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Using Bayesian Networks for Risk Assessment in Healthcare System

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Abstract

To ensure patient safety, the healthcare service must be of a high quality, safe and effective. This work aims to propose integrated approaches to risk management for a hospital system. To improve patient's safety, we should develop methods where different aspects of risk and type of information are taken into consideration. The first approach is designed for a context where data about risk events are available. It uses Bayesian networks for quantitative risk analysis in the hospital. Bayesian networks provide a framework for presenting causal relationships and enable probabilistic inference among a set of variables. The methodology is used to analyze the patient's safety risk in the operating room, which is a high risk area for adverse event. The second approach uses the fuzzy Bayesian network to model and analyze risk. Fuzzy logic allows using the expert's opinions when quantitative data are lacking and only qualitative or vague statements can be made. This approach provides an actionable model that accurately supports human cognition using linguistic variables. A case study of the patient's safety risk in the operating room is used to illustrate the application of the proposed method.

Keywords: risk assessment, patient's safety, fuzzy Bayesian network, fuzzy logic, Bayesian network

1. Introduction

Medical error is a leading cause of death and injury. Each year, between 210,000 and 440,000 patients who go to the hospital for care suffer from some types of preventable harm that contribute to their death [1]. High error rates with serious consequences are most likely to occur in the operating room [2]. A strong patient's safety culture in the operating room is very



important to improve quality and reduce risks of adverse event and medical errors. Thus, a flexible risk analysis technique becomes crucial.

A lot of methods and techniques, such as fault tree analysis (FTA) and failure mode and effect criticality analysis (FMECA), have been used for safety risk analysis in the healthcare system. However, these methods have a limitation when dealing with rare event and complex systems. Khakzad indicated FTA unsuitable for complex problems with its limitation in explicitly representing dependencies of events, updating probabilities, and coping with uncertainties [3], while FMECA does not take into account multiple failure scenarios and causes. Bayesian Network (BN) is a powerful method for risk analysis. In contrast with other classical methods of dependability analysis, Bayesian networks provide a lot of benefits. Some of these benefits are the ability to model complex systems, to make predictions as well as diagnostics, to compute exactly the occurrence probability of an event, to update the calculations according to evidences, to represent multimodal variables, and to help modeling user-friendly by a graphical and compact approach [4].

In this chapter, we propose two methods which can help to assess patient safety in different contexts using Bayesian network.

2. Case of the data availability about risks

In this part, we propose a method for the context of data availability. We will explain how we can use the classical Bayesian network for safety assessment in healthcare system.

2.1. Methodology of risk analysis of the operating room

In the following, a methodology of risk analysis of the operating room using Bayesian networks is proposed. The methodology follows four steps (**Figure 1**) and it is part of continuous improvement process (CIP) [5].

The first step involves determining the aim of the risk assessment process, the description of the problem, and the definition of the scope.

Example: risk of patient's safety in the operating room.

The second step is to identify potential risks that can affect the quality and the efficiency of the operating room process. In this step, we may encourage creativity and involvement of the operating room team.

The third step is the risk modeling. It consists in the development of the Bayesian networks graph (definition and choice of the variables to represent the nodes, describe the states of each node, and build the structure of Bayesian networks in terms of links between the predefined nodes) and establishment of the quantitative relation between nodes through conditional probability. In this step, we can use the hospital data source and the expert's judgment to feed the model.

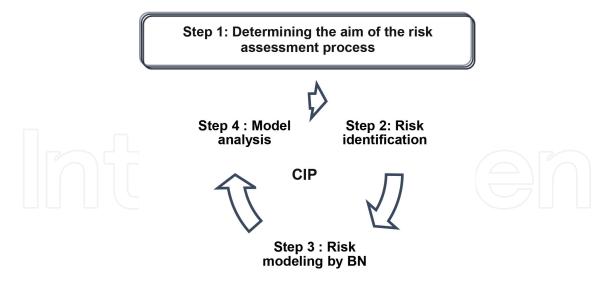


Figure 1. Methodology of risk analysis for operating room using Bayesian network.

The last step is the analysis of the results: The model should give the best understanding of the risk problem. It is useful to discuss the goodness or appropriateness of the model. It is important to validate and calibrate the model using all available source of information (expert judgment, observation, statistical data...). We should then analyze and interpret the result of risk measures to support decision-making for safety improvement.

Finally, continuous improvement efforts must incorporate a risk assessment process to ensure the effectiveness and the quality of the process. The model must be updated with the new risks and factors.

2.2. Application: patient safety risk analysis in the operating room

2.2.1. Determining the aim of the risk assessment process

The operative processes include the preoperative, intraoperative, and postoperative stages of a surgery. We are going to study the operating room processes and in particular, the intraoperative stage. It starts when the patient enters the operating room and all members of the surgical team are expected to be in the operating room at this particular time. The process ends when the patient is able to leave the operating room. During this process, the patient is monitored, anesthetized, and prepped and the operation is performed. Because of the lack of availability of actual data risk, we will forward a risk analysis based on different sources accidents described in the international literature. We will limit our study to events that cause a significant deviation of the operating room process compared to normal process and which have serious consequences for the patient (re-intervention, hospitalization in intensive care, extension of the period of hospitalization, additional care, death...).

2.2.2. Development of the Bayesian network model

To create and validate the structure of the network, we use Hugin software and more precisely Hugin Lite Evaluation.

Figure 2 illustrates the Bayesian network model of patient's safety showing interrelationships of events that may lead to patient's injury. The model has 13 nodes with one utility node. The nodes are assessed using a literature source. We present below the description of each nodes.

Surgery infection: the incidence of surgical site infections (SSI) depends upon the patient risk factors, surgical procedure, and practices observed by the operating team.

Surgical foreign body: leaving things inside the patient's body, after surgery, is an uncommon but a dangerous error. Sponges and scissors used during surgery have been left inside patients' bodies.

Operating on the wrong part of the body or wrong-site or wrong-patient or wrong-procedure surgeries: the frequency of surgery admissions experiencing a wrong site or wrong side or wrong patient or wrong procedure or wrong implant is 0.028 per 1000 admissions [6].

Medication error: wrong-dose, wrong-time, wrong-medication, or transcription errors. "A medication error is any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures and systems including prescribing, order communication, product labelling, packaging and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; use" [7]. In a review of medical records from hospitals in two American states, there was a significantly higher incidence of preventable drug-related adverse events in patients aged >64 than in patients aged 16–64 years (5% compared with 3%) [8]. Errors are also significantly more likely in children.

Anesthesia equipment failure: anesthesia equipment problems may contribute to morbidity and mortality. The frequency of anesthetic equipment problems is 0.05% during regional anesthesia, and 0.23% during general anesthesia [9].

Operation error: an error may occur in surgery due to different adverse events.

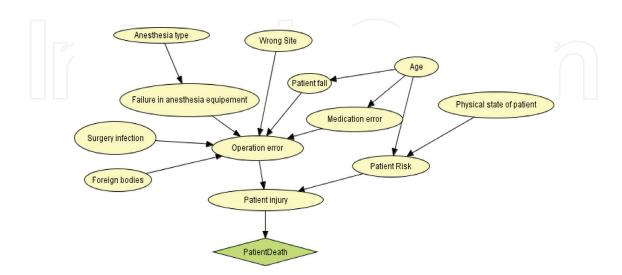


Figure 2. Bayesian network for patient safety model for the operating room.

Patient injury: an error may or may not cause an adverse event. Adverse events are injuries that cause harm to the patient (death, life-threatening illness, disability at the time of discharge, prolongation of the hospital stay, etc.).

In the following, some risk factors are given:

Patient risk: we consider two states for patient's risk, high and normal. The risk in surgery can come from patients themselves.

Age: for the age factor, we assume that the patient may be child, elderly, or adult. The age can increase the patient's risk, the risk of fall, and the risk of medication error. These risks are much higher for elderly and child than adult.

Anesthesia type: we consider two categories of anesthesia, regional and general. We assumed that "failure in anesthesia equipment" depends on anesthesia type as explained in [9].

The conditional probabilities of states of different nodes and the marginal probabilities of some adverse events have been given as input data. Each risk of adverse events is considered with two states (true if the risk exists and false if not). The probabilities are given in **Tables 1–7**.

To aggregate the impact of injuries into a single risk measure, we use utility node "Patient Death." So the task is to find the probability of patient's death after a surgery by using only the correlations and the marginal frequencies.

Operation error	True		False	
Patient risk	High	Normal	High	Normal
No	0.01	0.01	0.99	1
Small	0.18	0.81	0.009	0
Severe	0.81	0.18	0.001	0

Table 1. Conditional probability for patient injury.

Age	Adult	Elderly	Child
True	1.16E-5	1.16E-4	1.16E-4
False	0.9999884	0.999884	0.999884

Table 2. Conditional probability for patient fall.

Age	Adult	Elderly	Child
True	0.03	0.05	0.06
False	0.97	0.95	0.94

Table 3. Conditional probability for medication error.

Physical state	Weak			Normal	Normal		
Age	Adult	Elderly	Child	Adult	Elderly	Child	
High	0.6	0.8	0.9	0	0	0	
Normal	0.4	0.2	0.1	1	1	1	

Table 4. Conditional probability for patient risk.

Anesthesia type	Regional		General
True	5×10^{-5}		2.3×10^{-3}
False	$1 - (5 \times 10^{-5})$		0.9977

Table 5. Conditional probability for failure in anesthesia equipment.

Risk	Probabilities
Surgery infection	2.5×10^{-2}
Wrong site	2.6×10^{-5}
Foreign bodies	10^{-3}

Table 6. Probability of some adverse events.

Factor	State	Occurrence
Anesthesia type	Regional	0.5
3.1	General	0.5
Physical state	Weak	0.1
	Normal	0.9
Age	Adult	0.5
	Elderly	0.2
	Child	0.3

Table 7. Probability of some factors.

2.2.3. Analysis of the result

After the structure of the Bayesian network is completed and probabilities are determined, the inference can be performed to estimate the probability of patient's safety risk. We conduct the calculation using Hugin software. The dependency and the correlation among risks and factors are captured in nodes "Operation error" and "Patient injury." Hence, the task is to find the probabilities of patient's death after surgery by using only the correlations and the probabilities of adverse events and the frequency of influencing factors. The probability of the death of patient is 6.37×10^{-3} . If the state of one or more variables is known, the model can be updated and the probability of patient injury and operation error will change. This should result in

Risk	Probabilities
Death of patient	6.37×10^{-3}
Death of weak physical state patient	0.02
Death of normal physical state patient	5.03×10^{-3}
Death of child patient	8.2×10^{-3}
Death of adult patient	4.98×10^{-3}
Death of elderly patient	7.08×10^{-3}
Death of elderly patient	7.08

Table 8. Probability of the death of patient.

decision of not to operate the patient or postpone the surgery. For instance, the risk is much higher when the patient has a weak physical state; it is 0.02 instead of 5.03×10^{-3} for the risk of death if the patient has a normal physical state. Knowing the age of patient, we can estimate the risk of death; it is 4.98×10^{-3} for adult, 7.08×10^{-3} for elderly patient, and 8.2×10^{-3} for child (**Table 8**). It should be noted that the model and data used in this chapter have limitations. The model should be enhanced by taking into account different causes of adverse events. Data should be prevented from an adverse event database reporting system and from expert's judgment.

Several actions can be done to reduce risk and improve the safety of the patient in operating room. For instance, we can reduce the risk of retained foreign body during operation by using an appropriate sponge count and obtaining X-rays if needed to check for any retained foreign body. If we reduce this risk by 95%, the risk of the death of patient becomes 6.28×10^{-3} . Furthermore, if we reduce the risk of surgery infection by 80%, the risk of the death of patient passes to 4.5×10^{-3} instead of 6.28×10^{-3} . By acting only on "retained foreign body" and "surgery infection" adverse events, the risk can be reduced by 30%.

3. Case of the lack of data about risk

Due to the lack of data about adverse event and the fact that the adverse event reporting system does not exist, the input data of risk modeling will be provided by expert's opinion. The quality of such data must be discussed. We must help experts to provide reliable quantitative data. This can be done with the fuzzy set theory. Including the expert's judgment in the risk model is essential for providing a reliable risk picture supporting the decision-making. The second approach uses the FBN to analyze risk. Fuzzy Bayesian networks are a powerful approach for risk modeling and analysis. This is especially noticed when quantitative data are lacking and only qualitative or vague statements can be made as well when historical adverse events data are unavailable or insufficient to be used for safety assessment [10]. In this part, we present a real case of the children hospital in Rabat. To feed the model by the probabilities, we interviewed experts of the operating room. The calculation of probabilities is done out of Hugin software to conduct the fuzzy inference.

3.1. Methodology of risk analysis for the operating room using fuzzy Bayesian network (FBN)

In the following, a methodology of risk analysis of the operating room using FBN is proposed. The methodology follows five steps (**Figure 3**) and is part of the continuous improvement process (CIP). The first three steps are the same as the first proposed methodology explained above.

The fourth step is the fuzzy assessment of probability. We investigate the expert's judgment to feed the model. Experts use a linguistic variable to describe the probabilities of occurrence of adverse events. We transform the linguistic expressions into fuzzy numbers. Since we have more than one expert, we must aggregate the different opinions. For that, we use the weight of the expert to take into account the reliability of the data.

The last step is the analysis of the results: we should then analyze and interpret the results of risk measures to support decision-making for safety improvements.

Finally, the model must be implemented in Upgrading way as explained in the first method.

3.2. Application: patient safety risk analysis in the operating room

3.2.1. Risk modeling

Let us consider the previous example that we modify according to expert's opinion. **Figure 4** illustrates the BN model of patient's safety after modification. It shows interrelationships of events that may lead to patient's injury. The model has eight nodes with one utility node added to estimate the risk of the patient's death after surgery due to an error.

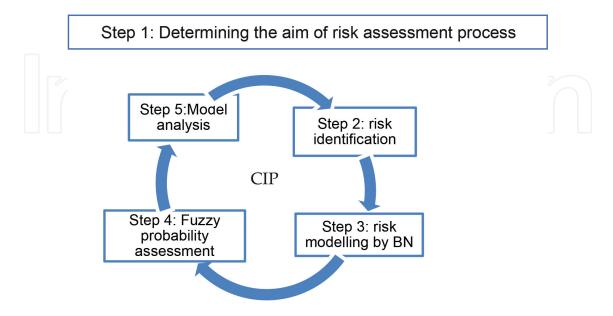


Figure 3. Methodology of risk analysis for operating room using fuzzy Bayesian network.

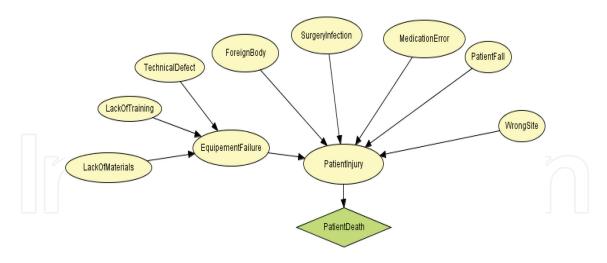


Figure 4. Bayesian network for patient safety model for the operating room.

3.2.2. Fuzzy probability assessment

Surgeons and operating team of the children's hospital IBN SINA of RABAT Morocco were asked to give judgments about the fuzzy probabilities regarding all the nodes. They use linguistic terms to describe the fuzzy probabilities and then refine them with membership functions. For example, "Very low" was assigned to node "PatientFall" and "Average" was assigned to technical defect and then were defined by the membership function (a, b, c). The other probabilities are given in **Table 11** according to the answers given by experts. The likelihood of each criterion (**Table 9**) was represented by a range of five discrete values identified by the following linguistic terms: "extremely low" (L1), "very low" (L2), "low" (L3), "average" (L4), and "high" (L5). The severity of each adverse event (**Table 10**) was represented by a range of five discrete values identified by the following linguistic terms: "negligible" (S1), "minor" (S2), "medium" (S3), "major" (S4), and "catastrophic" (S5). These five values represent the states of the node "patient's injury."

We interviewed three individuals from the operative team (surgeon, crew chief, and anesthesia nurse). They have a different point of view and confidence level toward their own subjective judgments due to the difference in background, working experience, and risk attitudes. Thus, a certain deviation exists in the data reliability among different interviewed individuals.

Set	Linguistic variable	Meaning
L1	Extremely low	Never seen
L2	Very low	One time in my career
L3	Low	Occur in another hospital
L4	Average	Occur in our hospital
L5	High	Occur in my domain

Table 9. Scale of the likelihood.

Set	Linguistic variable	Meaning
S1	Negligible	Consequence minor without prejudice (simple delay)
S2	Minor	Incident with prejudice (disorganization)
S3	Medium	Incident with impact postponement, prolongation of hospitalization, not expected transfer in reanimation)
S4	Major	Serious Consequence (re-intervention; permanent or partial disability)
S5	Catastrophic	Very serious Consequence (disability, death)

Expert	Weight
E1	W1 = 1/2
E2	W2 = 1/3
E3	W3 = 1/6

Table 11. Weight of expert's opinion.

Table 11 represents the weight of each expert. Expert 1 has more experience and more precise answers about adverse events than the others, so he was given the higher weight 1/2, 1/3 was assigned to expert 2, and 1/6 to expert 3.

To deal with the deviation of experts answers, the aggregated fuzzy importance of each criterion, whose properties are used to produce a scalar measure of consensus degree, is computed by the weight of the criteria according to the judgment of the expert (Eq. (1)).

$$M_{1} = \begin{pmatrix} \mu^{e1b1} & \cdots & \mu^{ekb1} \\ \vdots & \ddots & \vdots \\ \mu^{e2bn} & \cdots & \mu^{ekbn} \end{pmatrix}$$
 (1)

The expert's judgment about the likelihood and the severity of adverse events is given in Table 12. For instance, the probability ("high," "L5") and the severity ("catastrophic," S5) have been assigned to the node "foreign body" by expert E1; expert E2 had a different judgment about the likelihood of the same event (L3, "Low"). As you can see, experts have different opinions; that is why we used the weight of each expert.

Table 13 represents the fuzzification of the probabilities linguistic variable. For example, the triangular fuzzy number (0.00, 10^{-8} , 2×10^{-8}) is assigned to the linguistic variable ("Extremely low," "L1"). The point (10^{-8} , 1), with membership grade of 1, is the mean value; 0 and 2×10^{-8} are the left hand and right hand spreads of the triangular number, respectively (Table 13).

M₂ represents the vector of probabilities of basic nodes obtained using Eq. (2) and the matrix of fuzzy probabilities estimated by experts and the weight of each expert are given in Table 5. This step aims to determine the fuzzy probabilities of basic events.

$$M_{2} = \begin{pmatrix} \mu^{b1}(x) \\ \vdots \\ \mu^{bn}(x) \end{pmatrix} = \begin{pmatrix} \mu^{e1b1} & \cdots & \mu^{ekb1} \\ \vdots & \ddots & \vdots \\ \mu^{e2bn} & \cdots & \mu^{ekbn} \end{pmatrix} \times \begin{pmatrix} w1 \\ \vdots \\ wk \end{pmatrix}$$
 (2)

Table 14 describes the conditional probability of the node "Equipment Failure" represented by the variable N1, this variable has two states, namely true if the risk exists and false if not. If one of the three events B1, B2, and B3 occurs, the risk exists. 1f and 0f represent the crisp values 1 and 0 considered here as fuzzy number 1f (1,1,1) and 0f (0,0,0).

Nodes	Variable	E1	E1 E2		E3			
		L	S	L	S	L	S	
Lack of training	B1	L4	S3	L3	S3	L4	S4	
Lack of materiel	B2	L4	S3	L3	S3	L4	S4	
Technical defect	В3	L4	S3	L3	S2	L4	S4	
Patient fall	B4	L2	S3	L3	S2	L1	S2	
Medication error	B5	L5	S5	L3	S5	L2	S3	
Surgery infection	В6	L5	S4	L3	S4	L3	S3	
Foreign body	В7	L5	S5	L3	S5	L2	S4	
Wrong site	B8	L4	S4	L3	S4	L2	S3	

Table 12. Expert's judgment about the likelihood and the severity of adverse events.

Set	Linguistic term	Function			
L1	Extremely low	$\mu_1(x) = (0.00, 10^{-8}, 2 \times 10^{-8})$			
L2	Very low	$\mu_2(x) = (1.5 \times 10^{-8}, 10^{-7}, 10^{-6})$			
L3	Low	$\mu_3(x) = (0.9 \times 10^{-6}, 10^{-5}, 2 \times 10^{-5})$			
L4	Average	$\mu_4(x) = (1.5 \times 10^{-5}, 10^{-4}, 2 \times 10^{-4})$			
L5	Very high	$\mu_5(x) = (1.5 \times 10^{-4}, 10^{-3}, 2 \times 10^{-3})$			

Table 13. Fuzzification of likelihood.

N1	B4	В5	В6	В7	В8	S1	S2	S3	S4	S5
True	False	False	False	False	False	$0_{\rm f}$	$0_{\rm f}$	1_{f}	$0_{\rm f}$	$0_{\rm f}$
False	True	False	False	False	False	$0_{\rm f}$	$1_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$
False	False	True	False	False	False	$0_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$	$1_{\rm f}$
False	False	False	True	False	False	$0_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$	$1_{\rm f}$	$0_{\rm f}$
False	False	False	False	True	False	$0_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$	$1_{\rm f}$
False	False	False	False	False	True	$0_{\rm f}$	$0_{\rm f}$	$0_{\rm f}$	$1_{\rm f}$	$0_{\rm f}$

Table 14. Conditional occurrence probability of "patient injury".

B1	B2	В3	N1 = True	N1 = False
True	True	True	1_{f}	0_{f}
		False	1_{f}	0_{f}
	False	True	1_{f}	0_{f}
		False	1_{f}	0_{f}
False	True	True	$1_{ m f}$	$0_{\rm f}$
		False	$1_{\rm f}$	0_{f}
	False	True	1 _f	0_{f}
		False	0_{f}	1_{f}

Table 15. Conditional occurrence probability of "equipment failure".

Table 15 represents the conditional probability of the node "Patient injury," the node has five states S1–S5 according to the severity of the harm caused to the patient. Here, the conditional probability is considered as crisp value according to the expert's opinion. Based on the harm observed, experts gave a precise answer about severity.

3.2.3. Result and sensitive analysis

After the structure of the BN is developed and probabilities are determined, the inference can be performed to estimate the probability of patient's safety risk. The dependency and the correlation among risks and factors are captured in node "Patient injury." Hence, the task is to find the probabilities of patient's death after surgery by using the correlations and the fuzzy probabilities of adverse events. Using the fuzzy Bayesian rule, the probability that the injury severity will be catastrophic can be calculated as given in Eq. (3):

$$P(T = S5) = \sum_{i} P(B = b_i) \otimes P(T = S5/B = b_i)$$
 (3)

The probability that the injury severity will be catastrophic (S5) is $(1.5 \times 10^{-4}, 10^{-3}, 2 \times 10^{-3})$. Assuming that 80% of patients having a catastrophic injury die, the probability of the death of a patient after surgery due to an adverse event is $(1.2 \times 10^{-4}, 0.8 \times 10^{-3}, 1.6 \times 10^{-3})$. Using the center of the gravity method (Eq. (4)), we obtained COG = $(8.4 \times 10^{-4}, 1/3)$. The probability of the death of a patient after surgery is the x-axis 8.4×10^{-4} .

$$Z_{COG} = \frac{\int_{z} \mu_{A}(z)zdz}{\int_{z} \mu_{A}(z)dz}$$
 (4)

Several actions can be done to reduce risk and improve the safety of the patient in operating room. Using this model, if we reduce the risk of retained foreign body by 60%, the risk of the death of patient becomes 3.36×10^{-4} .

If the state of one or more variables is known, the model can be updated and the probability of patient injury will change.

One of the main advantages of BN is their ability to help us to conduct inverse interference. For example, it is interesting to know, when a death is observed, what the posterior probability of a patient's infection is. In addition, if the model contains more details witch integrate the main

causes of adverse events, we can obtain more interesting results such as the probability of the death of the patient due to human error or lack of training or malfunction in the organization.

The model presented must be updated when new information is available to better estimate the risk of patient safety in the operating room. The model should be enhanced by taking into account different causes of adverse events. The use of adverse event database reporting system may be very useful for getting statistics and determining the probabilities of occurrence of some adverse events. The model allows integrating a mixture source of information (probabilities from database and expert's opinion).

4. Conclusion

Safety is very essential in the healthcare system. Therefore, we should use effective and flexible methods for risk analysis to improve safety. Bayesian Networks methods are used to model and analyze risk in the operating room. The second method uses, in addition to Bayesian Network, the fuzzy logic. It allows us to use the data provided by expert and deal with the vagueness and imprecision of information. Fuzzy Bayesian network seems more flexible and interpretable than conventional Bayesian network, especially in the context of lack of data concerning risk events. This approach supports human cognition using linguistic variables which is closer to reality.

The application of the two approaches has been explained by the use of a simple model. The aim of this chapter is to propose flexible and effective methods in different context (data availability and lack of data) using Bayesian network.

However, when the size of the graph is important, the model becomes incomprehensive. We can resolve that by using object-oriented Bayesian network (OOBN). OOBN is a type of Bayesian network, comprising both instance node and usual node. An instance node is a subnetwork representing another Bayesian network. Using OOBNs, a large complex Bayesian network can be constructed as a hierarchy of sub-networks with desired levels of abstract and different levels of detail [11]. For instance, we can transform the node 'surgery infection' to a sub-network by analyzing and modeling the causes of this kind of injuries. Therefore, model construction is facilitated and communication between the model's subnetworks is more effectively performed. OOBN has a better model readability which facilitates the extension and improvement of the model.

Remedy actions are always conducted by doctors and nurses upon hazardous occurrences. Timely rescue can largely reduce the practical risks of patient's injury. By contrast, delayed remedies are of less use. It is therefore necessary to take into account the time. Consideration and incorporation of time-dependent in the risk assessment to represent equipment failure or human reliability are very important. This can be done through dynamic Bayesian network (DBN) models. DBN is an extension of Bayesian network; it is used to describe how variables influence each other over time based on the model derived from past data. A DBN can be thought as a Markov chain model with many states or a discrete time approximation of a differential equation with time steps. A dynamic Bayesian network methodology has been developed to model domino effects in [12]. Another application of DBN is presented in [13] to evaluate stochastic deterioration models.

The Bayesian network presented is a model for assessing risk of patient's safety in operating room. The model aims to capture and measure risks in the background knowledge (namely common causes and observed adverse events). Including the expert's judgment in the risk model is essential for providing a reliable risk picture supporting the decision-making. The use of adverse event database reporting system may be very useful for getting statistics and determine the probabilities of occurrence of the adverse events.

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