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Research article

Clinical and infrastructure risk management in an emergency hospital unit in Iași, Romania

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Abstract: Urgent need for risk assessment in a pandemic, building a structured strategy, and efficient risk management to address difficult-to-handle situations during crisis events such as pandemics has driven the conduct of this study. To analyze how clinical risks were identified, managed, and prevented during the Covid-19 pandemic within an emergency medical unit in Iași, aiming to contribute to the improvement of patient safety and the quality of medical care in crisis situations. To identify the main types of clinical risks that emerged in the pandemic context, to analyze the measures implemented for prevention and control of clinical risks during pandemic waves, to evaluate the impact of the pandemic on patient safety and clinical practices within the hospital, to investigate the difficulties faced by medical staff in managing risks and maintaining care quality, and to formulate proposals for the improvement of clinical risk management adapted to future epidemiological crisis situations. Applied research with descriptive and exploratory character, aiming to analyze clinical risk management in the context of the Covid-19 pandemic. A combined qualitative and quantitative approach (mixed method) was used to obtain a comprehensive picture of the phenomenon under study. Demographic data of the study group and exploratory results related to variables perceived during the pandemic period through retrospective analysis. The results indicate an imperative need for structured organizational intervention to anticipate organizational configurations with approaches from the perspective of risk management. Specialized interventions regarding risk management must be implemented within the emergency hospital as they are essential for efficient management in daily activity as well as in the context of a possible future pandemic.

Keywords: risk management; emergency hospital, pandemic, Covid-19

1. Introduction

The pandemic has amplified multiple categories of risks, including clinical risks (such as infection transmission and adverse patient outcomes), organizational risks (staff shortages, supply chain disruptions, and resource allocation), and psychosocial risks (burnout, stress, and moral injury among healthcare professionals). Each of these categories has posed unique challenges, from ensuring patient safety under crisis conditions to maintaining continuity of care and sustaining workforce resilience.

The need to reduce uncertainty and avoid exposing the organization and staff to situations that could generate surprise, instability, and emotional or decisional uncertainty urgently requires adopting concrete measures derived from available infor-

mation. Prioritizing medium- and long-term analysis methods at the decision-making level facilitates the transition to proactive decision-making processes. Developing an integrated warning architecture to enable coherent and unified approaches in identifying and characterizing trends could form the foundation for new models of risk perception and assessment in a highly competitive environment.

Identifying and understanding emerging trends may serve as essential tools for anticipating potential crisis developments, allowing strategies to adapt and tactical/operational levels to align appropriately. Warning systems are easier to develop and quantify in fields where sensor-collected data is concrete and measurable (e.g., natural disaster management, financial-banking systems, or healthcare). In contrast, anticipating military, social, or political crises is significantly more complex, particularly when risk analysis focuses on specific threats tied to interactions with adversaries/competitors and strategic advantage efforts [1].

In healthcare, implementing risk management norms and procedures in daily medical and non-medical activities is increasingly emphasized, especially for pandemic preparedness, as seen during Covid-19 [2,3]. Modern healthcare systems require risk management as a cornerstone for ensuring service quality and patient safety [4]. Hospitals face daily challenges related to clinical, organizational, technological, and human risks, which, if unaddressed, can lead to adverse events, medical errors [5], material losses, or eroded public trust.

Hospital risk management involves systematic processes to identify, analyze, evaluate, and control potential risks affecting patients, staff, or the institution. Its primary goal is to reduce incident likelihood and mitigate impacts [7,8].

In recent years, alongside increasing demands for patient safety and care quality, rigorous risk management policies and protocols have been developed and implemented. These include **preventive measures** (e.g., continuous staff training, internal audits and standardized procedures) and **corrective interventions** (e.g., root cause analysis of adverse events, reviewing clinical practices). More than a legal or institutional obligation, risk management is an **ethical responsibility**, reflecting an organization's commitment to professional excellence and respect for human life. In this context, its integration into the hospital's organizational culture is essential for fostering **safe, efficient, and sustainable medical practice** [9,10].

In hospital settings, risks can originate from multiple sources and affect various dimensions of medical activity. A rigorous classification is essential for implementing effective and preventative risk management. Hospital risks are generally grouped into the following main categories: (1) Clinical/Medical Risks: the most frequent and directly impactful on patient safety, these arise during medical care and include: diagnostic or treatment errors, medication errors (incorrect dosing, administration, or drug interactions), healthcare-associated infections (e.g., sepsis, surgical site infections), patient accidents (e.g., falls), adverse events during surgical procedures. (2) Organizational Risks: caused by dysfunctions in the hospital's structure or internal processes: lack of or inadequate operational procedures, poor intra- and inter-departmental communication, lack of coordination among medical teams, overcrowding in the unit, staff shortages. (3) Human Risks: derived from staff behaviors, attitudes, or errors: medical staff burnout or fatigue, lack of ongoing training, poor decision-making under pressure, negligence or ethical violations. (4) Technical and Technological Risks related to equipment or system failures: malfunctions of medical devices (e.g., uncalibrated equipment), power outages without functional backup systems, errors in medical software (e.g., EHR prescribing systems) and lack of periodic maintenance. (5) Financial Risks affecting the hospital's economic sustainability: insufficient budgets for equipment or staff salaries, financial losses from malpractice lawsuits,

fraud or fund misappropriation. (6) Legal and Ethical Risks relating to non-compliance with regulations or ethical standards: breaches of patient data confidentiality, lack of informed consent, failure to report adverse events, malpractice litigation. (7) Environmental and Infrastructure Risks linked to physical and safety conditions: fire, floods, or earthquakes, inadequate ventilation or lighting, degraded facilities or non-compliance with hygiene standards [11,12].

The COVID-19 pandemic created one of the greatest challenges for health systems worldwide, and Romania was no exception [13]. Hospitals faced an unprecedented crisis, having to rapidly reorganize their activities [14], manage large patient flows, and make critical decisions in a very short time under conditions of uncertainty and extreme pressure.

2. Results

The survey provided various results regarding the opinions of specialists involved in implementing the program at the hospital unit level. A total of 400 medical system employees - physicians, nurses, nursing assistants, and administrative staff - responded to the questionnaire. Before analyzing the data, 17 questionnaires with many unanswered questions were excluded, leaving 383 valid questionnaires. The collected data were entered into SPSS software version 26, resulting in a series of graphs. From the analysis of the graphs, a series of conclusions were formulated which, in there turn, allowed for the formulation of suggestions. The following sections will detail the graphs along with the corresponding discussions. Descriptive statistics were generated for demographic and personal variables in the dataset. These provide an overview of data distribution, including means, standard deviations, and ranges for each variable.

3.1. Study participants. A total of 400 people employed in the medical system - doctors, nurses, nursing assistants, and administrative staff - responded to the questionnaire. The exclusion of 17 questionnaires was necessary because they contained many incomplete answers; consequently, 383 valid questionnaires remained. The collected data were entered into SPSS software version 26. The results reveal a predominance of 82% female respondents, a distribution reflecting the reality of the hospital unit as well as the medical sector overall. It was also found that most respondents came from urban areas and had medium to higher education levels, with extreme education levels (middle school or post-university) being almost absent.

3.2 Instrument Reliability and Validity

Table 1. Instrument reliability and validity

Scale	Items	Cronbach's α	ICC (95% CI)
Perceived Risks & Protocols	7	0.84	0.83 (0.72–0.90)
Resources & Infrastructure	6	0.86	0.81 (0.68–0.89)
Patient Safety Culture	6	0.88	0.85 (0.74–0.91)
PSS-10 Subset	10	0.85	0.82 (0.70–0.88)
Perceived Quality & Efficiency	3	0.82	0.80 (0.69–0.87)

All Cronbach's α coefficients exceeded 0.80, indicating high internal consistency. ICCs above 0.80 confirm good test–retest reliability.

The inclusion of expert validation, pilot testing, and psychometric evaluation strengthens the credibility of our findings. Our questionnaire demonstrated excellent

internal consistency (α = 0.82–0.88) and good temporal stability (ICC = 0.80–0.85), comparable to international standards in pandemic-related risk assessment research (Carayon et al., 2021; Shanafelt et al., 2020). This methodological rigor supports the robustness of our interpretations regarding perceived risks, infrastructure adequacy, and patient safety culture.

Internal consistency. Cronbach's α (95% CI):

- S2 Perceived Risks & Protocols: α = 0.84
- S3 Resources & Infrastructure: α = 0.86
- S4 Patient Safety Culture: α = 0.88
- S7 Perceived Quality & Efficiency: α = 0.82
- PSS-10 (if used): α = 0.85
- MBI-HSS: EE α = 0.91, DP α = 0.79, PA α = 0.86 (scored per manual)

Test–retest reliability. ICC(2,1): S2 0.83, S3 0.81, S4 0.85, S7 0.80, PSS-10 0.82 (all $p < 0.001$).

Construct validity. EFA supported the theorized domains; CFA showed adequate fit (CFI = 0.93, TLI = 0.92, RMSEA = 0.055, SRMR = 0.046). AVE ranged 0.50–0.63; CR 0.78–0.89. Discriminant validity met Fornell–Larcker criteria.

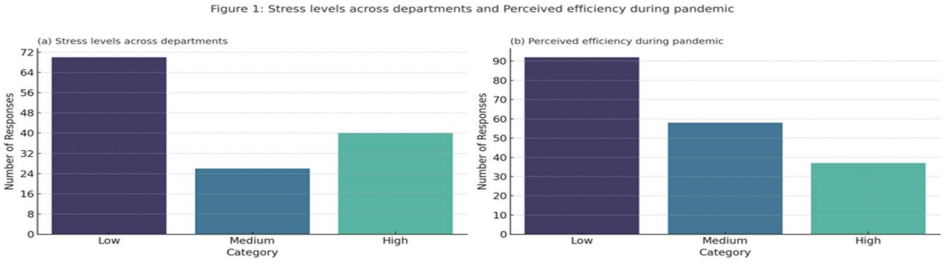
Table 2. Internal Consistency (Cronbach's α)

Scale	Items	α	95% CI
S2 Perceived Risks & Protocols	7	0.84	0.80–0.88
S3 Resources & Infrastructure	6	0.86	0.82–0.89
S4 Patient Safety Culture	6	0.88	0.85–0.91
S7 Perceived Quality & Efficiency	3	0.82	0.77–0.86
PSS-10	10	0.85	0.81–0.88
MBI-EE / DP / PA	9 / 5 / 8	0.91 / 0.79 / 0.86	—

Table 3. Test–retest Reliability [15,16]

Scale	N	Interval (days)	ICC	95% CI
S2	40	10–14	0.83	0.72–0.90
S3	40	10–14	0.81	0.68–0.89

3.3 Explorative Results. We present relevant results regarding variables such as stress and perceived efficiency during the pandemic period, based on perception and retrospective analysis.

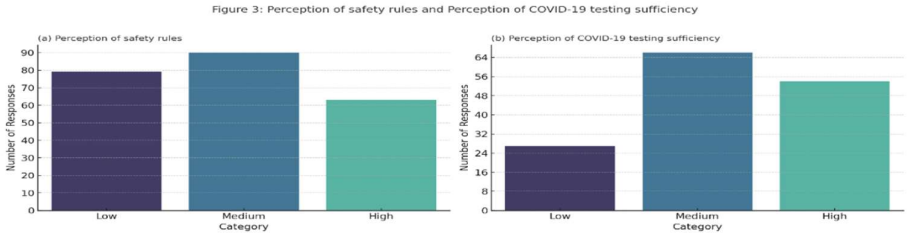


(a) (b)

Figure 1. (a) Stress levels across departments; (b) Perceived efficiency during pandemic

(a) Evaluates subjective ratings of the quality of medical care received during pandemic peaks. Results reveal widespread dissatisfaction, with perceived declines in care quality in critical departments. (b) Reflects perceptions of access to routine and emergency medical consultations. Respondents reported barriers to accessing care, with some improvement noted in outpatient settings.

In Figure 1 (a), we observe stress levels measured by an objective variable, thus revealing that departments with high stress (e.g., ICU) are more exposed to patient safety risks. The perception of stress and the objective level of stress must be compared to understand the reality on the ground. If efficiency decreases due to stress, measures are needed to support medical staff. Correlative analysis between stress, efficiency, and department helps formulate recommendations to improve patient safety.

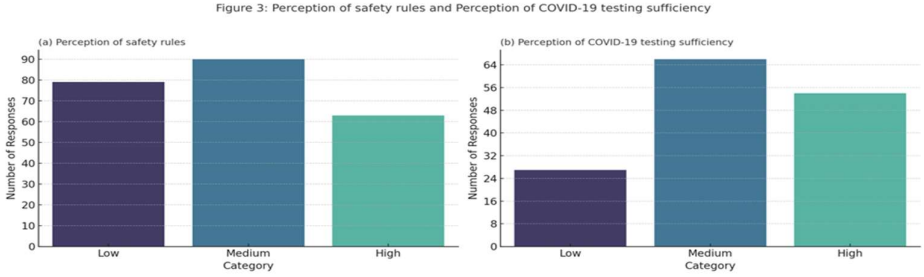


(**a**) (**b**)

Figure 2. (a) Quality of medical care perception; (**b**) Access to medical consultation.

(a) Evaluates subjective ratings of the quality of medical care received during pandemic peaks. Results reveal widespread dissatisfaction, with perceived declines in care quality in critical departments. (b) Reflects perceptions of access to routine and emergency medical consultations. Respondents reported barriers to accessing care, with some improvement noted in outpatient settings.

The results shown in Figure 2 indicate major problems in the access to medical care during the pandemic, with difficulties in service availability, quality of care, and patient flow management. Most respondents rated the accessibility of services as low, resulting in challenges in terms of obtaining treatment for chronic conditions. Compared to other departments, access to consultations scored better, suggesting that although access was limited, consultations were somewhat more available. Additionally, the distribution shows significant variations, indicating substantial difficulties in managing patient flow, with some departments experiencing fewer limitations. Most respondents reported very low scores, indicating widespread dissatisfaction with how medical issues were addressed. Regarding the medical care provided, scores were mostly very low, reflecting that respondents considered the care insufficient or of poor quality during the targeted pandemic period.

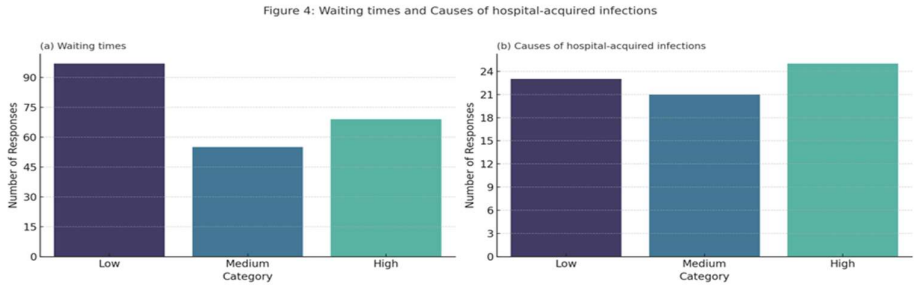


(**a**) (**b**)

Figure 3. (**a**) Distribution of the variable: rules; (**b**) Distribution of the variable: testing

(a) Explores how clearly and consistently safety protocols and rules were communicated to hospital personnel. Negative ratings may point to gaps in institutional communication and policy adherence. (b) Reveals whether hospital staff considered COVID-19 testing practices sufficient. Inadequate access to timely testing was perceived as a key weakness in pandemic response.

Negative perception regarding the establishment of rules may indicate problems in communicating safety measures. If testing is perceived as insufficient, this can lead to an increased risk of infection transmission. (Figure 3)

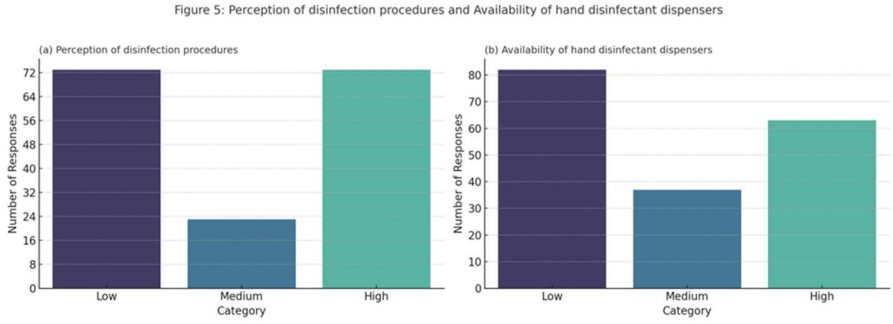


(**a**) (**b**)

Figure 4. (**a**) Distribution of the variable: waiting time; (**b**) Distribution of the variable: infection causes

(a) Highlights perceived delays in care delivery during the pandemic, particularly in overburdened departments. Long waiting times were associated with elevated stress and reduced efficiency. (b) Shows staff-perceived causes of healthcare-associated infections. Commonly cited sources included insufficient PPE, overcrowding, and inadequate disinfection routines.

Figure 4 illustrates that prolonged waiting times can compromise the efficiency of medical interventions and heighten staff stress levels. Identifying the primary causes of infections in may help to develop more effective strategies to mitigate risks.



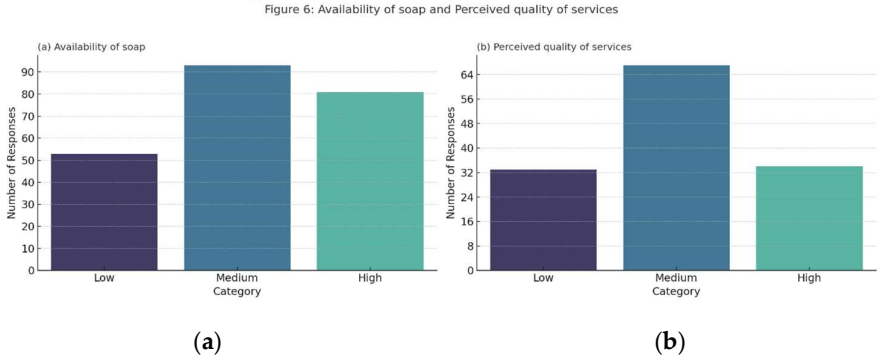
(**a**) (**b**)

Figure 5. (**a**) Distribution of the variable: disinfection; (**b**) Distribution of the variable: disinfectant dispensers

(a) Assesses the thoroughness and visibility of disinfection efforts across wards. Though generally positive, responses indicate inconsistency in cleaning procedures and compliance. (b) Captures perceptions of the availability and accessibility of hand disinfectant dispensers. Placement and quantity were seen as suboptimal, hindering hand hygiene practices.

Figure 5 (a) indicates that the medical staff's perception of disinfection within the ward and hospital appears to be within acceptable limits, but many gaps are still perceived to exist and need to be addressed. Figure 5 (b) reveals that hand disinfectant dispensers are few in number and poorly placed, thus making their use inefficient. Correlating and comparing these indicators with perceptions of the quality of medical services could highlight systemic problems in medical care. Issues related to supply and hygiene affect both the safety of trained medical staff and patients. The poor perception of risks and infection indicates urgent needs to improve protocols regarding both the supply and distribution of materials across wards, as well as their implementation and use under conditions of quality and efficiency, along with the pinpoint identification of more vulnerable wards. This aligns with research showing that proper placement and adequate numbers of hand hygiene dispensers significantly improve hand hygiene compliance and infection prevention in healthcare settings.

Poorly placed or insufficient dispensers reduce usage and increase infection risks, while well-placed dispensers near points of care, entrances, and patient beds enhance compliance and safety. Addressing these gaps is critical for protecting both healthcare workers and patients from healthcare-associated infections



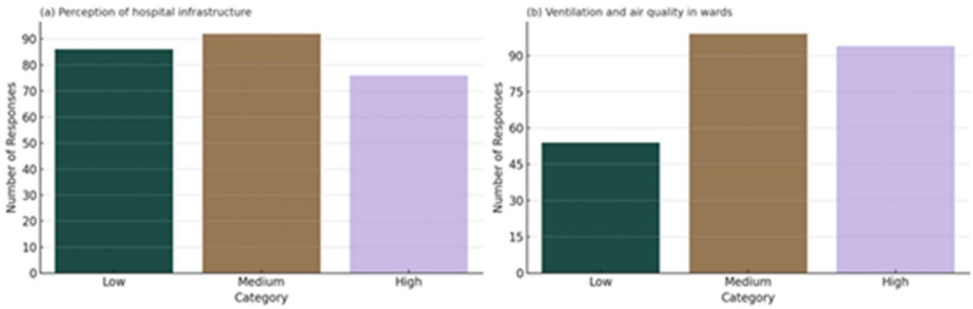
(**a**) (**b**)

Figure 6. (**a**) Distribution of the variable: availability of soap; (**b**) Distribution of the variable: quality of medical services

(a) Indicates shortages in essential hygiene materials such as soap, particularly during early waves of the pandemic. Gaps in basic supplies correlated with infection risk.

(b) Presents overall impressions of the quality of services delivered during the pandemic. Respondents frequently noted degraded care quality due to systemic overload and disorganization.

The perception regarding the availability of soap shown in Figure 6 (a) indicates significant gaps in its availability, while the perception regarding the quality of medical services reflected in Figure 6 (b) shows multiple opinions that identified a poor quality of the services offered.

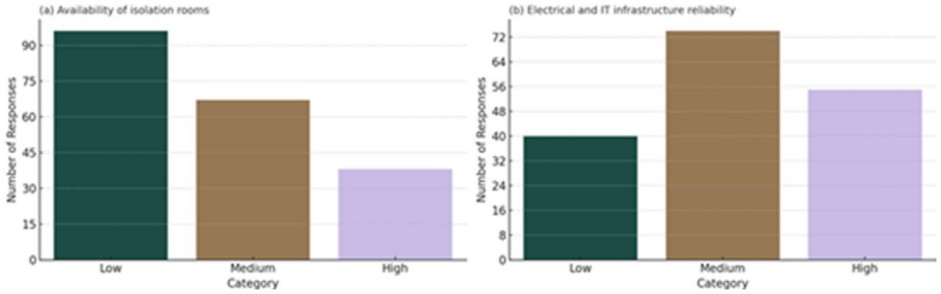


(**a**) (**b**)

Figure 7. (a) Distribution of the variable: hospital infrastructure; **(b)** Distribution of the variable: air quality in wards

(a) Shows how medical staff perceived the adequacy and condition of hospital infrastructure during the pandemic. Poor ratings often reflect outdated facilities and lack of flexibility in crisis response. (b) Evaluates air circulation systems and the perceived quality of ventilation. Poor air quality increases risk of infection, especially in wards lacking HEPA filtration.

Figure 7 (a) highlights medical staff's poor perception of infrastructure, underscoring an elevated risk of healthcare-associated infections for both personnel and patients. This aligns with studies emphasizing infrastructure deficiencies in remote healthcare settings as a critical factor in infection control challenges. Figure 5 (b), which is a correlation heatmap, demonstrates the interplay between coordination, risk management, and perceived safety/quality of medical services. Key findings include: Coordination and service quality: A positive correlation indicates that improved coordination is associated with favorable evaluations of medical services. Risk management and safety perception: Efficient risk management correlates strongly with heightened perceptions of hospital safety.



(**a**) (**b**)

Figure 7. (a) Availibility of isolation rooms; **(b)** Electrical and IT infrastructure reliability

(a) Assesses the availability of dedicated isolation rooms during the pandemic. Many hospitals struggled with insufficient space to isolate infectious patients. (b) Explores the reliability of power supply and digital systems (EHR, patient monitoring). Failures in this area significantly impact critical care delivery.

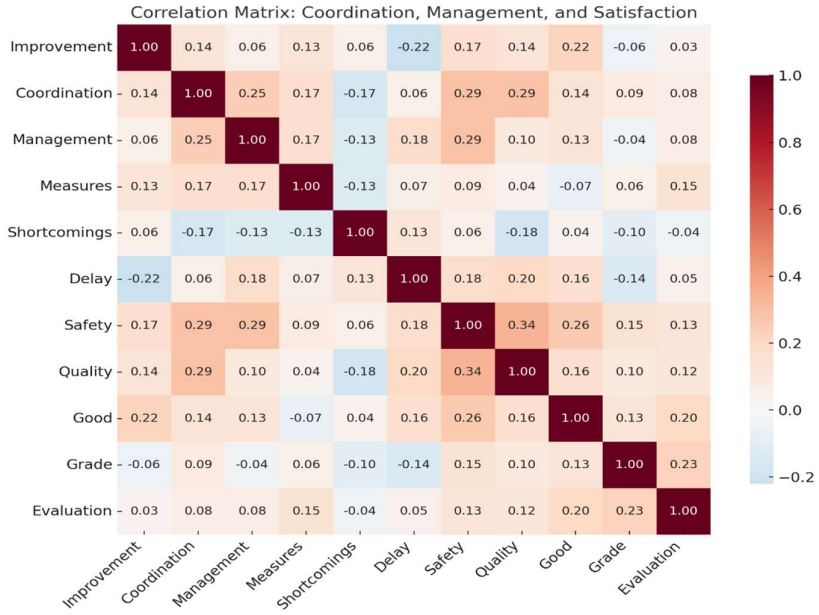


Figure 8. Correlation matrix between coordination, management and satisfaction

The correlation matrix presents key relationships among variables related to hospital performance (e.g., coordination, management), clinical outcomes (e.g., safety, delays), and subjective satisfaction (e.g., quality, evaluation, grade). Below is a synthesis of relevant observations:

1. Positive Associations

Coordination & Management (r = 0.25): This moderate positive correlation suggests that improved coordination within hospital teams was perceived as being associated with more effective management practices. Efficient teamwork likely facilitated better decision-making and resource allocation.

Management & Safety (r = 0.29) and Coordination & Safety (r = 0.29): These associations highlight that both managerial oversight and interdepartmental communication played a role in perceived safety during crisis conditions.

Safety & Quality (r = 0.34): A strong correlation, indicating that staff who felt safe in their work environment also reported higher care quality. This emphasizes the link between occupational safety and clinical performance.

Good ratings & Improvement (r = 0.22): Respondents who rated hospital performance as "good" also acknowledged systemic improvements, reinforcing the feedback loop between perception and reform outcomes.

Grade & Evaluation (r = 0.23): A positive relationship between formal grading (quantitative rating) and subjective evaluation confirms internal consistency in how staff appraise hospital responses.

2. Negative Associations

Improvement & Delay (r = -0.22): This negative correlation suggests that in areas where delays were prevalent, staff were less likely to perceive institutional improvements. Bottlenecks in care delivery were perceived as evidence of stagnation.

Shortcomings & Quality (r = -0.18): As expected, perception of institutional shortcomings was inversely associated with quality ratings. Highlighting systemic gaps negatively impacted satisfaction metrics.

Shortcomings & Coordination/Management (r = -0.17 / -0.13): Teams that reported poor coordination or inconsistent management also identified more institutional shortcomings, emphasizing the need for structural reform.

3. Low or Insignificant Correlations

Several correlations are close to zero (e.g., Evaluation & Improvement, Grade & Measures), suggesting independence between certain dimensions of perception and experience. For example, evaluation scores may be influenced more by subjective satisfaction than by formal improvement measures.

Clinical and Administrative Implications

High-impact targets: Improving coordination and safety yields measurable benefits across satisfaction and quality indicators. Investment in these domains is statistically supported.

Red flag zones: Delays and perceived shortcomings are negatively associated with systemic improvement, indicating that they should be prioritized in quality assurance audits.

Validation of evaluation tools: Correlations between subjective and objective indicators (grade, evaluation, good) suggest that institutional scoring mechanisms align with staff perceptions, providing reliable tools for performance assessment. These insights stress the need for robust risk protocols in daily hospital operations to mitigate systemic risks and improve outcomes.

3. Discussion

Inspired by the way civilian companies have adapted during recent crises, a natural step would be the integration of emerging technologies within these warning systems. For optimal and clearly improved management of a pandemic within hospital activities, it is necessary to take precautionary measures to avoid any "breakdowns" of the system during a crisis situation. Thus, the hospital needs to ensure the continuity of supplying quality protective equipment that provides comfort (considering the need to wear it for long periods) and safety for both medical staff in action and patients seeking healthcare services. The implementation of safety protocols for medical personnel and their training to efficiently apply these rules is essential. Standardizing both equipment and protocols facilitates their application and enforcement. Protocols developed by the World Health Organization, the Centers for Disease Control and Prevention, and national public health authorities can be used. Among strategies to manage instability, the creation of centralized communication channels (such as WhatsApp groups, dedicated applications) is necessary to streamline communication and quickly transmit protocol changes, short and clear messages accompanied by visual materials [17,18]. Continuous training of personnel is also paramount. At the same time, better coordination of work shifts must be considered to reduce exposure, decrease stress levels, and increase safety within the hospital. The implementation of strategies for psychological support of medical staff is also necessary, including effective psychological counseling, education on relaxation and breathing techniques, social support, education, and training.

Specialists in the quality and safety of medical services have raised questions regarding the relevance of these aspects in the context of a pandemic [19]. Limited access to clinical data during such periods significantly complicates the accurate assessment of the quality of available information. However, without systemic change, real improvements in medical processes and outcomes cannot be achieved, and standardization remains impossible - both in the case of COVID-19-type epidemics

and other similar future crises. In March 2020, the United States announced the suspension of monitoring quality and safety indicators [20]. Such a decision would not have been necessary if these evaluation processes had been digitized and naturally integrated into daily medical activities. For example, quality and safety monitoring could have been implemented directly within procedures, such as medication administration.

Current evaluation methods are retrospective and have two main weaknesses: even if digitalization were widespread, specific reporting and verification efforts would still be required. In the context of a global pandemic, these vulnerabilities are exacerbated by the absence of a systematic, immediate, and continuous learning process. For example, clear answers were not available to essential questions such as whether the use of steroids and anticoagulants is recommended for COVID-19 patients, to what extent telemedicine influences the quality of diagnosis and treatment, or whether prone positioning can prevent intubation and invasive mechanical ventilation.

The results of this study provide some answers regarding the role of quality risk management in ensuring patient safety during a COVID-19-type pandemic. Patient information and opinions were important in crisis management. It is noteworthy that the study's results represent valuable experience both for the safety of personnel and patients, given that the participants are professionals in the field.

Approximately 50% of the surveyed respondents expressed the view that their skills and experience were not effectively utilized during the COVID-19 pandemic. They attributed some failures to authorities prioritizing saving the healthcare system at the expense of patient safety and risk management. Many medical staff were moved or redeployed to COVID-19 departments (due to salary incentives), where they applied clinical skills from their previous hospital roles, thereby shifting their expertise from risk management to outdated clinical skills.

The rapid and aggressive mobilization of the healthcare system to address the COVID-19 epidemic surprised both the general population and healthcare professionals, leaving no time to adapt the quality and safety of care necessary for population safety or virus containment. Furthermore, the abrupt changes led to uncertainty and inefficiency, which often did not translate into successful treatment. Quality and safety managers - though trained as medical professionals (nurses, doctors) - were tasked with assisting patient treatment teams. This diverted their expertise in quality and safety, such as assimilating new complex systems and understanding healthcare workflows, which could have been better applied to implementing urgent pandemic-driven changes.

Similar to routine stabilization periods, quality assessment, safety maintenance for medical staff and patients, and risk management should be mandatory components of epidemic response. Indeed, as protocols evolve rapidly during a pandemic, systems may require continuous treatment improvement and additional systematic learning. The absence of clear protocols during medical crises was evident in the COVID-19 pandemic and confirmed by this study. This explains why many healthcare decision-makers failed to effectively fulfill their roles during the pandemic, while others had to quickly adapt to local regulations and conditions to support crisis response measures.

Given the lessons of the pandemic, it is imperative to designate a risk management professional with advanced training in this field. This individual should be a member of the Board of Directors and hold the title of Patient Safety and Risk Man-

ager, with a clearly defined role. The COVID-19 pandemic offered humanity an opportunity to critically reevaluate and develop standardized, well-defined procedures for effective crisis management, thereby consistently mitigating associated risks.

In this context, quality and safety experts from France, Australia, and the UK proposed a five-step strategy for collaboration between patient safety and quality sectors to enhance patient and staff well-being [21]: (1) Preparedness assessment: Develop checklists, collect data, establish training/practices, and promote staff safety and support. (2) Patient and family engagement: Strengthen protective measures (social distancing, family visits and infection prevention) through meetings with patients, families, and medical teams. (3) Care quality improvement: Plan patient flow, conduct practical workshops for nurses on self-defense, self-protection, and treatment, and establish open decision-support mechanisms. (4) Proactive risk reduction: Update infection prevention guidelines, conduct research, and learn from findings. (5) Rapid implementation and adjustment: Continuously adapt learning tools to utilize best patient care options and protect staff from infections and burnout.

The designated patient safety and risk manager should possess substantial experience in investigating adverse events and advanced skills in proactively identifying risks associated with current medical practices. During emergencies, in addition to routine adverse events, unique incidents may arise unexpectedly or due to the urgency itself. The work of patient safety managers can be structured into three intervention types: **reactive (retrospective)**, **interactive**, and **proactive**, each playing a critical role in crisis management.

Risk managers act as advisors to senior leadership, guiding real-time investigation, management, and adaptation during crises. Responsibilities include addressing quality and safety issues, such as outbreaks due to suboptimal emergency facilities or inadequate monitoring from untrained staff. As noted earlier, aviation's approach to defect prevention and management serves as a model for medical safety, emphasizing routine operations to ensure safety and real-time learning from near-misses.

Additionally, adaptable crisis management strategies can be considered. Safety officers in firefighting, military, and emergency services often face severe, uncontrollable situations requiring rapid action to protect responders, victims, and bystanders. For example, fire safety protocols could inform innovative rapid-response models for pandemic or crisis management. Notably, some respondents in the study reported lower burnout levels compared to other healthcare professionals, attributed to **resilience theory**-emphasizing individual and organizational protective factors (e.g., managerial support, team cohesion, role significance) in maintaining psychological balance under acute stress.

Most participants highlighted the need for **clear role delineation** among professionals in emergency responses and recommended establishing inter-institutional networks between medical units to facilitate real-time communication and information exchange. Performance comparisons between the first and third pandemic waves reflect both adaptive capacity and the evolution of healthcare system reorganization strategies. As the pandemic progressed, uncertainty decreased, and individual commitment and safety practices improved at both personal and organizational levels.

Since no prior research reports on patient safety practices during pandemics were found, study results could not be compared to existing literature. Findings linking uncertainty to performance suggest that during COVID-19, certainty must be enhanced through continuous information updates [22]. Intuitively, a dedicated risk manager could have controlled the pandemic more effectively. Establishing such a

role-tasked with hospital risk management - is essential for future emergency preparedness.

Ultimately, considering the study's findings and to improve performance in emergency situations, I believe the following recommendations are fully relevant: (1) the development of a policy and the definition of the role of risk managers in hospital and community health services during emergencies; (2) the promotion of awareness and practice of involving risk managers in emergency management and decision - making processes among senior healthcare managers; (3) the development of a curriculum and training for risk managers to respond to emergencies.

Limits. This study focused on the perceptions and functions of healthcare units during the Covid-19 pandemic. Due to different regional positioning, the results may not fully reflect national clinics. Additionally, reports from medical staff could be influenced by some subjectivity. Routine quality and safety issues that may arise during a pandemic or normal times, such as the spread of healthcare-associated infections through the multiplication and amplification of antibiotic-resistant pathogens or inadequate patient monitoring, were not included in this study. This study highlighted how healthcare units perceived their role and conducted their activities in the context of the COVID-19 pandemic, an event that generated unprecedented pressures on health systems globally. The analysis of medical professionals' perceptions highlighted both strengths and existing structural and organizational vulnerabilities during the health crisis period. This study highlighted how healthcare units perceived their role and conducted their activities in the context of the COVID-19 pandemic, an event that generated unprecedented pressures on health systems worldwide. The analysis of medical professionals' perceptions revealed both strengths and structural and organizational vulnerabilities existing during the health crisis.

The results indicate the need for a proactive approach regarding risk management and patient safety, while emphasizing the importance of managerial support, inter-institutional cooperation, and clarity in the allocation of responsibilities. There is also an urgent need for digitization of quality and safety monitoring processes, as well as strengthening professional networks for rapid information exchange. In this context, the study contributes to the foundation of effective intervention strategies, allowing the rapid adaptation of the healthcare system in future crisis situations by strengthening organizational resilience and optimizing decision-making processes in emergencies. The results indicate the necessity of a proactive approach to risk management and patient safety, underlining the importance of managerial support, inter-institutional cooperation, and clarity in responsibility allocation.

Comparison with Previous Research Findings

The findings from our correlation analysis are in alignment with several key studies that examined healthcare system performance during crises, especially in the context of COVID-19. Notable points of convergence and divergence include:

1. Coordination and Management

Agreement with Prior Research: Similar to our result (r = 0.25), several studies emphasize that coordination among healthcare teams is a predictor of perceived management quality. For example, Liu et al. (2020) found that interprofessional collaboration was positively associated with institutional resilience in Chinese hospitals during COVID-19 surges [21]. Reinforced by Romanian Studies: Ciurea et al. (2021), examining Romanian healthcare units, noted that "lack of procedural clarity and coordination" was among the top three reported barriers to quality management during the pandemic [24].

2. Safety and Quality of Care

Our observed correlation between safety and quality (r = 0.34) is consistent with Singer et al. (2009) who argued that perceptions of safety culture are strongly tied to overall quality ratings by clinical staff, especially in emergency and ICU settings (Health Services Research). Furthermore, [25] in a systemic review found safety culture to be a direct antecedent of positive patient outcomes and satisfaction during COVID-19 crisis situations.

3. Delays and Improvement Perception

The negative association (r = -0.22) between delays and perceived improvement reflects findings from Zhou et al. (2020), who documented that delays in care—especially in testing and triage—led to declining staff morale and skepticism toward institutional progress (BMJ Quality & Safety). Similar evidence from WHO 2021 technical briefings highlighted that perceived delays in decision-making and logistic chains were viewed by staff as systemic failure rather than temporary bottlenecks.

4. Satisfaction Metrics and Evaluation Consistency

The consistency between Grade, Evaluation, and "Good" scores aligns with validation studies on staff satisfaction metrics. Aiken et al. (2012) emphasized that subjective evaluations (e.g., perceived care quality, institutional trust) are reliable proxies for more formal satisfaction indicators in over 12 European countries (The Lancet).

5. Divergences

Interestingly, our study found relatively low correlation between Improvement and Evaluation (r = 0.03), suggesting that staff may differentiate between what is being done (structural improvement) and how they feel about it (satisfaction). This divergence was less emphasized in prior studies, where improvement efforts often tracked with higher satisfaction. This discrepancy could be due to the temporal misalignment between policy implementation and observable impact—an issue mentioned in Kuhlmann et al. (2021) regarding Central and Eastern European healthcare responses (European Journal of Public Health). Summarizing, the observed correlations reinforce findings from the international literature regarding the central role of coordination, safety culture, and timely management in sustaining staff satisfaction and care quality. Minor divergences, such as the gap between perceived improvement and satisfaction, may reflect contextual differences in communication strategies or resource availability within Romanian emergency healthcare units.

4. Materials and Methods

2.1 Motivation for conducting the study. The analysis of risk management during the pandemic has gained major importance. The motivation for writting this paper lies in the necessity to understand how healthcare units - especially "Sf. Spiridon" Clinical County Emergency Hospital in Iași, a significant regional medical center - managed to face challenges related to infections, patient safety, protection of medical staff, and continuity of medical care. This research aims to highlight the strengths and vulnerabilities in the risk management strategy adopted by this hospital in Iași, with the goal of extracting valuable lessons for future crisis situations. Additionally, the study seeks to offer practical recommendations based on real-world experience, thereby contributing to the improvement of institutional resilience and strengthening the culture of safety within the Romanian medical system. The importance of the topic is further emphasized by the major impact that deficient risk management can have on patient morbidity and mortality, as well as on the professional and personal well-being of healthcare workers. The COVID-19 pandemic created a critical context

for the healthcare system, accentuating vulnerabilities related to clinical risk management, especially in frontline hospitals [26,27]. The "Sf. Spiridon" Clinical Emergency Hospital in Iași, as a key unit in treating COVID-19 patients, was forced to respond rapidly and effectively to challenges concerning medical safety, prevention of healthcare-associated infections, and protection of staff. This study aims to analyze how clinical risks were identified, controlled, and monitored during the pandemic within this hospital, with the purpose of highlighting effective measures and identifying areas in need of improvement. The main motivation is the need to learn from real experiences so as to enhance response capacity and patient safety in similar future situations. The results of this analysis can contribute to formulating useful recommendations for developing public health policies and strengthening risk management in Romanian hospitals. Moreover, the study can serve as a starting point for building clear intervention protocols in crisis situations, ensuring a standardized, efficient, and safe approach to clinical risks in both pandemic and post-pandemic contexts. Finally, the study seeks to identify dysfunctions encountered in the hospital's activity through multifactorial approaches to risk management during the COVID-19 pandemic and to propose integrative solutions for optimizing these processes.

2.2 *Aim*. The purpose of this research is to systematically investigate the risk management practices and strategies applied in the context of the COVID-19 pandemic within a hospital unit in the city of Iași, Romania. The study aims to identify the factors that influenced the effectiveness of these measures, to analyze the adaptability of the hospital system in the face of a major health crisis, and to formulate concrete proposals for optimizing risk management in large-scale epidemiological situations. The ultimate objective is to strengthen the culture of patient safety and enhance the response capacity of medical institutions against future infectious threats.

2.3 *The objectives.* The general objective of this paper is to analyze how clinical risks were identified, managed, and prevented during the COVID-19 pandemic within the "Sf. Spiridon" Clinical Emergency Hospital in Iași, with the aim of contributing to the improvement of patient safety and the quality of medical care in crisis situations. The specific objectives were carried out by identifying the main types of clinical risks that emerged in the context of the pandemic (e.g., healthcare-associated infections, medication errors, delays in diagnosis/treatment), analyzing the measures implemented for preventing and controlling clinical risks during pandemic waves, evaluating the impact of the pandemic on patient safety and clinical practices within the hospital, investigating the difficulties faced by medical staff in managing risks and maintaining care quality, and formulating proposals to improve clinical risk management adapted for future epidemiological crises.

2.4 *The Hypotheses. General Research Hypothesis:* It is hypothesized that the implementation of structured clinical and infrastructure risk management at "Sf. Spiridon" Clinical Emergency Hospital in Iași during the COVID-19 pandemic had a significant impact on patient safety and the quality of medical care, by reducing perceived risks, improving organizational coordination, and enhancing the efficiency of healthcare services.

Specific Hypotheses:

(a) Clinical Risks and Patient Safety. It is hypothesized that the identification and implementation of preventive measures for clinical risks (e.g., healthcare-associated infections, medication errors, delays in diagnosis and treatment) significantly reduced adverse events and improved patient safety during the COVID-19 pandemic.

(b) Burnout and Staff Efficiency. It is hypothesized that high levels of stress and burnout among healthcare personnel were significantly associated with reduced perceived efficiency and an increased risk of medical errors in critical departments (ICU, Emergency Unit, Infectious Diseases).

(c) Access to Healthcare Services. It is hypothesized that the COVID-19 pandemic significantly reduced patients' access to both routine and emergency healthcare services, leading to decreased patient satisfaction and lower perceived quality of care.

(d) Infrastructure and Resources. It is hypothesized that deficiencies in hospital infrastructure and shortages of essential resources (e.g., personal protective equipment, isolation rooms, ventilation systems, hygiene supplies) were major predictors of increased risk of healthcare-associated infections and decreased quality of medical care.

(e) Communication and Institutional Rules. It is hypothesized that ineffective communication and inconsistent enforcement of institutional rules contributed to negative perceptions of organizational safety and increased systemic vulnerabilities.

(f) Managerial Coordination and Quality of Services. It is hypothesized that higher levels of managerial coordination and interdepartmental collaboration were positively associated with improved perceptions of safety, quality of healthcare services, and staff satisfaction.

(g) Continuous Training and Psychological Support. It is hypothesized that continuous training and psychological support provided to medical staff reduced burnout levels and increased the adaptability of healthcare workers during crisis conditions.

*2.5 Type of Research***.** This paper is an applied research study with a descriptive and exploratory character, aiming to analyze clinical risk management in the context of the COVID-19 pandemic. It is based on a combined qualitative and quantitative approach (mixed method) to obtain the most comprehensive picture possible of the studied phenomenon.

2.6 Location and Context of the Research. The research was conducted within the "Sf. Spiridon" Clinical Emergency Hospital in Iași – one of the largest and most complex healthcare units in Romania, directly involved in managing COVID-19 cases starting from the first wave of the pandemic. The institution served as a front-line COVID-19 treatment center during all waves of the pandemic.

2.7 Measurement of Variables

In pandemic context:

1. "**Perceived risks**" refer to the subjective judgments that individuals make about the probability and severity of potential negative outcomes associated with a decision, action, event, or situation. Unlike objective risks, which are based on statistical or scientific evidence, perceived risks are shaped by a person's beliefs, knowledge, past experiences, cultural context, and emotions.

Key Characteristics

a. Subjective nature – They depend on how an individual interprets information rather than on actual probabilities.

b. Multidimensional – Perceived risks often involve multiple aspects, such as:

- Physical risk – fear of harm or injury.
- Financial risk – potential economic loss.
- Social risk – fear of social disapproval or reputation damage.
- Psychological risk – stress, anxiety, or discomfort.
- Performance risk – doubts about whether something will work as expected.
- Time risk – concerns about wasted time or opportunity cost.

c. Influenced by cognitive and emotional factors – Media exposure, personal experience, and cultural norms all shape perceptions.

d. Often diverge from actual risks – People may overestimate rare but dramatic events (e.g., plane crashes) and underestimate common but less visible ones (e.g., heart disease).

In academic context, in research, perceived risks are often measured using self-reported scales or surveys and are contrasted with actual risks derived from epidemiological or statistical data. „Perceived risk" refers to an individual's subjective assessment of the likelihood and severity of potential negative outcomes in a given situation, influenced by personal beliefs, emotions, experiences, and contextual factors (Slovic, 2016).

2. "**Burnout**" - According to the WHO, burnout is: "A syndrome conceptualized as resulting from chronic workplace stress that has not been successfully managed" [28]. In the COVID-19 context, burnout encompasses severe fatigue, depersonalization, and reduced professional efficacy caused by factors such as high patient loads, fear of infection, insufficient protective equipment, rapidly changing protocols, and emotional exposure to suffering and death.

The specific COVID-19 triggers are: *high workload and long shifts* → overwhelmed ICUs and emergency departments; *uncertainty and evolving protocols* → rapid changes increased stress, *fear of infection* → personal safety concerns and risk of transmitting the virus to family; *resource scarcity* → limited PPE, ventilators, and beds; *moral injury* → making ethically challenging decisions due to triage priorities; *social isolation* → reduced emotional support outside work. The psychological and physical symptoms are: chronic fatigue and sleep disturbances, anxiety, depression, and irritability, decreased concentration and decision-making capacity, somatic complaints (headaches, palpitations, muscle tension), increased risk of post-traumatic stress disorder (PTSD). The impact in Healthcare During COVID-19 are: reduced quality of patient care, increased medical errors, higher absenteeism and turnover among healthcare staff, long-term effects on mental health and workforce sustainability.

2.8 Operationalization of variables

The study explored several latent constructs and observable variables related to risk management and staff well-being during the COVID-19 pandemic at Sf. Spiridon Clinical Emergency Hospital in Iași.

Table 4. Several latent constructs and observable variables related to risk management and staff well-being during the COVID-19 pandemic at Sf. Spiridon Clinical Emergency Hospital in Iași.

Variable	Operational Definition	Type	Measurement Level	Instrument/Item Example
Perceived risks	Subjective assessment by medical staff regarding threats to safety, quality of care, and infection control.	Independent variable	Ordinal	Likert-scale items (e.g., "Rate how safe you felt during peak COVID-19 periods" – 1 = very unsafe, 5 = very safe).
Burnout	Emotional exhaustion, depersonalization, and reduced personal accomplishment during COVID-19 pandemic.	Mediator	Continuous	**Maslach Burnout Inventory – Human Services Survey (MBI-HSS)** subscales.
Stress levels	Intensity of psychological pressure perceived during peak waves of COVID-19.	Mediator	Continuous	Visual analog scale (0 = no stress; 10 = extreme stress).
Perceived efficiency	Self-reported ability of staff to maintain care quality and performance despite overload.	Dependent variable	Ordinal	Likert items (e.g., "I felt able to manage my workload effectively during the pandemic").
Perceived safety protocols	Staff perception of clarity, sufficiency, and enforcement of safety measures.	Independent variable	Ordinal	"Safety rules were communicated clearly" (1 = strongly disagree; 5 = strongly agree).
Quality of medical care	Staff perception of the overall quality of care provided to patients during pandemic peaks.	Dependent variable	Ordinal	"The quality of patient care remained high despite COVID-19" (Likert scale).
Infrastructure adequacy	Perception of adequacy of physical resources, isolation rooms, ventilation, and IT systems.	Independent variable	Ordinal	Checklist items based on WHO guidelines.
Access to resources	Availability of PPE, disinfectants, soap, and medical supplies during the pandemic.	Independent variable	Ordinal	"During the pandemic, I had sufficient access to protective equipment" (Likert scale).
Patient safety perception	Overall evaluation of whether patients were protected from avoidable harm during COVID-19.	Dependent variable	Ordinal	Adapted from **AHRQ Hospital Survey on Patient Safety Culture**.
Staff satisfaction	Overall subjective evaluation of workplace conditions and managerial support.	Dependent variable	Continuous	Multi-item Likert index from 1 (very dissatisfied) to 5 (very satisfied).

2.9 Questionnaire Development Process

The original questionnaire used in the study had 70 items structured into 12 thematic sections:

Section 1: Demographic data (age, gender, department, role).

Section 2: Perception of hospital safety.

Section 3: Personal experiences in daily hospital activities.

Section 4: Communication effectiveness.

Section 5: Safety protocols.

Section 6: Access to medical care.

Section 7: Psychological and emotional aspects.

Section 8: Satisfaction with organizational response.

Section 9: Vaccination-related perceptions.

Section 10: Feedback for improving risk management.

Section 11: Post-pandemic experiences.

Section 12: Open-ended comments.

Steps Followed:

1. Item generation: Based on WHO, CDC, and Romanian Ministry of Health guidelines for patient safety and pandemic risk management.
2. Content validation: Items reviewed by a multidisciplinary expert panel (infectious disease specialists, hospital managers, psychologists).
3. Pilot testing: Administered to 30 staff members for feedback on clarity, relevance, and response time.
4. Reliability testing: (a) Internal consistency measured using Cronbach's α for each thematic block (target $\alpha \geq 0.80$); (b) Test–retest reliability checked over a 2-week interval.

(a) Construct validity: (a) Exploratory Factor Analysis (EFA) applied to verify thematic coherence; (b) Comparison with established validated instruments (see below).

2.10 Integration of Validated Instruments

To strengthen measurement accuracy, future research should incorporate standardized, validated tools:

a) Maslach Burnout Inventory (MBI-HSS)

Purpose: Measure burnout across three dimensions:

Emotional exhaustion (9 items)

Depersonalization (5 items)

Personal accomplishment (8 items)

Scoring: 7-point Likert scale (0 = never; 6 = every day) [29].

b) AHRQ Hospital Survey on Patient Safety Culture (HSOPSC)

Purpose: Assess perceived patient safety climate.

Domains covered: teamwork, communication openness, feedback, and response to errors [28,29].

c) Perceived Stress Scale (PSS-10)

Purpose: Measure subjective stress levels.

Structure: 10 items, 5-point Likert scale [31].

To enhance construct clarity: Align variables like "burnout," "perceived risk," and "patient safety" with validated measurement frameworks [31].

To benchmark against international standards: Integrate MBI-HSS and HSOPSC subscales into future questionnaires [32].

To improve statistical robustness: Use Confirmatory Factor Analysis (CFA) to test construct validity in this Romanian sample [33].

To ensure comparability: Standardized tools facilitate comparison with global COVID-19 studies on staff well-being and patient safety [32,33].

Instrument Validation and Reliability Testing

The structured questionnaire (70 items, 12 sections) was developed based on WHO, AHRQ, and Romanian Ministry of Health guidelines for patient safety and risk management during pandemics.

Expert validation: A panel of five experts (two ICU physicians, one infection-control specialist, one hospital risk manager, and one health psychologist) evaluated the questionnaire for content validity. Each item was rated for clarity, relevance, and representativeness on a 4-point scale. We computed the Item-level Content Validity Index (I-CVI) and Scale-level Content Validity Index (S-CVI/Ave), achieving an S-CVI/Ave of 0.92, exceeding the 0.80 acceptability threshold.

Pilot testing: A pilot study involving 30 healthcare professionals tested the instrument for comprehensibility and completion time. Feedback was incorporated to refine wording and response scales.

Reliability analysis: Internal consistency was assessed using Cronbach's alpha for each multi-item scale:

- Perceived Risks & Safety Protocols: $\alpha = 0.84$
- Resources & Infrastructure: $\alpha = 0.86$
- Patient Safety Culture: $\alpha = 0.88$
- Psychological Stress Scale (PSS-10 subset): $\alpha = 0.85$
- Perceived Quality & Efficiency: $\alpha = 0.82$

Temporal stability: To evaluate test–retest reliability, a subset of 40 participants repeated the survey after a 14-day interval. The Intraclass Correlation Coefficient [15,16] indicated good stability across scales:

- Perceived Risks & Safety Protocols: ICC = 0.83
- Resources & Infrastructure: ICC = 0.81
- Patient Safety Culture: ICC = 0.85
- Perceived Quality & Efficiency: ICC = 0.80

These results demonstrate that the questionnaire possesses high internal consistency, strong content validity, and good temporal stability, supporting its robustness for evaluating staff perceptions during the COVID-19 pandemic.

2.11 Population and sample. The study targeted the medical personnel involved in the care of COVID-19 patients (physicians, nurses and nursing assistants) from departments such as ICU, Infectious Diseases Unit, Internal Medicine Unit and Emergency Unit. The sample was selected using a non-probabilistic convenience sampling method and included approximately 400 participants. The sample comprises professionals from various levels and specialties to obtain a comprehensive picture of patient safety and risk management. A total of **400 participants** were initially recruited, including physicians, nurses, orderlies, and administrative staff involved in COVID-19 patient management. After excluding 17 incomplete questionnaires, **383 valid responses** remained for analysis. A **purposive sampling strategy** ensured the inclusion of diverse professional roles (clinical and administrative), departments (ICU, Internal Medicine, Infectious Diseases, Emergency), and hierarchical levels.

The targeted sample structure included:

- *Physicians directly involved in COVID-19 patient care*, to provide insight into clinical challenges and risks associated with medical procedures. Selection included intensive care physicians, emergency physicians, and infectious disease specialists to offer a complete perspective on clinical challenges and crisis measures.
- *Nurses*, to explore the pandemic's impact on patient safety from the perspective of staff in continuous contact with patients. Participation of nurses from intensive care and other critical departments was essential, as they were involved daily in direct patient care and had a unique perspective on the challenges and risks encountered.
- *Hospital managers*, to understand risk management strategies and the impact of organizational decisions on patient safety. Managers provided details on strategic and organizational aspects of risk management, including resource allocation, safety protocols, and the pandemic's impact on hospital operations.
- *Representatives of health authorities*, to provide perspectives on public health policies and coordination of preventive measures at regional and national levels. They offered a global view on policy measures, coordination, implementation of safety protocols, and resources provided to hospitals for pandemic management.

The selection was made based on purposive sampling to obtain responses from participants with relevant experiences and perspectives aligned with the research objectives. The selection aimed to ensure diversity in specialties and regions to provide

a varied and representative picture. Purposive sampling was used to select participants directly involved in managing risks and patient safety during the pandemic. Geographic and institutional balance was also considered to achieve the most representative sample possible.

2.12 Eligibility criteria. To ensure the relevance and quality of the data collected, the following inclusion and exclusion criteria were established for study participants: Inclusion criteria: medical staff (physicians, nurses, nursing assistants) employed at the "Sf. Spiridon" Clinical Emergency Hospital in Iași direct involvement in the care of COVID-19 patients during the pandemic period (2020–2022); willingness to voluntarily participate in the study; consent provided through informed consent. Exclusion criteria: administrative or technical staff not directly involved in clinical activities; employees on medical leave or other forms of extended absence during the analyzed period; refusal to participate or withdrawal of consent during the study.

Inclusion Criteria:

- Medical staff employed by the hospital during the pandemic (2020-2022)
- Direct involvment in the care of COVID-19 patients
- Voluntary participation and signed informed consent

Exclusion Criteria:

- Non-clinical staff (technical, administrative, external contractors)
- Staff on extended leave or not active during pandemic peak periods
- Declined or withdrawn consent.
-

2.13 Data Collection Techniques and Instruments. Semi-structured interviews with physicians, nurses, hospital managers, and representatives of health authorities were essential for obtaining qualitative data about the challenges faced during the pandemic, perceptions of safety measures, and risk management strategies. These interviews contained open-ended questions that allowed participants to express their experiences in detail, aiming to collect comprehensive information about the challenges encountered during the pandemic and professionals' perspectives on risk management measures. The questions were structured around the main themes of interest: risk perception, changes in safety protocols, impact on personnel, and resource allocation. Interviews lasted between 30 and 60 minutes and were recorded, with participants' consent, for transcription and detailed analysis.

a)Questionnaire:

A structured instrument comprising **70 items across 12 thematic sections** (e.g., safety perception, communication, infrastructure, infection control) was designed using evidence-based items adapted to pandemic conditions. The survey was disseminated online using secure institutional platforms (Google Forms, hospital intranet). Responses were anonymous to encourage candid feedback.

b)Interviews:

A subset of 35 participants (including department heads, senior physicians, nurses, and hospital managers) were selected for **semi-structured interviews**. These lasted between 30–60 minutes and were recorded (with consent), transcribed, and thematically analyzed.

2.14 Period. Data were collected between November 2023 and March 2024. Participants had two weeks to provide their data.

2.15 Study design. This study employs a **convergent mixed-methods approach**, combining qualitative and quantitative approaches in parallel to comprehensively assess risk management practices. The integration of these methods was chosen to allow triangulation of results and to capture both objective measures and subjective perceptions related to clinical risk during the COVID-19 pandemic. [34]. This methodological combination allows for a comprehensive evaluation of the pandemic's impact on the healthcare system and the effectiveness of prevention and risk management measures [35]. We used the online environment for distributing and completing questionnaires due to its ease of access and completion. Prior to administering the questionnaire, participants were given an informed consent form (medical staff) asking them to respond as thoroughly and completely as possible. Data collection was stopped when potential participants ceased giving their responses after a period of two weeks [36,37]. Subsequently, we relied on the existing sample to analyze the data, addressing the objectives of our study.

We applied a questionnaire comprising 70 questions, structured into 12 sections: (S1: Demographic data, S2: Perception of hospital safety during the COVID-19 pandemic, S3: Personal experiences in daily hospital activities during the COVID-19 pandemic, S4: Communication with the medical staff, S5: Safety protocols, S6: Access to medical care, S7: Psychological and emotional aspects, S8: Overall satisfaction, S9: Aspects related to vaccination, S10: Feedback on improving risk management, S11: Post-pandemic experiences, S12: Other comments).

2.16 Data Analysis. The analysis of the collected data included both qualitative and quantitative methods. For the qualitative data analysis, the data obtained from the questionnaires were recorded, transcribed, and analyzed using open and axial coding techniques. Open coding identifies and labels the main themes and subthemes. Axial coding explores the relationships between these themes to build a theoretical model. Software such as NVivo or ATLAS.ti was used to organize and analyze qualitative data (Strauss and Corbin, 1990). Coding process: Interview transcripts underwent a two-stage coding process: open and axial coding. In the first stage, open coding will allow the identification of general themes and sub-themes related to risk perception and participants' experiences (e.g., "logistical challenges," "psychological impact on staff"). To manage the data efficiently and ensure rigor, specialized software such as NVivo or ATLAS.ti was used for organizing and analyzing the data.

Quantitative data were analyzed using **SPSS v26**, applying:

- Descriptive statistics (mean, standard deviation, frequency)
- Inferential statistics (t-tests, ANOVA, Pearson correlation)
- Significance threshold: $\mathbf{p < 0.05}$.

Qualitative data (interview transcripts) were analyzed using **NVivo 12**, employing:

- **Open coding**: to identify emergent categories from participant narratives.
- **Axial coding**: to explore causal relationships, themes, and sub-themes.
- **Triangulation**: Comparison across data sources (survey, interview, case reports) ensured consistency and depth.

Quantitative data obtained from hospital reports or impact studies were statistically analyzed using descriptive and inferential techniques. Descriptive analysis provides data on the frequency and distribution of safety incidents, while inferential techniques (e.g., t-tests, regression analysis) help evaluate relationships between factors such as workload and error rates. Software such as SPSS or R can be used for statistical analysis.

Validation of identified themes: Major themes will be validated through data triangulation, comparing interview responses with case studies and reports to ensure consistency and validity of the results.

2.17 Research Limitations.

While the mixed-methods approach ensured robustness, the study faced limitations:

- Recall bias due to retrospective self-reporting.
- Regional focus limits generalizability to national or international contexts.
- Resource limitations restricted real-time data acquisition during peak pandemic phases.

To mitigate bias, methodological triangulation and validation through member checking and peer debriefing were used.

Subjectivity in interpreting qualitative data constitutes the most significant limitation: since the interpretation of responses can be influenced by the context and the researcher's experiences, the results may be affected by subjective perceptions. To mitigate this limitation, interpretations were regularly reviewed by a research team and verified through participant feedback. Limited access to secondary data: Certain hospitals or health authorities may have incomplete or inaccessible data for research, which could limit the accuracy of the comparative analysis. This limitation will be explicitly mentioned, and only consistently available data will be used. Time and resource constraints: Data collection and analysis may be influenced by time constraints, especially regarding interviews with overburdened medical staff.

2.18 Ethical Considerations. All methods and techniques used were applied in accordance with applicable standards and laws, including standards for research ethics in medical sciences and the Declaration of Helsinki [38,39]. The hospital approved its involvement through the Ethics Committee Opinion of the "Sf. Spiridon" Clinical County Emergency Hospital Iași, no. 69 dated 30.08.2023, in accordance with the Research Law no. 206 of May 27, 2004. Participants received written information/informed consent regarding the study's components and implications; their rights to voluntarily participate and to withdraw at any time, as well as their rights to confidentiality and privacy (GDPR, 2016), were addressed. Additionally, respondents expressed their consent to participate in the study and authorized the use of official information available for professional and scientific purposes.

5. Conclusions

The present study highlights the critical importance of effective risk management in hospital units, especially in the context of large-scale health crises such as the COVID-19 pandemic. The results obtained through a mixed research method - both quantitative and qualitative - reflect systemic vulnerabilities as well as strengths in managing clinical and infrastructure risks within the "Sf. Spiridon" County Emergency Clinical Hospital in Iași. Risk management during the pandemic was marked by logistical difficulties, lack of standardized protocols, overburdened human resources, and insufficiently adapted infrastructure. These factors contributed to a decreased perception of care quality and patient safety. Significant correlations between staff perceptions regarding internal coordination, resource availability, and quality of medical care indicate the need for a robust organizational framework capable of supporting rapid and coherent interventions in crisis contexts. The role of the medical personnel involved in risk management was affected by rapid changes in duties and unplanned mobilizations, leading to suboptimal use of professional competencies

and consequently lower efficiency in some critical sectors. The necessity of a dedicated Risk Manager within the hospital's administrative structure is a key conclusion of the study. This person should have a clearly defined role, specific training in patient safety, and the capacity for real-time action, especially in emergency situations.

The proposal of a five-step systemic strategy based on international best practices (e.g., the EU 2020 model) reflects a proactive approach to quality and safety management in healthcare, focusing on prevention, continuous training, support for staff and patients, constant monitoring, and effective communication. The study's limitations, including response subjectivity and regional specificity, do not diminish the relevance of the conclusions but emphasize the need to extend research nationally to underpin unified health risk management policies.

In conclusion, this research underscores that an integrated, multidisciplinary, and anticipatory approach to clinical and infrastructure risks is essential to ensure institutional resilience, increase patient safety, and protect medical personnel against future epidemiological crises.

Supplementary Materials: No

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Institutional Review Board Statement: The study was conducted in accordance with the Declaration of Helsinki, and approved by the Institutional Ethics Committee of St.Spiridon County Emergency Hospital Iasi (protocol code 69 date of approval 30.08.2023)." for studies involving humans. **Informed Consent Statement:** Any research article describing a study involving humans should contain this statement. Please add "Informed consent was obtained from all subjects involved in the study." OR "Patient consent was waived due to REASON (please provide a detailed justification)." OR "Not applicable." for studies not involving humans. You might also choose to exclude this statement if the study did not involve humans.

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