The Determinants of Patient Safety Outcomes; A Systematic Review

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Abstract

Background: Patient safety is a key dimension of healthcare quality, yet preventable adverse events remain a global concern. Evidence suggests that safety outcomes are shaped by interacting determinants at individual, organizational, and system levels, necessitating a comprehensive synthesis of current research.

Objective: This systematic review aimed to identify and synthesize key determinants of patient safety outcomes and examine their associations with adverse events, near misses, reporting practices, and overall safety performance.

Methods: Following PRISMA 2020 guidelines, peer-reviewed studies published between 2020 and 2025 were systematically searched across major electronic databases. Eligible studies examined determinants influencing patient safety outcomes in healthcare settings. Data were extracted and thematically synthesized, with determinants categorized into behavioral, organizational, and contextual domains.

Results: Patient safety outcomes were influenced by multiple interacting determinants. Behavioral factors included clinical competence, communication, fatigue, and professional conduct. Organizational determinants encompassed safety culture, leadership support, staffing adequacy, workload, reporting systems, and organizational learning. Contextual factors involved policy environments, resource availability, accreditation processes, and broader system constraints. These determinants were consistently associated with adverse events, healthcare-associated infections, medication errors, near misses, and mortality.

Conclusions: Patient safety outcomes are multifactorial, arising from interactions across individual, organizational, and contextual levels. Improving safety requires integrated, system-wide strategies that address workforce behavior, organizational structures, and contextual conditions. A holistic, learning-oriented approach is essential to reduce preventable harm and enhance healthcare system resilience.

Keywords
Patient safety outcomes; patient safety determinants; safety culture; adverse events; systematic review

1. Introduction

Patient safety has become a central priority in modern healthcare systems due to the persistent occurrence of preventable harm, adverse events, and system failures that compromise patient outcomes and public trust. Despite advances in medical technology and clinical knowledge, unsafe care remains a significant global challenge, affecting patients across diverse healthcare settings and levels of care. Patient safety outcomes such as adverse events, near misses, healthcare-associated infections, medication errors, and preventable mortality are now widely recognized as core indicators of healthcare quality and system performance (Said, 2025). Evidence indicates that patient harm is rarely the result of a single error or isolated action. Instead, unsafe outcomes typically emerge from the interaction of multiple determinants operating at individual, organizational, and system levels. Behavioral and individual factors, including clinical competence, communication practices, fatigue, and decision-making skills, play a critical role in shaping safety-related behaviors and performance (Parry et al., 2023). Organizational determinants such as leadership support, safety culture, staffing adequacy, and reporting mechanisms further influence how risks are identified, managed, and mitigated within healthcare environments (Mrayyan, 2022). At the system level, contextual and regulatory conditions including accreditation processes, policy frameworks, and health system infrastructure can either strengthen or undermine patient safety efforts (Scanlan et al., 2024).

Patient safety culture has been repeatedly highlighted as a foundational determinant linking organizational practices to safety outcomes. A positive safety culture encourages open communication, non-punitive reporting, teamwork, and continuous learning, which are essential for preventing harm and improving outcomes (Sarfo et al., 2023). Conversely, weak safety cultures characterized by blame, poor leadership engagement, and inadequate feedback mechanisms have been associated with underreporting of incidents and higher rates of adverse events (Konlan & Shin, 2022). Workforce-related determinants have also received increasing attention in patient safety research. Empirical evidence demonstrates that inadequate nurse staffing, excessive workload, and missed care are consistently associated with adverse patient outcomes, including infections, falls, and mortality (Dall'Ora et al., 2022). Similarly, behavioral risks such as fatigue, incivility, and ineffective communication have been shown to negatively affect both safety culture and patient safety outcomes (Freedman et al., 2025). In recent years, growing attention has also been directed toward system-level enablers of patient safety, including incident reporting systems, learning mechanisms, and regulatory oversight. Robust reporting and learning systems are essential for identifying hazards, understanding patterns of harm, and supporting organizational learning (Fekadu et al., 2025). However, evidence suggests that

many healthcare organizations particularly in resource-constrained settings continue to face challenges related to reporting practices, data quality, and effective use of safety information (Wickham, 2022).

Although a substantial body of literature has examined specific aspects of patient safety, existing evidence remains fragmented. Many studies focus on isolated determinants or specific clinical contexts, limiting a comprehensive understanding of how multiple determinants interact to shape patient safety outcomes. Furthermore, variations in study design, measurement approaches, and healthcare settings complicate the synthesis of findings and the translation of evidence into practice (Rahmawati & Sari, 2025). Therefore, a systematic synthesis of the determinants influencing patient safety outcomes is essential to consolidate current evidence, identify recurring patterns, and highlight gaps requiring further investigation. This systematic review aims to examine and integrate empirical evidence on behavioral, organizational, and contextual determinants of patient safety outcomes across healthcare settings. By providing an integrated overview of these determinants, the review seeks to inform healthcare leaders, policymakers, and researchers about priority areas for intervention and future research to enhance patient safety and reduce preventable harm.

2. Methodology

This study adopted a systematic review design to identify, appraise, and synthesize empirical evidence on the determinants of patient safety outcomes across healthcare settings. The review process was conducted in accordance with internationally recognized systematic review standards and followed a transparent, reproducible approach consistent with recent patient safety reviews (Said, 2025). A comprehensive literature search was undertaken across major electronic databases commonly used in patient safety and health services research. These databases included PubMed, CINAHL, Scopus, Web of Science, and Embase. The search strategy combined controlled vocabulary terms and free-text keywords related to patient safety outcomes, adverse events, medical errors, safety culture, leadership, staffing, reporting systems, organizational factors, and contextual or system-level determinants. The search was limited to peer-reviewed studies published in English within the last decade to ensure methodological rigor and contemporary relevance (Sarfo et al., 2023).

Eligibility criteria were defined a priori. Studies were included if they empirically examined determinants, predictors, or influencing factors associated with patient safety outcomes in healthcare settings. Both quantitative and qualitative study designs were eligible, including cross-sectional studies, longitudinal studies, systematic reviews, meta-analyses, and scoping reviews. Studies focusing exclusively on technical efficacy without reference to patient safety outcomes were excluded. Dissertations and policy-oriented reviews were included only when they provided explicit evidence on patient safety outcomes or system-level determinants (Wickham, 2022). The study selection process involved two sequential screening stages. First, titles and abstracts were independently

screened to remove clearly irrelevant records. Second, full-text articles were assessed against the inclusion and exclusion criteria. Any uncertainties regarding eligibility were resolved through careful reassessment of study objectives and reported outcomes.

This structured screening approach reduced selection bias and enhanced the reliability of study inclusion (Fekadu et al., 2025). Data extraction was conducted using a standardized extraction framework designed to capture key study characteristics and findings. Extracted information included author(s), year of publication, study design, healthcare setting, population, determinants examined, and reported patient safety outcomes. To facilitate cross-study comparison and synthesis, determinants were categorized into behavioral or individual factors, safety culture, leadership and management, staffing and workload, reporting systems, organizational factors, and contextual or system-level factors. This categorization strategy reflects approaches used in prior patient safety syntheses (Rahmawati & Sari, 2025).

Quality appraisal was undertaken to assess the methodological robustness of the included studies. Systematic reviews and meta-analyses were appraised using established critical appraisal frameworks, while primary studies were evaluated based on study design appropriateness, clarity of outcome measurement, and risk of bias. Studies were not excluded solely on the basis of quality; instead, appraisal outcomes were used to inform interpretation of the findings (Breno et al., 2025). Given the heterogeneity of study designs, outcome measures, and healthcare contexts, a narrative synthesis approach was employed. Findings were synthesized thematically, focusing on patterns and relationships between determinants and patient safety outcomes rather than pooled effect sizes. This approach enabled integration of evidence across diverse methodologies and settings while preserving contextual relevance (Konlan & Shin, 2022). The overall study selection process is illustrated in Figure 1, which presents the identification, screening, eligibility, and inclusion stages in accordance with PRISMA 2020 reporting standards.

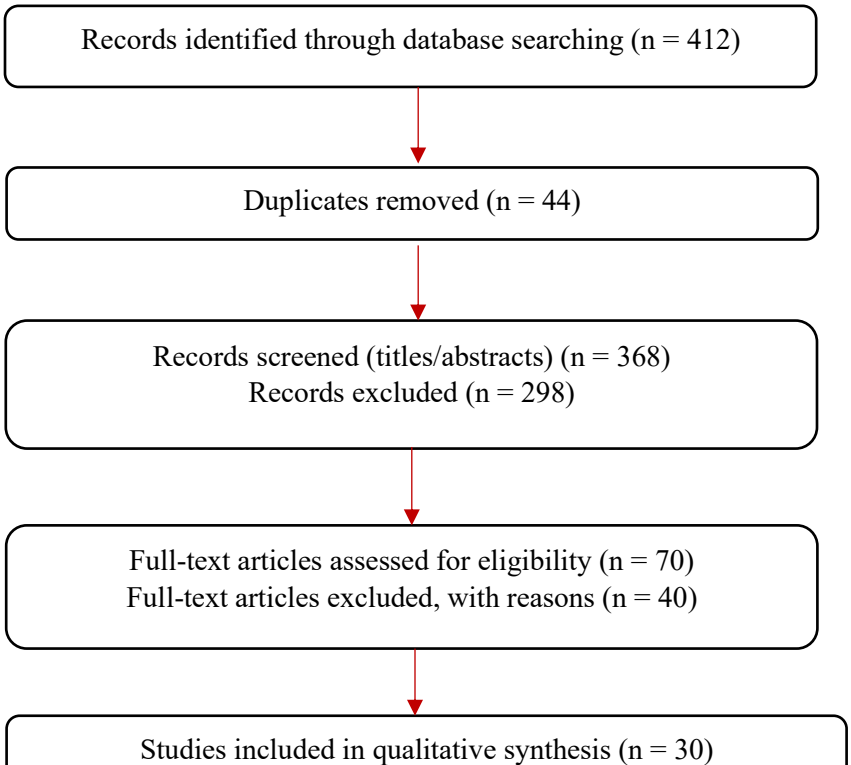

Figure 1. PRISMA 2020 Flow Diagram

3. Results

3.1 Study Selection and Characteristics

The systematic search and screening process resulted in the inclusion of 30 studies that met the predefined eligibility criteria and were retained for final synthesis. These studies were published between 2022 and 2026 and represent a wide range of healthcare contexts, including acute hospitals, intensive care units, dialysis services, emergency departments, and community and maternal health settings (Said, 2025). The included body of evidence comprised systematic reviews, meta-analyses, scoping reviews, cross-sectional studies, longitudinal studies, and mixed-methods investigations. This methodological diversity reflects the multifaceted nature of patient safety research and allowed for a comprehensive examination of determinants influencing patient safety outcomes across different levels of healthcare systems (Sarfo et al., 2023).

Geographically, the studies covered high-income, middle-income, and resource-constrained settings, with substantial representation from Africa, Asia, Europe, and North America. Several studies specifically focused on low- and middle-income countries, highlighting contextual and system-level challenges that uniquely influence patient safety outcomes (Konlan & Shin, 2022). Across the included studies, patient safety outcomes were operationalized using a variety of indicators, including adverse events, near misses, healthcare-associated infections, medication-related harm, mortality, and patient safety grades. Determinants were examined at behavioral or individual, organizational, and contextual or system levels, allowing for structured synthesis and comparison. A detailed overview of study characteristics, determinants assessed, and reported outcomes is presented in Table 1 (Literature Review Matrix).

Table 1. Literature Review Matrix

No.	Author(s) & Year	Behavioral / Individual Factors	Safety Culture	Leadership / Management	Staffing / Workload	Reporting Systems	Organizational Factors	Contextual / System Factors	Patient Safety Outcomes
1	Said (2025)	✓	✓	✓	✓	✓	✓	✓	✓
2	Sarfo et al. (2023)		✓		✓	✓	✓		✓
3	Breno et al. (2025)								✓
4	Chance et al. (2024)		✓			✓	✓		✓
5	Singh et al. (2024)		✓	✓		✓	✓		✓

6	Ikoona et al. (2025)	✓		✓			✓	✓	✓
7	Ghabi et al. (2024)	✓			✓				✓
8	Parry et al. (2023)	✓							✓
9	Pickup et al. (2025)	✓					✓	✓	✓
10	Sheehan et al. (2022)	✓					✓	✓	✓
11	Mrayyan (2022)	✓	✓	✓		✓	✓		✓
12	Koshiol et al. (2026)		✓	✓		✓	✓	✓	✓
13	Zhao et al. (2024)			✓			✓		
14	Dall'Ora et al. (2022)				✓				✓
15	Fekadu et al. (2025)					✓	✓	✓	✓
16	Wickham (2022)						✓	✓	✓
17	Hoffmann et al. (2025)		✓	✓	✓	✓	✓		✓
18	Omaghomi et al. (2024)			✓			✓	✓	
19	Osifowokan et al. (2025)						✓	✓	✓
20	Scanlan et al. (2024)		✓				✓	✓	
21	Alanazi et al. (2023)		✓		✓				✓
22	Baartmans (2024)						✓	✓	✓
23	Freedman et al. (2025)	✓	✓	✓	✓	✓	✓		✓
24	Alfayez et al. (2025)	✓	✓	✓		✓	✓		
25	Isaksson et al. (2022)		✓			✓	✓		✓
26	Caturegli et al. (2025)	✓							✓
27	Setiawan & Kusumapradja (2024)		✓	✓			✓		
28	Konlan & Shin (2022)	✓	✓	✓		✓	✓	✓	✓
29	Rahmawati & Sari (2025)	✓	✓	✓	✓	✓	✓		
30	Omwenke et al. (2026)	✓					✓	✓	✓

3.2 Determinants of Patient Safety Outcomes

Analysis of the included studies revealed that patient safety outcomes are influenced by a complex interplay of determinants operating across multiple levels of healthcare delivery. At the behavioral and individual level, factors such as clinical competence, decision-making, communication practices, fatigue, and professional behavior were consistently identified as influential determinants. Evidence indicates that deficits in communication and clinical judgment increase the likelihood of errors and adverse events (Parry et al., 2023). Fatigue and cognitive overload among healthcare professionals were also shown to compromise vigilance and safety performance (Pickup et al., 2025). Safety culture emerged as a central organizational determinant across a large proportion of studies. Positive safety cultures characterized by teamwork, open communication, non-punitive responses to

errors, and continuous learning were associated with improved patient safety outcomes (Mrayyan, 2022). Conversely, weak safety cultures were linked to underreporting of incidents and persistent safety risks (Sarfo et al., 2023).

Leadership and management practices were repeatedly highlighted as critical enablers of patient safety. Supportive leadership, visible commitment to safety, and alignment between executive leadership and frontline practice were found to strengthen safety culture and reporting behaviors (Koshiol et al., 2026). In contrast, inadequate leadership engagement and poor managerial support were associated with reduced staff participation in safety initiatives (Zhao et al., 2024). Staffing and workload determinants were prominently featured in empirical studies, particularly in high-risk clinical environments. Evidence consistently demonstrated that inadequate staffing levels and excessive workload increase the risk of missed care and adverse events (Dall'Ora et al., 2022). High nurse workload in intensive care units was directly associated with increased adverse events, infections, and mortality (Ghabi et al., 2024).

Reporting systems and learning mechanisms were also identified as essential organizational determinants. Studies emphasized that accessible and well-functioning incident reporting systems facilitate identification of hazards and promote organizational learning (Fekadu et al., 2025). However, barriers such as fear of blame, lack of feedback, and punitive cultures limited the effectiveness of reporting practices in many settings (Alfayez et al., 2025). Finally, contextual and system-level factors, including policy frameworks, accreditation processes, regulatory oversight, and resource availability, shaped the environment in which patient safety practices were implemented. Variations in health system capacity, policy alignment, and regulatory enforcement influenced the consistency and effectiveness of safety interventions (Omaghomi et al., 2024).

3.3 Patient Safety Outcomes Associated with Identified Determinants

The reviewed studies reported a broad range of patient safety outcomes linked to the identified determinants. Adverse events such as falls, pressure ulcers, healthcare-associated infections, and medication-related harm were the most frequently reported outcomes. Higher levels of missed nursing care and inadequate staffing were consistently associated with increased rates of adverse events (Breno et al., 2025). Healthcare-associated infections were particularly sensitive to organizational and staffing determinants. Studies conducted in intensive care settings demonstrated that improved staffing levels and stronger safety cultures were associated with lower infection rates (Alanazi et al., 2023). Near misses and incident reporting outcomes were closely linked to safety culture and reporting systems. Facilities with non-punitive cultures and structured reporting mechanisms demonstrated higher reporting rates and better identification of latent safety threats (Isaksson et al., 2022).

Mortality and severe harm outcomes were associated with systemic and contextual determinants, including staffing adequacy, continuity of care, and access to appropriate

services. Longitudinal evidence supported a plausible causal relationship between low nurse staffing and increased mortality risk (Dall'Ora et al., 2022). In addition, several studies reported improvements in patient safety grades, quality indicators, and overall safety performance in organizations that implemented integrated safety strategies encompassing leadership engagement, reporting systems, and continuous learning (Freedman et al., 2025). Collectively, these findings demonstrate that patient safety outcomes are not driven by isolated factors but rather by the interaction of behavioral, organizational, and contextual determinants across healthcare systems.

4. Discussion

4.1 Interplay of Behavioral, Organizational, and Contextual Determinants

The findings of this systematic review demonstrate that patient safety outcomes are shaped by the dynamic interaction of behavioral, organizational, and contextual determinants rather than by isolated factors. Behavioral and individual-level determinants, such as clinical competence, communication practices, fatigue, and professional conduct, influence how healthcare professionals recognize risks, adhere to safety protocols, and respond to emerging threats (Said, 2025). Ineffective communication and cognitive overload have been shown to directly compromise clinical decision-making, increasing the likelihood of adverse events and near misses (Parry et al., 2023). However, individual behaviors do not operate independently of the organizational environment. Organizational determinants particularly safety culture, leadership engagement, staffing adequacy, and learning systems either amplify or mitigate behavioral risks. Evidence from multiple studies indicates that supportive leadership and positive safety culture enhance staff willingness to report incidents, engage in teamwork, and participate in continuous improvement activities (Mrayyan, 2022).

Conversely, environments characterized by punitive responses, weak leadership visibility, and inadequate feedback discourage reporting and conceal latent safety threats (Sarfo et al., 2023). Contextual and system-level determinants further condition the effectiveness of both behavioral and organizational factors. Health system policies, accreditation processes, regulatory frameworks, and resource availability shape institutional priorities and constrain operational capacity. In resource-limited settings, contextual challenges such as staff shortages, infrastructure constraints, and policy misalignment intensify organizational pressures and increase individual workload, thereby elevating patient safety risks (Konlan & Shin, 2022). The evidence suggests that patient safety outcomes emerge from a layered system in which weaknesses at one level propagate across others, reinforcing the need for integrated, systems-based safety strategies (Koshiol et al., 2026).

4.2 Policy, Practical, and Theoretical Implications

From a policy perspective, the findings underscore the importance of embedding patient safety within national health strategies and regulatory frameworks. Policymakers should

prioritize the development of non-punitive reporting policies, standardized safety indicators, and accreditation mechanisms that emphasize learning and improvement rather than compliance alone (Scanlan et al., 2024). Strengthening regulatory oversight of incident reporting systems and ensuring alignment between policy objectives and frontline practice are essential for sustainable safety improvements (Fekadu et al., 2025). In terms of practical implications, healthcare organizations should adopt multilevel interventions that simultaneously address workforce behavior, organizational structures, and contextual constraints. Leadership development programs that promote visible safety commitment and psychological safety can foster stronger safety cultures and reporting behaviors (Zhao et al., 2024).

Optimizing staffing models and workload distribution is critical in high-risk settings, as consistent evidence links inadequate staffing with adverse outcomes and preventable harm (Dall'Ora et al., 2022). Practical interventions should also emphasize fatigue management, communication standardization, and structured handover processes to reduce human error (Pickup et al., 2025). The theoretical implications of this review support contemporary systems and human factors models of patient safety. The findings align with sociotechnical and high-reliability organization theories, which conceptualize safety as an emergent property of interactions among people, processes, and environments (Sheehan et al., 2022). The review reinforces the inadequacy of linear, blame-oriented models and highlights the need for theoretical frameworks that account for complexity, adaptation, and learning within healthcare systems (Rahmawati & Sari, 2025).

4.3 Comparison with Existing Reviews, Limitations, and Future Research

Compared with previous reviews, this study extends the literature by integrating behavioral, organizational, and contextual determinants into a single analytical framework focused explicitly on patient safety outcomes. Earlier reviews have often concentrated on specific domains such as safety culture or staffing in isolation (Sarfo et al., 2023). This review builds on that work by demonstrating how these domains interact and collectively influence outcomes across diverse healthcare settings (Said, 2025). Despite its contributions, this review has several limitations. The heterogeneity of study designs, outcome measures, and healthcare contexts limited the feasibility of quantitative synthesis and precluded meta-analysis. Many included studies relied on cross-sectional designs, which restrict causal inference (Mrayyan, 2022).

Additionally, variations in definitions of patient safety outcomes and reporting practices may have influenced the consistency of findings (Isaksson et al., 2022). Language restrictions and reliance on published literature may also have introduced publication bias (Wickham, 2022). Future research should prioritize longitudinal and interventional study designs to better establish causal pathways between determinants and patient safety outcomes. Greater emphasis is needed on under-researched contexts, particularly in low- and middle-income countries, where systemic constraints pose unique safety challenges (Omwenke et al., 2026). Further research should also explore the integration of digital

health technologies, artificial intelligence governance, and advanced reporting analytics in strengthening patient safety systems (Osifowokan et al., 2025). Collectively, these research directions will support the development of evidence-based, context-sensitive strategies to reduce preventable harm and improve patient safety outcomes globally.

5. Conclusion

This systematic review synthesised contemporary evidence on the determinants of patient safety outcomes across diverse healthcare settings. The findings demonstrate that patient safety outcomes are not driven by single factors but emerge from the complex interaction of behavioral, organizational, and contextual determinants operating at multiple levels of healthcare systems. Individual factors such as professional competence, communication practices, fatigue, and adherence to safety protocols influence frontline performance, while organizational conditions including leadership support, staffing adequacy, safety culture, and learning systems shape how risks are identified, managed, and mitigated. Contextual influences, including policy environments, resource availability, and system-level governance, further condition the effectiveness of safety initiatives and organizational responses. Overall, the review highlights that improving patient safety outcomes requires a holistic, systems-based approach rather than isolated interventions. Sustainable improvements depend on strengthening leadership commitment, fostering non-punitive reporting cultures, optimizing workforce capacity, and aligning organizational practices with broader health system policies. By addressing patient safety determinants in an integrated manner, healthcare organizations and policymakers can reduce preventable harm, enhance care quality, and promote resilient healthcare systems capable of delivering safe and effective care across varying contexts.

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