Alarm Hazards on the Pediatric Intensive Care Unit

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Abstract

Medical machines alert nurses on a pediatric intensive care unit (PICU) to changes in a patient's status or treatment by producing alarms. The current organization of medical alarms causes hazards that can be detrimental to a patient's care. An excessive number of alarms, lack of alarm integration into central points, or inappropriate alarm boundary configuration are examples of these hazards.

This study addressed alarm hazards on the University Medical Center Groningen's (UMCG) PICU by answering three questions: how can alarm hazards in the ICU environment best be analyzed, what are the most prominent alarm hazards found on the UMCG's PICU, and how can a cognitive engineering solution address the most prominent alarm hazard?

The study we present used a cognitive work analysis to find all relevant aspects in the work of critical care nurses regarding alarms. The analysis provided a formalization of the nurses' work domain, tasks, and strategies.

We used a risk analysis on the obtained framework to find the most prominent alarm hazards. This risk analysis method was based on a combination of the SHERPA and HFMEA methods, and obtained its information from experienced PICU nurses. Results showed the most prominent hazards to be the setting of alarm boundaries for patient monitors and IV pumps, the malfunctioning of pagers, and a lack of knowledge to identify the cause of alarms.

We addressed the latter by building a knowledge-based system prototype that supports decision making and training by suggesting diagnoses for patient monitor alarm combinations. The system was built using knowledge and rules elicited from the most experienced PICU nurses. The validity and effectiveness of the system was confirmed during expert reviews. Although the resulting system is only a prototype, the application of knowledge-based systems to reduce alarm hazards looks very promising.

The full research provided a theoretically grounded approach for improving alarm hazards in critical care that can be used as a paradigm by researchers, ICU managers, and medical device manufacturers interested in improving alarms.

Table of Contents

1. Introduction

One of the main goals and concerns for any hospital is to guarantee the safety and proper treatment of patients, especially those who are admitted because of a serious condition. An essential part of this process is accomplished by alarms. A large number of machines and sensors can measure the state of a patient's various physiological variables. When deviations from safe values occur, these machines can sound alarms to call the attention of the hospital staff to the changing situation, after which some appropriate action can be performed to adjust treatment or remedy the situation.

The current setup of medical alarms causes nuisances and hazards in its environment. Alarm hazards have been number 1 on the ECRI-list of medical technology risks (ECRI Institute, 2013) for numerous years. Multiple mechanisms play a role to maintain the risk of this category at such a high level. Having an excessive number of alarms contributes to alarm fatigue. False alarms usually make up between 80 and 90 percent of alarms during patient monitoring, and only a small percentage of alarms convey an actual risk (Kestin, Miller, & Lockhart, 1988). This can lead to caregivers being overwhelmed by too many simultaneous alarms, distracted from patient care, or desensitized to alarms. Another risk surrounding alarms can be found in alarm configuration. An inappropriate configuration of alarms and their boundaries can either lead to valid alarms being missed or be the origin of many unnecessary alarms. Other problems commonly cited include a lack of integration between devices (Logan, 2011), the annoying nature of alarm sounds (Logan, 2011), and the dissonance between perceived urgency and actual urgency of alarms (Finley & Cohen, 1991).

To address alarm hazards in the increasingly complex medical environment, it is clear that medical engineers will have to take into account the capabilities of humans and the way they work within the boundaries of their environment. The expertise most suited to deal with these engineering challenges can be found in the field of cognitive engineering. Cognitive engineering can be defined as "an interdisciplinary approach to the analysis, modeling, and design of engineered systems or workplaces, especially those in which humans and automation jointly operate to achieve system goals" (Lee et al., 2013). It provides tools, methods, and models that focus on the cognitive constraints of a working environment and the development of technologies to support that work.

The original motivation for this research was to find a solution for the reported troubles of the University Medical Center Groningen (UMCG) pediatric intensive care unit (PICU) nursing staff to integrate alarms from separate medical devices into the main alarm monitoring system. This led to perilous situations when a patient is placed in an isolated private room as these rooms are nearly soundproof and obscure a direct view of the devices from the central monitoring desk. After preliminary observations and analysis during which we observed the work of nurses and the alarms and devices on the PICU, the complex nature of alarm hazards on the IC unit became apparent. We made the decision to extend the research to an analysis of the entire alarm environment of the PICU in order to propose answers to the following questions:

- How can alarm hazards in the ICU environment best be analyzed?
- What are the most prominent alarm hazards found on the UMCG's PICU?
- How can a cognitive engineering solution address the most prominent alarm hazard?

We used methods from cognitive engineering, specifically Cognitive Work Analysis and Healthcare Failure Mode & Effect Analysis, to analyze the work and working environment of the staff

of the pediatric intensive care unit (PICU) of the UMCG regarding alarms and alarm hazards. Furthermore we proposed a knowledge-based tool that enhances decision making when diagnosing monitor alarms and can be used to train ICU nurses on the quick recognition of several alarm combinations.

1.1 Structure of the Thesis

This thesis consists of 5 chapters. Chapter 2 provides general information about the pediatric ICU environment, medical machines, and medical measurements. Chapter 3 presents the theoretical framework of the thesis. In this chapter we talk about human factors on the ICU, theory and previous research about several alarm hazards, analysis methods, and alarm improvement methods. Chapter 4 talks about the research of this study: the execution of a cognitive work analysis, a risk analysis, and the design and creation of a knowledge-based system for monitor alarms. Finally, chapter 5 discusses the implications, criticism, and conclusions of the work outlined in this thesis.

2. Background

The research we present in this thesis refers to the UMCG's PICU environment and its actors and machines. The research results include an analysis of all factors in the working environment that play a role when dealing with alarms and an analysis that determined what the most pressing risks are. To fully appreciate the work we present in the next chapters, it is important to have an overview of what this working environment is and what the function is of the machines in this environment. Section 2.1 outlines what a (pediatric) ICU is, section 2.2 explains what machines are used for alarms, and section 2.3 describes the most important physiological variables that are used during patient monitoring.

2.1 The Pediatric ICU

When somebody has to be admitted to the hospital because of a life-threatening condition, and one of their vital body functions is threatened or needs to be closely monitored, they are referred to an ICU. To illustrate, this can occur when said person just underwent an operation (e.g. heart surgery or major abdominal surgery), had a serious accident, has serious pneumonia or sepsis, has severe hart functioning problems, or is affected by some neurological disease (e.g. a coma or paralysis). In these and other cases, the patient needs intensive, 24 hour a day care and monitoring that can be provided by an ICU.

An ICU is a specialized working environment that is ran by specially trained physicians called intensivists, and critical care nurses. An ICU nurse differs from a regular nurse in that he/she must be able to correctly monitor vital body functions, by for example making sure the complex medical equipment setup functions well, and adequately respond to changes in vital signs. ICU patients are generally much less stable than other types of patients, and need constant vigilance and interventions. Usually a critical care nurse is trained to perform more technical nursing actions because they provide more complex care.

The body of an infant or a teenager is substantially different physiologically from that of an adult. Patients who are under 18 and in need of admittance to an ICU, can be treated at an ICU for children called a pediatric ICU. These are usually located in academic hospitals, and include their own specially trained pediatric intensivists and pediatric IC nurses. Next to the regular nursing responsibilities such as monitoring data, starting and maintaining infusion therapy, operating equipment, and administering and recording medication, a pediatric ICU nurse has to coordinate with other members of the ICU to assess, plan, and apply patient care. Because patients are not of age, a parent or guardian has to be included in this group.

2.2 Medical Machines

Physicians and nurses on the PICU have a large array of monitoring machines and other medical systems at their disposal. This section will describe the relevant medical machines that produce alarms and are used on the PICU of the University Medical Centre Groningen (UMCG) where this research took place. Consecutively it will explain what the different physiological values are that are commonly monitored.

The following machines can all output alarms to their environment. They can trigger acoustic alarms by means of a repeating tone, visual alarms by blinking lights, or display information on a screen.

2.2.1 Patient monitor

The UMCG's PICU uses the Philips IntelliVue MP70 patient monitor (Figure 1). This monitor can use a wide variety of sensory information as input to display on an interface. The monitor can collect and display information about the heart and its rhythm, the respiratory system, blood pressure (BP), consciousness and EEG signals, oxygen saturation, cardiac output, and temperature. Boundaries can be set in these signals, either by the caregiver or by the standard settings, to give an alarm when these boundaries are exceeded. These boundaries are usually displayed next to the value they refer to in the form of alarm limits. The monitor can give up to 70 different alarm messages. These messages are characterized by a priority level of either low or high. Low priority alarms flash a yellow light and broadcast a soft tone while high priority alarms flash a red light and broadcast a higher and louder tone. The monitor can be operated with a touchscreen that can be used to suppress alarm signals or configure the screen value and curve layout. There is a set of preconfigured screens that are commonly used.

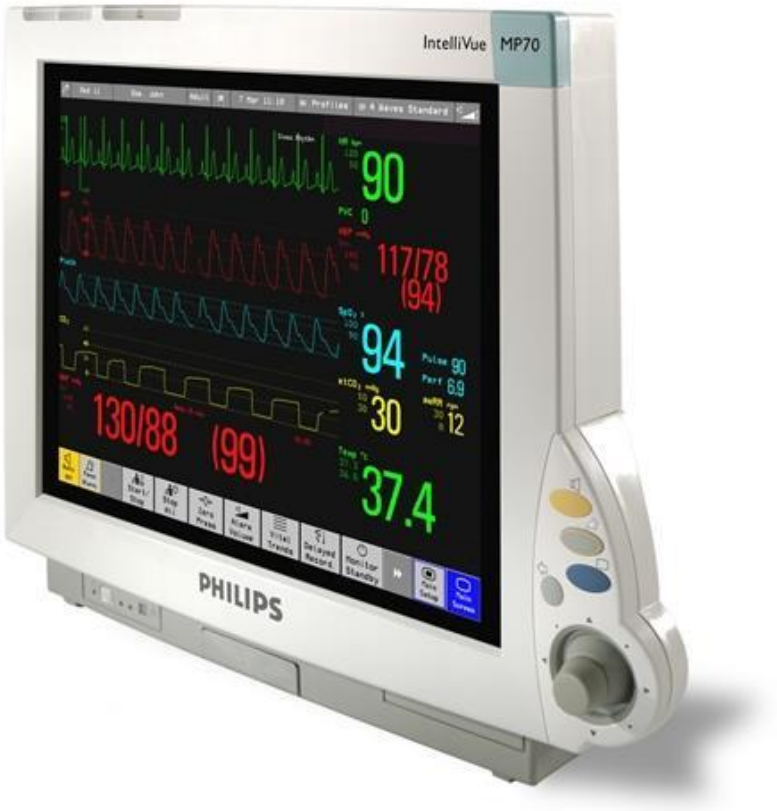


Figure 1. The Philips IntelliVue MP70 patient monitor.

2.2.2 Infusion pump

An infusion pump is a device that delivers medication or nutrients to a patient through intravenous therapy. It pumps a fluid directly into a vein by means of a connecting tube. There are two classes of pumps, small volume pumps that can infuse several types of medicines, and large volumetric pumps that can carry nutrient solutions. The UMCG's PICU uses the Asena GH for the former type (Figure 2), and the Asena GW volumetric pump for the latter. Multiple pumps of the type displayed in Figure 2 are commonly stacked on top of each other in a docking station.

The pump's docking station alarms when the pump is empty, a set volume has been delivered to the patient, when an obstruction is detected, or when the battery is empty. The machines can alarm visually and auditory, through lights and a beeping tone.

Figure 2. An Asena GH infusion pump

2.2.3 Ventilator

A medical ventilator is a machine that can partially or fully take over the body function of breathing for a patient. It does so by mechanically moving air into and out of the lungs. The PICU at the UMCG uses two different types of ventilators, namely the Evita XL (Figure 3), and the SensorMedics High Frequency Oscillatory (HFO) Ventilator 3100A/B (Figure 4). The first can provide visual feedback about each breath on a display.

A ventilator can sound an alarm when constraints on frequency of breath, air pressure, or volume are broken. These alarms are both acoustic and visual, they display a yellow or red light that indicates alarm severity.

2.2.4 Other machines

There are more machines at the PICU that give out alarms. Some of these machines are either less commonly used or take a less prominent and critical place. Also, not all of the alarming machines are by definition the concern of the regular nursing staff. These machines include: a humidifier that is attached to the ventilator, a heat lamp, a criticool (a hypothermia machine), a PiCCO (a cardiac output machine), several communication devices in the form of intercoms, pagers, and baby monitors, and special machinery, such as a dialysis machine, an Extra Corporeal Life Support (ECLS) machine, and a MARS (a machine for liver dialysis).

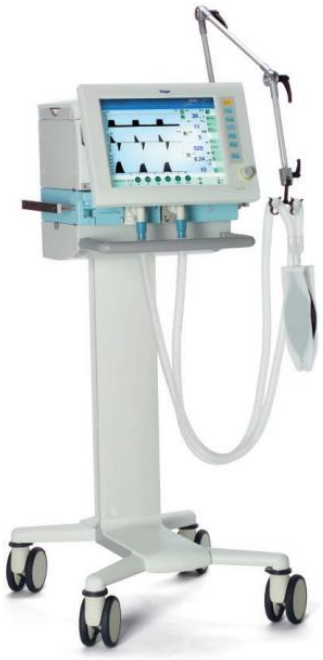


Figure 3. An Evita XL ventilator

Figure 4. A SensorMedics HFO 3100A/B

2.3 Physiological variables

A patient monitor can derive values and waveforms for several vital parameters from processed physiological data. The following values and waveforms are commonly displayed on a patient monitor, and are used as a basis for alarms and information about the patient's state.

2.3.1 Heart rate information

Information about the heart rate is displayed as a number that indicates the number of beats, or contractions, per minute. The heart pumps blood through the circulatory system and makes it reach every party of the body. Heart rate is typically measured with electrodes that are placed on the chest. It can also be derived via pulse oximetry, or via an invasive catheter in a vein.

Heart activity can be displayed as an electrocardiogram (ECG). This is a curve that represents electrical activity of the heart over time. This is useful to detect trends or certain arrhythmias. The ECG curve is displayed as an example in Figure 1 as the top (green) graph. The number adjacent to it is the current heart rate.

2.3.2 Respiratory information

Respiratory information is gathered to monitor the breathing of the patient, along with oxygen saturation. When the breathing of a patient is stimulated with a ventilator through the insertion of an endotracheal tube, the airflow in this tube can be measured to derive values for respiration rate (the frequency of breathing in and out), volume, pressure, the amounts of CO_2 in the expired air, and the amounts of O_2 in the incoming air. As an example, ventilation pressure is displayed in Figure 1 as the fourth (yellow) curve.

The effectiveness of the respiratory system can also be measured by looking at the oxygen saturation in the blood. Oxygen saturation refers to the proportion of oxygen-saturated hemoglobin compared to all hemoglobin. This value is expressed as a percentage of blood oxygen level, and normally should be between 95 and 100 percent. Saturation can be measured in different tissues. It can be measured intravenously, by means of a catheter or extracorporeal machine, displayed as SvO_2. More commonly it can be measured by a pulse oximeter sensor or clip on the skin, called peripheral capillary oxygen saturation, displayed as SpO_2. This clip can be placed on a finger or on a toe for small children, but is very receptive to interference. In Figure 1, the pulse oximeter signal is displayed as the third (blue) curve, the SpO_2 value is depicted next to it.

2.3.3 Blood pressure

Blood pressure refers to the pressure that blood exerts on the arteries in the circulatory system. The pressure is usually displayed as two values, systolic pressure over diastolic pressure, and is measured in millimeters of mercury.

Blood pressure can be measured in an invasive or non-invasive way. Non-invasive values, displayed as NBP on the patient monitor, are measured with a cuff and are somewhat less accurate than invasive measurements. Invasive blood pressure is measured through either an arterial line by placing a cannula in an artery, displayed as Arterial Blood Pressure (ABP), or through a central line by measuring at a central venous catheter, called Central Venous Pressure (CVP). The second (red) curve in Figure 1 shows an example of an ABP curve, with the two BP values and BP mean between parentheses next to it.

3. Theoretical Framework

This chapter discusses the theoretical framework for this thesis. It is divided into parts on human factors and different work aspects of an ICU, different types of alarm hazards at an ICU, methods to analyze work and risks on the ICU, and finally possible solutions for improving alarms and their environment will be discussed. Each part contains general information about the relevant subject matter and gives an overview of previous research and the current state of affairs.

3.1 Human Factors and Work Aspects of the ICU

To analyze and improve human interaction with complex sociotechnical systems, cognitive ergonomics have to be taken into account. The science that applies knowledge about human behavior and performance to systems to enhance safe and effective use is called human factors. Over the past 70 years, a large body of work has been developed using these human factors (e.g. fatigue or situation awareness) to increase our understanding of how performance and safety in a work environment can be improved using human factors principles. In the current study we present an analysis that attempted to find all the relevant (human) factors that have an effect on working with alarms on an ICU. This chapter explains what we expect to find by explaining what aspects of critical care working domains researchers commonly describe and study.

3.1.1 Performance-shaping factors and skills

A wide arrangement of performance-shaping factors can be defined that impact human capabilities when working in a critical care environment. Barach and Weinger (2007) categorize these as individual factors (e.g. clinical knowledge or skills), task factors (e.g. task distribution or workload), team and communication factors (e.g. teamwork and communication), environment of care factors (e.g. noise or lighting), equipment and tool factors (e.g. device usability or alarms), and organizational and cultural factors (e.g. policies or training). The most important and influential factors that are relevant in the context of alarms on an ICU are: the people and their skills and errors, monitoring technology and alarms, and the acoustic environment and unit layouts.

Taking care of critically ill patients is often a difficult task, especially when the environment presents many performance obstacles. Gurses & Carayon (2007) found that the most common performance degrading factors that ICU nurses face include: a noisy work environment, distractions from the patient's relatives, and hectic and crowded work environments. In addition to the regular performance obstacles found on ICU's, distractions from family are enhanced on a pediatric ICU because the patient's parents or guardians have to be involved in the care process. Taking these obstacles into account, it may come as no surprise that burnout syndrome among ICU nursing staff is generally high (Poncet et al., 2007; Topf & Dillon, 1988). In addition to environmental factors, the way nurses are trained and instructed has an impact on performance, especially when working with alarms. When determining the way to respond to alarms, nurses generally use their perceived urgency and information about the criticality, signal duration, rarity of alarm, and alarm duration, all influenced by workload and task complexity (Cvach, 2012).

Next to technical skills, people on an ICU need many nontechnical skills. When investigating critical care nursing on the ICU, Reader et al. (2006) identified four core nontechnical skill categories: task management, team working, situation awareness, and decision making. They further underline the importance of nontechnical skills for the ICU by stating that 50 percent of incidents can be

attributed to a nontechnical skill deficit, with task management (e.g. planning, prioritizing) being the largest contributor.

Activity on an ICU is supported by several cognitive processes. After observing and interviewing physicians, Fackler et al. (2009) found five broad categories of these cognitive processes. These are pattern recognition (identifying fragments of a mental model), uncertainty management (when patient functioning or treatment are not clear), the adjustments between strategic and tactical thinking (long-term and goal oriented, or short-term and task oriented), team coordination and maintenance of common ground (the distribution of cognitive work and expertise among different ICU members), and creation and transfer of meaning through stories (story creation and sharing as a means of understanding the patient). The previous shows what cognitive processes and nontechnical skills we expect to find when analyzing work with medical alarms.

3.1.2 Errors

Difficulties because of performance obstacles or deficits in technical or nontechnical skills can lead to errors. Because of their potential severe and often preventable nature, errors on ICU's are extensively researched. Donchin et al. (1995) collected 554 errors over a 4 month period on an ICU, averaging 1.7 errors daily per patient. They attributed many of these errors (37%) to verbal communication problems between physicians and nurses while verbal communication between nurses and physicians only made up 2% of their observed daily activity. The nature of errors on an ICU is also investigated by Rothschild et al. (2005). They observed 391 ICU patients during one year for a total of 1490 patient-days. They found a rate of 80.5 adverse events, 36.2 preventable adverse events, and 149.7 serious errors per 1000 patient days. Most errors occurred during ordering and administration of medication, and most performance errors were slips and lapses. The authors state that failure to carry out intended treatment was the leading type of error. Graf et al. (2005) used incident reports from the ICU staff of 216 patients and found that during 64 days 50 medical errors were reported for 32 of the patients. They judge 73% of errors to be human failures, and 92% of errors as avoidable.

The reported studies show that most errors on an ICU are preventable and caused by human performance problems. Ordering and administration of medication, and verbal communication between physicians and nurses are especially prone to errors. Furthermore these studies underline the need to take human factors into account to address these errors in order to increase patient safety.

3.1.3 Monitoring technology and alarms

Although the introduction of medical devices and technologies should help improve patient care and reduce errors, the way technologies and devices are designed is often flawed, as shown by the large number of adverse events and serious errors that is commonly observed during critical care (Rothschild et al., 2005). A human factors approach to medical devices that takes into account sociotechnical aspects is needed (Harrison et al., 2007). The most important interactive technologies on an ICU are the patient monitors, and the alarms that every medical device produces.

The patient monitors are mainly used by nurses to check on patients' physiological values. Their goal is to help determine the status, stability, and changes of health. However, it does not offer an integrated assessment of its measurements. To increase situational awareness, underlying physiological relationships should be apparent (Endsley, 1995). Efforts are being made to design

alternative monitor displays that do follow cognitive ergonomics principles. These displays are generally graphic of nature, and use distinct shapes to visualize physiological values and connections as emergent features of these shapes. This method of designing displays has been tested extensively in the field of anesthesiology (Drews & Westenskow, 2006; Sanderson et al., 2005). For example, Agutter et al. (2003) used a graphic display to show hemodynamic variables as emergent features. Anesthesiologists showed a significantly faster diagnosis of a simulated event than subjects who used a standard display, and initiated treatment sooner. More recently it is also being researched in an ICU setting. Anders et al. (2012) used an integrated graphical information display, a display that organizes disparate physiological information on a single timeline. The display improved ICU nurses' abnormal variable detection compared to regular displays without increasing workload. Drews & Doig (2014) used a 'configural vital signs' display, a display that shows trend data, numerical data, and the so-called current state object that integrates multiple variables (e.g. blood pressure and heart rate) into one display element. The spatial location, shape, and size of markers in this current state object provide integrated information about vital signs variability. Testing the display on ICU nurses showed improvements in the speed and accuracy of physiological data interpretation when compared to a traditional numerical format monitor.

Important and ever present elements of an ICU are device alarms. While intended to aid ICU nurses by increasing awareness, alarms often do the opposite by lowering awareness and disrupting workflow, both caused by the large number of alarms and false alarms (Cvach, 2012; Korniewicz et al., 2008; Logan, 2011). When researching alarms on an ICU, researchers usually find false alarm rates of up to 90% (Imhoff & Kuhls, 2006). Edworthy & Hellier (2006) review five areas with regard to alarm problems and design that should be the focus of alarm improvement efforts: reducing the number of alarms, false alarm rates, design of alarms and the application of auditory cognition, intelligent alarm systems, a worldwide standard for alarm design. Section 3.4 elaborates further on improving alarms.

3.1.4 The acoustic environment

The acoustic environment for alarms in an ICU is often poor: the recommended maximum noise level is regularly exceeded by a large amount because background noise is too high (e.g. Cordova et al., 2013). Background noise leads to a poor signal to noise ratio that impairs auditory vigilance (Solet & Barach, 2012). A poor acoustic environment affects both patients and caregivers. Noise causes stress in patients (Shumaker & Pequegnat, 1989) and impairs sleep, which in turn hinders healing (Adam & Oswald, 1984). Furthermore, noise causes stress (Morrison et al., 2003) and burnout (Topf & Dillon, 1988) in caregivers. Solet & Barach (2012) attempt to tackle the problem by looking at a noise-path-receiver model for audio transmission. General improvements in this model entailed reducing or eliminating noise sources, modifying the transmission of noise, and protecting the receiver of the noises. They propose improvements that include using less noisy medical equipment, creating a general acoustic hospital planning by for example using sound absorbent surface materials or by protecting the receiver by using single-patient rooms. The latter, using single patient rooms, is a measure that is increasingly used in hospitals, and its beneficial effects on patient health is supported by research (Knutt, 2005; Zimring et al., 2004). It can however have the drawbacks of lesser job satisfaction of the clinical staff because of isolation, and higher costs than shared rooms (Drews, 2013). Moreover, announcing device alarms from within an isolated room to nurses outside of this room can be problematic. Device standardization for integration with other alarms that announce themselves elsewhere (e.g. monitor alarms) is needed to support this setup.

In conclusion, this section has described the commonly analyzed work aspects and human factors regarding alarms on an ICU. The literature reveals the work and problem solving that researchers attribute to critical care personnel, and how the environment of sounds and machines interacts with the people and their work.

3.2 Alarm Hazards

As the previous section explained, because the implementation of alarm systems in medical environment is often lacking with respect to human factors, adverse events and potential severe errors can occur. The current study includes a risk analysis where the most prominent alarm hazards on an ICU were identified. To ascertain the scientific relevance of the implementation of said risk analysis and its results, it is very useful to create an overview of alarm hazards that researchers commonly find when studying ICU's. The most prominent problems that can be distinguished in an alarm setup are the causation of alarm fatigue, the lack of appropriate alarm urgency and interpretation indicators, and the lack of proper alarm integration. This section explains how each hazard is caused, why it is a hazard, and what typical solutions are.

3.2.1 Alarm fatigue

Because device alarms on an ICU are normally set for a high sensitivity to not miss any important events, a large number of false positives, or false alarms, are generated. The number of non-relevant alarms on ICU's is normally found to be over 80% (Imhoff & Kuhls, 2006; Kestin et al., 1988; Siebig et al., 2010), while Lawless (1994) found 94% of alarms on a pediatric ICU to be clinically unimportant. Chambrin et al. (1999) found in an observational study on multiple ICUs about monitor alarms a sensitivity of 97% (the percentage of true medical events that are detected), and a specificity of 58% (the percentage of medically unimportant events identified as such). Furthermore they scored their positive predictive value at only 27% (the percentage of alarms that is medically relevant), with a negative predictive value of 99% (the percentage of potential alarm occurrences that correctly not produced an alarm, calculated using the mean interval between observed alarms). These results show that, while safe with respect to true alarms, this type of sensitivity causes a lot of false alarms, or so called nuisance alarms.

Exposure to nuisance alarms causes alarm fatigue, the effect of becoming desensitized to alarms (Borowski et al, 2011). Research shows that people adjust their response to an alarm according to how reliable they perceive that alarm to be (Bliss et al., 1995; Bliss & Dunn, 2000). This probability matching of response rate to alarm reliability is often called the 'cry wolf' effect, and causes people to be less trusting of alarms, up to the point where alarms are even turned off (Logan, 2011). Additional factors that contribute to alarm fatigue are a high background noise level and a poor acoustic environment. A high background noise level increases cognitive load and stress, and a poor acoustic environment complicates the discernment and attribution of alarms (Baker, 1984; Solet & Barach, 2012).

There are two general directions in which solutions to combat alarm fatigue are sought. The first direction is the modification of the mechanisms for alarm generation to reduce the percentage of false alarms. There should be better guidelines for alarm parameter settings and priority levels (Chambrin, 2001). Graham & Cvach (2010) found that correctly individualizing alarm parameters along with wider default parameter settings reduces the percentage of critical monitor alarms by 43%. The widening of alarm parameters can be seen as increasing specificity by lowering sensitivity.

Another way to accomplish this is by using intelligent alarm systems that interpret medical data, and only produce the clinically relevant alarms (Edworthy & Hellier, 2006). In the case of technical, device malfunction alarms, machines and sensors that are prone to these alarms because of signal interference should be handled with extra care. Users should be advised to be especially careful with the placement and maintenance of the parts of these machines (e.g. placement of electrodes on a patient) (Cvach, 2012).

The second direction is the modification of the alarm sounds and audibility. Too many standard alarms that do not convey any specific information hinder recognition and the correct allocation of urgency. This can be addressed by using specific alarms for specific physiological functions, and using distinct sounds as their alarms that are standardized among different devices (Block et al., 2000), although some proposed melodic alarm standards are still too hard to learn and recognize (Wee & Sanderson, 2008). According to Edworthy and Hellier (2006), an ideal alarm sound should be easy to localize, resistant to masking by other sounds by being acoustically rich, should allow communication by not being continuous sounds, and be easy to learn and retain by varying in more ways than just pitch. Upholding these guidelines by means of better regulations for medical device design should improve the acoustic environment and lessen alarm fatigue problems.

3.2.2 Alarm urgency and interpretation

Nurses use perceived urgency as a part of their strategy to determine the way to respond to an alarm (Cvach, 2012). For people to ascribe a certain priority to an alarm, the alarm first has to be correctly identified. Identification of auditory alarms on an ICU can be poor. Momtahan et al. (1993) found that the staff on an ICU only correctly identified about half of the alarms that can be found in their environment, and that alarm importance was not positively correlated with identification. Although the alarms in this study were mostly sounds without context, it shows that the auditory signals do not contain any additional information about the alarm's meaning other than what is explicitly learned. As a consequence this causes problems to identify the correct urgency of an alarm. Mondor and Finley (2003) found that people do not perceive the correct urgency even for alarms that have been specifically designed to distinguish between multiple levels of urgency. Finley and Cohen (1991) found that the perceived urgency scores that anesthetists assigned to monitor alarms did not positively correlate with the actual clinical urgency scores as determined by a group of senior anesthetists.

Solutions to tackle the alarm urgency and interpretation problems usually entail standardization of alarm function and urgency sounds among different devices. Research suggests that urgency can be conveyed and tweaked by differences or changes in pitch, complexity of harmonics, or speed and spacing of repetitions, and by using a standard that everybody knows (Finley & Cohen, 1991; Hellier & Edworthy, 1989). Standardizing alarm sounds is often seen as a good way to reduce the number of alarms that nurses must learn to recognize (Phillips & Barnsteiner, 2005) and thus should help with identification. Chambrin (2001) also advocates the use of standardized alarms. Each type of alarm and situation should have a set priority level that has been established beforehand, with their own corresponding auditory characteristics, including whether they should present an auditory alarm at all. For example, standards exist for the alarms of a ventilator, among other devices, that define only an electrical or pneumatic failure and high airway pressure as high priority alarms that require an intervention and an audible alarm (Chambrin, 2001). Implementing priority measures like these can help reduce the number of alarms (Edworthy &

Hellier, 2006), and should help convey the correct level of urgency, increasing overall performance for nurses and trust in alarms.

3.2.3 Alarm integration

For a critical care nurse to perform well when diagnosing patients and responding to alarms, a good level of situation awareness is critical. As Endsley (1995) defines it, situation awareness is an understanding of the state of the environment that forms the basis for decision making and performance. Because errors on an ICU should be prevented as much as possible, supporting systems that increase situation awareness are highly recommendable. A promising way to design such a system is to give an integrated assessment of a patient's status instead of the simple, naïve data that is usually provided. Current medical machines generally do not provide such an assessment, which impedes the easy understanding of underlying relationships of values and alarms (Drews & Westenskow, 2006; Drews, 2013). Integration of alarm information into mobile communication systems could also aid situational awareness, and is seen as a useful addition by a majority of medical personnel (Korniewicz et al., 2008). In addition to aiding situational awareness, integrating multiple alarm systems should also be beneficial by reducing the number of alarms (Logan, 2011), part of a solution for the aforementioned alarm fatigue and urgency issues.

Research in the area of integrated assessment focusses on integrating information into alarms and displays, such as the work by Anders et al. (2012) who developed a display that organizes physiological information on a single timeline, which improved ICU nurses' abnormal variable detection compared to regular displays. Another part of research in this area focusses on ways to integrate multiple physiological signals and device data into a single diagnosis. An expert system can be used at the monitor level to produce a smart alarm. Oberli et al. (1999) were able to use an experimental expert system that employs fuzzy logic to reduce the number of false alarms to only 1% while maintaining a higher sensitivity and higher positive predictive value than naïve signals. Multiple physiological parameters can be integrated to improve the informational value of alarms and thus situation awareness. Schoenberg et al. (1999) obtained promising results by integrating data for heart rate, blood pressure, and oxygen saturation using a logic module that contains algorithms about trends. This approach greatly improved the positive predictive value of alarms. Another path to integrating alarms and information that is increasingly used is that of decision support systems that can use information from multiple aspects of a clinical situation to provide an integrated assessment (Sucher et al., 2008). The importance and benefits of integrating multiple devices and signals in an ICU are clear, and technology is slowly catching up. This is for example shown by the work of King et al. (2009), who programmed the technology for a medical device coordination framework that can be used to investigate medical device integration and coordination.

3.3 Analyzing the ICU

This section discusses different ways to analyze work on an ICU. The section starts by defining the ICU as a sociotechnical system and it states the need to include human factors principles. The section then goes on to discuss different analysis methods, paying special attention to cognitive work analysis and risk analysis because these methods were employed by the current study.

When looking at performance and safety in an ICU environment, the best method for analysis is through human factors and cognitive ergonomics methods, which are grounded in the

sociotechnical systems perspective (Drews, 2013). Trist (1981) describes three interwoven levels, ranging from a micro level to a macro level, on which socio-technical analyses are performed. These levels can be pinpointed in the context of an ICU setting. As the first level he identifies the primary work systems that carry out the activities within an organization that define its functional purpose. This can be identified as the (pediatric) ICU in the context of this study. Secondly he identifies the level of whole organization systems, which can range from self-standing workplaces to corporations that and maintain a steady state with their environment. In the context of this study this refers to an entire hospital. Thirdly he describes macrosocial systems that operate at an overall level within a community or sector. This can be regarded as an entire healthcare system that includes all of the previous systems. From this construction it becomes evident that alarms and alarm safety in an ICU take place on the micro level of primary work systems, and are only a part of a complete sociotechnical system.

From a human factors perspective it is desirable that technology is tailored to the needs of the workers within a clinical working environment. For this approach to be successful, the requirements and needs of workers and their work have to be analyzed to ascertain what the critical problems and questions are, and to not fall victim to the large amount of fallacies that are commonly found when working with healthcare information technology (HIT) (Karsh et al., 2010). These fallacies include the fallacy that HIT's risks are minor, HIT does not need the same regulations as medical devices, or that HIT's problems are exclusively caused by humans.

There is no one best analysis method to analyze an ICU. There are many tools and methods available to describe and obtain information about the processes and work involved with alarms in a healthcare environment, each with their strengths and weaknesses. Because part of the current study is finding the most appropriate analysis method or combination of methods, creating an overview of commonly used analysis methods is advantageous by increasing the number of options. The most commonly used methods are: observation with or without the explicit annotation of alarms, eliciting knowledge through critical decision making, surveys on opinions about medical alarm systems, performing a cognitive task analysis (CTA) or a cognitive work analysis (CWA).

An example of analysis through observation is the work of Görges et al. (2009). They observed and recorded alarms on an ICU and the response and whereabouts of health care team members. Their results showed that implementing a 14 second alarm delay before alarm presentation removed 50% of nuisance alarms, and they recommend the automatic detection of activities such as suctioning, washing, repositioning, and oral care, during which alarms should be disabled. Another example is the work by Siebig et al. (2010), who collected physiological data and alarm annotations on an ICU. They observed the work and alarms by means of video cameras and annotated alarm events. Results showed an average of six alarms per hour, of which only 15% were clinically relevant.

Directly asking people about their work is another way to obtain information. This can be done through (online) surveys to obtain general information and statistics, as demonstrated by the work of Korniewicz et al. (2008) on opinions about the effectiveness of clinical alarms, or through means of an interview to define people's expertise and decision making in a more detailed way. One method that uses interview techniques is the critical decision method (CDM) for eliciting knowledge, and is described in detail by Klein et al. (1989). Their work shows that CDM is useful to define parts of

expertise that are not factual and objective knowledge, but rather tacit or contextual knowledge, or recognition-primed decisions as they call it. These are decisions that are made on the basis of critical information and prior knowledge. The CDM method can be described in five steps: select an incident, obtain an unstructured incident account, construct a timeline of the incident, identify the point where a critical decision was make, and finally probe the decision point with additional questions to determine the relevant factors such as cues, knowledge, goals, or options. The resulting information can then culminate in a decision model, an inventory of critical cues, a situational assessment, or a specific case study.

Another way of analyzing work on an ICU is using a cognitive task analysis. Clark et al. (2008) and Schraagen et al. (2000) provide an extensive description of CTA and its varieties and developments. They define a CTA as a structure of protocols for observation and interviews to extract knowledge from experts, which often includes the aforementioned methods of observation and CDM. A CTA attempts to model the mental operations and processes that take place during tasks that require situation assessment and decision making. As described by Clark et al. (2008), a typical CTA starts by collecting preliminary knowledge through documentation, observations, or unstructured interviews. It then uses this to identify the relevant knowledge representations by identifying subtasks and the knowledge required to perform them. After this, a CTA uses a focused knowledge elicitation method, e.g. CDM, to obtain the desired task and knowledge information. This data is then verified by subject experts and formatted for the intended purpose, such as models that reveal problem-solving strategies and underlying skills. An example of the application of a CTA in an ICU environment is provided by Fackler et al. (2009) who performed an extensive CTA to analyze the most prominent cognitive activities in critical care medicine. By carrying out observations and interviews, they were able to define the broad categories of cognitive activities of critical care providers, and thus demonstrated CTA's usefulness in an ICU environment.

3.3.1 Cognitive work analysis

Although a well-performed CTA is comprehensive with respect to mental processes such as decision making and pattern recognition, its structure is often insufficient to cover the relevant non-mental aspects of a task domain. An alternative method that can include both cognitive and physical aspects (e.g. medical devices or sounds) of a task domain is the cognitive work analysis. CWA is a framework that can be used to create a model of work within a complex sociotechnical system. The analysis method emerged as a paradigm through the combination of analysis methods from the cognitive engineering area. Rasmussen et al. (1994) and Vicente (1999) were the first to formally define and record CWA as a work analysis method in their respective books, which was later followed with additional descriptions and applications by Bisantz and Burns (2008), and Jenkins et al. (2009).

A CWA models how work within a sociotechnical system is performed by modeling types of behavior-shaping constraints. These constraints define boundaries on action, through which the space of action possibilities emerges. It revolves around the interactions between people, technical systems, and their working environment. Within a micro level sociotechnical system, as described by Trist (1981), four layers can be distinguished, as stated by Moray & Huey (1988). Starting from the outmost layer these are: an environmental context, an organizational infrastructure, workers, and a technical or engineering system. The innermost layer (i.e. the technical system) was traditionally seen as being the only system, which is later viewed as erroneous (Vicente, 1999). The application of

CWA makes clear that the additional layers and the interactions between them must also be taken in to account.

As Vicente (1999) describes in great detail, CWA works on the sociotechnical structure by defining behavior-shaping constraints during multiple phases of analysis that reveal and narrow the options for action. A typical CWA can consist of up to five different phases: a work domain analysis, a control task analysis, a strategies analysis, an organizational analysis, and finally a competencies analysis. These phases can be characterized by five questions that define the basis of analysis: why, what, how, by whom, and by what means (Kilgore et al., 2008). It is not desirable to define one correct way to perform a CWA (Vicente, 1999), as it should be tailored to find a specific domain's constraints that address the specified goals of the analyst and design problem. Consequently, not every phase has to be executed in every CWA; often only a subset can be performed. The following is a general description of what every phase analyzes, what constraints it attempts to reveal, and how it can be performed as proposed by Vicente (1999), and research examples where applicable.

1 Why: work domain analysis

This analysis tries to find the purpose of a sociotechnical system. The analysis adds constraints on purposes, priorities, and processes. This phase is performed to identify the system's underpinnings and to specify the system information requirements needed to fulfill the overall purposes. This can be done by creating a decomposition of the work field, called an abstraction decomposition hierarchy that consists of a part-whole decomposition and an abstraction hierarchy. The analysis creates a two-dimensional field onto which actions or systems can be mapped. One dimension depicts a decomposition hierarchy with multiple levels of resolution, ranging from most coarse to finest level of component (e.g. from total system to component). Along the other dimension an abstraction hierarchy is depicted with multiple levels of abstraction, ranging from most abstract level of purpose to the most concrete level of form. As stated by Vicente (1999), each level represents a different 'language' with which to represent the work domain. The number of levels and their contents are found during the analysis. Table 1 depicts a typical ADH field as described by Vicente (1999).

Hajdukiewicz et al. (1998) used this approach to analyze the work domain of anesthesiologists in the operating room, and constructed a work domain representation of the human body in the form of an abstraction decomposition hierarchy. In the work domain analysis part of their research, Effken et al. (2011) used semi-structured interviews to map the environmental constraints for the work of nurse managers. Their questions focused on the environment's constraints that are posed on their managing capabilities.

Analysis begins with the identification of thematic units. These can then be clustered as themes, and decomposition and abstraction levels can be assigned. Similar themes are then combined to find the higher level concepts and to ultimately build a complete abstraction-decomposition grid.

Table 1. A prototype ADH (adapted from Vicente, 1999).

Whole-Part / Means-Ends	Total System	Subsystem	Function Unit	Subassembly	Component
Functional Purpose					
Abstract Function					
Generalized Function					
Physical Function					
Physical Form					

2 What: control task analysis

This phase determines what is necessary to achieve the system's purposes, by finding the system wide tasks to be performed. It adds constraints on activities. Two tools can be identified to model the structure of tasks: the decision ladder and the contextual activity template (Jiancaro et al., 2013). The decision ladder was first described by Rasmussen (1974). It is a template for an information processing structure that includes data-processing activities, states of knowledge resulting from data processing, and connections between them. Steps in a task can be mapped on the decision ladder template, using the possible connections to move between data-processing and knowledge states. Figure 5 illustrates the basic structure of the ladder. A signal from the work domain causes a need for activation after which the work domain is observed and the current system state is identified. This system state is interpreted to determine consequences for the performance criteria of interest. An evaluation determines what the most important performance criteria are, on the basis of which a task is defined to accomplish the performance criteria. Finally, the procedure to perform this task is generated and executed. Within the structure, opportunistic movements from one node to another are possible. A 'leap' can connect two circles when two states of knowledge can be directly associated with each other, and a 'shunt' can connect a square with a circle when a process can be regarded as stereotypical for an expert.

An alternative for this CWA phase is proposed by Naikar et al. (2003) and is called a contextual activity template. This technique can mainly be used for team design. After a work domain analysis, an activity analysis is performed that tries to find the set of work situations or work problems that a worker can encounter. At the end a so-called tabletop analysis is performed that evaluates various team designs, by specifying various team design variables and scenarios that can be encountered, using input from experts on work demand distribution and work problem distribution, and finally providing an analysis that evaluates the different team concepts. Naikar et al. (2003) applied this method to chart team design requirements in a military air force early warning system.

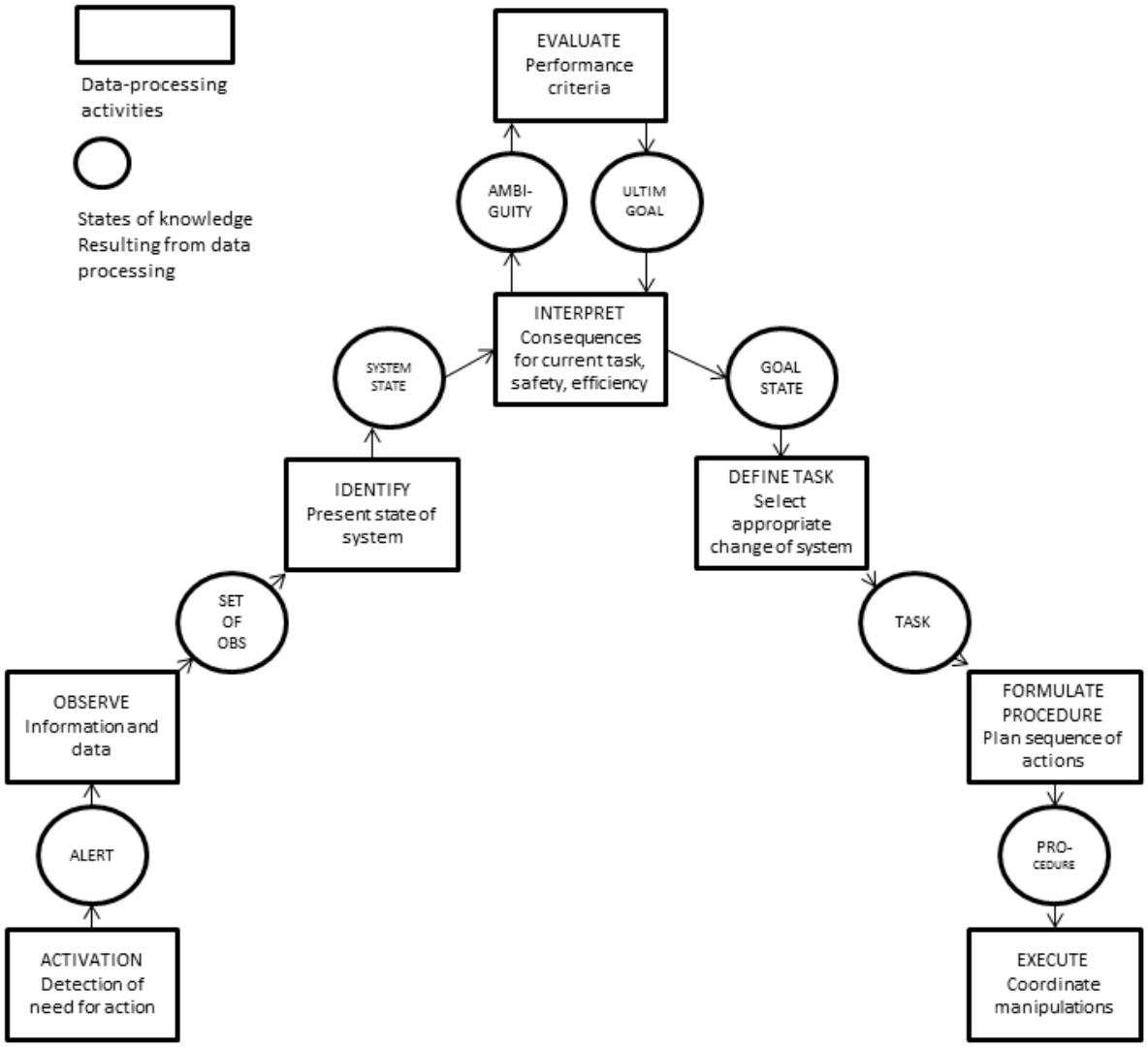


Figure 5. The decision ladder template (adapted from Vicente, 1999).

3 How: strategies analysis

This phase determines what the different ways are that the tasks identified in the control task analysis are carried out. It adds constraints on strategies by determining what strategy or combination of strategies is employed to complete the necessary information-processing activities. As a modeling tool, an information flow map can be used (Rasmussen, 1981). An information flow map can be used to show the structure of possible mental processing activity, and is highly context specific in its construction (Vicente, 1999). As he points out, there is no set taxonomy or formalism to construct an information flow map. Information on the description of strategies can come from a descriptive field study, an 'a priory analysis' when the application domain is highly structured and well understood, or a model from some already existing established theory. A strategies analysis can yield implications for human factors design by showing the relative cognitive loads between different strategies and can be used to designate a division of labor between worker and system tools (Vicente, 1999).

4 By whom: organizational analysis

In this part of a CWA the roles and responsibilities of the system's actors (both human and machine) are determined. It adds constraints on function allocation and communication. Regarding modeling tools, Vicente (1999) shows that this phase can reuse the tools from the previous phases. The constructed abstraction-decomposition field, decision ladder, and information flow maps can be utilized to distribute their requirements across the system's actors. In other words, the actors within the analyzed system can be mapped onto the available analysis tools to show with what parts of the systems the actors interact. The resulting analyses are called responsibility maps by Jiancaro et al. (2013), and are demonstrated by Rasmussen et al. (1990). An organizational analysis can be used to design an organizational and communication structure that builds on the requirements identified in the previous steps.

5 By what means: competencies analysis

This final phase of CWA analyzes the competencies that are necessary for an individual to perform in the sociotechnical system. This analysis reveals constraints on cognitive capabilities, and makes use of the skills-rules-knowledge (SKR) taxonomy, as developed by Rasmussen (1983). This tool offers a framework that allows competencies to be defined as skill-based behavior, rule-based behavior, and knowledge-based behavior. This analysis phase can provide implications for system design such as interface design and training, and shows for each level of cognitive control the competencies a worker should possess.

Research examples in critical care

A good example that demonstrates all phases of a CWA in a medical environment is the research of Effken et al. (2001). Their research used a CWA for interface design in an ICU setting by studying clinicians. As a work domain analysis they used an abstraction-decomposition hierarchy that resulted in a version of the human body abstraction-decomposition model by Hajdukiewicz (1998), modified for hemodynamic management. For a control task analysis they used a decision ladder to determine a set of work domain data to be included in their display. In their strategies analysis they identified four strategies that are commonly found: topographic search, pattern recognition, decision tables, and hypothesis and test. Observations were used for the organizational analysis to determine who uses which data. They found that monitors are watched almost exclusively by nurses, who also assess the accuracy of the monitored data, while physicians make decisions based on data in a patient's record and flowsheets. Finally, in their skill analysis they found that expert clinicians can distinguish key data elements faster than novices, who consider each element in the order that they present themselves. The research eventually led to the design of a prototype ecological interface.

Another example is the work by Pingenot et al. (2009), whose research also used all five phases of CWA to analyze the work of nurses and clinicians on an ICU regarding the use of a medication system. They used observations and interviews as a means of data collection. As a work domain analysis, they used the abstraction-decomposition template for the human system (Hajdukiewicz et al., 1998). Observational data was categorized and clustered into the cells of the ADH matrix, while distinguishing between nurses and doctors to see which parts make up the work domain. As a control task analysis, decision ladders were developed that map the general medication process by observing the way in which medication decisions were made. Their strategies analysis consisted of the mapping of the information flow by identifying the knowledge required for specific decisions and the activities necessary to access this knowledge. They found that the strategies most

commonly used are pattern recognition, decision tables, and hypothesis and testing. The organizational analysis in their research described the situation of the system in the social environment. They discussed the allocation of roles for accomplishment of each task based on the actor that has the skills or knowledge to accomplish that task. Finally, their competencies analysis was inferred from the rest of the study. They state that nurses make skill-based decision and rule-based decisions such as checks for drug interactions, dosages, and unit protocols. Physicians and the most senior nurses made knowledge-based decisions, specifically decisions in new and unknown situations or when choosing between competing goals.

In their review of effectiveness of a large body of CWA researches in acute care, Jiancaro et al. (2013) analyzed CWA's beneficial use in areas of electronic health records, decision support, and incident investigation. They argue that applying CWA to a complex biological system such as critical care patients or an uncertain 'organic' and ever changing social system such as an ICU is still a challenge. Proper assessment of its feasibility is often challenging, as that information is usually not available in a study, but the authors suppose that given the costs of health care systems, CWA before the implementation of health care systems should be highly beneficial.

3.3.2 Risk analysis

Within the medical system it is worthwhile to use a risk analysis to determine where the most severe risks are located, after which the obtained knowledge can be used to prevent severe mistakes from happening. Within the present project this is also useful, as it allows the identification of the most severe risks on the ICU, on the basis of which recommendations for improvement can be made and a solution proposal can be developed. Three common methods for risk analysis can be distinguished: Healthcare Failure Mode and Effects Analysis (HFMEA), Systematic Human Error Reduction and Prediction Approach (SHERPA), and Prevention and Recovery Information System for Monitoring and Analysis (PRISMA).

HFMEA is a method to analyze what the failure states and their severity are within a medical process. DeRosier et al. (2002) describe the process of conducting an HFMEA in detail. It starts by detailing and defining the topic on which HFMEA is going to be applied. After this, a multidisciplinary team of subject experts is assembled who consecutively create a graphical description of the process or processes in a flow diagram. This allows them to identify all steps and sub-process steps. This description is then fed into a hazard analysis where every relevant failure state is scored on probability and criticality according to pre-defined scales. Taking this hazard score, the single point criticality (whether the entire system fails if this part fails), detectability (whether the hazard is obvious), and controllability (whether a control measure is already in place) of the failure mode into account, the team then determines whether corrective and preventive actions are necessary. The effectiveness of HMFEA in Dutch health care was analyzed by Habraken et al. (2009), who included user feedback from 13 different HFMEA analyses. The authors note that while the analyses are generally seen as successful and beneficial, there are some drawbacks. HFMEA is time consuming, and the lack of a formalized taxonomy makes the hazard analysis step and the identification of failure mode causes difficult to carry out.

SHERPA was originally developed by Embrey (1986). As described and applied in a medical setting by Lane et al. (2006), it uses a task analysis as input and identifies through use of an error taxonomy what types of errors can occur in which stages of the process in a highly structured way.

Subject matter experts can link an error mode to every lowest level action in a task hierarchy by allocating these tasks to a category in the SHERPA behavior taxonomy. This taxonomy consists of five categories: action, retrieval, checking, selection, and information communication, each with a set of possible error modes. After the most likely error type is picked, these error modes, their consequences and possibilities for recovery are then written down in a table and subsequently their probabilities are scored. Using these steps, this tool allows for analysis of the system's biggest hazards against their remedial measures currently in place. Lane et al. (2006) mention that the SHERPA taxonomy in healthcare has the drawback of needing a very time consuming and extensive task analysis. Furthermore, because highly unlikely actions and errors are inherently excluded from the analysis, a SHERPA typically does not take the full scope of error-producing activity into account.

PRISMA was developed and later described in more detail for a medical environment by Van der Schaaf and Habraken (2005). The method uses a system approach to human error, which assumes that errors are the cause of a collaboration of factors of the entire system, rather than just human failure. First an incident is described and all of its underlying causes are identified and modeled in the form of a tree that leads all the way back to the root causes of the incident. Those causes are then classified by linking them to one of a set of predefined categories, which include technical, organizational, and human behavioral categories. By registering these classifications for a large number of incidents, the most frequent causes became apparent. By subsequently using a structural approach for improvement of the system based on this so-called PRISMA profile, rather than adjusting the system after each individual incident, measures should be much more effective (Van der Schaaf & Habraken, 2005). A drawback of this analysis method is that it needs a large body of detailed incident reports that is often not readily available for the intended research area.

In summation, this section described the three risk analysis methods that are frequently used to discover hazards on an ICU. It explained how each method is performed and what key weaknesses each entail. This overview is used by the current study to construct a risk analysis method that can be built on results of a work analysis, and avoids their key weaknesses where possible.

3.4 Improving Alarms

The ultimate goal of studies on critical care alarm hazards is to contribute (methods for) improvements to alarm systems in order to improve the ICU work environment. When looking at ways to improve alarms, researchers have a large array of tools and methods already available to them. Effective approaches to improve alarms target alarm hazards such as the causation of alarm fatigue, the lack of appropriate alarm urgency and interpretation indicators, and the lack of proper alarm integration (Chambrin, 2001; Imhoff et al., 2009; Graman & Cvach, 2010). This chapter provides an overview of the most prominent techniques found in literature to improve alarms. These techniques are: improving or implementing priority levels, using specific parameter settings, using an alarm delay and naïve signal filtering, using graphical monitor interface designs, or using a multi-parametric approach. Examined or suggested methods often encompass multiple of these techniques to yield the best results. This information is used by the current study in order to select the most appropriate technique to apply as a solution for found alarm hazards.

3.4.1 Priority levels

These improvements target the perceived urgency of alarms, and try to bring it on level with the actual urgency that the alarms have. As proposed by Chambrin (2001) among others, each type

of alarm should have a standardized priority level assigned to it. Solet and Barach (2012), and Edworthy and Hellier (2006) support this statement by suggesting the more strict use of already existing alarm standards and codes, using this to make alarms easily recognizable or to create specific alarms for each physiological body function. This type of alarm improvement was also suggested by Görges et al. (2009) in their research. They made infusion pumps only produce a low priority reminder instead of a full-blown alarm as they generally do not indicate actual patient troubles but rather mechanical problems or empty infusates. Graham & Cvach (2010) moved duplicate alarms to a lower priority level so an alarm does not sound twice for the same complication.

3.4.2 Specific parameter settings

Using parameter settings more intelligently can be a significant alarm improvement, and is usually part of alarm improvement suggestions (Chambrin, 2001; Graham & Cvach, 2010; Solet & Barach, 2012). This type of solution is proposed because smarter alarm configuration and threshold settings can reduce the number of false alarms. In addition to the widening of alarm limits, Graham & Cvach (2010) also invested in educating the staff in the best practice of managing and troubleshooting a monitor system and customizing alarm parameters. Görges et al. (2009) suggested monitoring fewer variables of a ventilator, because some variables turned out to be irrelevant while still producing alarms. As part of the improvements by Welch (2011) on pulse oximetry, he shows that decreasing the SpO_2 alarm threshold from 90% to 88% already decreases the number of alarms by 45% without missing important events.

3.4.3 Alarm delay and naïve signal filtering

To make sure that an alarm is actually a relevant alarm and not a brief sensory artifact or physiological anomaly, a delay can be built into the production of the alarm. In addition, the physiological signal can be filtered by looking at a progressing mean and median value (Chambrin, 2001). This concept is shown by studies on alarm data sets. Görges et al. (2009) showed that the application of a 14 second alarm delay removes 50% of the ineffective alarms. Furthermore, they propose an alarm silence button that allows for a delay to be manually activated when nursing activities are taking place, or a system for the automatic detection of such activities, such as mattress sensors that detect patient repositioning. Rheineck-Leyssius and Kalkman (1998) reduced pulse oximetry alarms by applying filtering epochs that both delay an alarm and filter over a progressing mean value. They found an optimal epoch of approximately 40 seconds, which produced more reliable alarms than merely lowering the alarm threshold. Welch (2011) also demonstrated this technique on pulse oximetry data. Delaying the alarm for 15 seconds reduced the number of alarms by 70%. He states that a delay or averaging time of more than 16 seconds is not advisable, as significant events can be masked. When combining his 15 second delay with the aforementioned lowering of the alarm threshold from 90% to 88%, he reported a reduction in alarm frequency of 83%.

3.4.4 Graphical monitor interface design

Another technique that can improve alarms is the design of displays on which alarms and their relevant information are shown in a smarter way. This approach can be used to integrate information and diagnoses into alarms. Examples of this are provided by Effken et al. (2001), who developed an interactive graphical display with the use of a CWA, and Agutter et al. (2003), who developed a graphic display using the emergent features of the spatial location of displayed physiological variables. More recent efforts include the work by Anders et al. (2012), who created a

contextual trend display to show different physiological variables on a single timeline, and the work of Drews and Doig (2014), who created a 'configural vital signs' display that can integrate multiple physiological variables into one display element to provide an integrated assessment of vital sign variability. This type of solution has been especially popular in the field of anesthesiology (Sanderson et al., 2005; Drews & Westenskow, 2006).

3.4.5 Multi-parametric approach

A widely applied and suggested approach to improve alarms entails using a multi-parametric technique or algorithm that can extract meaningful events from multiple sensory inputs, which results in an intelligent alarm system (Chambrin, 2001; Edworthy & Hellier, 2006; Imhoff et al., 2009; Siebig et al., 2010; Solet & Barach, 2012). A subdivision can be made in this category by making a distinction between decision support systems and machine learning methods. The difference between both approaches is that decision support systems use extracted knowledge and rules to provide diagnoses and assessments, while machine learning techniques are used to extract and reveal these rules and knowledge.

Sucher et al. (2008) created an overview of the use of clinical decision support systems that implement so-called evidence-based guidelines that allow the systems to suggest therapies. The authors provided an overview of what the process from guidelines to decision support looks like. They conclude that using a well-proven implementation of decision support tools can decrease variability in care because of the standardized decision making it offers. Additionally, these tools can be used to test interventions and validate potential improvements. An application of this decision support paradigm can be found in the work by Oberli et al. (1999) and Schoenberg et al. (1999), who both used trend algorithms that provide an integrated assessment of multiple physiological measurements. These algorithms produced alarms with a significantly higher positive predictive value than standard alarms. An example that uses human factors is the work by Pott et al. (2005). They developed a knowledge-based system prototype for anesthesiology by using a model of determinants of situation awareness.

The machine learning approach is characterized by finding models for automatic classification of events in medical data. Tsien (2000) described the process that is needed to discover events in monitoring data. The first step is event identification by establishing the nature of the relevant events. This is followed by annotation of the collected data, by noting event occurrences. Subsequently the annotated data is preprocessed by adding class labels or other relevant features, and divided into a training set, test set, and an optional evaluation set. The training set is then used to derive a model, whose accuracy can be determined using the test set and evaluation set. She applied this method on patient monitor data from an ICU using a decision tree as well as a neural network to create models that classify alarms as true or false. Both methods produced promising results. Sieben and Gather (2007) applied automatic classification using a decision tree variant called random forests. Multiple decision trees are created on random subsets of the training sample, after which these trees vote on the class of an alarm to label the alarm as true or false. This random forests method allows for tweaking of the sensitivity as needed with respect to missing potential true alarms and positive predictive value.

Ideally, both multi-parametric approaches are combined by finding the most optimal models and rules with machine learning and applying these with decision support tools. A large amount of

tools are available to support the development of this alarm improvement solution by either extracting knowledge or implementing knowledge, including: expert systems or decision support systems, discovery of new information through data mining or case-based reasoning, machine learning methods (e.g. neural networks, Bayesian belief networks, genetic algorithms, decision trees), and data visualization methods (Hanson et al., 2001). Hanson et al. (2001) concluded that the ICU is an especially suitable environment for adaptation of these tools because of the large amount of available data, and the large potential gains in patient care and safety that can be made.

4. Current Study

Although the subjects of human factors and alarm hazards in an ICU environment have been topics of large interest for many decades as described in the previous chapter, there is still no clear and best way to analyze work with alarms on the ICU and implement alarm system improvements. The area of human factors and cognitive engineering provides many tools and methods to investigate a working environment.

The approach of the current study is for one part based on the cognitive work analysis method, and for the other part on the risk analysis methods HFMEA and SHERPA. The CWA method is described by Rasmussen et al. (1994) and Vicente (1999), and CWA's usefulness in a healthcare setting has been demonstrated by many researches (e.g. Effkent et al., 2001; Pingenot et al., 2009; Jiancaro et al., 2013). Consecutively the study wanted to determine what the most prominent alarm hazards are that can be found in the work analysis results. To accomplish this, the performed CWA was combined with a risk analysis method taken from HFMEA and SHERPA to use SHERPA's error taxonomy to quantitatively identify hazards, and HFMEA's framework to qualitatively analyze these hazards. The benefits of both methods are separately demonstrated in critical care settings by Habraken et al. (2009) and Lane et al. (2006). Finally, the study wanted to propose a cognitive engineering solution for one of the most prominent hazards. The method was combined with a decision-centered approach that used a multi-parametric design to develop an application for alarm improvement that addresses the most critical hazard. The resulting prototype for a knowledge-based system can support and train decision making for patient monitor alarms.

The current study investigates the following questions:

1. How can alarm hazards in the ICU environment best be analyzed?
2. What are the most prominent alarm hazards found on the UMCG's PICU?
3. How can a cognitive engineering solution address the most prominent alarm hazard?

Section 4.1 describes the execution and implementation of a CWA. Its results are used as a starting point for the risk analysis that is described in section 4.2. Lastly section 4.3 elaborates on the development of a knowledge-based system prototype that can be used to address the most prominent alarm risk found in the previous part of the research.

4.1 Cognitive Work Analysis

This chapter explains the reasons behind the choices that were made when implementing the CWA method, the detailed method used to perform a CWA, and the obtained and processed results.

4.1.1 Implementation

To address the research questions, a way had to be found to analyze work with alarms in an ICU environment in an extensive enough way so that all relevant factors are found. This extensive approach allows for a subsequent risk analysis to be sure to have taken all relevant possibilities into account, thus providing a well-grounded answer to the second question. The performance of the chosen method and the results that are obtained answer the first question. As described in chapter 3, this study uses a CWA because it offers the required depth by allowing inclusion of as many aspects of the system as needed, both cognitive and physical.

Because the CWA that is performed in the current study served as a source from which risks in the work environment are identified, it should be as extensive as possible and include information about all 5 phases of CWA. Phase one (work domain analysis) created a field description by constructing an abstraction decomposition hierarchy (ADH). The analysis identified the elements of both ADH dimensions by means of interviews with nurses that included questions about the contents of their work domain with regard to alarms and devices that produce alarms.

Phase two (control task analysis) determined the system-wide tasks that are performed. This analysis used a decision ladder as a modeling tool. A decision ladder is more appropriate than a contextual activity template because the goal of this phase in the current study is to identify the tasks that are performed on alarms, instead of designing a team composition. The found tasks are mapped onto the template of a decision ladder (Figure 5). Information about this phase was collected by asking nurses interview questions about the process of working with alarms, typical causes and responses to alarms, and by using CDM by talking about specific scenarios.

Phase three (strategies analysis) determined the strategies used by nurses when working with alarms and performing the tasks identified by phase two. Information flow maps were constructed by asking nurses questions about typical responses to alarms, and by using CDM to extract information from specific scenarios.

Phase four (organizational analysis) defined the system's actors and their roles and responsibilities. Results obtained during the previous phases of CWA can be used to determine who or what performs the tasks and who or what is a relevant actor in the different elements of the system. Additional data for this phase was gathered by asking nurses interview questions about who works on the PICU, what components of the alarm system they work with, and about the nature of responsibility during that work.

Phase five (competencies analysis) gathered information about the necessary competencies in the form of skills, rules, and knowledge that the nurses need to have in order to work within the work domain. Information for this phase gathered by directly asking nurses interview questions about the skills, rules, and knowledge they have to obtain when they work with alarms on the PICU.

4.1.2 Method

Five semi-structured interviews were conducted with nurses and nurse managers of the pediatric ICU on the UMCG. The UMCG's PICU consists of 3 separate color-coded units that can together hold up to 20 beds. A total of 10 people participated in the interviews; 2 nurse managers and 8 nurses. Subjects were interviewed in pairs of 2 during a time overlap in shift changes. The interviews were conducted in Dutch.

During the interviews, a list of questions and lines of conversation according to an interview schema was used as a starting point for conversation and digression about the relevant aspects of CWA. The interview schedule was only visible to the interviewer, and contained additional notes and information requirements that had to be met to progress to the next question. A list of alarms and machines that produce alarms was used during the interviews to establish the work domain. This list was composed during previous preliminary observations and orientation on the unit's alarms during which work of nurses on the unit was observed and the machines and alarms of the unit were noted. The following interview materials are paraphrased, see appendix A for the original interview schedule and list of machines in Dutch.

After informed consent that guaranteed anonymity was obtained, the subjects were briefly introduced to the purpose of the study. At the start of the interview, they were presented with the list of alarms and machines that produce alarms. First, information was obtained about the contents of the work domain in terms of machines, alarms, and its actors for phase one and four of the analysis. This was achieved by the first topic of conversation that included the possible addition or removal of alarms or machines from the list, and the way each member of the list obtains information for alarms, and how these alarms are presented to their environment. The second question asked participants to talk about the most likely cause and response to alarms on the list, and yielded information for all five phases of CWA. To determine what the system's actors and their responsibilities are for phases four and five of the CWA, the third line of conversation included questions about who works on the PICU, how many people are typically present per patient, what their responsibilities are, and what the rules for cooperation are. To obtain information for phases two and three, the tasks that are performed on alarms and the strategies that are used during these tasks, question four employed CDM by asking participants to remember a recent alarm situation during which action was required. Questions were asked about the cause and solution to this alarm situation and how this solution was found. To determine the competencies of the domain's actors for phase five of the analysis, question five asked participants about what and how they were taught about working with alarms on the PICU. The question determined what the rules, protocols, or guidelines are that nurses follow regarding alarms. The sixth question asked the subjects about their preference in properties and functions that a hypothetical new alarm (supporting) system should have. This question did not produce information for the CWA, but was included to gauge opinions and collect preliminary information for a potential follow-up system design. Finally, participants were asked if there were other issues they wanted to discuss regarding the interview topics, after which the interview was concluded.

The interviews were recorded using a voice recorder, and anonymously transcribed for further analysis. The list of alarms and machines that produce alarms was updated directly after each interview in accordance with the subjects' suggestions and comments. Appendix A includes the latest version.

4.1.3 Results

1. Work domain analysis

To construct an abstraction decomposition hierarchy (ADH), first a collection of parts, factors, and concepts that play a role in the work domain was gathered from the transcribed parts of the conversations about the contents of the work domain. Beginning at the smallest parts that can be modeled, these were then aggregated into meaningful wholes until the highest level of category, the entire system, was reached. Sorted into categories these parts, factors, and concepts can be found in Table 2.

Table 2. A cloud of parts, factors, and concepts.

Category	Parts
Environment	Beds, boxes, nurses, physicians
Alarms	Acoustic, lights, on-screen information, critical/noncritical alarm levels
Machines	Patient monitor, IV pump, feeding tube, Evita ventilator, Fisher & Paykel humidifier, heat lamp, pager, baby monitor, bed, mattress, dialysis machine, Extra Corporeal Life Support (ECLS), Criticool, High Frequency Oscillation ventilator (HFO), Continuous Cardiac Output monitoring (PiCCO), refrigerator
Sensors	Electrodes, strap, IV, catheter, sensors in the machines (e.g. temperature, electricity, pressure, humidity)
Patient	Heartbeat information, saturation, blood pressure, ventilation information, temperature, noise, movement, color

Sorting these categories yielded the whole-part decomposition of the alarm system on the ICU in 4 parts. The most detailed level is the patient and his/her physiological features. This is part of the sensory system that extracts information from the patient, which is part of the system of machines that interprets the sensory system. The machines system is part of the total system, the environment to which it outputs.

The interview data called for a decomposition of the abstraction hierarchy in 5 levels on which analysis takes place. These levels are the same abstraction levels as the ADH prototype by Vicente (1999) shown in Table 1, because the interview made clear that each of these levels is a relevant way to talk about the domain. The levels are:

- Functional Purpose: the purposes for which the system was designed.
- Abstract Function: The intended causal structure of the process in terms of mass, energy, information, or value flows.
- Generalized Function: The basic functions that the system is designed to achieve.
- Physical Function: The characteristics of the components and the connections between them.
- Physical Form: The appearance and spatial location of the components.

Combining both decompositions yielded the ADH as depicted in Table 3. The relevant parts of the ADH field that became apparent from the interview data are explained in their respective places. People tend to think about a work domain at a coarser level when using higher levels of abstraction. At lower levels of abstraction, people tend to think about the work domain in finer decomposition

levels. Because of this, representations can be best explained along the diagonal. The generation of an alarm occurs from right to left, from patient to environment.

Table 3. The ADH of the PICU's work domain.

Whole-Part / Means-Ends	Total System /Environment	Machines	Sensors	Patient
Functional Purpose	Alert caregivers to changes in a patient's health			
Abstract Function	Bring information from machines to the environment by means of sound or visual cue	Translate and interpret information from the sensors for use of caregiver		
Generalized Function		Receive input from its sensors	Extract information from the patient	Homeostasis: maintenance of internal environment
Physical Function		Effectuate treatments, connect sensory input to treatment adjustment or output to the environment	Conversion of analog (physiological) information to a signal that machines can interpret	States of physiological information and interactions: heartbeat, saturation, blood pressure, ventilation, temperature, noise, movement, skin color
Physical Form		Medical devices in the environment; most are adjacent to patient beds	Sensors in or on the patient (electrodes, strap, IV, catheter), sensors in the machines	Patient being monitored in a bed/box

2. Control task analysis

Two tasks that are performed with regards to alarms were identified: setting of alarm boundaries and responding to an alarm.

When setting alarm boundaries, the extreme boundaries are normally given by a physician or are recorded in a so-called KIDDO list, a system that keeps track of a patient data such as administered medication. The nurse then sets his/her own boundaries by taking into account the general health and history of the child, plus the maximum signal derivation at which he/she wants to

be warned of status changes. It is a nurse's responsibility to minimize unnecessary alarms by keeping the boundaries and machines up to date with the latest patient status and interactions. This task is outlined on the decision ladder in Figure 6; its steps are further explained in Table 4.

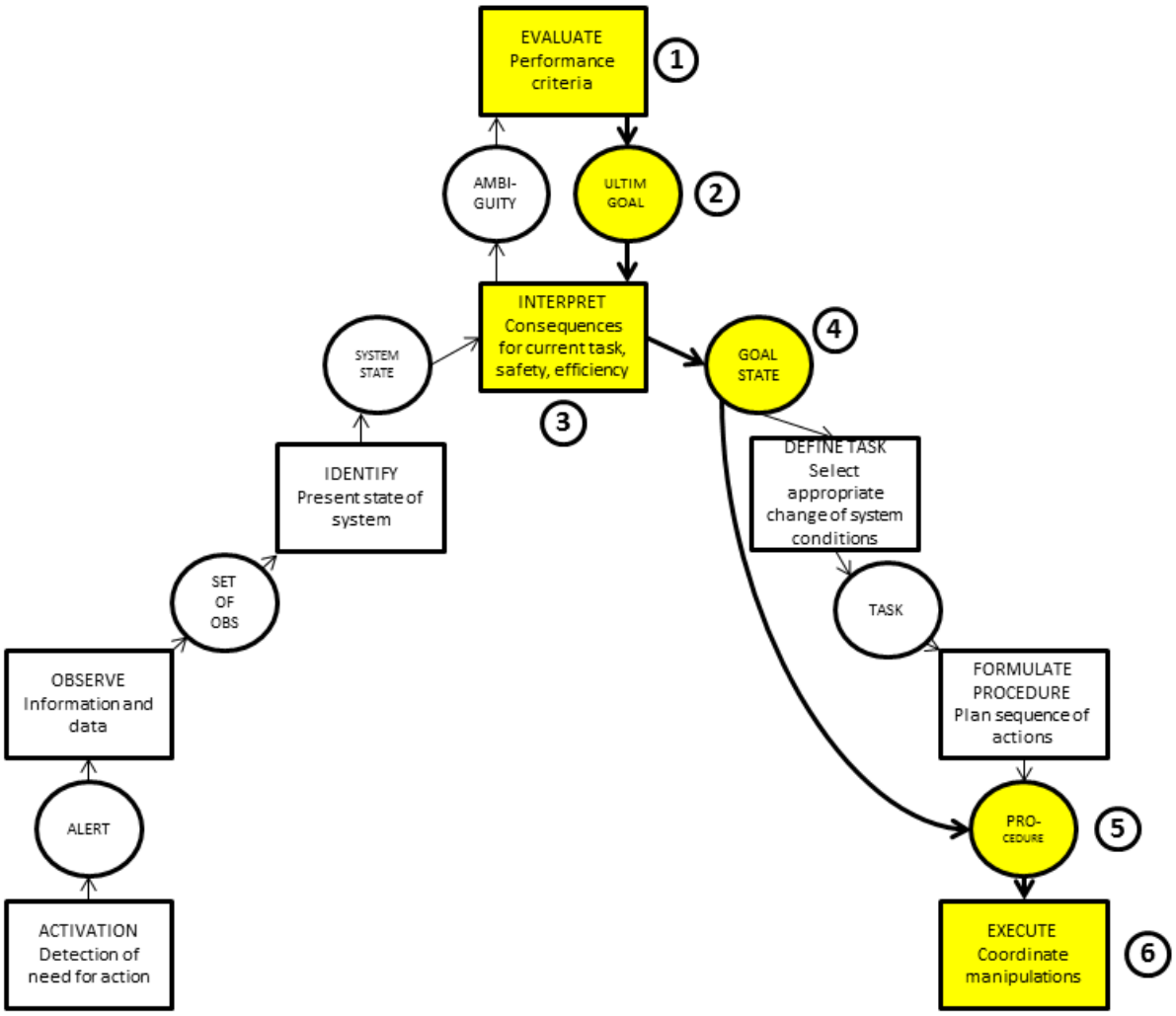


Figure 6. Decision ladder for the task of setting alarm boundaries.

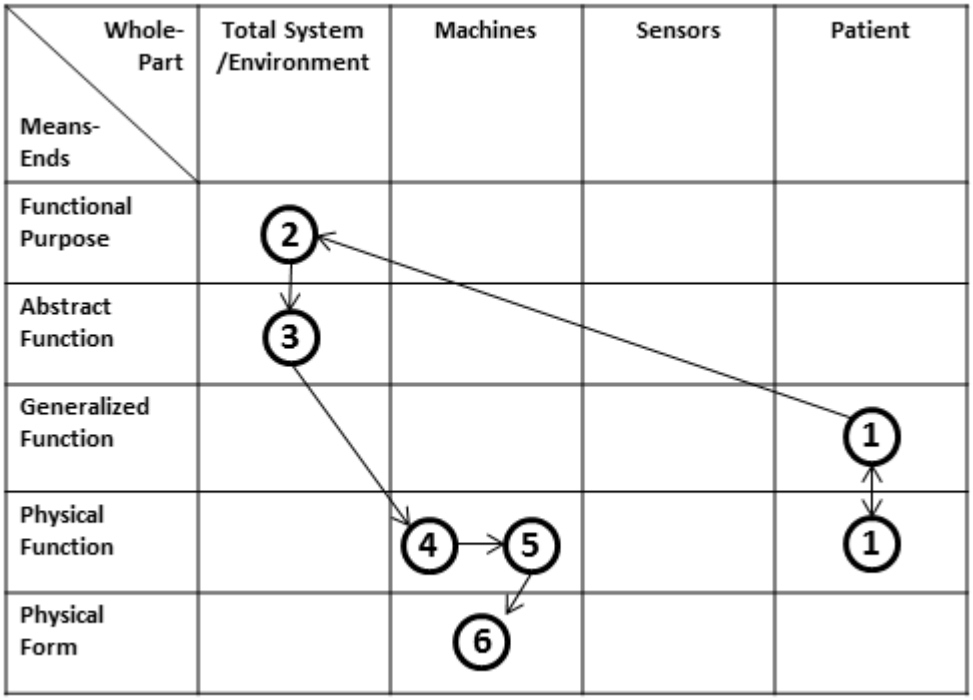
Table 4. The steps for the setting of alarm boundaries task explained.

Step	Description
1	Evaluate the given information from the patient's general health, history, KIDDO list
2	Ultimate goal state that represents the desired alarm monitoring policy
3	Think about the desirability of this policy and how this impacts safety and efficiency
4	Final goal state including the decided upon alarm boundaries
5	The procedure that needs to be executed to achieve the goal state defined in step 4
6	Execute the procedure, set the alarm boundaries according to plan

The task starts at the evaluation data-processing activity because the nurse starts by thinking about what the most important performance criteria are, specifically what alarm boundaries he/she wants to set. The task does not start at the activation data-processing step, because there is no need for activation triggered from the surrounding, the nurse sets the machine alarms because this is part

of their patient monitoring policy. In this depiction there is a leap from step 4 to 5, because the state of knowledge during step 4 can be directly associated with the state of knowledge for step 5, no complex task and procedure generation is necessary. This task was mapped onto the work domain as shown in Table 5. This representation shows on which level in the work domain each step operates.

Table 5. Mapping the task of setting alarm boundaries onto the work domain.



The second alarm-related task that was identified was responding to alarms. This action starts when a nurse is alerted by an alarm. He/she will then try to validate the alarm by checking the medical relevance of the alarm to determine that the alarm is not just an artifact caused by signal interference or patient movement but instead conveys the need for action. In addition the nurse checks whether the alarm regards a patient under his/her responsibility. Checking relevance is done by inspecting both the patient and the pattern of physiological data that is presented on the monitor and on other equipment. If the alarm is deemed relevant, an action is performed accordingly by using a standard, well-known response that is learned from experience, by following instructions on a screen, or by looking for the cause of the alarm. Relevant or not, the alarm is suppressed as soon as possible.

This task was captured by the decision ladder shown in Figure 7; its steps are further explained in Table 6. Two possible shunts were identified, from step 3 to 7 or 9. These are paths that represent stereotype processes. The processing of information in step 3 leads directly to the state of knowledge of the task or the procedure that needs to be executed.

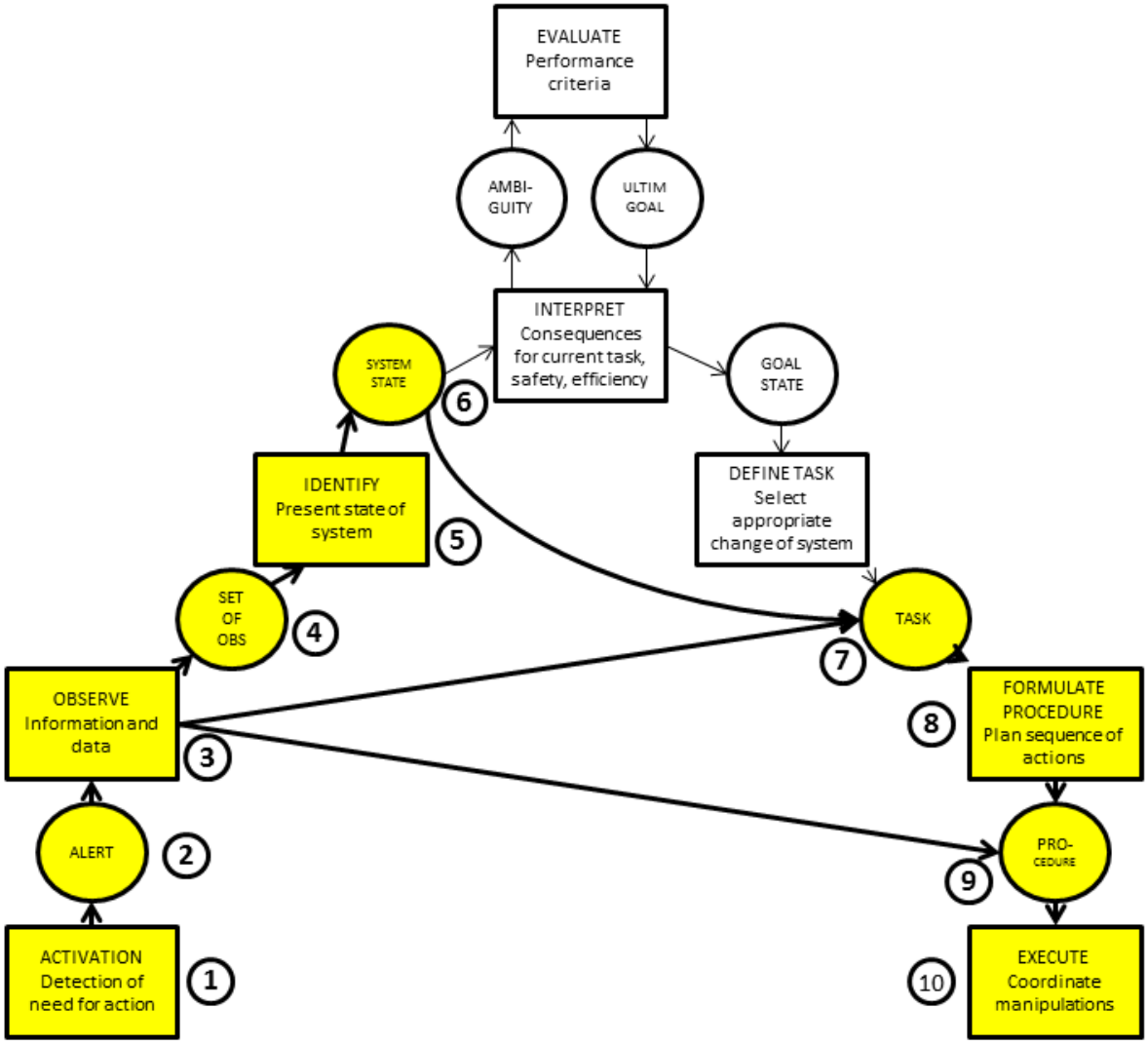


Figure 7. Decision ladder for the task of responding to alarms.

Table 6. The steps for the responding to alarms task explained.

Step	Description
1	An alarm reaches the nurse
2	The nurse is alerted to the alarm
3	The nurse observes the available information to determine the cause and validity of the alarm. The patient and machine data are observed.
4	The set of observations as a knowledge state
5	When the response is not immediately clear, this step takes a closer look at the state of the system. The state of the patient's physiological values (the so-called ABC-method), and the surrounding equipment are subjected to a closer inspection
6	Knowledge about the system state as a result from step 5
7	The task to perform is known, directly associated with the system state: either knowledge about solving the alarm, or asking for assistance
8	The series of actions to fulfill the task becomes clear
9	The knowledge about the procedure to be performed
10	The execution of the procedure, e.g. turning the alarm off, equipment/medicine maintenance, asking a physician for help

To show on what level in the work domain each step operates, the responding to alarms task was mapped onto the work domain as shown by Table 7. In this depiction the task is only modeled up to step 6 because steps 7 to 10 require a specific task example to determine their place on the work domain. The found task, procedure, and its execution can range from manipulation of the patient, sensors, machines, or other aspects of the environment.

Table 7. Mapping steps 1 to 6 of the task of responding to alarms onto the work domain. Arrows are omitted for improved clarity.

Whole-Part / Means-Ends	Total System /Environment	Machines	Sensors	Patient
Functional Purpose	①			
Abstract Function	② ⑥	④		
Generalized Function		③ ⑤		
Physical Function				③ ⑤
Physical Form			⑤	③

3. Strategies analysis

In the interview data about responses to alarms, participants were found to use a pattern recognition strategy to determine the relevancy of an alarm. Only certain patterns of alarms or combinations of alarms and patient state are directly relevant and warrant a response other than ignoring or suppressing the alarm. This strategy can also directly yield a response to a stereotypical situation. To illustrate, when one of the interview participants was asked how he/she determines whether an alarm is relevant or not, he/she responded: *"Dat zie je aan de monitor. Dat zie je gewoon. Je leert kijken naar bepaalde dingen. Zien hoe een kind is, stabiel of instabiel. Ja dat zijn zoveel facetten."* The participant indicated that multiple factors together, learned from experience, form a pattern from which he/she recognized whether an alarm is important or not. The interview responses showed that knowledge about when these patterns create the need for action is not explicit, but rather tacit knowledge that nurses gather from experience. A participant stated when talking about responding to alarms: *"Je gaat in hoofdzaak uit van wat je ziet. Dat is een paar seconden, dat is niet iets waar je lang over nadenkt voor je de volgende stap neemt, dat gaat heel snel."* This statement shows that initial pattern recognition occurs within a few seconds, during which the need for action is determined.

An information flow map for the identified pattern recognition strategy is shown in Figure 8. The depiction involves data-driven pattern recognition that includes a minimal amount of information processing. The failed system represents the system of patient and machines that has output an alarm to its environment. From this failed system a pattern of data is recognized by a nurse, who attaches a label to the pattern that can be either the root cause of the alarm, or a task or action that needs to be performed.

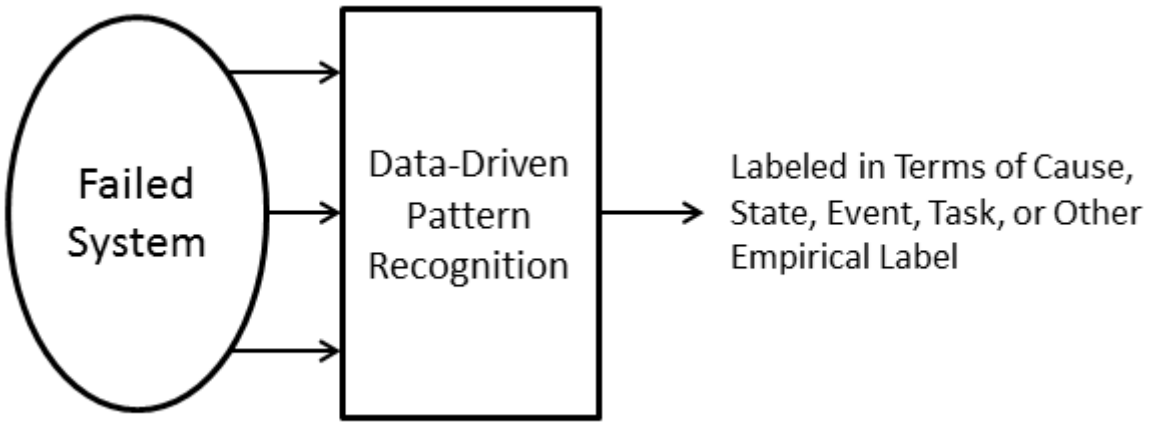


Figure 8. Pattern recognition strategy (adapted from Rasmussen, 1981).

When the initial pattern recognition does not lead to an immediate identification of the alarm in terms of root cause, action, or task, participants were found to use a decision table search strategy, where they check a standard list of possibilities. For example, when one of the interview participants was asked about what the most frequent causes of alarms are, he/she responded: *"je kijkt naar de patient en checkt de ABC (airway, breathing, ciculation) factoren, en daarna ga je verder kijken. Is het de apparatuur die tekort schiet, is het reëel of niet reëel, is het een meetfout?"* This response is an example of a decision table search strategy. When the root cause of an alarm it not immediately clear, he/she verifies the functioning of the available machines and tries to determine if the alarm is caused by an artifact. This strategy can be visualized as an information flow map as shown in Figure 9. This decision table strategy heavily relies on the library of failed state symptoms. This library, or decision table, is a collection of rules that directly associates data patterns with system states. Rules from the library of failed state symptoms are checked against the observed pattern. The order in which rules from the decision table are checked is determined by pattern match expectation, from most expected first to least expected last. In other words, the failed state symptoms that are the most prototypical for the observed failed system are checked first against the pattern. For example, when asked about responses to alarms, a participant stated: *"Als het (the patient monitor) bijvoorbeeld een lage saturatie aangeeft verwacht je een blauw kind, dus je kijkt naar het kind. Als het kind mooi roze is ligt het probleem niet bij het kind, maar bij de sensor."* This response shows the decision table rule: IF low saturation alarm THEN check if the patient's skin color is blue. When this pattern match succeeds, a label is attached to the pattern by stating that the patient has low oxygen saturation. When this pattern match fails, the next decision table rule is checked: IF low saturation alarm THEN check if the sensors are malfunctioning. The main difference between decision table search strategy and pattern recognition is that the decision table search strategy is knowledge-driven, rather than data-driven like pattern recognition.

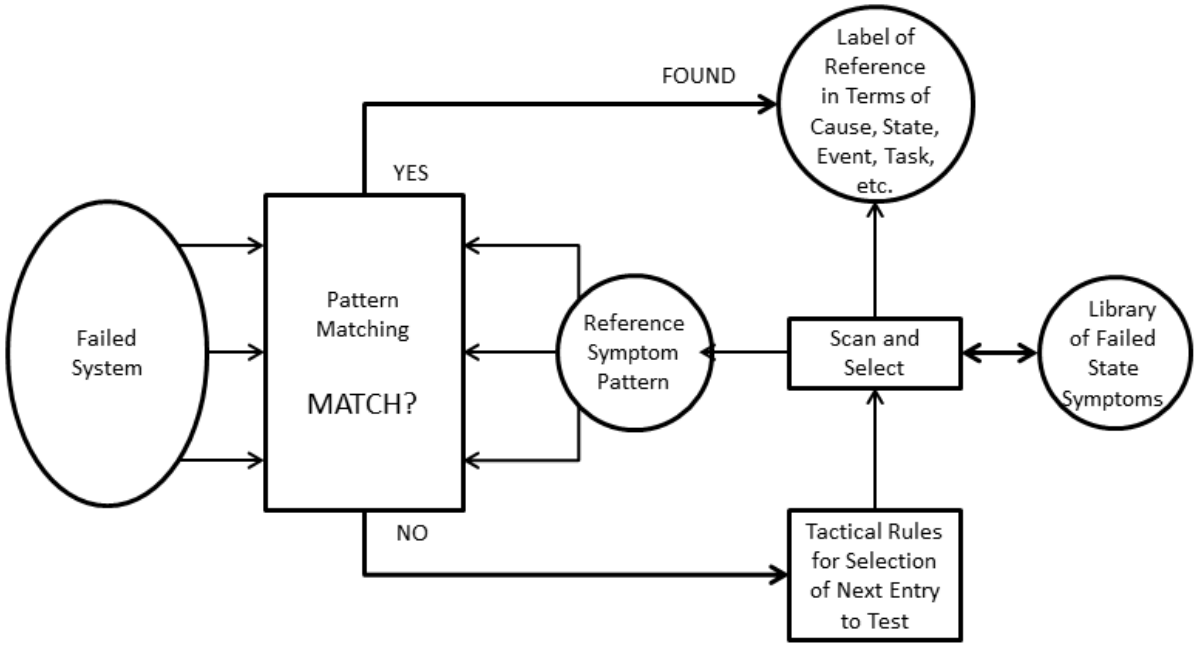


Figure 9. Decision table search strategy (adapted from Rasmussen, 1981). When initial pattern matching fails, a loop is executed where a new set of possible symptom patterns is tried for a match with the failed system.

Nurses were not found to use a hypothesis test strategy; they usually consulted a specialist to make diagnoses when both the aforementioned strategies of pattern recognition and decision table search fail, instead of testing hypotheses themselves.

4. Organizational analysis

The interview data showed that there are always between 3 to 5 nurses present on each of the three sections of the PICU. This translates to 1 or 2 patients per nurse. These nurses are fully responsible to respond and manage all discussed aspects of alarms for the patients under their care. There are no set rules for collaboration to respond to and manage alarms. Instead collaboration on alarm response is done by estimating the need to respond to another nurse's alarm based on experience, or by means of verbal communication by asking a colleague for help. Most participants stated they do not normally respond to other nurses' alarms, with the exception of a prolonged critical alarm.

5. Competencies analysis

There is no manual or list of protocols that is used to instruct new employees on the skills, rules, or knowledge that they need to manage alarms. Instead nurses are taught by working under supervision of a more experienced nurse for a period of about 12 weeks. During this supervised work period, emphasis is placed on taking full responsibility for the patient's alarms, and new employees are taught that looking at the child is more important than fully trusting on the monitors. What normal alarm boundaries for physiological signals are is taught during a nurse's training. This knowledge is further fine-tuned to take into account specific patient types during their supervised working period. Finally, nurses are instructed to silence and anticipate alarms where possible to decrease nuisance alarms.

Other results

Additional data was gathered by interview questions not directly related to CWA. When asked about what the most important properties of an ideal alarm system are in their opinion, participants stated that they prefer a system with a high usability. Alarm systems are preferably mobile and accessible from multiple locations, while all locations can access all alarms and measurements to allow remote control and an integrated assessment. During one interview the preference was stated that the volume of medical devices should be editable in order to not wake up sleeping patients when handling the devices. For example, adjusting treatment on an IV pump is accompanied by a loud beep for each button press. Participants preferred a clear distinction between critical alarms and non-critical alarms, and were in most cased skeptical to the idea of relinquishing too much control to an automated system. Participants reported that their largest annoyances when working with alarms are alarms with an unknown cause and alarms from machines that are unknown to the nursing staff.

4.1.4 Conclusion

In this chapter we answered part of the first research question (How can alarm hazards in the ICU environment best be analyzed?) by performing a cognitive work analysis. In order to make sure that an alarm hazard analysis includes all hazards that should be taken into account, an analysis method had to be found to analyze what aspects of the PICU work domain play a role in critical care alarm hazards. In the current study we proposed the use of CWA because this method offers a way to extensively analyze a sociotechnical system like an ICU by including as many aspects as needed, both cognitive and physical. Using the CWA method, we created a formalization of the work domain of PICU nurses and identified and analyzed two alarm related tasks: setting alarm boundaries and responding to alarms. In addition, two strategies were identified and explained: pattern recognition for the initial recognition of alarm urgency, and decision table search strategies to identify the root cause of an alarm or the need for a task or action. Finally, we obtained information about the organization of work with alarms on the PICU, and we identified the skills, rules and knowledge that nurses learn in order to work with alarms on the ICU.

The CWA we performed is part of the proposed method to analyze alarm hazards on the ICU. Because the CWA method was extensive with respect to the different aspects of a work domain it included, the risk analysis described in the next section based on its results can be sure to include the most important alarm hazards.

4.2 Risk Analysis

The risk analysis for this research used the previously performed CWA as an input. The analysis used a combination of Healthcare Failure Mode and Effects Analysis (HFMEA) and Systematic Human Error Reduction and Prediction Approach (SHERPA). The method produced an overview of the most severe alarm risks that are in need of preventive action as an output. This chapter explains the reasons behind the choices that were made when implementing the risk analysis, the detailed method that was used, and the obtained results.

4.2.1 Implementation

To analyze the risks on the PICU, a risk analysis method had to be found that can be based on the results of a CWA, and produce an overview of potential errors and their hazardousness. None of the in chapter 3 discussed risk analysis methods (HFMAE, SHERPA, PRISMA) are fully compatible to receive a CWA as input and supply a sufficiently qualitative and quantitative analysis. Drawbacks of PRISMA are that the analysis does not use a comprehensive task or work analysis, and it only includes and analyzes errors from incident reports. An error has to have already occurred to be included in the analysis; potential hazards that have not yet led to an error are inherently not included in this method. Because of this it does not help to predict and prevent new potential errors and hazards, making it unsuitable for this research. Furthermore, a problem with SHERPA is that the method needs a hierarchical task analysis as an input. Additionally, while the method is quantitatively thorough by using an extensive error taxonomy for every step of a task, the probability and criticality of potential errors has to be estimated, which impedes the method's explanatory power. Finally, a critical step in the process of HFMEA entails creating a graphical description of the process to find possible failure modes. This process of finding possible failure modes is based solely on the analyst's personal experience. This process is not well-defined, and it is unsuitable for the purpose of this research because the current study wants to be sure that all relevant hazards are analyzed.

Solutions to the aforementioned problems were found and implemented by using the framework of HFMEA. The current risk analysis used this framework because it is more flexible as to what its input is, as opposed to SHERPA and PRISMA who need either a HTA or detailed incident reports. This way, the CWA results can be used as an input. To overcome the ill-defined descriptions of finding failure modes to score in HFMEA, the current analysis used the defined action categories and error modes from SHERPA to increase its objectivity while maintaining the scoring method of HFMEA. The SHERPA taxonomy for error modes can be found in Table 8.

The analysis cannot be split into studying hazards for single alarms. During the previous analysis it became apparent that how relevant and how critical an alarm is, is determined by a combination of alarms and trends, and rarely from a single alarm. This finding makes the scoring of a single alarm meaningless. Because of this, the current analysis studies alarm hazards in the context of the medical machines instead of alarm hazards in the context of every single alarm. Placing the alarm hazards in this context of machines has the effect that participants inherently take critical alarm combinations of multiple alarms on these machines into account when scoring the risks. Consequently every possible alarm from a machine is reflected in the hazard scores.

Table 8. SHERPA error modes (Lane et al., 2006).

Error type	Code	Error mode
Action errors	A1	Operation too long/short
	A2	Operation mistimed
	A3	Operation in wrong direction
	A4	Operation too little/much
	A5	Misalign
	A6	Right operation on wrong object
	A7	Wrong operation on right object
	A8	Operation omitted
	A9	Operation incomplete
	A10	Wrong operation on wrong object
Checking errors	C1	Check omitted
	C2	Check incomplete
	C3	Right check on wrong object
	C4	Wrong check on right object
	C5	Check mistimed
	C6	Wrong check on wrong object
Retrieval errors	R1	Information not obtained
	R2	Wrong information obtained
	R3	Information retrieval incomplete
Communication errors	I1	Information not communicated
	I2	Wrong information communicated
	I3	Information communication incomplete
Selection errors	S1	Selection omitted
	S2	Wrong selection made

The first steps of the risk analysis use the SHERPA taxonomy to define the failure modes (the ways a system can fail) of the tasks found during the control task analysis. These tasks are exclusively performed on an alarm or machine. Subsequently as a second step, these failure modes were defined for every machine, mapping them onto the domain. Step three entails complementing these failure states with additional error modes found in the strategies, organizational, and competencies analysis. The error modes within the strategies, organizational, and competencies analysis phases were found through personal experience and estimation based on previously collected information because these three analysis phases do not follow the formal structure of the domain and control task analyses to allow for a SHERPA error identification. The next parts follow the standard procedure of the HFMEA method. A team of subject matter experts scored the resulting list of failure modes on their probability and severity, both an integer ranging from 1 to 4 as shown in Tables 9 and 10. The range and definition of severity scores are taken from the HFMEA definition as defined by DeRosier et al. (2002). The definition of the probability scores was chosen to accurately reflect the range of frequencies at which alarm incidents occur on an ICU, which ranges from daily as its most frequent option, to very remote (i.e. once a year or less) as its least frequent option. This distribution of probability scores was estimated on the basis of preliminary observations of alarms on the PICU. Multiplying the probability and severity scores yields a hazard score that can range from 1 to 16. Failure modes with a hazard score of 8 or above are deemed important enough to warrant control measures and are taken to the next step. In this final step, the subject matter experts estimate

whether an effective control measure for the failure mode in question is already in place, or whether its detectability is so large that the hazard is obvious and readily apparent. If either of the propositions is answered positively, the failure mode does not warrant further investigation. The HFMEA as defined by DeRosier et al. (2002) includes a third measure called criticality, which determines if the failure mode is a single point weakness in the process. This means that if this failure mode occurs, the entire system fails. This measure was excluded from this analysis because failure modes were included in the risk analysis on the basis of being single point weaknesses. The entire task, strategy, or unit organization fails if one of the included failure modes occurs.

Table 9. Probability scores for HFMEA.

Probability	Description
1	Remote: every year or less
2	Uncommon: every month
3	Occasional: every week
4	Frequent: every day

Table 10. Severity scores for HFMEA.

Severity	Description
1	Minor event: no harm to patient
2	Moderate event: impermanent harm to patient
3	Major event: minor permanent harm to patient
4	Catastrophic event: death or major permanent harm to patient

4.2.2 Method

In the setting of alarm boundaries task, we identified two failure modes by identifying the single point weaknesses using SHERPA's taxonomy for every step of the task. The first failure mode is the incorrect setting of alarm boundaries by a nurse caused by wrong obtained information from an external source or incorrect personal estimation. The second failure mode is the wrong operation on the right object, meaning the alarm boundaries are set wrong not because of incorrect intentions, but because the procedure was not carried out as intended, or the machine malfunctioned. These failure modes are shown in Table 11. In the same way, we identified three failure modes in the alarm response task by identifying the single point weaknesses using SHERPA's taxonomy for every step of the task. The first failure mode represents the error that occurs when a nurse is not alerted to the failed system. The second failure mode represents the error when the patient and machine system does not offer enough information to diagnose the cause of an alarm, or the system is not sufficiently investigated by a nurse. The third failure mode represents a wrong response to an alarm. These three failure modes are shown in Table 12. Subsequently failure modes in the identified strategies of

pattern recognition and decision tables were identified based on our personal estimation and included in Table 13. Failure modes during pattern matching are most importantly estimated to be the exclusion of critical aspects of the pattern. Aspects of the pattern that are used during pattern recognition are the alarm, the state of the machines, and the state of the patient. The former two are already covered by failure modes in the task analysis. The last, not including the patient in the pattern for pattern recognition, is a pattern recognition failure mode and was included in Table 13. We identified one failure mode through personal estimation within the decision table search strategy that occurs when there are no more rules in the decision table and a pattern match still has not been found. This failure mode entails a personal lack of knowledge of a nurse who uses the strategy to diagnose an alarm. This decision table failure mode was included in Table 13. Finally, Table 13 includes a failure mode found in the organizational analysis not yet covered by the previously found failure modes: too many tasks or the presence of too few staff. We identified this critical point weakness of the organization of the PICU by means of personal estimation based on the information that the organizational analysis provided. The five failure modes identified in the task analyses, depicted in Tables 11 and 12, were subsequently defined for every relevant machine found in the work domain (e.g. setting the wrong alarm boundaries for a patient monitor or setting the wrong alarm boundaries for an IV pump)The failure modes for setting of alarm boundaries was pruned from 7 of the total 12 machines because preliminary analysis showed that these machines either do not offer the functionality of setting custom alarms, or the setting of alarms does not fall under the nurses responsibility. The described process yielded the experimental materials used during data collection. The full lists are included in appendix B and C.

Table 11. Identified failure modes in the setting of alarm boundaries task with their respective SHERPA codes and their possible consequences.

Step	Failure mode	Consequence
1-3	R2: Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough
5-6	A7: Wrong operation on right object, through either operation failure or machine failure	Alarm does not function as desired

Table 12. Identified failure modes in the responding to an alarm task with their respective SHERPA codes and their possible consequences.

Step	Failure mode	Consequence
1-2	I1: Information not communicated	The alarm does not reach the nurse
3-6	C1&C2: Check omitted or incomplete, insufficient information collected about the system state	A nurse does not know what causes the alarm (insufficient system information)
7-10	S2: Wrong procedure selection	Inadequate or wrong procedure executed

Table 13. Identified failure modes in both strategies and organization and their possible consequences.

Step	Failure mode	Consequence
Pattern recognition	Not being able to see or hear the patient	Incorrect response to an alarm
Decision Table	Failed state symptoms library depleted, no pattern match found	A nurse does not know what causes the alarm (because of insufficient personal knowledge or experience)
Organization	Too many tasks or too few staff	Nobody immediately available to respond to an alarm

As a second step in the risk analysis, we conducted interviews in two parts to determine what the most important risks are. The first part determined the hazard scores for every failure mode; the second part determined what failure modes need the PICU's attention by obtaining scores on controllability and detectability from the PICU's nurses. The interviews were conducted on the PICU of the UMCG. Two interviews were conducted to obtain the hazard scores, and one interview was conducted to obtain the controllability and detectability scores. Subjects were interviewed during a time overlap in shift changes. A total of 7 experienced nurses participated, 3 participated for the first interview of the first part, 2 participated for the second interview of the first part, and 2 participated for the second part. The interviews were conducted in Dutch.

The experiments started with a brief introduction on the topic of the risk analysis. Subsequently we presented the subjects a list of all failure modes and two tables that explained the scores for probability and severity. The materials are included in appendix B. For the final interview, subjects were presented with a list of all failure modes that obtained a hazard score of 8 or above. These materials are included in appendix C. After explaining terms where necessary, subjects were asked to verbally score each member of the list on probability and severity during part 1, and score control measures and detectability positively or negatively during part 2, while the interviewer noted the scores and responses. When participants gave different scores during the interviews for part 1, the mean of the scores was used. During part 2, if the answer to the controllability of a failure mode was positive, the question about detectability was skipped because both questions have to be answered negatively for the failure mode to need the PICU's attention.

4.2.3 Results

After the first part of the risk analysis where 49 failure modes were scored on probability and severity, their hazard score was calculated by multiplying both scores. A total of 14 failure modes were found hazardous enough by scoring 8 or above to be taken into account for part 2. These failure modes are highlighted in appendix D. 13 failure modes were deemed not relevant or possible at all by the participating nurses, and the remaining 22 failure modes received a hazard score below 8. The full results of part 1 are included in appendix D.

The second part of the risk analysis, where 14 hazardous failure modes were scored on control measures and detectability, yielded 4 alarm risks that need the PICU's attention because they scored negatively on both controllability and detectability. These failure modes are shown in Table 14. Out of the 14 failure modes, 4 scored 'No' on both control measure and detectability, 2 failure

modes scored ‘Yes’ on control measure, and 8 failure modes scored ‘No’ on control measure, but ‘Yes’ on detectability. The full results that include all 14 failure modes are shown in appendix E.

Table 14. The alarm hazards that scored 'No' on both control measure and detectability, and warrant further attention.

Part	Failure Mode	Possible Consequence	Probability (1-4)	Severity (1-4)	Hazard Score (1-16)	Control Measure (Y/N)	Detectability (Y/N)
Monitor	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	4	4	16	N	N
IV Pump	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	3	4	12	N	N
Pager	Information not communicated	The alarm does not reach the nurse	3	4	12	N	N
Decision Tables	Failed state symptoms library depleted, no pattern match found	A nurse does not know what causes the alarm (because of insufficient personal knowledge or experience)	4	4	16	N	N/Y Depends on person

The first two items in Table 14 represent the case where alarm boundaries are set incorrectly for patient monitor alarms or IV pumps, which happens daily for patient monitors or weekly for IV pumps. Both failure modes can potentially have severe consequences that include death or major permanent harm to a patient. The consequences can be severe because when alarm boundaries are not tight enough, important alarms can be missed because the alarm did not sound. When alarm boundaries are too tight, the device causes nuisance alarms that can desensitizes nurses to the device’s alarms, or even cause the device’s alarms to be turned off. In both cases, nurses can potentially miss important alarms. For both machines, there is no mechanism in place that controls

this hazard, and in severe cases the system failure can only be detected when the failure has already occurred.

The third item in Table 14 represents the case where a nurse is paged on a pager that has some technical malfunction (e.g. dead batteries). This failure mode occurs weekly, and can have potentially severe consequences. When a nurse or physician does not receive a page to help at an incident, valuable time is lost that can potentially cause death or major permanent harm to a patient. There is no control measure in place that stops this from happening, and the system failure is often only detected when a paging has already failed.

The final item in Table 14 entails the failure mode when a decision table search strategy cannot label an alarm in terms of its root cause or required task or action. In other words, the nurse has insufficient personal knowledge or experience to diagnose the alarm situation. This is a failure mode that occurs daily, and can potentially have severe consequences for a patient when an urgent alarm situation is not labeled as such. There is no control measure in place that eliminates the likelihood that this failure occurs. Participants reported that the detectability of this failure mode depends on the way that a nurse works; some nurses are likely to immediately detect this failure and take appropriate action by for example asking for help, while other nurses are less likely to immediately detect this failure mode by for example placing too much trust in their own knowledge. The latter group can cause severe incidents by not identifying urgent alarm situations on time.

4.2.4 Conclusion

In this chapter we answered the first and second research question (how can alarm hazards in the ICU environment best be analyzed, and what are the most prominent alarm hazards found on the UMCG's PICU?) by implementing and performing a risk analysis method that finds the most prominent alarm risks on an ICU. In order to find the most prominent alarm risks, a method had to be found that can use a CWA as a source from which to chart potential risks. This risk analysis method must produce useful results in order to make recommendations for alarm improvements.

A combination of the SHERPA and HFMEA methods was used to identify failure modes within the CWA results using SHERPA's error taxonomy, and to score these failure modes on hazardousness, controllability, and detectability using HFMEA's framework. We identified a total of 49 failure modes, 4 of which were found to need the PICU's attentions after scoring by nurses. These 4 most prominent failure modes are: the incorrect setting of alarm boundaries on patient monitors and IV pumps, the malfunctioning of pagers, and a lack of knowledge to identify the cause of alarms. We demonstrated the usefulness of the employed risk analysis method by showing how it can take every phase of CWA into account, on the basis of which the most important alarm risks can be identified.

4.3 Knowledge-based System

The cognitive work analysis and risk analysis described in the previous chapters identified the most important alarm hazards on the PICU. In addition to identifying these hazards, the current study wants to address the most prominent alarm hazard by proposing a cognitive engineering solution. The hazard regarding a lack of knowledge during decision table search strategy is best suited to be addressed using cognitive engineering, because we can propose a knowledge-based system as a solution. This chapter explains how we created this knowledge-based system, which answers the third research question of this study: How can the most prominent alarm hazards be addressed?

4.3.1 Choice of Domain

This part of the study is based on the results obtained by the risk analysis, which are outlined in Table 14, where the four most prominent alarm hazards were identified. Due to the nature of time constraints of the project, only one of these hazards was chosen for a follow-up study. We classified the technical malfunctioning of a pager as a purely technical issue that can easily be addressed by manufacturers, which does not warrant its own follow-up analysis. During the gathering of background information by observing the PICU work and machines, we estimated that the setting of alarm boundaries hazard for both machines is most likely caused by poor visibility of the set boundaries. This hazard could be addressed in a technical way by manufacturers by increasing visibility of alarm boundaries on their machines. The final hazard entailed the failure mode that an adequate response to an alarm fails due to a lack of knowledge during decision table search strategy. We selected this hazard for the follow-up study of this project because we can address this hazard with a cognitive engineering solution, namely a knowledge-based system. A knowledge-based system is a system that uses explicit knowledge to make inferences about problems that support human decision making and task performance.

The decision table search strategy risk involves the inability of nurses on the PICU to respond to an alarm of any machine because the nurses cannot diagnose the alarm situation. In some alarm situations, nurses cannot immediately diagnose the alarm in terms of root cause or required action based on preliminary pattern matching. In these situations, nurses further investigate the system of patient and machines to check for familiar patterns of information. When nurses do not find a familiar pattern match after further investigation, the alarm can be either ignored or further investigated using advice from physicians or colleagues. This failure mode becomes a high scoring hazard because it can delay the response to a critical alarm, or cause predictive patterns for hazardous incidents to be missed.

This part of the study charted the important aspects of the domain where this hazard occurs, and how these aspects and knowledge can be represented as a knowledge-based system to address the hazard.

4.3.2 Knowledge Elicitation

To address the decision table knowledge hazard, a knowledge-based system must include knowledge and rules about the meaning of alarm patterns in order to support the failed state symptoms library of nurses while they execute this strategy. To build this system, we needed to elicit knowledge from experienced nurses about two things: what parts of an alarm situation pattern are most important to include in the system, and what is the meaning of these patterns. We only included the most important parts of an alarm situation pattern, because information gathering

during CWA showed that charting knowledge on the meaning of every alarm and alarm combination on the PICU fell outside the scope of this project. To illustrate, the domain analysis showed that up to 16 different alarm-producing machines can be in use on the PICU. These machines can in most cases produce multiple types of alarms. Gathering knowledge about the meaning of every combination of every alarm of every machine combined with every possible patient illness, history, and treatment is an unfeasible task. Preliminary analysis and conversations with the PICU staff showed that the patient monitors form the most important part of most patterns on which alarm related decisions are based. Therefore the knowledge gathering limited itself to the alarms and alarm combinations of this machine, i.e. the Phillips IntelliVue MP70 patient monitor. This monitor can give up to 70 different alarm messages on a wide range of physiological measurements.

Two unstructured interviews were conducted with a total of three of the most experienced nurses of the UMCG's PICU to determine what the most important physiological measurements and alarms are that form an alarm situation pattern, and how these alarms can be diagnosed. One nurse was interviewed during the first interview; two nurses were interviewed during the second interview. Participants were interviewed during a quiet time between shift changes. The interviews were conducted in Dutch.

After an explanation of the goal of the interviews, the conversation was guided by four questions, displayed in Dutch in appendix F. During the first question we talked about what sources of knowledge there are about patient monitor alarms other than a nurse's training and experience (e.g. training books or guides). This information can be used to find additional sources of knowledge with which to build the knowledge-based system. During the second question we talked about the difference in monitor alarm handling between experienced and less experienced nurses. This information is useful because it defines the way that nurses work with monitor alarms, and shows whether experienced and less experienced nurses can be supported by a knowledge-based system in the same way. During question three of the interview we talked about what physiological measurements of the patient monitor nurses predominantly use, and additionally what type of alarms are produced for these measurements. To make sure that that every possible data measurement option is discussed during this part of the interview, we created a list of possible physiological measurements, taken from the patient monitor manual. We included this list in the interview schedule in order to confirm or refute the usage of these measurement options. During the final interview topic, we gathered information about what the most common and most crucial alarm and data-event combinations are, and what the corresponding diagnosis or action should be.

4.3.3 Analysis & Representation

We analyzed the notes from the interviews and talks to determine how nurses structure the alarm pattern elements within the domain of the patient monitor. The first question showed that participants were not aware of additional sources that include information about the meaning of alarms, other than initial nurse training and experience during supervised training. All participants stated that there is a difference in monitor alarm handling between experienced nurses and less experienced nurses. Less experienced nurses tend to pay the most attention to numerical measurements, whereas more experienced nurses attach more value to the curves and emerging trends of physiological measurements. Question three showed what the most important aspects of a monitor alarm pattern are that nurses use to infer the meaning of an alarm. All participants stated that the most important physiological measurements are heart rate (HR), blood oxygen saturation

(Sat), and blood pressure (BP). The corresponding alarms for all three measurements are the alarms for high and low values.

Because of the structure of the monitor alarm domain that the third question found (HR, Sat, BP, and their high and low alarms), we structured the fourth question to find the meaning and required actions for combinations of these three measurements and their alarms. For example, one question was “What is a possible diagnosis or required action when the patient monitor shows a low saturation alarm or trend, a high heart rate alarm or trend, and no blood pressure alarm or trend?”

The full results are included in Dutch in appendix G. In addition to providing the possible diagnoses, all participants mentioned that a large body of additional detailed patient information is required to obtain a reliable diagnosis (e.g. patient history or medication). The knowledge and actions represented in appendix G should therefore only serve as suggestions and possibilities instead of facts.

4.3.4 Application Design

We used the previously found monitor alarm pattern knowledge to design a knowledge-based system application that can support a nurse’s decision making regarding patient monitor alarms. The application supports decision making by receiving alarm or trend combinations as input and subsequently showing a nurse possible diagnoses and actions for these alarms or trends. The application addressed the hazard regarding a lack of knowledge during decision table search strategy by adding information to a nurse’s decision table pattern matching that a nurse might not have found otherwise.

The application was developed in Java, using elements from SWT (standard widget toolkit). The application takes input from a user, who can set the relevant alarms or trends for the alarm situation. The user can choose one out of three options (high, none, or low) for each of the three physiological measurements (HR, Sat, and BP). Every selection of an alarm option displays the resulting knowledge. The graphical user interface is shown in Figure 10. On the left side are 9 radio buttons where alarms or trends can be selected as input. The knowledge and suggestions are displayed on the right. At the bottom left are two additional buttons: the top button ‘Reset’ sets all three alarm categories to ‘Geen’ (none), and the bottom button ‘Toon alle informatie’ (show all information) opens a window, displayed in Figure 11, that shows every rule and all of the knowledge present in the system when manual inspection is required.

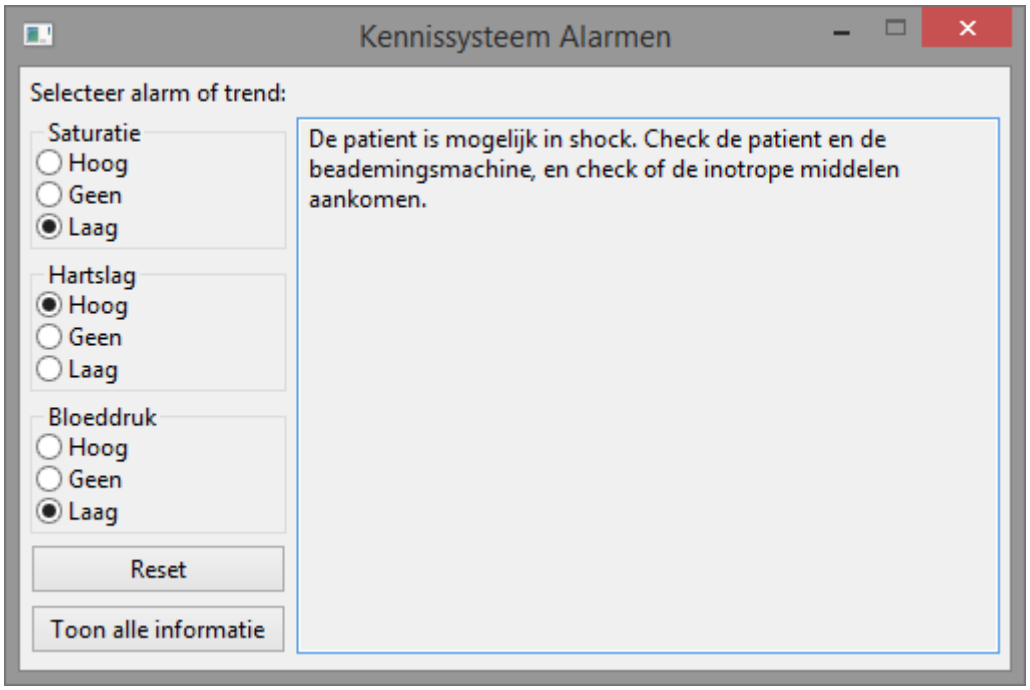


Figure 10. The GUI of the knowledge-based system showing an example alarm combination.

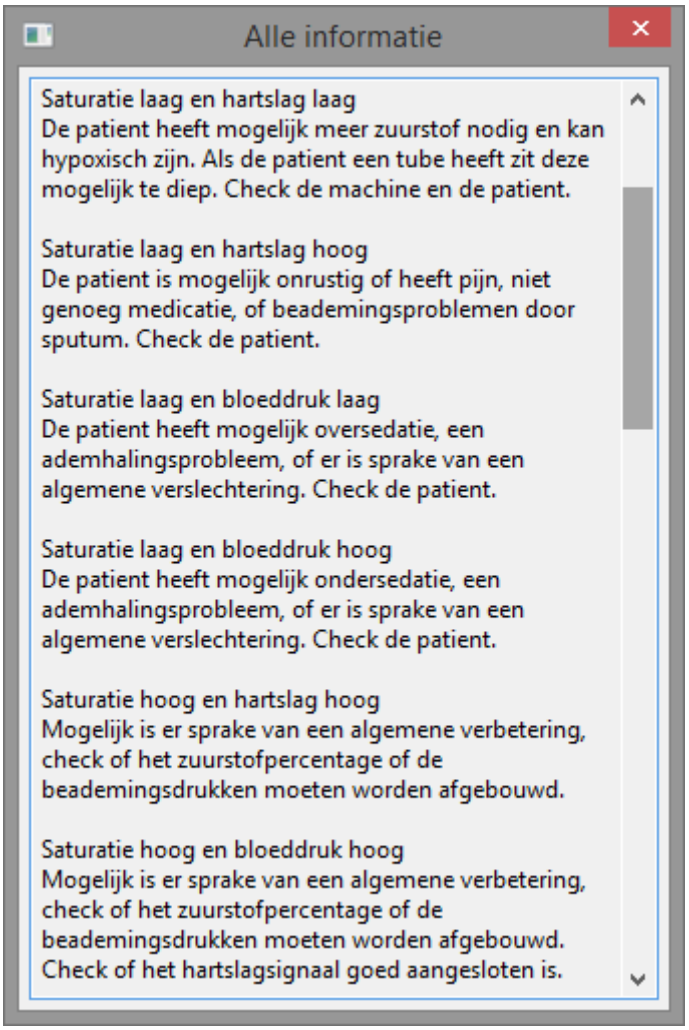


Figure 11. The window that shows all rules and knowledge present in the knowledge-based system.

4.3.5 Evaluation

To obtain an assessment on the validity of the developed knowledge-based system, and to obtain design recommendations, we conducted expert reviews. During these reviews, we gathered the opinions of the domain's experts via a demonstration of the prototype application and unstructured conversations. One review was conducted by a nurse manager, and one by an intensivist, both employees of the UMCG's PICU. The reviews verified the validity of the knowledge present in the system, and both reviewers attested to the viability of the knowledge-based system approach as implemented by the prototype application. A knowledge-based system with information about alarms and trends to support decision making was seen as a useful addition to a nurse's working environment. Even though the knowledge currently present in the system cannot be used to make a completely accurate diagnosis, the system still supports nurses by adding options and suggestions for alarm diagnoses they might not have generated otherwise.

Additional results included the comment that it is a very difficult task to expand the proposed knowledge-based system to a level where all information to make a reliable diagnosis is taken into account. A complete knowledge-based system would have to include information on an incredible amount of patient cases, backgrounds, exceptions, and every combination of alarms possible to successfully make full diagnoses. This statement confirmed our decision to limit the knowledge-based system to the diagnoses of one machine.

When asked about possible redesigns, one reviewer recommended the implementation of a training mode. The most utility of the prototype application was estimated as allowing PICU nurses to train and examine themselves on the meaning of different alarm and trend combinations. Following this recommendation, we added a training mode to the application. A checkbox to toggle between training mode and normal mode was added to the top of the GUI, as shown in Figure 12. When the training mode is activated by checking this box, answers to alarm or trend combinations are initially hidden from view. A mouse click in the area where information is normally displayed reveals the answer. This mode allows nurses to examine themselves by thinking about the possible diagnoses before reading what the system outputs.

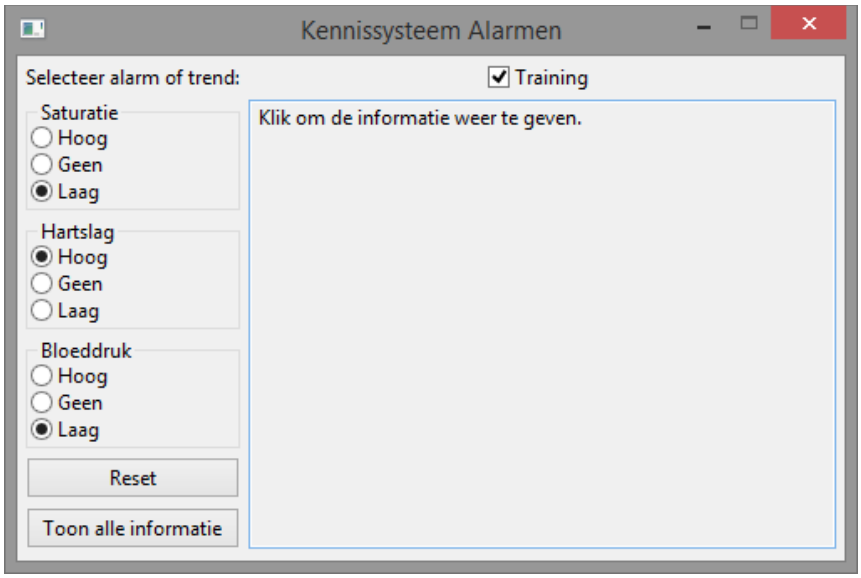


Figure 12. The knowledge-based system's GUI with training mode enabled. A mouse click in the large text field displays the knowledge.

5. Discussion

In this thesis we discussed and implemented a method to analyze alarm hazards on a PICU. We performed a cognitive work analysis that found all aspects in a PICU work domain regarding alarm hazards. On the basis of the found CWA results, we performed a risk analysis using a combination of the SHERPA and HFMEA methods that identified potential failure modes and their significance in the PICU. To address one of the most prominent alarm hazards, we developed a knowledge-based system that can aid nurses during work with patient monitors by suggesting possible diagnoses for alarm or trend combinations.

This chapter contains a discussion and interpretation of the methods and results of this study. Section 5.1 presents a discussion of the CWA, section 5.2 covers a discussion of the risk analysis, and in section 5.3 we discuss the knowledge-based system. Finally, we make suggestions for future research in section 5.4.

5.1 Cognitive Work Analysis

In this section of the study, we give an answer to the first part of the first research question: how can alarm hazards in the ICU environment best be analyzed? We posed this question because no clear best method to analyze alarm hazards on an ICU can easily be identified. Several paradigms and research methods to analyze work and hazards exist (e.g. CTA, HTA, SHERPA, HFMEA, PRISMA), each with their own strengths and weaknesses. Finding the most valid method or combination of methods for the study's environment and purpose is an important consideration. The execution of the method and the value of the obtained results can serve as an evaluation of the performed method in comparable environments or studies.

The answer that we proposed to the first research question included the performance of a CWA to find all relevant aspects of the ICU domain, both physical and cognitive. Because we wanted to be sure that a subsequent risk analysis finds all important risks, including all aspects of the environment that are relevant with respect to alarm hazards was the most important consideration for this part of the study. CWA excels as a method when an extensive work analysis is required, because when compared to competing methods (i.e. CTA, HTA), it offers the most flexibility because it can include as many aspects as needed, cognitive and physical. The CWA yielded an overview of the aspects of a PICU domain that play a role with respect to alarms. In addition it identified distinct alarm hazard producing tasks, strategies, and organizational aspects.

The results that the CWA method produced show that this method as it is described by Rasmussen et al. (1994) and Vicente (1999) is a valid method for an ICU alarms setting that can be adapted to the environment and research needs. The fact that we could use the produced results in combination with other methods for further analysis attests to the fact that the CWA method produces useful results. Furthermore, in this section of the study we provided a detailed method to perform and adjust a CWA, and we included the precise manner of information extraction. This ensured that the analysis is a precisely reproducible CWA demonstration, in contrast to similar studies that often do not provide details of information extraction. We also showed on what levels alarm hazards in an ICU operate, how the domain can be formalized in an ADH, and how the two alarm relating tasks that nurses perform are executed. These findings are especially useful for similar studies and medical technology manufacturers to take into account. Finally, we confirmed the usage

of pattern recognition and decision tables strategies by nurses in critical care, results that were also found in similar studies by Effken et al. (2001) and Pingenot et al. (2009). These studies also found the usage of topographic search and hypothesis and test strategies, of which we found no evidence in this research. The likely cause of this difference in identified strategies is the fact that the current research included exclusively nurses, whereas both the aforementioned studies included both clinicians and nurses.

Although the CWA that we performed can be regarded as extensive because it uses all available phases, we had to be specifically tailor the analysis for the PICU where it took place, because ultimately we wanted to find the most prominent alarm hazards for that specific unit. This specific tailoring of the analysis caused an increase in specificity of the analysis, which inherently reduced the generalizability of the results. When the same method is performed on a different PICU, results regarding the domain and unit organization will most likely differ from the ones we found in this study because different machines, rules, and organizational rules can be used by other PICU's. Additionally, because we extracted information by means of conversation and interviews, some subjectivity is brought into the research, because interviewees speak from their personal experiences, interpretation, and ideas that are not always grounded in theory. Furthermore, analyzing interview results and creating the CWA results required us to make a number of estimations, based on experience and interpretation. Such estimations included defining the members of the ADH dimensions, the way tasks are mapped onto a decision ladder template, and the aspects to include in organizational and competencies analyses. Although one correct way to perform a CWA cannot be defined, the method is still restricted by using a pre-defined paradigm. Because of this, we can never be absolutely sure whether we included every relevant aspect; instead we only included knowledge as far as the CWA estimated.

5.2 Risk Analysis

In the risk analysis part of this study we partly answered the first research question: how can alarm hazards in the ICU environments best be analyzed? The CWA together with the risk analysis formed the complete proposition with which we answered this research question. Furthermore, in this part of the study we answered the second research question: what are the most prominent alarm hazards found on the UMCG's PICU? We posed this question because several potentially hazardous situations were identified by the ICU's employees. We needed to perform a formal analysis to determine what the most important hazards are, on the basis of which we can recommend improvements that yield the largest gains in safety.

The answer that we proposed to the first question entailed using a combination of the pre-defined SHERPA and HFMEA risk analysis methods to circumvent the weaknesses of both methods and use the strongest parts of both methods. Specifically, we added SHERPA's formal error taxonomy to HFMEA's flexible scoring framework to answer the second research question: what are the most prominent alarm hazards found on the UMCG's PICU? Using the described risk analysis method, we identified four alarm hazards as the most hazardous according to the features of hazard score, controllability, and detectability.

The method we used to perform a risk analysis together with a CWA show the way that a complete alarm hazards analysis can be performed. Furthermore we showed a successful way to adapt and combine risk analysis methods to fit the specific needs of a study. The original HFMEA

process, as described by DeRosier et al. (2002) is commonly criticized in two ways, as Habraken et al. (2009) explain. In the first place a HFMEA is very time consuming, and secondly, the lack of a formalized taxonomy makes the hazard analysis step and the identification of failure modes difficult to carry out. Although using a CWA as a source for failure modes can still be very time consuming, we showed a way to circumvent the second point of criticism by identifying failure modes using the formalized taxonomy of SHERPA, instead of relying on opinions. SHERPA for medical analysis, as described by Lane et al. (2006), also receives the criticism of being time consuming, because the method needs an extensive (hierarchical) task analysis. Admittedly a CWA is still time consuming, but the results we were able to produce include more than just tasks descriptions like a HTA. This shows that using a CWA and applying SHERPA to CWA's task analyses is a better choice when a wide analytical scope is needed. Furthermore, because highly unlikely actions and errors are inherently excluded from a SHERPA analysis, the full scope of error-producing activity is not taken into account. We avoided this drawback of SHERPA by taking as many actions and errors producing aspects of the work domain into account during the CWA, before we applied the SHERPA analysis. This way, the relevant error producing activity is separated from the irrelevant during the risk analysis instead of before. Specifically, this identification was done by nurses during the first risk analysis interview, where they identified 13 of the 49 failure modes as not relevant or possible. In addition to our implementation of the method, the results of this part of the study can serve as a guideline for medical device manufacturers or ICU nursing policy creators by identifying the most important alarm hazard issues on a PICU.

Because the risk analysis method we used is custom made, and not in its entirety a reproduction of a well-grounded and tested analysis method, risk analysis' explanatory power and validity might be less than a method that is extensively tested and proven. Until the concept of the employed method is reproduced and tested several more times, acceptance of its validity will be lower than each method performed separately.

An inherent weak point of the results we obtained is that the results are specific for the UMCG's PICU, because the goal of the project included this same specificity. In contrast to the method, the results we showed are less generalizable to other PICU's because these ICU's will most likely work with different machines, personnel compositions, and policies.

Finally, a weakness of the way we obtained the results is that the failure modes had to be manually scored by subject matter experts. Although the fact that the participants were experts gives at least an indication as to what hazards are important, this manner of scoring is also open to interpretation. This process can harm the objectivity of the obtained results of all failure modes. The way that the scoring took place contributed to this criticism. It leaned on a subject's interpretation of the different risks that are included within some failure modes and machines. This is illustrated by the observation that the original motivation that sparked the discussion underlying this study, the integration of medical devices in isolation rooms into the main alarm monitoring system, is not reflected in the results. Specifically, the 'information not communicated' hazard for the HFO machine was seen as non-relevant. Causes of this can be that the subjects' interpretation of the failure mode differed from its intended content, or that the error represented by the failure mode was insufficiently extensive to lead the subjects' interpretation to include the case of isolated rooms as well. Perhaps different nurses have different opinions on how to score the failure modes. We tried to circumvent this subjectivity by interviewing in groups of 2 and 3, and by using either an averaged

hazard score or an agreed upon classification of controllability and detectability. A subjective interpretation can have large consequences for the hazard analysis results when for example some nurses think a failure mode that received a hazard score of 16 is obvious, and other nurses do not think this hazard is obvious, because this classification is the basis on which failure modes were discarded or emphasized as prominent alarm hazards.

5.3 Knowledge-based System

In this part of the study we provided an answer to the third research question: how can a cognitive engineering solution address the most prominent alarm hazard? We posed this question in order to show how a cognitive engineering solution can connect to the previously obtained risk analysis results, and in order to make a recommendation for alarm improvement to the PICU on which the study took place. Before we answered the research question, the most suitable of the prominent alarm hazards was chosen for further analysis. We used a decision-centered design approach to build a knowledge-based system prototype that can aid nurses' decision making when dealing with patient monitor alarms. Experts evaluated the system and attested to the usefulness and validity of the approach. We redesigned the prototype to allow for training by means of self-examination.

The analysis that we performed in this section of the study shows how alarm hazards that involve knowledge and pattern recognition can be addressed by adding knowledge to recognizable patterns in order to support decision making during alarm response. The results we provided about what knowledge is used on patient monitors is especially useful for medical device manufacturers who want to offer intelligent alarm solutions for ICU's. Furthermore, by building the knowledge-based system we showed how the knowledge of a domain can be captured to provide decision support, and how cognitive strategies (i.e. pattern recognition and decision tables) can be supported. Finally, we showed how a very complex and extensive domain like alarm response on an ICU can be delimited to include as much useful information as needed, while maintaining manageable complexity.

A point of criticism is that the system is based on the assumption of perfectly set alarm boundaries, which is not always the case as the risk analysis results show. Each physiological trend that carries a medical meaning should give an alarm or indication for the system to function. Another problem is the required trade-off between specificity and complexity of the system. The domain of alarm response on an ICU is a very complex structure with an incredible amount of possible diagnoses and data combinations. The more specific a knowledge-based system wants to be, the more complexity it needs to incorporate. We did not maximize specificity because of the infeasible amount of data and rules this would require. Because a viable balance within this trade-off had to be estimated, the specificity that we used for our system could be a choice of too much subjectivity. Incorporating the alarms of an addition machine in the system could potentially increase specificity by much more than it increases complexity. Currently we do not have the data to extensively evaluate what the optimal point is in this specificity-complexity tradeoff, instead we made an estimation of the level of complexity that we could manage.

Because we built the system using knowledge that was obtained on one PICU, its generalizability is unclear. Different PICU's might use knowledge in different ways by offering a different training or by using different machinery.

As a final point of criticism we want to note that expert reviews alone are insufficient as a method for evaluation. Our system should be evaluated with an experiment that determines both the usability of the system and the amount of knowledge that the system adds to a nurse's decision making. Such an experiment would better serve as a formal evaluation of a knowledge-based system than just expert reviews. The available testing environment and test subject pool was the same as the environment and subject pool with which the system was built, which would have made knowledge testing awkward. Nurses who are trained the same way in the same place will more likely make the same diagnoses than nurses from different ICU's.

5.4 Future Directions

All three parts of the current study (work analysis, risk analysis, and knowledge-based system) can form a basis for future research. When looking at work analysis on an ICU, it is useful to compare different methodologies by performing a HTA, CTA, and CWA on the same work. This can lead to a formalized description of the differences in strengths and weaknesses between the different analysis methods. Future studies can use this information to choose the analysis method that yields the most useful results for their purposes. Furthermore, future studies can attempt to replicate the results of both our work analysis and risk analysis on different ICU's. When the results are similar to ours, generalization of our current study is improved, and it can be more easily recommended for similar future studies. When results differ from ours, the found differences between ICU's can be highlighted to show what parts of work and alarm risks on an ICU are constant and what parts vary and are specific to an ICU or ICU type (e.g. PICU versus ICU). Both outcomes would aid future studies in their choices of methodology.

The knowledge-based system prototype can be verified more clearly. A future study can evaluate the usefulness of the knowledge currently present in the system by comparing the number of correct alarm diagnoses nurses make with and without aid of the system. Furthermore, the usefulness of the system as a training device can be tested by measuring the amount of correct alarm diagnoses of nurses before and after training sessions with the system. Whether an increment in correct diagnoses can be found indicates how viable the implemented knowledge specificity is.

Future development of the knowledge-based system is possible in two directions: as a decision support system or as a training system. To develop the system as a decision support system for alarms, a direct integration into the alarm generating machines is desirable, because the system should have a live feed of physiological and machine data. This way the system can automatically display the relevant knowledge or diagnoses instead of requiring manual input, which can be too slow in the time-sensitive environment of critical care alarms. When development as a training system is desired, the system's knowledge should be increased to cover more aspects of the ICU work domain by for example including more machines and patient information. The system's training functionality can be expanded to allow for smart examination (e.g. using a smart question sequencing algorithm, keeping scores, setting difficulty, or giving hints).

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Appendix

A. Interview Protocol

Interviewvragen

1) Dit is een overzicht van alarmen die ik heb verzameld op de IC, zijn er mogelijke alarmen toe te voegen aan dit overzicht?
Hoe komt de apparatuur aan de nodige informatie om een alarm te geven?
Hoe geeft het apparaat een alarm?

- Soorten alarmen doorlopen

- Welke informatie nodig voor alarm en hoe doorlopen

- Hoe geeft het apparaat een alarm (Pieptoon? Licht? Etc.)

2) Kunt u van elk alarm in dit overzicht aangeven wat typisch de oorzaak is en wat de normale reactie is?

- Lijst alarmen doorlopen, soms meer dan 1 stap reactie nodig

3) Hoeveel mensen werken er normaal op een afdeling, en wat zijn hun verantwoordelijkheden en taken met betrekking tot alarmen? Wie letten er normaal gesproken op de alarmen? Wordt er samengewerkt als dit nodig is?

- Wie werken in de omgeving om te reageren op alarmen of het instellen van

- Wie reageren er normaal gesproken op

- Hoeveel mensen zijn verantwoordelijk voor een alarm dat afgaat

4) Kunt u zich een recentelijke relevante alarmsituatie herinneren waarbij gehandeld moest worden? Kunt u mij zo gedetailleerd mogelijk vertellen hoe dit tot stand kwam, vanaf eerste alarm tot oplossing van het probleem?

- Details over strategie die gebruikt wordt om te bepalen wat de reactie moet zijn
    - pattern recognition
    - decision tables
    - hypothesis and test strategies
- Mogelijk 2x

5) Wordt iemand extra dingen geleerd over alarmering wanneer diegene begint met werken op deze IC? Bestaat er een handboek of overzicht van standaard protocollen wat betreft alarmen?

- Hoe wordt mensen op deze IC geleerd met de alarmen om te gaan

- Zijn er protocollen en officiele richtlijnen

6) Wat zijn de belangrijkste eigenschappen en functies waaraan een nieuw alarmsysteem of alarm ondersteunend systeem zou moeten voldoen?

- Technische informatie over systeem/interface

7) Zijn er tot slot nog dingen die u kwijt wilt over alarmering op de afdeling?

- Eventueel nog ongenoemde zaken die aandacht nodig hebben

Alarm	Input	Output
Monitor alarmen		
- Hartslag/ritme		
- Bloedzuurstof (SPO2)		
- Bloeddruk/ Arterielijn (ABP)		
- Centraal-Veneuze Druk (CVD)		
- Ademhaling		
Infuuspomp - Volumetrisch - Spuit		
Sondevoedingspomp		
Evita beademing		
- Fisher & Paykel		
Warmtelamp		
Koelkast		
Babyfoon		
Situationele apparatuur		
Matras		
Dialyse		
ECLS		
Criticool		
Warmtouch		
MARS		
HFO		
PICCO		

B. Risk Analysis Materials Part 1

Probability	
1	Remote: every year or less
2	Uncommon: every month
3	Occasional: every week
4	Frequent: every day

Severity	
1	Minor event: no harm to patient
2	Moderate event: impermanent harm to patient
3	Major event: minor permanent harm to patient
4	Catastrophic event: death or major permanent harm to patient

Part	Failure mode	Possible consequence	Probability (1-4)	Severity (1-4)
Monitor	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough		
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired		
	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
IV Pump	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough		
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired		
	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
Feeding Tube	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough		
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired		

	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
Evita Ventilator	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough		
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired		
	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
F&P Humidifier	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
Heat Lamp	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough		

	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired		
	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
Pager	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
Baby Monitor	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
ECLS	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		

Criticool	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
HFO	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
PiCCO	Information not communicated	The alarm does not reach the nurse		
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)		
	Wrong procedure selection	Inadequate or wrong procedure executed		
Pattern Recognition	Not being able to see or hear the patient	Incorrect response to an alarm		
Decision Tables	Failed state symptoms library depleted, no pattern match found	No idea what causes the alarm (because of insufficient personal knowledge or experience)		
Organizational	Too many tasks or too few staff	Nobody immediately available to respond to an alarm		

C. Risk Analysis Materials Part 2

Part	Failure Mode	Possible Consequence	Hazard Score (1-16)	Control Measure* (Y/N)	Detecta-bility** (Y/N)
Monitor	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	16		
IV Pump	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	12		
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	10,5		
Evita Ventilator	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	12		
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	12		
	Wrong procedure selection	Inadequate or wrong procedure executed	9		
Pager	Information not communicated	The alarm does not reach the nurse	12		
Baby Monitor	Information not communicated	The alarm does not reach the nurse	8		
Criticool	Wrong procedure selection	Inadequate or wrong procedure executed	8		

HFO	Check omitted or incomplete, in-sufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	8		
	Wrong procedure selection	Inadequate or wrong procedure executed	8		
Pattern Recognition	Not being able to see or hear the patient	Incorrect response to an alarm	16		
Decision Tables	Failed state symptoms library depleted, no pattern match found	No idea what causes the alarm (because of insufficient personal knowledge or experience)	16		
Organizational	Too many tasks or too few staff	Nobody immediately available to respond to an alarm	16		

*** Control Measure:** eliminates or significantly reduces the likelihood of the failure occurring; is an effective control measure in place?

****Detectability**: the likelihood of detecting failure or the effect of the failure before it occurs; is the hazard obvious?

D. Risk Analysis Part 1 Results

Part	Failure mode	Possible consequence	P (1-4)	S (1-4)	H P*S
Monitor	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	4	4	16
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	1	1	1
	Information not communicated	The alarm does not reach the nurse	1	4	4
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	4	1	4
	Wrong procedure selection	Inadequate or wrong procedure executed	1-2	1	1,5
IV Pump	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	3	4	12
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	3	3-4	10,5
	Information not communicated	The alarm does not reach the nurse	1	4	4
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	1	1	1
	Wrong procedure selection	Inadequate or wrong procedure executed	1	1	1
Feeding Tube	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	2	2	4
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	2	1	2

	Information not communicated	The alarm does not reach the nurse	1	1	1
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	2	1	2
	Wrong procedure selection	Inadequate or wrong procedure executed	1	1	1
Evita Ventilator	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	4	3	12
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	4	3	12
	Information not communicated	The alarm does not reach the nurse	X	X	
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	4	1	4
	Wrong procedure selection	Inadequate or wrong procedure executed	3	3	9
F&P Humidifier	Information not communicated	The alarm does not reach the nurse	X	X	
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	3	1	3
	Wrong procedure selection	Inadequate or wrong procedure executed	X	X	
Heat Lamp	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	2	2	4

	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	1	2	2
	Information not communicated	The alarm does not reach the nurse	X	X	
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	2	1	2
	Wrong procedure selection	Inadequate or wrong procedure executed	X	X	
Pager	Information not communicated	The alarm does not reach the nurse	3	4	12
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	X	X	
	Wrong procedure selection	Inadequate or wrong procedure executed	X	X	
Baby Monitor	Information not communicated	The alarm does not reach the nurse	2	4	8
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	1	1	1
	Wrong procedure selection	Inadequate or wrong procedure executed	X	X	
ECLS	Information not communicated	The alarm does not reach the nurse	X	X	
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	1	4	4
	Wrong procedure selection	Inadequate or wrong procedure executed	1	4	4

Criticool	Information not communicated	The alarm does not reach the nurse	1	1	1
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	1	1	1
	Wrong procedure selection	Inadequate or wrong procedure executed	2	4	8
HFO	Information not communicated	The alarm does not reach the nurse	X	X	
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	2	4	8
	Wrong procedure selection	Inadequate or wrong procedure executed	2	4	8
PiCCO	Information not communicated	The alarm does not reach the nurse	X	X	
	Check omitted or incomplete, insufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	X	X	
	Wrong procedure selection	Inadequate or wrong procedure executed	X	X	
Pattern Recognition	Not being able to see or hear the patient	Incorrect response to an alarm	4	4	16
Decision Tables	Failed state symptoms library depleted, no pattern match found	No idea what causes the alarm (because of insufficient personal knowledge or experience)	4	4	16
Organizational	Too many tasks or too few staff	Nobody immediately available to respond to an alarm	4	4	16

E. Risk Analysis Part 2 Results

Part	Failure Mode	Possible Consequence	Hazard Score (1-16)	Control Measure (Y/N)	Detecta-bility (Y/N)
Monitor	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	16	N	N
IV Pump	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	12	N	N
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	10,5	Y Alarm when not started/malfunction	
Evita Ventilator	Wrong information obtained from either a physician, a list, or from personal estimation	Alarm boundaries not tight enough	12	N	Y Obvious from measure ments
	Wrong operation on right object, through either operation failure or machine failure	Setting correct boundaries failed: alarm does not function as desired	12	Y	
	Wrong procedure selection	Inadequate or wrong procedure executed	9	N	Y Obvious from measure ments
Pager	Information not communicated	The alarm does not reach the nurse	12	N	N
Baby Monitor	Information not communicated	The alarm does not reach the nurse	8	N	Y Black screen is obvious
Criticool	Wrong procedure selection	Inadequate or wrong procedure executed	8	N	Y Obvious by temp measure ment

HFO	Check omitted or incomplete, in-sufficient information collected about the system state	No idea what causes the alarm (insufficient system information)	8	N	Y
	Wrong procedure selection	Inadequate or wrong procedure executed	8	N	Y
Pattern Recognition	Not being able to see or hear the patient	Incorrect response to an alarm	16	N	Y
Decision Tables	Failed state symptoms library depleted, no pattern match found	No idea what causes the alarm (because of insufficient personal knowledge or experience)	16	N	N/Y Depends on person
Organizational	Too many tasks or too few staff	Nobody immediately available to respond to an alarm	16	N	Y

F. Knowledge Elicitation Interview

1) Is er een (hand)boek of een andere bron waar regels en informatie wat betreft monitoralarmen in staan?

2) Is er een verschil wat betreft omgang met monitoralarmen tussen ervaren en minder ervaren verplegers?

3) Welke meetwaardes die de monitor kan weergeven worden gebruikt? Welke alarmen worden daarbij gebruikt?

Hart
ECG
Arrhythmia
QT
ST
Pulse

Respiratory
CO2
O2
Resp
Spirometry
tcpO2
tcpCO2

Consciousness
BIS
EEG

Saturatie
SpO2
SvO2/SO2

Cardiac output
CCO

Temperature
TEMP
Blood temperature (C.O.)

Bloodpressure
Invasive pressure CPP
NBP
PRESS

4) Wat zijn de meest voorkomende en meest cruciale alarm/data-event combinaties? Welke diagnose en/of actie hoort hierbij?

G. Knowledge Elicitation Results

Sat Low
De patient heeft mogelijk meer zuurstof nodig, check de machine en de patient. Als het een cardiopatient betreft, check of de shunt dicht zit.

Sat High
De patient heeft mogelijk minder zuurstof nodig, check de machine en de patient.

Sat Low & HR Low
De patient heeft mogelijk meer zuurstof nodig, en kan hypoxisch zijn. Als de patient een tube heeft zit deze mogelijk te diep. Check de machine en de patient.

Sat Low & HR High
De patient is mogelijk onrustig of heeft pijn, niet genoeg medicatie, of beademingsproblemen door sputum, check de patient.

Sat Low & BP Low
De patient heeft mogelijk oversedatie, een ademhalingsprobleem, of er is sprake van een algemene verslechtering, check de patient.

Sat Low & BP High
De patient heeft mogelijk ondersedatie, een ademhalingsprobleem, of er is sprake van een algemene verslechtering, check de patient.

Sat High & HR High
Mogelijk is er sprake van een algemene verbetering, check of het zuurstofpercentage of de beademingsdrukken moeten worden afgebouwd.

Sat High & BP High
Mogelijk is er sprake van een algemene verbetering, check of het zuurstofpercentage of de beademingsdrukken moeten worden afgebouwd. Check of het hartslagsignaal goed aangesloten is.

HR High & BP High
Er is mogelijk sprake van ondersedatie, of te veel inotrope middelen. Onderzoek de patient voor de oorzaak.

HR High & BP Low
Er kan sprake zijn van ondervulling, een vocht tekort, of geef medicijnen zodat de bloeddruk weer op een goed niveau komt. Onderzoek de patient voor een volledige diagnose, check of deze een hartritmestoornis heeft.

HR Low & BP High
De patient heeft mogelijk last van inklemming of een vagale reactie. Verlaag de eventuele hersenzwelling met medicijnen.

HR Low & BP Low
Mogelijk treedt een harttamponade op, of is er sprake van oversedatie. Check de patient en check de machines voor hartdruk metingen. Draagt de patient een pacemaker? Check of deze nog goed werkt.

Sat High & HR High & BP High
Mogelijk is er sprake van ondersedatie, check de patient.

Sat High & HR High & BP Low
Er is mogelijk een probleem met de inotrope medicatie of een circulatieprobleem, check de patient.

Sat High & HR Low & BP High
De patient heeft mogelijk last van sputum, check of de patient moet hoesten.

Sat High & HR Low & BP Low
De inotrope medicatie loopt mogelijk niet goed, of er is oversedatie. Check de patient.

Sat Low & HR High & BP High
De patient heeft mogelijk stress of pijn. De oorzaak hiervan kan ondersedatie of een beademingprobleem zijn. Onderzoek de patient.

Sat Low & HR High & BP Low
De patient is mogelijk in shock, check de patient en de beademingsmachine, check of de inotrope middelen aankomen.

Sat Low & HR Low & BP High
De patient heeft mogelijk last van inklemming of een vagale reactie, verlaag de eventuele hersenzwelling met medicijnen. Ook kan er sprake zijn van een beademingsprobleem, check of de patient moet hoesten.

Sat Low & HR Low & BP Low
Er is mogelijk een circulatoir of ventilatoir probleem, de patient kan hypoxisch zijn. Het kan ook een probleem met inotrope middelen zijn. Dit kan veroorzaakt worden door een probleem met de tube, check de patient en neem de oorzaak van het probleem weg. Geef meer zuurstof of verhoog de beademing wanneer nodig.