NASTAVNO-NAUČNOM VEĆU FARMACEUTSKOG FAKULTETA UNIVERZITETA U BEOGRADU

KOMISIJI ZA POSLEDIPLOMSKU NASTAVU – DOKTORSKE STUDIJE

ACADEMIC COUNCIL OF THE FACULTY OF PHARMACY, UNIVERSITY OF BELGRADE

COMMITTEE FOR POSTGRADUATE STUDIES – DOCTORAL STUDIES

Na sednici Nastavno-naučnog veća Farmaceutskog fakulteta Univerziteta u Beogradu, održanoj 1.2.2018. godine, imenovana je Komisija za ocenu i odbranu završene doktorske disertacije koja je prijavljena pod naslovom **"Prospektivna sistemska analiza rizika u procesu izdavanja lekova u javnoj apoteci - perspektiva unapređenja kvaliteta usluga i bezbednosti pacijenata"**, kandidata magistra farmacije, specijaliste Tatjane Stojković, u sastavu:

At the session of the Academic Council of the Faculty of Pharmacy, University of Belgrade, held on 1.2.2018, the Committee for the evaluation and defense of the doctoral dissertation entitled ***"Prospective systemic risk analysis of the medicines dispensing process in the community pharmacy setting - perspective of pharmaceutical service quality and patient safety improvement"****, of the candidate M.Sc. Pharm. Spec. Tatjana Stojković, was appointed in the structure:*

1. Dr sc. Valentina Marinković, vanredni profesor, Univerzitet u Beogradu - Farmaceutski fakultet, mentor rada/*Associate professor, Faculty of Pharmacy, University of Belgrade, PhD tutor*
2. Dr sc. Ulrich Jaehde, redovni profesor, Univerzitet u Bonu - Institut za farmaciju/*Full professor, Institute of Pharmacy, University of Bonn*
3. Dr sc. Ljiljana Tasić, redovni profesor, Univerzitet u Beogradu - Farmaceutski fakultet/ *Full professor, Faculty of Pharmacy, University of Belgrade*
4. Dr sc. Dušanka Krajnović, vanredni profesor, Univerzitet u Beogradu - Farmaceutski fakultet/*Associate professor, Faculty of Pharmacy, University of Belgrade*

Nakon pregledane doktorske disertacije podnosimo Nastavno-naučnom veću Farmaceutskog fakulteta sledeći/*After evaluation of the doctoral dissertation, the nominated Committee members present to the Academic Council of the Faculty of Pharmacy, University of Belgrade the following*

IZVEŠTAJ
REPORT

A. Prikaz sadržaja doktorske disertacije
A. Overview of the content of doctoral dissertation

Doktorska disertacija kandidata Tatjane Stojković pod naslovom "Prospektivna sistemska analiza rizika u procesu izdavanja lekova u javnoj apoteci - perspektiva unapređenja kvaliteta usluga i bezbednosti pacijenata" napisana je jasnim i preglednim stilom na 138 strana, ima 20 tabela, 7 slika i 235 literaturnih navoda. Sadržaj doktorske disertacije je izložen u sledećim poglavljima: Uvod, Ciljevi doktorske disertacije, Metode, Rezultati, Diskusija, Zaključak i Literatura.

Uvod je podeljen u četiri veće celine. U okviru prve celine opisan je koncept bezbednosti pacijenata, kao i odnos između ovog pojma i kvaliteta zdravstvene zaštite. U drugoj celini dat je prikaz taksonomije u oblasti bezbednosti pacijenata, uz pregled definicija najznačajnijih termina. Treća celina je posvećena medicinskim greškama, gde je dato objašnjenje značenja ovog pojma i razmera njegovih posledica, kao i pregled uzroka i klasifikacije medicinskih grešaka, pri čemu je posebna pažnja posvećena greškama koje nastaju u procesima propisivanja, izdavanja i primene lekova. U četvrtom poglavlju je dat prikaz modela za prospektivno upravljanje rizikom u procesima pružanja zdravstvene zaštite, sa posebnim osvrtom na Analizu načina (oblika) i efekata otkaza (FMEA), uz sistematski pregled sposobnosti navedenog alata da smanji rizike za bezbednost pacijenata u procesu izdavanja lekova. Posebna manja celina posvećena je upravljanju rizicima u procesu izdavanja lekova u Republici Srbiji i SR Nemačkoj, uz razmatranje podataka koji se prikupljaju, tipova istraživanja koja se sprovode i postojanja prospektivnog delovanja u ovoj oblasti u navedenim zemljama.

Ciljevi ove doktorske disertacije su predstavljali sprovođenje prospektivne sistemske analize rizika u procesima izdavanja lekova u javnim apotekama u Republici Srbiji i SR Nemačkoj, radi identifikacije potencijalnih grešaka, kvantifikacije i rangiranja prioriteta pridruženih rizika, kao i definisanja korektivnih mera za unapređenje bezbednosti pacijenata i kvaliteta farmaceutske zdravstvene zaštite. Cilj je bio i sprovođenje komparativne analize rizika u procesu izdavanja lekova u javnoj apoteci u Republici Srbiji, kao zemlji u razvoju, i SR Nemačkoj, kao razvijenoj zemlji. Dodatno, cilj je bio i ispitati stavove i uverenja farmaceuta u vezi sa potencijalnim

uzrocima grešaka u procesu izdavanja lekova u javnoj apoteci i merama za njihovu prevenciju, kao i aktuelne prakse (ne)prijavljivanja nastalih incidentnih događaja u Republici Srbiji.

U poglavlju Metode su detaljno opisane metode korišćene u istraživanju. U prvoj i drugoj studiji u okviru doktorske disertacije, sprovedena je prospektivna sistemska analiza rizika u procesu izdavanja lekova u javnoj apoteci primenom FMEA metode, najpre u Republici Srbiji u periodu od januara do maja 2016. godine, a zatim u SR Nemačkoj u oktobru 2016. godine. Na početku obe studije su multidisciplinarni timovi, koji su se sastojali od moderatora i eksperata u izdavanju lekova, primenom tehnike 'oluja ideja' kreirali dijagram toka analiziranog procesa, i identifikovali potencijalne greške, zajedno sa njihovim uzrocima i posledicama. Zatim je izvršena kvantifikacija pridruženih rizika, izračunavanjem broja prioriteta rizika (RPN) za svaku potencijalnu grešku, na osnovu ocenjivanja njene ozbiljnosti ("O"), učestalosti ("U") i detektabilnosti ("D") od strane svakog člana tima. Dobijeni podaci su zatim analizirani u Microsoft Office Excel^{TM} 2010 i predstavljeni kao medijane vrednosti za "O", "U" i "D" za svaku grešku. Najzad, definisane su korektivne mere i njihovi potencijalni efekti su procenjeni za greške sa najvišim vrednostima RPN-ova. U trećoj fazi istraživanja u okviru doktorske disertacije sprovedena je kvalitativna komparativna analiza rizika u procesu izdavanja lekova u javnim apotekama u Republici Srbiji i SR Nemačkoj. Vršeno je poređenje sličnosti i razlika u organizaciji ovog procesa u farmaceutskim praksama obe zemlje, kao i u kritičnim potencijalnim greškama, njihovim uzrocima i posledicama, prioritetnim korektivnim merama i potencijalu za smanjenje rizika primenom FMEA metode. U četvrtoj fazi istraživanja u okviru doktorske disertacije sprovedena je studija preseka u periodu od januara do juna 2016. godine, distribuiranjem upitnika nacionalnom reprezentativnom uzorku farmaceuta u državnim i privatnim javnim apotekama u Republici Srbiji. Korišćen upitnik je preuzet iz studije sprovedene od strane Peterson i sar. [1], i neznatno modifikovan. Nakon toga je draft verzija upitnika pretestirana na pogodnom uzorku od 38 farmaceuta zaposlenih u javnim apotekama sa ciljem provere razumljivosti i čitljivosti pitanja, njihovog dizajna, kao i izvodljivosti studije. Po završetku pilot studije, izvršene su neznatne izmene upitnika i finalna verzija je distribuirana diplomiranim farmaceutima/magistrima farmacije sa licencom-odobrenjem za samostalni rad, zaposlenim u državnim i privatnim javnim apotekama. Sa ciljem definisanja nacionalnog reprezentativnog uzorka farmaceuta zaposlenih u javnim apotekama, kao okvir za uzorkovanje je definisan Imenik redovnih članova Farmaceutske Komore Srbije (FKS), a kako bi se u istraživanju obezbedila obuhvaćenost farmaceuta iz svih geografskih područja, uzorak je dalje stratifikovan podelom predviđenog okvira uzorkovanja u homogene subgrupe (stratume) prema pripadnosti redovnih članova odgovarajućem ogranku FKS. Upitnik je sadržao delove u vezi sa socio-demografskim karakteristikama ispitanika, njihovim stavovima u vezi sa faktorima koji predisponiraju nastanak grešaka u izdavanju lekova, potencijalno efikasnim korektivnim merama, kao i praksom u prijavljivanju nastalih incidentnih događaja. Prikupljeni podaci iz popunjenih upitnika su uneti, kodirani i analizirani metodama deskriptivne i inferencijalne statistike. Statistička obrada je izvršena korišćenjem IBM SPSS 21.0 softverskog paketa (IBM SPSS Statistics for Windows, Version 21.0. Armonk, NY: IBM Corp.). Numerički podaci su

predstavljeni u vidu frekvence (procentualnog učešća) u slučaju kategorijskih varijabli, odnosno kao medijana, opseg i interkvartilni opseg za kontinuirane varijable. Povezanost između varijabli je analizirana primenom neparametarskih testova inferencijalne statistike, pri čemu je Mann-Whitney-U test korišćen za kontinuirane, a Chi-kvadrat test za kategorijske varijable. Nivo statističke značajnosti je postavljen na konvencionalni nivo $p \leq 0.05$ za sve analize.

The doctoral dissertation of candidate Tatjana Stojković entitled "Prospective systemic risk analysis of the medicines dispensing process in the community pharmacy setting - perspective of pharmaceutical service quality and patient safety improvement" has been written in a clear and transparent style on 137 pages, with 20 tables, 7 figures and 235 references. The content of doctoral dissertation is presented in the following sections: Introduction, Aims of doctoral dissertation, Methods, Results, Discussion, Conclusion and References.

The Introduction section is divided into four major parts. Within the first part, the concept of patient safety is described, as well as the relationship between this term and the quality of health care. In the second part, the taxonomy in the field of patient safety is presented, along with a review of the definitions of the most important terms in this area. The third part is dedicated to medication errors, where an explanation of the meaning of this term and the extent of its consequences is provided, along with an overview of the causes and classification of medication errors, with particular attention being paid to the errors arising in the processes of prescribing, dispensing and administering drugs. The fourth part provides an overview of the models employed for prospective risk management in the health care processes, with a particular focus on the Failure Mode and Effects Analysis (FMEA), and a systematic review of the ability of this tool to reduce patient safety risks in the medicines dispensing. A special minor part is dedicated to the risk management in the medicines dispensing processes in Serbia and Germany, with taking into consideration the data which are collected, the types of research that are being performed and the existence of prospective activities in this area in both countries.

The aims of this doctoral dissertation were to conduct prospective systemic risk analyses of the medicines dispensing processes in the community pharmacy settings in Serbia and Germany, so as to identify, quantify and prioritize potential failure modes, as well as to define adequate measures for patient safety and pharmaceutical service quality improvement. The aim also was to conduct a comparative risk analysis of the medicines dispensing processes in the community pharmacy settings in Serbia, as developing country, and Germany, as developed country. Finally, the aim was to assess Serbian pharmacists' attitudes and beliefs regarding the causes of dispensing errors and potential preventive measures to avoid them in the community pharmacy setting, as well as their practice in (non)reporting of patient safety incidents incurred.

The Methods section provides a thorough description of the methods employed in the research. In the first and second studies of doctoral dissertation, prospective systemic risk analyses of the medicines dispensing processes in the community pharmacy settings were performed by using FMEA, firstly in Serbia from January to May 2016, and then in Germany in October 2016. At the beginning of both studies, multidisciplinary teams consisting of a leader and process experts

employed brainstorming techniques to map medicines dispensing processes and identify failure modes, along with their causes and effects. Then, the associated risks were quantified by calculating Risk Priority Numbers (RPNs) for each failure mode based on its severity (S), occurrence (O) and detectability (D) by each team member independently. The obtained data were analyzed in Microsoft Office Excel 2010 and expressed as the median value for S, O and D of each failure mode. Finally, corrective actions were developed and their potential effects were evaluated for the failure modes with the highest RPNs. In the third research study of doctoral dissertation, a qualitative comparative risk analysis of the medicines dispensing processes in the community pharmacy settings in Serbia and Germany was conducted. The main similarities and differences were compared in relation to the organization of dispensing processes in both countries' pharmacy practices, as well as regarding the main critical failure modes identified, their causes and efects, corrective actions defined, as well as the potential for patient safety risk reduction obtained by employing FMEA. In the fourth phase of doctoral dissertation research, a cross-sectional survey was performed from January to June 2016 by distributing a self-administered questionnaire to a nationwide, representative sample of community pharmacists in Serbia. The questionnaire was adopted from the study conducted by Peterson et al. [1], and slightly modified. After that, a draft version of the questionnaire was piloted on a convenience sample of 38 pharmacy practitioners so as to assess its readability, feasibility, question design and comprehension. Following the pilot study, some minor changes were made and the final version was distributed to the licensed community pharmacists from both state- and privately-owned community pharmacies. The sampling frame for obtaining a nationwide, representative sample for survey included a list of community pharmacists registered as regular members of the Pharmaceutical Chamber of Serbia (PCS), and in order to obtain the involvement of pharmacists from all geographical areas in the research, the sample was further stratified by dividing the sampling frame into homogeneous subgroups (strata) according to which particular regional PCS branch the pharmacists were regular members of. The questionnaire included sections related to the participants' socio-demographic characteristics, their attitudes towards factors leading to the dispensing errors occurrence and potentially effective corrective actions, as well as their practice in reporting of dispensing errors. The data obtained from the completed questionnaires were entered, coded and analyzed using methods of descriptive and inferential statistics. Statistical analysis was performed using IBM SPSS Statistics for Windows (Version 21.0. Armonk, NY: IBM Corp.). Numerical data were reported as frequencies (percentage) for categorical variables and median, range and interquartile range for continuous variables. The associations between variables were analyzed with non-parametric methods of inferential statistics, using Mann-Whitney-U test for continuous and Chi-square test for categorical variables. The threshold of statistical significance was set to a conventional level at $p \leq 0.05$ for all analyses.

B. Opis postignutih rezultata
B. Description of the results obtained

U poglavlju Rezultati dat je pregled rezultata dobijenih na osnovu sprovedenih istraživanja. Rezultati su prikazani u vidu slika i tabela i grupisani u četiri veće celine. U prve dve celine dati su rezultati sprovođenja prospektivne sistemske analize rizika u procesu izdavanju lekova u javnim apotekama u Republici Srbiji i SR Nemačkoj. FMEA analiza sprovedena u Republici Srbiji je identifikovala 30 potencijalnih grešaka, među kojima su najviše vrednosti RPN-ova bile pripisane neuspehu u identifikaciji ili rešavanju terapijskih problema za datog pacijenta (RPN 48), kao i izdavanju pogrešnog leka, ili leka pogrešne jačine, farmaceutskog oblika ili količine (RPN 40). Rezultati istraživanja dalje pokazuju da su predložene korektivne mere demonstrirale značajan potencijal za smanjenje rizika (50.3% u proseku), od kojih su najefikasnije uključivale implementaciju elektronskog prenosa recepata u apoteke, uvođenje dodatne kontinuirane medicinske edukacije farmaceuta iz oblasti farmakoterapije, kao i unapređenje komunikacionih veština sprovođenjem odgovarajućih obuka. Dodatno, FMEA analiza sprovedena u SR Nemačkoj je identifikovala 39 potencijalnih grešaka, među kojima su najkritičnije vrednosti RPN-ova pripisane neuspehu u proceni adekvatnosti propisane terapije za datog pacijenta (RPN 45), izostanku odstupanja od izdavanja neadekvatne potpune paralele leka (RPN 36), kao i izdavanju pogrešnog leka, ili leka pogrešne jačine, farmaceutskog oblika ili količine (RPN 30). Takođe je pokazano da predložene korektivne mere imaju značajan potencijal za smanjenje rizika (25.5% u proseku), od kojih su najefikasnije uključivale podizanje nivoa svesti farmaceuta i farmaceutskih tehničara o značaju procene adekvatnosti potpune paralele koja se izdaje u zavisnosti od fonda zdravstvenog osiguranja, uvođenje njihove obavezne kontinuirane edukacije iz oblasti farmakoterapije, kao i elektronskog prenosa recepata u apoteke.
U trećoj celini su dati rezultati komparativne analize identifikovanih rizika i predloženih korektivnih mera u vezi sa procesom izdavanja lekova u Republici Srbiji i SR Nemačkoj. Uprkos određenim organizacionim i proceduralnim razlikama u procesu izdavanja lekova u Republici Srbiji i SR Nemačkoj, pokazano je da su najkritičniji rizici u obe zemlje bili pripisani pogrešnoj proceni adekvatnosti propisane terapije za datog pacijenta, ili njenom izostanku, a pre svega u vezi sa doziranjem i interakcijama lekova (RPN 48 u Republici Srbiji i 45 u SR Nemačkoj). Izdavanje pogrešnog leka, ili leka pogrešne jačine, farmaceutskog oblika ili količine je takođe identifikovano kao visoko rizično (RPN 40 i 30), kao i nepotpuno savetovanje pacijenata (RPN 36 i 30). Glavne zajedničke korektivne mere su uključivale edukaciju zaposlenih iz oblasti farmakoterapije i kliničke farmacije, smanjenje preopterećenja radom normiranjem i strukturiranjem usluge, kao i uvođenje elektronskog prenosa recepata u apoteke. Dodatno, značajno smanjenje rizika je dobijeno u obe zemlje nakon hipotetičke implementacije korektivnih mera, pri čemu je suma vrednosti RPN-ova snižena od 583 do 293 za proces izdavanja lekova u Republici Srbiji, i od 781 do 573 u SR Nemačkoj.
U četvrtoj celini su dati rezultati istraživanja stavova i prakse farmaceuta u vezi sa upravljanjem rizicima u procesu izdavanja lekova u javnoj apoteci u Republici Srbiji. U istraživanju je

učestvovalo 1004 ispitanika, pretežno ženskog pola (94.9%), prosečne starosti 41±10 godina i radnog iskustva 14±10 godina. Više od trećine farmaceuta (35.4%) izrazilo je mišljenje da je rizik od nastanka grešaka u izdavanju lekova u porastu. Dodatno, približno jedna polovina ispitanika (49%) potvrdno je odgovorila na pitanje da li je na njihovom radnom mestu načinjen propust u izdavanju lekova koji nije uočen pre nego što je pacijent napustio apoteku. Prosečan broj ovih incidentnih događaja u proteklih 6 meseci bio je 2 (opseg 1-20), dok je njihov ukupan broj bio 941. Najznačajniji uzročni faktori prema stavu farmaceuta obuhvatali su nečitak rukopis lekara (44.3%), ometanje u radu (39.2%), preopterećenje radom (37.8%), kao i nedovoljan kadar (36.3%). Sa druge strane, potencijalno najefikasnije korektivne mere prema stavu farmaceuta obuhvatale su sprovođenje dodatne edukacije farmaceuta u vezi sa kliničkom farmacijom i novo registrovanim lekovima (71%), zatim smanjenje preventabilnih smetnji u radu (63.9%), angažovanje više od jednog farmaceuta u smeni (61.9%), kao i aktivno uključivanje pacijenata prilikom njihovog savetovanja (60.3%). Većina učesnika u studiji (85.2%) je izjavila da redovno prijavljuje incidentne događaje nastale u toku izdavanja lekova. Iako je većina ispitanika (83.6%) izjavila da nema strah od prijave grešaka, čak 16.5% učesnika je priznalo da ima strah ponekad ili uvek. Veliki udeo ispitanika (87.4%) je izrazio pozitivan stav po pitanju prijavljivanja svih tipova nastalih propusta, bez obzira na stepen njihove ozbiljnosti. Ipak, samo 58.1% ispitanika je izjavilo da bi koristilo nacionalni sistem za dobrovoljno prijavljivanje grešaka u izdavanju lekova, u slučaju njegovog uspostavljanja. Stavovi farmaceuta u vezi sa uzročnim faktorima i korektivnim merama, kao i praksa u prijavljivanju incidenata u značajnoj meri su zavisile od njihove starosti, radnog iskustva i tipa apoteke.

The Results section provides an overview of the results obtained from the conducted research studies. The results are presented in the form of figures and tables, and grouped into four major parts. The results of the prospective systemic risk analyses of the medicines dispensing processes in the community pharmacy seetings in Serbia and Germany are presented in the first two parts.
FMEA conducted in Serbia yielded 30 failure modes, out of which the highest RPNs were assigned to the failure in identifying and resolving drug-related problems (DRPs) (RPN 48) and to dispensing of the wrong medicine, strength, form, or quantity (RPN 40). The corrective actions proposed demonstrated a considerable potential for risk reduction (50.3% on average) in majority of failure modes, the most effective of which included implementing electronic transmission of prescriptions to the pharmacy, introducing pharmacists' education in pharmacotherapy, and organizing communication training.
Furthermore, FMEA conducted in Germany identified 39 failure modes, out of which the highest criticality scores were assigned to inadequate assessment of therapy appropriateness (RPN 45), reluctance to deviate from rebate contracts (RPN 36) and dispensing of the wrong medicine, strength, form, or quantity (RPN 30). The corrective actions proposed demonstrated a considerable potential for risk reduction (25.5% on average) in majority of failure modes, the most effective of which were raising pharmacists and pharmaceutical technical assistants' (PTAs) awareness of the necessity to check the rebate contract product's appropriateness,

introducing obligatory pharmacists and PTAs' continuing education in pharmacotherapy, and implementing electronic transmission of prescriptions to the pharmacy.

The results of a comparative risk analysis of the medicines dispensing processes in the community pharmacy settings in Serbia and Germany are presented in the third part. Despite some organizational and procedural differences across settings, the highest risk potential in both countries was assigned to the incorrect or lacking assessment of therapy appropriateness, particularly regarding dosing and drug interactions (RPN 48 in Serbia and 45 in Germany). Dispensing of the wrong medicine, its strength or form were also ranked high (RPN 40 and 30), as well as incomplete patient counseling (RPN 36 and 30). The main common corrective actions included education and training in clinical pharmacy, workload reduction by service structuring, and introducing computerized prescribing and electronic transmission of prescriptions to the pharmacy. Additionally, significant risk reduction was obtained in both countries after the hypothetical implementation of corrective actions proposed, where the sum of RPNs was reduced from 583 to 293 in Serbian, and from 781 to 573 in German dispensing process.

The results of the study of Serbian pharmacists' attitudes and beliefs related to the risk management in the medicines dispensing process in the community pharmacy setting are presented in the fourth part. The study included 1,004 participants (the response rate 88.5%), mainly female (94.9%), with the mean age 41±10 years and mean registration length 14±10 years. More than third the participants (35.4%) indicated an increasing risk of dispensing errors. Additionally, almost half the respondents (49%) demonstrated awareness of dispensing errors being committed at their place of practice during the past 6 months, noticed only after the patient had already left the pharmacy. The median number of such occurrences was 2 (range 1-20), while the total number of dispensing errors reported was 941. The main contributing factors identified were illegible prescriber's handwriting (44.3%), interruptions and distractions during dispensing (39.2%), as well as pharmacists' work overload (37.8%) and understaffed shifts (36.3%). The major corrective actions suggested included providing pharmacists with additional education related to clinical pharmacy and newly licensed medicines (71%), reducing the avoidable interruptions during dispensing (63.9%), increasing the number of pharmacy staff per shift (61.9%), and providing proper counseling to patients along with involving them more actively (60.3%). The majority of respondents (85.2%) stated that they routinely reported dispensing incidents occurred. Although most of the participants (83.6%) declared having no fear to report dispensing errors, 16.5% of them admitted to having such fear sometimes or always. The large proportion of practitioners (87.4%) demonstrated positive attitude towards reporting any type of dispensing errors, regardless of their severity. However, only 58.1% of the participants stated that they would use voluntary dispensing error reporting system, if established. Pharmacists' attitudes towards the main contributing factors and corrective actions, as well as their practice in reporting of dispensing incidents were found to be significantly associated with age, work experience and type of community pharmacy.

C. Uporedna analiza rezultata kandidata sa podacima iz literature
C. Comparative analysis of the candidate's results with literature data

U poglavlju Diskusija su dobijeni rezultati detaljno analizirani i upoređeni sa podacima iz literature. U doktorskoj disertaciji predstavljena su prva saznanja o korisnosti i adekvatnosti FMEA metode za unapređenje bezbednosti pacijenata i kvaliteta farmaceutske usluge u javnim apotekama, odnosno na primarnom nivou zdravstvene zaštite. Sprovedene studije su prospektivno identifikovale veliki broj mogućih grešaka kao i potencijalno efikasnih korektivnih mera u procesu izdavanja lekova u javnim apotekama, kako u Republici Srbiji, tako i u SR Nemačkoj. Dodatno, uprkos određenim organizacionim i proceduralnim razlikama u izdavanju lekova u javnim apotekama ove dve zemlje, utvrđena je sličnost između najkritičnijih rizika za bezbednost pacijenata u ovom procesu.

Jedan od najznačajnijih rezultata sprovedenih studija odnosi se na identifikaciju potencijalnog neuspeha u proceni adekvatnosti propisane terapije za datog pacijenta, kao najkritičnijeg propusta u izdavanju lekova u obe zemlje. Dobijeni rezultati su ukazali na nedostatak farmakoterapijskog znanja i veština farmaceuta i farmaceutskih tehničara za rešavanje kliničkih problema, kao jedan od najznačajnih zajedničkih uzroka koji doprinosi neuspehu u proveri adekvatnosti terapije za datog pacijenta u obe zemlje. Ovo je u skladu sa rezultatima drugih studija, gde su ovi faktori identifikovani kao značajne barijere za pružanje farmaceutske zdravstvene zaštite [2-6]. U skladu sa tim, u obe analize je kao jedna od ključnih mera za unapređenje bezbednosti ovog koraka u procesu izdavanja lekova predloženo uvođenje kontinuirane medicinske edukacije iz oblasti farmakoterapije.

Limitirana interprofesionalna saradnja kao i neefikasna komunikacija između zdravstvenih radnika su takođe identifikovani kao jedni od najznačajnijih zajedničkih uzroka neuspeha u identifikaciji i rešavanju terapijskih problema tokom izdavanja lekova u Republici Srbiji i SR Nemačkoj. U skladu sa tim, u najznačajnije predložene korektivne mere u obe analize spada sprovođenje zajedničkih edukacija i obuka farmaceuta sa drugim zdravstvenim radnicima, a pre svega lekarima, što je u skladu sa drugim studijama u kojima je pokazano da saradnja lekara i farmaceuta može dovesti do unapređenja terapijskih ishoda za pacijente i povećanja njihove bezbednosti [7-9].

Izdavanje pogrešnog leka ili leka pogrešne jačine, farmaceutskog oblika ili količine takođe je identifikovano kao visoko rizičan propust u javnim apotekama u Republici Srbiji i SR Nemačkoj. Ovo je u skladu sa rezultatima studija grešaka u izdavanju lekova, gde ovaj tip incidenta spada među najfrekventije kako u javnim, tako i u bolničkim apotekama [10, 11]. Tehnikom ‘oluje ideja’ je u obe analize uočeno da su nečitak rukopis lekara, korišćenje nestandardizovanih skraćenica prilikom propisivanja lekova, kao i nedostatak elektronskog prenosa recepata u apoteku, i posledično ručno sprovođenje transkripcije podataka sa recepata u kompjuterski sistem apoteke, najznačajniji specifični uzroci ovih grešaka. U skladu sa tim, uvođenje elektronskog propisivanja i prenosa recepata iz doma zdravlja u apoteku je u analizama u obe zemlje identifikovano kao potencijalno najefikasnija korektivna mera za smanjenje grešaka u fazama izbora leka i transkripcije podataka sa recepta tokom izdavanja lekova u javnim

apotekama. Ovo je u skladu sa drugim istraživanjima, gde je potvrđena efikasnost ove intervencije za unapređenje bezbednosti pacijenata u farmaceutskoj praksi [12-14]. Dodatno, u analizi sprovedenoj u Republici Srbiji su lekovi sličnog naziva i/ili vizuelno sličnog pakovanja takođe identifikovani kao značajni faktori koji doprinose nastanku grešaka u izboru odgovarajućeg leka za izdavanje, što je u skladu sa drugim studijama [10, 15]. Kao značajna strategija za proaktivno delovanje, predloženo je razdvajanje ovih lekova prilikom skladištenja, uz uvođenje dodatnih mera opreza, što se predlaže i kao jedna od osnovnih mera u dokumentu Kolaborativnog centra za rešenja za bezbednost pacijenata Svetske Zdravstvene Organizacije [16].

Zajednički propusti u izdavanju lekova u Republici Srbiji i SR Nemačkoj identifikovani su i u vezi sa savetovanjem pacijenata. Jedan od ključnih zajedničkih uzroka ovih tipova propusta u obe analize uključivao je neefikasnu komunikaciju farmaceuta i farmaceutskih tehničara sa pacijentima. U skladu sa tim je u obe FMEA analize kao jedan od osnovnih predloga za smanjenje rizika za nastanak grešaka u savetovanju pacijenata definisano neophodno unapređenje komunikacionih veština farmaceuta i farmaceutskih tehničara organzivanjem odgovarajućih obuka. Ovo je u skladu sa dostupnom literaturom, gde se naglašava neophodnost sprovođenja dugoročnih kontinuiranih kurseva sa ciljem razvoja kompetencija i veština farmaceuta za pravilno savetovanje pacijenata, kao i promene njihove prakse i obrazaca ponašanja u ovom procesu [17-19].

Dodatno, nedovoljno podsticanje aktivnog uključivanja pacijenata u upravljanje terapijom, ili izostanak ove aktivnosti, je u analizi sprovedenoj u SR Nemačkoj identifikovan kao visoko rizičan propust u vezi sa savetovanjem pacijenata (RPN 30). U skladu sa uvođenjem pristupa orijentisanosti ka pacijentu (*patient-centred approach*) kao zlatnog standarda u pružanju zdravstvene zaštite [20], menja se i odnos farmaceuta i pacijenata u apoteci, pri čemu pacijent postaje aktivan partner u komunikaciji, sa kojim je neophodno uspostaviti profesionalan odnos, zasnovan na poverenju, otvorenoj komunikaciji i zajedničkom donošenju odluka [17]. U skladu sa tim, u analizi sprovedenoj u SR Nemačkoj je kao ključna korektivna mera za smanjenje rizika od paternalističkog pristupa u izdavanju lekova i povećanje aktivnog uključivanja pacijenata tokom njihovog savetovanja, predloženo sprovođenje edukacije farmaceuta i farmaceutskih tehničara u vezi sa novim pristupom komunikaciji sa pacijentima, čija se neophodnost ističe i u drugim studijama [18, 21].

Još jedan visoko kritičan propust koji je vezan za fazu savetovanja prilikom izdavanja lekova, a identifikovan kao specifičan za farmaceutsku praksu u SR Nemačkoj, uključivao je izostanak savetovanja pacijenta kada se vrši isporuka leka na kućnu adresu (RPN 30). Problem indirektne isporuke lekova ističe i Farmaceutski odbor Australije u smernicama za izdavanje lekova, gde se navodi da je ovaj način pružanja farmaceutske usluge suboptimalan, upravo zbog potencijalno kompromitovane komunikacije [22]. Posledično, članovi FMEA tima su u analizi u SR Nemačkoj kao osnovnu meru za smanjenje ovog rizika definisali kreiranje vodiča za sprovođenje savetovanja pacijenta u slučaju isporuke leka na kućnu adresu, kojim bi se postigla standardizacija ovog procesa i unapređenje njegove bezbednosti.

Najznačajniji zajednički opšti uzroci grešaka, prospektivno identifikovani u FMEA analizama u Republici Srbiji i u SR Nemačkoj, uključivali su nedostatak standardizacije procesa izdavanja lekova, kao i preopterećenje radom farmaceuta i farmaceutskih tehničara i njihovo ometanje u radu (učestali telefonski pozivi, visok nivo buke itd.). U skladu sa tim, jedna od ključnih zajedničkih korektivnih mera obuhvatala je standardizaciju procesa izdavanja lekova u javnim apotekama obe zemlje, definisanjem odgovarajuće standardne operativne procedure. Dodatno, kao ključna zajednička korektivna mera za preopterećenje radom zaposlenih u javnim apotekama u Republici Srbiji i SR Nemačkoj, definisano je normiranje i strukturiranje usluge definisanjem maksimalnog broja recepata po farmaceutu, koje je već uvedeno u praksu u nekim zemljama, kao što je Australija [23].

Identifikovane posledice grešaka u izdavanju lekova u javnim apotekama Republike Srbije i SR Nemačke su bile slične, uključujući pre svega rizik za pacijenta, ali i potencijalni negativni efekat na sistem u slučaju nastanka propusta. Ipak, članovi FMEA timova su u obe analize prospektivno definisali korektivne mere koje su pokazale značajan potencijal za redukciju datih rizika nakon sprovedene komparativne analize inicijalnog i hipotetički redizajniranog procesa izdavanja lekova, od 50.3% u Republici Srbiji i 25.5% u SR Nemačkoj.

Kada su u pitanju rezultati istraživanja stavova i prakse farmaceuta u vezi sa upravljanjem rizicima u procesu izdavanja lekova u javnoj apoteci u Republici Srbiji, više od jedne trećine učesnika (35.4%) u ovoj studiji je izrazilo mišljenje da je rizik od nastanka grešaka u izdavanju lekova u porastu, što je niža vrednost u odnosu na 44.7%, 62% i 82.2% kolega iz Etiopije [24], Saudijske Arabije [25] i Australije [1], respektivno, koje su imale ovakav stav. Dodatno, približno 21% ispitanika smatrao je da je broj grešaka koje nastaju u izdavanju lekova u porastu, pri čemu su i u ovom slučaju farmaceuti koji su učestvovali u sličnim studijama sprovedenim u Etiopiji [24], Saudijskoj Arabiji [25] i Australiji [1] u većem procentu iskazali ovakvo mišljenje (42.6%, 55.5% i 47.1%, respektivno).

Brojni uzročni faktori su od strane farmaceuta percepirani kao značajni za nastanak grešaka u izdavanju lekova, pri čemu su nečitak rukopis lekara (44.3%), ometanje u radu (39.2%), preopterećenje radom (37.8%), kao i nedovoljan broj farmaceuta (36.3%) bili najznačajniji. Ovo je u skladu sa prospektivno identifikovanim uzrocima grešaka u FMEA analizi sprovedenoj u Republici Srbiji, kao i rezultatima drugih studija u kojima su ispitani stavovi farmaceuta u vezi sa ovim pitanjem [1, 24, 25]. Dodatno, dobijeni rezultati ukazuju na to da starost i radno iskustvo farmaceuta u Republici Srbiji, kao i tip javne apoteke u kojoj su zaposleni, značajno utiču na percepciju doprinosa navedenih faktora nastanku grešaka.

Kada su u pitanju intervencije za sprečavanje nastanka grešaka u procesu izdavanja lekova, brojne korektivne mere su od strane farmaceuta percepirane kao potencijalno efikasne strategije za smanjenje rizika, od kojih su najznačajnije obuhvatale sprovođenje kontinuirane edukacije farmaceuta (71%), smanjenje smetnji pri radu (npr. telefonski pozivi) (63.9%), angažovanje više od jednog farmaceuta u smeni (61.9%), posvećivanje više vremena pacijentima prilikom izdavanja leka (60.3%), kao i organizovanje edukacija farmaceuta o intervencijama za upravljanje rizicima (57.8%). Ovo je u skladu sa stavovima farmaceuta u Australiji, Saudijskoj

Arabiji i Etiopiji u vezi sa ovim pitanjem [1, 24, 25]. I u slučaju korektivnih mera za prevenciju nastanka grešaka u izdavanju lekova je uočeno da određene karakteristike farmaceuta u Republici Srbiji, kao što su starost, dužina radnog staža i tip apoteke, značajno utiču na percepiranje njihove efikasnosti u proaktivnom smanjenju rizika.

Podatak da je većina farmaceuta u sprovedenoj studiji u Republici Srbiji (85.2%) izjavila da redovno prijavljuje propuste i neželjene događaje nastale u toku izdavanja lekova ukazuje na relativno zadovoljavajuću praksu prijavljivanja u ovoj zemlji. Ipak, iako je većina ispitanika (N=818, 83.6%) izjavila da nema strah od prijavljivanja grešaka zbog potencijalnog kažnjavanja od strane nadređenog, čak 16.5% učesnika (N=161) je priznalo da ima strah ponekad ili uvek. Kao glavni uzrok postojanja straha zdravstvenih radnika da prijavljuju nastale propuste navodi se kultura krivljenja, koja se smatra izuzetno zastupljenom u javnim apotekama [26]. U skladu sa tim, dobijeni rezultati ukazuju na neophodnost dalje izgradnje kulture bezbednosti u javnim apotekama u Republici Srbiji. Jedan od potencijalnih načina za njeno postizanje jeste uspostavljanje centralizovanog, nacionalnog sistema za dobrovoljno prijavljivanje grešaka u izdavanju lekova, koje bi bilo anonimno, što je već implementirano u brojnim zemljama, uključujući Australiju, SAD, Dansku, Kanadu, Holandiju i Englesku i Vels [27]. Ipak, samo 58.1% ispitanika u Republici Srbiji je izjavilo da bi koristilo nacionalni sistem za dobrovoljno prijavljivanje grešaka u izdavanju lekova, zbog čega je neophodno sprovoditi prilagođene edukacije sa ciljem podizanja nivoa svesti farmaceuta u Republici Srbiji u vezi sa značajem medicinskih grešaka i njihovog prijavljivanja putem ovakvog sistema po njegovom uspostavljanju.

In the Discussion section, the obtained results were thoroughly analyzed and compared with the literature data. This doctoral dissertation provides first findings on the suitability and usefulness of the FMEA method for improving patient safety and the quality of pharmaceutical services in community pharmacies, i.e. at the primary level of health care. The studies performed have prospectively identified various failure modes and potentially effective corrective actions in the medicines dispensing process in community pharmacies, both in Serbia and Germany. Additionally, despite certain organizational and procedural differences in the dispensing of medicines in Serbian and German community pharmacies, a similarity between the most critical patient safety risks in these processes has been found.

One of the most significant findings of the FMEA studies performed refers to the identification of a failure in assessing the appropriateness of therapy prescribed for a particular patient, as the most critical activity in the medicines dispensing in both countries. The results obtained indicate that insufficient pharmacists and PTA's therapeutic knowledge and a lack of their clinical problem-solving skills, represent one of the most significant common causes which contribute to the failure in assessing the appropriateness of therapy for a particular patient in both countries. This is in line with the results of other studies, where these factors have been identified as significant barriers to the provision of pharmaceutical care [2-6]. Accordingly, the introduction of pharmacists and PTAs' continuing education and training in pharmacotherapy and clinical

problem-solving is proposed as one of the key measures for improving the safety of this step in the medicines dispensing processes in both countries.

Limited inter-professional collaboration and ineffective communication between health care providers have also been identified as one of the most significant common causes of a failure in identifying and resolving DRPs during the medicines dispensing processes in both Serbian and German FMEA studies. Accordingly, the most significant corrective measures suggested in both FMEA analyses included conducting joint continuing education and training of pharmacists with other health care professionals, primarily physicians, which is in line with other studies which demonstrated that the collaboration between physicians and pharmacists can lead to the improvement of patient outcomes and their safety [7-9].

Dispensing of the wrong medicine, strength, form or quantity has also been acknowledged as one of the greatest points of concern in the community pharmacy settings in both Serbia and Germany. This is in line with the results reported in other studies, where this type of safety incident has been among the most frequent ones in both hospital and community pharmacies [10, 11]. The brainstorming technique employed by teams in both FMEA studies revealed that the illegible prescriber's handwriting, the use of ambiguous, non-standardized abbreviations when prescribing medicines, as well as the lack of electronic transmission of prescriptions to the pharmacy, and consequent manual transcription of data from prescriptions into the pharmacy software, were the most significant common specific causes of this type of failure modes in the medicines dispensing process. Therefore, the implementation of electronic prescribing systems, integrated with pharmacies, is perceived as one of the most efficient strategies for reducing possible selection and transcription errors during the dispensing processes in both Serbian and German community pharmacies. This is in line with other studies, where the effectiveness of this intervention for improving patient safety and reducing error rates in pharmacy practice has been confirmed [12-14]. In addition, in the FMEA analysis carried out in Serbia, sound-alike/look-alike medicines have also been identified as significant factors that contribute to the occurrence of errors in the selection of the appropriate medicine for dispensing, which is consistent with other studies [10, 15]. Accordingly, storing look-alike/sound-alike medicines separately with additional warnings has been proposed by the FMEA team members as a significant strategy for proactive action and reducing patient safety risk in the dispensing process in Serbian community pharmacies, which is in line with the suggestions given by World Health Organization Collaborating Center for Patient Safety Solutions [16].

Common risks in the medicines dispensing processes in Serbian and German community pharmacies have also been identified in relation to patient counseling. One of the key common causes of these types of failures in both FMEA analyses included ineffective communication between pharmacy staff and patients. Therefore, one of the main corrective actions for reducing risk in patient counseling proposed in both FMEA analyses, included improvement of the quality of communication with patients, by organizing adequate training programs for pharmacy staff. This is in line with the available literature, where the necessity of introducing continuous communication courses for pharmacists and PTAs has been emphasized, in order to develop

their competence and skills in patient counseling, as well as to obtain changes in their practice and behavior patterns in relation to this process [17-19].

Furthermore, one of the top critical points of concern identified in German FMEA study included insufficient promotion of patients' active involvement in the therapy management during counseling or a complete lack thereof (RPN 30). In accordance with the introduction of the patient-centered approach as a 'gold standard' in the provision of health care [20], the relationship between pharmacists and patients has also been changing, whereby the patient becomes an active partner in communication, with whom it is necessary to establish a professional relationship based on trust, open communication and joint decision-making [17]. Accordingly, in the FMEA study carried out in Germany, a key corrective measure proposed for reducing the risk of employing paternalistic approach in the medicines dispensing, i.e. for increasing active involvement of patients in the therapy management, included organizing pharmacists and PTAs' training courses on patient-oriented counseling, which is in line with other studies [18, 21].

Another highly critical failure mode related to the activity of patient counseling, identified as specific for the pharmacy practice in Germany, included the absence of counseling when the medicine is home delivered (RPN 30). The issue of indirect supply of medicines has also been highlighted by the Pharmacy Board of Australia in its Guidelines for dispensing of medicines, where it is stated that this method of delivering pharmaceutical services may be suboptimal due to potentially compromised communication [22]. Consequently, the German FMEA team members have proposed developing guidelines in relation to the performance of telephone counseling after the medicine home delivery as the main corrective action for standardization of this process and improvement of its safety.

The most significant common general causes of dispensing errors, prospectively identified in both Serbian and German study settings, included the lack of medicines dispensing standardization in community pharmacies, as well as pharmacists and PTAs' work overload and interruptions and distractions (excessive noise, frequent telephone calls etc.). Accordingly, one of the main common general corrective measures in both countries included standardizing the medicines dispensing process in community pharmacies by developing appropriate standard operating procedure and organizing the corresponding training for pharmacists and PTAs. Additonally, one of the most significant common general corrective actions for reduction of pharmacy staff work overload in both Serbian and German community pharmacies included service structuring, that is, defining a maximum safe dispensing workload per a pharmacist, which has already been established in some countries, e.g. Australia [23].

The potential effects resulting from the identified failure modes in the medicines dispensing processes in Serbian and German community pharmacies were similar, including first of all a wide range of potentially adverse situations for the patients, but also some negative impacts on the system in case of error occurrence. However, the team members in both FMEA studies have prospectively identified corrective actions which demonstrated a significant potential for

reducing the abovementioned risks in a comparative analysis of the initial and hypothetically redesigned medicines dispensing processes, by 50.3% in Serbia and 25.5% in Germany.

When it comes to the results of the study of Serbian pharmacists' attitudes and beliefs related to the risk management in the medicines dispensing process in the community pharmacy setting, more than the third of the participants in this study (35.4%) indicated that the risk of dispensing errors was increasing, which was lower compared to 44.7%, 62% and 82.2% of the community pharmacists from Ethiopia [24], Saudi Arabia [25] and Australia [1], respectively, who demonstrated this attitude. Additionally, about 21% believed that the actual errors in dispensing were becoming more common in pharmacy practice, which was once again lower compared to the proportion of respondents who demonstrated such opinion in similar studies performed in Ethiopia [24], Saudi Arabia [25] and Australia [1] (42.6%, 55.5% and 47.1%, respectively).

Numerous causative factors were perceived by pharmacists as significant contributors to the occurrence of errors in the medicines dispensing, where illegible prescriber's handwriting (44.3%), interruptions and distractions during dispensing (39.2%), as well as pharmacists' work overload (37.8%) and understaffed shifts (36.3%), were the most significant ones. This is in line with the causes of dispensing errors which were prospectively identified in the FMEA study carried out in the Serbian community pharmacy setting, as well as with the results of other studies which examined pharmacists' attitudes on this issue [1, 24, 25]. In addition, the results obtained indicated that the age and work experience of Serbian community pharmacist, as well as the type of pharmacy where they were employed, influenced significantly their perception of the contribution of the abovementioned factors to the occurrence of errors.

As for the strategies for prevention of dispensing errors occurrence, numerous corrective actions were perceived by pharmacists as important strategies for risk amelioration, of which providing pharmacists with continuing education, particularly in relation to the newly registered drugs (71%), reducing the avoidable interruptions during dispensing (63.9%), increasing the number of pharmacy staff per shift (61.9%), devoting more time to patients' counseling along with involving them more actively in the therapy management (60.3%) and organizing pharmacists' training in the risk minimization strategies and interventions (57.8%), were considered to be the most effective ones. This is consistent with the views of pharmacists in Australia, Saudi Arabia, and Ethiopia on this issue [1, 24, 25]. In addition, the results obtained indicated that certain characteristics of Serbian community pharmacists, such as age, work experience and type of pharmacy where they were employed, influenced significantly their perception of the effectiveness of corrective actions proposed in proactive risk reduction.

The fact that majority (85.2%) of respondents stated that they had routinely reported dispensing incidents and adverse events incurred, indicate good community pharmacists' practice in reporting of dispensing errors. However, although most (83.6%) of the participants declared having no fear about being blamed and\or sanctioned by their superiors should they decide to report dispensing errors, as many as 16.5% of them admitted to having such fear sometimes or always. One of the main reasons for the fear of health care providers to report incidents incurred, includes the existence of the blame culture, which is considered to be highly present in

community pharmacies [26]. Accordingly, the results obtained indicate the need for further building of patient safety culture in Serbian community pharmacies. One of the potential ways to achieve this is to establish a centralized, national voluntary reporting system for errors in the medicines dispensing, which would be anonymous, which has already been developed in a number of countries, such as Australia, the US, Denmark, Canada, the Netherlands, and England and Wales [27]. However, only 58.1% of community pharmacists in Serbian study stated that they would use voluntary dispensing error reporting system, if established, which is why it is necessary to conduct tailored educations with the aim of raising awareness of Serbian community pharmacists regarding the significance of medication errors and their reporting through this type of system.

D. Objavljeni i saopšteni rezultati koji čine deo doktorske disertacije
D. Published results that form part of the doctoral dissertation

Radovi koji čine deo doktorske disertacije sa SCI liste
Papers that form part of the doctoral dissertation published in SCI journals

Stojković T, Marinković V, Jaehde U, Manser T. Using Failure mode and Effects Analysis to reduce patient safety risks related to the dispensing process in the community pharmacy setting, Research in Social & Administrative Pharmacy 2017; 13:1159-1166.

Tip rada: Originalan naučno istraživački rad/*Type of paper: Original article*
IF: 2,403 (2016); ISSN: 1551-7411 (M21)
Rang časopisa 66/265 u kategoriji Public, Environmental & Occupational Health/*Journal ranking 66/265 in the category Public, Environmental & Occupational Health*

Stojkovic T, Rose O, Woltersdorf R, Marinkovic V, Manser T, Jaehde U. Prospective Systemic Risk Analysis of the Dispensing Process in German Community Pharmacies. The International Journal of Health Planning and Management 2018; 33:e320-e332.

Tip rada: Originalan naučno istraživački rad/*Type of paper: Original article*
IF: 1,241 (2016); ISSN: 0749-6753 (M23)
Rang časopisa 56/77 u kategoriji Health Policy & Services; 180/265 u kategoriji Public, Environmental & Occupational Health/*Journal ranking* 56/*77 in the category Health Policy & Services; 180/265 in the category Public, Environmental & Occupational Health*

Rad u vrhunskom međunarodnom časopisu (M21)
Paper in the extraordinary international journal (M21)

Stojković T, Marinković V, Manser T. Using Prospective Risk Analysis Tools to Improve Safety in Pharmacy Settings: A Systematic Review and Critical Appraisal. Journal of Patient Safety 2017, doi: 10.1097/PTS.0000000000000403.

Rad u vodećem časopisu nacionalnog značaja (M51)
Paper in the leading national journal (M51)

Stojkovic T, Marinkovic V, Krajnovic D, Tasic Lj, Milosevic-Georgiev A. Patient safety and medication errors in the provision of health care services-challenges for contemporary practice. Acta Medica Medianae 2016;55(2):57-64.

Saopštenje sa međunarodnog skupa štampano u celini (M33)
Presentation at the international meeting, published in extenso (M33)

Stojkovic T, Marinkovic V, Krajnovic D, Zekovic M, Tasic Lj. Medication errors in the health care delivery-a review of the literature. 6th Congress of Pharmacy in Macedonia with international participation, June 1-5 2016, Ohrid, Macedonia. Macedonian pharmaceutical bulletin 2016. Supplement Vol. 62: p.81-82.

Saopštenja sa međunarodnih skupova štampana u izvodu (M34)
Presentations at the international meetings, published as abstracts (M34)

Stojkovic T, Rose O, Woltersdorf R, Marinkovic V, Manser T, Jaehde U. Failure Mode and Effects Analysis: a useful tool for prospective risk assessment in community pharmacies. 46th ESCP Symposium on Clinical Pharmacy, October 9-11, 2017, Heidelberg, Germany.
Stojković T, Marinković V, Manser T, Woltersdorf R, Rose O, Jaehde U. Comparing findings from prospective risk analyses of the dispensing processes in Serbian and German community pharmacies. 10th PCNE Working Conference 2017, February 1-3 2017, Bled, Slovenia. Int J Clin Pharm, doi: 10.1007/s11096-017-0462-2.
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Stojković T, Marinković V, Krajnović D, Zeković M, Tasić Lj. Dispensing errors in the outpatient setting: pharmacists' perspective. Nordic Social Pharmacy and Health Services Research Conference (NSPC) 2017, June 7-9 2017, Kuopio, Finland. Book of abstract. p.31.
Stojković T, Marinković V, Zeković M, Krajnović D, Tasić Lj. Community pharmacists' practice in reporting of dispensing errors in Serbia. III Scientific Symposium "Health Outcomes & Social Pharmacy", Central & Eastern European Symposium, March 23-24 2018, Belgrade, Serbia. Book of abstracts. p.80.

E. Zaključak - obrazloženje naučnog doprinosa doktorske disertacije
E. Conclusion – explanation of the scientific contribution of doctoral dissertation

Podaci prezentovani u ovoj doktorskoj disertaciji pružaju originalan doprinos unapređenju kvaliteta usluga i bezbednosti pacijenata u farmaceutskoj praksi na primarnom nivou zdravstvene zaštite. Na osnovu iznetih rezultata i diskusije doneti su sledeći zaključci.

Sprovedene FMEA studije prospektivne sistemske analize rizika u izdavanju lekova u javnim apotekama u Republici Srbiji i SR Nemačkoj omogućile su identifikaciju velikog broja grešaka i korektivnih mera u obe zemlje. Dodatno, uprkos određenim organizacionim i proceduralnim razlikama u ovom procesu u Republici Srbiji, kao zemlji u razvoju, i SR Nemačkoj, kao razvijenoj zemlji, najkritičniji rizici za bezbednost pacijenata su bili isti. Takođe, u obe analize je uočen značajan potencijal za smanjenje rizika u slučaju implementacije kombinacije predloženih intervencija, što ukazuje na njihovu efikasnost u proaktivnom delovanju na detektovane sistemske slabosti i bezbednosne probleme u analiziranim procesima izdavanja lekova.

Dobijeni rezultati predstavljaju prva saznanja o primeni FMEA metode u farmaceutskoj praksi na primarnom nivou zdravstvene zaštite, i obezbeđuju potvrdu koncepta da je ovaj alat prospektivne sistemske analize rizika koristan i adekvatan za unapređenje bezbednosti pacijenata i kvaliteta farmaceutske usluge u procesu izdavanja lekova u javnim apotekama, na osnovu čega se podstiče njegova dalja primena u ovim zdravstvenim ustanovama u budućnosti. Takođe, iako dobijena saznanja ne mogu biti u potpunosti primenjena u javnim apotekama drugih zemalja, zbog razlika u sprovođenju izdavanja lekova, navedeni metodološki pristup smanjenju rizika povezanih sa ovim procesom svakako jeste prenosiv.

Dodatno, kvantifikacija potencijala predloženih korektivnih mera za unapređenje bezbednosti pacijenata i njihova prioritizacija u sprovedenim FMEA analizama predstavljaju osnovu za dalju farmakoekonomsku evaluaciju i procenu njihove troškovne-isplativosti, što je od velikog značaja pri donošenju odluke o implementaciji u uslovima limitiranih resursa u zdravstvenim sistemima. U skladu sa tim, prospektivna sistemska analiza rizika treba da čini sastavni deo svake strategije za unapređenje bezbednosti pacijenata i kvaliteta zdravstvenih usluga.

Dobijeni rezultati istraživanja stavova farmaceuta u Republici Srbiji u vezi sa upravljanjem incidentima u izdavanju lekova ukazuju na njihovu svesnost o postojećim rizicima vezanim za ovaj proces, kao i aktuelnom nastanku grešaka. Dodatno, identifikovani su najznačajniji uzročni faktori i strategije za prevenciju propusta prema stavu farmaceuta, koji su u skladu sa rezultatima FMEA analize i koje bi trebalo implementirati sa ciljem proaktivnog delovanja na sistemske slabosti i sprečavanja nastanka preventabilnih neželjenih događaja pre nanošenja štete pacijentu.

Iako dobijeni rezultati ukazuju na zadovoljavajuću praksu farmaceuta u vezi sa prijavljivanjem grešaka u izdavanju lekova, dalja izgradnja kulture bezbednosti u javnim apotekama, kao i sprovođenje prilagođenih edukacija o medicinskim greškama su neophodni za unapređenje bezbednosti pacijenata i kvaliteta farmaceutske zdravstvene usluge.

The data presented in this doctoral dissertation provide an original contribution to improving the quality of services and patient safety in pharmaceutical practice at the primary level of health care. The following conclusions were drawn from the presented results and discussion.

The FMEA studies of prospective systemic risk analyses of the medicines dispensing processes performed in the community pharmacy settings in Serbia and Germany have identified various failure modes and potentially effective corrective actions in both countries. Furthermore, despite certain organizational and procedural differences in the performance of this process in

community pharmacies in Serbia, as developing country, and Germany, as developed country, the most critical patient safety risks were found to be similar. Additionally, a significant potential for risk reduction in case of implementation of suggested remedial measures has been observed in both analyses, thereby indicating their possible effectiveness in proactive action on detected systemic weaknesses and safety issues in the analysed processes.

The results obtained represent the first findings on the application of the FMEA method in pharmacy practice at the primary level of health care, and establish a proof of concept that this approach is suitable and useful for improving patient safety and the quality of pharmaceutical services in the process of medicines dispensing in community pharmacies, thereby encouraging its further application in these health care facilities in the future. Also, even though the findings obtained may not be generalizable across national contexts due to the differences in the way the dispensing process is organized, the methodological approach that can help reduce the risks associated with the dispensing process in community pharmacies certainly is transferrable.

Furthermore, the quantification of the potential of corrective measures to increase patient safety, and their consequent prioritization in the performed FMEA studies, can be used as a yardstick for their further cost-effectiveness analysis, which is of great importance in often resource-limited health care environments. Thus, prospective systemic risk analysis should form an integral part of any strategy for improvement of patient safety and pharmaceutical service quality.

The results of the study on Serbian community pharmacists' attitudes towards risk management in the medicines dispensing suggest that they are aware of the existing risk related to this process, as well as the factual errors occurrence. Additionally, the main causative factors and corrective actions have been identified, which should be further put into practice in order to manage dispensing risks prospectively and prevent the occurrence of adverse events before causing harm to the patient. Finally, although the results obtained indicate good Serbian community pharmacists' practice in reporting of dispensing errors, further building of patient safety culture in community pharmacies as well as conducting tailored educations regarding medication errors is necessary, in order to improve patient safety and pharmaceutical service quality.

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F. Mišljenje i predlog komisije
F. Opinion and proposal of the Committee

Na osnovu izloženog, Komisija zaključuje da je kandidat magistar farmacije, specijalista Tatjana Stojković uspešno realizovala postavljene ciljeve istraživanja i da rezultati prikazani u ovoj doktorskoj disertaciji predstavljaju značajan naučni doprinos u oblasti Socijalna farmacija i istraživanje farmaceutske prakse, i predlaže Nastavno-naučnom veću Farmaceutskog fakulteta Univerziteta u Beogradu da prihvati pozitivnu ocenu doktorske disertacije pod naslovom: **"Prospektivna sistemska analiza rizika u procesu izdavanja lekova u javnoj apoteci - perspektiva unapređenja kvaliteta usluga i bezbednosti pacijenata"** i omogući kandidatu da pristupi javnoj odbrani iste.

On the basis of the aforementioned, the Committee concludes that the candidate M.Sc. Pharm. Spec. Tatjana Stojković has successfully implemented the set goals of the research and that the results presented in this doctoral dissertation represent a significant scientific contribution in the field of Social pharmacy and pharmacy practice research, and proposes to the Academic Council of the Faculty of Pharmacy, University in Belgrade to accept a positive evaluation of the doctoral dissertation entitled ***"Prospective systemic risk analysis of the medicines dispensing process in the community pharmacy setting - perspective of pharmaceutical service quality and patient safety improvement"*** *and enable the candidate to access its public defense.*

Članovi komisije/Committee members

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U Beogradu/*In Belgrade,*
30.3.2018.