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Using Failure mode and Effects Analysis to reduce patient safety risks related to the dispensing process in the community pharmacy setting

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1. Introduction

Dispensing of medicines, one of the central activities in pharmaceutical practice, is susceptible to errors, thereby posing a constant potential threat to patient safety.[1] Errors that may arise during this process include any deviation from the prescriber's order made by staff in the pharmacy when distributing medications to nursing units or to patients in an ambulatory pharmacy setting".[2] Besides this, in accordance with pharmacists' emerging role in providing pharmaceutical care and optimizing the use of medicines for individual needs,[3] failures to identify and correct prescribing faults, as well as to prevent administration errors by appropriate patient counselling, have been acknowledged as important additional categories of dispensing incidents.[4]

These types of safety-related concerns are particularly relevant at the primary care level, where the vast majority of patients are habitually issued medicines. International studies undertaken in community pharmacies have reported a wide range of dispensing error rates, varying from 0.04%[5]–24%.[6] These findings indicate a need for further safety improvement. Especially because pharmacies dispense enormous quantities of medicines even a low occurrence rate equals a substantial number of actual failures.[4] For example, an error rate of 1.7% corresponds to approximately 4 errors in a pharmacy filling 250 prescriptions daily, that is, 51.5 million errors in a pharmacy processing 3 billion prescriptions on a yearly basis.[7] Furthermore, it has been determined that nearly one half of serious safety incidents related to drug dispensing have been highly preventable.[8] Accordingly, the awareness of the importance of proactive risk mitigation has been raised, and the Institute of Medicine suggested that the research focus in this area should shift from basic epidemiological studies on incidence of dispensing errors to advanced, prospective systemic risk analyses.[9]

The most commonly applied method for this type of assessment is Failure Mode and Effects Analysis (FMEA), defined as "a proactive tool used to identify potential vulnerabilities in complex, high-risk processes and to generate remedial actions to counteract them before they result in adverse events".[10] Originally devised and utilized for the purposes of high-risk industries, such as aerospace, nuclear power and military, FMEA has been in use since 1960s. However, it was only in 2001 that its wide application in the field of healthcare began, when the Joint Commission issued a recommendation that all accredited hospitals in the US should perform at least one proactive risk assessment annually employing this method.[11] Consequently, a special version of FMEA adjusted for the healthcare setting was created, called Healthcare Failure Modes and Effects Analysis.[12] This five-step, team-based approach includes identifying potential failure modes, gauging their causes and effects, and quantifying related risks with the aim of envisaging and developing further corrective actions.[12,13]

FMEA, as a prospective risk management tool, has already been applied to a wide range of various healthcare processes. Regarding the research done in pharmacy practice, studies have been mainly centered around dispensing high-alert medications, e.g. chemotherapy or pediatric drugs, including prescribing and/or administration phases as well, though only in the hospital care setting.[14–22] Based on a comprehensive literature search, no published study on employing this tool at the primary care level, i.e. in a community pharmacy, has been identified. This research gap should be recognized as highly significant, because a great number of patients are provided with health assistance, and afterwards issued medicines at that very level.

Therefore, the aim of this study was to conduct a prospective risk analysis of the medicines dispensing process in the community pharmacy setting to identify, quantify and prioritize potential

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failure modes, as well as to define adequate measures for the risk reduction.

2. Methods

2.1. Study design

For the purposes of this study, FMEA was performed during a four-month period, namely from January to May 2016. The research was reviewed and approved by the Ethics Committee for Clinical Trials of the Faculty of Pharmacy, University of Belgrade, Serbia. The analysis followed the five standard steps of an FMEA: (i) choosing a suitable process for studying, (ii) assembling a multidisciplinary team, (iii) diagramming the process in question, (iv) conducting a risk analysis and, finally, (v) developing corrective actions and measuring the outcomes obtained.[12] All participants were required to meet four times, spaced monthly, with a 2-h average meeting length of time. In each session, team members were supplied with appropriate material so as to produce a written record of their suggestions on a given topic, which were subsequently discussed with the aim of achieving a consensus. Data analysis was conducted by synthesizing all individual outputs, so that the final version of each document could be obtained in writing. In addition to this, quantitative data related to the risk quantification were analyzed in Microsoft Office Excel 2010.

2.2. FMEA steps

2.2.1. Choosing a suitable process for studying

As previously mentioned, the high-risk process that was finally selected for a prospective assessment was dispensing of all categories of medicines in the community pharmacy setting in Serbia. This activity was chosen not only for its considerable implications for patient safety, but also on the grounds of the existing research gap related to the dispensing incidents at the primary care level and the evident need to consider a more comprehensive group of medications than only high-alert ones.

2.2.2. Assembling a team

A ten-member team was assembled, consisting of a leader, who conducted FMEA and managed the entire process of analysis (TS); eight frontline community pharmacists as process experts, completely familiar with drug dispensing on a daily basis, and thus, capable of proposing steps towards systemic risks mitigation and assigning corrective actions, as well as one manager representative in charge of quality assurance in the community pharmacy setting. The participants were from both state- and privately-owned pharmacies, with the mean registration length 9.63 ± 8.78 years.

2.2.3. Diagramming the dispensing process

At first, a diagramming of the process and sub-processes in question was conducted. The team members gathered to discuss the sequence of steps and various practical aspects related to the general dispensing procedure, e.g., the manner in which medicines are customarily prescribed and data entered into the pharmacy computer software (either handwritten or electronic), type of the dispensing system employed (be it manual or automated), as well as how medication therapy reviews are usually performed etc. After a common agreement was arrived at, a unique dispensing flow chart was created.

2.2.4. Conducting a risk analysis

The next phase included conducting a risk analysis, which started with identifying the potential failure modes and gauging the underlying causes and possible effects. That assessment was primarily obtained by the brainstorming technique, where the team members nominated specific systemic weaknesses, along with the related root causes and consequences, on the basis of their subjective estimations and experience. After all panelists had produced a written record of their suggestions, various individual perspectives were openly shared and discussed, so that a consensus over this point could be reached.

Once all possible failure modes were established and consecutively listed in an FMEA spreadsheet, the attributed risks were quantified to allow their further prioritization. The panel members rated the main three characteristics of each potential failure independently, starting from its severity (the seriousness the effect has on the patient or healthcare system, should the failure occur, marked as “S”), then likelihood of its occurrence (the probability of a failure actually happening, marked as “O”) and detectability (the prospect of detecting the failure before it starts affecting the patient, marked as “D”). For this activity, a 5-point ranking scale was used, created by combining two pre-defined scales (Table 1),[15,23] while the final results were expressed as the median value for S, O and D of each failure mode. This central tendency measure was chosen as the most appropriate for dealing with ordinal data, which were also found to be slightly skewed. Finally, the Risk Priority Numbers (RPNs) for each potential failure mode were calculated by multiplying the scores of the characteristics considered (SxOxD), thereby yielding a range of values from 1 (minimum) to 125 (maximum). The failure modes were subsequently prioritized according to the RPNs arranged in a descending order, and 70% of potential errors with the highest scores were selected for further processing, according to a pre-defined cutoff value.[23]

2.2.5. Developing corrective actions and performing the risk re-assessment

The final step of the analysis included the development of corrective actions for the top critical failure modes, as well as the risk re-assessment in a hypothetical case of their implementation. At the outset, the brainstorming technique was employed once again, in order to define all possible organizational, environmental, technological and individual measures that could reduce the risks in question. Afterwards, the team members discussed the feasibility of each of the actions proposed, shortlisting them until a definite number of recommendations was defined. As a final step, a comparative analysis of the old and new, hypothetically re-engineered dispensing process was performed. The criticality of each selected failure mode was quantified once again, so as to enable risk reduction evaluation and major residual risks' identification.

3. Results

The medicine dispensing process in the community pharmacy setting was divided into 10 major steps, as shown in the flow diagram developed upon the team members' discussion and agreement (Fig. 1). The prospective risk analysis yielded a total of 30 potential failure modes distributed throughout the whole process, along with 19 causes and 12 effects. The sum of all RPNs amounted to 639, ranging from 48 down to 4. Eleven both general and stage-specific corrective actions were proposed, and a significant potential for the risk reduction after their hypothetical implementation has been demonstrated.

3.1. FMEA of the dispensing process

3.1.1. Failure modes

After the items were sorted in a descending order, the first 21 out of 30 failure modes were identified as the top critical events

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