Original Article

Nurse risk managers' criteria for dealing with near-miss events

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Summary **From the preventive point of view, it is very valuable for Japanese hospital safety managers to select important cases not only from among accident events, but also from near-miss events that involve errors that may result in the occurrence of future serious adverse events. The objective of this study is to investigate factors that determine the type of analysis that applies to hypothetical near-miss events. We sent self-administered questionnaires to 393 nurse risk managers from general hospitals in Japan. Hypothetical near-miss events were presented, and respondents assessed hypothetical events. Type of Analysis, Probability, Organizational Risk (effect on reputation and effect on cost), and Severity (possibility of harm, degree of harm, possibility of recovery, and possibility of delayed discharge) were included in the questionnaire. Response rate was 47.3% (186/393) and finally 175 nurses are analyzed. The respondents were 58 full-time safety managers (33.1%) and 117 who were safety managers concurrently with other work (66.9%). As a result of logistic regression analysis, probability, effect on reputation, possibility of harm and possibility of delayed discharge were significant ($p < 0.05$). Japanese safety managers consider near-miss events that have a lower probability to be more important. This finding differs from existing prioritization systems that were principally made for actual adverse events. It may suggest the problem of uncritically applying scales for accident events to near-miss events.**

Keywords: Patient safety, risk management, adverse event, near-miss, incident report

1. Introduction

An incident reporting system is a risk assessment tool in which the health care staff voluntarily reports adverse events that occurred in their work places. This assessment tool is convenient, and many health care facilities use it. It is said that incident reporting systems cannot provide the true incidence of adverse events (*1,2*). However, such a system is able to gather data not only on incidents as actual adverse events (errors that were not prevented) – which is called an accident – but also on incidents as potential adverse events (errors that were prevented by planned or unplanned barriers) – which is called a near-miss. Although the difference between them is usually unclear in a reporting system, considering the nature of near-miss events that were prevented, an analysis focusing on near-miss events plays an important role in preventing actual adverse events (*3,4*).

In many health care facilities, when the staff discovers an accident or a near-miss, he or she reports it to the appropriate supervisor (*e.g.* risk manager). The supervisor records the reported incidents, analyzes them using descriptive statistics, and informs staff of the results of analysis. Particularly important cases are analyzed in detail to identify the cause and corrective action is implemented (we call this detailed analysis an expanded analysis). From the preventive point of view, an expanded analysis is one of the most important stages in safety management activities to reduce adverse events systematically. However, except for some facilities in the U.S., there is no common methodology as to how safety managers can prioritize the huge number of reports of adverse events to select important cases for expanded analysis. Some facilities

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in the U.S. have developed criteria and an algorithm to select events that require close attention (*5*).

The Japanese health care systems is increasingly recognizing the importance of medical safety managers, and in 2002 national hospitals were ordered to assign a full-time risk manager to each facility. But many safety managers perform safety management activities concurrently with their usual work as health care providers. Because they cannot spend a large amount of time on safety management activities, they tend to select more accident events than near-miss events for expanded analysis, especially when they are newly appointed or busy. But as described above, from the preventive point of view, it is very valuable for safety managers to select for close scrutiny important cases not only from among accident events, but also from near-miss events that involve errors that may result in the occurrence of future serious adverse events.

In view of these considerations, it would be quite useful for future safety managers in health care facilities to know how present safety managers select important cases for expanded analysis. In this study, we developed questionnaires based on prioritization systems that were developed by two health care facilities in the U.S. and sent them to nurses appointed as risk managers, asking which type of analysis they apply to hypothetical near-miss events. The objective of this study is to investigate factors that determine the type of analysis applied to near-miss events.

2. Methods

2.1. *Participants and study design*

Participants were 393 general hospitals in Japan listed on "Byoin-Yoran 2001-2002 (Japanese hospital directory 2001-2002)" (*6*) that have 500 or more beds. Not included were hospitals in which half or more beds are for long-term or psychiatric care. We sent a self-administered questionnaire by post to each of these hospitals and requested one of the nurses appointed as safety manager to answer the questionnaire.

2.2. *Development of items*

We referred to the Risk Assessment Index (RAI) of the Medical Event Reporting System for Transfusion Medicine (MERS-TM) (*3,7*) and the Safety Assessment Code (SAC) used in the Veterans Health Administration (VHA) to develop the items on the questionnaire (*8*). RAI and SAC are scales for scoring adverse events to determine the type of analysis and way of handling the event.

Both scales assess events from the viewpoint of severity of harm to the victim, probability of recurrence in the facility, and organizational risk (*e.g.* damaged reputation or financial loss) and generate a score for each event. When scores are higher there is a greater need for an expanded analysis. To assess the severity of a near-miss event, RAI considers potential harm, while SAC considers the most likely "worst case".

In the questionnaire that we developed, first we described hypothetical near-miss events, and then, with regard to each hypothetical case, asked about the probability of occurrence of such a near-miss event in their facility, organizational risk, and type of analysis that they would select for the event if it had actually occurred in their facility. Furthermore, we asked about consequences to the victim if the hypothetical near-miss event were not prevented. Specifically, the questionnaire consisted of four subsections: Probability, Type of Analysis, Organizational Risk, and Severity.

The Probability subsection consists of one item, with 4 possible responses (a, several times or more per month; b, several times within per half year; c, several times per year; d, once or less per year). The Type of Analysis subsection also has one item but with 5 possible responses (a, expanded analysis; b, investigation to find common problems; c, descriptive data analysis; d, no analysis; e, other type of analysis). The Organizational Risk subsection consisted of two items, one on the effect on the institution's reputation and the other on costs; each could be answered by: a, large effect; b, small effect; or c, no effect. The Severity subsection included 4 possible scenarios. The first was the possibility of harm (a, almost certain; b, highly possible; c, rare); the second was possible degree of harm (a, fatal; b, Activities of Daily Living (ADL) disability highly possible; c, ADL disability only slightly possible); the third is the possibility of recovery from the resultant harm (a, no recovery highly possible; b, recovery highly possible), and the fourth is the possibility of delayed discharge (a, highly possible; b, only slightly possible). The 7 items on the Probability, Organizational Risk, and Severity subsections were factors that determined the type of analysis for a near-miss event.

Possibility of harm was based on the RAI. Possible degree of harm, possibility of recovery, and possibility of delayed discharge were based on severity categories of the SAI that include concrete descriptions of injuries that the victim could suffer.

2.3. *Development of hypothetical near-miss events*

To develop hypothetical near-miss events, we referred to the 2nd Summary and Tabulation of Network Maintenance Projects for Medical Safety (project including incident collection) by the Ministry of Health, Labor and Welfare (*9*). First, we selected some incidents from the released summary and tabulation to satisfy the following: Description objective, Description detailed, Incident nurse discovered, and Prevention possible in the interval between occurrence of error and actual or

possible harm to patient.

Incidents in the released summary and tabulation include many events in which errors were not prevented, because the definition of the incident is not identical with that of the near-miss event in this study. Therefore, we converted those incidents into near-miss events with minimal adjustments and developed 10 hypothetical near-miss events. From several discussions with 11 nurses with 5 to 19 years of nursing experience, we removed one hypothetical near-miss event. Finally, we used 9 hypothetical near-miss events in our questionnaire.

Characteristics of events are based on the results of interviews with several risk managers in Japan, and consist of 7 items as shown in Table 1. The 7 items are: type of event with regard to whether it was related to medication or other causes; whether event was discovered by a planned barrier or by chance; whether or not the error was discovered near the patient or far from the patient; whether only a nurse is related between the error and discovery or many occupations participated; if the discoverer was the nurse who made the error, a colleague or a patient; if the patient contributed to the error, and, finally, if a nurse was responsible for the error or the other occupations were responsible.

Table 1. Characteristics of hypothetical near-miss events

Event number	1	2	3	4	5	6	7	8	9
Type of event									
Medication related	●	●	●	●					
Others					●	●	●	●	●
Cause of discovery									
Planned barrier	●				●	●	●		
Chance		●	●	●				●	●
Place of discovery									
Far from the patient	●	●							
Near the patient			●	●	●	●	●	●	●
Related occupation									
Only nurses				●			●	●	●
Many occupations	●	●	●		●	●			
Discoverer									
Nurse making the error			●		●	●	●		●
Colleague	●	●						●	
Patient				●					
Patient contribution									
Did not contribute	●	●	●	●	●				●
Contributed						●	●	●	
Responsibility									
Nurse	●	●		●		●	●	●	●
Other occupation			●		●				

2.4. *Development of questionnaire*

To reduce the burden of the participants, we randomly ordered the 9 hypothetical near-miss events and used five events (events 1 to 5) in the first questionnaire, five events (events 2 to 6) in the second questionnaire, and so on, repeating the process nine times. The result was 9 different questionnaires sent to participants at random.

2.5. *Statistical analysis*

We converted answers from participants to Type of Analysis into a categorical variable with three levels (expanded analysis, investigation to find common problems (common problem investigation), and others). We used chi-square tests to examine the relations between Type of Analysis and determinant factors (Probability, Organizational Risk (2 items), and Severity (4 items), the characteristics of participants and characteristics of events). Length of appointment and length of time reporting system that was implemented were converted into dichotomous variables by considering their distributions.

We used logistic regression analysis with the forced entry method to investigate factors that determined the type of analysis applied to a near-miss event, using dummy variables for 9 types of events to adjust for the effect of differences among these events. As the dependent variable, we used Type of Analysis with the three levels described above and dichotomous variables (expanded analysis and others), implementing multiple logistic regression analysis and binary logistic regression analysis, respectively. As explanatory variables, we selected the variable from the determinant factors that had *p*-values on chi-square tests less than 0.1.

These statistical analyses were implemented for all the participants (total group), participants who were full-time safety managers (full-time group), and participants who were safety managers concurrent with other work (concurrent group), respectively.

We analyzed the data using the statistical package SPSS 10.1J for Windows, and used a 5% significance level.

3. Results

3.1. *Characteristics of participants*

Responses to our request for participation were received from 186 of the nurses appointed as safety managers (response rate, 47.3%; number of hypothetical near-miss events, 930). Excluded from participation were nurses who left any question on characteristics of participants unanswered. Similarly, when a question about an event was missing, that event was excluded from analysis. As a result, 175 nurses participated in this study and 808 hypothetical near-miss events were answered.

Characteristics of participants are shown in Table 2. There were 58 full-time safety managers (33.1%). For statistical analysis, length of appointment was divided into less than 2.5 years and 2.5 years or more, and length of time reporting system that was implemented was

Table 2. Characteristics of participants

Participants	Frequency (%)/Mean (S.D.)					
	Total (n = 175)		Full-time (n = 58)		Concurrent (n = 117)	
Sex						
Male	6	(3.4)	1	(1.7)	5	(4.3)
Female	169	(96.6)	57	(98.3)	112	(95.7)
Age	50.0	(5.1)	48.6	(5.1)	50.7	(5.0)
Length of employment	20.8	(10.3)	15.7	(10.9)	23.4	(8.9)
Length of appointment	2.3	(2.8)	1.1	(1.1)	2.9	(3.1)
Emplyment status						
Vice director of nursing division or higher	58	(33.1)	5	(8.6)	53	(45.3)
Others	117	(66.9)	53	(91.4)	64	(54.7)
Appointment form						
Full-time	58	(33.1)				
Concurrently with other work	117	(66.9)				
Area from which reports are submitted						
Including other division	82	(46.9)	50	(86.2)	32	(27.4)
Nursing division only	93	(53.1)	8	(13.8)	85	(72.6)
Authority						
Review of related documents	139	(79.4)	53	(91.4)	86	(73.5)
Interview with staff	108	(61.7)	52	(89.7)	56	(47.9)
Interview with patient	53	(30.3)	27	(46.6)	26	(22.2)
Administration of staff education	139	(79.4)	52	(89.7)	87	(74.4)
Development or revision of manuals	135	(77.1)	45	(77.6)	90	(76.9)
Determination of instruments and materials used	72	(41.1)	26	(44.8)	46	(39.3)
Recommendation for preventing adverse events	136	(77.7)	49	(84.5)	87	(74.4)
Announcement of information about events	104	(59.4)	50	(86.2)	54	(46.2)
Holding the risk management committee meeting	75	(42.9)	32	(55.2)	43	(36.8)
Number of beds						
~ 599	82	(46.9)	24	(41.4)	58	(49.6)
600 ~ 699	39	(22.3)	16	(27.6)	23	(19.7)
700 ~ 799	26	(14.9)	12	(20.7)	14	(12.0)
800 ~	28	(16.0)	6	(10.3)	22	(18.8)
Length of time reporting system implemented	7.6	(6.5)	6.6	(6.6)	8.1	(6.5)

divided into less than 5 years and 5 years or more.

3.2. *Determinant factors of Type of Analysis (all participants)*

3.2.1. *Relations between Type of Analysis and individual determinant factors*

We examined the relations between Type of Analysis and individual determinant factors (Table 3). All of the factors had a significant relationship with Type of Analysis ($p < 0.05$). Moreover, 3 items under characteristics of events (place of discovery, patient contribution, and responsibility) had a significant relationship with Type of Analysis ($p < 0.01$).

3.2.2. *Determinant factors of Type of Analysis*

We implemented a multiple logistic regression analysis using Type of Analysis as the dependent variable with three levels that consisted of "expanded analysis", "common problem investigation", and "others". We used "others" as a reference category. As a result of forced entry of determinant factors and dummy variables for events (Cox and Snell R square = 0.243, Nagelkerke R square = 0.283, MacFadden R square = 0.142), the factors that made the safety managers implement expanded analysis were: low probability (once or less per year, $p < 0.01$; several times per year, $p < 0.05$; several times pre half year, $p < 0.05$), effect on reputation (large effect, $p < 0.001$), high possibility of harm (almost certain, $p < 0.05$), and appointment form (full-time safety manager, $p < 0.01$). Factors that compelled the safety managers to implement common problem investigations were: only a large effect on reputation (large effect, $p < 0.001$) and high degree of harm (high possibility of ADL disability, $p < 0.01$).

Next, we implemented a binary logistic regression

Table 3. Relations between Type of Analysis and individual determinant factors

Individual determinant factors	*n*	Expanded analysis	Common problem investigation	Others
Probability***				
Once or less a year	234	78%	12%	10%
Several times a year	242	50%	31%	19%
Several times half a year	206	49%	33%	19%
Several times or more a month	126	37%	34%	29%
Effect on reputation***				
Large effect	217	70%	22%	8%
Small effect	330	50%	29%	21%
No effect	261	47%	27%	25%
Effect on cost**				
Large effect	178	65%	23%	12%
Small effect	377	52%	29%	19%
No effect	253	51%	26%	23%
Possibility of harm***				
Almost certain	144	70%	18%	12%
Highly possible	331	50%	33%	18%
Rare	333	38%	33%	30%
Degree of harm***				
Fatal	242	69%	17%	14%
ADL disability highly possilble	306	52%	34%	14%
ADL disability only slightly possible	260	47%	28%	26%
Possibility of recovery*				
No recovery highly possible	572	63%	21%	16%
Recovery highly possible	236	53%	29%	19%
Possibility of delayed discharge***				
Highly possible	352	62%	23%	15%
Only slightly possible	456	48%	31%	21%
Appointment form**				
Full-time	266	60%	28%	12%
Concurrently with other work	542	54%	26%	21%
Length of time reporting system implemented*				
≥ 5 years	396	59%	22%	19%
< 5 years	412	52%	31%	17%
Length of appointment*				
≥ 2.5 years	299	53%	24%	23%
< 2.5 years	509	57%	28%	15%

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

analysis using Type of Analysis as the dichotomous dependent variable that consisted of "expanded analysis" and "others". The result of this analysis is shown in Table 4 (dummy variables for the events are not on this table). Probability (once or less per year, $p < 0.001$; several times per year, $p < 0.05$), effect on reputation (large effect, $p < 0.001$), possibility of harm (almost certain, $p < 0.05$), and possibility of delayed discharge (high possibility, $p < 0.05$) had significant effects. Regarding Probability, the lower the chance of probability, the higher the odds ratio, which means there was an increased tendency to select for expanded analysis. Appointment form ($p < 0.01$) and length of reporting ($p < 0.01$) were also significant, suggesting that full-time safety managers and those in a facility with a reporting system in place for 5 years or more analyzed near-miss events in detail.

3.3. *Determinant factors of Type of Analysis (full-time group)*

Of the participants, 58 were full-time safety managers (Table 2) and these participants provided information for 266 hypothetical near-miss events.

The result of chi-square tests suggested that Type of Analysis for the full-time group had a significant relationship with all items within Probability, Organizational Risk, and Severity ($p < 0.01$), but not with length of appointment and length of time the reporting system was implemented. About the relationship between Type of Analysis and characteristics of events, place of discovery, related

Table 4. Binary logistic regression analysis

Individual determinant factors	Total (n = 808)	Full-time (n = 266)	Concurrent (n = 542)
	OR	OR	OR
Probability			
Once or less a year	4.267***	13.672***	3.124**
Several times a year	1.886*	3.034*	1.560
Several times half a year	1.563	1.497	1.604
Several times or more a month			
Effect on reputation			
Large effect	2.831***	1.131	1.199
Small effect	1.232	2.357	3.117***
No effect			
Effect on cost			
Large effect	0.716	0.560	1.144
Small effect	0.859	0.855	0.682
No effect			
Possibility of harm			
Almost certain	2.243*	2.288	0.893
Highly possible	1.362	2.278	1.835
Rare			
Degree of harm			
Fatal	0.842	0.633	0.819
ADL disability highly possilble	0.778	1.336	0.787
ADL disability only slightly possible			
Possibility of recovery			
No recovery highly possible	0.807	0.507	0.790
Recovery highly possible			
Possibility of delayed discharge			
Highly possible	1.650*	4.888**	1.249
Only slightly possible			
Appointment form			
Full-time	1.688**		
Concurrently with other work			
Length of time reporting system implemented			
≥ 5 years	1.713**	1.451	1.835**
< 5 years			
Length of appointment			
≥ 2.5 years	0.974	0.272*	1.127
< 2.5 years			
Cox & Snell R^2	0.196	0.318	0.178
Nagelkerke R^2	0.263	0.431	0.238

* $p < 0.05$, ** $p < 0.01$, *** $p < 0.001$.

occupation, patient contribution, and responsibility were significant ($p < 0.05$).

We implemented a binary logistic regression analysis for the full-time group using Type of Analysis as the dichotomous dependent variable. As shown in Table 4, items within Probability (once or less per year, $p < 0.001$; several times per year, $p < 0.05$) and possibility of delayed discharge (high possibility, $p < 0.01$) had significant effects.

3.4. *Determinant factors of Type of Analysis (concurrent group)*

We equally implemented statistical analysis for safety managers who assumed that role concurrently with other duties. In this category were 117 participants (Table 2) and 542 hypothetical near-miss events.

As a result of chi-square tests, 6 items (probability, effect on reputation, possibility of harm, degree of harm, possibility of delayed discharge, and length of implementation of a reporting system) had a significant relationship to the Type of Analysis with the concurrent group ($p < 0.05$). In the test of the relationship between Type of Analysis and characteristics of events, significance was identified for place of discovery, patient contribution, and responsibility ($p < 0.01$).

As to the binary logistic regression analysis for the concurrent group using Type of Analysis as the dichotomous dependent variable, as shown in Table 4, Probability (once or less per year, $p < 0.01$), effect

on reputation (large effect, $p < 0.001$), and length of implementation of reporting system ($p < 0.01$) had significant effects.

4. Discussion

4.1. *Characteristics of participants*

Because there are few studies on safety managers in Japanese health care facilities, we have little information to make comparisons regarding the characteristics of subjects of our studies with those of other safety managers. Length of appointment of our participants was relatively short (mean; 2.3 years), suggesting that many facilities had only recently established a safety management section or that the term for a safety manager is relatively short. Of the respondents, 33.1% served as vice director of the nursing division or had some other upper-level position. In this study, we requested one of the nurses who was appointed as safety manager to answer the questionnaire, so administrative staff such as a so-called general risk manager tended to answer the questionnaire. We must keep in mind that the administrative view of the participant might affect responses.

That 33.1% of the respondents were full-time safety managers supports results of research of the Japanese Nursing Association in 2001 that approximately 60% of health care facilities with risk managers do not have a full-time risk manager.

4.2. *Characteristics of events*

We examined the validity of hypothetical near-miss events in this study. Seven items under "characteristics of events" were significantly associated with 4 items of Type of Analysis for the total group, 3 items for the full-time group, and 3 items for the concurrent group. Three of the items were identical for each group except for 1 item in the total group (discoverer). Safety managers in all groups selected more detailed analysis for events that were discovered far from the patient, to which the patient contributed, and for which a nurse was responsible.

The results with regard to both patient contribution and responsibility were as would be expected. Events that were discovered far from the patient were related to important medications such as noradrenalin or insulin in this study, so a relation between the place of discovery and detailed analysis can also be expected. There was consistency between characteristics of events and selection of Type of Analysis, and therefore the hypothetical near-miss events in this study are valid.

4.3. *Determinant factors of Type of Analysis*

We referred to American scales for determination of Type of Analysis and treatment to develop items in our questionnaire. The results suggest that Japanese safety managers also use potential severity to assess near-miss events (errors that were prevented by planned or unplanned barriers). The higher the potential severity, the more frequently expanded analysis is selected for the event.

There is a difference in regard to Type of Analysis with Probability. Both SAC and RAI select more expanded analysis for events with higher probability (*3,10*). But in this study, safety managers tended to select more frequently expanded analysis for events of lower probability. The results of logistic regression analysis also support this finding.

This difference might depend on the type of event. While SAC and RAI deal with both accident events and near-miss events, the events in this study are all near-miss events. Because a patient can suffer harm from an actual adverse event, the higher the Probability of the event, the more important the event is. Many papers support this relationship (*11-13*). By contrast, although there are many articles that suggest the importance of a near-miss event, there are few articles about the relationship between Probability and importance of near-miss events (*14,15*). In this study safety managers consistently selected more expanded analysis for events of lower Probability. These findings suggest the problem that the scales principally made for actual adverse events were uncritically applied to near-miss events.

The results of logistic regression analysis for the total group shows that 1 item of Organizational Risk (effect on reputation) and 2 items on Severity (possibility of harm and possibility of delayed discharge) are significant. In this study, non-significant items for Severity (degree of harm and possibility of recovery) require a relatively vivid imagination about a patient's injury and its results, and also the effect on cost. It is difficult for safety managers to have such a clear imagination. In contrast, significant items require relatively little imagination about the event. Thus, it is easier for safety managers to make predictions regarding significant items than non-significant ones. The hypothetical events used in this study provide no information about the individual patient. In an actual near-miss event, expanded patient information might affect the selection, especially prediction of Severity.

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