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ЕЖЕМЕСЯЧНЫЙ НАУЧНЫЙ ЖУРНАЛ

Медицинские новости Грузии
საქართველოს სამედიცინო სიახლენი

GEORGIAN MEDICAL NEWS

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GMN: Georgian Medical News is peer-reviewed, published monthly journal committed to promoting the science and art of medicine and the betterment of public health, published by the GMN Editorial Board since 1994. GMN carries original scientific articles on medicine, biology and pharmacy, which are of experimental, theoretical and practical character; publishes original research, reviews, commentaries, editorials, essays, medical news, and correspondence in English and Russian.

GMN is indexed in MEDLINE, SCOPUS, PubMed and VINITI Russian Academy of Sciences. The full text content is available through EBSCO databases.

GMN: Медицинские новости Грузии - ежемесячный рецензируемый научный журнал, издаётся Редакционной коллегией с 1994 года на русском и английском языках в целях поддержки медицинской науки и улучшения здравоохранения. В журнале публикуются оригинальные научные статьи в области медицины, биологии и фармации, статьи обзорного характера, научные сообщения, новости медицины и здравоохранения. Журнал индексируется в MEDLINE, отражён в базе данных SCOPUS, PubMed и ВИНТИ РАН. Полнотекстовые статьи журнала доступны через БД EBSCO.

GMN: Georgian Medical News – საქართველოს სამედიცინო სიახლენი – არის ყოველთვიური სამეცნიერო სამედიცინო რეცენზირებადი ჟურნალი, გამოიცემა 1994 წლიდან, წარმოადგენს სარედაქციო კოლეგიისა და აშშ-ის მეცნიერების, განათლების, ინდუსტრიის, ხელოვნებისა და ბუნებისმეტყველების საერთაშორისო აკადემიის ერთობლივ გამოცემას. GMN-ში რუსულ და ინგლისურ ენებზე ქვეყნდება ექსპერიმენტული, თეორიული და პრაქტიკული ხასიათის ორიგინალური სამეცნიერო სტატიები მედიცინის, ბიოლოგიისა და ფარმაციის სფეროში, მიმოხილვითი ხასიათის სტატიები.

ჟურნალი ინდექსირებულია MEDLINE-ის საერთაშორისო სისტემაში, ასახულია SCOPUS-ის, PubMed-ის და ВИНТИ РАН-ის მონაცემთა ბაზებში. სტატიების სრული ტექსტი ხელმისაწვდომია EBSCO-ს მონაცემთა ბაზებშიდან.

WEBSITE

www.geomednews.com

К СВЕДЕНИЮ АВТОРОВ!

При направлении статьи в редакцию необходимо соблюдать следующие правила:

1. Статья должна быть представлена в двух экземплярах, на русском или английском языках, напечатанная через **полтора интервала на одной стороне стандартного листа с шириной левого поля в три сантиметра**. Используемый компьютерный шрифт для текста на русском и английском языках - **Times New Roman (Кириллица)**, для текста на грузинском языке следует использовать **AcadNusx**. Размер шрифта - **12**. К рукописи, напечатанной на компьютере, должен быть приложен CD со статьей.

2. Размер статьи должен быть не менее десяти и не более двадцати страниц машинописи, включая указатель литературы и резюме на английском, русском и грузинском языках.

3. В статье должны быть освещены актуальность данного материала, методы и результаты исследования и их обсуждение.

При представлении в печать научных экспериментальных работ авторы должны указывать вид и количество экспериментальных животных, применявшиеся методы обезболивания и усыпления (в ходе острых опытов).

4. К статье должны быть приложены краткое (на полстраницы) резюме на английском, русском и грузинском языках (включающее следующие разделы: цель исследования, материал и методы, результаты и заключение) и список ключевых слов (key words).

5. Таблицы необходимо представлять в печатной форме. Фотокопии не принимаются. **Все цифровые, итоговые и процентные данные в таблицах должны соответствовать таковым в тексте статьи.** Таблицы и графики должны быть озаглавлены.

6. Фотографии должны быть контрастными, фотокопии с рентгенограмм - в позитивном изображении. Рисунки, чертежи и диаграммы следует озаглавить, пронумеровать и вставить в соответствующее место текста **в tiff формате**.

В подписях к микрофотографиям следует указывать степень увеличения через окуляр или объектив и метод окраски или импрегнации срезов.

7. Фамилии отечественных авторов приводятся в оригинальной транскрипции.

8. При оформлении и направлении статей в журнал МНГ просим авторов соблюдать правила, изложенные в «Единых требованиях к рукописям, представляемым в биомедицинские журналы», принятых Международным комитетом редакторов медицинских журналов - <http://www.spinesurgery.ru/files/publish.pdf> и http://www.nlm.nih.gov/bsd/uniform_requirements.html. В конце каждой оригинальной статьи приводится библиографический список. В список литературы включаются все материалы, на которые имеются ссылки в тексте. Список составляется в алфавитном порядке и нумеруется. Литературный источник приводится на языке оригинала. В списке литературы сначала приводятся работы, написанные знаками грузинского алфавита, затем кириллицей и латиницей. Ссылки на цитируемые работы в тексте статьи даются в квадратных скобках в виде номера, соответствующего номеру данной работы в списке литературы. Большинство цитированных источников должны быть за последние 5-7 лет.

9. Для получения права на публикацию статья должна иметь от руководителя работы или учреждения визу и сопроводительное отношение, написанные или напечатанные на бланке и заверенные подписью и печатью.

10. В конце статьи должны быть подписи всех авторов, полностью приведены их фамилии, имена и отчества, указаны служебный и домашний номера телефонов и адреса или иные координаты. Количество авторов (соавторов) не должно превышать пяти человек.

11. Редакция оставляет за собой право сокращать и исправлять статьи. Корректур авторам не высылаются, вся работа и сверка проводится по авторскому оригиналу.

12. Недопустимо направление в редакцию работ, представленных к печати в иных издательствах или опубликованных в других изданиях.

При нарушении указанных правил статьи не рассматриваются.

REQUIREMENTS

Please note, materials submitted to the Editorial Office Staff are supposed to meet the following requirements:

1. Articles must be provided with a double copy, in English or Russian languages and typed or computer-printed on a single side of standard typing paper, with the left margin of 3 centimeters width, and 1.5 spacing between the lines, typeface - **Times New Roman (Cyrillic)**, print size - 12 (referring to Georgian and Russian materials). With computer-printed texts please enclose a CD carrying the same file titled with Latin symbols.

2. Size of the article, including index and resume in English, Russian and Georgian languages must be at least 10 pages and not exceed the limit of 20 pages of typed or computer-printed text.

3. Submitted material must include a coverage of a topical subject, research methods, results, and review.

Authors of the scientific-research works must indicate the number of experimental biological species drawn in, list the employed methods of anesthetization and soporific means used during acute tests.

4. Articles must have a short (half page) abstract in English, Russian and Georgian (including the following sections: aim of study, material and methods, results and conclusions) and a list of key words.

5. Tables must be presented in an original typed or computer-printed form, instead of a photocopied version. **Numbers, totals, percentile data on the tables must coincide with those in the texts of the articles.** Tables and graphs must be headed.

6. Photographs are required to be contrasted and must be submitted with doubles. Please number each photograph with a pencil on its back, indicate author's name, title of the article (short version), and mark out its top and bottom parts. Drawings must be accurate, drafts and diagrams drawn in Indian ink (or black ink). Photocopies of the X-ray photographs must be presented in a positive image in **tiff format**.

Accurately numbered subtitles for each illustration must be listed on a separate sheet of paper. In the subtitles for the microphotographs please indicate the ocular and objective lens magnification power, method of coloring or impregnation of the microscopic sections (preparations).

7. Please indicate last names, first and middle initials of the native authors, present names and initials of the foreign authors in the transcription of the original language, enclose in parenthesis corresponding number under which the author is listed in the reference materials.

8. Please follow guidance offered to authors by The International Committee of Medical Journal Editors guidance in its Uniform Requirements for Manuscripts Submitted to Biomedical Journals publication available online at: http://www.nlm.nih.gov/bsd/uniform_requirements.html
http://www.icmje.org/urm_full.pdf

In GMN style for each work cited in the text, a bibliographic reference is given, and this is located at the end of the article under the title "References". All references cited in the text must be listed. The list of references should be arranged alphabetically and then numbered. References are numbered in the text [numbers in square brackets] and in the reference list and numbers are repeated throughout the text as needed. The bibliographic description is given in the language of publication (citations in Georgian script are followed by Cyrillic and Latin).

9. To obtain the rights of publication articles must be accompanied by a visa from the project instructor or the establishment, where the work has been performed, and a reference letter, both written or typed on a special signed form, certified by a stamp or a seal.

10. Articles must be signed by all of the authors at the end, and they must be provided with a list of full names, office and home phone numbers and addresses or other non-office locations where the authors could be reached. The number of the authors (co-authors) must not exceed the limit of 5 people.

11. Editorial Staff reserves the rights to cut down in size and correct the articles. Proof-sheets are not sent out to the authors. The entire editorial and collation work is performed according to the author's original text.

12. Sending in the works that have already been assigned to the press by other Editorial Staffs or have been printed by other publishers is not permissible.

**Articles that Fail to Meet the Aforementioned
Requirements are not Assigned to be Reviewed.**

ავტორთა საყურადღებო!

რედაქციაში სტატიის წარმოდგენისას საჭიროა დავიცვათ შემდეგი წესები:

1. სტატია უნდა წარმოადგინოთ 2 ცალად, რუსულ ან ინგლისურ ენებზე, დაბეჭდილი სტანდარტული ფურცლის 1 გვერდზე, 3 სმ სიგანის მარცხენა ველისა და სტრიქონებს შორის 1,5 ინტერვალის დაცვით. გამოყენებული კომპიუტერული შრიფტი რუსულ და ინგლისურენოვან ტექსტებში - **Times New Roman (Кириллица)**, ხოლო ქართულენოვან ტექსტში საჭიროა გამოვიყენოთ **AcadNusx**. შრიფტის ზომა – 12. სტატიას თან უნდა ახლდეს CD სტატიით.

2. სტატიის მოცულობა არ უნდა შეადგენდეს 10 გვერდზე ნაკლებს და 20 გვერდზე მეტს ლიტერატურის სიის და რეზიუმეების (ინგლისურ, რუსულ და ქართულ ენებზე) ჩათვლით.

3. სტატიაში საჭიროა გაშუქდეს: საკითხის აქტუალობა; კვლევის მიზანი; საკვლევი მასალა და გამოყენებული მეთოდები; მიღებული შედეგები და მათი განსჯა. ექსპერიმენტული ხასიათის სტატიების წარმოდგენისას ავტორებმა უნდა მიუთითონ საექსპერიმენტო ცხოველების სახეობა და რაოდენობა; გაუტკივარებისა და დაძინების მეთოდები (მწვავე ცდების პირობებში).

4. სტატიას თან უნდა ახლდეს რეზიუმე ინგლისურ, რუსულ და ქართულ ენებზე არანაკლებ ნახევარი გვერდის მოცულობისა (სათაურის, ავტორების, დაწესებულების მითითებით და უნდა შეიცავდეს შემდეგ განყოფილებებს: მიზანი, მასალა და მეთოდები, შედეგები და დასკვნები; ტექსტუალური ნაწილი არ უნდა იყოს 15 სტრიქონზე ნაკლები) და საკვანძო სიტყვების ჩამონათვალი (key words).

5. ცხრილები საჭიროა წარმოადგინოთ ნაბეჭდი სახით. ყველა ციფრული, შემავსებელი და პროცენტული მონაცემები უნდა შეესაბამებოდეს ტექსტში მოყვანილს.

6. ფოტოსურათები უნდა იყოს კონტრასტული; სურათები, ნახაზები, დიაგრამები - დასათაურებული, დანომრილი და სათანადო ადგილას ჩასმული. რენტგენოგრაფიის ფოტოსურათები წარმოადგინეთ პოზიტიური გამოსახულებით **tiff** ფორმატში. მიკროფოტოსურათების წარწერებში საჭიროა მიუთითოთ ოკულარის ან ობიექტივის საშუალებით გადიდების ხარისხი, ანათალების შედეგების ან იმპრეგნაციის მეთოდი და აღნიშნოთ სურათის ზედა და ქვედა ნაწილები.

7. სამამულო ავტორების გვარები სტატიაში აღინიშნება ინიციალების თანდართვით, უცხოურისა – უცხოური ტრანსკრიპციით.

8. სტატიას თან უნდა ახლდეს ავტორის მიერ გამოყენებული სამამულო და უცხოური შრომების ბიბლიოგრაფიული სია (ბოლო 5-8 წლის სიღრმით). ანბანური წყობით წარმოდგენილ ბიბლიოგრაფიულ სიაში მიუთითეთ ჯერ სამამულო, შემდეგ უცხოელი ავტორები (გვარი, ინიციალები, სტატიის სათაური, ჟურნალის დასახელება, გამოცემის ადგილი, წელი, ჟურნალის №, პირველი და ბოლო გვერდები). მონოგრაფიის შემთხვევაში მიუთითეთ გამოცემის წელი, ადგილი და გვერდების საერთო რაოდენობა. ტექსტში კვადრატულ ფხიხლებში უნდა მიუთითოთ ავტორის შესაბამისი N ლიტერატურის სიის მიხედვით. მიზანშეწონილია, რომ ციტირებული წყაროების უმეტესი ნაწილი იყოს 5-6 წლის სიღრმის.

9. სტატიას თან უნდა ახლდეს: ა) დაწესებულების ან სამეცნიერო ხელმძღვანელის წარდგინება, დამოწმებული ხელმოწერითა და ბეჭდით; ბ) დარგის სპეციალისტის დამოწმებული რეცენზია, რომელშიც მითითებული იქნება საკითხის აქტუალობა, მასალის საკმაობა, მეთოდის სანდოობა, შედეგების სამეცნიერო-პრაქტიკული მნიშვნელობა.

10. სტატიის ბოლოს საჭიროა ყველა ავტორის ხელმოწერა, რომელთა რაოდენობა არ უნდა აღემატებოდეს 5-ს.

11. რედაქცია იტოვებს უფლებას შეასწოროს სტატია. ტექსტზე მუშაობა და შეჯერება ხდება საავტორო ორიგინალის მიხედვით.

12. დაუშვებელია რედაქციაში ისეთი სტატიის წარდგენა, რომელიც დასაბეჭდად წარდგენილი იყო სხვა რედაქციაში ან გამოქვეყნებული იყო სხვა გამოცემებში.

აღნიშნული წესების დარღვევის შემთხვევაში სტატიები არ განიხილება.

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APPLICATION OF THE FAILURE MODE AND EFFECTS ANALYSIS METHOD IN HEALTHCARE: A CASE STUDY OF A UNIVERSITY MEDICAL CENTER IN KAZAKHSTAN

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Abstract.

Background: Patient safety remains a major concern for healthcare systems worldwide, requiring proactive risk management approaches to prevent adverse events. Failure Mode and Effects Analysis (FMEA) is a well-recognized tool; however, published data on its application in healthcare settings in Central Asia are extremely limited.

Aim of study: The aim of this study was to analyze the application of FMEA in the process of prescribing and administering medications at a University Medical Center in Kazakhstan and to evaluate the impact of FMEA-based interventions on the frequency of medication errors.

Material and Methods: The study was conducted as a quality improvement project with two components. First, a narrative literature review was performed using the PubMed and Web of Science databases (2020–2026): of 917 identified records, 34 articles meeting the inclusion criteria were selected and analyzed.

Second, a prospective FMEA study was conducted at the University Medical Center (UMC) in Astana, Kazakhstan, from December 2023 to March 2024. A multidisciplinary expert team, consisting of healthcare professionals and quality management specialists (medical director, head of the quality management unit, head of pharmaceutical services, head of nursing, and two clinical pharmacologists), assessed failure modes in the medication prescribing and administration process using standard scales of Severity (S), Occurrence (O), and Detectability (D) (each scored on a 10-point scale).

Risk Priority Numbers (RPNs) were calculated, and targeted corrective actions were implemented for high-risk failure modes. A follow-up reassessment was conducted in January 2026.

Results: Seven failure modes were identified across six stages of the process. Baseline RPN values ranged from 150 to 400 (total RPN = 1990). The highest risks were associated with discrepancies between medication orders in the medical record and the medication chart (RPN = 400) and prescribing errors (RPN = 350).

Following the implementation of corrective measures—including electronic prescribing, physician self-check checklists, and mobile medication verification—the total RPN decreased by 57.8% to 840. The number of reported medication errors decreased by 49% in 2025 compared to 2024, while the proportion of errors detected before drug administration increased from 30% to 70%.

Conclusions: FMEA demonstrated its effectiveness as a proactive tool for identifying and reducing medication safety

risks at UMC. The findings support broader implementation of this method in healthcare systems across Central Asia; however, its generalizability to resource-limited settings requires further investigation.

Key words. Patient safety, FMEA, risk management, healthcare quality, Kazakhstan.

Introduction.

Despite significant advances in patient safety, adverse events and medical errors remain major causes of morbidity and mortality in hospitals. To prevent these events, Failure Mode and Effects Analysis (FMEA) is widely used as a systematic and proactive tool for identifying potential process failures and prioritizing them based on their severity, likelihood of occurrence, and detectability.

However, there is a lack of published data on the implementation of FMEA in healthcare organizations in Central Asia, and no available evidence from Kazakhstan.

The implementation of FMEA in healthcare organizations in Kazakhstan faces several systemic barriers, including limited human and material resources and insufficient digitalization, which affect the feasibility of applying FMEA as well as the timeliness and completeness of required data collection. These challenges are due to the regional characteristics of the country's healthcare system.

Most healthcare organizations in Kazakhstan are located in regional (oblast-level and rural) settings, accounting for approximately 70–85% of all facilities, whereas only about 15–30% are concentrated in major cities such as Astana, Almaty, and Shymkent. As a result, healthcare organizations in peripheral areas face not only workforce shortages but also insufficient training among senior managers and risk management specialists.

Additional barriers include organizational constraints, particularly the lack of integration of FMEA into routine quality and patient safety management processes within healthcare organizations. Internal audit programs are conducted separately from FMEA activities, which creates a high risk of generating incomplete recommendations for systemic improvements.

Taken together, these factors significantly limit the use of proactive risk analysis methods in healthcare practice across Kazakhstan.

Thus, the objectives of this study were:

- 1) to conduct a review of contemporary literature on the application of FMEA in healthcare;
- 2) to demonstrate its practical application through an FMEA case study conducted at a university medical center in

Kazakhstan, with the potential for scaling this experience within the national healthcare system.

To achieve the stated aim, this work combines two complementary components: a narrative review of contemporary literature (2020–2026) on the application of FMEA in healthcare, and a prospective thematic study (quality improvement case study) conducted at the University Medical Center (UMC) in Astana, Kazakhstan.

This two-component structure, on the one hand, synthesizes international experience in the application of FMEA in medication safety and related processes, and on the other hand, demonstrates the practical applicability of the method within the context of a Kazakhstani healthcare organization.

The manuscript is structured in accordance with the IMRaD format and the SQUIRE 2.0 recommendations: the “Materials and Methods” section describes the literature review strategy and the FMEA methodology applied at UMC; the “Results” section presents both the synthesis of the literature and the findings from the practical implementation of FMEA; and the “Discussion” section compares the results with current international literature and interprets them in the context of healthcare systems with limited resources.

Materials and Methods.

This study was designed as a quality improvement project, specifically a prospective thematic study (quality improvement case study) accompanied by a narrative literature review. The reporting of results followed the recommendations of SQUIRE 2.0 [1].

A literature review on the application of FMEA in healthcare organizations was conducted using the PubMed and Web of Science databases. The following keywords and combinations were used: “Failure Mode and Effects Analysis,” “FMEA,” “patient safety,” “risk management,” “quality improvement,” “healthcare,” and “Kazakhstan.”

The literature analysis included original studies, reviews, scoping reviews, and systematic reviews published between 2020 and 2026. The inclusion criteria were: (1) application of FMEA in hospital settings and patient care processes; (2) focus on patient safety, quality improvement, or risk management; and (3) original studies, reviews, or practical case applications. Exclusion criteria included publications outside the specified time frame, studies not aligned with the case study healthcare setting, conference abstracts without full texts, opinion articles, and studies lacking sufficient methodological details.

The search and screening were performed by a single author. Relevant data were extracted and synthesized thematically to identify common risk areas, implementation approaches, and reported patient safety improvements associated with FMEA.

To enhance transparency, selected elements of the PRISMA guidelines were applied, including a description of the search strategy, inclusion and exclusion criteria, and the study selection process (Figure 1). A total of 917 records were identified, of which 46 duplicates were removed. After screening titles and abstracts, 546 records were excluded. A total of 325 full-text articles were assessed for eligibility, of which 291 were excluded. Finally, 34 studies were included in the review.

Case Study Methodology (FMEA).

A case study was conducted at a University Medical Center in Kazakhstan to demonstrate the practical application of FMEA. The study was carried out from December 1, 2023, to March 30, 2024. A follow-up reassessment was conducted after the implementation of interventions in January 2026.

The Corporate Fund “University Medical Center” (hereinafter – UMC) is part of the integrated academic healthcare system of Nazarbayev University (NU Medicine), established based on international standards and the experience of the University of Pittsburgh School of Medicine (UPSOM) and its affiliated medical center, UPMC.

UMC provides medical care across a wide range of specialties, including obstetrics and gynecology, pediatrics, pediatric surgery, traumatology, urology, endocrinology, pulmonology, gastroenterology, neurology, oncohematology, cardiology, and cardiac surgery, etc.

In addition, UMC is actively engaged in educational and research activities in the relevant fields. UMC is accredited as an academic medical center by Joint Commission International and applies continuous quality improvement methodologies, professional development of healthcare staff in leading international medical institutions, and the implementation of a patient-centered care model.

For the conduct of FMEA, a multidisciplinary expert team was established, consisting of healthcare professionals and quality management specialists: the head of the quality management unit (facilitator), medical director, head of pharmaceutical services, head of nursing services, and two clinical pharmacologists.

A process map of the selected healthcare delivery pathway was developed, and potential failure modes were identified at each stage.

Each failure mode was evaluated using the standard FMEA framework based on three parameters, each scored on a 10-point scale:

- Severity (S): the impact of the failure on the patient (1 = negligible impact, 10 = death or catastrophic harm);
- Occurrence (O): the likelihood of the cause occurring (1 = extremely unlikely, 10 = almost inevitable);
- Detectability (D): the ability to detect the failure before it reaches the patient (1 = almost certain detection, 10 = virtually undetectable).

The rating scales were adapted from the IEC 60812 and contextualized for application within UMC. Full definitions of the scoring scales are provided in Supplementary Table S4.

A consensus was reached through structured group discussion. In cases where rating discrepancies exceeded 2 points, the team engaged in further deliberation until agreement was achieved. The final scores represent the consensus of all six team members.

The Risk Priority Number (RPN) was calculated as:

$$\text{RPN} = \text{S} \times \text{O} \times \text{D}$$

Risk levels were stratified according to the UMC risk ranking scale (Table 1).

For the most critical failure modes, corrective and preventive actions were proposed. To identify potential root causes for each failure mode, an Ishikawa (fishbone) diagram and root cause analysis were applied.

The results of the case study were analyzed in conjunction with the findings of the literature review to assess the alignment between identified risks and improvement strategies.

The process of “prescribing and administering medications to patients” was selected based on the annual ECRI Top 10 Patient Safety Concerns 2023 and recommendations of the Institute for Safe Medication Practices, which identified non-compliance with the “five rights” of medication safety and prescribing errors due to inaccurate medication lists as critical issues.

According to the Institute for Healthcare Improvement (IHI) and Duguid, inconsistent knowledge and documentation of medication records account for up to 50% of medication errors in hospitals and up to 20% of adverse drug events [2]. These findings are supported by internal UMC incident statistics for 2021–2023 (Figure 3).

Results.

In accordance with the two-component study design, the results are presented in two consecutive subsections. The subsection “Findings from the Literature Review” summarizes the narrative review findings regarding areas of FMEA application, methodological approaches, and reported intervention effects. The subsection “Case Application: University Medical Center of Kazakhstan” presents the results of the practical FMEA conducted at UMC, including identified failure modes, baseline and post-intervention RPN values, as well as trends in reported medication errors following the implementation of corresponding corrective measures.

The comparison between the literature-based evidence and empirical findings is presented in the Discussion section.

Findings from the Literature Review:

Out of 917 articles retrieved through keyword-based searches, 34 articles were selected. These publications were divided into two categories (“Clinical care and diagnostic processes” and “Hospital management”) and analyzed in terms of areas of FMEA application and methodological approaches. The studies were further thematically categorized into four domains: (a) medication safety, (b) safety of surgical and procedural interventions, (c) laboratory and diagnostic processes, and (d) non-clinical hospital processes. The characteristics of the included studies are presented in Supplementary Table SI.

FMEA demonstrates high practical value for improving healthcare quality and reducing errors and is widely used to optimize hospital processes [3].

Effective applications of FMEA have been described across diagnostic and treatment processes. For example, in oncology care (brachytherapy [4], radiation oncology [5]), hemodialysis procedures [6], medication safety including biotherapeutic agents [7], surgical patient management [8,9], central venous catheter placement [10], prevention of sharp objects injuries [11], and laboratory processes such as improving quality management of emergency general blood test [12] and pre-analytical blood gas analysis [13], as well as prior to implementation of computerized prescription systems [14], among others.

FMEA is applicable throughout the entire lifecycle of a technological process, including the identification of risks during updated workflows [4], and the development of new control tools and decision-making frameworks to eliminate

failures at critical process stages [6].

In addition, the use of risk analysis methods may increase awareness among staff involved in risk assessment regarding potential safety hazards [15], thereby contributing to a reduction in occupational injury incidents and improve managerial satisfaction [11].

The implementation of FMEA has been shown to be effective in identifying adverse events related to patient safety in association with patient safety culture, accelerating recovery, and reducing health-related risks [16], improving medication safety during the medication use process [17,18], as well as ensuring the safety of high-risk procedures [19].

Across the analyzed literature, established FMEA methodologies were applied. Each failure mode is evaluated based on Severity (S), Occurrence (O), and Detectability (D), typically determined through consensus, followed by the development of a risk matrix categorizing risk levels into high (red), medium (yellow), and low (green) risk zones [20].

The consequences, causes, and corrective actions for each failure mode are documented. FMEA ratings are used to develop targeted system improvement recommendations in order to prevent errors before failures occur across various processes, including non-clinical settings [3,21–26].

Recommended approaches to consensus building (interdisciplinary Delphi discussion group, brainstorming method) [24,27], pairwise comparison to identify risks that are difficult to assess [28], application of logistic regression [29], algorithmic prediction of failure modes in healthcare (APFMH) [24], FMEA information fusion method based on two-component linguistic information and interval probability [30].

Successful applications of FMEA have also been reported in non-clinical hospital processes, including medical waste management [31], assessment of DMRA risk for indoor contaminants [26], fire prevention and control systems [32], and improving operational safety and reliability across various sectors [33].

Thus, FMEA is a key factor in quality improvement and one of the most frequently used risk assessment methods [34]. Its implementation as a standard tool in healthcare institutions, although it requires a lot of expenses, can serve as an important mechanism for preventing risks of incidents related to biological hazards, epidemics, and environmental contamination, thereby enhancing the safety of both patients and healthcare workers [35]. The development of a rule-based system may act as a repeatable and explainable decision-support tool, particularly in high-risk environments such as healthcare [36].

The methodological findings related to FMEA implementation – such as achieving consensus within a multidisciplinary team and refining approaches to information processing during the FMEA process—formed the basis for further refinement of FMEA at the University Medical Center. This contributed to strengthening risk prevention within the quality improvement system and enhancing the safety of both patients and healthcare personnel.

The generalized international data serve as a conceptual framework for the second subsection of the results. They define the expected spectrum of failure modes in medication

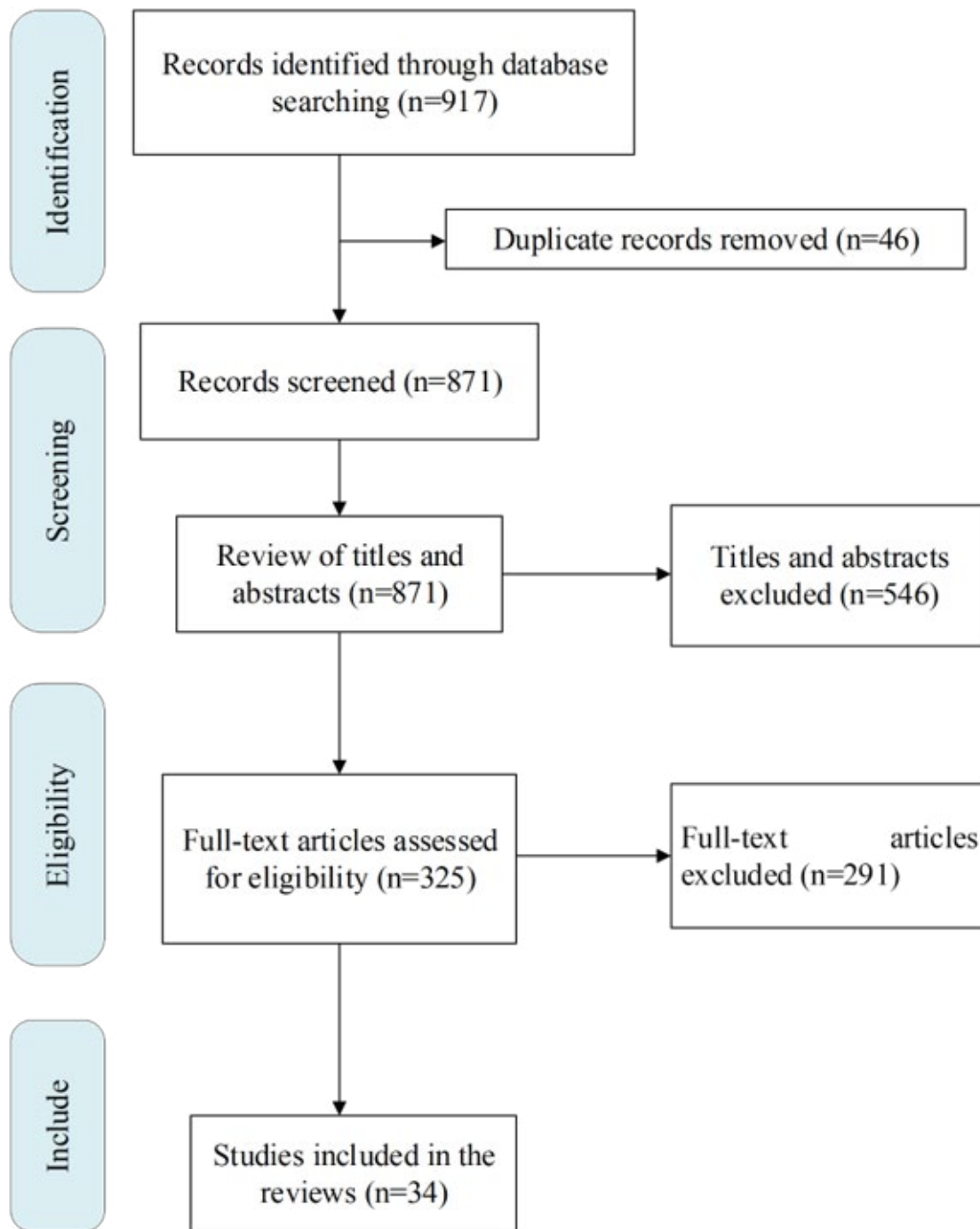


Figure 1. Selection process flow diagram.



Figure 2. FMEA Process Steps. Adapted from Thornton et al. [37].

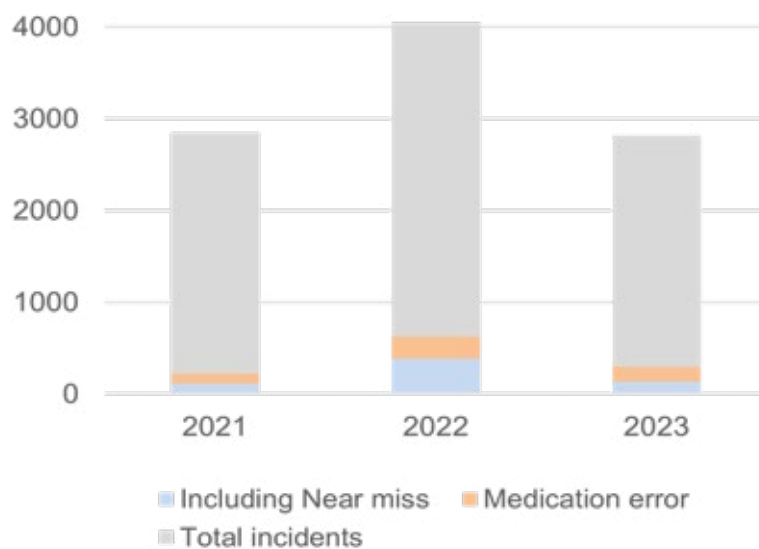


Figure 3. Incidents and Medication Errors at “UMC”, 2021–2023.

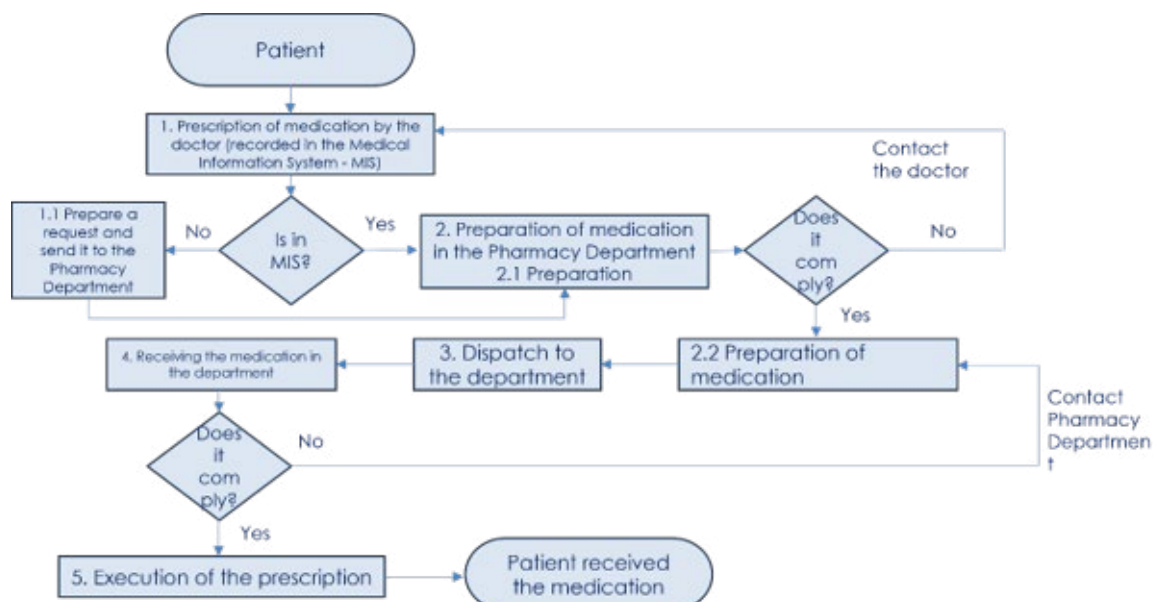


Figure 4. Flowchart: “Prescribing and Administering Medications to Patients”.

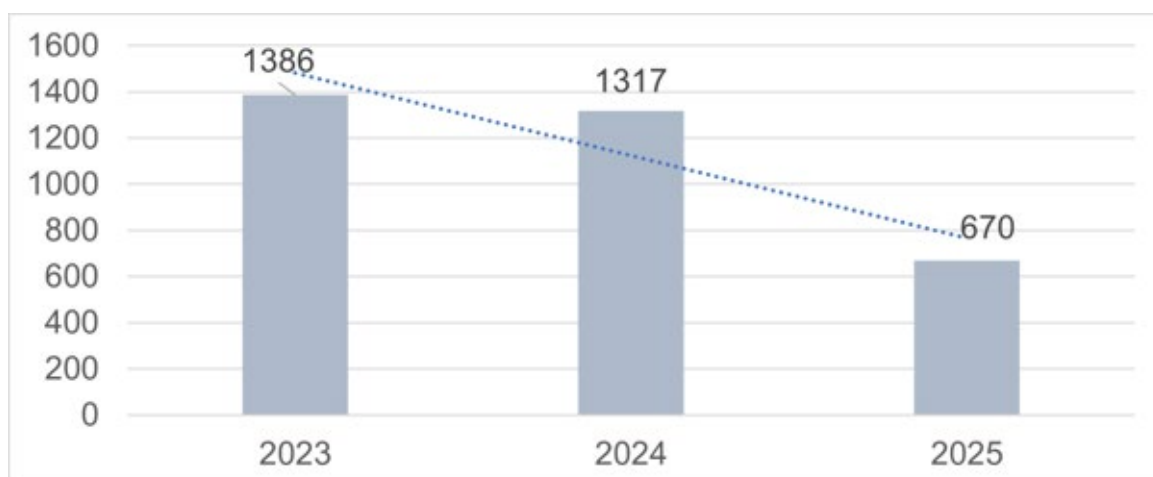


Figure 5. Trend in the number of medication errors.

Table 1. Risk Ranking Scale.

RPN	Risk level	Required actions
0–100	Low	Continuous monitoring Routine process management
101–200	Managed risk	Management attention required Establish strategic team to eliminate or reduce risk Ongoing monitoring
201–400	High risk	Inform responsible manager Establish strategic team: urgent mitigation or risk reduction required
401–1000	Critical risk	Inform responsible manager Immediate action required: Establish strategic team: immediate elimination or reduction of risk

Table 2. Time-Motion Study Results.

№	Medication	Scheduled administration time	Order/request sent from department	Dispatch time from CPD	Arrival to the department	Medication taking delay (min)	Cause
1	Antibiotic	10:00	9:30	10:30	10:34	34	Late order submission from department
2	Cytostatic	09:30	10:10	10:15	10:30	60	Late order submission from department
3	Antibiotic	11:00	10:00	10:30	10:35	—	—
4	Solution for IM/IV injections	09:00	09:20	10:30	10:40	100	Late order submission from department
5	Cytostatics	11:00	Day before	10:19	10:30	—	—
6	Cytostatics	11:00	Day before	10:19	10:30	—	—
7	Antibiotic	11:45	10:45	11:00	11:05	—	—
8	Antibiotic	10:00	10:00	10:30	10:35	35	Late order submission from department
9	Hormonal drug (additional)	10:00	10:00	09:40	09:44	—	No delay: incorrect timing entry
10	Hormonal drug	10:15	10:00	09:44	09:49	—	No delay: incorrect timing entry
11	Hormonal drug	11:00	09:00	09:41	09:43	—	—
12	Antibiotic	10:00	Day before	09:59	10:04	4	Delivery delay
13	IV solution	11:00	Day before	10:30	10:45	—	—
14	IV solution	11:00	Day before	09:35	09:46	—	—
15	Cytostatic	10:00	09:30	10:15	10:30	30	Delivery delay
16	Cytostatic	11:30	10:10	11:15	11:30	—	—
17	Hormonal drug	09:00	09:00	09:30	09:35	35	Late order submission from department
18	Antibiotic	09:00	08:30	09:20	09:24	24	Delay in CPD
19	IM/IV solution	09:00	08:20	09:30	09:40	40	Delay in CPD
20	Cytostatic	09:30	09:00	09:15	09:20	—	—
21	Antibiotic	10:45	10:00	10:40	10:45	—	—
22	Antibiotic	10:00	09:00	09:30	09:40	—	—
23	Antibiotic	11:00	10:00	10:15	10:20	—	—
24	Hormonal drug	11:00	10:00	09:41	09:43	—	—
25	Hormonal drug	11:00	10:00	10:50	10:55	—	—
26	IM/IV solution	09:00	09:20	09:30	09:40	—	—
27	IM/IV solution	09:00	09:20	09:30	09:40	—	—
28	Cytostatics	09:30	09:00	09:30	09:35	5	Late order submission from department
29	Antibiotic	11:00	11:00	11:15	11:20	20	Late order submission from department
30	Cytostatics	11:00	Day before	10:20	10:30	—	—

Table 3. FMEA table.

Process Step	Potential Failure Mode	Potential Effect(s) on Patient Safety	Potential Cause(s)	S	O	D	RPN	Recommended Actions
1. Medication prescription	1) Incorrect prescription: "Wrong patient" "Wrong medication" Incorrect dosage prescribed discrepancy in dosing frequency/timing of administration discrepancy in route and rate of administration	Harm to the patient Adverse drug reaction, treatment delay	Human error, lack of double-check 1) Incorrect selection (selective verification of prescriptions) 2) Technical error	10	5	7	350	Physician self-check; Head of department/senior physician/ on-duty physician; Clinical pharmacologist. Checklist: "Verification of medication prescription by physician" based on the criteria: medication, patient, dose, frequency/timing, route and rate of administration. MIS automation of the "route of administration" field and labeling of look-alike/sound-alike medications. Implement electronic prescription and peer review
	2) Discrepancy between medication orders in the medical record and the Medication Administration Record	Harm to the patient Adverse drug reaction, treatment delay	1) Technical error (lack of control)	10	5	8	400	Verification of medication orders in the Medication Administration Record against the medical chart by nursing staff
1.1 Preparation of a medication request in the CPD (in case of MIS failure)	Discrepancy between the medication request and the physician's orders: 1) "Wrong patient" 2) "Wrong medication" 3) Dose discrepancy	Harm to the patient Adverse drug reaction, treatment delay	Technical error Unclear communication language: lack of communication between physician and nurse Lack of control	10	4	8	320	Verification of the medication request against the Medication Administration Record based on the criteria: medication, patient, dose. Communication between the CPD specialist and ward nurse in cases of unclear prescriptions.
2. Preparation of medications in the CPD 2.1 Preparation 2.2 Compounding / preparation of medications	Wrong medication prepared 1) "Wrong patient" 2) "Wrong medication" 3) Dose discrepancy	Harm to the patient Adverse drug reaction, treatment delay	Technical error Unclear communication language: lack of communication between physician and nurse Lack of control	10	4	8	320	1) Second-person verification of physician orders; cross-checking the received request/Medication Administration Record with medications being prepared or compounding based on the criteria: medication, patient, dose. 2) Communication with the physician and/or nurse in cases of unclear prescriptions.
3. Dispatch of medications from the CPD	Incorrect medication sent or sent to the wrong department Delay in medication dispatch to the clinical department	Harm to the patient Adverse drug reaction, treatment delay	Incorrect label/ sticker applied	10	3	8	240	1) Verification of correct dispatch by the pharmacist and CPD nurse 2) Ensuring an adequate number of couriers and organizing courier work according to an optimized schedule 3) Tasking IT support to improve MIS performance for faster label/sticker printing 4) Regulating the process of sending prepared medications via the pneumatic tube system
4. Receipt of medications from the CPD	Delivery of incorrect medication, Medication not received at the scheduled time "Wrong patient" "Wrong medication" Incorrect dosage prescribed discrepancy in dosing frequency/ timing of administration discrepancy in route and rate of administration	Harm to the patient Adverse drug reaction, treatment delay	1) Incorrect sticker/ label 2) Pneumatic tube system failure	10	3	5	150	Return to the CPD

5. Medication administration (execution of prescriptions)	Incorrectly administered medication order "Wrong patient" "Wrong medication" Incorrect dosage prescribed discrepancy in dosing frequency/timing of administration discrepancy in route and rate of administration	Harm to the patient Adverse drug reaction, treatment delay	1) Failure to verify the Medication Administration Record and patient identification 2) Inattention	10	3	7	210	Double-check: second nurse verification Checklist: "Verification of Medication Administration by Nurse" based on the criteria: medication, patient, dose, frequency/timing, route and rate of administration Implementation of a mobile version of the MIS For administration of narcotic and psychotropic medications – verification/control by the attending or on-duty physician
							1990	

Table 4. Comparison of Risk Priority Numbers Before and After FMEA-Based Improvements.

Failure Mode	Initial RPN	Interventions Implemented	Post-Intervention RPN
Incorrect prescription	350	E-prescribing, audit Implementation of the "Physician Medication Prescription Verification Checklist"; MIS automation of the "route of administration" field; look-alike/sound-alike medications highlighted using lowercase formatting in the system.	140
Discrepancy between medication prescription in the patient medical record and the Medication Administration Record	400	Verification of prescriptions in the Medication Administration Record against entries in the patient medical record by nursing staff	140
Discrepancy between the medication request in CPD and physician orders	320	Verification of the request against the Medication Administration Record by nursing staff	140
Incorrect medication prepared in CPD	320	Second-person verification of physician orders; cross-checking of the request with the Medication Administration Record by CPD pharmacist/nurse/clinical pharmacologist	140
Incorrect medication sent from CPD or sent to the wrong department	240	Verification of correspondence between request and dispatched medication: name, department, time; by CPD pharmacist and nurse	100
Incorrect medication delivered or medication not received at the scheduled time	150	Verification of received medication against the request based on criteria: medication, patient, dose, time; by nursing staff	80
Incorrect medication administration	210	Implementation of the "Checklist for Medication Administration execution by Nurse"; introduction of a mobile MIS version (on tablets), allowing nurses to verify prescriptions in real time before administration	100
	1990		840

management processes, the range of achievable RPN reduction, and a set of corrective interventions whose effectiveness has already been demonstrated in studies conducted in academic medical centers with a comparable level of quality management system maturity.

These benchmarks are subsequently applied to the process of "prescribing and administering medications to patients" at UMC. This approach enables not only the description of the local risk profile, but also an assessment of whether the effects achieved at UMC are comparable to those reported in the international literature.

Case Application: University Medical Center of Kazakhstan.

The practical application of FMEA is illustrated using a case study conducted at the University Medical Center in Astana, Kazakhstan, from December 1, 2023, to March 30, 2024.

The selected process for FMEA was "prescribing and

administering medications to patients." The FMEA process was conducted according to a standard methodology consisting of five steps (Figure 2).

The selection of the 2024 process was based on the annual ECRI Top 10 Patient Safety Concerns 2023 and the Institute for Safe Medication Practices (ISMP), which identify critical issues that threaten the safety of patients and healthcare workers when processes and systems are not properly aligned. Addressing these issues is typically complex and requires a system-level approach.

Among the 10 key concerns highlighted by ECRI in 2023 were the "risks of non-compliance with the 'five rules' of medication safety" and "medication prescribing errors arising from inaccurate patient medication lists." According to the Institute for Healthcare Improvement (IHI) and Duguid, inconsistent knowledge and record keeping about medications cause up to 50% of medication errors in hospitals and up to 20% of adverse

drug events. At least one in six patients may have a clinically significant medication discrepancy on intrahospital transfers [2].

The data were compared with the number of incidents and medication errors recorded at UMC over the past three years (2021–2023), which confirmed the relevance of the problem for UMC as well (Figure 3).

At the next stage, a multidisciplinary team of stakeholders was established, including the head of the quality management unit, the medical director, the head of pharmaceutical services, the head of nursing services, and clinical pharmacologists. The facilitator role was assigned to the head of the quality management unit, who is experienced in teamwork and the FMEA methodology, oversees the analysis process, and supports the team in applying a systematic approach to identifying failure causes and implementing appropriate corrective actions.

To identify the medication prescribing and administration process and to detect risks for FMEA, the team used a brainstorming method, with sufficient time allocated for discussion. Team meetings were scheduled in a way that did not interfere with routine daily duties.

During the Process Mapping stage, the team developed a flowchart of the process “prescribing and administering medications to patients,” breaking it down into individual steps (Figure 4).

The fourth stage involved assessing the significance of potential failure consequences. All team members were focused on identifying opportunities for process improvement, with detailed discussions conducted step by step throughout the process. The level of risk was determined using the UMC Risk Ranking Scale (Table 1).

Risk assessment of failure modes was performed across the steps of the process flowchart “prescribing and administering medications to patients.” All process failures were rated with a severity score of 10, as each of them could lead to severe patient harm, including a fatal outcome.

Step 1 – Prescription of medications by the physician in the Medical Information System (MIS).

At the first stage, “prescribing medication by the physician,” potential failure modes in the patient medical record within the MIS include violations of the “5 Rules” of medication safety due to incorrect drug selection caused by human factors or technical errors. The occurrence rating was assessed as 5 points, based on the estimated frequency of approximately once per month. The detectability rating was defined as 7 points, as the error can only be identified through a scheduled selective review by the head of department. The resulting RPN was 350 (high risk).

In addition, a failure at the prescribing stage may occur due to discrepancies between medication orders in the medical record and the Medication Administration Record, since the process of transferring prescriptions from the medical record to the Medication Chart—used by nurses and clinical pharmacy department specialists—is not automated in the MIS. The occurrence rating was assessed as 5 points, and the detectability rating as 8 points, as such discrepancies are identified only during specific inspection procedures. The resulting RPN was 400 (high risk).

Corrective actions to minimize risk were defined as follows:

- 1) Strengthening control measures: At the physician level, self-checking using a “Physician Medication Prescription Checklist”, along with selective audits by the head of department, senior physician/on-duty physician, and clinical pharmacologist. The review is based on the following criteria: medication, patient, dose, frequency/timing, route and rate of administration.

- 2) Verification of prescriptions: Nursing staff perform cross-checking of medication orders in the Medication Administration Record against entries in the patient’s medical chart.

- 3) MIS automation: Automation of the generation of the Medication Administration Record within the Medical Information System (MIS) based on physician orders recorded in the patient’s medical record.

Step 2 – Transfer of the Medication Administration Record to the Clinical Pharmacy Department (CPD).

The next step of the process involves the electronic transmission of the Medication Administration Record to the Clinical Pharmacy Department (CPD) for medication preparation, which is performed automatically within the Medical Information System (MIS). However, in the event of MIS failure, when electronic transmission to the CPD is not possible, a paper-based order form (“Request”) is completed by the nurse of the department.

In such cases, manual transcription of prescriptions from the Medication Administration Record into the paper Request introduces a potential risk of discrepancies (e.g., incorrect medication, wrong patient, or dosing inconsistencies) compared to the physician’s order. The occurrence rating was assessed as 4 points, (failures in the MIS occur with an average probability). The detectability rating was 8 points. The resulting RPN was 320 (high risk).

The following measures were defined to minimize the risk:

- 1) Verification of the Request against the Medication Administration Record by nursing staff using the criteria: medication, patient, dose.

- 2) Direct communication between Clinical Pharmacy Department specialists and nursing staff in cases of unclear or ambiguous prescriptions.

Step 3 – Preparation of medications in the Clinical Pharmacy Department (CPD).

At the medication preparation stage in the CPD, identified risks include the preparation of the wrong medication, medication intended for the wrong patient, or incorrect dosage. These risks may arise due to technical errors, unclear prescriptions, lack of communication between the physician, nurse, and CPD specialist, or insufficient control mechanisms.

The occurrence rating was assessed as 3 points, while the detectability rating was 8 points. The resulting RPN was 240 (high risk).

Step 4 – Dispatch of medications from the Clinical Pharmacy Department (CPD).

The dispatch of medications from the CPD is associated with risks of sending incorrect medications, delivering them to the

wrong department, or experiencing delays. The causes of these failures were identified based on incident reports and an audit conducted in the Clinical Pharmacy Department. The analysis revealed cases of delayed or incorrect delivery of medications from the CPD to clinical departments, as well as illegible medication orders in paper-based Medication Administration Records due to MIS failures.

According to incident reports for June and July 2023, a total of 53 system-related incidents were recorded:

- 1) Delayed delivery of medications to clinical departments – 11 incidents;
- 2) MIS failures – 37 incidents;
- 3) Pneumatic mail failures – 1 incident;
- 4) Incorrect dispatch of medications from CPD related to violations of the “5 Rules” of medication safety – 4 incidents.

For the audit, the objective was to identify the main problems associated with delayed dispatch and delivery of medications from CPD to clinical departments. To this end, a time-motion analysis was conducted to evaluate the time required for medication dispatch and delivery from CPD to clinical units, as well as staff workload involved in the delivery process (Table 2).

The average processing time for an order in the CPD (from request to dispatch) across 22 cases (excluding “day-before” cases and cases with incorrectly recorded times) was 35.3 minutes (min–max: 10–70 minutes). The average delivery time of medications from the CPD to the department was 8 minutes (min–max: 2–15 minutes).

The wide variability in dispatch times prompted further analysis of courier workflow. Couriers are responsible for the manual delivery of medications that cannot be transported via the pneumatic mail, as well as for loading other medications into the pneumatic mail. At the time of the tracer study, the CPD staffing included five couriers. Two out of five were on scheduled annual leave. According to the shift schedule, two couriers are assigned to the daytime shift, while one courier covers the night shift. However, on the day of the assessment, only one courier was available during the daytime shift. Due to the absence of the second courier, prolonged delays were observed in the dispatch of prepared medications from the CPD to clinical departments. Additionally, when the courier was physically present in clinical departments, delays in sending medications via the pneumatic mail were also observed during daytime hours.

A delay in medication dispatch due to pneumatic mail failures was observed in one case (1.9%). During the waiting period caused by capsule backlog and due to a shared pathway for incoming and outgoing capsules, the risk of incorrect delivery of capsules to inappropriate departments increased.

An additional cause of delayed medication dispatch from the CPD was intermittent slowdowns in the Medical Information System (MIS), which led to difficulties in printing labels/stickers.

Upon receipt of prepared medications via the pneumatic mail in clinical departments, insufficient control by nursing staff was noted, particularly regarding the recording of the exact time of medication receipt.

Thus, delays in the dispatch and delivery of medications from the CPD to clinical departments are associated with insufficient organization of the medication dispatch process.

At the stage of receiving prepared medications from the CPD, identified risks include delivery of incorrect medication and delayed arrival beyond the prescribed time due to incorrect labeling and pneumatic mail failures. The occurrence rating was assessed as 3 points and the detectability rating as 5 points. The resulting RPN was 150 (managed risk).

Step 5 – Medication administration (drug administration to the patient).

At the execution stage of medication orders, incorrect administration may occur in the following categories: “wrong patient,” “wrong medication,” “incorrect dose,” as well as discrepancies in frequency/timing of administration, route, or rate of administration. These failures may arise if verification between the received medication and the Medication Administration Record is not performed, due to patient misidentification, or due to inattentiveness.

The occurrence rating was assessed as 3 points, and the detectability rating as 7 points. The resulting RPN was 210 (high risk).

The identified potential risks were classified as high risk based on the RPN values. To minimize these risks, corrective measures were defined as follows:

- 1) Strengthening verification control:
Ensuring proper dispatch control by the pharmacist and nursing staff of the Clinical Pharmacy Department (CPD).
- 2) Adequate staffing and courier workflow optimization:
Increasing the number of couriers and reorganizing their schedule to ensure the availability of two couriers during the daytime shift.
- 3) Optimization of pneumatic mail operations:
Regulating the process of medication dispatch via the pneumatic mail and addressing system failures associated with incorrect routing of capsules to departments.
- 4) Medical Information System (MIS) interventions:
 - Eliminating technical issues related to system delays and slow performance;
 - Automating the “route of administration” field and implementing labeling for medications with similar names.
- 5) Strengthening double-check procedures:
Enhancing double verification using checklists for both CPD staff and nursing personnel in clinical departments.

All potential causes and recommended mitigation actions for each failure mode were documented in the FMEA table (Table 3).

This structured approach ensured that each failure mode was linked to its root causes and that clear, actionable risk reduction measures were defined.

The next step involved staff training in the relevant departments, for which a Medication Prescribing Process Questionnaire was used. It included correct answers to questions used during the control of medication prescribing by physicians, medication preparation in the Clinical Pharmacy Department, and medication administration by nursing staff. After training, the questionnaire was used as a reference tool (Table SII).

In accordance with the recommended measures, a checklist-based control system was implemented: the “Checklist for Verification of Physician Medication Prescriptions” and the

“Checklist for Verification of Medication Administration execution by Nurses.”

The full versions of the physician prescription verification checklist and the nursing execution checklist are provided in the Supplementary Materials (Supplementary Table SIII: Checklist for Physician Prescription Verification; Supplementary Table SIV: Checklist for Nursing Execution Verification).

The checklists were used by physicians and nurses for self-control in 100% of cases, as well as for selective audits at the level of the head of department and internal quality assurance unit experts. The implementation of these control activities also ensured compliance with the requirements of the Ministry of Health of the Republic of Kazakhstan regarding internal quality assessment procedures.

Automation within the Medical Information System (MIS) of medication prescribing by physicians, the “route of administration” field, and the labeling of look-alike/sound-alike medications, as well as the introduction of a mobile version of the MIS on tablets, helped to eliminate technical errors. These interventions removed the need for manual reconciliation of prescriptions in the Medication Administration Record with nursing documentation after physician orders, as well as the use of paper-based Medication Administration Records during patient care.

Following these interventions, the RPN was reassessed after improvements based on the FMEA methodology (Table 4).

As a result of the repeated FMEA after the implementation of corrective actions, the RPN at each stage of the medication prescribing and administration process was reduced, i.e., shifted from a high-risk level to a managed-risk level for medication errors, due to a decrease in the occurrence rating and an improvement in detectability.

The risk of incorrect prescribing decreased by 60%; discrepancies between medication orders in the medical record and the Medication Administration Record decreased by 65%; errors in medication preparation in the CPD decreased by 56.3%; errors in dispatch from the CPD and delivery to clinical departments decreased by 58.3% and 46.7%, respectively; and medication administration errors decreased by 52.4%. Overall, the total RPN decreased by 57.8%, or 2.4-fold.

The implementation of FMEA-based interventions over one year led to a reduction in medication errors. Specifically, the absolute number of reported medication errors decreased from 1,317 in 2024 to 670 in 2025, representing a 49% reduction (Figure 5). The proportion of errors detected before medication administration increased from 30% to 70%.

At UMC, approaches to the identification and reporting of medication errors are defined in accordance with the Joint Commission International Accreditation Standards for Hospitals. A medication error is defined as any preventable event that may lead to inappropriate medication use or pose a risk to patient safety.

Medication errors include: incorrect frequency of administration, incorrect dose, wrong medication, administration to the wrong patient, medication unavailability, vial damage, expired medication, improper storage, overdose, incidents reported by clinical pharmacists as Near Miss events, incorrect dilution, drug allergy, wrong route of administration, incorrect

timing of administration, incorrect infusion rate, and incorrect administration date.

A potential medication error (near miss, medication-related near miss) is defined as any deviation from the expected medication-use process at any stage (labelling, prescribing, or administration) that did not affect the patient outcome in this instance because it was detected and prevented before causing potential harm, but which could lead to a medication error and serious consequences if repeated.

A medication error or hazardous situation (“near miss”) may be identified at any stage of the medication-use process, including prescribing, preparation, administration, and patient monitoring after administration. Reporting of such events is permitted for any participant in the care process, including physicians, nurses, patients, and others, through submission of an “Incident Report” to the quality management department.

Discussion.

This study addresses an identified gap in the literature by presenting the first documented application of FMEA in a healthcare organization in Kazakhstan. It also demonstrates the successful implementation of FMEA in the processes of medication prescribing and administration at the University Medical Center, resulting in a 57.8% reduction in the total RPN and a 49% decrease in medication errors over one year. To the best of our knowledge, this is the first published FMEA study from a healthcare institution in Central Asia.

The growing body of international literature on FMEA application in medication safety provides a context for evaluating the UMC experience. In a teaching hospital in Sri Lanka, Anjalee et al. applied FMEA to the medication dispensing process, identifying 90 failure modes across two independent pharmacist teams [38]. The most frequently identified cause was overcrowded dispensing counters, which contributed to 57 failure modes. The study demonstrated that FMEA can be effectively used by pharmacists in resource-constrained settings to systematically identify and prioritize failure modes in the dispensing process.

In India, Jain conducted an FMEA study in a multi-specialty hospital in Gurgaon [39]. Authors identified 11 failure modes in the medication management process, with transcription errors accounting for 37% and administration errors for 29% of observed medication errors. After implementing corrective actions, the study achieved approximately 40% average and up to 60% reduction in RPN values for prioritized failure modes. Similarly, in Jordan, Haroun et al. applied FMEA to the nursing blood sampling process at King Hussein Cancer Center, identifying eight critical failure modes with RPN exceeding 200 and achieving a 58% reduction in RPN after implementing corrective actions across five improvement themes [40]. These international experiences demonstrate that FMEA can be successfully implemented across diverse healthcare settings, from tertiary care hospitals in South Asia to specialized cancer centers in the Middle East, with consistent results in identifying high-risk failure modes and achieving meaningful risk reduction.

The profile of the most significant failure modes identified at UMC is consistent with findings from recent HFMEA studies of medication management processes in secondary

care hospitals. In particular, Sova et al. [41], who applied HFMEA to an electronic medication management process in a multidisciplinary hospital in Finland, identified 35 failure modes, among which the most critical were failures at the stage of transferring prescriptions into the electronic patient record and at the medication reconciliation stage. These correspond directly to the failure clusters in our dataset with the highest RPN values (discrepancy between medication orders in the medical record and the Medication Administration Record, RPN = 400; prescribing errors, RPN = 350).

The similarity in risk profiles observed across academic medical centers with different levels of digitalization supports the conclusion that critical process vulnerabilities are systemic rather than local in nature. It also suggests that the prioritization of interventions conducted at UMC follows patterns consistent with those described in the international literature [17,18,41].

The content of the corrective interventions selected by the FMEA team at UMC (electronic prescribing, physician and nurse self-checklists, and mobile bedside medication verification) aligns with the priorities outlined in the Targeted Medication Safety Best Practices of the Institute for Safe Medication Practices [42] and in the updated AHRQ review Making Healthcare Safer IV by the Agency for Healthcare Research and Quality [43]. In these frameworks, computerized provider order entry with clinical decision support (CPOE-CDS) is identified as one of the most evidence-based interventions for reducing prescribing errors.

Meta-analytic evidence demonstrates approximately a 48% reduction in prescribing error probability when transitioning from paper-based prescribing to CPOE, and a 30.1% reduction in orders containing at least one error following implementation of electronic systems [43, 44]. The observed 49% reduction in reported medication errors at UMC falls within this range. The fact that this reduction was achieved without full end-to-end automation of the medication-use process suggests that these results may represent a conservative estimate of the potential impact of further digitalization of the medication management cycle.

The findings gain additional significance in the context of the World Health Organization Global Patient Safety Report [45]. According to this report, the majority of preventable harm is concentrated in low- and middle-income countries. For example, approximately 134 million adverse events are reported annually in hospitals in these countries, with more than half of preventable medication-related harm occurring at the prescribing stage.

The relevance of FMEA implementation in low- and middle-income countries (LMICs) has been increasingly recognized. For instance, In Iran, Yousefinezhadi et al. applied process FMEA to improve intensive care unit reliability in two Tehran hospitals [46]. It helped them identify 378 potential failure modes in one hospital and 184 in another. Thus, the study demonstrated that FMEA empowers staff to identify, evaluate, and analyze failure modes without feeling blamed by management, which is a critical factor for sustainable quality improvement in resource-limited settings.

In China, Xu et al. conducted a multicenter FMEA study across multiple hospitals to optimize acute kidney injury management

[47]. The analysis identified 22 failure modes, with the highest RPN (224) associated with pharmacists failing to provide correct dosage adjustment plans. After implementing a clinical decision support system (CDSS), the total RPN decreased by 87.5%, demonstrating the potential for significant risk reduction even in complex clinical pathways.

The application of FMEA at the medical center addresses two key objectives. First, it introduces a risk management tool validated by international practice. Second, it establishes a methodological and educational foundation for scaling this approach to regional and rural healthcare organizations, where workforce shortages and limited digital infrastructure require particularly careful prioritization of interventions. In practical terms, the application of the same FMEA methodology in multiple healthcare organizations across Kazakhstan, from urban academic centers to rural district hospitals, would allow a direct comparison of failure-mode profiles, RPN distributions, and magnitudes of risk reduction.

When interpreting the results obtained, it is necessary to consider the recognized methodological limitations of FMEA itself. Numerous reviews [3,35] note that the multiplicative nature of the RPN ($S \times O \times D$), the subjectivity of expert judgments, and low inter-rater reproducibility may lead to an overestimation of the precision of quantitative outputs.

In our study, this limitation was partially mitigated through the achievement of group consensus within a multidisciplinary team, the use of standardized scoring scales adapted from IEC 60812, and the combination of FMEA with Ishikawa diagrams and root cause analysis. Nevertheless, formal assessment of inter-rater reliability was not performed, which is consistent with limitations reported in the literature and defines a direction for further methodological development. Future work should focus on testing simplified scoring systems [17] and approaches based on pairwise comparisons [28] or failure mode prediction models [24]. This caveat is particularly relevant because even small variations in individual ratings of Severity, Occurrence, or Detection can produce meaningful shifts in the resulting RPN and, consequently, in the prioritization of corrective actions.

In addition, our results are consistent with findings from the literature on FMEA in medication safety. Anjalee et al. [18], in a systematic review of FMEA applications in medication-use processes, reported RPN reductions ranging from 40% to 70% across included studies, placing our observed reduction of 57.8% within the expected range. Duncan et al. [10] similarly demonstrated significant risk reduction in central venous catheter placement using a comparable multidisciplinary FMEA approach.

The magnitude of risk reduction observed at UMC (57.8%) is consistent with ranges reported in recent systematic reviews. A comprehensive scoping review analyzed 163 FMEA studies in healthcare settings published between 2003 and 2023, finding that FMEA was successfully applied across diverse clinical areas including medication safety, surgical processes, and infection prevention [35]. The review noted that FMEA implementation was particularly effective when combined with complementary tools such as root cause analysis and Ishikawa diagrams, as practiced at UMC.

Additionally, El-Awady provided an overview of FMEA as a patient safety tool [22]. It was noted that the method originated in high-risk industries including aerospace and chemical manufacturing before being adapted for healthcare. The review highlighted that the Joint Commission on Accreditation of Healthcare Organizations (JCAHO) recognized FMEA as an effective proactive risk analysis method when researching safety improvement techniques for healthcare services. This cross-industry validation supports the transferability of FMEA methodology to medication management processes in different healthcare contexts, including the Central Asian setting described in the present study.

An important observation is that the Severity (S) rating remained unchanged at a value of 10 for all failure modes, as the nature of potential harm (up to and including patient death) was not altered by the interventions. Risk reduction was achieved exclusively through a decrease in Occurrence (O) and improvements in Detectability (D). This pattern is consistent with FMEA literature, where Severity is typically considered an intrinsic property of the failure mode that is not modifiable through process improvements [3]. The relatively smaller reduction in risk associated with detectability (46.7%) may indicate that certain detection mechanisms still depend on staff vigilance, which is inherently less reliable than automated, system-based controls.

This study builds on the traditional strengths of FMEA, namely its systematic approach, proactivity, multidisciplinary collaboration, risk prioritization, and formalized documentation. The FMEA report is also used as a tool for staff training and process standardization at UMC.

A number of contextual factors may have influenced the observed improvements in addition to the FMEA interventions. The parallel implementation of a mobile MIS, the institutional focus on reaccreditation by the Joint Commission International, and overall staff awareness of the ongoing study (the so-called Hawthorne effect) may all have contributed to the results. Furthermore, the increase in the proportion of errors detected prior to administration (from 30% to 70%) may partially reflect an improvement in the reporting culture within the organization, rather than solely improvements in detection processes. These confounding factors should be taken into account when interpreting the magnitude of the observed improvements.

The findings on the application of FMEA in both clinical and non-clinical processes will serve as a foundation for expanding the use of this method and for selecting future FMEA topics at UMC.

Limitations.

This study has several limitations.

First, it was conducted in a single academic medical center with Joint Commission International accreditation and relatively advanced infrastructure. Therefore, the findings may not be fully generalizable to regional or rural healthcare organizations in the country, where resource and workforce constraints are more pronounced.

Second, despite achieving team consensus, FMEA scoring remains inherently subjective and dependent on the experience and expertise of participants. A different team might assign

different scores to the same failure modes. Inter-rater reliability was also not formally assessed.

Another limitation is that the narrative review was restricted to two databases, and screening was performed by a single reviewer without formal quality appraisal of included studies, which may have introduced selection bias. In addition, the before–after study design without a control group does not allow all observed improvements to be attributed solely to FMEA interventions. Temporal trends, concurrent institutional changes, and improvements in reporting culture may have also contributed and should be considered when interpreting the findings and formulating conclusions.

Despite these limitations, FMEA demonstrated its value as a tool for early identification and mitigation of risks in clinical processes.

Conclusion.

The results of the case study conducted at the University Medical Center practically demonstrated the applicability of risk analysis approaches in improving the quality of healthcare delivery.

FMEA is an effective proactive tool for enhancing patient safety and can be successfully adapted in healthcare organizations in Kazakhstan. A standardized methodology combined with locally adapted checklists and integration with IT systems represents a reproducible model for other healthcare institutions in the region. Future research should focus on multicenter implementation, controlled study designs, and evaluation of the long-term sustainability of improvements.

Conflict of interest statement.

The authors declare that they have no conflicts of interest.

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Абстракт.

Введение: Безопасность пациентов остаётся одной из ключевых проблем систем здравоохранения по всему миру и требует проактивных подходов к управлению рисками для предотвращения нежелательных событий. Анализ видов и последствий потенциальных отказов (Failure Mode and Effects Analysis, FMEA) является широко признанным инструментом, однако опубликованные данные о его применении в медицинских организациях Центральной Азии крайне ограничены.

Цель исследования: проанализировать применение FMEA в процессе назначения и введения лекарственных препаратов в Университетском медицинском центре в Казахстане и оценить влияние мероприятий, разработанных на основе FMEA, на частоту медикаментозных ошибок.

Материалы и методы: исследование выполнено в рамках проекта по улучшению качества и включало два компонента. Во-первых, проведён нарративный обзор литературы по базам данных PubMed и Web of Science (2020–2026): из 917 найденных записей отобрано и проанализировано 34 публикации, соответствующие критериям включения. Во-вторых, в период с декабря 2023 года по март 2024 года в Корпоративном фонде «Университетский медицинский центр» (УМЦ, г. Астана, Казахстан) проведено проспективное FMEA-исследование. Мультидисциплинарная экспертная группа (медицинский директор, руководитель службы менеджмента качества, руководитель фармацевтической службы, главная медсестра и два клинических фармаколога) оценивала виды отказов в процессе назначения и введения лекарственных средств с использованием стандартных шкал значимости (S), частоты возникновения (O) и обнаруживаемости (D), каждая по 10-балльной шкале. Рассчитывались числа приоритета риска (Risk Priority Number, RPN); для отказов высокого риска внедрялись целевые корректирующие мероприятия. Повторная оценка проведена в январе 2026 года.

Результаты: на шести этапах процесса выявлено семь видов отказов. Исходные значения RPN находились в диапазоне от 150 до 400 (суммарный RPN = 1990). Наибольшие риски были связаны с расхождениями между назначениями в медицинской карте и листом врачебных назначений (RPN = 400) и с ошибками назначения (RPN = 350). После внедрения корректирующих мер — электронных назначений, чек-листов самоконтроля врача и мобильной верификации лекарств — суммарный RPN снизился на 57,8% и составил 840. Число зарегистрированных медикаментозных ошибок уменьшилось в 2025 году на 49% по сравнению с 2024 годом, при этом доля ошибок, выявленных до введения препарата, возросла с 30% до 70%.

Выводы: FMEA продемонстрировал эффективность как проактивный инструмент выявления и снижения рисков лекарственной безопасности в УМЦ. Полученные результаты поддерживают более широкое внедрение этого метода в системах здравоохранения стран Центральной Азии; вместе с тем его применимость к учреждениям с ограниченными ресурсами требует дальнейшего изучения.

Ключевые слова: безопасность пациентов, FMEA, управление рисками, качество медицинской помощи, Казахстан.