The minimal invasive surgery operation room

Elements which indicate risks for the quality and safety

Health Sciences
Masterthesis v 1.1
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July, 2008

Table of content

Abstract

Background Minimal invasive surgery or keyhole surgery is an important development in surgery and is the overall name for all endoscopic procedures. The benefits of minimal invasive surgery have been well recorded. This type of surgery is technically more complex and sensitive then the traditional 'open' surgery methods and therefore demands other technical skills of the operating staff, equipment and instrumentation [36]. This has led and leads to new problems during these high-tech procedures, creating opportunities for errors or complications to occur [86].

The Health Care Inspectorate has published a study in November 2007 that is called '*Risico's minimal invasieve chirurgie onderschat; kwaliteitssysteem voor laparoscopische operaties ontbreekt*'. This study contains a critical review on the quality of minimal invasive surgery in the Netherlands. The study assessed the manner in which patient safety is assured, the quality of the procedures in terms of practitioners skills and training.

The Academic Medical Center St Radboud in Nijmegen introduced a dedicated minimal invasive surgery operation room. There is also a multidisciplinary monthly meeting to discuss subjects about and surrounding laparoscopic and minimal invasive surgery.

The research question: *Which elements indicate risks for the quality and safety in a minimal invasive surgery operation room? How are these elements prioritized in the hospital?* is answered by means of an qualitative explorative research in this thesis.

Method and data collection A systematic literature review has been performed to get more insight and understanding from previous performed studies. The systematic literature review was also input for the expert analysis. To assess the knowledge of the experts in the hospital the Delphi method (repetition with controlled feedback) is used.

Three interview cycles and one plenary discussion were held to explore and prioritized the elements which can indicate risks for the quality and safety (patient and employee) of the minimal invasive surgery operation room. In the first round the current situation was explored and together with the systematic literature review this was the input for the second interview cycle. In the first interview cycle and the literature review 89 elements and 14 points of emphasis have been formulated. In the second interview cycle these elements have been ranked and prioritized. The third cycle the results of this ranking and prioritizing are discussed with the experts to validate the results. In the fourth and last cycle a plenary group discussion was held, about the elements which are clustered into four groups.

Results of analysis Out of the 89 elements, by means of the four cycles, 30 elements which indicate risks were ranked by the experts of the hospital. These elements had a stated priority above four and were all applicable to the hospital. For each element the Hospital Specific Priority Size (mean divided by the standard deviation) has been calculated so that the level of consensus was of influence on the final raking of the element.

Conclusion The elements are clustered into four clusters (organization, training, instrumentation and complication) according to the subcommittees of the multidisciplinary laparoscopic committee and provide incentives for the subcommittees. The minimal invasive surgery operation room needs to be organized more adequately, basic skills for the training of future and currently active surgeons should be made, the instrumentation and communication about instrumentation needs to be improved together with the involved departments and complications need to be registered and evaluated. Coordination, communication and mutual agreement are the basic principles the hospital should work on.

Discussion There are several factors that had influence on the execution of this research. The Health Care Inspectorate report of November 2007 and the purchase of the Da Vinci robot. The expert analysis via the Delphi method, The original distinction between risk elements and point of emphasis. All these factors have influence on the validity of this research.

Recommendation The multidisciplinary laparoscopic committee should discuss the elements which indicate risks and perform a Health Failure Mode and Effect Analysis to get more insight in the root cause and effect of the elements.

Introduction

This paper presents the research performed in the last stage of the Master Health Science from the University of Twente. The research is performed in the UMCN St Radboud in Nijmegen. It provides an overview of the element which indicate risks for the quality and safety in a minimal invasive surgery operation room. In the first chapter the background of this research is described. After the background, the research question and the sub questions are introduced with the conceptualization of the used concepts. In the third chapter the method and the research design are explained. In the fourth chapter the data collection methods are described. Per step taken in the data collection the aim, method, results and discussion are elaborated. After the data collection the results of the analyses are described. In this results chapter first the results of the literature review are provided. In the second part the elements that indicate risks for the quality and safety for the organization are elaborated. The conclusion can be found in chapter six. The discussion about the research method and the results is described in chapter seven. After the conclusion and discussion recommendations are given to the hospital about how could be handled after this report. Finally the glossary and references are presented.

Hopefully, this research provides more insight in the elements which can indicate risks for the quality and safety in a minimal invasive surgery operation room.

Background

In this chapter the background for this research is described.

Minimal invasive surgery

Minimal invasive surgery or keyhole surgery is an important development in surgery and is the overall name for all endoscopic procedures. It can, for example, be applied in the abdomen (laparoscopy), chest (thorascopy), joints (artheroscopy), gastrointestinal tract (coloscopy of the colon), uterus (hysteroscopy), blood vessels (angioscopy) [19]. During this type of surgery minimal incisions are made in the body through which the surgeon brings instrumentation and visual tools into the body. Since 1990 the MIS has become part of the procedural repertoire of virtually all surgical disciplines.

The benefits of minimal invasive surgery have been well recorded; they include less trauma, better cosmetics (less scars), less postoperative pain, faster recovery, fewer postoperative complications and reduced hospital stay. Some disadvantages are that there is loss of tactile feedback, the need for increased technical expertise and possible longer duration of the surgery [25, 28]. Advances in technology, specially in fiber optics and the video imaging, have made the relatively recent rapid progress in laparoscopic surgery possible [25, 73]. This type of surgery is technically more complex and sensitive then the traditional 'open' surgery methods and therefore demands other technical skills of the operating staff, equipment and instrumentation [36]. This has led and leads to new problems during these high-tech procedures, creating opportunities for errors or complications to occur [86]. Relatively few researches have been held to investigate the quality and safety in a minimal invasive surgery operation room.

Health Care Inspectorate

The Health Care Inspectorate has published a study in November 2007 that is called '*Risico's minimal invasieve chirurgie onderschat; kwaliteitssysteem voor laparoscopische operaties ontbreekt*'. This study contains a critical review on the quality of minimal invasive surgery in the Netherlands. The study assessed patient safety, the quality of the procedures in terms of practitioners skills and training. The focus of the Health Care Inspectorate was on the more common laparoscopic procedures within general surgery and gynecology. The information was based on questionnaires and interviews. The questionnaires where spread in 92 hospitals and interviews were conducted during visits to twenty randomly selected hospitals [36]. In the conclusions of the research, four major bottle necks where formulated, training, policy, quality assurance and instrument safety.

The training in laparoscopic techniques was found to be variable and inadequately structured during the research period (2004-2006). The standards (skills) for (future) surgeon are inadequately formulated. There is no quality assurance method covering basic laparoscopic skills, in order to ensure responsible use of laparoscopic surgical techniques.

The quality of laparoscopic operation is not adequately assured for the almost all laparoscopic procedures. Hospital registration systems are not always structured in such a way that a clear record of laparoscopic procedures and any related complications and incidents can be presented. Moreover, they do not facilitate an effective evaluation of the procedures and the outcomes. Patient safety has not been adequately safeguarded in most Dutch hospitals by means of complication registration and evaluation.

According to the Health Care Inspectorate there is a lack of protocols for the inspection, maintenance and replacement of laparoscopic instrumentation and related equipment.

Good and adequate policy can facilitate these processes. Clear guidelines and protocols need to be formulated by users committees. When the hospital policy for laparoscopic surgery is inadequate the patient safety is assured is insufficiently[36].

As a result of the study every hospital that performs minimal invasive surgery has to make a plan of action about how to improve the current situation on the mentioned elements.

The Academic Medical Center St Radboud

The Academic Medical Center St Radboud in Nijmegen combines research knowledge with patient care and education. Approximately 8,500 people work in this hospital and around 3,000 students. The mission statement is: "Driven by knowledge, empowered by people"[83].

Specific minimal invasive operation room

In September 2007 the hospital introduced a dedicated operating room (OR) for minimal invasive surgery (MIS), manufactured by Storz, type OR1. Four departments (paediatrics surgery, general surgery, gynaecology and urology) have access to the OR1. Each department can plan operations on a specific day. The OR1 is a pilot operating room introduced to give input for the four new minimal invasive surgery operating room's which are currently build and are taken in production in 2011. The OR1 has also been introduced to train surgical team especially the scrub nurses. There are also several mobile laparoscopic trolleys available for minimal invasive surgery in other operation rooms.

Multidisciplinary laparoscopic committee

In the hospital there is a multidisciplinary monthly meeting of the multidisciplinary laparoscopic committee to discuss subjects about and surrounding laparoscopic and minimal invasive surgery. Examples of the subjects are the purchase and use of the Da Vinci (operating robot), training of residents and the recently started construction of new operation rooms. The aim of the multidisciplinary laparoscopic committee is creating cooperation between the four departments, providing high-level clinical care, training and education, do research and look for innovation. One of the products of the discussion group is the plan of action requested by Health Care Inspectorate. In this plan the approach is given how the hospital is going to improve laparoscopic and minimal invasive surgery. This study is part of the plan of action because it is an inventory of elements that indicate risks for the quality and safety was made.

Organizations

In this paragraph the coherence and interdependence between parts of the hospital is shortly explained according to theory of Thompson. This explanation is necessary to understand the impact of other department of the hospital on the elements which indicate risks in the minimal invasive operation room.

An organization, especially a hospital, is composed of interdependent parts. These parts can depend on each other in different ways. The first way is the pooled interdependence. Each part of the organization provides a discrete contribution to the whole organization. The second way is the sequential interdependence. The interdependence between parts is specified. Part C can only act when part A and B have acted. The last way of interdependence is the reciprocal interdependence. This is a combination of pooled and sequential interdependence but each part dependents on some or all other parts in the organization. These three ways of interdependence provide information about the complexity of the organization. The most complex organization, like the hospital, contains all three types of interdependence [81]. The minimal invasive surgery operation room depends heavily on other departments and part of the hospital. These other department are for example the recovery room, central sterilization department and nursing departments. Visa versa these department also depend on the minimal invasive surgery operation room.

The coordination of the organization becomes more complicated when the complexity of the organization increases. The coordination can, for example, be achieved by standardization of procedures. By the development of routines and rules which contribute to the technical primary process and are supplementary to the actions taken in other parts of the organization. The second coordination method is the coordination by plan. This requires schemes by which the different actors involved in the technical primary process work. The last coordination method is the coordination by mutual adjustment. This means that every action taken in the organization is coordinated by feedback. The actors need to communicate adequately and constantly. The higher the level of complexity the harder the coordination is and the more the parts of the organization depend on communication [81]. A hospital is a very complex organization. Therefore a hospital depends heavily on communication.

Research question

From the information stated above the following research question has been formulated:

Which elements indicate risks for the quality and safety in a minimal invasive surgery operation room? How are these elements prioritized in the hospital?

The minimal invasive surgery operation room (MIS OR) is a complex and demanding organization. In which logistical, organizational, economical, technical, cultural and other elements come together in the technical primary process. The technical primary process of the minimal invasive surgery operation room are the patients which undergo an operation or so called transformation. For the operation staff and facilities are necessary, together with the patient this is the input for the transformation process. The transformation is the minimal invasive operation. The output are the operated patients. These operated patients should have received a safe and qualitative operation. This process is made graphically visible through a transformation box. The transformation box of an minimal invasive surgery can be viewed in figure 1: *minimal invasive surgery transformation process* [74].

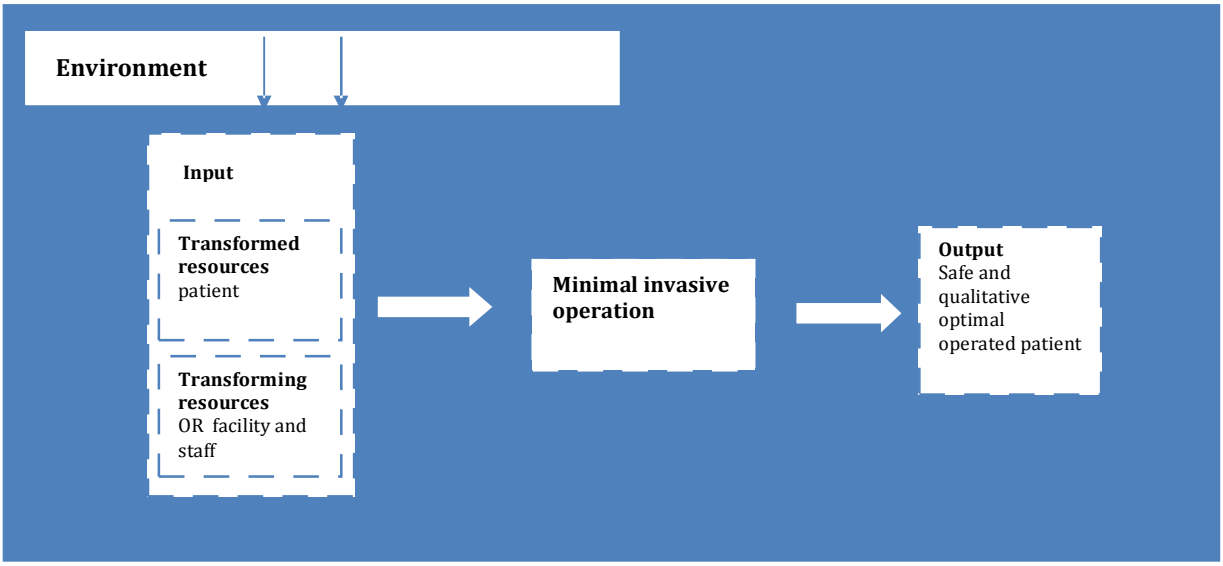

Figure 2: Minimal Invasive Surgery transformation process (adapted model of Slack et al., 2007 [74]).

There are several factors in the environment of the technical primary process that have influence on the input and transformation process and hence on the output of the transformation process. These factors are called elements. An *element* is an environmental fluctuation which interferes with the orderly operation of the minimal invasive surgery operation room and therefore is a risk for the quality and safety. The elements are made graphically visible through the arrows in Figure 1. The amount of influence is different per element and the arrows are an indication of elements that influence the technical primary process. For the construction of the research of elements which indicate risks several concepts are used. The conceptualization of these concepts are elaborated below.

The *technical primary process* of the minimal invasive surgery operation are the interacting and interrelating activities that are necessary to operate and hence transform the patient. The elements, that indicate risks in the technical primary process, can endanger the transforming process immediately. The input, output or the transformation box is directly influenced by these elements.

The *environment* of the minimal invasive surgery operation room are all the interacting and interrelating activities that are of influence on the quality and/or safety of the technical primary process of the minimal invasive surgery room. These elements are indicated with arrows in Figure 1. In the initial design of this research a distinction is made between elements that indicate risks and points of emphasis. This distinction is later partly removed (see interview discussion cycle 2) because points of emphasis are

practical application which indirectly yield risks for the quality and safety. The core of a point of emphasis is risk elements but has an outer layer which is a practical application. The distinction between risk element and focus point cannot be made because the root cause of the elements were not investigated.

The *prioritized elements that indicate risks* are the elements in the technical primary process which are ranked and prioritized by the experts from the hospital in the second interview cycle. Prioritizing is done because not all the obtained elements are equally important.

Risk is a combination of the probability of occurrence of harm and the severity of that harm. Harm is physical injury or damage to the health of people, or damage to property the environment [47]. For this thesis this means, the risk for the quality and safety of the patient and the employee in the minimal invasive surgery operation room. Harm is seen as an deviation from standard that causes a problem for the safety of the patient and employee or leads to a less optimal and beneficial situation for the patient.

The *quality* of an operating room is the level in which the minimal invasive surgery operation room satisfies to the pre-described requirement and delivers a constant output. In this research quality is expressed by qualitative good care for patients. Patients in the minimal invasive operation room are achieving intended care or cure and the results (operated patient) of this intended care or cure is constant.

There are two types of *safety* described in this research, patient safety and employee safety. In general patient safety refers to the concept that patients in health care settings are achieving intended outcomes [27] that are free from unacceptable risk [27]. The concept of employee safety is generally defined as in terms of good ergonomics and comfortable workspace. Ergonomics examines and seeks to minimize risk factors between human beings and the task and environments that occupy them [44]. In this paper employee safety is defined as the employee in a health care setting is not achieving damage because of their work in the minimal invasive surgery operation room, ergonomics is therefore part of this concept. Patient and employee safety are fundamental for quality care [27]

The main research question will be answered by means of the following sub questions:

- Which elements indicate risks for the safety of patients, safety of practitioners or quality in a minimal invasive surgery operation room?
- Which elements indicate risks for the safety of patients, safety of practitioners or the quality in the minimal invasive surgery operation room of the hospital according to the expertise of the experts?
- What is the effect size of these risks?
- What is the chance of occurrence that the element leads to a problem?
- What is the priority the element should have to reduce the risk for the quality or safety?

The *effect size* is the amount of damage (severity) that the element causes when it leads to an incident.

Chance is the likelihood of an element leading to a risk combined with the likelihood of detection.

The main focus of this study as on the minimal invasive surgeries performed in the specific minimal invasive surgery operating room (OR1). Laparoscopic operations, minimal invasive surgery in the abdomen, are the majority of the operations performed by the specialties working in the OR1. Hence, the main focus of this thesis is on laparoscopic procedures performed by pediatric, urological, gynecological and general surgeons. Accordingly laparoscopic surgery has also been the most significant process in general surgery over the last ten years and is being applied increasingly as an alternative to conventional surgery [7, 8].

Methods

In this chapter the methods are elaborated. First the research design is discussed. After that the systematic literature review and finally the expert analysis.

Research design

In this study the operation room is seen as a part of an organization that facilitates the cure process of the hospital. The units of analysis are the involved actors of the (new) minimal invasive surgery operation rooms. This is an deductive research, starting with a systematic literature review. With the information from the literature several rounds of interviews were held, to explore the present situation. This exploratory qualitative study is of value in getting more insight in the element that indicate risks in the minimal invasive surgery operation room by making a inventory of the elements that indicate risks. The research design is made visible in figure 2 : *Research design.*

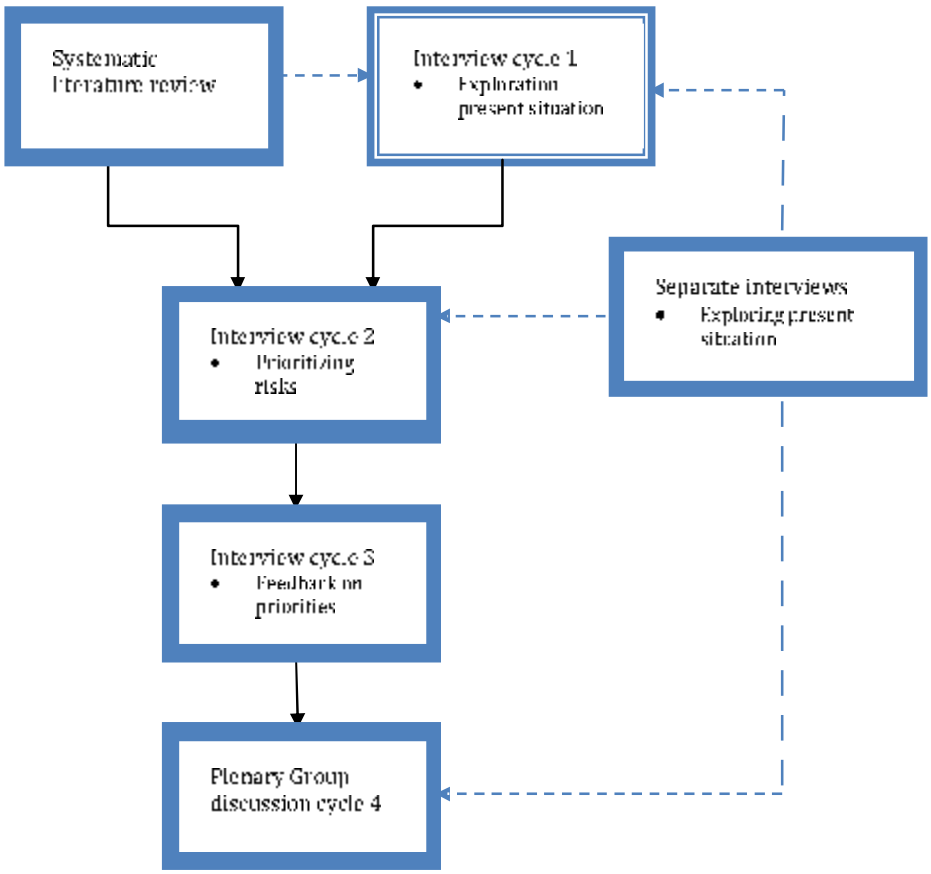

Figure 2: Research design

Systematic literature review

A systematic or sometimes called critical literature research is performed to get more insight and understanding from previous performed studies about elements that indicate risks for the quality and safety in the (minimal invasive surgery) operation room. There can also other reasons to conduct a systematic literature review, to avoid duplication, 'discover' gaps in research and 'place' the research among the work of others [30]. Systematic means that the literature is assessed more objective, it can be generalized more easily and has statistically more power [30]. Using a systematic literature review has the advantage that there is a interplay between the empirical data collected and the theory. A disadvantage of the systematic literature review is that it is time consuming. In this research the literature review will be input for the first and second interview cycle.

The electronic databases for searching were Pubmed, Medline, Picarta, JStore, Web of science and Sciencedirect. The key terms that are used are combinations of: patient, employee, operating room, operating theater, minimal (ly) invasive surgery, minimal access surgery, endoscopic surgery, laparoscopic surgery, ergonomics, policy, instrumentation, training error, complications, safety, quality, risks. The references of the articles are scanned for other related articles. A total 241 articles were found. After reading the abstract 102 articles remained. In total of 66 articles had information about elements which can lead to risks and were put in a table (Appendix I). 30 articles did not have information about elements but had useful information for this research and / or the insight of the researcher. The remaining six articles did not have any information for the report.

Important in a systematic literature review is the assessment of the relevance and value of each found article [19]. This can be done by defining inclusion and exclusion criteria. The inclusion criteria for this research are:

- articles that are written in English and Dutch, about quality and safety in minimal invasive surgery operation rooms,
- studies in which the mentioned operation room's are comparable to the minimal invasive surgery operation room,
- recommendations about effectiveness and efficiency of performance for operating rooms and minimal invasive surgery operation room,
- review and discussion papers about minimal invasive operations or operations with the possibility to generalize to minimal invasive surgery or minimal invasive surgery operation rooms.

Exclusion criteria are:

- papers about the performance of specific operations and performances without possibilities to generalize,
- studies about scheduling efficiency (amount of non operating activities) and financial efficiency,
- studies about risks of patient flow, used operation techniques, economical risks and medical / disease specific risks,
- articles that are published before 1993 and not written in English or Dutch,
- articles with complications and incidents after surgery and elements during the pre- and postoperative organization.

The elements found in the literature were divided into three categories organizational, instrumental and interpersonal. In the organizational category are the elements that indicate risks in the organization of the minimal invasive surgery, like quality assurance and policy. In the instrumentation and equipment category specific elements surrounding the instrumentation and equipment are discussed. The last category is the interpersonal category. In this category the elements were human interaction is actively involved are included. Examples are culture, ergonomics and communication.

These three categories are partly in accordance with the report from the Health Care Inspectorate of November 2007. Four bottlenecks were formulated in this report, training, policy, quality assurance and instrument safety. These were combined in the first two categories. The organizational category with the training, policy and quality assurance. Training is included in this category in spite of the fact that training does not only lie in the organization. The training of residents and currently active surgeons needs to be organized adequately before it can be adopted in the technical primary process. Therefore it is included in this category. The second category equipment and instrumentation was enlarged because of the OR1 in the hospital (equipment) and because instrument safety is only part of the instrumentation elements which can indicate risks. The third category(interpersonal) was added during the literature review because human interaction and human factors have a large influence on the quality and safety according to the literature.

Expert analyses

To assess the risk for the quality and safety in a specific operating room expert knowledge can be used. In this research this is done via the Delphi method. The Delphi method is used to analyze the elements in the minimal invasive surgery operation room which can indicate risks for the quality and safety according to the experts in the hospital

Delphi

In 1963, Dalkey and Helmer introduced an additional feature to the use of systematic group judgment, namely iteration with controlled feedback [87, 17]. The set of procedures that have evolved from this work has received the name Delphi. In this study the Delphi method was used to access the local knowledge of the experts in the hospital.

With the Delphi method a systematic group judgment with iteration and controlled feedback can be performed. The main principle of group judgment is that several heads are better then one. In general, the Delphi procedures have three features: (1) anonymity, (2) controlled feedback, and (3) statistical group response. Anonymity, effected by the use of the questionnaire, is a way of reducing the effect of dominant individuals. Controlled feedback, the results of previous rounds is communicated back to the experts (iteration), is a device to reduce noise. The statistical group response is a device to assure that the opinion of every member of the group is represented in the final response. With several rounds of interviews or meetings the knowledge of the experts can be revealed and assessed.

The Delphi method is a rapid and relatively efficient way to assess the local knowledge of the experts. It creates a highly motivating environment for the experts to react, and the feedback can be novel and interesting for all the experts. Finally, important for this research, the method creates, by using confidentiality and group responses, an arena where the actors are released from their social context [17]. The factors that influence the performance of a minimal invasive operation room cannot only be based on statistical 'hard' data or well validated theories. There is an organization with people involved with social and cultural backgrounds that influence the decisions that are taken. All the experts that are involved have their own opinion about the situation or the elements that influence the situation. However, not all these experts have the same opportunities to ventilate their opinion, knowledge or believes because of the social context they are in. To explore all the believes and reveal the elements that can indicate risks the systematic group judgment of the Delphi method is used. The results of the Delphi method are the subjective knowledge and expertise of the experts in the hospital.

There are some critical aspects to the use of the Delphi method. The experts need to be chosen very careful because they need to have enough expertise and knowledge to assess the problem. When they do not have enough knowledge the results of the analysis can be inadequate and not valid. Another aspect is that the anonymity of the experts needs to be kept. This is especially hard when individual expertise or knowledge statements are presented which are traceable towards an individual expert. A solution would be to make the statements more anonymously but then they can loose there sharpness. The statements can also be neglected because of the use of consensus. One person can believe an elements is of importance while the other experts do not believe so. Because the Delphi methods uses consensus the statement is therefore not included in the research while it can be of the outmost importance. Another aspect is that the Delphi method uses subjective knowledge and expertise of the experts. The expertise does not have to be comparable with the empirical world. The facilitator, in this case the researcher, should have be focused on these weaknesses and prevent them as much as possible during the several interview rounds.

Data collection

The problem discussed in this paper is: "*Which elements indicate risk for the quality and safety in the minimal invasive surgery operation room and which priority does these elements have?*"

Via a systematic literature review and the first interview cycle the elements that indicate risks were explored. After the exploration the elements were prioritized and discussed.

Important in this study was to have a complete set of actors. The actors are selected according to the literature review, consultation of the supervisor of this research from the hospital, who is the chairman of the multidisciplinary laparoscopic committee in the hospital, snow ball sampling [22] and the insight of the researcher. The inclusion criteria for the actors were that they should have or could have insight in the elements which indicate risks for the quality and safety. Excluded are the actors that have purely logistic, economical/financial, technical or medical requirements or do not have insight in present active situation. An as broad as possible range of actors is obtained. Hence, more insight in the situation and more support in the organization is created.

There are three types of experts contacted via the e-mail. The first are the experts that have direct influence on the technical primary process like scrub nurses, surgeons and anesthesia. The second type has because of their job description direct influence on the technical primary process like the central sterilization department and the expert sterile medical instrumentation and equipments. These two types of experts were asked to join the Delphi method with three interview cycles and a discussion session. The third type of experts was asked to contribute to this research via separate interviews. These were experts from the quality assurance departments, the central operation room organization department, the organization of a surgical department or are connected to the minimal invasive surgery on a national level. First the separate interviews are described and afterwards the interview cycles.

Separate interviews

Aim [5]

The aim of the separate interviews is to gain insight in the present situation (and organization) of minimal invasive surgery in the hospital. The question answered with these separate interviews is *How is the present situation of quality and safety for the minimal invasive surgery operation room organized and which elements indicate risks?*

Design

The experts in this cycle were approached by e-mail and are, accept two, employees of the hospital. During the interviews, which took approximately one hour, an unstructured in-depth interview was held according to the systematic literature review (original question) and the expertise of the researcher (follow up questions). The questions were asked by the researcher, recorded and confidential stored.

Method

Seven experts were emailed to contribute to the research through separate interviews. Three of them (50 %) contributed in the same period as the first interview cycle. Two experts (33 %) contributed in the same period as the second interview cycle. The last two experts were no employees of the hospital. They where a gynecologist from another academic medical centre in the Netherlands and member of the Dutch Committee of Endoscopic Surgery and a professor of minimal invasive surgery and a general surgeon in two medical centers in the Netherlands. These experts contributed in the same period as the third interview cycle.

Result

The separate interviews provided insight in the way the quality and safety of the minimal invasive surgery operation room are organized and can be organized in the hospital. The gathered expertise was used to look at minimal invasive surgery from different perspectives.

Discussion

The knowledge gathered during these six interviews provided relevant information for the way the information from the interview cycles can be interpreted.

Interview cycle 1

Aim

The aim of the first interview cycle was to asses the knowledge of the local experts so an overview could be made of the elements that indicate risks for the quality and safety according to the experts. This cycle was also to get more insight in the present situation of minimal invasive surgery in the hospital. The question answered with this cycle was *Which elements indicate risks for the quality and safety in the hospital?*

Design

During the first round the actors were asked for elements in the minimal invasive surgery operation room that indicate risk for the quality and safety. This was reported together with the literature review in an inventory list (see page 19). The experts in this cycle were approached by e-mail and are all employees of the hospital. During the interviews, that took approximately one hour, an unstructured in-depth interview was held. This means that there was a basic structure for the interviews but there was enough room to go deeper into the answers of the interviewee. The questions were asked by the interviewer, recorded and confidential stored. The interview questions were partly from the systematic literature review (original questions) and partly from the insight of the researcher (follow up questions). The systematic literature review was used as background information to understand the current situation and the elements provided from this cycle. The elements from the systematic literature review were not used in this cycle because that would have led to an unnecessary bias. During the interviews the interviewees were encouraged to share their expertise on this topic as much and relevant as possible.

Method

In total 17 (14 original and three via snow ball sampling) experts were asked by e-mail to join three interview cycles and all 17 responded and made appointments (response rate 100 %). Later three surgeons (17,6 %) did not contributed the interview because of planning problem. Therefore they did not contribute to the first interview cycle. During the first interview cycle one of the experts did not have enough knowledge to complete the other cycles and was therefore added to the separate interviews.

The information from the first interview came therefore from 13 interviews. There were five scrub nurses (38.5 %), five surgeons (38.5 %) and three (23 %) others included. The other group includes persons from the Central Sterilization Department (CSD), management and anesthesia.

Results

The 17 experts that were included in this round contributed with 38 elements which can lead to risks for the quality and safety. A total of 14 points of emphasize have been formulated. These points of emphasis do not directly indicate risks for the quality and safety but put the emphasis on practical hospital specific and OR1 specific problems. Together with the 66 elements found with the systematic literature review the elements were input for the second interview round. The total list of elements which can lead to risk for the quality and safety contains 89 elements due to an overlap of 15 elements.

Discussion

Two remarkable aspects can be detected in this interview cycle. The first is that in the literature no points of emphasis are mentioned but from the interview cycle 14 points of emphasis have been formulated. The points of emphasis mentioned during the interviews are specific for the hospital and minimal invasive surgery in the OR1. Examples are the improvement of digital images, the amount of monitors, dedicated teams and the working space of the anesthesia. These points of emphasis do not directly indicate risks for the quality and safety. The core of a point of emphasis is a risk element but the outer layer is a practical problem. Hence, points of emphasis are practical application which indirectly yield risks for the quality and safety. The risks root cause per point of emphasis should have been revealed before they were introduced in the research. This is not done in this research because of the exploring and inventory nature of the research. The remaining of the outer layer of the point of emphasis in the research has led to an unnecessary bias in the research.

The second remarkable aspect is that there was an overlap of only 15 elements between the systematic literature review and the interviews in this cycle. This means that the experts provided 38 elements of which there is theoretical evidence for 15 of these elements. This could have happened because of four reasons. The first is that the systematic literature review is not done properly. The second reason is that the experts chosen for this research are not the correct experts. The experts are chosen by

means of different ways and are the experts with the most amount of knowledge on this subject available in the hospital. The third plausible reason is the expertise of the experts is not comparable with the known theoretical knowledge about this subject. The last plausible reason is that the questions asked in this round were not the correct questions to assess the expertise of the experts. Which of these reasons is the case in this research should be made clear further in this research. This aspect is further discussed in the discussion chapter.

Interview cycle 2

Aim

The main purpose of this second round is to the analysis of the interview data and to rank and prioritize the elements which indicate risks. The central question in this cycle was therefore *Which priority should each element have?*

Design

In the second round a questionnaire was used, to discussed the elements which indicate risks for the quality and safety, which took approximately one hour. The elements revealed in the first round of interviews and the elements found in the literature were input for this round of interviews.

- Is the element applicable to the hospital (yes, no or partly)?
- What is the effect of the element on the quality and safety?
- What is the chance that the risk that is indicated by the element occurs?
- Which priority should the element get in decreasing the risk?

The interviewee ranked these questions for the elements using a type Lickert scale (1 very low and 5 very high). The Lickert scale is a format to determine the relative score of different items (elements). Chosen is for a five point scale because it provides the expert to answer neutral on an element. A disadvantage is that the expert ranks the element neutral without thorough thinking about the element. This is prevented by asking follow up questions when elements are ranked with an three ("Why is this elements ranked with a three"?).

During the first interview cycle 14 points of emphasis have been formulated, an example is that scrub nurses should get more working / bureau space. For these points of emphasis the applicability, effect and chance could not be asked. The interviewee was therefore asked whether or not he or she agreed with the point of emphasis and what the priority should be for the point of emphasis. In this round the questions (elements) were asked by the interviewer, recorded and confidentially stored using the statically software program called SPSS.

Method

In total 16 experts contributed to this round. There were six scrub nurses (37.5 %), seven surgeons (43.8 %) and three others (18.7 %).

For all the risk elements that were applicable to the hospital (>50 % of the experts agreed or partly agreed) and had a mean score of the calculated and/or given priority of above four the hospital specific priority size (HSPS) has been calculated. The HSPS is calculated by means of dividing the mean score per elements by the standard deviation. By calculating this HSPS the amount of agreement or consensus (spread around the mean) was taken into consideration. A high HSPS means that the subjects not only rate the elements as important but also agree about its priority [44]. A HSPS calculation is necessary because of the relative small answering scale (1-5) that was used. The mean of elements can lay closely together but the level of consensus can be different. The focus of this research was on the elements were most of the experts thought the priority should be on.

A disadvantage of the HSPS calculation is that the elements with a low priority score cannot be taken in consideration because elements with a low priority but with a high consensus can score high on the HSPS. Only the elements with a high or very high priority (above four) therefore taken in consideration therefore this is not a disadvantage for this research. Not all the calculated priorities had a mean above four. Hence, the HSPS was not calculated for these elements to prevent that they bias the HSPS. During the first interview cycle 14 point of emphasis were mentioned. The effect and chance of these points could not be asked in the second cycle because of the type of point of emphasis. Therefore that these point of emphasis do not have an calculated priority in the tables.

Results

Every risk element and focus point is put in a table with the results of the systematic literature review and the results of the first two interview cycle. This table can be found in appendix I. In total 30 elements that indicate risks were applicable to the hospital and had a priority above four. Four of the points of emphasis had a priority above four and were therefore taken in consideration.

Discussion

There are two points of discussion for this second interview cycle. The first are the sharpness of the definitions. These definitions were not always formulated sharp enough so a discussion could arise about the exact conceptualization of some elements. The scheduled time was three quarters of an hours which could be stretched towards an hour in most cases but even that hour was sometimes to short because of discussion about the definition. This was the case during the first three interviews in spite of the testing of the questionnaire at forehand. The other thirteen interviews did not had this problem this clear because of adjustments in the questionnaire and definitions had been made. The question remains whether all the experts understood the exact definition of the elements and interpreted it in the same way. This is nearly always the case in subjective expertise analysis and is prevented as much as possible by giving exact the same definition per element during the interviews. The results of the first three experts are in line with the results of the other experts.

Interview cycle 3

Aim

In the third round the results of the first and second interview cycle were discussed. This discussion is taken into account in the final clustering of the elements which indicate risks. The question answered during this interview cycle was *what is the opinion of the experts about the ranked and prioritized elements and points of emphasis?*

Design

The discussion was based on the results of the first two cycles of interviews (see figure 3: *Results of different cycles of the research* page 19). The unstructured interview in this round took approximately half an hour per actor and was confidentially stored.

Method

Nearly all the experts that were included in the second round and one surgeon (excluded in the first two rounds because of the timeframe, n = 17) contributed to this round. A total of six scrub (35.3 %) nurses, eight surgeons (47.1 %) and three others (17.6 %) were included in this round.

Results

After the discussion with each individual experts the elements are clustered into four clusters. These clusters are in accordance with the sub committees of the multidisciplinary laparoscopic committee, organization, training, instrumentation and complication. Each cluster provides the minimal invasive surgery subcommittees incentives to work on. There is a cluster organization in which all the elements that need to be organized are included. The cluster training includes the elements which have coherence with training. In the cluster instrumentation all the elements about instrumentation are included. In the final cluster the elements which have to do with complications are included.

Discussion

During the second interview cycle a bias could have been introduced in the research because of the way the questions were asked and the way the definitions were given. To make sure there was no bias the exact definition of the ranked elements was repeated in this cycle and the expert was asked whether the element was positioned correctly. Non of the elements were excluded or repositioned after the recheck of the definitions used. Therefore the potential bias of the second interview cycle has been decreased or even removed.

Discussion cycle 4

Aim

In the final round a plenary discussion was held about the results of the research to come to more consensus about the clustering of the risk elements and point of emphasis. The central question in this discussion was*Are there clusters made correctly and what is the hospital going to do with this analysis?*

Design

An plenary discussion session was held where all the experts (interview cycle and separate) were invited. Four clusters were made according the comments given in the third interview cycle and the insight of the researcher. The experts could react on this clustering and comment on the prioritized elements and points of emphasis. Most importantly the experts had the ability to directly comment on each others thoughts and believes.

Method

A total of nine experts and the two supervisors of the hospital contributed to this round.

Result

The final discussion clearly showed that some elements are caused by inadequate communication. Further investigation of the elements that are caused by inadequate communication or other elements is necessary. The discussion showed that the research has and is beneficial for the hospital and that there should be an ongoing discussion about these elements and further investigation about cause and effect is necessary.

Discussion

The discussion in this round went as expected. There was an equal division of experts over the three groups. There were four surgeons, three scrub nurses, and two experts from the group others. Together with the two supervisors from this research this was a well balanced discussion group.

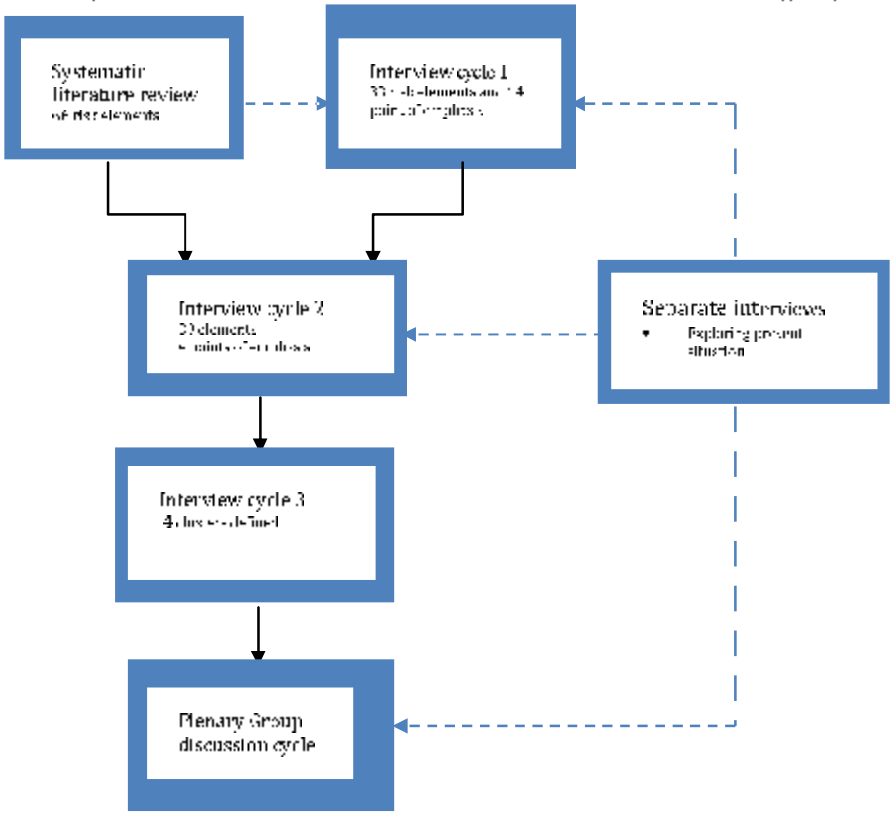

Figure 3: Results of different cycles of the research

Results of analyses

In this chapter the results of the systematic literature review, the interview cycles and the discussion cycle are discussed. First the results of the systematic literature review and the first two interview cycles are discussed by means of an inventory list. The elements and points of emphasis which are applicable to the hospital and have a stated priority above four are elaborated further in the second part of this chapter.

Inventory of elements which can indicate risks

In the table presented below all the elements which could indicate risks found in the literature and the first interview cycle are presented. The definition and additional information per element can be found in appendix I.

The elements are divided into three categories. In the organizational category are the elements that indicate risks in the organization of the minimal invasive surgery, like quality assurance and policy. In the instrumentation and equipment category specific elements surrounding the instrumentation and equipment are discussed. The last category is the interpersonal category. In this category the elements were human interaction is actively involved are included. Examples are culture, ergonomics and communication. The elements are ranked according to the stated priority they received in the second interview round. See the paragraph systematic literature review page 9 and 10 about the categorization of the elements.

Organizational elements

Element	Source	Stated priority
Inexperience surgeon	Alfredsdottir et al., 2008, Berland et al., 2008, Carthey et al., 2003, Dagi et al., 2007, Derossis et al., 1998, Gawanda et al., 2003, Hanna et al., 1997, IGZ, 2007, Jacklin et al., 2008, Park et al., 2004, Reason, 1995, Schaefer et al., 1995, Slack et al., 2007,Tang et al., 2006, Wetzel et al., 2006	4.57
Low minimal invasive surgery volume	Gawanda et al., 2003, Expert A	4.50
No (national) trainings program	Derossis et al., 1998, IGZ, 2007, Slack et al., 2007	4.40
No basic level required before surgeons may operate minimal invasive	Expert A, Expert G, Expert J, Expert M, Expert L	4.43
No protocol training in a skills lab	Expert A, Expert L	4.38
Administrative failure	Endozien, 2007, Gawanda et al., 2003, Reason, 1995, Schaefer et al., 1995	4.29
Lack of protocols or inappropriate protocols for quality assurance	Alfredsdottir et al., 2008, Cuschieri, 2005, Gawanda et al., 2003, Helmreich et al., 1996, IGZ, 2007, Nugteren et al., 2007, Expert A, Expert L	4.29
Unfamiliarity with existing protocols	Expert E	4.21
Scrub nurse has inexperience with the OR1	Expert A	4.15
Instruction of less experienced personnel during the operation	McDonald et al., 2006, Primus et al., 2007	4.15
No (digital) registration of complications	IGZ, 2007, Nugteren et al., 2007, Expert G, Expert J, Expert M	4.13

Table 1.1: Prioritized organizational elements

Element	Source	Stated priority
Absence of super-vision when necessary	Endozien, 2007	4.08
No structured multidisciplinary meeting to evaluate complication	IGZ, 2007, Nugteren et al., 2007	4.06
Lack of cognitive skills	Yule et al., 2006	4.00
Unstructured and divers training	Endozien, 2007, Gawanda et al., 2003, IGZ, 2007, Nugteren et al., 2007 Reason, 1995, Singh et al., 2007	4.00
Input or diagnostic failure	Catchpole et al., 2007, Cuschieri, 2005, Endozien, 2007, Kehlet et al., 2002, Satava, 2005, Schimpff, 2007	4.00
No adequate time out protocol or time out	Dagi et al., 2007, Lingard et al., 2005, Reason, 1995, Expert E, Expert F	3.93
Testing only core knowledge and technical skills	Aggarwal et el., 2006, Aggerwal et al., 2004, Helmreich et al., 1996, Schaefer et al., 1994, Tang et al., 2005, Yule et al, 2006	3.85
Discrepancy between OR1 and the other OR's	Expert G, Expert J, Expert M	3.85
No basic level required before a scrub nurse may assist the MIS	Expert F	3.82
No protocol introduction new techniques	Expert G	3.81
Resistance against protocols	McDonald et al., 2006	3.81
No basic level required for residents before they may operate minimal invasive	IGZ, 2007, Nugteren et al., 2007	3.77
No anesthesia protocol for MIS	ExpertB	3.67
No purchase protocol	Nugteren et al., 2007	3.50
Not using the OR1besides office hours	Expert E, Expert M	3.50
High workload	Alfredsdottir et al., 2008, Berguer, 1999, Berland et al., 2008, Christian et al., 2005, Endozien, 2007, Gawanda et al., 2003, Lee et al., 2007, Reason, 1995, Wetzel et al., 2006	3.50
No adequate video registration system for the evaluation and registration of complication	IGZ, 2007, Nugteren et al., 2007	3.40
Unfamiliarity of students with the OR as working place	Lingard et al., 2002, Lyon, 2003, Lyon, 2004, McDonald et al, 2006, Pandy et al., 2006, Rochlin, 1999	3.29
Unfamiliarity with the guideline for sterilization	Expert C, Expert F, Expert I, Expert L	3.27
More operation time and facilities necessary	Cushieri, 1995	3.14
Multiple competing tasks	Alfredsdottir et al., 2008, Christian et al., 2005, Dagi et al., 2007, Reason, 1995, Wetzel et al., 2006	2.81
No attention sterilization during purchase	Expert C, Expert D, Expert G, Expert I	2.53
Subjectivity in the trainer-trainee relation	Endozien, 2007, Jacklin, 2008, Najmaldin, 2007, Pandy et al. 2006, Reason, 1995	2.50

Table 1.2: Prioritized organizational elements

Point of emphasis	Source	Stated priority
Evaluating existing equipment before purchasing new	Expert H	4.13
Improvement of digital storage of images	Expert A, Expert M	4.00
Surgical super-users	Expert F	3.50
MIS OR near the trauma room	Expert F	2.57

Table 1.1: Prioritized organizational points of emphasis

Equipment and instrumentation elements

Element	Source	Stated priority
Unreliable equipment	Catchpole et al., 2007, Endozien, 2007, Gawanda et al., 2003, Primus et al., 2007, Satava, 2005, Slack et al., 2007, Tang et al., 2005, Tang et al., 2006, Wetzel et al., 2006	4.60
The set is not cleaned properly	Expert M	4.36
No adequate protocol for the cleaning of instrumentation	IGZ, 2007, Nugteren et al., 2007, Expert H, Expert I, Expert M	4.29
Diathermia and other electrosurgical instrumentation problems	Cuschieri, 2005, Endozien, 2007, Machatuta et al., 2007, Smith, 2000 Tang et al., 2005	4.27
No registration of instrumentation tests available for every user	Expert I	4.13
The set is improperly adjusted	Expert M	4.13
The set is incomplete	Expert M	4.07
No adequate protocol for the handling of instrumentation	Nugteren et al., 2007, Reason, 1995, Expert G, Expert M	4.07
Only visual control instrumentation	Expert H	4.08
No employee has the responsibility for the sterilization of instruments	Expert F	4.00
Adjustability of the table columns	Mattern et al., 2007	3.93
Inadequate placement of monitors	Mattern et al., 2007	3.77
Working with gas	Expert A	3.07
Manually cleaning instrumentation	Expert I	3.69
Insufficient illumination	Mattern et al., 2007	3.64
Insufficient air-conditioning	Mattern et al., 2007	3.14
Not following the instructions of the manufacturer	Reason, 1995	3.40
Insufficient positioning devices on the ground	Cuschieri, 1995, Helmreich et al., 1996, Mattern et al., 2007	3.00
Noise level/acoustics	Moorthy et al., 2004, Primus et al., 2007, Reason, 1995, Sevdalis et al., 2007, Wetzel et al., 2006	2.71
Inadequate operation tables	Mattern et al., 2007	2.64
Tripping over cables	Berguer, 1999, Cuschieri, 1995, Helmreich et al., 1996, Mattern et al., 2007, Expert A	2.64
Inadequate placement of lights	Mattern et al., 2007	2.31

Table 3: Prioritized equipment and instrumentation elements

Point of emphasis	Source	Stated priority
Xenon illumination	Expert E, Expert F	4.08
Handling the instrumentation ceiling tower	Expert E, Expert F, Expert H, Expert N	3.77
To much pendels on the ceiling	Expert E, Expert H, Expert K, Expert M, Expert N	3.54
Working space scrub nurse	Expert N	3.46
Surgeons should not use the touch screen	Expert F, Expert H, Expert J, Expert L	3.21
Voice control system (sesam)	Expert A, Expert H, Expert J, Expert K, Expert L, Expert N	2.93
Working space anesthesia	Expert B	2.79
To much monitors in the OR1	Expert E, Expert F, Expert G, Expert J, Expert L, Expert N	2.77
Plasma monitor	Expert E, Expert G, Expert J, Expert K, Expert N	2.77

Table 4: Prioritized equipment and instrumentation points of emphasis

Interpersonal elements

Element	Source	Stated priority
Unrecognized perforation of organs	Cuschieri, 2005, Endozien, 2007, Jacklin et al., 2008, Slack et al., 2007, Smith, 2000, Tang et al., 2005,Tang et al., 2006, Thomson et al., 2005	4.73
No direct vision on complication	Slack et al., 2007, Thompson et al., 2005	4.67
Not working as a team	Alfredsdottir et al., 2008, Catchpole et al., 2007, Cuschieri, 2005, Dagi et al., 2007, Edozien, 2007, Firth-Cozens, 2004, Healey et al., 2006, Helmreich et al., 1996, McDonald et al., 2006, Reason, 1995, Satava, 2005, Schaefer et al., 1995, Schimpff, 2007, Expert A, Expert L	4.38
In adequate communication	Aggerwal et al., 2004, Alfredsdottir et al., 2008, Carthey et al., 2003, Catchpole et al., 2007, Dagi et al., 2007, Endozien, 2007, Firth-Cozens, 2004, Gawanda et al., 2003, Healey et al., 2006, Helmreich et al., 1996, Kneebone et al., 2007, Lingard et al. 2006, Lingard et al., 2002, Lingard et al., 2004, Lingard et al., 2005, McDonald et al., 2006, Mills et al., 2008, Ranger et al. 2004, Reason, 1995, Satava, 2005, Schaefer et al., 1994, Schaefer et al., 1995, Sevdalis et al., 2007, Yule et al, 2006, Expert A, Expert B, Expert C, Expert F, Expert M, Expert L, Expert N	4.38
Lack of vision through bleeding	Expert A	4.29
Inevitability mistakes	McDonald et al., 2006	4.27
Fatigue or lack of sleep	Aggerwal et al., 2004, Berguer, 1999, Endozien, 2007, Reason, 1995, Taffinder et al, 1998, Wetzel et al., 2006	4.21
Inadequate placement trocars	Ahmed et al., 2007, Jansen et al., 2004, Slack et al., 2007	4.14
Lack of non technical skills of a surgeon	Gawanda et al., 2003, Helmreich et al., 1996, McDonald et al., 2006, Mills et al., 2008, Schaefer et al., 1994,Schaefer et al., 1995,Yule et al, 2006	4.14
Inadequate use of instrumentation	Joice et al., 1998	4.07
Reliance on memory	Endozien, 2007, Lingard et al., 2005, Reason, 1995, Schimpff, 2007	4.00
No direct access to bleeding	Cushieri, 1995	3.93
Not working in a chain	Expert B, Expert D, Expert F, Expert I	3.88
Positioning of the patient	Ahmad et al., 2007, Berguer, 1999, Bolton et al., 2006, Slack et al., 2007, Expert A, Expert E	3.86
Stress	Alfredsdottir et al., 2008, Aggerwal et al., 2004, Berguer, 1999, Berland et al. 2008, Firth-Cozens, 2004, Helmreich et al., 1996, Lee et al., 2005, Schaefer et al., 1994,Schaefer et al., 1995, Wetzel et al., 2006 Yule et al., 2006, Expert A	3.86

Table 5.1: Prioritized interpersonal elements

Element	Source	Stated priority
Standing or static work posture	Berguer, 1999, Cuschieri, 1995, Lee et al., 2005, Mattern et al., 2007	3.85
Bad emotional climate	Berland et al., 2008, Firth-Cozens, 2004, Helmreich et al., 1996, Kneebone et al., 2007, Lyon, 2003, Lyon, 2004	3.71
Information loss	Christian et al., 2005, Firth-Cozens, 2004	3.56
Operating with elevated arms	Cushieri, 1995, Mattern et al., 2007	3.46
Poor posture through team members	Mattern et al., 2007	3.46
Uncomfortable instrumentation	Berguer, 1999, Cuschieri, 1995, Mattern et al., 2007	3.46
Lack of social support	Berland et al., 2008	3.43
Communication breakdown	Alfredsdottir et al., 2008, Christian et al., 2005, Dagi et al., 2007, Firth-Cozens, 2004, Helmreich et al., 1996, Lingard et al., 2005, Lingard et al., 2006, Schaefer et al., 1995, Sevdalis et al., 2007, Schimpff. 2007, Yule et al, 2006	3.44
Distraction and / or interruption	Catchpole et al., 2007, Cuschieri, 1995, Dagi et al., 2007, Endozien, 2007, Gawanda et al., 2003, Helmreich et al., 1996, Lee et al., 2007, McDonald et al., 2006, Moorthy et al., 2004, Primus et al., 2007, Reason, 1995, Schaefer et al., 1995, Sevdalis et al., 2007, Wetzel et al., 2006 Expert A Expert H	3.40
Feeling unsafe	Rochlin, 2007	3.21
Discrepancy ergonomics and sterilization	Lee et al., 2007, Expert C	3.13
Standing on one leg	Mattern et al., 2007	3.08
Adjustability ceiling towers and monitors	Berguer, 1999, Cuschieri, 1995, Mattern et al., 2007, Reason, 1995, Expert E	3.08
Demanding psychomotor skills	Dongen et al., 2008, Gallagher et al., 2003, Hance et al., 2005, Kneebone et al., 2007, Najmaldin, 2007, Schimpff. 2007, Taffinder et al., 1998	3.00
Less degrees of freedom	Berguer, 1999, Gallagher et la., 2003, Joice et al., 1998	3.00
Strong hierarchy	Schimpf, 2004	2.93
Limited tactile feedback	Berguer, 1999, Eltaib et al., 2003, Najmaldin, 2007, Stefanidis et al., 2007	2.85
Fulcrum effect	Berguer, 1999, Gallagher et al., 2003, Najmaldin, 2007	2.77

Table 5.2: Prioritized interpersonal elements

Point of emphasis	Source	Stated priority
Dedicated teams	Expert A, Expert F, Expert G, Expert J, Expert K, Expert M, Expert L	4.33

Table 6: Prioritized interpersonal point of emphasis

Element which indicate risks for the hospital

The 89 elements that indicate risks for the quality and safety and the 14 points of emphasis have been prioritized by the experts of the hospital. The elements and points of emphasis with a stated priority above four and of which more than 50 % of the experts agreed or partly agreed about the applicability are elaborated in this part of the results. The elements which did not meet the required requirements were not taken into further consideration.

In total 30 elements that indicate risks were applicable to the hospital and had a priority above four. Four of the points of emphasis had a priority above four and were therefore taken into consideration. These elements and points of emphasis are divided over four clusters. These clusters are in accordance with the sub committees of the multidisciplinary laparoscopic committee, organization, training, instrumentation and complication and are the result of the third interview cycle. Each cluster provides the minimal invasive surgery subcommittees incentives to work on.

Per cluster a diagram has been made. In the diagram a central concept is put in the middle. Each central subject is surrounded by all elements that indicate risks and sometimes the prioritized points of emphasis (green) that are connected with the central concept. The diagram does not mirror the empirical world but is merely a presentation of the gathered elements.

The elements and points of emphasis are ranked according to the Hospital Specific Priority Size (HSPS). By calculating this HSPS (mean divided by the standard deviation) the amount of agreement or consensus (spread around the mean) was taken into consideration. A high HSPS means that the subjects not only rate the elements as important but also agree about its priority [24]. Per element a table is presented with the applicability of the element to the hospital and the percentage of experts that did not have enough knowledge to rank the element. The percentages were rounded up.

For each cluster a short report of the first interview cycle is given, to get insight in the current situation and the way the experts initially viewed the concepts discussed in this research.

Organization

The organization cluster is the first cluster elaborated in this chapter. First the results from the first interview cycle are discussed to get more insight in the current situation of the cluster. After warts the final clustering of the organizational elements are discussed.

During the first interview cycle the organization of the minimal invasive surgery operation room is mainly discussed by means of quality and quality assurance. Two experts mentioned that their department works adequate on quality assurance because only a select group of people is in the minimal invasive surgery operation team. When the team is expanded more performances need to be standardized for quality assurance Expert A, J. By decreasing the working area and improving the minimal invasive surgery volume the quality will also increase Expert A. It is for minimal invasive surgery, more than for conventional surgery, important that the professionals in the operation room work as a team. The whole team should have enough adequate knowledge to perform the operation Expert J.

Nearly all performances of the scrub nurses are in protocols. The performances which are not in protocols are standardized and protocols are made for these performances Expert G, E, F, H, K, N.

The organizational cluster include all the elements that indicate risks for the organization. The six elements in the diagram are no particularly for minimal invasive surgery operation room but can be applied to other operation room or parts of the organization. For the improvement quality and safety of the minimal invasive surgery operation room focus should lay on these elements, according to the experts. To optimally improve these items a quality aim should be developed. All actors involved, should be focused on the application and executing of this quality aim [18].

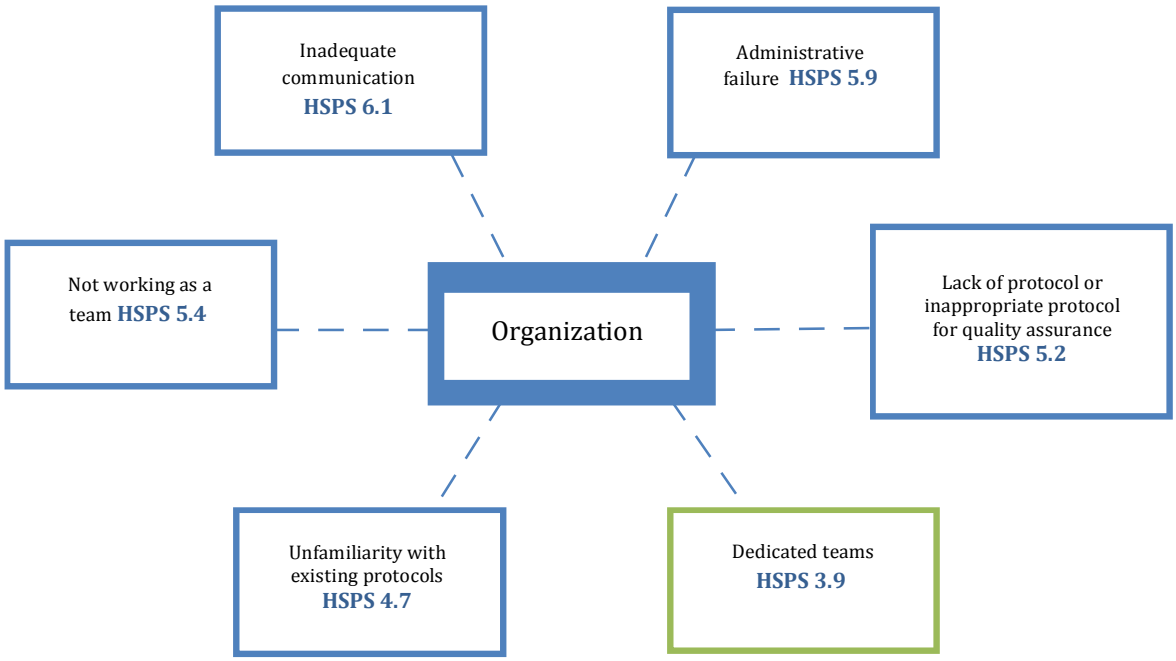

Figure 4: Diagram of the elements that indicate risks for the organization of the minimal invasive surgery operation room.

Inadequate communication (HSPS 6.1)

Inadequate communication can be measured to the level how well a surgeon and other team members communicate patient related information to the other staff members. Examples are the clarity, timing, audibility and content of communication [9]. Communication failure or inadequate communication underlies almost all medical accidents [23, 47, 48, 88]. Good and adequate communication can also decrease risks and complications in the operating room [47, 48, 54, 70, 82]. Therefore communication should have and remain under the attention in the process of improving quality and safety.

The experts prioritized this element relatively low in comparison with the other elements that indicate risks. Inexperienced surgeons (HSPS 8.9) and low hospital volume (HSPSS 8.7) score for example much higher. The retrieved theory underlines the importance of adequate communication to prevent risks from happening. This is not comparable to the prioritizing of the experts. The experts see inadequate communication as less important in comparison with the literature known about risks in the operation room. There was no deviation between the prioritizing of the three groups of experts (surgeons, scrub nurses or others).

Inadequate communication			
Applicable	Yes (37 %)	No (31 %)	Partly (31 %)
Expert did not have enough knowledge to rank and prioritize this element			

Administrative failure (HSPS 5.9)

Mistakes made in the administrative area can lead to errors in the operation room. Examples are typing errors, wrong file with the patient or incomplete files. These failures can be prevented with checklists and time out protocols.

Administrative failure			
Applicable	Yes (25 %)	No (31%)	Partly (31 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Not working as a team (HSPS 5.4)

The staff is working in the same location, sharing workspace and overlapping responsibilities and goals, each with a clear distinction in their role but not working as a team [70]. For a surgical intervention working in a team can work two-tailed. On the one hand errors often occur in team settings in which many professionals work together (anesthesia, surgeons, scrub nurses, most of the time residents and other specialist involved in the operating room) [26]. On the other hand enhancement of team performance in the operating should lead to increased safety. Successful surgery depends on effective teamwork [33]. Several specialism like anesthesia, surgeons, and scrub nurses are working in the operation room. They have their own culture and ways of intervening with each other. Communication is essential in working as a team. Working as a team will lead to a safety culture, which is necessary in a complex organization were there is a constant interaction between the operating team, equipment, instrumentation and the patient. In a safety culture all the members of the team take their responsibility and act accordingly. No individuals are blamed for their actions [53].

As can be seen from the literature working in a team is important. This elements scores relatively low according the prioritizing of the experts. This is due to the fact that one expert (surgeon) prioritized the element 'not working in a team' with a low priority. The other experts ranked this element four or higher. The low priority score has influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element.

Not working as a team			
Applicable	Yes (13 %)	No (38 %)	Partly (50 %)
Expert did not have enough knowledge to rank and prioritize this element			

Lack of protocols or inappropriate protocol for quality assurance (HSPS 5.2)

Quality and quality assurance is important during minimal invasive operation. One way of ensuring quality is having valid and reproducible performances. This can be achieved by standardizing work through adequate and appropriate protocols. The standardization and making protocols of work tasks, in the form of evidence-based guidelines, checklist and systematic processes, are seen as reducing the opportunities situation to become hazardous for the quality and safety especially it will limit the potential of wrong-doing or human error [15, 53, 57, 60]. Clear, uniform protocols for every procedure help to reduce the human errors and complications during the operation [23, 18] [Expert D]. For the scrub nurse most performances are standardized in work instruction and in protocols.

Currently there are no surgical protocols [Expert F] for, for example the positioning of a patient during specific operation. This can has a result that the patient needs to be repositioned when the surgeon arrives. This repositioning can lead to delay of the operation and extra work for the operation team. The main problem of standardization and protocols are that comparable surgical operations are performed differently between departments and even between surgeons in the same department. Hence, detailed protocols in how a certain operation should be precisely performed do not exist. This causes limitations with regard to the training of residents and it makes it difficult for the other members of the operating team to develop a routine. Protocols or a step-by-step plan should be made per operation to enlighten the most important steps. Surgeons can have their own deviation from these steps but they have to discuss it at forehand with the team during for example the time out. The steps in the step-by-step plan can be seen as checks during the operation. These steps can also function as guidelines for the making of digital images. When performances are standardized and in protocols they have to be managed, evaluated and improved. This is ongoing a cycle of quality. Like the plan-do-check-act quality circle of Demming [85].

In total four experts said that protocols for quality assurance is partly applicable to the hospital. Three of these experts are scrub nurses and scrub nurses do have quality assurance protocols. One surgeons prioritized this element with a low priority (two). This has influence on the HSPS because the other experts rank this element with a four and higher. Because of this one surgeon the element about quality assurance protocols has a relative low HSPS.

Lack of protocols or inappropriate protocols for quality assurance			
Applicable	Yes (63 %)	No	Partly (25 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Unfamiliarity with existing protocol (HSPS 4.7)

Protocols and standardization of minimal invasive surgery procedures are the basis for the quality assurance in the execution of the operations [15]. The Health Care Inspectorate agrees that protocols are important to assure quality [36]. Having good protocols is only part of quality assurance, knowing that performances are standardized and handling accordingly is another part.

The central operation room managers are trying to reduce the unfamiliarity of the scrub nurses with protocols [Expert D and F]. In spite of this effort some protocols remain unfamiliar for the scrub nurses. An example is the protocol for the cleaning of instrumentation by the CSD. Scrub nurses do not have to perform the described actions their selves but it is more efficient when they are familiar with the protocols further in the logistic chain. This way they can provide the instrumentation as optimal as possible for the CSD.

Two expert (a scrub nurse and a surgeon) did prioritize this element with a low (two) and modest priority (three). The other expert ranked this with a high and very high priority. Therefore the HSPS is relatively low.

Unfamiliarity with existing protocol			
Applicable	Yes (50 %)	No (25 %)	Partly (19 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Dedicated teams (HSPS 3.9)

An dedicated team is a team with members which are dedicated to a surgerical department (specialty) and often work together on specific operations. Examples are the teams of the operating room of the Da Vinci and the OR1. Minimal invasive surgery is, as mentioned before, technical driven. Therefore dedicated teams are more important for minimal invasive surgery in comparison with conventional surgery. Dedicated teams know each other very well and anticipate better on each other. Research shows that teams which have work together some time, have better results which is due to better communication [27]. The consequence is that the planning, especially for scrub nurses, with dedicated teams is more difficult. The shift (operations outside office hours), holidays and when people are ill are much harder to schedule and to participate on when there are dedicated teams [Expert D]. Therefore this point of emphasis scores low. In spite of the fact that a well-rehearsed (dedicated) operation room team is an advantage in reducing the operating time, stress level and other interpersonal aspects [6]. When the performances and operation in the minimal invasive surgery operation room are standardized and discussed during the time out, the need for dedicated teams will probably decrease. Hence, the focus should lay on the standardization of performances.

Dedicated teams			
Agree?	Yes (88 %)	No	Partly (6 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Training

The second cluster of elements that indicate risks is the cluster training. First the results from the first interview cycle are discussed to get more insight in the current situation of the cluster. After warts the final the trainings cluster is discussed.

During the first interview cycle the training of future surgeons and scrub nurses is discussed with almost all experts. The experts which are not directly involved in the technical primary process agree that all personnel needs to get and most importantly remain skilled. The obligatory free nature of the skills lab needs to disappear and the surgeons should meet the predefined requirements before they may operate minimal invasively. Gynecology has formulated basic requirements for their future surgeons by means of gradation of the difficulties of the operation [Expert J, K].

For the scrub nurses and the anesthesia there are also no requirements before they may assist and facilitate the minimal invasive operation. The experts do not think that the scrub nurses and anesthesia need to have requirements because they do not operate the patient but facilitate the surgeon.

The improvement of the training of new surgeons and currently active surgeons has been one of the key items of the multidisciplinary laparoscopic committee. Surgeons with adequate knowledge, skills and experience will operate more optimal in comparison with surgeons who are inexperience without adequate knowledge and skills. The skills training of residents and the preservation of skills these is vital for minimal invasive surgery, because minimal invasive surgery requires specific skills of surgeons.

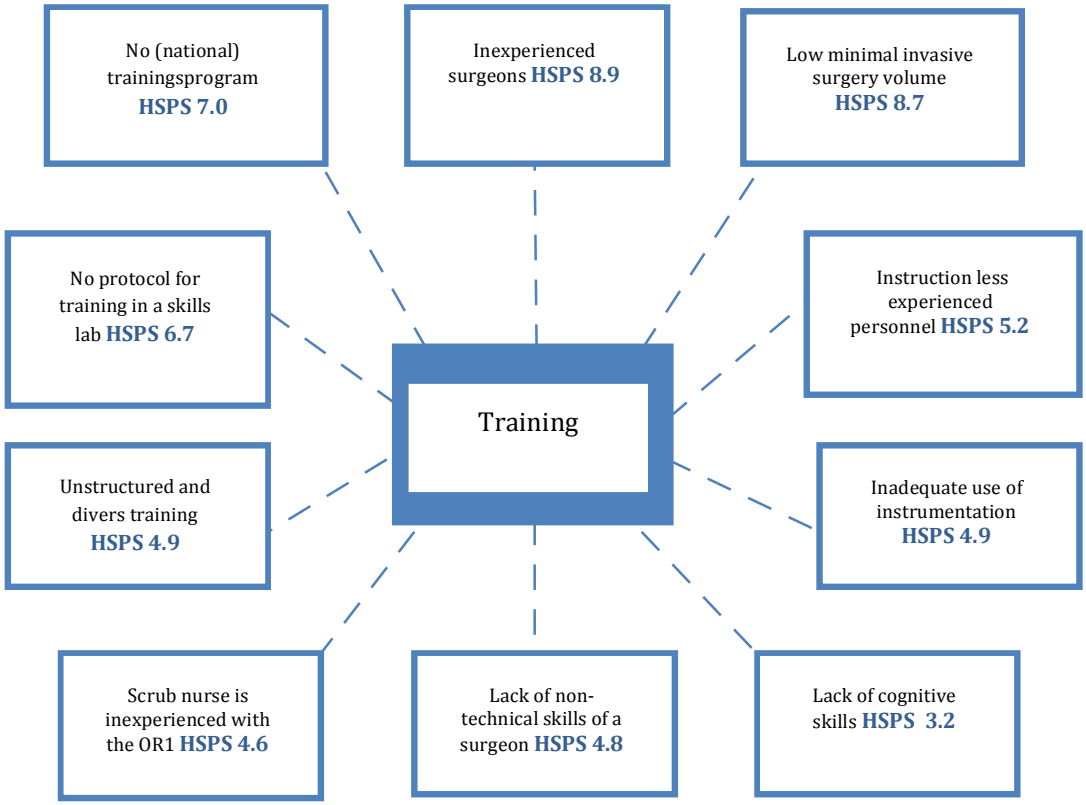

Figure 5: Diagram of the elements that indicate risks for the training in the minimal invasive surgery operation room.

Inexperienced surgeon (HSPS 8.9)

Inexperienced surgeons means that the surgeons has no or not enough knowledge to perform minimal invasive surgery or specific minimal invasive operations. The level of knowledge and required skills depends on the type of surgery. These requirements should be preferably formulated by the specific national committees per specialism, which are connected to the NVEC (Dutch Committee of Endoscopic Surgery). Examples of the specific national committees are the WGE for the gynecologist and the WEC of the general surgeons.

Expert E said 'There are surgeons which do not have enough skills to operate. Hence, external experts or internal experts are asked to supervise'. Several experts found it remarkable that this element was ranked this high for the OR1 [Expert D, F, M, O]. This can be due to the fact that specific skills are required of the surgeons and that some surgeons do not have all the skills necessary to perform optimal minimal invasive surgery. This is comparable with the literature. All the experts ranked this element with a high or very high priority. Skills training and basic skills levels are necessary to avoid that inexperienced surgeons operate minimal invasively.

Inexperienced surgeons			
Applicable	Yes (13 %)	No (19 %)	Partly (56%)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Low minimal invasive surgery volume (HSPS 8.7)

Low minimal invasive surgery volume means that specific minimal invasive operation are not performed frequently. This has as a result that surgeons cannot develop or maintain their skills adequately. Minimal invasive surgery is a technical driven type of surgery which also demands special skills of the surgeons. A certain amount of minimal invasive surgery volume is necessary to obtain skills and remain skilled. The minimal volume for specific operations of a hospital should be decided on by the NVEC or the specific national committees per specialism.

There was a wide range of answers to the question if the low minimal invasive surgery volume was applicable to the hospital. There was more consensus about the priority the elements should have. In total seven experts ranked it as a high priority and seven as a very high priority.

Low minimal invasive surgery volume			
Applicable	Yes (31 %)	No (31 %)	Partly (25 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

No (national) trainings program (HSPS 7.0)

There is no trainings program or national norms for the training and education of currently active surgeons and surgeons still in their learning curve, whom perform or want to perform minimal invasive surgery. Trainings programs, whether national or not, have influence on the performance of a surgeon. Not having an adequate trainings program for currently active surgeons and residents can increase the chance that a surgeon makes a mistake at the sharp end of the surgery [23]. Hence, a good trainings program with adequately formulated requirement by the specialties in the hospital or there national endoscopic committee will contribute to the quality and safety in the operating room.

One surgeons prioritized this element with a modest priority. This expert believes that it is not the priority of the hospital to organize trainings programs for minimal invasive surgery but a national priority. The other experts prioritized this element with a high or very high priority.

No (national) trainings program			
Applicable	Yes (69 %)	No (13 %)	Partly (13 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

No protocol training in a skills lab (HSPS 6.7)

Skills labs have been developed to train basic endoscopic surgical skills outside of the operating room [21]. Currently the main part of the surgical training takes place in the operating room. Whereas outside the operating room (for example in a skills lab) some basic skills are learned [18]. Hence, training in a skills lab with a adequate training protocol should be obligatory which is not the case currently specific for minimal invasive surgery. Before a complex task can be and may be performed a wide range of minimal invasive requirements like eye-hand coordination need to be mastered. Other examples of these to be mastered procedures are time and motion (number of movement), respect to tissue instrumentation handling, knowledge of instrumentation, flow of the operation [71]. These procedures should be trained or performed on a regular basis to maintain skills level [74]. Tests should be developed to see if a surgeons masters the required skills and consequences should be taken when the surgeon does not meet the required skills. These basic skills should be taught in the trainings programs maybe in a skills lab to reduce the number of inexperienced surgeons.

It is important that the training in a skills lab supplements the national or specific trainings program to the desired skills level. One expert (scrub nurse) prioritized this element with a modes priority. The other experts ranked it with a high or very high priority.

No protocol training in a skills lab			
Applicable	Yes (81 %)	No	Partly
Expert did not have enough knowledge to rank and prioritize this element			(19 %)

Instruction less experienced personnel (HSPS 5.2)

During the operation team members can give less experienced personnel instructions about the use of instrumentation or equipment. The inexperience is due to a lack of knowledge. For example a scrub nurse who suggests to a surgeon to use another electrosurgical tool because it works more efficient or a surgeon who has to explain how to use the illumination switch. This can lead to distraction, which should be avoided an operation room. It can also be an advantage because new skills and experience can be introduced to the entire team through the knowledge of one team member. The priority is of the experts is comparable with the literature.

Instruction less experienced personnel			
Applicable	Yes (50 %)	No	Partly (31%)
Expert did not have enough knowledge to rank and prioritize this element			(19 %)

Unstructured and diverse training (HSPS 4.9)

During their training residents should learn basic surgical skills. At the moment there is no structure in the education and training of residents and currently active surgeons. Nugteren et al. stated in the Healthcare Inspectorate Report of November 2007 that less than 20 % of the trainings facilities had requirements formulated before a resident could operate minimal invasive under supervision or independent [26]. In the hospital there is also diversity in the trainings facilities and requirements for the resident. There is also no clear structure in the training. In spite of the clear relationship between the rates of injury (complication), the complexity of the surgery and the learning curve of the surgeon. Other elements that enhance the surgery are correct instrument choice, adequate exposure and visualizations of the anatomy and good surgical techniques. All these elements should be included in the learning curve of the surgeon [81].

Minimal invasive surgery requires a high degree of technical skills and training [74]. The most fundamental laparoscopic skills, such as object manipulation, suturing and cutting require bimanual coordination [44]. These are different from the conventional 'open' surgery on the optics and instrumentation. Surgeons must learn to operate with long instruments, which amplify tremor and are harder to control than instruments for conventional surgery. The instruments (retractors) are limited in their range of motion by the trocars and the constraint of length and width of these instruments have limiting engineering design. During laparoscopic surgery the surgeon looks at a monitor to see his handling. The surgeon works with two-dimensional vision (depth is lacking) and the monitor is most of the time positioned in another direction then the hands of the surgeon are [20, 40]. The instruments also

provide just a limited amount of tactile feedback [62]. These aspects should be trained and evaluated. This training can be done in the operating room and with a virtual skills trainer (skills lab).

In comparison to the literature this element score relatively low. This is due to the fact that four experts prioritized this element with a modest priority. Three of these experts are surgeons and one scrub nurse. These modest priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element. Therefore this element has a HSPS of 4.9.

Unstructured and divers training			
Applicable	Yes (63 %)	No (13 %)	Partly (6 %)
Expert did not have enough knowledge to rank and prioritize this element			(19 %)

Inadequate use instrumentation (HSPS 4.9)

Certain instrumentation can be used in different ways and also used inadequately. Inadequate use of instrumentation is not optimal for instrumentation and is also not optimal for the quality of the operation. Instrumentation should be used only for the performances for which it is intended.

Inadequate use instrumentation			
Applicable	Yes (38 %)	No (19 %)	Partly (31 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Lack of non-technical skills of a surgeon (HSPS 4.8)

For a long time technical skills were the only skills required for a surgeon. Now a day's technical skills are seen as one of the skills required to perform a successful operation. Teamwork, communication, situation awareness, judgment and leadership are the so called non-technical skills which are also part of the range of skills that a surgeon needs to have to perform a successful operation [88, 5]. These skills were not formally though in the surgical curriculum for a long time but were acquired over time. In the recent education curriculum the training of non-technical skills is possible. Skills like team interaction and communication in a 'safe' setting with the proper feedback are in this education program [76]. For effective non-technical skills assessment, the system needs to be explicit, transparent, reliable and valid [89]. This element is a specification of the element communication and working in a team. This element focuses on the non-technical skills of a surgeon.

Because of this element is a specification for surgeons of two other elements this element has a lower HSPS. Here is one expert (surgeon) which prioritized this element with a low priority and one expert (scrub nurse) prioritized this element with a modest priority. These priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element.

Lack of non-technical skills of a surgeon			
Applicable	Yes (13 %)	No (25 %)	Partly (50 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Scrub nurse is inexperience with the OR1 (HSPS 4.6)

The scrub nurse has no experience or too little experience with the specific minimal invasive surgery operation room. The OR1 has specific equipment and is more technical driven than the other separate minimal invasive surgery trolleys. Hence, every scrub nurse needs to be trained to work on the OR1. Not everyone has had this training but the central operating room are actively training the staff. When this is done the OR1 can also be used beside office hours. This has two advantages according to the experts interviewed, the OR1 is more efficient and more ergonomically in comparison with the separate trolleys.

Scrub nurse is inexperienced with the OR1			
Applicable	Yes (25 %)	No (19 %)	Partly (38 %)
Expert did not have enough knowledge to rank and prioritize this element			(19 %)

Lack of cognitive skills (HSPS 3.2)

Traditionally surgical training is based on the technical skills of a surgeon. Non-technical skills and cognitive skills did not have the primary focus during training and education for a long time. In the current curriculum of the training and educations of surgeons these skills are included. Non-technical skills are for example leadership and communication. Cognitive skills are the assessment of risks,. The training of cognitive skills is important for minimal invasive surgery because minimal invasive surgery can lead to other complications then conventional surgery. Complications can occur outside the vision of the surgeon and lead to delays in the recovery. Therefore surgeons need to be well trained not only in the techniques of the surgery but also in the recognition of early signs of abnormal recovery to minimize complications [87] [Expert K. The training of cognitive skills should be part of the other trainings program like the training in a skills lab and the basic requirements for a surgeon.

The lack of cognitive skills scores relative low in comparison with the other elements. Assessment of risk, planning, anticipation, prediction of difficulty about possible actions is one of the basic skills a surgeon should have. This element score relatively low because one expert (surgeon) prioritized this element with a very low priority, one expert (surgeon) prioritized this element with a low priority and one expert (scrub nurse) prioritized this element with a modest priority. The other expert prioritized this element with a high or very high priority. These priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element.

Lack of cognitive skills			
Applicable	Yes (31 %)	No (19 %)	Partly (38 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Instrumentation

The third set of elements that indicate risks is the cluster instrumentation. First the results from the first interview cycle are discussed to get more insight in the current situation of the cluster. After warts the final the instrumentation cluster is discussed.

The instrumentation and equipment of the minimal invasive surgery operation room is a vividly discussed subject. All experts had some comments on the instrumentation or equipment. Whether is was the Xenon illumination, the table or the cleaning or testing of instrumentation.

Good and adequate functioning instrumentation and equipment the will increase quality and safety of the minimal invasive surgery operation room. The introduction of the OR1 has been a good step forwards to uniformed instrumentation. Although the emphasis should remains necessary on adequate and uniform instrumentation and equipment. This is also one of the conclusion in the Health Care Inspectorate report of November 2007 [36]. The elements in this cluster are not specifically for minimal invasive surgery. Although good and adequate instrumentation is more important for minimal invasive surgery in comparison to conventional surgery because minimal invasive surgery is more technical driven then conventional surgery. In the instrumentation cluster there is also an equipment point of emphasis, namely the xenon illumination. The other point of emphasis in this cluster is the evaluation before new instrumentation is purchased.

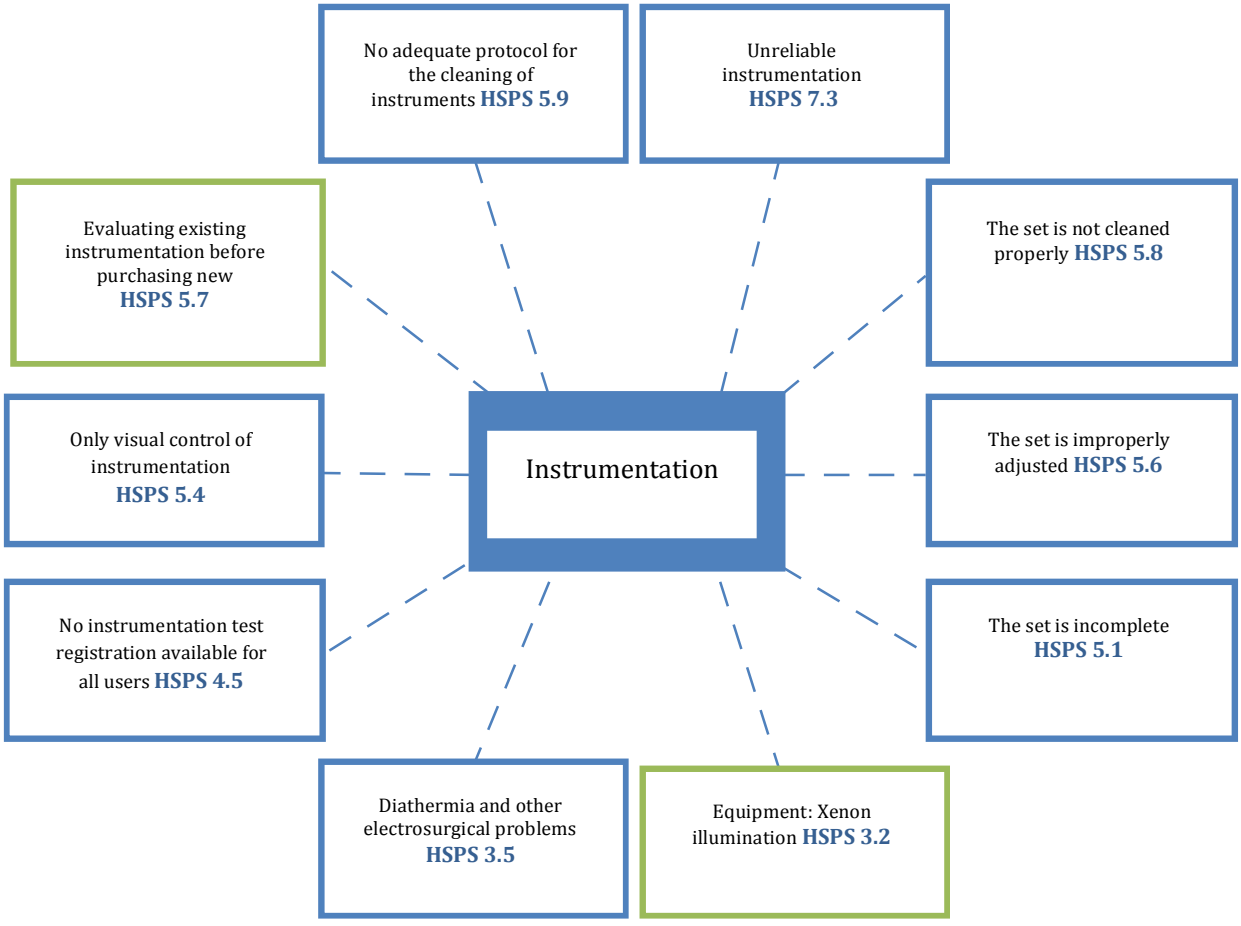

Figure 6: Diagram of the elements that indicate risks for the instrumentation of the minimal invasive surgery operation room.

Unreliable equipment and instrumentation (HSPS 7.3)

Unreliable and not adequately functioning instrumentation and equipment can have two consequences. The first is distraction and delay of the procedure. A new set has to be brought in the operating room and the routine of the operation can therefore be disturbed. The second consequence is that damage can occur through the use electrosurgical instrumentation (see heading Diathermia and other electrosurgical problems) [87]. Important for an operation is that not only the surgeon but the whole surgical team has no tension during a minimal invasive operation. Unreliable and not functioning equipment and instrumentation can raise the stress level of the team which does not contributed the efficiency and effectiveness of an operation. Not having adequate and reliable equipment and instrumentation can increase the chance that a surgeon makes a mistake at the sharp end of the surgery [23]. Important for the CSD that there is more information about the type of unreliability and the amount of unreliability [Expert I].

One expert (surgeon) prioritized this element with a modest priority. Four expert, from all three groups, with a high priority and the rest of the expert as a very high priority. This result is comparable with the literature.

Unreliable equipment and instrumentation			
Applicable	Yes (38 %)	No (31 %)	Partly (25 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

No adequate protocol for the cleaning of instruments (HSPS 5.9)

According to some experts there is no adequate protocol for the cleaning and sterilization of specific minimal invasive instrumentation. In the operating room the tubes and hollow instrumentation should be flushed after the operation with water. All the scrub nurses flush the hollow instrumentation but there is protocol available. The cleaning at the CSD is done via protocols but not all the interviewed experts had this knowledge. Communication is the problem that is indicated with this element and not as the experts rank the lack of a cleaning protocols of instrumentation. All the actors which are involved in the minimal invasive surgery operation room need to be aware of the protocols for quality assurance and risk prevention even when it is not in their own department. Especially the surgeons because they are responsible for the patient during the operation.

Two experts (surgeon and scrub nurse) prioritized this element with a modest priority. The other experts with a high or very high priority. These priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element. This elements needs to be further evaluated so the real ranking and reason for this ranking is revealed.

No adequate protocol for the cleaning of instruments			
Applicable	Yes (69 %)	No (6 %)	Partly (13 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

The set is not cleaned properly (HSPS 5.8)

Sometimes an instrumentation set comes on the operation room and is not cleaned properly. Visually residues from former operation can be detected. This should not happen in case of cross infection (prions) and other types of infection with pathogens. A hospital is a cure facilities and does not want to make patients more ill then they already are. This can lead to a risk although this is not specific for minimal invasive operation it is more relevant because of the more technical, complex and sensitive instrumentation used during minimal invasive surgery.

Some experts have firsthand experience with not properly cleaned instrumentation and some experts do not have this experience. Therefore there are differences in the ranking of this element. The profession (surgeon, scrub nurse or other) has no influence on the way this element is prioritized.

The set is not cleaned properly			
Applicable	Yes (25 %)	No (38 %)	Partly (25 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Evaluate existing equipment before purchase (HSPS 5.7)

Existing equipment and instrumentation should be evaluated more before purchasing new equipment and instrumentation. Currently new instrumentation and equipment are purchased without always actively evaluating the current used 'old' instrumentation and equipment [Expert H].

All the expert agree (100 %) on the fact that existing equipment should be evaluated before purchasing new. This was point of emphasis formulated from the first interview round.

Evaluate existing equipment before purchase			
Agree?	Yes (100 %)	No	Partly
Expert did not have enough knowledge to rank and prioritize this element			

The set is improperly adjusted (HSPS 5.6)

The instrumentation in the set is not always adjusted in the right way. Some instrumentation is adjusted in the operating room and other is adjusted after cleaning by the central sterilization department. When the set is not properly adjusted this can cause delays (see paragraph unreliable equipment).

Because the first hand experience most experts have with improperly adjusted instrumentation the stated priority is high. One expert (surgeon) prioritized this element with a low priority while the other prioritized it as high or very high. This low priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element.

The set is improperly adjusted			
Applicable	Yes (38 %)	No (31 %)	Partly (25 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Only visual control instrumentation (HSPS 5.4)

Not all the instrumentation is checked via a validated electronic test. Some instrumentation like the lumen, glasvibers and optics are only test visually. Currently this cannot be done in a different way because of practical problems (the best way to test is unknown, [Expert C, I]) but in the near future this should be done electronically so that it is reproducible and therefore valid. There is also instrumentation that can be checked electronically but this is currently not done in the hospital. This is the case for electrosurgical instrumentation and diathermy instrumentation. Minuscule cracks can occur in the outer tube. This can lead to electrosurgical complications, like perforation of organs. These minuscule cracks can be detected with a test but the control is currently done only visually because no tests norms are available. It is unknown when instrumentation is adequate and when it is inadequate. Clear national norms need to be formulated to adequately test instrumentation.

Only visual control instrumentation			
Applicable	Yes (57 %)	No (13 %)	Partly (13 %)
Expert did not have enough knowledge to rank and prioritize this element			(19 %)

The set is incomplete (HSPS 5.1)

The set is sometimes not complete in the operating room. The CSD can label the set when they also noticed that the set is incomplete, or the set arrives incomplete in the operation room. In both cases the scrub nurse can have to take a new set which results in more equipment in the operation room and delay in the procedure. Complete well cleaned sets are necessary to have efficient and effective minimal invasive operations.

Five experts (surgeons) rank this element as not applicable to the hospital. This can be due to the fact that scrub nurses solve this problem before the operation. Surgeons do not see that the set was incomplete [Expert D, E, F, K, N]. Two expert (surgeons) therefore prioritize this element with a low and modest priority. These priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element.

The set is incomplete			
Applicable	Yes (31 %)	No (31 %)	Partly (31%)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

No instrumentation test registration that is available for all users (HSPS 4.5)

The results of the instrumentation and equipment tests are not registered and available for all the users. Tests should be registered to see what the most optimal frequency of the tests are. The results of these tests should be accessible for all the users of the instrumentation. So the users have the possibility to see what the frequencies of the tests are and what the results of the test were.

No instrumentation test registration that is available for all users			
Applicable	Yes (69 %)	No (19 %)	Partly (6 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Diathermia and other electrosurgical problems (HSPS 3.5)

Electrosurgical surgery is one of the most frequent used energy system for the coagulation or ablation of tissue. Coagulation is the lumping together of blood and ablation of tissue is the removal of tissue with the use of vaporization. Electrosurgical safety is essential because it can lead to unwanted diathermia which can lead to damage and complications [10, 57]. Examples are unwanted burns and perforation of organs during laparoscopic surgery because the use of monopole diathermia. With the use of monopole diathermia there is an elevated chance that it will lead to complications. There are a few surgeons who use monopole diathermia during minimal invasive surgery even when the risks are known [Expert, A, F, G, J, K, M]. This elements scores relatively low in comparison to the literature and especially in comparison with the report of the Health Care Inspectorate [36].

Diathermia and other electrosurgical problems			
Applicable	Yes (56 %)	No (31 %)	Partly (6 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Xenon illumination (HSPS 3.2)

Several experts mentioned the insufficient illumination of the surgical environment during the start up procedure of the xenon illumination [Expert E, F, H, K]. During the start up procedure the intensity of the illuminations is not optimal. This procedure takes approximately 30 seconds. When for example an acute laparotomy has to be performed due to an unexpected bleeding this start up time takes to long. Therefore the illumination remain on during the minimal invasive operation. This is not ideal because of the heat production and the contrast of the illumination. During minimal invasive surgery the illumination is dimmed or made green for the contrast on the monitor. This is a point of emphasis formulated from the first interview cycle.

Xenon illumination			
Agree?	Yes (56 %)	No (19 %)	Partly (6 %)
Expert did not have enough knowledge to rank and prioritize this element			(19 %)

Complication

The last cluster that is elaborated in this chapter, is the complication cluster. First the results from the first interview cycle are discussed to get more insight in the current situation of the cluster. After warts the final the complication cluster is discussed.

The registration of complications is according of the experts in the first interview cycle very important. A good complication registration is necessary for qualitative and safe operations. Important is that there is a uniform registration method and that the complications are frequently discussed within the teams [Expert G, J]. At the moment there no complication registration for minimal invasive surgery in the hospital [Expert G].

The main purpose of better quality and safety is the decrease of complications. Complication registration is the first step in the reduction of complication. The registered complication need to be discussed preferable in a multidisciplinary meeting with all the actors involved. After the discussion actions need to be taken to prevent the complications if the complication were preventable. The other diagrams for organization, training and instrumentation can be part in a bigger diagram for the reduction of complications.

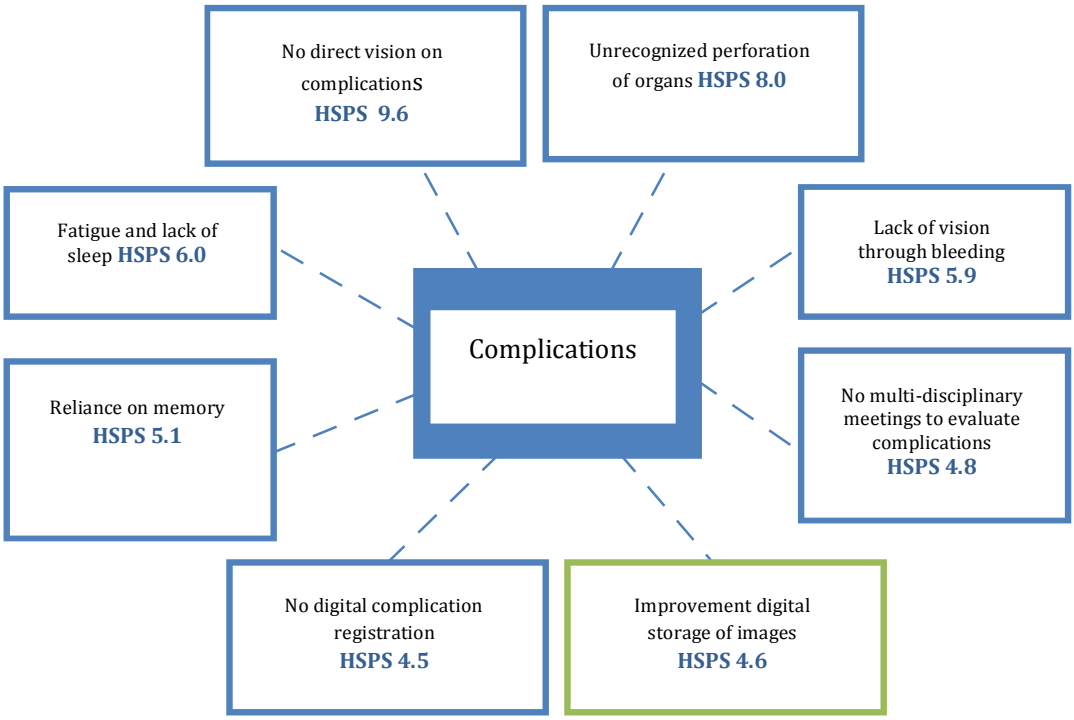

Figure 7: Diagram of the elements that indicate risks for the approach of complications of the minimal invasive surgery operation room.

No direct vision on complications (HSPS 9.6)

Complication can lay outside the range of sight of the surgeon. This can be due to the fact that a surgeon operates while looking at a 2D images from a 3D situation this brings along unique surgical errors and elements that can lead to risks. One of the main elements is the misinterpretation of the situation [15], for example not noticing from a complication because it lays outside the image displayed on the monitor. This has to do mainly with the fact that complication can lay outside the focus field of the surgeon.

This element is ranked higher than expected from the literature. This can be due to the fact that this is one of the biggest bottle necks of minimal invasive surgery and the small congress that was held in April of 2008. During this congress an example was given by the Health Care Inspectorate of an complication that

was revealed a few days after the operation but was caused during the operation. The expert agree on the fact that this is the most important element that indicates a risk.

No direct vision on complications			
Applicable	Yes (56 %)	No	Partly (38 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Unrecognized perforation of organs (HSPS 8.0)

An organ can be pierced or perforated during a minimal invasive operation. The perforation can be detected during the operation or after closure. The treatment of a for example bowel injury recognized after the laparoscopic surgery will require laparotomy not only to repair the site of the bowel injury, but also to enable a full inspection of the small and large bowel. Failure to recognize can even be life threatening [76]. This is an example which can occur when there is no direct vision on complications.

This elements is ranked with a very high priority by thirteen experts. Two experts (both scrub nurses) prioritized this element with a modest and high priority. In comparison to the literature this element scores high.

Unrecognized perforation of organs			
Applicable	Yes (44 %)	No	Partly (50%)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Fatigue or lack of sleep (HSPS 6.0)

Fatigue and lack of sleep can have influence on the duration of the operation and the number of errors made [84]. Fatigue means that the surgeons is tired and lack of sleep means that the surgeons did not have enough hours sleep. Fatigue and lack of sleep can lead to concentration difficulties and a higher level of stress. Hence, enough sleep and starting rested on an operation is important.

Fatigue or lack of sleep			
Applicable	Yes (25 %)	No (25 %)	Partly (38 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Lack of vision through bleeding(HSPS 5.9)

A surgeons needs to be constantly aware of the fact that he or she may not be able to immediately control bleeding because it is impossible to apply finger or hand compression until a suitable clamp is applied to the bleeding vessel [14]. When a bleeding occurs the vision can decrease or even disappear. Blood absorbs the light from the optics and the blood can block the view of the surgeon because it is in front of the camera. A surgeons has to be constantly aware of this and anticipate when necessary.

Two experts (surgeons) prioritize this element with a modest priority. The other experts with a high and very high priority. This element is in accordance with the literature.

Lack of vision through bleeding			
Applicable	Yes (56 %)	No	Partly (31 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

Reliance on memory (HSPS 5.1)

One safety lesson from 'high reliability organizations' (such as airlines) is that errors are less likely to happen if processes are standardized and if there is less reliance on memory [23]. Not only standardization but also the check and re-check of information during the operation is important to decrease the reliance on memory. This can be done for example with protocols and checklists but also the pro-active and self-disciplinary attitude of the surgical team.

Reliance on memory			
Applicable	Yes (19 %)	No (13 %)	Partly (56 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

No structured multidisciplinary meetings to evaluate complications (HSPS 4.8)

A multidisciplinary meeting is a meeting were the specialties involved are discussing the occurred complication. When the complication is for example due to instrumentation the CSD, surgeon, scrub nurse, anesthesia and the supporting departments should be present.

Important for a good evaluation of complications is that surgeons define complications and errors strictly and be proactive in the development and usage of a system. This system is to prevent and minimize the effect of these surgical complications and errors. Important is that the number of conversions is also registered and discussed. When laparoscopic operation (minimal invasive surgery in the abdomen) are not going as planned or it takes too long a surgeon can decide to make a conversion. The laparoscopic surgery becomes a laparotomy. This is what some authors call the "Achilles heel " of laparoscopic surgery [15, 57]. When do you converse and how do you report it? Is it an new surgery or a complication during the laparoscopy? Important is that the number of conversions is registered and evaluated. Why was there a conversion and was the handling adequate? This is a subject were all the specialties can learn from and therefore important to discuss in a multidisciplinary meeting.

In the third round several experts [Expert F, J, L] said that although the lack of a structured multidisciplinary meeting does not lead to a direct risk for the quality and safety it is an important aspect in the improvement of quality and safety. General surgery has a multidisciplinary complication meeting but not specific for minimal invasive surgery [Expert O]. This element is prioritized relatively low in comparison with the other elements and the literature. This due to three experts (two surgeons and one exert from the group others) that have ranked this element with a low and modest priority. These priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element.

No structured multidisciplinary meeting to evaluate complications			
Applicable	Yes (56 %)	No (19 %)	Partly (25%)
Expert did not have enough knowledge to rank and prioritize this element			

Improvement digital storage of images (HSPS 4.6)

In the OR1 images can stored during the operation. At present there is no structure in the storage of these images. The pictures of videos are copied on a DVD and not stored in the electronic patient record (EPR). These DVD's can be used for several purposes and stored accordingly in different ways. The images can be used to show the patient, to evaluate with a resident or to put in the patient record. There should be a clear protocol or at least a standardization of the purpose of the storage and the way and place it should be stored. The voluntary basis on which the storage now takes place should disappear because it does not work adequate and efficient.

Improvement digital storage of images			
Agree?	Yes (75 %)	No (6 %)	Partly (6 %)
Expert did not have enough knowledge to rank and prioritize this element			(13 %)

(digital) Complication registration (HSPS 4.5)

A full understanding of complications associated with minimal access surgery is necessary to minimize, recognize and threat complications [23, 66, 82]. Not only the complication during the surgery (immediate) should be registered but also the intermediate (first 4 weeks) and long term complications (after 4 weeks) should be registered so the complications can be managed appropriately. An shortcoming of most complication registrations is that not all the incidents are captured [23]. Therefore the complication registration should be broader than just the complications immediate (during the surgery) complications. The rates of injury (complication) are related to the complexity of the surgery and the learning curve of the surgeon [82].

The digital registration of complications is only one aspect. More importantly is that the complications are evaluated and discussed during multidisciplinary meetings. Feedback is the *raison d'être* of the reporting of complications. The video registration of operations (video or pictures) can be very useful for the evaluation of the complication after a surgery but also in the post operative stage [53]. In the hospital there is no digital complication registration. Most experts agree that it is very important to have an adequate digital complication registration. The HSPS score is relative low in comparison with the other elements and the literature. This due to the fact that not having a complications registrations does not lead to risks. Complication registration together with multidisciplinary evaluations is very important in the reduction of complications in the minimal invasive surgery operation room. Two experts (scrub nurses) prioritized this element with a modest priority and one expert (surgeon) has prioritized this element with a low priority. These priority scores have influence on the mean score and more importantly on the standard deviation which results in a relative low score for this element.

(digital) Complication registration			
Applicable	Yes (75 %)	No	Partly (19 %)
Expert did not have enough knowledge to rank and prioritize this element			(6 %)

Conclusions

The operation room is a complex and multi-facet facility in the cure process of every hospital. There are several elements from the environment that influence the primary technical process. The elements, presented in table 7, are elements that indicate risks for the quality and safety in an minimal invasive operation room. These fluctuations can interfere with the primary technical process in the organization and hence reduce the performance in the technical primary process. The elements are ranked according to the hospital specific priority size (HSPS) see interview cycle 2 methods.

Element	HSPS
No direct vision on complications	9.6
Inexperienced surgeons	8.9
Low minimal invasive surgical volume	8.7
Unrecognized perforation of organs	8.0
Unreliable instrumentation	7.3
No (national) trainings program	7.0
No protocol for training in a skills lab	6.7
Inadequate communication	6.1
Fatigue or lack of sleep	6.0
No adequate protocol for the cleaning of instrumentation	5.9
Administrative failure	5.9
Lack of vision through bleeding	5.9
The set is not cleaned properly	5.8
Evaluating existing instrumentation before purchasing new	5.7
The set is improperly adjusted	5.6
Not working as a team	5.4
Only visual control of instrumentation	5.4
Instruction less experienced personnel	5.2
Lack of protocol or inappropriate protocol for quality assurance	5.2
The set is incomplete	5.1
Reliance on memory	5.1
Unstructured and divers training	4.9
Inadequate use instrumentation	4.9
Lack of non-technical skills of a surgeon	4.8
No multidisciplinary meeting to evaluate complications	4.8
Unfamiliarity with existing protocols	4.7
Improvement digital storage images	4.6
Scrub nurse is inexperienced with the OR1	4.6
No digital complication registration	4.5
No instrumentation test registration available for all users	4.5
Dedicated teams	3.9
Diathermia and other electrosurgical problems	3.5
Lack of cognitive skills	3.2
Xenon illumination	3.2

Table 7: Prioritized elements and points of emphasis, which indicate risks for the quality and safety, which are applicable to the hospital.

The four clusters, organization, training, instrumentation and complication, provide the subcommittees of the multidisciplinary laparoscopic committee incentives to work with to increase the anticipation ability of the minimal invasive surgery operation room and organize the interdependence more optimal.

Organization

One way of reducing the elements that indicate risks is the handling of the interdependence of the minimal invasive surgery operation room with the other parts of the organization like the CSD and the recovery room by means of standardization, mutual adjustment and coordination by plan [81]. The minimal invasive surgery operation room is a complex organization therefore depends heavily on good and adequate communication. Performances can be captured by standardization or a step-by-step plans. There are also performances which cannot be captured by standardization or step-by-step plans. For these performances agreements should be made about the way these performances are communicated towards the different actors. This can be for example done via time out protocols and checklists. Time outs are a topical example of a communication checklist. A time out is a short checklist that checks whether the patient has allergies, the pre-medication is given, the type of procedure (standard or not), the positioning of the patient and possible special conditions. Important is that the protocol is not redundant, time-consuming and inconvenient. It should have added value to the quality and safety in the operation room.

Thompson underlines the importance of communication in a complex and multifaceted parts of the organization [81].

During the first interview cycle it became clear that there are no protocols for the surgeons and anesthesia. Some surgeons see the necessity of standardization and some surgeons would like to remain autonomous. This partition can also be found in the literature. A consensus can be found in a step-by-step plan. Certain steps in an operation are high lighted and the surgeon is free to fill in the rest of the actions. The predefined step can be photographed or recorded and put in the file or EPR of the patient. As mentioned before working in a team is for minimal invasive surgery more important in comparison with conventional surgery. All professionals in the operation room, scrub nurses, surgeons and anesthesia, should therefore work together on an adequate step-by-step plan per minimal invasive surgery performances. The shared interest and responsibilities should be clear.

Training

The improvement of the training of new surgeons and currently active surgeons has been one of the key items of the multidisciplinary laparoscopic committee. Surgeons with adequate knowledge, skills and experience will operate more optimal in comparison with surgeons who are inexperience without adequate knowledge and skills. The skills training of residents and the preservation of skills these is vital for minimal invasive surgery, because minimal invasive surgery requires specific skills of surgeons. Therefore the training of future surgeons and currently active surgeons is very important.

Basic skills levels should be required for all the surgeons, future and currently active, before they may operate minimal invasively. The inexperience of minimal invasive surgery operation room personnel, mainly surgeon, should be reduced. Skilled, well trained, experienced surgeons can be achieve when the multidisciplinary laparoscopic committee makes arrangements about the skills requirements with the departments which provide surgeons and other personnel about the skills levels and the maintaining of this skills level.

In the cluster 'Training' there was a difference between the final results and the first interview cycle. The main focus of the first interview cycle lay on future surgeons while the final cluster includes elements for currently active and future surgeons. The experts did not think about currently active surgeons while thinking about education and training. During the second interview the training and education of currently active surgeons has been introduced to the experts. Inexperienced surgeons and the other trainings elements are prioritized as very important.

Instrumentation

The technical driven nature of the minimal invasive surgery instrumentation makes instrumentation a vividly discussed subject. For the instrumentation of the minimal invasive surgery operation room it is important that all the concerning departments are actively involved. In this case the central sterilization department and expert sterile medical instrumentation and equipments need to be considered for the elements that indicate risks for the quality and safety of instrumentation and equipment. Objective test needs to be developed to check the minimal invasive instrumentation, optics, lumen and electrosurgical instrumentation, frequently so the risks of working with these instrumentation can be reduced. It is essential that the CSD has enough capacity (staff and facilities) to carry out these tests. The cooperation between the central operation rooms and the CSD needs to be extended to keep the communication short, hence, problems or risks can be resolved instantly.

During the first and other interview cycles the instrumentation is discussed with every expert. There is no discrepancy between the first interview cycle and the final results of this research. Except that the

instrumentation elements are prioritized elements are ranked higher than would have expected from the literature.

Complication

Together with a good functioning complication registration, multidisciplinary meetings are vital to identify, to manage and to minimize complications that can occur during laparoscopic and other minimal invasive surgeries. This can be done with a adequate digital complication registration combined with an multidisciplinary meeting to discuss and evaluate the complications. Errors cannot be totally eliminated but complications should be prevented as much as possible. This requires actions from all members of the surgical team but also the sterilization department and the recovery room. Hence, the whole surgical team should be part in the multidisciplinary committee in which the complications are discussed. The other elements like fatigue and reliance on memory should be discussed in the multidisciplinary committee and prevented as much as possible.

Communication

Communication, coordination and mutual agreement are the concepts which underlie almost all elements that indicate risks or the points of emphasis applicable to the hospital. Communication was one of the key items from the first interview cycle. During the first interview cycle all experts gave examples of inadequate communication between different parts of the organization. According to the literature communication failure or inadequate communication underlies almost all medical incidents[23, 47, 48, 88]. Good and adequate communication can also decrease risks and complications in the operating room [47, 48, 54, 70, 82]. Therefore communication should have and remain under the attention in the process of improving quality and safety. Even when communication has the eight position on the priority list. This should be one of the items the hospital should work on. The communication and the improvement of the other elements needs to be coordinated. And as mentioned above this can only done adequate when there is consensus and mutual agreement between all actors involved. The experts and other actors involved need to come to an agreement about the basic requirements of instrumentation, skills of future surgeons and currently active surgeons, the registration of complications and how these aspects need to be organized. The aspect need to be thoroughly communicated to the organization and all the actors involved. Every actor needs to know his or her responsibilities.

When the minimal invasive surgery operating room environment is organized in an adequate way the quality and safety of the minimal invasive surgery operation room will increase because the anticipation ability on fluctuation from the environment will increase. The interdependence between departments will improve and therefore the quality and safety of the minimal invasive surgery operation room will increase. To handle most of the risk elements and points of emphasis mentioned in this report the source of the problem should be revealed. Or as Reason [64] described vividly: 'Unsafe acts are like mosquitoes. They can be swatted or sprayed, but they still keep coming. The only effective remedy is to drain the swamps in which they breed.' In case of the minimal invasive surgery operation room the cause of the elements that indicate risks for the quality and/or safety for the patient or the employee should be removed. The results of this research are no rocket science but so called old wine in new bottles. The elements and points of emphasis with a high priority in this research are elements the emphasis should be on, to provide more quality and have more safety for the patients and employees during minimal invasive operations and within the minimal invasive surgery operation room. The improvement of the risk elements and points of emphasis is not a one moment improvement but should be a continuous cycle. The exact cause of the current situation per risk element should be made clear. The actions that are needed should planned and executed. After actions are taken, the new situation should examined. Plans need to be made and executed to improve the quality and safety even further. Perfection in the primary technical process requires complete knowledge of cause and effect relations and control over the elements that indicate risks [81].

Discussion

This research is discussed by the means of three general subjects, reliability, generalizability and research ethics.

Reliability

Reliability refers to the extent to which the data collection techniques or analysis will yield consistent findings [69].

Health Care Inspectorate

The Health Care Inspectorate report of November 2007 has had and has influence on the way the experts look at the quality and in the minimal invasive operation room. The main bottles necks formulated in the Health Care Inspectorate report were training, policy, quality assurance and instrument safety. These are comparable with the four clusters, organization, training, instrumentation and complication formulated in this research. The Health Care Inspectorate report has been a incentive for this study and therefore has influence on the results.

DaVinci robot

Half way through the research a operation robot type Da Vinci has been introduced in the hospital. This was not done in the most optimal way especially concerning the sterilization of instrumentation. This has had a clear influence on the way the experts ranked the instrumentation and equipment related elements and points of emphasis. Some elements and points of emphasis have a higher priority then expected from the literature in comparison with other elements.

Delphi method

The experts for the Delphi need to be chosen carefully because the expertise that is used in the interview. In this research three groups of experts were made. The first group included nine surgeons from four different departments. The second group included six scrub nurses from the different departments. The last groups was the others group. This group included anesthesia, expert sterile medical instrumentation and equipments and a expert from the central sterilization department. The expertise of the expert was not sufficient on certain subjects. Therefore there was just small overlap between the elements found in the literature and elements gathered in the first interview cycle. This reveals one of the most important elements, communication.

The second aspect of the Delphi method is that it is a method which can be used to gather subjective expertise of local experts. The subjective expertise is sometimes not comparable with the 'real' objective data. This discrepancy indicates that other elements contributing to the expertise of the experts. The exact cause or basic element of the mentioned element is sometimes hard to retrieve via the Delphi method because the method only focuses on consensus and not on cause and effect relations. The construct of the element is not found only the relative opinions of the experts.

Points of emphasis

During the first interview cycle fourteen points of emphasis have been formulated. These points of emphasis do not directly indicate risks for the quality and safety. The core of a point of emphasis is a risk element but the outer layer is a practical problem. These points of emphasis should have been excluded from the interview because they do not directly provide an answer to the research question. Points of emphasis are practical application which indirectly yield risks for the quality and safety. The core of a point of emphasis is risk elements but has a outer layer of practical application The risks per point of emphasis should have been revealed before they were introduced in the research. This is not done in this research because of the exploring and inventory nature of the research. The remaining of the outer layer of the point of emphasis in the research has led to an unnecessary bias in the research.

Overlap between systematic literature review and interview cycle 1

During the first interview cycle 38 element which indicate risks for the quality and safety have been gathered. From the systematic literature review 66 elements have been retrieved. There was an overlap of 15 elements. This means that the experts provided 38 elements of which there is theoretical evidence for 15 elements. This small overlap could have occurred because of four reasons. The first is that the systematic literature review is not done properly. The second reason is that the experts chosen for this research are not the correct experts. The experts are chosen by means of different ways and are the experts with the most amount of knowledge on this subject available in the hospital. The third plausible reason is the expertise of the experts is not comparable with the known theoretical knowledge about this subject. The last plausible reason is that the questions asked in this round were not the correct questions to assess the expertise of the experts.

The interview in the first cycle was to gather element and to explore the current situation. Therefore some experts can have had their focus on the explanation of the current situation and less on the gathering of elements which indicate risks. This is prevented as much as possible by asking follow up questions and during the interview rephrasing the answers towards elements which indicate risks. The experts asked for the first interview cycle are directly linked to the technical primary process. Therefore it is possible that the experts do not see situations as risky, the expert cope with the situation on an every day basis. Like the standing or static work posture and the noise level. Or the expert do not see the elements because they are not applicable to the hospital. For example, strong hierarchy, absence super-vision when necessary and tripping over cables. Not all the elements found in the literature were conceptualized and clearly explained in the articles. Some elements were only mentioned without further explanation of the used concepts. Therefore some elements gathered from the systematic literature review were no elements which indicate risks. They merely present the situation as it is. For example less degrees of freedom because of the instrumentation, limited tactile feedback and the fulcrum effect. The plausible reason for the small overlap is a combination of the arguments given above. This has influence on the validity of this thesis. Most of the 'new' elements from the first interview cycle are about instrumentation and equipment (see discussion DaVinci), the descprepancy between OR1 and other OR's and the basic skills of a scrub nurse.

Generalizability

Generalizability means the extent to which the findings of this research are applicable to other settings [69]. This report contains expert several different departments, pediatrics surgery, general surgery, gynecology, urology, anesthesia, the central sterilization department and some supporting departments. Per department one, two or three experts were interviewed. These departments have their own specific working ethos. Gynecology operates minimal invasive for three decades and the other departments just a few years. This has influence on the way things are organized per department. This research provides an overall view of the elements that indicate risks but does not give specific departments incentives to work on. This makes the generalizability to the different specific departments a challenge. The most ideal situation would be to do this research per departments of the hospital to see which elements that indicate risk are obtained. This is not possible for one hospital because the number of experts of minimal invasive surgery per department is too small. Per specialty this requires a national inquiry (to get the number of experts big enough) but that makes generalizability to specific hospital difficult especially when departments work together like in this hospital. Therefore this is the most practical solution even when it is not the most optimal. For the generalizability towards other hospitals the same bottle neck occurs. Overall the elements and points of emphasis are generalizable towards other hospitals which perform minimal invasive surgery in a specific operation room or were several minimal invasive specialties are actively working together.

Ethics

Research ethics means that the research and the researchers behavior are appropriate towards the subject (experts) of the study and those who are affected by it [69]. In this research it was important that the actors should get and have the feeling that there input is as important as the other inputs in the research. The authorization level did not play a role in making the list and clusters of risk elements and point of emphasis.

The experts were contacted by e-mail and voluntarily contributed to this research. They had the right to withdraw from the research in any stage. The information and responses given by the experts were recorded and confidentially stored. The experts had the possibility to give their approval over the stored

information in the first round. This was only important for the first cycle because opinions were asked only in this round. Specific judgments about departments were made general so this could not be traceable towards experts. This way the privacy of the experts was guaranteed.

Discussion research done by researcher

The next time this type of research is performed the concepts used need to be free of discussion before the interviews are conducted. A water tight definition per element or subject should be made. This way no discussion about definitions occurs during interviews and the gathered data is more valid.

Another point chance for the next research, is that the gathered data should be judge more critically. Which data provides answers to the research question? This was not done perfectly in this research. Hence, fourteen points of emphasis have been formulated (see paragraph about points of emphasis).

The most important change for the next research to limit the gathered data. In this research the effect and chance of occurrence is asked to calculate the calculated priority with the Hazard Scoring Matrix of the Health Failure Mode and Effect Analysis. The calculated priority was gathered to get more insight in the difference between the actual priority and the priority given because of the expertise. This difference does not contribute to answering this research question. Therefore this information was not used further. The information per element can be used for further research about why these elements are revealed and why there is a discrepancy between the calculated and stated priority.

In the original research design the Health Failure Mode and Effect Analysis (HFMEA) would be used to analyze the elements gathered from the literature and the interview cycles. The HFMEA is a tool to understand and reduce medical errors. Failure modes refers to a weakness or vulnerability in any part of a process or a chain of events that has the potential to cause a risk for the quality and safety. An failure occurs when a process begins to produce something that is not planned and unwanted. The HFMEA starts with identifying a high risk processes and the selection of one of these processes. After the selection the process is analyzed by means of several steps [1]. The technical primary process of the minimal invasive operation room is to wide. Specific actions or processes within the technical primary process are candidates for further analyses. Hence, that this analyze was excluded from this research during the conduction of the research. The HFMEA is a perfect method to analyze the gathered elements which indicate risks (see chapter recommendations).

In the initial research a distinction is made between risk element and point of emphasis. This implies that point of emphasis are less important and do not lead to risks. This was not the case in this situation. The root cause per element and point of emphasis should have been investigated.

Recommendations

Communication, coordination and mutual agreement are the basic concepts which the multidisciplinary laparoscopic committee and the subcommittees should keep in mind while improving the elements which indicate risks for the quality and safety. Before the committees can handle these concepts, further exploration of the element which indicate risks and the points of emphasis should be performed. This can be done, for example, via the Healthcare Failure Mode and Effect Analysis. The HFMEA is a seven step analysis method[1] [12].

1. The first step is to develop a list of high risk processes in the organization and select one of these processes. Processes that have variable input, are complex, non-standardized, heavily dependents on human intervention, performed under tight or loose time constraints are candidates for consideration [1]. The process that has been chosen is the minimal invasive surgery. This is a wide concept so it should be narrowed down to one or two performances which can be easily be generalized to other performances. The multidisciplinary laparoscopic committee should discuss and choose the performances that are investigated further. An example of a performance which can be investigated is a laparoscopic cholecystectomy because of the complexity of the operation.
2. The second step is the assembly of a multidisciplinary team with members with different points of view of and on patient care. The multidisciplinary laparoscopic committee is a good start for such a team. Experts of the technical and organizational parts of the organization can be asked to join the team.
3. The third step is to examine the process by making a flowchart, a cause and effect diagram or a timeline. Visually mapping the process can be a powerful aid in understanding the process and provides a common reference point in discussion [12]. This should help the multidisciplinary laparoscopic committee to clarify the process.
4. The fourth step is to identify (potential) variation in what is desired and what is reality. The discrepancy between these two is the first failure mode identification. What can go wrong? If it goes wrong, how bad might it be (severity)? How likely is it to go wrong (frequency)? Are there systems in place to detect if something goes wrong (detectability) [12]? This should make clear were the variation is in the process and which action should be taken to decrease the variation. This explorative study has illuminated some aspect in the process which yield or could yield variation or risks for the quality and safety. Some elements and points of emphasis discussed in this thesis are not always the root cause of a variation or risk but can be indicators of underlying risks. For example the lack of a cleaning protocols yields the risk of inadequate communication. Per element the multidisciplinary laparoscopic committee should investigated the cause and which variation the element causes. Until the fundamental cause of the problem is identified, corrective actions will not succeed or only temporarily [12].
5. The fifth step is the ranking of the failure or risk with the Hazard Scoring Matrix (HSM). With the HSM the probability and severity of a potential risk can be predicted. For each risk elements a risk priority number (RPN) can be made. The RPN is based on the likelihood of occurrence (OC), the severity if it occurred (SV) and the likelihood of detection (DT), RPN = OC x SV x DT [1]. This way a objective measure for the priority is used, this explorative study used a subjective measure via the expert analyze with the Delphi method.
6. The sixth step is making a plan of action. Any plan of improvement should be aimed at minimizing the severity, the frequency or maximizing detectability of the failure mode. The best strategy is to eliminate the chance of the failure to ever happen, unfortunately this is the most difficult one to establish. The other strategies are; making the action which should be taken easier and making the failure easier to detect [12].
7. The last step is the monitoring and evaluating of the chosen strategies [12].

To adequately perform a HFMEA and perform the plan of action in step 6 of the HFMEA mutual agreement, communication and coordination should take place. Much of the identified elements in this thesis depend on good and adequate communication. When the fundamental elements are revealed exact influence per element is known and actions can be taken. These action can only succeed when there is mutual agreement about the fundamental cause and the action which should be taken. The coming to mutual agreement and the actions which should be taken need to be coordinated and the good and adequate communicated to all the actors involved. Therefore communication, coordination and mutual agreement are of the out most importance in reducing the, in this thesis indicated, risks for the quality and safety in the minimal invasive surgery operation room.

Acknowledgement

In this final part of the report I would like to personally give gratitude to all the people that made it possible for me to complete this thesis. I would like to thank the hospital and especially the pediatric, urological, gynecological and general surgical departments for letting me investigate the quality and safety of minimal invasive surgery.

Furthermore I would like to thank all the experts that I interviewed trough the separate interviews and the interview cycles. Their contribution has made it possible to produce this paper.

Special thanks goes to Dr. Rene Wijnen and Martin Janssen, my supervisors from the hospital whose help, stimulating questions and feedback has helped me to write this report.

Furthermore I would like to thank Prof. J. J. Krabbendam and Prof. W. van Rossum for their time, help and contribution which enabled me to complete this scientific thesis.

Finally I would like thank Kevin Sponselee. His discussions, critical reviews and patience contributed greatly in this final stage of my master Health Science.

Glossary

Consensus: Correspondence or agreement of the answers and conceptions of the different experts.

CSD: In the central sterilization department in a hospital instrumentation is cleaned, sterilized and tested.

Delphi method: Method that uses systematic group judgment with recurrence and controlled feedback to perform a expert analysis.

Health Care Inspectorate: The Netherlands Health Care Inspectorate protects and promotes health and healthcare by ensuring that care providers, care institutions and companies comply with laws and regulations [34].

HSPS: The hospital specific priority size is a measure to take the level of consensus (spread around the mean) into the priority size.

Laparoscopic surgery: Minimal invasive surgery in the abdomen.

Minimal invasive surgery: or keyhole surgery is a type of surgery were the surgeon makes several small incision in the body through which retractors are inserted in the body.

Minimal invasive surgery operation room: The operation room in which the minimal invasive surgery takes place. This is different from conventional operation room because of the type of instrumentation and equipment required.

Multidisciplinary laparoscopic commitee: A monthly meeting to discuss laparoscopic or laparoscopic surgery related subjects in a multidisciplinary setting (werkgroep laparoscopie).

NVEC: The national Dutch committee of endoscopic surgery with is actively involved in the development and organization of minimal invasive surgery in the Netherlands. The NVEC has several subcommittees for all the surgical specialties that are members of the NVEC.

Optimal performance : Optimal performance is expressed in the quality of the organization of the minimal invasive surgery operation room and the amount of safety for both the patients and the employers working in the minimal invasive surgery operation room.

*OR1:*Specifc operation room for the performance of minimal invasive surgery.

Point of emphasis: This is a practical application that can yield a elements which can indicate a risk in the core.

Quality: The quality of an operating room is the level in which the minimal invasive surgery operation room satisfies to the pre described requirement.

Risk element: An elements which indicates risks for the quality and safety in the minimal invasive surgery operation room.

Safety: There are two types of safety considered in this research, patient safety and employee safety. Patient safety refers to the concept that patients in health care settings are achieving intended outcomes. Employee safety is defined in terms of the employee in an health care setting is not achieving unintended outcomes because of their work in the minimal invasive surgery operation room.

Systematic literature review: A systematic or sometimes called critical literature review is performed to get more insight and understanding from previous performed studies.

Nederlandse samenvatting

Inleiding

Minimaal invasieve chirurgie is een belangrijke nieuwe ontwikkeling in de chirurgie en is de verzamelnaam voor alle endoscopische operaties. Minimaal invasieve chirurgie heeft de afgelopen jaren veel ontwikkelingen doorgemaakt en zal naar verwachting ook nog veel ontwikkelingen doormaken. Er is desondanks relatief weinige onderzoek gedaan naar kwaliteit en veiligheid van minimaal invasieve chirurgie.

In november 2007 is er een rapport verschenen van de Inspectie voor de GezondheidsZorg *'Risico's minimaal invasieve chirurgie onderschat; kwaliteitssysteem voor laparoscopische operaties ontbreekt'*. In dit rapport zijn de verschillende knelpunten voor minimaal invasieve chirurgie in Nederland beschreven; training, beleid, kwaliteitsgarantie en instrumentatieveiligheid.

Het Universitair Medisch Centrum St Radboud te Nijmegen is een academisch ziekenhuis in het oosten van Nederland. In dit ziekenhuis bevindt zich een specifieke minimaal invasieve operatie kamer (OR1). Tevens is er een werkgroep laparoscopie aanwezig.

Onderzoeksvraag

De onderzoeksvraag voor dit onderzoek was:

Welke elementen indiceren risico's voor de kwaliteit en/of veiligheid in een minimaal invasieve operatie kamer? Welke prioriteiten dienen deze elementen binnen het ziekenhuis te hebben?

Methode

Doormiddel van een systematisch literatuuronderzoek en een expertanalyse is antwoord gegeven op de bovenstaande onderzoeksvraag.

Systematisch literatuuronderzoek

Een systematisch literatuur is uitgevoerd om meer inzicht te krijgen vanuit eerdere uitgevoerde onderzoeken naar elementen die risico's voor de kwaliteit en veiligheid binnen de (minimaal invasieve) operatie kamer kunnen indiceren. Er zijn verschillende elektronische databases gebruikt, namelijk Pubmed, Medline, Picarta, JSore, Web of Science en Sciencedirect. De, in de literatuur gevonden, elementen zijn onderverdeeld in drie categorieën; organisatorisch, instrumenteel en intermenselijk. In totaal zijn er 66 elementen die risico's indiceren voor de kwaliteit en/of veiligheid gevonden in de literatuur.

Expert analyse

Om de expertise van de experts in het ziekenhuis te vergaren, is gebruik gemaakt van de Delphi methode. De Delphi methode is een methodiek om consensus te creëren over een onderwerp doormiddel van bevragen en gecontroleerde feedback. Doormiddel van vier rondes is consensus gecreëerd over de elementen die binnen het ziekenhuis risico's voor de kwaliteit en veiligheid indiceren.

Dataverzameling

Doormiddel van separate interviews, drie interview rondes en een plenaire discussie is de expertise van de experts binnen het ziekenhuis verzameld, op het gebied van elementen die risico's indiceren voor de kwaliteit en veiligheid.

Zeven experts (vijf binnen en twee buiten het ziekenhuis) hebben bijgedragen aan de separate interviews. Deze separate interviews hadden als doel de kennis over de huidige situatie te vergroten.

In de eerste interviewronde is een ongestructureerd, diepte interview gehouden van ongeveer één uur. Zeventien experts zijn gevraagd welke elementen risico's indiceren in de minimaal invasieve operatie kamer. In totaal zijn er tijdens deze ronde 38 elementen en 14 aandachtspunten geformuleerd. Er was een overlap van 15 elementen met het systematisch literatuuronderzoek.

In de tweede interviewronde zijn de 89 elementen en 14 aandachtspunten geprioritiseerd doormiddel van een gestandaardiseerde vragenlijst. Tijdens deze ronde zijn de experts onder andere gevraagd om ieder element een prioriteit van één tot vijf te geven, waarbij één een lage prioriteit is en vijf een hoge prioriteit weergeeft. Voor alle elementen of aandachtspunten toepasbaar op het ziekenhuis en een prioriteit boven de vier is de ziekenhuis specifieke prioriteitsgrootte (HSPS) berekend. Deze

prioriteitsgrootte is berekend door de gemiddelde prioriteit per element te delen door de standaard afwijking. Hierdoor is de mate van consensus, over de prioriteit van het element, meegenomen in de uiteindelijke positionering van het element. In totaal zijn er 30 elementen toepasbaar op het ziekenhuis en met een prioriteit boven de vier waarvoor de HSPS is berekend. Tevens zijn er vier aandachtspunten met een prioriteit boven de vier.

Tijdens de derde interviewronde zijn 30 elementen en 4 aandachtspunten doorgesproken met zeventien experts. Naar aanleiding van deze interviewronde zijn er vier cluster van elementen die risico's indiceren en aandachtspunten voor de kwaliteit en/of veiligheid geformuleerd, organisatie, training, instrumentatie en complicatie.

In de vierde en laatste ronde is een plenaire discussie gehouden over de vier clusters van elementen en de meest opvallende elementen en aandachtspunten. In totaal hebben negen experts en de twee supervisors een bijdrage geleverd aan deze laatste ronde.

Resultaten van de analyse

De onderstaande elementen en aandachtspunten zijn geclusterd in vier clusters die overeenkomen met de vier subwerkgroepen in de werkgroep laparoscopie van het ziekenhuis. De elementen en aandachtspunten zijn gerangschikt doormiddel van de ziekenhuis specifieke prioriteitsgrootte.

Organisatie

In het eerste cluster zijn de elementen en het aandachtspunt verwerkt die te maken hebben met de organisatie van minimaal invasieve chirurgie en de minimaal invasieve operatie kamer.

Element en aandachtspunt	HSPS
Inadequate communicatie	6.1
Onvolkomenheid in de administratieve componenten van het ziekenhuis	5.9
Niet werken als een team	5.4
Er zijn onvoldoende toepasbare protocollen voor kwaliteitsbewaking of de aanwezige protocollen zijn onvoldoende geschikt voor kwaliteitsbewaking.	5.2
Onbekendheid met het feit of verrichtingen protocollair zijn vastgelegd	4.7
Dedicated team	3.9

Training

In het tweede cluster zijn de elementen die risico's indiceren voor de training van reeds actieve en chirurgen in opleiding geclusterd.

Element	HSPS
Onervaren of onvoldoende ervaren chirurgen	8.9
Laag minimaal invasief operatie volume	8.7
Geen (nationaal) trainingsprogramma	7.0
Geen protocol voor het trainen in een skills lab	6.7
Instructie van minder ervaren personeel tijdens de operatie	5.2
Ongestructureerdheid en diversiteit in het trainingsprogramma	4.9
Inadequate gebruik van instrumentarium	4.9
Onvoldoende of niet aanwezig zijn van niet-technische vaardigheden van de chirurg	4.8
De OK-verpleegkundige heeft onvoldoende ervaring met de OR1 als werkruimte	4.6
Onvoldoende of niet aanwezig zijn van cognitieve vaardigheden van de chirurg	3.2

Instrumentatie

In dit derde cluster zijn alle elementen en aandachtspunten rondom instrumentarium geclusterd.

Element	HSPS
Onbetrouwbaar of onvoldoende functionerend instrumentarium	7.3
Niet aanwezig zijn van een goed reiningsprotocol voor het instrumentarium	5.9
De set is niet goed gereinigd	5.8
Evaluatie van bestaand instrumentarium voordat nieuw instrumentarium wordt aangeschaft	5.7
De set is niet goed in elkaar gezet	5.6
Alleen visuele controle van instrumentarium	5.4
De set is incompleet	5.1

Geen registratiesysteem voor de uitslag van instrumentariumtesten dat beschikbaar is voor iedere gebruiker	**4.5**
Diathermie of ander electro-chirurgische problemen	3.5
Xenon verlichting	3.2

Complicatie

De laatste elementen en aandachtspunten zijn geclusterd rondom complicaties.

Element	HSPS
Geen direct zicht op een complicatie	9.6
Ongeziene perforatie van organen	8.0
Vermoeidheid of gebrek aan slaap	6.0
Onvoldoende of geen zicht door een bloeding	5.9
Vertrouwen op geheugen	5.1
Geen gestructureerd multidisciplinaire overleg om complicaties te bespreken	4.8
Verbetering digitale beeldenopslag	4.6
(digitale) complicatie registratie	4.5

Conclusie

De operatie kamer is een complex faciliteit in het cure proces van een ziekenhuis. Er zijn verschillende elementen die van invloed zijn op het technisch primaire proces binnen een minimaal invasieve operatie kamer. De organisatie van de minimal invasieve operatie kamer dient te verbeteren door het maken van afspraken met andere afdelingen en onderdelen van het ziekenhuis waarvan de minimaal invasieve operatie kamer afhankelijk is. Voorbeelden hiervan zijn de centrale sterilisatie afdeling en de verkoeverkamer. Daarnaast dienen er stappenplannen per verrichting of operatie gemaakt te worden zodat er aan kwaliteitsbewaking gewerkt wordt.

Het risico dat geïndiceerd wordt met de training en opleidingselementen kan gereduceerd worden door het vereisen van basisvaardigheden aan chirurgen of artsen in opleiding voordat er minimaal invasief geopereerd mag worden.

In overleg met de centrale sterilisatieafdeling en de deskundige steriele medische hulpmiddelen zal er gekeken moeten worden naar de instrumentatie elementen. Goede en adequate communicatie met alle betrokkenen is hierbij van belang.

Complicaties kunnen worden gereduceerd door een goed werkend complicatie registratie met een gestructureerd multidisciplinair overleg, waarbij alle betrokkenen aan deel nemen. Communicatie, coördinatie en consensus blijken dan ook de belangrijkste actiepunten voor de verschillende werkgroepen te zijn.

Discussie

De introductie van de DaVinci robot heeft invloed gehad op de wijze waarop de experts keken naar met name de aanschaf van instrumentarium in het ziekenhuis.

De Delphi methode maakt gebruik van subjectieve expertise/meningen van experts in de organisatie. Deze expertise komt niet altijd overeen met de empirische data.

Tijdens de eerste onderzoeksopzet is er een indeling gemaakt van elementen die risico's indiceren en aandachtspunten. De onderverdeling is echter niet zo duidelijk doordat aandachtspunten vaak een praktische verpakking zijn van elementen die een risico indiceren. Doordat dit een inventariserend en explorerend onderzoek was, zijn de exacte oorzaken van elementen niet achterhaald.

Aanbeveling

De vier clusters van elementen bieden de subwerkgroepen van de werkgroep laparoscopie handvaten om aan te werken. Daarnaast dient er verder onderzoek gedaan de worden naar de causale relaties tussen elementen en de exacte betekenis van elementen.

References

1. ASHRM (The American Society for Healthcare Risk Management) (2002). Strategies and tips for maximizing failure mode and effect analysis in your organization. Chicago, White paper.

2. Aggarwal, R., Hance, J., Undre, S., Ratnasothy, J., Moorthy, K., Chang, A. and Darzi, A. (2006). Training junior operative residents in laparoscopic suturing skills is feasible and efficacious. *Surgery.* Vol. 139 ; No 6 : pp 729-734.

3. Aggerwal, R., Undre, S., Moorthy, K., Vincent, C. and Darzi, A. (2004). The simulated operating theatre: comprehensive training for surgical teams. *Quality and safety in the health care.* Vol. 13 ; No 1 : pp 27-32.

4. Ahmed, G., Duffy, J. M. N. and Watson, A. J. S. (2007). Laparoscopic entry techniques and complications. *International journal of gyneacology and obstetric.* Vol. 99; No 1: pp 52-55.

5. Alfredsdottir, H. and Bjornsdottir, K. (2008). Nursing and patient safety in the operating room. *Journal of advances nursing.* Vol. 61; No1 : pp 29-37.

6. Berguer, R. (1999). Surgery and ergonomics. *Archives of surgery.* Vol. 134 ; No 8 : pp 1011-1016.

7. Berland, A., Natvig, G. K. and Gundersen, D. (2008). Patient safety and job-related stress: A focus group study. *Intensive and critical care nursing.* Vol. 24 ; No 2 : pp 90-97.

8. Bolton, T. and Spencer, R. (2006). Positioning of the surgical patient. *Clinical aneasthesia.* Vol. 7 ; No 10 : pp 360-363

9. Carthey, J., de Leval, M. R., Wright, D. J., Farewell, V. T., Reason, J. T. and all UK peadiatric cardiac centers (2003). Behavioral markers in surgical excellence. *Safety science.* Vol. 41 ; No 5 : pp 409-425.

10. Casseres, Y. A., Albayrak A., Schot, C. Grimbergen, C. A., Bonjer, H. J. and Meijer, D. W. (2003). Kwaliteit van endoscopische apparatuur en instrumentarium: een voorlopige rapportage. *Nederlands tijdschrift voor de Heelkunde.* Vol. 12 ; No 5 : 171-174

11. Catchpole K. R., Giddings, A. E. B., Wilkinson, M., Hirst, G., Dale, T. and de Leval, M. R. (2007). Improving patient safety by identifying latent failures in successful operations. *Surgery.* Vol. 142 ; No 1 : pp 102-110.

12. Cheung, D. S., Maygers, J., Khouri-Stevens, Z., Groughy de, L. and Magnuson, T. (2006). Failure modes and effects analysis : Minimizing harm to our bariatric patients. Bariatric nursing and surgical patient care. Vol. 1 ; No 2 : pp 107-114.

13. Christian, C. K., Gustafson, M. L., Roth, E. M., Sheridan, T. B.,. Gandhi, T. K., Dwyer, K., Zinner, M. J., and Dierks, M. M. (2005). A prospective study of patient safety in the operating room. *Surgery* Vol. 139 ; No 2: pp 159-173.

14. Cuschieri, A. (1995). Whither minimal access surgery: tribulations and expectations. *The American journal of surgery.* Vol. 169 ; No 1 : pp 9-19.

15. Cuschieri, A. (2005). Reducing errors in the operating room: Surgical profiency and quality assurance of execution. *Surgical endoscopy and other interventional techniques.* Vol. 19 ; No 8 : pp 1022-1027.

16. Dagi, T. F., Burguer, R., Moore, S. and Reines, H. D. (2007). Preventable errors in the operating room – part 2 : Retained objects, sharps injuries, and wrong site surgery. *Current problems in surgery.* Vol. 44 ; No 6 : pp 352-381.

17. Dalkey N. C. & Helmar O. (1963). An experimental application of the Delphi method to the use of experts. Management Science 9, no 3.

18. Dankelman, J. and Grimbergen, C. A. (2005). Systems approach to reduce errors in surgery. *Surgical endoscopy and other interventional techniques.* Vol. 19 ; No 3 : pp 1017-1021.

19. Dankelman, J., Grimbergen, K. A. and Stassen, H. G. (2005). Engineering for patient safety : issues in minimally invasive procedures. Human error and safety.

20. Derossis, A. M., Fried, G. M., Abrahamowicz, M., Sigman, H. H., Barkun, J. S. and Meakins, J. L. (1998) Development of a model for training and evaluation of laparoscopic skills. *The American journal of surgery.* Vol. 175 ; No 6 : pp 182-187.

21. Dongen, van K. W., van der Wal, W. A., Borel Rinkes, I. H. M., Schijven, M. P. and Broeders, I. A. M. J. (2008). Virutal reality training for endoscopic surgery : voluntary or obligatory? *Surgical endoscopics and other interventional techniques.* Vol. 22 ; No 3 : pp 664-667.

22. Dunn, W.N. (2008) Public policy analysis. An introduction. 4th Edition. Upper Saddle River, New Jersey: Pearson Prentice Hall.

23. Edozien, L. C. (2007). Risk management in gynaecologie: principles and practice. *Best practice and research clinical obstretics and gyneacology.* Vol. 21 ; No 4 : pp 713-725.

24. Elkhuizen, S. (2007). Patient oriented logistics. Studies on organizational improvement in an academic hospital. Thesis, Academic Medical Centre, University of Amsterdam pp 9-33.

25. Eltaib, M. E. H. and Hewit, J. R. (2003). Tactile sensing technology for minimal invasive surgery a review. *Mechatronics.* Vol. 13 ; No 10 : pp 1163 – 1177.

26. Espin, S., Levinson, W., Regehr, G., Baker, R. and Lingard, L. (2006). Error or "act of God"? A study of patients' and operating room team members' perceptions of error definition, reporting, and disclosure. *Surgery.* Vol. ; 139 No : 1 pp 6-14.

27. Firth-Cozens, J. (2004). Why communication fails in the operating room. *Quality and Safety Health Care.* Vol. 13 ; No 5: p 327.

28. Gallagher, A. G., Smith, D. C., Bowers, S. P., Symour, N. E., Pearson, A., McNatt, S., Hananel, D. and Satava, R. M. (2003). Psychomotor skills assessment in practicing surgeons experiences in performing advanced laparoscopic procedures. *The journal of American college surgery.* Vol. 197 ; No 3 : pp 479-488.

29. Gawanda, A. A., Zinner, M. J., Studdert, D. M. and Brennan, T. A. (2003). Analysis of errors reported by surgeons at three teaching hospitals. *Surgery.* Vol. 133; No 6 : pp 614-621.

30. Grix, J. (2004). The foundations of research. *Palgrave study guides.*

31. Hanna, G. B. Frank, T. G. and Cuschieri, A. (1997). Objective assessment of endoscopic knot quality. *The American journal of surgery.* Vol. 174 ; No 4: pp 410-413.

32. Hance, J., Aggarwal, R., Moorthy, K., Munz, Y. , Undre, S. and Darzi, A. (2004). Assessment of psychomotor skills acquisition during laparoscopic cholecystectomy. *The American journal of surgery.* Vol. 190 ; No 3 : pp 507-511.

33. Healey, A. N., Undre, S. and Vincent, C. A. (2006). Defining the technical skills of teamwork in surgery. *Quality and safety in the health care.* Vol. 15 ; No 5: pp 231-324.

34. Health care inspectorate. Retrieved on 22 mei 2008. Website: http://www.igz.nl/uk/

35. Helmreich, R. L. and Davies, J. M. (1996). Human factors in the operating room: interpersonal determinants of safety, efficiency and morale. *Bolliére's Clinical Anaesthesiology.* Vol. 10 ; no 2 : 277-295.

36. Inspectie voor de gezondheidszorg (IGZ). (2007). Risico's minimaal invasieve chirurgie onderschat; kwaliteitssysteem voor laparoscopische operaties ontbreekt. November 2007. Retrieved on 1th of februari 2008.

37. ISO 2007

38. Jacklin, R., Sevdalis, N., Harries, C., Darzi, A. and Vincent, C. (2008). Judgment analysis: a method for quantitative evaluation of trainee surgeon' judgments of surgical risk. *The American journal of surgery.* Vol. 195 ; No 2: 183-188.

39. Jansen, F. W., Kolkman, W., Bakkum, E. A., de Kroon, C. D., Trimbos – Kemper, T. C. M. and Trimbos, B. J. (2004). Complications of laparoscopy: An inquiry about closed – versus open-entry techniques. *American journal of obstetrics and gynaecology.* Vol. 190 ; No 3 : pp 634-638.

40. Joice P., Hanna, G. B. and Cuschieri, A. (1998). Errors enacted during endoscopic surgery: a human reliability analysis. *Applied ergonomics*. Vol. 26 ; No 6 : pp 409-414.

41. Kehlet, H. Douglas and Wilmore, D. W. (2002). Multimodal strategies to improve surgical outcome. *The American journal of surgery.* Vol. 183 ; No 6 : pp 630-641.

42. Kneebone, R. L., Nestel, D., Vincent, C. and Darzi, A. (2007). Complexity, risk and simulation in learning procedural skills. *Medical education.* Vol. 41 ; No 9 : pp 808-814.

43. Lee, A. C., Rafiq, A., Merrell, R., Ackerman, R. and Dennerlein, J. T. (2005). Ergonomics and human factors in endoscopic surgery: a comparison of manual vs telerobotic simulation systems. *Surgical endoscopy and other interventional techniques.* Vol. 19 ; No 8 : pp 1064-1070.

44. Lee, G., Lee, T., Dexter, D., Klein, R. and Park, A. (2007). Methodological infrastructure in surgical ergonomics: a review of task, models and measurement systems. *Surgical innovations* Vol. 14; no 3 : PP 153-167

45. Lingard, L., Espin S., Whyte S., Regehr G., Baker G. R., Reznick, R., Bohnen ,J., Orser, B., Doran, D. and Grober, E. (2004). Communication failures in the operating room: an observational classification of recurrent types and effects *Quality and safety in the Health Care.* Vol. 13 ; No 6 : pp 330-334.

46. Lingard, L., Espin S., Rubin, B., Whyte S., Colmenares, M., Baker G. R., Doran D., Grober, E., Orser, B., Bohnen J., and Reznick R. (2005). Getting teams to talk: development and pilot implementation of a checklist to promote interprofessional communication in the OR. *Quality and safety in the Health Care.* Vol. 14 ; No 5 : pp 340-346.

47. Lingard, L., Regehr, G., Espin, S. and Whyte, S. (2006). A theory-based instrument to evaluate team communication in the operating room: balancing measurement authenticity and reliability. *Quality and safety in Health Care.* Vol. 15 ; No 6: pp 422-426.

48. Lingard, L., Reznick, R., DeVito, I. And Espin, S. (2002). Forming professional identities on the health care team: discursive constructions of the 'other' in the operating room. *Medical education.* Vol. 36 ; No 8 : pp 728-734.

49. Lyon, P. M. A. (2003). Making the most of learning in the operating theatre: student strategies and curricular initiatives. *Medical Education.* Vol. 37 ; No 8: pp 680–688.

50. Lyon, P. M. A. (2004). A model of teaching and learning in the operating theatre. *Medical education.* Vol. 38 ; No 12 : 1278 – 1287.

51. Machatuta, N. A. and Sale, S. M. (2007). Fires and explosions. *Anaesthesia and intensive care medicine.* Vol. 8 ; No 11 : pp 457-460.

52. Matern, U. and Koneczny, S. (2007). Safety, hazard and ergonomics in the operating room. *Surgical Endoscopy and other interventional Techniques*. Vol. 21; No 11: 1965-1969

53. McDonald, R., Waring, J. and Harrison, S. (2006). Rules, safety and the narrativisation of identity: a hospital operating theatre case study. *Sociology of Health and Illness.* Vol. 28 ; No 2: pp 178-202.

54. Mills, P., Neily, J. and Dunn, E. (2008) Teamwork and communication in surgical teams: Implications for patient safety. J*ournal of the American College of Surgeons*. Vol. 206 ; No 1: pp 107-112 .

55. Moorthy, K., Munz, Y., Undre, S. and Darzi, A. (2004). Objective evaluation of the effect of noise on the performance of a complex laparoscopic task. *Surgery.* Vol. 136 ; No 1: pp 25-30.

56. Najmaldin, A. (2007). Skills training in pediatric minima access surgery. *Journal of pediatric surgery.* Vol. 42 ; No 2 : pp 284-289.

57. Nugteren, W. A. H., Schellekens, W. M. L. C. M. and van der Wal, G. (2007). Laparoscopisch opereren kan en moet veiliger. Kwaliteitsbewaking ontbreekt. *Medisch contact.* Vol. 47 pp 1957-1959.

58. Pandy, V., Wolfe, J. H. N., Moorthy, K., Munz, Y., Jackson, M. J. and Darzi, A. W. (2006). Technical skills continue to improve beyond surgical training. *Journal of vascular surgery.* Vol. 43 ; No 3 : pp 539-545.

59. Park, H. J., Lee, S. Y., and Lee C. S. (2004) Complications associated with the nurse procedure: Analysis of risk factors and suggested measures for prevention of complications. *Journal of Pediatric Surgery,* Vol. 39, No 3: pp 391-395.

60. Parker, D and Lawton, R. (2000). Judging the use of clinical protocols by fellow professionals. *Social science and medicine.* Vol. 51 ; No 5 : pp 669-677.

61. Primus, A. P., Healey, A. N. and Undre, S. (2007). Distraction in the urology operating theatre. *The Autors Journal Compilation.* p 493.

62. Powers, T. W., Murayama, K. M., Toyama, M., Murphy, S., Denham, E. W., Derossis, A. M. and Joehl, R. J. (2002). Housestaff performance is improved by participation in a laparoscopic skills curriculum. The *American Journal of Surgery*. Vol. 184 ; No 6 : 626–630.

63. Ranger, C. A. and Bothwell, S. (2004). Making sure the right patient gets the right care. *Quality Safety Health Care.* Vol. 13 ; No 5 : p 329.

64. Reason, J. (1995). Safety in the operating theatre part 2: Human error and organizational failure. *Current anaesthesia and critical care.* Vol. 6 ; No 2 : pp 121-126.

65. Rochlin, G. I. (1999) Safe operation as a social construct. *Ergonomics.* Vol. 42 ; No 11 : 1549-1560.

66. Satava, R. M. (2005). The nature of surgical error. A cautionary take and a call to reason. *Surgical endoscopy and other interventional techniques.* Vol. 19 ; No 8 : pp 1014-1016.

67. Schaefer, H. G., Helmreich, R. L. and Scheidegger, D. (1994). Human factors and safety in emergency medicine. *Reuscitation.* Vol. 28 ; No 3: pp 221-225.

68. Schaefer, H. G., Helmreich, R. L. and Scheidegger, D. (1995). Safety in the operating theatre – part 1: Interpersonal relationships and team performance. *Current anaesthesia and critical care.* Vol. 6 ; No 1 : pp 48-53.

69. Saunders, M., Lewis, P. & Thornhill, A. (2007). *Research Methods for business students*. Fourth edition, Prentice Hall.

70. Schimpff, S. C. (2007) Improving operating room and perioperative safety: Background and specific recommendation. *Surgical innovation.* Vol. 14 ; No 2 : pp 127-135.

71. Scott, D. J., Bergen, P. C., Rege, R. V., Laycock, R., Tesfay, S. T., Valentine, R. J., Euhus, D. M., Jeyarajah, D. R., Thompson, W. M. and Jones, D. B. (2000). Laparoscopic Training on Bench Models: Better and More Cost Effective than Operating Room Experience? *Journal of the College of American surgeons.* Vol. 191 ; No 3 : pp 272-283.

72. Singh, P. B., Saw, N. K., Mokete, M., Martin, F. L. and Matanhelia, S. S. (2007). An integrated laparoscopic simulator to develop surgical skills outside the operating theatre: a novel means to improve training facilities in the UK. *International journal of surgery.* Vol. 5 ; No 1 : pp 1-7.

73. Slack, N., Chambers, S. and Jonhston, R. (2007). Operation management. With Companion Website With Gradetracker Student Access Card.

74. Slack, A. and McVeigh, A. (2007) Laparoscopy and laparoscopic surgery. *Obstetrics, gynaecology and reproductive medicine*. Vol. 17 ; no 4 : pp 112-118.

75. Sevdalis, N., Healey, A. N. and Vincent C. A. (2007). Distracting communications in the operating theatre. *Journal of Evaluation in Clinical Practice* Vol. 13 ; No 3 : pp 390–394.

76. Smith, A. R. B. (2000). Post-operative complications following minimal access surgery. *Baillière's Clinical obstetrics and gynaecology.* Vol. 14; no 1 : pp 123-132.

77. Stefanidis, D., Korndorffer, J. R., Heniford, B. T. and Scott, D. J.l (2007). Limited feedback and video tutorials optimize learning and resource utilization during laparoscopic simulator training. *Surgery.* Vol. 142 ; No 2 : pp 202-206.

78. Taffinfer, N. J., McManus, I. C., Russell, R. C. G. and Darzi, A. (1998). Effect of sleeping deprivation on surgeons' dexterity on laparoscopic simulator. *The lancet*, Vol. 352 ; No 9135 : p 1191.

79. Tang, B. and Cuschieri, A. (2006). Conversions during laparoscopic cholecystectomy: Risk factors and Effects on patient outcome. *Journal of gastrointestinal surgery.* Vol. 10 ; No 7 : pp 1081-1091.

80. Tang, B., Hanna, B. and Cuschieri, A. (2005). Analysis of errors enacted by surgical trainees during skills training courses. *Surgery.* Vol. 138 ; No 1 : pp 14-20.

81. Thompson, J. D., Zald, M. N. and Scott, W. R. (2007). Organizations in action. Social science bases of administrative theory. *Transaction publishers, New Brunswick.*

82. Thomson, A. J. M. and Rowland D. J. (2005) Immediate to long-term complications following minimal access surgery in gynaecology. *Reviews in gynaecological practice.* Vol. 5 ; No 1: pp 123-129.

83. University Medical Center St Radboud (2007). Last updated on April 20th 2007. Retrieved on February 4th 2008. Website: http://www.umcn.nl/overhetumc.

84. Wetzel. C. M., Kneebone, R. L., Woloshynowych, M., Nestel, D., Moorthy, K., Kidd, J. and Darzi, A. (2006). The Effects of stress on surgical performance. *The American journal of surgery.* Vol. 191 ; No 1 : pp 5-10.

85. Vanhaecht, K. and Sermeus, W. (2002). Draaiboek voor de ontwikkeling, implementatie en evaluatie van aan klinisch pad. 30 stappenplan van het netwerk klinische paden. *Acta Hospitalia.* Vol. 42.

86. Verdaasdonk, E. (2008). Virtual reality training and equipment handling in laparoscopic surgery (proefschrift).

87. Vliet, H. (2005). Structurele kwaliteitscontrole van lichtkabels, optieken en diathermisch endoscopisch instrumentarium in het Onze Lieve Vrouwe Gasthuis te Amsterdam.

88. Yanow, D. (2000). Conducting interpretive policy analysis. Sage University papers on qualitative research methods. Vol. 47. Thousand Oaks, CA: Sage.

89. Yule S., Flin R., Paterson-Brown S., and Maran N. (2006). Non-technical skills for surgeons in the operating room: A review of the literature. *Surgery* Vol. 139 ; No 2 : pp 140-149.

90. Picture on front page of Lupine made by S. T. J. Weideveld.

Appendix: The minimal invasive surgery operation room

Elements which indicate risks for the quality and safety

July, 2008

Appendix I: Elements which indicate risks for the quality and safety

Introduction

In this appendix the results of the literature study and the interview cycles is combined. A total of 66 elements that indicate risks where found in the literature and 38 from the interviews. There was an overlap of 15 elements. In total 89 elements which indicate to risks where gathered. During the interviews also 14 point of emphasize where formulated. These 89 elements which indicate risks and 14 point of emphasize are ranked and prioritized by the interviewee in the second round. The following questions were asked.

- Is the element applicable to the hospital, Yes, No or Partly?
- What is Effect on the quality and safety of employees and patient (1 – very low and 5 – very high)?
- What is the Chance that the element will lead to a risk (1 – very low and 5 – very high)?
- Which Priority should the element get to improve (1 – very low and 5 – very high)?

When the Chance and the Effect are known the Priority can also be calculated (P = C x E) (ASHRM, 2002). This Calculated Priority is also given in the table per element.

To rank the point of emphasizes two questions are asked:

- Do you agree with the statement/point of emphasize, Yes, No and Partly?
- Which priority should the element get to improve (1 – very low and 5 – very high)?

For each answering possibility the number of participants that has given the answer is given (n =) and the percentage of the total that has given the answer (%), is given. Some interviewee did not have enough knowledge to rank and prioritize the element these where labeled with an 8. The data is progressed as missing but the reason for missing is known. Some interviewee made some comments about the element or how to improve them, these are mentioned in the comments row. The prioritized list of elements applicable to the hospital and with a mean priority (stated and / or calculated) above 4 can be found in the report chapter results and are shaded in this appendix.

The elements are divided into three categories. In the organizational category are the elements that indicate risks in the organization of the minimal invasive surgery, like quality assurance and policy. In the instrumentation and equipment category specific elements surrounding the instrumentation and equipment are discussed. The last category is the interpersonal category. In this category the elements were human interaction is actively involved are included. Examples are culture, ergonomics and communication. The elements are ranked according to the stated priority they received in the second interview round.

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Organizational elements

Element: Inexperience surgeon						
Definition: The surgeon has no experience or not enough experience with minimal invasive operations or specific MIS operations to operate.						
Source articles and interviews	Alfredsdottir et al., 2008 Berland et al., 2008 Carthey et al., 2003 Dagi et al., 2007 Derossis et al., 1998 Gawanda et al., 2003 Hanna et al., 1997 IGZ, 2007 Jacklin et al., 2008 Park et al., 2004 Reason, 1995 Schaefer et al., 1995 Slack et al., 2007 Tang et al., 2006 Wetzel et al., 2006					
Type of risk	Latent (quality) and active (safety) element					
Applicable hospital	Yes n = 2 (13 %)		No n = 3 (19 %)	Partly n = 9 (56 %)		8 n = 2 (13 %)
Effect mean = 4.29 std = 0.73	1	2	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Chance mean = 4.00 std = 0.68	1	2	3 n = 3 (19 %)	4 n = 8 (50 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 4.14 std = 0.63	1	2	3 n = 2 (13 %)	4 n = 7 (44 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Priority mean = 4.57 std = 0.51	1	2	3	4 n = 6 (38 %)	5 n = 8 (50 %)	8 n = 2 (13 %)
Hospital Specific Effect Size	4.57 / 0.51 = 8.9					
Comments	Expert D: 'Together with training this is essential'. Expert E: 'This can be reduced trough adequate training of surgeons.' Expert F: 'This is essential for operation especially minimal invasive.' Expert K: 'A experienced surgeons is present during this kind of operations.'					

Element: Low minimal invasive surgery volume						
Definition: The volume of minimal invasive operation in a hospital is low so surgeons cannot develop and maintain their skills enough.						
Source articles and interviews	Gawanda et al., 2003 Expert A					
Type of risk	Latent element can be an active element for specific operations					
Applicable hospital	Yes n = 5 (31 %)		No n = 5 (31 %)	Partly n = 4 (25 %)		8 n = 2 (13 %)
Effect mean = 4.14 std = 0.01	1	2	3 n = 1 (6 %)	4 n= 10 (63 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Chance mean = 3.93 std = 0.97	1	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 8 (50 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 4.01 std =0.50	1	2	3 n = 1 (6 %)	4 n = 9 (56 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Priority mean = 4.50 std = 0.52	1	2	3	4 n = 7 (44 %)	5 n = 7 (44 %)	8 n = 2 (13 %)
Hospital Specific Effect Size	4.50/ 0.52 = 8.7					
Comments	Expert E: 'depends on the type of surgery' and 'there is a strong coherence with the experience of the surgeon also Expert F.' Expert J: 'Not only looking at the number but at the quantity/ quality relation.'					

Element: No (national) trainings program						
Definition: There are no (national) norms for the training and education of surgeons that perform or want to perform laparoscopic surgery.						
Source articles and interviews	Derossis et al., 1998 IGZ, 2007 Slack et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)	No n = 2 (13 %)		Partly n = 2 (13 %)	8 n = 1 (6 %)	
Effect mean = 3.73 std = 1.03	1	2 n = 3 (19 %)	3 n = 1 (6 %)	4 n = 8 (50 %)	5 n = 3 (19 %)	8 n = 1 (6 %)
Chance mean = 3.53 std = 1.13	1	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 3 (19 %)	8 n = 1 (6 %)
Calculated Priority mean = 3.63 std = 1.03	1	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Priority mean = 4.40 std = 0.63	1	2	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 7 (44 %)	8 n = 1 (6 %)
Hospital Specific Effect Size	4.40 / 0.63 = 7.0					
Comments	Expert A: 'Our specialty has a trainings program.' Expert J: 'This should be organized nationally.' Expert P: 'The training is done outside the hospital.'					

Element: No basic level required before surgeons may operate minimal invasive.						
Definition: There are no specific requirements for a surgeon to start operating minimal invasive.						
Source articles and interviews	Expert A Expert G Expert J Expert M Expert L.					
Type of risk	Latent element					
Applicable hospital	Yes n = 6 (38 %)	No n = 6 (38 %)		Partly n = 2 (13 %)	8 n = 2 (13 %)	
Effect mean = 3.93 std = 1.385	1 n = 2 (13 %)	2	3 n = 1 (6 %)	4 n = 5 (31 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Chance mean = 3.79 std = 1.369	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 3.857 std = 1.351	1 n = 2 (13 %)	2	3 n = 1 (6 %)	4 n = 6 (38 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Priority mean = 4.43 std = 1.089	1 n = 1 (6 %)	2	3	4 n = 4 (25 %)	5 n = 9 (56 %)	8 n = 2 (13 %)
Comments	Expert M 'surgeons should have an certificate before they can operate minimal invasive					

Element: No protocol training in a skills lab						
Definition: The skills trainingen in the skills lab are voluntary and not obligatory. There is no guideline or protocol for this type of training.						
Source articles and interviews	Expert A Expert L					
Type of risk	Latent element					
Applicable hospital	Yes n = 13 (81 %)		No	Partly	8 n = 3 (19 %)	
Effect mean = 3.54 std = 1.20	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Chance mean = 3.62 std = 1.12	1	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 3 (19 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.58 std = 1.08	1	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 3 (19 %)	8 n = 3 (19 %)
Priority mean = 4.38 std = 0.65	1	2	3 n = 1 (6 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 3 (19 %)
Hospital Specific Effect Size	4.39 / 0.65 = 6.7					
Comments	Expert A and P: 'We are working on this.'					

Element: Administrative failure						
Definition: There is a failure in de bureaucratic of administrative departments which leads to errors in the OR. Examples are typing errors and wrong file with the patien..						
Source articles and interviews	Endozien, 2007 Gawanda et al., 2003 Reason, 1995 Schaefer et al., 1995					
Type of risk	Latent element					
Applicable hospital	Yes n = 4 (25 %)		No n = 5 (31 %)	Partly n = 5 (31 %)	8 n = 2 (13 %)	
Effect mean = 3.93 std = 1.27	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 4 (25 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Chance mean = 2.71 std = 0.73	1 n = 5 (31 %)	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 2 (13 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.32 std = 1.15	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 5 (31 %)	4 n = 1 (6 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Priority mean = 4.29 std = 0.73	1	2	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Hospital Specific Effect Size	4.29 / 0.73 = 5.9					
Comments	Expert A: 'This can happen'. Expert D: 'This can be prevented by a time outs'. Expert B: 'I have nearly any experience with this happening.' Expert J: 'The EPR can be used to prevent this.' Expert K: 'Can be prevented with an checklist.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Lack of protocols or inappropriate protocols for quality assurance						
Definition: No quality assurance trough adequate management, evaluation and improvement of protocols or failure to use the protocols adequately.						
Source articles and interviews	Alfredsdottir et al., 2008 Cuschieri, 2005 Gawanda et al., 2003 Helmreich et al., 1996 IGZ, 2007 Nugteren et al., 2007 Expert A Expert I.					
Type of risk	Latent element					
Applicable hospital	Yes n= 10 (63 %)	No		Partly n=4 (25 %)	8 n=2 (13%)	
Effect mean = 3.07 std = 0.83	1	2 n = 3 (19 %)	3 n = 8 (50 %)	4 n = 2 (13 %)	5 n = 1 (6%)	8 n = 2 (13 %)
Chance mean = 2.93 std = 0.73	1	2 n = 4 (25 %)	3 n = 7 (44 %)	4 n = 3 (19 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 3.00 std =0.68	1	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 2 (13 %)	5 n = 1 (6 %	8 n = 2 (13 %)
Priority mean = 4.29 std = 0.83	1	2 n = 1 (6 %)	3	4 n = 7 (44 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Hospital Specific Effect Size	4.29 / 0.83 = 5.2					
Comments	Expert C: 'unknown'. Expert D and E: 'For the OR1 there are protocols only no surgical ones.'					

Element: Unfamiliarity with existence protocols						
Definition: Unfamiliarity if performances are in protocols or standardized and where they can be found.						
Source articles and interviews	Expert E					
Type of risk	Latent element					
Applicable hospital	Yes n = 8 (50 %)	No n = 4 (25 %)		Partly n = 3 (19 %)	8 n = 1 (6 %)	
Effect mean = 3.00 std = 0.83	1 n = 1 (6 %)	2 = 3 (19 %)	3 n = 6 (38 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.06 std = 1.03	1 n = 1 (6 %)	2 n = 4 (25 %)	3 n = 6 (38 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.93 std = 0.98	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 6 (38 %)	3 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 4.21 std = 0.89	1 n = 1 (6 %)	2	3 n = 1 (6 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Hospital Specific Effect Size	4.21 / 0.89 = 4.7					
Comments	Expert F: 'This depends of the culture in the OR' Expert J: 'most of the protocols are known.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Scrub nurse has inexperience with the OR1						
Definition: The scrub nurse has no experience or too little with the OR1 as workplace.						
Source articles and interviews	Expert A					
Type of risk	Latent element					
Applicable hospital	Yes n = 4 (25 %)	No n = 3 (19 %)	Partly n = 6 (38 %)	8 n = 3 (19 %)		
Effect mean = 3.46 std = 1.13	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Chance mean = 2.92 std = 1.04	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 6 (38 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.19 std = 0.99	1	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 4.15 std = 0.90	1	2 n = 1 (6 %)	3 8 n = 1 (6 %)	4 n = 6 (38 %)	5 n = 5 (31 %)	8 n = 3 (19 %)
Hospital Specific Effect Size	4.15 / 0.90 = 4.6					
Comments	Expert D and F: 'Currently here is work on actively'.					

Element: Instruction of less experienced personnel during the operation						
Definition: Instruction of less experienced personnel about instrumentation or equipment during the operation due to inexperience of team member.						
Source articles and interviews	McDonald et al., 2006 Primus et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 8 (50 %)	No	Partly n = 5 (31 %)	8 n = 3 (19 %)		
Effect mean = 3.31 std = 0.95	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5	8 n = 3 (19 %)
Chance mean = 3.00 std = 1.23	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.15 std = 0.97	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 6 (38 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 4.15 std = 0.80	1	2	3 n = 3 (19 %)	4 n = 5 (31 %)	5 n = 5 (31 %)	8 n = 3 (19 %)
Hospital Specific Effect Size	4.15 / 0.80 = 5.2					
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No (digital) registration of complications						
Definition: There is no or no adequate complication registration to keep track of complications and analyze these complications.						
Source articles and interviews	IGZ, 2007 Nugteren et al., 2007 Expert G Expert J Expert M					
Type of risk	Latent element					
Applicable hospital	Yes n = 12 (75 %)	No		Partly n = 3 (19 %)	8 n = 1 (6 %)	
Effect mean = 3.60 std = 0.83	1	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 9 (56 %)	5 n = 1 (6 %)	8 n = 1 (6 %)
Chance mean = 2.60 std = 1.24	1 n = 3 (19 %)	2 n = 5 (31 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 1 (6 %)
Calculated Priority mean = 3.10 std =0.91	1	2 n = 1 (6 %)	3 n = 9 (56 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 1 (6 %)
Priority mean = 4.13 std = 0.92	1	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 1 (6 %)
Hospital Specific Effect Size	4.13/ 0.92 = 4.5					
Comments	Expert A: 'There is a video registration system'. Expert C: 'Registration is a right but you have to do something with it'.					

Element: Absences of super-vision when necessary						
Definition: There is no supervision when it is necessary or required.						
Source articles and interviews	Endozion, 2007					
Type of risk	Active element					
Applicable hospital	Yes	Non = 11 (69 %)		Partly n = 3 (19 %)	8 n = 2 (13 %)	
Effect mean = 3.77 std = 1.24	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Chance mean = 3.46 std = 1.45	1 n = 2 (13 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.62 std = 1.21	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Priority mean = 4.00 std = 1.32	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 1 (6 %)	4 n = 3 (19 %)	5 n = 7 (44 %)	8 n = 3 (19 %)
Comments	Expert J: 'Depends on the level op experience of the resident'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No structured multidisciplinary meetings to evaluate complications						
Definition: There are no structured multidisciplinary meeting to evaluate the use of minimal invasive surgery and the complications which can occur.						
Source articles and interviews	IGZ, 2007 Nugteren et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 9 (56 %)		Non = 3 (19 %)		Partly n = 4 (25 %)	8
Effect mean = 3.63 std = 0.81	1	2 n = 1 (6 %)	3 n = 6 (38 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8
Chance mean = 3.00 std = 0.97	1	2 n = 6 (38 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8
Calculated Priority mean = 3.31 std = 0.79	1	2 n = 1 (6 %)	3 n = 9 (56 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8
Priority mean = 4.06 std = 0.85	1	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 8 (50 %)	5 n = 5 (31 %)	8
Hospital Specific Effect Size	4.06 / 0.85 = 4.8					
Comments	Expert A: 'Not on all aspects / levels there is a lack of evaluation'. Expert I: 'The CSD is not involved or too late involved.' Expert J: 'Learning from each other's mistakes is important.' Expert K: 'The meetings are not structured' and 'It is important that the source of the problem is known'. Expert M: 'General surgery has a general complication discussion not specific for minimal invasive surgery'.					

Element: Lack of cognitive skills						
Definition: Surgeons has no or not enough cognitive skills like assessment of risk, planning, anticipation, prediction of difficulty or decisions about possible actions.						
Source articles and interviews	Yule et al, 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 5 (31 %)		Non = 3 (19 %)		Partly n = 6 (38 %)	8 n = 2 (13 %)
Effect mean = 3.64 std = 1.28	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Chance mean = 3.43 std = 1.28	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.54 std = 1.25	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Priority mean = 4.00 std = 1.21	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 1 (6 %)	4 n = 5 (31 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Hospital Specific Effect Size	4.00 / 1.24 = 3.2					
Comments	Expert F: 'This is the responsibility of the surgeon.' Expert J: 'There is broad cognitive training but not specific for MIS.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Unstructured and divers training						
Definition: There is no structure in the training of resident and a high amount of diversity in the training programs.						
Source articles and interviews	Endozien, 2007 Gawanda et al., 2003 IGZ, 2007 Nugteren et al., 2007 Reason, 1995 Singh et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 10 (63 %)		No n = 2 (13 %)		Partly n = 1 (6 %)	8 n = 3 (19 %)
Effect mean = 3.31 std = 0.95	1	2 n = 2 (13 %)	3 n = 7 (44 %)	4 n = 2 (13 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Chance mean = 3.00 std = 1.09	1	2 n = 5 (31 %)	3n = 5 (31 %)	4 n = 1 (6 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.15 std = 0.99	1	2 n = 2 (13 %)	3 n = 7 (44 %)	4 n = 2 (13 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Priority mean = 4.00 std = 0.82	1	2	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Hospital Specific Effect Size	4.00 / 0.82 = 4.9					
Comments	Experts R: 'there is no standardized routine way of educating residents.' Expert K: 'residents are never alone in the OR and therefore this does not lead to a risk.'					

Element: Input or diagnostic failure						
Definition: The diagnose and decision making previous to the OR are inadequate, missing or wrong.						
Source articles and interviews	Catchpole et al., 2007 Cuschieri, 2005 Endozien, 2007 Kohlet et a.., 2002 Satava, 2005 Schimpff, 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 3 (19 %)		No n = 6 (38 %)		Partly n = 5 (31 %)	8 n = 2 (13 %)
Effect mean = 4.15 std = 1.14	1 n= (%)	2	3 n = 1 (6 %)	4 n = 5 (31 %)	5 n = 6 (38 %)	8 n = 3 (19 %)
Chance mean = 2.85 std = 1.73	1 n= (%)	2 n = 1 (6 %)	3 n = 1 (6 %)	4 n = 3 (19 %)	5 n = 3 (19 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.50 std = 1.17	1 n= (%)	2	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 3 (19 %)	8 n = 3 (19 %)
Priority mean = 4.00 std = 1.47	1 n= (%)	2 n = 1 (6 %)	3	4 n = 3 (19 %)	5 n = 7 (44 %)	8 n = 3 (19 %)
Comments	Expert R: 'OR personnel has no insight in wrong diagnosises.' Expert J: 'our specialism uses differentiated diagnosis to prevent wrong diagnosis.' Expert M: 'nearly ever happens.' Expert P: 'I perform only one type of surgery.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No adequate time out protocol or time out						
Definition: There is no adequate time out protocol or time out (briefing) to check and recheck important information like, if the right patient is on the table, right surgery, discuss special aspects and so on.						
Source articles and interviews	Dagi et al., 2007 Lingard et al., 2005 Reason, 1995 Expert E Expert F					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)		No	Partly n = 4 (25 %)	8 n = 1 (6 %)	
Effect mean = 3.27 std = 1.16	1 n = 1 (6 %)	2 r = 2 (13 %)	3 n = 7 (44 %)	4n = 2 (13 %)	5 n = 3 (19 %)	8 n = 1 (6 %)
Chance mean = 3.00 std = 1.07	1	2 r = 6 (38 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Calculated Priority mean = 3.13 std = 1.01	1	2 r = 2 (13 %)	3 n = 9 (56 %)	4 n = 1 (6 %)	5 n = 3 (19 %)	8 n = 1 (6 %)
Priority mean = 3.93 std = 1.10	1	2 r = 2 (13 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 6 (38 %)	8 n = 1 (6 %)
Comments	Expert D: 'This will come in the near future'. Expert K: 'There has been a time out pilot on some departments.' Expert J and L: 'The outpatient clinics have time outs because of the experience of the scrub nurses.' Expert N: 'Scrub nurses solve or handle this before the operation.'					

Element: Testing only core knowledge and technical skill						
Definition: Testing only core knowledge and technical skills important domains like interpersonal skills, professionalism and integration of core knowledge and non technical skills are neglected.						
Source articles and interviews	Aggarwal et al., 2006 Aggerwal et al., 2004 Helmreich et al., 1996 Schaefer et al., 1994 Tang et al., 2005 Yule et al, 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 9 (56 %)		No n = 2 (13 %)	Partly n = 2 (13 %)	8 n = 3 (19 %)	
Effect mean = 3.62 std = 1.04	1 n = 1 (6 %)	2	3 n = 4 (25 %)	4 n = 6 (38 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Chance mean = 3.23 std = 1.09	1 n = 1 (6 %)	2 r = 2 (13 %)	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.42 std = 0.93	1 n = 1 (6 %)	2	3 n = 2 (13 %)	4 n = 9 (56 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 3.85 std = 0.99	1	2 r = 1 (6 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Discrepancy OR1 and other OR's						
Definition: There is a difference in the knowledge and competence of personnel between the OR1 and the other OR's where laparoscopic surgery is performed.						
Source articles and interviews	Expert G Expert J Expert M					
Type of risk	Latent element					
Applicable hospital	Yes n= (%)		No n= (%)		Partly n= (%)	8 n = 3 (19 %)
Effect mean = 3.46 std = 1.13	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Chance mean = 3.23 std = 1.17	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.35 std = 1.13	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Priority mean = 3.85 std = 0.99	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 1 (6 %)	4n = 7 (44 %)	5 n = 3 (19 %)	8 n = 3 (19 %)
Comments	Expert A: 'Especially for the exchange of employees. Sometimes not the most adequate people are operating.'					

Element: No basic level required for a scrub nurse may assist a MIS.						
Definition: At the moment it is unknown who can work in the OR1 and has enough knowledge to assist MIS operations.						
Source articles and interviews	Expert F					
Type of risk	Latent element					
Applicable hospital	Yes n = 10 (63 %)		No		Partly n = 1 (6 %)	8 n = 5 (31 %)
Effect mean = 2.91 std = 0.94	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5	8 n = 5 (31 %)
Chance mean = 2.82 std = 0.98	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5	8 n = 5 (31 %)
Calculated Priority mean = 2.86 std = 0.95	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5	8 n = 5 (31 %)
Priority mean = 3.02 std = 1.17	1	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 5 (31 %)
Comments	Expert J: 'it is better to learn everything in practice.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No protocol introduction new techniques						
Definition: There is no protocol for the way new operation techniques or new technical techniques should be embedded into the existing assemble of techniques.						
Source articles and interviews	Expert G					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)		No n = 2 (13 %)		Partly n = 3 (19 %)	8
Effect mean = 2.94 std = 1.24	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8
Chance mean = 3.13 std = 1.15	1 n = 1 (6 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8
Calculated Priority mean = 3.03 std = 1.18	1 n = 1 (6 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8
Priority mean = 3.01 std = 1.05	1 n = 1 (6 %)	2	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 4 (25 %)	8
Comments	Expert J: 'It is logical how new techniques should be introduced.' Expert K: 'Clinical lessons are provided by the manufacturer.'					

Element: Resistance against protocols						
Definition: Surgeons and other personnel have resistance against protocols because they feel that it affects their autonomy.						
Source articles and interviews	McDonald et al., 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 8 (50 %)		No n = 6 (38 %)		Partly n = 2 (13 %)	8
Effect mean = 3.19 std = 1.28	1 n = 3 (19 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 8 (50 %)	5 n = 1 (6 %)	8
Chance mean = 3.00 std = 1.10	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5	8
Calculated Priority mean = 3.09 std = 1.11	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 9 (56 %)	5	8
Priority mean = 3.81 std = 1.11	1	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 5 (31 %)	8
Comments	Expert B: 'OR personnel is very flexible towards the specialist and accumulates to the specialist'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No basic level required for residents before they may operate minimal invasive.						
Definition: There are no specific requirements for a resident to start operating minimal invasive. A so the test the level of experience and knowledge about MIS is lacking.						
Source articles and interviews	IGZ, 2007 Nugteren et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 8 (50 %)		No n = 4 (25 %)		Partly n = 1 (6 %)	8 n = 3 (19 %)
Effect mean = 3.23 std = 1.01	1	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Chance mean = 3.08 std = 1.038	1	2 n = 5 (31 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.15 std = 1.03	1	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 3.77 std = 0.83	1	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments						

Element: No anesthesia protocol						
Definition: There is no specific protocol for the anesthetics during minimal invasive operations.						
Source articles and interviews	Expert B					
Type of risk	Latent element					
Applicable hospital	Yes n = 10 (63 %)		No n = 1 (6 %)		Partly n = 1 (6 %)	8 n = 4 (25 %)
Effect mean = 3.17 std = 1.12	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 4 (25 %)
Chance mean = 3.17 std = 0.81	1	2 n = 2 (13 %)	3 n = 7 (44 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 4 (25 %)
Calculated Priority mean = 3.17 std = 0.83	1	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 4 (25 %)
Priority mean = 3.67 std = 0.78	1	2 n = 2 (13 %)	3 n = 6 (38 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 4 (25 %)
Comments	Expert B: 'The anesthetist is very inventive and accumulates according to the situation.' Expert J: 'There should be a national protocol for anesthesia during MIS.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No purchase protocol						
Definition: No structure and procedures in the purchase of minimal invasive surgery equipment and instrumentation.						
Source articles and interviews	Nugteren et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)	No n = 2 (13 %)	Partly n = 2 (13 %)	8 n = 1 (6 %)		
Effect mean = 2.71 std = 1.14	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.43 std = 0.85	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 6 (38 %)	4 n = 1 (6 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 2.57 std = 0.92	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5	8 n = 2 (13 %)
Priority mean = 3.50 std = 1.02	1	2 n = 2 (13 %)	3 n = 6 (38 %)	4 n = 3 (19 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Comments	Expert A: 'To achieve uniformity a purchase protocol is necessary'.					

Element: Not using OR1 besides office hours						
Definition: The OR1 is not used outside office hours. MIS is then performed with trolleys.						
Source articles and interviews	Expert E Expert M					
Type of risk	Latent element					
Applicable hospital	Yes n = 14 (88 %)	No	Partly	8 n = 2 (13 %)		
Effect mean = 2.50 std = 1.09	1 n = 2 (13 %)	2 n = 7 (44 %)	3 n = 1 (6 %)	4 n = 4 (25 %)	5	8 n = 2 (13 %)
Chance mean = 2.36 std = 1.01	1 n = 2 (13 %)	2 n = 8 (50 %)	3 n = 1 (6 %)	4 n = 3 (19 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 2.43 std = 0.96	1 n = 2 (13 %)	2 n = 6 (38 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5	8 n = 2 (13 %)
Priority mean = 3.50 std = 1.29	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Comments	Expert A: 'not even an point of emphasize'. Expert F: 'when all personnel has enough knowledge the OR1 can be used outside office hours.' Expert K: 'not using the OR1 besides office hours is good for the quality.' Expert L: 'we want to use the OR1 besides office hours in the future.' Expert M and O: 'not using OR1 besides office hours leads to quality assurance and to less risks'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: High workload						
Definition: The (experienced) workload of all the employees in the minimal invasive surgery operation room is to high						
Source articles and interviews	Alfredsdottir et al., 2008 Berguer, 1999 Berland et al., 2008 Christian et al., 2005 Endozien, 2007 Gawanda et al., 2003 Lee et al., 2007 Reasor, 1995 Wetzel et al., 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 8 (50 %)		No n = 3 (19 %)		Partly n = 5 (31 %)	8
Effect mean = 3.38 std = 1.03	1	2 n = 3 (19 %)	3 n = 7 (44 %)	4 n = 3 (19 %)	5 n = 3 (19 %)	8
Chance mean = 3.25 std = 0.69	1	2 n = 2 (13 %)	3 n = 8 (50 %)	4 n = 6 (38 %)	5	8
Calculated Priority mean = 3.31 std = 0.83	1	2 n = 2 (13 %)	3 n = 8 (50 %)	4 n = 3 (19 %)	5 n = 3 (19 %)	8
Priority mean = 3.50 std = 0.89	1	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 9 (56 %)	5 n = 1 (6 %)	8
Comments	Expert C: 'CSA has high workload too'.					

Element: No adequate video registration system for the evaluation and registration of complication						
Definition: There is no or no adequate video registration to keep track of complications and analyze them.						
Source articles and interviews	IG7, 2007 Nugteren et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 8 (50 %)		No n = 3 (19 %)		Partly n = 4 (25 %)	8 n = 1 (6 %)
Effect mean = 2.93 std = 0.96	1 n = 1 (6 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5	8 n = 1 (6 %)
Chance mean = 2.13 std = 1.13	1 n = 6 (38 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5	8 n = 1 (6 %)
Calculated Priority mean = 2.53 std = 0.95	1 n = 1 (6 %)	2 n = 5 (31 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5	8 n = 1 (6 %)
Priority mean = 3.40 std = 1.24	1 n = 2 (13 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Comments	Expert A: 'OR1 has video registration other not'. Expert F: 'This is not even a Point of emphasize.' Expert E and K: 'Depends on what is done with the video registration'. Expert L: 'There is some video registration.' Expert P: 'Complication can be prevented when this is used properly.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Unfamiliarity of students with the operation room as working place						
Definition: Resident is not familiar with the demands of the working environment, does not know protocol, culture and tension in OR. This can lead to fear of doing something wrong and intimidation.						
Source articles and interviews	Lingard et al., 2002 Lyon, 2003 Lyon, 2004 McDonald et al, 2006 Pandy et al., 2006 Rochlin, 1999					
Type of risk	Latent element					
Applicable hospital	Yes n = 4 (25 %)		No n = 5 (31 %)		Partly n = 5 (31 %)	8 n = 2 (13 %)
Effect mean = 2.93 std = 1.07	1 n = 1 (6 %)	2 r = 4 (25 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.71 std = 1.20	1 n = 2 (13 %)	2 r = 5 (31 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.82 std = 1.12	1 n = 1 (6 %)	2 r = 4 (25 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 3.29 std = 1.33	1 n = 2 (13 %)	2 r = 1 (6 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Comments	Expert H: 'A resident has been in the OR before they operate.'					

Element: Unfamiliarity guideline sterilization						
Definition: There is a guideline for the sterilization of instruments that can be used during the purchasing of instrumentation and equipment but the surgeons and OR personnel are unfamiliar with the guideline (from the CDSMH).						
Source articles and interviews	Expert C Expert F Expert I Expert L					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)		No n = 3 (19 %)		Partly n = 1 (6 %)	8 n = 1 (6 %)
Effect mean = 2.27 std = 1.34	1 n = 6 (38 %)	2 r = 3 (19 %)	3 n = 3 (19 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 1 (6 %)
Chance mean = 2.27 std = 1.03	1 n = 4 (25 %)	2 r = 5 (31 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5	8 n = 1 (6 %)
Calculated Priority mean = 2.27 std = 1.12	1 n = 4 (25 %)	2 r = 5 (31 %)	3 n = 4 (25 %)	4 n = 1 (6 %)	5 n = 1 (6 %)	8 n = 1 (6 %)
Priority mean = 3.27 std = 1.31	1 n = 1 (6 %)	2 r = 4 (25 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 4 (25 %)	8 n = 1 (6 %)
Comments	Expert H: 'For some instrumentation it is unknown.' Expert L 'I am total unfamiliarity with the CSA and their activities'.					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: More operating time and facilities						
Definition: MIS requires more operating time and facilities, has higher technical demands then open-surgery.						
Source articles and interviews	Cuschieri, 1995					
Type of risk	Latent element for the optimal performance.					
Applicable hospital	Yes n = 12 (75 %)	No		Partly n = 2 (13 %)	8 n = 2 (13 %)	
Effect mean = 3.07 std = 1.21	1 n = 1 (6 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Chance mean = 2.43 std = 1.22	1 n = 3 (19 %)	2 n = 6 (38 %)	3 n = 2 (13 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.75 std = 1.11	1 n = 1 (6 %)	2 n = 5 (31 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 3.14 std = 1.35	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments	Expert A: 'only planning's problems.' Expert F: 'the quicker the operation the better it is for the patient.' Expert K: 'only in the learning curve this will take longer.'					

Element: Multiple competing tasks						
Definition: There are tasks that are not primary patient centered which can compete with patient centered tasks.						
Source articles and interviews	Alfredsdottir et al., 2008 Christian et al., 2005 Dagi et al., 2007 Reason, 1995 Wetze et al., 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)	No n = 1 (6 %)		Partly n = 4 (25 %)	8	
Effect mean = 2.63 std = 0.96	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 6 (38 %)	4 n = 3 (19 %)	5	8
Chance mean = 2.44 std = 0.89	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 8 (50 %)	4 n = 1 (6 %)	5	8
Calculated Priority mean = 2.53 std = 0.90	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 6 (38 %)	4 n = 3 (19 %)	5	8
Priority mean = 2.81 std = 1.11	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 6 (38 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No attention sterilization during purchase						
Definition: During purchase of instrumentation or equipment the sterilization and disinfestations are not taken or not taken enough into consideration.						
Source articles and interviews	Expert C Expert D Expert G Expert I					
Type of risk	Latent element					
Applicable hospital	Yes n = 5 (31 %)		No n = 7 (44 %)		Partly n = 3 (19 %)	8 n = 1 (6 %)
Effect mean = 2.93 std = 1.49	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 3 (19 %)	5 n = 3 (19 %)	8 n = 1 (6 %)
Chance mean = 2.73 std = 1.31	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Calculated Priority mean = 2.83 std = 2.37	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Priority mean = 2.53 std = 1.36	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 5 (31 %)	8 n = 1 (6 %)
Comments						

Element: Subjectivity in the trainer-trainee relation						
Definition: There can be subjectivity in the trainer-trainee relationship and hence in the assessment. The assessment is being influenced by the overall perceived performance (halo effect) or the pretty blue eyes.						
Source articles and interviews	Endozion, 2007 Jacklin, 2008 Najmaldin, 2007 Pandy et al. 2006 Reason, 1995					
Type of risk	Latent element					
Applicable hospital	Yes n = 4 (25 %)		No n = 4 (25 %)		Partly n = 4 (25 %)	8 n = 4 (25 %)
Effect mean = 2.58 std = 1.00	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5	8 n = 4 (25 %)
Chance mean = 2.33 std = 0.99	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 5 (31 %)	4 n = 1 (6 %)	5	8 n = 4 (25 %)
Calculated Priority mean = 2.46 std = 0.89	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 6 (38 %)	4 n = 1 (6 %)	5	8 n = 4 (25 %)
Priority mean = 2.50 std = 1.17	1 n = 2 (13 %)	2 n = 5 (31 %)	n = 3 (19 %)	4 n = 1 (6 %)	5 n = 1 (6 %)	8 n = 4 (25 %)
Comments	Expert K: 'Not even a Point of emphasize.'					

Organizational points of emphasis

Evaluate existing equipment before purchase new						
Definition When new equipment or instrumentation is purchased the 'old' instrumentation should be evaluated.						
Source articles and interviews	Expert H					
Type of risk	Latent Point of emphasize					
Agree	Yes n= 16 (100 %)	No		Partly	8	
Priority mean = 4.13 std = 0.72	1	2	3 n = 3 (19 %)	4 n = 8 (50 %)	5 n = 5 (31 %)	8
Hospital Specific Priority Sizen	4.13 / 0.72 = 5.7					
Comments						

Improvement of digital storage of images						
Definition The digital storage of photo's or short movies has to be improved. The current system is too voluntary.						
Source articles and interviews	Expert A Expert M					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 12 (75 %)	No n = 1 (6 %)		Partly n = 1 (6 %)	8 n = 2 (13 %)	
Priority mean = 4.00 std = 0.88	1	2	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Hospital Specific Priority Size	4.00 / 0.88 = 4.6					
Comments	Expert G: 'With the introduction of CD's this has already improved.' Expert F: 'This is the responsibility of the surgeon.' Expert L: 'This should be clear per surgeon.'					

Surgical super-users						
Definition Three super users from the scrub nurses where assigned when the OR1 was introduced. The surgical departments should have done the same so the implementation would have been easier.						
Source articles and interviews	Expert F					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 10 (63 %)	No		Partly n = 4 (25 %)	8 n = 2 (13 %)	
Priority mean = 3.50 std = 1.16	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

MIS OR near the trauma room						
Definition In the new estate there should be a MIS OR near the trauma OR.						
Source articles and interviews	Expert F					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 5 (31 %)		No n = 8 (50 %)		Partly n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 2.57 std = 1.355	1 n = 5 (31 %)	2 n = 3 (19 %)	3 n = 1 (6 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments						

Equipment and instrumentation elements

Element: Unreliable equipment						
Definition: The equipment does not function as desired.						
Source articles and interviews	Catchpole et al., 2007 Endozien, 2007 Gawanda et al., 2003 Primus et al., 2007 Satava, 2005 Slack et al., 2007 Tang et a ., 2005 Tang et al., 2006 Wetzel et al., 2006					
Type of risk	Active element					
Applicable hospital	Yes n = 6 (38 %)		No n = 5 (31 %)		Partly n = 4 (25 %)	8 n = 1 (6 %)
Effect mean = 4.13 std = 1.13	1	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 3 (19 %)	5 n = 8 (50 %)	8 n = 1 (6 %)
Chance mean = 3.93 std = 1.23	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 6 (38 %)	8 n = 1 (6 %)
Calculated Priority mean = 4.03 std = 1.03	1	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 7 (44 %)	8 n = 1 (6 %)
Priority mean = 4.60 std = 0.63	1	2	3 n = 1 (6 %)	4 n = 4 (25 %)	5 n = 10 (63 %)	8 n = 1 (6 %)
Hospital Specific Hospital Size	4.60 / 0.63 = 7.3					
Comments	Expert G: 'This is an old element because of the uniformity of the instrumentation this nearly ever happens.' Expert I: 'The CSD needs to have more information about this element to work on it.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: The set is not cleaned properly.						
Definition: The set is not cleaned properly.						
Source articles and interviews	Expert M					
Type of risk	Latent element					
Applicable hospital	Yes n = 4 (25 %)		No n = 6 (38 %)		Partly n = 4 (25 %)	8 n = 2 (13 %)
Effect mean = 3.64 std = 1.15	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 6 (38 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Chance mean = 3.14 std = 1.46	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 1 (6 %)	4 n = 4 (25 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.39 std = 1.15	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Priority mean = 4.36 std = 0.75	1	2	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 7 (44 %)	8 n = 2 (13 %)
Hospital Specific Hospital Size	4.36 / 0.75 = 5.9					
Comments	Expert A: 'Do not know if this is an problem. There are no unexplained infectious complications.' Expert N: 'Scrub nurses solve or handle this before the operation.'					

Element: No adequate protocol for the cleaning of instruments						
Definition: No procedures to control the equipment like control of diathermy instruments and cables and fiber control optics.						
Source articles and interviews	IGZ, 2007 Nugteren et al., 2007 Expert H Expert I Expert M					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)		No n = 1 (6 %)		Partly n = 2 (13 %)	8 n = 2 (13 %)
Effect mean = 3.86 std = 1.03	1	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Chance mean = 3.64 std = 1.08	1	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.75 std = 1.01	1	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 5 (31 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Priority mean = 4.29 std = 0.73	1	2	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Hospital Specific Hospital Size	4.29 / 0.73 = 5.9					
Comments	Expert M 'There is no structural control of instrumentation'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Diathermia and other electrosurgical instrumentation problems						
Definition: When using monopolary instrumentation and other electrosurgical instrumentation unwanted diathermy can occurs which can lead to complications.						
Source articles and interviews	Cuschieri, 2005 Endozien, 2007 Machatuta et al., 2007 Smith, 2000 Tang et al., 2005					
Type of risk	Active element					
Applicable hospital	Yes n = 9 (56 %)	No n = 5 (31 %)		Partly n = 1 (6 %)	8 n = 1 (6 %)	
Effect mean = 4.07 std = 1.34	1 n = 1 (6 %)	2 n = 2 (13 %)	3	4 n = 4 (25 %)	5 n = 8 (50 %)	8 n = 1 (6 %)
Chance mean = 3.47 std = 1.51	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 1 (6 %)	4 n = 4 (25 %)	5 n = 5 (31 %)	8 n = 1 (6 %)
Calculated Priority mean = 3.77 std = 1.25	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 6 (38 %)	8 n = 1 (6 %)
Priority mean = 4.27 std = 1.22	1 n = 1 (6 %)	2 n = 1 (6 %)	3	4 n = 4 (25 %)	5 n = 9 (56 %)	8 n = 1 (6 %)
Hospital Specific Hospital Size	4.27 / 1.22 = 3.5					
Comments	Expert A, C and P: 'We do not use monopole instrumentation'. Expert F: 'This can also occur during conventional surgery and the use of other electrosurgical instruments.' Expert K: 'Only using bipolar.' Expert J and M: 'We use monopole instrumentation.' Expert N: 'This can also occur when the retractor is against the trocar and the diathermia is used.'					

Element: No registration of instrumentation test available for every user						
Definition: There is no or no adequate registration of the tests performed by the central sterilization department which is accessible by all users.						
Source articles and interviews	Expert I					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)	No n = 3 (19 %)		Partly n = 1 (6 %)	8 n = 1 (6 %)	
Effect mean = 3.60 std = 1.12	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 1 (6 %)	4 n = 9 (56 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Chance mean = 3.20 std = 1.15	1	2 n = 6 (38 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Calculated Priority mean = 3.40 std = 1.06	1	2 n = 3 (19 %)	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Priority mean = 4.13 std = 0.92	1	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 1 (6 %)
Hospital Specific Hospital Size	4.13 / 0.92 = 4.5					
Comments	Expert F: 'This is especially important for the light cables and the electrosurgical instrumentation.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: The set is improperly adjusted						
Definition: The set is not properly adjusted by the central sterilization department or the scrub nurse						
Source articles and interviews	Expert M					
Type of risk	Active element					
Applicable hospital	Yes n = 6 (38 %)		No n = 5 (31 %)		Partly n = 4 (25 %)	8 n = 1 (6 %)
Effect mean = 3.00 std = 1.07	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 6 (38 %)	5	8 n = 1 (6 %)
Chance mean = 2.53 std = 1.06	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5	8 n = 1 (6 %)
Calculated Priority mean = 2.77 std = 0.94	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 8 (50 %)	4 n = 3 (19 %)	5	8 n = 1 (6 %)
Priority mean = 4.13 std = 0.74	1 n = 1 (6 %)	2	3	4 n = 10 (63 %)	5 n = 4 (25 %)	8 n = 1 (6 %)
Hospital Specific Hospital Size	4.13 / 0.74 = 5.6					
Comments	Expert B: 'This is noticeable immediately and is anticipated on'.					

Element: The set is incomplete						
Definition: The set arrives at the operation room incomplete.						
Source articles and interviews	Expert M					
Type of risk	Latent element					
Applicable hospital	Yes n = 5 (31 %)		No n = 5 (31 %)		Partly n = 5 (31 %)	8 n = 1 (6 %)
Effect mean = 2.67 std = 1.11	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5	8 n = 1 (6 %)
Chance mean = 2.20 std = 1.02	1 n = 5 (31 %)	2 n = 3 (19 %)	3 n = 6 (38 %)	4 n = 1 (6 %)	5	8 n = 1 (6 %)
Calculated Priority mean = 2.43 std = 0.92	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 7 (44 %)	4 n = 2 (13 %)	5	8 n = 1 (6 %)
Priority mean = 4.07 std = 0.80	1	2 n = 1 (6 %)	3 n = 1 (6 %)	4 n = 9 (56 %)	5 n = 4 (25 %)	8 n = 1 (6 %)
Hospital Specific Hospital Size	4.07 / 0.80 = 5.1					
Comments	Expert B, I and N: 'Scrub nurses solve or handle this before the operation.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No adequate protocol for the handling of instruments						
Definition: There is no protocol for the compatibility, cleaning, sterilization and maintenance of MIS equipment.						
Source articles and interviews	Nugteren et al., 2007 Reason, 1995 Expert G Expert M					
Type of risk	Latent element					
Applicable hospital	Yes n = 4 (25 %)	No n = 6 (38 %)		Partly n = 4 (25 %)	8 n = 2 (13 %)	
Effect mean = 3.43 std = 1.34	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Chance mean = 3.43 std = 1.02	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.43 std = 1.14	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5n = 4 (25 %)	8 n = 2 (13 %)
Priority mean = 4.07 std = 1.33	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 2 (13 %)	5 n = 8 (50 %)	8 n = 2 (13 %)
Comments	Expert H: 'For the central sterilization department there is a protocol for the scrub nurses not.'					

Element: Only visual control instrumentation						
Definition: There is only a visual control of the minimal invasive instrumentation						
Source articles and interviews	Expert H					
Type of risk	Latent element					
Applicable hospital	Yes n = 9 (56.3 %)	No n = 2 (13 %)		Partly n = 2 (13 %)	8 n = 3 (19 %)	
Effect mean = 3.31 std = 1.18	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Chance mean = 3.31 std = 1.11	1	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.31 std = 1.09	1	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Priority mean = 4.08 std = 0.76	1	2	3 n = 3 (19 %)	4 n = 6 (38 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Hospital Specific Hospital Size	4.08 / 0.76 = 5.4					
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No employee has the responsibility for the sterilization of instruments						
Definition: There is no norm making employee who has the responsibility for testing and assuring quality of the minimal invasive surgery instruments and / or equipment.						
Source articles and interviews	Expert F					
Type of risk	Latent element					
Applicable hospital	Yes n = 4 (25 %)		No n = 7 (44 %)		Partly n = 2 (13 %)	8 n = 3 (19 %)
Effect mean = 3.54 std = 1.05	1	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Chance mean = 3.31 std = 1.11	1	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.42 std = 1.04	1	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Priority mean = 4.00 std = 1.16	1	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 3 (19 %)	5 n = 6 (38 %)	8 n = 3 (19 %)
Comments						

Element: Adjustability of table columns						
Definition: The columns of the operation tables are not adjustable or not adjustable in the right way (trendelenburg and anti trendelenburg).						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 1 (6 %)		No n = 9 (56 %)		Partly n = 4 (25 %)	8 n = 2 (13 %)
Effect mean = 3.36 std = 1.39	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Chance mean = 2.79 std = 1.37	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.07 std = 1.20	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Priority mean = 3.93 std = 1.07	1 n = 1 (6 %)	2	3 n = 2 (13 %)	4 n = 7 (44 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Comments	Expert L: 'The table cannot go low enough and therefore the surgeon has to stand on a plateau which is not easy when a footswitch is required.' Expert N: 'Table columns are not always movable with touch screen.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Inadequate placement of monitors						
Definition: The monitors are not placed in the most optimal angle to watch on and practitioners can hang their heads.						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 6 (38 %)		No n = 5 (31 %)		Partly n = 2 (13 %)	8 n = 3 (19 %)
Effect mean = 3.08 std = 0.95	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5	8 n = 3 (19 %)
Chance mean = 2.62 std = 1.12	1 n = 3 (19 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.85 std = 0.92	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Priority mean = 3.77 std = 1.17	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 3 (19 %)	8 n = 3 (19 %)
Comments	Expert J: 'Not even a Point of emphasize.'					

Element: Working with gas						
Definition: Gas in pumped into the patient this will change the physical outputs for the patient for example the cadio vascular pressures.						
Source articles and interviews	Expert A					
Type of risk	Active element					
Applicable hospital	Yes n = 11 (69 %)		No n = 2 (13 %)		Partly n = 1 (6 %)	8 n = 2 (13 %)
Effect mean = 2.71 std = 1.44	1 n = 4 (25 %)	2 n = 3 (19 %)	3 n = 1 (6 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.29 std = 1.27	1 n = 6 (38 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 2.50 std = 1.19	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5	8 n = 2 (13 %)
Priority mean = 3.07 std = 1.73	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 1 (6 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Comments	Expert A: 'The pressure gives specific risks further not.' Expert J: 'When the gas is leaking this is a problem.' Expert K: 'Only when the peritoneum is not properly placed.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Manually cleaning instrumentation						
Definition: The central sterilization department cleans the instruments manually and not in a machine. The manually cleaning is not reproducible and valid.						
Source articles and interviews	Expert I					
Type of risk	Latent element					
Applicable hospital	Yes n = 5 (31 %)		No n = 7 (44 %)		Partly n = 2 (13 %)	8 n = 2 (13 %)
Effect mean = 3.14 std = 1.17	1 n = 1 (6 %)	2 r = 3 (19 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Chance mean = 2.92 std = 1.19	1 n = 1 (6 %)	2 r = 4 (25 %)	3 n = 5 (31 %)	4 n = 1 (6 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Calculated Priority mean = 3.00 std = 1.10	1	2 r = 4 (25 %)	3 n = 6 (38 %)	4 n = 1 (6 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Priority mean = 3.69 std = 1.25	1	2 r = 3 (19 %)	3 n = 3 (19 %)	4 n = 2 (13 %)	5 n = 5 (31 %)	8 n = 3 (19 %)
Comments	Expert C: 'Will always stay in the pre cleaning process.'					

Element: Insufficient illumination						
Definition: The illumination is insufficient, especially during dangerous situations, for example when unexpected bleeding occurred.						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 1 (6 %)		No n = 12 (75 %)		Partly n = 1 (6 %)	8 n = 2 (13 %)
Effect mean = 3.07 std = 1.33	1 n = 2 (13 %)	2 r = 3 (19 %)	3 n = 3 (19 %)	4 r = 4 (25 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Chance mean = 2.64 std = 1.39	1 n = 4 (25 %)	2 r = 3 (19 %)	3 n = 2 (13 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.86 std = 1.26	1 n = 2 (13 %)	2 r = 3 (19 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Priority mean = 3.64 std = 1.65	1 n = 3 (19 %)	2 r = 1 (6 %)	3	4 n = 4 (25 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Insufficient air-conditioning						
Definition: The air-conditioning is not working in a way, too hot or too cold, that contributes to the optimal performance of the minimal invasive surgery operation room.						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 2 (13 %)	No n = 10 (63 %)		Partly n = 2 (13 %)	8 n = 2 (13 %)	
Effect mean = 2.57 std = 1.28	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.21 std = 1.12	1 n = 5 (31 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 2.39 std = 1.18	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 3.14 std = 1.35	1 n = 3 (19 %)	2	3 n = 5 (31 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments						

Element: Not following instructions manufacturer						
Definition: The manual, check procedure or work instructions of the manufacturer are not red and / or followed.						
Source articles and interviews	Reason, 1995					
Type of risk	Latent element					
Applicable hospital	Yes n = 3 (19 %)	No n = 7 (44 %)		Partly n = 5 (31 %)	8 n = 1 (6 %)	
Effect mean = 3.07 std = 1.22	1 n = 1 (6 %)	2 n = 5 (31 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Chance mean = 2.80 std = 1.08	1 n = 1 (6 %)	2 n = 6 (38 %)	3 n = 3 (19 %)	4 n = 2 (13 %)	5 n = 4 (25 %)	8 n = 1 (6 %)
Calculated Priority mean = 2.93 std = 1.05	1	2 n = 6 (38 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 1 (6 %)
Priority mean = 3.40 std = 1.06	1	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 6 (38 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Comments	Expert N: ' the work instructions are used for the others it is unfamiliar.' Expert P: 'only during the purchase of instrumentation.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Insufficient positioning devices on ground						
Definition: Devices like foot activations/switches are positioned inadequately during the operation.						
Source articles and interviews	Cuschieri, 1995 Helmreich et al., 1996 Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 4 (25 %)		No n = 6 (38 %)		Partly n = 3 (19 %)	8 n = 3 (19 %)
Effect mean = 2.77 std = 1.36	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Chance mean = 2.15 std = 1.21	1 n = 5 (31 %)	2 n = 4 (25 %)	3 n = 1 (6 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.46 std = 1.16	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Priority mean = 3.00 std = 1.35	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments	Expert K: 'When the position of the device is unknown this can lead to a risk.' Expert N: 'The cable is to short.'					

Element: Noise level / acoustics						
Definition: Bad acoustics and a lot of noise in the operation room make good and effective communication hard.						
Source articles and interviews	Moorthy et al., 2004 Primus et al., 2007 Reason, 1995 Sevdalis et al., 2007 Wetzel et al., 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 7 (44 %)		No n = 5 (31 %)		Partly n = 2 (13 %)	8 n = 2 (13 %)
Effect mean = 2.43 std = 1.02	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5	8 n = 2 (13 %)
Chance mean = 2.29 std = 1.07	1 n = 4 (25 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 2.357 std = 0.93	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 6 (38 %)	4 n = 1 (6 %)	5	8 n = 2 (13 %)
Priority mean = 2.71 std = 1.38	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Inadequate operating tables						
Definition: The operating elements of the operation tables are inadequate or the table surface is too narrow or too broad.						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Latent element					
Applicable hospital	Yes	No n = 12 (75 %)		Partly n = 2 (13 %)	8 n = 2 (13 %)	
Effect mean = 2.57 std = 1.22	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.29 std = 1.27	1 n = 5 (31 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 1 (6 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.43 std = 1.19	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 2.64 std = 1.22	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5	8 n = 2 (13 %)
Comments	Expert J and K: 'this can be the case for morbid obese patients.'					

Element: Tripping over cables						
Definition: Practitioners can trip over cables and tubes which lay on the floor or suspend freely between wall sockets, equipment and patient.						
Source articles and interviews	Berguer, 1999 Cuschieri, 1995 Helmreich et al., 1996 Mattern et al., 2007 Expert A					
Type of risk	Active element					
Applicable hospital	Yes n = 5 (31 %)	No n = 6 (38 %)		Partly n = 3 (19 %)	8 n = 2 (13 %)	
Effect mean = 2.43 std = 1.16	1 n = 3 (19 %)	2 n = 5 (31 %)	3 n = 4 (25 %)	4 n = 1 (6 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.36 std = 1.39	1 n = 6 (38 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.393 std = 1.24	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 2.64 std = 1.216	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Comments						

Element: Inadequate placement of lights						
Definition: The lights in the operation room do not work as desired.						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 9 (56 %)		Non = 3 (19 %)		Partly n = 1 (6 %)	8 n = 3 (19 %)
Effect mean = 2.15 std = 0.80	1 n = 3 (19 %)	2 n = 5 (31 %)	3 n = 5 (31 %)	4	5	8 n = 3 (19 %)
Chance mean = 1.92 std = 0.86	1 n = 5 (31 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4	5	8 n = 3 (19 %)
Calculated Priority mean = 2.038 std = 0.69	1 n = 3 (19 %)	2 n = 5 (31 %)	3 n = 5 (31 %)	4	5	8 n = 3 (19 %)
Priority mean = 2.31 std = 1.03	1 n = 2 (13 %)	2 n = 7 (44 %)	3 n = 3 (19 %)	4	5 n = 1 (6 %)	8 n = 3 (19 %)
Comments						

Equipment and instrumentation points of emphasis

Xenon illumination						
Definition The xenon illumination that is used during conventional operating takes to long to restart because of the cooling down process.						
Source articles and interviews	Expert E Expert F					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 9 (56 %)		Non = 3 (19 %)		Partly n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 4.08 std = 1.26	1 n = 1 (6 %)	2	3 n = 3 (19 %)	4 n = 2 (13 %)	5 n = 7 (44 %)	8 n = 3 (19 %)
Hospital Specific Hospital Size	4.08 / 1.26 = 3.2					
Comments	Expert B: 'It is difficult to work with'. Expert H: 'The xenon is insufficient during the start up period.' Expert J and L, M: 'This is not an issue. You can leaf the lamps on.'					

Handling instrumentation ceiling tower						
Definition The instrumentation ceiling tower cannot be moved easily and is wrongly situated to the ceiling and has not all degrees of freedom that is sometimes wanted/necessary.						
Source articles and interviews	Expert E Expert F Expert H Expert N					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 8 (50 %)		Non = 2 (13 %)		Partly n = 3 (19 %)	8 n = 3 (19 %)
Priority mean = 3.77 std = 1.42	1 n = 2 (13 %)	2	3 n = 2 (13 %)	4 n = 4 (25 %)	5 n = 5 (31 %)	8 n = 3 (19 %)
Comments						
Too much pendels on the ceiling						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Definition All equipment, monitors, illumination is situated on the ceiling. This is too much, the degrees of freedom are decreased and equipment can not be positioned in the most efficient way.						
Source articles and interviews	Expert E Expert H Expert K Expert M Expert N					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 8 (50 %)	No n = 3 (19 %)	Partly n = 2 (13 %)	8 n = 3 (19 %)		
Priority mean = 3.54 std = 1.33	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Comments						

Working space scrub nurse						
Definition It would be easier if the scrub nurse would have more working space / bureau.						
Source articles and interviews	Expert N					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 10 (63 %)	No n = 3 (19 %)	Partly	8 n = 3 (19 %)		
Priority mean = 3.46 std = 1.45	1 n = 2 (13 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Comments						

Surgeons should not use the touch screen						
Definition The surgeon can move the table into for example trendelenburg by using the touchscreen this should not be used or properly discussed with the anesthesia.						
Source articles and interviews	Expert E Expert H Expert J (easy to use) Expert L (nice to use)					
Type of risk	Active Point of emphasize					
Agree	Yes n = 4 (25 %)	No n = 6 (38 %)	Partly n = 4 (25 %)	8 n = 2 (13 %)		
Priority mean = 3.21 std = 1.19	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Voice control system (sesam)						
Definition The voice control system is not adequate and should be improved to work properly or even not installed in the new operation rooms.						
Source articles and interviews	Expert A (using it) Expert H Expert J Expert K Expert L Expert N (others do not use it)					
Type of risk	Latent Point of emphasize					
Agree	Yes n= 13 (81 %)	No		Partly n = 1 (6 %)	8 n = 2 (13 %)	
Priority mean = 2.93 std = 1.27	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Comments						

Working space anesthesia						
Definition It is necessary that the anesthetist has enough space to work. The OR1 is adequate.						
Source articles and interviews	Expert B					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 11 (69 %)	No n = 2 (13 %)		Partly n = 1 (6 %)	8 n = 2 (13 %)	
Priority mean = 2.79 std = 1.58	1 n = 5 (31 %)	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments						

Too much monitors						
Definition There are too much monitors in the OR1. There are five monitors (+ plasma monitor) three would be sufficient.						
Source articles and interviews	Expert E Expert F Expert G Expert J (monitors are nice) Expert L (monitors are nice) Expert N					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 8 (50 %)	No n = 3 (19 %)		Partly n = 2 (13 %)	8 n = 3 (19 %)	
Priority mean = 2.77 std = 1.42	1 n = 4 (25 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Comments						

Plasma monitor						
Definition: The plasma monitor is too big for the operation room hence there is an unclear image on the monitor.						
Source articles and interviews	Expert E Expert G Expert J Expert K Expert N					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 8 (50 %)		No n = 4 (25 %)	Partly n = 1 (6 %)	8 n = 3 (19 %)	
Priority mean = 2.77 std = 1.59	1 n = 5 (31 %)	2	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments						

Interpersonal elements

Element: Unrecognized perforation of organs						
Definition: Unrecognized perforation of organs (for example the bowel) during surgery and delay in diagnosis after surgery can increase the mortality and morbidity of patients.						
Source articles and interviews	Cuschieri, 2005 Endozien, 2007 Jacklin et al., 2008 Slack et al., 2007 Smith, 2000 Tang et al., 2005 Tang et al., 2006 Thomson et al., 2005					
Type of risk	Active element					
Applicable hospital	Yes n = 7 (44 %)		No n = (%)	Partly n = 8 (50 %)	8 n = 1 (6 %)	
Effect mean = 4.73 std = 0.59	1	2	3 n = 1 (6 %)	4 n = 2 (13 %)	5 n = 12 (75 %)	8 n = 1 (6 %)
Chance mean = 4.07 std = 1.44	1 n = 2 (13 %)	2	3 n = 2 (13 %)	4 n = 2 (13 %)	5 n = 9 (56 %)	8 n = 1 (6 %)
Calculated Priority mean = 4.40 std = 0.74	1	2	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 8 (50 %)	8 n = 1 (6 %)
Priority mean = 4.73 std = 0.59	1	2	3 n = 1 (6 %)	4 n = 2 (13 %)	5 n = 12 (75 %)	8 n = 1 (6 %)
Hospital Specific Priority Size	4.73 / 0.59 = 8.0					
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No direct vision on complication						
Definition: The surgeon and the anaesthetist do not have direct vision on the condition of the patient which can lead to undetected complications						
Source articles and interviews	Slack et al., 2007 Thomson et al., 2005					
Type of risk	Active element					
Applicable hospital	Yes n = 9 (56 %)	No		Partly n = 6 (38 %)	8 n = 1 (6 %)	
Effect mean = 4.40 std = 0.63	1	2	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 7 (44 %)	8 n = 1 (6 %)
Chance mean = 4.13 std = 1.06	1	2 n = 2 (13 %)	3 n = 1 (6 %)	4 n = 5 (31 %)	5 n = 7 (44 %)	8 n = 1 (6 %)
Calculated Priority mean = 4.27 std = 0.70	1	2	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 7 (44 %)	8 n = 1 (6 %)
Priority mean = 4.67 std = 0.49	1	2	3	4 n = 5 (31 %)	5 n = 10 (63 %)	8 n = 1 (6 %)
Hospital Specific Priority Size	4.67 / 0.49 = 9.6					
Comments						

Element: Not working as a team						
Definition: All staff members work as individuals and not as a team						
Source articles and interviews	Alfredsdottir et al., 2008 Catchpole et al., 2007 Cuschieri, 2005 Dagi et al., 2007 Edozien, 2007 Firth Cozens, 2004 Healey et al., 2006 Helmreich et al., 1996 McDonald et al., 2006 Reason, 1995 Satava, 2005 Schaefer et al., 1995 Schimpff, 2007 Expert A Expert L					
Type of risk	Latent element					
Applicable hospital	Yes n = 2 (13 %)	No n = 6 (38 %)		Partly n = 8 (50 %)	8	
Effect mean = 3.75 std = 0.78	1	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 9 (56 %)	5	8
Chance mean = 3.44 std = 1.21	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 6 (38 %)	5 n = 3 (19 %)	8
Calculated Priority mean = 3.59 std = 0.94	1	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 3 (19 %)	8
Priority mean = 4.38 std = 0.81	1	2 n = 1 (6 %)	3	4 n = 7 (44 %)	5 n = 8 (50 %)	8
Hospital Specific Priority Size	4.38 / 0.81 = 5.4					
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Inadequate communication						
Definition: Failure to communicate properly.						
Source articles and interviews	Aggerwal et al., 2004 Alfredsdottir et al., 2008 Carthey et al., 2003 Catchpole et al., 2007 Dagi et al., 2007 Endozien, 2007 Firth-Cozens, 2004 Gawanda et al., 2003 Healey et al., 2006 Helmreich et al., 1996 Kneebone et al., 2007 Lingard et al. 2006 Lingard et al., 2002 Lingard et al., 2004 Lingard et al., 2005 McDonald et al., 2006 Mills et al., 2008 Ranger et al. 2004 Reason, 1995 Satava, 2005 Schaefer et al., 1994 Schaefer et al., 1995 Sevdalis et al., 2007 Yule et a , 2006 Expert A Expert B Expert C Expert F Expert M Expert L Expert N						
Type of risk	Latent element					
Applicable hospital	Yes n = 6 (38 %)		No n = 5 (31 %)		Partly n = 5 (31 %)	8
Effect mean = 3.81 std = 0.98	1	2	3 n = 3 (19 %)	4 n = 10 (63 %)	5 n = 3 (19 %)	8
Chance mean = 3.25 std = 1.07	1 n = 1 (6 %)	2 r = 2 (13 %)	3 n = 7 (44 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8
Calculated Priority mean = 3.51 std = 0.85	1	2 r = 1 (6 %)	3 n = 3 (19 %)	4 n = 10 (63 %)	5 n = 2 (13 %)	8
Priority mean = 4.38 std = 0.72	1	2	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 8 (50 %)	8
Hospital Specific Priority Size	4.38 / 0.72 = 6.1					
Comments						

Element: Lack of vision through bleeding						
Definition: Through bleeding the vision can decrease which can lead to accidents.						
Source articles and interviews	Expert A					
Type of risk	Latent element					
Applicable hospital	Yes n = 9 (56 %)		No		Partly n = 5 (31 %)	8 n = 2 (13 %)
Effect mean = 4.07 std = 0.73	1	2	3 n = 3 (19 %)	4 n = 7 (44 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Chance mean = 3.93 std = 0.83	1	2 r = 1 (6 %)	3 n = 2 (13 %)	4 n = 8 (50 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 4.00 std = 0.65	1	2	3 n = 2 (13 %)	4 n = 9 (56 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Priority mean = 4.29 std = 0.73	1	2	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Hospital Specific Priority Size	4.29 / 0.73 = 5.9					
Comments	Expert B: 'The light intensity changes and there is also heat production because of a bleeding.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Inevitability mistakes						
Definition: Medical professionals do not want to learn from mistakes from themselves or others because mistakes are inevitable and not preventable.						
Source articles and interviews	McDonald et al., 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 1 (6 %)		No n = 7 (44 %)		Partly n = 7 (44 %)	8 n = 1 (6 %)
Effect mean = 3.80 std = 0.94	1	2 n = 1 (6 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5 n = 4 (25 %)	8 n = 1 (6 %)
Chance mean = 3.73 std = 1.10	1	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 4 (25 %)	8 n = 1 (6 %)
Calculated Priority mean = 3.77 std = 0.90	1	2	3 n = 5 (31 %)	4 n = 6 (38 %)	5 n = 4 (25 %)	8 n = 1 (6 %)
Priority mean = 4.27 std = 0.80	1	2	3 n = 3 (19 %)	4 n = 5 (31 %)	5 n = 7 (44 %)	8 n = 1 (6 %)
Comments						

Element: Fatigue or lack of sleep						
Definition: Disturbed or lack of sleep and fatigue have effects on the psychomotor skills of the surgeon necessary for the laparoscopic operation.						
Source articles and interviews	Aggerwal et al., 2004 Berguer, 1999 Erdozien, 2007 Reason, 1995 Taffinder et al, 1998 Wetzo. et al., 2006					
Type of risk	Active element					
Applicable hospital	Yes n = 4 (25 %)		No n = 4 (25 %)		Partly n = 6 (38 %)	8 n = 2 (13 %)
Effect mean = 3.57 std = 0.85	1	2 n = 1 (6 %)	3 n = 6 (38 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Chance mean = 3.64 std = 1.15	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 6 (38 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.607 std = 0.964	1	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 6 (38 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Priority mean = 4.21 std = 0.70	1	2	3 n = 2 (13 %)	4 n = 7 (44 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Hospital Specific Priority Size	4.21 / 0.70 = 6.0					
Comments	Expert E: 'for the surgeons this is even a bigger risk for the other staff in the operation room this is not necessary a big riks.' Expert F: 'especially with residents and the pediatric surgeons.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Inadequate placement of the trocars						
Definition: The positioning of the trocars is not done in the correct way or the position of the trocars is inadequate						
Source articles and interviews	Ahmed et al., 2007 Jansen et al., 2004 Slack et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 5 (31 %)		No n = 6 (38 %)		Partly n = 3 (19 %)	8 n = 2 (13 %)
Effect mean = 3.57 std = 0.76	1	2 r = 2 (13 %)	3 n = 2 (13 %)	4 n= 10 (63 %)	5	8 n = 2 (13 %)
Chance mean = 3.43 std = 0.56	1	2 r = 2 (13 %)	3 n = 4 (25 %)	4 n = 8 (50 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 3.50 std = 0.68	1	2 r = 1 (6 %)	3 n = 4 (25 %)	4 n = 9 (56 %)	5	8 n = 2 (13 %)
Priority mean = 4.14 std = 0.864	1	2 r = 1 (6 %)	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Comments						

Element: Lack of non-technical skills of a surgeon						
Definition: To achieve and maintain high surgical performance, attention needs to be paid to non-technical skills such as team working, leadership, situation awareness, decision making, task management and communication.						
Source articles and interviews	Gawanda et al., 2003 Helmreich et al., 1996 McDonald et al., 2006 Mills et al., 2008 Schaefer et al., 1994 Schaefer et al., 1995 Yule et al, 2006					
Type of risk	Latent element					
Applicable hospital	Yes n = 2 (13 %)		No n = 4 (25 %)		Partly n = 8 (50 %)	8 n = 2 (13 %)
Effect mean = 3.57 std = 0.85	1	2 r = 2 (13 %)	3 n = 3 (19 %)	4 n = 8 (50 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 3.36 std = 1.22	1 n = 1 (6 %)	2 r = 3 (19 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.46 std = 0.89	1	2 r = 2 (13 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Priority mean = 4.14 std = 0.86	1	2 r = 1 (6 %)	3 n = 1 (6 %)	4 n = 7 (44 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Hospital Specific Priority Size	4.14 / 0.86 = 3.2					
Comments	Expert G: 'This means that the surgeon does not perform his team roll adequately.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Inadequate use of instrumentation						
Definition: The surgeon does not use the instrumentation optimally. Like the electrosurgical hook or the graspers.						
Source articles and interviews	Joice et al., 1998					
Type of risk	Latent element					
Applicable hospital	Yes n = 6 (38 %)		No n = 5 (31 %)		Partly n = 3 (19 %)	8 n = 2 (13 %)
Effect mean = 3.36 std = 0.929	1	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 6 (38 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 3.14 std = 1.167	1 n = 2 (13 %)	2 n = 1 (6 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.250 std = 0.893	1	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 6 (38 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 4.07 std = 0.829	1	2	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 5 (31 %)	8 n = 2 (13 %)
Hospital Specific Priority Size	4.07 / 0.83 = 4.9					
Comments						

Element: Reliance on memory						
Definition: There is no communication or checks between team members they rely partly on their memory.						
Source articles and interviews	Endozion, 2007 Lingard et al., 2005 Reason, 1995 Schimpff, 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 3 (19 %)		No n = 2 (13 %)		Partly n = 9 (56 %)	8 n = 2 (13 %)
Effect mean = 3.71 std = 0.825	1	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Chance mean = 3.50 std = 1.092	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 6 (38 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.607 std = 0.813	1	2	3 n = 6 (38 %)	4 n = 6 (38 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Priority mean = 4.00 std = 0.784	1	2	3 n = 4 (25 %)	4 n = 6 (38 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Hospital Specific Priority Size	4.00 / 0.78 = 5.1					
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: No direct access to bleeding						
Definition: Immediate control over major bleeding is not possible, finger or hand comparison is not possible till clamp is placed.						
Source articles and interviews	Cuschieri, 1995					
Type of risk	Active element					
Applicable hospital	Yes n = 8 (50 %)		No n = 1 (6 %)		Partly n = 5 (31 %)	8 n = 2 (13 %)
Effect mean = 3.79 std = 0.89	1	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 6 (38 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Chance mean = 3.43 std = 1.02	1 n = 1 (6 %)	2	3 n = 7 (44 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.61 std = 0.90	1	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Priority mean = 3.93 std = 1.14	1	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 6 (38 %)	8 n = 2 (13 %)
Comments						

Element: Not working in a chain						
Definition: It is important that every member in the patient chain knows it place, takes actions accordingly and responsibility.						
Source articles and interviews	Expert B Expert D Expert F Expert I					
Type of risk	Latent element					
Applicable hospital	Yes n = 5 (31 %)		No n = 3 (19 %)		Partly n = 8 (50 %)	8
Effect mean = 3.31 std = 0.70	1	2 n = 2 (13 %)	3 n = 7 (44 %)	4 n = 7 (44 %)	5	8
Chance mean = 2.75 std = 0.93	1 n = 2 (12.5 %)	2 n = 3 (19 %)	3 n = 8 (50 %)	4 n = 3 (19 %)	5	8
Calculated Priority mean = 3.03 std = 0.70	1	2 n = 3 (19 %)	3 n = 7 (44 %)	4 n = 6 (38 %)	5	8
Priority mean = 3.88 std = 0.89	1	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 4 (25 %)	8
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Positioning patient						
Definition: The patient is not positioned in the right way on the table or the position of the patient (for example trendelenburg when lateral is required).						
Source articles and interviews	Ahmad et al., 2007 Berguer, 1999 Boltor et al., 2006 Slack et al., 2007 Expert A Expert E					
Type of risk	Active element					
Applicable hospital	Yes n = 7 (44 %)		No n = 3 (19 %)		Partly n = 4 (25 %)	8 n = 2 (13 %)
Effect mean = 3.07 std = 1.07	1	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.93 std = 1.27	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.00 std = 1.02	1	2 n = 5 (31 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 3.06 std = 1.03	1	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 4 (25 %)	8 n = 2 (13 %)
Comments	Expert K: 'The respiratory pressures change.'					

Element: Stress						
Definition: Stress in the operation room can lead to a risk for the quality and safety.						
Source articles and interviews	Alfredsdottir et al., 2008 Aggerwal et al., 2004 Berguer, 1999 Berguer, 1999 Berland et al. 2008 Firth Cozens, 2004 Helmreich et al., 1996 Lee et al., 2005 Schaefer et al., 1994 Schaefer et al., 1995 Wetzel et al., 2006 Yule et al., 2006 Expert A					
Type of risk	Latent element					
Applicable hospital	Yes n = 5 (31 %)		No n = 2 (13 %)		Partly n = 7 (44 %)	8 n = 2 (13 %)
Effect mean = 3.13 std = 1.09	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 5 (31 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Chance mean = 3.50 std = 1.23	1 n = 2 (13 %)	2	3 n = 3 (19 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Calculated Priority mean = 3.46 std = 1.14	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Priority mean = 3.06 std = 0.77	1	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 9 (56 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Standing / static posture						
Definition: The common working posture, standing, is considered to be uncomfortable and painful.						
Source articles and interviews	Berguer, 1999 Cuschieri, 1995 Lee et al., 2005 Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 10 (63 %)		No n = 2 (13 %)		Partly n = 1 (6 %)	8 n = 3 (19 %)
Effect mean = 3.08 std = 1.04	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 6 (38 %)	5	8 n = 3 (19 %)
Chance mean = 2.77 std = 1.17	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.92 std = 0.93	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 6 (38 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Priority mean = 3.85 std = 1.07	1	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Comments	Expert F: 'That is the own responsibility of every specialist.'					

Element: Bad emotional climate						
Definition: The emotional relationships between practitioners in a team is uncomfortable (A good emotional climate can dampen the negative consequences of stress.)						
Source articles and interviews	Berlanc et al., 2008 Firth Cozens, 2004 Helmreich et al., 1996 Kneebone et al., 2007 Lyon, 2003 Lyon, 2004					
Type of risk	Latent element					
Applicable hospital	Yes n = 1 (6 %)		No n = 9 (56 %)		Partly n = 4 (25 %)	8 n = 2 (13 %)
Effect mean = 3.14 std = 1.35	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Chance mean = 2.79 std = 1.31	1 n = 4 (25 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 6 (38 %)	5	8 n = 2 (13 %)
Calculated Priority mean = 2.96 std = 1.25	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Priority mean = 3.71 std = 0.83	1	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Information loss						
Definition: Important information is lost because of inadequate communication or communication breakdown.						
Source articles and interviews	Christian et al., 2003 Firth Cozens, 2004					
Type of risk	Latent and active element (depends on level in the organization)					
Applicable hospital	Yes n = 3 (19 %)		Non = 7 (44 %)		Partly n = 6 (38 %)	8
Effect mean = 3.19 std = 1.17	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 7 (44 %)	5 n = 1 (6 %)	8
Chance mean = 2.69 std = 1.01	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 5 (31 %)	4 n = 4 (25 %)	5	8
Calculated Priority mean = 2.94 std = 0.91	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 7 (44 %)	4 n = 6 (38 %)	5	8
Priority mean = 3.56 std = 0.73	1	2 n = 1 (6 %)	3 n = 6 (38 %)	4 n = 8 (50 %)	5 n = 1 (6 %)	8
Comments						

Element: Operating with elevated arms						
Definition: The OR tables that go to high or too low requires that practitioners work with elevated arms.						
Source articles and interviews	Cuschieri, 1995 Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 7 (44 %)		Non = 2 (13 %)		Partly n = 4 (25 %)	8 n = 3 (19 %)
Effect mean = 2.92 std = 1.38	1 n = 3 (19 %)	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Chance mean = 2.54 std = 1.45	1 n = 5 (31 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Calculated Priority mean = 2.73 std = 1.29	1 n = 3 (19 %)	2 n = 1 (6 %)	3 n = 5 (31 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 3.46 std = 1.20	1 n = 1 (6 %)	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments	Expert P: 'Neckpain is a result'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Poor posture through team members						
Definition: Fellow team members hindering one another which leads to poor posture.						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 4 (25 %)		No n = 2 (13 %)		Partly n = 7 (44 %)	8 n = 3 (19 %)
Effect mean = 2.69 std = 1.25	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5	8 n = 3 (19 %)
Chance mean = 2.62 std = 1.33	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 2 (13 %)	4 n = 5 (31 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.65 std = 1.18	1 n = 3 (19 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Priority mean = 3.46 std = 1.13	1 n = 1 (6 %)	2 n = 1 (6 %)	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments						

Element: Uncomfortable instrumentation						
Definition: The retractors are uncomfortable are sometimes hard to hold. This can lead to pressure areas and cramps.						
Source articles and interviews	Berguer, 1999 Cuschieri, 1995 Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 3 (19 %)		No n = 8 (50 %)		Partly n = 2 (13 %)	8 n = 3 (19 %)
Effect mean = 2.85 std = 1.21	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Chance mean = 2.46 std = 1.33	1 n = 4 (25 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Calculated Priority mean = 2.65 std = 1.05	1 n = 2 (13 %)	2 n = 3 (19 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 3.46 std = 1.45	1 n = 2 (13 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 4 (25 %)	8 n = 3 (19 %)
Comments						

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Lack of social support						
Definition: The lack of social support can lead to negative effects on the work.						
Source articles and interviews	Berland et al., 2008					
Type of risk	Latent element					
Applicable hospital	Yes	Non – 8 (50 %)		Partly n – 6 (38 %)	8 n – 2 (13 %)	
Effect mean = 2.71 std = 1.20	1 n – 2 (13 %)	2 n – 5 (31 %)	3 n – 3 (19 %)	4 n – 3 (19 %)	5 n – 1 (6 %)	8 n – 2 (13 %)
Chance mean = 2.43 std = 1.16	1 n – 4 (25 %)	2 n – 3 (19 %)	3 n – 4 (25 %)	4 n – 3 (19 %)	5	8 n – 2 (13 %)
Calculated Priority mean = 2.57 std = 1.04	1 n – 2 (13 %)	2 n – 4 (25 %)	3 n – 5 (31 %)	4 n – 3 (19 %)	5	8 n – 2 (13 %)
Priority mean = 3.43 std = 1.09	1 n – 1 (6 %)	2 n – 1 (6 %)	3 n – 5 (31 %)	4 n – 5 (31 %)	5 n – 2 (13 %)	8 n – 2 (13%)
Comments						

Element: Communication breakdown						
Definition: Performance and patient safety depends heavily on how well information flows between phases. A breakdown in the information flow can lead to communication problems.						
Source articles and interviews	Alfredsdottir et al., 2008 Christian et al., 2005 Dagi et al., 2007 Firth Cozens, 2004 Helmreich et al., 1996 Lingard et al., 2005 Lingard et al., 2006 Schaefer et al., 1995 Sevdalis et al., 2007 Schimpff, 2007 Yule et al, 2006					
Type of risk	Latent and active element (depends on level in the organization)					
Applicable hospital	Yes n – 7 (44 %)	Non – 2 (13 %)		Partly n – 7 (44 %)	8	
Effect mean = 3.13 std = 1.15	1 n – 2 (13 %)	2 n – 2 (13 %)	3 n – 5 (31 %)	4 n – 6 (38 %)	5 n – 1 (6 %)	8
Chance mean = 2.63 std = 1.09	1 n – 3 (19 %)	2 n – 4 (25 %)	3 n – 5 (31 %)	4 n – 4 (25 %)	5	8
Calculated Priority mean = 2.88 std = 0.98	1 n – 2 (13 %)	2 n – 2 (13 %)	3 n – 5 (31 %)	4 n – 7 (44 %)	5	8
Priority mean = 3.44 std = 0.81	1	2 n – 2 (13 %)	3 n – 6 (38 %)	4 n – 7 (44 %)	5 n – 1 (6 %)	8
Comments	Expert K: 'The important information will be repeated or checked.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Distraction/interruption						
Definition: A break in the attention from the operator's primary task or an interruption that can lead to a pause in that task. This can come from unplanned visits, excessive talking, raised noise levels or duration of the operation.						
Source articles and interviews	Catchpole et al., 2007 Cuschieri, 1995 Dagi et al., 2007 Endozien, 2007 Gawanda et al., 2003 Helmreich et al., 1996 Lee et al., 2007 McDonald et al., 2006 Moorthy et al., 2004 Primus et al., 2007 Reason, 1995 Schaefer et al., 1995 Sevdalis et al., 2007 Wetzel et al., 2006 Expert A Expert H					
Type of risk	Active element					
Applicable hospital	Yes n = 10 (63 %)		No n = 5 (31 %)	Partly n = 1 (6 %)	8 n = 1 (6 %)	
Effect mean = 3.13 std = 1.13	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 6 (38 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Chance mean = 2.87 std = 1.25	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Calculated Priority mean = 3.00 std = 1.13	1 n = 1 (6 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Priority mean = 3.40 std = 0.91	1	2 n = 2 (13 %)	3 n = 7 (44 %)	4 n = 4 (25 %)	5 n = 2 (13 %)	8 n = 1 (6 %)
Comments						

Element: Feeling unsafe						
Definition: Employee do not feel safe in the OR as an working environment.						
Source articles and interviews	Rochlin, 1999					
Type of risk	Latent element					
Applicable hospital	Yes		No n = 12 (75 %)	Partly n = 2 (13 %)	8 n = 2 (13 %)	
Effect mean = 2.93 std = 1.44	1 n = 4 (25 %)	2 n = 1 (6 %)	3 n = 2 (13 %)	4 n = 6 (38 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Chance mean = 2.64 std = 1.55	1 n = 6 (38 %)	2	3 n = 2 (13 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.79 std = 1.44	1 n = 4 (25 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 3.21 std = 1.48	1 n = 3 (19 %)	2 n = 1 (6 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 3 (19 %)	8 n = 2 (13 %)
Comments	Expert F: 'This can be prevented with adequate training and tests.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Discrepancy ergonomics and sterilization						
Definition: There can be a discrepancy between the ergonomics of an instrument and the cleaning and sterilization.						
Source articles and interviews	Lee et al., 2007 Expert C					
Type of risk	Active element					
Applicable hospital	Yes n = 7 (44 %)		No n = 3 (19 %)		Partly n = 5 (31 %)	8 n = 1 (6 %)
Effect mean = 2.60 std = 1.24	1 n = 4 (25 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 5 (31 %)	5	8 n = 1 (6 %)
Chance mean = 2.73 std = 1.28	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 6 (38 %)	5	8 n = 1 (6 %)
Calculated Priority mean = 2.67 std = 1.23	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 5 (31 %)	5	8 n = 1 (6 %)
Priority mean = 3.13 std = 1.46	1 n = 3 (19 %)	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5 n = 3 (19 %)	8 n = 1 (6 %)
Comments	Expert N: 'Compromises are made. Not always the optimal way to operate is choosen.'					

Element: Standing on one leg						
Definition: Certain footswitches require that a practitioner stands on one leg.						
Source articles and interviews	Mattern et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 3 (19 %)		No n = 7 (44 %)		Partly n = 3 (19 %)	8 n = 3 (19 %)
Effect mean = 2.46 std = 1.13	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Chance mean = 2.38 std = 1.12	1 n = 3 (19 %)	2 n = 5 (31 %)	3 n = 2 (13 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.42 std = 1.08	1 n = 2 (13 %)	2 n = 6 (38 %)	3 n = 2 (13 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Priority mean = 3.08 std = 1.12	1	2 n = 5 (31 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments	Expert P: 'This is only for a few seconds.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Adjustability ceiling towers and monitors						
Definition: The pencels on the ceiling cannot rotate 360 ° and therefore the monitors can not always be positioned in the most adequate way.						
Source articles and interviews	Berguer, 1999 Cuschieri, 1995 Matzern et al., 2007 Reason, 1995 Expert E					
Type of risk	Active element					
Applicable hospital	Yes n = 9 (56 %)		No n = 2 (13 %)		Partly n = 2 (13 %)	8 n = 3 (19 %)
Effect mean = 2.38 std = 1.12	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 5 (31 %)	4 n = 2 (13 %)	5	8 n = 3 (19 %)
Chance mean = 2.46 std = 1.20	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.42 std = 1.15	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Priority mean = 3.08 std = 1.32	1 n = 3 (19 %)	2	3 n = 4 (25 %)	4 n = 5 (31 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Comments						

Element: Demanding psychomotor skills						
Definition: The psychomotor skills of laparoscopic operation are demanding. It can involve complex two handed skills with precise use of a foot pedal/switch.						
Source articles and interviews	Dongen et al., 2008 Gallagher et al., 2003 Hance et al., 2005 Kneebone et al., 2007 Najmaldin, 2007 Schimpff, 2007 Taffinder et al., 1998					
Type of risk	Latent element					
Applicable hospital	Yes n = 11 (69 %)		No		Partly n = 2 (13 %)	8 n = 3 (19 %)
Effect mean = 2.62 std = 1.04	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Chance mean = 2.46 std = 1.13	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.54 std = 1.05	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5	8 n = 3 (19 %)
Priority mean = 3.00 std = 1.23	1 n = 2 (13 %)	2 n = 2 (13 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Comments	Expert L and K: 'This can be learned by training.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

Element: Less degrees of freedom						
Definition: The instrumentation has less degrees of freedom then the hand has (four versus seven).						
Source articles and interviews	Berguer, 1999 Gallagher et al., 2003 Joice et al., 1998					
Type of risk	Active element					
Applicable hospital	Yes n = 10 (63 %)		No		Partly n = 3 (19 %)	8 n = 3 (19 %)
Effect mean = 2.46 std = 0.97	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5	8 n = 3 (19 %)
Chance mean = 2.31 std = 0.95	1 n = 2 (13 %)	2 n = 7 (44 %)	3 n = 2 (13 %)	4 n = 2 (13 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.39 std = 0.90	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5	8 n = 3 (19 %)
Priority mean = 3.00 std = 1.00	1 n = 1 (6 %)	2 n = 3 (19 %)	3 n = 4 (25 %)	4 n = 2 (13 %)	5	8 n = 3 (19 %)
Comments	Expert P: 'This can learned during training.'					

Element: Strong hierarchy						
Definition: There is an strong hierarchy in the OR.						
Source articles and interviews	Schimpff, 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 3 (19 %)		No n = 7 (44 %)		Partly n = 4 (25 %)	8 n = 2 (13 %)
Effect mean = 2.50 std = 1.29	1 n = 4 (25 %)	2 n = 4 (25 %)	3 n = 1 (6 %)	4 n = 5 (31 %)	5	8 n = 2 (13 %)
Chance mean = 2.50 std = 1.45	1 n = 5 (31 %)	2 n = 3 (19 %)	3 n = 1 (6 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Calculated Priority mean = 2.50 std = 1.36	1 n = 4 (25 %)	2 n = 4 (25 %)	3 n = 1 (6 %)	4 n = 4 (25 %)	5 n = 1 (6 %)	8 n = 2 (13 %)
Priority mean = 2.93 std = 1.33	1 n = 2 (13 %)	2 n = 4 (25 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 2 (13 %)
Comments						

Element: Limited tactile feedback						
Definition: There is less and limited tactile feedback because of the instruments. Important properties like viscosity and surface structure cannot be assessed easily.						
Source articles and interviews	Berguer, 1999 Eltaih et al., 2003 Najmaldin, 2007 Stefanidis et al., 2007					
Type of risk	Active element					
Applicable hospital	Yes n = 10 (63 %)	No		Partly n = 3 (19 %)	8 n = 3 (19 %)	
Effect mean = 2.77 std = 1.01	1 n = 1 (6 %)	2 n = 5 (31 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Chance mean = 2.54 std = 1.27	1 n = 4 (25 %)	2 n = 2 (13 %)	3 n = 3 (19 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Calculated Priority mean = 2.65 std = 1.07	1 n = 1 (6 %)	2 n = 4 (25 %)	3 n = 4 (25 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Priority mean = 2.85 std = 1.41	1 n = 2 (13 %)	2 n = 5 (31 %)	3 n = 1 (6 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments	Expert F and K: 'This can be learned by training.'					

Element: Fulcrum effect						
Definition: The retractors move in the opposite direct outside the patient from inside the patient.						
Source articles and interviews	Berguer, 1999 Gallagher et al., 2003 Najmaldin, 2007					
Type of risk	Latent element					
Applicable hospital	Yes n = 10 (63 %)	Non = 1 (6 %)		Partly n = 2 (13 %)	8 n = 3 (19 %)	
Effect mean = 2.62 std = 1.193	1 n = 3 (19 %)	2 n = 3 (19 %)	3n = 3 (19 %)	4 n = 4 (25 %)	5	8 n = 3 (19 %)
Chance mean = 2.38 std = 1.387	1 n = 4 (25 %)	2 n = 5 (31 %)	3	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Calculated Priority mean = 2.500 std = 1.258	1 n = 3 (19 %)	2 n = 3 (19 %)	3 n = 3 (19 %)	4 n = 3 (19 %)	5 n = 1 (6 %)	8 n = 3 (19 %)
Priority mean = 2.77 std = 1.481	1 n = 3 (19 %)	2 n = 4 (25 %)	3 n = 1 (6 %)	4 n = 3 (19 %)	5 n = 2 (13 %)	8 n = 3 (19 %)
Comments	Expert H, I, and K: 'This can be learned by training.'					

Prioritized interpersonal points of emphasis

Point of emphasize: Dedicated teams						
Definition Working in dedicated specialized teams is more efficient and convenient for the users.						
Source articles and interviews	Expert A Expert F Expert G Expert J Expert K Expert M Expert L					
Type of risk	Latent Point of emphasize					
Agree	Yes n = 14 (88 %)	No		Partly n = 1 (6 %)	8 n = 1 (6 %)	
Priority mean = 4.33 std = 1.11	1 n = 1 (6 %)	2	3 n = 1 (6 %)	4 n = 4 (25 %)	5 n = 9 (56 %)	8 n = 1 (6 %)
Hospital Specific Priority Size	4.33 / 1.11 = 3.90					
Comments	Expert D: 'The introduction of dedicated teams has consequences which should be though about the consequences.' Expert L: 'It is perfect the way it is now.'					

Appendix I: The minimal invasive surgery operation room, Elements which indicate risks for the quality and safety.

References

ASHRM (The American Society for Healthcare Risk Management) (2002). Strategies and tips for maximizing failure mode and effect analysis in your organization. Chicago, White paper.

Aggarwal, R., Hance, J., Undre, S., Ratnasothy, J., Moorthy, K., Chang, A. and Darzi, A. (2006). Training junior operative residents in laparoscopic suturing skills is feasible and efficacious. *Surgery*. Vol. 139 ; No 6 : pp 729-734.

Aggerwal, R., Undre, S., Moorthy, K., Vincent, C. and Darzi, A. (2004). The simulated operating theatre: comprehensive training for surgical teams. *Quality and safety in the health care*. Vol. 13 ; No 1 : pp 27 32.

Ahmed, G., Duffy, J. M. N. and Watson, A. J. S. (2007). Laparoscopic entry techniques and complications. *International journal of gynecology and obstetric*. Vol. 99; No 1: pp 52 55.

Alfredsdottir, H. and Bjornsdottir, K. (2008). Nursing and patient safety in the operating room. *Journal of advances nursing*. Vol. 61; No1 : pp 29 37.

Berguer, R. (1999). Surgery and ergonomics. *Archives of surgery*. Vol. 134 ; No 8 : pp 1011-1016.

Berland, A., Natvig, G. K. and Gundersen, D. (2008). Patient safety and job related stress: A focus group study. *Intensive and critical care nursing*. Vol. 24 ; No 2 : pp 90 97.

Bolton, T. and Spencer, R. (2006). Positioning of the surgical patient. *Clinical anesthesia*. Vol. 7 ; No 10 : pp 360 363

Carthey, J., de Leval, M. R., Wright, D. J., Farewell, V. T., Reason, J. T. and all UK peadiatric cardiac centers (2003). Behavioral markers in surgical excellence. *Safety science*. Vol. 41 ; No 5 : pp 409-425.

Catchpole K. R., Giddings, A. E. B., Wilkinson, M., Hirst, G., Dale, T. and de Leval, M. R. (2007). Improving patient safety by identifying latent failures in successful operations. *Surgery*. Vol. 142 ; No 1 : pp 102 110.

Christian, C. K., Gustafson, M. L., Roth, E. M., Sheridan, T. B., Gandhi, T. K., Dwyer, K., Zinner, M. J., and Dierks, M. M. (2005). A prospective study of patient safety in the operating room. *Surgery* Vol. 139 ; No 2: pp 159-173.

Cuschieri, A. (1995). Whither minimal access surgery: tribulations and expectations. *The American journal of surgery*. Vol. 169 ; No 1 : pp 9 19.

Cuschieri, A. (2005). Reducing errors in the operating room: Surgical proficency and quality assurance of execution. *Surgical endoscopy and other interventional techniques*. Vol. 19 ; No 8 : pp 1022 1027.

Dagi, T. F., Burguer, R., Moore, S. and Reines, H. D. (2007). Preventable errors in the operating room part 2 : Retained objects, sharps injuries, and wrong site surgery. *Current problems in surgery.* Vol. 44 ; No 6 : pp 352-381.

Derossis, A. M., Fried, G. M., Abrahamowicz, M., Sigman, H. H., Barkun, J. S. and Meakins, J. L. (1998). Development of a model for training and evaluation of laparoscopic skills. *The American journal of surgery.* Vol. 175 ; No 6 : pp 482-487.

Dongen, van K. W., van der Wal, W. A., Borel Rinkes, I. H. M., Schijven, M. P. and Broeders, I. A. M. J. (2008). Virutal reality training for endoscopic surgery : voluntary or obligatory? *Surgical endoscopics and other interventional techniques.* Vol. 22 ; No 3 : pp 664-667.

Edozien, L. C. (2007). Risk management in gynaecologic: principles and practice. *Best practice and research clinical obstretics and gynaecology.* Vol. 21 ; No 4 : pp 713 725.

Elkhuizen, S. (2007). Patient oriented logistics. Studies on organizational improvement in an academic hospital. Thesis, Academic Medical Centre, University of Amsterdam. pp 9-33.

Eltaib, M. E. H. and Hewit, J. R. (2003). Tactile sensing technology for minimal invasive surgery a review. *Mechatronics.* Vol. 13 ; No 10 : pp 1163 – 1177.

Firth Cozens, J. (2004). Why communication fails in the operating room. *Quality and Safety Health Care.* Vol. 13 ; No 5: p 327.

Gallagher, A. G., Smith, D. C., Bowers, S. P., Symour, N. E., Pearson, A., McNatt, S., Hananel, D. and Satava, R. M. (2003). Psychomotor skills assessment in practicing surgeons experiences in performing advanced laparoscopic procedures. *The journal of American college surgery.* Vol. 197 ; No 3 : pp 479-488.

Gawanda, A. A., Zinner, M. J., Studdert, D. M. and Brennan, T. A. (2003). Analysis of errors reported by surgeons at three teaching hospitals. *Surgery.* Vol. 133; No 6 : pp 614 621.

Hanna, G. B. Frank, T. G. and Cuschieri, A. (1997). Objective assessment of endoscopic knot quality. *The American journal of surgery.* Vol. 174 ; No 4: pp 410-413.

Hance, J., Aggarwal, R., Moorthy, K., Munz, Y., Undre, S. and Darzi, A. (2004). Assessment of psychomotor skills acquisition during laparoscopic cholecystectomy. *The American journal of surgery.* Vol. 190 ; No 3 : pp 507-511.

Healey, A. N., Undre, S. and Vincent, C. A. (2006). Defining the technical skills of teamwork in surgery. *Quality and safety in the health care.* Vol. 15 ; No 5: pp 231-324.

Helmreich, R. L. and Davies, J. M. (1996). Human factors in the operating room: interpersonal determinants of safety, efficiency and morale. *Baillière's Clinical Anaesthesiology.* Vol. 10 ; No 2 : 277 295.

Inspectie voor de gezondheidszorg (IGZ). (2007). Risico's minimaal invasieve chirurgie onderschat; kwaliteitssysteem voor laparoscopische operaties ontbreekt. November 2007. Retrieved on 11th of February 2008.

Jacklin, R., Sevdalis, N., Harries, C., Darzi, A. and Vincent, C. (2008). Judgment analysis: a method for quantitative evaluation of trainee surgeon' judgements of surgical risk. *The American journal of surgery.* Vol. 195 ; No 2: 183-188.

Jansen, F. W., Kolsman, W., Bakkum, E. A., de Kroon, C. D., Trimbos – Kemper, T. C. M. and Trimbos, B. J. (2004). Complications of laparoscopy: An inquiry about closed versus open entry techniques. *American journal of obstetrics and gynaecology.* Vol. 190 ; No 3 ; pp 634-638.

Joice P., Hanna, G. B. and Cuschieri, A. (1998). Errors enacted during endoscopic surgery: a human reliability analysis. *Applied ergonomics.* Vol. 26 ; No 6 ; pp 409-414.

Kohler, H. Douglas and Wilmore, D. W. (2002). Multimodal strategies to improve surgical outcome. *The American journal of surgery.* Vol. 183 ; No 6 ; pp 630-641.

Kneebone, R. L., Nestel, D., Vincent, C. and Darzi, A. (2007). Complexity, risk and simulation in learning procedural skills. *Medical education.* Vol. 41 ; No 9 ; pp 808-814.

Lee, A. C., Rafiq, A., Merrell, R., Ackerman, R. and Dennerlein, J. T. (2005). Ergonomics and human factors in endoscopic surgery: a comparison of manual vs telerobotic simulation systems. *Surgical endoscopy and other interventional techniques.* Vol. 19 ; No 8 ; pp 1064-1070.

Lee, G., Lee, T., Dexter, D., Klein, R. and Park, A. (2007). Methodological infrastructure in surgical ergonomics: a review of task, models and measurement systems. *Surgical innovations* Vol. 14; no 3 ; PP 153-167

Lingard, L., Espin S., Whyte S., Regehr G., Baker G. R., Reznick, R., Bohnen J., Orser, B., Doran, D. and Grober, E. (2004). Communication failures in the operating room: an observational classification of recurrent types and effects *Quality and safety in the Health Care.* Vol. 13 ; No 6 ; pp 330-334.

Lingard, L., Espin S., Rubin, B., Whyte S., Colmenares, M., Baker G. R., Doran D., Grober, E., Orser, B., Bohnen J., and Reznick R. (2005). Getting teams to talk: development and pilot implementation of a checklist to promote interprofessional communication in the OR. *Quality and safety in the Health Care.* Vol. 14 ; No 5 ; pp 340-346.

Lingard, L., Regehr, G., Espin, S. and Whyte, S. (2006). A theory-based instrument to evaluate team communication in the operating room: balancing measurement authenticity and reliability. *Quality and safety in Health Care.* Vol. 15 ; No 6: pp 422-426.

Lingard, L., Reznick, R., DeVito, I. And Espin, S. (2002). Forming professional identities on the health care team: discursive constructions of the 'other' in the operating room. *Medical education.* Vol. 36 ; No 8 ; pp 728-734.

Lyon, P. M. A. (2003). Making the most of learning in the operating theatre: student strategies and curricular initiatives. *Medical Education.* Vol. 37 ; No 8: pp 680–688.

Lyon, P. M. A. (2004). A model of teaching and learning in the operating theatre. *Medical education.* Vol. 38 ; No 12 : 1278 – 1287.

Machatuta, N. A. and Sa.e, S. M. (2007). Fires and explosions. *Anaesthesia and intensive care medicine*. Vol. 8 ; No 11 : pp 457-460.

Matern, U. and Koneczny, S. (2007). Safety, hazard and ergonomics in the operating room. *Surgical Endoscopy and other interventional Techniques*. Vol. 21; No 11: 1965-1969

McDonald, R., Waring, J. and Harrison, S. (2006). Rules, safety and the narrativisation of identity: a hospital operating theatre case study. *Sociology of Health and Illness*. Vol. 28 ; No 2: pp 178 202.

Mills, P., Neily, J. and Dunn, E. (2008) Teamwork and communication in surgical teams: Implications for patient safety. *Journal of the American College of Surgeons*. Vol. 206 ; No 1: pp 107 112 .

Moorthy, K., Munz, Y., Undre, S. and Darzi, A. (2004). Objective evaluation of the effect of noise on the performance of a complex laparoscopic task. *Surgery*. Vol. 136 ; No 1: pp 25 30.

Najmaldin, A. (2007). Skill training in pediatric minimal access surgery. *Journal of pediatric surgery*. Vol. 42 ; No 2 : pp 284-289.

Nugteren, W. A. H., Scheltcers, W. M. L. C. M. and van der Wal, G. (2007). Laparoscopisch opereren kan er nooit veiliger. Kwaliteitsbewaking ontbreekt. *Medisch contact*. Vol. 47 pp 1957 1959.

Pandy, V., Wolfe, J. H. N., Moorthy, K., Munz, Y., Jackson, M. J. and Darzi, A. W. (2006). Technical skills continue to improve beyond surgical training. *Journal of vascular surgery*. Vol. 43 ; No 3 : pp 539-545.

Park, H. J., Lee, S. Y., and Lee C. S. (2004) Complications associated with the nurse procedure: Analysis of risk factors and suggested measures for prevention of complications. *Journal of Pediatric Surgery*, Vol. 39, No 3: pp 391 395.

Primus, A. P., Healey, A. N. and Undre, S. (2007). Distraction in the urology operating theatre. *The Autors Journal Compilation*. p 493.

Ranger, C. A. and Bothwell, S. (2004). Making sure the right patient gets the right care. *Quality Safety Health Care*. Vol. 13 ; No 5 : p 329.

Reason, J. (1995). Safety in the operating theatre – part 2: Human error and organizational failure. *Current anaesthesia and critical care*. Vol. 6 ; No 2 : pp 121 126.

Rechlin, G. I. (1999) Safe operation as a social construct. *Ergonomics*. Vol. 42 ; No 11 : 1549 1560.

Satava, R. M. (2005). The nature of surgical error. A cautionary take and a call to reason. *Surgical endoscopy and other interventional techniques*. Vol. 19 ; No 8 : pp 1014-1016.

Schaefer, H. G., Helmreich, R. L. and Scheidegger, D. (1994). Human factors and safety in emergency medicine. *Resuscitation.* Vol. 28 ; No 3: pp 221-225.

Schaefer, H. G., Helmreich, R. L. and Scheidegger, D. (1995). Safety in the operating theatre - part 1: Interpersonal relationships and team performance. *Current anaesthesia and critical care.* Vol. 6 ; No 1 : pp 48-53.

Schimpff, S. C. (2007) Improving operating room and perioperative safety: Background and specific recommendation. *Surgical innovation.* Vol. 14 ; No 2 : pp 127-135.

Singh, P. B., Saw, N. K., Mokete, M., Martin, F. L. and Matanhelia, S. S. (2007). An integrated laparoscopic simulator to develop surgical skills outside the operating theatre: a novel means to improve training facilities in the UK. *International journal of surgery.* Vol. 5 ; No 1 : pp 1-7.

Slack, A. and McVeigh, A. (2007) Laparoscopy and laparoscopic surgery. *Obstetrics, gynaecology and reproductive medicine.* Vol. 17 ; no 4 : pp 112-118.

Sevdalis, N., Healey, A. N. and Vincent C. A. (2007). Distracting communications in the operating theatre. *Journal of Evaluation in Clinical Practice* Vol. 13 ; No 3 : pp 390-394

Smith, A. R. B. (2000). Post operative complications following minimal access surgery. *Baillière's Clinical obstetrics and gynaecology.* Vol. 14; no 1 : pp 123-132.

Stefanidis, D., Korndorffer, J. R., Heniford, B. T. and Scott, D. J. (2007). Limited feedback and video tutorials optimize learning and resource utilization during laparoscopic simulator training. *Surgery.* Vol. 142 ; No 2 : pp 202-206.

Taffinder, N. J., McManus, I. C., Russell, R. C. G. and Darzi, A. (1998). Effect of sleeping deprivation on surgeons' dexterity on laparoscopic simulator. *The lancet,* Vol. 352 ; No 9135 : p 1191.

Tang, B. and Cuschieri, A. (2006). Conversions during laparoscopic cholecystectomy: Risk factors and effects on patient outcome. *Journal of gastrointestinal surgery.* Vol. 10 ; No 7 : pp 1081-1091.

Tang, B., Hanna, B. and Cuschieri, A. (2005). Analysis of errors enacted by surgical trainees during skills training courses. *Surgery.* Vol. 138 ; No 1 : pp 14-20.

Thomson, A. J. M. and Rowland D. J. (2005) Immediate to long-term complications following minimal access surgery in gynaecology. *Reviews in gynaecological practice.* Vol. 5 ; Supl 1: pp 123-129.

Wetzel, C. M., Kneebone, R. L., Woloshynowych, M., Nestel, D., Moorthy, K., Kidd, J. and Darzi, A. (2006). The effects of stress on surgical performance. *The American journal of surgery.* Vol. 191 ; No 1 : pp 5-10.

Yule S., Flin R., Paterson-Brown S., and Maran N. (2006). Non-technical skills for surgeons in the operating room: A review of the literature. *Surgery* Vol. 139 ; No 2 : pp 140-149.