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## Drug-related problems identified by pharmacist-led medication review in Slovak hospitalised patients

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Medication review is an effective tool for identification of drug-related problems (DRPs). It has become an integral part of healthcare systems worldwide, however, it is still rare in Slovakia. Therefore, the aim of the present study was to assess the implementation of a medication review in hospitalised patients and to describe prevalence and nature of DRPs. A prospective 3-month study was conducted at Cardiology Department of Teaching Hospital in Nitra. All patients admitted during this period were included and their medications were reviewed regularly during the whole hospitalisation. Information on patient status and medication was obtained from admission reports, medication charts, laboratory results, ward rounds and consultations with attending physicians. Identified DRPs were classified using APS-Doc classification. A total of 261 medication records were analysed (52.1% women; average age 71.4±12.7 years). Geriatric patients (≥ 65 years) accounted for 72.8%. The patients had on average 7.7±4.0 drugs in medication history. Polypharmacy (≥ 5 drugs) was found in 75.1% of them. At least one DRP was identified in 78.2% of all records. Totally, 514 DRPs were recorded. The most frequent DRPs were clinically significant drug-drug interactions (n = 121; 23.5%), incomplete or missing drug history (n = 73; 14.2%) and inappropriate time of administration (n = 67; 13.0%). All identified potential and manifested DRPs were consulted with attending physicians. This study describes early outcomes of implementation of regular medication review in hospitalised patients in one Slovak hospital. Our results highlight the need for a wide implementation of medication review in hospitalised patients.

### 1. Introduction

Drug-related problems (DRPs) are regarded as substantial risk of harm and have the potential to interfere with desired therapeutic goals (Pharmaceutical Care Network Europe). Not rarely, they result in treatment failure, adverse drug reactions (ADRs), intoxication or at worst – in death. In a recent study conducted in a Spanish hospital, DRPs accounted for 35% of emergency department admissions (Baena et al. 2014). Depending on patient characteristics and study design, DRPs are present in up to 88% of patients (Chan et al. 2014) which highlights the need for regular assessment of medication. Medication review conducted by clinical pharmacists has become an integral part of healthcare in various healthcare settings worldwide, including hospital (Richardson et al. 2014) and ambulatory settings (Nicolas et al. 2013), nursing homes (Brulhart and Wermeille 2011) and community pharmacies (Granas et al. 2010). Positive impact on patient safety and treatment effectiveness has been reflected in reduced medication errors (Buckley et al. 2013; Nguyen et al. 2014), reduced costs (Kopp et al. 2007; Aljbouri et al. 2013), improved patient adherence to treatment and drug related knowledge (Sokol et al. 2005, Hatah et al. 2014).

In Slovakia, high incidence of inappropriate prescription and ADR-related hospitalisations were identified (Wawruch et al. 2008, 2009). Several studies investigating DRPs in Slovak community pharmacies have been conducted recently (Balážová and Kuželová 2012; Virág and Kuželová 2012; Masaryková et al. 2014), however, data on hospitalised patients are still missing. Therefore, the aim of this study was (1) to evaluate the role of pharmacist in identification of DRPs and (2) to explore prevalence and nature of DRPs in hospitalised patients at a cardiology clinic.

### 2. Investigations and results

#### 2.1. Patient demographics and characteristics

During the 3-month study period, 261 medication records were analysed and included in the study (52.1% female, mean age 71.4±12.7 years). Geriatric patients aged ≥ 65 years accounted for 72.8% (n = 190). Data on medication history were available in 250 patients (95.8%). Out of them, 90.8% patients were on previous medication (average 7.7±4.0 medications in medication history, range 1 - 17), while 5.0% of patients took no medication prior to admission. Polypharmacy defined as using ≥ 5 medications (Gnjidic et al. 2012) was recorded in 196 (75.1%) admission records. Demographics and characteristics of the study group are summarized in Table 1.

**Table 1: Study population characteristics**

Medication records analysed, n (%)	261 (100%)
<b>Gender</b>	
Female	136 (52.1%)
Male	125 (47.9%)
<b>Age</b>	
Mean age, SD (years)	71.4 ± 12.7
Range (years)	20 - 100
≥ 65 years	190 (72.8%)
<b>Medication history</b>	
Mean number of medicines, SD	7.7 ± 4.0
Range	0 - 20
Not available	11 (4.2%)

**Table 1: Study population characteristics**

Medication records analysed, n (%)	261 (100%)
0 medications prior admission	13 (5.0%)
1 – 4 medications	41 (15.7%)
≥ 5 medications (polypharmacy)	196 (75.1%)
<b>Medication review</b>	
medication records with DRP	204 (78.2%)
medication records without DRP	57 (21.8%)
<b>Primary diagnosis at admission</b>	
Heart failure	73 (28.0%)
Acute coronary syndrome	22 (8.4%)
Patient scheduled for permanent pacemaker insertion	20 (7.7%)
Syncope and/or fall	19 (7.3%)
Multimodal dyspnea	19 (7.3%)
Arterial hypertension, decompensated	17 (6.5%)
Atrial fibrillation, first episode	17 (6.5%)
Pulmonary embolism	15 (5.7%)
Noncardial chest pain	12 (4.6%)
Ischemic heart disease	10 (3.8%)
Other diagnoses	37 (14.2%)
<b>Kidney function</b>	
Mean estimated glomerular filtration rate (ml/min)	58.5 ± 25.2

## 2.2. Incidence of DRPs

DRPs were identified in 78.2% (n = 204) of the medication records (Table 1, Table 2). Totally, 514 DRPs were recorded, with an average of 2.0 DRPs per record (1-9 DRPs). Just one DRP was identified in 24.1% (n = 63) of all reviewed records, and 54.0% contained two or more DRPs (Table 2).

**Table 2: Incidence of drug-related problems per one medication record**

Number of DRPs per one record	n = 261, (%)
no DRP	57 (21.8)
1 DRP	63 (24.1)
2 DRPs	57 (21.8)
3 DRPs	41 (15.7)
4 DRPs	24 (9.2)
5 DRPs	6 (2.3)
6 DRPs	6 (2.3)
7 DRPs	5 (1.9)
8 DRPs	1 (0.4)
9 DRPs	1 (0.4)

## 2.3. Causes of DRPs

The biggest group of the identified DRPs included severe drug–drug interactions (DDI 1; n = 121, 23.5%; Table 3). The DDIs with risk ratings D (consider therapy modification) and X (avoid combination) accounted for 81.0% and 8.3%, respectively. In the remaining 10.7% of the DDIs, drugs not listed in the Lexicomp® database (Lexicomp) were involved (Lexicomp interaction analysis from January 7 to March 30, 2014), hence missing the risk rating. Severity (clinical significance) of the interactions were therefore obtained only from the Summary of Product Characteristics (SmPC) available on State Institute for Drug Control. In our group of patients 23 of such drugs were prescribed. Drugs most commonly involved in DDIs were clopidogrel (25.6%), amiodaron (18.2%), warfarin (9.9%), nonsteroidal anti-inflammatory drugs (NSAIDs, 8.3%) and verapamil (5.8%). The second most frequently detected DRP was incompleteness of drug history (Rx 5; 14.2%) as the drug history was incomplete or was completely missing in 73 admission records.

**Table 3: Identified drug-related problems**

Categ.	Subcategory	n (%)
<b>Drug</b>		
Rx 1	Incorrect spelling of the trade name	5 (1.0)
Rx 2	Drug no longer available	-
Rx 3	Prescribing outside the formulary	-
Rx 4	Prescription made out to wrong patient	-
Rx 5	Incomplete drug history (the patient takes further drugs that are not listed in the medical schedule)	73 (14.2)
Rx 6	Discontinuation of ambulatory medication (complete drug history available, but not each drug is prescribed)	-
Rx 7	Inadequate generic substitution	1 (0.2)
Rx 8	Transcription error/unintended discontinuation of drug therapy (during the hospital stay)	-
Rx 9	Unintended prescribing of the same drug	3 (0.6)
Rx 10	Unintended prescribing of a product from the same class of drugs	4 (0.8)
Rx 11	No/inadequate drug monitoring	6 (1.2)
Rx 12	Patient is receiving wrong medication	-
Rx 13	The patient does not know his medication (not applicable in patients with dementia or unconsciousness)	15 (2.9)
<b>Dosage form/ drug strength</b>		
DS 1	Wrong dosage form prescribed	-
DS 2	No dosage form prescribed, when different dosage forms are available	-
DS 3	Wrong drug strength prescribed	-
DS 4	No drug strength prescribed, when different dosages are available	1 (0.2)
<b>Dosage</b>		
DOS 1	Patient does not know his dosage (not applicable in patients with dementia or unconsciousness)	-
DOS 2	Prescription of an incorrect dosage or no dosage prescribed	2 (0.4)
DOS 3	Dose too low	10 (1.9)
DOS 4	Dose too high	23 (4.5)
DOS 5	Inappropriate administration interval	5 (1.0)
DOS 6	No dosage adjustment in case of renal failure	27 (5.3)
DOS 7	No dosage adjustment in case of liver failure/heart failure	-
<b>Indication</b>		
IND 1	Medication inappropriate (better option available)	41 (8.0)
IND 2	No indication	12 (2.3)
IND 3	Drugs missing (no drug prescribed in patients with an existing indication) or suboptimal dosage	15 (2.9)
<b>Contraindication</b>		
CI 1	Contraindication not accounted for	28 (5.4)
<b>Drug-drug Interaction</b>		
DDI 1	Drug–drug interaction as indicated by literature (only clinically significant)	121 (23.5)
DDI 2	Symptoms of a drug–drug interaction	-
DDI 3	Patient's fear of drug–drug interaction	-
<b>Adverse drug reaction</b>		
ADR 1	Symptoms of an adverse drug reaction	17 (3.3)
ADR 2	Patient's fear of an adverse drug reaction	2 (0.4)
<b>Administration/ compliance</b>		
AC 1	Lack of patient's knowledge about correct administration	1 (0.2)
AC 2	Patient does not take the drug	7 (1.4)

**Table 3: Identified drug-related problems**

Categ.	Subcategory	n (%)
AC 3	Patient alteration of the recommended dosage (without consultation with pharmacist or physician)	-
AC 4	Inappropriate duration (too short, too long)	-
AC 5	Inappropriate time of administration	67 (13.0)
AC 6	Administration not prescribed/documented	-
<b>Application</b>		<b>14 (2.7)</b>
AP 1	Dosage form may not be divided	2 (0.4)
AP 2	Drug/dosage form may not be administered via feeding tube	-
AP 3	Drug incompatible with solution (infusion)	-
AP 4	Different drugs are incompatible within the solution (infusion)	11 (2.1)
AP 5	Volume of the solution is inappropriate	-
AP 6	Kind, place or rate of administration is inappropriate	1 (0.2)
AP 7	Sequential therapy is not used where indicated (e.g. antibiotics)	-
<b>Other</b>		<b>14 (2.7)</b>
O 1	No interruption of administration prior to surgery as required	-
O 2	Patient allergic to medication according to drug history but not accounted for	-
O 3	Other*	14 (2.7)

\* newly added category

The third most common type of DRPs identified were those related to inappropriate time of administration (AC 5; n = 67, 13.0%). Majority (82.1% of the group) were caused by proton pump inhibitors (PPIs) administered in evening dose in case of once a day regimen. Inappropriate medication (IND 1) identified in 41 cases (8.0%) included mainly long-term using of Ginkgo or piracetam for treatment of dementia in elderly (22.0%), nonselective betablockers for heart failure in chronic obstructive pulmonary disease (9.8%) and long-term use of NSAIDs together with warfarin (7.3%).

As for contraindicated drugs (CI 1; 5.4%), the most frequently prescribed were NSAIDs in patients with serious cardiovascular diseases (42.9%), such as arterial hypertension, heart failure or myocardial infarction; and metformin in advanced chronic kidney disease (CKD; 32.1%).

Dosage adjustment in patients with advanced CKD (DOS 6; 5.3%) was missing mainly in statins (77.8%) and antihypertensive agents (11.1%).

Administration of dose too high (because of age or drug-drug interactions or manifesting ADRs) was recorded in another 23 cases (DOS 4; 4.5%), including mainly statins (34.8%), warfarin (26.1%), digoxin and diuretics (13.0 % each).

Symptoms of ADRs were recorded in 17 cases (ADR 1; 3.3%). Muscle pain related to statin therapy (23.5%), warfarin-related bleeding (17.6%) and clinical manifestation of digoxin toxicity (11.8%) were the most frequently reported.

We also identified 14 DRPs beyond the scope of the original APS-Doc classification. For these DRPs, we introduced a new subcategory "O 3 - Other" containing following items: incomplete list of diagnoses, i.e. diagnoses from previous examinations not listed in current admission report or mentioned only verbally by patient (n = 8); insufficient monitoring of laboratory parameters (n = 1); unclear of unspecified drug allergies (n = 2); unreadable record on diagnose (n = 1); duplication in drug classes (intended but inappropriate, n=1); discrepancy in medication history (n = 1).

#### 2.4. Conclusion

Medication review allows early anticipation and elimination of potential drug-related problems. This study demonstrates the great variety of DRPs that can be identified in hospitalised patients

during medication review. Especially risk population, for example patients with advanced age, polypharmacy or renal failure is more prone to suffer from inappropriate medication, drug combination or wrong doses. Identification of DRPs and their causes helps to point out the problematic areas and improve the quality and safety of treatment process. APS-Doc classification instrument proved its applicability in Slovak hospital setting.

### 3. Discussion

In our study, at least one DRP was found in more than three-quarters of reviewed medication records, with average 2.0 DRPs per record. In previous studies, DRPs were identified in 18% to 88% of patients (Chan et al. 2012; Malý et al. 2013; Nicolas et al. 2013). However, it is of note that the number of identified DRPs depends on multiple factors, including study design, type of setting and participants' characteristics or classification system used. Therefore, the comparison with other studies should be made very carefully.

The rather high incidence of DRPs in our study might be explained by great portion (72.8%) of elderly participants. It has been demonstrated, that elderly patients are more prone to DRPs. Age per se is not an individual risk factor for DRPs, but ageing is associated with increasing morbidity along with polypharmacy which, on the contrary, is considered to be one of the major risk factors for DRPs (Blix et al. 2004; Chan et al. 2012).

DDIs were the most frequent DRPs identified. Similar results were obtained in studies by Schorr et al. (2014) and Richardson et al. (2014), however, they reported significantly lower incidences of DDIs (23.5% in our study versus 14.5% and 13.9% respectively). Such a difference might be due to several reasons. Firstly, the majority of our participants were old and extensive polypharmacy was identified. Secondly, drugs like amiodaron, warfarin and verapamil were frequently prescribed in the study participants. All these drugs are known to have a strong potential for interacting. Clopidogrel accounted for the majority of DDI (25.6% of all DDIs). Although its interaction potential is lower, clopidogrel was frequently prescribed concurrently with proton pump inhibitors. Despite inconsistent reports, the combination is discouraged due to risk of antithrombotic treatment failure and alternative acid-lowering medications should be considered (Lexicomp). Thirdly, the drug interaction database was used as it increases the possibility of identification of DRPs (Nicolas et al. 2013) which was found very helpful for limited experience of the research pharmacist. On the other hand, not all DDIs listed in databases have the same clinical relevance and require the same urgent action. Lexicomp® database uses a 5-level severity scale (A, B, C, D and X) which helps clinicians to consider the need of particular management of the interaction.

While risk ratings A, B and C indicate interactions of lesser clinical importance with no intervention required, risk ratings D and X require considering therapy modification and avoiding the combination, respectively. Therefore, the latter two were considered and recorded as potential DRPs. Based on our previous experience, addressing only clinically important DDIs is an acceptable model of communication for prescribers. A similar approach was used by others (Chan et al. 2012).

Similarly to the study of Pottel et al. (2012), not all drugs were recognized by the Lexicomp® database. In our study group 23 such drugs were prescribed. The information on potential DDIs was obtained only from SmPCs but severity ratings were not expressed or were expressed in different manners. Based on SmPCs, rilmendin, urapidil, naftidrofuryl, molsidomin and vinpocetin were involved in 13 potential DDIs. We also noticed several discrepancies in severity rating between SmPC and Lexicomp® database.

In 14.2% of admission reports, drug history was either incomplete or completely missing. The hospital has its own electronic database of medical records which is not connected with other healthcare facilities in the country. With few exceptions, interconnection of healthcare providers is missing in Slovakia. Therefore, information on treatment prescribed in another facility is sometimes difficult to complete and often remains unclear or not updated. In such cases, patient or his family are the only sources of information at the time of admission. Patient's unawareness of medication hence

may contribute to discontinuation of treatment. As commented in 15 admission records, patients did not know purpose, names or dosing of their medicines. The pharmacist did not interview the study participants, so data on patient unawareness might be underestimated. To our knowledge, no study exploring the extent of medication discrepancy at admission level in Slovak hospitals was conducted. We assume that medication reconciliation providing the most accurate list of all medications should also be involved in hospital care and might increase the effectivity of medication review. The prospective design of the study allowed the research pharmacist to monitor the patients' status and changes in therapy during the whole hospitalisation. The pharmacist regularly participated in ward rounds and discussed the identified DRPs with attending physicians. Such a design has proved as very useful for better understanding of treatment strategies and avoids overestimating the number of DRPs, i.e. it helps to distinguish between 'real' and 'false' DRPs (Blix et al. 2004). In our study, the DRPs were identified and classified by only one research pharmacist. Hence, consistency of the findings is ensured. On the other hand, involving multiple researchers and using a method of consensus prevents misclassification and bias. Another limitation is the uncentric design, hence the results are not generalizable on different specializations and settings. Further, due to personnel constraints, not all critical situations that had the potential to generate DRPs were analysed. For example, intravenous therapy is associated with high error rates (Nguyen et al. 2014), but was not examined in detail in our study. Further studies should focus on these areas as well.

This study describes early outcomes of implementation of medication review led by pharmacist in hospital care in Slovakia. To our knowledge, this is the first study using the APS-Doc system to classify problems related to pharmacotherapy at a cardiology clinic. Our results show the high incidence of potential DRPs in hospitalised patients and confirm the need for a regular review of medication conducted by pharmacists.

## 4. Experimental

### 4.1. Setting and patients

The study was conducted prospectively in Teaching Hospital in Nitra, Slovakia. A cardiology clinic was chosen because of the high percentage of geriatric patients who are known to be in substantial need of pharmacotherapy rationalisation. Patients were recruited consecutively during a 3-month period from January to March 2014. Based on admission report, the following data were recorded for each patient: age, gender, diagnoses, medication history, drug allergies, urination and stool problems, status of consciousness, mobility and continence. During hospitalisation, medication charts, examinations and all relevant laboratory results including renal function, liver function, haematology results, and other monitoring parameters as stated in medical records were recorded. The research pharmacist participated in multidisciplinary ward rounds four times a week. During these rounds all additional information on health status and treatment progression were obtained. No patient interviews were made by the pharmacist. According to the latest PCNE classification this design corresponds to the intermediate type of medication review (Type 2b) which is usually carried out in hospital pharmacies (Pharmaceutical Care Network Europe).

### 4.2. Identification and classification of drug-related problems (DRP)

Medication reviews were performed by the one pharmacist in all participants within 48 hours after admission. Patients admitted during weekends and bank holidays were assessed on the next working day. Afterwards, the medication charts were periodically reviewed until discharge from hospitalisation on the department. Summaries of product characteristics and related treatment guidelines were used as sources of drug information, such as indication, contraindication, dosing, interactions, etc.

Detailed description of drug-drug interactions (DDIs) was obtained from Lexicomp® database (Lexicomp) where each DDI is assigned a risk rating A, B, C, D or X expressing its clinical significance. In our study, all DDIs were taken into account, but only D and X were recorded as they were subjects of immediate consultation with attending physicians. Accuracy of medication in elderly patients ( $\geq 65$  years) was assessed using STOPP and START criteria (O'Mahony et al. 2010).

A modified APS-Doc classification system (Hohmann et al. 2012) was used to categorize DRPs as its validity and usability in hospital setting had been tested by multiple studies (Hohmann et al. 2012, Schorr et al. 2014). For those DRPs not included in original APS-Doc classification a new category 'O 3 - Other' was introduced.

### 4.3. Statistical analysis

The data were analysed descriptively using Microsoft Excel 2013 and IBM SPSS statistics 20 for Windows.

### 4.4. Ethical approval

The study was approved by Ethics Committee of Teaching Hospital Nitra, Slovakia.

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**Conflicts of interest:** None declared.

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