Optimising the pharmacotherapy of vascular surgery patients at hospital admission and at discharge (PHAROS): study protocol for quasi-experimental clinical uncontrolled trial

Slavka Porubcova, Kristina Lajtmanova, Kristina Szmicsekova, Veronika Slezakova, Jan Tomka, Tomas Tesar

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Slavka Porubcova[1, 2*] PharmD; Kristina Lajtmanova[2*] PharmD; Kristina Szmicsekova[2, 3*] PharmD, PhD; Veronika Slezakova[2*] PharmD, PhD; Jan Tomka[4*] MD, PhD; Tomas Tesar[1*] PharmD, PhD

[1]Department of Organisation and Management of Pharmacy Faculty of Pharmacy, Comenius University Bratislava SK
[2]Hospital Pharmacy, The National Institute of Cardiovascular Diseases Bratislava SK
[3]Department of Pharmacology Faculty of Pharmacy, Comenius University Bratislava SK
[4]Department of Vascular Surgery, The National Institute of Cardiovascular Diseases Bratislava SK
[*]these authors contributed equally

Corresponding Author:
Tomas Tesar PharmD, PhD
Department of Organisation and Management of Pharmacy
Faculty of Pharmacy, Comenius University
Odbojarov 10
Bratislava
SK

Abstract

Background: Patient safety is the absence of preventable harm to a patient during the process of providing health care and reduction of the risk of unnecessary harm associated with health care to an acceptable minimum. It is coming in the forefront of interest worldwide in healthcare delivery.

Objective: The aims of this protocol are to assess the impact of pharmaceutical care in collaboration with physicians on the prevalence of drug-related problems at hospital admission and discharge in vascular surgery patients.

Methods: The study is conducted in the Vascular Surgery Department at the National Institute of Cardiovascular Diseases in Bratislava, Slovakia during 1-year period, included adult patients with carotid artery disease or lower extremity artery disease, taking ?3 medications. The estimated population for this clinical uncontrolled trial is approximately 100. Medication reconciliation and medication reviews will be performed by hospital pharmacists at both admission and discharge. Pharmacist-proposed interventions will be documented and communicated to the physician, patients will be educated about their medications upon discharge.

Results: The key focus area of this project will be the identification of drug-related problems, their occurrence and type. As a part of further research, analysis will be performed to describe the degree of acceptance of the proposed changes in pharmacotherapy by physicians, groups of drugs based on the Anatomical Therapeutic Chemical classification system with the highest incidence of drug-related problems and identify patients at highest risk for drug-related problems taking in consideration their personal and health information.

Conclusions: This study should demonstrate that pharmacist-led interventions in collaboration with physicians could reducing the risks of pharmacotherapy and optimising medicines management and control systems for patient safety. Clinical Trial: ClinicalTrials.gov
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[1]Hospital Pharmacy, The National Institute of Cardiovascular Diseases, Bratislava, Slovakia

[2]Department of Organisation and Management of Pharmacy, Faculty of Pharmacy, Comenius University in Bratislava, Slovakia

[3]Department of Pharmacology, Faculty of Pharmacy, Comenius University in Bratislava, Slovakia

[4]Department of Vascular Surgery, The National Institute of Cardiovascular Diseases, Bratislava, Slovakia

*Corresponding author

E-mail: tesar@fpharm.uniba.sk (TT)

[¶] These authors contributed equally to this work.

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Introduction

Background

Pharmaceutical care was first defined in 1990 by Hepler and Strand as “the responsible provision of drug therapy for the purpose of achieving definite outcomes that improve a patient’s quality of life” [1]. Worldwide, pharmaceutical care is currently considered a patient-centred approach, replacing the previous product orientation (dispensing medications) [2,3]. The pharmacist actively cooperates not only with the patient but also with healthcare professionals in health promotion, disease prevention, evaluation, monitoring, adjustment and initiation of drug use in order to ensure an effective and safe drug regimen, achieve positive clinical results and reduce the economic costs of care [2,4].

Currently, patient safety is coming in the forefront of interest worldwide in healthcare delivery [5,6]. Patient safety is the absence of preventable harm to a patient during the process of providing health care and reduction of the risk of unnecessary harm associated with health care to an acceptable

minimum. Hospital pharmacists [4,7] can make a significant contribution to the safe, effective and rational use of medicines by hospitalised patients, especially high-risk medication and look-alike and sound-alike medications, through their close surveillance as well as advising on the most appropriate use of medicines [7]. Identification of drug-related problems (DRPs) and proposal of their solution by hospital pharmacists is a tool to ensure safe and effective pharmacotherapy for patients [8,9].

The Pharmaceutical Care Network Europe Association (PCNE) defines a DRP as a problem, event, or circumstance related to pharmacotherapy that affects or has the potential to affect a desired therapeutic effect [10]. An example is the arbitrary withdrawal of metformin by patients due to persistent diarrhoea [11]. PCNE has developed a classification system as a tool to accurately identify DRPs. The current version is V9.00 from 2019 [10].

DRPs are generally all problems related to the use of a drug [10]. DRPs include adverse drug reaction (ADR), an unintended reaction after medication administration [11–14] and medication errors (ME), any phenomenon that may lead to improper use of a drug under the control of a healthcare professional or patient [15–17].

It is not a common practice in Slovakia to report all DRPs [18]. In 2019, only 1,128 suspected ADRs were reported, of which only 8% were reported from pharmacists. Overall, up to 26% of reports were classified as severe (i.e., required hospitalisation of the patient or caused permanent harm to the patient). Although state authorities have seen an increase in the number of spontaneous reports, their number probably does not correspond to their actual occurrence. Currently, we do not have statistically evaluated healthcare costs in Slovakia due to ME [18].

We distinguish between intentional and unintentional DRPs [10,19,20]. There is no uniform classification of the severity of DRPs. It is necessary to focus on the identification and elimination of unintentional DRPs.

At the same time, according to current statistics, the average age of the population is increasing worldwide, which is directly related to the higher prevalence of polymorbidity and polypharmacy in the population [21–23].

There are certain indicators on the basis of which an increased incidence of unintentional DRPs can be expected. In a hospital environment, these are:

- the high number of drugs used is related to low adherence, potential interactions, accumulation of ME, more frequent hospitalisations and increased treatment costs [24–27],
- a low level of understanding among patients of the therapy being used [28–30),
- old age of the patient [21–23,28],
- absence of caregivers in elderly patients [29].

These indicators may be associated with the incidence of treatment errors related with primary care.

Prior work

There are several strategies on how pharmacists can help reduce DRPs [31]. The first method is medication reconciliation (MedRec), followed by a medication review (MedRev) with a pharmaceutical intervention and finally education of the patient about the proper use of drugs [32–34].

Prescription errors in admitting a patient to hospital are common. According to the meta-analysis of Tam et al. from 2005, this error occurs in up to 67% of patients [35]. Using MedRec, Vira et al. identified at least one DRP in 60% of the total number of patients studied, with 18% being clinically significant [36]. The incidence of inadvertent drug discrepancies in a sample of 180 patients who underwent MedRec on admission and discharge was 1.4 discrepancies per patient [37].

DRP has been found to occur mainly during transit between environments, such as admission to a hospital from home, transit between different hospitals or transferring a patient to another department within a hospital [38]. Studies looking at discrepancies in admissions and discharges are controversial. While Lehnbom et al. describes the highest incidence of discrepancies in discharging a patient from hospital [39], Pippins et al. found a higher proportion of admission discrepancies compared to discharges (72% vs 26%) [37]. Despite these differences, the authors agree that discharging a patient from hospitalisation is the riskiest step, as there an increased incidence of clinically serious errors in the patient's pharmacotherapy was observed [37,39].

According to the Organization for Economic Co-operation and Development report from October 2020, a pharmacy-led MedRec before discharge from hospital significantly reduces the risk of drug discrepancies and thus the risk of damage to health. Cost savings occur if the incidence of discrepancies is reduced by at least 11% [40]. Another meta-analysis of Mekonnen et al. from 2016 shows that pharmacist-led MedRec reduces the risk of adverse drug event-related hospital revisits by 67%, emergency admissions by 28%, and hospitalisation by 19% [41]. Pharmacist-led MedRec in transit across healthcare have reduced the number of patients with drug discrepancies by up to 66% [42].

MedRec takes place in several steps. The first step is to obtain the best possible medication history (BPMH) based on all available information, such as previous medical records, transfer reports, outpatient reports, outpatient telephone calls, information from a community pharmacy and discussion with the patient or family members [31,33,34,38,43]. Subsequently, this list is compared with the list of drugs that are currently prescribed to the patient. The list must include the name of the medicinal product, the strength, the dosage and the route of administration. These lists are compared

with each other; intentional or unintentional discrepancies are identified, and they are discussed with other healthcare professionals (physicians, nurses or others) and with the patient himself. The result is a new list of medicines that the patient should actually take [31,33,34,38,43].

Another tool for reducing the incidence of DRPs and optimising pharmacotherapy is a MedRev. Through a MedRev, medicines that do not need to be used are identified; the dose of the medicine is adjusted, or another medicine is added to the treatment. Drug interactions are controlled and the best route of administration is chosen [44].

Studies describing pharmaceutical intervention are mostly focused on a specific group of patients, e.g. patients with cardiovascular diseases [45], geriatric patients [46,47], patients with renal failure [48], or others [31]. Therefore, the total number and types of DRPs detected are not consistent within studies. Stemer et al. identified 487 DRPs during 138 medical visits, and 54.7% of pharmacist proposals for pharmacotherapy modification were accepted [49]. Hohn et al. by the optimisation of the pharmacotherapy of patients from the Department of Vascular Surgery in Germany describe the incidence of unintentional MEs at a rate of 0.41 per patient, with the most common influencing DRPs being antihypertensive (23.9%), antithrombotic (19.3%) and lipid lowering drugs (12.1%) [45]. In the group of patients with chronic renal insufficiency, pharmacists focused on the administration and dosing of patients with nephrotoxic potential. Acceptance of pharmaceutical interventions accounted for 74%. Improvement in renal function was observed in a group of patients who underwent pharmaceutical intervention, with the effect being more noticeable in more severe forms of chronic renal impairment [48]. In a group of 361 hospitalised geriatric patients, the pharmacist proposed 1000 interventions, and the acceptance rate was 54.8% [47]. According to a study by Gillespie et al., the presence of a pharmacist in a multidisciplinary team and pharmaceutical interventions contributed to a 16% reduction in repeat hospital visits and an 80% reduction in hospitalisation due to DRPs compared to the control group without pharmaceutical intervention [46]. Zhai et al. point to a possible reduction in mortality in patients with cardiovascular disease at a university hospital in China due to the identification and elimination of DRPs by pharmacists in collaboration with a physician [50]. Magalhães et al. compared medicines prescribed during hospitalisation with the list of medicines used before the admission of adult patients by the cardiology department at a university hospital in Brazil, focusing on unintentional discrepancies [51]. They identified 17.7% of unintentional discrepancies, the most common of which was a different dose at admission (24%). Further, 15.6% of detected unintentional discrepancies were classified as events that may cause harm to the patient’s health [51]. The definitions and categories of DRPs associated with pharmacotherapy also differ [19,20,31]. For the purposes of this biomedical research,

it is necessary to define the categories of individual problems.

Trial objectives

To assess the impact of pharmaceutical care in collaboration with physicians on the prevalence of DRPs at hospital admission and discharge in patients with carotid artery disease and/or lower extremity artery disease hospitalised at the Department of Vascular Surgery.

The key focus area of this project will be the identification of DRPs, their occurrence and type. As a part of further research, we want to analyse the degree of acceptance of the proposed changes in pharmacotherapy by physicians, ATC (Anatomical Therapeutic Chemical Classification) groups of drugs with the highest incidence of DRPs and identify patients at highest risk for DRPs taking in consideration their personal and health information.

Trial hypothesis

Null hypothesis: Pharmaceutical care provided at hospital admission and at hospital discharge does not reduce prevalence rates of DRPs in patients with carotid artery disease and/or lower extremity artery disease hospitalised at the Department of Vascular Surgery.

Alternative hypothesis: Pharmaceutical care provided at hospital admission and at hospital discharge reduces prevalence rates of DRPs in patients with carotid artery disease and/or lower extremity artery disease hospitalised at the Department of Vascular Surgery.

Methods

Study Intervention

MedRec, MedRev and patient education performed by a trained pharmacist according to the High 5s Project Standard Operating Protocol for Medication Reconciliation (WHO, 2014) and PCNE guidelines.

All comments with a proposal from the pharmacist will be recorded in writing together with a record of the therapy, entered in the patient’s medical record and communicated to the physician.

Study Design

A single-centre prospective, uncontrolled study

Study Setting

The hospital setting at the Department of Vascular Surgery at the National Institute of Cardiovascular Diseases in Bratislava, Slovakia.

Study Duration

The duration of this biomedical clinical trial is one year or until 100 patients are reached.

Study Population

Adult (≥18 years of age) Vascular surgery patients with carotid artery disease and/or lower extremity artery disease admitted for hospitalisation at the study setting during the course of the study.

Inclusion criteria

1. Age ≥18 years at the date of admission for hospitalisation
2. patients taking at least 3 medications
3. patients with carotid artery disease and/or lower extremity artery disease

Exclusion criteria

1. Acute patients
2. Patients transferred from other hospitals/wards
3. Not willing to sign the informed consent form for the study
4. Not understanding Slovak language
5. The presence of any mental disorder affecting memory and recall ability (such as Alzheimer's disease)
6. Any other reason at the discretion of the investigator why he/she deems the participant not eligible for study participation (all such reasons will be recorded)
7. Participation in another clinical study

Study sample size

The estimated patient population for this trial is approximately 100 patients based on previous similar studies.

Data sources and measurements

Data are drawn from the HIS, medical and nursing reports, patient interviews, contacting outpatients.

Timepoints for intervention

At hospital admission

Current condition at patient admission

A vascular surgery patient with carotid artery disease and/or lower extremity artery disease comes for a planned hospitalisation with a report from the attending physician, with or without an internal preoperative examination. The physician, in cooperation with the nurse, examines the patient on admission, draws information from the patient's medical records, and in the case of re-

hospitalisation, also from the hospital information system (HIS) and the internal preoperative examination. The physician will prepare an admission report, which will record the patient's previous illnesses, the current state of health, the reason for hospitalisation, as well as all associated illnesses. Patients often bring a list of medications they are taking; the physician will consult with the patient on the completeness of this list. He/she detects and then records possible allergies to drugs, food, other forms of intolerance or allergic manifestations. He/she is interested in the use of addictive substances, alcohol, drugs of abuse and the frequency of their use. The patient signs an informed consent that he or she consents to hospitalisation and treatment. The admission report, which also includes the drug course (current drug record – is updated once a day; if necessary, it is possible to insert notes, consultation examinations, orders for laboratory tests, etc.), will be prepared both in the HIS and in printed form. Each hospitalised patient has a printed medical record that is more comprehensive and contains more detailed information than the HIS records. It contains all the patient's health results, required examinations, daily drug courses, all daily updated nursing records, records of the patient's diet, etc. Based on the prescription of medications in the course, the nurse prepares and administers medications to the patient, a sudden change in pharmacotherapy by the physician is reported to the nurse orally, and then recorded in the course. Some patients keep some of their medication with themselves and dose it themselves according to the physician's instructions.

Medication reconciliation by pharmacists at patient admission

The patient is normally admitted to the planned hospitalisation by the physician in cooperation with the nurse, as described above. If the patient is over 18 years of age, takes more than three medicines, speaks and understands the Slovak language and has signed an informed consent to participate in biomedical research, after being placed in a bed, a pharmacist comes to the patient and performs an MedRec. During the MedRec, the pharmacist creates a record of the patient's therapy, the original of which is placed in the patient's medical record, and a copy is placed to pharmacist's records.

Steps in the MedRec:

a) As part of the invitation to hospitalisation (by telephone, in writing), the patient will be asked to bring all their medications and a complete medication list, which will be used in consultation with the pharmacist regarding their proper use.
b) Completion of the BPMH

The source of information can be a drug record, an admission report and course, historical records from the HIS, information from the patient or his/her family member. A BPMH is different and more complex than the routine history of primary treatment (which is often a rapid history of patient treatment). The BPMH includes the name of the medicine, the dose, the frequency and the route of

the medicines that the patient is currently taking, although it may differ from what was actually written in the drug list.

The types of drugs that need to be recorded for BPMH include:

- prescription drugs
- over-the-counter drugs
- nutritional supplements
- herbal medicines, medicinal teas
- recreational drugs
- regular consumption of certain foods (e.g. grapefruit)
- special emphasis should be placed on specific forms of medicines, such as inhalers, eye drops, topical semi-solid medicines, or medicines taken every few weeks (bisphosphonates)

One of the recorded parameters is patient understanding. This is evaluated in three steps – the patient knows/does not know the name of the drug (1/0), the patient knows/does not know the indication of the drug (1/0) and the patient knows/does not know the dosage of the drug (1/0).

If the patient is unable to attend the interview, other sources may be used to obtain a medical history or to clarify conflicting information. Other resources should never be a substitute for a thorough conversation with the patient and/or family members.

c) Verification and documentation of BPMH

BPMH list should be verified by more than one other source. Sources for the initial acquisition of an overview of pharmacotherapy are the admission report, the history of hospitalisation, outpatient reports, HIS and the course at admission.

Within the WHO standard operating procedure, a retroactive MedRec model will be used for our biomedical research. In a retroactive model, in accordance with the method described above, the patient is admitted by a physician in cooperation with a nurse by default, and a drug course – a daily prescription of drugs for the patient – is created. In this case, the BPMH is determined after admission by a physician/nurse.

The result of Part b) is a comparison of medicines prescribed to and actually used by patients (BMPH) with marked discrepancies.

During the process of obtaining BPMH, the pharmacist informs the patient to always share his/her doubts about the correct use of the medication with the medical staff.

Medication review with pharmaceutical intervention at patient admission

The basis for performing patient therapy optimisation is the acquisition of the BPMH and patient factors, such as the reason for hospitalisation, current health status, comorbidities, height, weight,

heart rate, blood pressure and the results of examinations of biochemical and haematological parameters.

The detected BPMH is written to the case report form (CRF). It is then analysed in the context of the patient's overall health condition and DRPs are identified. Each detected discrepancy is assigned an alphanumeric code according to the PCNE V9.00 classification. The patient's personal data is anonymised.

Discrepancies in therapy should be consulted with the treating physician within 24 hours of admission.

Evaluation of therapy based on DRPs and PCNE classification

After receiving the BPMH and a detailed study of the reason for hospitalisation, current medical condition, and any patient comorbidities, the pharmacist draws information about the patient's weight, height, heart rate and blood pressure from the admission report. Subsequently the results of biochemical and haematological examinations are studied. The pharmacist focuses on the results of examinations related to pharmacotherapy and the determination of the function of elimination organs. These are mainly the levels of serum potassium, serum creatinine, serum uric acid, liver transaminases, lipidogram and C-reactive protein. Renal function is calculated based on the Cockcroft and Gault creatinine clearance estimate.

Duplicate treatment

The pharmacist controls duplication in the drugs used, considering the use of the same substance in two drugs, use of the same substance in two dosage forms, use of two substances from the same pharmacological group, and double inhibition of the renin-angiotensin-aldosterone axis by angiotensin converting enzyme inhibitors and angiotensin II receptor blockers.

Duplicity is recorded in written form in the final evaluation of the patient's pharmacotherapy; duplication is discussed with the patient, who confirms or refutes the actual use of the duplicate drugs, and the most appropriate procedure is proposed in collaboration with the attending physician.

Indications of used drugs, contraindications

The pharmacist checks the indications of the drugs used according to the patient's comorbidities. The pharmacist checks whether all comorbidities are treated according to evidence-based medicine and according to treatment procedures developed by local, national or international authorities. The result of this step is the identification of missing drugs in patient´s pharmacotherapy.

Furthermore, drugs whose use has no clear indication are identified. In elderly patients (65 years and older), the pharmacist also considers the use of potentially inappropriate drugs. The pharmacist follows the EU (7) -PIM list [52], which was designed for patients aged 65 and over. The result of

this step is the identification of drugs that do not have a clear indication or are inappropriate due to the patient's age.

The pharmacist also checks whether the used drug is not in a particular patient.

Drugs that the patient should and should not take and drugs whose indications are not clearly known from the available data and contraindicated drugs are recorded in the final evaluation of the patient's pharmacotherapy, in cooperation with the attending physician; subsequently the most appropriate procedure is proposed.

Doses of drugs

The pharmacist checks compliance with the maximum recommended doses of drugs. The patient's age, weight or body surface and the function of the elimination organs are considered. Exceeding the maximum recommended dose is recorded in the final evaluation of the patient's pharmacotherapy, and in cooperation with the attending physician, the most appropriate procedure is proposed.

Dosage forms, administration of drugs

The pharmacist controls the suitability of the choice of dosage form, and when splitting or crushing tablets evaluates the possibility and impossibility of such a practice; in infusion solutions he/she evaluates the suitability of choice of vehiculum solution, the final concentration of the drug in solution, the drug stability and the compatibility of multiple drugs in infusion. For specific groups of patients requiring drug administration via enteral tube or percutaneous endoscopic gastrostomy, the pharmacist will evaluate the suitability of administration of the dosage form or suggest more suitable alternatives. The pharmacist checks the use of drugs in the context of food-drug interactions and the timing of their use during the day, identifies drugs that need to be taken on an empty stomach, necessarily to be taken with or after food, and drugs that need to be taken at a specific time of day.

All findings of incorrect drug administration are noted in the patient's final pharmacotherapy evaluation. The pharmacist will suggest suitable alternatives, and in cooperation with the attending physician the most suitable procedure is chosen.

Drug interactions

The pharmacist controls drug interactions using the computerised interaction database, the LexiComp®, pharmacological findings, published scientific papers and case reports.

Clinically significant drug interactions are recorded in the final evaluation of the patient's pharmacotherapy; the pharmacist suggests suitable alternatives, and in cooperation with the attending physician, the most suitable procedure is proposed.

Adverse drug reactions

If a newly manifested ADR not documented in the patient's medical history is suspected, the

pharmacist evaluates the degree of causality between the drugs used and the manifestations of the ADR, which is proven on the basis of laboratory parameters or the patient's subjective complaint. The pharmacist reports suspicions of ADR to State Institute of Drug Control via an electronic form available from https://portal.sukl.sk/eskadra/ .

ADRs are recorded in the final evaluation of the patient's pharmacotherapy.

The individual DRP findings shall be entered in the form as an appropriate code according to the PCNE classification [12].

The result of the pharmacist's intervention at the admission of the patient is the completion of the MedRec form at the admission and creation of an accurate list of medicines taken by the patient. All comments on pharmacotherapy with the proposed solutions are written in the form of a summary report and consulted with the physician.

At hospital discharge

Current condition at patient discharge

When discharging a patient, the attending physician evaluates the patient's state of health and prepares a discharge report with complete information about the procedures that the patient underwent during hospitalisation. The discharge report also includes current results of the patient's laboratory examinations, an overview of current pharmacotherapy and recommendations to the patient's general practitioner. The nurse will explain to the patient the regimen measures in relation to his or her state of health and give the patient medication for the next three days after discharge.

Medication reconciliation by pharmacists at patient discharge

The pharmacist performs MedRec when discharging a patient from the hospital, similar to the process by admission. When evaluating a patient's pharmacotherapy on discharge from hospital, the BPMH obtained at the patient's admission will be used as a source of information. The BPMH is then compared with the list of medicines that are recorded in the release report. The pharmacist will compare two lists of medicines, focusing on the identification of DRPs with special regard to the re-introduction of the chronic therapy which the patient was taking before hospitalisation. As part of this research, the pharmacist will meet with the patient during his discharge from the hospital and discuss with him the management of his further pharmacotherapy. Pharmacists provide an understandable summary list of a patient's medicines explaining the importance and the correct use of the medicine.

Medication review with pharmaceutical intervention at patient discharge

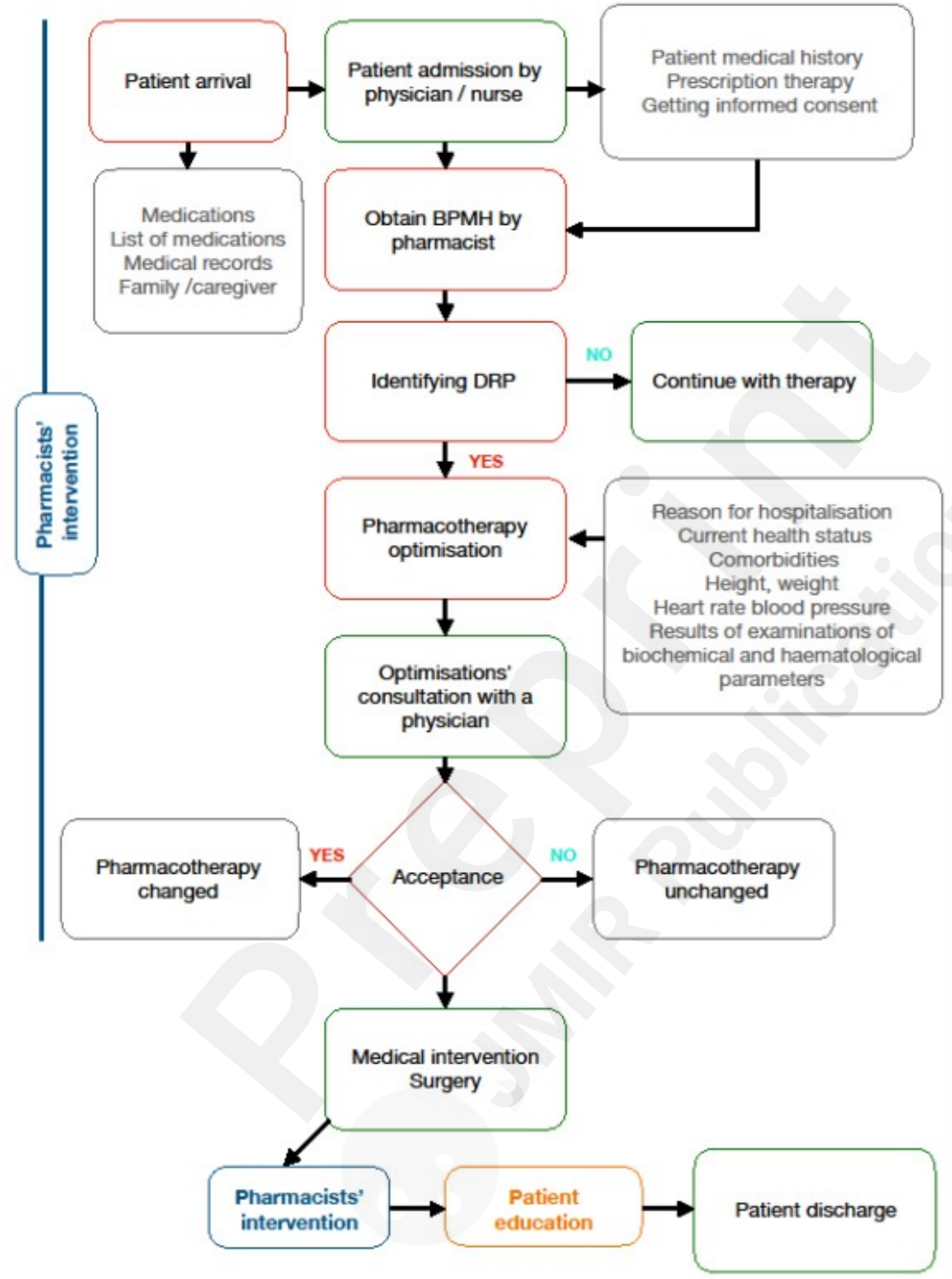
The pharmacist analyses the pharmacotherapy in the context of the patient's state of health and the results of laboratory tests, similar to the patient's admission, as described above. Detected DRPs are

then consulted with the treating physician and recorded in the CRF.

The result of the pharmacist's intervention at discharge is the completion of the MedRec form for discharge and the writing of all comments on pharmacotherapy in the form of a summary report. Discrepancies and comments are consulted with the physician.

The complete scheme of the procedure can be seen in Figure 1.

Figure 1 Procedure scheme



BPMH, Best Possible Medication History; DRPs, drug-related problems

Results

Primary outcomes

A change in the prevalence rate of DRPs at hospital admission vs. hospital discharge.

Secondary outcomes

a) acceptance rate of pharmaceutical intervention by physicians

b) patients' understanding of his/her pharmacotherapy

Variables

Number, type, frequency of DRPs

ATC of drugs causing DRPs

Medical, social and demographic characteristics of patients

Health condition of patients, comorbidities

Patient understanding of his/her pharmacotherapy assessed on a three-point scale at hospital admission

We will assess the patients' basic social, demographic, and clinical characteristics, with a particular emphasis on evaluating their pharmacotherapy and the incidence of DRPs. Additionally, we will examine the degree of acceptance of pharmacists' recommendations by physicians and the outcomes of DRPs resolutions. Our analysis will also identify the medications most frequently associated with the occurrence of DRPs. Patient´s understanding of his/her pharmacotherapy will also be evaluated.

Statistical methods

Continuous variables will be characterized as the mean with standard deviation. Categorical variables will be expressed as numbers and percentages.

DRPs, the number of drugs and active substances between two time points (hospital admission and discharge) will be compared by the paired Wilcoxon signed-rank test (non-normal distribution of the data) and the Shapiro–Wilk test (normal distribution of the data).

Patients' understanding of their pharmacotherapy at hospital admission will be evaluated using a three-point scale. The average score per medication will be calculated, categorizing patients into groups based on their understanding: good (2–3 points per medication), modest (1–2 points per medication), and poor (0–1 point per medication).

Conclusions

The study should evaluate that pharmaceutical care provided at hospital admission and at hospital discharge could reduce the prevalence rates of DRPs in our study setting. The pharmacist-led

interventions upon hospital admission and discharge, followed by patient education, might be implemented in the daily practice in healthcare.

Ethical Considerations

The pharmacists in cooperation with the Ethics Committee of the National Institute of Cardiovascular Diseases are responsible for ensuring that the study is performed in accordance with the protocol, current International Council for Harmonisation guidelines on good clinical practice, and applicable regulatory and country-specific requirements.

Each participant (or a legally acceptable representative) must give written consent according to local requirements after the nature of the study has been fully explained. The informed consent form must be signed before the performance of any research-related activity. The consent that is used must be approved by a reviewing Ethics Committee and be in Slovak language that the participant can read and understand.

Limitations of study

Our study has several limitations. Firstly, it is conducted as a single-centred trial, performed at specific department and specific indications therefore the results may not be automatically applicable under different conditions. Secondly, it is designed there is no control group. Although all investigators are trained in all study processes, some degree of subjectivity is possible in the assessment of DRPs. Moreover, the number of patients is also limited. However, trained hospital pharmacists will strengthen methodology used in our trial.

List of abbreviations

ADR	Adverse drug reaction
ATC	Anatomical Therapeutic Chemical Classification
BPMH	Best possible medication history
CRF	Case Report Form
DRP	Drug-related problem
HIS	Hospital Information System
ME	Medication error
MedRec	Medication reconciliation
MedRew	Medication review
PCNE	The Pharmaceutical Care Network Europe Association

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