

Application of Bow-tie methodology to improve patient safety

Application
of Bow-tie
methodology

425

Zhaleh Abdi

*National Institute of Health Research,
Tehran University of Medical Sciences, Tehran, Iran*

Hamid Ravaghi

*School of Health Management and Information Sciences,
Iran University of Medical Sciences, Tehran, Iran*

Mohsen Abbasi

*Department of Emergency Medicine,
Iran University of Medical Sciences, Tehran, Iran*

Bahram Delgoshaei

*School of Health Management and Information Sciences,
Iran University of Medical Sciences, Tehran, Iran, and*

Somayeh Esfandiari

Hasheminejad Hospital, Tehran, Iran

Received 4 October 2015
Revised 17 December 2015
Accepted 1 February 2016

Abstract

Purpose – The purpose of this paper is to apply Bow-tie methodology, a proactive risk assessment technique based on systemic approach, for prospective analysis of the risks threatening patient safety in intensive care unit (ICU).

Design/methodology/approach – Bow-tie methodology was used to manage clinical risks threatening patient safety by a multidisciplinary team in the ICU. The Bow-tie analysis was conducted on incidents related to high-alert medications, ventilator associated pneumonia, catheter-related blood stream infection, urinary tract infection, and unwanted extubation.

Findings – In total, 48 potential adverse events were analysed. The causal factors were identified and classified into relevant categories. The number and effectiveness of existing preventive and protective barriers were examined for each potential adverse event. The adverse events were evaluated according to the risk criteria and a set of interventions were proposed with the aim of improving the existing barriers or implementing new barriers. A number of recommendations were implemented in the ICU, while considering their feasibility.

Originality/value – The application of Bow-tie methodology led to practical recommendations to eliminate or control the hazards identified. It also contributed to better understanding of hazard prevention and protection required for safe operations in clinical settings.

Keywords Patient safety, Intensive care unit, Bow-tie methodology, Proactive risk assessment

Paper type Research paper

Introduction

Serious adverse events and medical errors threatening patient safety occur more frequently in intensive care unit (ICU) setting as compared with other non-critical settings in hospitals (Clancy, 2007). Medication errors and adverse drug events (ADEs)

This study was a part of the first author's PhD thesis (Grant No. TUMS/SHMIS-1390/488). The authors would like to express their deepest gratitude to Pieter Nederveen for his support.



International Journal of Health
Care Quality Assurance
Vol. 29 No. 4, 2016
pp. 425-440
© Emerald Group Publishing Limited
0952-6862
DOI 10.1108/IJHCA-10-2015-0121

are causing significant harms to patients hospitalized in the ICUs (Valentin *et al.*, 2006; Clancy, 2007). In addition, critically ill patients are particularly vulnerable to iatrogenic injuries such as nosocomial infections, because of their medical complexity and needs for high-risk interventions (Rothschild *et al.*, 2005). However, related studies revealed that around half of the adverse events in ICU are preventable (Rothschild *et al.*, 2005; Kopp *et al.*, 2006). This fact necessitates hospitals taking a more proactive approach to identify risks and implement strategies to alleviate their undesirable effects (Kessels-Habraken *et al.*, 2010).

The Swiss Cheese model of accident causation suggests that preventable adverse events and medical errors are often caused by a combination of work system factors rather solely by individual performance (Reason, 1995; Pronovost *et al.*, 2002). Inherent system failures have been recognized as the main reasons for majority of medical errors (Reason, 2000). This fact emphasizes the need of applying proactive risk assessment (PRA) methods, which can reduce or remove contributing factors associated with the incidence of adverse events (Clancy, 2007). PRA methods have been widely used to identify and eliminate potential hazards in hazardous industries (Vincent, 2003). Although a broad array of PRA methods are available to be used in the healthcare setting, only a limited number of such methods has been applied (Lyons, 2009). A review of the literature shows that the process-based tools such as failure mode and effect analysis (FMEA) and Healthcare FMEA have been widely used in health care setting (Card *et al.*, 2012). Typically, FMEA is used to identify single point failures and their mode and effect in a given process (Duwe *et al.*, 2005). FMEA has been criticized for some shortcomings since it concentrates on finding failures in a single process rather than proposing ways of achieving excellence in designing a system (Shebl *et al.*, 2009; Franklin *et al.*, 2012).

The objective of this study was to apply a PRA method to analyse the most important clinical risks in an ICU and devise the corresponding measures accordingly. Hence, the Bow-tie methodology, a barrier analysis method based on systemic approach, was applied to identify, prioritize, and control clinical risks threatening patient safety in the ICU. Only a few studies reported the application of Bow-tie in healthcare setting (Wierenga *et al.*, 2009; Kerckhoffs *et al.*, 2013). The original Bow-tie model was developed for application in high-risk industries to assess risks of major industrial accidents (Jacinto and Silva, 2010). However, as with many other risk assessment techniques, its use is quickly spreading to other fields (De Dianous and Fiévez, 2006). Combining both prospective and retrospective approaches, the Bow-tie methodology provides the users with the opportunity to realize the situations before and after the incidence of an event. This study is part of a larger safety improvement project aiming at improving patient safety culture in the ICU.

Methodology

Setting and design

The current study was conducted in a 12-bed semi-closed medical ICU in a teaching hospital affiliated to Tehran University of Medical Sciences (TUMS) between late 2011 and early 2014. This single case study used a participatory approach to collect and analyse data as well as implementing improvement interventions. Multiple methods of observation, group discussion, and interview were used to generate data. Ethical approval was granted by the Ethics Committee of TUMS.

Application of Bow-tie methodology to analyse and control clinical risks

Unit-based safety team. A multidisciplinary safety management team, consisting of four physicians (two intensivists, and two residents) and five nurses (one head-nurse, three staff nurses, and one infection control nurse), and one top management representative was formed in 2011. The team members met on a biweekly basis for 32 times. Team members were recruited on a voluntary basis. One of the intensivists (M.A) was the team leader. The Bow-tie methodology was initially presented to the members of the team by the facilitator (Z.A).

Description of the Bow-tie methodology. The Bow-tie methodology covers all steps in risk management cycle, including hazard identification, risk analysis, risk evaluation, and risk control. This methodology can offer a good overview of an adverse event scenario. The first step in creating a Bow-tie diagram is defining the top event. Top event, the centre of the Bow-tie diagram, is the event or situation at which no adverse consequences have occurred yet, but control over the process has been lost. A top event can be triggered by one or several threats. Threats are in the left side in the Bow-tie diagram. The top event leads to a number of consequences, which are placed in the right side of the Bow-tie diagram. The next step focuses on identifying preventive barriers (i.e. the barriers that already exist in the path of the threats to prevent their initiation) and protective barriers (i.e. the barriers that already exist in the path of the threats to protect from or mitigate the undesirable consequences of the treats) that are in place. Preventive barriers are in the left side of the model and protective barriers are in the right side of the model. Then the escalation factors that could lead to an increased risk by undermining the effectiveness of the available barriers should be determined. In the next step, the available mechanisms used to control the undesirable effects of these factors on the barriers need to be identified (i.e. secondary barriers). A full Bow-tie represents a possible scenario with all treats pathways and barriers identified. A Bow-tie diagram for the sequence of threats to consequences is as shown in Figure 1. This method uses the risk matrix to evaluate and

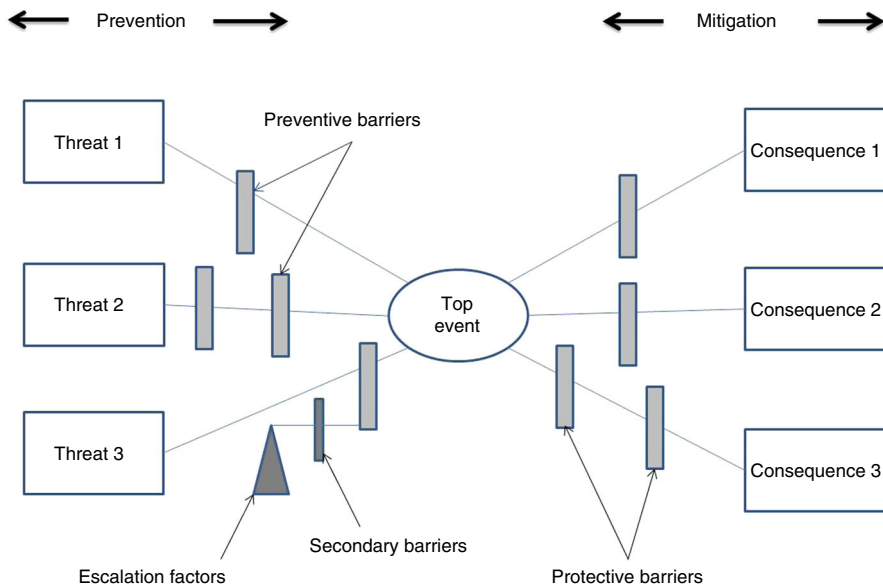


Figure 1.
The general Bow-tie
diagram

categorize the risks and then carries out more detailed analysis in terms of risk acceptance criteria. Finally, a set of improvement strategies are proposed considering the existence and effect of the contributing factors, the number of preventive and protective barriers, and their effectiveness. In the current study, the Bow-tie diagrams were created using Bow TieXP software (trial version).

Findings

Identify the hazards

In this step, the most important hazards threatening patient safety in the ICU were identified. Potential sources to identify hazards included sentinel event reports, events discussed at morbidity and mortality conference, and input from team members as follows: first, adverse drug incidents related to high-alert medications including insulin, anticoagulant (warfarin, heparin, enoxaparin), adrenergic agonist (epinephrine, dobutamine, dopamine, norepinephrine), propranolol, labetalol, digoxin, potassium chloride, neuromuscular blocking agents (atracurium, pancuronium), sedative (midazolam, fentanyl), anaesthetic agents (thiopental, propofol); second, ventilator-associated pneumonia (VAP); third, catheter-related blood stream infection (CRBSI); fourth, urinary tract infection (UTI); and finally, unplanned extubation (UE).

Risk analysis

In the current study, top event was translated into medical setting and defined as “a possible avoidable adverse event associated with medical care”. First, the cause-consequence model was developed for all identified top events ($n = 48$). Figure 2 shows a part of the insulin overdose diagram. All possible causes which could lead to an event were listed in the left side of the Bow-tie diagram (e.g. top event = insulin overdose, treat 1 (slip): nurse administered incorrect dose of insulin to the patient). Factors contributing to the possible human errors (slip/lapse/mistake/violation) were identified and classified according to the framework of the contributing factors to patient safety incidents proposed by Charles Vincent, based on the “system factors” approach (Taylor-Adams *et al.*, 2004). The classification has been reported to be successfully applied in the ICU Safety Reporting System project (Pronovost *et al.*, 2004). Contributing factors were sub-divided into seven main categories as follows: patient, provider, team, training and education, task, local environment, and organizational factors. Each of the main factors has a number of sub-factors. Table I shows the identified contributing factors to the incidence of CRBSI in the ICU. Possible contributing factors were determined according to the team members’ opinion and reported incidents in the ICU (e.g. one of the contributing factors to the nurse’s slip could be the poor handwriting of the physician, which was classified as a team factor). Potential consequences were identified as the effects of the risks on patients, ranging from no harm to severe harms, disability, or even death. The next step was to identify barriers (preventive barriers) that already existed in the path of the threats to prevent their initiation (e.g. human action barrier = nurse knowledge, nurse knew dose order was not standard for insulin). For each consequence, the available barriers that could detect the adverse event, protect from or mitigate its consequences were identified (protective barriers). Some of the identified protective barriers (recovery measures) were notifying other care givers (e.g. calling the physician), giving antidote and monitoring patient (e.g. injecting hypertonic solutions in case of insulin overdose), replacing the equipment (e.g. using a different glucometer) or documenting. These barriers were classified into four main categories:

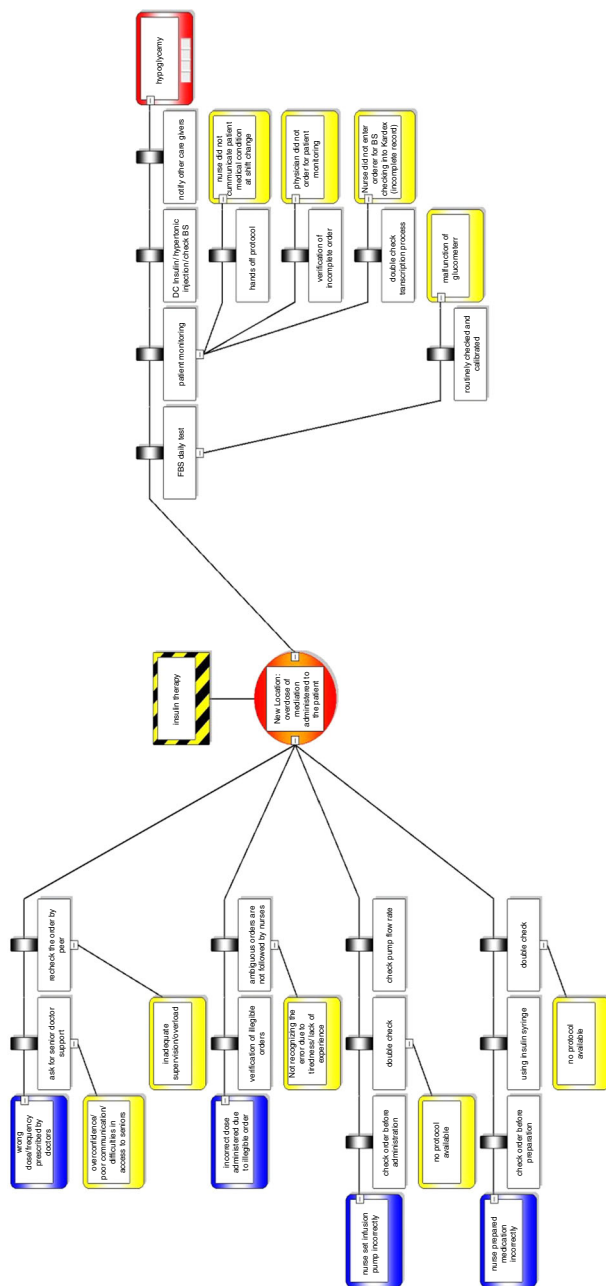


Figure 2.
Bow-tie diagram of
the insulin overdose

Table I.
Factors identified to
contribute to the
incidence of CRBSI
in the ICU

Factor (sub factor)	Example
<i>Patient factors (clinical or social characteristics of a patient that contribute to adverse event)</i>	
Medical condition and complexity	Patient with acute renal failure
Language and condition	Patient does not speak Persian
Personality and social factors	Patient agitation
<i>Provider factors (characteristics or state of a clinician that contributes to adverse event)</i>	
Knowledge, skills, and competence	Lack of skills in central vascular catheter insertion techniques
Fatigue	Being on call in ICU for 24 hours
Motivation and attitude	Does not adhere to infection control precautions (gloves, sterile gowns, masks, and drapes)
Physical or mental health	Anxiety, depression, or physical limitation
Failure to follow established protocol	Failure to follow maximal sterile precautions/or protocol for central catheter insertion
<i>Team factors (characteristics of the team contribute to adverse event)</i>	
Verbal/written communication during handover	No mention of patient history of underlying disease
Verbal/written communication during routine care	Illegible physician order regarding catheter removal
Supervision and seeking help	Did not seek advice regarding catheter insertion/absence of supervision
Team structure and leadership	ICU director were not available
<i>Training and education factors (characteristics of staff training (or lack thereof) that contribute to adverse event)</i>	
Knowledge, skills, and competence	No training on central catheter insertion
Failure to follow established protocol	Central catheter-nursing care not reviewed with nurse
<i>Task factors (characteristic of a specific task that contribute to adverse event)</i>	
Availability of protocols	No written protocol for catheter insertion and maintenance
Availability of test results	Portable X-ray machine was not available
Accuracy of test results	Error in labelling samples obtained from the catheter and a peripheral vein
<i>Local environment factors (characteristics of the work environment that contribute to adverse event)</i>	
Staffing levels	Inadequate assistants for nurses
Skill mix	No senior nurse assigned to a shift
Workload	Inadequate nurse-to-patient ratio
Equipment availability or maintenance	Malfunction of ultrasonography for catheter placement
Administrative and managerial support	Refusal to support medical ICU
Physical environment	Lack of adequate space around beds
<i>Organizational factors (decision (or indecision) by management that contributed to adverse event)</i>	
Financial resources	No financial support for providing protective equipment, antiseptic containing hubs, etc.
Time pressure	Pressure discharge patient prematurely

administrative, human action, physical, and natural. Finally, the escalation factors that could lead to increased risk by undermining the effectiveness of preventive and protective barriers were identified (e.g. nurse did not recognize the error because she was tired at the end of a double shift). The escalation factors, known as the secondary causes,

were classified also by using the contributing factors classification. Finally, the available mechanisms that were in place to control the undesirable effects of escalation factors on barriers were identified.

Risk analysis of high-alert medication process. Different techniques such as interview and observation were applied to develop a rich description of the high-alert medications process in the ICU. The most important adverse events related to high-alert medications were identified as follows: administering the wrong dosage of medication (overdose or under dose), administering medication to the wrong patient, administering the wrong type of medication (e.g. regular insulin instead of NPH insulin), administering medication via the wrong route, and inadequate monitoring after administration. A total of 44 potential ADEs were analysed of which 36 potential adverse events were classified as medium and high risks. In general, from the causes identified 26 per cent were individual factors, 14 per cent were team factors, 10 per cent were task factors, 35 per cent were education factors, 10 per cent were patient factors, 3 per cent were ICU environment factors, and 2 per cent were management factors. Table II shows some of the existing preventive and protective barriers identified in the risk analysis of high-alert medications.

Risk analysis of VAP, UTI, and CRBSI. Since multiple factors influence the development of health acquired infections (HAIs), including patient variables, patient care variables, and administrative variables, the team decided to take a

Available barriers	Escalation factors	Recommended barriers	Implemented (yes/no)
Before pouring the medication, checking the prescription label against the medication order to make sure that they match	Interruption and distraction	Making a designated area for preparing medication without interruption	Yes
Checking junior residents' orders by seniors/chief residents	High workload, not seeking advice	Increased monitoring, reviewing orders by clinical pharmacist/senior resident	Partially (the hire of a clinical pharmacist was not done because of high cost)
Independent double check policy (not required for all high-alert medications)	Non-compliance with policy due lack of motivation, lack of knowledge, or lack of supervision	Revised policy (which mandated double check for all high-alert medications). Assessing compliance with the double check policy	Yes
Handoffs report	Incomplete report due to lack of time/lapse of memory	Designing and implementing a checklist for verbal reporting	Yes
Seeking senior advice while prescribing	The attending physicians were not available at nights or during weekends	Implementing a plan mandating 24-hour presence of ICU intensivist/critical care fellows in the ICU	Yes
Using antidote to reverse the effects of high-alert medications overdose	Nurse does not know how to use antidote due to lack of experience	Preparing an antidote medication list and preparation guide	Yes

Table II.
Examples of
available barriers
and proposed
barriers in
medication process

different approach in comparing medication errors while analysing HAIs. Therefore, all the factors that prevented the standard measures of HAIs to be implemented in the ICU were known as the threats and contributing factors. In the current study, a number of human errors, such as non-compliance with guidelines (e.g. hand hygiene policy, full sterile barriers precautions during catheter insertion, peptic ulcer disease prophylaxis, catheter insertion protocol, catheter maintenance protocol, oral hygiene protocol, and PUD prophylaxis protocol) were identified as the threats. Factors that contributed to the occurrence of such errors were identified and grouped into relevant categories. The identified contributing factors to the incidence of CRBSI are listed in Table I. Existing preventive and protective barriers and their effectiveness were discussed. Totally, 58 barriers were identified in the three Bow-tie diagrams.

Risk analysis of UE. UE was defined as the inadvertent removal of endotracheal tube, either by a patient or a healthcare provider during routine care. The most important identified threats during the analysis included: lack of strong tube fixation, lack of patient monitoring by nursing staff, level of patient consciousness, and agitation and delirium. Other threats were restraint of agitated patient, lack of IV sedation, delay of planned extubation, and lack of education to elective patient. Contributing factors to the threats were brainstormed and classified accordingly. Existing barriers and their escalation factors were discussed by the team.

Risk evaluation

A picture of possible adverse events was gained in the previous step. Top events (clinical risks) were evaluated by establishing consequence severity and then estimating the likelihood of the consequence. This was done by using a standard risk matrix (Table III) that was previously developed by the National Patient Safety Agency (2008). The consequences were rated from 1 to 5, according to their respective impact on patient safety using a group consensus method. The consequences were assigned considering the worst possible outcomes. The likelihood of the risks was scored on the scale of 1-5, the higher the number the more likely the adverse outcome will occur. The likelihood of the risks occurring was assigned based on expert judgment and previous data. The risk scores were calculated by multiplying the consequence score by the likelihood score using a scale ranging from $1 \times 1 = 1$ to $5 \times 5 = 25$. Evaluated risks (adverse events) were ranked into four levels, that is, negligible risks (low risks, green part of the matrix), tolerable risks (moderate and high risks, yellow and orange parts of the matrix, respectively), and intolerable or unacceptable risks (extreme risks, red part of the matrix). In the current study, 39 out of 48 identified risks (or adverse events) were known as tolerable and extreme risks. Figure 3 is the risk matrix of insulin-related adverse events.

Risk control

In line with Bow-tie methodology, the acceptance of risk was established based on the number and the quality of risk controls against the estimated risks, as shown in Table IV. The team members discussed the number of existing preventive, protective, and secondary barriers, and factors undermining their effectiveness. The Bow-tie team argued the need for extra preventative measures to reduce the likelihood of an event occurrence, and protective measures to minimize and ameliorate the potential consequences. In this step, a list of improvement measures was

	Likelihood score				
	1	2	3	4	5
Consequence score	Rare	Unlikely	Possible	Likely	Almost certain
5 Catastrophic	5	10	15	20	25
4 Major	4	8	12	16	20
3 Moderate	3	6	9	12	15
2 Minor	2	4	6	8	10
1 Negligible	1	2	3	4	5

1-3	Low risk
4-6	Moderate risk
8-12	High risk
15-25	Extreme risk

	Consequence score (severity levels) and examples of descriptors				
	1	2	3	4	5
Domains	Negligible	Minor	Moderate	Major	Catastrophic
Impact on the safety of patients	Minimal injury requiring no/minimal intervention or treatment No time off work	Minor injury or illness, requiring minor intervention Requiring time off work for >3 days Increase in length of hospital stay by 3-4 days	Moderate injury requiring professional intervention Requiring time off work for 4-14 days Increase in length of hospital stay by 4 An event which impacts on a small number of patients	Major injury leading to long-term incapacity/disability Requiring time off work for >14 days Increase in length of hospital stay by >15 days Mismanagement of patient care with long-term effects	Incident leading to death Multiple permanent injuries or irreversible health effects An event which impacts on a large number of patients

Likelihood score	1	2	3	4	5
Descriptor	Rare	Unlikely	Possible	Likely	Almost certain
Frequency: How often might it/does it happen	This will probably never happen/recur	Do not expect it to happen/recur but it is possible it may do so	Might happen or recur occasionally	Will probably happen/recur but it is not a persisting issue	Will undoubtedly happen/recur, possibly frequently

Source: A risk matrix for risk managers (National Patient Safety Agency, 2008)

Table III.
Risk matrix

produced. It should be noted that in some cases adding extra barriers was practically impossible.

To reduce safety hazards, a set of interventions were suggested for those threats with inadequate number or effectiveness of barriers in their pathway. In cases where there were any missing barriers, new barriers were proposed. In cases where the

Figure 3.
Risk evaluation of
incidents related
to insulin

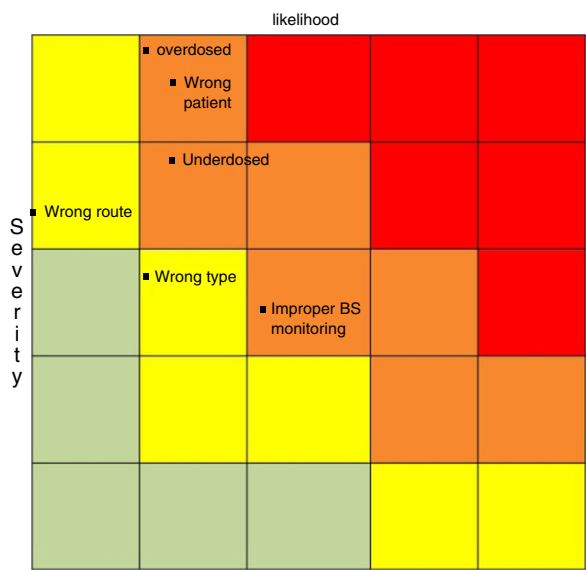


Table IV.
Risk acceptance
criteria

Region	Criteria
Tolerable	Requires a minimum of two effective barriers in place for all threats Requires a minimum of one effective recovery measure (barrier) for each identified consequence
Intolerable	Requires a minimum of one effective control in place for all escalation factors Requires a minimum of three effective barriers in place for all threats Requires a minimum of two effective recovery measures (barriers) for each identified consequence Requires a minimum of one effective control in place for all escalation factors

Source: Trbojevic (2001)

number of barriers was sufficient but there were a number of escalation factors, the team suggested strategies as secondary barriers to the undesirable effects of escalation factors. The choice of interventions was based on a review of international evidence and expert opinions. Improvement strategies were chosen according to the ALARP (as low as reasonably practicable) concept, which means weighing a risk against the resources required to control it. Hence, to choose feasible and scientifically sound measures, the improvement strategies were assessed using a priority selection matrix which included three criteria: cost of the given strategy, effectiveness, and acceptability. A set of recommendations were implemented in the ICU to improve patient safety. Table V shows the timeline of implemented strategies in the ICU from 2011 to 2014.

At the first step, an educational programme was designed to ensure that staff would realize the importance of patient safety and understand the principle of safe practice in ICU. The results of the risk assessment were presented to all ICU staff. Various workgroups were assigned to implement the recommendations in the ICU. Lack of

Activities	Date					
	December 2011- February 2012	March- April 2012	June- December 2012	January- May 2013	January- September 2013	October 2013-May 2014
Evaluating safety culture						
Monthly meetings						
Patient safety education						
Improvement medication process safety:						
(1) Monthly educational workshop on medication safety						
(2) Assigning a designated area for preparing medication quietly and without interruptions						
(3) Implementation of an insulin therapy protocol						
(4) Preparing a "Do Not Use" list for abbreviations in medication orders						
(5) Implementation of a double check policy in high-alert medications process						
(6) Preparing a protocol for administering antidotes						
(7) Regular monitoring of medication orders in terms of accuracy, completeness, and legibility						
Implementing daily goals checklist						
Intervention to reduce infection control:						
(1) Holding infection control training sessions						
(2) Standardising the process of CVCs and PVCs management						
(3) Initiation of hand hygiene compliance improvement campaign						
(4) Monitoring compliance with infection control precautions						
(5) Monitoring the "5 moments of hand hygiene"						
(6) Monitoring compliance with aseptic technique for catheter insertion and proper catheter care						
(7) Monitoring compliance with VAP bundle practices						
Intervention to reduce UE:						
(1) Educational course focusing on the importance of preventing unplanned extubation						
(2) Revising sedation and weaning protocols and pain control protocol						
(3) Standardising selected processes, including spontaneous breathing trail, and tracheal tube fixation						
(4) Improvement the layout of the ICU to facilitate patient monitoring						
(5) Educating patient before elective admissions						
(6) Monitoring the degree of compliance with pain, sedation, and weaning protocols						

Table V.
Timeline of
interventions
implemented to
improve safety

Notes: CVC, central venous catheter; PVC, peripheral venous catheter. The shading would show the time duration of each intervention

communication and teamwork among professional groups was identified as a major safety issue in the ICU in the qualitative assessment of the safety culture. One intervention was the introduction of a daily goals sheet, which was used during daily rounds. The purpose of this tool was to focus healthcare team on what needs to be accomplished in a day to safely move the patient closer to transfer out of the ICU or

discharge home. The safety team instituted several changes in the medication process and extubation procedure, which is reflected in Table V. To decrease the level of agitation among patients receiving mechanical ventilation, pain, and sedation protocol was revised and implemented. According to the analysis, some of the self-extubations occurred in patients scheduled for elective extubation within a few hours, which indicated that health care personnel needed to better manage weaning and extubation timing. Therefore, weaning protocol was revised and developed according to the evidenced-based clinical practice guideline. It included a criteria for starting the weaning process, methods of carrying out the spontaneous breathing trial (SBT), and criteria to the evaluation of SBT. Also, the degree of compliance with pain, sedation, and weaning protocols by staff was monitored regularly in the ICU. However, some of the proposed strategies including increasing the nurse to patient ratio from 1:2 to 1:1 as well as monitoring cameras were not implemented due to financial constraints. In general, the interventions to reduce CRBSI, VAP, and UTI mainly focused on increasing the use of evidence-based infection control practice in the ICU.

Discussion

Applying risk analysis methods was proposed as an effective strategy by governing bodies to reduce harms to patients (Briner *et al.*, 2013). Patients admitted to intensive care setting are more likely to experience adverse events as compared to others in non-critical settings (Boyle *et al.*, 2006). However, evidence suggests that about half of the adverse events are preventable (Stockwell and Slonim, 2006). This fact emphasizes the need of applying PRA methods which can reduce or remove contributing factors associated with the incidence of the adverse events (Clancy, 2007). The PRA methods should be seen in terms of their main goal, reducing errors by way of identifying contributing factors to errors and proposing appropriate strategies to address these factors. However, most of the times, they are applied in healthcare setting just for identifying errors without considering appropriate strategies to reduce or mitigate the errors (Lyons, 2009).

According to James Reason (1995), latent failures in the system could produce conditions in which frontline workers make an error or fail to catch and mitigate it. The Bow-tie methodology systematically addresses the work system factors that either contribute to the incident of an adverse event or undermine the effectiveness of the available barriers. Consequently, through the application of the methodology, any efforts aiming at improving safety need to consider the characteristic of the work system and system vulnerabilities threatening safety.

In addition to being able to drill down to underlying causes, Bow-tie diagrams depict the interactive relationship between individual, organizational, and cultural factors influencing the way in which risks are managed in the system (Hudson, 2010). At the first step, when the threats, consequences, and barriers are drawn, it provides a picture of the number of barriers, their effectiveness, and their integrity. At this step, the application of available barriers and safeguards is mainly influenced by the frontline workers intentions and behaviours (i.e. active failures or unsafe acts). Barrier may have holes where threats might pass. Short-term holes may be created by errors and violations (e.g. non-compliance with established protocols) of front-line staff due different causes. Violations are mostly resulting from a pathological culture (Amalberti *et al.*, 2006). Longer-lasting and more dangerous gaps are due to latent conditions, mostly created by inappropriate

decisions of managers at different layers of the organization (Reason, 2000). Bow-tie diagrams also provide an insight if barriers are independent. Sometimes the number of the barriers is enough; however, they involve the same person or team, which may be affected by same escalation factors. Poor organizational safety culture is a significant contributor to both active failures and latent conditions. In the current study, the behavioural aspects of safety culture in the ICU were examined before the application of the Bow-tie methodology through a qualitative analysis (Abdi *et al.*, 2013). Indeed, this was useful in understanding the role of cultural factors in safety management activates in the studied unit.

In safety science, the concept of error recovery, derived from industrial science and error theory, can be equally important to error prevention (Chozos, 2009; Carayon *et al.*, 2013). In Bow-tie methodology, detection and mitigating errors together represent error recovery. Previous studies have investigated strategies for error detection and recovery among clinical staff (Rogers *et al.*, 2008; Henneman *et al.*, 2010; Faye *et al.*, 2010). In the current study, different strategies for error recovery were explored, leading to an increased insight of staff into their role in the different phases of recovery process, including identifying, interrupting, and correcting errors.

One of the most widely used formal PRA techniques in healthcare setting is FMEA (Duwe *et al.*, 2005). Although FMEA is the most familiar PRA method within healthcare, it is not the only available method (Lyons, 2009; Franklin *et al.*, 2012). The main reasons for low usage of the PRA methods could be lack of awareness about available techniques or the challenge of choosing among a large number of available options (Lyons, 2009). In addition, most studies that applied PRA methods in healthcare setting have focused on limited and technical processes, such as medication administration process. In the current study, we tried to expand the Bow-tie methodology for risk management in other fields, such as HAIs and UE, other than medication error. Nosocomial infections are a major challenge to patient safety in the ICU (Burke, 2003). Although it is often impossible to identify a specific human error as the cause of an infection, clinicians' non-compliance with safe practice standards have been identified as the major contributing factors to nosocomial infections (Collins, 2008). In the current study, a number of human errors were identified as the main causes of the HAIs incidence in the ICU, which, according to evidence, are associated with higher rates of infections in the ICU.

Previous studies have stressed the need for developing context-specific PRA methods for healthcare setting (Lyons *et al.*, 2005). Studies applied Bow-tie methodology in healthcare setting reported a number of issues regarding the application of the method, including need for facilitator, problem with defining specific top events, and necessary to "think out of the box" to identify threats and risks (Wierenga *et al.*, 2009; Kerckhoffs *et al.*, 2013). In the current study, in order to increase the adaptability of the method, several strategies were employed, which consist of defining unit-specific top events, using a healthcare-specific classification for contributing factors, applying risk matrix developed for healthcare setting to evaluate risks, and using a priority selection matrix to select improvement strategies. To consider all possible threats, the contributing factor table was employed. Through the use of category headings, the contributing factor table provided a structured approach to brainstorm and analyse factors contributing to the incidence of adverse events beyond conventional threats and risks. In order to reduce the subjectivity of the risk analysis, the risk matrix developed for healthcare setting by NHS was applied instead of general risk matrix.

In addition, it was realized that the Bow-tie methodology was also successful in promoting clinicians' awareness about errors and errors provoking conditions within their environment and practice. It has been argued that carrying out a PRA method can accelerate the transition from a reactive safety culture to a proactive one through empowerment of frontline staff to identify safety-threatening risks, using their knowledge of what goes wrong and how to prevent it, and enhancing their commitment to new and existing risk controls (Kessels-Habraken *et al.*, 2009).

In spite of the numerous advantages, there were some problems with the application of the Bow-tie methodology in healthcare setting. This method is time-consuming, requires extensive labour work. Similar to other PRA methods, reliability of the outputs is surely contingent on the reliability of its inputs. Employing a number of data collection methods could influence the reliability of the results. Further, providing training to staff on the model and having facilitator(s) are important since the idea can be difficult to understand, particularly emphasizing the definition of a barrier and barrier factors. The Bow-tie model suggests having at least two preventive barriers for each threat in case of tolerable risk. However, in healthcare setting, there are activities which rely extensively on human action barriers, such as vigilance of a nurse or knowledge of a physician and therefore, it is not possible to set more barriers except those in the process of care.

Study limitations

This study has some limitations. First, the impact of the interventions on patient safety was not studied. Second, the results of the risk analysis only apply to this ICU and cannot be generalized. However, the method is applicable to other ICU and clinical settings.

Conclusion

In conclusion, Bow-tie methodology proves feasible for proactive risk management in the ICU. Its adaptability could be enhanced through the use of a number of tools. Based on the system approach, the Bow-tie allowed the generation of practical solutions to address work system deficiencies as well as overcoming and elevating them. It was also successful in promoting clinicians' awareness about errors and errors provoking conditions within their environment and practice. Visualization of causes, barriers, and consequences in Bow-tie diagrams facilitated comprehension of hazard prevention and protection required for safe operations in the clinical settings. Generally, Bow-tie appears capable of playing a useful role in safety improvement programmes.

References

- Abdi, Z., Delgoshaei, B., Ravaghi, H., Abbasi, M. and Heyrani, A. (2013), "The culture of patient safety in an Iranian intensive care unit", *Journal of Nursing Management*, Vol. 23 No. 3, pp. 333-345.
- Amalberti, R., Vincent, C., Auroy, Y. and de Saint Maurice, G. (2006), "Violations and migrations in health care: a framework for understanding and management", *Quality and Safety in Health Care*, Vol. 15 No. S1, pp. i66-i71.
- Boyle, D., O'Connell, D., Platt, F.W. and Albert, R.K. (2006), "Disclosing errors and adverse events in the intensive care unit", *Critical Care Medicine*, Vol. 34 No. 5, pp. 1532-1537.

-
- Briner, M., Manser, T. and Kessler, O. (2013), "Clinical risk management in hospitals: strategy, central coordination and dialogue as key enablers", *Journal of Evaluation in Clinical Practice*, Vol. 19 No. 2, pp. 363-369.
- Burke, J.P. (2003), "Infection control – a problem for patient safety", *New England Journal of Medicine*, Vol. 348 No. 7, pp. 651-656.
- Carayon, P., Xie, A. and Kianfar, S. (2013), "Human factors and ergonomics as a patient safety practice", *BMJ Quality & Safety*, Vol. 23 No. 3, pp. 196-205.
- Card, A.J., Ward, J.R. and Clarkson, P.J. (2012), "Beyond FMEA: the structured what-if technique (SWIFT)", *Journal of Healthcare Risk Management*, Vol. 31 No. 4, pp. 23-29.
- Chozos, N. (2009), "Focusing accident analysis on error handling activities: three case studies in the NHS", *Risk Management*, Vol. 11 No. 3, pp. 159-178.
- Clancy, C.M. (2007), "Patient safety in the intensive care unit: challenges and opportunities", *Journal of Patient Safety*, Vol. 3 No. 1, pp. 6-8.
- Collins, A.S. (2008), "Preventing health care-associated infections", in Hughes, R.G. (Ed.), *Patient Safety and Quality: An Evidence-Based Handbook for Nurses*, Agency for Healthcare Research and Quality, Rockville, MD, pp. 2-547-2-575.
- De Dianous, V. and Fiévez, C. (2006), "ARAMIS project: a more explicit demonstration of risk control through the use of Bow-tie diagrams and the evaluation of safety barrier performance", *Journal of Hazardous Materials*, Vol. 130 No. 3, pp. 220-233.
- Duwe, B., Fuchs, B.D. and Hansen-Flaschen, J. (2005), "Failure mode and effects analysis application to critical care medicine", *Critical Care Clinics*, Vol. 21 No. 1, pp. 21-30.
- Faye, H., Rivera-Rodriguez, A.J., Karsh, B.-T., Hundt, A.S., Baker, C. and Carayon, P. (2010), "Involving intensive care unit nurses in a proactive risk assessment of the medication management process", *Joint Commission Journal on Quality and Patient Safety*, Vol. 36 No. 8, pp. 376-384.
- Franklin, B.D., Shebl, N.A. and Barber, N. (2012), "Failure mode and effects analysis: too little for too much?", *BMJ Quality & Safety*, Vol. 21 No. 7, pp. 607-611.
- Henneman, E.A., Gawlinski, A., Blank, F.S., Henneman, P.L., Jordan, D. and McKenzie, J.B. (2010), "Strategies used by critical care nurses to identify, interrupt, and correct medical errors", *American Journal of Critical Care*, Vol. 19 No. 6, pp. 500-509.
- Hudson, P.T. (2010), "Integrating organisational culture into incident analyses: extending the Bow tie model", *Proceedings of the SPE International Conference on Health, Safety and Environment in Oil and Gas Exploration and Production in Rio de Janeiro, Brazil*, Society of Petroleum Engineers, pp. 2662-2674.
- Jacinto, C. and Silva, C. (2010), "A semi-quantitative assessment of occupational risks using Bow-tie representation", *Safety Science*, Vol. 48 No. 8, pp. 973-979.
- Kerckhoffs, M.C., van der Sluijs, A.F., Binnekade, J.M. and Dongelmans, D.A. (2013), "Improving patient safety in the ICU by prospective identification of missing safety barriers using the Bow-tie prospective risk analysis model", *Journal of Patient Safety*, Vol. 9 No. 3, pp. 154-159.
- Kessels-Habraken, M., De Jonge, J., Van der Schaaf, T. and Rutte, C. (2010), "Prospective risk analysis prior to retrospective incident reporting and analysis as a means to enhance incident reporting behaviour: a quasi-experimental field study", *Social Science & Medicine*, Vol. 70 No. 9, pp. 1309-1316.
- Kessels-Habraken, M., Van der Schaaf, T., De Jonge, J., Rutte, C. and Kerkvliet, K. (2009), "Integration of prospective and retrospective methods for risk analysis in hospitals", *International Journal for Quality in Health Care*, Vol. 21 No. 6, pp. 427-432.
- Kopp, B.J., Erstad, B.L., Allen, M.E., Theodorou, A.A. and Priestley, G. (2006), "Medication errors and adverse drug events in an intensive care unit: direct observation approach for detection", *Critical Care Medicine*, Vol. 34 No. 2, pp. 415-425.

- Lyons, M. (2009), "Towards a framework to select techniques for error prediction: supporting novice users in the healthcare sector", *Applied Ergonomics*, Vol. 40 No. 3, pp. 379-395.
- Lyons, M., Woloshynowych, M., Adams, S. and Vincent, C. (2005), "Error reduction in medicine", working paper, final report to The Nuffield Trust, London, 24 October.
- National Patient Safety Agency (2008), "A risk matrix for risk managers", available at: www.npsa.nhs.uk/nrls/improvingpatientsafety/patient-safety-tools-and-guidance/risk-assessment-guides/risk-matrix-for-risk-managers/ (accessed 10 September 2011).
- Pronovost, P., Wu, A.W., Dorman, T. and Morlock, L. (2002), "Building safety into ICU care", *Journal of Critical Care*, Vol. 17 No. 2, pp. 78-85.
- Pronovost, P.J., Nolan, T., Zeger, S., Miller, M. and Rubin, H. (2004), "How can clinicians measure safety and quality in acute care?", *The Lancet*, Vol. 363 No. 9414, pp. 1061-1067.
- Reason, J. (1995), "Understanding adverse events: human factors", *Quality in Health Care*, Vol. 4 No. 2, pp. 80-89.
- Reason, J. (2000), "Human error: models and management", *BMJ*, Vol. 320 No. 7237, pp. 768-770.
- Rogers, A., Dean, G., Hwang, W. and Scott, L. (2008), "Role of registered nurses in error prevention, discovery and correction", *Quality and Safety in Health Care*, Vol. 17 No. 2, pp. 117-121.
- Rothschild, J.M., Landrigan, C.P., Cronin, J.W., Kaushal, R., Lockley, S.W., Burdick, E., Stone, P.H., Lilly, C.M., Katz, J.T. and Czeisler, C.A. (2005), "The critical care safety study: the incidence and nature of adverse events and serious medical errors in intensive care", *Critical Care Medicine*, Vol. 33 No. 8, pp. 1694-1700.
- Shebl, N.A., Franklin, B.D. and Barber, N. (2009), "Is failure mode and effect analysis reliable?", *Journal of Patient Safety*, Vol. 5 No. 2, pp. 86-94.
- Stockwell, D.C. and Slonim, A.D. (2006), "Quality and safety in the intensive care unit", *Journal of Intensive Care Medicine*, Vol. 21 No. 4, pp. 199-210.
- Taylor-Adams, S., Vincent, C. and Street, P. (2004), "Systems analysis of clinical incidents: the London protocol", *Clinical Risk*, Vol. 10 No. 6, pp. 211-220.
- Trbojevic, V.M. (2001), "Linking risk assessment of marine operations to safety management in ports", paper presented at the 6th Biennial Marine Transportation System Research and Technology Coordination Conference, Washington, DC, 14-16 November, available at: www.risk-support.co.uk/vmt_MTS2001.pdf (accessed 18 November 2011).
- Valentin, A., Capuzzo, M., Guidet, B., Moreno, R.P., Dolanski, L., Bauer, P. and Metnitz, P.G. (2006), "Patient safety in intensive care: results from the multinational Sentinel Events Evaluation (SEE) study", *Intensive Care Medicine*, Vol. 32 No. 10, pp. 1591-1598.
- Vincent, C. (2003), "Understanding and responding to adverse events", *New England Journal of Medicine*, Vol. 348 No. 11, pp. 1051-1056.
- Wierenga, P.C., Lie-A-Huen, L., de Rooij, S.E., Klazinga, N.S., Guchelaar, H.-J. and Smorenburg, S.M. (2009), "Application of the Bow-tie model in medication safety risk analysis", *Drug Safety*, Vol. 32 No. 8, pp. 663-673.

Corresponding author

Zhaleh Abdi can be contacted at: zh-abdi@razi.tums.ac.ir

For instructions on how to order reprints of this article, please visit our website:

www.emeraldgroupublishing.com/licensing/reprints.htm

Or contact us for further details: permissions@emeraldinsight.com

Reproduced with permission of the copyright owner. Further reproduction prohibited without permission.