Clinical risk analysis with failure mode and effect analysis (FMEA) model in a dialysis unit

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Abstract

Background: The aim of clinical risk management is to improve the quality of care provided by health care organizations and to assure patients’ safety. Failure mode and effect analysis (FMEA) is a tool employed for clinical risk reduction. We applied FMEA to chronic hemodialysis outpatients.

Methods: FMEA steps: (i) process study: we recorded phases and activities. (ii) Hazard analysis: we listed activity-related failure modes and their effects; described control measures; assigned severity, occurrence and detection scores for each failure mode and calculated the risk priority numbers (RPNs) by multiplying the 3 scores. Total RPN is calculated by adding single failure mode RPN. (iii) Planning: we performed a RPNs prioritization on a priority matrix taking into account the 3 scores, and we analyzed failure modes causes, made recommendations and planned new control measures. (iv) Monitoring: after failure mode elimination or reduction, we compared the resulting RPN with the previous one.

Results: Our failure modes with the highest RPN came from communication and organization problems. Two tools have been created to ameliorate information flow: “dialysis agenda” software and nursing datasheets. We scheduled nephrological examinations, and we changed both medical and nursing organization. Total RPN value decreased from 892 to 815 (8.6%) after reorganization.

Conclusions: Employing FMEA, we worked on a few critical activities, and we reduced patients’ clinical risk. A priority matrix also takes into account the weight of the control measures; we believe this evaluation is quick, because of simple priority selection, and that it decreases action times.

Key words: Clinical risk, Dialysis, FMEA

Introduction

In the last 2 decades several studies on medical errors have highlighted the fact that 3.7% of US hospital patients are prone to adverse events during their hospital stay (1-3). Clinical risk is the probability of a patient being subject to an adverse event (i.e., an unintended injury or complication that results in disability at the time of discharge, death or prolonged hospital stay) caused by health care management rather than by the patient’s underlying disease process (4). Clinical risk management consists of complex actions done to improve the quality of care provided by health care organizations and to assure patients’ safety. It takes into account all of the health care process fields. Failure modes are operationally defined as the different ways that a particular process or subprocess step can fail to accomplish its intended purpose (5-7).

After retrospective studies of adverse events, in 2001 the United States Joint Commission on Accreditation of Health Care Organizations involved health care organizations in providing annual proactive analysis as risk prevention (8). One of these instruments is failure mode and effect analysis (FMEA), which has been used since the 1970s in industrial fields (cars, aerospace and nuclear energy) (9). International models for technical and organizational applications such as ISO 9004:2000 use FMEA too (10). The Department of Veteran Affairs and the National Center for Patient Safety (NCPS) proposed Healthcare FMEA (HFMEA) as a tool to apply to health care activities (5).

FMEA is a comprehensive, collaborative team effort which proactively evaluates a health care process. The end points may be performing only analysis, making recommendations or implementing new strategies developed from FMEA. The first processing of clinical risk management in Italy was performed in Emilia Romagna (2001), Toscana (2003)
Bonfant et al: FMEA application in a dialysis unit

and Lombardia (2004). In 2004, the technical commis-

In 2005, the Aosta Valley Healthcare Organisation started an educational program for clinical risk management, as suggested by the Italian Health Ministry (11). Every medical unit had to apply FMEA in at least 1 of its processes and achieve the 3 end points described above. The Nephrology and Dialysis Unit analyzed chronic hemodialysis applied to outpatients. In this paper, we will focus our attention on the application of FMEA to nephrology, and we will discuss the results obtained.

**SUBJECTS AND METHODS**

The Nephrology and Dialysis Unit of the Regional Hospital of Aosta (Italy) has 6 beds for hospital care and 13 beds for hemodialysis; in 2007, we supplied 7,581 hemodialysis treatments to chronic nonhospitalized patients, 1,252 to acute and chronic hospitalized patients and 4,344 peritoneal home dialysis treatments.

FMEA was performed in May and July, reorganization plans were applied from August 2007 and audits were performed after 2, 4 and 10 months. Total work consisted of 40 field-training hours for each FMEA team member, within contract hours.

FMEA steps (10, 11):

1) Process study: team member selection, process examination and brainstorming, and phases and activities recording on FMEA worksheet;

2) Hazard analysis: listing activity-related failure modes and their potential effects. Many failure modes may have more than 1 effect. This step must be developed very exhaustively, because the information will be used to determine risk ratings. This step also includes describing control measures that eliminate or significantly reduce the likelihood of failure occurring, as well as assigning a severity score for each effect (S), which shows the seriousness of failure effects eventually happening, an occurrence score (O) for each failure mode (i.e., how often it may occur) and a detection score (D) (i.e., detecting failures or their effects likelihood before their occurrence). Effects severity and failure modes occurrence scores increase, while detection scores decrease (the more difficult the error detection, the higher the value): that is, the ability of detecting events before they occur reduces the degree of risk (10, 12). The coupling of scores with severity, occurrence and detection levels has to be established before risk analysis.

To calculate the risk priority numbers (RPNs) the 3 scores were multiplied. Total process RPN was calculated by adding single failure mode RPN.

3) Planning: prioritization is completed by plotting RPN (see Fig. 1). By looking at the priority matrix, the team decides which items to focus on and work on, analyzes failure modes causes, makes recommendations and plans new control measures to eliminate or reduce risk. The priority matrix we employed to define failure mode intervention priority was divided into 4 areas of decreasing weight, requiring related priority intervention: 1 = emergency (the highest), 2 = urgent, 3 = programming, and 4 = monitoring (the lowest).

4) Monitoring: after failure modes elimination or reduction, a resulting RPN is calculated and compared with the previous one.

Operative modalities are depicted in Figure 2 and Tables I and II.

**Statistical analysis**

Statistical evaluation of plan results was performed with a 2-tailed chi-square test. Results were considered statistically significant at p<0.05.
TABLE I
FAILURE MODE AND EFFECT ANALYSIS (FMEA) WORKSHEET

<table>
<thead>
<tr>
<th>Phase</th>
<th>Activity</th>
<th>Failure modes</th>
<th>Effects</th>
<th>Control measures</th>
<th>S</th>
<th>O</th>
<th>D</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>1.1</td>
<td>1.1.1</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.1.2</td>
<td></td>
<td></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.1.3</td>
<td></td>
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<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td></td>
<td></td>
<td>1.1.4</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>1.2</td>
<td></td>
<td>1.2.1</td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
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<td></td>
<td></td>
<td>1.2.2</td>
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<td></td>
</tr>
</tbody>
</table>

This worksheet was used to record information during the FMEA sessions, for writing and allocating a number to each process phase, activity and possible failure modes, their effects, and safeguards in place to avoid failure (control measures). A severity score (S) was assigned to failure effects, whereas occurrence (O) and detection (D) scores were given to failure modes. The risk probability number (RPN) was calculated by multiplying the 3 scores.

TABLE II
RATING SCALES EMPLOYED TO ASSIGN SEVERITY (S), OCCURRENCE (O) AND DETECTION (D) SCORES IN FAILURE MODE AND EFFECT ANALYSIS (FMEA) OF HEMODIALYSIS PROCESS

<table>
<thead>
<tr>
<th>Severity (S)</th>
<th>Occurrence (O)</th>
<th>Detection (D)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Score</td>
<td>Injury description</td>
<td>Score</td>
</tr>
<tr>
<td>1</td>
<td>No injury, or patient monitoring only</td>
<td>1</td>
</tr>
<tr>
<td>2</td>
<td>Temporary injury with need of additional interventions or treatments</td>
<td>2</td>
</tr>
<tr>
<td>3</td>
<td>Temporary injury with increased length of hospital stay or increased level of care</td>
<td>3</td>
</tr>
<tr>
<td>4</td>
<td>Permanent lessening of body function</td>
<td>4</td>
</tr>
<tr>
<td>5</td>
<td>Death or permanent loss of major functions</td>
<td>5</td>
</tr>
</tbody>
</table>

The risk priority number (RPN) was calculated by multiplying S, O and D scores.
Results

Table III shows the results we obtained applying FMEA to hemodialysis delivered to chronic outpatients. Activities, failure modes and control measure numbers are reported for each phase. Lowest and highest RPN values and total RPN are shown too. Figure 1 displays the distribution of failure modes in the priority matrix. Figure 3 shows the failure modes distribution for each process phase in the 4 matrix areas. None of the failure modes is located in area 1 (maximum intervention priority).

We focused our attention on items located in area 2 (Urgent intervention) (Tab. IV). We decided to work on some phase 4 (Patient admission) failure modes, formulating a plan called “Nephro1.” We also performed another plan called “Nephro2” concerning a phase 6 (Hemodialysis treatment) failure mode, located on the borderline between areas 2 and 3. Since time and operators available were restricted, we preferred to plan activities depending on our unit only and not on others (hospital management).

Nephro1 plan

The related failure modes reported in Table IV can produce an incorrect dialytic treatment. The cause of this is lack of information sharing.

We used as indicator nurses’ calls to physicians concerning unscheduled dialytic changes, noting them on a “non-conformity form” for 2 weeks. We found 47 calls in 374 dialytic treatments (12.6%).

Two tools have been created and applied to ameliorate information flow:
1) Original software called Dialysis Agenda, which is used both as a calendar with dialysis sessions (3/day) and as a planner to record information and trace it (author, hour, date of texts or their changes/deletions) and to check execution. The software is in a local network and can be used by all dialysis unit computers simultaneously.
2) Nursing datasheets: These record information about clinical and dialysis assistance problems (personal data, welfare, patient transportation from and to the hospital and communication problems).

After 2, 4 and 10 months, we repeated the audit with the “non-conformity form”; the indicator decreased from baseline to 2.9%, 5.2% and 3.7%, respectively (all p<0.001, vs. baseline value).

We obtained data on medical intervention rationalizations, information sharing between operators, prescription communication and ease and traceability of execution, and availability of clinical and welfare information for dialysis treatment. RPNs decreased from 32 and 40 to 12 (O score from 4 to 3 and from 5 to 3, D score both from 2 to 1); item 4.6.1 was not reexamined.
Nephro2 plan

**Item 6.2.1 periodic nephrological examination missing/partial (RPN value 27)**

Identification of clinical problems and laboratory tests or advice regarding prescriptions may be inadequate. The cause of this is that the monthly scheduled medical examination is not well organized and planned.

We offered 2 questionnaires about nephrological visit modality to nurses (n=13) and nephrologists (n=7), and we found evidence for the importance of a nurse being present during visits, as well as planning and organizing inadequacies. We reorganized the handling of nephrological examinations, and we changed both medical and nursing organization.

An audit with nurses 2 months later showed an increased satisfaction with visit planning from baseline 15.4% to 100% (p<0.001), which was confirmed at 10 months. Satisfaction regarding interruptions during medical examination rose from 7.7% to 47.7% at 2 months (p<0.002) and to 80% at 10 months (p<0.001). Activity overlap was still a problem; in fact the applied changes do not increase satisfaction enough (from 7.7% to 53% at 10 months). This difficulty has no easy solution, because dialytic treatment currently takes place dur-

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**TABLE III**

RESULTS OF FAILURE MODE AND EFFECT ANALYSIS (FMEA) OF HEMODIALYSIS PROCESS

<table>
<thead>
<tr>
<th>Phase</th>
<th>Number identified</th>
<th>RPN</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Activities</td>
<td>Failure modes</td>
</tr>
<tr>
<td>1</td>
<td>Drawing-up and updating of patients' dialysis session</td>
<td>7</td>
</tr>
<tr>
<td>2</td>
<td>Supplying material</td>
<td>5</td>
</tr>
<tr>
<td>3</td>
<td>Technical preparation</td>
<td>9</td>
</tr>
<tr>
<td>4</td>
<td>Patient admission</td>
<td>7</td>
</tr>
<tr>
<td>5</td>
<td>Hemodialysis start</td>
<td>5</td>
</tr>
<tr>
<td>6</td>
<td>Hemodialysis treatment</td>
<td>11</td>
</tr>
<tr>
<td>7</td>
<td>Hemodialysis end</td>
<td>10</td>
</tr>
<tr>
<td>8</td>
<td>Patient discharge</td>
<td>6</td>
</tr>
<tr>
<td>9</td>
<td>Monitoring and room cleaning</td>
<td>3</td>
</tr>
<tr>
<td>Total</td>
<td>63</td>
<td>92</td>
</tr>
</tbody>
</table>

This table describes the numbers concerning activities, failure modes and control measures identified for the 9 phases of the examined process. The risk priority numbers (RPNs) were calculated for each phase.
Phase and description of failure modes located in priority matrix area 2 (Fig. 1), requiring urgent intervention, are reported in the first 2 columns. Effects severity (S), failure occurrence (O) and detection (D) scores, and risk probability number (RPN) are reported in the third column. Recommendations suggested for clinical risk reduction are listed in the fourth column.

<table>
<thead>
<tr>
<th>Phase</th>
<th>Failure mode</th>
<th>Scores</th>
<th>Recommendation</th>
</tr>
</thead>
</table>
| 3. Technical preparation | 3.2.7 Aqueduct water pollution by substances which can accumulate and then be progressively released in the water-system (e.g., tri/tetrachloroethylene) | S = 4  
O = 2  
D = 4  
RPN = 32 | Increasing frequency of checks (by asking hospital top management) |
| 3. Technical preparation | 3.2.8 Dialysis water microbiological pollution | S = 5  
O = 2  
D = 3  
RPN = 30 | Increasing frequency of checks (by asking hospital top management) |
| 3. Technical preparation | 3.2.9 Dialysis water pyrogenic pollution | S = 5  
O = 2  
D = 3  
RPN = 30 | Increasing frequency of checks (by asking hospital top management) |
| 3. Technical preparation | 3.9.1 Wrong weight record | S = 4  
O = 3  
D = 2  
RPN = 24 | Increasing frequency of scales calibration (by asking hospital top management) |
| 4. Patient admission | 4.6.1 Missing or incomplete acquisition of interdialytic time anamnestic data | S = 3  
O = 4  
D = 2  
RPN = 24 | Nephro1 plan |
| 4. Patient admission | 4.7.1 Missing/partial nephrological evaluation | S = 4  
O = 4  
D = 2  
RPN = 32 | Nephro1 plan |
| 4. Patient admission | 4.7.2 Incomprehensible, incorrect or missing nephrological prescriptions | S = 4  
O = 5  
D = 2  
RPN = 40 | Nephro1 plan |
| 8. Patient discharge | 8.1.1 Missing/incorrect patient clinical evaluation | S = 4  
O = 2  
D = 3  
RPN = 24 | Increasing patient monitoring |
| 9. Monitoring and room cleaning | 9.1.1 Incorrect waste disposal | S = 4  
O = 3  
D = 2  
RPN = 24 | Implementing latest hospital procedures |
ing the visit. Results from the medical staff are similar, but the small number of nephrologists does not permit statistical evaluation.

**Results obtained with the Nephro2 plan**

Visit time was assured and optimized, interruptions were reduced, nurses actively participated, planning failures showed a significant reduction, RPN values decreased from 27 to 6 (O score from 3 to 2 and D score from 2 to 1). Total RPN value decreased from 892 to 815 (8.6%) after plans were implemented.

**Discussion**

There are a few studies in the literature that discuss FMEA applications in medicine, concerning methodological aspects, clinical device utilization and therapy administration (3, 13-16). A dialysis unit was usefully analyzed with FMEA in 1 paper, following a near-miss event (17).

Our regional health care organization management chose FMEA considering both the Italian Health Ministry suggestions (which take into account JC standard LD.5.2) and easy-fitting to all staff and organization levels.

Our work analyzes the whole complex hemodialysis process. Performing FMEA we detected a quite low mean RPN (approximately 10 out of a maximum of 125), despite a mean severity score of 3. This low RPN was due to control measures applied, such as international or national guidelines, procedures and operational instructions, and to systematic orientation and training of new staff members. These procedures were formalized and implemented in 2006, on the occasion of the accreditation required by the Aosta Valley regional administration.

Since then, new protocols and utilization modalities have been presented to staff members, and audit results have been communicated in periodic meetings.

Our failure modes with the highest RPNs came from communication and organization problems. The Italian Health Ministry also identified poor communication as a common cause of error in medicine (11). However, it must be kept in mind that the so-called communication problems may often hide unclear or unshared responsibilities, roles and procedures.

Employing FMEA we focused on a few critical activities to be ameliorated, and we improved processes and introduced some safety procedures, thus reducing the clinical risk index value. These procedures have usefully been studied to solve staff members’ practical problems. Organizational changes and new software have been well accepted by the staff. These changes are cost-free, because of better usage of operators’ time.

Thanks to FMEA, patients’ documentation is updated and made easily available, and nephrological examinations are regularly performed as planned.

Plotting failure modes on a matrix that also takes into account the weight of the control measures is a peculiarity of the FMEA model we employed, so that it is easy to identify priorities. We believe this results in quicker evaluations because the priority selection is simplified - and thus it reduces action times.

We have observed that team selection, motivation and training have great significance, because this analysis is subjective and depends on every member’s abilities and open-minded attitude. The first application of FMEA actively involved all of the team, and it required some work, but it was fulfilled in quite a short time (6 months).

We have applied the acquired know-how to 2 other processes (peritoneal dialysis and hemodialysis patient dressing): the resulting work was faster and easier. In all of the FMEA we performed, the reduction of total RPN resulted in a great improvement in the service to patients we provide.

FMEA will be coupled with incident reporting and clinical audits in the Aosta Valley Health Care Organisation, to verify control measures and their effectiveness.

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