University of Stavanger

Faculty of Science and Technology

MASTER'S THESIS

Study program/ Specialization: Master of Technology (engineering) in Risk Management / Risk Management	Spring semester, 2015 Open access
Writer: Marius Wormnæs	..... (Writer's signature)
Faculty supervisor: Roger Flage External supervisor(s): Morten Pytte (DNV GL)	
Thesis title: Leading indicators for real-time monitoring of risk in healthcare organizations.	
Credits (ECTS): 30	
Key words: Leading risk indicators Bayesian probability Bayesian belief networks Safety-II	Pages: 46 Stavanger, 15th June / 2015

Summary

Thousands of Norwegian patients experience serious injury and death every year due to preventable adverse events (Deilkås, 2014). Risk management in healthcare is a relatively new discipline. Methods from other high-risk sectors, for instance aerospace, have been adopted without sufficient success (Catchpole, 2013). Healthcare consists of highly complex sociotechnical systems and thus differs from other high-risk sectors.

Existing risk and safety management methods should be supplied with new approaches to prevent patient harm. This thesis is an attempt to contribute to the development of a leading risk indicator framework by proposing some fundamental characteristics.

Leading indicators can monitor real-time changes in risk related to patient harm. Adjustments to the activities based on information about changes in the risk picture can prevent adverse events and maximize patient safety.

This view of safety is in accordance with the concept of Safety-II (Hollnagel, Wears, & Braithwaite, 2015). The principle is to anticipate rather than experience hazards, and adapt to situations rather than respond to unwanted events.

Leading risk indicators that change before the risk level changes provide the opportunity to make adjustments before adverse events occur. According to Kjellén (2009), Vinnem (2014b) and Leveson (2015), that is a condition for indicators to be categorized as leading.

The System-Theoretic Accident Model and Processes (STAMP) identifies leading indicators by assessing the vulnerability of safety-critical assumptions (Leveson, 2015). In order to reduce heuristic biases, the vulnerability assessment is related to the plausibility and severity potential of a hazard.

Safety-critical assumptions include barriers, as well as other risk and safety influencing factors. The majority of barriers in healthcare are procedural, and human factors are important barrier influencing factors.

The presence of human factors is influenced by the safety culture of an organization. The safety culture includes the attitude, awareness and approach to safety of personnel at all levels (EUROCONTROL, 2008; Listyowardojo et al., 2014; Strauch, 2015).

Approaches and methods from other high-risk sectors have been reviewed. The thesis concludes that elements from approaches and methods may be combined as a basis for further development of an appropriate leading risk indicator framework.

The thesis also concludes that the use of Bayes Nets provides a powerful modeling tool of leading risk indicator systems. Certain elements of a leading risk indicator model are suggested.

Contents

1 Introduction 1
1.1 Background and motivation 1
1.2 Current situation 3
1.3 Project goal 3
1.4 Limitations 4
1.5 Thesis structure 4
1.6 Methods and data 5
2 Theory 6
2.1 Probabilities, uncertainties and risk 6
2.2 Safety 8
2.3 Scenarios, adverse events and hazards 8
2.4 Barriers and influencing factors 9
2.5 Human factors and safety culture 11
2.6 Bayesian Belief Networks 13
3 Healthcare 18
4 Results 20
4.1 Why leading indicators? 20
4.2 General requirements for the leading indicators 22
4.3 Proposed elements of a leading indicator 28
5 Discussion 37
6 Conclusion 38
7 List of references 40

1 Introduction

1.1 Background and motivation

Errors and mistakes in healthcare can lead to serious patient harm. Besides the physical consequences, both the patients and the involved healthcare personnel may experience emotional distress. Annually, a high number of patients are subjected to unnecessary infections, permanent disability and death, and such consequences represent a significant societal cost. In addition to reduced productivity and social support, the Norwegian System of Patient Injury Compensation (NPE) reimbursed harmed patients over 1 billion NOK in 2014 (Norsk pasientskadeerstatning, 2015).

In spite of numerous analyses of risk and adverse events, and introduced safety measures, increased knowledge and improved technology, the number of mishaps remains high. Adverse events refer to errors, mistakes or malfunctions that cause additional harm to patients. It is estimated that 13% of hospitalized patients experience unwanted consequences, and that 5% of the mistakes result in fatalities (Deilkås, 2014). In Norway alone, these numbers represent tens of thousands of affected patients and thousands of accidents with serious harm or death.

The high frequency of adverse events in healthcare is an area of concern. Hundreds of reports and thousands of pages are produced every year as an effort to reduce errors and mistakes, and to identify flaws in the safety systems. The vast numbers of rules, regulations, policies and procedures reflect the safety barriers that have been identified by numerous risk assessments. However, the increase in the number of barriers has not resulted in a proportional decrease of adverse events (Shojania & Thomas, 2013).

The European Union has initiated several projects aimed at increasing patient safety (European Commission, 2015) and the Norwegian Ministry of Health and Care Services has clearly stated that too many patients are subject to serious harm (Helse- og omsorgsdepartementet, 2014). Many organizations and institutions are conducting analyses, assessments and research in order to efficiently reduce patient risk.

A significant number of adverse events in healthcare are potentially preventable. Estimations are that

- 50% of all adverse events (Zegers et al., 2009),
- 52% of adverse drug reactions (Hakkarainen, Hedna, Petzold, & Hagg, 2012),
- 55% of surgical site and 65-70% of catheter-associated infections (Umscheid et al., 2011) and
- 60-70% of in-hospital cardiac arrests (Hodgetts et al., 2002)

may be avoided. There is a considerable improvement potential related to the preventable adverse events in healthcare.

Further development of existing and traditional methods of risk management must be complemented with new approaches in order to effectively increase patient safety. One of the main research priorities of DNV GL's Strategic Research & Innovation Program in Healthcare is:

> "System knowledge from a risk perspective with the objective to develop and test solutions for real time monitoring and management of hazards in healthcare." (Vincent et al., 2014)

This project is intended as a contribution to the development of such solutions.

1.2 Current situation

Risk management in healthcare organizations is predominantly based on analyses of incidents and accidents in order to achieve an acceptable level of risk (Helse Sør-Øst, 2013, 2015; Helsedirektoratet, 2014). The purposes of the analyses include understanding the chains of events and finding root causes for identifying and implementing safety measures.

Risk assessments are used to justify the implementation of new and improved technical equipment and procedures. Statistical methods and models provide information about the development of risk in the past, and past development is used to predict future risk. The efforts and resources spent on the development and application of these methods dominate risk management in healthcare as well as in other high-risk sectors.

There is an increasing interest across industries and sectors in the development of leading risk indicators (Kjellén, 2009; Leveson, 2015; Mearns, 2009; Petroleum Safety Authority Norway, 2015; Vinnem, 2014b). Even though there is a shared opinion that leading indicators represent an important contribution to risk management, the approaches and methods differ significantly.

Currently, there is no leading risk indicator method being used in healthcare organizations in Norway or internationally. Some leading risk indicator systems exist in a few other high-risk sectors, such as nuclear power, oil and gas, and aerospace. However, there are good reasons to believe that they should not be implemented in healthcare without thorough analysis and modification. Any risk management method applied anywhere should be tailored to the type of organization, the activities, the technology and the personnel.

1.3 Project goal

The goal of the project is to contribute to the development of a leading risk indicator framework for healthcare organizations by proposing some fundamental characteristics.

The purpose of the framework is to develop leading indicators in order to monitor real-time changes in the risk picture, where risk relates to patient harm. Information about changes in the risk picture can be used to make adjustments to the activities to prevent adverse events and maximize patient safety.

To achieve the goal, the following questions must be answered:

- How may elements from existing methods of risk and safety management provide a basis for a leading risk indicator method suitable for healthcare?
- How may the modeling of a set of leading indicators be approached in order to monitor real-time changes in risk?

1.4 Limitations

As a result of the defined project goal, the following limitations apply:

- The terms and definitions presented in chapter 2 of this thesis are limited to what is considered necessary in order to analyze and discuss the selected risk and safety management methods.
- The risk and safety management methods reviewed in the thesis are limited to a selection that is considered to contribute to the suggested leading indicator framework. The selection is not intended to be complete.
- The leading indicator framework is limited to healthcare organizations.
- The purpose of the leading indicators is not to provide forecasts or predictions for a period of time.
- The indicators are limited to patient risk. Any other kinds of risk, e.g. financial, reputational or environmental, are not included.
- The suggested indicator framework is limited to planned and controllable activities that are described by the rules, regulations, policies or procedures of the organization.
- The thesis is limited to adverse events that can be prevented by the existing safety system.

1.5 Thesis structure

Chapter 2 presents a theoretical background for fundamental leading risk indicator framework characteristics. Concepts of risk and uncertainty, probabilities, safety management, barriers and influencing factors provide an understanding of how risk can be indicated. A presentation of the basic construction and function of Bayesian Belief Networks, or Bayes Nets, as well as how they can be used for real-time and dynamic probability calculations is included.

Chapter 3 presents relevant characteristics of the healthcare sector, including typical adverse events.

Chapter 4 presents the contribution to the development of leading risk indicators for healthcare organizations. It includes proposed general requirements of a framework, and suggests elements of a leading indicator model, as well as how Bayes Nets can be used as a tool for modeling.

Chapter 5 presents discussions related to potential challenges and limitation of the proposed leading indicator framework characteristics and modeling.

Chapter 6 presents the thesis conclusion.

1.6 Methods and data

The main method in the project has been a qualitative literature review. Sources of data include articles and books from frequently cited and recognized authors such as professors Aven, Jan Erik Vinnem, Erik Hollnagel, Urban Anders Gunnar Kjellen and Nancy Leveson.

There is a vast amount of available literature related to risk, safety and healthcare. The scientific databases Scopus and ScienceDirect have mainly been used as sources. The search for relevant literature has been conducted by using certain words and phrases including, but not limited to:

- Leading risk indicators
- Safety and resilience
- Bayesian Networks
- Subjective, objective and Bayesian probabilities
- Uncertainties
- Barriers
- Risk influencing factors
- Patient safety
- Adverse events in healthcare

Other sources of qualitative data are institutions such as Helse Sør-Øst, Helsedirektoratet, Oslo Universitetssykehus, the World Health Organization (WHO) and the Institute for Healthcare Improvement, and regulatory and standardization institutions such as the Petroleum Safety Authority Norway, the Federal Aviation Administration (FAA) and the International Organization for Standardization (ISO).

As sources for quantitative data used to describe the situation in healthcare, some statistical databases such as Statistics Norway (SSB), the Norwegian System of Patient Injury Compensation (Norsk pasientskadeerstatning), the Norwegian Knowledge Centre for the Health Services (Nasjonalt kunnskapssenter for helsetjenesten) and the UK Department of Health/Patient Safety and Investigations have been used.

Data from Norwegian sources has been preferred. However, supplemental data mainly from the UK and US has been used when Norwegian data has been unavailable or insufficient.

The use of Bayes Nets includes both qualitative and quantitative methods. The modeling of the network itself is a qualitative process, and the process of probability updating when evidence is entered into the model is quantitative.

2 Theory

2.1 Probabilities, uncertainties and risk

A *frequentist probability* of an event is defined as the fraction of times the event occurs if an experiment or situation is repeated an infinite number of times (Aven & Reniers, 2013; Walpole, Myers, Myers, & Ye, 2011). The true probability is unknown, but can be estimated. Estimation is based on representative data from similar experiments, and the probability is the limit value of the frequency as the number of experiments goes towards infinity (Aven, 2012). The interpretation is based on the law of large numbers.

The Bayesian update of a probability is a systematic process of combining an existing model, the prior, with evidence-based data (Reddy, 2011). After the update, the posterior probability represents the combination of the previous knowledge and the new information. The posterior probability represents the prior of the next update.

Both frequentist and Bayesian update probabilities are objective, i.e. true, underlying probabilities are thought to exist (T. Aven & Kvaløy, 2002). The personal beliefs of the assessor are irrelevant, and there are standardized methods of estimating the probabilities.

A subjective probability is an assessor's measure of uncertainty of an event to occur (Aven, 2012). It can for instance be compared to randomly selecting one specific ball from an urn that contains a number of balls. An assigned, subjective probability of 0.1 of an outcome expresses an uncertainty similar to the probability of selecting one specific ball out of a total of 10.

A broad definition by Aven (2012) is that risk of an activity is the future *events* (A) and *consequences* (C), and the associated *uncertainties* (U), i.e. the outcome of the activity is not known.

A description of the risk consists of *specified events* (A') *and consequences* (C'), a *description of uncertainty* (Q), all based on the *background knowledge* (K) (Aven, 2012). The description of uncertainty can for instance be as a probability. Vulnerability is related to risk, and is defined as the consequences and associated uncertainties *given* that the event has occurred.

The uncertainties related to a probability model includes both how well the actual, underlying phenomenon is understood, and how the variation of the outcomes will be if the experiment is repeated over and over again under similar circumstances (Aven, 2011). The uncertainty that relates to the variations in a population or sample, i.e. the reason that a repeated experiment will produce different outcomes, is referred to as aleatory or stochastic uncertainty. The uncertainty related to lack of knowledge about the actual system, process or mechanism is referred to as epistemic uncertainty.

Uncertainty expressed as a subjective probability is based on all the knowledge and information that is assumed relevant (Fenton & Neil, 2012). It covers both epistemic and aleatory uncertainties.

A *risk management process* includes establishing the context, identifying hazards, analyzing risk, evaluating possible actions, and implementing the selected plan (International Organization for Standardization, 2009; Vinnem, 2014a). The risk description is the basis for making decisions related to risk, i.e. the risk treatment. The iterative process of risk management, based on ISO 31000 (International Organization for Standardization, 2009) is illustrated in Figure 1.

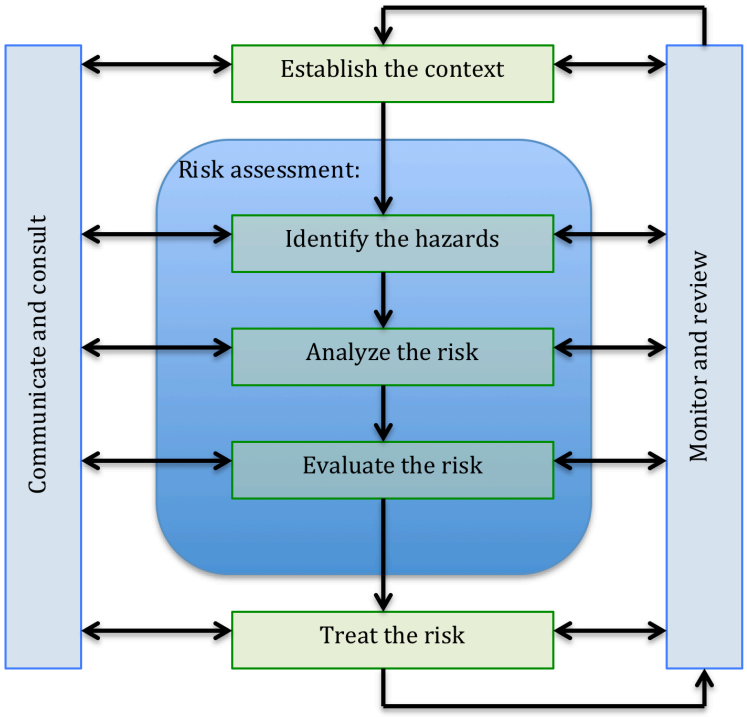

Figure 1 - The risk management process based on ISO 31000 (2009).

The risk management process must continuously be monitored and reviewed in relation to the established context (Vinnem, 2014a). In addition, the validity of the context itself must be monitored and reviewed. As new information is available, the basis for previous assumptions and suppositions might change and require updates of the context. Communication and consultations with all relevant stakeholders throughout the process are important in order to meet their expectations and fulfill the purpose of the risk management.

2.2 Safety

Safety is the ability to do things right (Hollnagel et al., 2015). It is not just the absence of risk or injuries, but the mechanisms in an organization that ensure that the activities result in desired outcomes. Performance variations must adjust the situation when the operational conditions change.

In healthcare, the processes are dominated by human activity. Safe operation is dependent on adjustments and responses by involved personnel to maintain control and make sure that processes develop according to plan (Hollnagel et al., 2015). In order to do so, hazardous events and consequences must be anticipated rather than experienced.

Safe operation is based on a number of underlying assumptions regarding the system controls (Leveson, 2015). An assumption is for instance the number of team members and their professions, or the functionality of an automatic system. When these assumptions are violated or weakened, the ability to prevent adverse events is reduced. Leading indicators that detect whether or not the activities and safety controls operate in accordance with system-critical assumptions can provide information of when preventive actions are required.

The probability of a hazard to occur is difficult to assess. In many cases, the probability is less interesting than the potential consequences should the hazard occur (Leveson, 2015). If an adverse event is plausible, protective measures should be implemented. Actions should be initiated if the leading indicator system detects that the vulnerability related to the hazards changes due to violations of safety-critical assumptions.

2.3 Scenarios, adverse events and hazards

A *scenario* can be defined as a possible course of events that follows an activity and ends with an observable outcome (Meinert, 2014). Scenarios are not predictions of outcomes, such as forecasts or prognoses, or limited to desired outcomes (Lindgren & Bandhold, 2003). A scenario is simply a course of events that may happen. The scenarios can be compared to the sample space of an experiment, i.e. all the plausible outcomes.

The term *event* is neutral and covers both hazards and opportunities (Aven, 2010). An *adverse event* is defined as a deviation or interruption from the planned course of events that results in *additional harm* to a patient (Leape & Abookire, 2005). Additional harm is pain or injury that results from the provision of care rather than the medical condition of the patient.

Hazards refer to adverse events that may or may not lead to additional injury, i.e. potential adverse events.

2.4 Barriers and influencing factors

An error, mistake or malfunction may cause a deviation from the normal, planned and desired chain of events that follow an activity. The purpose of introduced measures is to prevent identified and anticipated errors by reducing the probabilities of their occurrence. Since the probabilities can only be reduced, not eliminated (unless the activity is suspended), measures that control or mitigate the consequences given that an error has occurred should also be introduced.

Preventing, controlling or mitigating measures that intervene in a chain of events that results in an unwanted outcome are referred to as *barriers* or *barrier functions* (Sklet, 2006). The barriers protect victims from hazards, and are part of the safety system. For all practical purposes in this thesis, the terms barriers and barrier functions have the same meaning.

A barrier consists of barrier *elements*. These elements can be operational procedures performed by humans, technological systems or physical objects (Sklet, 2006; Vinnem, 2010). Organizational factors influence the elements of the barriers, but are not themselves parts of the barrier system. Team training, procedural drills, system maintenance and the use of written procedures have an impact on the probability that the barriers function as intended, but these elements do not intervene in the chain of events as it unfolds.

Thus, the organizational factors can be regarded as risk and performance influencing factors of the barrier system. The MTO perspective on barriers focuses on the interfaces between Man (humans), Technology and the Organization, and on how they interact and influence the risk and safety (Skjerve & Kaarstad, 2014).

A method for identifying barriers and barrier elements is similar to the risk management process illustrated by Figure 1 on page 7. The process includes establishing the context, performing risk assessment and risk treatment, but also includes specifying barrier performance standards (Petroleum Safety Authority Norway, 2013). The combination of the risk evaluation and the risk treatment form the barrier strategy.

A typical example of the iterative process of identifying new and improved barriers is illustrated in Figure 2. The illustration is based on the World Health Organization's research cycle (2015).

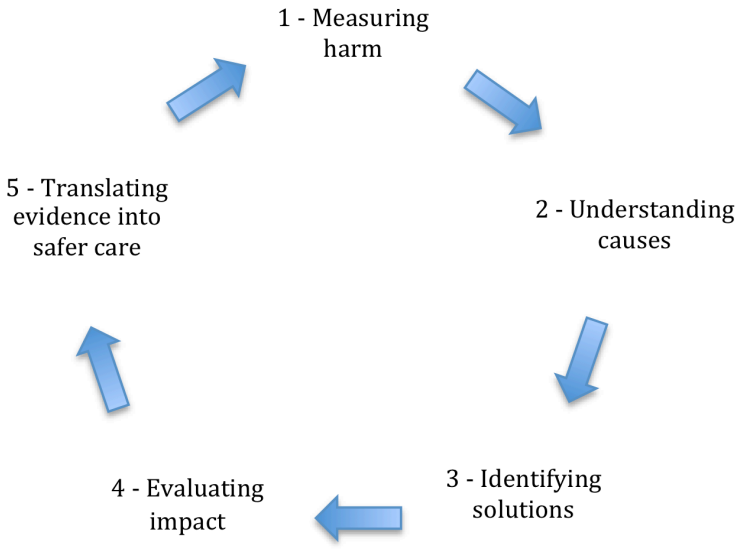

Figure 2 – Adapted from the research cycle as defined by the World Health Organization (2015).

The reliability and performance of the barriers influence the risk level in the organization (Petroleum Safety Authority Norway, 2015; Vinnem, 2010). Influencing factors are for instance preventive maintenance and corrective actions, and inspections and tests.

Figure 3 illustrates the preventive and controlling barriers in relation to the planned courses of events. Deviations caused by surprising events are not included in the illustration.

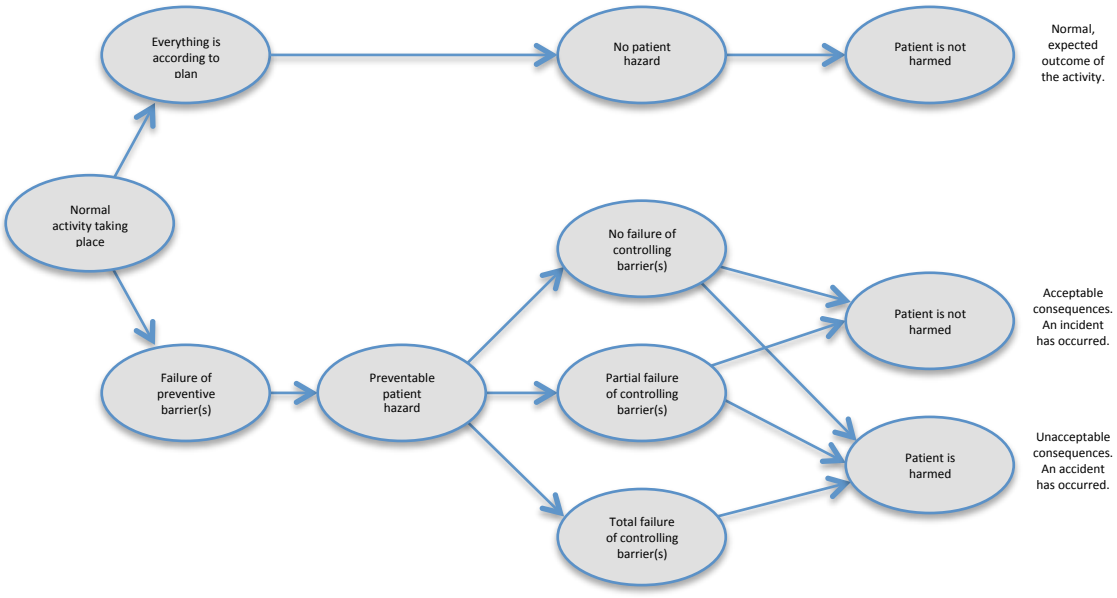

Figure 3 - Barriers in relation to planned courses of actions.

2.5 Human factors and safety culture

A human error or mistake should be anticipated anytime, i.e. the probability should never be considered to be zero. While most personal mistakes are relatively harmless, professional errors can have serious consequences. The probability is not constant, and changes according to a number of factors such as stress, fatigue and distractions. The characteristics of the interactions between a person and the surroundings that influence human performance are usually referred to as human factors and ergonomics (Flin, Winter, Sarac, & Raduma, 2009).

Human factors are involved in many incidents and adverse events, and the most typical are often referred to as the "Dirty Dozen" (Federal Aviation Administration, 2008):

- Fatigue.
- Stress.
- Distraction.
- Norms.
- Pressure.
- Complacency.
- Lack of communication.
- Lack of teamwork.
- Lack of assertiveness.
- Lack of awareness.
- Lack of resources.
- Lack of knowledge.

The presence of one or more of these factors increases the probability of a person to make a mistake. The factors occur as a result of individual reactions to changes in the working conditions, such as pressure and stress when the patient volume, i.e. the number of patients and their required treatments, increases. Long hours and rotating shift work lead to fatigue, and complacency and lack of awareness may result from repetitive activities.

There are several models that characterize the human factors according to technical, organizational and human levels, and how they influence each other, e.g. Moray (2000), Flin et al. (2009) and Boeing (2009). A principle found in all the models is that the factors related to the individual is influenced by team and group factors, and that factors related to teams and groups are influenced by organizational and management factors. Influences and expectations from external stakeholders, for instance regulatory and resource providing authorities have an influence on the organizational factors. Figure 4 shows a model adapted from Moray (2000) of the influences of factors at different levels in a sociotechnical organization between the patient and the authorities.

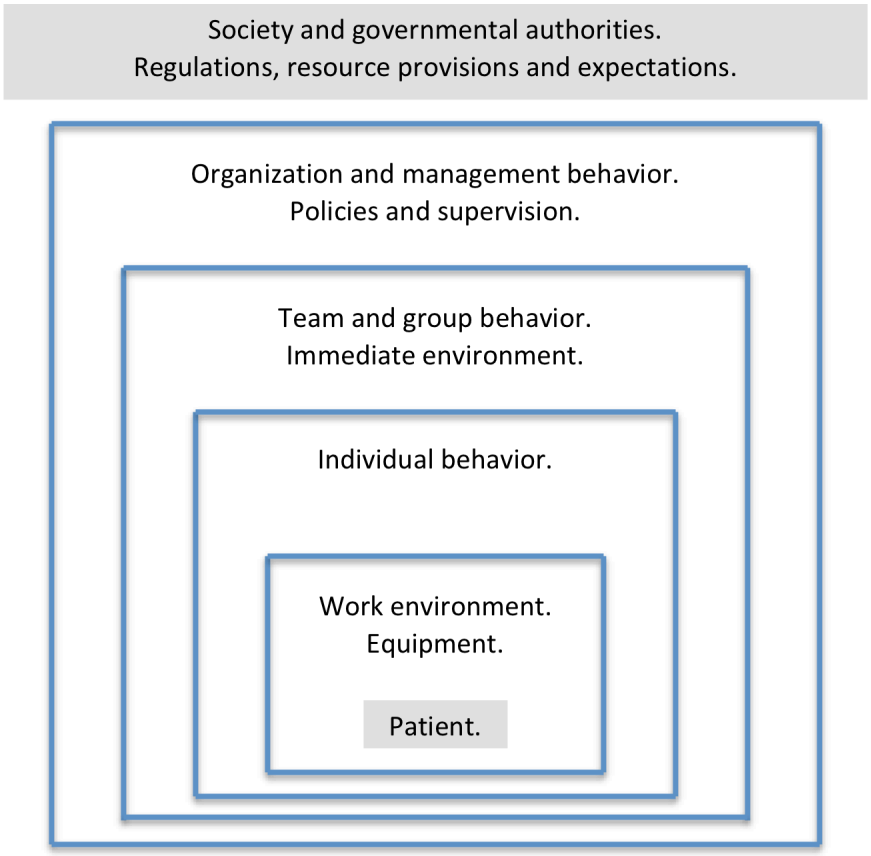

Figure 4 - Levels of human factor influences in a sociotechnical organization. Adapted from Moray (2000).

According to the Human Factors Analysis and Classification System (HFACS Inc., 2014), organizational climate, process and resource management influence supervision. Supervision influences environmental factors, personnel factors and the conditions of the operators. These factors represent preconditions for unsafe acts by the individuals.

Unsafe acts, i.e. deviations from the course of actions and procedures defined at the organizational level, can be intentional or unintentional. Unintentional deviations are categorized as errors, and intentional are regarded as violations (Boeing Commercial Aviation Services, 2009; HFACS Inc., 2014). Violations that are accepted by the team or group and done on a regular basis are routine violations.

The acceptance of violations is a manifestation of the organization's safety culture (Listyowardojo et al., 2014). The safety culture can be described as the actual as well as the intended approach and handling of established routines, and safety aspects and awareness of all personnel.

The safety culture represents a major influence on the occurrence and magnitude of human factors when external factors such as patient volume, available resources and elapsed time change (EUROCONTROL, 2008; Strauch, 2015). The individual, team and organizational response to changing conditions are quite stable, but differences between groups of personnel within an organization must be expected (Listyowardojo, 2012).

2.6 Bayesian Belief Networks

This chapter is based on the book "Risk Assessment and Decision Analysis with Bayesian Networks" by Fenton and Neil (2012).

Bayesian Belief Networks, of Bayes Nets for short, are probabilistic directed acyclic graphical models of variables, i.e. they provide a visual model of probability variables and their directed dependencies. Circular nodes represent the variables, and edges indicate the direction of probability dependence.

Consider the probability of a patient having a certain medical condition,

$$P(\text{condition})$$

and the probability of having a symptom given the condition

$$P(\text{symptom}|\text{condition})$$

Figure 5 illustrates the example as a Bayesian Network model.

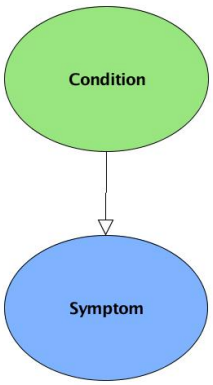

Figure 5 - A simple Bayesian Network.

The calculations in a Bayes Net are based on the Fundamental Rule of Conditional Probability:

$$P(B|A) = \frac{P(A \cap B)}{P(A)}$$

The rule can be rearranged to:

$$P(A \cap B) = P(B|A) \bullet P(A)$$

Similarly, if A and B are swapped:

$$P(B \cap A) = P(A|B) \bullet P(B)$$

Combining these gives Baye's Theorem:

$$P(A|B) = \frac{P(B|A) \bullet P(A)}{P(B)}$$

If, for instance, the probability of having the symptom is 95% when the condition *is* present, and the probability of having the symptom when the condition *is not* present is 1%, the probability table for the "Symptom" node is:

	Condition: No	Condition: Yes
Symptom: No	99%	5%
Symptom: Yes	1%	95%

The two possible states of the "Condition" node with the corresponding probabilities of having the symptom are illustrated in Figure 6.

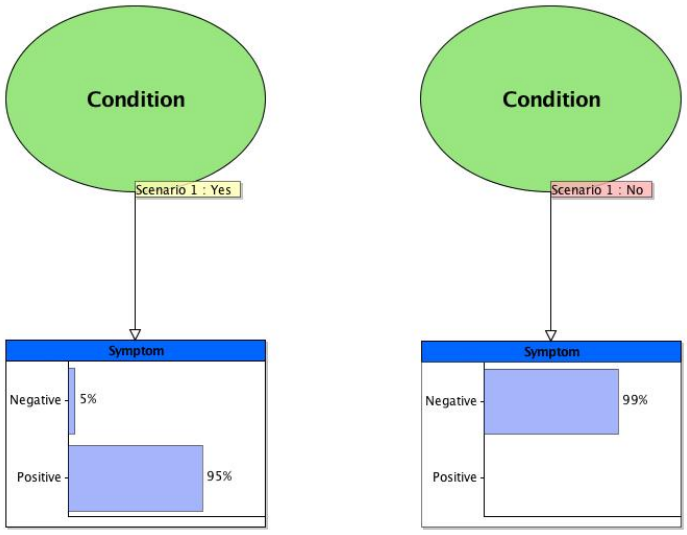

Figure 6 - The probabilities of "Symptom" given the two possible states of "Condition".

However, it might not be easy to determine whether or not somebody has the condition other than a frequentist probability based on statistics. This prior, unconditional probability of having the condition is 0.1%, i.e. that 1 out of 1000 has it.

When the prior probability is assigned to the “Condition” node, the updated probabilities are as illustrated in Figure 7.

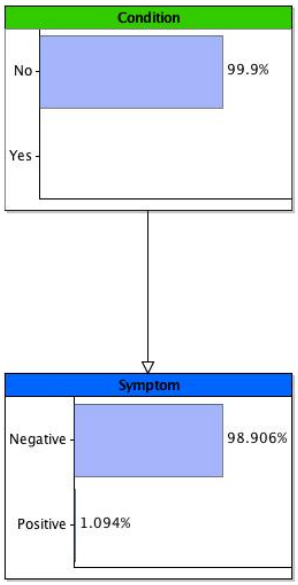

Figure 7 - The prior probabilities.

The updated prior probability of having the symptom, approximately 1.1%, is the proportion of patients that have the symptoms regardless of whether or not they have the condition. The positive symptom patients are the sum of patients that have the symptom *without* the condition and the patients that have the symptom *with* the condition.

The direction of updating can be either way. Baye’s Theorem shows that the processes of updating the probability of having the symptom given the condition, and updating the probability of having the condition given the symptom are mathematically equivalent.

It is important to note that the direction of the edge does not necessarily correspond to the obvious or believed direction of cause and effect. In a Bayesian Network, the direction only represents the direction of the conditional probability, in this case the probability of “Symptom” given “Condition”.

In some cases, the probability of the cause given the effect is easier to assign. For instance, the probability of a shortened life increases if a patient has high blood pressure, but the probabilities can be difficult to determine. Instead, the proportion of short-lived patients that also had high blood pressure can be used as basis for a conditional probability of high blood pressure given a shortened life.

It is in many cases easier to measure a symptom rather than the condition. An observation can be entered anywhere in a Bayesian Network as long as does not represent a violation. A violation is conflicting observations, such as observations that cannot occur simultaneously, or observations that are incompatible with conditional probabilities. For instance, if a node has

been assigned zero probability due to an observation somewhere in the Bayes Net, it cannot at the same time be set to non-zero as an additional observation.

The two possible observations of "Symptom" with the updated probabilities of "Condition" are illustrated in Figure 8.

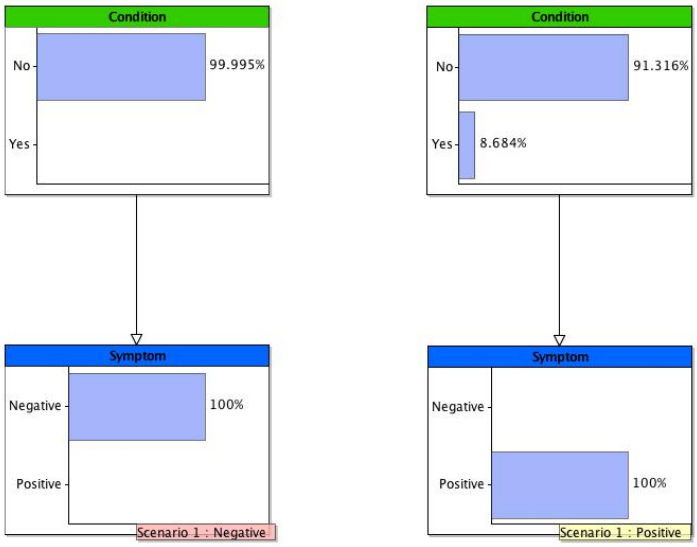

Figure 8 - Updated probabilities of "Condition" when "Symptom" is observed.

This illustrates a major advantage of using Bayesian Networks. If an observation is entered, the corresponding variable is fixed and the probability of the reason for the observation is updated. In the case of this example, a positive symptom is the result of either a true condition or a false positive. The probability of not having the condition, given a positive symptom, is still high, actually over 91%. This is due to the high number of false positives among the 99.9% that do not have the condition, compared to true positives. Having the symptom does not mean that the patient has the condition, but the probability has increased.

A Bayes Net consists of arcs, and nodes with corresponding node probability tables. The arcs indicate the directions of conditional probabilities, and points from a parent node to a child node. The probability of the child is given the probability of the parent(s), i.e.

$$P\left(\text{child}\middle|\text{parent(s)}\right)$$

Nodes can have several parents and/or children. An example of a slightly more complex model is illustrated in Figure 9.

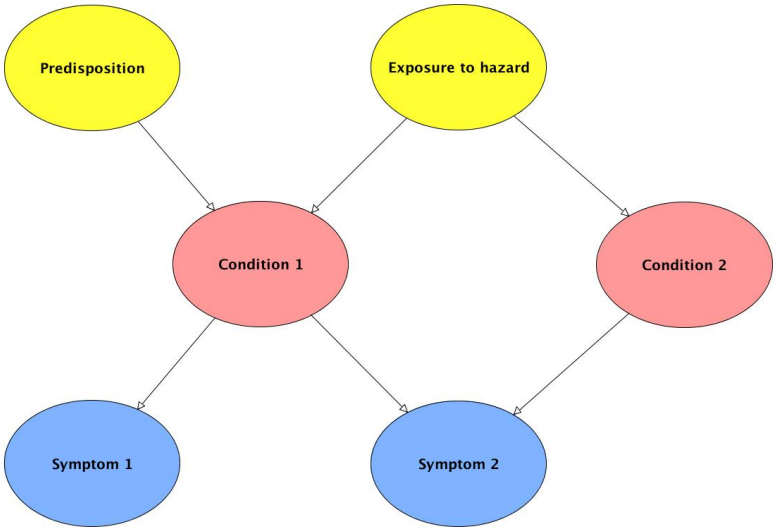

Figure 9 - Bayes Net with multiple parents and children.

The interpretation of the model in Figure 9 is that both predisposition and exposure to hazard influence the probability of having condition 1, but exposure to hazard also influences the probability of condition 2. Symptom 1 is dependent on condition 1 while symptom 2 is dependent on both conditions.

The Bayes Net can be used to predict conditions and symptoms by entering evidence in the nodes “Predisposition” or “Exposure to hazard”. If instead evidence is entered in either “Symptom” node, the Bayes Net can provide information about the most likely cause.

The mathematical update of probabilities is called propagation, and is performed both in the direction of parents-children, and in the direction of children-parents. When evidence is entered into one or more nodes, propagation will update all related node probability tables. Further, the tables that are related to those that have been changed will in turn be updated, and so on. This way, the evidence is propagated throughout the Bayes Net.

Bayes Nets have to be acyclic, i.e. the arcs cannot appear in a circle. For instance, the probability of A cannot be dependent on B while B is dependent on A.

3 Healthcare

The purpose of healthcare is to prevent, treat, rehabilitate and cure patients from diseases and injuries, and to provide relief from symptoms and pain. Providers of healthcare include hospitals, general practitioners, emergency medical services, psychiatric care, dentistry, nursing homes, rehabilitation therapy, and pharmaceutical services.

Healthcare is a high-risk activity that involves advanced knowledge and technology, and complex tasks that require consistent performance. Many different professions are involved in complex tasks and processes, and new and improved treatments and medications become available at a fast pace.

Approximately 1.8 million Norwegian residents are treated in general hospitals, and health and social services require around 250 000 man-years and close to NOK 300 billion annually (Statistics Norway, 2014, 2015a, 2015b). The healthcare sector is subject to relatively frequent politically motivated re-organizations.

However, in spite of all the provided resources and efforts in research and development, the number of patients that experience unnecessary harm is high. An estimated 13% of the 570 000 patient admissions at 18 public and 5 private hospitals in Norway in 2013 resulted in some sort of unwanted outcome (Deilkås, 2014). Of these admissions, that do not include those related to rehabilitation, pediatrics or psychiatrics, it is estimated that approximately 1500 of the adverse events resulted in patient deaths. Being a patient is associated with significant risk, and the safety improvement potential is huge.

In addition to the personal consequences experienced by patients, the organizational and societal costs are high. Prolonged hospitalization, and additional surgery and medication require resources that otherwise could benefit additional patients. There are limited resources such as funding, doctors, surgeons, nurses and other specialists, equipment and medication, and operating rooms and bedposts.

Most tasks and activities are defined and planned in advance, and well known by the healthcare workers. They are expected to know their own as well as their coworkers' roles, and communicate frequently with each other, the management and with patients.

An organization with extensive human interactivity combined with specialized knowledge and advanced technology is highly complex. The complexity is evident in the number of rules, regulations and policies that healthcare workers must follow. The number of policies that are applicable to health care workers can run in the thousands (Hollnagel et al., 2015).

There is considerable knowledge and a long history of risk management in other high-risk sectors such as aviation, oil and gas and nuclear power. Healthcare is at an early stage compared to other industries, and has failed to achieve similar results (Hudson, 2003). Methods that have proven to be effective in other sectors might not be suitable in healthcare (Catchpole, 2013). Healthcare has for instance a much higher proportion of human activity and interactions, and a wider set of goals and expectations from external stakeholders. The risk management methods must be tailored to the type of organization and the nature of the activities in order to function as intended and produce the desired effects.

A relatively high number of patients experience some sort of unwanted consequences such as additional pain, delayed dispatch, infections, additional surgery, permanent disability and death (Deilkås, 2014). Some of the most frequent adverse events in healthcare include:

- Various types of infections such as urinary tract, surgical site and lower respiratory tract infections
- Harm from medication error
- Postoperative bleeding
- Slips, trips and falls
- Pressure wounds.

In addition, patients are subject to retained foreign objects after surgery, and surgery on wrong body parts. Patient harm spans from unnecessary pain and suffering to permanent disability and death.

4 Results

An important goal of any healthcare organization is to provide as much high quality treatment, cure and rehabilitation as possible. The amount of healthcare that can be provided is dependent on the available resources such as staff, expertise, medication, equipment and facilities, as well as on the efficiency of the care that is provided. Improving the efficiency of the healthcare organization will increase the number of treated patients without spending additional resources.

In order to utilize the available resources and provide efficient healthcare, a high level of patient safety is required. Unnecessary patient harm drains resources. When patients need additional hospitalization, surgery and medication, or suffer permanent injury or death, other patients that could have been treated are harmed as well.

So far, the attempt to improve patient safety has almost exclusively been implementing new rules, regulations, policies and procedures to the existing safety system. Risk has been assessed using retrospective analyses, and introduced measures have been assumed to be effective (Helse Sør-Øst, 2013, 2015; Helsedirektoratet, 2014). This approach to safety management is based on an intention to restrict unwanted activity.

The achieved results in healthcare differ significantly from those achieved other high-risk sectors, and do not reflect the amount of resources spent (Hudson, 2003; Shojania & Thomas, 2013). Attempts to improve the reliability of the existing safety system and implemented barriers have been limited to campaigns that highlight critical issues.

Focus on barriers that fail frequently can improve performance. The same applies to barrier influencing factors. Using written procedures, performing tests and drills, and maintaining technical systems increase the probabilities of the related barriers to function as intended. Campaigns can raise the awareness of critical barriers, e.g. hand hygiene, the use of checklists and double control. However, campaigns may change the risk perception causing other safety-critical areas to be neglected.

4.1 Why leading indicators?

The development and implementation of leading indicators is considered an important improvement to risk and safety management (Kjellén, 2009; Leveson, 2015; Mearns, 2009; Petroleum Safety Authority Norway, 2015; Vinnem, 2014b). The Petroleum Safety Authority Norway accepts that leading indicators are estimated from lagging data. Kjellén, Vinnem and Leveson, on the other hand, argue that only indicators that change *before* the actual risk changes can be called leading.

If there is an increased risk of causing unnecessary patient harm, adjustments to counteract the changed circumstances must be made. Adjustments include for instance to reallocate personnel, equipment, medication and other resources in order to reduce the probability of harm to patients. Other adjustments can for instance be to rearrange tasks according to experience, fatigue or distractions.

Decisions to adjust are based on relevant information including the current risk picture, patient volume, and available resources. Leading risk indicators provide information about the current

risk picture as a function of the barrier influencing factors in relation to an ideal situation where all barriers have optimum performance. This information provides an opportunity to manage resources and plan activities in accordance to patient safety in a systematic manner.

The set of indicators present the risk picture for the patients *given the current circumstances*. As the risk and performance influencing factors in a health care organization change, the risk of causing additional harm to patients changes. Changes in the probabilities of the specific hazards, consequences, and related uncertainties represent changes in the risk picture. An indicator can be said to represent the current risk of performing a specific sub-activity *just the next one time*.

At a personal level, dynamic adjustments of activities that involve risk are frequent. Decisions regarding the next car trip, for instance, are based on real-time risk assessments rather than predictions based on statistical data from a large population. It is typical to assess the conditions of the vehicle, weather, road and traffic and the levels of stress, fatigue and distractions of the driver as important risk influencing factors. As the conditions change, the behavior of the driver changes.

Similar proactive adjustments are common in working situations, both at individual and team levels. Examples are changes in the priority of tasks due to fatigue or distractions, requests for second opinions or double control, and selection of specific tasks to specific team members that otherwise have the same formal competence. However, at administrative and organizational levels, these adjustments are rare or absent, even though the required resources to prevent adverse events from occurring are considerably less than the resources required to treat harmed patients.

The use of leading risk indicators can help identify critical barriers that are often in a weakened state, and strengthen barrier awareness.

Another purpose if leading risk indicators is to provide information about especially critical activities and necessary additional safety measures. This requires that frequencies of situations of increased risk are registered over time. Such information may support traditional risk management methods, and strengthen barrier awareness within the organization.

However, the framework should not be used as an attempt to determine the total risk level of the organization, or to compare the risk level between organizations. It is also a misuse of the method to monitor the performance or reliability of individuals or groups of employees.

4.2 General requirements for the leading indicators

Figure 1 on page 7 illustrated the ISO 31000 standard of conducting a risk management process. Risk management is typically a part of the design or modification phase of an installation or a project. It is an iterative process that is completed when the results are presented and implemented. The process is repeated whenever it is deemed necessary throughout the lifetime of the project.

Risk management based on real-time monitoring is different. The management process is not completed, but is ongoing as long as the indicators are monitored and risk treatment is performed. However, the model can be used as to illustrate the process related to leading risk indicators. Figure 10 is the ISO 3100 risk management process model from the leading risk indicator perspective.

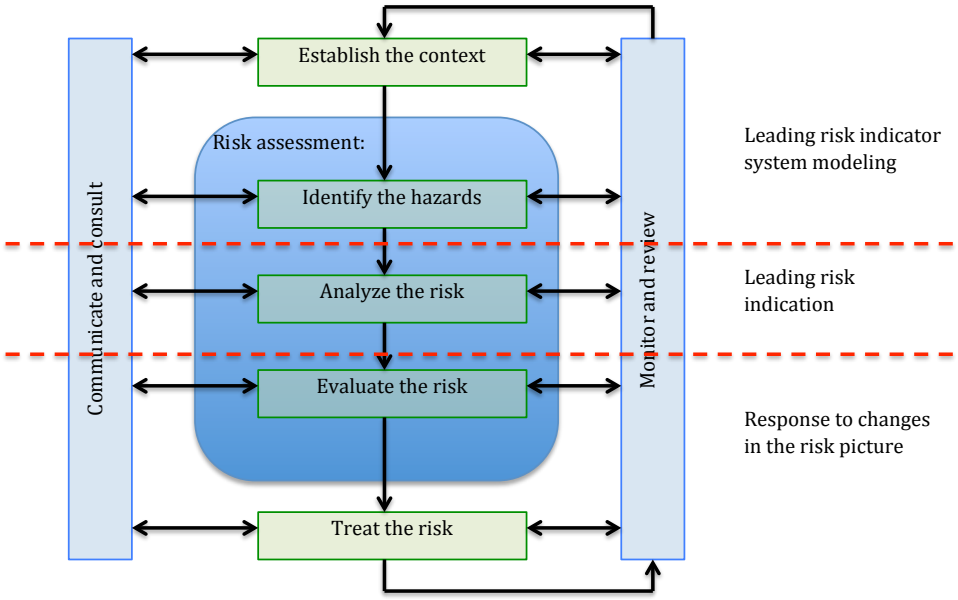

Figure 10 - The risk management process from a leading risk indicator perspective.

The purpose of the process is to treat the risk through adjustments of the activities. The risk evaluation is to decide on adjustments to be made based on the real-time risk monitoring, the patient volume and the available resources.

Besides defining the purpose of the process, establishing the context include describing the characteristics of the organization and the activities, and the related assumptions (International Organization for Standardization, 2009; Vinnem, 2014a). A healthcare organization is a highly complex sociotechnical system with predominantly human activity.

The purpose of the leading indicators is to predict adverse events in order to prevent their occurrence. This concept corresponds to the principle of Safety-II (Hollnagel et al., 2015). The flexibility of personnel in the organization is an adjustment tool that is necessary for

counteracting the changing conditions. The leading indicator system makes little sense without the definition of safety from Safety-II.

Assumptions include requirements for the operation and functionality of the safety system and the activities of the organization. Certain activities may require a minimum number of personnel with specialized qualifications. Other assumptions may be the availability of equipment and medication, and access to special rooms.

The approach of System-Theoretic Accident Model and Processes (STAMP)-model is to identify leading risk indicators by analyzing the safety-critical assumptions of the organization (Leveson, 2015). Safety-critical assumptions are the identified operational conditions, and necessary control of safety. The barriers are included in the safety-critical assumptions.

As previously defined, a scenario is any plausible the course of events that follow an activity, and ends with an observable outcome. If the course of events is according to the established rules, regulations, policies and procedures, and the outcome is reasonable given the medical condition of the patient, it is the anticipated scenario. A scenario that includes a hazard, and/or additional patient harm, is unacceptable and unwanted. Unacceptable scenarios are either incidents or accidents.

Some scenarios are irrelevant when considering a leading risk indicator system that predict adverse events that may be prevented given that an appropriate action is taken. The irrelevant scenarios are any that include:

- One or more *surprises*. A surprise can cause hazards or unwanted outcomes even if everything is going according to plan, or rectify a situation that is out of control. In both cases, the course of events follows a previously unknown pattern.
- Hazards that cannot be prevented by the exciting rules, regulations, policies or procedures.
- Consequences that cannot be avoided or mitigated by the exciting rules, regulations, policies or procedures.

A surprise can happen at any time. Since surprises are not identified before they occur, their causes and consequences are also unknown. If no established plan exists, there is no point in providing information that related to adjustments. To adjust in order to regain control after a surprising deviation has occurred may easily require improvisation. Improvisation cannot be modeled in a leading risk indicator system. Efforts should be aimed at identifying more hazards and related response plans.

A resilient and robust organization will experience fewer surprising outcomes. A more comprehensive analysis of possible hazards and effective measures of prevention and control will reduce the number of surprises and the probabilities of their occurrence. However, there are numerous tools that are available and being used in order to improve the robustness and resilience, such as HAZID and HAZOP, fault- and event trees, risk trend and accident/incident analyses and other traditional risk assessment methods.

The planed activities and identified hazard responses are embedded in the applicable rules, regulations, policies and procedures of an organization, and cover all the tasks needed in order to control the course of events related to the identified activities.

It is often considered necessary to quantify the probabilities of the events in the chain, as well as the risk reduction that the barriers represent. Such quantifications can be based on past frequencies of the events, and assessments of the reliability of the barriers. The risk reducing effects of the proposed barriers are related to the frequencies of the events that they either prevent or control, and the probabilities of the barriers to function when needed (Petroleum Safety Authority Norway, 2013; Vinnem, 2010).

Frequency of an event is the number of times it occurs in relation to the total number of experiments, i.e. the population. How the population is defined depends on the purpose of the analysis. One way of estimating the reliability of a barrier is by calculating the frequency of successful barrier operations, either when it was needed or during testing (Petroleum Safety Authority Norway, 2013; Vinnem, 2010).

A wide definition of similarity of experiments can be applied to increase the amount of available data (Aven, 2011). The tradeoff is that the data is less representative. To find the balance between enough data and sufficient quality is not always trivial.

If little or no representative data exists or can be produced, frequentist probability estimation is of little value. In such cases, a *subjective probability* is assigned (Aven & Reniers, 2013). A subjective probability is a hypothesis based on all available knowledge that is considered to be relevant, and represents the assessor's uncertainty about the outcome. The assigned probability is dependent on personal beliefs and perceptions.

The distinction between aleatory and epistemic uncertainty reflects how uncertainty may be reduced (Kiureghian & Ditlevsen, 2009). Epistemic uncertainty is considered to be reducible, as increased knowledge can improve the accuracy of the models. The aleatory uncertainty is connected to the randomness of the processes, and is thus irreducible. Consequently, a categorization of the uncertainties in a risk assessment can affect decisions related to the risk treatment.

However, the uncertainty expressed by a subjective probability includes both the epistemic and the aleatory uncertainty. The uncertainty relates to one unique event where the development of a model is pointless. Still, there might be information included in a model that is based on frequentist estimations. In that case, it makes sense to distinguish the uncertainties in order to avoid ambiguity.

Consider a patient that suffers from rapid and irregular heart rhythm that occurs periodically and lasts for a while. This condition is referred to as paroxysmal atrial fibrillation, and it is decided to treat the patient by radiofrequency ablation surgery using catheters inserted through a vein in the groin (Anfinsen, 2011). The surgery involves destroying heart tissue with high frequency current in order to isolate areas of abnormal electrical activity. The success rate of a single operation is estimated to be 60-70%, and it is routinely performed at major hospitals. Statistics show that the frequency of complications is 2-5%.

There is a high probability that the course of events will be according to plan. The plan, at an organizational level, is defined by the rules, regulations, policies or procedures. The most probable scenario is that the patient will be admitted to the hospital and examined, operated and observed for some time, and then dispatched for recovery at home.

The patient may or may not be cured from the initial condition. However, the normal and planned outcome from a patient safety point of view is that the patient only experiences the harm or injury that must to be anticipated due to the medical condition and treatment.

When analyzing the planned processes activities of the organization, a breakdown into sub-activities should be performed. Any main process that is a planned part of the and

A meaningful sub-activity is one that describes a task or a step that is necessary in order to accomplish an identifiable part of a given process. The level of detail is determined by the purpose of the analysis, for instance to map out the barriers related to patient safety.

In a complex sociotechnical organization like healthcare, variations in human performance as well as safety culture are important risk and safety influencing factors. The presence of human factors is influenced by external factors, and on internal factors such as organizational and individual response to changes of the external factors. The safety culture of an organization can be described as the attitude, awareness and approach to safety of personnel at all levels, including both intentions and performance of operations (EUROCONTROL, 2008; Listyowardojo et al., 2014; Strauch, 2015).

These are examples of factors that influence on an individual level:

- Physical health
- Fatigue
- Time constraints
- Peer pressure
- Complacency
- Body size/strength
- Personal event
- Workplace distractions/interruptions during task performance
- Memory lapse
- Visual perception
- Risk-taking behavior (Boeing Commercial Aviation Services, 2009)

Human factors are influenced by the safety culture. When external, non-controllable factors change, there are different possible reactions within an organization. An increase in patient demand, for instance, may be perceived as positive pressure in some cases, and in other cases as negative pressure that causes stress.

Similar diverse reactions may occur from other external factors such as external stakeholder expectations and supply of resources. Examples of safety cultural factors are:

- Trust.
- Values.
- Attitude towards consistency and quality.
- Risk perception.
- Punitive or non-punitive reactions to human errors.
- Norms.
- Complacency.
- Lack of communication.

- Lack of teamwork.
- Lack of assertiveness.
- Lack of awareness.
- Lack of resources.
- Lack of knowledge (and lessons learned).
- Sense of vulnerability.

Safety culture is a latent problem in the organization and a factor that influence the barriers. It affects the rate at which the barriers deteriorate due to external influencing factors. The safety culture affects the resilience and robustness that the organization has against the risk influencing factors. For instance, one reaction to stress and fatigue can be acceptance of taking short cuts or violating procedures.

The events and consequences can be assigned probabilities and probability distributions, for instance based on similar activities in the past. If relevant data does not exist, subjective probabilities can be assigned based on expert knowledge. In both cases, there are uncertainties related to the probabilities and distributions.

The same applies to shorter time spans, for instance just the next day or the next hour, or to unique and non-repeatable activities such as performing one surgical procedure on one patient. In such cases, probabilities of specific events and consequences must be *assigned* based on knowledge about the activity and the circumstances rather than *estimated* using frequentist methods (T. Aven & Kvaløy, 2002).

Consider the activity of performing some minor surgery on a patient. Examples of specific events are a nerve that is cut over, or a wound that gets infected. For each of the events, different consequences are specified. For instance, a cut nerve can cause sensory loss or paralysis, and an infection may lead to extended hospitalization or death.

The main activities typically include a number of sub-activities with several specific events and consequences. A comprehensive model of the activity with events, consequences, probabilities and uncertainties expresses the knowledge of the risk related to the activity. The risk description (A', C', Q, K) can be said to represent the identified *risk picture* of the activity.

The risk picture will include simplifications and assumptions. Models are simplifications that are assumed to represent important characteristics of the actual phenomena. Examples of models are chains of events, cause and effect relationships, and statistical and probability distributions.

When statistical data is collected and used as basis for probabilities, it is assumed to be relevant. How often an event occurred last year is in many cases a good prediction of how often it will occur this year. The probability of patients getting infections can for instance be assessed based on the frequency of infections in the past, and with an interval to indicate the uncertainty. The probability distribution of a specific consequence, e.g. patient death, can be expressed as a function with specified parameters based on historic data, with an expressed uncertainty related to the values of the parameters.

For large populations or long periods of time, the frequencies of events and consequences are stable under similar circumstances. Small variations will occur, but meaningful predictions

based on statistics can be made. However, if there are significant changes in circumstances, the amount of relevant data can be too small to provide predictions based on frequentist arguments.

Past frequencies are often regarded as valid predictions of the future. There can be good reasons to expect similar outcomes under similar circumstances, even if the available data is just a sample of a larger population.

The type of probability that is the limit value of the fraction of times a specific outcome occurs if an experiment/measurement is repeated indefinitely is usually referred to as a frequentist probability. However, it can be difficult to determine whether or not the circumstances are sufficiently similar. Sometimes the situation is too different to argue that valid data exists. When a situation is unique and non-repeatable, the assigned probabilities are subjective, i.e. a more or less educated guess.

The line between the frequentist and the subjective probabilities can be difficult to determine. It is possible to argue that to decide that a stochastic variable is subject to frequentist probabilities is in itself a subjective judgment. The decision is whether or not the factors that affect the outcomes are sufficiently similar to call the experiments repetitive.

Risk analyses are often based on quantification of probabilities. However, such assigned probabilities introduce uncertainties. Past results and historic data may not be representative for the stochastic variable in question. The factors that influence the current risk could be changed to such a degree that existing data is obsolete and incorrect.

The purpose of the set of leading risk indicators is to predict adverse events in order to prevent them from happening.

4.3 Proposed elements of a leading indicator

The modeling of the leading indicator system must be according to the context and the assumptions underlying the safety system. The selected set of indicators must provide information that is useful for the decision makers. The potential adverse events related to the set of indicators are identified and preventable, and there are defined responses.

Identification of potential adverse events with the associated scenarios, safety-critical assumptions, and the preventive and controlling barriers is the basis of selecting a set of leading indicators.

One indicator relates to one specific event that has the potential to cause additional patient harm, i.e. one specific hazard. A surprise can certainly cause a hazard, or even rectify a hazardous situation, but the purpose of this project is to develop a framework that provides indication of how the risk picture deviates from the normal situation where *everything goes according to plan*.

Leading risk indicators should be based on subjective rather than frequentist probabilities, based on background knowledge of the activities, the related hazards that can occur, and the performance and risk influencing factors. When looking at one such indicator using Bayesian framework, the assigned probability of a specified hazard (A'), when a sub-activity is to be performed, can be expressed as:

$$P\left(A' \mid K\right)$$

The subjectively assigned probability of the hazard A' to occur, given the background knowledge.

There are several ways of categorizing safety barriers (Sklet, 2006). In this framework, the purpose of a barrier is either to prevent a hazard or to control the consequences. In both cases, the barriers are designed to intervene in the chain of events that starts with a normal activity and ends in a specific outcome for the patient, i.e. one scenario.

Barriers cannot be viewed separately from the organization and the factors that influence their performance. They are not individual items with independent statistical or probabilistic properties. They are integrated parts of a system that influences their performance, and they influence the performance of the system. It is necessary to consider the barriers in their context.

As time progresses, and the number of analyses increases, it can get harder to find effective risk reducing measures. The simple and obvious weaknesses, and their related barriers, have already been identified, and subsequent analyses tend to reveal more complex chains of events that require more complex solutions. It may seem easier to introduce new barriers instead of removing or changing elements that are already present.

It is increasingly difficult to keep everything under control as the number of rules and regulations, required and recommended procedures, and technological and automated systems

increases. The probability of introducing ineffective or conflicting increases. In addition, the people involved can get a feeling of distance from the threats, and the barrier awareness declines.

After a number of analyses, most of the individual events that make up the unwanted outcomes are identified. When unwanted outcomes result in serious consequences, it is typically an unusual combination of rather well known elements. When individual events occur relatively frequent, the events can seem less serious and the related barriers seem less important. The treatment of the barriers becomes inconsistent, and their reliability more uncertain.

Factors that influence the probability of barriers functioning as intended could interfere with each other, and resonance or threshold effects can occur. Such behavior is difficult to determine with a linear approach. However, most barriers introduced in healthcare are the result of linear analyses of chains of events that have resulted in unwanted outcomes.

Fatigue, stress, distraction, norms, pressure, complacency, or lack of communication, teamwork, assertiveness, awareness, resources or knowledge (the dirty dozen) increase the probability of human failure.

Human failures are: wrong procedure is followed even if the right procedure is known, known items are forgotten, and wrong conclusions are drawn even if clear and understandable evidence is present.

Technical equipment fails due to e.g. component malfunction, power failures, accidental or wrong use. Several factors together can increase failure rates and wear.

Any error, mistake or malfunction can occur at any time. Certain factors increase the probabilities, as well as influence the performance of controlling barriers.

When functioning as intended, the preventive barriers are always present when the activity is taking place. They are defenses against the occurrence of known hazards. If a preventive barrier fails, a hazard can occur. If a hazard does occur, the controlling barriers are designed to intervene in the chain of events that follow to provide some kind of protection. The protection can be to avoid any unacceptable consequences, or to mitigate the degree of seriousness. Thus, the controlling barriers are passive as long as there are no hazards. The condition of a controlling barrier influences the probability that it will be able to control the consequences as intended when a hazardous situation occurs.

A definition of the scenarios that are relevant for a leading indicator risk picture based on the framework presented in this thesis is as follows:

Identified and preventable hazards occur due to failures of the preventive barriers. If a hazard occurs, a planned response from the controlling barriers is required in order to reduce patient harm.

The defined patient harm categories must not be a natural effect of the disease or injury that the patient suffers from, or an anticipated result of the treatment of the patient. Additionally, the unintentional harm to the patient must be evident within a reasonable period of time.

A proposed selection of harm categories is presented below:

Level of severity:	**Patient experience:**	**Category**	
None	The course of events and the outcome is as expected.	A	Incidents
Low	Monitoring is required to make sure no harm is experienced.	B	Accidents
Moderate	Temporary harm or injury. Hospitalization is required or prolonged. Treatment or intervention necessary to prevent permanent harm or death.	C	
Severe	Permanent injury or harm. Permanent need for treatment.	D	
Fatal	Death.	E	

For some types of hazards, patient harm can be avoided all together if the course of events is adequately controlled. Sufficiently early and correct response to a wrong dose or type of medication can in many cases ensure that the outcome is no harm.

In other cases, it might not be possible to avoid even serious consequences. For example, if a patient suffers from a cardiac arrest, the best outcome is a category c consequence. So, given the nature of the hazard, the minimum consequences can be anything from no harm to a life-threatening situation that requires immediate response.

The worst-case scenario when a hazard has occurred is that the course of events that follows is not controlled at all. The type of hazard determines this consequence potential, and it can be anything from temporary harm that requires intervention to death of the patient. An uncontrolled hazardous event that does not lead to any harm is not really a hazard as it is defined here, or is a surprise, and is thus not relevant.

Between the two extremes, i.e. when the control of the consequences is at its best or when consequence control fails completely, there are other possible outcomes. If the consequences are partly controlled, patient harm that fits other categories can be the result.

Given that the hazardous event occurs, the probabilities related to the different consequences can be expressed as:

$$P\left(C' = c \mid A',\ K\right) = f_1(c)$$

The subjectively assigned probabilities of the specified consequences express the uncertainty of the outcome.

Consider a patient that gets an infection following treatment of a wound from surgery. A preventable mistake, error or malfunction has occurred, typically related to personnel hygiene or equipment sterilization. It is necessary to respond in order to reduce the probability of consequences such as prolonged hospitalization, additional surgery or death. The minimum consequence of an infection is no harm, if the correct response is initiated at an early stage.

Another patient is connected to a heart-lung machine. A malfunction of the machine can cause the blood flow to the heart and brain of the patient to stop, a situation that in a relatively short period of time will lead to brain damage and death. In order to minimize the probabilities of the consequences, given that the hazard has occurred, a quick response from the medical staff is required. The minimum consequence is that a life-saving intervention is necessary.

The outcome of a hazard, given that the controlling barriers function to some degree, can be anything from the minimum to the maximum consequences. It is important to note that the consequence categories are not mutually exclusive, as combinations of consequences are possible. However, from a patient point of view, the most serious category of any combination of consequences is usually the only one of interest.

The basic components of the leading risk indicator are illustrated in Figure 11.

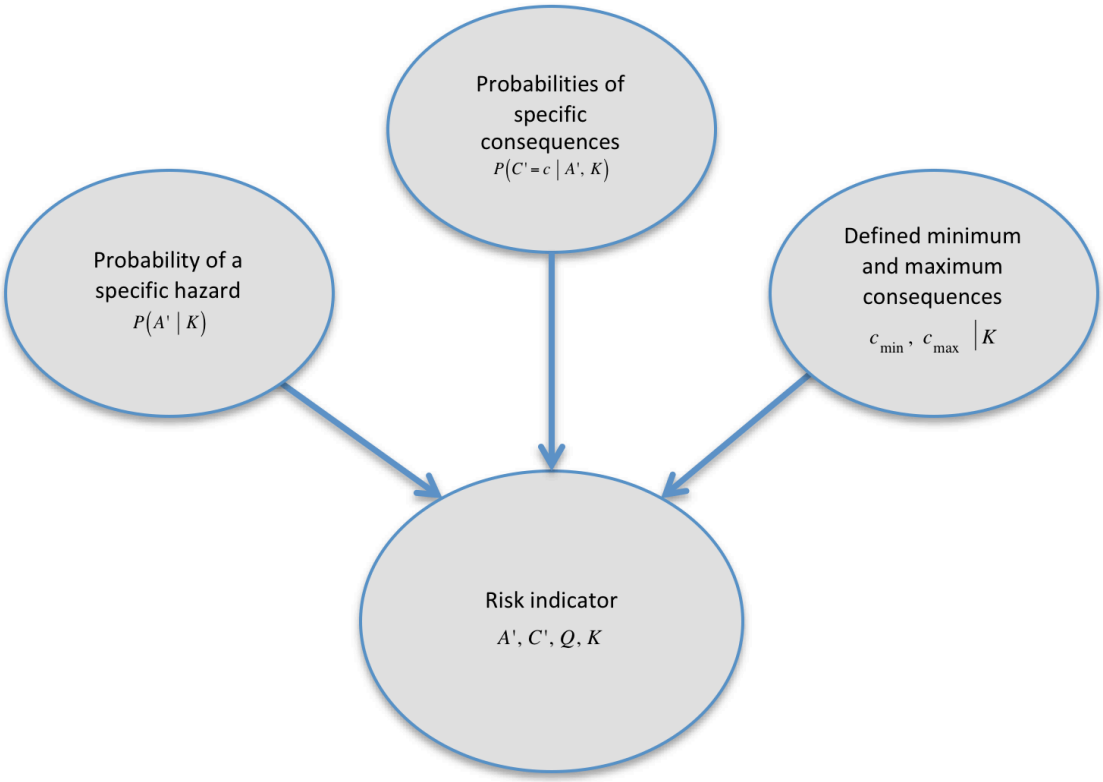

Figure 11 - The basic components of a leading risk indicator.

When looking at known hazards, with already introduced barriers of prevention, the probabilities are dependent on the *probability of correct barrier response*. Such barriers can be human procedures, technological systems, or a combination of both. The identified hazards will not occur when the preventive barriers function as intended. Examples of barriers are sterilization procedures, double control of medication, and automated life support systems.

A hazard can be the result of a single barrier failure. For instance, the preventive barriers related to the hazard of post-operation wound infection include staff hand hygiene, the use of sterile gloves and bandages, and necessary cleaning of the area using antiseptics. A single failure of any of these barriers will cause an infection.

Other hazards require multiple barriers to fail. Heart-lung machines are equipped with back up batteries in case of power loss. The hazard of loss of blood circulation in a patient is the result of multiple, simultaneous malfunctions.

When taking preventive barriers into consideration, the assigned probability of an identified hazard can then be expressed as:

$$P\left(A' \mid B_1,\ B_2,\ldots,\ B_n,\ K\right) =$$

Similarly, the controlling barriers can be taken into consideration. The expression related to the specified consequences becomes:

$$P\left(C' = c \mid B_{n+1},\ B_{n+2},\ldots,\ B_m,\ A',\ K\right) =$$

The assigned probability distribution of the specified consequences, given that the specific hazard A' has occurred and the uncertainties of the controlling barriers (the B_i 's).

Some barriers can be both preventive and controlling. One example is to give patients antibiotics before surgery to both prevent infection in the wound as well as increasing the probability of avoiding or reducing the consequences should it be infected. However, such dual type barriers are not very typical.

Figure 12 shows the influence of the states of the barriers on the leading risk indicator components.

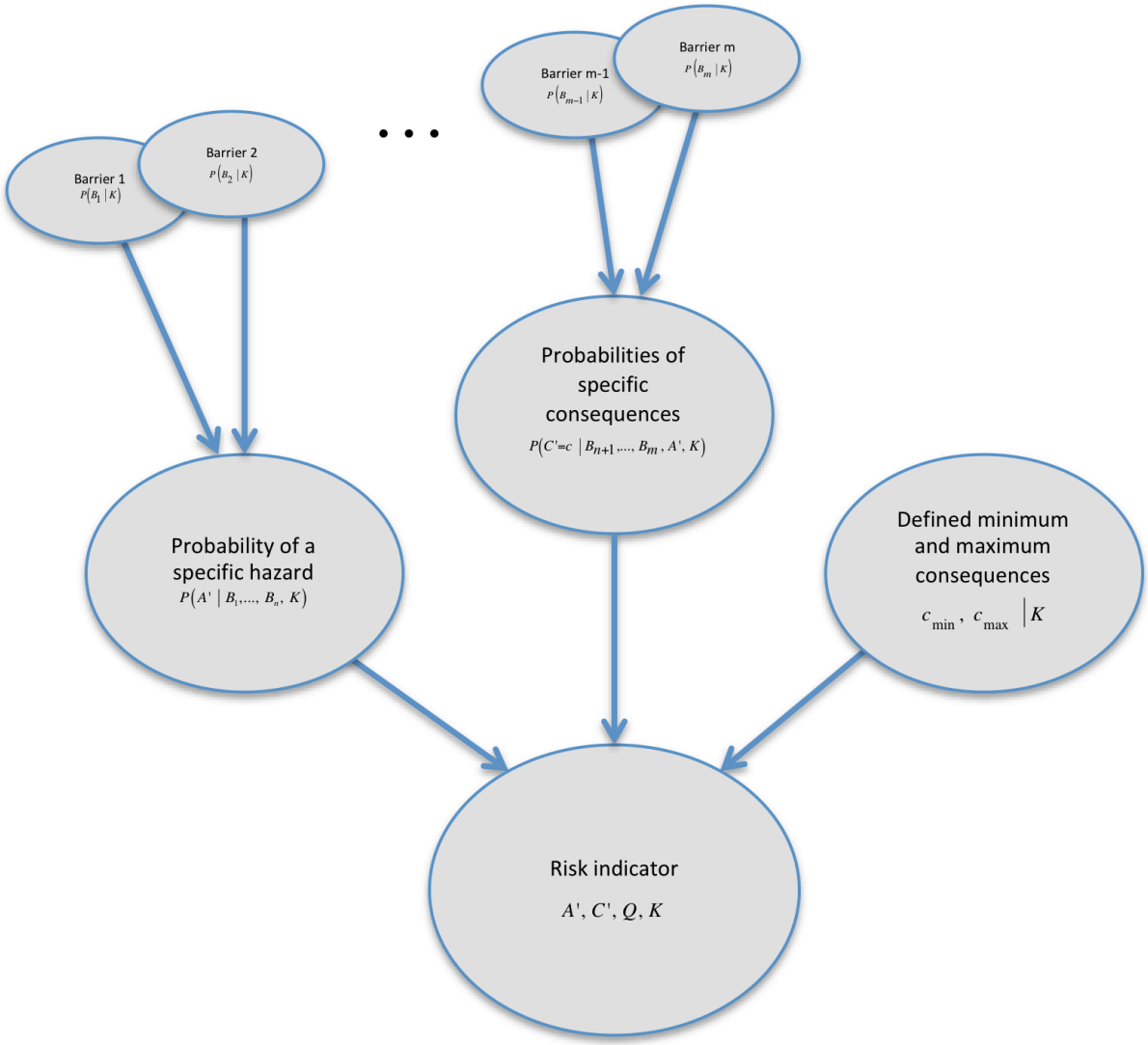

Figure 12 - The basic components of a leading risk indicator with preventive and controlling barriers.

Similarly to how the states of the barriers influence the probabilities of the hazards and the consequences, there are factors that influence the states of the barriers. Examples of factors that influence *procedural barriers* are workload, fatigue and safety culture. Barriers that are *technological systems* are influenced by for instance operating conditions, maintenance and handling.

Consider the following situation: a patient is going through a minor surgical procedure performed by a doctor and a nurse. They will use some equipment, and an identified, preventable hazard A' is that the wound gets infected. The modeling of the problem and the assigned probabilities are all based on background knowledge.

There are four preventive barriers included in the model:

- B_{11} : Doctor's hygiene
- B_{12} : Nurse's hygiene
- B_{13} : Equipment sterilization
- B_{14} : Sterilization of the area of surgery

Due to the workload, fatigue and the safety culture of the personnel involved, the barriers are impaired. The uncertainties of the preventive barriers influence the probability of the patient getting infected. Since an infection can occur as a result of failure of any of the four barriers.

If the patient gets an infection, the outcome can be no harm, extended hospitalization, another surgical procedure, permanent harm or death. The probability distribution of the possible outcomes is dependent on whether or not the infection is discovered sufficiently early, that the patient is given antibiotics, and that the wound is cleaned and/or drained (treated). These controlling barriers are B_{21}, B_{22} and B_{23}.

Obviously, scenarios whit a combination of barriers that do and do not function will have probability of patient death. There is however no reason to suspect a significantly increased probability of patient death related to such scenarios, unless expert judgment determines that it is in fact the case.

The patient would probably not be very interested in the exact probability of a fatal outcome. However, the patient would be concerned as long as a fatal outcome is plausible. The efforts made to prevent a patient getting an infection should reflect the plausibility of the worst-case scenario, i.e. death.

Several influencing factors will affect more than one barrier. Since health organizations include a lot of human activity, the influence of working conditions including human factors will be substantial. Another important factor related to human barriers is the safety culture. Both working conditions and safety culture will affect several of the barriers, both preventing and controlling, that are related to specified patient hazards.

The selection of indicators in the risk picture, preventive and controlling barriers, and risk and performance influencing factors must be:

- Relevant
- Sufficient
- Unambiguous
- Clear
- Measurable
- Possible to handle
- Maintainable

While the probabilities of the hazard and the consequences are dynamic and change in order to provide a real-time risk picture of the activity, the minimum and maximum consequences are not. They are assigned based on expert knowledge, and is only changed when deemed necessary due new information or improved knowledge.

Here it is necessary to point out a distinction between looking at past and future unwanted outcomes. When looking at statistics and historic events in the past, it makes sense to take the frequency of different outcomes into the risk assessment of an activity. But when considering the future risk of performing the activity just one more time, it is often relevant to just assess how much the probability of the worst-case outcome has changed in order to determine whether or not extra precautions should be initiated, or the activity should be suspended.

One of the assigned probabilities is related to whether any consequences other than the minimum can be avoided. If the controlling barriers function as intended, the outcome will be the determined minimum. The other is the probability of worst-case scenario when the controlling barriers are impaired.

Due to the complex system of influencing factors in a barrier safety system, Bayes Net should be used as modeling tool. The use of node probability tables rather than likelihood functions provides an opportunity to model resonance and threshold effects. Further, the possibility of entering observed evidence in any node is useful when simulations or sensitivity analyses are conducted.

5 Discussion

The development of a leading indicator framework, and the modeling of a set risk indicators are not straightforward tasks. The selection of influencing factors can be too large or too small. If the selection is too large, it may be difficult to read useful information from the model since irrelevant factors may be present in the model. Too few factors increase the risk of missing important predictions, as influencing factor may remain hidden.

A scientific challenge related to the leading indicator model is that the model itself is impossible to either confirm or reject through hypothesis analysis. The leading risk indicator model cannot be repeatedly tested under similar circumstances.

The leading risk indicators must provide information that is commonly understood. Further, the information provided by the indicators may be misused. The necessary level of discretion should be defined and ensured as a part of any indicator model.

A leading risk indicator system must be tailored to the organization. Specific features of a leading indicator model reflect the different professions in the organization, the safety culture and the number and characteristics of the patients. Every organization is unique, and requires a unique leading indicator system.

It is human to make mistakes – it must be anticipated that a leading risk indicator system is designed and modeled with one or more errors. After all, it must be made by humans.

6 Conclusion

Tens of thousands of patients in Norway are exposed to adverse events every year, and thousands experience serious injury and death (Deilkås, 2014). A majority of the adverse events are preventable (Hakkarainen et al., 2012; Hodgetts et al., 2002; Umscheid et al., 2011; Zegers et al., 2009). The challenges related to patient safety in healthcare are obvious.

Risk management in healthcare is a relatively new discipline. Methods from other high-risk sectors, for instance aerospace, have been adopted and implemented without achieving the same rate of success (Catchpole, 2013). Healthcare, consisting of highly complex sociotechnical systems that are dominated by human action and interaction, differs from transport and production industries. Different characteristics of organizations require different methods.

To prevent harm to patients, traditional risk and safety management should be supplied with new approaches. This thesis discusses the use of leading indicators for real-time monitoring of risk as a new approach within healthcare. The development of a leading risk indicator framework requires the establishment of some fundamental characteristics.

The purpose of real-time monitoring of risk is to adjust the activities of an organization to prevent potential hazards from developing into adverse events. When operational circumstances change, adjustments counteract the changes to ensure that the outcomes of the activities are as planned.

Such adjustments are in accordance with the concept of Safety-II (Hollnagel et al., 2015). The principle of safety management in Safety-II is to anticipate rather than experience hazards, and to adapt to situations rather than to respond to unwanted events. Variations in human performance are not only causes of errors. They also provide an ability to adjust the activities.

In order to anticipate hazards and make adjustments before adverse events occur, the risk indicators must change ahead of the changes in risk level. According to Kjellén (2009), Vinnem (2014b) and Leveson (2015), that is a condition for indicators to be categorized as leading.

The System-Theoretic Accident Model and Processes (STAMP) approach to leading indicators is to assess vulnerability of safety-critical assumptions rather than probabilities of events (Leveson, 2015). In order to reduce heuristic biases, the vulnerability assessment is related to the plausibility and severity potential of a hazard instead of quantifications of the related probability of occurrence.

Safety-critical assumptions include, but are not limited to, preventive and controlling barriers and their influencing factors. In healthcare, since the majority of barriers are procedural, human factors are essential in assessing barrier vulnerability.

The presence of human factors is influenced by external factors such as patient volume, available resources and elapsed time, and on internal factors such as organizational and individual response to changes of the external factors. The safety culture of an organization can be described as the attitude, awareness and approach to safety of personnel at all levels, including both intentions and performance of operations (EUROCONTROL, 2008; Listyowardojo et al., 2014; Strauch, 2015).

In this project, approaches and methods from other high-risk sectors have been reviewed from the perspective of real-time risk monitoring in healthcare. The thesis concludes that elements from the reviewed approaches and methods may be combined as a basis for further development of an appropriate leading risk indicator framework. The elements are:

- A leading indicator framework should be based on the principle of Safety-II
- The real-time risk picture is related to the organization's ability to prevent adverse events
- The analysis of the organization's ability to prevent adverse events should be based on safety-critical assumptions including barriers and their risk influencing factors
- The leading indicator system should be tailored to the specific organization

The use of Bayes Nets provides a powerful modeling tool, which makes it possible to indicate influencing factors and dependent probabilities without assuming causational relationships. Accidents and incident can be modeled as situations where events occur simultaneously rather than in a linear, chronological order. In addition, Bayes Nets use node probability tables that allow resonance effects to be implemented in a model.

When selecting a set of leading indicators for real-time monitoring of risk, the set should only include indicators suitable for activity adjustments.

The following is a suggested approach to modeling each leading risk indicator:

- Each indicator should relate to one identified, preventable hazard
- Each indicator should be assigned two categories, one reflecting the best and one the worst plausible outcome should the hazard occur
- The indicator should reflect changes in the plausibility of the hazard as a function of the identified influencing factors
- The influencing factors should be measurable
- Human factors should be regarded as important influences on risk and safety
- The safety culture should be regarded as an important influence on how human factors appear

7 List of references

Anfinsen, O.-G. (2011, 30th September). Kateterbehandling ved atrieflimmer. Retrieved 20th May, 2015, from https://helsenorge.no/undersokelse-og-behandling/kateterbehandling-ved-atrieflimmer

Aven, T. (2010). *Misconceptions of Risk*: Wiley.

Aven, T. (2011). On Different Types of Uncertainties in the Context of the Precautionary Principle. *Risk Analysis, 31*(10), 1515-1525. doi: 10.1111/j.1539-6924.2011.01612.x

Aven, T. (2012). *Foundations of Risk Analysis*: Wiley.

Aven, T., & Kvaløy, J. T. (2002). Implementing the Bayesian paradigm in risk analysis. *Reliability Engineering & System Safety, 78*(2), 195-201. doi: http://dx.doi.org/10.1016/S0951-8320(02)00161-8

Aven, T., & Reniers, G. (2013). How to define and interpret a probability in a risk and safety setting. *Safety Science, 51*(1), 223-231. doi: http://dx.doi.org/10.1016/j.ssci.2012.06.005

Boeing Commercial Aviation Services. (2009). *Maintenance Error Decision Aid (MEDA) User's Guide*. http://www.faa.gov/: Federal Aviation Administration, Retrieved from http://www.faa.gov/about/initiatives/maintenance_hf/library/documents/media/media/meda_users_guide_updated_09-25-13.pdf.

Catchpole, K. (2013). Spreading human factors expertise in healthcare: untangling the knots in people and systems. *BMJ Quality & Safety*. doi: 10.1136/bmjqs-2013-002036

Deilkås, E. T. (2014). Rapport fra Nasjonal Journalundersøkelse med Global Trigger Tool 2013. Oslo.

EUROCONTROL. (2008). Safety Culture in Air Traffic Management, A White Paper. Retrieved from: https://www.eurocontrol.int/sites/default/files/article/content/documents/nm/safety/safety-atm-whitepaper-final-low.pdf

European Commission. (2015, 23rd May). Projects. Retrieved 23rd May, 2015, from http://ec.europa.eu/health/patient_safety/projects/index_en.htm

Federal Aviation Administration. (2008). Human Factors Training. Retrieved from Human Factors Guide for Aviation Maintenance and Inspection website: http://www.hf.faa.gov/hfguide/08/08_concepts.html

Fenton, N., & Neil, M. (2012). *Risk Assessment and Decision Analysis with Bayesian Networks*: Taylor & Francis.

Flin, R., Winter, J., Sarac, C., & Raduma, M. (2009). Human factors in patient safety: review of topics and tools (M. a. M. W. G. o. W. P. Safety, Trans.): University of Aberdeen, Scotland.

Hakkarainen, K. M., Hedna, K., Petzold, M., & Hagg, S. (2012). Percentage of patients with preventable adverse drug reactions and preventability of adverse drug reactions--a meta-analysis. *PLoS One, 7*(3). doi: 10.1371/journal.pone.0033236

Helse Sør-Øst. (2013). Regional strategi for Kvalitet og pasientsikkerhet 2014-2016: Helse Sør-Øst,.

Helse Sør-Øst. (2015, 27th May). Pasientsikkerhet - Resultatutvikling. Retrieved 2nd June, 2015, from http://www.helse-sorost.no/fagfolk_/temasider_/pasientsikkerhet_/Sider/Resultatutvikling.aspx

Helse- og omsorgsdepartementet. (2014). *Kvalitet og pasientsikkerhet 2013*. Regjeringen.no Retrieved from https://www.regjeringen.no/nb/dokumenter/Meld-St-11-20142015/id2345641/.

Helsedirektoratet. (2014, 20th March 2014). The Norwegian Patient Safety Programme: In Safe Hands. Retrieved 2nd June, 2015, from http://www.pasientsikkerhetsprogrammet.no/_attachment/485

HFACS Inc. (2014). The HFACS Framework. Retrieved 15th May, 2015, from http://hfacs.com/definitions.html

Hodgetts, T. J., Kenward, G., Vlackonikolis, I., Payne, S., Castle, N., Crouch, R., . . . Shaikh, L. (2002). Incidence, location and reasons for avoidable in-hospital cardiac arrest in a district general

hospital. *Resuscitation, 54*(2), 115-123. doi: http://dx.doi.org/10.1016/S0300-9572(02)00098-9
Hollnagel, E., Wears, R. L., & Braithwaite, J. (2015). From Safety-I to Safety-II: A White Paper. Retrieved from: http://resilienthealthcare.net/onewebmedia/WhitePaperFinal.pdf
Hudson, P. (2003). Applying the lessons of high risk industries to health care. *Quality and Safety in Health Care, 12*(suppl 1). doi: 10.1136/qhc.12.suppl_1.i7
International Organization for Standardization. (2009). ISO 31000 - Risk management: International Organization for Standardization,.
Kiureghian, A. D., & Ditlevsen, O. (2009). Aleatory or epistemic? Does it matter? *Structural Safety, 31*(2), 105-112. doi: http://dx.doi.org/10.1016/j.strusafe.2008.06.020
Kjellén, U. (2009). The safety measurement problem revisited. *Safety Science, 47*(4), 486-489. doi: http://dx.doi.org/10.1016/j.ssci.2008.07.023
Leape, L., & Abookire, S. (2005). WHO Draft guidelines for adverse event reporting and learning systems: World Alliance for Patient Safety.
Leveson, N. (2015). A systems approach to risk management through leading safety indicators. *Reliability Engineering & System Safety, 136*(0), 17-34. doi: http://dx.doi.org/10.1016/j.ress.2014.10.008
Lindgren, M., & Bandhold, H. (2003). *Scenario Planning: The Link Between Future and Strategy*: PALGRAVE MACMILLAN.
Listyowardojo, T. A. (2012). *Improving safety culture in health care: implications of individual and institutional variability.* (PhD), University of Groningen, Groningen, Netherlands. Retrieved from http://www.rug.nl/research/portal/publications/improving-safety-culture-in-health-care(c70e1265-e3b8-4d4e-ae10-c0f220511c99).html
Listyowardojo, T. A., Ray-Sannerud, B., Turk, E., Lyons, M., Pytte, M., Leyshon, S., & Vallevik, V. (2014). Mixed Methods: Improving the assessment of safety culture in healthcare: DNV GL Strategic Research & Innovation.
Mearns, K. (2009). From reactive to proactive – Can LPIs deliver? *Safety Science, 47*(4), 491-492. doi: http://dx.doi.org/10.1016/j.ssci.2008.07.028
Meinert, S. (2014). *Field manual - Scenario building* Retrieved from https://www.etui.org/Publications2/Guides/Field-manual-Scenario-building
Moray, N. (2000). Culture, politics and ergonomics. *Ergonomics, 43*(7), 858-868.
Norsk pasientskadeerstatning. (2015). Utbetalinger. Retrieved 4th May, 2015, from http://www.npe.no/no/Om-pasientskader/Statistikk/Utbetalinger-per-ar/
Petroleum Safety Authority Norway. (2013). *Principles for barrier management in the petroleum industry*. Petroleum Safety Authority Norway Retrieved from http://www.psa.no/getfile.php/PDF/Barrierenotatet 2013 engelsk april.pdf.
Petroleum Safety Authority Norway. (2015). Risikonivå i norsk petroleumsvirksomhet - sammendragsrapport 2014. Stavanger.
Reddy, T. A. (2011). *Applied Data Analysis and Modeling for Energy Engineers and Scientists*: Springer US.
Shojania, K. G., & Thomas, E. J. (2013). Trends in adverse events over time: why are we not improving? *BMJ Quality & Safety, 22*(4), 273-277. doi: 10.1136/bmjqs-2013-001935
Skjerve, A. B., & Kaarstad, M. (2014). *The MTO perspective and selected research activities at the Halden Reactor Project*. Paper presented at the IAEA Technical Meeting on the Interaction between Individuals, Technology and Organization - A Systemic Approach to Safety in Practice, Wien. http://www.ife.no/en/publications/2014/mto/the-mto-safety-perspective-and-selected-research-activities-at-the-halden-reactor-project
Sklet, S. (2006). Safety barriers: Definition, classification, and performance. *Journal of Loss Prevention in the Process Industries, 19*(5), 494-506.
Statistics Norway. (2014). Health care personnel, 2013, 4th quarter. Retrieved 4th May, 2015, from https://www.ssb.no/en/arbeid-og-lonn/statistikker/hesospers

Statistics Norway. (2015a). Health accounts, 2014. Retrieved 4th May, 2015, from https://www.ssb.no/en/nasjonalregnskap-og-konjunkturer/statistikker/helsesat
Statistics Norway. (2015b). Patient statistics, 2014. Retrieved 4th May, 2015, from https://www.ssb.no/en/helse/statistikker/pasient
Strauch, B. (2015). Can we examine safety culture in accident investigations, or should we? *Safety Science, 77*(0), 102-111. doi: http://dx.doi.org/10.1016/j.ssci.2015.03.020
Umscheid, C. A., Mitchell, M. D., Doshi, J. A., Agarwal, R., Williams, K., & Brennan, P. J. (2011). Estimating the Proportion of Healthcare-Associated Infections That Are Reasonably Preventable and the Related Mortality and Costs. *Infection Control & Hospital Epidemiology, 32*(02), 101-114. doi: doi:10.1086/657912
Vincent, C., Turk, E., Listyowardojo, T. A., Pytte, M., McAdam, S., & Leyshon, S. (2014). Priorities in Risk Management for Patient Safety: DNV GL.
Vinnem, J. E. (2010). Risk indicators for major hazards on offshore installations. *Safety Science, 48*(6), 770-787. doi: http://dx.doi.org/10.1016/j.ssci.2010.02.015
Vinnem, J. E. (2014a). *Offshore Risk Assessment vol 1.: Principles, Modelling and Applications of QRA Studies* (3rd ed.): Springer London.
Vinnem, J. E. (2014b). *Offshore Risk Assessment vol 2.: Principles, Modelling and Applications of QRA Studies* (3rd ed.): Springer London.
Walpole, R. E., Myers, R. H., Myers, S. L., & Ye, K. (2011). *Probability and Statistics for Engineers and Scientists* (9th ed.): Pearson.
World Health Organization. (2015). Patient Safety. Retrieved 8th June, 2015, from http://www.who.int/patientsafety/research/strengthening_capacity/classics/en/
Zegers, M., de Bruijne, M. C., Wagner, C., Hoonhout, L. H. F., Waaijman, R., Smits, M., . . . van der Wal, G. (2009). Adverse events and potentially preventable deaths in Dutch hospitals: results of a retrospective patient record review study. *Quality and Safety in Health Care, 18*(4), 297-302. doi: 10.1136/qshc.2007.025924