Sistemska tveganja za varnost v primarnem zdravstvenem varstvu: raziskava z mešanimi metodami

Systemic safety risks in primary healthcare: a mixed-methods study

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Izvleček

Uvod: *Varnost pacientov v osnovnem zdravstvenem varstvu je vse bolj prepoznana kot sistemski pojav, vendar empirični dokazi še vedno primanjkujejo. Namen raziskave je bil analizirati varnostna tveganja z vidika zdravstvenih delavcev in pacientov ter razviti integrativni konceptualni model varnosti.*

Metode: *Izvedena je bila dvo-stopenjska raziskava z mešanimi metodami v Zdravstvenem domu Ljubljana. Kvantitativni del je vključeval retrospektivno analizo podatkov o prijavljenih varnostnih dogodkih v obdobju 2015–2024 ter proaktivno oceno tveganj z metodo FMEA. Kvalitativni podatki so bili zbrani s strukturiranimi vprašalniki med zdravstvenimi delavci (n = 20) in pacienti (n*

Abstract

Introduction: *Patient safety in primary healthcare is increasingly recognized as a systemic phenomenon, yet empirical evidence is limited. This study aimed to analyse safety risks from the perspectives of healthcare professionals and patients and to develop an integrative conceptual model of safety.*

Methods: *A two-phase mixed-methods study was conducted at Ljubljana Community Health Centre (Ljubljana, Slovenia). Quantitative analysis included retrospective data on reported safety incidents from 2015 to 2024 and proactive risk assessment using Failure Mode and Effects Analysis (FMEA). Qualitative data were obtained through structured questionnaires with*

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= 9), vključno z odprtimi vprašanji, analiziranimi z metodo vsebinske analize.

Rezultati: *Identificiranih je bilo 554 varnostno relevantnih dogodkov, pri čemer so bila organizacijska in procesna tveganja najpogostejša. Komunikacija se je izkazala za osrednje presečno tveganje, ki deluje kot prispevni dejavnik, ranljiv proces in neposreden vir napak. Organizacijska tveganja so pogosta, vendar imajo večinoma zmerne posledice, medtem ko so terapevtska tveganja redkejša, a z večjo klinično težo. Človeška napaka je bila večinoma zaznana kot sekundarni, sistemsko pogojen dejavnik. Pacienti so poročali o visoki zaznani varnosti, vendar bi morebitna napaka pomembno vplivala na zaupanje. Ključni prispevni dejavniki vključujejo časovni pritisk, pomanjkanje kadra, nejasne postopke in komunikacijske izzive.*

Zaključek: *Varnostna tveganja v osnovnem zdravstvenem varstvu so pretežno sistemske narave. Komunikacija, organizacija dela in časovni pritisk predstavljajo ključne vzvode varnosti, simulacije pa obetavno strategijo za proaktivno prepoznavanje in obvladovanje latentnih tveganj.*

healthcare professionals (n = 20) and patients (n = 9), including open-ended questions analysed by content analysis.

Results: *A total of 554 safety-related events were identified; organizational and process-related risks were most frequent. Communication emerged as a central cross-cutting risk, functioning simultaneously as a contributing factor, vulnerable process, and direct source of error. Organizational risks were frequent but generally associated with moderate consequences, whereas therapeutic risks were less frequent but carried higher clinical severity. Human error was predominantly perceived as a secondary, system-dependent factor. Patients reported high perceived safety. However, potential errors were associated with a substantial impact on trust. Key contributing factors included time pressure, staff shortages, unclear procedures, and communication challenges.*

Conclusion: *Safety risks in primary healthcare are predominantly systemic. Communication, organization of work, and time pressure represent key leverage points, while simulation emerges as a promising strategy for proactive identification and mitigation of latent risks.*

INTRODUCTION

Quality and safety of clinical processes in primary healthcare constitute a cornerstone of modern health systems. The primary level of care serves the largest proportion of the population and encompasses a broad spectrum of clinical situations. Primary care represents the first and continuous contact between patients and the healthcare system. Therefore, errors and deficiencies at this level may have long-term and cumulative consequences for individual and population health (1, 2).

Patient safety has evolved into an independent scientific discipline over the past two decades that extends beyond the traditional understanding of clinical quality. The focus has shifted from the individual responsibility of healthcare professionals to systemic factors, organizational culture, and the complexity of healthcare processes. Nevertheless, most empirical research, interventions, and standards remain centred on hospital settings, while primary healthcare continues to be relatively underexplored (3-5).

Patient safety in primary healthcare is a key component of high-quality care. Although outpatient work is less intensive than hospital care, numerous safety risks may affect treatment outcomes, patient satisfaction, and system efficiency. The characteristics of the primary care environment, such as fragmented processes, high staff workload, multiple transitions between levels of care, and reliance on communication and coordination, create a complex network of potential errors and incidents. Safety risks in primary healthcare are multifaceted and extend beyond purely clinical errors. Monitoring and risk assessment should include retrospective data, proactive methods,

individual clinical risk assessments, and measurement of safety climate. A systematic approach and a strong safety culture are essential for reducing adverse events, improving patient safety, and increasing the reliability of care in primary healthcare. Incorporating risk assessment and safety culture analysis enables the identification of priority areas for improvement, leading to better clinical outcomes and a reduction in adverse events.

The most common safety risks in primary healthcare include medication-related errors, communication and coordination challenges, process-related risks, organizational complications, and physical risks to patients (8). Errors in prescribing, dispensing, or administering medications are among the most frequently documented safety risks in primary care. Unclear information about allergies, insufficient verification of drug interactions, and inconsistent work practices contribute to an increased likelihood of errors (1, 8). Transitions between levels of care constitute a systematic source of risk. The absence of consistent documentation during transitions (e.g., hospital discharge to outpatient care) leads to the loss of important information and increases the likelihood of clinical errors (8, 9). Inefficient or non-standardized work processes and insufficient standardization contribute to errors that may not directly result in clinical harm but affect overall quality and safety (8, 10). Although physical injuries occur less frequently in outpatient settings than in hospitals, physical injuries remain a serious source of risk, particularly in relation to falls within clinic premises or among patients with mobility limitations (11).

The aim of this study was to comprehensively analyse the perception of safety risks in primary healthcare from the perspectives of healthcare professionals and patients, to identify key contributory factors, vulnerable processes, and areas of potential error, and to develop an integrative conceptual model of patient safety based on quantitative and qualitative data. The purpose of the study was exploratory and quality-improvement oriented rather than analytical or predictive.

MATERIALS AND METHODS

The situation analysis was conducted as a two-phase mixed-methods study: 1) A retrospective descriptive-analytical study aimed at systematically analysing safety risks in primary healthcare at Ljubljana Community Health Centre [LCHC] (Ljubljana, Slovenia) over an extended time. The study was based on secondary analysis of existing data on reported adverse events and incidents and on the application of a standardized proactive risk analysis method [FMEA] (12); and 2) A qualitative study used structured online questionnaires containing several open-ended questions.

Risk analysis

Data sources

The analysis included data on reported safety risks and incidents at LCHC from 2015 to 2024. The data were derived from internal adverse event and incident reporting records collected within the existing quality assurance and patient safety system. All events documented as safety-relevant during the observed period were included in the analysis, regardless of severity level or outcome.

Risk categorization

The identified risks were classified into the following four thematic domains:

1. physical harm to patients and employees;
2. adverse events related to medication administration;
3. incidents in work processes; and
4. organizational and systemic risks.

For the purposes of this study, a safety risk refers to any condition or circumstance with the potential to cause harm to patients or healthcare professionals. An adverse event is an incident that results in harm to a patient. An incident refers to any unintended event or circumstance that could have or did affect the safety of healthcare delivery, regardless of whether harm occurred. The term "safety-related event" is used as an umbrella term encompassing safety risks, incidents, near misses, and adverse events identified through the institutional reporting system (13). The

classification was based on content analysis of event descriptions and was performed to enable longitudinal comparability and clearer trend analysis.

Quantitative risk analysis

The number of reported risks was calculated for each risk domain for each year of the observed period. Data were analysed using descriptive statistics and absolute frequencies (n) were reported. The quantitative component was designed to provide a descriptive overview of reported safety risks within the institution rather than to test predefined hypotheses. Therefore, descriptive statistics were considered appropriate for the analysis of the complete institutional dataset.

Risk prioritisation was performed using Failure Mode and Effects Analysis (FMEA), which was adapted to the primary healthcare setting and the objectives of this study (12).

In addition to the conventional FMEA dimensions, the assessment incorporated patient impact as a separate criterion to better reflect the potential clinical consequences of safety events in routine primary healthcare practice.

Each identified risk was assessed according to the following four criteria:

- frequency (F), occurrence rate of the risk;
- severity (S), expected seriousness of the consequences should the event occur;
- likelihood (V), probability that the event would recur under similar circumstances; and
- patient impact (P), expected influence of the event on patient care and clinical outcomes.

Each criterion was rated on a five-point scale (1–5). Frequency categories were established using the average annual number of reported events for each risk domain during the study period. The thresholds were determined according to the distribution of reported events within the LCHD to facilitate local risk prioritisation, as follows:

- ≥ 30 events/year (very frequent) = 5;
- 20–29 events/year (frequent) = 4;
- 10–19 events/year (occasional) = 3;
- 5–9 events/year (rare) = 2; and
- < 5 events/year (very rare) = 1.

To prioritise risks, an adapted risk priority number (RPN) was calculated using the following equation: $RPN = (F \times V) + (S \times P)$.

This adapted calculation was developed specifically for the present study to distinguish the clinical severity of an event from its potential impact on patient care, unlike the conventional FMEA approach (14), which typically combines severity, occurrence, and detectability. The modified approach was intended to support local prioritisation of patient safety risks (15) rather than to serve as a validated alternative to the classic FMEA model. The resulting RPN values were used to rank identified risks and to inform the prioritisation of improvement measures within the institution.

Qualitative part

Participants

Two groups of participants were included: 1) healthcare professionals employed in primary healthcare (n = 20); and 2) patients receiving care in primary healthcare (n = 9).

Participation was voluntary and anonymous. All individuals who completed the questionnaire (fully or partially) during the data collection period were included in the analysis.

Research instruments

Data were collected using two structured questionnaires (one for healthcare professionals and one for patients) Both questionnaires included a combination of closed-ended questions (nominal and ordinal variables) and open-ended questions.

The healthcare professional questionnaire included basic demographic data, perception of existing for underreporting, perception of safety culture, and open-ended questions on perceived risks and improvement suggestions. Patient questionnaire included basic demographic data, perception of safety of care, experience with care and communication with healthcare professionals, and perceived risks and suggestions for improvement.

Data collection procedure

The questionnaires were distributed electronically. The participants were informed about the purpose of the study, anonymity of participation, and the

voluntary nature of involvement before completing the questionnaires. No time limit was imposed for completing the questionnaires.

Data analysis

Data were analysed using descriptive statistics. Absolute (n) and relative frequencies (percentages) were calculated for each variable. The results are presented in frequency tables with variables listed in rows and response categories presented with corresponding frequencies and percentages.

Responses to the open-ended questionnaire items were analysed using qualitative content analysis (16). An inductive approach was adopted to identify recurring concepts and themes emerging from participant responses. The unit of analysis consisted of individual meaningful statements or phrases related to patient safety, perceived risks, contributing factors, vulnerable processes, safety events, and proposed improvement measures.

The analysis was performed in several stages. First, all responses were read repeatedly to achieve familiarity with the data. Meaning units relevant to the research aims were then identified and assigned initial descriptive codes. Similar codes were subsequently grouped into broader categories based on conceptual similarity. Finally, the categories were reviewed and refined through iterative comparison with the original data and integrated with the quantitative findings to develop the conceptual framework.

The coding and category development were performed independently by two members of the research team. Differences in coding and category assignment were discussed until consensus was reached. When necessary, the original questionnaire responses were re-examined to ensure that the final categories accurately reflected the views of the participants.

Several procedures were applied to enhance the credibility of the qualitative analysis, including independent coding, iterative review of the coding framework, consensus discussions between researchers, and continuous comparison of the developed categories with the original responses. The integration of qualitative findings with quantitative data provided an additional form of methodologic triangulation, which supported the consistency of the overall interpretation.

Integration of quantitative and qualitative findings

Following separate quantitative and qualitative analyses, findings were integrated using a convergent mixed-methods approach. Categories emerging from qualitative content analysis were compared to quantitative risk domains and synthesised into an integrative conceptual framework describing relationships between contributory factors, vulnerable processes, safety events, and proposed interventions.

Ethical approval and data protection

The study received ethical approval from the National Ethics Committee (No. 0120-481/2025-2711-3). Appropriate technical and organisational measures were implemented, including encryption, anonymisation and pseudonymisation of data, role-based access control, and storage in secure data repositories, to ensure the confidentiality of study participants. Data were managed in accordance with the Findable, Accessible, Interoperable, and Reusable (FAIR) principles and applicable data protection regulations.

RESULTS

Risk analysis

Number of risks by domain and year

Analysis of the aggregated data showed the following distribution of risks across domains (Table 1):

- physical harm (consistently present throughout the entire study period and more pronounced fluctuations between year);
- other risk domains (the highest absolute number of events, indicating a broad range of organizational and process-related risks);
- medication administration (a lower number of events but with high clinical significance); and
- incidents (a moderate number of events, primarily related to disruptions in work processes0.

Table 1: *Safety risks in the Ljubljana Community Health Centre from 2015 to 2024*

Year	Physical threat		Other risk areas		Medication application		Safety incidents		SUM
	N	%	N	%	N	%	N	%	
2016	26	33.3	24	30.8	14	17.9	14	17.9	78
2017	11	14.9	38	51.4	10	13.5	15	20.3	74
2018	25	26.0	42	43.8	16	16.7	13	13.5	96
2019	6	7.2	59	71.1	11	13.3	7	8.4	83
2020	8	17.4	15	32.6	8	17.4	15	32.6	46
2021	7	17.1	20	48.8	5	12.2	9	22.0	41
2022	9	27.3	15	45.5	4	12.1	5	15.2	33
2023	6	18.8	16	50.0	5	15.6	5	15.6	32
2024	9	12.7	43	60.6	10	14.1	9	12.7	71
SUM	107	19.3	272	49.1	83	15.0	92	16.6	554

Table 2: *FMEA risks in the Ljubljana Community Health Centre from 2015 to 2024*

Risk Area	Examples of reported events	Frequency (F)	Severity (S)	Likelihood (V)	Impact on Patient (P)	RPN	Risk Level	Proposed Measures
Physical hazards	Falls, needle-stick injuries, workplace violence	4	3	4	4	28	Critical	Facility improvements, non-slip surfaces, regular inspections, training
Medication administration	Wrong dose, wrong medication, omitted medication	3	5	3	5	30	Critical	Double-checking, standardized procedures, additional training
Incidents	Documentation errors, delayed referrals, workflow disruptions	3	2	3	2	13	Moderate	Process optimization, improved communication
Organizational risks	Staff shortages, scheduling problems, communication failures	2	3	2	3	12	Moderate	Review of work organization, long-term workforce planning

Results of FMEA

The analysis of reported safety risks in the LCHC during the study period (2015–2024) revealed the presence of risks in several content areas. The areas analysed included physical threats to patients and employees, adverse drug administration events, incidents in work processes, and organizational and systemic risks. The number of reported risks varied between years during the study period under review. The largest absolute number of events was recorded in the area of organizational and systemic risks, followed by risks in the area of physical threats, incidents in work processes, and adverse drug administration events. The number of reported events varied between years with higher and lower values detected depending on the individual year and area (Table 2).

Table 3: *Characteristics of healthcare workers*

Variable	Category	Frequency (n)	Share (%)
Your role in the health centre	Management position	7	35
	Physician	6	30
	Nurse / medical technician	6	30
	Other healthcare professional	1	5
Work experience in primary healthcare	> 20 years	9	45
	11–20 years	9	45
	< 5 years	1	5
	5–10 years	1	5

Table 4: *Characteristics of patients*

Variable	Category	Frequency (n)	Share (%)
Gender	Female	8	88.9
	Male	1	11.1
Age group	51–70 years	4	44.4
	31–50 years	3	33.3
	Up to 30 years	2	22.2

Qualitative results

Sample characteristics

The characteristics of study participants are presented in Tables 3 and 4.

Safety perceptions

Qualitative and quantitative data identified communication-related issues across multiple analytical categories, including perceived risks, contributing factors, vulnerable processes, and areas of potential error (Table 5). Organizational risks were frequently identified in the retrospective analysis, whereas therapeutic risks were reported less often but yielded higher FMEA severity scores. Healthcare professionals most often identified time pressure, staff shortages, unclear procedures, and poor internal communication as contributing factors to safety events. Human error was also reported, typically in conjunction with organizational and communication-related factors. Vulnerable processes most frequently included clinical care, medication-related procedures, communication and documentation, and work organization. Participants identified near misses, minor events, and adverse events as relevant types of safety events and proposed measures, including standardization of procedures, improved communication, organizational improvements, increased staffing, and simulation-based training. Patients associated patient safety with clear communication, understanding of instructions, and trust in healthcare professionals.

Table 5: *Integrative coding matrix of security perception in the Ljubljana Community Health Centre*

Analytical Level	Main Category	Key Codes (Summary)	Related Questionnaire Questions	Integrative Meaning
1. PERCEIVED RISKS	Communication risks	Unclear communication, incorrect instructions, information transfer	Perceived risks, areas of errors	Horizontal risk, present across all processes
	Therapeutic risks	Incorrect dosage, polypharmacy, medication administration	Perceived risks, vulnerable processes	Low frequency, high severity
	Organizational risks	Scheduling, waiting, patient triage	Areas of errors	Process triggers of errors
	Violence against staff	Verbal, non-verbal, psychological violence	Perceived risks	Staff safety as a prerequisite for patient safety
2. CONTRIBUTING FACTORS (CAUSES)	Organizational factors	Time pressure, staff shortages	Contributing factors of events	Structural pressure on the system
	Communication factors	Poor internal communication	Contributing factors of events	Amplifier of other risks
	Process factors	Unclear procedures, lack of standardization	Contributing factors of events	Increases variability
	Individual factors	Human error	Contributing factors of events	Secondary, consequential factor
3. VULNERABLE PROCESSES	Clinical processes	Patient management, diagnostics	Vulnerable processes	High complexity
	Therapeutic processes	Prescribing, administration	Vulnerable processes	Critical clinical point
	Communication and documentation	Handovers, records	Vulnerable processes	Key to continuity
	Work organization	Substitutions, workload	Vulnerable processes	Contextual vulnerability
4. AREAS OF POTENTIAL ERRORS	Communication and instructions	Misunderstanding, misinterpretation	Areas of errors	Most common direct source of errors
	Waiting organization	Delays, omissions	Areas of errors	Indirect safety consequences
	Medications	Incorrect use	Areas of errors	High risk of harm
5. EVENTS	Near misses	Near misses	Events	High learning potential
	Minor events	No consequences	Events	Indicate system weaknesses
	Adverse events	Clinical complications	Events	Visible manifestation of risks

Analytical Level	Main Category	Key Codes (Summary)	Related Questionnaire Questions	Integrative Meaning
6. LEARNING MECHANISMS	Simulations	Triage, communication, medications	Simulations	Proactive learning without harm
	Event analysis	Reflection	Multiple questions	Transition from reactive to learning system
7. MEASURES	Standardization	Protocols	Measures	Reducing variability
	Communication	Clear instructions	Measures, patient safety	Key safety lever
	Organization and staffing	More time, more staff	Measures	Reducing system pressure
	Technical and spatial	Equipment, privacy	Measures	Supporting safe communication
8. OUTCOME	Patient safety	Understanding, trust	Patient safety	Final system outcome

DISCUSSION

Summary of main findings

The findings of this study suggest that safety risks in primary healthcare are influenced by a range of organizational and process-related factors. Both quantitative and qualitative data identified communication-related issues across multiple domains, including perceived risks, contributing factors, vulnerable processes, and potential areas of error. Organizational risks were reported more frequently, whereas therapeutic risks occurred less often but were associated with higher FMEA severity scores. These findings suggest that different categories of risk may require different approaches to prioritisation and management.

Comparison to other studies

The findings herein are consistent with previous research findings and suggest that patient safety in primary healthcare is shaped by interactions between organizational, human, and process-related factors rather than by individual errors alone (5, 17).

Communication and information transfer were identified across several domains of the analysis, including perceived risks, contributing factors, vulnerable processes, and potential sources of error. This pattern suggests that communication may represent an important cross-cutting component of patient safety, rather than being limited to a single aspect of care (18).

The communication-related issues identified in this study extended beyond interactions between healthcare professionals and patients to include intra-team communication, handovers, documentation practices, and organizational processes, such as scheduling and waiting-list management. These findings are consistent with previous studies indicating that unclear, incomplete, or poorly coordinated information exchange may contribute to safety incidents, particularly in time-pressured environments (9).

The findings also suggest differences between the frequency and potential impact of different types of risks. Organizational risks, including scheduling, waiting, and patient triage, were more frequently reported, whereas therapeutic risks were less common but received higher severity ratings in the FMEA.

Although this pattern should be interpreted cautiously, the pattern may indicate that prioritising safety improvements should consider both the frequency of events and the potential clinical consequences, which is consistent with the principles of proactive risk assessment (12, 19).

Healthcare professionals rarely described human error as an isolated cause of safety events. Instead, human error is typically discussed together with organizational factors, such as time pressure, staffing shortages, unclear procedures, and communication challenges (20,2 1).

Patients generally reported feeling safe during the most recent healthcare encounter and most did not express concerns about potential errors. At the same time, participants indicated that a safety incident could substantially affect trust in the healthcare institution. Although these findings are based on a small patient sample, the findings suggest that trust may be closely linked to patients' perceptions of communication quality and the clarity of information provided by healthcare professionals (22).

Implications for practice

The integrative analysis suggests that patient safety in primary healthcare is influenced by interactions between organizational factors, communication, clinical processes, and learning from safety events. Participants most frequently proposed interventions aimed at improving communication, standardising procedures, reducing organizational workload, and increasing the time available for patient interactions. Taken together, these findings suggest that improving patient safety may require a combination of organizational, process-related, and communication-focused interventions. Simulation-based education may represent one approach for supporting proactive identification of latent safety risks and strengthening teamwork and communication in a controlled environment.

Given the exploratory nature of this study and the single-centre design, these implications should be interpreted cautiously. Nevertheless, the findings are consistent with current patient safety literature supporting system-oriented approaches to safety improvement (18, 23, 24). Future studies involving multiple healthcare settings and larger samples are needed to confirm these observations and to evaluate the effectiveness of simulation-based interventions in primary healthcare.

Limitations of the study

The findings of this study should be interpreted in light of several limitations. First, the qualitative component included a relatively small number of healthcare professionals (n = 20) and patients (n = 9), which may limit the transferability of the findings to other primary healthcare settings. In particular, the small patient sample requires cautious interpretation of patient perspectives because these views may not reflect the experiences of the broader patient population. Second, participation in the questionnaire was voluntary, introducing the possibility of sampling bias because individuals with a particular interest in patient safety may have been more likely to participate. Third, the study was conducted in a single primary healthcare institution, which may limit the generalisability of the findings to other healthcare organisations with different organisational structures, resources, or safety cultures. Finally, the adapted FMEA approach used in this study was developed to support local risk prioritisation and has not been externally validated. Despite these limitations, the convergence of quantitative and qualitative findings provides a more comprehensive understanding of patient safety risks in the studied setting and offers a basis for future multicentre research.

The retrospective analysis relied on reported safety events, which may underestimate the true occurrence of incidents because reporting systems are susceptible to underreporting and reporting bias.

The modified FMEA approach was developed to support local risk prioritisation and has not been externally validated. Consequently, the calculated risk priority numbers should be interpreted as decision-support measures within the study setting rather than as universally applicable risk estimates.

The quantitative component of the study was designed as a descriptive analysis of all safety-related events reported within the LCHC during the study

period. Because the dataset comprised the complete institutional database of reported events rather than a sample drawn from a larger population, the primary objective was to describe the distribution and characteristics of safety risks rather than to test predefined hypotheses or estimate population parameters. Consequently, descriptive statistics, including absolute frequencies and percentages, were considered the most appropriate analytical approach. Risk prioritisation was subsequently performed using the adapted FMEA methodology to support the identification of areas requiring safety improvement.

CONCLUSION

Patient safety in primary healthcare represents a dynamic outcome of a complex system. Communication, time pressure, and work organization emerge as key levers of safety, while simulation appears as a promising system-level approach for identifying and addressing latent risks. The findings of this study provide an empirical basis for the further development of simulation-based programs aimed at improving the quality and safety of clinical processes in primary healthcare.

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