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A Review of Human Factors Reliability Analysis in Surgical Operations under the Smart Medical

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Abstract

The continuous progression in scientific research and technological innovation, alongside the burgeoning field of artificial intelligence, has catalyzed the assimilation of intelligent human-machine integration systems into the surgical domain. Despite the significant enhancement in surgical precision and patient convenience afforded by the adoption of surgical robots, the practical application of this technology is not without its risks. This paper reviews the literature on HRA within surgical contexts, scrutinizing the typology of human errors, their underlying factors, utilization of HRA techniques, and the assessment of surgeons' skills, to champion the need for HRA methodologies that are specific to the healthcare sector. Our analysis of 37 articles suggests that HRA implementation in healthcare is still in its infancy. The predominant method, Observational Human Factors Reliability Analysis (OCHRA), has been in use since 1999, yet it is limited in its capacity to evaluate internal error patterns and falls short in methodological advancement compared to techniques utilized in industries like nuclear energy and aviation. Therefore, the healthcare community must earnestly reevaluate the suitability and sophistication of existing methods, ensuring they capture the intricate interplay of cognitive processes inherent in medical practice. This critical step is essential in the development of tailored methodologies that are contextually grounded and cognitively oriented. Furthermore, investigating the modulating factors of human error behavior in intelligent human-robot integration systems is set to become a focal point for future research into personnel reliability within this evolving domain.

Keywords: Surgical, medical, human reliability analysis methods, healthcare, assessments of surgical skills of surgeons, smart medical.

1. Introduction

The healthcare domain is expansive, encompassing activities from drug distribution to medical equipment utilization, and from surgical procedures to nursing services. All these facets of medical intervention demand the attentiveness and expertise of healthcare practitioners. Furthermore, the development of surgical intelligence is indeed an important trend in the medical field, but the human factor is still an indispensable part of the application of intelligent technology. Doctors' professional skills, decision-making and interpersonal skills will continue to play a key role in ensuring the safety and success of surgery, supported by intelligent technology. A comprehensive report released by the U.S. Institute of Medicine, a division of the National Academy of Medicine, indicated that medical errors in the United States accounted for nearly 98,000 fatalities annually [1], underlining the criticality of human reliability in healthcare. Human reliability analysis (HRA) has emerged as a proven approach for addressing safety issues in medical care [2,3]. The efficacy of transferring risk analysis methodologies from traditional high-risk sectors to healthcare has been well-documented [4,5].

Surgical practice, as a fundamental component of medical services, involves the use of surgical instruments and equipment to perform physical manipulations inside the body, including extirpation, reconstruction, or implantation, by professionals such as surgeons. Evidence suggests that surgical complications contribute to nearly half of all adverse healthcare events and 13% of in-hospital deaths [1, 6-7]. Given this high incidence of adverse outcomes, the applicability of human factors reliability analysis (HFRA) in surgery has received significant attention from medical experts [8]. The swift progression of technology has significantly propelled the evolution of digital intelligence within the medical domain. This transformation has showcased its profound capabilities in augmenting the efficiency of medical practitioners, mitigating the hazards faced by patients, and conserving precious healthcare resources. Nonetheless, this digital revolution introduces distinct challenges, particularly concerning the seamless incorporation of medical professionals into robotic systems. Addressing these integration complexities is imperative to realize the full potential of digital intelligence in clinical settings while ensuring the safety and efficacy of patient care. Therefore, this study seeks to contribute to the field by conducting a comprehensive literature review on human factors reliability in surgical settings, to underpin theoretical groundwork for an HRA methodology tailored to the surgical environment.

The subsequent structure of the paper delineates the process of systematically reviewing the literature. Section 2 delineates the detailed analysis of the literature review process. Section 3 communicates the findings from the literature analysis, while Section 4 delves into the discussion of these results, offering a nuanced understanding of the applicability and potential of HRA in surgical contexts.

2. Materials and Methods

The research methodology employed in this study is delineated as follows:

(1)A comprehensive literature search was conducted using the keywords "healthcare," "medical," "surgery," and "human reliability" across four prominent medical databases—PubMed, Science Direct, Web of Science, and IEEE—as well as Google Scholar, to identify relevant foreign-language publications.

(2) Concurrently, a domestic literature search was performed on the China National Knowledge Infrastructure (CNKI) using the Chinese equivalents of the aforementioned keywords, focusing on "medical," "surgical," and "human factors."

(3) The literature was initially screened by examining titles and abstracts to ascertain relevance to the research theme.

(4)A subset of the identified literature was selected for thorough reading and critical analysis based on its alignment with the research objectives.

Following these procedures, a total of 52 foreign-language and 8 Chinese-language publications were preliminarily identified. Subsequently, 44 of these articles were subjected to in-depth review and analysis. Notably, the foreign-language articles were sourced from esteemed journals, including but not limited to the Annals of Surgery, Surgery, Applied Ergonomics, Safety Science, and journals within the Reliability Engineering and System Safety domains.

3. Results

By the diverse research aims, the thematic content of the extant literature was systematically categorized into three principal domains: (1) Identification of Human Factors Failure Patterns and Causal Analysis (45%); (2) Establishment of Human Reliability Analysis Methods (37%); and (3) Assessments of Surgical Skills of Surgeons (18%). The division of content is graphically represented in Figure 1. A preliminary analysis of these articles revealed a notable preference for the application of Observational Clinical Human Reliability Assessment (OCHRA) techniques across all these research areas. Specifically, the OCHRA methodology was utilized in 37% of the analyzed articles, demonstrating its versatility and utility for different types of studies within the field. This classification underscores the broad scope of research being conducted within the healthcare domain, highlighting the need for comprehensive methodologies aimed at understanding human factors' reliability in medical settings.

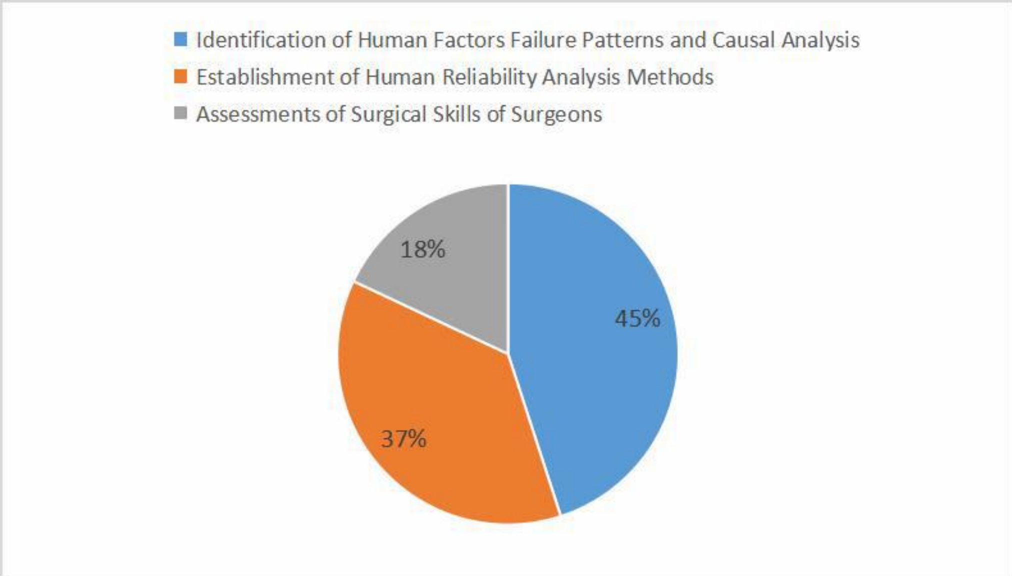

Figure 1 Proportion of each research theme

An exploration of the Chinese literature indicates that significant contributions to the field of medical human factors research are attributed to the endeavors of Dr. Haizhe Jin from Northeastern University and Professor Minzhi Xie from Shanghai University of Science and Technology. An examination of Dr. Haizhe Jin's contributions, as detailed on Northeastern University's website, indicates that by 2020, he had authored 10 scholarly articles in both Chinese and English, with five of these focusing on medical human factors. His research has particularly concentrated on the identification of medical human factor error factors [9-10], human factor errors associated with medical equipment usage [11], the influence of pharmacists' workload on violation-type errors in medication management [12], and a comprehensive review of medical human factor analysis techniques [13].Similarly, Professor Minzhi Xie's research, as showcased on the University of Shanghai for Science and Technology's website, includes seven first-authored journal articles by 2020, two of which delve into medical human factors. His studies have been directed toward identifying human factor error factors in emergency rooms [14] and classifying human factor error factors in adverse medication events [15].

This section will proceed to elucidate the findings of the literature analysis, categorized under the aforementioned three research themes.

3.1 Identification of human factors failure patterns and causal analysis

The literature on surgical error patterns predominantly utilizes the Observational Clinical Human Reliability Assessment (OCHRA) methodology, as presented in Table. The inception of OCHRA can be traced back to 1998, through a study by JOICE which examined the types and rates of errors in laparoscopic surgery [16]. The framework for this technique comprises three core components:(1)Task Analysis: The surgical procedure is methodically dissected into a series of subordinate tasks, providing a structured breakdown necessary for comprehensive evaluation.(2)Error Classification: The application of the Systematic Human Error Reduction and Prediction Approach (SHERPA) is utilized, with a focus on the ten External Error Modes (EEM), allowing for a detailed examination of the error patterns encountered during surgery.(3)Data Analysis: Through meticulous observation of surgical procedures via video recordings, subject matter experts tabulate the occurrence of each EEM across different tasks. This information is subsequently subjected to statistical analysis to discern patterns and tendencies in procedural errors.

Despite its prevalence, an inherent limitation of the OCHRA approach lies in its exclusive focus on external error patterns. These manifestations of error are notably accessible through direct observation. However, this methodological emphasis overlooks the intricate realm of cognitive errors and their theoretical categorization. Human behavior represents a convoluted interplay of mental processes [17], and within these cognitive activities, a variety of error types may emerge [17]. The mechanism of mental errors is paramount in identifying human factor-related error patterns and has substantial implications for their classification [18].

This critique underscores the need for methodologies that encompass the full spectrum of human error, extending from observable behavioral manifestations to the nuanced cognitive processes that underlie them. Insights into these cognitive elements would enrich our understanding of surgical errors and contribute to the development of more holistic and effective strategies for error mitigation and prevention.

Indeed, as investigative assessments in this domain have expanded, there has been a discernable shift in the research literature, with studies now increasingly orienting towards a more holistic understanding of error patterns within the operating theatre context. This academic trajectory has led to a concerted focus on not only the immediate procedural errors but also on the underlying internal factors and those situated at the higher strata of responsibility, particularly within managerial echelons. The progression in scholarly inquiry indicates a maturation of the field, where a comprehensive approach is now being adopted to explore the multifaceted nature of human error within the surgical environment. Such an inclusive perspective recognizes that both local and systemic factors contribute to a complex interplay, which may culminate in lapses that impact patient safety and operational efficacy. Consequently, the advancement of error analysis in surgical settings underscores the necessity of a systematic assessment, one that encompasses all levels of potential causes, from the most immediate and tangible to the more abstract and managerial. By doing so, it allows for the development of targeted strategies aimed at reducing and preventing errors, thereby enhancing patient outcomes and operational efficiency. This represents a pivotal development within the domain of surgical safety research, signifying a move towards a more integrated and proactive approach to error management.

MITCHELL addresses this necessity by employing the Human Factors Classification Framework (HFCF) to categorize adverse clinical events within hospital settings [19]. This framework delves into a spectrum of precursory events, contributing factors, and root causes. The HFCF reveals that rule-based errors predominantly intersect with the execution of medical or monitoring tasks; skill-based errors are largely linked with cases of misdiagnosis; and organizational (66.9%) and patient-related (53.2%) factors are frequently identified as significant contributors.

In an attempt to understand the human factors underlying surgical errors from a multidisciplinary viewpoint, DALEN et al. advocate for analyzing these issues from a team perspective [20]. They highlight that surgical members from diverse specialties and varying levels of expertise converge on a shared mental model while collaborating on surgical procedures. The HFACS model has been applied to scrutinize the human factors in laparoscopic surgery across organizational, environmental, and individual dimensions. The findings indicate that personal factors, notably the surgeon's stress, workload, and team cohesion, play a pivotal role, with potential antecedents including burnout, job satisfaction, and organizational commitment. Further, environmental factors, such as surgeons' inattention and anomie, along with organizational environmental elements like the team's capacity for managing unexpected situations, personal preparedness, and communication dynamics, are highlighted as significant contributors to error.

These studies underscore the complexity of identifying and managing errors in surgical environments, underscoring the importance of a thorough assessment that extends beyond the immediacy of the surgical procedure. By considering the Human Factors Classification Framework and the HFACS model, researchers can uncover a more complete picture of the landscape of errors, thereby informing more comprehensive safety strategies.

A review of the current literature indicates a notable preference for employing the Observational Clinical Human Reliability Assessment (OCHRA) to discern error patterns, with a predominant emphasis on the analysis of external error modes. Surgery, characterized by its complexity and the necessity for multidisciplinary collaboration, unfolds within a high-pressure context where the cognitive processes of surgeons exert a profound influence on surgical outcomes. Further compounding this, the ambiance of the surgical milieu, including the caliber of communication and leadership dynamics, is intricately tied to the surgeon's performance [21] and is reflective of underlying organizational management factors.

JAMES, in his seminal work "Human Error," posits a tripartite classification of errors: behavioral, environmental, and conceptual. While behavioral analysis offers a straightforward approach, it falls short in encompassing the theoretical spectrum of cognitive errors. The environmental classification, too, is fraught with limitations, as analogous settings do not uniformly engender identical error manifestations. Conversely, the conceptual stratum, predicated on the cognitive mechanisms underpinning error emergence and privileging theoretical insights over observable lapse characteristics or context, presents a more efficacious categorization. This approach is anchored in the elucidation of fundamental causal mechanisms. Consequently, forthcoming research within the healthcare sector should direct greater scrutiny toward the conceptual classification of errors. Notably, Reason's taxonomy delineates Skill-based lapses, Rule-based mistakes, and Knowledge-based errors, providing a paradigm for understanding the typology of errors.

Table 1 Summary of literature aimed at studying human-caused error patterns

Time	Types of Surgery	Method	Result
MALIK, 2003 [1,22]	Endoscopic Nasal Surgery	SHERPA	In the realm of execution-type errors, grasping errors were notably prevalent, constituting 67% of all such errors, with the Blakeslee forceps being frequently implicated in these incidents. Among the 69 reported cases of mucosal injuries, the improper application of force or haste during the insertion and extraction of instruments within the nasal cavity was attributed to over 50% of these occurrences. Furthermore, instances of "over-exertion," resulting from the exertion of excessive force, were found to be the cause of 34% of mucosal injury incidents.
TANG, 2004 [2,23]	Laparoscopic Cholecystectomy	OCHRA	The analysis encompassed a comprehensive review of 38,062 procedural steps within 200 laparoscopic cholecystectomy interventions conducted by a cohort of 26 surgeons. The study culminated in the identification of a total of 2,242 errors. Notably, the dissection of the gallbladder's triangular section within the second task area was associated with a disproportionately higher incidence of errors compared to those in the first and third areas of the operation. Additionally, the combined blunt and sharp dissection approach was observed to produce an appreciably lower error rate than when the blunt dissection technique was employed exclusively. Significantly, the most severe ramifications were evidenced in the instances where electrified instruments were utilized for the severing of tissues, suggesting potential hazards associated with this method.
TANG, 2004 [3,24]	Laparoscopic Pyloromyotomy (LPM)	OCHRA	A total of 310 procedural errors were detected during the evaluation of surgical procedures, comprising 77 consequential and 233 non-consequential errors. The majority of these events, constituting 80% of the total, were attributable to execution errors. The analysis highlighted that specific instruments were correlated with elevated error rates: the grip forceps with a 68% error rate, retractable blades showing a 79% incidence of missteps, and splitting forceps demonstrating a 77% propensity for user error. Significantly, Task III of the Laparoscopic Pyloromyotomy (LPM) procedure has been identified as the most hazardous zone, where errors were most likely to occur. Over-application of force during Task III was found to be particularly detrimental, contributing to complications such as stenosis and bleeding of the pyloric tissue. The predominant patterns of external errors that led to these adverse effects involved incorrect movement vectors and inaccurate tissue plane orientation during the dissection process. These findings underscore the critical importance of precise technique and proper instrument handling in surgical practice, particularly in the context of delicate anatomical areas such as the pyloric region.
TANG, 2005 [4,25]	Laparoscopic Cholecystectomy	OCHRA	Upon meticulous examination, 60 trainee surgeons' procedural performances were assessed, revealing a total of 1067 instances of error. Among these were 331 consequential lapses, characterized by their potential to significantly impact patient outcomes, alongside 736 minor, nonconsequential errors. Detailed analysis indicated three critical pitfalls as the underpinning causal factors for these mistakes: (1) the routine exclusion of essential procedural elements, (2) the execution of surgical steps in an incorrect sequence, and (3) the application of excessive force. Collectively, these three categories of errors were found to constitute a staggering 92% of all identified consequential lapses, underscoring their significant impact on trainee performance and patient safety.
ANDREW,2007 [5,26]	Cardiovascular Surgery	HFACS	Utilizing a modified Human Factors Analysis and Classification System (HFACS) framework originally developed within the aviation domain, this study identifies and quantifies critical performance-affecting factors within the operating theatre through the administration of a structured questionnaire. This

			approach allows for an estimation of the relative significance of each factor about surgical outcomes. The analysis reveals that numerous incidents can be attributed to organizational influences that compromise the effectiveness of the supervisory oversight process, thus providing valuable insights into potential areas for improvement in both procedural and management strategies within the surgical environment.
GAUBA, 2008 [6,27]	Phacoemulsification for Cataract Extraction	OCHRA	Upon meticulously analyzing a total of 330 procedural steps across 33 operations, a comprehensive identification of 228 errors has been conducted. Of these, 66.2% (151 instances) were categorized as execution errors, while the remaining 33.8% (77 instances) were classified as procedural errors. In the domain of soft lens extraction procedures, surgeons part of group 3 were found to commit a higher frequency of errors in comparison to their counterparts in groups 1 and 2. Notably, the level of surgical experience appeared to exert a considerable influence on the error rate, underscoring the importance of experience in mitigating potential procedural errors.
JOE, 2012 [7,28]	Medical Incident Report Analysis	Root cause analysis and CREAM	In a comprehensive investigation, 87 incident reports underwent a sophisticated analysis through the application of the Root Cause Analysis (RCA) technique. Concurrently, 58 cases were subjected to a secondary analysis with the Cognitive Reliability and Error Analysis Method (CREAM). A comparative evaluation of the outcomes from these methodologies revealed a divergence in their findings. This divergence highlights a significant aspect: The CREAM framework effectively identifies root causes emanating from organizational and leadership deficiencies, a domain that is often overlooked or excluded by the RCA approach. Consequently, this study underscores the limitations of RCA in encompassing the full spectrum of contributory factors, especially those related to systemic issues, emphasizing the necessity for a holistic approach to error analysis in healthcare.
LATIF, 2015 [8,29]	Laparoscopic Nephrectomy	SHERPA	Upon integrating the concept of Emotion Economy into the existing SHERPA Framework, an analysis of 86 instances of errors was conducted, revealing a significant association with deficits in action economy. The findings suggest that the augmented SHERPA framework, incorporating insights from the Emotion Economy, holds considerable promise. This framework demonstrates potential applications in surgical error prevention strategies and the training of surgeons, offering an enriched approach to procedural safety and performance improvement within surgical contexts.
MITCHELL, 2016 [8,19]	Clinical Incident Analysis	HFCF	The application of the Human Factors Classification Framework (HFCF) to scrutinize a dataset comprising 498 medical incidents has yielded insightful results. Specifically, the analysis highlighted that rule-based errors were predominantly linked with the execution of medical procedures and monitoring activities, while skill-based errors were notably tied to diagnostic inaccuracies. Further, it was identified that among the various contributing elements, those related to organizational factors (66.9%) and patient-related issues (53.2%) stood out as the most prevalent. These findings underscore the impact of these categories on the incidence of medical errors and thus serve as a critical point of reference for the development of more robust prevention strategies and training programs in the healthcare domain.
RUTTE, 2016 [9,30]	Sleeve Gastrectomy	OCHRA	In an analysis of medical procedures, a total of 213 technical errors were pinpointed, with the majority occurring during large curvature manipulations and during the suturing of the stomach. Of these identified cases, a notable 44.6% resulted in consequential errors that necessitated additional surgical operations, totaling 96 interventions. Furthermore, statistical analysis revealed that errors in the procedure of opening the lesser curvature and the repositioning of the anastomosis were significantly correlated with postoperative complications. These associations underscore the critical nature of these procedural steps and the need for precision in surgical technique to minimize the risk of adverse outcomes.
DALEN, 2020 [9,20]	Laparoscopic Surgery	HFACS	In examining individual factors, it was found that the significant influences on surgeons include elevated stress levels, substantial workloads, and notably perceived team dynamics. These influences may stem from factors such as work-related burnout, job satisfaction, and organizational commitment. Within the environmental factors, surgeons exhibited a higher incidence of distractions and anomalies. In the context of organizational environmental factors, the ability to swiftly and effectively manage unexpected events, individual preparedness strategies, and the efficacy of team communication protocols were identified as crucial determinants.

3.2 Establishment of human reliability analysis methods

In the narratives of academic discourse on the development of surgical Human Reliability Analysis (HRA) methodologies, the initial phases were predominantly characterized by the prevalence of OCHRA, a methodological approach that holds the highest frequency of application in the surgical domain [8]. Throughout recent years, a growing consensus has emerged among scholars for integrating human reliability assessment techniques that have achieved substantive maturation in the realm of nuclear industries, including the HEART (Human Error Assessment and Reduction Technique) method.

A synthesis of pertinent literature is tabulated in Table 2 for comprehensive reference.

In pursuit of innovation within this field, a significant contribution emerged from INOUE, along with colleagues from the Graduate School of Medicine at Kyoto University in Japan, with the creation of the EDIT (Error type, Direct Threat, Indirect Threat) model. This model integrates quantitative risk assessment to facilitate a nuanced analysis of medical errors [31-32]. EDIT seeks to elucidate the organizational factors that precipitate medical errors, presenting medical tasks within practice modules, accompanied by a sophisticated coding system for the event narrative. The coding schema delineates seven classification dimensions for medical errors: patient category, work shift, practice module, connection chain (error type, direct threat, and indirect threat), medication handling, event severity, and potential harm. The model calibrates two critical parameters: the error rate of specific practice modules and the scaled weights of the seven identified elements. The model's validity has been confirmed through its application to the analysis of 5339 incident reports associated with nursing incidents, demonstrating its robustness in the context of medical error identification and classification [31-32].

The CASTIGLIA group at the University of Palermo, Italy, applied fuzzy set theory to conduct a comprehensive risk analysis on the potential exposure of medical personnel during brachytherapy procedures [33]. In their approach, which is rooted in the HEART (Human Error Assessment and Reduction Technique) method, they innovatively adapted the weighted Proportion of Affect (POA) for error-producing conditions (EPC) to be determined through fuzzy set theory, thus incorporating more effectively the inherent uncertainties associated with EPCs. Furthermore, the assessment of fuzzy potential dose was conducted for identified accident scenarios to evaluate relative risks. The findings highlighted the substantial significance of human-related errors in simulated adverse events. The conclusions from this investigation offer procedural and safety equipment recommendations to mitigate the likelihood of radiation exposure incidents.

The CHADWICK group from the National University of Ireland posited that the proactive identification of potential failures paired with the development of preemptive defensive strategies could be achieved through safety measures. Employing the HEART methodology, they conducted an analysis of key nursing tasks within contemporary radiotherapy systems [34]. They expanded upon the traditional single-expert approach by implementing a team of experts to conduct the assessment, which facilitated the quantification of task failure probabilities and culminated in the prioritization of factors critical to the successful completion of these tasks. This adaptation of HEART as a potential HRA (Human Reliability Analysis) tool for healthcare applications is suggested with optimism by the authors.

To address risk assessment in radiological medical processes, SANDS and colleagues from University Hospital Galway, Ireland, proposed a combined methodology that integrates Failure Mode and Effects Analysis (FMEA), Fault Tree Analysis (FTA), and the SPAR-H method [35]. This approach demonstrated a high level of confidence in predicting the likelihood of human-induced errors compared to actual observations, thereby providing a robust framework for the evaluation of radiological safety protocols.

In the realm of human factors reliability analysis (HRA) in medical procedures, research by the ONOFRIO team from the Politecnico di Milano has significantly advanced the field. Despite an increasing interest in applying HRA to surgical practices, the available literature remains notably limited. In response, the team delved into the core of HRA by examining "behavioral formative factors," as part of a 2015 literature review where they identified ten factors and classified them using the SHEL framework [36]. The team augmented this classification with a "distraction" factor in subsequent validation studies with minimally invasive surgery as the context. The year 2018 saw a pivotal advancement with the application of focus groups and semi-structured interviews to further refine these classifications, resulting in the identification of 21 influencing factors (IFs). This research culminated in a comprehensive analysis of IF quantification on surgeon performance, achieved through the distribution of a questionnaire to surgical practitioners[8].

Table 2 Summary of the literature to establish HRA methods

Time	Types of Surgery	Method	Result
JOICE,1999[16]	Laparoscopic Surgery	OCHRA	The utilization and practicality of an observational human factors reliability analysis technique in evaluating human errors during endoscopic surgeries have been rigorously validated and affirmed.
INOUE, 2002[31]; 2004[32]	Nursing Tasks	EDIT	The development of an advanced human reliability analysis model capable of discerning organizational factors underlying medical errors has been accomplished. Concurrently, this model facilitates in-depth analysis of decision-making processes rooted in specific human behavioral patterns.
CASTIGLIA, 2010[33]	Radiotherapy	Enhanced HEART	Employing fuzzy theory, the method successfully derives the proportions of expert influence on the weights assigned to Event and Procedural Elements (EPCs), demonstrating its capability to reliably analyze human error contributions within event sequences.
CHADWICK，2012[34]	Radiotherapy	Enhanced HEART	The HEART methodology has been enhanced by transitioning from a singular expert assessment to a collaborative approach utilizing a panel of experts, thereby establishing a robust Human Factors Reliability Analysis (HFRA) method tailored for critical care tasks within contemporary radiotherapy systems.
SANDS, 2015[35]	Radiotherapy	FMEA、FTA、SPAR-H	This method demonstrates a high degree of reliability in forecasting the likelihood of human-induced errors, aligning closely with empirical observations.
ONOFRIO, 2015[36]	Minimally Invasive Surgical Procedures	SHEL、Literature Review and Field Study	Drawing upon the literature, ten distinct behavior-forming factors were extracted and organized systematically according to the SHEL model. Throughout the observational phase, meticulous attention was paid to monitoring the behavior of individuals associated with these systematically categorized factors. Moreover, to enhance the observational analysis, the element of "distraction" was incorporated into the scrutinizing process.
MOHAMMADFAM, 2016[40]	Nursing Tasks	CREAM and SPAR-H	Upon comparative analysis of the CREAM and SPAR-H methodologies within the domain of nursing, CREAM has demonstrated superior applicability for conducting human factors reliability analysis in nursing practices.
ONOFRIO, 2018[8]	Surgical Interventions	Expert Judgment, Interviews, and Focus Groups	The classification of 21 Influencing Factors (IFs) has been validated through an extensive survey of expert surgeons specializing in minimally invasive open surgical procedures. This survey, comprising 215 responses, served as a quantitative assessment tool to determine the influence of each IF on the performance metrics of the surgical staff.
ONOFRIO, 2020[37]	Robot-Assisted Radical Prostatectomy	Enhanced HEART	A novel methodology was established for the analysis of dynamic human reliability in the context of robotic surgery. This approach was subsequently applied to the domain of robot-assisted radical prostatectomy, and the findings indicated that team-specific factors exerted the most significant influence on the variability of patient outcomes.
PANDYA, 2017[38]，2020[39]	Radiotherapy	GTT-PSFs	A robust Human Factors Reliability Analysis (HFRA) framework has been constructed, fundamentally grounded in the concept of Generic Task Types (GTTs) in conjunction with the influence of Performing Shaping Factors (PSFs). This model is designed to provide a structured approach for assessing and understanding the reliability of human actions within complex systems.
Ping Li，2014	Use of Surgical Instruments	CREAM	This methodology enables the quantitative assessment of the likelihood of operator errors throughout the utilization of medical devices, thereby enhancing the comprehensiveness of medical device risk evaluations.
Danni Fu，2019[41]	Ophthalmic Surgery	Potential Operational Error Identification（POEI）	A comprehensive human factors error identification framework tailored for ophthalmic surgical procedures has been developed, encompassing both external and internal error models. Additionally, a qualitative correlation has been delineated between behavioral shaping factors and internal error patterns, thereby providing a nuanced understanding of potential error sources within the complex environment of ophthalmic surgeries.

In their 2020 achievement, the ONOFRIO team introduced a novel approach tailored for robotic-assisted surgery—a dynamic HRA method[37]. This method represents an enhanced version of the HEART methodology, a development marked by two key innovations: (1) the 21 identified IFs replace the original HEART's Error Producing Conditions (EPCs), and (2) a wider range for the Proportion of Affect (POA) from [0, 1] to [0, 100] allows for better uncertainty estimation of EPCs. This evolution in HRA methodology underscores a significant contribution to the broader healthcare domain.

Concurrently, the PANDYA team at the Paul Scherrer Institute (PSI) in Switzerland has presented a groundbreaking HRA framework for radiotherapy. Their approach, which leverages a Generic Task Types - Performing Shaping Factors framework, offers a systematic process for analyzing human reliability [38]. By mapping generic tasks onto macro-cognitive functions and then identifying failure patterns, they dissected specific failure causes, and associated failure principles, and ultimately delineated behavioral shaping factors. To attest to their method's efficacy, the team employed expert judgment to gather data and Bayesian networks for the quantification of human error probabilities in 2018. They compared these values with those obtained from established HRA methodologies, evidencing the method's feasibility through a comparative analysis of 32 datasets. Their results highlighted discrepancies, with slight deviations in most scores and a few outliers, reflecting the unique challenges of the radiotherapy context and expert analysis. This pioneering work by the PANDYA team not only validates their framework within radiotherapy settings but also expands its potential for broader applicability in similar task domains, given minimal variations in task specifics and environments [39].

The MOHAMMADFAM team from Hamadan University of Medical Sciences in Iran aimed to examine the comparative utility of the CREAM and SPAR-H methods in human factors reliability analysis specific to nursing tasks [40]. Employing a hierarchical task analysis, the researchers evaluated 31 distinct nursing tasks, subsequently computing error probabilities for each task using both methods. Their findings revealed that the SPAR-H method yielded higher overall probabilities of human-induced errors compared to the CREAM method; nonetheless, both methodologies produced comparable results when assessing tasks with elevated human error potential.

To further evaluate the methodologies, the MOHAMMADFAM team sought expert evaluations of seven dimensions, including training curriculum, implementation cost, time expenditure, consideration of social factors, organizational considerations, personal factors, and preventive measures. The expert scores indicated a preference for the CREAM method, leading the authors to conclude this approach's enhanced suitability for human factors reliability analysis in nursing contexts.

In a separate domestic study by Dani Fu from Jilin University's School of Mechanical and Aerospace Engineering [41], innovation was introduced to the traditional human error identification framework. A multidimensional external failure pattern classification framework was developed, segmenting human psycho-cognitive failures across four integral dimensions: omission, quality, time, and sequence. Moreover, an internal failure pattern classification framework was established, alongside a system of behavioral formative factors in the domain of ophthalmic surgery. This investigation identified and qualitatively linked behavioral formative factors with internal failure patterns, considering the influence of situational environments on cognitive functions. This contribution to the field not only updates our understanding of human error identification but also aids in the design of mitigation strategies for surgical environments, especially within ophthalmology.

The current frontier in the field of Human Reliability Analysis (HRA) for medical procedures, as depicted by the available literature, indicates that we are still in the early stages of development. Whether it's adapting established HRA methods from other disciplines or creating novel approaches tailored for healthcare and surgical tasks, the process remains preliminary. The complexities identified by Lyons, such as the diverse nature of patients and the surgical environment, underline the considerable challenge in quantifying human error probabilities [5, 42]. Furthermore, the selection of HRA methods for healthcare applications necessitates a careful assessment to ensure they address the specific demands of the medical domain.

In addressing the challenges of establishing HRA within healthcare, MARK from the University of Warwick highlighted critical issues in his 2020 publication in the Reliability Engineering and System Safety journal [43]. These include:(1) the reliability of healthcare processes, characterized by low reliability and inadequate documentation of tasks and procedures; (2) the variability in performance, where the inclusion of Performance Shaping Factors (PSFs) in many HRA methods may lead to a convergence of human error probabilities towards one, underlining the need for mechanisms to cope with this variability; (3) the regulatory context, which is currently lacking a comprehensive global safety framework for the healthcare sector, particularly in addressing injury events and performance assessment; and (4) the patient's role, which moves beyond passive involvement and requires active participatory in their recovery process, a fact that HRA methodologies need to account for. Lyons from the University of Cambridge, in a 2009 study published in Applied Ergonomics, offered insights into the factors to consider when integrating HRA into healthcare systems [5]. His perspectives include:(1) expertise composition, emphasizing the importance of incorporating both human factors specialists and domain-specific experts; (2) temporal feasibility, recognizing the need to assess the practicality of technology implementation in terms of its time requirements; (3) informational adequacy, highlighting the significance of the information available for selecting an appropriate HRA method; and (4) technological readiness, identifying the equipment and software necessary for data acquisition, especially for observational techniques requiring video recording instruments.

These considerations, both in the development and adoption of HRA for healthcare, are crucial for advancing a more robust and nuanced approach to human reliability in medical operations.

3.3 Assessments of surgical skills of surgeons

The majority of extant literature evaluating surgeon proficiencies has embraced the OCHRA method to discern variations in skill quality among practitioners. This approach involves scrutinizing metrics such as task execution time and quantifying the frequency of procedural errors during comparable surgical tasks through OCHRA analysis. Furthermore, scholarly pursuits have focused on engineering robust instruments aimed at gauging these competencies. Table 3 aggregates the details of these studies.

MISKOVIC devised a Competency Assessment Tool [44], a comprehensive surgical performance evaluation mechanism that incorporates semi-structured interviews and the Delphi method to triangulate expert perspectives. This technique involves verifying content validity via analysis of the mean and variance of expert assessments, while structural validity is confirmed by scrutinizing participant performance scores. Concurrent validity is established by juxtaposing performance outcomes with the tally of errors determined through the OCHRA technique. The instrument's dependability is further established through the application of Generalizability Theory. CHANG introduced an Objective Structured Assessment of Technical Skills (OSATS) [45] tailored for laparoscopic suturing and in vivo knot-tying surgeries, which comprises a Procedure-specific Checklist (PSC) and a Global Rating Scale (GRS). This framework enables the systematic assessment of surgeons' operative execution via the employment of the Wilcoxon rank-sum test to analyze OSATS scores, complementing this with Spearman's correlation analysis to ascertain intra-rater and inter-rater reliability metrics.

The NAZARI team at Erasmus University Medical Center in Rotterdam has crafted an OCHRA checklist for the Lichtenstein Open Inguinal Hernia Repair (LOIHR) procedure [46]. This endeavor was underpinned by a meticulously formulated step-by-step task analysis framework, with the OCHRA checklist's accuracy affirmed through Likert scale evaluations and corroborated by a one-sample Wilcoxon test. This methodical approach ensures the checklist's precision, which, alongside the framework, facilitates effective training and skill assessment for surgeons. Moreover, it is instrumental in enhancing surgical outcomes.

The training and assessment of skills in surgical disciplines, necessitated by their high-stakes nature [21], highlight the imperative of robust, multi-faceted evaluation mechanisms. The inherent scarcity of opportunities for practical experience and critical reflection in surgical environments underscores the importance of comprehensive skill assessment before active practice. Surgeons must achieve a requisite level of expertise before engaging in real surgical interventions, thereby minimizing the potential for human error.

The development of tailored training programs and the establishment of thorough assessment scales are pivotal in mitigating the incidence of human errors in surgical practice. These tools, while instrumental in the professional development of surgeons, also serve to bolster the safety and efficacy of surgical procedures, ensuring that patients receive the highest standard of care.

Table 3 Summary of literature to assess physician skills for research purposes

Time	Types of Surgery	Method	Result
Tang, 2006[47]	Laparoscopic Surgery	Objective Structured Clinical Examination (OSCE) and Objective Structured Clinical Evaluation (OCHRA)	A pronounced negative correlation was observed between the tally of technical anomalies detected by Objective Structured Clinical Evaluation, utilizing an electrosurgical hook or laparoscopic scissors during a discrete task, and the numerical evaluation received from an Objective Structured Clinical Examination (OSCE), as indicated by coefficients of -0.864 and -0.808. Statistical analysis revealed significant discrepancies among trainees concerning their aggregate scores on the OSCE and performance metrics recorded by the Objective Structured Clinical Rating Approach (OCHRA), including procedural timing, cumulative error count, and the identification of related errors.
TALEBPOUR，2009[48]	Laparoscopic Surgery	OCHRA	After completing the 14th anastomosis, surgeons attained a level of proficiency in executing microscopic palliative bypass procedures, marked by a substantial decline in technical inaccuracies and a concomitant improvement in procedural efficiency, as evidenced by a reduction of the economy-of-movement index from 7-5 to 3-2. The majority of these errors were concentrated in tasks involving intravital suturing. The pivotal behavioral determinants for these procedural lapses included attentional deficits (n = 1321), judgment missteps (n = 209), inadequate photographic technique (n = 193), physical fatigue (n = 128), and compromised collaborative efforts (n = 108).
MISKOVIC, 2012[44]	Laparoscopic Colorectal Resection	OCHRA	Three hundred and ninety-nine procedural failures were identified in total. Statistical analysis revealed a significant disparity in the cumulative error counts among the expert group, the pass group, and the failure group. Upon comparing only the pass and fail groups, while excluding the expert group from this analysis, it became evident that tissue-handling errors exhibited notable variability. Notably, the D/E ratios of the representative cases from these pass-and-fail groups were conspicuously lower than those observed for the expert group.
MISKOVIC, 2013[49]	Laparoscopic Colorectal Surgery	Semi-Structured Interview Method and Delphi Method	A novel surgical performance assessment instrument has been developed, offering a robust and dependable mechanism for evaluating technical proficiency in laparoscopic colorectal procedures.
CHANG, 2016[45]	Laparoscopic Suturing and In Vivo Knot-Tying Surgery	OSATS	Following the development of a sophisticated Objective Structured Assessment of Technical Skills (OSATS), the tool has been validated to provide a robust evaluation of laparoscopic suturing and in vivo knot-tying competencies. Notably, the instrument has exhibited strong internal consistency, signifying its reliability in conducting longitudinal assessments of surgical proficiency.
NAZARI, 2020[46]	Inguinal Hernia Repair Surgery	OCHRA	Employing a systematic approach, the LOIHR task descriptions and the OCHRA checklist were meticulously formulated to ensure accuracy. Furthermore, the OCHRA checklist has demonstrated its value as an effective instrument for both surgical training and comprehensive skills assessment.

3.4 The application and challenges of intelligent integration in surgical procedures

The continuous progression in scientific research and technological innovation, alongside the burgeoning field of artificial intelligence, has catalyzed the assimilation of intelligent human-machine integration systems into the surgical domain. This integration is notably symbolized by the "da Vinci" surgical robot, a technological marvel that has significantly elevated the precision and efficiency of surgical procedures[50]. A prime example of this advancement is manifested at the Xiangya Hospital of Central South University, where the introduction of the "da Vinci" robot in 2020 has led to the successful completion of over 1,000 robotic surgeries in conjunction with outpatient procedures, allowing for the expedited discharge of patients within 24 hours.

Within this context of "human-machine fusion," a collaborative paradigm that synergies human intellect with machine intelligence, the significance of the human role seems to be relatively diminished when compared to traditional industrial settings. However, an extensive body of evidence[51] underscores the indelible contribution of human operators in maintaining the integrity of human-machine systems. Especially in scenarios where automation or intelligent systems encounter dysfunction, the necessity of human intervention and support becomes paramount.

In the arena of intelligent human-robot integrated surgery, a divergence from conventional surgical practices is observed, with the human and robotic entities each performing within their unique spheres of expertise [52]. Surgeons are tasked with the delicate balance of monitoring and decision-making at the surgical site amid the dynamic flux of surgical environments as well as coordinating with the intelligent robotic systems and their fellow team members. The potential for human error in these intricate interactions is an inherent reality [53,54].

Accounting for these variables, the enhancement of the reliability of intelligent human-robot integrated surgeries and the reduction of surgical errors are critical focal points of current and future research in the medical reliability domain. It is incumbent upon us to refine both human and machine elements to effectively mitigate the ramifications of procedural errors. Future research initiatives should be dedicated to interdisciplinary approaches that amalgamate engineering, medical, and human factors discipline to devise holistic strategies aimed at fortifying the resilience of these sophisticated surgical systems.

Despite the significant enhancement in surgical precision and patient convenience afforded by the adoption of surgical robots, the practical application of this technology is not without its risks. The FDA's official website [55] provides a detailed record of adverse events related to the da Vinci surgical robotic system and its ancillary equipment from 2010 to December 17, 2020. This data reveals that the cumulative incidence of such events reached 3,226, with equipment malfunctions accounting for the majority at 1,208, representing approximately 38% of all reported incidents. Injuries inflicted on patients by the surgical robotic systems constituted 1,123 instances, approximately 35% of the total. Notably, there were 264 incidents leading to patient fatalities, which equates to around 8% of all adverse events. Additionally, 631 events were attributed to various other and indeterminate causes, comprising roughly 19% of the total.

Drawing from an examination of da Vinci adverse event data spanning the period from 2008 to 2018, Rao Lan et al. [56] propose that enhancing the training and skill assessment of surgeons could be instrumental in diminishing the likelihood of such adverse events. This underscores the necessity for a concerted effort to refine the competencies of medical practitioners, ensuring they are adept at navigating the complexities introduced by robotic technology in the operating room. The findings from this analysis highlight the critical role of continuous education and skill development in the pursuit of improved patient outcomes and the mitigation of surgical risks associated with robotic systems.

To date, the laparoscopic surgical robots widely implemented globally operate in a non-autonomous state, devoid of independent cognition and consciousness. Their movements are predominantly governed by the primary console manipulated by the surgeon. This technology can be construed as an intricate and sophisticated surgical instrument, specifically designed to replicate the precise hand movements of the surgical team. In the dynamic interplay of human-machine interaction, the proficiency level of the surgeon is a direct determinant of the surgical robot's operational efficacy, significantly influencing the likelihood of procedural errors and the overall therapeutic outcome [57].

In contrast to traditional laparoscopic procedures, the transition to robotic-assisted surgery presents unique challenges. The absence of haptic feedback and the requirement to adapt to a 3D visual distortion, due to the lack of direct instrument manipulation, result in a diminished efficiency in transferring conventional laparoscopic techniques to the realm of robotic surgery. Historically, the assessment of surgical operational skills has predominantly relied on the subjective evaluations of experts. This approach is not only economically inefficient and time-consuming but also deficient in terms of fairness, objectivity, and the absence of robust, data-driven evaluative criteria [58-60].

Consequently, the provision of efficacious theoretical guidance for surgeons in the realms of robot-assisted minimally invasive surgical training and operational skills assessment assumes a critical role. Ensuring the procedural standardization and safety is paramount, enabling a tangible reduction in surgical errors attributable to the medical staff, thereby enhancing the success rates of surgical interventions and elevating the benchmarks of medical safety.

4. Discussion

An investigation of thirty-seven scholarly articles concerning human reliability analysis in the context of medical and surgical practices has revealed that the deployment of these methodologies within the healthcare domain remains in its nascent stages. Notably, Observational Human Factors Reliability Analysis (OCHRA), which is both the earliest and most utilized technique for this purpose, has been applied within medicine since 1999. However, this approach is restricted to examining external failure modes, neglecting the comprehensive assessment of internal error patterns, and its methodological sophistication lags behind established applications in sectors such as nuclear energy and aviation.

In recent scholarship, modifications to the HEART method have been tailored for specific healthcare settings, but the original HEART method, an early iteration in the field of human factors reliability analysis, relies heavily upon expert opinion. It predominantly focuses on behavioral analysis from a phenomenological standpoint, with limited attention to the cognitive aspects of human performance. Notably, the evolutionary trend in human factors analysis has increasingly emphasized the consideration of cognitive processes; hence, the healthcare industry must rigorously evaluate the relevance of HEART and other methods, such as THERP and SPAR-H, while accounting for the cognitive dimensions of human behavior.

For the development of newly tailored human reliability methodologies within specific medical sectors, a thorough contextual analysis of task profiles and operational environments is essential, followed by adapting the core methodology processes to the unique characteristics of healthcare settings.

Perspectives on human factors reliability analysis in medicine are still in their infancy domestically, particularly in contrast to the robust body of international literature that exists. Current efforts are concentrated on dissecting medical error mechanisms, lacking a cohesive framework of human factors reliability analysis.

The health and well-being of individuals are inextricably linked to the medical field, rendering medical safety a focal point of global concern. The enhancement of healthcare service quality and the reduction of human error in medical procedures are integral to the progression of societal and economic development. Consequently, the establishment of a comprehensive and nuanced approach to human factors reliability analysis in medicine, particularly within surgical domains, is not merely beneficial but essential to the community's welfare.

Therefore, investigating the modulating factors of human error behavior in intelligent human-robot integration systems is set to become a focal point for future research into personnel reliability within this evolving domain. The trajectory of this research will predominantly manifest in three key areas:

(1) Cognitive and Behavioral Attributes of Surgeons in Intelligent Human-Robot Integration and the PIFs Framework: Constructing cognitive-behavioral models for surgeons engaged in intelligent human-robot integration offers a deeper, more precise understanding of the triggers behind human errors in this context. Such models can facilitate the extraction of Performance Influencing Factors (PIFs) that are closely aligned with the behavioral idiosyncrasies of intelligent human-robot integration in surgery, elucidating the underlying issues associated with human errors. These insights will provide a theoretical foundation for the identification of surgical errors, optimization of surgical protocols, and enhancement of surgical training, thereby supporting pertinent research initiatives.

(2) Coupling Dynamics of PIFs in Surgeons Engaged in Intelligent Human-Robot Integration: Unveiling the interplay amongst PIFs specific to surgeons in intelligent human-robot integration environments not only clarifies the mechanisms through which PIFs contribute to human errors but also offers a theoretical underpinning for analyzing personnel reliability in such complex surgical scenarios. This, in turn, facilitates a more accurate assessment of human errors and other related objectives.

(3) Dynamic Predictive Model of Surgeon Behavioral Errors in Intelligent Human-Robot Integrated Surgery with Consideration of PIF Coupling: By dynamically representing the influence of PIFs in intelligent human-robot integrated surgery on the surgeon's operational behavior, this model enables the forecasting of variations in surgical error probabilities over time. Such predictive capabilities are essential for the early detection and mitigation of risks associated with medical human factors errors.

In essence, these three prongs of research will be instrumental in advancing our understanding and management of human errors in the sophisticated landscape of intelligent human-robot integration within surgical settings.

5. Conclusion

The conclusions drawn from the analysis of human reliability analysis in healthcare and surgical practices depict a field undergoing significant developmental growth. The deployment of human factors reliability methodologies in healthcare, while emerging, is still in a formative phase. Despite OCHRA's foundational role since its introduction in 1999, its exclusive focus on external failures obscures a comprehensive understanding of human error, signaling needed advancements in its approach. The HEART method, adapted to healthcare, faces limitations, especially regarding its heavy reliance on expert judgment and its cognitive process oversight, which fails to align with the contemporary emphasis on the cognitive elements of human performance.

The evolution of human factors reliability analysis necessitates an adaptation that considers not only behavioral but also cognitive dimensions, especially in the context of healthcare. Therefore, the healthcare community must earnestly reevaluate the suitability and sophistication of existing methods, ensuring they capture the intricate interplay of cognitive processes inherent in medical practice. This critical step is essential in the development of tailored methodologies that are contextually grounded and cognitively oriented. Furthermore, investigating the modulating factors of human error behavior in intelligent human-robot integration systems is set to become a focal point for future research into personnel reliability within this evolving domain.

Furthermore, the nascent state of domestic literature in human factors reliability analysis underscores the need for a holistic framework that encompasses not only error mechanisms but also a comprehensive approach to improving healthcare service quality and reducing human error in medical procedures. Such a framework is pivotal for establishing a robust foundation for patient safety and enhancing the reliability of medical processes, which are vital for the advancement of societal health and economic prosperity.

In conclusion, achieving a more nuanced understanding of human factors reliability in medicine, particularly in surgical domains, transcends the realm of mere benefit; it is a critical component of the healthcare community's ongoing commitment to providing high-quality, safe, and error-neutral services. Embracing this integrated approach is essential to safeguarding the welfare of the populace and to honing the healthcare system's ability to meet the challenges of the present and future.

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