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Original Article

FMEA-based risk management improves the ability of oral healthcare personnel to prevent needlestick injuries

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Abstract: Objective: To explore the application value of the Failure Mode and Effects Analysis (FMEA) method in the risk management of needlestick injuries among oral healthcare personnel. Methods: A total of 37 healthcare workers from the dental department of Zhujiang Hospital, Southern Medical University, were selected as study subjects. Routine risk management procedures were followed from January 2021 to December 2021, serving as the control group, while FMEA-based risk management was implemented from January 2022 to December 2022, representing the research group. The Risk Priority Number (RPN) was calculated, and interventions were implemented for the top five identified failure modes. The RPN score, incidence of needlestick injuries, healthcare personnel's knowledge and awareness levels, prevention behavior, and rate of satisfaction with management were compared between the two groups. Results: FMEA-based risk management identified weak knowledge of protection, disorganized placement of sharp instruments, failure to adhere to operational standards, improper operational procedures, and insufficient regulations for preventing needlestick injuries as the top five failure modes. The RPN scores for these modes were significantly lower in the research group ($P<0.05$). The research group also experienced a lower frequency and incidence of needlestick injury ($P<0.05$), along with higher levels of healthcare knowledge, awareness of prevention, and prevention behavior ($P<0.05$). Additionally, satisfaction with management was higher in the research group compared to the control group ($P<0.05$). Conclusion: FMEA-based risk management can improve the ability of oral healthcare personnel to prevent needlestick injury, reduce the occurrence of such incidents, and enhance satisfaction with management. This approach holds promise for wider adoption.

Keywords: Failure mode and effects analysis, oral healthcare facility, healthcare personnel, needlestick injuries, protection, risk management

Introduction

In contemporary healthcare settings, needlestick injuries pose a significant occupational hazard for healthcare personnel, carrying the risk of transmitting bloodborne diseases and causing substantial harm to personal health and safety [1]. Beyond the physical consequences, these incidents also inflict mental and psychological distress on affected individuals and generate considerable economic burdens for healthcare institutions. Among healthcare workers, nursing staff face a particularly elevated risk of needlestick injury and associated bloodborne disease transmission [1]. Similarly, oral healthcare personnel confront heightened susceptibility to such injuries due to the specialized procedures involving intricate, small-sized, and sharp instruments [2, 3].

The Failure Mode and Effects Analysis (FMEA) method stands out as a risk management tool designed to identify, analyze, evaluate, and control possible risks, aiming to prevent adverse events. Renowned for its simplicity, adaptability, and capacity to prioritize significant risk factors [4, 5], FMEA has gained recognition as an important prospective risk analysis approach, endorsed by the International Organization for Standardization (ISO) Technical Committee since 2008 and widely embraced in medical risk management across developed nations [6, 7]. While FMEA has been applied to enhance needlestick injury protection among outpatient dental medical staff, scant literature exists on

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its specific application in preventing needlestick injuries among oral healthcare personnel [8, 9].

Therefore, this study focuses on analyzing failure modes associated with needlestick injuries among oral healthcare personnel using the FMEA method. By examining various factors contributing to these injuries, this study aims to identify areas for improvement to mitigate their occurrence Furthermore, through the lens of FMEA, this study endeavors to unveil the preventive potential of this methodin reducing the prevalence of needlestick injuries among oral healthcare personnel. In doing so, this study may offer insight for prevention, especially in the oral healthcare setting.

Data and methods

General information

We selected 37 medical staff members from the Department of Stomatology Outpatient Clinic of Zhujiang Hospital, affiliated with Southern Medical University, as our research subjects. This study received approval from the Ethics Committee of Zhujiang Hospital, Southern Medical University, and all participants provided informed consent.

Inclusion criteria: (1) no long-term transfers or leaves (cumulative >15 days) during the study period; (2) age over 18 years without a history of mental illness; (3) informed and voluntary participation in the study. Exclusion criteria: (1) serious events affecting outpatient work, such as severe emotional distress or critically illness of immediate family members, during the study period; (2) severe dysfunction of the heart, liver, kidneys, or other organs; (3) unwillingness to cooperate or incomplete data. The routine risk management in the control group was conducted from January 2021 to December 2021, while the risk management based on the FMEA method in the research group was implemented from January 2022 to December 2022.

Methods

Control group: Routine risk management was implemented, including routine introduction of needlestick injury hazards, relevant protective training, and management according to departmental regulations and procedures.

Research group: Risk management based on the FMEA method was implemented following the control group period. This involved several key steps: (1) Team formation: An FMEA team comprising eight members from the Infection Management Department, Nursing Department, and Stomatology Department was established. All team members received standardized training in FMEA-related knowledge to ensure consistency in the risk management process and mitigate result biases. (2) Risk identification: Through brainstorming sessions, literature review, and drawing from practical work experience, the FMEA team identified relevant factors and links contributing to needlestick injury through discussions. (3) Risk analysis and evaluation: A “Needlestick Injury Risk Assessment Form” and scoring criteria were developed based on the identified risk factors. Each member of the FMEA team independently scored the form, evaluating the severity (S), likelihood of occurrence (O), and detectability (D) of each risk point. The S, O, and D were scored on a scale of 1-5 points, with 1 indicating highly unlikely and 5 indicating highly likely. The Risk Priority Number (RPN) for each failure mode was calculated using the formula: RPN = S × O × D, with higher RPN value suggesting higher risk [10]. The top 5 risks were then identified for further risk management, including weak knowledge of protection, disorder placement of sharp instruments in the treatment tray without standardized guidelines, non-compliance with operating procedures, lack of standardized operating procedures, and incomplete preventive measures for needlestick injuries (**Table 1**). (4) Risk response measures: Based on the risk assessment results and RPN calculations, corresponding risk prevention and control measures were developed for the top 5 failure modes. These measures primarily focused on addressing weak protection knowledge (by incorporating prevention measures for needlestick injuries and bloodborne pathogen infections into the risk management plan, conducting regular training and assessments on needlestick injury prevention for healthcare workers in the department, and strengthening healthcare workers’ protection knowledge and awareness through workshops, scenario simulations, and random checks), disorderly and non-standard placement of sharp instruments (by implementing standardized placement guidelines for sharp instruments during treatment,

Table 1. Risk assessment form for needlestick injury

Factor	S	O	D	RPN value	Ranking
Medical staff					
Weak protection knowledge.	4	5	4	80	4
Protection equipment					
The utilization rate of safety equipment is low, and protection equipment cannot be obtained nearby.	4	2	2	16	7
Volume-to-caliber ratio of the sharp container does not match.	4	2	1	8	10
Insufficient number of recycling containers, inappropriate specifications, and unreasonable placement.	4	2	1	8	10
The sharp medical waste in the recycling container was not disposed of in time.	4	1	1	4	12
Work environment					
Poorly lit, crowded, noisy.	4	3	1	12	8
The placement of sharps in the treatment tray is messy and there is no uniform standard.	4	5	5	100	1
Items not ready.	4	3	2	24	6
Operational behavior					
Behaviors that do not follow the operating norms, including: returning the needle cap; failing to remove the bur in time after the doctor's diagnosis and treatment, etc.	4	5	4	80	4
Lack of concentration during operations.	4	3	1	12	8
The operation process is not standardized.	4	5	5	100	1
System guarantee					
The systems, regulations, procedures, standards, and contingency plans related to preventing needlestick injuries have not been established, revised, and optimized.	4	5	5	100	1

Note: S, scoring the severity; O, likelihood of occurrence; D, detectability; RPN, Risk Priority Number; RPN = S × O × D.

using specific boxes to classify and store sharp instruments during treatment, and placing sharp instruments in a standardized manner on the dental instrument cleaning table), non-compliance with operating procedures (by strengthening training on standardized operating procedures for healthcare workers, including proper removal of needle caps after treatment), non-standard operating procedures (by developing standardized operational procedures for the oral outpatient clinic, including personal protection, environmental preparation, item preparation, patient preparation, and standardization of the operation process), and incomplete guidelines for preventing needlestick injuries (by establishing systems for the occurrence and management of needlestick injury, including evaluation for needlestick injury prevention and establishing a risk management for needlestick injury).

Indicator observation

The primary indicators were RPN and incidence of needlestick injury incidents. The secondary indicators included the mastery rate of healthcare workers' knowledge of protection, awareness of prevention score, prevention behavior score, and management satisfaction level. (1) RPN: RPN was calculated using the FMEA method formula, where a higher score indicates a higher risk coefficient of failure. (2) Needlestick injury incidents: The frequency of needlestick injuries and the number of affected individuals were recorded, and the incidence rate was calculated as the number of occurrences divided by the total population. (3) Mastery rate of healthcare workers' knowledge of protection: This was assessed using a self-made questionnaire "Knowledge of Needlestick Injury Protection for Dental Clinic Healthcare Workers", comprising 20 items scored from 1 to 5 points per item. A higher score indicates better protection knowledge, with scores below 60 indicating inadequate knowledge (not mastered), scores between 60 and 80 indicating basic knowledge (basic understanding), and scores above 80 indicating proficient knowledge (mastered). The mastery rate (%) = (the number of items with basic understanding + the number of mastered)/the total number * 100. (4) Awareness of prevention score and prevention behavior score: A self-made questionnaire "Prevention Awareness and Behavior of Needlestick Injury Protection for Dental Clinic Healthcare Workers" was used for evaluation. For awareness, the subjects responded to the questionnaire with score of 4 (very necessary) to 0 (unnecessary). For the evaluation of behavior, the subjects responded with score of 4 (always) to 0 (never). (5) Satisfaction rate of management: A self-made questionnaire "Satisfaction with Needlestick Injury Management for Dental Clinic Healthcare Workers" was employed for assessment using a scale of 1 to 5, covering aspects such as training, regulations, signage, and work environment. Scores below 12 indicate dissatisfaction; scores between 12 and 16 indicate basic satisfaction; and scores above 16 indicate satisfaction. Satisfaction rate (%) = (the number of basic satisfaction + the number of satisfaction)/the total number * 100.

Statistical methods

Statistical analyses were performed using SPSS version 22.0 software. Continuous variables were presented as mean ± standard deviation (SD), and comparisons between the two groups were conducted using the independent samples t-test. Categorical variables were expressed as frequencies or percentages, and the chi-square test was used for comparison. A *p*-value less than 0.05 was considered significant.

Results

Basic data

This study included 37 oral healthcare personnel, comprising 10 males and 27 females. The age ranged from 23 to 70 years, with an average age of (34.7+5.54) years old. The length of service varied from 1 to 40 years, with an average of (9.27±1.48) years. Among them, 6 had junior college or lower degrees, 12 had bachelor's degrees, and 19 had master's degrees or above.

Comparison of RPN scores between the two groups

Risk management based on the FMEA method in the research group identified weak protection knowledge, disorganized placement of sharp instruments, failure to follow opera-

Table 2. Comparison of RPN scores between the two groups

Group	*n*	Weak protection knowledge	Disorganized placement of sharps	Operational norms not implemented	Irregular operating procedures	Inadequate regulations to prevent needlestick injury
Control group	37	80.13±10.31	99.46±13.52	78.35±10.07	98.16±12.76	97.12±12.25
Research group	37	18.36±2.67	12.37±2.04	24.31±3.71	8.15±1.27	8.26±1.33
t		35.280	38.744	30.630	42.697	43.866
P		<0.001	<0.001	<0.001	<0.001	<0.001

RPN, Risk Priority Number.

Table 3. Comparison of needlestick injury incidents between the two groups

Group	*n*	Number of incidents	Incidence rate
Control group	37	2.57±0.52	8 (21.62)
Research group	37	1.50±0.33	2 (5.41)
t/χ^2		10.383	4.163
P		<0.001	0.041

tional protocols, non-standardized operational procedures, and inadequate guidelines for preventing needlestick injuries as the top 5 failure modes. The RPN scores in the research group were significantly lower than those in the control group (P<0.01), as shown in **Table 2**.

Comparison of needlestick injury incidents between the two groups

In the control group, the average number of needlestick injury occurrences was 2.57±0.52, with an incidence of 21.62%, while in the research group, it was 1.50±0.33, with an incidence of 5.41%. The research group exhibited a lower frequency and incidence rate of needlestick injury compared to the control group (P<0.05), as shown in **Table 3**.

Comparison of mastery rate of protection knowledge between the two groups

In the control group, 6 subjects did not master the knowledge, 14 had a basic understanding, and 14 mastered the knowledge, while in the research group, these figures were 0, 19, and 18 subjects, respectively. The research group demonstrated a higher mastery rate of healthcare workers' knowledge of protection compared to the control group (P<0.05), as shown in **Table 4**.

Comparison of prevention awareness and behavior between the two groups

In the control group, the prevention awareness score was 33.55±4.89 and the prevention behavior score was 47.13±7.56, while in the research group, the awareness score was 49.64±6.32 and behavior score was 69.36±6.34. The research group showed higher scores in both prevention awareness and behavior compared to the control group (P<0.01), as shown in **Table 5**.

Comparison of satisfaction rate of management between the two groups

In the control group, 8 subjects were dissatisfied with the management method, 17 were basically satisfied, and 12 were satisfied, while in the research group, there were 1, 20, and 16 subjects, respectively. The research group exhibited a higher rate of management satisfaction compared to the control group (P<0.05), as shown in **Table 6**.

Discussion

Use of the FMEA method has garnered considerable attention in the medical field [6, 7]. In this study, we applied the FMEA method to manage the risks associated with needlestick injury among dental outpatient medical staff. Our findings revealed that the research group exhibited lower RPN scores for the top five failure modes compared to the control group. Additionally, the research group demonstrated a higher level of knowledge regarding protective measures. These results suggest that risk management strategies based on the FMEA method effectively enhance the needlestick injury protection capabilities of medical staff. This improvement can be attributed to the successful identification of needlestick injury-relat-

Table 4. Comparison of mastery rate of protection knowledge between the two groups

Group	*n*	Not mastered	Basic understanding	Mastered	Mastery rate
Control group	37	6 (16.22)	17 (45.95)	14 (37.83)	31 (83.78)
Research group	37	0 (0.00)	19 (51.35)	18 (48.65)	37 (100.00)
χ^2					4.534
P					0.033

Note: The mastery rate (%) = (the number with basic understanding + the number attaining mastery)/the total number * 100.

Table 5. Comparison of prevention awareness and behavior scores between the two groups

Group	*n*	Awareness of prevention	Prevention behavior
Control group	37	33.55±4.89	47.13±7.56
Research group	37	49.64±6.32	69.36±6.34
t/χ^2		7.569	6.348
P		<0.001	<0.001

Table 6. Comparison of satisfaction rate of management between the two groups

Group	*n*	Dissatisfied	Basically satisfied	Satisfied	Satisfaction rate
Control group	37	8 (21.62)	17 (45.95)	12 (32.43)	29 (78.38)
Research group	37	1 (2.70)	20 (54.05)	16 (43.24)	36 (97.30)
χ^2					4.554
P					0.033

ed risk factors [11, 12]. Through the FMEA method, we identified the top five failure modes, which included insufficient knowledge of protective measures, improper placement of sharp instruments, failure to adhere to operational protocols, non-standardized operating procedures, and deficiencies in preventive measures for needlestick injuries. To address these factors, a range of targeted measures were implemented. These measures encompassed the establishment of systems for both the occurrence and management of needlestick injuries, the introduction of comprehensive training programs, the implementation of assessment and evaluation systems to enhance knowledge related to needlestick injury prevention, the deployment of risk management systems specifically tailored for needlestick injury protection, the standardization of operating procedures, and the provision of regular training and assessment. By implementing these measures, the risk of needlestick injury was effectively reduced, reflected by a significant decrease in the RPN values associated with the identified failure modes. As a result, the awareness, knowledge, and skills of medical staff regarding needlestick injury prevention were enhanced.

The dental department is considered a high-risk area for occupational exposure due to the inherent nature of its work, which involves the examination, diagnosis, and treatment of oral diseases. With a considerable influx of mobile patients on a daily basis and the use of various sharp instruments, medical personnel within this department frequently encounter scenarios that elevate the likelihood of needlestick injuries [13, 14]. Our study results demonstrated that the research group exhibited a reduced frequency and rate of needlestick injuries compared to the control group. This observation highlights the efficacy of risk management strategies grounded in the FMEA method in mitigating needlestick injury occurrence among dental outpatient medical staff. The success in reducing needlestick injury among dental outpatient medical staff can be attributed to the identification of risk factors through the application of the FMEA method. This proactive approach allowed for the early estimation of potential risks within high-risk areas [15, 16], facilitating the timely revision of nursing systems and operational procedures. Subsequently, the prompt implementation of appropriate preventive measures by medical staff effectively improved their awareness, knowledge, and skills concerning needlestick injury prevention. Consequently, these concerted efforts have resulted in the prevention of accidents during their work, thereby improving overall occupational safety and reducing the incidence of needlestick injury among medical staff [17, 18].

Moreover, our study revealed that the research group exhibited higher satisfaction with management compared to the control group. This outcome suggests that implementing risk management strategies based on the FMEA method can improve the management satisfaction of dental outpatient medical staff. This improvement can be attributed to the proactive identification of potential failures and the subsequent formulation of effective solutions. By addressing these identified risks in a timely manner, the awareness and skills of dental outpatient medical staff regarding needlestick injury protection are significantly bolstered. Consequently, reduced the occurrence of needlestick injuries and fostered greater recognition and acceptance of management efforts, which was reflected in the overall management satisfaction [19, 20].

In conclusion, the application of risk management strategies grounded in the FMEA method enhances the needlestick injury protection capabilities of dental outpatient medical staff, reduces the incidence of needlestick injury, and elevates management satisfaction. Therefore, advocating for its clinical implementation is strongly recommended. However, it is imperative to acknowledge a limitation of our study, particularly its small sample size. Thus, further multi-center studies with larger sample sizes are warranted to validate these findings.

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Disclosure of conflict of interest

None.

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References

[1] Lv Q and Bi XQ. Occupational exposure risks and progress in prevention and control of oral outpatient medical personnel. Chin J Disinfect 2023; 40: 150-154.

[2] Shintani T, Iwata T, Okada M, Nakaoka M, Yamasaki N, Fujii T and Shiba H. Clinical outcomes of post-exposure prophylaxis following occupational exposure to human immunodeficiency virus at dental departments of hiroshima university hospital. Curr HIV Res 2020; 18: 475-479.

[3] Wang DH and Wang Q. Analysis of occupational exposure causes and preventive measures for blood collection and supply personnel. Chin J Blood Transfus 2021; 34: 1266-1268.

[4] Liu HC, Zhang LJ, Ping YJ and Wang L. Failure mode and effects analysis for proactive healthcare risk evaluation: a systematic literature review. J Eval Clin Pract 2020; 26: 1320-1337.

[5] Pei XL, Hao L, Wang S, Guan L, Liu HJ, Cai X, Dong YT and Meng J. The role of failure mode and effects analysis in constructing a safe infusion demonstration ward. Chin J Emerg Resusc Disaster Med 2022; 17: 1295-1299.

[6] Leeftink AG, Visser J, de Laat JM, van der Meij NTM, Vos JBH and Valk GD. Reducing failures in daily medical practice: healthcare failure mode and effect analysis combined with computer simulation. Ergonomics 2021; 64: 1322-1332.

[7] Zhao X, Wang LH, Zhao X, Chen LO, Zhao HJ, Zhang JL, Ma WH and Han X. Hospital infection risk management practices of disinfection supply center based on the failure mode and effect analysis method. Chin J Nosocomial Infect 2020; 30: 945-950.

[8] Zhang H and Sheng XY. Application of failure mode and effect analysis in the safety management of neonatal indwelling venous catheter in nursing. Nurs Pract Res 2023; 20: 282-285.

[9] Anjalee JAL, Rutter V and Samaranayake NR. Application of Failure mode and effect analysis (FMEA) to improve medication safety: a systematic review. Postgrad Med J 2021; 97: 168-174.

[10] Shu YM, Peng CM, Huang Y and Wu YB. Application of failure mode and effect analysis nursing model in the safe management of patients with sinusitis combined with adenoid hypertrophy in the operating room. Pract J Clin Med 2022; 19: 147-150.

[11] Chilakamarri P, Finn EB, Sather J, Sheth KN, Matouk C, Parwani V, Ulrich A, Davis M, Pham L, Chaudhry SI and Venkatesh AK. Failure mode and effect analysis: engineering safer neurocritical care transitions. Neurocrit Care 2021; 35: 232-240.

[12] Sun L, Xu YL and Meng Y. Application of medical failure mode and effect analysis in preoperative safety management of emergency ec-

topic pregnancy patients. Shanghai Nurs 2022; 22: 55-58.
[13] Wang Y, Zhang LJ, Zhang S, Cao X and Li S. Impact of 5S management model on nursing quality and adverse events in oral outpatient department. Int J Nurs 2023; 42: 5-8.
[14] Jeon S, Chong MJ, Jin G, Walsh LJ, Zachar J and Zafar S. A retrospective analysis of non-sharps-related injuries in a dental school. Int Dent J 2022; 72: 470-475.
[15] van Daalen FV, Smeulers M, Bartels EJH, Holleman F, Visser CE and Geerlings SE. A healthcare failure mode and effect analysis to optimise the process of blood culture performance. Neth J Med 2020; 78: 341-348.
[16] Liu JY, Zhang XY, Ren MX, Shen X, Jiang Y and Ma DM. Application of FMEA in preventing surgical site infection in patients with critical chest trauma. Chin J Nosocomial Infect 2019; 29: 2971-2975.
[17] Subriadi AP and Najwa NF. The consistency analysis of failure mode and effect analysis (FMEA) in information technology risk assessment. Heliyon 2020; 6: e03161.
[18] Wang CY, Shen Y and Lu XF. Application of medical failure mode and effect analysis in safe handover in anesthesia recovery room. J Nurs Contin Educ 2021; 36: 1782-1785.
[19] Liu Y, Zhu W, Le S, Wu W, Huang Q and Cheng W. Using healthcare failure mode and effect analysis as a method of vaginal birth after caesarean section management. J Clin Nurs 2020; 29: 130-138.
[20] Zhang S, Zheng J, Liu XF, Jiang SY, Guo XY and Li BB. Application of HFMEA model in pressure management of cuff in patients with artificial airway. Chin J Crit Care Med 2023; 269-273.