demography, and disease epidemiology (Kuhn-Thiel et al. 2014; Renom-Guiteras et al. 2015). Although today the STOPP / START and Beers criteria remain the most cited (Pazan et al. 2019a), many national instruments continue to be developed. In particular, Norway has developed its own NORGEP (Norwegian General Practice) and NORGEP-NH (Norwegian General Practice Nursing Home) criteria for patients aged ≥ 70 (Rognstad et al. 2009; Nyborg et al. 2015). Consensus lists of PIMs for geriatric patients and criteria for their use were com-

pared in the Republic of Austria (Mann et al. 2012) and the Czech Republic (Fialova et al. 2013). Besides Europe or North America, where most geriatric tools have been developed (Motter et al. 2018; Pazan et al. 2019a), lists of PIMs were also published in Asia, Oceania, and South America, namely in Taiwan, Pakistan, South Korea, Thailand, Japan, Australia, and Chile (Motter et al. 2018). In total, 73 geriatric tools were included in the systematic review in 2019 (Pazan et al. 2019a).

Ukraine does not currently have its own national list of PIMs for geriatric patients, nor the criteria for their use. However, one of the annexes to the State Drug Formulary contains recommendations for the use of drugs in elderly patients. Thus, the research aimed to study the possibilities of applying the State Drug Formulary as a special tool for providing rational pharmacotherapy of elderly patients, in particular, in the provision of pharmaceutical care.

Materials and methods

The object of the research was Annex 5 (with the special aspects of the use of formulary drugs in the elderly) of the State Drug Formulary (2017–2019, issues 9–11), approved by the Ministry of Health of Ukraine. According to the results of the analysis of its contents, the drugs ($n = 842$) were divided into groups (Table 1). The requirements for the inclusion of drugs in the next stage of the research were special warnings and / or recommendations ($n = 322$), which were the subject of our research. The drugs were excluded from the research according to the following characteristics: no special warnings or recommendations provided ($n = 357$), information for the drugs was lacking or experience limited ($n = 36$), drugs were not used at all in patients of this age group ($n = 12$). Drugs, the use of which in elderly patients does not require dose adjustment, formed a significant group ($n = 115$). The use of these drugs in the elderly is the same as in adult patients (without special aspects), thus, they were also excluded from our research.

The next stage of the study included only those drugs, the use of which in elderly patients should take into account special warnings and / or recommendations ($n = 322$). To systematize this information of the State Drug Formulary, the Classification for Drug-Related Problems (DRPs) of the Pharmaceutical Care Network Europe (PCNE) (V 9.00, 2019) (further – the DRPs Classification)

Table 1. The distribution of drugs of the State Drug Formulary according to their use in elderly.

№	Group of drugs	Number of drugs
Drugs included in the research		
1.	Drugs with the special warnings and / or recommendations for use	322
Drugs not included in the research		
2.	Drugs without special warnings and / or recommendations for use	357
3.	Drugs that not require dose adjustment for use	115
4.	Drugs with lacking information or limited experience for use	36
5.	Drugs that are not used in elderly patients	12
Total		842

(van Mil et al. 2019) was chosen. In addition to the PIMs, the concept of which underlies most geriatric tools, the Classification allows identifying a number of other DRPs and their causes that may occur in the elderly.

The choice of the DRPs Classification for the presentation of information from the State Drug Formulary, which is a guide to the rational use of drugs (Ministry of Health of Ukraine 2009), was also due to the ease of use of such a format for the provision of pharmaceutical care. Pharmaceutical care allows for optimizing the use of drugs and improve the health of individuals (Allemann et al. 2014), involves the elderly, in particular by identifying, resolving, and preventing DRPs (van Mil 2019).

Results

As a result of the information of the State Drug Formulary analysis, the list of drugs (n = 322), which for elderly patients requires consideration of special warnings and / or recommendations, was formed. The representatives of all 14 groups of the ATC classification were among them. However, more than a half (56.8%) of them belonged to the drugs for treatment of nervous (N), cardiovascular (C) systems, and antiinfectives for systemic use (J). Applying the DRPs Classification has made it possible to present special warnings and recommendations in the format of possible causes for potential DRPs, causes of problems associated with treatment effectiveness, safety, and others. The total number of causes of DRPs (n = 344) was bigger than the number of selected drugs because for some drugs more than one cause of DRPs were identified (Table 2).

The identified possible causes belong to the nine headings of the DRPs Classification, seven of which may appear at the stage of drug prescribing and two – during their use.

Among the recommendations of the State Drug Formulary, the share of warnings related to the drug selection (n = 98) of different pharmacotherapeutic groups was considerable (Fig. 1). Contraindications to the use of drugs in patients of a specific age group were a small group of warnings (n = 7). More often, a guide recommends avoiding the prescribing and use of drugs in elderly patients (n = 22) or use them with caution (n = 69). According to the DRPs Classification, even if the requirements of the guidelines are accomplished, the drug may be inappropriate because it is contraindicated for some other reasons, in particular, due to reaching old age. Following the stated reason, encoded C 1.2 by the DRPs Classification, these formulary drugs for patients of this age category were identified by us as inappropriate. The selection of inappropriate drugs accounted for 28.5% of all possible causes of potential DRPs identified (based on the State Drug Formulary information).

The sporadic recommendations to avoid the combination of drugs in the pharmacotherapy of elderly patients were also detected (n = 2). In the DRPs Classification it corresponds to the code C 1.4 (Table 3). Inappropriate drugs combination accounted for 0.6% of all identified causes of DRPs.

The State Drug Formulary reminders of the necessary prescriptions of drugs to elderly patients (n = 2) allow preventing absence of pharmacotherapy contrary to the existing indications. According to the DRPs Classification it corresponds to the code C 1.6 (Table 4). Among all identified, this cause of DRPs equaled 0.6%.

Table 2. The distribution of possible causes of DRPs based on the State Drug Formulary information.

Nº	Possible causes for potential DRPs	Code V 9.00 of the PCNE Classification	Number (%)
The cause of the DRP is related to the selection of the drug (prescribing and drug selection stage)			
1.	Inappropriate drug within guidelines but otherwise contraindicated	C 1.2	98 (28.5%)
2.	Inappropriate combination of drugs, or drugs and herbal medications, or drugs and dietary supplements	C 1.4	2 (0.6%)
3.	No or incomplete drug treatment in spite of existing indication	C 1.6	2 (0.6%)
The cause of the DRP is related to the selection of the dose or dosage (prescribing and drug selection stage)			
4.	Drug dose too low	C 3.1	2 (0.6%)
5.	Drug dose too high	C 3.2	127 (36.9%)
6.	Dosage regimen not frequent enough	C 3.3	1 (0.3%)
The cause of the DRP is related to the duration of treatment (prescribing and drug selection stage)			
7.	Duration of treatment too long	C 4.2	3 (0.9%)
The cause of the DRP is related to the way the drug is got (drug use stage)			
8.	Drug administered via wrong route	C 6.6	1 (0.3%)
Other causes of the DRP (drug use stage)			
9.	No or inappropriate outcome monitoring	C 9.1	108 (31.4%)
Total			344 (100.0%)

Table 3. The causes of DRPs related to the inappropriate combination of drugs.

Nº	Drugs	ATC code	Warnings and recommendations of the State Drug Formulary	Number of drugs
1.	Calcium folinate	V03AF03	The risk of toxic effects increases in combination with 5-fluorouracil	1
2.	Telmisartan	C09CA07	The combination with drugs that inhibit cyclooxygenase should be used with caution	1
Total				2

Table 4. The causes of DRPs related to the none or incomplete drug treatment despite existing indications.

Nº	Drugs	ATC code	Warnings and recommendations of the State Drug Formulary	Number of drugs
1.	Pneumococcus, purified polysaccharides antigen conjugated	J07AL02	People over 50 have an increased risk of invasive pneumococcal disease	1
2.	Prednisolone	H02AB06	Prevention of osteoporosis is recommended	1
Total				2

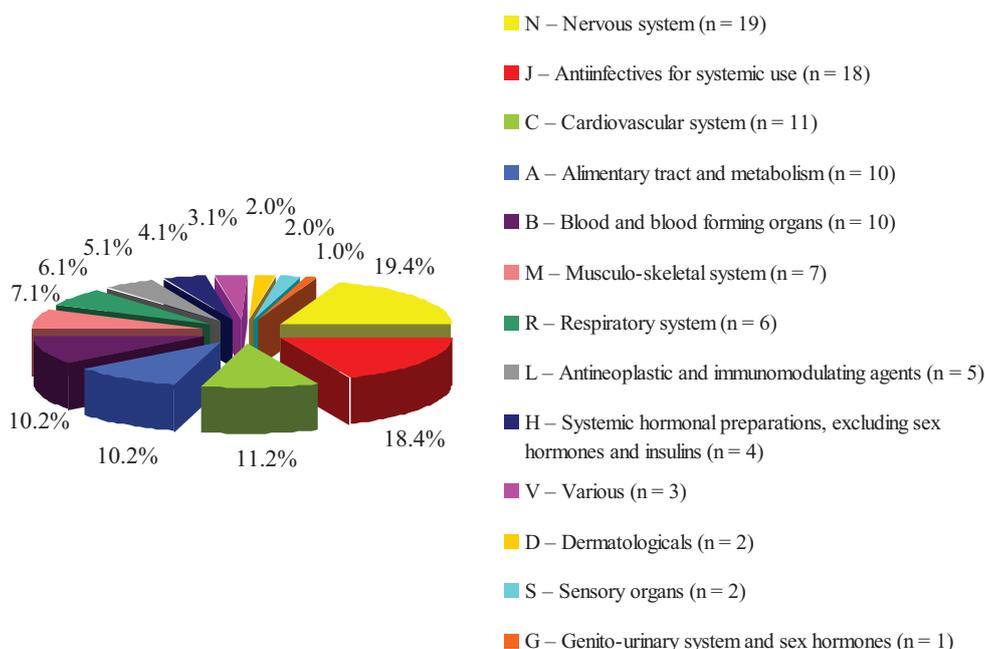


Figure 1. The distribution of inappropriate drugs according to the ATC classification.

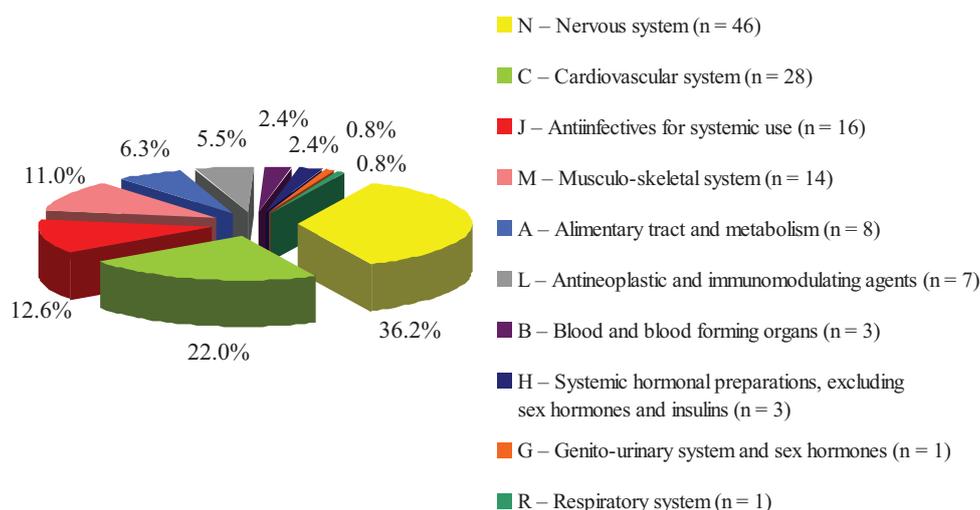


Figure 2. The distribution of drugs with potentially high dose according to the ATC classification.

Most frequently, the information on the State Drug Formulary related to the special aspects of drug dosing when being prescribed to elderly patients. The cases where the recommendations allow preventing the use of drugs in excessively low dosage ($n = 2$), corresponded to the code C 3.1 of the DRPs Classification (Table 5). The excessively low dose of drugs accounted for 0.6% of all identified causes of DRPs.

Instead, the recommendations for reducing the therapeutic dosage determined for adult patients, and the use of the lowest effective dosage were common ($n = 127$) among drugs of many pharmacotherapeutic groups (Fig. 2). According to the DRPs Classification, the use of drugs in excessively high dose corresponded to the code C 3.2. It accounted for 36.9% of all causes of DRPs, determined based on information of the State Drug Formulary.

The recommendations not to exceed the intervals between the use of drugs ($n = 1$) corresponded to the code

C 3.3 of the DRPs Classification. For persons over 60 the State Drug Formulary recommended not to exceed 3 years when applying booster doses of the inactivated vaccine for prevention of tick-borne encephalitis (J07BA01). Among all identified, this cause of DRPs equaled 0.3%.

The recommendations related to the limitation of the drug use duration ($n = 3$) according to the DRPs Classification corresponded to the code C 4.2 (Table 6). The excessively long duration of treatment equaled 0.9% among all the identified causes of DRPs.

At the stage of drug use, we identified the causes of DRPs that belonged to the two headings of the Classification. The special aspects of the method of drug administration ($n = 1$) corresponded to the code C 6.6 of the DRPs Classification. It accounted for 0.3% among the causes of DRPs identified based on the State Drug Formulary information. Rapid bolus administration of Propofol

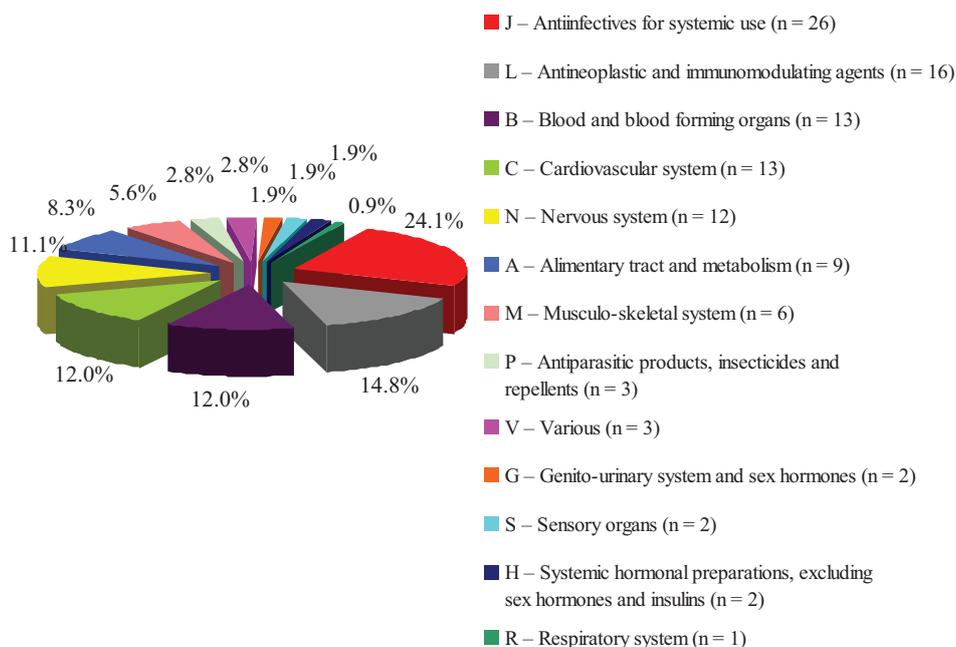


Figure 3. The distribution of drugs, which require monitoring, according to the ATC classification.

Table 5. The causes of DRPs related to the potentially low dose of drugs.

Nº	Drugs	ATC code	Warnings and recommendations of the State Drug Formulary	Number of drugs
1.	Hepatitis B, purified antigen	J07BC01	Additional doses should be considered for persons aged over 40	1
2.	Ergocalciferol	A11CC01	The need for vitamin D ₂ may increase because of a decrease in its absorption	1
Total				2

Table 6. The causes of DRPs related to the excessively long treatment.

Nº	Drugs	ATC code	Warnings and recommendations of the State Drug Formulary	Number of drugs
1.	Bendazol	C04AX	Not recommended for a long-term treatment of arterial hypertension	1
2.	Bisacodyl	A06AB02	Long-term administration may intensify asthenia, cause orthostatic hypotension, and coordination disorders associated with electrolyte loss	1
3.	Triamcinolone	D07AB09	Use topically for a short time	1
Total				3

(N01AX10) is not recommended in the elderly. However, a significant share (Fig. 3) belonged to the recommendations of monitoring the function of the kidneys, liver, cardiovascular system, the gastrointestinal tract mucosa, hematological parameters, electrolyte balance, etc. when drugs are used (n = 108). Observance of the State Drug Formulary recommendations can prevent the cause of C 9.1 of the DRPs Classification. Absence or inappropriate outcome monitoring accounted for 31.4% among all the identified possible causes of potential DRPs.

Discussion

The results of the bibliographic search showed that special geriatric tools are used in the world to rationalize the pharmacotherapy of elderly patients (Motter et al. 2018; Yena et al. 2018; Curtin et al. 2019; Pazan et al. 2019a), and are mainly focused on a specific country (Kuhn-Thiel et al. 2014). Ukraine does not currently have its own national list of PIMs for geriatric patients, nor the criteria for their use. For this reason, we focused on the possibility of using

the State Drug Formulary for this purpose. Annex 5 of the State Drug Formulary contains information on limits, including contraindications to the use of the formulary drugs in the elderly, which in fact corresponds to the concept of PIMs that underlies most geriatric tools (Renom-Guiteras et al. 2015; Motter et al. 2018; American Geriatrics Society Beers Criteria Update Expert Panel 2019).

After the development and publication of the State Drug Formulary in Ukraine with an annex containing recommendations for the use of drugs in the elderly (2009, issue 1), scientists analyzed and systematized the information of the annex (Smetanina 2011; Levytska et al. 2014). However, this has not previously been done through the prism of DRPs that are involved in the identification of PIMs. A Drug-Related Problem (DRPs) is an event or circumstance involving drug therapy that actually or potentially interferes with desired health outcomes (van Mil et al. 2019). Each DRP has one or more causes, most of which, as stated by the experts, are medication errors (van Mil et al. 2019). According to the interpretation, medication errors are preventable events (National Coordinating Council for Medication Error Reporting

and Prevention 2020). Therefore, the occurrence of most DRPs can be prevented. In our opinion, the presentation of special warnings and recommendations of the State Drug Formulary when providing pharmaceutical care, together with the causes of DRPs, which they allow to prevent, emphasizes the importance of their observance. As a result, it helps to optimize the use of drugs in the elderly.

Among the nine identified headings, some of the causes of DRPs were infrequent. The vast majority of special warnings and recommendations of the State Drug Formulary corresponded to the three causes of the DRPs according to the Classification (C 1.2, C 3.2, C 9.1 – 96.8%), which we considered in more detail.

According to the DRPs Classification, even if the guidelines are followed, the drug may be inappropriate because it is contraindicated for other reasons (van Mil et al. 2019). One of the such reason is that the patient has reached old age, which is characterized by certain physiological changes, comorbidity, polypharmacy and, as a consequence, susceptibility to adverse drug reactions and complications of pharmacotherapy (Masnoon et al. 2018; Motter et al. 2018; Yena et al. 2018; Curtin et al. 2019; Pazan et al. 2019a). Potentially inappropriate for the elderly are drugs that should not be prescribed in this patient group because the risk of adverse events outweighs the clinical benefit, particularly when there is evidence in favor of safer or more effective alternative therapy for the condition (Renom-Guiteras et al. 2015).

Applying the classification of DRPs to the State Drug Formulary information allowed to identify the causes encoded by C 1.2 and to form a list of PIMs (n = 98) among the formulary. In our opinion, the next stage of work with the list should be the application of the consensus technique on a panel of experts. This methodology is the most widely used (Masnoon et al. 2018; Motter et al. 2018; Pazan et al. 2019a) because the issue of developing special evidence-based tools for comorbid geriatric patients remains unresolved (Masnoon et al. 2018). Besides, the list we have received cannot be considered complete, as there are PIMs not included into the State Drug Formulary, and, therefore, it can be expanded.

After the choice of drugs, the next step in the rationalization of pharmacotherapy of elderly patients is the

choice of the drug dosage. This issue is addressed in 80.5% (n = 29) of the lists of PIMs included in the systematic review in 2018 (Motter et al. 2018) and 63.0% (n = 46) of geriatric tools in the systematic review in 2019 (Pazan et al. 2019a). The choice of drug dosage for patients of this age group, which in the vast majority of cases is potentially high – C 3.2 (n = 127), was associated with the largest share of all identified causes of DRPs in our study. It should be noted that following the recommendations of the State Drug Formulary for elderly patients, the dosage should be adjusted not only in the case of PIMs but also other formulary drugs.

At the stage of drug use, one of the possible causes of DRPs, according to the PCNE Classification, is the missing or inappropriate monitoring of the outcome (van Mil et al. 2019). The monitoring of drug use is also considered in some geriatric tools. In particular, among those included in the systematic review in 2019, 38.4% of tools (n = 28) provide for the control of renal function (Pazan et al. 2019a). When the tools with the patient-in-focus listing approach (PILA), are used, positive study outcomes are noticed more often, however, most of the developed tools have the drug-oriented listing approach (DOLA) (Pazan et al. 2019a). The possible causes of DRPs (n = 108), identified in the analysis of the State Drug Formulary information, point out the necessity of monitoring of the renal, liver, cardiovascular systems, the gastrointestinal tract mucosa function, hematological parameters, electrolyte balance, etc., and, thus, lead medical practice closer to the needs of the particular patient.

Conclusion

The systematization of the State Drug Formulary information according to the DRPs Classification allowed to identify PIMs for the elderly (n = 98), and form a list of drugs, the dosage of which in patients of this age group should be adjusted (n = 127), and the drugs that need to be monitored (n = 108). It can serve as a basis for the development of a special geriatric tool to ensure rational pharmacotherapy and be used in geriatrics to provide proper pharmaceutical care.

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