A MODEL FOR RISK ASSESSMENT IN HEALTH CARE USING A HEALTH CARE FAILURE METHOD AND EFFECT ANALYSIS

MODEL OCENJEVANJA TVEGANJ V ZDRAVSTVU Z UPORABO METODE ANALIZE MOGOČIH NAPAK IN NJIHOVIH POSLEDIC, PRILAGOJENE ZA ZDRAVSTVO

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Abstract

Objective: *The purpose of this research is to track and reduce risks so as to prevent errors within the process of health care. The aim is to design an organizational information model using error prevention methods for risk assessment.*
Method: *In order to assess the risk of errors, the Health Care Failure Mode and Effect Analysis is used. To determine the causes of the errors, the Root Cause Analysis is used.*
Results: *Results of the process analysis following corrective measures shows that the risk assessment of individual error causes reduced by73.6 percent. Re-evaluation of the risks to the whole process shows that the overall risk score was decreased by 45.5 percent. The proposed model has a significant impact on professional attention, communication and information, critical thinking, experience and knowledge. The average impact of information communication technology on the reduction of medication administration errors is 56 percent. These findings represent an increase in the quality of care.*
Conclusions: *The results of our research are theoretically and practically useful and verifiable in other environments, if the level of the organizational culture and the culture of recording errors in combination with the precise recording of data to assess the risk of errors in the process. The model provides a standardized data format that can be used for the purpose of defining factors for the occurrence of errors, for developing a base of knowledge for learning from mistakes and for continuous verification and adaptation to changes in the environment in order to prevent errors.*

Key words: health care, patient safety, errors, information communication technology

Izvirni znanstveni članek
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Izvleček

Namen: *Namen raziskave je zmanjševanje tveganj in posledično preprečevanje napak v procesu zdravstvene oskrbe. Cilj raziskave je oblikovanje organizacijsko-informacijskega modela preprečevanja napak z uporabo metod za ocenjevanje tveganj v kliničnem okolju.*
Metode: *Za ocenitev tveganj za nastanek napak v procesu zdravstvene oskrbe smo uporabili metodo analize mogočih napak in njihovih posledic, prilagojeno za zdravstvo. Za ugotovitev vzrokov za nastanek napak smo uporabili metodo analize temeljnih vzrokov.*
Rezultati: *Izsledki analize v kliničnem okolju kažejo, da je z uvedbo korektivnih ukrepov ocena tveganj posameznih vzrokov zmanjšana za 73,6 %. Opazen je vplivi na celoten proces in se je skupna ocena tveganj zmanjšala za 45,5 %. Predlagan model pomembno vpliva na strokovno pozornost, komunikacijo in informiranje, kritično razmišljanje ter na izkušnje in znanje. Povprečen vpliv informacijsko-komunikacijske tehnologije na pravilno izvajanje postopka aplikacije zdravil je 56-odstoten. S tem se je zvišala kakovost zdravstvene oskrbe.*
Zaključek: *Izsledki raziskave so teoretično in praktično uporabni in preverljivi v drugih okoljih, če le stopnja organizacijske kulture in kulture evidentiranja napak izpolnjuje zahteve po natančnem evidentiranju podatkov za ocenitev tveganj za nastanek napak v procesu zdravljenja. Model omogoča standardiziran zapis podatkov, ki se*

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lahko uporablja v namen opredelitve dejavnikov za nastanek napak, izgradnjo baze znanj za učenje iz napak ter za kontinuirano verifikacijo in prilagajanje organizacije spremembam v okolju s ciljem preprečevanja napak.

Ključne besede: zdravstvo, varnost bolnika, napake, informacijsko-komunikacijska tehnologija

1 INTRODUCTION

Patient safety is the reduction of the risk of unnecessary harm associated with healthcare to an acceptable minimum, whic his fundamental to ensuring quality of health care (1). The reducing of risk is an important topic in the field of health care, not only for the public but also for politicians, administrators and the economy as a whole (2-7). In the Final Technical Report of Conceptual Framework for the International Classification for Patient Safety by the World Health Organisation (WHO), Patient safety is defined as the reduction of the risk of unnecessary harm associated with healthcare to an acceptable minimum. An acceptable minimum refers to the collective notions based on the given current knowledge, resources available and the context in which care was delivered; these are weighed against the risk of non-treatment or other administration of another treatment. At the same time, the patient safety incident is determined as an event or circumstance that could have resulted, or did result, in unnecessary harm to a patient. Errors may be manifested by doing the wrong thing (commission) or by failing to do the right thing (omission) during either the planning or execution phase (1). More commonly, errors are caused by faulty systems, processes and conditions that lead people to make mistakes or fail to prevent them (6, 8).

Health care errors are often termed as medical errors and described as human errors within health care. An error is defined as the failure of a planned action to be completed as intended or the use of a wrong plan to achieve an aim (1, 2, 9). To assess the risk of errors, various methods of analysis can be used such as: Preliminary Hazard Analysis - PHA; Method Organised for a Systemic Analysis of Risks - Mosar), Fault Tree Analysis - FTA; Root Cause Analysis - RCA), Hazard Analysis and Critical Control Points - HACCP; Failure Mode and Effect Analysis - FMEA and others. Each organization must decide which tool is best suited to theproduct or service. It is important who the clients are and what knowledge exists within the organization. In itself, a single method is not a panacea but should be used in combination with other methods and tools for problem solving to eliminate or reduce risks (3, 10, 11). Safety is measured by proactive methods and means continuous control and adjustment of the system's basic processes (1, 2, 4, 6).

There is significant attention in scientific journals and other relevant sources given to the empirical study of methods of analysis for risk assessment in the industry. In health care, it is possible to trace some of this research and analysis in the international environment (11-13). To date, there have been no studies conducted in Slovenia as presented in the paper.

The purpose of our research is to reduce risks and hence prevent errors in the process of the delivery of health care. The aim is to design an organizational information model using error prevention methods for risk assessment in a clinical setting. The model is based on selected indicators of quality nursing care, resulting from world-known theoretical and practical models combined with experience in Slovenian health care.

This article presents the use of HFMEA in combination with other methods, techniques and tools for risk assessment model developing. The new organizational information model and software solution designed to prevent errors within the process of health care is described. The article concludes with a discussion of implications from this study for both health care providers and health policy officials involved in outcome-based, quality improvement initiatives.

2 METHODS

The risk assessment model was developed by combination of four methods: the Health care Failure Mode and Effect Analysis (HFMEA) in order to assess the risk of errors; the Root Cause Analysis (RCA) in order to determine the causes of the errors: the Method of Structured Analysis for the analysis of work processes and information system design; Dynamic systems development method (DSDM) for the development of software prototype.

HFMEA is a method designed to identify the possibility of deviations from the planned process, to assess the risks associated with these variations and to identify and implement corrective actions to address these. The HFMEA driven transformation process is aimed at reducing the risk of errors. In planning corrective actions, it is necessary first to focus on events that show the occurrence of a high frequency of errors and the high severity of the damage. Evaluation of HFMEA works best at the level of sub processes or specific

parts where there is the greatest probability of errors occurring. HFMEA is a prospective method because it helps identify where and when possible system failures could occur and to prevent those problems before they happen. It is a 5-step process that uses an interdisciplinary team to proactively evaluate a health care process: Define the HFMEA Topic; Assemble the Team; Graphically Describe the Process; Conduct a Hazard Analysis; Actions and Outcome Measures (3).
RCA explores not only causes of a technical nature but also other factors such as human, environmental and organizational causes. It is a method to identify sources of errors or failure in order to prevent repeating the same mistakes and is used after the occurrence of errors or system failure. It is applied in a retrospective way, looking for the basic reason and causes of error or risk. An underlying cause may result in more than one deviation, defect, error or risk and can in turn cause related incidents (14).
Causes can be traced back to root causes with the application of the following questions: What is the problem; What happened; and What are the measures to be undertaken? In health care, it is used in the search for causes of errors and complications or fatal outcomes (15-18).
The Method of Structured Analysis is a front-end methodology that allows users and/or systems analysts to convert a real-world problem into a pictorial diagram or other logical representation. This is subsequently used by systems developers and/or programmers to design an information system. The major steps in structured analysis are: Study the current business environment; Model the old logical system; Model the new logical system; Model the new physical environment; Evaluate alternatives; Select the best design; and Create the structured specification (19).
DSDM is one of a number of methods for developing software solutions. There are four stages of the DSDM Project life-cycle: The Feasibility Study; The Business Study; Functional Model Iteration; System Design and Build Iteration; and Implementation. The main focus of System Design and Build Iteration is to integrate the functional components from the previous phase into one system that satisfies user needs and can be subdivided into four sub-stages: Identify Design Prototype; Agree Schedule; Create Design Prototype; and Review Design Prototype. The deliverable for this stage is a Prototype prepared for testing. The prototype should be integrated into the information system and implemented in practice when the design and functions are consolidated (20).

3 MODEL DEVELOPMENT DESCRIPTION

To develop the model, we followed the steps of HFMEA but also used other methods, techniques and tools for the realization of the individual steps of HFMEA. So, for the use in practice HFMEA was extended with other methods and tools (Figure 1).

Step 1. Defining a Topic
The first step in conducting HFMEA is selection of a suitable topic or problem. Based on published research results (21-24) and structured interviews with health care providers at the selected clinical departments, we determined the medication administration process to be a process with a high risk of error. Then we continued through the next steps of the HFMEA method.

Step 2. Assembling a Team
In 2010, a multidisciplinary team of professionals (doctors, nurses, pharmacists and informatics with specialized knowledge of work processes in health care) was assembled to ensure that various viewpoints were considered. Members from different professions ensured that the group looked at how the process is actually carried out, encouraged a critical view with regard to accepted standards and practices and recognized vulnerabilities that could be overlooked by individual professions. Group meetings where held at different frequencies according to the phase of the research and development of a prototype. In developing the prototype, we also included a group of end users.

Step 3. Describing a Process
To transform the abstract problem into a logical design the Method of Structured Analysis was used. The health care process in a hospital and the detailed process of medication administration are shown in flow charts.

Step 4. Analysing Hazards
To identify and assess potential vulnerabilities, we used a HFMEA Hazard Scoring Matrix (Table 1) and the HFMEA Decision Tree (3).

Table 1. HFMEA Hazard Scoring Matrix (3).
Tabela 1. HFMEA Točkovna matrika tveganj (3).

Probability/ Verjetnost	Severity of Effect / Resnost učinka			
	Catastrophic / Katastrofalen	Major / Resen	Moderate / Srednje resen	Minor / Manj resen
F = Frequent / Pogosto	16	12	8	4
O = Occasional/ Občasno	12	9	6	3
U = Uncommon / Izredno	8	6	4	2
R = Remote / Redko	4	3	2	1

By using the HFMEA Hazard Scoring Matrix, it is possible to determine the severity and probability of the potential failure mode. The severity score is a measure of the potential effect of the failure mode. In these steps, we are looking to answer the question: What would be the impact on patients or patient care if failure should happen? The severity categories include catastrophic, major, moderate and minor, with specific operational definitions developed. The probability ratings include frequent (several times in 1 year), occasional (several times in 2 years), uncommon (sometime in 2 to 5 years) and remote (5 to 30 years). In planning corrective actions, it is necessary to focus on events that are estimated within the 4 categories. This table was developed by a workgroup at the Department of Veterans Affairs, U.S. National Centre for Patient Safety (NCPS) specifically for this purpose (3). The Decision Tree helps us to determine whether we act on the basis of criticality, if control measures have been identified and whether there is a possibility of hidden risks. The aim of this process is to focus only on the critical parts of the process. The process of decision-making is looking for answers to specific questions: How I measure any error must be assessed? What is the weak point? What is an effective control measure? What may be an example of the risks that can be detected? We assessed an error inviolation of "Rule5 R" for medication administration: Right Patient, Right Medication, Right Dose, Right Route and Right Time. Rule 10 R also indicates Right Documentation; Right Assessment; Right to Refuse Medication; Right Evaluation; Right Patient Education. In our research, it is assumed that the physician determines the proper administration for the right reason. "Rule 5 R" is one of the important indicators of the quality of nursing care. Assessment of the risk of adverse events or errors helps in identifying which areas are priorities to focus on, and this also allows you to search for opportunities for improvements.

For each error, we identified possible causes of errors by the Method of RCA. To search for possible causes of errors, an Ishikawa diagram is used. It rates whether: unreadable record, prescription for application is given orally; incorrect copy of data; replacement documentation; patient is incapable of communication, wrong choice of medication; miscalculation, a mistake on the infusion pump, lack of medication or materials, lack of knowledge or experience; or inadequate organization, are possible causes for errors or violation of "Rule 5 R".

Step 5. Identifying Actions and Expected Outcomes
Next, we identify corrective actions that may affect the risk factors for the occurrence of errors or deviations in the process: the implementing bar codes, computerized planning and implementing health care process, computerized human resource planning and control of medications stock. We described expected outcomes and identified a single person responsible for completing or ensuring completion of each action. The HFMEA Worksheet was used to record the assessments, corrective actions, follow-up responsibilities and outcome measures.
We then developed a new model of the process (Figure 2) and a new flow chart diagram for medication administration (Figure 3). To realize the corrective action, the project 'Electronic supported healthcare at General Hospital Celje' was established. For this purpose, we used the Dynamic systems development method. The software solution was developed and integrated into the Hospital information system to support the comprehensive health care process. The prototype was developed used modern information communication technology (ICT), including the results of risk assessments and embedded security mechanisms to prevent errors. A prototype solution is based on the following criteria:

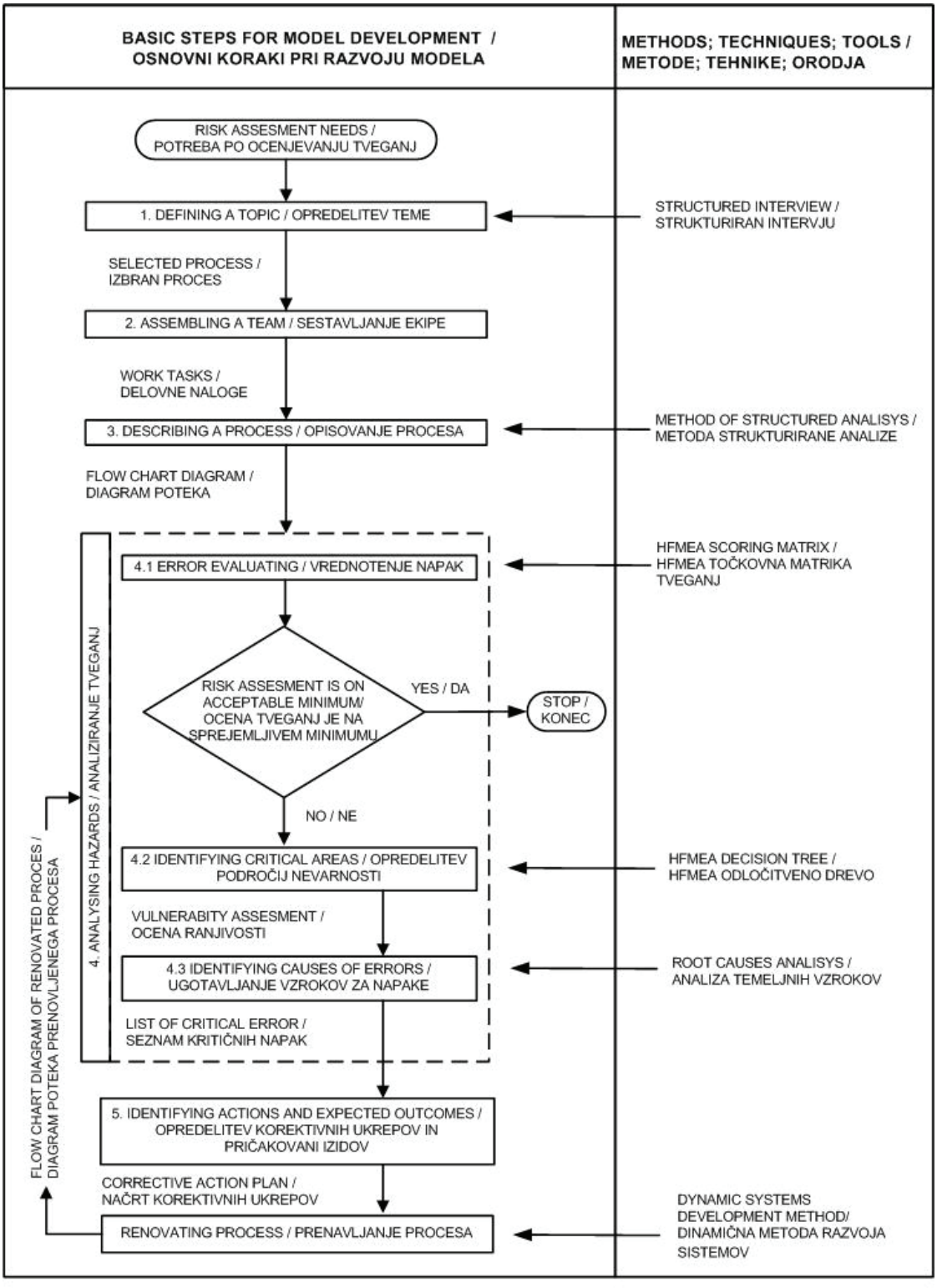
- user-friendly interface;

- easy and quick access to information through one entry point;
- use classifications and standard procedures;
- use of modern technology;
- possibility of recording deviations from the planned process;
- possibility of preventing illogical orders and procedures.

The multidisciplinary team agreement was the need to keep the form of access to medical records as the paper version – i.e. in a spreadsheet.

Through this process, we identified a set of procedures that can be improved with the help of ICT and thus achieve better performance of health workers. We identified and defined standard sets: patient personal data; hospitalization data; diagnosis; procedures/ interventions; drug therapy; diet; vital signs; fluid balance; lab reports; x-ray; other diagnostic tests; allergies; infections; activities / physiotherapy; (nursing care); consultant reviews; and general observations. When designing a solution, we considered the possibility of easy adaptation to view medical records and treatment plans according to the needs of different users. A prototype solution was tested at the Paediatric Unit of the General Hospital Celje, Slovenia. Testing was performed two times following the scenarios that support the work process. Analysis of assessments of scenarios shows that the user interface for access to medical records meets the expectations of users. Navigation between open windows was rated as "excellent". Of the 12 scenarios, 75% were rated as "very good." Users did not express any functional requirements for major changes but only minor improvements to the graphical interface. Finally, we evaluated the software solution with a SWOT (Strengths, Weaknesses, Opportunities and Threats) analysis.

A new organizational information model requires the renovation of existing process and a new way of thinking. After the corrective actions, the performance of new/modified processes was measured (Table 2, 3 and 4). We estimated that the new IT organizational model could also be implemented at other departments in the hospital.



LEGEND: HFMEA – HEALTH CARE FAILURE MODE AND EFFECT ANALYSIS
LEGENDA: HFMEA – METODA ANALIZE MOŽNIH ZDRAVSTVENIH NAPAK IN NJIHOVIH POSLEDIC

Figure 1. *Basic steps for model development.*
Slika 1. *Osnovni koraki pri razvoju modela.*

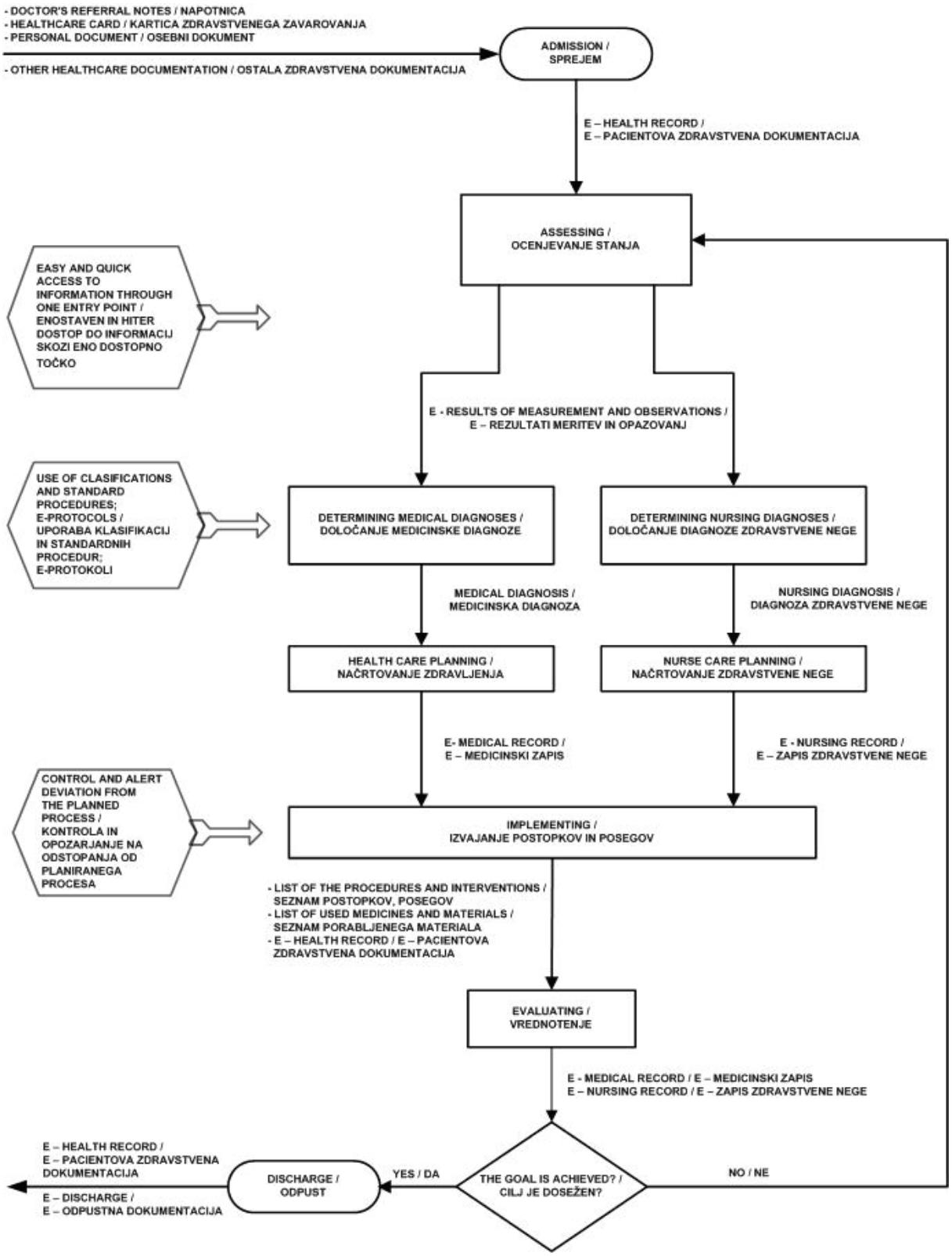


Figure 2. *Model of hospital process supported by ICT.*
Slika 2. *Model procesa bolnišnične obravnave ob uporabi IKT.*

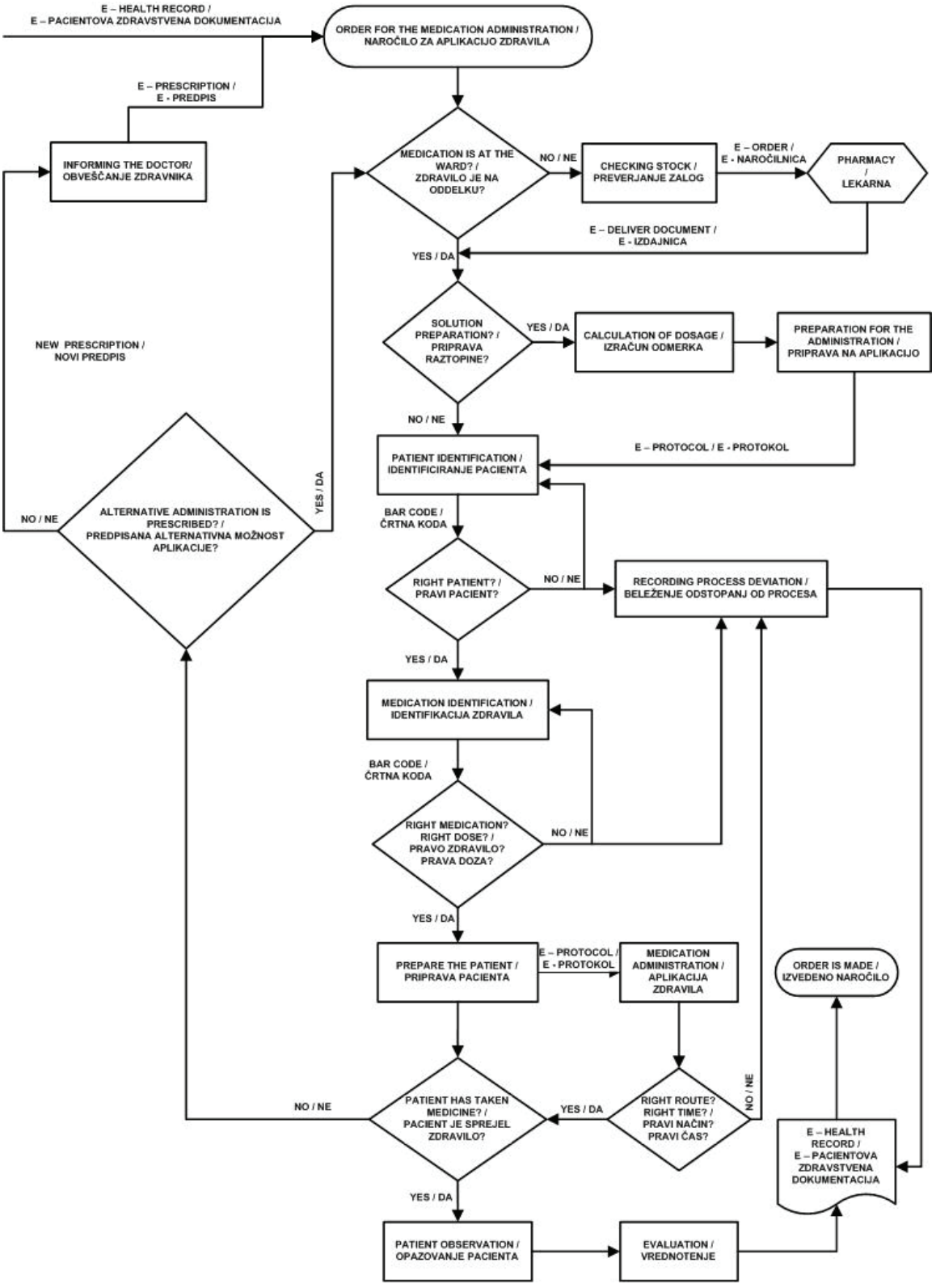


Figure 3. *Flow chart diagram for medication administration following corrective measures.*
Slika 3. *Diagram poteka pri aplikaciji zdravila po izvedbi korektivnih ukrepov.*

4 RESULTS

Before this research project, there was no systematic recording of errors or deviations from the planned processes. In assessing the criticality of errors and vulnerabilities, we used a structured interview, HFMEA Scoring Matrix and the Decision Tree. For each error, we identified possible causes of errors by the Method of RCA: unreadable record, prescription for application is given orally; incorrect copy of data; replacement documentation; patient is incapable of communication; wrong choice of medication; miscalculation; a mistake on the infusion pump; lack of medication or materials; lack of knowledge or experience; inadequate organization. We grouped them into categories: professional attention; communication and information; knowledge and experience; creative and critical thinking; working conditions. The new organizational information model and software solution has a significant impact on professional attention, communication and information, critical thinking, knowledge and experience (Figure 4). ICT has the highest impact on communication and information and consequently professional attention. By providing easy and quick access to information through one entry point, we enabled high availability of information and ease of understanding and therefore creative and critical thinking. Electronic ordering and barcodes allow for 100 percent reduction of causes of errors.

Through embedding security mechanisms into software solutions, ICT has an influence on critical thinking and cognitive ability and therefore critical thinking and knowledge. The computerized method of drug medication dose calculation corresponded to a 67 percent reduction of the causes of errors.

ICT does not have a direct impact on the working conditions but enables better organization of work. The average impact of ICT on medication administration by the “5R rule” is 56 percent or a reduced probability of error by this value. These outcomes have increased the quality of care. The electronic support of processes, planning, staff and medicine stocks could further reduce the impact on the probability of error by65 percent (Table 4).

Table 2. The risk assessment of individual error causes.
Tabela 2. Ocena tveganj posameznih vzrokov za nastanek napak.

Potential Error Causes / Možni vzroki za napako	**PRA / POT**	**Corrective action / Korektivni ukrepi**	**RACA / OTKU**
A1a Replacement documents / Zamenjava dokumentacije	8	unique identification using barcode / nedvoumna identifikacija z črtno kodo	0
A1b Patient is incapable for communication / Pacient ni zmožen komunikacije	8	unique identification using barcode / nedvoumna identifikacija z črtno kodo	0
A1c Incorrect copy of data / Napačen prepis podatkov	8	all orders are electronically / vsa naročila so v elektronski obliki	0
A2a Unreadable record orders / Neberljiv zapis naročila	12	all orders are electronically / vsa naročila so v elektronski obliki	0
A2b Incorrect copy of data / Napačen prepis podatkov	4	all orders are electronically / vsa naročila so v elektronski obliki	0
A2c Wrong medication / Napačno zdravilo	4	unique identification using barcode / nedvoumna identifikacija z črtno kodo	0
A2d Order for the administration is given orally / Naročilo za aplikacijo je podano ustno	8	any oral order is subsequently verified electronically / vsako ustno naročilo je pozneje elektronsko verificirano	4
A3a Unreadable record orders / Neberljiv zapis naročila	12	all orders are electronically / vsa naročila so v elektronski obliki	0

A3b Incorrect copy of data / Napačen prepis podatkov	12	all orders are electronically / vsa naročila so v elektronski obliki	0
A3c Miscalculation / Napačen izračun	12	computerized method of calculation / elektronsko podprt postopek izračuna	4
A3d Order for the application is given orally / Naročilo za aplikacijo je podano ustno	8	any oral order is subsequently verified electronically / vsako ustno naročilo je pozneje elektronsko verificirano	4
A3e Error on the infusion pump / Napaka na infuzijski črpalki	4	regular service and calibration / redni servisi in kalibracija	4
A4a Unreadable record orders / Neberljiv zapis naročila	4	all orders are electronically / vsa naročila so v elektronski obliki	0
A4b Incorrect copy of data / Napačen prepis podatkov	4	all orders are electronically / vsa naročila so v elektronski obliki	0
A4c Lack of knowledge and experience / Pomanjkanje znanj ali izkušenj	4	control knowledge and skills / preverjanje znanja in veščin	4
A5a Unreadable record orders / Neberljiv zapis naročila	8	all orders are electronically / vsa naročila so v elektronski obliki	0
A5b Incorrect copy of data / Napačen prepis podatkov	4	all orders are electronically / vsa naročila so v elektronski obliki	0
A5c Inadequate organization / Neustrezna organizacija	8	appropriate allocation of personel and tasks / ustrezno razporejanje kadra in opravil	4
A5d Order for the application is given orally / Naročilo za aplikacijo je podano ustno	8	any oral order is subsequently verified electronically / vsako ustno naročilo je pozneje elektronsko verificirano	4
A5e Lack of medicines or materials / Pomanjkanje zdravil ali materiala	4	electronic alert to the critical status of individual stocks / elektronsko opozarjanje na kritično stanje posameznih zalog	2
Overall risk assessment / Skupna ocena tveganj	144		38

LEGEND: PRA = PRELIMINARY RISK ASSESSMENT
RACA = RISK ASSESSMENT AFTER CORRECTIVE ACTION
LEGENDA: POT = PREDHODNA OCENA TVEGANJ
OTKU= Ocena tveganj po uvedbi korektivnih ukrepov

Table 3. *The overall risk assessment of medication administration process.*
Tabela 3. *Skupna ocean tveganj pri aplikaciji zdravil.*

Type of error / Oblika napake	Preliminary risk assessment/ Predhodna ocena tveganj	Risk assessment after corrective action / Ocena tveganj po uvedbi korektivnih ukrepov
A1 Medicine received the wrong patient/ Zdravilo je prejel napačen pacient	8	4
A2 Administered the wrong medication/ Aplicirano je napačno zdravilo	12	4
A3 Administered the wrong dose/ Aplicirana je napačna doza	12	4
A4 Not administered on the right route/ Ni aplicirano na pravi način	4	4
A5 Application is not at the right time/ Aplikacija ni ob pravem času	8	4
Overall risk assessment/ Skupna ocena tveganj	44	20

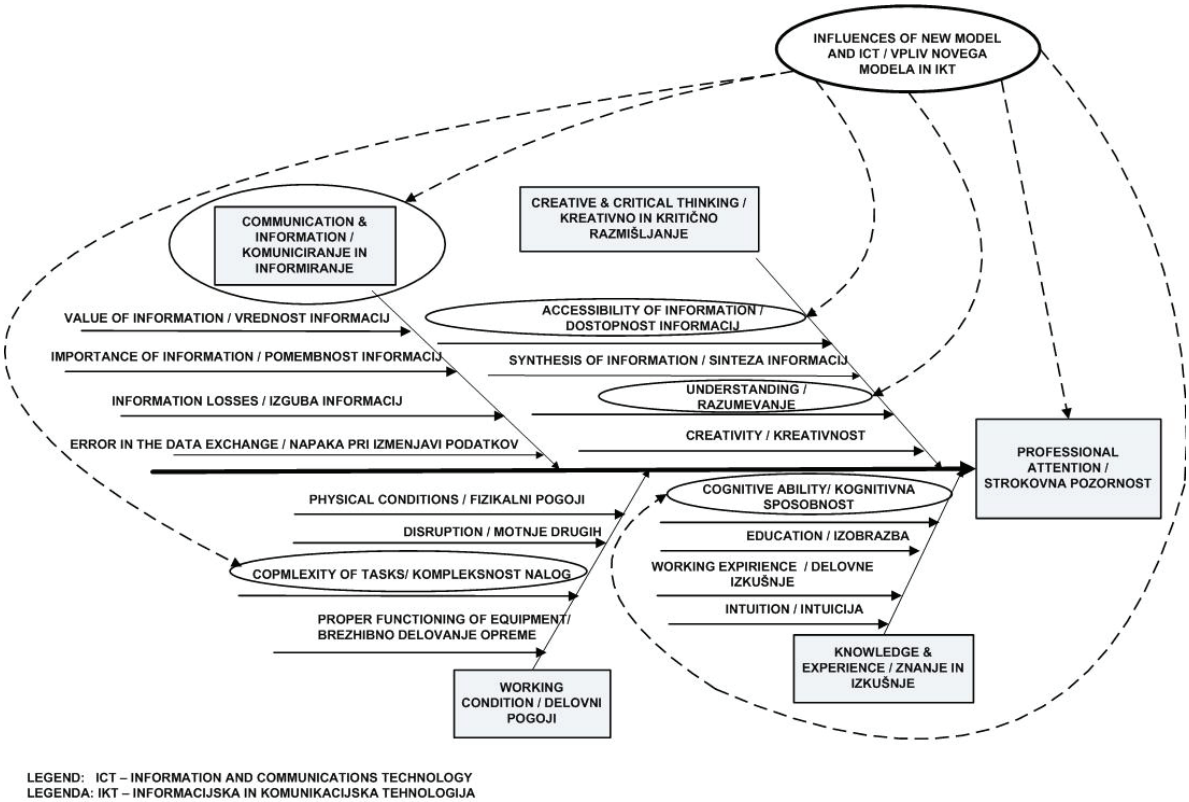


Figure 4. *The influence of the new model and ICT on the risk factors that affect professional attention.*
Slika 4. *Vpliv novega modela in IKT na dejavnike tveganj, ki vplivajo na strokovno pozornost.*

Table 4. *The impact of corrective actions on critical factors.*
Tabela 4. *Vpliv korektivnih ukrepov na dejavnike tveganj.*

Causes of errors/ Vzrok napake	Group of risk factors/ Skupina dejavnikov tveganj	Corrective actions to reduce risk factors/ Vpliv korektivnih ukrepov na dejavnike tveganj		Risk assessment/ Ocena tveganj		Impact on reducing errors/ vpliv na zmanjšanje napak	
		Human/ Človek	ICT/ IKT	before/ pred	after/ po	ICT/ IKT	ICT and human/ IKT in človek
replacement documents/ zamenjava dokumentacije	professional attention/ strokovna pozornost	verification of data, two-way communication with the patient/ preverjanje podatkov, dvosmerna komunikacija s pacientom	identification by using barcode	8	0	100 %	100 %
patient is incapable of communication/ pacient ni zmožen komunikacije	professional attention/ strokovna pozornost	verification of documentation, exchange of information with colleagues/ preverjanje podatkov v dokumentaciji, izmenjava informacij z sodelavci	identification by using barcode/ identifikacija z uporabo črtne kode	8	0	100 %	100 %
incorrect copy of data/ napačen prepis podatkov	professional attention/ strokovna pozornost	repeated checking of recorded data/ večkratno preverjanje napisanih podatkov	all orders are electronically/ vsa naročila so v elektronski obliki	8	0	100 %	100 %
wrong medication/ napačna izbira zdravila	professional attention/ / strokovna pozornost	check record on medicine/ preverjanje zapisa na zdravilu	identification by using barcode/ identifikacija z uporabo črtne kode	4	0	100 %	100 %
unreadable record orders/ neberljiv zapis naročila	professional attention/ strokovna pozornost communication and information/ komunikacija in informiranje	verification of data/ preverjanje podatkov two-way communication nurses – doctor/ dvosmerna komunikacija z zdravnikom	all orders are electronically/ vsa naročila so v elektronski obliki	12	0	100 %	100 %

order for the application is given orally/ naročilo za aplikacijo je podano ustno	professional attention/ strokovna pozornost communication and information/ komunikacija in informiranje	verification of data/ preverjanje podatkov two-way communication nurses – doctor/ dvosmerna komunikacija z zdravnikom	computerized method of verification/ elektronska verifikacija	8	4	50 %	50 %
miscalculation/ napačen izračun	professional attention/ strokovna pozornost knowledge, experience / znanje, izkušnje creative and critical thinking/ kreativno in kritično razmišljanje	understanding and integration of data/ razumevanje in povezovanje podatkov consultation with colleagues/ posvet z sodelavci	computerized method of calculation/ elektronsko podprt postopek izračuna	12	4	67 %	67 %
error on the infusion pump/ napaka na infuzijski črpalki	professional attention/ strokovna pozornost working conditions/ delovni pogoji	check sheets servicing and calibration/ preverjanje liste servisiranja in kalibracij	no direct influence/ ni direktnega vpliva	4	4	0 %	0 %
lack of knowledge or experience/ pomanjkanje znanj ali izkušenj	knowledge, experience / znanje, izkušnje	control knowledge and skills/ preverjanje znanja in veščin	no direct influence/ ni direktnega vpliva	4	4	0 %	0 %
inadequate work organization/ neustrezna organizacija dela	working conditions and complexity of tasks/ delovni pogoji in kompleksnost delovnih nalog	appropriate allocation of personel/ ustrezno razporejanje kadra in opravil	no direct influence / ni direktnega vpliva	8	4	0 %	50 %

lack of medicines or materials/ pomanjkanje zdravil ali materiala	complexity of tasks/ kompleksnost delovnih nalog	regular stock checks/ redno preverjanje zalog provide 24-hour support for distribution of medicines and materials/ zagotoviti 24-urno podporo distribucije zdravil in materiala	no direct influence/ ni direktnega vpliva	4	2	0 %	50 %
Average impact/ Povprečen vpliv						56 %	65 %

LEGEND: ICT = INFORMATION AND COMMUNICATIONS TECHNOLOGY
LEGENDA: IKT = INFORMACIJSKA IN KOMUNIKACIJSKA TEHNOLOGIJA

5 DISCUSSION

Research shows that prescription medication errors at the time of hospital admission are disturbingly common and potentially harmful to patients. Up to 27 percent of all hospital prescribing errors can be attributed to incomplete medication histories at the time of admission (25). In Slovenia, a study on the prescribing of excessive drugs done on a large number of elderly patients in outpatient treatment showed inappropriate prescriptions in 6 percent of cases according to combined criteria (26). Leape and colleagues reported more than 15 types of medication errors: wrong dose, wrong choice, wrong drug, known allergy, missed dose, wrong time, wrong frequency, wrong technique, drug-drug interaction, wrong route, extra dose, failure to act on test, equipment failure, inadequate monitoring, preparation error and other (27). Rates of medication errors vary depending on the detection method used. Phillips and colleagues found that most of the common types of errors resulting in patient death involved the wrong dose (40.9 percent), the wrong medication (16 percent) and the wrong route of administration (9.5 percent) (28). Grasso and colleagues found that 4.7 percent of doses were administered incorrectly (29). Other research shows that most frequent types of medication errors were wrong time (33.6 percent), wrong dose (24.1 percent) and wrong medication (17.2 percent) (30).

In risk analysis for sub process" Medication administration incompliance with Rule 5 R", which is one of the indicators of quality in nursing, we assumed that the doctor's prescription was correct.

"Rule 5 R" is critical for nurses, and the complexity of the medication administration process has led to the formulation of the rights of nurses in the area of medication administration. The essential environmental conditions conducive to safe medication practices include: the right to complete and have a clearly written order; the right to have the correct drug route and dose dispensed from pharmacies; the right to have access to drug information; the right to have policies on safe medication administration; the right to administer medications safely and to identify problems in the system; and the right to stop, think and be vigilant when administering medications (31).

Due to excessive workloads, staffing inadequacies, fatigue, illegible provider handwriting, flawed dispensing systems and problems with the labelling of drugs, nurses are continually challenged to ensure that their patients receive the right medication at the right time. While performing applications of medication, nurses must be wary of health information about a patient's condition (vital signs, laboratory findings and others) and observe how the patient accepts the treatment. Even when "Rule 5 R" is properly applied, errors may occur due to carelessness of other relevant information. For example: if the patient has a prescribed medication to lower blood pressure, the nurse should check the patient's blood pressure before running the application. In addition, before the administration of potassium, one must check the level of potassium in the blood. A high degree of professional attention is very important. Information system scan help in demonstrating the correlation between the individual vital signs and medications in order to support the provision of quality and safe patient treatment. They support cognitive processes and can have a positive impact on the professional attention of health care providers (32).

An issue with ICT evaluation in health is the complexity of the evaluation object. Researchers use a variety of

methods and criteria for assessing the impact of ICT on the participants in the health care process (33- 36). In our study, we assess the impact of ICT on the individual causes of errors by the HFMEA. Similar studies in other literature were not found.

Based on the analysis of the revised process, it is concluded that the new organizational model of information and ICT have a significant impact on communication and information, critical thinking, experience and knowledge and professional attention, which is the basis for safe patient treatment (Figure 4). It has a positive impact on the quality and rational use of resources (personnel, time, material, equipment). The new model enables the acquisition of new knowledge and experience, which are the basis for analysis and continuous improvement processes.

The software solution provides easy access to the demographic and clinical data of the patient through a single entry point, transparency, health care and higher efficiency as support for daily activities, planning and implementation process of health care; decision-making, scientific research and education. In further development, it is necessary to support the nursing process as a whole and attempt to standardize the information in a narrative form. The solution is a good basis for further development in terms of incorporation of mechanisms to prevent errors in the various stages of the health care treatment. The database of derogations is the basis for further analysis and improvement processes. Encouraging other medical departments to implement the solution will enable the distribution of information regarding cases of “good practice”, experiences and benefits. Solutions not only automate certain processes but also assist in the organization of work, control the implementation of planned operations and support cognitive processes.

The combination of using ICT and a new way of organizing information prevents loss of data between health care staff. It has a positive impact on the flow of information and communication, which is a fundamental characteristics of the process of care. Electronic support is a utility for recording a large amount of important information, integration of distributed resources and support of decision-making, planning and evaluation of health care processes.

6 CONCLUSION

Patient safety is fundamental to ensuring quality of health care. It is based on preventive approaches and systematic analysis of reports of patients and medical personnel safety incidents. The systematic approach to safety provides a systematic design of safe structures, procedures and processes, together with remedial actions in response to an adverse event. The proposed organizational information model is a tool to reduce risks in the process of health care. It is an object-oriented model that allows full access to all electronic patient health records. The model enables process transparency and easy validation and verification of the various stages in the treatment process and encourages the critical thinking of healthcare providers, thus enabling them to make better decisions. Detection and error recording are key steps in the process of learning from mistakes and have a positive impact on quality.

To develop the model, we have chosen methods that together provide a coherent set of risk assessments in health care that is supported by testing in practice. The results showed that the risk assessment of selected process was decreased by 45.5 percent.

By embedding security mechanisms in software solutions, we can provide comprehensive information for members of the healthcare team, improve communication, influence critical thinking and decision-making and influence the level of attention of health care providers, which is the basis for ensuring the quality of safe patient care. A systemic approach to ensuring safety provides systematic design of safe structures, procedures and processes, together with corrective responses to adverse event. The use of modern ICT is one of the steps in the process to prevent errors in health care, but it requires a high level of attention. This attention is not a separate activity and it needs to be seen as part of an overall strategy for risk management in the new processes.

The need to carry out risk analyses in the health care process and the use of methods and tools that are available are guidelines only. In our study, the method used HMEA and RCA for errors causing the most serious risk.

The proposed organizational information model and software solution has a significant impact on professional attention, communication and information, critical thinking, experience and knowledge.

The results are both theoretically and practically useful and verifiable in other environments if the level of the organizational culture and the culture of recording errors is linked to the precise recording of data to assess the risk of errors in the process of health care. From a practical view, the model provides a standardized data format that can be used for the purpose of defining factors for the occurrence of errors, for developing a base of knowledge for learning from mistakes and for

continuous verification and adaptation to changes in the environment in order to prevent errors.

The possibility for further research is reflected in the electronic support planning and implementation of clinical pathways. Therefore, it is necessary to build an expert system that is based on carefully identified protocols for the proposed clinical pathway and pointing out any discrepancies.

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