Evaluating the effectiveness of two Health Failure Mode and Effect Analysis methods

A case-study at the University Medical Center Groningen

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PREFACE

This thesis is written as final assignment for the master Technology and Operations Management at the University of Groningen. The thesis was written and conducted at the University Medical Center Groningen. The objective of this research was to evaluate if the modified light version of the HFMEA, developed by the UMCG, was indeed effective enough to be used in a healthcare setting. Results were gathered by means of interviews and questionnaires to provide a comprehensive package of information.

Investigating the effectiveness of the risks analysis methods has been complex and challenging. It was challenging to develop the right definition of effectiveness and determine a measurable instrument to assess this effectiveness. During my research I obtained valuable and interesting insights in risk management and the UMCG. The experience has been great, exhaustive and interesting to me.

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ABSTRACT

Purpose: The Health Failure Mode and Effect Analysis (HFMEA) is a commonly used method in healthcare to conduct a prospective risk analysis. Limitations of the HFMEA led to the development of several modified versions, including the One Hour PRA which diminishes these limitations using interviews and one team meeting instead of several multidisciplinary team meetings. This study evaluates the effectiveness of the HFMEA and the One Hour PRA methods and provides managerial implications to improve risk management in healthcare. Its contribution to theory is the evaluation of the effectiveness of differences between team meetings and interviews in risk analysis.

Method: Interviews with coordinators of both risks analysis methods were conducted and two questionnaires were distributed among the coordinators and participants of both risks analysis methods. One questionnaire entailed the evaluation of the output of both methods, the improvements, and was administrated to the coordinators. The other questionnaire evaluated the perception of the participants of both methods. All were conducted at the University Medical Center Groningen (UCMG) among different departments. A cross-case analysis was used to analyze the difference between departments and methods.

Results: Thirteen interviews and twenty-five questionnaires were completed during this study. Twenty-two questionnaires were usable for data analysis. There are multiple positive and negative differences between both methods. Important difference were time-investment, scheduling, depth of information and social-cultural differences.

Conclusion: Team meetings in the HFMEA provide more in-depth information in complex processes than interviews. However, due to limitations of the HFMEA the modified light version, using interviews, provided to be an effectiveness alternative. It provides less depth than the HFMEA but still proves out to be the answer to scheduling problems and social-cultural differences between groups.

1 INTRODUCTION

Today, more people die world-wide as a result of errors and failures in acute healthcare than of traffic accidents and natural disasters (Runciman, Merry & Walton, 2007). These are the result of what Baker et al. (2004) identify as adverse events. Adverse events are accidental errors, injuries or complications that lead to disability, death or an extended stay in a hospital caused by healthcare professionals instead of the disease of the patient (Baker et al., 2004). It is however possible that some of the events cannot be avoided, e.g. reactions to medications. On the other hand, research revealed that from all adverse events 37% to 51% could have been prevented (Brennan et al.,2004). For the Netherlands this percentage is somewhat lower but still too high. The NIVEL report (2012) explains that 20,9% of the healthcare in the Netherlands related harm could have been prevented. These adverse events could however be prevented with the effective application of risk management (Tonneau, 1997; Blinderman, 2009; Barach & Small, 2000; Kessels-Habraken, de Jongen, van der Schaaf & Rutte, 2010; Al-Assaf, Bumpus, Carter & Dixon, 2003). Risk is defined as: ''the chance of something happening that will have a (negative) impact on the patient'' (Runciman et al., 2007). In risk management the aim is to minimize the probabilities and impacts of adverse events, which leads to a rise of positive events (Cagliano, Grimaldi & Rafele, 2011).

To assess risks two approaches can be used, retrospective and/or prospective risk analysis (Kessels-Habraken et al. 2010). Traditionally there has been a strong focus on retrospective risk management, which is learning from what already happened. The other way to assess risk in situations, pathways or in operating certain equipment is to conduct a prospective risk analysis. This risk analysis is conducted before incidents occur, thus dealing with risks before things happen (Kessels-Habraken et al. 2010). A major advantage of prospective risk analysis is that it prevents failures that could lead to adverse events (van Schoten et al., 2014). As mentioned by Brennan et al. (2004) preventing the adverse events (prospective risk analysis) is prioritized above retrospective adverse events control (retrospective risk analysis). The high numbers of adverse events in healthcare highlight the need for a strong and effective risk analysis to understand errors and failures, their likelihood and their severity. One of the most adopted prospective risk analysis tools in healthcare is the Health Failure Mode and Effect Analysis (HFMEA) to minimize the probabilities of the occurrence of adverse events and to generate remedial actions (Cagliano et al., 2011; Franklin Shebl & Barber, 2012; Habraken, van der Schaaf, Leistikow & Reijnders-Thijsen, 2009; Vlayen, 2011; Velez-Diaz-Pallares, Delgado-Silveira, Carreto-Accame & Bermejo-Vicedo, 2012; Luo & Lee, 2015). The HFMEA uses a multidisciplinary team that first describes, sometimes graphically, the high-risk process in the healthcare setting in order to successfully identify the risks and failures (Franklin et al., 2012). Moreover, the team measures the failures based on three aspects; severity, probability and the detectability. These aspects jointly form the Risk Priority Number (RPN) which is used to determine the order in which the actions need to be taken (Habraken et al., 2009).

Van Schoten et al. (2014) stresses that despite the awareness about risks the HFMEA creates

among employees it still is a very time-consuming tool which can only focus at a single process or equipment at the time. Because of the time consuming meetings and the necessary involvement of highly multidisciplinary teams of busily engaged professionals, whose main concern is the treatment of patients, the attendance of professionals in those meetings becomes a difficult practice. In addition, interrelationships within teams can affect the freedom of speech during these meetings (Brilstra & Kleve, 2014). The presence of a direct supervisor can be a reason for a subordinate to not fully express his feelings or opinion about a certain matter. These drawbacks led to the development of several modified light versions. One of these modified light versions is the One Hour Prospective Risk Analysis (PRA). In this modified version, developed by the University Medical Center Groningen (UMCG), the team meetings are replaced by individual interviews to reduce time, scheduling problems and minimize social imbalances (Brilstra & Kleve, 2014).

The use of individual interviews is interesting since the HFMEA is in the essence based on the multidisciplinary teams meetings. These meetings enhance the input and performance of the risk analysis (Ashley, Armitage, Neary & Hollingsworth, 2010). Replacing the meetings with interviews may therefore affect the depth and validity of the risk analysis output (Charness & Sutter, 2012). One could therefore argue whether the light version of the HFMEA is as effective as a traditional HFMEA. Here effectiveness is defined as; ‘‘the extent to which a given intervention produces the outcomes to individuals who are offered that intervention’’ (Donaldson, Mugford & Vale, 2002). Moreover, there is not much conformity among researchers regarding the effectiveness of group meetings versus interviews in prospective risks analyses (Guerrero & Bradley, 2013). Ashley et al. (2010) argues that the effectiveness of the HFMEA is not yet been tested in literature. Furthermore, according to Barach & Small (2000) the need for a well-structured prospective risk technique assessment becomes clear given the lack of extensive reviews of the validity of risks analyses. Therefore, Carlson (2012) identified ten quality objectives which a (H)FMEA or modified version should satisfy in order to be effective. These objectives are based on years of experience with FMEAs at multiple companies and used in this research to evaluate the risk analysis methods on their effectiveness.

The objective of this research is to evaluate both methods on their effectiveness in healthcare. The HFMEA and modified versions are already applied in healthcare but still need to be evaluated extensively, since healthcare organization do not execute their risks analyses as they should (Habraken et al., 2009). In addition, it identifies and improves aspects of both methods for managerial implications. Especially in a high risk, complex and diverse hospital setting as the UMCG, safety and quality should be guaranteed and therefore applying an effective risk analysis method is a must. Evaluating whether interviews cover the same in-depth information and effectiveness as the multidisciplinary team meetings can therefore provide valuable information for literature and further research, since no such research is conducted on this topic to my knowledge.

Following this introduction a theoretical framework reviews the literature starting from risk

analysis in healthcare narrowing it down to the HFMEA and One Hour PRA. This literature review includes high risk industries, the team meetings versus interviews, the essence of a risk analysis and provides a framework for the findings. Furthermore, a questionnaire was conducted among participants of both risks analyses and among the coordinators and risk/quality managers aimed at investigating their feeling and attitude concerning both risk analysis methods. It also measured the realized improvements provided by the risk analysis. Interviews are added to gain an in-depth view of the opinions of the coordinators. Then a discussion and conclusion will summarize the findings and provide managerial implications.

1.1 RESEARCH QUESTIONS

The main research question in this research will be: ‘‘To what extent is the modified light version of the HFMEA as effective as a traditional HFMEA?’’

The sub questions are phrased as follows:

- How do both methods score on quality objectives related to conducting a prospective risk analysis?
- How do both methods score on team process?
- How do both methods score on overall process?
- To what extent are the improvements proposed by the methods implemented in practice?

2 THEORETICAL BACKGROUND

In this section an overview of the literature is provided. In the first section, 2.1, the background on risks and risk management is provided. Section 2.3 explains the application of FMEA in the healthcare industry is described. In section 2.4 the HFMEA model is described and the strengths and weaknesses are discussed. Section 2.5 addresses the modification of the HFMEA. The differences between team meetings and interviews are stressed in 2.6 and the quality objectives are described in 2.7.

2.1 RISK MANAGEMENT

A central aspect of every organizations strategy management is its risk management (Condamin, Louisot & Naim, 2007). Risk management is reducing and controlling the risks that arise or exist in a company (Cagliano, Grimaldi, &Rafele, 2015). It is a crucial component for success in modern business operations. A reason for this is that risks management helps to increase quality and saves time and costs by reducing failures. As described in the introduction, risks are uncertain events that may (negatively) impact the business or in this research the patient safety (Runciman et al., 2007). These risks need to be controlled, reduced and minimized where possible. However, before such actions can be taken the risks need to identified and assessed based on likeliness and severity (Hudson, 2003). This helps to prioritize the identified risks in order to determine which risks needs to be dealt with first.

The treatment of patients in a hospital environment is still a high risk practice (Hudson, 2003). Patient safety is related to the risk management of the organization in which they are treated (Kessel-Habraken et al. 2010). Vlayen (2011) defines managing patient safety as; ‘‘the way in which risks on unintentional harm to patients are assessed and handled in the organization that carries out the care’’. Moreover, the organization of care, the hospital, is responsible for the safety of their patients. Clancy (2006) stresses that the need for healthcare providers to acknowledge and assess potential avoidable risks of patients needs to evolve by reducing avoidable risks. In healthcare the risks that cannot be avoided are called adverse events. These events are unintended and can lead to disability, death or an extended hospital stay (Cagliano et al., 2011). Therefore identifying, controlling and reducing risks is an important and continuous process.

2.2 REASON’S MODEL

Reason’s theory about failures states that adverse events are not caused by a single error, but are in most cases the result of a chain of errors where the human error is often the weakest component (Reason, 2002). More specifically, the adverse event is the result of multiple elements in the process and not the responsibility of a single person or department. The model developed by Reason (2002) assumes that an adverse event can be prevented by barriers formed between the source and the person or process that needs to be protected. The barriers imply a complete set of preventive measures and actions taken to reduce or stop the adverse event (Cagliano et al., 2011). This process is more commonly known as the cheese model, due its Swiss cheese looking barrier shapes (figure 1). The holes in every ‘slice’ represent the errors that are weaknesses in de-

fenses to stop the adverse event from occurring. Here it is important to reduce the number of holes in the barriers or set-up more barriers to stop the adverse event from occurring (Barach, 2002).

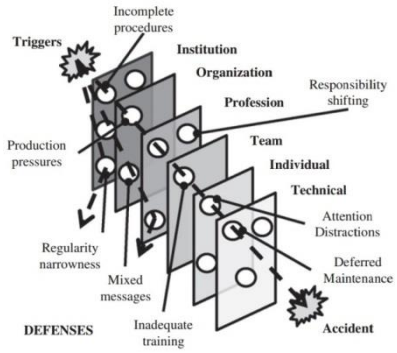

Figure 1. Reason's model (Barach, 2002)

Applying Reason's model into practice requires to identify, assess and reduce the errors and prevent the risks from occurring. According to Kessels-Habraken et al. (2010) these barriers can be set up using prospective or retrospective risks analysis tools. The first is dealing with risks before they occur and the latter implies setting up barriers after an incident occurred. Here the prospective nature of analyzing risk is preferred. One of the most commonly used methods for identifying and assessing risks before they occur is the (Health) Failure Mode and Effect Analysis (FMEA) (Habraken et al., 2009).

2.3 DEVELOPMENT OF FMEA IN HEALTHCARE

The FMEA was first developed by the aerospace industries in the 1950s to deal with potential avoidable risks (Hudson, 2003; Luo & Lee, 2015). In the aviation industry every potential failure or error that can occur might result in a catastrophic end (Marx & Slonim, 2003). Together with the aerospace industry other high risk industries such as the defense, automotive and oil and gas industry quickly adopted the FMEA to minimize and control their risks (Hudson, 2003; Luo & Lee, 2015). The healthcare industry much later borrowed the FMEA from the high risk industries, but it quickly became one of the most commonly used tool in healthcare (Franklin et al., 2012; Habraken et al., 2009; Vlayen, 2011; Velez-Diaz-Pallares et al. 2012; Luo & Lee, 2015). The FMEA method was in 2001 combined with ideas from Root Cause Analysis, Critical Control Point and Hazard Analysis by the US Department of Veterans Administration National Center for Patient Safety into the Healthcare FMEA (HFMEA) to identify and assess patient risks (Vlayen, 2011; Habraken et al., 2009).

2.4 HFMEA

As briefly discussed in the introduction section, the HFMEA is a prospective risk analysis which is necessary to identify, assess and improve safety in a high risk healthcare setting (Marx and Slonim, 2003). It is a systematical tool to categorize potential risks and examine those which need immediate in-depth action (Velez-Diaz-Pallares et al. 2012). Before the analysis is conducted, the HFMEA coordinators and supervisors describe the main processes and sub processes in sufficient detail and develop a process flowchart (van Tilburg, 2006). They also try to preliminary identify risks to help the participants. Next, a multidisciplinary team first reviews the described process and identifies all possible failures, errors and risks in this process (Habraken et al., 2009). When all team members agree on all the potential risks, the team determines the severity of the risk and the probability or fre-

quency of occurrence (Franklin et al, 2012). The product of these numbers then compute to a Risk Priority Number (RPN). This hazard score is used to determine the necessity to lower potential risks. The HFMEA Decision Tree tool guides this process. In most cases a 5 x 5 risk matrix is used to graphically display the failure modes (see appendix A, table 10). However, many possible versions of the risk matrix exist, e.g. 4x4, and what is used depends on users' preferences. The risk matrix guides the user to the importance of the action that should be taken (see appendix A, table 11). At last, the team determines the actions and controls that need to be taken, with the use of the risk matrix, to eliminate or mitigate the identified failures and errors (Habraken et al., 2009).

2.4.1 Strengths of the HFMEA

The HFMEA tool is a widely used prospective risk analysis tool used in high risk industries to identify potential risks and defects in products or processes (Marx & Slonim, 2003). One of the strengths of the model is its prospective nature, i.e. understanding and identifying risks before failures and errors actually occur. Waiting for incidents to occur, retrospective, to take action in a high risk environment can be fatal. Especially in a healthcare setting where patients are involved, identifying potential failures beforehand can save lives. Marx and Slonim (2003) also stress that a major strength of the HFMEA is its bottom up approach. More specifically, it starts asking questions about potential failures, than seeks the potential effects of the failures and tries to solve or minimize the failures before failures even occur. As discussed in the previous section, the HFMEA is conducted with the group meetings to raise discussion about potential failures or errors (Habraken et al., 2009). These group meetings are a key aspect in the HFMEA, since they provide input for identifying and assessing potential risks. Using a multidisciplinary team to assess potential failures helps in providing a comprehensive and diverse input. Moreover, as is stressed by Reason (2002) failures do not occur from a single error, but a chain of errors eventually will lead to a failure. In order to predetermine the failures that can occur all users, people that are responsible and that can affect the failure can provide valuable input to the risk analysis. When people that have an influence on the failure are left out it can be that some errors are not addressed and dealt with in the risks analysis.

2.4.2 Weaknesses of the HFMEA

These team meetings are at the same time a serious weakness of the HFMEA. Habraken et al. (2009) discuss that the duration of team meetings in their research was 1.5 hours per meeting. This is based on their research with 13 risk analysis conducted in the Dutch healthcare (Habraken et al., 2009). In other words, having several multidisciplinary team meetings of 1.5 hours is time consuming and thereby costly. Furthermore, in most cases more than one meeting is needed in order to fully cover all aspect of the HFMEA, normally three to four. The large amount of time for a HFMEA model to be conducted is one of the main weaknesses (Potts, Anderson, Colligan, Leach, Davis & Berman, 2014; Vlayen, 2011; Habraken et al., 2009; Franklin et al., 2012; Moyer, Singh & Finkel, 2010; van Tilburg et al. 2006). From a proportionality point of view one should consider whether time invested in a HFMEA procedure is justified by its results, economically and in terms of patient care. In 1,5 hours a HFMEA team also could have performed a routine surgical proce-

dure. Apart from that the planning and scheduling of team meetings has shown to be difficult in a healthcare setting (Brilstra and Kleve, 2014). Another limitation of the HFMEA is the complex method of mapping processes and assessing risks (Vlayen, 2011). In addition, Marx and Slonim (2003) and Vlayen (2011) stress that the HFMEA is mostly used on a local level without guidance of institutional experience to guide the process which limits the focus on safety issues due a poor direction and help from the coordinator of the HFMEA. Contributing to that, the HFMEA is not suitable for combinations of multiple risk points that can result in a potential failure due the focus on singular errors identification (Vlayen, 2011). Also, Brilstra and Kleve (2014) express that interrelationships between team members can affect the output of participants in a HFMEA analysis. In this way the possibility exists that some failures and errors are not fully or even completely addressed. Wreathall and Nemeth (2004) explain that tunnel vision and analyst bias can harm the results of the HFMEA. In other words, when the participant focuses too much on specific failures other potential errors or failures can be overlooked. Analyst bias is the participants' awareness and integrity that can influence the results since the participants unwillingly prefer a specific solution or situation.

Moreover, an interesting limitations which accounts for the HFMEA is the use of the RPN. The basis of the RPN is on one hand the perceived possible outcome and on the other hand a prediction of how likely it is for this risk scenario to actually result in the perceived harm. It is not that difficult to imagine a whole range of possible outcomes and classify these according to a 4 or 5 point scale. Assessing the likelihood is almost identical to predicting the future. The outcome of the multiplication is more or less an educated guess, far from precise. Keskin and Özkan (2009) argue in their paper that the calculation of the RPN is limiting the usage and application of the FMEA. As mentioned before, the RPN is, in most cases, determined by the product of the severity, likelihood and the detectability. Sometimes only the severity and likelihood are used. Furthermore, the limitation of the RPN is that it can mislead practitioners and thereby undermines potential important failures. E.g. a potential failures with severity 8 and likelihood of 3 (RPN: 24) is more important to deal with that a failure with severity 4 and likelihood 7 (RPN: 28). However, the RPN suggest that the second failure requires more priority and action as the first one. Concluding the variance of the ratings enables the FMEA to priorities less important and severe failures above failures that require immediate action (Keskin & Özkan, 2009). Marx and Slonim (2003) stress that when these limitations or weaknesses are taken into account one could believe that there is reason to believe that the HFMEA method falls short of meaningful results. Shebl et al. (2009) therefore stresses that healthcare organization should not solely rely on the use of the HFMEA in assessing patient safety.

2.5 MODIFICATION OF THE TRADITIONAL MODEL

Despite the strength of the HFMEA several modified versions are developed in the high risk industries to overcome its main weaknesses. Srivasta and Mondal (2014) write in their paper about a modified version that adds two more columns to its documentation. The average output and output range are included for determining the risks in machine and plant maintenance

operations. Likewise, Carlson (2012) introduces the Failure Mode Effects and Criticality Analysis (FMECA) as an modification that adds a critically number to the RPN to provide an even more detailed analysis. In addition, he stresses that many more variants exist based on the basic FMEA principles in order to fit to their own unique applications, e.g. FMEDA, FMMEA and RCM (Carlson, 2012). All these modified version are developed to fit in their own setting with their own participants. They all differ in application and steps to be taken, but all basic principles correspond to the FMEA to still guarantee success (Carbone & Tippett, 2004).

As mentioned, this research emphasizes on two HMFEA methods. As described in the previous section, the HFMEA has several weaknesses that limit the tool in its practice. For this reason the UMCG developed a light and quick HFMEA, the so called ‘‘One hour Prospective Risk Analysis (One hour PRA). As with other modified versions, the One Hour PRA is brought to life to remedy several disadvantages of the HFMEA and to fit its unique hospital setting. The model is developed to deal with the planning and scheduling problems, due to immediate job-related responsibilities, i.e. the treatment of patients. It also accommodates the inter-relationship between team members which could bear on their output (Brilstra and Kleve, 2014). The One hour PRA is different from the traditional HFMEA to the extent that it makes use of interviews instead of multidisciplinary team meetings to identify and assess risks. In this technique professionals are invited to one-on-one interviews with the coordinators to collect potential failures or errors beforehand. The risk assessment phase is also individually conducted with the professional. At last, the evaluation and improvement phase is carried out in one multidisciplinary team meeting, similar to the traditional HMFEA, to ensure comprehensive and diverse in-depth input. In addition, with the One Hour PRA the participants propose as list of 9 improvements; 3 extremely urgent, 3 less urgent, 3 quick wins (Brilstra and Kleve, 2014). This differ from the HFMEA were the RPN is used as grip to assess which improvements to implement first. The modifications to the traditional HFMEA are to limit the time-consuming meetings to one team meeting and to eliminate negative influences of inter-relationships between professionals. However, as mentioned by Carlson (2012) and Carbone & Tipper (2004) the modifications of the FMEA should fit the unique situation and make sure that the basic principles of the FMEA are safeguarded. The emphasis therefore is to assess whether the One Hour PRA has not deviated too much from the original concept to the extent that validity and success of the analysis are diminished.

2.6 TEAM-MEETINGS VERSUS INDIVIDUAL INTERVIEWS

An important difference between the two methods is the way in which information is gathered. Although the interviews give in-depth information and minimize scheduling and planning, it is to be argued whether it provides the same amount of valid and diverse information as the dialogue in team meetings. Literature about organizational behavior clearly explains that groups make better decisions than the combination of individuals do (Stasser & Dietz-Uhler, 2001). This is due more polarized judgments, group interactions and a combination of social influences and cognition perspectives that lead to more thorough and in-depth decision-making (Stasser & Dietz-Uhler, 2001). Levine and Moreland (2006) describe three arguments

why individuals make better decision when they are formed into groups namely; (i) groups are better in defining the relevance of problems than individuals, (ii) group decisions are most of the time more unbiased because of exposure of individuals to interaction within the groups and (iii) decisions made in groups obtain more support and have therefore more success in implementation. Argote and Ingram (2000) add to this stating that benefits from groups arise because performance will increase due the presence of others and the dialogue between members. At last, Guerrero and Bradley (2012) investigated the group versus the individual performance in the FMEA. They discuss that in some cases the participants are geographically not able to physically meet, therefore carrying out the FMEA individually. Their findings show that group performance in the FMEA appears to be superior to performance of individuals. Group performance in the FMEA leads to significantly less variation in output. This relates to this research to the extent that it shows that group performance is considered to be more effective and have a greater performance than the combined input of individuals'.

In contrast to that, team meetings also have several well-known weaknesses. Groupthink is a major weakness in the decision-making process of groups. Groupthink is the pressure of individuals towards conformity in the presence of a group (Sims & Sauser, 2013). This limits the individuals their own judgments and expressions what can lead to bad decision-making. Moreover, group polarization is another weakness when participating in a team. This implies that the decisions made by a team are more extreme than when the participant is alone (Rao & Steckel, 1991). Group polarization affects the effectiveness of the meetings, due wrong decisions being made. Individual performance is thereby better when there are cultural differences in a process (Saab, Cleveland & Ho, 2015). Having a group of people with major differences in culture blocks the performance of the whole group. This is an interesting statement, since a hospital is known for its social and culture differences between departments and specialism (Kronenfeld, 2010).

2.7 QUALITY OBJECTIVES

Besides investigating the differences in effectiveness between team meetings and individual interviews a (H)FMEA, the risks analysis effectiveness depends on meeting its quality objectives. Carlson (2012) observed many organizations performing (H)FMEAs and thereby making a variety of mistakes that occurred repeatedly. Based on this judgment he developed 10 quality objectives that a (H)FMEA has to meet in order to be effective (see table 1). These can be assessed by a questionnaire conducted after the (H)FMEA took place (Carlson, 2012). Namely, Carlson stresses that the main objective of the FMEA is the process towards identifying risks. In other words, being aware of the risks that are present and together think of improvement to reduce them by being able to express ones feelings and opinions (Carlson, 2012). This is an interesting thought since it provides a clear, but abstract, goal to assess a risks analysis on its effectiveness. Assessing a risk analysis on its output is almost, maybe completely, impossible (Franklin et al., 2012). One can never know all the risks. In addition, prioritizing and providing the risk with a RPN has a subjective nature. The objectives of a risks analysis developed by Carlson (2012) is used in this

research to determine the effectiveness of the HFMEA and One Hour PRA, because it provides insights in what user think of the methods. Assessment based on user-feedback provides insights in the process of being aware of risks and finding ways to control them.

No.	Quality objective
1	Improvements are the primary objective
2	Addressing all high risks modes with appropriate actions
3	Indicators to measure the improvements are developed
4	The 'lessons learned' are used as input for the risk analysis
5	The risk analysis provides the sufficient level of detail and characteristics of the process
6	The risks analysis is conducted at the right time in order to be most efficient
7	The right people participate in the risk analysis
8	The participants have sufficient knowledge of the risk analysis method
9	The improvements are achievable for the responsible people
10	The time invested by the team is used effectively and efficiently with value-adding results

Table 1: Quality objectives (Carlson, 2012)

3 METHODOLOGY

In this section the methodology of this research is described. The first point that is addressed is the research design used to evaluate the effectiveness of the two prospective risk analyses methods. After that, the setting of the research is discussed followed by the data collection and data analysis.

3.1 RESEARCH DESIGN

A descriptive case-study at the UMCG is conducted by means of interviews and questionnaires to obtain in-depth data from coordinators and user-feedback from participants. This due the descriptive natures of this research. Much data in case-studies is collected through interviews; it gathers in-depth, flexible data and has the ability to improve hard to reach populations (Voss, 2009). To evaluate the application of both methods and to gather data about the experiences interviews with coordinators are conducted, these are the different cases in this study. The coordinators of both the HFMEA and the One Hour PRA were interviewed with the use of an interview protocol. Furthermore, the case study made it possible that both methods were investigated in their own setting (Voss, 2009). The interviews captured the differences between both models and discussed preliminary results obtained from the user-feedback questionnaires. These questionnaires highlight the quality objectives by Carlson (2012), the team process, the overall process and other descriptive information. At last, the coordinators were asked to fill in a questionnaire that focused on the output of the risks analyses. Namely, the improvements and whether these improvements are implemented and if not, why not. These instruments combined provide an extensive framework to answer the research questions.

3.1.1 MEASURING EFFECTIVENESS

As mentioned previously, the UMCG is a complex organization where departments are mostly self-contained. In addition, the HFMEA process and One Hour PRA are slightly changed and adapted to the needs of every departments in the hospital. This makes measuring the effectiveness complex but interesting. This research therefore conducts interviews with the coordinators of both risk analyses complemented with a questionnaire distributed among participants. The definition of effectiveness is operationalized as follows to measure the effectiveness of both risk analysis;

- Effectiveness is measured in terms of user-feedback. How do both methods comply with the quality objectives (Carlson, 2012), the complete process and team or individual performance assessed?

The three variables overlap each other on several aspects. This provides in thorough evaluation on these aspects in different perspective (e.g. team process and overall process). The improvements questionnaire thereby aids the quality objectives in assessing the methods.

3.2 SETTING

The questionnaires are conducted throughout multiple departments in the University Medical Center Groningen. The UMCG is the largest

healthcare provider in the north of the Netherlands. It provides specialized care to patients and strives to be a leading academic hospital (UMCG, 2014). Some highly complex treatments are nowhere else performed in the Netherlands but in the UMCG. Safety and risk control are paramount in their operations in order to achieve and maintain the highest possible level of care. Especially due to the innovative and complex nature of the hospital it is important to continuously assess the risks that are abounded with it since some aspects and equipment are used for the first time. The high risk healthcare environment of the UMCG can therefore provide valuable data about how effective the prospective risk analyses are used.

3.3 DATA COLLECTION

For this research primary data is gathered by means of interviews with the coordinators and questionnaires distributed among participants. In the UMCG every department is responsible for the assessment of risks in their operations. Therefore every department has its own quality manager(s) to coordinate the risk analyses. The coordinators of different departments throughout the hospital were contacted by means of telephone and email to see if they were willing to be interviewed. Their names were gathered with the use of the risk manager of the UMCG who helped finding the right people. The interviews were scheduled based on the availability of the coordinators and were conducted at their own offices in the Dutch languages. In the end, twelve coordinators responded to the invitation and were interviewed. Each interviewed lasted approximately 20 – 30 minutes and was recorded by mobile phone. The coordinators helped in distributing the user-feedback questionnaire among the participants of both risks analyses. The questionnaires were distributed hospital wide to a variety of departments to capture the most feedback from participants. In addition to that, coordinators of both the HFME and One Hour PRA were asked to fill in an questionnaire concerning the implementation of the improvements.

3.3.1 SAMPLE

The sample of this research consists out of the coordinators and multidisciplinary team members that participated in the risks analysis, either the HFMEA or the One Hour PRA. This in order to provide a complete perspective of the opinions and feelings of the participants in the analysis. In this way many departments and functions are represented in the research. For the interviews and the improvements questionnaire the different coordinators from different departments represented the sample, where the latter focuses if improvements are indeed implemented. This is done in order to capture the cultural differences at each department. As Kronenfeld (2010) explains; there are many social and cultural differences between the departments in a hospital. By capturing all departments the generalizability of the results in increased.

The sample size of the questionnaire is however a major concern in this research. Making sure that especially nurses and doctors, professionals, participate in this research by filling in the questionnaires is difficult. As is mentioned that planning and scheduling meetings for the HFMEA is hard due to the fact that medical personnel their main concern and job is the treatment of patients, filling in the questionnaire is secondary.

3.3.2 INSTRUMENTS

The interviews were conducted with the use of an interview protocol (appendix C) to ensure validity of the instrument. This protocol consisted out of 8 open questions which contained questions about experience of the coordinators with both models and questions that addressed preliminary results obtained from the questionnaires. Every interview was recorded by mobile phone to capture the complete interview.

In addition, the instruments that are used for this research are two questionnaires distributed among employees of the UMCG with the use of the online questionnaire tool Qualtrics. The first questionnaire is the quality questionnaire which is distributed to the participants of both risk analyses. This questionnaire focusses on three main variables, namely;

- The quality objectives defined by Carlson (2012)
- The team process during the risk analysis (Wetterneck, Hundt & Carayon, 2009)
- Their perception about the overall process of the risk analysis (Habraken & van der Schaaf, 2015)

All the questions used to address the topics displayed above are used in previous research before, except from the questions about the quality objectives (Carlson, 2012). Unfortunately, the questions are not validated, which is a limitation in this research. Next to this, a questionnaire concerning the degree of completion of proposed safety constraints is developed. In this questionnaire the coordinators of the risk analysis are asked to name five improvements for each of the risk analysis that is done and indicate whether these improvements are carried out and if not, why not.

3.4 DATA ANALYSIS

A cross-case analysis is used to search for patterns between departments and between the HFMEA and One Hour PRA. To analyze the data that is gathered by means of interviews and questionnaires it is first documented and organized to structure the information. As mentioned previously, the interviews are recorded which enables the researcher to carefully re-listen the interviews over and over again. Notes are made about the first impressions of every interview. After that, the interview are re-listened again and coding is used. This made it possible to reduce the data and establish a chain of evidence (Miles & Huberman, 1994). The quality objectives, the characteristics of the team process and overall process are applied as descriptive codes (see table 2). Moreover, quotes from the interviews are matched with the codes per risk analysis methods, HFMEA and One Hour PRA (Hyde, 2000). After all interviews are re-listened several times to see if every quotes is gathered, the quotes are assessed on a positive, negative or neutral criteria. More specifically, this meant that every quotes is reviewed on its relation to the code, see if the quotes implies a positive, negative or neutral statements with regard of the code.

Source	Codes
Carlson (2012)	*Realizable Improvements*
	Appropriate actions
	Indicators of improvements
	Lessons learned
	Detailed process
	Right time
	Right people
	Knowledge of participants
	Achievable improvements
	Effective time-management/ time investment
Wetterneck et al. (2009)	*Team functioning*
	Feeling comfortable
	Understanding of others/ New insights
	Team process direction
	Personal contributions
	Opinion expressing
	Different job functions
	Opinion pushing
	Overall effectiveness
	Useful meetings
Habraken & Van der	*Helpful risk analysis*
Schaaf (2009)	*Safer process*
	Recommendation to others
	Willingness to participate
	Incident reporting
	Determining risks
	Planning

Table 2: Descriptive codes

After the descriptive codes have been developed they are further grouped with the use of the input-process-output model (IPO). Sales et al. (2008) explains that the use of a IPO model is a prevailing framework to describe a team performance. That is exactly what is done in this research, the performance throughout the analysis. This type of grouping is also used in Wetterneck et al. (2009) to reduce the information. The IPO framework describes the factors that are present and needed to start a process, during a process and deliver the outcomes and provides grip to analyze the data. It helps to analyze the in a structured manner and allows a chain of evidence to be established (Voss, 2009). The input, process and output is used to describe the aspects of the methods throughout the analysis, e.g. the input takes cares of all aspects, such as planning, needed in preparation of the risk analysis. An exception is being made concerning the team process variable. All codes in this variable are concerned with the process in the IPO framework, therefore the following grouping codes are used; team process, communication and inter-relationships. These are determined

by looking at the statements of the coordinators.

Because the online questionnaire tool Qualtrics is used to conduct the questionnaire the data analysis process is for the large part already done by the tool itself. It provides the researcher with the mean, standard deviation and many more descriptive statistics. In addition, the questionnaires hold information about the type of risk analysis, title, date, function of participant and department. This helps to structure the data and systematically display the information.

3.5 RELIABILITY AND VALIDITY

In order to ensure the construct validity in this research multiple sources of evidence are used, i.e. literature, interviews and questionnaires. In addition, the case study design was review by the risk manager of the UMCG. Voss (2009) suggest to conduct pattern matching in the analysis to increase the internal validity of the research. This pattern matching and cross-case analysis is adapted in this research. The external validity of this research is a point of interest. The UMCG provides an extensive practical case due the complexity size and high risk environment. However, since only the UMCG is used the external validity of this research is not completely guaranteed. The reliability is ensured by means of an interview protocol and by recording the interviews. In addition, the questions in the questionnaires were already used in previous research.

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4 RESULTS

In this chapter the results from the interviews and the questionnaire are reported. First the descriptive information is provided concerning the participants and processes that are investigated. After that the data from the interviews and questionnaires are combined to determine how they related with the codes that were developed. The data is reported sequentially to first the quality objectives, the team process and the overall process. In every topic the interviews are used to provide in-depth information and the questionnaire is used to support these findings.

4.1 DESCRIPTIVE STATISTICS

After approaching the coordinators of both the HFMEA and the One Hour PRA 16 responded to help to distribute the questionnaires among the participants. From the coordinators who were approached one person replied too late in order to assist. Therefore, the response rate of all coordinators is 94%. This high response rate is probably due to the fact that all coordinators saw the potential benefits in researching both risk analysis methods. The coordinators distributed the questionnaire among participants of the HFMEA and/or the One Hour PRA. It is therefore hard to review what the response rate of the questionnaires participants is. However, in the end 25 people responded, whereby three respondents did not mentioned if they took part in a HFMEA or One Hour PRA which made it impossible to include those responses. To summarize, 22 completely filled in questionnaires were obtained. The number of respondents can be attributed to the fact that in most cases the risk analyses involved professionals whose primary concern and task is the treatment of patients. As can be seen table 3, the respondents for a large part consisted of staff employees. The coordinators and the researcher therefore had to depend on the goodwill of the respondents. Table 3 presents the descriptive statistics of all 22 questionnaires. From the table it can be seen that 10 respondents participated in a One Hour PRA analysis and 12 were part of a HFMEA analysis. The number of participant in both analyses ranged from 3 – 20 with a mean of 7.6 for the One Hour PRA and for the HFMEA the number of participants ranged from 2 – 17 with 8.4 as the mean. Interesting to see is that in none of the analyses a patient was invited to participate, since Habraken et al.(2015) explains the added value of patient involvement. In addition, the participants of a One Hour PRA were less likely to be completely present during a meeting than the participants of a HFMEA, respectively 4 and 2 times.

ID(n)	Type of risk analysis	Healthcare process	Function	Amount of participants	Patiënt as participant
1	One hour PRA	Lung transplant process	Riskmanager	7	No
2	HFMEA	EVLP	Riskmanager	5	No
3	HFMEA	Information systems obstetrics	Riskmanager	17	No
4	One Hour PRA	Purchasing process	Manager	6	No
5	HFMEA	Leadless pacemaker implantation	Nurse	8	No
6	HFMEA	Thopaz drainage	Headnurse	7	No
7	HFMEA	Hybrid AF	Master Physician assistant	16	No
8	HFMEA	Respiratory equipment	Specialist nurse	6	No
9	HFMEA	Thopaz drainage	Senior nurse	7	No
10	HFMEA	Generic care pathway	Nurse	9	No
11	One Hour PRA	-	Staff	3	No
12	One Hour PRA	Device for mechanical chest compressions	Nurse	3	No
13	One Hour PRA	MIE	Staff	20	No
14	One Hour PRA	Care pathway liver transplant	Nurse	-	No
15	One Hour PRA	False detections	Staff	6	No
16	One Hour	MIE	Anesthesiologist	-	No

	PRA				
17	One Hour PRA	Tubefixation	Nurse	8	No
18	HFMEA	Magnetic Resonance Imaging (MRI)		2	No
19	HFMEA	Primary processes	Manager	10	No
20	HFMEA	Radiology	Laborant	8	No
21	HFMEA	Primary processes	Laborant	6	No
22	One Hour PRA	MIE		-	No
		Mean HFMEA		8.4	
		Mean One Hour PRA		7.6	

Table 3: Descriptive statistics of the questionnaire

Furthermore, table 4 provides information about the output of both methods. It describes that a filled in matrix was 10 times the end product of a risk analysis with regard to the HFMEA and 7 times for the One Hour PRA. This difference can be due to the variation in the number of respondents between both methods. In addition, it shows that documentation was mentioned three times for the HFMEA and four time concerning the One Hour PRA. Other output include; the decision to not proceed with the implementation, insights in the investigated process, improvements documentation, and as one respondent stats 'A lot of administration, that could have been prevented with normal reasoning and thinking'. This shows there is little variation in output of both methods and provides input for the documentation objective of Carlson (2012). Table 5 shows that interestingly 5 respondents thought the HFMEA took too much times to conduct against only one respondent for the One Hour PRA. Besides, one respondent was of the opinion that the analysis was too short.

With the interviews a 100% response rate was achieved. All the 13 coordinators that were approached by e-mail and telephone were willing and had the time to be interviewed. The interviews on average took approximately 23 minutes to complete and in three cases two coordinators were interviewed simultaneously, resulting in 9 conducted interviews.

Question	HFMEA				One Hour PRA			
	Filled in risk matrix	Documentation of the analysis	Something else	Total responses	Filled in risk matrix	Documentation of the analysis	Something else	Total responses
What did the risk analysis delivered?	10 (91%)	3 (27%)	2 (18%)	11	7 (78%)	4 (44%)	3 (33%)	9

Table 4: Deliverables of a risk analysis

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Question	HFMEA				One Hour PRA			
	Good	Too long	Too short	Total responses	Good	Too long	Too short	Total responses
The time spent on the risk analysis was	7	5	0	12	8	1	1	10

Table 5: Time spent on a risk analysis

4.2 DATA ANALYSIS

In order to determine the effectiveness of both risk analysis methods the output of the qualitative data analysis is reviewed on the relationship between the outcomes for the HFMEA and the One Hour to see whether the statements in the interviews and the data obtained from the questionnaires provide an answer to each; quality objectives, team process and overall process. The complete qualitative data analysis can be found in table 12 (Appendix B). Due the small number of respondents of the questionnaire no test could have been carried out (Forza, 2009). The questionnaires therefore supports the interviews and provides descriptive statistics.

4.2.1 QUALITY OBJECTIVES

There is not much variation in the type of responses concerning the ***input*** grouping code for both methods. Both methods use information from previous analysis and manuals from manufacturers as input for the risk analysis ('you use the outcomes as evaluation for the next analysis'). One respondent thereby indicated she prefers the HFMEA if there are already some risks known that are present in the process ('the HFMEA is preferred if you already know certain risks in a complex process'). Furthermore, the respondents described that there is much importance in conducting a HFMEA or a One Hour PRA at the right time. However, they also state that you at least need to know some of the potential risks ('The basics of risks analysis is that you at least know something of the potential risks'). It is thereby mentioned that in one case people ultimately realized conducting at least a One Hour PRA beforehand would have been suitable ('Finally they realized it was maybe a good idea to have conducted at least a One Hour PRA beforehand'). The questionnaire also shows that participants scored a little different on the right time quality objective, 3.25 for the HFMEA and 3.70 in case of the One Hour PRA (see table 6). The coordinators showed different opinions when the needed knowledge of the participants was discussed. One respondent indicated that the One Hour PRA was simple to understand ('for the people involved the method is relatively simple to understand'). Another respondent explained that participants certainly need some knowledge about the method ('It is definitely a requirement that you have knowledge of the complete process and method'). This is stated likewise for the HFMEA. The ***process*** code indicated that both methods describe the researched process in detail during the analysis. Moreover, two coordinators stressed that a HFMEA could contribute more, because every step of the process is analyzed by a multidisciplinary team ('A HFMEA could add more because you go through every step of the process'). In case of the One Hour PRA this process is done with one participant ('I first, in detail discussed the whole process with a doctor'). Table 5 shows that participants indicate that the HFMEA better provides the right amount of detail than during a One Hour PRA (respectively 4.42 and 4.00). The process of both methods is furthermore described by one of the respondents that the HFMEA is a preferred method due to the fact that it places more emphasis to all the people that are involved ('…a preferred method because it places more emphasize on the groups that are affected by the process'). Besides that, the respondents indicated the importance of having the right people involved in the risk analysis ('It has everything to do with the right time and target people; because you approach the right people for the analysis, you know that they have the experience to makes sure risks can be reduced'). The process is concluded with different statements about the ef-

fective time-management for both methods. With regard to the HFMEA only negative statements were found. The method is described as a time consuming analysis ('the discussions do not always contribute in comparison to the time investment'). Contrary, the respondents positively explained that to conduct a One Hour PRA less time is needed ('An advantage of the One Hour PRA is that you need less time'). This variation is supported by the questionnaire, table 4 and 5 show the different opinions of the respondents concerning the time spent for both methods. The ***output*** factors of both methods explain that improvements suggested by the HFMEA were sometime hard to implement ('Some are more difficult to implement as others'). In addition, a coordinator described that in one case an action was suggested that people were not able to implement ('a lot of people were not used working with this particular high risk instrument'). Looking at the One Hour PRA it was stated that a negative aspect of the method is that not all most important risks are treated, it primarily focusses on what the participants think is best and urgent to improve ('The focus on the three most important problems and risks only. Personally I do not think that does justice to other risks'). Moreover, the questionnaire describes that the One Hour PRA is preferred when it comes to indicating measurements for the improvements, showing a higher mean than the HFMEA(see table 6). The interviews pointed out that the coordinators all made sure that the improvements were in fact executed in both methods. They indicated that a risk analysis is only finished when all improvements are implemented ('…finished when all suggested improvement are implemented').

Question	HFMEA			One Hour PRA		
	Mean	Standard deviation	Total responses	Mean	Standard deviation	Total responses
The risk analysis delivers enough realisable improvements	4.08	0.79	12	4.00	0.82	10
The risk analysis treats all high risks with effective and executable actions	3.92	0.79	12	3.90	0.74	10
The indicators for measuring the effectiveness of the improvements are established	3.33	1.23	12	3.95	1.33	9
Previous process improvements and 'lessons learned' are taken into account	4.00	0.95	12	3.90	1.37	10
The risk analysis provides the right amount of process detail to determine the risks and improvements	4.42	1.00	12	4.00	0.67	10
The risk analysis was conducted at the right time	3.25	1.36	12	3.70	0.95	10
The right people took part on the risk analysis	4.25	0.97	12	4.30	0.48	10
The participants had the right knowledge to conduct the risk analysis	4.17	1.03	12	4.10	0.57	10
The suggested improvements are feasible	4.17	0.83	12	4.20	0.42	10

The time spent on the risk analysis is effectively used	3.25	1.42	12	3.70	1.06	10

Response scale (1 – 5): Completely disagree – Completely agree

Table 6: Questionnaire output quality objectives

4.2.2 TEAM PROCESS

Different from the quality objectives and the overall process, the team process codes are grouped into the codes; team process, communication and inter-relationship. This is done because the statements about the team process all concerned the process stage in the IPO-model. The ***team process*** code was expressed differently for both methods during the interviews. It can be made clear that many of the coordinators saw the added value of team meetings to assess risks. They explain that during team meetings you are affected by the opinions of others resulting in better ideas (…'the added value of getting together during a HFMEA'; during the meetings not only you are influenced by other people around you, you also get ideas from the interaction'). Thereby, the coordinators saw a disadvantage for the One Hour PRA since diverging opinions and working individually can affect the process and outcomes ('a disadvantage of the One Hour PRA is that you work very individually and therefore focusing too much on a single process during the team meetings'). The questionnaire thereby shows a slight variation between the HFMEA and One Hour PRA in team functioning, respectively 4.08 and 3.80 (see table 7). Furthermore, both methods focused on change and patient safety during the process ('everybody was prepared and focused to improve patient safety'). A respondent also mentioned that when conducting a HFMEA groups can be too big in order to be effective ('…large groups can be less effective') and the participants cannot do their primary work tasks when participating in a risk analysis ('it takes a lot of time to conduct team meetings, during that all participants cannot work on their primary tasks'). The grouping code ***communication*** shows that, according to the coordinators, during a HFMEA and a One Hour PRA the participants had the opportunity to give their personal contributions. In both methods the coordinators made sure that even when someone did not say anything during the meeting the person could express himself after the meeting ('Afterwards I always ask people who did not had a chance to say anything if they still have some interesting points'; I made sure that everybody had the opportunity to tell their story'). The questionnaire shows that participants for the HFMEA scored 4.42 on the statements if they could contribute and participants of the One Hour PRA 4.20. Moreover, the coordinators explained that all of them never experienced that a participant was not able to express his or her opinion ('Never experienced that people do not want to express their opinion in a group meeting'). Besides that, a respondent stressed that a One Hour PRA could be preferred if there would be people that have problems speaking in group meetings. During this One Hour PRA they experienced people with an outspoken opinion but that did not affect the overall risk analysis process and outcomes ('There were people who had an outspoken opinion, but because we were together we were able to discuss about it'). During a HFMEA this was not experienced but coordi-

nators repeatedly stated that they expected that the team would then intervene ('…I think the group will correct that person'). The questionnaire shows that participants slightly agreed more if someone in the group pushed hard their opinion for the HFMEA (3.00) then in case of the One Hour PRA (2.80). ***Inter-relationships*** between participants did not affect the meetings according to the coordinators. One respondent mentioned that during a One Hour PRA it is told to take in mind that everybody is equal during the meetings ('as a starting ritual I always tell them we are all equal in this meeting, but we have the expertise of all our different job functions'). The same respondent expressed that during the One Hour PRA the department realized how their actions affected other departments. This was also experienced during the HFMEA since the meetings were an eye-opener to some people ('That was a complete eye-opener for the other department'). In addition, it helped to bring across the size and scope of the process ('People finally realized the magnitude of the problem…'; 'you become aware of each other's problems'). Finally, a coordinator expressed: 'I think the group process in a HFMEA works inspiring, you look into each other's working habits'). However, the participants feedback showed that the HFMEA scored a 3.42 on the statement if they got a better insight in each other work and the One Hour PRA 3.80.

	HFMEA			One Hour PRA		
Question	Mean	Standard deviation	Total responses	Mean	Standard deviation	Total responses
The team functioned properly	4.08	0.9	12	3.80	0.92	10
I felt comfortable during the team meetings	4.67	0.49	12	4.10	0.32	10
I got a better understanding of the work of other team members after the participation in a multidisciplinary team	3.42	1.38	12	3.80	0.92	10
The team process led directly to the goal of the risk analysis	3.50	1.17	12	3.60	0.97	10
My contributions during the team meetings were	4.42	0.51	12	4.20	0.42	10

Question	HFMEA			One Hour PRA		
	Mean	Standard deviation	Total responses	Mean	Standard deviation	Total responses
taken into account						
I was able to express myself during the risk analysis	4.58	0.51	12	4.50	0.53	10
Differences in job function did not affect my opinion	4.42	0.67	12	4.22	0.67	9
I experienced that some participants pushed hard to promote their opinion and points of view	3.00	1.48	12	2.80	1.40	10
The overall effectiveness of the team during the risk analysis was good	3.92	0.9	12	3.90	0.99	10

Response scale (1 – 5): Completely disagree – Completely agree

Table 7: Questionnaire output team process

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4.2.3 OVERALL PROCESS

Like the quality objectives, the overall process codes are subdivided with the use of the IPO-model. The grouping code ***input*** related different to both methods. The most discussed topic during the interviews is related to the planning sub-code. The planning and scheduling of the meetings have been referred to as the most difficult aspect of doing risk analysis. For the HFMEA 11 negative statements were found in the interviews. These statements addressed how hard it is to arrange a meeting for a multidisciplinary team who has other tasks then a risk analysis ('A disadvantage of the HFMEA is to get a complete group together'). In addition, when a person cannot attend the HFMEA, the meeting sometimes has to be re-scheduled, making it even harder to conduct ('we re-schedule the meetings when important people cannot be present'). Opposite to that, the coordinators were more positive about scheduling a One Hour PRA. Arguments included; 'a better method in a sense of logistics'; 'It is very easy to see people for a short time'; With the One Hour PRA we could easily fit in the interviews in between other primary tasks'. However, the coordinators also mentioned that with the One Hour PRA the time investment is transferred from the participants to the coordinators ('If I need to interview 10 people it will take me a month'). One respondent could not see improvements in planning with the One Hour PRA ('I cannot see the added value of scheduling with the One Hour PRA'). Furthermore, coordinators explained that

they experienced that in both methods most participants were willing to participate due to the fact that it concerned their own processes and equipment. On the other hand, a coordinator mentioned that it still is a necessary evil for some people ('… it still is a necessary evil'). One respondent combined the willingness to participate with the scheduling factors, expressing that scheduling becomes more difficult every next time ('To get people together one meeting is not a problem. But to get everyone together the next time is difficult'). The ***process*** code shows that there exist variation in the statements of coordinators concerning the methods. In relation to the HFMEA the coordinators indicated that the supervisor should guard the meeting to make sure the discussions are aimed at the goal ('as supervisor your job is to make sure the meetings are useful and discussions do not digress'). The One Hour PRA was thought of being frivolous meetings, placing stickers on poster. On the other hand, two coordinators mentioned that the end-meeting was indeed very useful ('With the One Hour PRA I did not experienced that meetings were useless'). The questionnaire describes less variation between the methods (see table 8). ***Output*** for both methods is aimed at improving the safety of the process. The HFMEA should thereby be used if there are major patient risks involved as is argued by two coordinators ('When there are major patient risks, one should conduct a HMFEA, because it is more extensive'). The questionnaire shows the participants of the HFMEA scored 3.83 on the statement that the process became safer and the One Hour PRA 3.70. Moreover, one respondent questioned whether an extensive HFMEA was necessary if there is only a small change in working habits. Another coordinator supported this by explaining that if the method is used for small processes it can be time-consuming ('I am afraid that because we also focus on small processes the time to implement will increase').

	HFMEA			One Hour PRA		
Question	Mean	Standard deviation	Total responses	Mean	Standard deviation	Total responses
The meetings were useful	4.17	1.19	12	4.00	0.82	10
The risk analysis was meaningful	4.08	1.08	12	4.10	0.99	10
The investigate process is safer after conducting the risk analysis	3.83	1.11	12	3.70	0.95	10
I obtained other insight thanks to the risk analy-	4.25	1.14	12	3.90	1.10	10

Question	HFMEA			One Hour PRA		
	Mean	Standard deviation	Total responses	Mean	Standard deviation	Total responses
sis						
I recommend other to participate in a risk analysis	4.17	1.11	12	4.30	0.67	10
Participating in a risk analysis was fun to do	3.83	1.11	12	3.80	1.23	10
I will certainly join a next risk analysis	4.08	1.08	12	4.00	1.05	10
I will report incidents sooner as a result of participating in the risk analysis	3.25	0.97	12	3.50	1.35	10
It is easy to determine the likeliness of a risk	2.58	1.24	12	2.50	1.27	10
The result of the risk analysis does not outweigh the time investment	2.75	1.71	12	2.00	0.67	10
The risk analysis was easy to plan in my schedule	3.00	1.34	11	3.50	1.08	10

Response scale (1 – 5): Completely disagree – Completely agree

Table 8: Questionnaire output overall process

4.3 IMPROVEMENTS QUESTIONNAIRE

The improvements questionnaire collected from the coordinators resulted in 10 responses with regard to the improvements of the HFMEA and only three responses concerning the One Hour PRA. This makes it almost impossible to conclude anything from these findings. However, it can be seen from table 9 that the time to conduct a One Hour PRA (mean 19 hours) for the coordinators took much more time in comparison with the HFMEA (mean 5.6 hours). In addition, the results does not show any particular differences in implementing the improvements between both methods.

ID	Type	Time investment (hours)	Improvement 1	Improvement 2	Improvement 3	Improvement 4	Improvement 5
1	HFMEA	6	In progress	In progress	In progress		
2	HFMEA	6	Completed	Completed			
3	HFMEA	5	Completed	Completed	Completed	Completed	Completed
4	One Hour PRA	25	Completed	Completed	Completed	Completed	In progress
5	HFMEA	9	In progress	In progress	In progress	Completed	Not started
6	HFMEA	3	Completed	Completed	Completed	Completed	
7	HFMEA	1	Completed	Completed	Completed	Completed	Completed
8	One Hour PRA	15	Completed	Completed	Completed	In progress	
9	One Hour PRA	17	Completed	In progress	Completed	Completed	
10	HFMEA	6	Compelted	Completed	In progress		

11	HFMEA	4	Completed	Completed	Completed	Completed	Point of interest
12	HFMEA	4	Completed	Almost completed	Completed	Completed	Completed, not running optimally
13	HFMEA	12	In progress	In progress	In progress	In progress	In progress

Table 9: Output improvements questionnaire

5 DISCUSSION

The interviews combined with the user-feedback questionnaire and the improvements questionnaire provide valuable insights in the objective of this research to compare the modified light version of the HFMEA with the traditional HFMEA. This research is aimed at evaluating how both methods score on different aspects of the risk analysis process. Moreover, the output of the qualitative data analysis and questionnaires are investigated on patterns that exists between practice and literature.

Sub question 1: How do both methods score on the quality objectives?

As is described in the results section of this research, both methods scored relatively similar on several quality objectives, including output oriented aspects. This concerns the interviews with the coordinators but also the questionnaires distributed among participants. However some interesting points were discovered when the quality objectives were compared. The One Hour PRA was brought to life to cover several disadvantages of the HFMEA including its time-consuming nature (Brilstra & Kleve, 2014). The results indicate that the coordinators indeed were of the opinion that the One Hour PRA could be conducted in less time as the HFMEA, thereby making it more attractive for busy working professionals. This was confirmed by the information gathered from the participants who expressed the less time-consuming nature of the One Hour PRA. According to the interviews the HFMEA approximately uses three meetings averaging 1.5 hours per meeting. This assumes an average of 4.5 hours is spent on all meetings. If the time for preparation (0.5 – 1 hour) is added the time easily adds up to 5 á 6 hours. The One Hour PRA only uses short interviews, on average 0.5 hours, and one end-meetings of 1 to 1.5 hours. Adding the preparation time results in maximum spent time of 2 á 3 hours. This is half of the time spent on the HFMEA. On the other hand, the One Hour PRA shifts the time investment from the participants to the coordinators. Which results in an extensive workload for the coordinators. This is shown by table 8 where the differences in time spent between the analyses can easily been seen. Contrary to that, the HFMEA is very time and resource intensive making it harder to plan the different meetings. This supports the literature where the large time investment is being regarded as the major disadvantage of the HFMEA (Potts et al., 2014; Vlayen, 2011; Franklin et al., 2012). As was indicated by the coordinators, the One Hour PRA proved out to be the solution and an aid to the practitioners in conducting a risks analysis. It helps to be less time and resources intensive and participants do not need a large amount of knowledge of the method in comparison to the HFMEA. In contrast, the HFMEA uses more detailed process descriptions during the analysis. This enables a more in-depth analysis, resulting in more and better defined risks and improvements (Marx & Slonim, 2003). Moreover, the HFMEA scores all risks with the use of the RPN resulting in a ranking of the risks. The improvements developed by the One Hour PRA are by way of contrast set up by the participants in order of what they think is most urgent, less urgent and quick wins (Brilstra & Kleve, 2014). One could argue whether these results are the same kind of appropriate and effective improvements as the HFMEA does. But literature indicates there are also some doubts

about the use of the RPN, which may be not much more than an educated guess (Keskin & Özkan, 2009). Mathematically unsound invalid and unreliable (Shebl et al., 2009). These problems with scoring risks and using a risk matrix are supported by the user-feedback questionnaire and in accordance with the results from earlier case studies (Wetterneck et al., 2004).

Sub question 2: How do both methods score on the team process?

The team process of both methods is where the fundamental differences between both methods are present. The HFMEA makes use of team meetings and the One Hour PRA first uses interviews to identify risks and conducts a final team meeting to select the risks that are most urgent to treat and to develop improvements. The coordinators stressed that multidisciplinary team meetings had much added value to assessing risks. During such meetings interaction and discussion stimulates decision-making and can increase the development of ideas (Stasser & Dietz-Uhler, 2001). In contrast, several coordinators mentioned that the individual nature of the One Hour PRA may harm the depth of the analysis and it could also limit the scope of the analysis. This is interesting because literature states that interviews in fact give the most in-depth information (Stasser & Dietz-Uhler, 2001). Generally speaking it is difficult to draw conclusions on the outcome of FMEA sessions, as Shebl et al. (2009) has shown. These findings show the important differences between the methods. It could thereby be argued whether or not the One Hour PRA is extensive enough to discover all risks and improvements. On the other hand, group size can limit the HFMEA in effectiveness. Conclusions from the interviews show that the larger the team size during the HFMEA the higher the probability that the team is less effective due long discussions. Moreover, the long team meetings result in a longer absence from an employee's primary work tasks. Whereas with the One Hour PRA this absence in time is minimized (approximately 2 to 3 hours). In addition, coordinators stress that knowing and understanding each other's work can provide an immense contribution to the performance. A point of criticism in literature are the cultural differences in a team which can limit the performance (Saab, Cleveland & Ho, 2015). A hospital is known for its social and cultural difference between departments (Kronenfeld, 2010). However, the interviews and questionnaire both show that in case of the HFMEA and the One Hour PRA these differences did not affect the performance of the group by any means. Even so, the coordinators made sure all participant could contribute and express their thoughts and feelings. If in case those differences could arise the coordinators agreed that the One Hour PRA should be used to conduct the risk analysis.

Sub question 3: How do both methods score on the overall process?

The comments of the coordinators confirm, that planning is the most difficult aspect of conducting a risk analysis. The comments revealed that arranging a meeting for the HFMEA is problematic due to all the different agendas. Making it even harder when a participants cancels the meeting just prior before the meeting commenced. In contrast the One Hour PRA uses short interview sessions to first obtain insight an risks present in the process. This makes planning

the more easy to do. One coordinator mentioned that the interview enabled him to sometimes quickly consult the participant between other activities. However, the One Hour PRA also ends with a team meeting where preferably all participants should be present but this only concerns one meeting. Results point out that scheduling a single meeting is not the most difficult, but to schedule the next meeting and the one after that is difficult. In this situation the One Hour PRA definitely scores better, it provides benefits with regard to scheduling. Interestingly, one of the coordinators mentioned that the One Hour PRA end-meeting was frivolous and did not do justice to risk analysis. The argument for that was based on placing the stickers on posters. However, it could provide a new less formal way of doing risks analysis. Making it more fun for participants and provide the space for personal contributions. As one respondent said; 'you have to come up with new things to make somebody enthusiastic'. Furthermore, both methods scored similar with respect to the output, respondents all stressed that the methods provided a safer process and increased patient safety. This is not very remarkable since this is the original goal of the risk analysis.

Sub question 4: To what extent are the improvement proposed by the methods implemented in practice?

As mentioned in the results section, the outcomes of the improvements survey provided more HFMEA improvements than One Hour PRA. However, the results that are obtained pointed out that most of the improvements for both the HFMEA and One Hour PRA are implemented. There is not a significant difference between both methods concerning the improvements. What stood out was that most of the improvements of the HFMEA were not implemented because of vague and bureaucratic circumstances. This might be the result of ambiguously defined improvements or a lack of pointing out persons responsible for implementing the improvement.

Research question: To what extent is the modified light version of the HFMEA as effective as the traditional HFMEA?

To answer this question the previous discussed sub questions are combined to evaluate the advantages and disadvantages of both methods. As was mentioned in the introduction, 'effectiveness is the extent to which a given intervention produces the outcomes to individuals who are offered that intervention' (Donaldson et al., 2002). In this research this outcome is a safer healthcare process and the methods to achieve this are the HFMEA and the One Hour PRA. The HFMEA thereby provides more in-depth information when complex processes are being assessed with the use of multidisciplinary team meetings. However, the lack in time efficiency and planning forms a constraint to this method. Risk analysis is still being perceived by some people as necessary evil and participants are in most cases too busy doing their primary tasks, that is the treatment of patients. The One Hour PRA therefore offers a solution to aid the participants, making it a less time-consuming and resource intensive method. However, the method uses a different approach to assess and score the potential risks, i.e. extremely urgent, less urgent and quick wins. One can argue if this methods is as effective as the RPN method. However, literature shows the RPN method is still far from reliable (Shebl et al., 2009). In addition, as participants did not saw differences be-

tween interviews and team meetings, the coordinators did. They argued that the interviews could maybe provide less in-depth information. Which confirms results from literature (Stasser & Dietz-Uhler, 2001). But does this limit the effectiveness of the One Hour PRA? Does this method provide poorer improvements than the HFMEA? Not in any form. As is explained by Carbone & Tippett (2004) the modified versions should correspond to the basic principles of the FMEA to guarantee success, but most important it should fit its unique situation. Especially, that last part does apply for the One Hour PRA. A hospital is an organization where social and cultural differences exist (Kronenfeld, 2010). This was also experienced during this research, since one department had professionals who were by definition not keen on doing anything else than patient care while other departments had professionals who saw the potential benefits of the risk analysis. The One Hour PRA provides a suitable solution for those departments where risk analysis is still being perceived as a necessary evil. It takes the least amount of time and provides well assessed risks and improvements. And when participants are able to think and become aware of the risks that are present, a safer process can be achieved. Despite of the lack of depth in the One Hour PRA due less detailed process descriptions and the use of interviews it is still a valuable and effective method to conduct risks analysis.

6 CONCLUSION

This case study at the UMCG provides valuable insights in the perceptions of the participants and coordinators of both the HFMEA and the One Hour PRA. The study evaluated the effectiveness of the HFMEA and its modified light version the One Hour PRA with the use of interviews and questionnaires. Three variables where used to assess the effectiveness of both methods, quality objectives, team process and overall process. These variables were used in the questionnaires and interviews and provided information to determine the effectiveness of the modified light version. The interviews were coded into descriptive codes and interpretive, grouping codes to reduce and order the data. Cross-case analysis was used to see difference between departments and methods. Based on the interviews and the questionnaire it can be concluded that the modified light version, used in the UMCG, is an effective method to conduct a risk analysis. The team meetings in a HFMEA can provide more in-depth information in complex processes than with the use of interviews. However, team meetings have well-known disadvantages. Literature describes for example group polarization and groupthink, but this is on the other hand not supported by the interview and questionnaires. Although the individual interviews can limit the depth of information the modified light version. It still turns out the be an effective method to assess risks. It provides an answer to the scheduling problems, social and cultural differences and the HFMEAs time-consuming nature. Concluding, this research contribution to the literature of risk management and healthcare is that differences between team meetings and interviews are present and related to the depth of information but do not greatly affect the effectiveness and performance of a risk analysis method. Especially in settings where scheduling is a problem a risk analysis using interviews can provide the solution without diminishing the performance.

6.1 MANAGERIAL IMPLICATIONS

The managerial implications from this research to the coordinators and supervisor of the risks analyses are to first consider the environment in which the analysis takes places and to determine the scope of the process. This helps in assess if a traditional full HFMEA (social-cultural balanced environment and large complex processes) is needed or a modified light version with interviews (social-cultural imbalanced, small processes) might work. However, the choice is also a matter of preference. Moreover, managers should be aware that the meetings and the discussions do not digress too much from their original goal. This could also lead to ineffective time-management making the participants less enthusiastic and willing to participate in a next meeting or risk analysis. This leads to an important implication, to make sure to create willingness among employees. This because the risk analysis is still not very much adapted in every organization and department therefore making its sometimes a necessary evil where coordinators depend on the goodwill of participants.

6.2 LIMITATIONS

This research has several limitations to the outcomes of the analysis. First the small number of respondents in both the user-feedback questionnaire and the improvements questionnaire. Many participants did not fill in the question-

naire. It was therefore impossible to perform a statistical test with the data. The data formed supportive information to the interviews. In addition, the distribution of the questionnaires was mainly done by the coordinator because of their close relationship with the participants, using their goodwill. They could have subjective in choosing the respondent, resulting in missed responses. Moreover, the questionnaires also addressed participants who conducted the risk analysis more than 6 months ago. This could have affected their feelings and thoughts due to the long time between the actual analysis and the questionnaire. This made it hard to conclude aspect from the output. Moreover, the questions were used in previous research but not validated. Another limitation was that the improvement questionnaire was subject to a higher level of HFMEA responses and only three responses from coordinators conducting a One Hour PRA. Furthermore, the coding is done by only one researcher which limits the validity and reliability. Researcher bias could have affected the coding process due to the subjective nature of assigning the codes. In addition, the analysis was done at the UMCG hospital, and results may therefore be hard to generalize across other hospital. On the other hand, the size and complexity of the UMCG should have captured all aspects and factors influencing the risks analyses.

6.3 FUTURE RESEARCH

Future research should focus on the nature of assessing and prioritizing risks. As is discussed in literature and supported by the findings of this research, determining how to score the risks turns out to be difficult and vague. Of course, it will always be subjective but participants has no clear view of assigning the RPN. Also, the validity of the RPN is questioned in literature. It is therefore interesting if other risk assessment tools can be used or developed to provide more validity and reliability to the method. Furthermore, a longitudinal study in the field of prospective risk analyses could provide more depth and validity to the results, because in most cases risk analyses take a long to complete.

7 ABBREVIATIONS

FMEA: Failure Mode and Effect Analysis

HFMEA: Health Failure Mode and Effect Analysis

PRA: Prospective Risk Analysis

RPN: Risk Priority Number

UMCG: University Medical Center Groningen

8 REFERENCES

Al-Assaf, A.F., Bumpus, L.J., Carter, D., & Dixon, S.B. 2003. Preventing Errors in Healthcare: A Call for Action. ***Hospital Topics,*** 81(3): 5 -12.

Argote, L., & Ingram, P. 2000. Knowledge transfer: A basis for competitive advantage in firms. ***Organizational Behavior and Human Decision Processes,*** 82(1): 150 – 169.

Ashley, L., Armitage, G., Neary, M., & Hollingsworth, G. 2010. A Practical Guide to Failure Mode and Effects Analysis in Health Care: Making the Most of the Team and Its Meetings. ***The Joint Commission Journal on Quality and Patient Safety,*** 36(8): 351 – 358.

Baker, G.R., Norton, P.G., Flintoft, V., Blais, R., Brown, A., Cox, J., Etchells, E., Ghali, W.A., Hebert, P., Majumdar, S.R., O'Beirne, M., Palacios-Derflingher, L., Reid. R.J., Sheps, S., & Tamblyn, R. 2004. The Canadian Adverse Events Study: the incidence of adverse events among hospital patients in Canada. ***Canadian Medical Association Journal,*** 170(11): 1678 – 1688.

Barach, P., & Small, S.D. 2000. Reporting and preventing medical mishaps: lessons from non-medical near miss reporting systems. ***British Medical Journal,*** 320: 759 – 763.

Barach, P. 2002. Lessons from the USA. In Emslie, S., Knox, K., & Pickstone, M (Eds.), ***Improving Patient Safety: Insights from American, Australian and British healthcare***, ECRI and Department of Health: London, United Kingdom.

Brennan, T.A., Leape, L.K., Laird, N.M., Localio, A.R., Lawthers, A.G., Newhouse, J.P., Weiler, P.C., & Hiatt, H.H. 2004. Indicidence of adverse events and negligence in hospitalized patients: results of the Harvard Medical Practice Study I. ***Quality & Safety in Health Care,*** 13(2): 145 – 152.

Brilstra, S.M., & Kleve, G.R. 2014. Manual One Hour PRI.

Brodie, A., & Kinross, J., & Bailey, M., & Aggarwal, R., & Vincent, C. 2009. Using Failure Mode and Effect Analysis to identify hazards within resuscitation. ***International Journal of Risk & Safety in Medicine,*** 21(4): 201 – 215.

Blinderman, C.D. 2010. Opiods, Iatrogenic Harm and Disclosure of Medical Error. ***Journal of pain and symptom management,*** 39(2): 309 – 322.

Cagliano, A.C., Grimaldi, S., & Rafele, C. 2011. A systemic methodology for risk management in healthcare sector. ***Safety Science,*** 49(5): 695 – 708.

Cagliano, A.C., Grimaldi, S., & Rafele, C. 2015. Choosing project risk management techniques: A theoretical framework. ***Journal of Risk Research,*** 18(2): 232 – 248.

Cannon, M.D., & Edmondson, A.C. 2005. Failing to learn and learning to fail (intelligently): how great organizations put failure to work to innovate and improve. ***Long Range Planning,*** 38: 299 – 319.

Carbone, T.A., & Tippet, D.D. 2004. Project Risk Management Using the Project Risk FMEA. ***Engineering Management Journal,*** 16(4): 28 – 35.

Carlson, C. S. 2012. ***Effective FMEAS.*** Hoboken: John Wiley & Sons Inc. Publication.

Charness, G., & Sutter, M. 2012. Groups Make Better Self-Interested Decisions. ***Journal of Economic Perspectives,*** 26(3): 157 – 176.

Clancy, C. M. 2006. Care Transistions: a threat and an opportunity for patient safety. ***AM J Medical Quality,*** 21(4): 15 – 17.

Condamin, L., Louisot, J.P., & Naim, P. 2007. ***Risk Quantification Management, Diagnosis and Hedging.*** John Wiley & Sons Ltd.

DeRosier, J., Stalhandske, E., Bagain, J.P., Nudell, T. 2002. Using Health Care Failure Mode and Effect Analysis: The VA National Center for Patient Safety's Prospective Risk Analysis System. ***The Joint Commission journal on quality improvement,*** 28(5): 248 – 267.

Donaldson, C., Mugford, M. & Vale, L. 2002. ***Evidence-base Health Economics: From effectiveness to efficiency in systematic review.*** London: BMJ Books.

Guerrero, H., & Bradley, J. 2013. Failure Mode and Effects Analysis: An Evaluation of Group versus Individual Performance. ***Production and Operations Management,*** 22(6): 1524 – 1539.

Habraken, M.M.P., Van der Schaaf, T.W., Leistikow, I.P., & Reijnders-Thijsen, P.M.J. 2009. Prospective risk analysis of health care processes: A systematic evaluation of the use of HFMEA in Dutch health care. ***Ergonomics,*** 62(7): 809 - 819

Hudson, P. 2003. Applying the lessons of high risk industries to health care. ***Quality and Safety in Health Care,*** 12(1): i7 – i12.

Hyde, K.F. 2000. Recognizing deductive processes in qualitative research. ***Qualitative Market Research: An International Journal,*** 3(2): 82 - 89.

Franklin, B., & Shebl, N., & Barber, N. 2012. Failure mode and effects analysis: too little for too much? :607 – 612.

Forza, C. 2009. Surveys. In Karlsson, C (Eds), ***Researching Operations Management***: 162 – 195. New York: Routledge

Kaestli, L. Z., Cingria, L., Fonzo-Christe, C., & Bonnabry, P. 2014. Prospective risk analysis and incident reporting for better pharmaceutical care at paediatric hospital discharge. ***International Journal of Clinical Pharmacy,*** 36(5): 953-962**.**

Keskin, G.A., & Özkan, C. 2009. An alternative evaluation of FMEA: Fuzzy Art algorithm. ***Quality and Reliability Engineering International,*** 25(5): 647 – 661.

Kessels-Habraken, M., De Jongen, J., Van der Schaar, T. & Rutte, C. 2010. Prospective risk analysis prior to retrospective incident reporting and analysis as a means to enhance incident reporting behaviour: A quasi-experimental field study. ***Social Science & Medicine,*** 70(9): 1309 – 1316.

Kleve, G.R. 2014. Manual Health Failure Mode and Effect Analysis.

Kronenfeld, J.J. 2010. Social Factors Leading to Differences in Health and Health Car: The Influence of Factors Such as Race/Ethnicity, Geography and Gender. ***Research in the Sociology of Health Care,*** 28: 3 – 17.

Langelaan, M., Bruijne, M.C., de Baines, R.J., Broekens, MA., Hammink, K., Schilp, J., Verweij., L., Asscheman, H., & Wagner, C. 2013. ***Monitor Zorggerelateerde Schade 2011/2012: dossieonderzoek in Nederlandse ziekenhuizen.*** Amsterdam, Utrecht, EMGO+ Instituut/VUmc, NIVEL.

Levine, J.M., & Moreland, R.L. 2006. ***Small groups:*** New York: Psychology Press.

Luo, S., & Lee, G. 2015. Total Quality Management & Business Excellence Applying failure mode and effects analysis for successful knowledge management. ***Total Quality Management & Business Excellence,*** 26(1-2): 62 – 75.

Marx, D., & Slonim, A. 2003. Assesing patient safety risk before injury occurs: an introduction to sociotechnical probabilistic risk modelling in health care. ***Quality & Safety in Health Care,*** 12(2): i33 – i38.

McHugh, M. 2012. Interrater reliability: the kappa statistic. ***Biochemia Medica,*** 22(3): 276 – 282.

Michaelsen, L.K., Watson, W.E., & Black, R.H. 1989. A realistic test of individual versus group consensus decision making. ***Journal of Applied Psychology,*** 74(5): 834 – 839.

Miles, H., & Huberman, M. 1994. ***Qualitative data analysis: a sourcebook,*** Beverly Hills, CA: Sage Publications.

Molitor, F., Kravitz, R.L., Yue-yun, T., & Fink, A. 2001. Methods in Survey Research: Evidence for the Reliability of Group Administration vs Personal Interviews. ***American Journal of Public Health,*** 91(5): 826- 827.

Moyer, H., Singh, H., Finkel, K.L., & Giardino, A.P. 2010. Transitions from neonatal intensive care unit to ambulatory care: description and evaluation of the proactive risk assessment process. ***Quality & Safety in health care,*** 19(3): i26 – i30.

Potts, H.W.W., Anderson, J.E., Colligan, L., Leach, P., Davis, S., & Berman, J. 2014. Assessing the validity of prospective hazard analysis methods: a comparison of two techniques. ***BMC Health Services Research,*** 14(1): 1 – 10.

Rao, V.R., & Steckel, J.H. 1991. A Polarization Model for Describing Group Preferences. ***Journal of Consumer Research,*** 18(1): 108 – 118.

Reason, J. 2002. Combating omission errors through task analysis and good reminders. ***Quality and Safety in Health Care,*** 11(1): 40 -44.

Runciman, B., Merry, A., & Walton, M. 2007. **Safety and ethics in healthcare: A guide to getting it right.** Alderschot, UK: Ashgate.

Saab, G., Cleveland, M., & Ho, L. 2015. Individualism – Collectivism and the quantity versus quality dimensions of individual and group creative performance. ***Jour-***

nal of Business Research, 68(3): 578 – 586.

Sales, E., Cooke, N.J., Rosen, M.A. 2008. On teams, teamwork, and team performance: discoveries and developments. ***Human Factors,*** 50: 540 – 547.

Senders, J. 2004. FMEA and RCA: the mantras of modern risk management. ***Quality and Safety in Health Care,*** 13(4): 249 -250.

Shebl, N.A., Franklin, B.D., & Barber, N. 2009. Is Failure Mode and Effect Analysis Reliable? ***Journal of Patient Safety,*** 5(2): 86 – 94.

Sims, R.R., & Sauser, W.I. 2014. Toward a Better Understanding of the Relationships among Received Wisdom, Groupthink and Organizational Ethical Culture. ***Journal of Management Policy & Practice,*** 14(4): 75 -90.

Srivastava, N. K., & Mondal, S. 2014. Development of a Predictive Maintenance Model Using Modified FMEA Approach. ***IUP Journal of Operations Management,*** 13(2): 7- 16.

Stasser, G. B., & Dietz-Uhler. 2001. Collective choice, judgment and problem solving. In M. A. Hogg & R. S. Tindale (Eds), ***Blackwell Handbook of Social Psychology: Group Processes:*** 31 – 35. Oxford: Blackwell Publishers.

Tonneau, D. 1997. Management tools and organization as key factors towards quality care: reflections from experience. ***International Journal for Quality in Health Care,*** 9(3): 201 – 205.

UMCG. 2014. Http://www.umcg.nl/NL/UMCG/overhetumcg/Pages/default.aspx

Van Schoten, S, M., Baines, R.J., Spreeuwenberg, P., Bruijne, M.C., Groenewegen, P.P., Groeneweg, J., & Wagner, C. 2014. The ecometric properties of a measurement instrument for prospective risk analysis in hospital departments. ***BMC Health Service Research,*** 14(1): 1 – 8.

Van Tilburg, C., Leistikow, I., Rademaker, C., Bierings, M.B., & van Dijk, A.T.H. 2006. Health Care Failure Mode and Effect Analysis: a useful proactive risk analysis in a pediatric oncology ward. ***Quality and Safety in health care,*** 15: 58 – 63.

Velez-Diaz-Pallares, M., & Delgado-Silveira, M., & Carreto-Accame, M., & Bermejo-Vicedo, T. 2012. Using Healthcare Failure Mode and Effect Analysis to reduce medication erros in the process of drug prescription, validation and dispensing in hospitalized patients. ***BMJ Quality & Safety,*** 22: 42 – 52.

Vlayen, A. 2011. Evaluation of Time- and Cost-Saving Modifications of HFMEAL An experimental Approach in Radiotherapy. ***Journal of Patient Safety,*** 7(3): 165 – 168

Voss, C. 2009. Case Research in Operations Management. In Karlsson, C (Eds), ***Researching Operations Management***: 162 – 195. New York: Routledge

Wetterneck, T.B., Hundt, A.S., & Carayon, P. 2009. FMEA Team Performance in Health Care: A Qualitative Analysis of

Team Member Perceptions. ***Journal of Patient Safety,*** 5(2): 102 – 108.

Wreathall, J., & Nemeth, C. 2004. Assessing risk: the role of probabilistic risk assessment (PRA) in patient safety improvement. ***Quality and Safety in health care,*** 13: 206 – 212.

APPENDIX A: RISK MATRIX

Severity/ Frequency	**1 Highly Unlikely**	**2 Unlikely**	**3 Possible**	**4 Probably**	**5 Almost certain**
5 Catastrophic	5 Moderate	10 High	15 Extreme	20 Extreme	25 Extreme
4 Major	4 Moderate	8 High	12 Extreme	16 Extreme	20 Extreme
3 Moderate	3 Low	6 Moderate	9 High	12 Extreme	15 Extreme
2 Small	2 Low	4 Moderate	6 Moderate	8 High	10 High
1 Very Small	1 Low	2 Low	3 Low	4 Moderate	5 Moderate

Table 10: Risk matrix (Kleve, 2014)

Color	Risk level and consequence
	Extreme, not acceptable Requires immediate improvement measure
	High, problematic Control, improvement measure needed
	Moderate, undesirable Control, improvement measure desirable
	Low, acceptable Accept risk

Table 11: Clarification of risk matrix (Kleve, 2014)

APPENDIX B: QUALITATIVE DATA ANALYSIS

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
Carlson (2012)	*Realizable Improvements*	HFMEA	'Too much emphasize on the severity of the problems'(#7). 'A lot of improvements were suggested after the analyse. Some are more difficult to implement than others'(#5). 'I experience that sometimes the improvements are too abstract and hard to implement'(#6).	3			Output
		One Hour PRA	'…it is mainly about what do you think is best and most urgent to improve'(#7). 'The improvements should be assigned to someone and there should be someone who guards this process'(#6).			2	
	Appropriate actions	HFMEA	'A lot of people were not used working with this particular high risk instrument'(#5).	1			Output
		One Hour PRA	'You do not, per definition, get the most important risks and actions'(#7). 'Solemnly a focus on the three most important problems and risks. Personally I don't think that does justice to the other risks'(#5). 'All identified risks were sent back to all the people that were affect to see if they agreed'(#6).	1	2		
	Indicators of improvements	HFMEA	'You can only work with the instrument after you finish the e-learning. And this process is strictly followed by the supervisors'(#5).	1			Output
		One Hour PRA	'..you need people who guard and monitor the improvements even if they are implemented'(#6).			1	

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
	Lessons learned	HFMEA	'The HFMEA is preferred if you already know certain risks in a complex process'(#6). 'It has to do with the information you get from the producer'(#4).	1		1	Input
		One Hour PRA	'You use the outcomes as evaluation for the next analysis'(#6). 'You first look at the manuals provided by the producers'(#7)	2			
	Detailed process	HFMEA	'It is also about discussing the complete process of healthcare'(#8). 'If you know your process you automatically identify the risks in this process'(#8). 'A HFMEA could add more because you go through every step of the process'(#7). '…the method goes more in-depth'(#9). 'I think it is a great advantage that you really describe the complete process detailed and in-depth'(#9). 'For me it is to visualize where risks can arise that can be determined beforehand'(#2). 'Together you map the complete process'(#1)	5		1	Process
		One Hour PRA	'I first in detail discussed the whole process with a doctor'(#6). 'I clearly identified all the steps that needed to be investigated'(#6).	2			
	Right time	HFMEA	'There is much added value in starting at the right time'(#8). 'In the best case you should conduct a risk analysis before you implement a machine. But sometimes you don't know the risks that are concerned with a machine'(#4).		1	1	Input
		One Hour PRA	'Finally they realized it was maybe a good idea to have conducted at least a One Hour PRA beforehand'(#9). 'If it is not conducted at the right time things can happen that you	1	1		

Codes		Quote	Comment type			Grouping code
			+	-	+/-	
		could have prevented'(#2).				
	Both	'The basics of risks analysis is that you at least know something of the potential risks'(#7). 'We determine how much its used. This helps us to see when we have to implement a HFMEA'(#5). 'People do not always realize the importance of doing a risks analysis at the right time'(#6).	1	1	1	
Right people	HFMEA	'…all the right people sit together'(#8). '..a preferred method because it places more emphasize on the groups that are affected by the process'(#5). '..where people who are involved can tell their own story'(#9). '..because you approach the right people for the analysis, you know that they have the experience to make sure risks can be reduced'(#9). 'Employees should take part, they have other insights that someone of the management team'(#4).	3		1	Process
	One Hour PRA	'They were affect by the complete process. They therefore had to take part in the One Hour PRA'(#6). 'The One Hour PRA. It has everything to do with the time and the target people. In the end you have a group meetings as well'(#2).			2	
Knowledge of participants	HFMEA	'When people have done a HFMEA before they have better knowledge for the next analysis'(#8). 'What I experience in practice with this method is that you develop a root cause tree. Often this is made by experts who conduct the analysis. This is then presented to all the people involved. I noticed that the affected people get frustrated because they experience that the experts do	1	1		Input

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
			not have practical experience in their working environment'(#6).				
		One Hour PRA	'For the people involved the method is relatively simple to understand'(#6). 'It is definitely a requirement that you have knowledge of the complete process and method'(#2).	1		1	
	Achievable improvements	HFMEA	'…improvements were mentioned and you see that everybody has the intention and willingness to implement the improvements, increasing patient safety'(#5). 'A HFMEA is finished when all suggested improvements are implemented'(#1).	1		1	Output
		One Hour PRA	'One improvement could not directly be implemented but was revised to make sure the improvement was indeed achievable'(#6). 'People continuously asked about the process of the improvements that needed to be implemented'(#6). 'If you can show the results that improvements are implemented, I think people will become more enthusiastic about doing a One Hour PRA'(#6). 'We check, after a month or 3 months, if the improvements are implemented. If not, than we get back to people and tell them they took the responsibility to implement the improvement(#3)'.	3		1	
	Effective time-management/ time investment	HFMEA	'The discussions do not always contribute in comparison to the time investment'(#7). 'It takes a lot of time to let all 20 people have their say in a meetings'(#9). 'Sometimes not every part of the process is equally important to everyone. Sometimes a discussing takes too long, but on the other hand		3	1	Process

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
			some long discussions really have added value'(#1). 'It should not take more than 1.5 a 2 hours'(#4).				
		One Hour PRA	'Time investment is large because you have to return all documented interviews back to the respondents. Then wait for them to reply, which mostly takes a couple of days or weeks. After that you, as a coordinator, have to document everything and I doubt the reliability of this working method'(#8). 'An advantage of the One Hour PRA is that you need less time'(#9). 'For the participants I prefer the One Hour PRA because of the small time investment'(#2).	2	1		
		Both	'There is a chance that when you go for a diagnosis nothing is found. That is the same for risk analysis. But after that you at least have the confirmation that no important risks are present'(#7). ' I prefer doing a risks analysis when you already have the feeling that things are wrong'(#7). 'Everything you do contributes in the process, even when there is no significant end result'(#6).			3	
Wetterneck et al. (2009)	*Team functioning*	HFMEA	'Because we are in a group we define better risks'(#8). 'there is added value of sitting together in the HFMEA'(#8). 'I think there is much added value in multidisciplinary assessing risks'(#8). 'During the meeting you are influenced by other people around, but you also get ideas from the interaction. I think this is more valuable than individually conducting interview'(#3). 'We see the added value of multidisciplinary teams, together discussing the potential risks'(#1).	5			Team process

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
		One Hour PRA	'Four persons, four different opinions. We had a very hard time getting all the heads in the same direction. Their interest and opinions diverged. And that's a pitfall for the One Hour PRA'(#6). 'A disadvantage of the One Hour PRA is that you work very individually and therefore focussing too much on a single process during the team meetings'(#4)	2			
	Feeling comfortable	HFMEA	'…there is a possibility that people are not really keen on working together'(#8).	1			Communication
		One Hour PRA	'The supervisor has the responsibility to make sure that everybody feels comfortable and has the opportunity to express themselves'(#6).		1		
		Both	'….familiarization. I mean if you are familiar with a method you will be more comfortable in doing it again'(#7).		1		
	Understanding of others/ New insights	HFMEA	'When you see that people listen and react to each other and understand the risks that are present at their work'(#5). 'It is being communicated inside the groups with as a results a startle. That was a complete eye-opener for the other department'(#5). People finally realized the amplitude of the problem after the department was able to discuss their potential risks during the meetings'(#5). 'You become aware of each other's problems'(#9). '…because there is much added value in knowing what your colleagues do'(#1). 'I think the group process in a HFMEA works inspiring, you look into each other's working habits'(#4).	5	1		Inter-relationships

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
		One Hour PRA	'The One Hour PRA also gives the opportunity to see what their actions mean for other people'(#6). 'With the use of the One Hour PRA their department really understood what they did and how that affected everybody'(#6). 'Important is to make sure that everybody knows what each other's tasks are in the process'(#9). 'You become aware that their exists mutual understanding between groups and that's the biggest win'(#2).	4			
	Team process direction	HFMEA	'…focus together towards the change'(#8). '..that could be a reason to conduct group meetings. To put all the heads in the same direction'(#6).			2	Team process
		One Hour PRA	'Everybody was prepared and focussed to improve patient safety'(#6). 'Everyone had the focus and no beepers went off'(#3).	1		1	
	Personal contributions	HFMEA	'Afterwards I always ask people who did not had a chance to say anything if they still have some interesting points'(#8). 'The role of the supervisor is very important'(#8). 'Everybody has the opportunity to bring forward their risks'(#5). 'Everybody has their own input'(#9).	3		1	Communication
		One Hour PRA	'I made sure that everybody had the opportunity to tell their story. I, for example, went to a nurse afterwards and asked her if see said everything she wanted to say'(#6).	1			
	Opinion expressing	HFMEA	'Has everything to do with the time'(#8). 'All people have the opportunity to express their feelings'(#5). 'If we would sit multidisciplinary around a table there would be	2	1	2	Communication

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
			people that would not express their feelings and thought'(#3). 'The openness to speak is normal here, but you always have people who do not speak very open in group meetings'(#1). 'I never experienced that people do not want to express their opinion in a group meeting'(#1).				
		One Hour PRA	'If people have a hard time discussing in public, the One Hour PRA is preferred'(#8). 'Everybody can have the same amount of input'(#6). 'The people in my department are used to swim against the current and thus not afraid to express their feelings'(#6).	3			
	Different job functions	HFMEA	'I always have the feeling everybody is treated equally during the meetings'(#1).	1			Inter-relationships
		One Hour PRA	'It did not matter in that group if you were a nurse, doctor or anesthesiologist because everybody had to place their stickers on the poster'(#6). 'As a starting ritual I always tell them we are all equal in this meeting, but we have the expertise of all our different job functions'(#6).	2			
	Opinion pushing	HFMEA	'….often see that due communication and interaction between people change their initial statement'(#8). 'I personally never experienced that someone pushed his identified risk. If so, I think the group will correct that person'(#8). 'It only has an impact when the risks are in the high numbers'(#7).	1		2	Communication
		One Hour PRA	'In this particular case the people were very persistent in their opinion, leaving no room for other opinions'(#6). 'These assertive people have the tend to overrule other people'(#6). 'In our case nobody pushed	2	1	1	

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
			their opinion'(#2). 'There were people who had an outspoken opinion, but because we were together we were able to discuss about it'(#3).				
	Overall effectiveness	HFMEA	'Larger groups can be less effective'(#1). .. 'I takes a lot of time to conduct team meetings, all participants cannot work on their primary work tasks'(#4).	2			Team process
		One Hour PRA					
Habraken & Van der Schaaf (2009)	*Useful meetings*	HFMEA	'..as supervisor your job is to make sure the meetings are useful and the discussions do not digress'(#8). 'I am afraid that if you not guard the large meetings in the right way it can quickly get out of hand in sense of time. That you digress from the original path'(#2). 'Sometimes discussion very much digress of the original goal'(#4).	2	1		Process
		One Hour PRA	'With the One Hour PRA it's more a frivolous meetings, I have mixed feelings the this methods'. I dislike walking along side poster, where you can just leave some stickers'. 'I have the feeling that when risks are not addressed, people afterwards look weird at you and doubt the necessity of the analysis'(#5). 'With the One Hour PRA I did not experienced that meetings were useless'(#2). 'The end meeting was absolutely useful'(#3).	2	1		
	Helpful risk analysis	HFMEA	'Sometime there are only slight changes in process. This is where I doubt if a complete HFMEA is necessary'(#8). 'I am afraid that	1		1	Output

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
			because we also focus on small processes the time to implement will increase'(#8).				
		One Hour PRA	'Beforehand you have to think where the constraints are in your process'(#7). '…on beforehand see what the goal is of all participants'(#6).			2	
		Both	'If a department has a preference for a particular method, than that's fine for me. It is not about the method, but to achieve the goal'(#7).			1	
	Safer process	HFMEA	'You are busy with patient safety'(#8). 'When there are major patient risks you should conduct a HFMEA, because its more extensive'(#5). 'The HFMEA is more extensive, therefore you should use it for processes that immediately affect patient safety'(#9).	2		1	Output
		One Hour PRA	'We explicitly asked the nurses what they think should be improved to guarantee better patient safety'(#6).	1			
		Both	'To map potential failures and guarantee a more patient safety. But also more safety for the employee'(#4). 'You are busy increasing the safety of the process'(#3).	2			
	Recommendation to others	HFMEA					
		One Hour PRA					
	Willingness to participate	HFMEA	'…after time people become aware of the need for a HFMEA'(#8). 'If you have done the HFMEA before you most likely prefer it	5	1		Input

Codes		Quote	Comment type			Grouping code
			+	-	+/-	
		the next time'(#7). 'In the beginning this is very hard. But if you involve people….you see that people become aware of all the problems. And they all enjoyed it'(#9). 'In the beginning people asked if they need to participate, but now.. we never experience that people do not want to participate'(#1). 'It's still being seen as a necessary evil'(#4). 'People need to see the end results, to become enthusiastic'(#4).				
	One Hour PRA	'Not everybody is keen on doing risk analysis. However, it should be questioned whether it's a good thing to concede and just tell them you visit for several minutes'(#8).		1		
	Both	'To get people together in one meeting is not a problem. But to get everyone together the next time is difficult. ..it depends on the primary working tasks'(#7). 'I never experienced that people are not willing to participate'(#5). 'It is about a change that they want and thus they are willing to participate''(#6). 'Some people did not even had to work but came on a voluntary. I think that shows that people are willing to participate'(#6). 'If you can explain why a risk analysis is necessary, people are willing to participate'(#2). 'People finally realized that they had the opportunity to express their feelings'(#3).	4	1	1	
Incident reporting	HFMEA					
	One Hour					

	Codes		Quote	Comment type			Grouping code
				+	-	+/-	
		PRA					
	Determining risks	HFMEA	'Brainstorming could deliver more risks'(#7).	1			Process
		One Hour PRA	'After sending all individually identified risks to the participants we together determined the risk we want to deal with'(#6).	1			
		Both	'I don't necessarily care how people score the risks'(#7). 'You need experience to determine all possible risks'(#9).			2	
	Planning	HFMEA	'In small groups we can arrange it in 1 or 2 weeks'(#8). 'Planning group meetings is in my concern never a big problem'(#7). 'Planning a HFMEA is difficult because you have to plan at least two hours per meeting'(#6). 'It is very labour extensive'(#6). 'A disadvantage of the HFMEA is to get a complete group together'(#9). '…difficult to find a moment in the planning when everybody is available'(#9). 'To get everybody together for one time is hard, let alone multiple times. As for example with the HFMEA'(#2). 'Planning is very difficult'(#1). 'We sometime have to cancel the complete meeting, because multiple people are unable to be present'(#1). 'We re-schedule the meetings even important people cannot be present'(#1). 'For us as coordinators scheduling is very difficult'(#4). 'We have a big problem to get everybody together for the risk analysis'(#4).	1	1 1	1	Input
		One Hour PRA	'Well, if you cannot get people sit together'(#8). '…a better methods in sense of logistics'(#8). '… the less people, the easier it goes'(#8). 'If I need to interview 10 people it	7	4	1	

Codes	Quote	Comment type			Grouping code
		+	-	+/-	
	will also take me a month'(#8). 'It is very easy to see people for a short time. They often have some time to talk to you. That's never a problem'(#7) . 'It saves time and time is money'(#5). 'Because it is small and takes not much times, it is easy to schedule'(#6). 'With the One Hour PRA we could easily fit the interviews between other primary task'(#6). 'It is already hard to plan the only meetings for all people'(#2). 'I think it's very hard to bring all the people together, however we managed to do it in quite a short time period. People have to make time for the risk analysis'(#3). 'With the One Hour PRA it is still difficult to plan the group meeting. Sometimes we only need a single two-hour meetings'(#1). ' I cannot see the added value of scheduling with the One Hour PRA'(#1).				

Table 13: Qualitative data analysis

APPENDIX C: INTERVIEW PROTOCOL

1. What is the goal of a risk analysis?
2. Which method do you prefer, the HFMEA or the One Hour PRA? And why?
3. The HFMEA uses team meetings and the One Hour PRA mainly individual interviews during the process. What do both methods deliver?
4. How do you experience scheduling a risk analysis (the HFMEA and One Hour PRA)?
5. How do you experience that people are enthusiastic and willing to participate in a risk analysis (the HFMEA and One Hour PRA)?
6. How do you experience that participants push their opinion during a HFMEA or a One Hour PRA? What do you experience as positive during a team-process, and what can be improved during a HFMEA and/or One Hour PRA?
7. How useful is the time spent on a risk analysis (the HFMEA and One Hour PRA)? How do you think this can be improved this?
8. Do you experience that the risk analysis is conducted at the right time? What are the consequences if this fails?

APPENDIX D: QUALITY QUESTIONNAIRE

Risk analysis: Quality survey

Type of risk analysis: HFMEA / One Hour PRI

Subject/ title risk analysis:_____

Date risk analysis:_____

Number of participants:_____

Patient participant: Yes / No

6 I was present the entire risk analysis: Yes / No

1) Gender: Male ☐ Female ☐
2) Age: ____
3) Function: _____

4) Department: _____

5) How many years have you been working at the UMCG? ____ years

A. The following statements are about the extent to which the risk assessment meets the quality objectives (Carlson, 2012).

1= Strongly disagree
2= Disagree
3= Neutral

4= Agree
5= Strongly agree

	Strongly disagree				**Strongly agree**
1) The risk analysis provides enough realizable process improvements.	1	2	3	4	5
2) The risk analysis treats all high risks with effective and executable actions.	1	2	3	4	5
3) The indicators to measure the effectiveness of the improvements are developed	1	2	3	4	5
4) Prior process improvements and 'lessons learned' are included as input for the next risk analysis.	1	2	3	4	5
5) The risk analysis provides sufficient details of the process to identify risks and derive effective improvements.	1	2	3	4	5
6) The risk analysis is carried out at the right time.	1	2	3	4	5
7) The right people took part in the risk analysis.	1	2	3	4	5
8) The participants are in the possession of the right knowledge to carry out the risk analysis.					
9) The proposed actions/improvements are feasible.					
10) The time spent on the risks analysis is effectively utilized.					

B. What did the risk analysis deliver?

- ❑ A complete filled-in risk matrix
- ❑ A report of the analysis
- ❑ Something else, namely_____

	Good (1)	Too long (2)	Too short (3)
1) The time spent on the risk analysis was	❍	❍	❍

C. The following statements are about the overall process of the risk analysis (Habraken & van der Schaaf, 2015).

1= Strongly disagree
2= Disagree
3= Neutral
4= Agree
5= Strongly agree

	Strongly disagree				**Strongly agree**
1) The meetings were useful	1	2	3	4	5
2) The risk analysis was useful	1	2	3	4	5
	1	2	3	4	5
3) The investigated process has become safer due	1	2	3	4	5

	Strongly disagree				**Strongly agree**
to executing a risk analysis.					
4) I obtained new insights in the process thanks to the risk analysis.	1	2	3	4	5
5) I encourage others to take part in the risk analysis	1	2	3	4	5
6) The risk analysis was fun to do	1	2	3	4	5
7) I will definitely take part in a next risk analysis.	1	2	3	4	5
8) After the risk analysis I report incidents much sooner.	1	2	3	4	5
9) Assessing the probability of risks in the risk matrix is easy.	1	2	3	4	5
10) The results of the risk analysis outweigh the time investment.	1	2	3	4	5
11) I was able to easy plan the risks analysis in my agenda.	1	2	3	4	5

D. The following statements are about the team process during a risk analysis (Wetterneck, Hundt & Carayon, 2009).

1= Strongly disagree
2= Disagree
3= Neutral
4= Agree
5= Strongly agree

	Strongly dis-agree				**Strongly agree**
1) The team functioned properly.	1	2	3	4	5
2) I felt comfortable during the team meetings	1	2	3	4	5
	1	2	3	4	5
3) After participating in a multidisciplinary team I have a better understanding of what is going on with other members.	1	2	3	4	5
	1	2	3	4	5
4) The team process led directly to the goal of the risk analysis.	1	2	3	4	5
	1	2	3	4	5
5) My opinions and suggestions were included in the team process.	1	2	3	4	5
	1	2	3	4	5
6) I dared to express myself during the risk analysis.					
7) Differences in functions did not affected my opinion.					

	Strongly dis-agree	**Strongly agree**
8) I experienced that some participants pushed forward their opinions and interest		
9) The effectiveness of the team during the risk analysis was good.		

Do you have any further comments, tips or suggestions how risk analysis can be improved in the future?

_____
_____
_____
_____

Thank you for your time!

6

APPENDIX E: IMPROVEMENTS QUESTIONNAIRE

Risk analysis: Improvement questionnaire

Type of risk analysis: HFMEA / One Hour PRI

Risk analysis:_____

Date risk analysis:_____

Department:_____

Estimated time investment:_____

What are from your point of view the 5 most important improvements developed in the risk analysis?

1)_____

2)_____

3)_____

4)_____

5)_____

For every improvement, is it already implemented? No, why not? Yes, what is exactly implemented?

1) Yes / No

_____

2) Yes / No

_____
_____

_____
_____

_____
_____
_____

3) Yes / No

_____
_____

_____
_____

_____
_____
_____

4) Yes / No

_____
_____

_____
_____

_____
_____
_____

5) Yes / No

_____
_____

_____
_____

_____
_____
_____