EXPERT REVIEW OF MEDICAL DEVICES
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SYSTEMATIC REVIEW

Medical device errors in intensive care units and patient safety: a systematic review

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ABSTRACT

Introduction: Medical device errors in Intensive Care Units (ICUs) position a critical threat to patient safety due to the complexity of devices, high patient alertness, and demanding clinical situations. Despite rising support on medical technologies, evidence on the nature of causes and prevention of device-oriented errors in ICUs remains fragmented.

Methods: The PRISMA guidelines were followed throughout the systematic review, and the review was registered in PROSPERO (CRD42023424716). Studies published between 2010 and 2025 were accounted through 17 databases. The studies on medical device errors in adult, pediatric, and neonatal ICUs were encompassed, and the outcomes were synthesized qualitatively.

Results: Seventy-two studies were covered and infusion pumps, syringe pumps, ventilators, and monitoring equipments were majorly associated with medical device errors. Errors were primarily related with human factors, device design flaws, and system failures. Infusion pump errors occurred in 60% of infusion initiations (80,209/133,601), while 89% of arrhythmia alarms were false positive among 2.5 million monitor alerts recorded in a cohort of 461 ICU patients.

Conclusion: Medical device errors in ICUs are multifactorial. Effective prevention requires integrated approaches encompassing human factors engineering, focused training, improved device design, and a strong resilient patient safety culture.

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KEYWORDS
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1. Introduction

Developing a patient safety culture (PSC) has been strongly linked with achieving better patient outcomes in hospital settings [1]. Globally, medical errors are still a major cause of patient harm and, despite the fact that safety improvements have been the top priority, they continue to challenge healthcare systems worldwide [2–4]. Within high-risk hospital wards, Intensive Care Units (ICUs) are particularly high-risk clinical environments where the effects of errors are made worse because of high patient acuity, complicated workflows, and heavy dependence on advanced medical technologies [5]. In such environments, the healthcare staff regularly work with various life-support equipment and have to swiftly change the device settings in response to the patient condition, thus any error is more likely if the protective measures are insufficient [6,7]. Besides, environmental factors and the large number of device alarms make staff experience cognitive overload and alarm fatigue, which have been identified as threats to patient safety in ICUs [8,9].

The term medical error typically refers to failures in diagnosis, medication, and clinical procedures. The paper highlights one of the various kinds of medical devices-related errors. Medical device errors include failures, malfunctions, or harm resulting from the use or misuse of devices intended for patient monitoring, treatment, or life-support. Thus, these errors are quite different from ones such as prescribing or procedural mistakes, since they stem from the interaction between the user, the device, and the clinical environment situation that is especially complicated in ICU settings.

The rapid increase in the use of sophisticated medical devices has led to a lag in the development of solid maintenance, management, and training systems in many hospitals [10,11]. In ICUs, where technology is instrumental to patient survival, the successful alleviation of the problem of device-related errors relies not only on the technical soundness of the equipment but also on the capability of clinical teams that are facilitated and supported by clinical engineering services that are responsive [12]. As a result, the interaction between healthcare professionals in ICUs and devices, the design limitations that are manufacturer-related, and the application of Human Factors Engineering (HFE) principles are vital aspects for ensuring patient safety [13].

Several research works already exist bringing new information in the area. Still, a comprehensive understanding of the types of medical device errors and effective mitigation strategies across different ICU contexts is still very limited. Parts of the studies include device failure surveillance [14], ventilator-related critical incidents [15], and alarm fatigue [16]. Besides that, some of the research work has been around device maintenance performance [17] and evidence, based management approaches [18]. However, these studies are mostly about a single device or a single discipline and do not often consider user training, device usability, and system-level factors as one integrated ICU framework.

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Article highlights

- Medicaldevice errors in ICUs represent a serious patient safety issue that ismultifactorial in nature.
- Infusionpumps, syringe pumps, and ventilators are the three most common pieces ofequipment cited in the reported errors.
- Humanfactors, such as insufficient training and alarm fatigue, among others, havebeen identified as major contributors to device-related errors.
- Dueto considerable clinical and methodological differences among the studiesincluded, a systematic literature review was chosen.
- Errorprevention necessitates a comprehensive plan that unites technology, training,and a well-established safety culture.

1.1. Research objectives

To discover, through a systematic approach, and subsequently analyze, the types of medical device errors that are encountered in ICUs, find their underlying causes that include human factors as well as technological limitations, and determine the subsequent impact of these mistakes on patient safety outcomes. This elaborate study intends to show the correlation between device failure and patient safety incidents, thereby, assisting in the generation of targeted strategies for the prevention of errors and elevated patient care in critical care settings.

1.2. Rationale of the study

Medical device remains indispensable for the supply of quality patient care in the ICUs; nevertheless, errors have the potential to cause serious patient morbidity and mortality. Most of these errors are attributed to device misuse by the user, device malfunction, or lack of proper training. Recognizing the types and factors of errors committed is the appropriate approach to develop strategies for patient safety. This study is geared toward solving these problems and sustaining a reliable culture in critical care environments.

1.3. Research questions

As an advanced and contemporary concept, the research topic demands thorough search and an extensive information-collection exercise over the different types of ICUs in hospitals. This makes the research question more dovetailed to the five sub-questions.

This SLR endeavors to reveal the significant solutions to the mentioned research questions.

RQ1: What are the common types of medical device errors in ICU, error frequency, and severity?

RQ2: What are the causes of medical device error in ICU devices?

RQ3: What are the initiatives or management practices for medical device error prevention in ICU devices?

RQ4: How are prior research and the present research distributed over different research themes?

RQ5: What are the mitigation ways or suggestions to avoid use error, device error, and manufacturer error of medical devices?

The research questions were formulated to address the research goal by providing a clear understanding of the different state-of-the-art methods discussed in the literature about the medical device errors that impact the safety of patients.

2. Methods

A systematic literature review is a major step to determine and understand the research objectives at the initial state. It indulges in defining the inclusion and exclusion criteria [19] protocol, which deliberates the rationale to identify and assess the published research for review analysis [20,21]. This systematic literature review followed PRISMA guidelines and was registered with PROSPERO (CRD42023424716). The review aimed to identify studies examining medical device errors in ICUs and their impact on patient safety.

2.1. Search strategy

The study conducted a comprehensive search of 17 electronic databases including PubMed, Scopus, Web of Science, CINAHL, IEEE Access, JSTOR, Embase, Biomed Central, PLOS, Emerald, ProQuest, Springer, Elsevier, Wiley, Taylor & Francis, Frontier, and Google Scholar. The search covered publications from January 2010 to April 2025.

The following search strategy was adapted for each database: ((('medical device*' OR 'medical device*' OR 'medical instrument*') AND ('error*' OR 'failure*' OR 'malfunction*')) AND ('intensive care unit*' OR 'ICU' OR 'critical care*')) AND ('patient safety' OR 'adverse event*'))

The complete search strings for each database are provided in Supplementary Material S1.

2.2. Eligibility criteria

2.2.1. Inclusion criteria

- Studies addressing medical device errors in MDICU, Pediatric Intensive Care Units (PICU), or Neonatal Intensive Care Units (NICU).
- Studies with defined search processes, data extraction, and research questions related to medical device failures.
- Studies investigating medical device errors in ICUs and their impact on patient safety.
- Studies focusing on ventilators, infusion pumps, dialysis machines, cardiac machines, ECG machines, defibrillators, syringe pumps, or patient monitoring devices.
- Case studies or observational studies.
- Articles published between January 2010 and April 2025.
- Studies presented in English.

2.2.2. Exclusion criteria

- Duplicate reports or articles reporting similar research.

- Informal literature reviews without defined research questions, search processes, or data extraction phases.
- Articles not written in English.
- Articles published before 2010.

2.3. Study selection

The study selection procedure complied with the PRISMA standards (Figure 1). Initially, two independent reviewers evaluated the titles and abstracts, and then independently conducted a full-text review of the potentially relevant articles. Differences in opinion were settled through consultation with the third reviewer.

2.4. Data extraction and management

Reviewers collected data with the help of a uniform data collection form. The data extracted included research characteristics, types of the device, error categories, factors, occurrence, severity, and strategies for prevention. Any disagreements between the reviewers were solved through the intervention of the third reviewer.

2.5. Quality evaluation

Due to the mixed nature of the designs of the studies included (for instance, observational studies, case reports, qualitative analyses), it was considered that a uniform quality appraisal instrument such as CASP or JBI would be less appropriate than

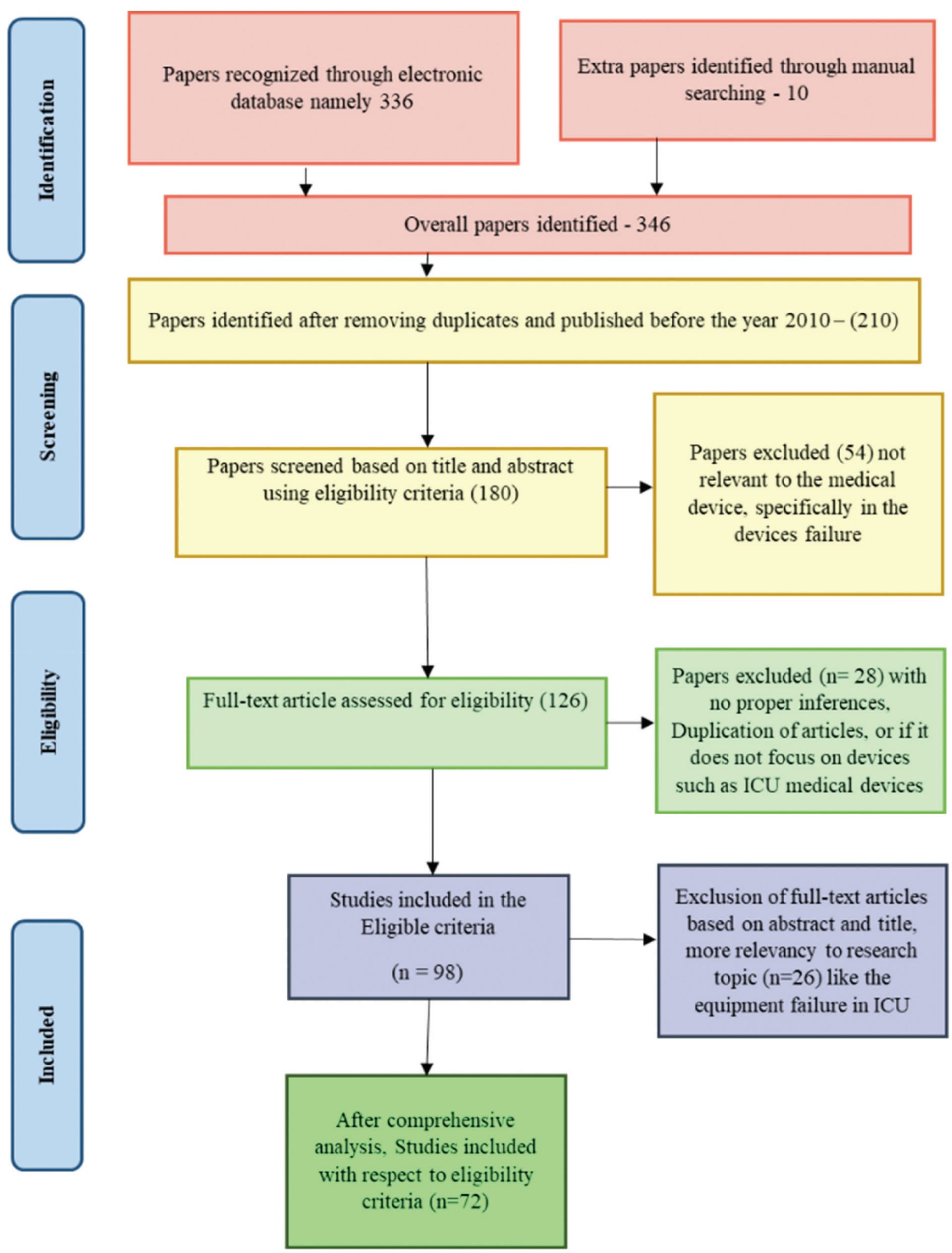

Figure 1. PRISMA guidelines for the search process.

a manually tailored, qualitative evaluation. This method gave the freedom that was required to judge the distinct advantages and disadvantages of the different approaches of the methodologies within our particular research context. Two reviewers independently evaluated the appropriateness, clarity, and contribution to the field of each included study by applying three main criteria:

QE1 (Relevance and Scope): Does the research paper thoroughly examine relevant research into medical device errors in the ICU environment?

QE2 (Clarity and Justification): Are the implications presented by the paper clear and are the outcomes, conclusions and inferences logical and justifiable?

QE3 (Future-Oriented Contribution): Does the research offer practical solutions or indicate clear directions for further research or work?

Each of these criteria was associated with a quality rating for each study: 'High,' 'Medium,' or 'Low.' The differences between the two reviewers in the quality ratings were discussed to reach an agreement. The main aim of this hand quality assessment was not to exclude certain studies but to give a systematic account of the methodological rigor and reliability of the findings of the selected studies. The evaluation was vital as it was the main factor that guided the later weighting and interpretation of the evidence during the data synthesis stage, thus enabling the separation of strong, definitive evidence from that which is more tentative or illustrative.

2.6. Data synthesis and analysis

The study initially evaluated whether a meta-analysis could be carried out to combine the results of the studies included in the research quantitatively. However, owing to the enormous clinical, methodological, and statistical heterogeneity among the 72 studies, a quantitative synthesis has been ruled out as an improper and potentially misleading one. The diversity was manifested in several aspects:

Study Designs: The different types of work were the different approaches used by the various papers, among which were case reports, single-center observational studies, multicenter cohort studies, qualitative analyses, and quality improvement projects.

Interventions and Devices: The research was directed toward the different equipment (e.g. ventilators, infusion pumps, syringe pumps, monitors) in the ICU, while the investigations were on disparate interventions that it was out of the question to compare one with the other.

Outcome Measures: The outcomes were assessed and documented in an extremely diverse manner. Some research works presented error frequencies as percentages, some as rates per device-days, while some only gave the thematic descriptions of the errors without any quantitative data.

The researchers reckon that given such a profound heterogeneity the statistical pooling of the data would generate an average that would be devoid of any meaning. As a result, their study implemented the systematic literature review (SLR) which is in line with the established frameworks for the integration of diverse evidence synthesis in systematic reviews (2006). Employing this approach meant going through a systematic procedure of data extraction, thematic analysis, and sorting the findings by device categories, error types, causes, and prevention strategies. The method made it possible for us to give a detailed, contextualized, and comprehensive review of the current evidence, unearthing the patterns, bringing out the key lessons, and pointing at the inconsistencies and gaps in the literature.

The records selection process adhered to PRISMA 2020 is visually represented in Figure 1. In total, 346 records were initially found 336 records via electronic database searches, and 10 additional records through manual searches. Once duplicates ($n = 96$) were removed, 250 unique records were left for screening. During the title and abstract screening, 130 records were excluded for not being focused on intensive care unit (ICU) settings or medical device-related errors. The other 120 articles were then reviewed to access full-text eligibility. Out of these 120 full, text papers, 48 were rejected due to the following reasons: not dealing with medical device errors ($n = 21$), lack of methodological detail or absence of outcome data ($n = 15$), wrong study setting (non, ICU) ($n = 8$), or non, English language ($n = 4$). At last, a total of 72 studies complied with all the eligibility criteria and were incorporated in the qualitative synthesis.

3. Results

3.1. Study characteristics and results of individual studies

3.1.1. Medical device failure in different ICU devices

Errors arising from the use of medical devices in ICUs can be divided into two main types: errors in device usage and errors related to the manufacturer [22]. The nature of device usage errors is seemingly more straightforward than that of device malfunctions, whereas the ICU is still exposed to frequent high-stakes incidents and medication errors [23]. Medical devices in ICU settings are a must for patient diagnosis, treatment, and monitoring; however, there is a complex interplay between advanced medical technologies, patient acuity, and healthcare complexity that leads to considerable challenges for patient safety [5].

Device usage errors are those that happen during device operation and are usually associated with human factors, while manufacturer-related errors derive from design or production areas. According to the Clinical Engineering Division (CED) of the International Federation of Medical and Biomedical Engineering, systematic reporting of failure identification and prevention measures plays a crucial role to address device errors [14]. To obtain information on failure frequency of the medical devices, CED started worldwide surveys and followed-up with guidelines for the improved management of clinical devices, leading, in fact, to remarkable decreases in failure rates [24]. The bad design of the medical devices is a factor that can lead directly to usage errors. In the PICU and ICU departments, nurses are continuously and frequently interacting with critical medical devices [25] like noninvasive monitoring devices as well as therapeutic apparatus systems such as ventilators, defibrillators, and ventricular assist devices.

These indispensable medical devices are used extensively and, basically, everywhere [26]. Cases of manufacturer-related errors dominate in the production of medical devices and the design of devices, with almost 50% of these errors related to instances where device design does not align with specifications [23,27]. In addition, design flaws were identified as major sources of the operational errors that caused adverse events [28]. To enhance the dependability of lean systems, Sawhney proposes a revised Failure Mode and Effects Analysis (FMEA) method [29]. This method systematically ranks failure modes based on risk assessment metrics closely aligned with lean principles, ensuring that interventions are focused on the most vulnerable areas. The following subsections report device-specific findings using this error classification framework.

3.1.2. Infusion pumps

Identifying the risk points of the implementation of smart infusion pumps is imperative for the improvement of safety measures and the efficaciousness of medical devices [30]. Less device errors can directly enhance patient outcome maintaining the provision of excellent health care still essential [31]. The study suggests that discrepancies in medication orders in the Computerized Physician Order Entry (CPOE) may cause errors that a smart infusion pump can recognize, thereby indicating their safety function in the administration process [32]. The lean approach is very effective, it managed a 50% reduction of administration errors in the time period of 6 month [33]. Risk points of the implementation phases of smart pumps were identified with the aim of making necessary changes [34]. Among the various means of identification, the interviews with the nurses revealed handling gaps most clearly, whereby the issues raised were attending lapses, memory failures, and programming problems [35]. Poor documentation such as incomplete tubing labels and missing records, however, doubles these mistakes [36].

The use of smart infusion pumps may lead to a considerable decrease in medication errors. Infusion pumps are one of the leading sources of medication errors in Intensive Care Units (ICUs) [37]. In a multihospital observational study involving 133,601 infusion starts, 60% (80,209/133,601) were associated with at least one infusion-related error [38]. These errors were mainly labeling errors, bypassing the pump or drug library, and incorrect infusion rates. Human factors analysis categorized these errors into programming, drug library, administration, and equipment issues, often linked to workarounds. Prevention strategies include enhanced training, standardized drug libraries, clearer interfaces, and routine checks [39]. Prevention includes enhanced training, standardized drug libraries, clearer interfaces, and routine checks [40]. Identified a risk profile in the ICU for harmful errors in medication [41]. The associated risk factors for medication errors reports consist of the Institute for Safe Medication Practices (ISMP) medication safety standards (high alert), prescribing stage of the medication usage process, and delivery service/equipment failure process [42]. The pivotal finding is that line labels and organizers markedly improved infusion identification accuracy and speed in simulated ICU settings [43]

A smart infusion device with automated medication replacement and real-time monitoring was developed to improve safety and reduce staff workload [44]. An analysis of the reliability of the time it takes to fix an infusion pump shows that the lack of proper failure data makes it difficult to plan maintenance [45]. Therefore, it emphasizes how important it is to have dependable maintenance data and to choose the right devices strategically for the safety of patients.

3.1.3. Syringe pumps

Syringe pumps, which deliver drugs like vasoactive medications, can cause very serious side effects that may result in the death of the patient if the malfunctioning or stopping of the device is not recognized [46]. In the research of 205 elastomeric pump cases, the major technical problems were injection difficulties (20%), flow rate anomalies (30%), and chemotherapy product leakage (44%) [47]. Several case reports have documented significant clinical implications such as the development of refractory hypotension due to syringe pump malfunctioning when driving pressures suddenly dropped causing blood pressure to fluctuate dangerously [48]. A lean strategy lowered errors in medication with syringe pumps noticeably from 17.7% (55/310) to 2.3% (7/307) within 18 months ($p < 0.0001$) [33]. Some of the main factors leading to dosing errors are the compatibility of the syringe-pump, the size of the syringe, the compliance of the infusion line, resistance, and vertical displacement. The suggestions are that one should use the tested syringes, employ the smallest sizes, and install the sensitive occlusion alarms [49]. Considerable variations was identified in fluid delivery, deformation of the syringe, friction, and irregularities in flow, which posed serious risks to critically ill patients [50]. Most recommendations included the use of validated syringes, reducing the number of brands, and setting up a strong operational system [51]

In a pediatric ICU study involving $n = 50$ nurses, 60% (30/50) demonstrated adequate operational competency in syringe pump use, whereas only 2% (1/50) were able to perform device maintenance procedures [52]. The combination of interventions, according to the data, brought about a large increase in the recording of medication and errors. Thus, the interventions not only made the transparency more visible but also patient safety was enhanced [53]. The syringe replacements were identified as the most critical moments, particularly in the case of vasoactive drugs [54]. The errors in memory lapses, attention slips, and failure in planning during infusion pump management and monitor programming have led to the occurrence of adverse events. These events necessitated the recommendations for daily checking of equipment and improved staff training as measures to strengthen patient safety [55].

Major temporary dosing errors resulting from flow rate changes in multi-infusion systems were recorded with peak errors ranging from +48.2% to −32.5% and start-up delays of up to 42.6 minutes [56]. The implementation of a non-punitive error reporting culture, was instrumental for the increased reporting of errors and decrease in actual harm [53]. A total of 133,601 infusion events over 20 months in a cardiothoracic

ICU were evaluated, which led to the identification of 717 overdose alerts and 66 reprogramming events. Smart pumps with standardized drug libraries were the means by which the errors were intercepted effectively [57]. Alarm rates were at their highest during the wee hours, thus the necessity for uninterrupted monitoring and feedback systems was brought into focus [58].

3.1.4. Ventilators

Mechanical ventilation is an essential life-support strategy in intensive care units for critically ill patients [59]. While a self-inflating bag valve resuscitator is a form of ventilator, it is manually operated, whereas a mechanical ventilator functions automatically [60]. Borel's customization of the monitoring process to minimize mechanical ventilation complications may cause errors resulting in ventilator-induced lung injury [61]. Observational data indicate that more than 50% of ICU patients require mechanical ventilation within the first 24 h of admission in many critical care settings [62,63].

Lung and chest wall observance, optimize positive end expiratory pressure (PEEP), and decrease the risk of ventilator-induced lung injury [64]. A feed-forward neural network can help to validate the efficacy and stability of computer-aided simulation of ventilator design [65]. Fuzzy logic-based computer-aided decision-making system for ventilator settings lowers human error [16]. Negative impacts and defects have helped identify and resolve issues with medical devices [15]. A study in done is US revealed,4,305 hospitals account for 83% of US intensive care beds, and 52,118 critical ventilators [66]. Efforts have been made to improve ventilator quality as manufacturers try to implement easy-to-get ventilator displays [67]. In India, as per the published reports, the important clinical impacts linked with prolonged mechanical ventilation are longer stay period, notable morbidity, increased mortality rates, and higher healthcare costs [68].

Failure Mode and Effects Analysis (FMEA) with fuzzy logic was used to prioritize ventilator failure modes, the identified issues were related to power supply failure, sensor malfunction, software failure, airway obstruction, alarm malfunction, battery failure, hygiene, or contamination issues and display failure as most likely [69]. Predictive maintenance systems using Pareto and FMEA analysis have been proposed to identify failure-prone components, with Internet of Things (IoT) based architectures enable real-time monitoring and early problem identification [70,71]. Machine learning (ML) methods, including Random Forest and XG Boost, have also been utilized as reliable predictors of mechanical ventilator failures [72]. Ventilator-associated pneumonia has been reported to affect 5–15% of mechanically ventilated ICU patients, with mortality rates reaching up to 70% in high-risk populations, depending on illness severity and clinical context [70]. Prolonged ventilation escalates hospital stays, morbidity, mortality, and healthcare costs [73]. The use of ventilator bundles has demonstrated significant reductions in ICU mortality and VAP rates in meta-analyses [74]. Prolonged mechanical ventilation, age, reintubation, and enteral feeding are established risk factors for major nosocomial infections in pediatric ICUs [75].

Mechanical ventilation was used in 39.5% of ICU patients on an hourly basis, thus indicating a noteworthy surge capacity alongside a non-uniform distribution of ventilator usage in different types of units and hospitals [76]. Strategies like the usage of a low tidal volume, an optimal (Positive End-Expiratory Pressure) PEEP, and the methodical regulation of oxygen and carbon dioxide levels, contributed to better survival rates, favorable neurological outcomes as well as less occurrence of ventilator-induced lung injury [77]. The length of time during which mechanical ventilation is required depends on the extent of the disease and patient characteristics, predictive models using Acute Physiology and Chronic Health Evaluation III (APACHE III) scores can help optimize care strategies [78]. In-service training and education of ICU nurse on VAP preventive measures significantly reduced VAP incidences, ICU stays and ventilator days, this emphasized the critical role of nursing staff in VAP prevention [79]. Improper setting increases Non Invasive Ventilation (NIV) failure risk, this worsens outcome and necessitates early failure recognition [80].

3.1.5. Monitoring devices

The physiological monitors in ICUs continuously produce alerts. The various kinds of alarms can lead to alarm fatigue among the medical staff who consequently overlook or even disable the sound of the alerts exposing the patients to diverse risks [9]. Yanar aimed at recording alarm frequency was carried out in 461 ICU patients, the study period covered a full month. More than 2.5 million alarms revealed that 88.8% of arrhythmia alarms were false positives [81]. The condition of detection of an alarm that is false, but regarded as true, has been overstated which may result in staff behaving in an indifferent manner thus delaying response to the incident or even turning off the alarm. The issue is attributed to the insistent nature of the device algorithms that orient on sensitivity more than specificity. In a 1-month observational study of 461 ICU patients, more than 2.5 million monitor alarms were recorded, of which 88.8% of arrhythmia alarms were false positives [82]. Along with the problem of alarm fatigue, the patient monitoring system can be overloaded with a vast amount of data that are difficult to handle due to inadequate technology integration [83].

A system dynamics model was proposed to stimulate alarm management strategies, this emphasized the need for the Internet of Medical Things (IoMT) integration in lowering the unrequired interventions. Hospital management should consider staff competency, periodic training, standardization of hospital policies, and the setting of personal alarms for each patient in order to establish safety as a daily practice [84]. Alarm fatigue was identified as a top technology hazard, linked to preventable adverse events and deaths [17]. A survey of ICU staff found that alarms were often silenced or turned off due to disruption in various countries, including Australia, the US, South Korea, and Germany [9]. The potential of Artificial Intelligence (AI) for monitoring purposes was viewed favorably by the majority of respondents in a German university hospital survey, who felt it would be useful for the early detection of problems to reduce mortality risk [85]. Table 1 provides a comprehensive comparative analysis of the common medical device errors identified across the major ICU equipment reviewed in this study.

Table 1. Summary table on medical device errors in ICU.

Study	Device/context	Error type/issue	Frequency/severity	Cause/contributing factors	Prevention/mitigation strategy	Main findings
[5]	Critical Care Units (General)	Patient safety challenges (complexity, acuity, technology use)	Not specified	High patient acuity, complex care, technology use, human factors	Interdisciplinary communication, safety culture, standardized procedures, tech integration, education, AI/predictive analytics	Emphasizes multifaceted strategies and innovations for improving patient safety in critical care
[29]	Lean Manufacturing Systems	Failure Modes related to equipment and process inefficiencies.	Severity: Varies based on impact on production efficiency and safety.	Lack of robust risk assessment in traditional FMEA.	Implementation of the modified FMEA approach to prioritize failure modes.	The modified FMEA significantly improves the identification and prioritization of failure modes in lean systems.
[33]	Infusion/Syringe Pump	Medication errors	17.7% to 2.3% (reduced after intervention)	Lack of SOP, human error	Two-nurse verification, SOPs, lean approach	Lean approach significantly reduces errors
[36]	Infusion Pump	IV infusion errors	Common and serious	Poor documentation, high-risk meds, complex ICU	Improved documentation, process improvement	Need for better processes in prescribing, prep, admin
[37]	Infusion Pump	Medication errors	Not specified	Workarounds, lack of training, poor interface	Human factors analysis, multidisciplinary teams, smart pumps, continuous training	Targeted deployment and training reduce errors
[38]	Infusion Pump	Wrong rate, bypassing pump, drug library errors	60% of administrations	Workarounds, poor training	Standardized drug libraries, training	High error rate, few harmful, smart pumps help
[40]	Smart Infusion Pumps in Advanced Healthcare Systems	Medication Administration Errors related to intravenous (IV) medication delivery.	Potentially severe consequences including adverse drug events and increased morbidity.	Human factors, including user error during pump programming.	Implementing standardized protocols for IV medication administration using smart pumps.	The implementation of smart pumps can significantly reduce IV medication errors, by improving patient safety.
[86]	Smart Vasoactive Drug Infusion Pumps	Medication Administration Errors during the changeover of infusions.	Frequent need for changeovers due to shifting patient needs in critical care.	Manual changeovers leading to potential errors in dosage and timing.	Training for healthcare staff on the effective use of smart pump technology.	A strategy for improving medication delivery practices
[43]	Infusion Pump	Identification errors	Not specified	Poor identification, lack of labels	Line labels, organizers	Labels and organizers improve safety
[87]	Infusion Pumps	Manual medication replacement errors, staff workload	Not specified	Manual processes, lack of automation	Smart infusion device with real-time monitoring, automation	Automated system reduces errors, improves medication delivery accuracy, and lessens staff workload
[48]	Syringe Pump	Malfunction, bolus doses	2 cases (refractory hypotension)	Device malfunction, syringe type	Change syringe type	Syringe type change resolves issue
[49]	Syringe Pump	Dosing errors	Not specified	Compatibility, size, line compliance, resistance, displacement	Validated syringes, smallest size, minimize compliance/resistance, avoid displacement	Recommendations to improve safety
[50]	Syringe Pump	Fluid delivery variations, deformation, stiction, flow irregularities	Not specified	Hyperbaric environment, device design	Use reliable syringes (e.g. BBraun)	BBraun syringe improves performance
[51]	Syringe Pump	Safety risks	Not specified	Human error, syringe-device incompatibility	Validated syringes, minimize brand variety, robust systems	Recommendations to ensure accurate delivery
[52]	Syringe Pumps (PICU)	Maintenance errors by nurses	98% unsatisfactory in maintenance	Lack of training in maintenance	Ongoing training programs for nurses	High maintenance error rates highlight need for continuous training to reduce device-related errors
[53]	Intensive Care Unit (ICU)	Medication errors	Increased frequency of medication errors, varying severity	Lack of a supportive reporting culture and fatigue in ICU staff	Implementing structured reporting systems, increasing awareness of safety standards	Cultural shifts and systemic changes were crucial for reducing errors in ICU settings.
[54]	Syringe Pump	Bolus formation	Not specified	Pump position, central venous pressure	Neutral displacement connectors	Connectors reduce bolus risks
[55]	Infusion/Syringe Pump	Memory lapses, attention slips, planning failures	Not specified	Human factors	Daily equipment checks, staff training, system improvements	Recommendations to reduce errors
[56]	Syringe Pump	Dosing errors	Peak errors +48.2% to −32.5%	Flow rate changes, start-up delays	Awareness, monitoring	Awareness can mitigate risks
[57]	Infusion Pump	Overdose alerts, reprogramming	717 overdose alerts, 66 reprogramming events	Not specified	Smart pumps, standardized libraries, continuous monitoring	Smart pumps intercept errors effectively

(*Continued*)

Table 1. (Continued).

Study	Device/context	Error type/issue	Frequency/severity	Cause/contributing factors	Prevention/mitigation strategy	Main findings
[61,64]	Ventilator	Usage, monitoring, lung injury	Not specified (common in ICU)	Poor settings, monitoring, user-device mismatch	Optimization, monitoring (e.g. oesophageal pressure, capnography)	Improved monitoring reduces risk
[65]	Ventilator	Design validation	Not specified	Not specified	Simulation, neural network	Validates ventilator design stability
[16]	Ventilator	Human error, settings errors	Not specified	Poor settings, lack of decision support	Fuzzy logic decision support	Reduces human error, supports lung protection
[15]	Ventilator	Usability issues, failures	Not specified	Unfamiliar devices, poor design	Incident alarming systems, reporting	Systems help resolve problems, but gaps remain
[69]	Ventilator	Failure modes	5 major, 4 minor modes	Complex service data, uncertainty	FMEA with fuzzy logic, predictive measures	Prioritized failure modes, targeted prevention
[70,71]	Ventilator	Component failure	Not specified	Component wear, design flaws	IoT-based predictive maintenance	Early detection, improved reliability
[72]	Ventilator	Device failure	Not specified	Device wear, usage patterns	AI-based predictive maintenance	Machine learning predicts failures accurately
[82]	Monitoring Device	False alarms	88.8% false positives	Algorithm sensitivity, user settings	Alarm customization, staff education	High false alarm rate leads to alarm fatigue
[83]	Monitoring Devices	Alarm fatigue, information overload, integration issues	Not specified	Excess data, frequent false alarms, poor integration	Improved system design, better care coordination	Highlights need for better monitoring system design to enhance safety
[84]	Monitoring Device	Alarm management	Not specified	Inappropriate settings, algorithm shortcomings	IoMT integration, staff education, policy standardization	System dynamics model improves management
[17]	Monitoring Device	Alarm fatigue	Not specified	High-acuity, multiple devices	Alarm customization, staff education	Alarm fatigue linked to preventable adverse events
[18]	Medical Devices (General)	Maintenance/reporting errors	Not specified	Lack of standardization in maintenance data	Standardized EBM framework, XML protocol	Improves maintenance precision, data exchange, and long-term device safety

3.2. Categories of medical device errors in ICU and their prevention measures for patient safety

While mechanical ventilation in the ICU can be a life-saving intervention for critically ill patients experiencing respiratory failure, it also has the potential to cause harm if not administered correctly [88].

User-interface and programming errors accounted for 60% of infusion pump-related errors, based on analysis of 133,601 infusion events in a multihospital observational study [38] and are common to all device categories. Their prevention is possible through standardized protocols, thorough training, and smart systems with integrated safety features [39,40].

Device design and manufacturing errors refer to the defects in device design, manufacturing defects, or insufficient specification. Almost half of the manufacturer-related errors happen when the device design deviates from the requirements [27]. The instances are failures in the cuff of an endotracheal tube [89] and syringe pump breakdowns leading to dangerous blood pressure variations [48]. The prevention method includes performing various tests, raising the standards of the design, and having the feedback channel between the healthcare professionals and the device producers [28].

System and process errors are those which stem from the healthcare system, e.g. maintenance procedures, documentation quality, and alarm management efficiency. According to the data, 88.8% of arrhythmia alarms in monitoring devices are false positives, thus, causing alarm fatigue [82]. A key aspect of system-level safety is ensuring device reliability, defined as probabilistic error-free equipment. One of the most important elements of system-level safety is ensuring the reliability of devices, which is defined as the likelihood of error-free functioning of equipment, and thus contributes to patient safety and quality. The role of alerts and incident reporting systems is paramount as they aid healthcare risk managers in supervising equipment usage, providing education, and collecting details on unexpected incidents, thus, facilitating problem-solving and innovation [90]. The cuffed ventilators, which have an inflatable balloon at the distal end, can be ventilated at a higher positive pressure due to airway security being enhanced and the risk of aspiration lowered [91]. The advancement in the preventive method includes the establishment of evidence-based maintenance architectures [18] standardizing alarm parameters, and improving data transmission systems [92].

Human and environmental factor errors originate from the limited human cognition, distracting surroundings, and factors of the culture of the organization. Studies show that errors in memory, attention, and planning are most of the time on the operation of a device [55]. The prevention measures are creating a non-punitive reporting culture [53], improving the workplace to eliminate the distractions, and starting the double-check procedure in the case of the most critical interventions [33].

3.3. Limitations of prior research

A series of patient safety problems and corresponding solutions in the ICUs are highlighted in the study [14]. However, the publication does not delve deeply into the different kinds of medical device errors that might be found in various ICUs; thus, it lacks the detailed knowledge of these errors and how often they occur. The study by Akiyama et al. sheds light on ventilator-related critical incidents. However, it does not explain the types of errors that vary depending on the ventilator model and how that might influence patient safety in different ICU settings, thereby resulting in a gap in understanding device-specific hazards [15]. However, Wanzala et al. suggests a new method to study alert fatigue in ICU settings. Nevertheless, this research does not touch upon the intersection of alert fatigue and medical device errors, which implies a situation for going deeper with both alarm management and error prevention strategies [16]. The study by Cho et al. demonstrates strategies to improve the maintenance performance of medical devices. However, the research fails to recognize the significance of combining maintenance activities with user training and device usability evaluations, thus revealing a gap in the coupling of strategies for error prevention and the best use of devices in ICUs [17]. While the evidence-based management proposed by the fundamental study by Crapanzano et al., is insightful, yet it does not clearly demonstrate the extent to which systematic management interventions lead to a decrease in certain kinds of medical device errors in ICU areas; thus, it is a scarcely researched domain that could contribute practical solutions [18]. These uncovered gaps serve to guide subsequent investigations toward a deeper understanding of medical device errors in the ICU, supporting the enhancement of patient safety as well as furnishing policy suggestions for effective management of medical devices in the critical care sector.

4. Results

To further understand the research landscape, a bibliometric analysis of the 72 refined papers was conducted, illustrating trends in year-wise distribution, journal-wise distribution, and research themes.

Figure 2 shows the year-wise distribution of the selected studies. A high concentration of research ($n = 42$) occurred before 2020, with a relative decline in annual publications from 2020 to 2024, followed by a resurgence in 2025 ($n = 8$). This trend may reflect a shift in research priorities or emerging challenges in the field.

Table 2 presents a synthesis of findings from the included studies on the level of patient harm caused by different categories of equipment failure which stated that temporary harm was exceeding in numbers than permanent harm. Our analysis of the reported data indicates that across the 72 included studies, inadequate training was identified as a contributing factor to temporary patient harm in 42% of studies (30/72), while incorrect device use or settings were reported in 36% of studies (26/72) were the most frequently cited contributors to temporary harm among patients across the reviewed literature.

Figure 3 presents the distribution of ICU device types examined across the 72 research papers. The data indicate that ventilators ($n = 13$), syringe pumps ($n = 10$), and infusion pumps ($n = 10$) were the most frequently studied devices in the context of medical device failures.

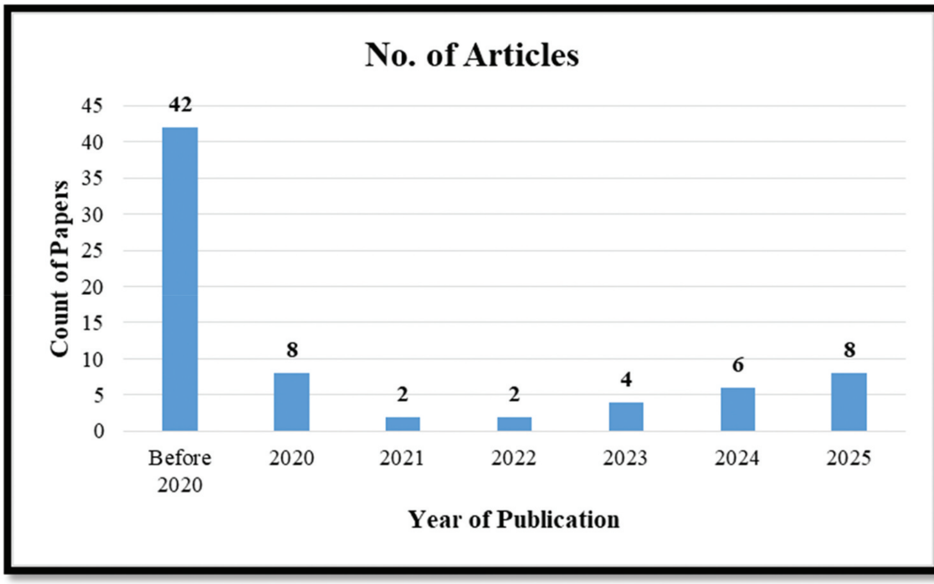

Figure 2. Year-wise distribution.

Table 2. Type of equipment failure problem and level of harm on patient.

($N = 72$)	Mechanical failure - faulty equipment	Incorrect use or setting	Failure of equipment	Inadequate training	Lack of proper cleaning of devices	Human based error-carelessness
Permanent Harm	4%	6%	2%	7%	6%	5%
Temporary Harm	25%	36%	28%	42%	7%	3%
No obvious harm	68%	55%	65%	48%	83%	84%
Unclear	3%	3%	5%	3%	4%	8%
Total	100%	100%	100%	100%	100%	100%

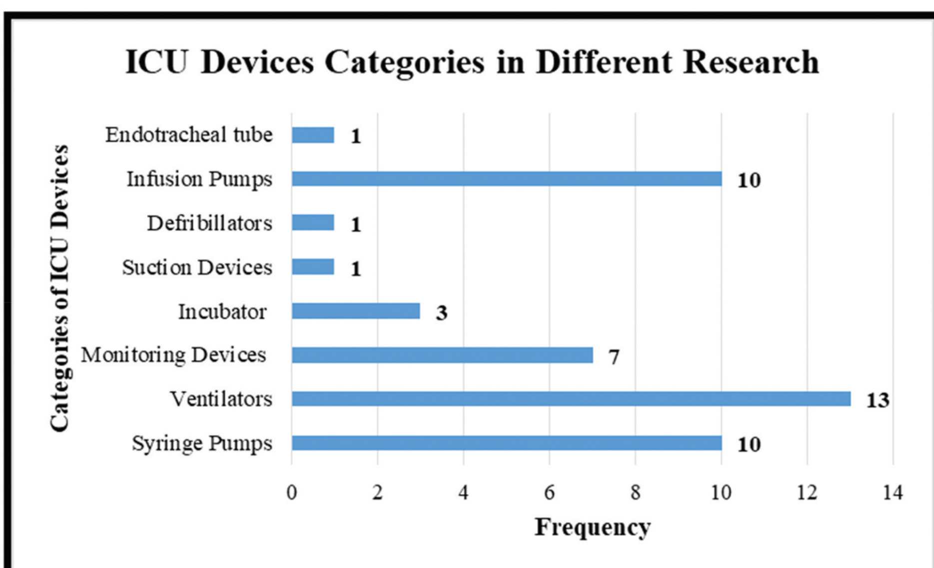

Figure 3. Types of ICU devices, exhibiting device failure.

Figure 4 illustrates the synthesized assessment of the causes behind ICU device failures as reported in the literature. Design issues ($n = 13$) and equipment mishandling errors ($n = 9$) were the most frequently reported contributors.

Figure 5 shows the distribution of research across journals. The analysis revealed that BMJ/BMJ Quality & Safety and Critical Care/Critical Care Medicine each accounted for 10% of the total research output, highlighting the

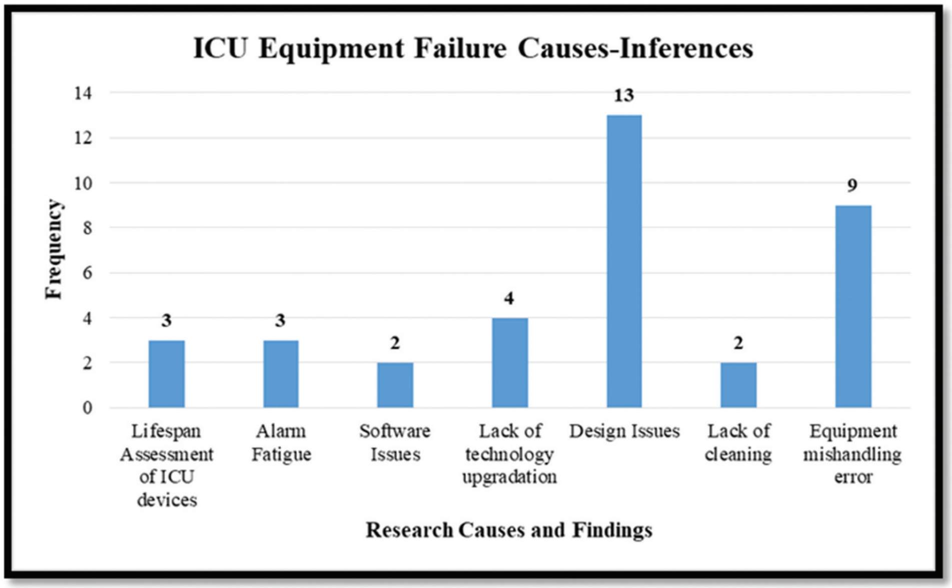

Figure 4. Causes and inferences of ICU equipment failure.

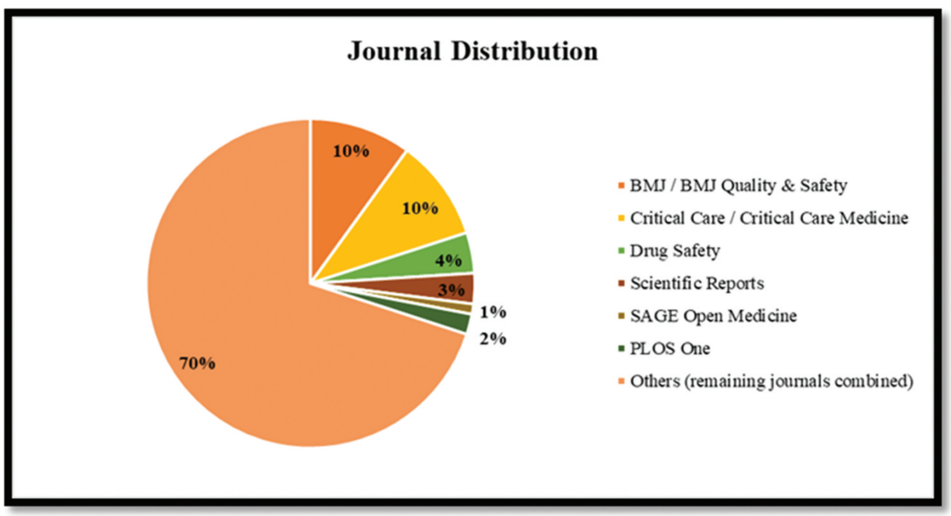

Figure 5. Journal wise distribution.

significant contributions from leading critical care and safety-focused journals.

Figure 6 illustrates the prevailing research themes identified from the 72 selected papers. The most prominent theme was the study of medical device and its associated errors in specific ICU devices (35%), followed by analyses of the impact of medical device errors on patient safety (22%) and research on medical device maintenance and management (21%). Finally, medical device failure incidents in the ICU and other medical device-related safety issues in the ICU hold 11% each.

5. Discussions

5.1. Interpretation of findings guided by quality appraisal

The interpretation and synthesis of the results are influenced by the manual quality appraisal conducted during the study selection phase. This ensured that our conclusions are weighted according to the quality of the source evidence. For instance, studies that fulfilled all three quality criteria were rated ‘High,’ e.g. large-scale multicenter observational studies on infusion pump errors [38], were given

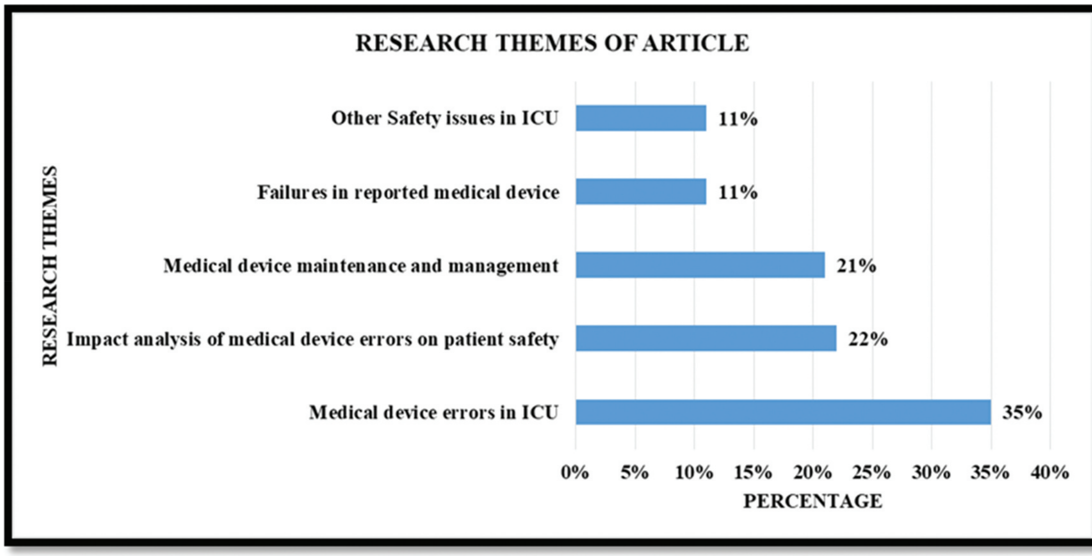

Figure 6. Distribution of selected papers based on the research themes.

greater weight in forming our key conclusion about error prevalence and causes. These study findings were considered as strong, reliable evidence. On the other hand, research rated as 'Medium' or 'Low' in quality was mainly small single-center reports or studies with less clearly defined methodologies; these were approached more cautiously. The findings from an individual case report on syringe pump malfunction illustrated the potential severity and clinical impact of specific errors. However, the error rates were not generalized from these cases to the whole population. Instead, they were highlighted as critical risk points in recommendations [48]. Furthermore, the quality evaluation revealed a recurring limitation across the literature as most of the studies were rated 'Low' for QE3 (future-oriented contribution). This research gap underscores the need for future studies to not only identify problems but also propose and test concrete solution. This quality -weighted approach allowed us to present a balanced and credible overview, distinguishing between well -established trends and important, yet less substantiated, observations.

5.2. Findings

This systematic review has unveiled that medical device errors in intensive care units are a multifactorial phenomenon that has been reported worldwide. Errors in the studies included in this review were traced to improper use of devices as well as to manufacturing defects, and approximately half of the incidents were user-related while the other half were due to device design or manufacturing issues. Infusion pumps, syringe pumps, ventilators, and patient monitoring devices were frequently mentioned as the main devices behind the incidents, showing that the errors are mainly concentrated in the life-supporting and highly-dependent technologies. Across the literature, medical device errors were consistently classified into four interrelated categories: user interface and programming errors, device design and manufacturing errors, system- and process-related errors, and human and environmental factor-related errors. Moreover, these categories were usually reported as overlapping rather than independent. For instance, one study revealed the extremely frequent errors in using infusion pumps and one large multi-center observational study estimated that up to 60% of infusion pump administrations contained at least one error [38]. Such errors were often the result of complicated interfaces, work pressure, and use of workarounds. Similarly, monitoring devices were found to have contributed to these problems, especially with false alarms which made up a large majority of the alerts. For example, in one observational study, 88.8% of arrhythmia alarms were identified as false positives [82], highlighting system-level alarm management challenges.

Human causes were often said to have influenced the complexity of a device and the environmental conditions in the ICU at the same time. The studies have shown that forgetting, losing one's attention and being unable to organize were among the major causes which resulted in errors during devices use [55] especially in such places of the high alarm burden and cognitive load. Nurses throughout various ICU settings were beset with responding to a very large number of alarms per patient per shift; thus, confirming the fact that human performance limitations co-exist with device and generated alert systems [9].

Problems with manufacturers were mentioned as well, especially those pertaining to product design and specification mismatches. A number of researches have revealed that a great number of the manufacturer-related errors were in fact linked to the product designs which were not fully compatible with the medical needs or the operational contexts [27]. Moreover, the failure of maintenance, related issues including the delayed detection of the fault and the lack of complete servicing records were cited as examples of contributing factors to the malfunction of ventilators and infusion systems [70,71], thus, highlighting the connection between physical reliability and safety at the system level.

Within the literature that has been examined, a few papers have studied the role of emerging technologies like automated monitoring systems, predictive maintenance methods, and decision support algorithms in the improvement of device reliability, alarm management, and fault detection. These publications typically presented feasibility, performance metrics, or initial use results as their main points rather than clinical effectiveness [16].

5.3. Recommendations

5.3.1. Training programs

Periodically implemented simulation exercises that are focused largely on high-risk devices and error scenarios, particularly for infusion pumps, syringe pumps, and ventilators. Such practical, simulated situations help healthcare providers familiarize with possible device failures and critical incidents in a secure environment. These hand-on training will help to develop muscle memory and improve preparedness.

Thus, developing muscle memory and enhancing their preparedness level. Incorporate HFE principles into training programs to help healthcare providers understand the interaction between technology and human performance. These training help understand why errors occur and how device design, workflow processes, and environmental factors can contribute to or mitigate risks.

Establish standardized competency assessments for critical medical devices, with regular recertification requirements. This ensures that all personnel operating life-sustaining equipment maintain a high-level proficiency and are up to date with the latest device functionalities and safety protocols.

5.4. Limitations

While medical device maintenance is a prevalent focus, there is the necessity of more research to discuss the reliability and preventive measures of these devices. Bahreini's study identified key parameters influencing device maintenance and management such as documentation, inspection, service design, implementation, preventive maintenance, training feasibility, and human resources [11]. Equipment maintenance and error reduction in healthcare settings should also be explored through utilization parameter in ICUs, SOPs, and proactive equipment replacement plans. Future research should broaden the scope of study beyond specific devices and prioritize the inclusion of a wide range of medical devices to address patient safety concerns [93].

Critical diagnostic and therapeutic devices are inevitable in ICU and Operating Theatre (OT) environments, and their malfunctions can lead to life-threatening implications. Given their prominence, it is critical to ensure comprehensive insights into the reliability and error prevention mechanism for medical devices within critical healthcare settings. This systematic review is confined by the heterogeneity of the included studies and limited the possibility of meta-analysis of the data. The quality of the evidence differs in various device types, with infusion pumps and ventilators being more extensively studied than other devices. In addition, the focus on English-language publications may have introduced language bias. Future studies should consider research in other languages and use uniform methods to conduct a more comprehensive quantitative analysis.

6. Summary of the study

Medical device errors are inevitable occurrences in ICU settings, and they have the potential to seriously compromise patient safety and quality of care. Several research studies have been done to investigate the kinds, reasons, and outcomes of medical device errors in ICUs. The present study has systematically reviewed the literature on medical device errors in ICUs and has given a thorough evaluation of their frequency, severity, causes, prevention, and remedial measures. The predominant themes and deficiencies in the existing knowledge have been identified and the paper stresses the necessity of comprehensive research on this issue. The research results provide a roadmap for healthcare professionals to formulate focused interventions and protocols to avert medical device errors. If emphasis is placed on patient safety and device upkeep, ICUs will be able to offer the best possible care, thereby lowering the occurrence of adverse events and improving patient safety and quality at the same time. The findings from this systematic review can fundamentally change ICU's safety policies and practices, creating a critical care environment that is both safer and more efficient.

7. Conclusion

Medical errors due to the malfunction of ICU medical devices are among the leading causes of patient harm. The complexity and extensive use of medical devices contribute to an ongoing risk of device-related errors. It is crucial to investigate these errors and find strategies for managing and preventing both manufacturing and usage problems before devices are deployed in the healthcare settings. One of the main ways to reduce medical device errors is through detailed device assessment and the use of HFE in device design and implementation. Healthcare organizations should upgrade training programs to enable doctors, nurses, and allied healthcare professionals to be more efficient in recognizing device-related incidents, near misses, and adverse events. In the majority of public hospitals, medical device maintenance services are more focused on corrective repairs than on preventive measures, thus showing a gap when compared to private hospitals. The literature reveals that public hospitals have difficulties with the implementation of high-quality control systems and insufficient technical knowledge for the maintenance and repair of devices. Errors in ICU devices are mostly due to negligence in maintenance, shift toward advanced technology without proper training, mechanical failures, improper staff handling practices, and lack of awareness about the occurrence of errors. The main problems were observed with ventilators, infusion pumps, and syringe pumps. Future research should be committed to the formulation of proper maintenance policies, positioning the care of ICU devices as a priority, as well as educating the healthcare staff in the correct use and identification of medical device-related errors, this will ultimately ensure in-patient safety across healthcare facilities.

8. Expert opinion

The systematic review sets up an essential structure to acknowledge the issue of device failures that is far beyond simple listing. It explains the network of factors that are related to errors in high-acuity ICU environments. The findings indicate that errors related to medical devices should not be treated as separate incidents; rather, they should be recognized as emergent phenomena of a complex socio-technical system that comprises the device, the user, the environment, and organizational procedures. Understanding this interaction is the means of creating safety systems that can endure further failures.

Famously, one implication of this study has been a shift in the attribution of the error blame from individual negligence to systemic vulnerabilities. Consequently, it provides a thorough evidential base, which hospital administrators may use to advocate for the necessary investment in extensive training programs integrating HFE, while procurement departments may be given the priority of safety devices being equipped with features such as standardized drug libraries for smart pumps. In addition, it supports the economic rationale for the implementation of AI-driven predictive maintenance that has the potential to turn the costly reactive repairs into scheduled, budget-friendly interventions, thereby lowering downtime and patient risk simultaneously. Such changes cannot be realistically done without facing a number of obstacles, among which are cultural resistance to non-punitive error reporting and financial inertia linked with technology upgrades. The authors advise a phased implementation plan that would initially focus on devices that are both high-risk and high-impact, such as ventilators and infusion pumps. The most important factor that can lead to the success of such an undertaking is the establishment of a safety culture. In such a culture, staff members are allowed and feel obliged to report near-misses without the concern of being punished. The results of the review supply the motivation for such a cultural transition, as they prove that being open and learning from errors is more beneficial for patient safety than punishing.

The primary source of difficulty and major flaw of the present area is the division of both knowledge and data. Most of the time, research is separated by the kind of the device for instance only ventilator studies or by the discipline, for instance, only clinical studies; thus, a complete understanding is not possible. This methodological heterogeneity, which called for a systematic literature review, is a sign of this larger issue. To address this issue, the industry has to head toward the use of standard reporting taxonomies for medical device errors and also the co-operation of interdisciplinary research teams that involve clinicians, engineers, and human factors specialists. The ultimate aim of the research carried out in the future should be the creation of a proactive, foreseeing, and self-correcting ICU environment wherein possible failures are predicted and alleviated prior to the time when they can cause injuries.

Integration of AI and ML should incorporate retrospective analysis and real-time clinical decision support, making it the most promising area for future research. AI algorithms can integrate data from several devices and thus be able to detect patient states that are of high risk or equipment failures that are about to occur. This, in turn, will give the clinicians informed courses of action, not just another alarm. In addition, the idea of 'digital twins' which are virtual and dynamic models of the ICU setup, has a lot of potential to be used for safety simulations when new devices, protocols, or staffing models are introduced. The future of this field is an interoperable, data-driven 'smart ICU' where devices are in a seamless communication loop, and AI serves as an ever-watchful guardian that learns continually to enhance patient outcomes.

Within the next five to 10 years, the quality of care will definitely be transformed from a reactionary, schedule-based maintenance plan to a condition-based, predictive maintenance plan, which will be facilitated by IoT sensors and ML. The ability to predict with high accuracy when a device is going to fail will be in our hands, hence the interventions will be arranged prior to the time the device is faulty. Nevertheless, the change in technology will bring along with it the need for a similar change in clinical training. Standard practice will include ongoing simulation and skills assessment not only in the use of the device but also in the management of an AI-augmented workflow. The most significant thing, however, will be the establishment of a closed feedback loop where data on device performance is used as information for both real-time clinical decisions and long-term device design, thus resulting in the healthcare system becoming a learning one that is continually evolving to improve patient safety.

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Author contributions

Z.Z. came up with the initial concept and design; Z.Z. and S.J handled the data collection. Z.Z., S.J., and A.D. carried out the data analysis and interpretation; Z.Z. wrote the initial draft, and S.J. and A.D edited it for key intellectual elements.

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