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Original Article

Effects of healthcare failure mode and effect analysis on the prevention of multi-drug resistant organisms infections in oral and maxillofacial surgery

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Abstract: Objective: Care models of Healthcare Failure Mode and Effect Analysis (FMEA) were evaluated for the prevention of multi-drug resistant organisms (MDRO) infections in oral and maxillofacial surgery. Methods: Two hundred patients who received oral and maxillofacial surgery from January to December 2017 were enrolled as the control group, and another 200 patients who received oral and maxillofacial surgery from January to December 2018 were enrolled as the FMEA group. The incidence of MDRO, the implementation of preventive and control measures, the mastery of preventive and control knowledge, and oral self-care ability were compared between the two groups. Risk Priority Number (RPN) and behavioral changes of health care personnel were observed in FMEA group. Results: The FMEA group had a lower incidence of MDRO (2.00%) than the control group (6.00%) and a higher rate of acquisition of prevention and control knowledge (93.00%) than the control group (84.50%) ($P < 0.05$). Patients in FMEA group were higher than those in the control group in terms of compliance towards isolation signs and precautions, appropriate use of PPE, implementation of disinfection measures, hand hygiene and exercise of self-care agency (ESCA) scale scores ($P < 0.05$). The total RPN score of the FMEA group before and after management was 1384 and 180, respectively, and the reduction rate of total RPN scores was 86.99%. Scores with regard to knowledge, attitude, and behavior of health care personnel were increased after FMEA treatment ($P < 0.05$). Conclusion: The nursing model of FMEA for oral and maxillofacial surgery can prevent MDRO infections, reduce RPN, improve the implementation of preventive and control measures as well as oral self-care ability and the acquisition of knowledge.

Keywords: Oral and maxillofacial surgery, healthcare failure mode and effect analysis, multi-drug resistant organisms

Introduction

Oral and maxillofacial surgery is mainly performed in maxillofacial fracture repair, soft-tissue repair, and treatment of cleft lip and palate, head and neck tumors, *etc*. Due to the rich blood circulation and complex anatomical structure of the oral and maxillofacial region, surgery can easily destroy the micro-ecological balance of the oral cavity, and coupled with the widespread use of antimicrobial drugs, it is easy to cause hospital infections and prolong hospitalization time [1-3]. Multi-drug resistant organism (MDRO) is one of the main pathogenic bacteria of hospital infections, and MDRO refers to bacteria that are resistant to the clinical application of ≥3 classes of antimicrobial drugs, due to the misuse of antimicrobial drugs and adaptive mutations [4]. Hospital infections have become a major challenge in hospital nursing management due to its rapid spread, complexity, and refractory nature. Therefore, how to strengthen the standardization and professionalism of nursing management and improve the efficiency of MDRO management has become a hotspot in the prevention and control of MDRO infection [5, 6].

Healthcare Failure Mode and Effect Analysis (FMEA) is a systematic, proactive method to evaluate the process to identify where and how it might fail and to assess the relative impact of different failures, in order to identify the parts of the process that most need to change, aim-

ing at improving the hospital infection management and preventing hospital infections [7, 8]. A study by Wu et al. [9] reported that the FMEA model was used in cardiology inpatients to help reduce the rate of hospital-acquired infections and improve hand hygiene compliance among caregivers. Currently, there are few clinical studies on the use of the FMEA model in oral and maxillofacial surgery. Therefore, the effectiveness of FMEA in the prevention of MDRO infections in oral maxillofacial surgery was conducted to provide a clinical reference.

Materials and methods

Clinical data

Two hundred patients admitted to the department of oral and maxillofacial surgery from January to December 2017 were enrolled as the control group. Another 200 patients admitted to the same department from January to December 2018 were selected as the FMEA group. Inclusion criteria: patients aged ≥ 18 years; patients with normal cognitive and communicative functions; patients with accurate comprehension of the scales; patients who met the indications for surgery; patients with high compliance towards nursing and investigation; and patients who voluntarily signed the informed consent. Exclusion criteria: patients who had concomitant systemic diseases such as salivary gland diseases, diabetes, *etc*.; mental disorders; recurrence after tumor resection; and women during pregnancy and lactation. The FMEA team consisted of 11 members, including one chief physician, one deputy chief physician, one nurse administrator, one professor of nursing, two co-chief nurses, and five nursing supervisors, aged 31-54 years, with a mean age of 39.6±3.2 years; with 10-34 years of experience and a mean experience of 19.6± 5.2 years. This study has been approved by the Ethics Committee of The Second Affiliated Hospital of Hainan Medical University.

Methodology

Establishment of FMEA team: With the chief physician as the team leader, FMEA model training was conducted for team members. The department regularly held meetings to brainstorm and analyze the main causes of MDRO infections in oral and maxillofacial surgery, assess risks, summarize the causes, and analyze the mechanism and efficacy. The severity (S), occurrence (O), and detection (D) were determined to calculate Risk Priority Number (RPN). RPN = S×O×D, scoring 1-1000. The risks of failure and improvement in demand are positively correlated with the scores.

Failure mode analysis: The priority of rectification of failure effects was determined according to the RPN and failure causes were discussed and analyzed according to the literature and clinical experience.

*Development of a proposed change (**Table 1**)*

Outcome measurements: (1) Incidence of MDRO infection. The incidence of MDRO infection in the two groups of patients refers to the Chinese Expert Consensus on the Prevention and Control of Hospital Infections [10]. The pathogenic bacteria mainly include *Acinetobacter baumannii*, *Escherichia coli*, *Pseudomonas aeruginosa*, and *Staphylococcus aureus*.

(2) Implementation of preventive and control measures. Compliance towards isolation signs and precautions, appropriate use of PPE, implementation of disinfection measures, and hand hygiene were compared between the two groups.

(3) Knowledge of prevention and control. The MDRO infection questionnaires were compiled by the Hospital Infection Prevention and Control Center and distributed to patients, including theoretical knowledge, key points of operation, and the importance of prevention and control, *etc*. Complete mastery: 85-100 points; partial mastery: 60-84 points; no mastery: 0-59 points. The total mastery rate = Partial mastery + Complete mastery.

(4) Oral self-care ability. On the basis of Exercise of Self-care Agency (ESCA) scale [11], patients' oral self-care abilities were assessed in four areas, including self-care responsibility (0-24 points), self-concept (0-32 points), health literacy (0-68 points), and self-care skills (0-48 points), with 172 points in total. The score is positively correlated with self-care abilities.

(5) RPN. The RPN for each failure mode was calculated before and after management in the FMEA group. The reduction rate = (Pre-nursing RPN - Post-nursing RPN/Pre-nursing RPN × 100%.

Table 1. Causes of failure modes and improvement measures in oral maxillofacial surgery regarding MDRO infection

Failure mode	Causes	Improvement measures	S	O	D	RPN
Inadequate surface disinfection	Incomplete disinfection; incorrect use of protective equipment	Strengthen the awareness of sterility of medical and nursing staff; Strengthen the frequency of disinfection; Clarify the criteria for wiping surfaces; Refine the operating procedures and environmental cleaning order; Wipe infusion pumps, monitors and blood pressure monitors and other medical equipment in the ward by the nurses.	7	6	6	252
Poor compliance with hand hygiene	Inadequate hand hygiene training, facilities and supervision	Make use of study days, morning meetings, *etc*., to carry out hand hygiene training or lectures; Instruct patients in six-step washing techniques; Attach importance to pre-service training, and on duty only after passing the examination; Learn knowledge of MDRO infection; Place hand disinfection items at the patient's bedside; Place quick-drying hand disinfectant in front of the ward door.	7	7	8	392
Inadequate visitor management	Inadequate supervision; no health promotion for visitors	Strengthen supervision and supervise the implementation of the work; Strictly limit the number of visitors and the time for visits; Conduct health education for patients and their families; Inform them of the risks of cross-infection and make them understand the necessity of restricting visits; Attention to personal protection, wear gloves and masks or isolation gowns when in contact with patients' mucous membranes, drains, blood and wounds.	3	6	7	126
Inadequate early warning mechanisms	Undefined management systems; improper early warning mechanisms	Establish early warning mechanisms for drug resistance; Install a sensing monitoring system for infection and control, which connected with the network of clinical electronic medical records and the microbiology room of the testing department. Pan-drug resistance and multi-drug resistance data was recorded in hospital sensing system.	6	6	5	180
Inadequate oral care and health education	The level of importance that each patient places on oral care is different; lack of sufficient professional knowledge; monotonous health education content and method	Strengthen the training and assessment of medical and nursing personnel; Encourage more communication between doctors, nurses and patients through playing videos, issuing health manuals, carrying out special lectures, establishing communication platforms and other forum; Observe whether the oral mucosa showed bad taste, ulcers and bleeding.	6	5	6	180
Irregularities in medical care procedures	Lack of standardized process; isolation measures not in place	Improve the diagnosis and treatment process; formulate a detailed handover system, requiring "one inspection", "four visits", "five checks" and "seven clearances"; Identify patients with high risk of MDRO infection and do the ward deployment work in advance; strengthen the management of nebulization, sputum, urinary catheterization and other operations; Once diagnosed, isolate the bedside, with private use of all kinds of items.	6	5	7	210
Isolation signs are not visible or not displayed	Failure to set isolation sign; failure to follow medical advice on exposure related isolation	Increase the number of quarantine signs and post them prominently; For suspected MDRO infections, they need to be managed by marking them in the medical record folder; When they are released from quarantine, they need to be notified.	3	6	8	144

Table 2. The baseline data ($\bar{X}$ ± sd)

Group	M/F	Age (years)	Body mass index (kg/m^2)	Education level	Type of disease
				Junior high school and below/high school and college/undergraduate and above	Maxillofacial tumor/Maxillofacial trauma/Congenital dysplasia/Cleft lip and palate/Other
Control group (n=200)	119/81	45.69±6.28	22.36±2.11	68/92/40	47/61/40/32/20
FMEA group (n=200)	123/77	44.98±5.17	22.19±2.54	62/95/43	49/56/42/34/19

Table 3. Comparison of MDRO incidence before and after FMEA model (%)

Group	*Acinetobacter baumannii*	*Escherichia coli*	*Pseudomonas aeruginosa*	*Staphylococcus aureus*	Total incidence
Control group (n=200)	6 (3.00)	1 (0.50)	1 (0.50)	4 (2.00)	12 (6.00)
FMEA group (n=200)	3 (1.50)	0 (0.00)	0 (0.00)	1 (0.50)	4 (2.00)
χ^2					4.167
P					0.041

(6) Behavioral change questionnaire. A self-administered questionnaire was used to assess the attitudes, knowledge and behaviors of the FMEA group before and after implementation of FMEA model. Attitudes were evaluated in terms of infection characteristics, routes of transmission, attitudes and the role of healthcare providers during prevention and control, with 12 items covering 12-60 points. Knowledges were evaluated in terms of disinfection of environmental surfaces, MDRO infection, PPE, key points of isolation, hand hygiene and dirt disposal, with 26 items covering 26-78 points; behaviors were assessed regarding antibiotic use, dirt disposal, personal protection, isolation, prescribing, and environmental disinfection, with 35 items covering 0-140 points.

Statistical analysis

Using SPSS 23.0, the measurement data conforming to normal distribution were expressed as $\bar{x}$ ± sd and examined using independent samples *t* test. Count data (%) were examined using χ^2 test. GraphPad Prism 8 was used for plotting charts. $P < 0.05$ indicated statistically significant difference.

Results

General information

There was no significant difference in age, body mass index and composition ratio of gender, education level and disease type between the two groups ($P > 0.05$), indicating that the two groups were comparable (**Table 2**).

FMEA model reduced the incidence of MDRO

The incidence of MDRO was 2.00% in the FMEA group (4/200), lower than 6.00% in the control group (12/200) ($P < 0.05$), indicating that the FMEA model could help reduce the incidence of MDRO in oral and maxillofacial surgery (**Table 3**).

FMEA model facilitated the implementation of preventive and control measures

The percentage of patients in the FMEA group with high compliance to preventive measures was higher than that in the control group ($P < 0.05$), suggesting that FMEA model could facilitate the implementation of preventive and control measures in oral and maxillofacial surgery (**Table 4**).

FMEA model enhanced the mastery of prevention and control knowledge

The total mastery rate was 93.00% in the FMEA group, higher than 84.50% in the control group ($P < 0.05$), showing that the FMEA model could enhance the mastery of prevention and control knowledge (**Table 5**).

FMEA model improved the oral self-care abilities

Patients in the FMEA group had higher ESCA scores than those in the control group ($P < 0.05$), indicating that the FMEA model was beneficial for improving patients' oral self-care ability (**Figure 1**).

Table 4. Comparison of the implementation of preventive and control measures (%)

Group	Isolation signs	Contact isolation precautions	Proper use of PPE	Disinfection measures implemented	Hand hygiene compliance
Control group (n=200)	156 (78.00)	141 (70.50)	167 (87.50)	161 (80.50)	170 (85.00)
FMEA group (n=200)	173 (86.50)	163 (81.50)	181 (90.50)	178 (89.00)	185 (92.50)
χ^2	4.949	6.634	4.332	5.590	5.634
P	0.026	0.010	0.037	0.018	0.018

Table 5. Comparison of mastery of knowledge of prevention and control [n (%)]

Group	Complete mastery	Partial mastery	No mastery	The mastery rate
Control group (n=200)	74 (37.00)	95 (47.50)	31 (15.50)	169 (84.50)
FMEA group (n=200)	101 (50.50)	85 (42.50)	14 (7.00)	186 (93.00)
χ^2				7.237
P				0.007

FMEA model reduced RPN

Pre- and post-RPN values were 1384 and 180, respectively in the FMEA group, with a reduction rate of 86.99%, indicating a significant improvement (**Table 6**).

FMEA model improved the knowledge, attitude, and behavior of health care workers in prevention and control

The knowledge, attitude, and behavior scores of health care workers were improved in the FMEA group ($P < 0.05$), indicating that FMEA model could improve the knowledge, attitude, and behavior of health care workers in prevention and control (**Table 7**).

Discussion

The oral cavity is directly connected with the external environment, and its internal environment is subjected to the reproduction and host of pathogenic microorganisms. Therefore, maintaining the ecological balance of the oral microbiome plays a key role in the prevention of infection. However, oral and maxillofacial surgery can lead to microbial imbalance, and coupled with the patient's reduced local defense functions, it is prone to inducing MDRO and hospital infections [12, 13]. MDRO infection was characterized by complex mechanism, refractory and widespread, which is not conducive to patients' physical and mental health and clinical treatment. Therefore, a standardized care management model is a critical part to prevent and control the outbreak of MDRO infection and reduce in-hospital infections [14, 15].

FMEA is a reliable and prospective analysis method that focuses on predicting and assessing the occurrence of medical events, and adopting preventive strategies according to the level of risk to reduce the occurrence of risk events [16]. Li [17] applied the FMEA model to identify the weakness during transfer of critical patients and promote the improvement of the first aid ability and transport capability of medical and nursing staff through staff training, qualification threshold, assessment and exercises; meanwhile, process control protocols were developed and risk factors with the transfer process were predicted. Transfer failures due to arbitrary changes in the process and self-simplification were avoided to ensure the safety of in-hospital transfer of critical patients. After the establishment of the FMEA team in this study, the team leader organized meetings to analyze the susceptibility of oral and maxillofacial surgery to infection, and it was found that the RPN values of seven items such as inadequate surface distinction, poor hand hygiene, inadequate visitor management, inadequate oral care and health education, confusing health care procedures, and lack of isolation signs or improper hanging of isolation are high. After the identification of failure mode and related reasons and the formulation of targeted preventive measures, the RPN values of the 7 items were reduced to varying degrees, among which oral care, health education, and the isolation signs showed significant improvement. The total reduction rate reached 86.99%, indicating that the improvement was

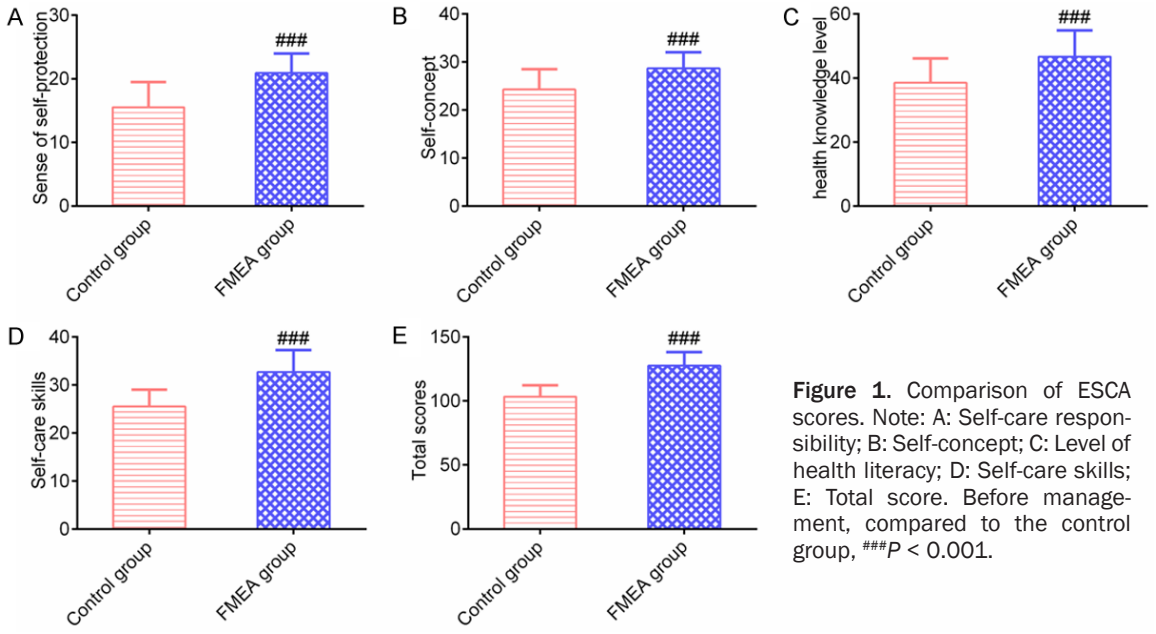

Figure 1. Comparison of ESCA scores. Note: A: Self-care responsibility; B: Self-concept; C: Level of health literacy; D: Self-care skills; E: Total score. Before management, compared to the control group, $^{###}P < 0.001$.

Table 6. Comparison of RPN in FMEA group

Item	Pre-management	Post-management	The reduction rate
Inadequate surface disinfection	252	32	87.30
Poor compliance with hand hygiene	392	56	85.71
Inadequate visitor management	126	16	87.30
Inadequate management of medical supplies	180	24	86.67
Inadequate oral care and health education	80	8	90.00
Irregularities in medical care procedures	210	28	86.67
Isolation signs are not visible or not displayed	144	16	88.89
Total scores	1384	180	86.99

Table 7. Comparison of scores on behavior change questionnaire ($\bar{x} \pm$ sd, min)

Group	Knowledge score	Attitude score	Behavioral score
Before management (n=11)	64.29±4.85	49.61±3.35	128.16±8.32
After management (n=11)	73.39±5.25	56.64±4.29	136.68±9.15
t	18.006	18.265	9.743
P	0.000	0.000	0.000

significant and the risk was effectively controlled.

This study has shown that the introduction of the FMEA model in the management of oral and maxillofacial surgical care can help reduce MDRO infection rates and improve patient knowledge and oral self-care abilities. The reason may be that this study followed the basic procedures of the FMEA model. Each member explored failure modes from human, mechanical, environmental and legal factors by brainstorming, identified defects and errors in systems or procedures, and calculated RPN to quantify potential risks, which helped determine the risk focus and priority of improvement goals, and promoted standardization of complex risk classification treatment [18, 19]. In the implementation of FMEA model, nursing supervisors and infection prevention & control department develop and perfect the relevant operating procedures and nursing system, which can implement the preventive measures and disinfection and isolation measures. These measures not only enhance the aware-

ness of health care personnel and nursing skills, but are also conducive to enhancing patients' awareness of MDRO infection and improving self-management ability. In addition to regular education, communication between doctors, nurses and patients were strengthened by the distribution of health manuals, playing videos or establishing WeChat groups, meeting the needs of patients and improving their level of comfort [20]. Regular targeted lectures, training on technical operations, theoretical knowledge and continuous quality improvement can improve the knowledge, behavior and attitude of medical staff on prevention and control of MDRO infections, and prevent infections caused by operation, medical technology, *etc*. [21, 22]. Invasive procedures such as indwelling catheters and tracheotomy can increase the chances of bacteria acquiring antibiotic resistance genes and easily induce MDRO infection. Therefore, strengthening management of catheterization and atomization is helpful to prevent pathogen colonization or transmission and prevent pathogenic microorganisms from directly entering the patient's body through the catheter. Following the surgery, affected by factors such as pain and restricted mouth opening, most patients undergoing oral and maxillofacial surgery have poor oral hygiene, while conventional oral care methods are difficult to prevent infection and clean the mouth. The flushing and cleaning method could flush foreign objects to avoid infection [23]. Hand hygiene is the most economical and simple way to prevent the spread of infection. The awareness of hand hygiene could be enhanced by six-step hand-hygiene technique recommended by the World Health Organization, placing quick-drying hand disinfectant in front of the ward, and training, which improves their compliance with hand washing, and prevents the spread of pathogenic bacteria [24, 25].

However, there are still some deficiencies in this study. Patients were not followed up after the study, and the follow-up effects of this nursing mode on patients after discharge were not studied, which will be investigated in the next study.

In summary, the FMEA model used in oral and maxillofacial surgery can prevent MDRO infection, reduce RPN values, improve the implementation of preventive and control measures, and improve patients' oral self-care ability and knowledge. However, the applicability of the FMEA model needs to be further analyzed due to the limitations of follow-up time and sample size.

Disclosure of conflict of interest

None.

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