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
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 method in 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, disorderly and non-standard placement of sharp instruments (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

<table>
<thead>
<tr>
<th>Factor</th>
<th>S</th>
<th>O</th>
<th>D</th>
<th>RPN value</th>
<th>Ranking</th>
</tr>
</thead>
<tbody>
<tr>
<td>Medical staff</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Weak protection knowledge.</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td>Protection equipment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The utilization rate of safety equipment is low, and protection equipment cannot be obtained nearby.</td>
<td>4</td>
<td>2</td>
<td>2</td>
<td>16</td>
<td>7</td>
</tr>
<tr>
<td>Volume-to-caliber ratio of the sharp container does not match.</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>Insufficient number of recycling containers, inappropriate specifications, and unreasonable placement.</td>
<td>4</td>
<td>2</td>
<td>1</td>
<td>8</td>
<td>10</td>
</tr>
<tr>
<td>The sharp medical waste in the recycling container was not disposed of in time.</td>
<td>4</td>
<td>1</td>
<td>1</td>
<td>4</td>
<td>12</td>
</tr>
<tr>
<td>Work environment</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Poorly lit, crowded, noisy.</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>The placement of sharps in the treatment tray is messy and there is no uniform standard.</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>100</td>
<td>1</td>
</tr>
<tr>
<td>Items not ready.</td>
<td>4</td>
<td>3</td>
<td>2</td>
<td>24</td>
<td>6</td>
</tr>
<tr>
<td>Operational behavior</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>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.</td>
<td>4</td>
<td>5</td>
<td>4</td>
<td>80</td>
<td>4</td>
</tr>
<tr>
<td>Lack of concentration during operations.</td>
<td>4</td>
<td>3</td>
<td>1</td>
<td>12</td>
<td>8</td>
</tr>
<tr>
<td>The operation process is not standardized.</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>100</td>
<td>1</td>
</tr>
<tr>
<td>System guarantee</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>The systems, regulations, procedures, standards, and contingency plans related to preventing needlestick injuries have not been established, revised, and optimized.</td>
<td>4</td>
<td>5</td>
<td>5</td>
<td>100</td>
<td>1</td>
</tr>
</tbody>
</table>

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-
FMEA-based risk management

**Table 2. Comparison of RPN scores between the two groups**

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Weak protection knowledge</th>
<th>Disorganized placement of sharps</th>
<th>Operational norms not implemented</th>
<th>Irregular operating procedures</th>
<th>Inadequate regulations to prevent needlestick injury</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>37</td>
<td>80.13±10.31</td>
<td>99.46±13.52</td>
<td>78.35±10.07</td>
<td>98.16±12.76</td>
<td>97.12±12.25</td>
</tr>
<tr>
<td>Research group</td>
<td>37</td>
<td>18.36±2.67</td>
<td>12.37±2.04</td>
<td>24.31±3.71</td>
<td>8.15±1.27</td>
<td>8.26±1.33</td>
</tr>
<tr>
<td>( t )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>( P )</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

RPN, Risk Priority Number.

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

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Number of incidents</th>
<th>Incidence rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>37</td>
<td>2.57±0.52</td>
<td>8 (21.62)</td>
</tr>
<tr>
<td>Research group</td>
<td>37</td>
<td>1.50±0.33</td>
<td>2 (5.41)</td>
</tr>
<tr>
<td>( t/\chi^2 )</td>
<td></td>
<td>10.383</td>
<td>4.163</td>
</tr>
<tr>
<td>( P )</td>
<td></td>
<td>&lt;0.001</td>
<td>0.041</td>
</tr>
</tbody>
</table>

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.

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 injuries 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 (P<0.01), as shown in Table 2. 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

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Not mastered</th>
<th>Basic understanding</th>
<th>Mastered</th>
<th>Mastery rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>37</td>
<td>6 (16.22)</td>
<td>17 (45.95)</td>
<td>14 (37.83)</td>
<td>31 (83.78)</td>
</tr>
<tr>
<td>Research group</td>
<td>37</td>
<td>0 (0.00)</td>
<td>19 (51.35)</td>
<td>18 (48.65)</td>
<td>37 (100.00)</td>
</tr>
</tbody>
</table>

$\chi^2$ 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

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Awareness of prevention</th>
<th>Prevention behavior</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>37</td>
<td>33.55±4.89</td>
<td>47.13±7.56</td>
</tr>
<tr>
<td>Research group</td>
<td>37</td>
<td>49.64±6.32</td>
<td>69.36±6.34</td>
</tr>
</tbody>
</table>

$t/\chi^2$ 7.569  6.348  
$P <0.001 $<0.001$

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

<table>
<thead>
<tr>
<th>Group</th>
<th>n</th>
<th>Dissatisfied</th>
<th>Basically satisfied</th>
<th>Satisfied</th>
<th>Satisfaction rate</th>
</tr>
</thead>
<tbody>
<tr>
<td>Control group</td>
<td>37</td>
<td>8 (21.62)</td>
<td>17 (45.95)</td>
<td>12 (32.43)</td>
<td>29 (78.38)</td>
</tr>
<tr>
<td>Research group</td>
<td>37</td>
<td>1 (2.70)</td>
<td>20 (54.05)</td>
<td>16 (43.24)</td>
<td>36 (97.30)</td>
</tr>
</tbody>
</table>

$\chi^2$ 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.

Acknowledgements

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Disclosure of conflict of interest

None.

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