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STRATEGIES FOR RISK ASSESSMENT IN MEDICATION MANAGEMENT: A SYSTEMATIC REVIEW OF THEIR IMPACT ON PATIENT SAFETY AND OPERATIONAL EFFICIENCY

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ABSTRACT

Introduction Medication management is a complex, high-risk component of healthcare and remains vulnerable to errors that might affect patient safety and operational efficiency. This systematic review aimed to evaluate risk assessment strategies used in medication management and to synthesize evidence regarding their impact on patient safety and operational performance.

Materials and methods A systematic review was conducted following PRISMA 2020 guidelines. Comprehensive searches of the Scopus and PubMed databases identified peer-reviewed studies published between 2020 and 2025. Using the PICOS framework, eligible studies evaluated risk assessment strategies within medication-use processes and reported patient-related safety and/or efficiency outcomes. Data were analysed through thematic synthesis.

Results Sixteen studies met the inclusion criteria. Proactive risk assessment strategies—notably Failure Mode and Effects Analysis and its variants—were widely implemented across medication-use processes, particularly in high-risk settings. Their use improved the identification and prioritization of medication-related risks, reduced error rates or risk scores, bolstered compliance with safety protocols, and optimized workflow organization and resource allocation. Technology-driven tools further enhanced effectiveness by enabling standardization and continuous monitoring.

Conclusions Structured risk assessment strategies measurably improve patient safety and operational efficiency in medication management. Further longitudinal and comparative research is required to evaluate long-term clinical and economic outcomes.

Keywords Pharmaceutical Oversight, Patient Welfare, Hazard Evaluation, Operational Effectiveness, Risk assessment.

STRATEGII DE EVALUARE A RISCURILOR ÎN MANAGEMENTUL MEDICAȚIEI: O REVIZUIRE SISTEMATICĂ A IMPACTULUI ACESTORA ASUPRA SIGURANȚEI PACIENTULUI ȘI EFICIENȚEI OPERAȚIONALE

Introducere Managementul medicației reprezintă o componentă complexă și cu risc ridicat a sistemului de sănătate, caracterizată prin vulnerabilități persistente, care afectează siguranța pacientului și eficiența operațională. Această revizuire sistematică a examinat strategiile de evaluare a riscurilor utilizate în managementul medicației și a sintetizat dovezile, privind impactul acestora asupra siguranței pacientului și eficienței operaționale.

Materiale și metode A fost realizată o revizuire sistematică conform ghidului PRISMA 2020. Căutările efectuate în bazele de date Scopus și PubMed au identificat studii evaluate de colegi (peer-reviewed), publicate în perioada 2020–2025. Utilizând cadrul PICOS, au fost incluse studiile care au evaluat strategii de evaluare a riscurilor în cadrul proceselor de utilizare a medicamentelor și au raportat rezultate privind siguranța și/sau eficiența. Datele au fost analizate prin sinteză tematică.

Rezultate Șaisprezece studii au îndeplinit criteriile de includere. Strategiile proactive de evaluare a riscurilor, în special analiza modurilor de defectare și a efectelor acestora (Failure Mode and Effects Analysis – FMEA) și variantele sale, au fost frecvent aplicate în procesele de utilizare a medicamentelor, în special în contexte cu risc înalt. Aplicarea acestora a îmbunătățit identificarea și prioritizarea riscurilor asociate medicației, a redus ratele erorilor sau scorurile de risc, a consolidat conformitatea cu practicile de siguranță și a optimizat organizarea fluxurilor de lucru și utilizarea resurselor. Instrumentele susținute de tehnologie au crescut eficiența prin facilitarea standardizării și monitorizării continue.

Concluzii Strategiile structurate de evaluare a riscurilor contribuie la îmbunătățirea siguranței pacientului și a eficienței operaționale în managementul medicației. Sunt necesare cercetări longitudinale și comparative suplimentare pentru a evalua rezultatele clinice și economice pe termen lung.

Cuvinte-cheie Supraveghere farmaceutică, siguranța pacientului, evaluarea riscurilor, eficiență operațională, managementul riscurilor.

INTRODUCTION

Drug medication management is a fundamental component of healthcare delivery, encompassing a series of interrelated processes including prescribing, dispensing, administration, and monitoring of medicines. The effectiveness of medication management systems is critical in ensuring patient safety, improving clinical outcomes, and optimizing the use of healthcare resources. Inadequate medication management has consistently been associated with medication errors and adverse drug events, which represent a major source of preventable patient harm across healthcare settings. The World Health Organization has emphasized medication safety as a strategic priority within its Global Patient Safety Action Plan 2021–2030, highlighting that systematic improvements in medication management processes are essential to reducing avoidable harm and strengthening patient safety across healthcare systems worldwide (1-3).

Despite ongoing global initiatives to enhance medication safety, medication-related errors and system inefficiencies continue to occur across healthcare settings. Recent evidence suggests that limitations in prescribing accuracy, medication dispensing processes, and interprofessional communication continue to be major contributors to preventable patient harm, adverse drug events, and avoidable healthcare costs. These challenges reinforce the need for systematic improvements in medication management to enhance patient safety and optimize clinical outcomes (4–6). Traditionally, medication safety initiatives have relied on reactive approaches, focusing primarily on incident reporting and retrospective analysis after errors occur. Although these methods are valuable for learning from past events, they do not reliably prevent harm before it arises and are limited in their ability to address underlying systemic risks. Growing evidence indicates that proactive strategies—such as systematic risk assessment, structured medication reconciliation, and multidisciplinary interventions designed to anticipate and mitigate potential errors—are more effective in preventing unintended medication discrepancies and improving patient safety outcomes (7). These approaches prioritize the early identification of vulnerabilities within the medication-use process and the implementation of preventive measures, rather than relying solely on retrospective analyses once errors have occurred.

Risk assessment has emerged as a key proactive approach within medication management. By systematically identifying, analysing, and prioritising potential risks, these approaches enable early intervention and informed decision-making across medication-related processes (8, 9). Methodologies such as Failure Mode and Effects Analysis, Hazard Vulnerability Assessment, and technology-supported risk assessment tools have been applied to identify vulnerabilities in prescribing, dispensing, and administration systems (10, 11). Beyond improving patient safety, these approaches have also been associated with improved workflow organisation and more efficient use of healthcare resources (12).

Although numerous studies have explored the use of risk assessment tools in specific areas of medication management—such as high-alert medications, pharmacy operations, and clinical trial drug handling—the available evidence remains fragmented. Most studies focus on individual interventions or local implementations, with limited synthesis of their broader implications for patient safety and operational efficiency (10-12). As a result, decision-makers lack a comprehensive evidence base to support the systematic integration of risk assessment into medication management systems.

To address this gap, the present study conducted a systematic literature review to identify and synthesise evidence on risk assessment strategies applied in

medication management across healthcare settings. This review was aimed to examine how these strategies are implemented and to assess their reported impact on patient safety and operational efficiency, thereby providing an evidence-informed foundation for future research and practice.

MATERIALS AND METHODS

Study design

This study was conducted as a systematic literature review (SLR) aimed at synthesizing empirical evidence on risk assessment strategies applied in medication management and their reported impact on patient safety and operational efficiency in healthcare settings. A systematic review design was employed to ensure a transparent, structured, and reproducible approach to identifying, selecting, and synthesizing relevant studies. The review was conducted in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) 2020 guidelines, which provide internationally recognized standards for the conduct and reporting of systematic reviews (13).

Review question

The review was guided by the following research question:

What risk assessment strategies are used in medication management in healthcare settings, and how do they impact patient safety and operational efficiency?

This research question was designed to capture both the implementation of risk assessment approaches within medication management systems and their reported impact on patient safety and operational performance.

Eligibility criteria

Eligibility criteria were predefined using the Population, Intervention, Comparison, Outcomes, and Study Design (PICOS) framework to ensure methodological consistency throughout the study selection and data extraction processes (14).

1. Population: Healthcare facilities, including hospitals and other clinical care settings where medication management processes are implemented.
2. Intervention: Risk assessment strategies applied within medication management, including structured analytical methods (such as Failure Mode and Effects Analysis and Hazard Vulnerability Assessment), risk-prioritisation tools, and technology-assisted risk assessment approaches.
3. Comparison: Conventional or non-risk-based medication management approaches, where applicable.
4. Outcomes: Outcomes related to patient safety (e.g. medication errors, adverse drug events, safety compliance) and/or operational efficiency (e.g. workflow optimization, resource utilization, process efficiency).
5. Study design: Empirical studies employing qualitative, quantitative, or mixed-methods designs.

Studies were excluded if they focused exclusively on pharmaceutical manufacturing processes, chemical impurity analysis, or non-clinical contexts unrelated to medication management within healthcare settings.

Search strategy:

A comprehensive literature search was conducted in the Scopus and PubMed databases to identify relevant peer-reviewed studies published between January 2020 and December 2025. These databases were selected to ensure broad coverage of biomedical, pharmaceutical, and healthcare management literature.

The search strategy combined controlled vocabulary terms and free-text keywords related to medication management, risk assessment, and healthcare outcomes. Boolean operators were applied to refine the search and enhance sensitivity. The core search string used was:

("medication management" OR "pharmacy management")

AND ("risk assessment" OR "risk management" OR "failure mode and effects analysis" OR "hazard vulnerability assessment")

AND ("patient safety" OR "medication error" OR "operational efficiency")

To minimise the risk of missing relevant studies, the reference lists of all included articles were also manually screened.

Study selection

All records retrieved from the database searches were exported and screened in two sequential stages. In the first stage, titles and abstracts were reviewed to exclude studies clearly irrelevant to the research question. In the second stage, full-text articles were assessed for eligibility according to predefined inclusion and exclusion criteria.

The study selection process followed the PRISMA flow structure, including identification, screening, eligibility assessment, and final inclusion (13). Any uncertainties encountered during the selection process were resolved through discussion to reach consensus.

Data extraction

Data were extracted from the included studies using a structured data extraction form developed specifically for this review. Extracted information included author(s), year of publication, study setting, study design, type of risk assessment strategy, outcomes related to patient safety and operational efficiency, and key findings.

The use of a standardized data extraction approach was intended to enhance consistency across studies and reduce the risk of selective reporting.

Quality appraisal and risk of bias assessment

The methodological quality of the included studies was assessed using appropriate critical appraisal tools according to study design. The appraisal focused on key methodological aspects, including clarity of study objectives, appropriateness of research design, robustness of data collection methods, and validity of outcome reporting.

Rather than serving as exclusion criteria, the results of the quality appraisal were used to support the interpretation of findings and to contextualize the strength and limitations of the available evidence.

Data synthesis

A thematic synthesis approach was employed to analyse and integrate findings from the included studies, allowing systematic comparison across heteroge-

neous study designs and contexts (15). Extracted data were initially coded to identify recurring concepts related to risk assessment strategies and their reported impacts. These codes were subsequently grouped into broader analytical themes reflecting patient safety outcomes and operational efficiency implications.

This approach enabled the identification of patterns, similarities, and differences across studies while accommodating variations in healthcare settings and methodological designs.

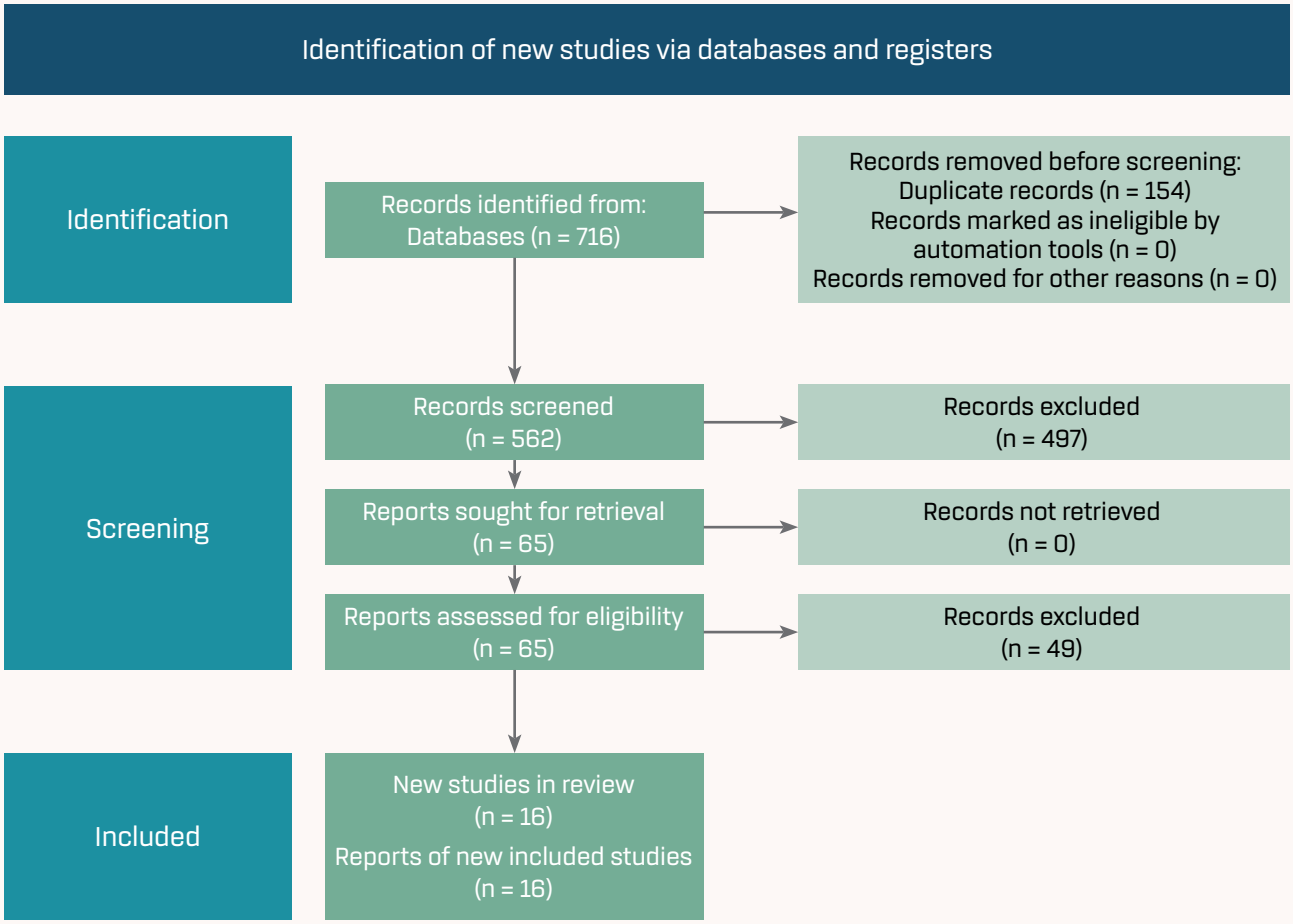

Figure 1. PRISMA approach.

The database search yielded a total of 716 records from Scopus and PubMed, with an additional 18 records identified through reference list screening. After removing 154 duplicates, 562 records remained for title and abstract screening. In accordance with PRISMA 2020 terminology, 'records' refer to database search results, while 'reports' refer to full-text articles assessed for eligibility. Of these, 497 records were excluded due to lack of relevance to medication management, risk assessment, or the outcomes of interest. Full-text review was conducted for 65 articles, of which 49 were excluded for reasons including non-clinical focus, absence of risk assessment strategies, or irrelevant outcomes. Ultimately, 16 studies were included in the qualitative synthesis.

RESULTS

Study selection

The study selection process is illustrated in the PRISMA 2020 flow diagram (Figure 1). Following database searches in Scopus and PubMed and additional screening of reference lists, a total of records was identified. After duplicate removal and title abstract screening, full-text articles were retrieved and assessed for eligibility. Studies were excluded at the full-text stage if they did not address risk assessment strategies in medication management or failed to report outcomes related to patient safety or operational efficiency. Ultimately, 16 studies met all inclusion criteria and were included in the qualitative synthesis. The study outcomes are summarized in the table below.

Characteristics of included studies

The characteristics of the included studies are described in Table 1. The studies were published between 2021 and 2025 and were conducted across a wide range of healthcare settings, predominantly hospital-based pharmacy services, including inpatient wards, outpatient pharmacies, oncology units, perioperative services, and centralized intravenous admixture units.

Table 1. Characteristics of the included studies (n = 16).

No	Research Name	Setting & focus	Risk assessment method
1	Anjalee JAL, Rutter V, Samaranayake NR. **Application of failure mode and effects analysis (FMEA) to improve medication safety**. *BMC Public Health*. 2021.	Outpatient hospital pharmacy; dispensing process	FMEA + failure mode prioritization → planning mitigation
2	Abbassi A, Ben Cheikh Brahim A, Ouahchi Z. **FMEA applied to improve medication management process in a teaching hospital pharmacy**. *Eur J Hosp Pharm*. 2023.	Teaching hospital pharmacy (Tunisia); medication management process	FMEA + simplified rating system proposal
3	Pueyo-López C, Sánchez-Cuervo M, Vélez-Díaz-Pallarés M, et al. **HFMEA in chemotherapy preparation process**. *J Oncol Pharm Pract*. 2021.	Centralized chemotherapy preparation	HFMEA (hazard scoring) → action plan
4	Caballero-Romero Á, Fernández S, Morillo AB, et al. **HFMEA & cost-minimization of three medication delivery services**. *Farm Hosp*. 2021.	Outpatient medication delivery (pickup vs community pharmacy vs home delivery)	HFMEA + cost analysis
5	ElLithy MH, et al. **FMEA analysis of challenges during pharmacy automation/robotics implementation**. *Saudi Pharm J*. 2023.	Implementation of hospital pharmacy automation/ robotics	FMEA for identification of implementation risks and barriers
6	Meknassi Salime G, Bhirich N, Chefchaouni AC, et al. **Assessment of Automation Models in Hospital Pharmacy**. *Hospital Pharmacy*. 2025.	Hospital pharmacy automation model (technology review and impact)	Systematic review of automation technologies (for the context of error prevention strategies)
7	Engström M, et al. **Impact of transition to a digital hospital on medication incidents**. *npj Digital Medicine*. 2023.	"digital hospital" transition; medication incidents	Before–after evaluation of drug incidents related to digitalization
8	Yu K, et al. **Technology implementation impacts on dispensing errors: validation through error reporting system**. *JMIR Med Inform*. 2025.	Drug technology and error reporting	Analysis of the impact of technology on dispensing errors

No	Research Name	Setting & focus	Risk assessment method
9	Zhang L, He X, Wang Y, et al. **FMEA for anesthetic & class I psychotropic drugs management (pilot)**. *Scientific Reports*. 2025.	High-risk medication management (anesthetics/ psychotropics)	FMEA + RPN for risk prioritization
10	Cai J, Li M-X, Lu S, et al. **FMEA to improve monoclonal antibody drugs management in PIVAS**. *Scientific Reports*. 2025.	PIVAS (IV admixture); mAb drugs	Multi-round FMEA → RPN decrease
11	Chen S, Zhang H, Zhi H, Wang J. **HFMEA to enhance patient-controlled analgesia management after anesthesia**. *Frontiers in Medicine*. 2025.	PCA management (post-anesthesia)	HFMEA + risk scoring → flow improvement
12	Ghoushchi SJ, Dorosti S, Ab Rahman MN, et al. **Theory-Based FMEA for Medication Errors**. *J Healthcare Engineering*. 2021.	Medication errors (theoretical model/ approach)	Theory-based FMEA (causal factor modeling)
13	Despott RA, Vella Bonanno P, Gauci C. **Risk management of medication errors: improving pharmacotherapeutic practice**. *Pharmacol Res Perspect*. 2025.	Pharmacotherapy practice; medication errors	Quality risk management approach
14	Ford EH, Michalek C. **Medication Safety Officers: a pillar of patient safety in hospital pharmacy**. *Farmacia Hospitalaria*. 2025.	The role of MUSO and drug safety strategies	Practice/policy articles: systems approach and safety programs
15	Sakly H, Chakroun I, Ben Jeddou K. **FMECA for temperature-sensitive drugs medication-use process**. *Can J Hosp Pharm*. 2022.	Cold chain / temperature-sensitive drugs	FMECA (5Ws & How + Ishikawa) → improvement priority
16	Joly-Mischlich T, Maltais S, Tétu A, et al. **FMEA before implementing CPOE in oncology clinic**. *J Oncol Pharm Pract*. 2023.	CPOE pre-implementation (oncology)	FMEA for vulnerability identification & redesign

Methodologically, the review encompasses quantitative observational designs, qualitative case studies, mixed-methods evaluations, and implementation-focused research. Most studies examined proactive risk assessment approaches, particularly Failure Mode and Effects Analysis (FMEA), Healthcare Failure Mode and Effects Analysis (HFMEA), or Failure Mode, Effects, and Criticality Analysis (FMECA). Several studies also examined technology-supported strategies, such as pharmacy automation, digital medication systems, and electronic prescribing, either as standalone interventions or in combination with structured risk assessment frameworks.

Across the included studies, outcomes were commonly reported in terms of patient safety indicators (e.g. medication errors, risk prioritisation, safety compliance) and operational efficiency measures (e.g. workflow optimisation, resource allocation, process standardisation).

Synthesis of findings

Thematic synthesis of the included studies identified three overarching themes:

1. Proactive risk assessment strategies in medication management,
2. Impact of risk assessment on patient safety, and
3. Impact of risk assessment on operational efficiency.

Most studies reported the implementation of structured, proactive risk assessment methodologies to identify vulnerabilities within medication management processes before adverse events occurred. FMEA-based approaches were the most commonly used strategies and were applied across multiple stages of the medication-use process, including prescribing, dispensing, preparation, storage, and administration.

Several studies described the use of FMEA, HFMEA, or FMECA to systematically map medication-use workflows, identify potential failure modes, and prioritize risks using scoring systems based on severity, occurrence, and detectability. These approaches were particularly prominent in high-risk settings, including chemotherapy preparation, management of high-alert medications, anaesthetic and psychotropic drug handling, and temperature-sensitive drug storage.

In addition to conventional FMEA-based methods, a subset of studies incorporated technology-driven risk assessment strategies, such as pharmacy automation, digital medication incident reporting systems, and electronic prescribing platforms. In these contexts, risk assessment was commonly integrated into broader system redesign initiatives, enabling continuous monitoring and iterative refinement of medication-use processes.

Impact of risk assessment strategies on patient safety

Across the included studies, implementation of risk assessment strategies was consistently associated with improvements in patient safety outcomes. Many studies reported more effective identification of latent risks within medication management systems, particularly those arising from complex workflows, high-risk medications, and transitions of care.

Several studies revealed reductions in medication error rates or risk priority numbers following the application of FMEA or HFMEA, indicating better control of high-risk failure modes. Other studies highlighted qualitative improvements, including increased staff awareness of medication-related risks, stronger adherence to safety protocols, and more structured documentation of medication processes.

Technology-driven interventions further enhanced patient safety by enabling real-time error detection, standardizing medication workflows, and facilitating more effective communication among healthcare professionals. Overall, the findings suggest that proactive risk assessment serves as an effective mechanism for strengthening medication safety by shifting the organisational efforts from reactive error correction toward anticipatory risk mitigation.

Impact of risk assessment strategies on operational efficiency

In addition to patient safety benefits, many included studies reported positive effects on operational efficiency. Risk assessment strategies enabled healthcare organisations to prioritise resources toward high-risk processes, thereby reducing unnecessary workload and improving workflow efficiency.

FMEA-based interventions were commonly associated with more streamlined medication preparation and dispensing processes, reduced process variability, and clearer role definition among pharmacy staff. Studies assessing pharmacy automation and digital medication systems reported further efficiency gains, including reduced manual handling, shorter turnaround times, and improved traceability of medication-related activities.

Importantly, several studies highlighted that improvements in operational efficiency did not compromise patient safety. Instead, efficiency gains were often described as complementary outcomes of more effectively designed, risk-informed medication management systems.

Summary of results

Overall, the findings of this systematic review indicate that risk assessment strategies are widely implemented across medication management processes and healthcare settings, with consistent evidence of benefits for both patient safety and operational efficiency. Although specific methods and outcomes varied among studies, the overall body of evidence supports structured and proactive risk assessment as a fundamental component of effective medication management systems.

DISCUSSIONS

This systematic literature review synthesized evidence from 16 international studies to examine how risk assessment strategies are implemented in medication management and how they influence patient safety and operational efficiency. The findings extend the existing medication safety literature by demonstrating that proactive, structured risk assessment functions not only as a patient safety intervention but also as a managerial tool that contributes to operational performance within healthcare systems.

Integration of risk assessment within medication management systems

The findings of this review indicate that risk assessment strategies are increasingly embedded across multiple stages of the medication-use process, including prescribing, preparation, dispensing, storage, and administration. This system-wide implementation reflects a transition from isolated safety measures toward more comprehensive risk management approaches. Previous literature has commonly examined medication errors as discrete events or focused on single interventions (1–3). In contrast, the studies included in this review highlight the role of risk assessment as an ongoing process that facilitates organizational learning and system redesign (15–17).

The predominance of FMEA-, HFMEA-, and FMECA-based approaches across diverse settings indicates that these methodologies remain central to proactive medication safety initiatives. Their adaptability in high-risk contexts, such as oncology services, perioperative care, and the management of high-alert or temperature-sensitive medications, highlights their relevance within complex medication systems (18–20). This finding supports earlier calls for system-based approaches to medication safety rather than reliance on individual vigilance alone (3, 21).

Implications for patient safety outcomes

Consistent with prior research, the findings of this review indicate that risk assessment strategies are associated with improved patient safety outcomes, particularly through more effective identification of latent risks and prioritization of high-risk failure modes (7, 10). Several included studies reported reductions in medication error rates or risk priority numbers following the implementation of structured risk assessment approaches (22). Others described qualitative improvements, including increased staff awareness, stronger adherence to safety protocols, and more consistent documentation practices (23, 24).

Importantly, the value of risk assessment extends beyond measurable reductions in error rates to its broader influence on safety practices. By rendering risks visible and actionable, risk assessment facilitates proactive decision-making and fosters a stronger culture of safety. This finding aligns with broader patient safety frameworks that emphasize anticipation and prevention rather than retrospective incident analysis (13, 25).

Operational efficiency as a complementary outcome

A key contribution of this review is the synthesis of evidence demonstrating that operational efficiency and patient safety are not competing priorities. Many of the included studies showed that risk assessment strategies supported more efficient resource allocation, reduced workflow variability, and improved process standardization (26, 27). These efficiency gains were commonly achieved through the prioritization of high-risk processes, allowing organizations to focus on improvement efforts to areas of greatest need.

Technology-enabled interventions further strengthened these outcomes. Studies assessing pharmacy automation, digital medication systems, and electronic prescribing platforms reported improvements in turnaround times, traceability, and coordination among professional groups (28, 29). Crucially, these efficiency improvements were achieved without compromising safety, suggesting that risk-informed system design can simultaneously advance quality and productivity within healthcare organizations.

Integration of risk assessment and digital health technologies

The review further highlights the synergistic relationship between risk assessment and digital health technologies. While structured methodologies such as FMEA provide a systematic framework for identifying and prioritizing risks, digital tools facilitate continuous monitoring, data integration, and feedback. Several studies demonstrated that integrating risk assessment with automation or electronic systems led to more sustainable and scalable improvements in medication management (29).

However, the findings caution against considering technology a standalone solution. Without an underlying risk assessment framework, technological interventions may fail to address deeper system vulnerabilities or may introduce new risks. This reinforces the importance of integrating digital solutions within a comprehensive risk management strategy rather than adopting them as isolated interventions.

Novelty and contribution of this review

The novelty of this systematic review lies in its integrated evaluation of both patient safety and operational efficiency outcomes within the context of medication management. Whereas previous reviews have primarily focused on medication errors or safety outcomes alone (30), the present review synthesizes evidence on how risk assessment strategies affect both safety and operational performance. It thereby integrates clinical safety research with healthcare management and operational practice.

Furthermore, this review extends existing knowledge by incorporating recent international studies (2021–2025) that reflect contemporary challenges, including digitalisation and automation of medication systems. The synthesis highlights emerging trends in the integration of risk assessment with digital health technologies, offering insights that are particularly relevant for healthcare systems undergoing technological transformation.

Implications for practice and policy

From a practical perspective, the findings suggest that healthcare organizations should incorporate structured risk assessment as a routine element of medication management, particularly in high-risk settings. Multidisciplinary collaboration is essential to ensure thorough risk identification and the development of effective mitigation planning. At the policy level, the evidence supports integrating proactive risk assessment into medication safety standards and quality improvement frameworks at both institutional and national levels.

Research gaps and future directions

Despite the positive findings, several gaps remain. Many included studies were context-specific and employed heterogeneous outcome measures, limiting comparability across settings. Quantitative evidence linking risk assessment strategies to long-term clinical outcomes and cost-effectiveness remains scarce. In addition, few studies have assessed the sustainability of risk assessment interventions over extended follow-up periods.

Future research should focus on longitudinal and comparative study designs to better quantify the impact of risk assessment strategies on both patient safety and operational efficiency. Further research is also needed to explore how risk assessment approaches can be optimally integrated with emerging digital technologies across diverse healthcare environments.

Summary of discussion

In summary, this systematic literature review demonstrates that structured risk assessment strategies play a critical role in enhancing medication management systems. By supporting proactive risk identification and informed decision-making, these strategies improve patient safety while enhancing the efficiency of healthcare operations. The findings highlight the value of risk-informed approaches as a foundation for high-quality, sustainable medication management.

LIMITATIONS

This systematic literature review has several limitations that should be considered when interpreting the findings. First, the review was limited to studies published in English and indexed in the Scopus and PubMed databases, which may have resulted in the exclusion of relevant studies published in other languages or indexed in additional databases. Second, substantial heterogeneity was observed across the included studies in terms of design, healthcare settings, and outcome measures, limiting the feasibility of quantitative synthesis and direct comparison.

Third, most studies were context-specific and conducted within single institutions or specialized clinical settings, which may limit the generalizability of the findings to other healthcare environments. In addition, variations in how patient safety and operational efficiency outcomes were defined and measured across studies may have influenced the interpretation of results. Finally, as with all systematic reviews, the findings depend on the quality and reporting of the included studies, and unreported biases within the primary literature may have affected the overall conclusions.

CONCLUSIONS

1. This systematic literature review synthesized evidence from 16 international studies to examine risk assessment strategies in medication management and their effects on patient safety and operational efficiency. The findings indicate that structured and proactive approaches particularly those based on Failure Mode and Effects Analysis and related methodologies are widely applied and associated with improvements in both safety outcomes and operational performance.
2. The review demonstrates that patient safety and operational efficiency are complementary rather than competing objectives. Risk-informed medication management systems support safer care delivery while simultaneously enhancing the efficient use of healthcare resources. The integration of risk assessment with digital health technologies further strengthens these outcomes through continuous monitoring, process standardization, and data-driven decision-making.
3. Overall, the evidence underscores the importance of embedding structured risk assessment into routine medication management practices, especially in high-risk clinical settings. Future research should prioritize robust longitudinal and comparative studies to better quantify the long-term clinical and economic impacts of risk assessment strategies across diverse healthcare environments.

ETHICAL APPROVAL

This study was a systematic literature review and did not involve the collection of primary data from human participants or animals. All studies included in this review had received ethical approval from the respective institutional ethics committees, as reported in the original publications, and were conducted in accordance with applicable ethical standards and informed consent requirements. Therefore, additional ethical approval was not required for the present review.

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