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Applying Healthcare Failure Mode and Effect Analysis and the Development of a Real-Time Mobile Application for Modified Early Warning Score Notification to Improve Patient Safety During Hemodialysis

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Objective: Patients undergoing hemodialysis are a high-risk population. This study identified possible errors by using a healthcare failure mode and effect analysis system to improve patient safety during hemodialysis.

Methods: A multidisciplinary collaborative team, including physicians, nurses, information technicians, and medical staff members, was assembled. A flow diagram was used to indicate each process of the hemodialysis procedure from evaluating patient condition to transporting the patient back to the ward from the hemodialysis center. We scored all possible failure modes using the hazard scoring method as a combination of the occurrence frequency and severity. These potential failure modes were used to identify and evaluate possible risks by using a risk scoring matrix.

Results: Thirty failure modes were identified across 6 processes, and their potential causes were explored. Four major strategies for addressing most of the failure modes were implemented: establishment of a mobile application that sends real-time automated alerts to the medical team based on the Modified Early Warning Score, design of a modified dialysis Identify-Situation-Background-Assessment-Recommendation checklist for dialysis, technician education and training, and internal auditing and monitoring of the implementation of the entire process. After the implementation of the strategies, the hazard scores of patients during dialysis dropped by 71.2% from 170 points to 49 points.

Conclusions: The healthcare failure mode and effect analysis system was useful for evaluating potential risk during dialysis. Using the mobile application reduced the occurrence of emergency resuscitation during hemodialysis and significantly improved the communication between medical personnel.

Key Words: hemodialysis, patient safety, HFMEA, MEWS, ISBAR, mobile application

Abbreviations: ACLS - advanced cardiovascular life support, CPR - cardiopulmonary resuscitation, CRP - C-reactive protein, HFMEA -

healthcare failure mode and effect analysis, HS - hazard score, MEWS - Modified Early Warning Score, ISBAR - Identify-Situation-Background-Assessment-Recommendation, SCD - sudden cardiac death, SBP - systolic blood pressure, URR - urea reduction ratio

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Patients undergoing hemodialysis are a high-risk population among all patients receiving medical care.^{1,2} These patients often have comorbidities such as hypertension, cardiovascular disease, and diabetes.^{2,3} Taiwan has the highest prevalence of end-stage renal disease worldwide, and more than 90% of patients with end-stage renal disease receive maintenance hemodialysis.⁴ The annual report on kidney disease is an authoritative source of data about the chronic kidney disease-related databases and examines the occurrence, prevalence, death and survival, medications, hospitalization, and expenses of end-stage renal disease in Taiwan. According to the 2019 annual report on kidney disease in Taiwan, the number of dialysis cases increased from 73,274 in 2013 to 82,031 in 2017. In 2017, the average mortality rate of patients on dialysis is 11.9% (12.1% in men and 11.7% in women),⁵ and the 5-year average survival rate of patients on dialysis from 2008 to 2012 was 54.6%, which is higher than that in Europe (42.5%) and that in Canada (44.3%). More than 750 million patients currently received treatment with dialysis or kidney transplant to survival every year worldwide.⁶ Dialysis can extend a patient's life but can also increase the risk of sudden cardiac death (SCD), especially when patients also have other comorbidities, such as hypertension, diabetes, and cardiovascular disease. In addition, cardiovascular disease, peptic ulcer, and stroke are the most common complications associated with dialysis. Sudden cardiac death is the most challenging complication of hemodialysis.^{2,7}

Identifying and minimizing human errors and potential risks are crucial steps to ensuring the safety of patients in hospitals. The prevention of harmful complications in patients undergoing hemodialysis should be a priority for hospital staff members. An early alert system was established to notify hospital staff when patients experience an unexpected condition that may make them unsuitable for dialysis. Healthcare failure mode and effect analysis (HFMEA) is a useful tool for evaluating an overview of the basic procedure and healthcare system.^{8–10} Healthcare failure mode and effect analysis focuses on how to reduce, predict, and prevent medical errors. In this project, we reviewed the entire hemodialysis procedure for our hospitalized patients from the time of patient assessment to the end of dialysis. Dialysis facilities are very complex; they involve personnel from multiple disciplines and use advanced technology to care for patients with multiple serious illnesses. A hemodialysis procedure can include errors and risks, such as patient falls, medication errors (including deviation from the dialysis prescription, allergic reactions, and medication omissions), access-related events (clotting, infiltrates, poor blood flow, or difficult

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cannulation), dialyzer errors (incorrect dialyzer setting or malfunction), equipment-related sepsis, and excess blood loss or prolonged bleeding.

To improve the safety of patients undergoing hemodialysis and to prevent any intraprocedural complications, an HFMEA system was applied at our hospital hemodialysis center. We established several recommended actions to prevent any failures and errors from occurring during hemodialysis and to improve the patient safety alert system in our hospital.

METHODS

Study Population

We applied an HFMEA system to analyze each step in the hemodialysis procedure in Taichung Tzu-Chi Hospital, which is a 600-bed general teaching hospital and includes 31 medical departments. The dialysis center is a hospital-based unit with 88 beds. We offer hemodialysis and continuous ambulatory peritoneal dialysis treatments to a diverse group of adult patients who have acute and chronic kidney diseases, such as uremia syndrome, drug toxicity, serve edema, metabolic acidosis, and plasma exchange. There are approximately 2500 patients regularly undergoing hemodialysis procedure in our hospital every year. In addition, the mean number of monthly hemodialysis treatment every month was more than 3000 persons for outpatient, approximately 150 persons for intensive care unit, and approximately 220 persons for hospitalization, respectively. This team resource management project was supported by the Taichung Tzu-Chi Hospital, Buddhist Tzu-Chi

Medical Foundation. This project was mainly focused on establishment a new notification system, and this system was applied to improve clinical patient care. Anonymous data were collection in this study. The informed consent was unnecessary and waived by the research ethics committee of Taichung Tzu-Chi Hospital. This study was approved by the research ethics committee of Taichung Tzu-Chi Hospital (REC 110-02).

Implementation of HFMEA

In this project, we adopted an HFMEA system to improve patient safety during hemodialysis (Fig. 1). The 4 primary components of this HFMEA system as follows: (1) 6 major hemodialysis procedure for hospitalized patients; (2) implementation of HFMEA has 6 major steps; (3) recommended actions for improvement; and (4) outcome measures. The HFMEA team comprised a medical director and 1 associate chief nurse, 3 supervisor nurses, 1 attending physician, 1 medical technologist, 5 dialysis technicians, 1 information technician, and 1 project instructor, all of whom received 1 month of HFMEA system training. Next, they adopted the steps of the HFMEA protocol to evaluate the risk of dialysis from December 2016 to November 2017.

The implementation of HFMEA has 6 major steps¹¹: step 1, define the topic and risk; step 2, assemble a collaborative healthcare team; step 3, describe a process map of the hemodialysis procedure; step 4, conduct the hazard analysis and possible failure steps; step 5, develop and implement actions to prevent subsequent occurrence; and step 6, monitor the outcome after implementation of new actions.

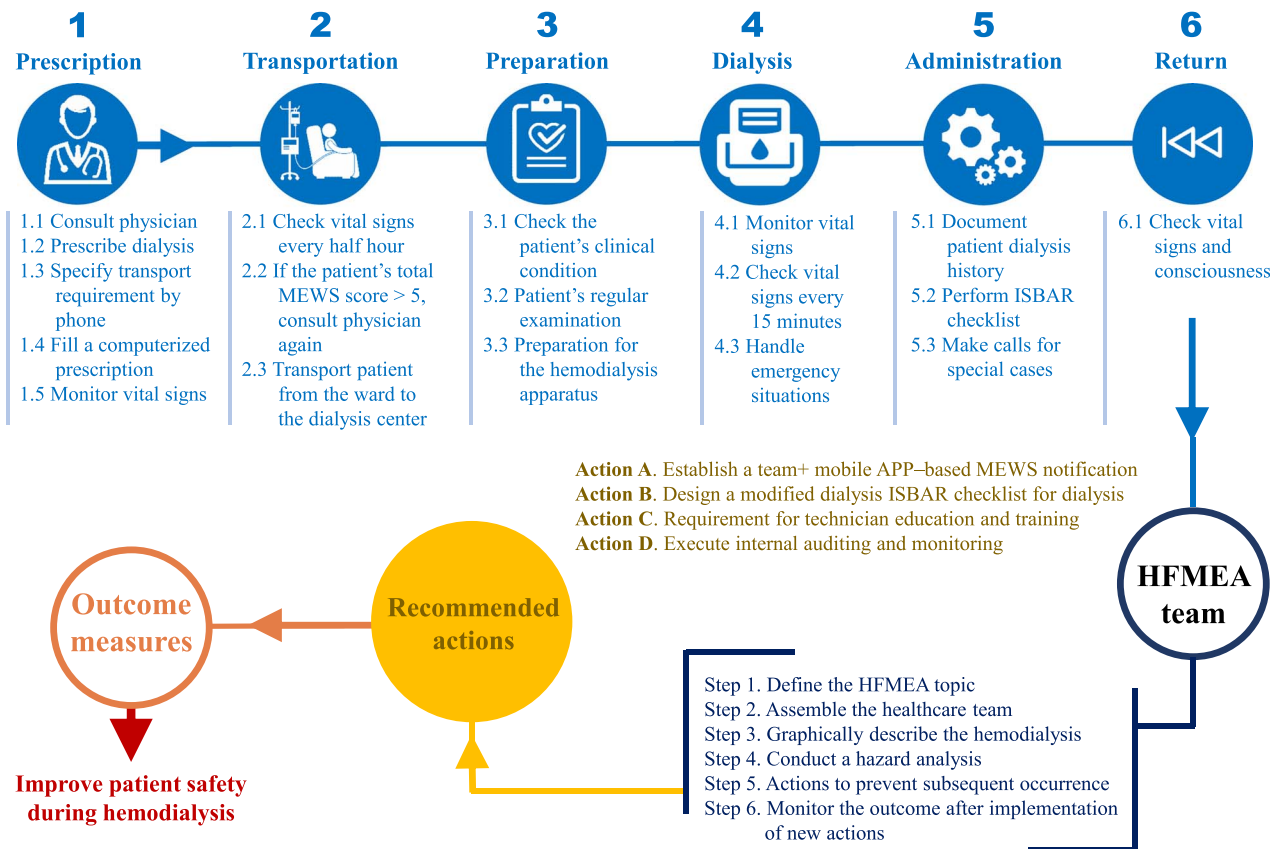


FIGURE 1. Application of HFMEA methodology to entire hemodialysis procedure for hospitalized patients. There are 4 primary components of this HFMEA system: (1) 6 major hemodialysis procedure for hospitalized patients; (2) implementation of HFMEA has 6 major steps; (3) recommended actions for improvement; and (4) outcome measures.

Step 1: Define the HFMEA Topic

This project aimed to improve patient care throughout the process of hemodialysis. We performed a retrospective analysis of 2672 patients who underwent hemodialysis between 2016 and 2017 in our hospital. Of them, 46 patients (1.72%) were recorded to have dialysis interruption, which results in insufficient dialysis time and incomplete procedures. The reasons for interruptions included unexpected complications, dialysis disequilibrium, and other severe adverse events. This project focused on preventing harm to the patients and reducing the incidence of unexpected adverse events and failure during hemodialysis.

Step 2: Assemble the Healthcare Team

A quality improvement team was assembled, including hemodialysis physicians, a head nurse, a quality control manager, and information technicians. The team used procedure flow diagramming and a hazard scoring matrix to identify and assess potential risk during dialysis. Leadership and support of all the departments involved was essential for inspiring and motivating team members to work together to achieve a goal. This team was responsible for identifying any possible failures or errors during hemodialysis, collecting data, and determining solutions or strategies to improve patient safety. The hemodialysis director was the project leader and was familiar with the operation in the hemodialysis center. The head nurse was responsible for the follow-up of any incidents and disruption in hemodialysis events such as the occurrence of SCD or complications.

Step 3: Graphically Describe the Hemodialysis

Figure 1 presents a detailed flow chart of the hemodialysis procedure constructed by the project members. The process map clarifies every step from the prehemodialysis assessment of patients, patient transfer from the ward to the hemodialysis center, preparation of hemodialysis machines, actual procedure of hemodialysis, and posthemodialysis monitoring of patient conditions.

Step 4: Conduct a Hazard Analysis

Each step of the procedure was identified and comprehensively analyzed. Next, the potential failure modes were identified for each step or subprocess. We calculated hazard scores to assess the risk of possible failure modes (see Risk Scoring Matrix). The risks were grouped according to their hazard scores and were recorded on the HFMEA worksheet. To determine the probability of failure, the score was evaluated by team members. Severity was scored according to mutual consensus among the team members with consideration for the weight of the severity of failure.

Step 5: Actions to Prevent Subsequent Occurrence

Several actions were implemented to solve grouped major failure problems. The team members helped redesign the procedure and improve existing strategies using the theory of problem solving by an inventive method and trained the staff members involved. The practicability of implementation of any actions was evaluated, and further occurrences of failure were monitored.

Step 6: Monitor the Outcome After Implementation of New Actions

By voting on new strategies and taking action, 4 major action solutions (A–D) were added to the hemodialysis procedure: establish a real-time team⁺ mobile application for Modified Early Warning Score (MEWS) notifications, design a modified dialysis Identify-Situation-Background-Assessment-Recommendation (ISBAR) checklist for dialysis, conduct technician education and training,

and undertake internal auditing and monitoring of the implementation of the procedure. A sequential procedure of hemodialysis was established. We also assessed and monitored the occurrence of interruptions during dialysis and the incident rate of complications among patients undergoing dialysis.

Risk Scoring Matrix

We used 2 factors—occurrence probability and event severity—to assess the risk (probability score) of possible failure modes. The score was obtained using a priority matrix through multiplication of the 2 factors (Fig. 2). Based on the criticality of the process, it was decided if additional safety measures were needed and what they comprise.¹² The hazard score was used to determine the risk assigned to a process, or steps in a process, as part of the HFMEA system. Each of the 11 team members independently assigned each step/process a failure mode numeric value quantifying the likelihood of occurrence and severity of impact. Next, the hazard score for the incidence of sequential processes of the dialysis procedure was jointly determined by the team members using the following formula: hazard score = severity × occurrence. In the HFMEA analysis, when the risk score is determined, the basis of the established HFMEA decision tree analysis or the failure mode should be more thoroughly investigated.¹³ The team members listed all possible failure modes for each process and identified all potential causes and consequences thereof. Finally, according to the hazard score value, the urgency of improvement was determined.

Modified Early Warning Score

Modified Early Warning Score is a part of the electronic medical records (EMR) for monitoring clinical deterioration and alerting the patient condition to the physician. Our hospital information system (HIS) is a comprehensive, integrated hospital management system, which was designed by our informatics technology department. This electronic health record system included all aspects of hospital operation and patient management, such as picture archiving and communication system, laboratory information system, nursing information system, radiology information system, etc. Therefore, we can integrate MEWS notification with this team⁺ APP together as a subsystem in our EMR. All our hospitalized patients have their vital sign check before transfer to hemodialysis. Modified Early Warning Score provides an instant and reliable prognostic score, which able to notify medical staff and monitor physiological deterioration in patients. In this project, we adapted MEWS exclusively for patients undergoing dialysis by including their vital signs and laboratory values for prompt detection of the risk of clinical deterioration during hemodialysis. A number of 0 to 3 was assigned to each of the 8 parameters (Table 1), which included respiratory rate, pulse rate, body temperature, and blood pressure as well as blood potassium, C-reactive protein (CRP), and hemoglobin (Hb) levels (Dimensions DXL; Siemens, Germany, and Sysmex XE-5000; Sysmex, Kobe, Japan). The scores for each parameter were recorded at the time of observation. A score of 0 was considered normal, scores of 1 and 2 were considered abnormal, and a score of 3 was considered critical. The scores for each parameter were summed to obtain the total score. If the total was 5 or higher, an early warning message was sent to the doctor in charge via real-time team⁺ APP.

RESULTS

Healthcare Failure Mode and Effect Analysis

By using the HFMEA analysis, we were able to proactively identify the potential causes of different failure modes and develop

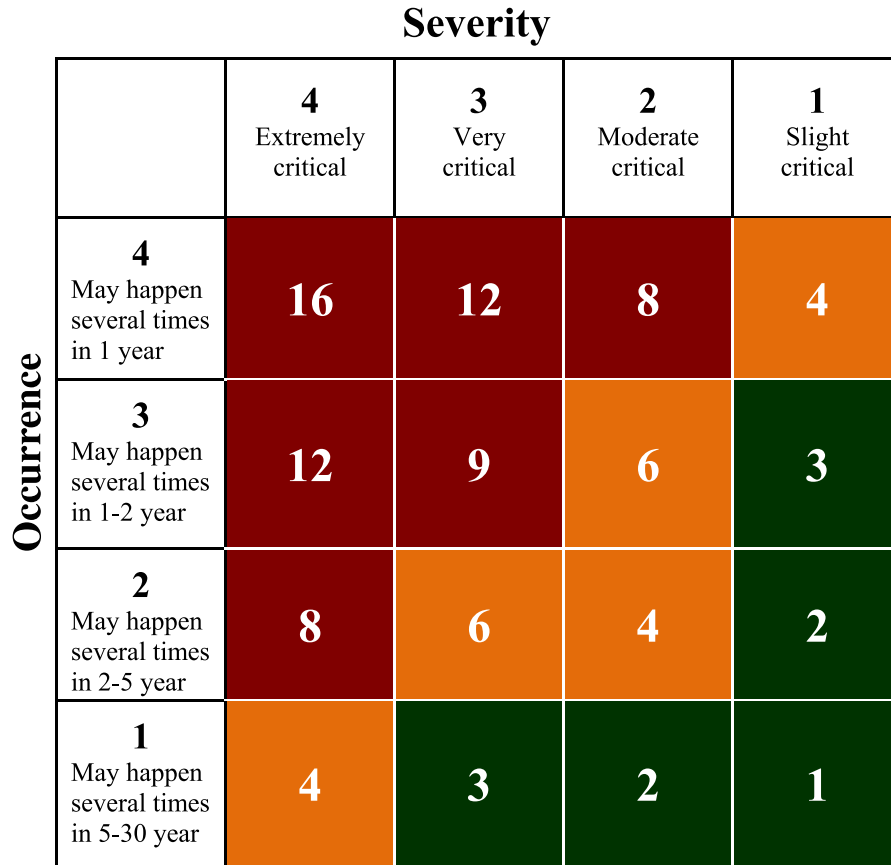


FIGURE 2. Hazard scoring matrix in healthcare failure mode and effect analysis. It was used to analyze the significance of each failure: potential failures were allocated a score for severity (1, slightly critical; 2, moderately critical; 3, very critical; and 4, extremely critical) and a score for the probability of occurrence (1, several times in 5–30 y; 2, several times in 2–5 y; 3, several times in 1–2 y, and 4, several times in 1 y).

countermeasures to minimize the occurrence of these failure modes, thereby reducing the risks associated with hemodialysis. Six major hemodialysis procedure processes were included in the HFMEA system in this study (Fig. 1): physician consultation, patient transfer from the ward to the dialysis center, patient preparation before dialysis, the dialysis procedure, patient condition after dialysis, and patient transfer back to the ward. All the potential causes for each failure mode that necessitate an action were listed. Each action was described, and outcome measures of each failure mode were identified. The team members cooperated and ensured the completion of each action.

Hazard Analysis

The team identified 6 processes, 16 subprocesses, and 30 potential failure causes (Table 2) and ranked potential failures based on the severity of their effects and occurrence. The hazard score was used to prioritize high-risk failure modes (Table 2) and determine the requirement for corrective action. The decision to pursue action is based on the detectability of the cause, the existence of current effective control measures, and the criticality of the outcome. A hazard score of 8 or higher triggered consideration of a potential action to control the failure. Of the 30 failure modes,

TABLE 1. Components of the MEWS System and Their Scores for Patients Undergoing Hemodialysis

Score	3	2	1	0	1	2	3
Respiratory rate, breath/min	—	≤8	—	9–14	15–20	21–29	>29
Pulse rate, bpm	—	≤40	41–50	51–100	—	111–129	>129
Body temperature, °C	—	≤35.0	35.1–36.0	36.1–38.0	38.1–38.5	≥38.6	—
SBP, mm Hg	≤70	71–80	81–100	101–199	—	≥200	—
Compare with previous SBP, %	≤45	≤30	≤15	Within 15	≥15	≥30	≥45
Blood potassium, mmol/L	—	—	≤2.5	>2.5–<7.0	≥7.0	—	—
CRP, mg/L	—	—	—	<1	1.01–9.99	>10	—
Hb, g/dL	<6	6.1–7.9	8.0–9.9	>10	—	—	—

TABLE 2. Healthcare Failure Mode and Effect Analysis Process of Hemodialysis Procedure

No.	Failure Modes	Potential Causes	Hazard Analysis							
			Hazard Score			Decision Tree Analysis				
			Occurrence	Severity	O × S	Single Weakness	Control	Detectability	Action	
1. Prescription										
1.1	1	No order sheet received	The physician did not verify the prescription order	3	2	6	Y	Y	→	—
	2	Physician consultation not provided in time	The physician was too busy to check on the patient	4	3	12	→	N	N	Action 1
	3	No time for a review of the patient’s history	The patient had an emergency and required urgent dialysis	3	2	6	Y	Y	→	—
1.2	4	No request sheet; only oral notification by physician	No computerized order entry was made by the physician	4	3	12	→	N	N	Action 2
	5	Dialysis not scheduled	The physician forgot to notify the dialysis department staff	3	1	3	N	→	→	—
	6	Notification received only by the dialysis center and not by the ward	The physician notified only the ward nurse but not the dialysis department staff	2	2	4	Y	Y	→	—
	7	No notification received by either the dialysis center or the ward	The physician forgot to notify the dialysis department staff and made no arrangements for dialysis	2	2	4	Y	Y	→	—
	8	Oral prescription provided but not scheduled in computer	The physician only notified the dialysis leader but did not schedule dialysis	1	1	1	Y	N	Y	—
1.3	9	Fee not charged	The medical assistant forgot to charge the fee	3	4	12	N	→	Y	—
	10	Delay in charging the fee	The medical assistant did not charge the fee on time	1	4	4	Y	Y	→	—
1.4	11	Failure to act on a MEWS notification	Malfunction of MEWS notification	1	4	4	N	N	Y	—
2. Transportation from the ward										
2.1	12	No communication between the ward and dialysis center	The ward nurse forgot to transfer the patient to the dialysis center	4	2	8	Y	N	N	Action 3
	13	Busy phone line and missed arrangements	The dialysis nurse was too busy to complete the handover sheet	4	2	8	Y	N	N	Action 4
	14	Insufficient patient history	Lack of a standard evaluation protocol	4	2	8	Y	N	N	Action 5
2.2	15	No confirmation of dialysis	The physician-in-charge could not be found	3	4	12	Y	N	N	Action 6
2.3	16	Ward nurse forgot to arrange patient dialysis	The patient was transferred hastily	4	2	8	Y	N	N	Action 7

(Continued next page)

TABLE 2. (Continued)

No.	Failure Modes	Potential Causes	Hazard Analysis							
			Hazard Score			Decision Tree Analysis				
			Occurrence	Severity	O × S	Single Weakness	Control	Detectability	Action	
3. Preparation										
3.1	17	MEWS notification not confirmed	The in charge nurse was too busy and forgot to check the patient's condition	4	2	8	Y	N	N	Action 8
3.2	18	Patient MEWS >5, but not under monitoring	Lack of vital sign monitoring equipment	3	4	12	→	Y	→	—
4. Dialysis										
4.1	19	No standard guidelines for patient evaluation during dialysis	Lack of standard guidelines to assess abnormal conditions during dialysis	4	2	8	Y	N	N	Action 9
4.2	20	Underestimated patient condition	Lack of experience in handling emergency situations	4	2	8	Y	N	N	Action 10
4.3	21	Inability to notify the physician-in-charge	The physician was too busy to check or answer the phone	1	4	4	Y	N	N	Action 11
	22	Inadequate handling of exceptions and errors	Patient was in unstable condition during dialysis	3	4	12	Y	N	N	Action 12
5. Administration										
5.1	23	Poor handwriting on the prescription	The handwriting was difficult to read	4	2	8	Y	N	N	Action 13
	24	Incomplete patient history	The dialysis technician did not follow the documented protocol for taking patient history	4	2	8	Y	N	N	Action 14
5.2	25	No documentation before patient transfer back to the ward	The technician was too busy or no computers were available to complete the handover document	3	2	6	Y	N	N	Action 15
	26	Incomplete patient records transferred between nurses	The dialysis technician did not follow the documented protocol for taking patient history	4	2	8	Y	N	N	Action 16
	27	Staff did not reevaluate the patient's condition	The ward nurse was too busy to check the handover message	4	2	8	Y	N	N	Action 17
5.3	28	Lack of communication between staff on different shifts	The technician was busy and did not perform handover on time	4	2	8	Y	N	N	Action 18
	29	Nurses on different shifts did not perform handover on time	The ward nurse was busy and did not answer the phone	4	2	8	Y	N	N	Action 19
6. Return										
6.1	30	No evaluation before patient transfer	The ward nurse was busy and forgot to check the patient's condition	4	2	8	Y	N	N	Action 20

20 indicated a hazard score of 8 or higher points. Table 2 also summarizes the decision tree used to determine whether recommended actions were necessary. Although failure modes 9 had scores higher than 8, their detection did not pose a risk to patient condition, so no recommendations action were required. Another failure mode 18 had the score of 12, the patient was at unstable condition, the dialysis procedure will not proceed. By contrast, although the score of failure mode 21 was less than 8, to notify physician is necessary so it required action. Therefore, 20 failure modes were identified for improvement. Subsequently, the risk was quantitatively classified to better prioritize corrective and preventive actions and the risk reduction measures required by the analysis. A decision tree was used to determine whether the failure mode warranted further action. A single point of weakness indicated that if this part of the process failed, the entire system would fail. This failure mode was critical for the entire system. An effective control indicated an available means to eliminate or significantly reduce the possibility of failure occurring. Detectability measured the likelihood of detecting failure or the effect of failure before it occurred. The lack of detection or the misdetection of these errors led to a potential risk. Thus, it was necessary to use diverse means and procedures and combine error detection and a search of possible failure modes, thus allowing both preventive and corrective actions to be planned. Identification of the major contributors to a failed process allowed strategies to be developed and implemented to prevent subsequent failures.

Recommended Actions for Improvement

We implemented 20 actions of 4 major strategies to correct those 20 undetectable failure problems (Tables 2, 3). Strategy A was to establish team⁺ mobile app-based MEWS notification system (Fig. 3). Strategy B was to design a modified dialysis ISBAR checklist for dialysis personnel (Fig. 4). Strategy C was technician intensive education and training. Strategy D was internal auditing and monitoring for the implementation of procedures.

Action A: Establish a Team⁺ Mobile Application-Based MEWS Notification

To improve the quality of hemodialysis care, a team⁺ mobile application-based MEWS notification system was established and implemented in our HIS for monitoring entire hemodialysis procedure for hospitalized patients (Fig. 3). Since 2010, a wireless vital signs monitoring system (Dinamap ProCare 300 Vital Signs

Monitor [GE Medical Systems, Information Technologies, Inc, Milwaukee, WI]) has been integrated into our HIS.¹⁴ The team⁺ mobile application (version 1.8.5.0, designed by team⁺ technology, Taiwan) was used for MEWS scoring (Table 1) for real-time warning and notification to physicians and nurses in charge to check patient condition. A total MEWS of 5 or higher indicated that the patient may be at risk of clinical deterioration and may require intensive care. The mobile application performed the following actions: (1) sent automated real-time alerts to the medical team members for the risk of clinical deterioration of patients undergoing dialysis, (2) registered the patient and charged the insurance fee before arranging transfer to the hemodialysis center, (3) established the criteria of consulting the physician, and (4) allowed easy access (e.g., by using a tablet) to the patient’s medical records via Wi-Fi HIS. When this application was used, the executive rate of alerts reached 100%.

Action B: Design a Modified dialysis ISBAR Checklist for Dialysis

A modified dialysis ISBAR checklist (Fig. 4) was designed to improve the communication between different medical personnel, thus alleviating communication problems and allowing essential information to be transferred more accurately. The ISBAR hand-over principles help in providing the best care to patients undergoing hemodialysis. Several communication problems were noted between ward nurses and dialysis nurses because of ineffective communication and unfriendly integration. This newly modified dialysis ISBAR checklist, which provides a patient’s history, such as diabetes and other care notes, location of fistula, and other hemodialysis records, improved the communication between the ward and the hemodialysis center, thereby also improving the relationship between them. At the end of this project, the accuracy of manually recorded patient history on the ISBAR checklist for patients undergoing hemodialysis was 100%.

Action C: Requirement for Technician Education and Training

Dialysis technicians are health professionals who operate kidney dialysis equipment and monitor patients undergoing dialysis. They are required to have extensive clinical and technical knowledge, such as that related to setting up the machine properly, troubleshooting to hemodialysis apparatus, and maintaining a sterile environment. A dialysis technician must also have on-the-job

TABLE 3. Strategies to Maintaining the Effectiveness and Patient Safety for Hemodialysis

Strategy	Outcome Measurements	Action
A. Establish a team + mobile application-based MEWS notification		
A.1 Real-time information platform for risk monitoring	Notification rate	1
A.2 Register patient and charge the insurance fee before transferring the patient to the hemodialysis center	Missed order rate	2
A.3 Establish criteria for consulting the physician	Unconfirmed events	6, 11
A.4 Use a Wi-Fi tablet to easily access patient medical records	Access rate	8
B. Design a modified dialysis ISBAR checklist for dialysis		
B.1 ISBAR operations implemented for communication among medical personnel	Handover complete rate	3, 4, 5, 7, 13, 15, 18, 19, 20
C. Requirement for technician education and training		
C.1 On-the-job training	Achievement rate	9, 12
C.2 ACLS training	Certification rate	10
D. Execute internal auditing and monitoring		
D.1 ISBAR should be completed at the time of intervention	ISBAR sheet check rate	14, 16
D.2 Nursing records	Complete rate	17

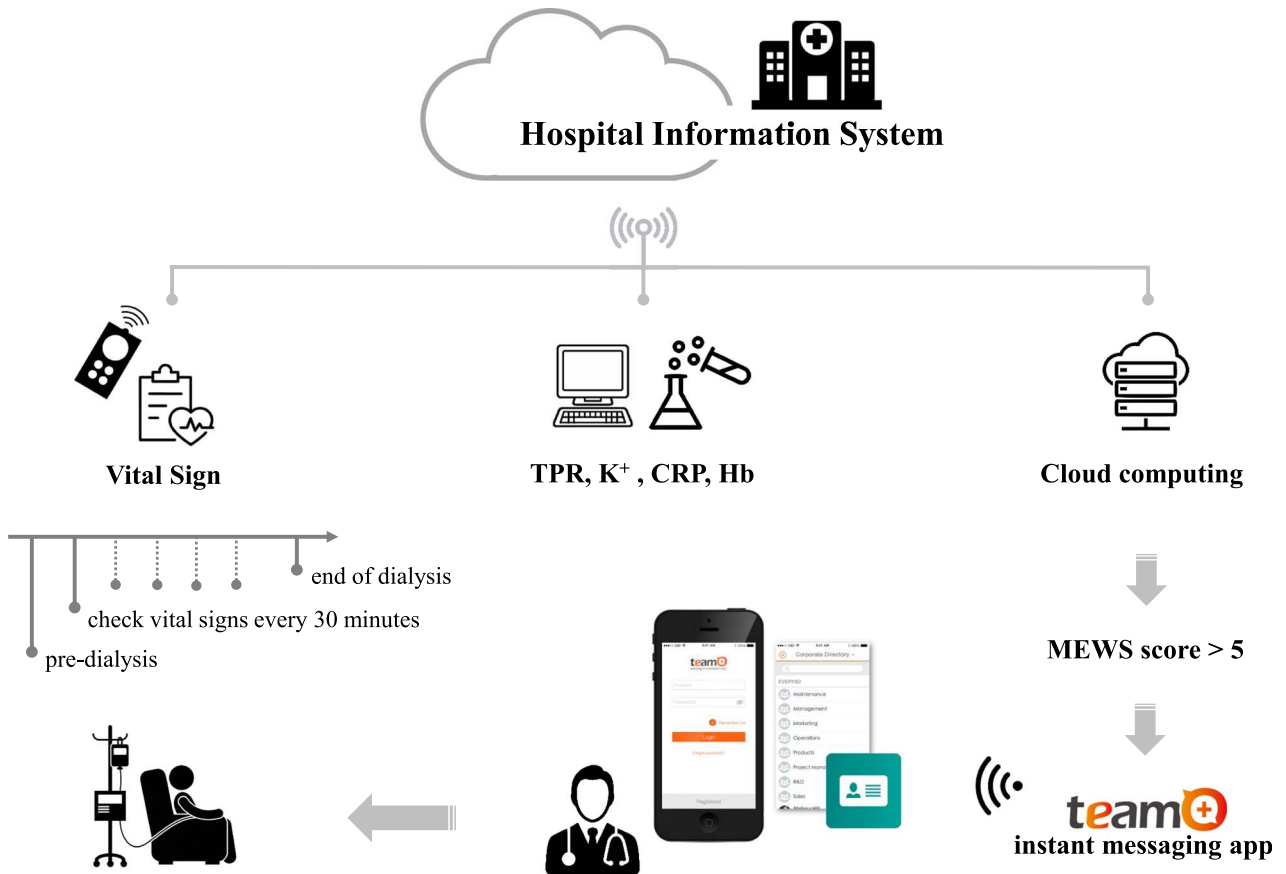


FIGURE 3. Establish a team+ mobile application–based MEWS notification. Cloud-based electronic vital signs data, including body temperature, pulse rate, breathing rate, and blood pressure. Laboratory samples from patient were evaluated for blood potassium, CRP, and Hb levels. The scores for each parameter were recorded at the time of observation. Cloud Computing for the MEWS score. A score of 0 was considered normal, scores of 1 and 2 were considered abnormal, and a score of 3 was considered critical. The scores for each parameter were summed to obtain the total score. If the total was 5 or higher, an early warning message was sent to the doctor in charge via real-time team+ mobile application.

training (for actions 9 and 12) and advanced cardiovascular life support (ACLS) certification (for managing cardiopulmonary arrest or other cardiovascular emergencies). Advanced cardiovascular life support training, including high-quality cardiopulmonary resuscitation (CPR) and high-performing resuscitation, can strengthen the ability of technicians to promptly deal with SCD.

Action D: Execute Internal Auditing and Monitoring

Clinical handover is the effective “transfer of professional responsibility and accountability for some or all aspects of care for a patient, or group of patients, to another person or professional group on a temporary or permanent basis.”¹⁵ The modified dialysis ISBAR checklist helps maintain good nursing records and take care of patient’s condition.¹⁶

Outcome Measures

After the application of various action strategies between January 2018 and December 2018, we compared the outcome measures before and after HFMEA implementation (Table 4). We monitored the occurrence of the following events during hemodialysis: emergency situations, cases of insufficient dialysis time, CPR incidence, and mortality rate. The frequency of CPR incidence and case of insufficient dialysis time significantly decreased. The risk index (hazard score) of the patient during dialysis

also dropped from 170 points to 49 points—a decrease of 71.2%. The hazard score of each failure mode evidently decreased (Table 1). As presented in Table 4, the average rate of incomplete hemodialysis procedures decreased from 2.18% to 1.06%. The p-chart is a type of control chart used to monitor the proportion of adverse events for improving the quality of healthcare processes and patient safety. Second, by using the new ISBAR checklist, the occurrence and duration of unpredictable CPR events increased from every 1 per 148 days to 1 per 357 days, implying a significant decrease in the occurrence of CPR events. In addition, the total hazard score decreased from 170 to 49 points. According to the Taiwan Society of Nephrology and the National Kidney Foundation, a minimum urea reduction ratio indicated dialysis efficiency of 65% is required for adequate hemolysis.¹⁷ In this project, the dialysis efficiency in our hospital was increased from 95.0% to 98.6%.

DISCUSSION

This HFMEA project prevented medical errors in our hospital and improved patient safety during hemodialysis. The HFMEA has been performed for several healthcare processes.^{18–20} We demonstrated that HFMEA is useful for analyzing the hemodialysis process. The hazard score was obtained through multiplication of the severity and probability of occurrence (Fig. 2). We also designed a MEWS notification system through the real-time team+ application for providing physicians and other medical personnel

Modified Dialysis ISBAR Checklist			
I dentification	Transfer date	Name	Medical record number
	Risk level for patient transfer: <input type="checkbox"/> A <input type="checkbox"/> B <input type="checkbox"/> C		
S ituation	Inform consent for hemodialysis	<input type="checkbox"/> Signed <input type="checkbox"/> None	
	Isolation	<input type="checkbox"/> None <input type="checkbox"/> Yes <input type="checkbox"/> Air isolation <input type="checkbox"/> Blood isolation <input type="checkbox"/> Sputum isolation	
B ackground	Diabetics	<input type="checkbox"/> None <input type="checkbox"/> Yes	
	Type of fistula	<input type="checkbox"/> AVF <input type="checkbox"/> AVG <input type="checkbox"/> Double lumen <input type="checkbox"/> Perm cath	
	Location of fistula	<input type="checkbox"/> Right lower wrist <input type="checkbox"/> Right lower arm <input type="checkbox"/> Right upper arm <input type="checkbox"/> Right groin <input type="checkbox"/> Left lower wrist <input type="checkbox"/> Left lower arm <input type="checkbox"/> Left upper arm <input type="checkbox"/> Left groin	
	Vital signs (15 minutes after transfer initiation)	GCS: E _____ V _____ M _____ Body temperature: _____ °C Pulse rate: _____ bpm Respiratory rate: _____ Breaths per minute Blood pressure: _____ / _____ mmHg <input type="checkbox"/> Trachea <input type="checkbox"/> Endo _____ cm	
	Laboratory testing	Hct: _____ % Hb: _____ g/dL Transfusion date: _____ / _____ U	
	IV line	<input type="checkbox"/> None <input type="checkbox"/> Yes	
	Care notes	<input type="checkbox"/> None <input type="checkbox"/> Yes Body weight: _____ Kg Midodrine: _____ pill, at: _____ hr _____ min	
A ssessment	Preparation	<input type="checkbox"/> Oxygen/ nasogastric tube: _____ cm <input type="checkbox"/> O ₂ Mask: _____ cm <input type="checkbox"/> BiPAP: O ₂ _____ cm <input type="checkbox"/> Other: _____	
R ecommendation	Hemodialysis procedure and patient monitoring records	Hemodialysis time: _____ : _____ to _____ : _____ Body temperature: _____ °C PR: _____ BMP Respiratory rate: _____ bpm Blood pressure: _____ / _____ mmHg, at: _____ hr _____ min SPO ₂ : _____ Before dialysis Body weight: _____ Kg After dialysis Body weight: _____ Kg Prescription dialysis time: _____ hr _____ min Actual dialysis time: _____ hr _____ min Care notes: <input type="checkbox"/> Low blood pressure <input type="checkbox"/> Change conscious GCS: E _____ V _____ M _____ <input type="checkbox"/> Other: _____	

FIGURE 4. Modified dialysis ISBAR checklist for patients scheduled to undergo hemodialysis. Risk level for transfer: A: high risk, the patient condition is unstable (e.g., HR ≥130/min or ≤50/min; systolic blood pressure [SBP] <90 mmHg or >200 mmHg with medicine treatment; RR ≥30/min or ≤6/min; SpO₂ ≤ 90% with oxygen treatment); B: moderate risk, patient is currently stable but experienced unstable condition in the past 24 hours; C: low risk, patient is at stale condition. BiPAP, biphasic positive airway pressure.

TABLE 4. Monitoring Outcomes Before and After the Implementation of Healthcare Failure Mode and Effect Analysis

Items	Before Implementation	After Implementation
Incomplete dialysis rate, %	2.18	1.06
Unexpected CPR events, interval days	149	357
Hazard score	170	49
Dialysis efficiency, %	95.0	98.6

with an early warning of a patient's condition before, during, and after the hemodialysis procedure, thus improving their awareness of the potential risks related to patients undergoing dialysis, especially during emergencies (Fig. 3).

The HFMEA team identified 30 failure modes and their potential causes (Table 2). Moreover, 4 major strategies, including establishing a team⁺ mobile application based on the MEWS system (Fig. 3, Table 1) and designing a specialized dialysis ISBAR checklist (Fig. 4), were implemented. These strategies helped our organization improve patient safety and helped us achieve our goals.

An exclusive dialysis MEWS system was used to evaluate the conditions of patients undergoing dialysis at our hospital (Table 1). When the score was 5 or higher, the HIS sent an automated notification to physicians. The physician could then evaluate the patient's condition to determine whether the patient should proceed with the dialysis procedure and/or required emergency measures, such as life-support equipment and oxygen monitoring, during hemodialysis. In addition, many physicians also provided feedback to the HFMEA team that the MEWS system helped them design the entire patient treatment plan more accurately and minimize the occurrence of unexpected accidents during dialysis. The nursing staff could also more carefully provide care for patients, especially those at high risk, and monitor their dialysis condition. After the implementation of this system, no CPR event was recorded during dialysis in our hospital.

Mobile applications are useful tools for improving the efficiency of technologies for recording patient health information and decision making for human health.^{21–23} Several failure steps identified in our study were caused by human errors, and reducing human clinical errors is crucial. The team⁺ mobile application could send real-time automated alerts based on the MEWS system to the healthcare team members for improving health outcomes. To improve patient safety and prevent the possible failure modes, it is vital to ensure a sufficient number of staff members as well as sufficient preparation time and patient evaluation.

Clinical ISBAR handover aims to ensure structured, accurate, and timely transfer of information, responsibility, and accountability.²⁴ Several studies have indicated that intrahospital transfers can be a hazardous aspect of hospital care and a threat to patient safety. Moreover, use of memorandum ISBAR handover checklists can improve communication among healthcare staff members. In this project, we redesigned the modified dialysis ISBAR checklist to enhance communication among hemodialysis team members. This checklist documented patient information, enabling the team to be more aware of and focused on the patient's condition. It changed the approach to communication among staff in different departments and improved patient safety during transfer. Through this HFMEA project, we could eliminate most failure modes; however, some unidentified or low-frequency failure modes may still occur. Here, continuous monitoring and auditing ensure the effectiveness of the whole implementation step.

This study had some limitations. Several human communication errors may still occur during rush hours in the hemodialysis center and wards. Although several important actions were implemented in our healthcare system to improve patient safety,²⁵ staff members still need time to become familiar with the whole operation procedure. For effective implementation of the recommended actions, the quality improvement team is continually monitor outcomes.

CONCLUSIONS

In summary, HFMEA was demonstrated to be valuable in reducing the risk associated with dialysis and improving patient safety and the overall healthcare processes. The implementation of different strategies reduced the incomplete dialysis rate from 2.18% to 1.06%, prolonged the interval of unexpected CPR from 149 to 357 days, reduced the hazard score from 170 points to 49 points, and increased the dialysis efficiency from 95.0% to 98.6%. Using HFMEA allowed the dialysis team to proactively assess risks to patients and plan solutions to medical errors before they occurred.

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