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Scuola di Ingegneria Industriale e dell'Informazione

Master Degree Course in Mechanical Engineering

HRA for Surgery: methodological improvements of HEART technique with applications in Robotic Surgery

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ABSTRACT

Patient safety is currently placed as a priority issue in the healthcare context, meeting the needs of people asking, with growing demand, safer and less risky services. Epidemiological data confirm that most of the surgical errors are caused by the lack of action -or inappropriate action- of the operator, due to the deficiency of technical -or not technical- skill of the individual or the group. The concept of “medical error” has undergone several interpretations over the centuries and it can be defined as “*medical treatment that moves the level of risk beyond the margins of acceptability of failure suggested by the medical practice, causing damage to the patient*”.

In the continual prospective evolution to improve care and safety in the healthcare domain, it is confirmed the need of “*Risk Assessment*” techniques, in order to implement corrective and / or preventive actions to reduce the vulnerability of the clinical process. The clinical risk needs to be addressed properly only within an integrated view for processes, with the adoption of a systemic approach in the risk management.

The healthcare facility is a highly complex and constantly technologically changing system, which encompass a wide diversity of human interactions. These affinities, identified with the industrial sector, have allowed the adoption of *Human Reliability Analysis* (HRA) techniques also in the healthcare sector. The HRA disciplines are based on the need to improve safety in high risk systems, characterized by complex man-machine interactions and by a variety of factors that highly influence human performances.

These techniques, well validated and applied in the industrial field, systematically implemented to prevent adverse events, find growing implementation in the healthcare sector, with recent increase in the number of practicals, especially in surgery (for example in endoscopic surgery, laparoscopic and radiotherapy).

Despite the significant increase of the consensus on the concept of “healthcare risk management”, the important differences between the clinical and industrial sectors have severely limited the applicability of HRA techniques in healthcare.

The aim of this work is thus to adapt and apply a Human Reliability methodological analysis in surgery, in order to limit the literature's gap and to contribute to the development of others methodologies.

In the discussion of the thesis it was wanted to test the applicability of HEART method (*Human Error Assessment and Reduction Technique*, Williams 1986), already validated, effective and efficient in industry, even in a surgical procedure. In this regard, it was necessary to model the industrial method in order to allow and facilitate its application in the medical-surgical field.

In particular, for the application it was chosen a progressive and innovative area as Minimally Invasive Robotic Surgery, with its greatest exponent which is the DaVinci Robot. The study focuses on the analysis of a surgical procedure of Radical Prostatectomy Robotics Retzius Sparing-Bocciardi Approach (BA-RARP).

Robotic surgery is a minimally invasive surgery for high precision surgeries, which has not only the aim to remedy the pathology of the patient, but also to reduce surgery-pain, minimizing disruption and maximizing therapeutic success and recovery. This technology, widely used in America and Europe (Italy is one of the leading countries in the use of the DaVinci Robot), is still at an early stage of study and analysis to assess safety, feasibility and clinical efficacy.

For this reason, it was considered necessary to carry out an evaluation of human reliability of this innovative clinical technology. Through the application of the modified HEART, it was possible to identify potential influencing factors on surgeons' performance and to assess their influence on the execution of critical tasks.

For this purpose, it was necessary the involvement of a team of robotic surgeons of the Niguarda Ca 'Granda Hospital in Milan, in order to collect data necessary for the qualitative and quantitative application of HEART technique.

Subsequently, the execution of a Scenario Analysis allowed to investigate the effect of these Influencing Factors on the nominal value of human error probability. Finally, some improvement actions have been identified and maximum potential ANLU reduction was calculated in the case in which all improvement strategies were implemented.

Materials and Method

The methodological steps developed to achieve the objective were:

- Literature analysis of HRA techniques applications in healthcare, in particular focusing on the HEART methodology;
- Literature analysis of Prostatectomy Robotics BA-RARP procedures' task analysis, with identification of the most critical tasks;
- Empirical observational activity of two robotic surgeries;
- Modelling of the HEART methodology: some modifications have been made to the traditional technique, in order to make it more feasible to the surgical practice;
- Collection of the values from experts (i.e. robotic surgeons);
- Application of the modified HEART methodology;
- Scenario analysis on the Influencing Factors considered more affecting surgeon's performance;
- Proposed improvement actions with the aim to reduce human error probability.

The literature review was developed in order to become more familiar with the specific medical terminology and with the analysed surgical procedure. It also allowed to obtain data and comparisons with similar HEART applications in the healthcare domain.
The research was conducted using computerized tools offered by the University Library System and through literature medical -and not- databases, such as *Pubmed*, *Scopus*, *Web of Science* and *Google Scholar*. To facilitate the research some keywords were used, such as "Human Reliability Analysis (or Assessment) AND Surgery (or Healthcare)" and "Robotic prostatectomy AND critical tasks (or Complex tasks)".

The empirical observational activity allowed to experience the operating environment and to share knowledge, learned from literature, with qualified operators. The two observed surgeries have been performed with the DaVinci robot, following BA-RARP procedure on two patients who required removal of the prostate for cancer disease. During the two surgeries it has been possible to film (from two different prospects) the procedural steps, to hypothesize critical tasks and to assess the observability of the contextual factors of the surgical taxonomy.

As noted from the literature analysis, traditional HEART technique cannot be directly applied, on the contrary it has been necessary to make some modifications ‘ad hoc’ for the healthcare sector, in order to obtain consistent and efficient results. Among the major innovations they are reported the use of a specific taxonomy of Influencing Factors validated in surgery (different from the one based on *Error Promoting Conditions* (EPC) of Williams) and the involvement of three experienced surgeons. They were asked to identify which factors of the taxonomy mostly influence their performances in the execution of the selected tasks, to quantify those effects and to estimate how much of that is attributable to the Williams’ EPC that best represents the factor.

The Scenario Analysis has been carried out on three different scenarios referred to three categories of IFs, which consider “Personal”, “Team” and “Organizational” aspects. In this way, it was possible to obtain ANLU value only referred to the selected scenario. Consequently, the category which mostly influence surgeon’s performance was identified and it was calculated the maximum percentage reduction of Human Unreliability rate, when the effect of this category is reduced, thanks to proposed improvement actions.

Results and Conclusions

The qualitative analysis, based on the direct observation and investigation of Influencing Factors, allowed to identify the relevance of different factors of the taxonomy, already highlighted in the literature.

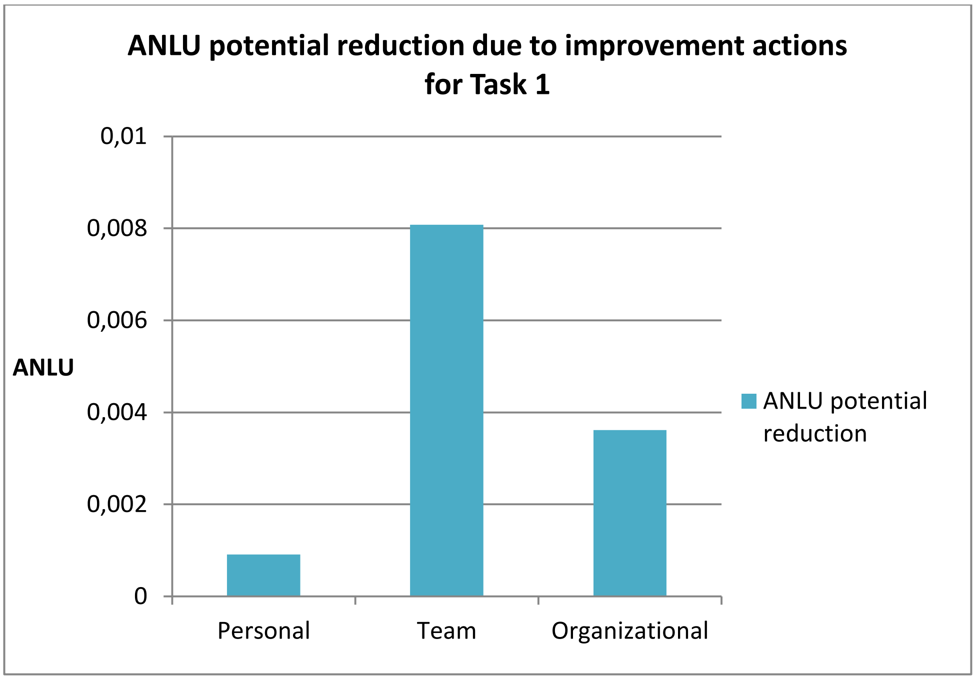
The quantitative analysis, with the application of the HEART modified methodology, confirmed the relevance of some factors on others. Additionally, it was possible to identify improvement strategies and actions for the selected scenario, with the aim to limit their negative influence on the execution of the critical tasks of the procedure.

For Task 1 “Isolation of lateral peduncles and of posterior prostate surface”, the most Influencing Factors resulted to be: “Poor management of errors” (IF 5), “Noise and Ambient Talk” (IF 1) and “Poor Coordination” (IF 10). All together they contribute to generate an Assessed Nominal Likelihood of Unreliability (ANLU) value equal to 0,085. A Scenario Analysis has been performed on those Influencing Factors and it was found that, it is recommended to develop improvement actions on "Team category" to obtain greater percentage reduction of the Human Unreliability rate (95,2% of maximum ANLU reduction for Task 1).

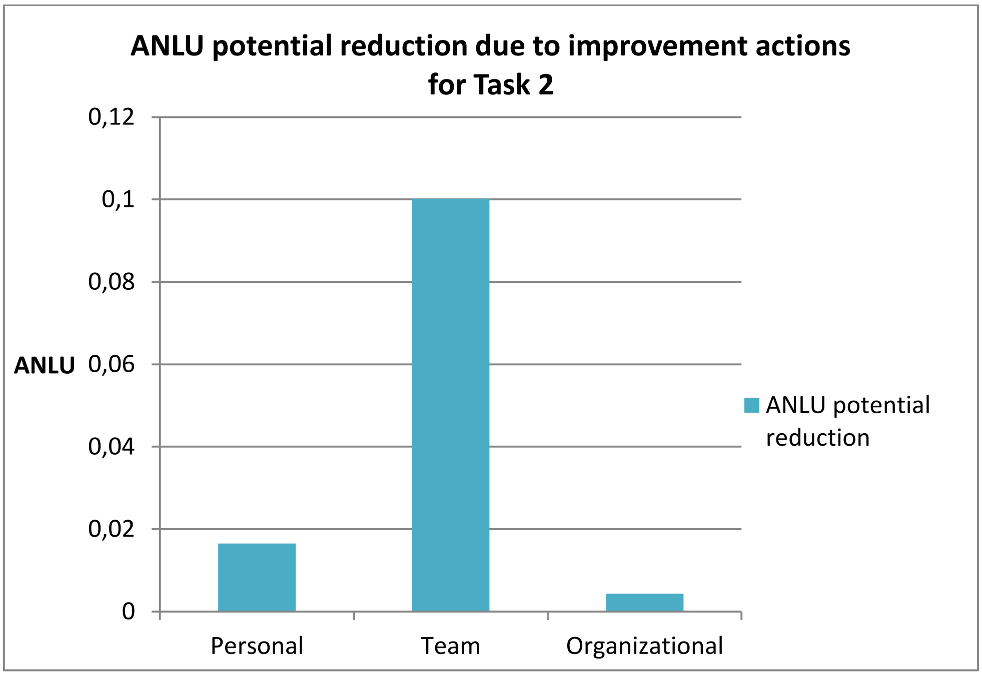
For Task 2 "Anastomosis", most influencing Factors, in descending order of impact, are: "Poor management of errors" (IF 5), "Unclear Communication" (IF 9), "Noise and Ambient Talk" (IF 1) and "Poor Coordination" (IF 10). All together they contribute to generate an Assessed Nominal Likelihood of Unreliability (ANLU) value equal to 1. In this case, Scenario Analysis showed that, adopting improvement actions on Team Factors (i.e. IF 9, IF 1 and IF 10), it would allow to reduce ANLU value of 99,6%.

The Histogram graphs below show results of Scenario Analysis, by representing maximum potential ANLU reduction that can be obtained thanks to improvement actions on the three Influencing Factors Categories.

ANLU reduction due to Improvement Actions for Task 1



ANLU reduction due to Improvement Actions for Task2



This study allowed developing and testing a modified HEART methodology for application in the healthcare sector, and surgery in particular. The attention was directed to the analysis of surgeon's reliability/unreliability in robotic surgery, since it is an innovative sector where minimally invasive surgery allows optimizing precision, speeding up recovery and limiting human errors.
This work contributed to reduce the gap observed in literature about Human Reliability Analysis techniques in the healthcare context, confirming the potentiality of HEART technique in applications different from the ones in the industrial field.

It is important for the development of study improvements that other procedures and surgical settings could experience this modified methodology, enhancing its diffusion, in order that this work does not remain a mere exercise of study. On the other hand, it is necessary to take into account that the applicability in complex areas needs a long time and readjustments.

We hope that this work will support future training of robotic surgeons and the design of new procedures, checklists and simulation scenarios. In fact, the study highlights major operational and organizational factors which influence surgeons' performance. Therefore, it is important to take those factors into account and try to reduce their effect by raising surgeons' awareness about errors promoting conditions and implementing improvement actions, such as those proposed in the study.

Additionally, the work represents a useful contribution to technology providers, as it shows the close relationship of human-machine interaction, displaying the impact of technology in human resources support and also highlighting critical aspects. Consequently, it is possible to deduce improvement actions, in order to develop implementations on the "tactile" functions, fusion image systems and network functions for real-time sharing of information, during the execution of a surgery, between specialized experts.

SOMMARIO

La sicurezza del paziente è attualmente collocata tra i temi prioritari in ambito sanitario, andando incontro alle esigenze della popolazione che chiede, con sempre maggior esigenza, servizi sicuri e meno rischiosi. I dati epidemiologici confermano che la maggior parte degli errori in chirurgia sia causata dal mancato intervento o ad un intervento inappropriato da parte dell'operatore, dovuto a deficit di abilità tecnica o non tecnica, individuale o di gruppo. Il concetto di "*errore medico*" ha subito diverse interpretazioni nel corso dei secoli e si può definire come "*un trattamento medico che sposta il livello di rischio al di fuori dei margini di accettabilità di insuccesso suggeriti dalla pratica medica, provocando danni al paziente*".

In un'ottica di continua evoluzione per migliorare le cure e la sicurezza in sanità, si conferma la necessità di applicare tecniche di "*Risk Assessment*" per implementare azioni correttive e/o preventive, al fine di ridurre la vulnerabilità del processo clinico. Il rischio clinico deve essere affrontato adeguatamente solo all'interno di una visione integrata per processi, con l'adozione di un approccio sistemico nella gestione del rischio.

La struttura sanitaria è un sistema estremamente complesso, in costante evoluzione tecnologica, che comprende una vasta diversificazione di interazioni umane e non solo. Queste affinità, identificate con l'ambito industriale, hanno permesso l'adozione di tecniche di Analisi di Affidabilità Umana - *Human Reliability Analysis* (HRA) anche nel settore sanitario. Le discipline di HRA si basano sulla necessità di migliorare la sicurezza nei sistemi ad alto rischio, caratterizzati da complesse interazioni uomo-macchina, e da una grande varietà di fattori che influenzano le performances umane.

Queste tecniche, ben validate ed applicate in ambito industriale, sistematicamente implementate per prevenire eventi avversi, trovano una crescente implementazione in sanità, con un aumento, negli ultimi anni, del numero delle applicazioni pratiche, soprattutto in chirurgia (ne sono un esempio la chirurgia endoscopica, laparoscopica e radioterapia).

Nonostante il significativo aumento del consenso sul concetto di "Gestione del Rischio Sanitario" degli ultimi anni, le importanti differenze tra

l’ambito clinico e quello industriale hanno severamente limitato l’applicabilità delle tecniche di HRA in sanità.

Lo scopo di questo lavoro è stato quindi quello di adattare ed applicare una metodologia di analisi di affidabilità umana in chirurgia, per limitare il gap in letteratura e contribuire allo sviluppo, all’applicazione e alla diffusione di altre metodologie. Nella trattazione della tesi si è voluto sperimentare l’applicabilità del metodo HEART (*Human Error Assessment and Reduction Technique,* Williams 1986), già validato, efficace ed efficiente in ambito industriale, anche in una procedura chirurgica.

A tal riguardo è stato necessario modellizzare ad hoc il metodo industriale per permetterne e facilitarne l’applicazione in ambito medico-chirurgico.

In particolare, per l’applicazione è stato scelto un ambito progressista ed innovativo come la chirurgia mininvasiva robotica, con il suo maggior esponente quale è il Robot DaVinci. Lo studio si sofferma sull’analisi di una procedura chirurgica di Prostatectomia Radicale Robotica Retzius Sparing-Approccio Bocciardi (BA-RARP).

La chirurgia robotica assistita da computer viene proposta e utilizzata come chirurgia minimamente invasiva per interventi che richiedono un’ elevata precisione, con l’obiettivo, non solo di porre rimedio alla patologia del paziente, ma anche di limitare la traumaticità dell’intervento, minimizzando i disagi ad esso legati e massimizzando il successo terapeutico e di recupero.

La tecnologia, per quanto già ampiamente diffusa in America ed Europa (l’Italia è uno dei paesi guida nell’utilizzo del Robot DaVinci), è ancora ad uno stadio precoce di studio ed analisi per valutarne sicurezza, fattibilità ed efficacia clinica.
Per questo motivo, è stato ritenuto necessario effettuare un’ analisi di affidabilità umana di questa innovativa tecnologia sanitaria, in modo da identificare, attraverso l’applicazione della tecnica HEART modificata, potenziali fattori influenzanti negativamente le performances dei chirurghi, valutarne l’influenza sull’esecuzione di tasks critici e proporne azioni migliorative.

A tal fine, è stato fondamentale il coinvolgimento di un’equipe di chirurghi robotici dell’Ospedale Niguarda Ca’ Granda di Milano, che ha permesso di raccogliere i dati necessari per l’applicazione qualitativa e

quantitativa della tecnica HEART e di avere validazione della task analisi e dei task critici analizzati.
Successivamente, l’esecuzione di un’analisi di scenario sui fattori maggiormente influenzanti ha consentito di creare diversi scenari di analisi, mostrando l’effetto di tali fattori sul valore nominale di probabilità di errore umano. Infine sono state identificate alcune azioni migliorative ed è stata calcolata la massima variazione percentuale del valore di Inaffidabilità Umana relazionata alla loro implementazione.

Materiali e metodi

Le fasi metodologiche sviluppate per il raggiungimento dell’obiettivo sono state:

- Analisi della letteratura sulle applicazioni di tecniche di HRA in sanità, in particolar modo, focalizzando sulla metodologia HEART;
- Analisi della letteratura sulla task-analysis della procedura di Prostatectomia Robotica BA-RARP, con identificazione dei tasks più critici;
- Attività empirica osservazionale di due interventi di chirurgia robotica;
- Modellizzazione della metodologia HEART, con apporto di modifiche alla tecnica tradizionale, al fine di renderla più funzionale alla pratica chirurgica;
- Raccolta dei pareri degli esperti;
- Applicazione della metodologia HEART modificata;
- Analisi di Scenario sull’influenza dei fattori considerati maggiormente condizionanti le performance dei chirurghi;
- Proposta di azioni migliorative finalizzate a ridurre la probabilità d’errore umano.

La ricerca bibliografica è stata sviluppata per familiarizzare con la terminologia medica specifica e con la procedura chirurgica analizzata. Inoltre, ha permesso di ottenere dati e confronti con simili applicazioni della tecnica HEART in sanità.
La ricerca è stata condotta usando gli strumenti informatizzati offerti dal Sistema Bibliotecario dell’Università e attraverso database di letteratura medica, e non, come ad esempio Pubmed, Scopus, Web of science and Google Scholar.

Per facilitare la ricerca sono state utilizzate delle parole chiave, come “Human Reliability Analysis (or Assessment) AND Surgery (or Healthcare)” e “Robotic prostatectomy AND critical tasks (or Complex tasks)”.

L’attività empirica osservazionale ha consentito di sperimentare sul campo l’ambiente operatorio e condividere con operatori esperti le conoscenze apprese in letteratura. I due interventi chirurgici osservati sono stati eseguiti con il Robot DaVinci, su due pazienti che necessitavano l’asportazione della prostata per patologie tumorali. Durante i due interventi è stato possibile registrare con la telecamera le fasi procedurali (da due differenti prospettive), ipotizzare dei task critici e valutare l’osservabilità dei fattori di contesto della tassonomia chirurgica.

Come già osservato dall’analisi di letteratura, non è stato possibile applicare direttamente la metodologia tradizionale HEART; al contrario è stato necessario formulare alcune modifiche ‘ad hoc’ per l’ambito sanitario, così da ottenere risultati efficienti e conformi. Tra le maggiori innovazioni si riportano l’utilizzo di una tassonomia specifica di fattori influenzanti validata in chirurgia (differente da quella delle Condizioni Favorevoli all’Errore - *Error Promoting Conditions* (EPC) di Williams) e il coinvolgimento di tre chirurghi esperti ai quali è stato sottoposto un questionario. Ai chirurghi è stato chiesto quali fattori della tassonomia maggiormente influenzino le loro performances nell’esecuzione dei task selezionati; è stato chiesto inoltre di quantificarne l’effetto e stimare quanto di questo sia attribuibile all’ EPC di Williams che meglio traduce il fattore.

Successivamente i Fattori Influenzanti selezionati sono stati suddivisi in tre categorie in base agli aspetti personali, di team ed organizzativi. Infine, un’analisi di Scenario è stata sviluppata per individuare su quale categoria converrebbe intervenire per ridurre maggiormente l’Inaffidabilità Umana.

Risultati e conclusioni

L’analisi qualitativa di osservazione e ricerca dei fattori influenzanti ha permesso di identificare la rilevanza di diversi fattori della tassonomia, già evidenziati anche in letteratura.

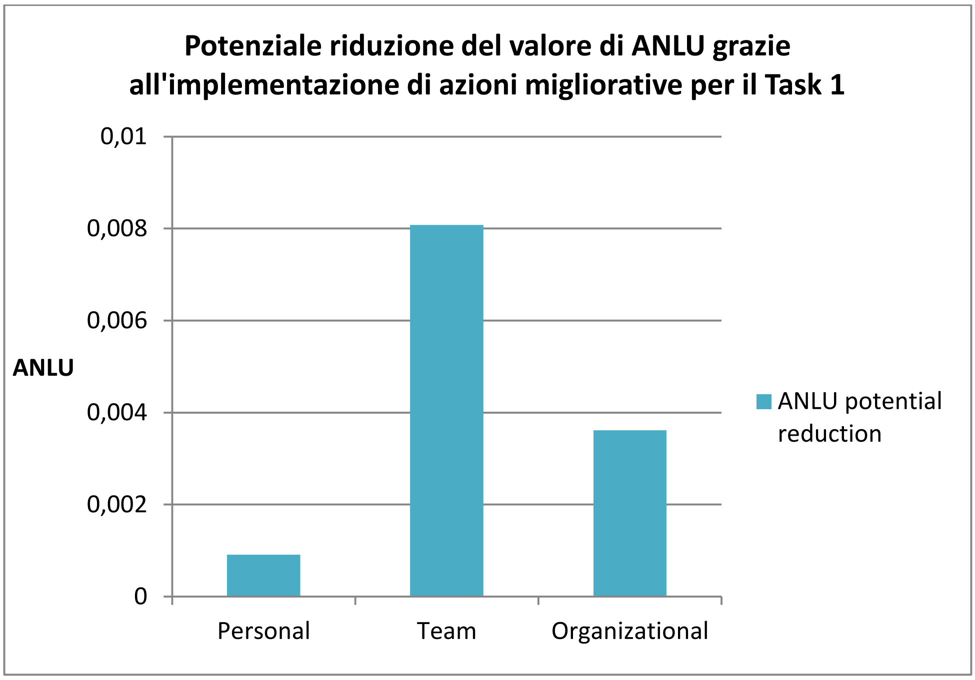
L'analisi quantitativa, con l'applicazione della metodologia HEART, ha confermato la rilevanza di alcuni fattori su altri, permettendo di identificare quelli che necessitano di misure di intervento volte a limitarne l'influenza negativa sull'esecuzione dei tasks della procedura.

Dall'analisi effettuata si evidenzia che, per il Task 1 "Isolamento dei peduncoli laterali e della superficie posteriore della prostata", i fattori maggiormente influenzanti, in ordine decrescente di influenza, sono: "Mancanza di gestione degli errori" (IF 5), "Rumore e voci di sottofondo" (IF 1) e "Scarsa Coordinazione" (IF 10). Questi fattori contemporaneamente contribuiscono a generare un valore di Inaffidabilità Umana pari a 0,085. Successivamente l'Analisi di Scenario ha dimostrato che, per ottenere una maggiore variazione percentuale dell'Inaffidabilità Umana, conviene sviluppare azioni migliorative sui fattori riferiti al Team (i.e. IF 1 e IF 10), consentendo una riduzione massima pari a 95,2%.

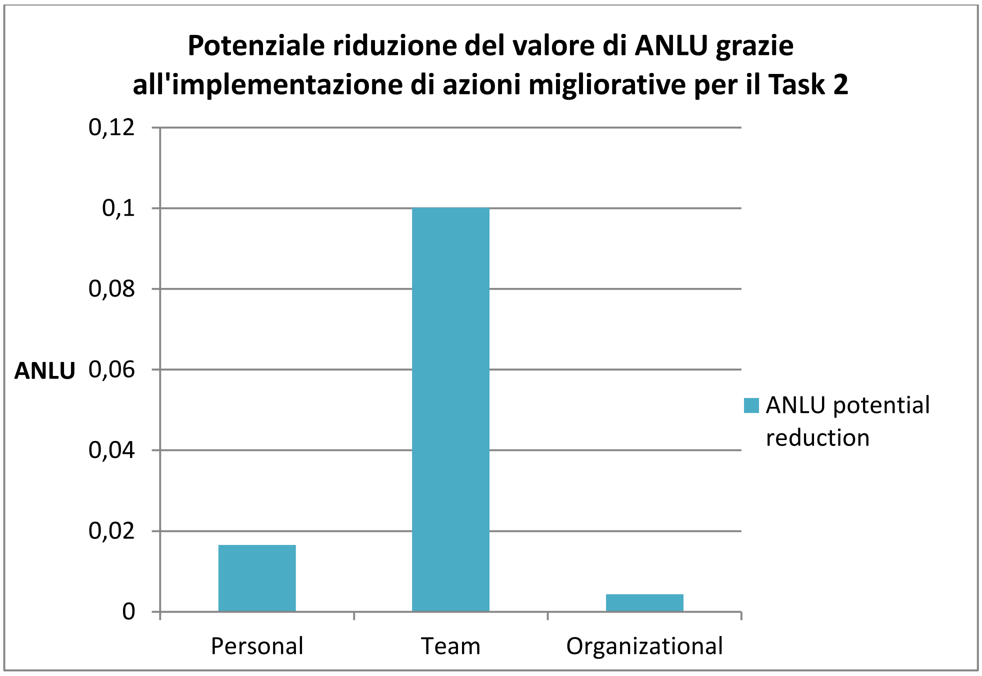
Per quanto riguarda l'analisi del Task 2 "Anastomosi", i fattori maggiormente influenzanti le performance del chirurgo sono risultati essere, in ordine: "Mancanza di gestione degli errori" (IF 5), "Comunicazione non chiara" (IF 9), "Rumore e voci di sottofondo" (IF 1) e "Scarsa Coordinazione" (IF 10). Nel caso studio, questi fattori insieme concorrono a generare una probabilità di Inaffidabilità Umana massima. È stato pertanto interessante sviluppare un'Analisi di Scenario per osservare come la probabilità di Inaffidabilità possa diminuire al variare dell'impatto dei fattori. Si è constatato che, attraverso delle azioni migliorative, conviene agire sui fattori di Team (i.e. IF 1, IF 9 e IF 10) per ottenere la massima riduzione percentuale del valore di Inaffidabilità Umana (pari al 99,6%).

Gli Istogramma seguenti mostrano la massima riduzione del valore di Inaffidabilità Umana per le tre categorie principali di fattori "Personali", "Team" e "Organizzativi", quando le strategie migliorative proposte vengono tutte implementate.

Riduzione dell'ANLU grazie alle azioni migliorative proposte_ Task 1



Riduzione dell'ANLU grazie alle azioni migliorative proposte_ Task 2



Questo lavoro ha contribuito a ridurre il gap osservato in letteratura per la diffusione di tecniche di analisi di affidabilità umana nel contesto sanitario, confermando le potenzialità della tecnica HEART nell'applicazione in aree differenti da quella industriale.
È importante, per gli sviluppi futuri, che questa metodologia modificata per l'ambito chirurgico possa essere sperimentata anche in altre procedure chirurgiche e/o settori medici, così che questo non rimanga un mero esercizio di studio, ma un contributo utile per la diffusione di tecniche di HRA in sanità.

Si auspica che il lavoro possa essere di supporto al training dei futuri esperti chirurghi robotici, alla progettazione di procedure, checklists e scenari di simulazione per l'apprendimento.
Ci si augura inoltre che questo studio possa anche essere di aiuto per diffondere l'applicabilità della pratica robotica, contribuendo a migliorarne i vantaggi significativi sia per la sicurezza del paziente che quelli per il chirurgo, accrescendo la consapevolezza circa i fattori facilitanti gli errori.

Il lavoro rappresenta un contributo utile anche per i fornitori di tecnologie, in quanto mette in mostra lo stretto legame di interazione uomo-macchina, mostrando l'impatto della tecnologia a supporto delle risorse umane ed evidenziandone anche gli aspetti critici. Pertanto è possibile dedurne delle azioni migliorative al fine di progettare sviluppi in tema di implementazione della funzione "tattile", sistemi di fusione di immagini e funzioni di network per la condivisione in tempo reale di informazioni sull'intervento tra professionisti specializzati.

INTRODUCTION

The healthcare system is rightly considered a socio-technical complex system because of the multiple interactions existing between a plurality of actors that contribute to the execution of clinical-care processes. This statement appears to be the reason why changes, toward a system characterized by patient safety, occur with very long time. "Quality of care" means not only talking about efficiency and effectiveness of performances, but also and especially about safety of the service offered. In addition, the current rise of the cultural level, even in the health sector, is reason of the increase of importance given to the right of health. Citizens are aware of the priority value that security has in the context of the provision of health, consequently they require more and more guarantees. If the patient, which will appeal to the health facility with an assistance request to improve his health condition, receives on the contrary a damage, there is the failure not only of individual performance, but of the entire system that does not achieved the purpose for which it was designed. In fact, the reality in which we live attends an ambivalent advertising campaign: on the one hand it demonstrates reassuring continuous advances in medicine, on other hand, it is ready to prejudicially condemn every adverse episode in healthcare, always pointing it as "poor healthcare". All that has encouraged the enactment of national and international regulations and more detailed definition of standards, dedicated to healthcare patient safety.

A significant contribution to the issue of patient safety in healthcare can be attributed to a document promoted by the Institute Of Medicine - IOM- in 1999, entitled "To err is human, Building a safer health care system" (Institute of Medicine, 1999).

Kohn's study was the trigger for many epidemiological studies regarding analysis of adverse events in different countries such as in Australia (Wilson RM, 1995; Kable AK, 2002), New Zealand (Davis, 2002, 2003), United Kingdom (Vincent, 2001), Denmark (Schioler et al., 2001), Canada (Baker GR, 2004), Spain (Aranaz-Andrés JM et al. 2007, 2008, 2011) and Sweden (Soop et al., 2009). Although it is difficult to compare largely heterogeneous data from different national health systems and contexts, it is interesting to highlight the new concept of "preventable error" in complex clinical settings brought by this.

About half of the adverse events could be prevented and therefore considered as an “organizational error”.

This publication represents a paradigm shift in the management of the health system with a view to improving the healthcare quality. The leading concept is based on the assumption that the error is an inevitable part of human reality and the complexity of a system is proportional to the multiplicity of verifiable errors. Often the possibility of the occurrence of an adverse in healthcare depends on the presence, in the system, of "latent failures". They are deficiencies or planning, organization and control errors, that remain silent in the system until a triggering factor, often human error, does not make them manifest in all their potential, causing a severe damage.

The approach introduced by the cited study, however, implies the concept that although making errors is part of human nature, also creating solutions is one of its ability. It should not be claiming to focus on a single solution, because complex problems require a multifactorial and interdisciplinary response. Therefore, it is crucial to put in place a series of measures through the involvement of all actors of the healthcare system, so that the probability of the occurrence of an error can become minimal.

Kohn’s original contribution also concerns the introduction of a new approach to the analysis of adverse events in healthcare, grounded on human error analysis theory, and characterised by an integrated consideration of cognitive and organizational factors. In this regard, James Reason's theory of Organisational Accident (Reason, 1990) paved the way and promoted a rapid diffusion of human factors investigation from aviation to healthcare.

Accordingly, in the last years, the healthcare sector has been investigated through a socio-technical persperctive and has been recognised as one of the most complex socio-technical systems because of its intrinsic characteristics (Amato et al., 2012). Infact, healthcare organisations are extremely complex environments in which even the simplest of the procedures turn out to be the sum of articulated processes requiring different human interactions, in a context under rapid evolution also from a technological point of view. In terms of complexity, the operating room has some key peculiarities: an environment characterized by increasingly complicate procedures, multi-professional staff with a very high level of interdependence, sophisticated technological equipment and devices, time constraints, and occurrence of unexpected critical conditions since the patient is under induced unstable and critical conditions.

Although, by experience, everyone knows that accidents have always been part of the human condition, researchers, focusing on socio-technical systems such as healthcare organisations, have recognised that there are accidents and risks , due to complex interactions between humans, technologies, and organizational factors. Respectively, organizational factors not only play an important role in accident analysis, but they also are a critical part of understanding and preventing human errors (Leveson et al., 2009).

In order to investigate human and organisational errors, a relevant contribution comes from organisation theory where the System Safety approach was proposed.

“The primary characteristics of a systems approach are:

- top-down systems thinking that recognizes safety as an emergent system property rather than a bottom-up, summation of reliable components and actions;
- focus on the integrated socio-technical system as a whole and the relationships between the technical, organizational, and social aspects;
- focus on providing ways to model, analyze, and design specific organizational safety structures, rather than trying to specify general principles that apply to all organizations” (Leveson et al., 2009).

Methodologies like Human Reliability Analysis (HRA), fits with the System Safety approach and have demonstrated to improve performance and reduce errors rate in safety-critical systems, such as in aviation and nuclear industry. The discipline of Human Reliability Analysis (HRA) stems from the need to study the contribution of human behaviour and decisions on safety performances of high-risk systems, characterized by a variety of factors in the work environment that influence human performance and by their multiple interactions. According to system safety approach, error rate depends on the quality of multiple interactions among components in the work system, classified according to the SHELL model (Edwards 1972, 1988): Liveware (L) - i.e. people -, Hardware (H) - i.e. technological resources (such as materials, interfaces, machines) - Software (S) - i.e. rules and procedures -, and the environment (E) in which Liveware-Hardware, Liveware-Software and Liveware-Liveware interactions take place.

Although in recent years, the prevention of "adverse events" in healthcare has become a priority issue, the terminology about “adverse events/mishaps” is still confusing; errors, faults, violations, complications, incidents, accidents, near misses, adverse reactions, are terms generally used as synonims by several researchers coming from different domanins (human factors, cognitive engineering, psychology, ergonomics, medicine, healthcare management).

In this context, the introduction of Human Reliability Analysis (HRA) discipline in healthcare is an emerging field (Lyons, 2009).

CHAPTER 1: HUMAN RELIABILITY ANALYSIS IN INDUSTRIAL AND HEALTHCARE SECTORS

1.1 Human Reliability Analysis in Industrial Sector

Introduction

Human error is a very big subject that is still being investigated. Humans, by their very nature, make mistakes: it should not come as surprise that 80% of high consequence accidents has been implicated to human operations errors (Madonna et al., 2009). Analysis of human error has matured over the past 60 years by analysing vulnerabilities of system safety in a variety of accidents, such as Three Mile Island (1979), Bhopal (1984), Chernobyl (1986) and Exxon Valdez (1989). More than 80% of all mishaps have human factors as a significant contributing causal factor in civil, nuclear and military aviation disruptions (Vestrucci, 1990; Wiegmann & Shappell, 2001).

It has been detected that more than 63% of shipboard collision, flooding and grounding and 40% of problems in missile testing are related to human initiated failures (Willis, 1962). Main human errors causes of nuclear incidents are related to design error (35%), operator error (12%), maintenance or installation error (12%) and error in procedure (10%) (Taylor, 1975).

Starting from the studies in military and civilian aviation accidents conducted in the mid-1990s, Dr Scott Shappell and Dr Doug Wiegmann developed the Human Factors Analysis and Classification System (HFACS) (Wiegmann & Shappell, 2000). It is a broad human error framework that was originally used by the US Air Force to investigate and analyse human factors aspects of aviation. HFACS is based upon James Reason's *Swiss Cheese Model* (Reason 1990) to systematically identify active and latent failures within an organisation that culminated in an accident. Human Reliability Analysis (HRA) discipline is then used to incorporate human risks into system safety analysis, with the ultimate goal of reducing the likelihood and consequences of human errors. For this reason, decision makers use it to identify and select ways to improve human performance (Madonna et al., 2009).

1.1.1 What is Human Reliability Analysis about?

Human Reliability Analysis (HRA) is an aspect of the risk analysis that aim to systematically identify and analyse causes and consequences of human errors (Groth, 2009). HRA is an essential component of Probabilistic Risk Assessment (PRA) for complex systems; it was born in the 50s in aeronautics and it evolved primarily in the nuclear sector. The purpose of this discipline is to estimate the human reliability, prevent errors and improve safety. Swain (1983) and Hollnagel (1998) defined HRA as follows:

"The Human Reliability Analysis is a method by which human reliability is estimated. Human reliability is the probability that a person correctly performs some system-required activity in a required time period and performs no extraneous activity that can degrade the system. In carrying out an HRA, it is necessary to identify those human actions that can have an effect on system reliability or availability" (Swain A.D, Guttmann H.E., 1983).

HRA aims to predict the likelihood that a human action may fail, by expressing it in terms of the probability of human erroneous action (Hollnagel, 1998). HRA involves the use of qualitative and quantitative methods to assess human contribution to risk. Some HRA methods provide guidance for identification human errors and assessment of Human Error Probability (HEP), in order to evaluate the probability that a human action can fail and consequently have an effect on the system reliability (Swain & Guttmann, 1983). HRA typically encompasses three phases: identify error sources, modelling human error including hardware failures and quantify the human error probabilities (HEPs) (Boring, 2010). Note that some HRA methods focus more -or only- on one phase, while there are families of HRA that encompass the complete spectrum of HRA process shown below.

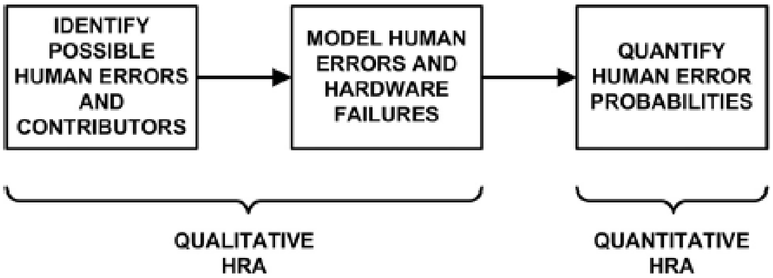


Figure 1: HRA phases

The qualitative analysis starts with the *Definition of the Problem* and the *Description of the System*: data collection is required to obtain useful information. It is performed through observation, questionaries, interviews, verbal protocol analysis, work sampling and so on.
The following *Task Description* is a useful phase for error analysis and quantification. It is better if it is done by someone familiar with HRA, but not too much with the task, in order to explore implicit assumption. Usually a *Task Simulation Method* is performed to analyse how performances of a task might change in different contexts. *Human Error Identification* is the primary aim of HRA, some techniques consider PSFs and require a certain amount of expertise in human factors. After the *Representation* phase, *Quantitative Analysis* is performed. Development of error probability is the most difficult aspect of HRA, because it consists in assigning numbers to uncertain events (Vestrucci, 1990). The quantification can be easier when tasks are highly structured. Finally, *Impact assessment* is defined and documentation is organize. In the last phase appropriate *corrective measures* are proposed for reducing the occurrence of errors and allowing to obtain acceptable level of safety and reliability. The flow chart below represents main phases of HRA process.

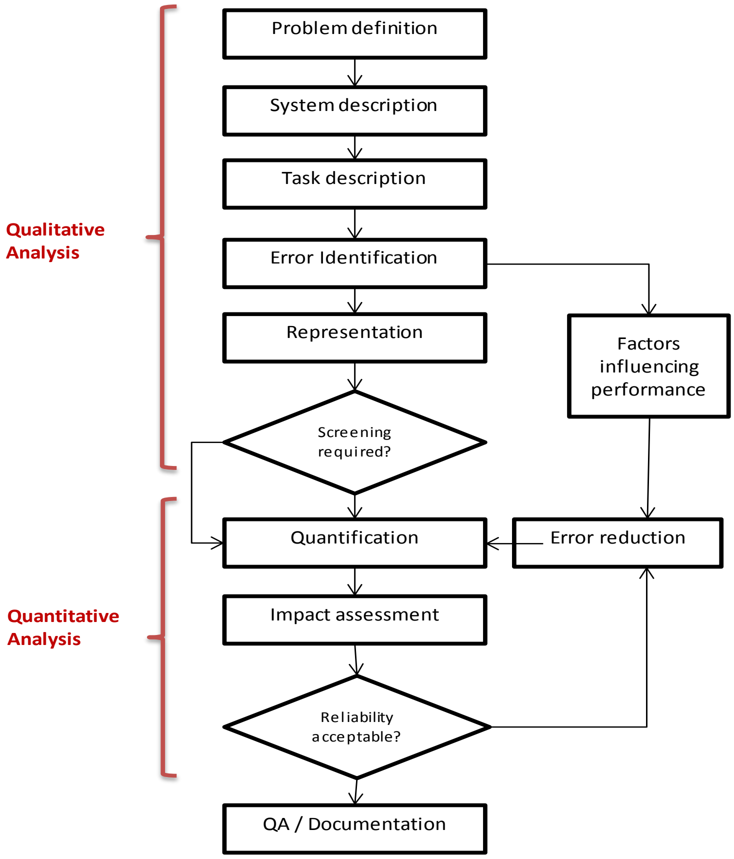


Figure 2: Flowchart representing main steps of HRA

1.1.2 The Issue of Data Availability and Quality in Real HRA Applications

Despite development of human reliability analysis, issues about better estimation of HEPs are still discussed. This is due to some problems plaguing HRA, mainly related to data collection and modelling. In fact, many data available for conducting HRA studies are inadequatly collected and they are gathered ony from emergency, incident or accident scenarios. On the other hand, it has been observed the lack of real and normal condition information (Groth, 2009). Deficiency of accurate data collection is due to several factors, such as data scarcity, availability, uncertainty and relevance. Considering that serious human error accidents (fortunaly) are rare, many difficulties can be generated for risk analysts in collecting statistical data. Sometimes, it also happens that data from industries are not available to resources, because of security concerns. Differently from machines' perfomances, human behaviour measurement is more difficult to observe and quantify because it is more subjective and qualitative and depends heavily on analyst judgment and analysis goals (Groth, 2009).

These considerations also result in less effective models, because they are generated by inadequate data and then subsequently modelling will impact data collection too. Before to develop a new model, an accurate analysis of data collection problems and a revision of limitations of older model are necessary. Another problem related to modelling is how human behaviour can be structured. In fact, some models treat it in a strictly binary structure (success vs failure); while, other models treat human behavior as random. Both views neglect interdependencies between aspects of human performance, limitating the impact and importance of many factors (Groth, 2009).

Additional problems related to HRA are different errors taxonomies and different contextual factors taxonomies (e.i. number of PSFs and which ones should be choosen), even in the same domain. As it will be shown later on, analysts proposed different errors taxonomies and influencing factors categories, but a uniform view of these concepts does not exist yet.

1.1.3 Definitions and Classifications of Human Errors

Being the objective of HRA the investigation the “Human Error”, all the HRA theorists have tried to technically define the concept of "error". There is not a unique definition of the term, in fact, even the most important and validated definitions differ from each other for restrictions, completeness and accuracy (Vestrucci, 1990). Almost all researchers, who have addressed the problem of human reliability, have sought to provide a technical definition of error. This process is very difficult because there is no agreement on what is the attributes related to the error: it can be either used to hihlight a cause, a consequence or an event (Hollnagel, 1998).

“Human error” can generally be defined as an inappropriate or undesirable human decision or behaviour that reduces, or has the potential for reducing, effectiveness, safety, or system performance. Therefore, it is considered an action whose result was not desired by a set of rules or an external observer. Below is reported the list of the most significant definitions:

- “Error will be taken as a generic term to encompass all those occasions in which a planned sequence of mental or physical activities falls to achieve its intended outcome, and when these failures cannot be attributed to the intervention of some change agency. (Reason, 1990)”
- “Human error occurrences are defined by the behaviour of the total man-task system (Rasmussen, 1987)”
- “Actions by human operators can fail to achieve their goal in two different ways: the actions can go as planned, but the plan can be inadequate, or the plan can be satisfactory, but the performance can still be deficient.(Hollnagel, 1993)”
- “Any one set of human actions that exceed some limit of acceptability (Rigby, 1970)”
- “A failure on the part of the human to perform a presented act(or the performance of a prohibited act) within specified limits of accuracy, sequence, or time, which could result in damages or disruption of scheduled operations (Hagen & Mays, 1981)”

Human error classifications

Over the years, many classifications were generated in order to classify errors.

“.. a taxonomy is a fundamental requirement for the foundation of empirical science. If we want a deep understanding of the nature, origins, and causes of human error, it is necessary to have an unambiguous classification scheme for describing the phenomenon we are studying (Senders and Moray, 1991).”

One of the easier way to classify errors might be done by considering some observable features: formal characteristics of erroneous behaviour (omission-commission, repetition, misordering), or their immediate consequences (nature and extent of damage and gravity of the injury).

Some of the more common classifications of human error include *“errors of commission”* and *“errors of omission”* (Swain, 1983). In this way there is not the intent to analyse the internal mental process of the operator, but only to relate the human output with the system (Hollnagel, 2000). These two types of errors are defined as follows:

- An error of omission is the failure to perform some of the actions necessary to achieve a desired goal.
- An error of commission occurs when an action is performed, but in an incorrect unrelated manner that prevents the achievement of the goal.

Some of the more significant human errors taxonomies are:

- *Swain and Guttman's classification*, based on the distinction between error of Omission, Commission and Violation (Swain and Guttman, 1983)
- *Reason's Taxonomy*, based on the distinction between error od Slip, Mistake and Lapse (Reason, 1990)
- *SRK or Rasmussen's Taxonomy*, based on three level (skill-, rule- and knowledge-) of operator's experience (Rasmussen, 1986)

Human errors depends on a series of external facotors related to the external working conditions and internal intrinsic characteristics of humans. Therefore, the analysis of the factors that could affect the performance of a human operator in executing a specific task is crutial in order to estimate probability of errors occurrence and identify strategies for errors reduction.

There are two major influencing elements that have been investigated:

- the working environment (Swain, 1969);
- the complexity of tasks to carry out, according to a Cognition Model of reference adopted for the operator (Rasmussen, 1981).

1.1.4 Modeling and Assessment of the Work Environment

As already mentioned, Human Reliability Analysis considers the study and evaluation of those external and internal factors that influence the efficiency and reliability of workers' performances.
First of all, the external factors to be considered are mainly technical or systemic casual events. They are due to environment, work equipment, used materials, workplace and work organization. On the other hand, more difficult to be identified are all those factors related to individual characteristics of the operator

and his physical conditions. All these factors affect and alter the working conditions and lead operators to erroneous behaviors.

Several HRA methods calculate human error probability (HEP) based on the state and level of influence of various “Performance Shaping Factors” (PSF) (Swain, 1983), also called “Performance Influencing Factors” (PIF) (Hollnagel, 1998) or “Error Promoting Conditions” (EPC) (Williams, 1986). A Performance Shaping Factor is any factor that enhances or degrades human performance and thus has an impact on the likelihood of error (Groth, 2009). Currently there is no standard set of PSFs used in HRA methods. PSFs are also used to predict conditions that lead to human errors. Some examples are fatigue, motivation, competence, attitude, attention, personality, level of training, stress, teamwork, experience and knowledge (Kirwan, 1994). Additional factors include management, communication, leadership, safety culture, environment, ergonomics, time and workload (Gertman & Blackman, 2001; Groth, 2009).

PFS are used both in qualitative and quantitative phases of HRA. Even if not every HRA method follows this approach, PFSs are used in qualitative phase to identify contributors to human performances and in the quantitative analysis to derive the overall HEP (Boring, 2010).
The process of the HEP estimation, used in many quantitative methods, requires to obtain the value of HEP basis, identify a set of PSFs that influence the task analysed, and each of these influencing factors is then multiplied by a weight factor that indicates the magnitude of the effect on the execution of the task:

$$Pr = Pr_{nominal} * \left[\sum PSF_i * W_i\right]$$

(where W_i is the weight of the i-PFS)

The PSFs largely infuence the HEP value: when external and internal PSFs match with the task operation requirements they can contribute to generate an optimum, high reliable, human performance. The PSF represents a positive effect and its level is less than one and it is used to decrease the overall HEP. On the other hand, the opposite situation is gained when external and internal PSFs dismatch between them and with the taks, in this case a distruptive stress occurs and lead to a suboptimum performance (Swain, 1983). Consequently, the PFS has a negative effect, its values is greater than one and increases the overall HEP. The neutral condition is gained when the PSF does not impact human performance. In this case the PSF multiplier is equal to one and does not modify the nominal HEP (Boring, 2010).

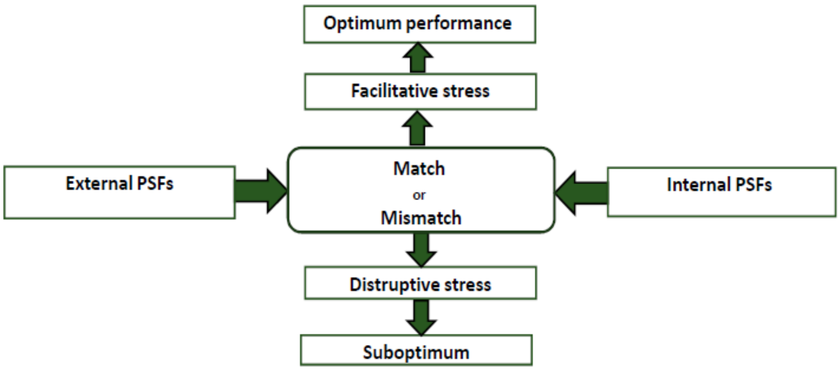


Figure 3: Influence of PSFs on human performance

The effects of PSF mustipliers on the nominal HEP are shown below, distinguishing the three possible cases explained before.

$$HEP_{overall} = HEP_{nominal} * PSF$$

$0 < PSF < 1$ $\quad HEP_{overall} < HEP_{nominal}$
reliability increases

$PSF = 1$ $\quad HEP_{overall} = HEP_{nominal}$
reliability stays same

$PSF > 1$ $\quad HEP_{overall} > HEP_{nominal}$
reliability decreases

Historically, the first use of PSFs in HRA to modify nominal or base failure rates is documented in THERP. Today this procedure is used in many methods, such as THERP (Swain and Guttman, 1983), CREAM (Hollnagel, 1998), HEART (Williams, 1986) and SPAR-H (Gertman et al., 2005).
Here are some sample tables concerning evaluation of PSFs and their degree of influence.

Table 1: PSF used in THERP method

External PSFs: • **Situational Characteristics** (a) Control Room Architectural Feature (b) Quality of the Working Environment (c) Works Hours and Work Breaks (d) Shift Rotation and Night Work (e) Availability/Adequacy of Special Equipment/Tools and Supplies (f) Manning Parameters (g) Organizational Structure and Actions by Others (h) Rewards, Recognition, and Benefits • **Task and Equipment Characteristics** (a) Perceptual Requirements (b) Motor Requirements (c) Control-Display Relationships (d) Anticipatory Requirements (e) Interpretation (f) Decision-Making (g) Complexity/Information Load (h) Frequency and Repetitiveness (i) Task Criticality (j) Long- and Short-Term Memory (k) Calculation Requirements (l) Feedback (m) Dynamic Versus Step by Step Activities (n) Team Structure (o) Main-Machine Interface Factors	• **Job and Task Instructions** (a) Operating Procedures (b) Oral Instructions • **Internal PSFs:** **Psychological Stressors** (a) Suddenness of Onset (b) Duration of Stress (c) Task Speed (d) Task Load (e) High Jeopardy Risk (f) Threat of Failure, Loss of Job (g) Monotonous, Degrading, or Meaningless Work (h) Long, Uneventful Vigilance Periods (i) Conflicts of Motives About Job Performance (j) Reinforcement Absent or Negative (k) Sensory Deprivation (l) Distraction (Noise, Glare, Movement, Flicker, Color) (m) Inconsistent	• **Physiological Stressors** (a) Duration of Stress (b) Fatigue (c) Pain or Discomfort (d) Hunger or Thirst (e) Temperature Extremes (f) Radiation (g) G-Force Extremes (h) Atmospheric Insufficiency (i) Vibration (j) Movement Constriction (k) Lack of Physical Exercise (l) Disruption of Circadian Rhythm • **Organizational Factors** (a) Previous Training/Experience (b) State of Current Practice or Skill (c) Personality and Attitudes (d) Motivation and Attitudes (e) Knowledge of Required Performance Standards (f) Sex Differences (g) Physical Condition (h) Attitudes Based on Influence of Family and Other Outside Persons or Agencies (i) Group Identifications

Table 2: PSF used in CREAM method

PSF	PSF State	Expected Effect on Performance Reliability
Adequacy of Organization	Very Efficient	Improved
	Efficient	Not significant
	Inefficient	Reduced
	Deficient	Reduced
Working Conditions	Advantageous	Improved
	Compatible	Not significant
	Incompatible	Reduced
Adequacy of HMI and operational support	Supportive	Improved
	Adequate	Not significant
	Tolerable	Not significant
	Inappropriate	Reduced
Availability of procedures/plans	Appropriate	Improved
	Acceptable	Not significant
	Inappropriate	Reduced
Number of simultaneous goals	Fewer than capacity	Not significant
	Matching current capacity	Not significant
	More than capacity	Reduced
Available time	Adequate	Improved
	Temperately inadequate	Not significant
	Continuously inadequate	Reduced
Time of day	Day-time	Not significant
	Night time	Reduced
Adequacy of training and preparation	Adequate, high experience	Improved
	Adequate, limited experience	Not significant
	Inadequate	Reduced
Crew collaboration quality	Very efficient	Improved
	Efficient	Not significant
	Inefficient	Not significant
	Deficient	Reduced

1.1.5 The Number Issue of PSFs

As already said there is vastness of factors that can influence human performance and HRA methods try to organize them into a usable set of factors. Even today there is an open debate about which PSFs, and how many of them, should be used to perform a meaningful Human Reliability Analysis. The appropriate number of PSFs used in HRA methods varies from one (in early time HRA methods) to sixty in more recent works (Groth, 2009). Recently, 15 essential PSFs for HRA were identifide by the US Nuclear Regulatory Commission in “Good Practices for Implementing Human Reliability Analysis” (NUREG, 1792). It is possible to compare these choosen 15 PSFs whit different metodologies: SPAR-H, in which the number of PSFs increased during its development from six to eight; CREAM, that considers nine PSFs, and Groth's Nine-Factor Model.

As can be seen in the crosswalk table below, many of the PSFs have one-to-one matches, while in others cases, some of the PSFs found in "Good Practices" are encompassed under a single PSF (i.e. in CREAM). It is possible to summarize that there is a general considerable overlap in the PSFs, although each method addresses a different emphasis and slightly different set of PSFs (Boring, 2010).

Table 3: Crosswalk of PSFs Between the Good Practices, SPAR-H, CREAM, and the 9-factor model

Good Practices [13]	SPAR-H [2]	CREAM [12]	9-Factor Model [11]
Training and Experience	Experience/Training	Adequacy of Training and Preparation	Training Knowledge
Procedures and Administrative Controls	Procedures	Availability of Procedures/Plans	Resources
Instrumentation	Ergonomics/HMI	Adequacy of HMI and Operational Support	Machine
Time Available	Available Time	Available Time	Loads/Perceptions
Complexity	Complexity	Number of Simultaneous Goals	Complexity
Workload/Time Pressure/Stress	Stress/Stressors	Number of Simultaneous Goals	Loads/Perceptions
Team/Crew dynamics	Work Processes	Crew Collaboration Quality	Team
Available Staffing	Work Processes	Adequacy of Organization	Resources
Human-System Interface	Ergonomics/HMI	Adequacy of HMI and Operational Support	Machine
Environment	Stress/Stressors	Working Conditions	Complexity
Accessibility/Operability of Equipment	Ergonomics/HMI	Adequacy of HMI and Operational Support	Machine
Need for Special Tools	Ergonomics/HMI	Adequacy of HMI and Operational Support	Resources
Communications	Work Processes	Crew Collaboration Quality	Team
Special [Equipment] Fitness Needs	Ergonomics/HMI	Adequacy of HMI and Operational Support	Resources
Consideration of 'Realistic' Accident Sequence Diversions and Deviations	--	–	–
–	Fitness for Duty	Time of Day	–
–	Work Processes	Adequacy of Organization	Organizational Culture
–	--	–	Attitude

A large number of PSFs is important to obtain greater detail of HRA in error identification, in quantification and for system design improvements. In this way it is possible to ensure that all factors able to affect human performance are taken into account and exact causes of errors can be identified. A nuanced list of

PSFs allow to have a useful and complete error estimation. Consequently, many recent HRA methods adopt a large set of PFSs and there is a tendency to increase the number of them covered by previous methodologies (Boring, 2010). However, a criticism on the large number of PSFs emphasizes the limitations on the quantitative aspect, given that an extensive list of PSFs is not strictly necessary to evaluate the HEP. Additionally, it should be considered that, in the case in which PSFs are not calibrated against validated data points, no greater precision in quantification would be gained by a larger number of PSFs.
Galyean claimed the advantages of having a small number of PSF: not only a simpler effort analysis, but also a greater control for double-counting of PSFs effect in quantfication. In fact, he stated that many HRA methods do not use orthogonal PSFs and it can lead to have spurious effects on the HEP calculation. Galyean analysis suggests that PSFs can be clustered into only three PSFs: the individual, the organization and the environment encompassing the large family of PSFs (Galyean, 2006).

Counterargument to Galyean's three-PSF model is based on the fact that, a part from the quantification phase of HRA, other phases do not benefit from small number of PSFs. In particular, during the *Identification Phase* having a greater number of PSF can help to meticulously pinpoint causes of errors. As already mentioned, in the *Quantification Phase* few PSFs can be enough to obtain a screening value of HEP, while a greater number of PSF is used to have a nuanced error estimation. However, it is important to consider that a screening value can be more accurate than a nuanced estimation when PSF do not come from empirical data. Finally, the *Modelling Phase* is not largely influenced by the number of PSFs (Boring, 2010).
To sum up, future efforts in increasing the number of PSF should continue to be developed where it is desirable to achieve greater nuance and detail in the analysis. On the other hand, PSFs should be cluster into a small number of PSFs when it is important to ensure orthogonal definitions and values (Boring, 2010).

1.1.6 Modelling Human Cognition

Some of the various HRA methods attempt to model human's interactions with the system, considering separate facets of human, machine and situational characteristics (Reason, 1990). First generation HRA methods are concerned primarily on human behavior and machine performance, as the two main deterministic factors in human-system interactions. More recently, the effects of the human decision making, the relationship between the situation and human cognition and the cognitive work environment, have been incorporated into system analysis too (Groth, 2009). Therefore, the analysis of issues related to work psychology have developed and have broadened its interests (Green and Hoc, 1991). In the last years, systems became more complex, consequently the associated system failures are becoming more complicated too. In this way, multidisciplinary approaches for complex situations have been developed in order both to describe and explain implied cognitive mechanisms.

Cognitive psychology approach aim to study human errors and to understand the mental processes responsible for committing them (Norman, 1981; Reason, 1990). Human error investigation starts from analysing the characteristics of human information processing. In this view, an error can be seen as a consequence of not having taken into account how a person perceives, attends, remember, makes decisions, communicates and acts in a particularly designed work system.

A first classical scheme, named "Skill-Rule-Knoledge" or "Step-Ladder", was proposed by Jens Rasmussen in the first 80s . He distinguishes three types of errors depending on the familiarity that the person has with the system. Investigating the level and degree of cognitive control involved in the erroneous behaviour, Rasmussen distinguished errors based on skills, rules and knowledge. Skill-based behaviours occurs when a person is very familiar with the task and his actions do not require conscious control. If one of these actions is poorly performed a skill-based error occurs. Behaviours based on rules occur when operations are performed with a set of well stored rules. In case of misinterpretation of the situational conditions, errors based on rules will occur. Finally, knoledge-based behaviours occur when a new problem situation is encountered and it is required to perfor non-familiar tasks. If the actions are not planned correctly, knowledge-based errors arise.

Other cognitive models were developed in order to find explanations of errors based on the cognitive behaviours. Some examples are "Fallible Machine" (Reason, 1990), "Simple Model of Cognition" (Hollnagel & Cacciabue, 1991) and "Contextual Control Model" (Hollnagel, 1993). Cognitive science offers the possibility to implement some cognitive simulations or models when the operator is involved in complex tasks, using interface design, analysis of human errors and reliability, and design of safety systems that compensate inherent weaker points of human cognition.

1.1.7 Historical Evolution of HRA in Industry

The origins of the interest in developing probabilistic risk assessments in HRA lie between the 1950s and 1960s years in aeronautic and US nuclear energy programme (Bedford and Cooke, 2001; United States Nuclear Regulatory Commission, 1975). The interest in the observation and analysis of human behaviour and its consequences for repetitive tasks in work operations began to be deepened through early methodologies and studies. These first techniques are commonly named as "first generation" methods. These tools were the first to be developed to help risk assessors predict and quantify the likelihood of human error (French et al, 2011).

The first and most famous methodology, actually used for human reliability analysis, is known as THERP (Technique for Human Error Rate Prediction, Swain and Guttmann 1983), which became available as a draft in 1981 and published formally in 1983. Others most largely used methods of the I generation are SLIM (Embrey et Al., 1984), HCR (Hannamann et al., 1984), HEART (Williams, 1985), BE-SAFE (Simpson, 1985), HERA (Kirwan, 1996) and HAZOP (Ibc, Vectra technologies Ltd, 1995).

The Human Reliability Analysis Event Tree method (HEART) (Williams, 1985) is a good example of a method that aims to use many of the same features, but in a simplified setting, to give a more straightforward approach. Recognising that many tasks have an associated time for completion, the Human Cognitive Reliability method (HCR) (Hannaman et al. 1984) models the time to successful completion. A wider review of these and many other methods is given in (Kirwan, 1994).

First generation approaches have a descriptive tendency of the events, centred on skill and rule base level of human action. The process starts from the attitude to break a task into elementary component parts and then consider the potential impact of modifying factors combined to determine a nominal Human Error Potential (HEP). Hollnagel (1993) referred to this general approach as decomposition, where the human operator is treated just as another component of the system. Main features developed in first generation methods, mainly in

THERP, account use of task analysis, nominal probabilities for task failure and early adjustment factors to take account different performance conditions.

Only the formal aspects of the external behaviour are observed and studied in terms of errors, regardless of the reasons and mechanisms that led them to the level of cognition. For this reason, first generation HRA methods are often called *behavioural*. A result of this total decontextualisation, these models do not take into account the level of experience of the operators and the socio-technical work environment; this causes substantial problems in the presence of common causes of failure, that naturally characterize human errors.

After the rapid development of HRA in the 1980s, it was necessary to critically analyse the established practices. Swain (1990) pointed out that the well-known HRA methods suffered from a number of shortcomings, which can be summarised as follows:

1. *Less-than-adequate data on human performance*: for quantitative predictions of human behaviour in complex systems.

2. *Less-than-adequate agreement in use of expert judgment methods*: lack of demonstration of satisfactory levels of between-expert consistency and accuracy of predictions.

3. *Less-than-adequate calibration of simulator data*: analysis of how raw data from training simulators should be modified to reflect real-world performance.

4. *Less-than-adequate proof of accuracy in HRAs*: lack of demonstration accuracy of HRAs for real-world predictions.

5. *Less-than-adequate psychological realism in some HRA approaches*: presence of questionable assumptions about human behaviour, sometimes even not traceable.

6. *Less-than-adequate treatment of some important performance-shaping factors (PSFs):* such as managerial methods and attitudes, organizational factors, cultural differences, and irrational behaviour.

All these factors affect the validity of these methods, therefore scientists, aware of these limits, often provided overestimated values of HEP with very wide limits of uncertainty (Swain, 1990).
In the nineties, as a result of complex analysis of catastrophic accidents such as those at Three Mile Island in 1979, Chernobyl in 1986 and the Space Shuttle Challenger in 1986, it was understood that accidents are not only generated by technical or human failures. Causes must be sought in the interaction of multiple components: technological, human, organizational, in relation to each other and with the external environment in which the organization operates. The problem of human reliability has increased its level of complexity. This challenge led to the development of several new methods focusing on the cognitive aspects of human behaviour, known as the "Second generation" methods of HRA, of which the best known are ATHEANA (A Technique for Human Error ANAlysis; Cooper et al., 1996), CREAM (Cognitive Reliability and Error Analysis Method; Hollnagel, 1998), and MERMOS (*Méthode d'Evaluation de la Réalisations des MissionsOpérateur pour la Sûreté;* Bieder et al., 1998). Second generation HRA methods attempted to incorporate contextual effects such as tiredness, stress, emotion, stress, training, group interactions and organisational structures (Hollnagel, 1993). They are based on new models of taxonomy, it is an example Norman Taxonomy that distinguishes errors in slips, mistakes and lapses.

Additionally, third generation HRA methods, also called simulation-based HRA, are dynamic modelling systems that attempt to reproduce human decisions and actions (Boring, 2007) allow for the potential variation in response.

1.1.8 First and Second generation HRA techniques

Even today there is no single consistent guidance that determines which methods can be considered uniquely first or second generation, but it is possible to identify some significant differences.

For example a main consideration is about the use of cognitive factors: Hollnagel arguments that first generation methods do not take into account cognition in modelling PSFs, differently from second generation ones. First generation methods focused on the operator actions (as phenotypes), with their consequences, and attempted to provide a quantitative estimation of human error (i.e., the HEP). The human influence in a work situation is expressed by means of the Performance Shaping Factors (PSFs), which are independently quantified and expressed by a single value to adjust the HEP. Despite all these disadvantages, behavioural techniques are widely used as easily and immediately reliability methods that want to take into account the human factor. In addition, The HRA community delineated that first generation methods intensely focus on errors of omission, while second generation mainly on those of commission.

HRA community made a simpler distinction between the various methods can be done in terms of chronology. In fact, the older methods, the first to be formulated, are those of first generation; while the descendants, most recent ones, are those of the second generation. In this way it is possible to justify from an historical point of view the rise of late cognitive psychological movements only developed in last decades in second generation methods (Boring, 2007).

First generation HRA has a macroscopic view and the behavioural analysis is always carried out making some simplifying assumptions with a reasonable degree of realism (Hollnagel, 2009). On the other hand, a more realistic set of assumptions would have consider that actions always take place in a context, that it is not possible to have a set of normal conditions for human actions and that PSFs are not independent of each other. Consequently, another distinction have been drawn based on the consideration of the context: adherents of the ATHEANA HRA method argument that only second generation techniques carefully consider and model the influences of context in which humans made errors. It was recognized that the variability of working conditions in most cases, have dominated the variability of the performance of the individual human. This led to a change in later methods, which now emphasize on performance conditions.

Second generation HRA changed the focus from the human action to the individual - working conditions and context interaction, considering also cognitive processes as perception, detection and interpretation. The cognitive analysis has a microscopic view and considers the genotype, also called “cognitive error”, instead of the phenotype or “error mode” specific of the first generation methods.

To sum up, in order to distinguish methods of the second generation, it is possible to identify four classificatory Cs factors —Cognition, Context, Commission and Chronology— even if, as already said, it is not possible to clearly determine the suitability or quality of a particular HRA method generation instead another (Gertman et al., 2005; Boring, 2007).

1.1.9 Towards the Third generation of HRA

Nowadays a lively debate is not only about the distinction between classification and methods of the first or second generation, but it also deals with the introduction of a new "third generation". In fact, interesting studies and researches on human performance simulation are currently being developed. The third generation is not replacing the methods of first and second generation, but is supporting them in parallel, encouraging them to continue to be researched and improved. First and second generation techniques are very useful to be implemented in classifying and quantifying efficiently human performance efficiently in static task of operating events. On the other hand, third generation provides a dynamic modelling system for HRA, reproducing human decisions and actions as the basis for its performance estimation (Boring, 2007). In order to analyse and reproduce the performance of humans in actual scenarios and environments both simulation (virtual environment and virtual performers) and simulators (virtual environment with human performers) may be used to produce a log of performance over time in different tasks (Bye, 2006).

A major advantage of simulation is that it can be run through a broad range of scenarios in a variety of normal and off-normal conditions, with easier and more cost effective repeated trials. Simulation-based HRA allows to model varieties of human behaviours across series of replications and consequently it may utilize a frequentist approach for calculating HEPs.
It is important to have awareness that there is still no modelling or simulation tool that yet completely or perfectly combines all the elements of simulation-based HRA (Boring, 2007). The work already underway is significant, but further research is still necessary to improve and ensure efficiency, accuracy and completeness in the knowledge of human performance.

1.2 Human Reliability Analysis in Healthcare

Themes of clinical error and healthcare risks are currently issues of great interest since they have a strong social impact (Verbano & Turra, 2010).
In recent years, the healthcare environment has been characterized by several technological and normative changes, as well as biomedical-scientific progress. In the past, for example, healthcare system used to rely only on human–human interaction (doctor-patient), while nowadays, thanks to new technological system development, doctors are asked to collaborate with machine (i.e. robotic assisted surgery). All that contributed to increasing the efficiency and medical goals, but at the same time has raised the level of organizational complexity in hospitals (Cagliano et al., 2011; Cuschieri, 2000). Healthcare theatre is characterized by hazardous activities carried out in large, complex organisations by dedicated highly trained people and by a continuously changing environment in terms of technology (e.g. high technology monitoring and vigilance of anaesthetists). Hospitals are characterized by a large number of processes, actors, multiple professional experiences, non-uniform management models, patient specificity and obviously surgery complexity (Cagliano et al., 2011).

In last decades, it has been observed greater attention to cost containment, reduction of inpatient days, but also an increase in staff working hours, greater stress and growing number of healthcare service users due to an increase in average lifetime. As a result, new managerial models and systemic approaches are needed to detect waste, errors and to reduce clinical risks impacting on patients (Cagliano et al., 2011).

The healthcare system is a socio-technical complex system in various aspects, on a par with other industrial contexts. Consequently, it is subjected to human errors, adverse events and system failures that cannot be eliminated, but at least should be controlled and prevented as much as possible (Verbano & Turra, 2010). An adverse event may result in disability, death or prolonged hospital stay. Clinical risks are related to a large set of activities that may affect patients' safety, both directly and indirectly, occurring during multiple hospital processes, from disease identification, therapy prescription, thorough preparation, distribution, administration and so on (Cagliano et al., 2011).

The closeness of the comparison between healthcare and industry depends on which aspect, which actor and which process is considered (Lyons, 2004). It is not possible to assume an easy and straightforward transition of the HRA application from industry to healthcare: parallels can be drawn underlining similarities and important differences. This is a complex and daunting task that starts from the awareness of the need of standardisation, evaluation, consistency in terminology and exploration of strengths and limitations of the various methods, in order to understand which are more feasible and suitable for the healthcare context (Lyons, 2004).

Industrial field is a complex system characterized by high level of repetitively, predictable hazards, largely routine works, based on the machine-environment-human interaction. Consequently retrospective analysis are performed, with estimation of nominal values that experts judgment use to develop HRA methodologies. On the contrary healthcare sector is much less predictable, because it faces very high levels of uncertainty. Even if same actions are routinely (such as blood products) and they can be organised on a production line basis, hospital theatre is highly unpredictable, potentially harmful (e.g. treatment of acute psychosis or emergency medicine) and mainly not repetitive: any surgery procedure is different from another and often complications occur. Sometime it may be difficult to diagnose diseases: they are complicated by multiple co-morbidities and consequently the results may not be clear (Lyons, 2004).

1.2.1 The Surgical Environment

The surgical operation room (OR) is a very complex place, where highly skilled and dedicated personnel interact with trained subspecialists using sophisticated equipment (Wahr et al., 2013). In this environment many potential factors may interfere with surgery and lead to failures, in particular when they combined together (Wong, Smith & Crowe, 2010). Main potential factors are determined by the patient, surgeon technical skills, surgeon-related factors (such as fatigue and stress), training, knowledge, organizational culture and quality of decision-making. Additionally, adverse events may arise due to cognitive aspect and nontechnical skills, which are behavioural and interpersonal skills not specific to the technical competence of a single profession, such as teamwork communication, cooperation, coordination and leadership (Amato et al., 2012).

In general, "once patient outcomes have been adjusted for patient risk factors, the remaining variance is presumed to be explained by individual surgical skill" (Vincent et al., 2004). In order to improve patient outcomes, it has been researched that physical environmental and ergonomics have a main role in optimizing the operating theatre: in fact, lighting, noise, music, theatre temperature, posture should be controlled and adjusted to make the surgeon more comfortable and consequently improve safety and quality (ElBardissi & Sundt, 2012; Wong, Smith & Crowe, 2010).

The Swiss cheese model (Reason, 1990), well-adopted in the industrial field, is also a good representation of healthcare high-risk procedures. This model well describes contribution of active and latent failures in organization, hospital management and individual human contributing errors. An adverse outcome (i.e. mortality or morbidity) arises when there is an alignment of all the 'holes' in each defensive layer (Wong, Smith & Crowe, 2010), as it is shown in the figure below (Wahr et al., 2013).

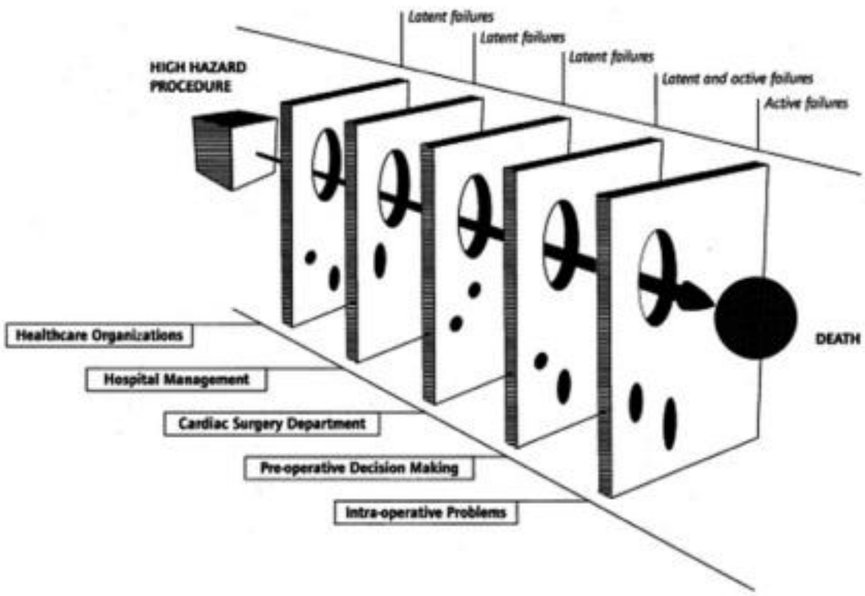


Figure 4: Reason's Swiss Cheese model applied to healthcare procedure

Risk management in healthcare is fundamental to improve the quality of the healthcare services and guarantee the safety of the patient. It is based on the implementation of a group of actions and defences able to encourage ideal working conditions and to stem the consequences of any potential error (Verbano & Turra 2010).

1.2.2 HRA Applications in Healthcare

Because of the human-centred nature of healthcare systems, managing the associated risks in healthcare have been developed according to Human Reliability Assessment methods (Cagliano et al., 2011). Surgical studies try to investigate surgical performances, outcome and complications that may arise as a result of surgical error. Moreover, it is fundamental to identify the performance shaping factors (PSFs) which affect human performances and may result in surgical complications, in order to implement corrective actions that reduce the likelihood of recurrence (Joice et al., 1998).

HRA is a useful tool used for both retrospective and prospective analysis that, as already said, is well developed in industries, such as nuclear power, chemical and petroleum industries. While incident investigation techniques is also used in healthcare sector (such as root cause analysis), adoption of the corresponding predictive safety assessment techniques is still sporadic and applied only in certain healthcare areas (Lyons, 2004). The rare application of error analysis techniques associated to risks in healthcare can be attributed to safety culture and to the fact that there is low awareness of the usefulness of these techniques in this area. As a result of that, HRA methods applicability and feasibility is not widely taken into account in the clinical context (Lyons, 2004).

The first healthcare application of HRA was adopted to address laparoscopic cholecystectomy surgery in 1998. It was based on direct observation to assess human error in endoscopic surgical performance (Joice et al., 1998). This modified HRA methodology, used in laparoscopic clinical surgery and in other clinical settings, became the basis for the validated system of Observational Clinical Human Reliability Assessment (OCHRA) (Tang et al., 2006).

“OCHRA has the additional merit of objective determination of the proficiency of a surgeon in executing specific interventions and is adaptable to the evaluation of safety and proficiency in clinical activities within the preoperative and postoperative periods" (Cuschieri & Tang, 2010).

Lyons underlines that application of HRA techniques should be used to support a lot of aspects, such as "in the design of surgical instruments, in decisions about the labelling of dangerous drugs, in designing a system of double checks for drug administration, in the design of work processes such as booking appointments or patient flow in Accident and Emergency, in identifying the factors that lead to high stress and liability to error in clinicians, and in the analysis of the range of factors involved in a serious incident and in the subsequent implementation of safety solutions across a clinical department or healthcare system" (Lyons, 2004). Thanks to these systematic applications it would be possible to obtain a more detailed and more comprehensive analysis than simple audit or common sense solutions (Lyons, 2004). An updated version of literature review (June 2007) includes primary HRA techniques with practical or only potential application in healthcare, shown in (Table 1- Lyons 2009).

The most relevant healthcare HRA applications are implemented in surgery, such as endoscopic laparoscopic surgery, radiotherapy, cataract surgery, as well as in nursing practice. Additionally, it has been observed that there is the tendency to modify existing HRA techniques to adapt them and make them more suitable for the healthcare sector.

From literature review it emerges that application of HEART technique prevails in the healthcare sector among other industrial methods. Recently authors used modified versions of HEART HRA technique for healthcare applications and, thanks to validated results, it was demonstrated the suitability of the technique in the mentioned sector (Chadwick & Fallon, 2011). In fact, some modifications, from the generic HRA method, are needed in order to make this technique more feasible to clinical practice. By applying HEART methodology it is possible to analyse the mechanisms underlying technical and human errors, committed during surgery, and consequently improve surgical safety.

Lyons considers that, since both HEART and THERP are well-validated quantitative-error-analysis techniques, broadly applied in the nuclear industry, they should be conceptually useful also in the healthcare sector. While the adaptation from industrial settings to healthcare problems is particularly challenging, time consuming and complex with THERP technique, instead HEART is conceptually less involved and produce more immediate practical outcomes (Lyons, 2004).

HEART technique has been proposed as a useful HRA tool for application in healthcare due to the fact that it is very simple and quick to be applied and its flexibility allows analysts to implement it in a wide range of contexts. It is a versatile simple human-reliability-calculation method, that requires relatively limited resources to complete an assessment. Moreover, it provides proposals on improvement measures for reducing the occurrence of errors (Bell & Holroyd, 2009).

1.2.3 HEART capabilities and limitations

"HEART was designed to assist engineers to assess the likelihood and impact of human unreliability on system performance. It was designed as a quick, easily understood, systematic, repeatable and responsive tool, which identifies the major influences on human performance (Chadwick & Fallon, 2011)".

The peculiarity of this method is the consideration of 38 Error-Promoting Condition (EPC) and that it refers to whole tasks, instead of sub-tasks. HEART technique results to be more feasible to healthcare application than others HRA methods due to its flexibility. Moreover, since it does not require a Hierarchical Task Analysis (HTA) it requires less effort and time (Chadwick & Fallon, 2011).

On the other hand, some limitations of this technique have been identified. First of all, the high degree of subjectivity in the determination of the EPCs and the Assessed Proportion of Affect (PoA). For this reason, Castiglia and colleagues proposed to introduce fuzzy linguistic expressions (Very low(VL), Low(L), Medium(M), High(H) and Very High(VH)) to better represent PoA factors. In fact, this is considered the most subjective and imprecise parameter (Castiglia et al., 2010).

The application of the HEART method led team members consider broadly the variety of factors and conditions that may influence the safe completion of the task. The choice of the EPCs that have major influence on the operator's task performance and their number are crucial issues that need to be consider carefully to have a right evaluation of possible errors.

Another disadvantage of HEART method is that it does not consider the interdependence between EPC and it must be considered that the hypothesis of independence is hardly applicable under real condition. A negative consequence that can happen is the potential double counting; in fact, some EPCs' elements are implicit in the task description. It has been also observed that "HEART technique requires greater clarity of description to assist users when discriminating between generic tasks and their associated EPCs; there is potential for two assessors to calculate very different HEPs for the same task" (Bell & Holroyd, 2009).

1.2.4 HEART applications in Healthcare

As already mentioned, some features of the traditional HEART technique have been modified, in order to obtain a more suitable method for healthcare application. A first example of modified HEART application is represented by Ward and colleagues investigation into a surgical incident involving the accidental retention of a guide wire for central venous catheterisation (CVC), inside a patient's venous system (Ward et al., 2004). Three critical sub-tasks were analysed individually, by a team comprising a safety engineer, a human factors expert and a medical student. Only 12 EPCs, rather than the original 38, were considered in the analysis. Additionally, Ward and colleagues underline pro e cons of HEART traditional technique, considering its usefulness in healthcare application and suggesting HEARTH, HEART for Healthcare. The researchers pointed out some difficulties encountered in the work, for example due to difficulties in the interpretation and translation of the descriptions, lack of accurate data and high degree of variability of the context (Ward et al., 2004).

A second example of modified HEART application was used to assess the impact of the so-called error-promoting-factors in radiological medical-operators' exposure, working in a high dose rate (HDR) brachytherapy irradiation facility (Castiglia et al., 2010). HEART technique has been modified on the basis of fuzzy set concepts to evaluate the probability of human errors, taking more directly into account the uncertainties of error-promoting factors.

A further study of application of modified HEART technique were developed by Chadwick and Fallon in 2011 to analyse a critical nursing task in a radiotherapy treatment process (Chadwick & Fallon, 2011). "Record Abnormal Blood Results" was the critical task analysed with HEART technique, by determining the factors that mainly influence the completion of the task. When errors occur in radiotherapy surgery there can be really serious consequences (also death). In the last decades, radiotherapy treatment has changed significantly with the introduction of computers controlled accelerators, sophisticated software-based treatment planning models and advanced technology systems, in order to support staff, to deliver advanced treatment modalities and to reduce potential risk of human errors (Chadwick & Fallon, 2011). On the other hand, the introduction of automation has led to the emergence of new errors, due to lack of integration of automated and human components (Reason, 1990). Modern radiotherapy treatment exhibits many similarities with engineering process systems, such as: underpinned by physics, predictable flows, advanced technology, sociotechnical systems, quality and safety systems and standards (Fallon et al., 2009). As already mentioned, the traditional HEART technique presents some limitations that needed to be modified: for example it is important that the nursing team formed the assessment team, the Assessed Proportion of Affect (PoA) for each EPC is determined through Graphic Rating Scale (GRS), some steps of the methodology have been modified, as well as the set of EPCs considered. In particular, the EPCs chosen by the modified HEART assessment team were *a shortage of time available for error detection & correction (contribution to unreliability: 49%), no obvious means of reversing an unintended action (31%), little or no independent checking or testing of output (14%), task pacing caused by the intervention of others (6%)* (Chadwick & Fallon, 2011).

Furthermore, another study investigated operator errors during high-dose-rate (HDR) therapy, that can led to adverse clinical effects, including death (Castiglia et al., 2014). HEART and THERP integrated methodology is proposed for the human error assessment of potential radiological over-exposure of patients during HDR treatments. THERP technique were used to draw the event-tree of errors in two different tasks *(Computation of dose distribution* and *Textual documentation of dosimetry details*), dividing them into subtasks and determining if the task were correctly performed or not. The stages of the task were reported in a logical order, that allowed a more accurate error assessment. For each subtask HEP probability was obtained using fuzzy HEART and assessing the following EPCs: *little or no independent checking or testing of output, mismatch between perceived and actual risk, information overload, transfer knowledge from one task to another, poor ambiguous or ill-matched feedback and ambiguity in the required performance standard* (Castiglia et al., 2014). An advantage of this modified approach is that it adopts, as well, a fuzzy linguistic expression (Very Low (VL), Low (L), Medium (M), High (H) and Very High (VH)), that simplify the consideration of expert judgements. In addition, some weakness of THERP method are exceeded, since the THERP and fuzzy HEART integrated methodology considers the state and the importance of different factors that determine the task performances (Castiglia et al., 2014).

The table below summarizes the results obtained by comparing HEART healthcare applications described above. In particular, it has been pointed out the clinical setting and objectives of the studies and the modifications applied to the traditional HEART technique, taking into account Error-Promoting Conditions (EPCs) considered.

Table 4: Literature review of HEART applications in healthcare sector

Authors	**Title**	**Clinical setting**	**Objectives**	**Variations from traditional HEART**	**Errors Promoting Condition (EPCs) considered**
Ward et al., (2004)	"Healthcare Human Reliability Analysis- by HEART"	Central Venous Catheterisation (CVC) procedure	To examine the risks surrounding guide wire use and potential for further occurrences of its retention within the patient's body.	Three critical sub-tasks were analysed individually The team was composed by safety engineer, human factors expert and a medical student. An abbreviate form of HEART was used comprising 12 EPCs instead of the original 38.	Not mentioned (12 EPCs rather than the original 38 were considered)
Castiglia et al., (2010)	"Risk analysis using fuzzy set theory of	Brachytherapy procedures	Risk analysis to evaluate the impact of Error-	Use of fuzzy linguistic expressions to represent by	1-17 EPCs of the original 38 were considered.

	the accidental exposure of medical staff during brachytherap y procedures”		promoting conditions on human error, contribution of single event to the uncertainty in the probability if system failure	words the values of PoA. Fuzzy linguistic variables (VL,L,M,H,VH) represented by triangular functions.	Relevant EPCs for the application: (2),(3),(4),(12)
Chadwick and Fallon., (2011)	“Human reliability assessment of a critical nursing task in a radiotherapy treatment process”	Radiotherapy treatment process	Prior identification of potential errors during a critical nursing task. Percentage contribution to unreliability and specification of appropriate defences against them.	Team to complete the assessment (not single expert assessor as in traditional HEART) composed by three of the department nursing staff. Team based step (2-7) of HEART differs from traditional. Nursing staff, responsible to complete the selected critical task, formed the assessment team (as opposed to an external expert assessor). Team members' expert PoA was identified by Graphic Rating Scales (GRS) method.	EPCs of Williams classification. Relevant EPCs for the application: (2),(7),(17),(36)
Castiglia et al., (2014)	“THERP and HEART integrated methodology for human error assessment”	High Dose Rate (HDR) treatments	Human error investigation during HDR treatment using THERP an HEART integrated methodology. Prioritization of an exhaustive list of erroneous tasks leading to potential radiological over-exposure	Fuzzy HEART method as proposed in (Castiglia et al., 2010) (and fuzzy interval of the error probability in the event-tree obtained by THERP). Two main tasks were analysed and each of them was divided into sub-tasks. Each	1-17 EPCs of the original 38 were considered. Relevant EPCs for the application: (8),(10),(11),(12),(13),(17)

			of patients.	sub-task were analysed by HEART technique (rather than whole task as in traditional HEART). Probability failure of the two main tasks was calculated by its fuzzy event-tree.	

Measurements of incident resulted difficult because of the lack of audits to make comparisons with, large variability existing in the healthcare context (between staff and EPCs in different locations). Difficulties were identified in interpreting and translating many descriptions (e.g. GTT and EPCs), originally developed in the nuclear industry field. At present, Human Failure experts, which would facilitate HEART application, are still scarce in healthcare analysis, as well as accurate data (e.g. incident reporting and analysis) that would compare results against reality (Ward et al., 2004).

Both Ward and Castiglia identified some advantages of HEART technique that results to be time efficient, easy to lean and apply, publicly available and possible to be applied across a range of domains. Moreover, HEART method suggests development of measurement of improvement or possible solution to be implemented.

Some of the weakness of the methodology identified by Castiglia consist in the fact that EPCs are not independent of each other and traditional HEART is extremely subjective and heavily depends on the experience of the analyst. For this reason a modified version of the methodology is illustrated considering the concept of fuzzy linguistic expression to represent the PoA that is considered the most subjective and imprecise parameter. Chadwick and Fallon recommended a detailed discussion of the HEART error categories and EPCS to be provided to assist future studies in the healthcare domain. In fact, during the analysis there were some misunderstandings of the use of definitions and it has been noticed that the study strongly depends on the contribution of a suitably experienced HRA and human-factors assessor. The resources pointed out the need of additional applications of HEART in healthcare sector to support the validity of the application of the tool and the usefulness of its quantitative probabilistic outputs (Chadwick & Fallon, 2011).

1.2.5 Needs and Gaps in applying HRA and HEART in Healthcare

There is considerable scope for many available HRA techniques to be applied to many aspects of healthcare (Lyons, 2004), but dedicated researches are necessary to support selection through collation of experts' experience and practical case studies (Cuschieri, 2000). In fact, literature demonstrates that there are inconsistencies or lack of specificity of resources required, such as time required for each type of technique, informational data about process and individual aspects involved in the analysis. These factors all contribute to lead healthcare professionals carrying out simpler analyses, because they have limited time and support to select an appropriate technique and invest in education for predictive safety analysis (Lyons, 2009).

In the last decades there is an increased consensus around concepts of "healthcare risk management" and "medical errors". Detailed studies are required to investigate surgical performance in terms of outcome and complications that may arise, in order to underline errors and corrective actions that can reduce the likelihood of their recurrence (Joice et al., 1998).

Chadwick and Fallon states that "it is acknowledged that the HEART technique may not be suitably developed or sufficiently generic for application to all healthcare related tasks without further development or modification. However, the technique provides a quick and highly usable method for the analysis of many healthcare tasks including data entry and data transfer" (Chadwick & Fallon, 2011).

Due to the limited number of applications in healthcare sector, it is difficult to express complete confidence in the results' validity. Need of additional application of HEART in healthcare is required to support its useful applicability. In fact, its validity has already been established in the industrial field (Kirwan et al., 1997), but further theoretical validations are needed in healthcare applications (Chadwick & Fallon, 2011).

1.3 Scope of the Work

Literature underscore the importance made by HRA techniques in the few surgery applications and the need to reduce the gap of applicability between the industrial and healthcare sector. In particular, the application of HEART technique in surgery requires a series of modifications placed to translate and convert this technique from the original industrial setting to the new one, reducing disadvantages and weaknesses. Starting from the needs and gaps found in literature, the following objects were identified for this work.

The first aim of this work is to develop a modified HEART ‘ad hoc’ for the healthcare sector. In order to do that, a specific taxonomy of Influencing Factors (IFs), validated in surgery, will be integrated in the technique, beside the original Williams’ EPC taxonomy. The new proposed method should be able to match the IFs relevant for a surgical environment with the original EPCs and to support a quantitative translation from one taxonomy to the other in a consistent way. The new proposal will be tested in a specific case study in robotic surgery.

This area was chosen because it well represents the complexity of healthcare systems and the close the man-machine interaction. Robotic surgery is an innovative sector, in ongoing development, which in recent years has had a huge worldwide spread. Its recent progress allows and requires implementation of studies, researches and specific methodologies applications of Human Reliability Analysis. In particular, robotic surgery has become the "gold standard" in the treatment of localized prostate cancer. The case study is based on the application of HEART methodology on a recent robotic prostatectomy technique performed with DaVinci robot, which allows to obtain excellent results both in oncological and functional terms. This innovative technique, called Retzius Sparing Radical Prostatectomy Robotics sec. Bocciardi (BA-RARP), uses only access through the Douglas, without the need to dissect the Santorini’s plexus, preserving numerous nerves and allowing to obtain fast continence’s recovery and improved recovery of erectile function.

The second aim of the work is to perform Scenario Analyses on the case study. In this way it is possible to investigate how likelihood of errors varies in different categories scenarios referred to personal, team and organizational aspects. Consequently, it was studied how Human Unreliability decreases by implementing some remedial actions proposed for each scenario category.

CHAPTER 2: THE EMPIRICAL SETTING

Introduction

In recent years Minimally Invasive Surgery (MIS) has undergone a remarkable development, through a very rapid evolution, that has seen the experimentation and adoption of more clinically effective prototypes, easy to handle and that can be integrated with various medicine branches. Modern surgery not only seeks to remedy the condition of the patient, but at the same time tries to minimize disruption and maximize treatment success (Hamad, 2010).

In particular, in the last ten years MIS market has been catalysed by the DaVinci robotic system, with a worldwide widespread distribution in advanced healthcare system. In the last decade Italy has implemented robotic surgery in its healthcare system and now it is one of the leading countries in Europe.

2.1 Minimally Invasive Surgery

Since the nineteenth century, the technological evolution had an incredible impact and a wide application in the medical-surgical sector. The technical and technological discoveries, such as the discovery of X-rays, have allowed to see the cavity and the inside of the human body, without necessity of significant incisions on the patient’s body. Since then, the diagnostics has undergone a huge evolution with many new techniques and innovative equipment. In addition, anaesthetic techniques were discovered in order to better control the pain and make patients accept surgeries with less fear and reluctance. Moreover, even the development of machinery for the instruments’ sterilization has contributed to the enormous development of surgical techniques, having a fundamental role in the control of infections (sometimes even fatal for the patient). All these factors have helped to reduce risks in surgery, to facilitate the execution and best outcome of the interventions, and consequently different new surgical techniques have been able to expand. In this way the traditional open surgery, typically invasive, gradually moved to the Minimally Invasive Surgery (MIS) or microsurgery. Minimally Invasive Surgery includes laparoscopic, endoscopic and more recently robotic surgery, which requires a separate discussion.

Endoscopy was born as a diagnostic and therapeutic technique, then it has developed until it became a surgical technique: in 1987, in Lyon, Philippe

Mouret performed the first successful cholecystectomy in humans. The new surgical technique, called Minimally Invasive, was born in Europe and quickly spread around the world. The minimally invasive approach has revolutionized the history of surgery. Its development is supported thanks to the numerous scientific evidences of the benefits of this discipline, such as its clear affirmation in oncology. The Minimally Invasive Surgery aims to achieve the same objectives of traditional surgical techniques, with the innovation to use mini-invasive access to the organs, through small incisions, specific instruments and video systems, in order to minimize surgical trauma to the patient. Mini-Invasive surgeries includes operations undertaken by laparoscopy, for organs contained in the abdominal and pelvic cavity, thoracoscopic, for organs contained in the thoracic cavity, and those interventions within hollow organs, such as transanal, transesophageal and transgastric surgeries. Today it is generally applied for cholecystectomy and antireflux surgery too and it is also emerging in other areas where traditional open surgery still resists. This change has been possible with the design and construction of new dedicated instruments, for example, the ultrasonic harmonic scalpel, the radio frequency one, the radiofrequency probe for cryosurgery, and so on.

The significant advantages which allowed the claim of this method are not only aesthetic, but mainly related to minor surgical trauma, which affects a quicker and less painful postoperative course, less exposed to infectious complications and faster reintegration of the patient into social and working life. Furthermore it is affirmed a considerable reduction of the time required to perform the surgery and best conditions of the patient. In fact, minimally invasive access involves less mental and physical impact for the patient, in addition to a significant reduction of surgical wound complications. As regards to the cost, it is considered that it doesn't constitute a decisive constraint, since Minimally Invasive Surgery allows a considerable economic saving due to the significant reduction in the hospital stay. This surgery technique neutralizes several disabilities, that for centuries had an impact on the development of the surgery, such as invasiveness, length interventions, risk of infection and high rates of hospital mortality. The benefits of MIS can be summarized as:

- small incisions;
- less mental and physical impact for the patient;
- less risk of infection;
- less wound surgery complications;

- hospital stays shorter;
- reduction of recovery times;
- less trauma for the patient;
- less pain;
- less blood loss;
- smaller skin scars.

However, Minimally Invasive Surgery is not a totally risks-free practice. Unfortunately, it is possible to have intraoperative complications, some very serious, especially due to, for example, an initial lack of experience, by the surgeons, in the use of complex technology components, poor coordination between team members or inadequate equipment and ergonomics of the workspace. In fact, studies show that many laparoscopic surgeons report neck, back, shoulder or hand pain and it has been reported that 87% of them regularly experience musculoskeletal pain during or after laparoscopy (Zihni et al., 2014). Furthermore, the use of minimally invasive instruments (e.g. trocars) denies surgeons the tactile feature of the operating gesture (Cao & Rogers, 2006). These limitations can be overcome through training activity, involving the use of simulators to pc, box trainer, educational videos, etc. (Guzzo & Gonzalgo, 2009). The development of these simulation supports has the aim to reduce, as much as possible, intra-operative complications associated to MIS surgery. The most significant disadvantages of this technology can be summarized as related to the following aspects:

- the need for the surgeon to move the instruments while watching a video monitor;
- expensive and special equipment required;
- maximum hand-eye coordination required, aggravated by the fact that the laparoscope is usually operated from the assistant and the hand-eye coordination of the operating surgeon is incredibly disturbed;
- the limited degrees of movement;
- the decrease / absence of the sense of touch;
- ergonomics problems;
- in laparoscopic surgery feedback is given from the laparoscope and therefore reproduced only in 2D vision.

Therefore, it is necessary that trainees and surgeons, approaching MIS for the first time, acquire skills in performing surgical procedures involving a minimally invasive access for the patient and in handling dedicated instrumentations, totally different from ones used in traditional open surgery (Hamad, 2010). In open surgery, the surgeon can manipulate patient’s tissues with his hands and with surgical tools, both providing a direct tactile feedback to the surgeon. Eye-hand coordination is normal and variations in the anatomy of the patient are carefully detectable thanks to eye and to direct touch. On the other hand, in Minimally Invasive Surgery, instead, the surgeon can access the tissue only through laparoscopic instruments; freedom of movement, perception of the forces and of the speed are lower compared to open surgery, and the number of degrees of freedom of the tools is considerably lower than that one of the hands. For these reasons, often surgeons agree to define laparoscopic surgery as more stressful than open surgery, due to the visual and instrumental obstacles, the higher level of concentration required and the important necessary training program (Guzzo & Gonzalgo, 2009; Berquer et al., 2002). Additionally, MIS requires additional safety concerns and precision requirements compared to traditional open surgery, and greater physical and visualmotor constraints on the surgeon (Cao & Rogers, 2006).

2.1.1 Robotic Surgery

Robotic surgery represents the most sophisticated new frontier of Minimally Invasive Surgery. Thanks to robotics it is possible to overcome some limitations of laparoscopic surgery allowing to extend the benefits of Minimally Invasive approach to complex surgery and to enhance the capabilities of surgeons performing open surgery (Binder et al., 2004).

The initial robot project were prepared by American Army and NASA in the 80s, and starting from 1995 it was developed by two American companies *Computer Motion* (Goleta, CA) and *Intuitive Surgical Inc.* (Mountain View, CA). The first company produced AESOP and ZEUS systems, that were approved from the Food and Drug Administration (FDA), respectively in 1997 and 2001. Intuitive Surgical Inc. produced the DaVinci robot, which received the FDA approval in 2000. Intuitive Surgical Inc. gradually obtained the market monopoly for robotic surgery with the DaVinci® system, especially after the acquisition of the rights of Computer Motion and the fusion of the two companies into only one in 2003 (Binder et al., 2004). The system has been rapidly adopted by hospitals in the United States and Europe for use treatments of a wide range of conditions: so far, the Intuitive Surgical has sold nearly 2500 robotic systems. The extent of robotic surgery practice varies widely due to a variety of factors, such as physician training, equipment availability and cultural factors. Over the years several applications have been developed in oncology, gynaecology, orthopaedics, maxillofacial, thoracic, paediatric, ophthalmology and cardiac surgery.

Robotic surgery, or robot-assisted surgery, allows doctors to perform many types of complex procedures with more precision, flexibility and control, which may have been difficult or impossible with other methods (Al-Naami et al., 2013). As already mentioned, robotic surgery has the intention to overcome limitations of laparoscopic surgery, for example flat two-dimensional vision, inconsistencies in instruments movements, unnatural surgeon positions, dissociation between vision and instrument control and inability to carry out micro sutures. Moreover, Robotic surgery maintains MIS positive aspects such as: reduced blood loss, less postoperative pain, early recovery of organ function, reduction of surgical infections, reduction of hospital stay and subsequent convalescence. Thanks to a computer and a remote handling system, the surgeon is able to reproduce the movements of the human hand in the surgical field (Al-Naami et al., 2013). The most widely used clinical robotic surgical system is composed by a camera arm and mechanical arms with surgical instruments attached to them. The first surgeon is seated at a computer console, detached from the operating table, and, from this position, he/she controls the robotic arms with high-definition, magnified, 3-D view of the surgical site. The surgeon leads other team members who assist the surgery at the operational table (Binder et al., 2004; Al-Naami et al., 2013).

2.1.2 DaVinci Robot

DaVinci System has a magnified 3D high-definition vision system, with magnification up to 15x and special wristed instruments that bend and rotate far greater than the human wrist. DaVinci Robot enables surgeons to operate with enhanced vision, precision, dexterity and control. This system incorporates the patented technology *EndoWrist*, which reproduces the movement degrees of freedom of surgeon forearm and wrist during the operation, providing up to 7 degrees of freedom (Ficarra et al., 2010).

DaVinci System allows a great versatility of movements, providing access to narrow and deep anatomical spaces (not always possible with laparoscopic); it gives highest surgical accuracy that cannot be compared with other techniques. Additionally, the 3D visualisation, freedom of instrument movement and intuitiveness of the surgical motion are able to the restore hand-eye coordination, that is usually lost in laparoscopic surgery (Al-Naami et al., 2013).

The DaVinci robot is the most advanced minimally invasive surgery system in the market. This robotic technology is available in two systems:

- Da Vinci Si: it arrived on the market in 1999 and it is considered the gold standard for medium complexity procedures in urology, gynaecology and general surgery in a single quadrant;
- Da Vinci Xi: it is an innovation system, introduced in Italy in 2014, it is the ideal tool for highly complex surgery and multi-quadrant surgical fields, allowing extreme freedom of movement. These features make it suitable for operations in the field of urology, gynaecology and general complex surgery, maximizing anatomical access and guaranteeing a 3D-HD vision.

The Da Vinci surgical robotic system is a master-slave telemanipulation system, consisting in a remote console, where the operating surgeon (master) directs the robotic surgical arms (slave) from a computer-video console (Ficarra et al., 2010). One of the robotic arms holds the videoscope, which provides binocular vision of the operative field, while the others hold instrument adapters to which specialised robotic instruments are attached. All instruments have articulated elbow and wrist joints, enabling a range of movement which mimics the natural motions of open surgery. The surgeon directs the robotic arms using master handles which sit below the video console and transmit the exact motions of the surgeon’s hands to the robotic arms. Additional videos can be positioned, inside the operation room, to facilitate the work of other members of the staff at the operating table. The computer console is able to filter hand/arm tremor and provides feedback, even if the majority of it is provided indirectly via the video monitor and the tensile feedback available from the robotic arms.

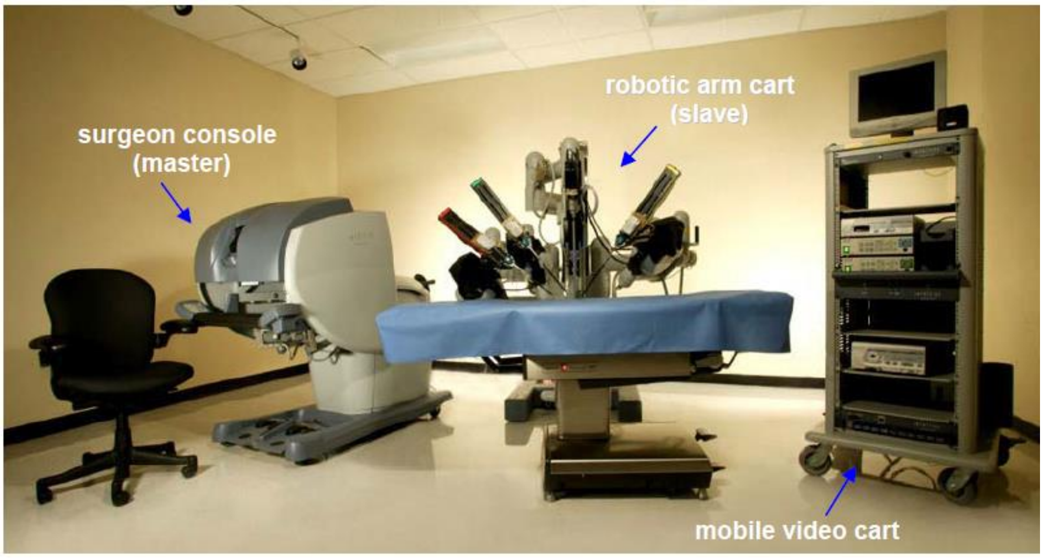


Figure 5: Typical set-up of robot system in operating room (Tooher & Pham, 2014)

Main features of the Da Vinci robotic system are:

- CONSOLE

The console provides the computer interface between the surgeon and the surgical robotic arms. It is positioned outside the sterile field, representing control center of the system, where the surgeon controls the 3D endoscope and the EndoWrist instruments by means of two manipulators (master) and pedals. The surgeon's hand movements are digitised and transmitted to the robotic arms which perform the identical movements in the operative field. Foot controls are used to activate electrocautery and ultrasonic instruments and for repositioning the master handles as necessary. The robotic arms are automatically deactivated whenever the surgeon's eyes are removed from the display. The surgeon has also the option to switch between full-screen view mode to a multi-image, which shows the 3D image of the surgical field along two other images (ultrasound, ECG), which provides auxiliary inputs. The reduction of tremor provide additional control that minimizes the impact of physiological tremor of surgeon's hands or involuntary movements.

- ROBOTIC ARM CART

The robotic arm cart is placed beside the patient on the operating table, holding the robotic arms on a central tower. One arm holds the videoscope and the others are used to attach the instrument adapters which are connected to robotic instrumentation through reusable trocars. The DaVinci system makes use of a technology in the remote center, a fixed point in space around which the robotic arms move (Tooher & Pham, 2014). This technology allows the system to manipulate instruments and endoscopes within the surgical site, while minimizing the force exerted on the body of the patient. It is also possible to perform manual positioning, in terms of height (relative to the base) and advancement and rotation of the group of arms up to a maximum of 270°.

- CART VIEW

It contains the central processing unit of images. It includes a 24-inch touchscreen, an ERBE VIO dV electrosurgical for delivering monopolar and bipolar energy, and adjustable shelves for optional auxiliary surgical equipment, such as insufflators. The DaVinci System Xi also includes a high-definition video (full HD).

- SURGICAL INSTRUMENTS AND ENDOWRIST™

The instruments EndoWrist® of DaVinci Xi have a diameter of 8mm and a length of about 60cm. They are equipped with a wrist that allows a freedom of movement on 7 axes and a rotation of almost 360°, mimicking the natural motions of open surgery. There are a range of different instruments available, which can each be used up to ten times. In the range of the robotic instruments we can find needle holders, graspers, scissors, small clip applier, microforceps, long tip forceps, ultrasonic shears, cautery with spatula, scalpel cautery, bipolar dissectors of different types and so on (Tooher & Pham, 2014).

2.1.3 Benefits and limitations

The Da Vinci robotic system offers several advantages, compared to open and laparoscopic surgery, for both operators and patients (Tooher & Pham, 2014), as shown in the table below:

Table 5: Major clinical and patient's advantages with DaVinci system (ab medica website)

Major clinical advantages	Major patient advantages

• Ease of access to difficult anatomies; • Excellent visualization of anatomical landmarks; • More detailed view of the cleavage planes; • Greater precision in the procedure; • Greater accuracy; • Ability to configure the accuracy of motion surgery	• **Small incisions with mild bleeding;** • **Less need for blood transfusions;** • **Less postoperative pain;** • **Reducing hospitalization time;** • **Reduced recovery times;** • **Faster recovery of normal activities**

Moreover, DaVinci system has several safety systems. For examples, when the camera is moved and repositioned the tools remain stationary; the system automatically enters “standby mode” when the surgeon removes the head from the console; and tools can be stopped during the repositioning of the robotic arms.

The robot does not replace the surgeon, but it becomes an extension, and its use is an important technological aid, but experience of the surgeon remains fundamental in the assessment, selection of information and execution of the operation. It is important to properly assess the status and condition of the patient, his/her disease and the "risk class" to which it belongs. For some patients, in fact, robotic surgery is definitely not suitable, unnecessarily expensive and perhaps even more risky than the traditional one; vice versa, for others it may be, in skilled hands, more precise and effective even of the laparoscopic surgery technique. Patients who are not candidates for non-robotic minimally invasive surgery are not candidates for DaVinci® Surgery too.

Robotic surgery offers many benefits over conventional laparoscopic or open surgery, however, there is a significant learning curve and substantial costs involved both in the initial purchase and ongoing servicing (Binder et al., 2004; Al-Naami et al., 2013). In fact, hardware and software updates are required, as with any computer-based equipment. Additional limitations of the DaVinci robotic surgery include: problems with the robotic set-up, in particular the additional time required to set-up the robotic system, and the size of the equipment; problems adjusting to the robotic system (primarily related to the learning curve and lack of experience); and problems of communication between the operating surgeon and the rest of the surgical team, particularly the

surgical assistant (Cao & Rogers, 2006). Robotic surgery undoubtedly disrupts the existing workflow and introduce modifications in the roles of every team member and teamwork, since it is based on a new way of conducing surgery (Lai & Entin, 2005). Moreover, technical difficulties may be encountered, related to the malfunction of the system, or collision of the robotic arms either with the patient, the surgeon or with each other, or problems with the instrumentation (Binder et al., 2004). Despite the improvements, there are still some unresolved problems typical of minimally invasive surgery: the assistant to the table, for example, remains bound to a two dimensional view.
Problems linked directly to the robot-machine instead concern the size and weight, which often encounter obstacles to adaptability of most operational rooms and therefore make it difficult handling and moving it (Lai & Entin, 2005; Cao & Rogers, 2006). Moreover, the high number of cables and wires inside the room, necessary to connect the various components of the system, can be dangerous both for the staff members and for the surgery itself, that can be compromised and therefore have a negative effect on the patient.

Da Vinci® Surgery may encounter severe complications, as any other surgery, which may require prolonged and/or unexpected hospitalization and/or reoperation. Examples of serious or life-threatening complications may be: injury to tissues/organs, bleeding, infection and internal scarring that can cause long-lasting dysfunction/pain. Main surgery risks can be attributed to equipment failure and human error. As reported from IntuitiveSurgical, specific risks include the following conditions: temporary pain/nerve injury associated with positioning; temporary pain/discomfort from the use of air or gas in the procedure; a longer operation and time under anaesthesia and conversion to another surgical technique, that results in a longer operative time, additional time under anaesthesia, additional or larger incisions and/or increased complications.

2.1.4 Robot applications

abmedica® reports inform that, over the last decade, the DaVinci System has brought minimally invasive surgery to over 2 million patients worldwide. In 2014 were made 570.000 robotic surgeries in the world, increasing of 9% compared to 2013. Gynaecology and General Surgery have driven the growth especially in the US; while Urology supported the robotics activities at international level. Since 2006, in Italy, there have been more than 45,000 robotic procedures that have seen the interest and involvement of a growing number of surgeons. This is also demonstrated by the increasing number of installations on the Italian territory, which now counts 74 installations. The graphs below show the increase of the number of procedure in the world in the last seven years and the DaVinci system installations' distribution in Italy.

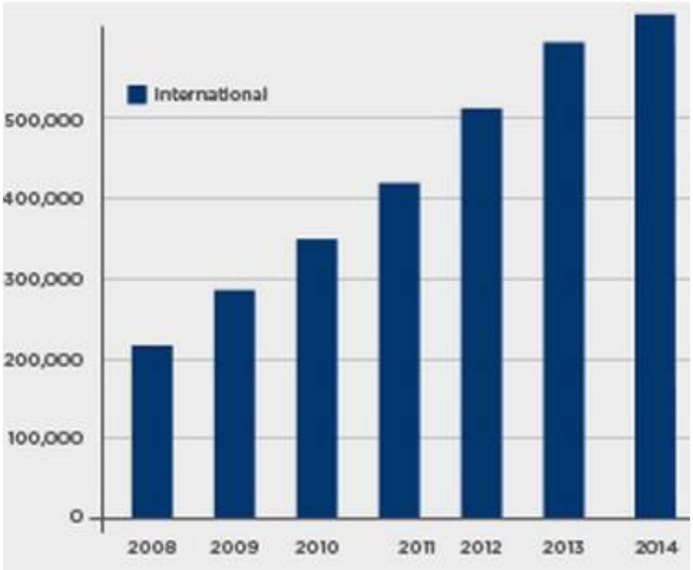


Figure 6: International increase of DaVinci surgical procedures

Figure 7: Italian DaVinci system distribution

Since its introduction on the market, the DaVinci Surgical System has been used successfully in thousands of procedures; its safety, effectiveness and superiority of the clinical results are proven in hundreds of scientific papers. The DaVinci surgical procedures are routinely performed in the specialties of:

- General and Vascular Surgery;
- Uro-Gynecological Surgery,
- Thoracic Surgery;
- Cardiac Surgery;
- Paediatric Surgery;
- Otorhinolaryngology,

The table below shows the main operations performed with the DaVinci robot, while the graph displays world installations of the DaVinci system.

Table 6: DaVinci surgical procedures

da Vinci® Procedures

Urology	Gynecology	Cardiothoracic	General
Prostatectomy	Hysterectomy	Mitral Valve Repair & Replacement	Gastric Bypass
Nephrectomy	Myomectomy	Single Vessel Beating Heart Bypass	Nissen Fundoplication
Partial Nephrectomy	Sacral Colpopexy	Multi-Vessel Beating Heart Bypass	Heller Myotomy
Pyeloplasty	Pelvic Lymphadenectomy	Single Vessel Arrested Heart Bypass	Gastrectomy
Cystectomy	Tubal Reanastomosis	Multi-Vessel Arrested Heart Bypass	Colon Resection
Donor Nephrectomy	Vaginal Prolapse Repair	IMA Harvesting	Thyroidectomy
Ureterolithotomy	Dermoid Cyst	Coronary Anastomosis	Arteriovenous Fistula
Pelvic Lymphadenectomy	Endometrial Ablation	Atrial Septum Aneurysm	Toupet
Adrenalectomy	Oophorocystectomy	Atrial Septal Defect Repair	Pancreatectomy
Cystocele Repair	Oophoroectomy	Tricuspid Valve Repair	Adrenalectomy
Excision of Renal Cyst	Ovarian Cystectomy	Thrombectomy	Hemi-Colectomy
Lymphadenectomy	Ovarian Transposition	Thymectomy	Sigmoidectomy
Testicular Resection	Salpingectomy	Esophagectomy	Splenectomy
Renal Cyst Decortication	Salpingo-Oophorectomy	Percardial Window	Pyloroplasty
Uretetro Transplant	Colposuspension (Burch)	Lobectomy	Gastroplasty
Nephropexy	Tubal Ligation	Pneumonectomy	Appendectomy
Ureterectomy	Tubalplasty	Pacemaker Lead Implantation	Intra-rectal Surgery
Rectocele Repair		Mediastinal Resection	Bowel Resection
Varicocele		Pulmonary Wedge Resection	Lumbar Sympathectomy
Ureteroplasty			Liver Resection
Ureteral Implantation			Cholecystectomy
Vaso-vasostomy			Hernia Repair

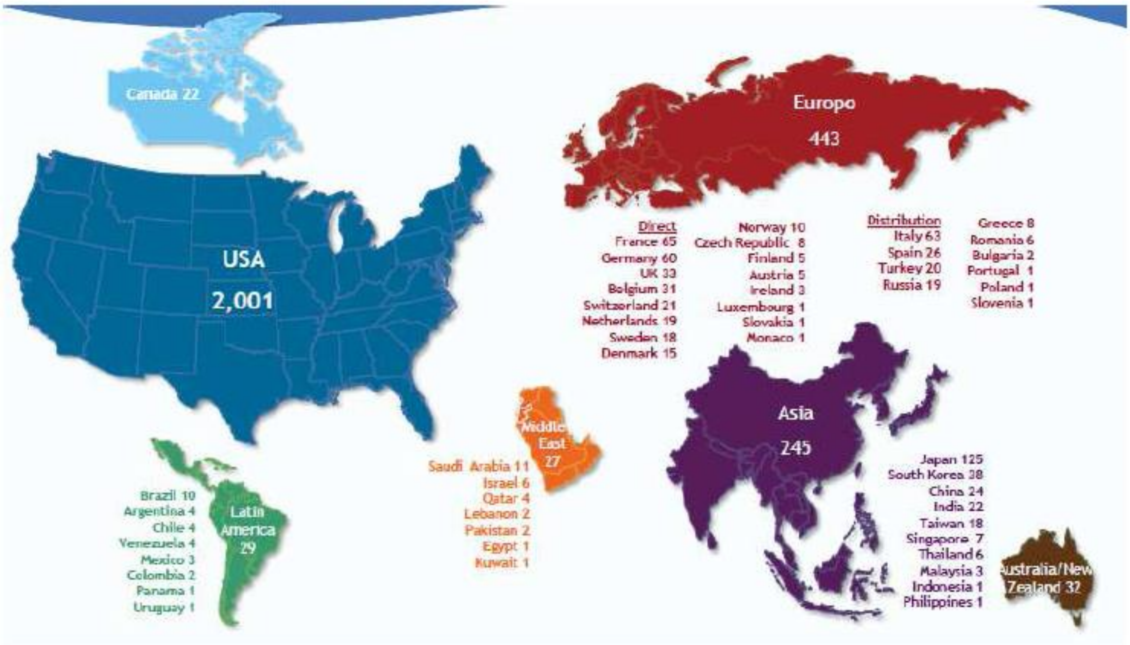


Figure 8: World distribution of DaVinci system

In particular, the series specialty in the world is divided as shown in the chart:

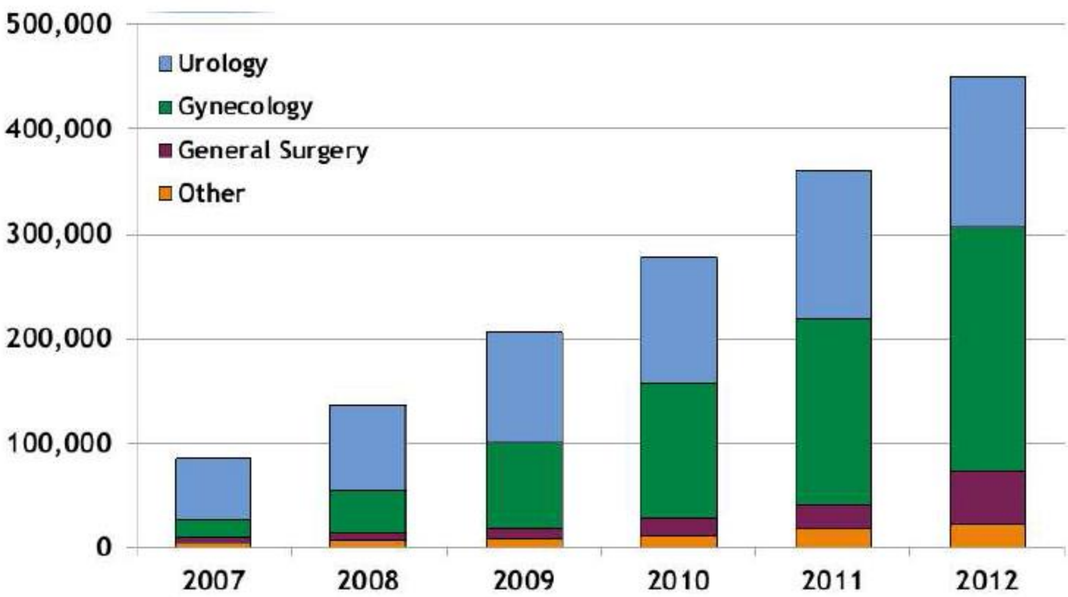


Figure 9: Increase of DaVinci speciality surgeries in recent years

Robotic Surgery has established itself as the best technique for the surgical treatment of prostate cancer. Today, in the US, over 80% of prostatectomies are performed with the aid of the DaVinci Surgical System. The immediate advantages of the use of this technology are a better and faster post-operative urinary continence and savings of optimal neurovascular bundles, with net benefits on erectile/sexual functions (more patients return to pre-surgery erectile function at 12-month check-up). Moreover, use of DaVinci robot in prostatectomy surgery allows to have more precise removal of cancerous, less chance of nerve and rectum injuries, less risk of deep vein thrombosis, lower risk of complications and shorter operating time (Rashid et al., 2006).
The introduction of robotics can offer to the patient oncological radicality and low impact on the quality of life, with early recovery of functional outcomes, compared to open surgery, and an earlier return to normal activities, thus improving the overall outcomes and satisfaction of the patient. The chart below shows the international increase of prostatectomy procedure performed with DaVinci robot.

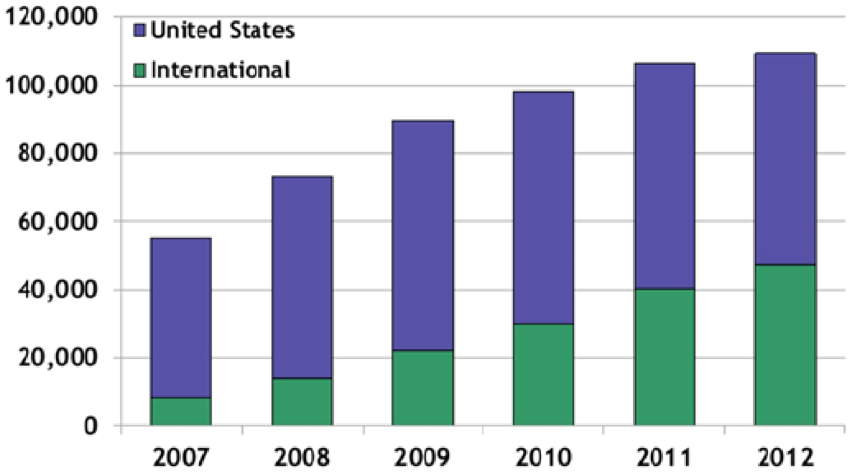


Figure 10: Trend of Prostatectomy surgeries performed with DaVinci system in recent years

CHAPTER 3: STUDY METHODOLOGY

Introduction

In last decades operations and safety performance analysts had a pressing need for an applicable human reliability data-base in several contexts. Sometimes it happens that a fully quantified data analysis is required, while in other case a qualitative level may be sufficient. At the end of the Nineteens, Williams developed *Human Error Assessment and Reduction Technique* (HEART) in response to the need of engineering community to have a quick, easy-understood and responsive method, which could be able to identify major influences on human performance, in a systematic industrial setting (Williams, 1986).

Given the generic nature of the HEART model, it is applicable to most human-machine-environment interaction tasks. This dissertation provides guidance for adapting the traditional methodology for specific applications outside of nuclear power.

There is considerable scope to develop and adapt HEART HRA technique for the analysis of many healthcare tasks, as it provides a quick and highly usable method for doing that (Chadwick & Fallon, 2011). For applications outside of the nuclear and process industry, the model need to be adapted through specific modifications. Future studies and dedicated resources are needed to support HEART method usefulness and applicability in this field. Literature demonstrates that collation of expert experience and practical case studies are still rare. The literature gap of HEART applications in healthcare stresses the concept that new theoretical validations are required to confirm its validity outside the industrial sector (Kirwan et al., 1997).

This chapter describes the proposed modifications to the HEART methodology, with the aim to develop a model 'ad hoc' for the surgery sector. A new HEART approach methodology was established to improve outcomes, which can be translated into clinical practice as surgical performances, thanks to modification, research and development.

3.1 HEART Traditional method in the Industrial sector

Human Error Assessment and Reduction Technique (HEART) is a first generation HRA method, initially published by Williams in outline form in 1985 and then described in more detail in 1988. Williams developed a simple and easy understandable technique to assist engineers, not only to assess likelihood and impact of human unreliability, but also to optimise overall system design (Williams, 1986). HEART is one of the few HRA methods that have been empirically validated (Kirwan et al., 1997). It has been successfully applied in many industries including nuclear, chemical, aviation and rail, with the aim to obtain reliable predictions about the probable extent of an error. It has been used as an aid in human reliability assessment, cost-effective design and operational performances decision making. HEART application allows to quantify error probability by applying multiplier factors associated to relevant Error Producing Conditions (EPC) of tasks being examined. HEART technique quantifies human errors of operator's actions, considering the type of job, ergonomics and environmental factors, that can affect task's performance. The probability of human error, expressed as likelihood of human unreliability, is then calculated as a function of the product of factors that have an effect on the task performance.

Williams' HEART technique is based on a number of premises. First of all, the basic human unreliability depends on the generic nature of the task to be performed. Secondly, given perfect conditions, the level of unreliability will be achieved consistently with a given nominal likelihood, within probabilistic limits. An important assumption of the HEART technique is that EPCs have generally consistent effects on human reliability. Indeed, the third premise focus on the fact that perfect conditions do not exist, therefore, the human reliability predicted will degrade as a function of the extent to which identified EPC might apply (Williams, 1986).

3.1.1 HEART design

The traditional HEART method structure can be divided in main functional steps, as shown in the diagram below:

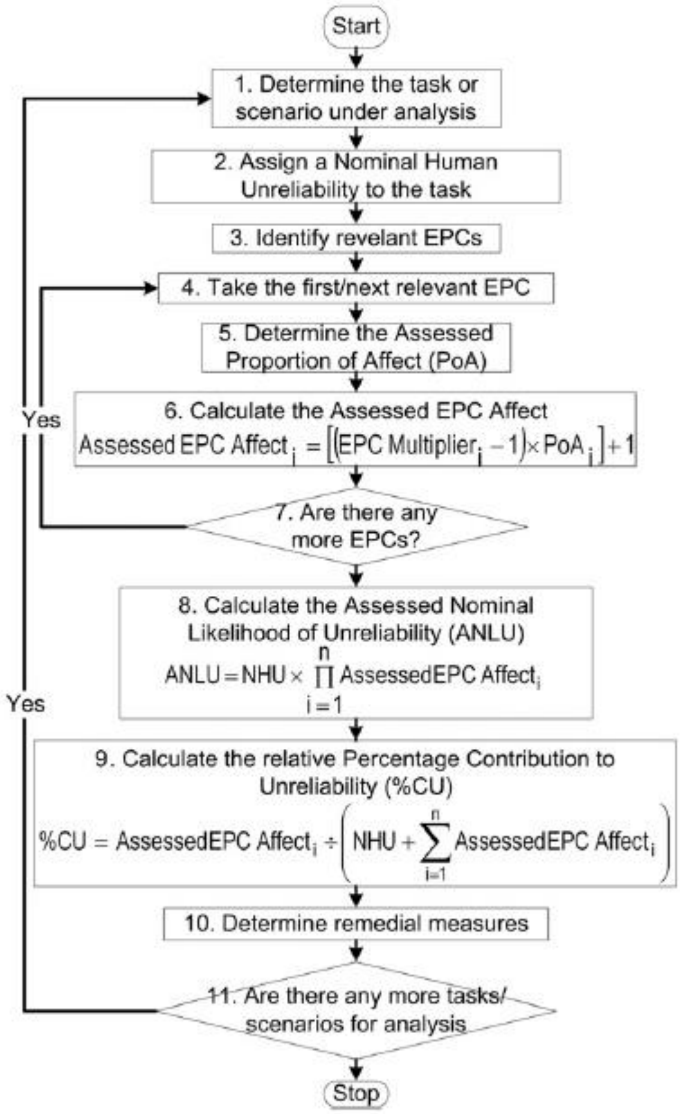


Figure 11: Flowchart representing main steps of traditional HEART methodology

The first step is the identification of the task under analysis (Step 1). There are eight Generic Task Types (GTTs) described in HEART method. The Nominal Human Unreliability (NHU), associated to the task, is then assigned using the HEART generic categories reported in the table below (Step 2).

Table 7: Generic Task Types (GTTs) and relative Nominal Human Unreliability (NHU)

Generic task	Proposed nominal human unreliability (5th–95th percentile bounds)
(A) Totally unfamiliar, performed at speed with no real idea of likely consequences	0.55 (0.35–0.97)
(B) Shift or restore system to a new or original state on a single attempt without supervision or procedures	0.26 (0.14–0.42)
(C) Complex task requiring high level of comprehension & skill	0.16 (0.12–0.28)
(D) Fairly simple task performed rapidly or given scant attention	0.09 (0.06–0.13)
(E) Routine, highly practised, rapid task involving relatively low level of skill	0.02 (0.007–0.045)
(F) Restore or shift a system to original or new state following procedures, with some checking	0.003 (0.0008–0.007)
(G) Completely familiar, well-designed, highly practised, routine task occurring several times per hour, performed to highest possible standards by highly-motivated, highly-trained & experienced person, totally aware of implications of failure, with time to correct potential error, but without the benefit of significant job aids.	0.0004 (0.00008–0.009)
(H) Respond correctly to system command even when there is an augmented or automated supervisory system providing accurate interpretation of system stage.	0.00002(0.000006–0.0009)

If none of these eight task descriptions fit the type of task under analysis, then the following values can be considered as reference points:

Generic Task	Proposed Nominal Human Unreliability (5-95th Percentile Bounds)
(M) Miscellaneous task for which no description can be found	0.03 (0.008-0.11)

By using the proposed Nominal Human Unreliability for the task, the analyst can examine what might happen to this value, if some of the Error Producing Conditions (EPC) are present to any extent.

From Table 8, the assessor chooses the relevant EPCs that mainly influence the operator's task performance (Step 3), paying attention not to double-count EPCs by overlaying them on generic tasks. Subsequently, the assessor determines the Assessed Proportion of Affect (PoA) (Step 5). Thanks to this value, that is rated on a scale from zero to one, it is possible to give a measure of each EPC effect magnitude. The Multiplier factor associated to each EPC is defined by Williams as "maximum predicted nominal amount by which unreliability might change going from good conditions to bad" (Williams, 1986). If an analyst perceives a multitude of applicable EPCs, then the model will tend towards further unreliability (pessimism) (Williams, 1986).

Table 8: HEART 38- Error-Producing Conditions (Williams, 1988)

Error-producing conditions	Multiplier
1. Unfamiliarity with a situation which is potentially important	17
2. A shortage of time available for error detection & correction	11
3. A low signal-to-noise ratio	10
4. A means of suppressing or overriding information or features which is too easily accessible	9
5. No means of conveying spatial & functional information to operators in a form which they can readily assimilate	8
6. A mismatch between an operator's model of the work & that imagined by a designer	8
7. No obvious means of reversing an unintended action.	8
8. A channel capacity overload, particularly one caused by simultaneous presentation of non-redundant information	6
9. A need to unlearn a technique & apply one which requires the application of an opposing philosophy	6
10. The need to transfer specific knowledge from task to task without loss	5.5
11. Ambiguity in the required performance standards	5
12. A mismatch between perceived & real risk	4
13. Poor, ambiguous or ill-matched system feedback.	4
14. No clear, direct & timely confirmation of an intended action from the portion of the system over which control is to be exerted.	4
15. Operator inexperience (e.g. a newly-qualified tradesman, but not an "expert")	3
16. An impoverished quality of information conveyed by procedures & person–person interaction.	3
17. Little or no independent checking or testing of output.	3
The following conditions are presented as they are frequently mentioned in the literature, but their affect on overall system unreliability may be not be very significant.	
18. A conflict between immediate and long-term objectives	2.5
19. No diversity of information input for veracity checks	2.5
20. A mismatch between the educational achievement level of an individual and the requirements of the task	2
21. An incentive to use other more dangerous procedures	2
22. Little opportunity to exercise mind and body outside the immediate confines of a job	1.8
23. Unreliable instrumentation (enough that it is noticed)	1.6
24. A need for absolute judgements which are beyond the capabilities or experience of an operator	1.6
25. Unclear allocation of function and responsibility	1.6
26. No obvious way to keep track of progress during an activity	1.4
27. A danger that finite physical capabilities will be exceeded	1.4
28. Little or no intrinsic meaning in a task	1.4
29. High-level emotional stress	1.3
30. Evidence of ill-health amongst operatives, especially fever	1.2
31. Low workforce morale	1.2
32. Inconsistency of meaning of displays and procedures	1.2
33. A poor or hostile environment (below 75% of health or life-threatening severity)	1.15
34. Prolonged inactivity or highly repetitious cycling of low mental workload tasks	1.1
35. Disruption of normal work–sleep cycles	1.1
36. Task pacing caused by the intervention of others	1.06
37. Additional team members over and above those necessary to perform task normally and satisfactorily	1.03
38. Age of personnel performing perceptual tasks	1.02

[a] Label changed from that used by Williams (1988), "Maximum predicted nominal amount by which unreliability might change going from 'Good' conditions to 'Bad'", se of use in the paper.

For each EPC, the Assessed EPC Affect is then calculated through the following formula (Step 6):

$$\text{Assessed EPC Affect}_i = [(\text{EPC Multiplier}_i - 1) * \text{PoA}_i] + 1 \qquad (3.1.1.1)$$

The following step (Step 8) is to calculate the Assessed Nominal Likelihood of Unreliability (ANLU) as:

$$\text{ANLU} = \text{NHU} * \prod_{i=1}^{n} \text{AssessedEPC Affect}_i \qquad (3.1.1.2)$$

At this point, it is possible to calculate the Percentage Contribution to Unreliability (%CU) of each EPC (Step 9):

$$\%\text{CU} = \text{AssessedEPC Affect}_i : (\text{NHU} + \sum_{i=1}^{n} \text{Assessed EPC Affect}_i) \qquad (3.1.1.3)$$

Finally, analysts determine appropriate remedial measures for the %CUs that have priority, that means for the most relevant EPCs which have greater values of %CU (Step 10). Implementation of appropriate corrective measures allows to obtain acceptable level of Assessed EPC Affect and subsequently of the Assessed Nominal Likelihood of Unreliability. Error reduction techniques can be employed either to combat the predicted effects of the EPCs, or to minimise the likelihood of human error occurring in a general sense. Williams meditates that "the first four types of generic task scenario may not be acceptable when high reliability is required during process operation, so any measures that can be employed to suppress and control these error-producing tasks would perhaps be worth exploring" (Williams, 1986).

Example of HEART Application in Industrial Sector

It is required to assess probability of a plant operator failing to carry out the task of "Isolating a plant bypass route". HEART technique can be applied as follows:

From Table 7, it can be established that the Generic Task Type for the situation is (F), which is defined as "Restore or shift a system to original or new state following procedures, with some checking", which has a Proposed Nominal Human Unreliability (NHU) value of 0.003.

The hypothesis to be considered are: the operator is in his 7^{th} hour of work, he is fairly inexperienced in fulfilling the task and therefore typically does not follow the correct procedure; the individual is unaware of the hazards created when the task is carried out. Additionally, there is talk circulating the plant that it is due to close down.

The next step is to define the Error Promoting Conditions, from Table 8, associated with the task: in this case five EPCs were chosen. For each influencing condition it is required to define a value from zero to one, the Assessed Proportion of Affect (PoA), which gives a measure of each EPC effect magnitude on operator's performance, taking into consideration assumptions and hypothesis for the case study. Consequently, for each EPC the Assessed EPC Affect and the Percentage Contribution to Unreliability (%CU) are calculated, following equations (3.1.1.1- 3.1.1.2). The table below summarizes all the results.

Table 9: Results of HEART Application of the Example

Relevant EPCs		PoA	Multiplier	Assessed Effect	%CU
9.	A need to unlearn a technique & apply one which requires the application of an opposing philosophy	0.8	6	(6-1)*0.8+1= 5.0	36.6
12.	A mismatch between perceived & real risk	0.7	4	(4-1)*0.7+1= 3.1	22.7
15.	Operator inexperience	0.7	3	(3-1)*0.7+1= 2.4	17.6
18.	A conflict between immediate and long-term objectives	0.7	2,5	(2,5-1)*0.7+1= 2.05	14.9
31.	Low workforce morale	0.6	1,2	(1,2-1)*0.6+1= 1.12	8.2

EPCs in the table are already arranged by decreasing % CU: completion of the task is mostly affected by EPC 9, as seen by its significant %CU (36.6).

The final step is to calculate the Assessed Nominal Likelihood of Unreliability (ANLU), following equation (3.1.1.2). It can therefore be formulated as:

ANLU = 0.003*(5*3.1*2.4*2.05*1.12) = 0.256 → 25.6%

3.2 Proposed Modified HEART for Surgery Application

The modified HEART methodology, proposed in this chapter, can be described through a series of modifications made from the traditional method, aiming to make it more feasible for clinical practice. First of all, a modified Human Reliability Analysis approach, based on direct observation, need to be adopted to experience and record surgery practices. This experience facilitate the categorisation of Error-Producing Conditions (EPCs) encountered in the healthcare sector. This study confirms the applicability and usefulness of an observational methodology in the assessment of human errors.

This modified methodology presents the concept that, in order to adapt a model from the industrial field to the surgery one, set of fundamental principles need to be followed.

It is a fundamental example the utilization of a new set of Influencing Factors (IF), already validated in surgery, that takes into account some specific features not considered in current HRA methods. The validated surgical taxonomy is very useful, because it allows to better contextualise each factor to the surgical situation. This taxonomy is composed by 20 Influencing Factors (IF) and it is well-design for surgical procedure and operating room environment.

The table below shows the list of IF taxonomy and for each factor the definition (or description) is provided.

Table 10: Validated surgical taxonomy of Influencing Factors

SURGICAL INFLUENCING FACTORS	
1	**Noise and ambient talk** Continuous or sudden noise; team members talking in the background or coming and going and moving around in a noisy way.
2	**Music** Presence of background music in operating room.
3	**Noisy use of social media** Team members talking about and obtrusively sharing social media content.

4	**Verbal interruptions** Verbal Interruptions that are either untimely or not patient relevant.
5	**Poor management of errors and threats to patient safety** Failure to share information promptly and openly about errors and threats to patient safety.
6	**Poor guidelines, procedures or checklists** Guidelines, procedures or checklists are inadequate: lacking, too complex, or not at right level.
7	**Rude talk and disrespectful behaviours** Derogartory remarks, behaviours showing lack of respect of OR team members, shouting and harsh tones of voice.
8	**Improper use of procedures and checklists** The improper use, or non-use, of the WHO checklist (or similar), protocols and procedures.
9	**Unclear or failed communication** Communication that should have been given wasn't or was inadequate or was misunderstood and not corrected.
10	**Poor or lacking coordination** Failure in coordinating team activities; failure to anticipate the needs of the lead surgeon or lead anaesthetist (surgeon at the console in robotic surgery).
11	**Poor decision making** Failure to consider, select and communiccate options; inadequacy or delay in implementing and reviewing decisions.
12	**Poor situation awareness** Failure to gather and/or to integrate information or failure to use information to anticipate future tasks, problems and states of the operation.
13a	**Lack of experience of surgical team colleagues** Lack of experience of within surgical team, with the surgical procedure or technology.
13b	**Lack of experience of anaesthetic team colleagues** Lack of experience of within anesthetic team, with the anaesthetic procedure or technology
14	**Fatigue** Mental fatigue or physical fatigue.

15	**Time pressure** Psychological stress resulting from experiencing a need to get things done in less time than is required or desired.
16	**Poor leadership** Failure to set and maintain standards or to support others in coping with pressure.
17	**Team member familiarity** Team members unfamiliar with each other and each other's competencies.
18	**Poor use of technology** Lack of ability to use relevant technology.
19	**Inadequate ergonomics of equipment and work place** Equipment and workplace not designed to optimize usability and reduce operator fatigue discomfort.
20	**Preoperative emotional Stress** Stress caused by factors not directly related to the team, the characteristics and evolution of the surgery, such as responsibility for the budget and other business objectives, organizational problems of the department, other critical patients or legal cases.

This list of Influencing Factors is very useful to describe the context in which the task is performed: the complexity of a system is a function of the operators, interactions - physical and organizational - between them and the environment in which they are inserted. Therefore, the modelling of the context is a peculiar feature of the HRA methods and is a key element in the approach of systemic error analysis.

In the taxonomy of factors they can be distinguished elements of SHEL model categories (Edwards, 1972). SHEL term is the acronym that represents the components:

- Software: Non-physical aspects of the system such as the procedures, manuals, rules, checklists, computational codes, symbology, and computer programs;
- Hardware: Not human components, such as machines, robot, monitoring systems, equipment and tools;

- Environment: The physical, social, economic and political context where components interact;
- Liveware: Individual factors, such as physical characteristics, personality, communication style, motivation, risk orientation, learning styles, stress tolerance, skills, knowledge, and attitudes.

The SHEL model is particularly useful in examining Human Factors issues in the operating theatre; it argues that medical errors are often coming from mismatches at the interface between healthcare systems' components (Molloy & O'Boyle, 2005).

The surgical validated taxonomy has been previously obtained through the following phases:

- Literature research of Human Factors in laparoscopic and robotic surgery;
- Identification of factors to place into the macrocategories;
- Observational activity of different laparoscopic and robotic surgeries (face validity): all the elements found in literature were observed in the surgical context too;
- Surveys and focus group with surgeons (in the Italian and Danish context): discussion and confrontation with surgeons regarding meanings, definitions and wording;
- Determination of the final taxonomy and validation from surgeons.

Thanks to the validated surgical taxonomy it is possible to identify and examine relevant psychological and behavioural elements of the surgeon (i.e. the Human Factors), and the interactions between the individual and other components of the system. This taxonomy has been subjected to the three surgeons involved in the analysis of the case study: they have been able to well understand the factors and easily make them match to the operating environment.

Language misunderstanding is a critical issues to take into account when HEART is applied in a different context from the industrial one (Chadwick & Fallon, 2011). In fact, also in literature there are evidences of difficulties due to the fact that HEART was written with an industrial language and it is not easy to translate it for healthcare applications. It is evident that, if Williams' taxonomy

is straight applied, possible misunderstanding of background and in the use of the generic error categories and EPCs may arise during the analysis. Chadwick assess that "without this knowledge and experience in applying the method, it would be difficult for novice healthcare users to correctly complete similar studies, particularly if they are without the support of experienced HRA practitioners. To assist future studies in the healthcare domain, it is strongly recommended that a detailed discussion of the HEART error categories and EPCs be provided, preferably including practical examples of their appropriate use in healthcare" (Chadwick & Fallon, 2011).
In fact, many of the terminologies adopted in traditional HEART tables and definitions are strictly related to industrial operations and may not have clear connections to surgery procedures. Personals from the surgery staff department are called to take part in the study to select Influencing Factors that they consider to have a major influence on their task performance. For this reason, it is very important that the assessment team need to be able to clearly understand and recognize any conditions of the specialised medical domain and to translate them into HEART restrictions.

Additionally, a team based approach is adopted in the modified HEART analysis, involving three specialized surgeons, rather than a single external expert assessor, required from the traditional HEART.
The team based steps of the technique, that differs from the traditional approach, are steps 2-7 of the HEART descriptive diagram (Figure 11). Steps 2-5 have been already identified by Chadwick as particularly "judgmental and unstructured", due to the fact that the traditional approach use a single expert assessor for completing the analysis. Consequently, the results significantly depend on the assessor's knowledge of the task and his personal opinion (Chadwick & Fallon, 2011).

This is a relevant issue, that is revised by selecting three members of the assessors team, in particular three surgeons and not others members of the staff. The choice comes from the consideration that assessors must contend with highly specialised medical tasks and procedures specifications. Surgeons involved in the study need to be all experienced, well trained, aware of the steps of the procedure, as well as the order in which they should be applied. Surgeons are responsible for selecting the appropriate Nominal Human Unreliability (NHU) category, associated Influencing Factors (IF) from the surgical validated taxonomy, and their corresponding Assessed Proportion of Affect (PoA). The

PoA, used to determine the extent to which each identified EPC affects operator performance, is rated on a scale from zero to one hundred, differently from traditional HEART where PoA is a value between zero and one. This choice has been defined in order to obtain a greater precision of the value, once it will be converted in certs.

Another difference, introduced in the modified method is that the surgeons are asked to assess another parameter referred to the PoA-estimation of the selected IFs. In fact, referring to the IF-estimation, they are asked to assess the amount of it attributable to the corresponding sub-factor. The pre-established sub-factor (EPC*), indicates the translation of Williams EPC that best interprets the IF considered. Subsequently, the team PoA results, and corresponding amount of sub-factor (PoA*), for each IF, are averaged and converted in cents.

Main differences between traditional and proposed modified HEART, are summarized in the table below:

Table 11: Main differences between traditional and proposed modified HEART methodology

Proposed modifications of HEART	Traditional HEART	Rationale
- **Observational data**	Data collections and comparison with similar applications. Availability of standardized procedures	Lack of accurate quantitative human reliability data, poor data audit from healthcare HRA applications. Observational data capture based on video recording of the operations and direct observational experience in surgery room.
- **Specific taxonomy for surgical context: 20-Influencing Factors**	Traditional 38-EPC taxonomy for the industrial practice	Useful list of context-sensitive Influencing Factors ad hoc for the clinical/surgical practice.
- **Assessor team composed by three**	Single assessor	Reduce subjectivity aspect, heavily based

people		on the experience of the single assessor.
- **Group of experts on the subject: surgeons**	External expert assessor	Experts with highly specialised medical domains, tasks and processes.
- **Rating Scales, from 0 to 100, is used to obtain PoA values for each EPC**	Calculation of PoA rated on a scale from zero to one	In this way it is possible to take into account, more precisely, the uncertainties of the EPC factors. Averaging PoA values for each EPC allows to obtain a balanced result.
- **Assessor team is asked to assess the amount of PoA (PoA*) attributed to the EPC, already established, that better means the examined IF (EPC*)**	Not present	In this way it is possible to create a weighted analysis
- **Component tasks are not always easily separable, it is necessary to identify the dimension and complexity of each task**	Easier task analysis, characterized by repetitive routinely operations	Hazard zones need to be identified that consist of a series of interrelated tasks. For example, in the anastomosis, the outcome does not depend on a single task (suturing or stapling) but also on preparation of the bowel end, ensuring a good blood supply, anastomosis without any tension, etc. (Cuschieri, 2000).

3.2.1 Modelling of the modified HEART method

At this point, it is fundamental to understand how results can be correctly translated, from the validated surgical taxonomy, into traditional HEART methodology. In order to do that, some premises are required. The diagram below represents main steps of this methodology, that are described in detailed below.

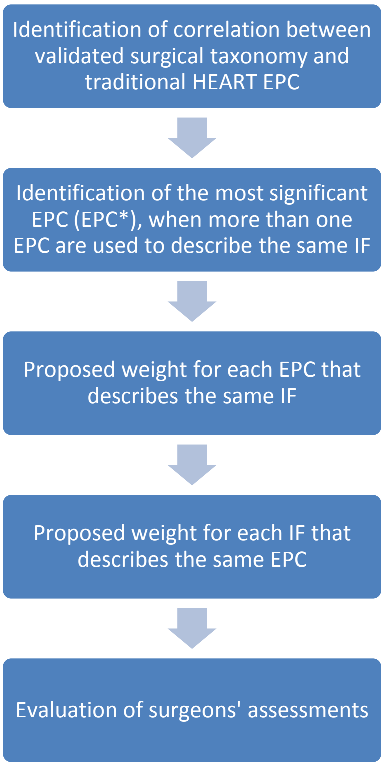


Figure 12: How translate Williams' EPC taxonomy into the new surgical one

- Identification of correlation between validated surgical taxonomy and traditional HEART EPC;

The comparison between the two taxonomies has been performed consulting the list of the EPC written by Williams in his original document "A proposed Method for Assessing and Reducing Human error" (Williams, 1986).

In the document there are not direct detailed information for users about error categories and EPCs. On the other hand there are specifications about possible remedial measures for each of the 38 Error-Producing Condition.

From the comparison between Williams' taxonomy and the validated surgical one, it has been observed that some of traditional HEART EPCs are not potentially influencing in surgical sector or they are specific only for the nuclear-industrial sector; consequently they have not been considered in the 20-Factors surgical taxonomy. In particular, Williams' EPCs that have not been considered in the modified model are EPC number 27, 28, 30, 31, 34, 38 (Table 12).

Table 12: Williams EPCs not considered in the surgical context

Williams EPCs excluded from surgical context		**Reason**
27	A danger that finite physical capabilities will be exceeded	This is a good example of a condition typical of the industrial sector, which can characterize operator workers performing physical tasks. On the other hand, this EPC is not attributable to healthcare context.
28	Little or no intrinsic meaning in a task	Also this EPC does not find meaning in the surgical sector. In fact, during surgery every task has its intrinsic and fundamental meaning and it cannot happen that one of those would lose it.
30	Evidence of ill-health amongst operatives, especially fever	It is, of course, assumed that a surgeon (and any other staff member) cannot have bad health conditions, when enters the operating room. Therefore, the condition proposed by Williams cannot occur in the operating room. In contrast, however, in an industry it may happens that an operator is present to work with fever when he/she is sick.
31	Low workforce morale	It is assumed that low workforce morale is not attributable to a surgeon. It can be an attribute for many industrial operators, but it doesn't represent the medical staff.
34	Prolonged inactivity or highly repetitious cycling of low mental workload tasks	This condition well represent supervision tasks, typical of nuclear plants, where operators have alienating work characterized by prolonged inactivity and repetitious tasks, such as pressing a bottom, screens supervisor and so on. On the other hand, these conditions do not occur in surgery procedure.
38	Age of personnel performing perceptual tasks	Age is not considered as an

		influencing factor of the operator's performance, but a condition that can modify the other influencing factors. For this reason, this EPC was not taken into consideration.

On the contrary it is possible to observe that certain factors, considered in the surgical validated taxonomy, are new and contextualized for today. In fact, some conditions were not foreseeable at the time of Williams. A good example of that is the use of devices and phones in the operating room, which is more and more frequent in last years. In some cases, they are sophisticated phones, that help the doctor to operate with high precision techniques. On the contrary, it is condemned, of course, the use of the smartphone that leads surgeons, nurses and health care staff to distraction. Diego Piazza, president of the Association of Italian Hospital Surgeons, said that "the regulation of mobile phones in Italian operating room depends on hospital directions and there are no national provisions". Indeed, it is surgeon's discretion to ensure the safety and privacy of the patient. On the other hand, it is important to consider that, in the course of extensive work, a surgeon cannot remain isolated for many hours. One possible solution may be to set up, out of the operating room, a desk where surgeons can leave their phones, possibly with an operator who can intercept emergency calls.

Only few of the factors can easily switch from one to the other taxonomy, with an unique (one to one) clear link, for example "operator inexperience" and "stress" are conditions directly taken into account by both taxonomies. Other conditions of the "20-factors" surgical taxonomy, instead, can be translated by more than one EPC of the traditional taxonomy, as well as, one EPC can be referred to more than one IF. Some difficulties have been encountered in these operations, due to the facts that:

- there are not previous examples of this type of comparison from which to take example;

- the correspondences between the two taxonomies were often valued subjectively;

- the comparison is influenced by the difficulty of translation and interpretation of conditions and clarity of definitions;

- there is not always a direct correspondence between factors of the two taxonomies.

The table below shows in a matrix way the correspondence between surgical validated taxonomy and Williams' EPC list.

Table 13: Matching between Williams and the surgery taxonomies

		Influenting Factors																			
		1	2	3	4	5	6	7	8	9	10	11	12	13	14	15	16	17	18	19	20
	1												X								
	2					X										X					
	3	X	X	X																	
	4			X																	
	5									X											
	6																		X		
	7					X															
	8									X											
	9								X												
	10										X										
	11								X												
	12					X															
	13							X													
	14								X												
	15													X							
	16							X	X									X			
	17											X									
	18					X															
EPC	19																		X		
	20																		X		
	21								X												
	22														X						X
	23																			X	
	24																X				
	25										X	X									
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	32								X												
	33																			X	
	34																				
	35														X						
	36				X																
	37				X																
	38																				

- Identification of the most significant EPC (EPC*), when more than one EPC are used to describe the same IF.

The difficulty related to this task concerns a literary problem: without any information regarding the original intent and subtleties of the traditional EPCs, it might be difficult to understand meaning of those conditions and be able to reflect them into surgical context.

As already mentioned, many Influencing Factors of the surgical validated taxonomy can be referred to more than one EPC. In these cases, it is mean-full to understand which of the EPCs better represent the IF (EPC*).

The identification has been performed considering the correlation between the effect of the EPC and the IF on human performance and thanks to the

experience gathered from literature resource, direct observational experience in surgery contexts and definitions of the factors.
The table below shows EPC underlined which represent the EPC*.

Table 14: Comparison between the two taxonomies and identification of EPC

	Validated surgical taxonomy			Traditional HEART EPC
1	Noise and ambient talk		3	A low signal-to-noise ratio
2	Music		3	A low signal-to-noise ratio
3	Noisy use of social media		3 4	A low signal-to-noise ratio A means of suppressing or overriding information or features which is too easily accessible
4	Verbal interruptions		36 37	Task pacing caused by intervention of others Additional team members over and above those necessary to perform task normally and satisfactory
5	Poor management of errors and threats to patient safety		2 7 12 18	A shortage of time available for error detection & correction No obvious means of reversing an unintended action A mismatch between perceived & real risk A conflict between immediate and long-term objectives
6	Poor guidelines, procedures or checklists		26	No obvious way to keep track of progress during an activity
7	Rude talk and disrespectful behaviours		16 13	An impoverished quality of information conveyed by procedures & person-person interaction Poor, ambiguous or ill-matches system feedback
8	Improper use of procedures and checklists		16 32 11 9 21 14	An impoverished quality of information conveyed by procedures & person-person interaction Inconsistency of meaning of displays and procedures Ambiguity in the required performance standards A need to unlearn a technique & apply one which requires the application of an opposing philosophy An incentive to use other more dangerous procedures No clear, direct & timely confirmation of an intended action from the portion of the system over which control is to be exerted.

9	Unclear or failed communication		8 5	A channel capacity overload, particularly one caused by simultaneous presentation of non-redundant information No means of conveying spatial & functional information to operators in a form which they can readily assimilate
10	Poor or lacking coordination		10 25	The need to transfer specific knowledge from task to task without loss Unclear allocation of function and responsibility
11	Poor decision making		25 17	Unclear allocation of function and responsibility Little or no independent checking or testing of output
12	Poor situation awareness		1	Unfamiliarity with a situation which is potentially important
13	Lack of experience		15	Operator inexperience
14	Fatigue		35 22	Disruption of normal work sleep cycles Little opportunity to exercise mind and body outside the immediate confines of a job
15	Time pressure		2	Time shortage (from Williams' description)
16	Poor leadership		24	A need for absolute judgements which are beyond the capabilities or experience of an operator
17	Team member familiarity		16	An impoverished quality of information conveyed by procedures & person- person interaction
18	Poor use of technology		6 20 19	Poor system/human user interface A mismatch between the educational achievement level of an individual and the requirements of the task No diversity of information input for veracity checks
19	Inadequate ergonomics of equipment and work place		33 23	A poor or hostile environment Unreliable instrumentation
20	Emotional perioperative stress		29 22	High level emotional stress Little opportunity to exercise mind and body outside the immediate confines of a job

- Proposed weight for each EPC that describes the same IF

When more than one EPC is used to describe the same IF, weights are assign to each of them, by considering how the corresponding EPC would well describe the effect of the influence of the Influencing Factor. This operation has been performed thanks to knowledge developed in direct experience, direct observation, video recordings in operating room and data available from literature.

Table 15: EPC Weights hypothesized

IF	Corresponding EPC	EPC_Weights
3	3 4	80% 20%
4	36 37	60% 40%
5	2 7 12 18	80% 5% 10% 5%
7	13 16	30% 70%
8	9 11 14 16 21 32	5% 0,5% 0,5% 88% 5,5% 0,5%
9	5 8	40% 60%
10	10 25	75% 25%
11	17 25	25% 75%
14	22 35	30% 70%
18	6 19 20	70% 20% 10%
19	23 33	30% 70%
20	22 29	30% 70%

- Proposed weight for each IF that refers to the same EPC

In the same way, when more than one EPC is referred to the same IF, it is necessary to assign weights to each of them. Also in this case, the task has been performed thanks to knowledge developed through literature review, direct experience of surgeries observation, recordings and available data.

Table 16: IF Weights hypothesized

EPC	Corresponding IF	IF_Weights
2	5 15	60% 40%
3	1 2 3	60% 10% 30%
16	7 8 17	20% 60% 20%
22	14 20	30% 70%
25	10 11	60% 40%

- Evaluation of the results obtained from surgeons' assessments

Once surgeons have answered the questionary about PoA assessments, it is possible to analyse results and translate them into HEART methodology. Generally, calculations are performed using Excel program to facilitate calculations and possible corrections. This phase is composed by the following steps.

- Starting from the list of IFs selected from the surgeons, as relevant for the critical task under analysis, it is necessary to identify corresponding EPC list from Table 14.
- Calculation of effective weight assigned to EPCs, based on surgeons' results. In order to do that, it is necessary to compare the values of PoA and PoA* assessments, obtained from the survey, and consequently retrieve the real weight assigned to EPC* from surgeons' opinion. After that, it is possible to readjust other EPC_weights referred to the same IF, based on the pre-assigned weights reformulated.
- Average of the three EPCj_PoA, in order to obtain only one balanced value:

$$AverageEPC\_PoA_j = \frac{\sum EPC\_PoA_i}{n}$$

Where n is equal to 3 (number of surgeons)

- Average of the three EPCj_PoA*:

$$AverageEPC\_PoA*_j = \frac{\sum EPC\_PoA*_i}{n}$$

Where n is equal to 3 (number of surgeons)

- Calculation of PoA referred to the EPC_j ($Total\ PoA_j$). In this task it is important to take into account all IF which refers to the same EPC, and summing their weighted contribution. This value will be used then for the following calculation.
- Calculation of the Assessed EPC Affect, for each EPC, using the following formula:

$$Assessed\ EPC\ Affect_j = \{[EPC\ Multiplier_j - 1] * \ Total\ PoA_j\} + 1$$

- Calculation of the Assessed Nominal Likelihood of Unreliability (ANLU) as

$$ANLU = NHU * \prod_{j=1}^{m} Assessed\ EPC\ Affect_j$$

- Calculation of EPC relative Percentage Contribution to Unreliability (%CU)

$$\%CU_j = \frac{Assessed\ EPC\ Affect_j}{\left(NHU + \ \sum_{j=1}^{m} Assessed\ EPC\ Affect_j\right)}$$

The modified HEART methodology is shown in the flowchart below, where in red colour are underlined the phases modified from traditional HEART technique.

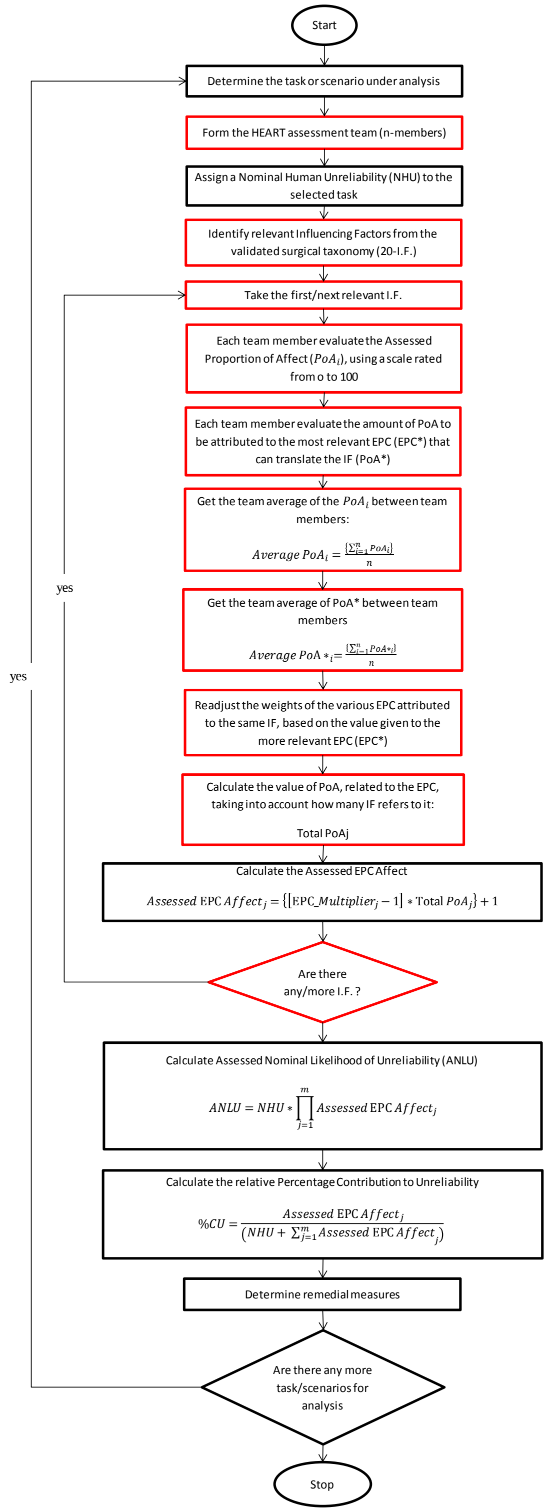

Figure 13: Modified HEART method

3.3 Description of Methodology's phases

Risk analysis and process safety, based on the strengths of various methods, such as HEART, work towards identifying points of vulnerability, assessing their likely impact, reducing human error probability and improving operational performances. Once the problem has been clearly defined, the following steps can be applied to perform the analysis.

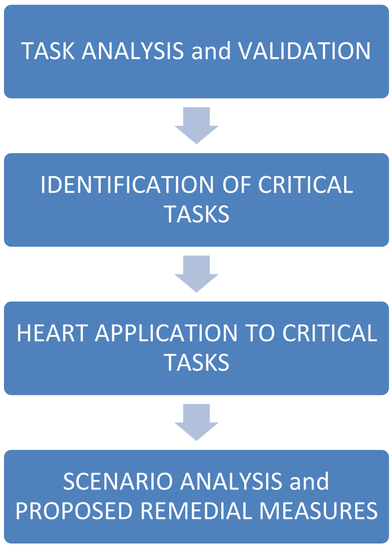

Figure 14: Methodology's phases

3.3.1 Task analysis design and validation

The first step is to create the detail of the task analysis of the procedure to analyse. The task analysis is a means of investigation, description and analysis of human activities to be performed to accomplish the functioning of a system. The task analysis assumes that all operations can be broken down into well identifiable sub-units. It is made in the preliminary stages of analysis of management and control of the performances, with the aim to improve the structure of the system. In doing that, it is possible to identify errors and inconsistencies with the procedure in use. This phase is also very important because it allows to make first hypotheses regarding the procedure of the study, which will be then confirmed, or not, in the later stages.

The task analysis provides several interesting outputs, such as documents describing the tasks, that individuals must do in carrying out some work, and

control of existing procedures. In addition, the task analysis turns out to be a useful means to distinguish more critical tasks, that will then require in-depth safety analysis.
Firstly, it is necessary to define what a "task" is: it is a group of consistent activities with a common goal, with a well-defined beginning and end, without importance in the size, the degree of complexity or the time it takes to be completed. Every task must have a specific objective and the output generated by one task often becomes the input for the next one. In the completion of a task many interactions occur, for example between operators and machines / equipment and / or between persons, and / or media, etc.
Generally, a task analysis can be structured in different phases as follows:

- data collection,
- limitation of the amount and degree of detail of the information,
- collection of more detailed information through interviews and observation,
- combination of information,
- validation,
- further implementation.

In the task analysis it is important that sources provide the point of view of the performer of the task. Also it is always essential to maintain objectivity, avoiding to replace private knowledge with information obtained from the sources.
In order to increase the degree of detail, knowledge and understanding of the tasks, it is suggested to contact the entity and request documentations, previous researches, interviews, previous studies, projects and any kind of documents describing specifically the procedure of the issue.
Literature research allows to obtain reliable material, possibly already validated, that determines studies of similar applications. It is important to carefully search and then select the information, not considering irrelevant or unnecessary ones. It is necessary to be sure about the reliability of the sources of information and that the texts are consistent with the field of research. Literature research must be constantly updated during the later stages of analysis to get more updated information.

After this preliminary investigation, that identifies the key objectives in this context, a direct evaluation and check of the tasks can be very useful. Simulation exercises are typically used in human error studies, in order to predict the occurrence of errors in real circumstances. Further studies validation, by observation and collection of data from the workplace, are required to confirm the accuracy of the prediction in reality (Joice et al., 1998).

Collection of more detailed information can be done through questionnaires, interviews and observation. Not all tasks may require this level of analysis. It is important to define the size of the sample, have individual or group interviews and questionnaires with well-structured questions. It should be emphasized that those who respond to the questionnaire shall be the executors of the task, and not their supervisors, managers or designers who have a different point of view. However, the analyst must take into account that these data are highly subjective and that the answers to the questions can be erroneous or not corresponding to the actual opinions.
Direct observation of different activities must take place in the least intrusive as possible way to ensure objective results. This medium permits to observe all the elements of the tasks, having something the useful possibility to film and record inside the working area. In this way it is possible to obtain permanent recording of the tasks, which allow later extractions of the required information. The validity of the data collected and / or timing monitored, is greater when there is no the feeling of intrusion in the working area, that may influence the behaviour of the performers.

At this point, it is possible to combine the information obtained in all different ways and draw a possible model of task analysis. The various tasks of the procedure must be expressed in a clear, precise and detailed way. They must maintain veracity, objectivity and sub-sequential chronological constraints.

The next step is the validation done by the performer. He must check that the model, proposed by the analyst, corresponds to reality and accurately represents the tasks. Any errors must be identified and corrected in the model. Only after further ultimate validation, the final task analysis can be used by the analyst for future analysis and methodologies for the identification of potential / existing risks.

Among all types of task analysis used by industry, the sequential task analysis is the one that is most applicable to surgery. Actions of the operator are considered in a chronological sequence. In surgical operation, task analysis includes all the component steps of the operation (procedure), all the equipment used, and the surgeon's experience with the procedure (Cuschieri, 2000).

The graph below represents a possible sequence of steps to perform, in order to obtain a task analysis in surgical sector. As it is possible to see it well represents significant phases explained before.

Figure 15: Tasks Analysis phases and Validation

3.3.2 Critical tasks identification

The HEART method is a good example of a method based on a straightforward approach (Williams, 1985). Its application requires the identification of one or more critical tasks to be analysed. Starting from literature resource it is possible to investigate which tasks are more critical than others. It is needed to find studies about the same procedure under analysis and, directly or indirectly, make hypothesis about which operations should be consider more critical.

At this point it is important to have the opinion from the person who is directly involved in the tasks performance.

Criticality of the tasks may be attributed to different features, according to the person’s opinion and the context. A task may be consider critical because it requires significant additional time compared to others, or a task that needs to be redone and adjusted several time, or may be a task that can have serious bad consequence for the completion of the task, for the performers (serious injuries or death) or for the system (damage or permanently compromise system), and so on. Critical tasks may be totally unfamiliar, performed with no real idea of consequences, or contrarily completely familiar, highly practised or even routinely; they may be fairly simple tasks requiring low level of skill and

attention or very complicated one, requiring high level of comprehensions and skills.
Generally two or three tasks are chosen as the most critical ones of the procedure and, after validation from the performer of the tasks, a specific risk analysis is executed.
The graph below summarised main phases of the identification process of critical tasks:

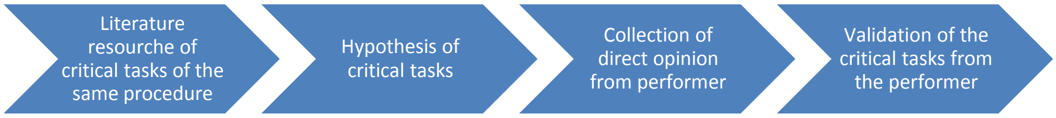

Figure 16: Phases for the Critical tasks identification

3.3.3 Application of HEART modified methodology

Human error evaluation is a crucial component of the process. All conceivable factors, that may influence human performance, have to be identified and categorised, in order to quantitate their effect on the system/outcome. A very accurate analysis of both procedural (inter-step) and execution (intra-step) errors, enacted by a surgeon during a specific operation, can be done. HEART technique, through quantitative steps, provides the overall rate of unreliability of the critical tasks (ANLU) and the percentage contribution of unreliability of each Error Producing Conditions (%CU). In this way it is possible to rank EPCs for their gross affect on the successful completion of the task.
First of all, it is required to select the task for analysis and people that take part in the study. It is required that the assessment team is composed by expert operators in the specialised domain, tasks and procedure analysed. Williams states “in order to be able to apply HEART technology to best effect, […] assessors are likely to need a good standard of education […] what they need in particular, is an ability to see operations from the human perspective, and appreciation of statistics and an understanding of the nature of human variability”(Williams, 1992).

Consistently with the necessary modifications ported to HEART methods, Nominal Human Unreliability (NHU) is assigned, by the assessor team, to the task category. Members of the team are asked to select the Influencing Factors (I.F.), provided in the validated surgery taxonomy list and to associate PoA value, rating from zero to one hundred. In accordance with the described HEART methodology, Assessed EPC Affect, Assessed Nominal Likelihood of Unreliability (ANLU), and the Percentage Contribution to Unreliability (%CU) are calculated.

At the assessment stage, finally, decisions are made on whether improvements in human reliability are needed with respect to the system/operation.

3.3.4 Scenario analysis

Scenario analysis is made to determine the effects of a single parameter on overall probability of success of the procedure. It is generally used to improve decision-making, especially through evaluation of the robustness of the proposed decision (Eschenbach, 1992). It also highlights the factors whose value should be better estimated, and those that should be retained under strict control during execution.

Generally, it can be called "what-if analysis", as it goes to evaluate what changes if different combinations of contexts' factors are applied. The Scenario analysis, then, aims to answer to question such as: "How does the error probability change in different scenarios?".

The process of Scenario Analysis for HRA is generally based on:

- Identification of operations where human error makes a substantial contribution,
- Examination of the most relevant Performance Shaping Factors for the task, that result in errors,
- Propose possible fixes,
- Recalculation of failure rate,
- Repeat if necessary

Scenario Analysis can be a complementary phase of the Reduction Technique part of HEART. Remedial measures can be identified to offer appropriate defences against human error and to combat the predicted negative effects of Error Producing Conditions.

Scenario analysis usually suggests fairly simple modifications. They can result in changes of the procedures, such as adding caution steps or additional checker and so on. Possible changes to the human-machine-environment interaction are often assume to improve operation's performances. The analysis is compelled to examine the changes' impact on the performances, taking also into account the cost of the changes. The unreliability rate is then recalculated and the process can be repeated until the analyst is satisfied with final results.

A well-used type of Scenario Analysis consists in considering a new situation where only the selected Influencing Factor (or Category of Factors) effects the overall probability, while others factors do not have anymore any influence on it. Additionally, through remedial measures it is possible to decrease the influence of the selected factor on human performance.

CHAPTER 4: CASE STUDY

Introduction

The aim of the case study is to validate the proposed modified HEART for surgery applications through the investigation of the nature and incidence of Error Producing Conditions enacted during DaVinci robot-assisted surgeries. Opportunities for future research and the enhancement of surgical training are envisaged as further potential outcomes of the study.

In the previous chapter the modified HEART technique, specifically designed for surgery applications, has been presented. Now, starting from the valuation of the surgical context and analysing a specific Radical Robotic Prostatectomy procedure, the HEART modified technique is applied, in order to evaluate task performance in robot-assisted minimal invasive surgery. The case study focuses on HEART application on two critical tasks identified by surgeons; a Scenario Analysis on most critical Influencing Factors is finally performed.

Today, prostate cancer, especially if intercepted in the early stages of the disease, has the opportunity to be fully removed, ensuring high probability of recovery, thanks to increasingly sophisticated surgical techniques and the use of the DaVinci robot. Despite that, sometimes it might happens that radical prostatectomy surgery has, more or less severe, urinary incontinence and impotence consequences. Some of these forms are often reversible with time, but in some cases they still strongly affect men’s quality of life. Nowadays, the robot-assisted radical prostatectomy (RARP) technique has become the surgical option of choice for clinically localized prostate cancer. Additionally, with an innovative technique, that uses retro-vescical access, it is possible to preserve many important nerves and therefore have greatly lower risk of incontinence and impotence (Bocciardi, 2014).

The young age of robotic surgery and the enormous development of the use of the DaVinci robot in prostatectomy surgery, justify the application of HEART methodology in that procedure.

Obviously, assessment of values necessary for the application of HEART technique, as well as validation of the task analysis and the choice of the critical tasks to be analysed, have required the opinion of experts, i.e. robotic surgeons.

Additionally, through observation of two robot-assisted prostatectomy surgeries at Niguarda Ca' Granda Hospital in Milan, it was possible to directly experience operating room environment, to record and to identify factors which influence human performance in the various stages of the surgery.

All that has been possible thanks to the collaboration with Ab Medica, an Italian company that deals with the spread and assistance of medical products in areas of robotics, MIS, interventional cardiology, radiology, anaesthesia and intensive care.

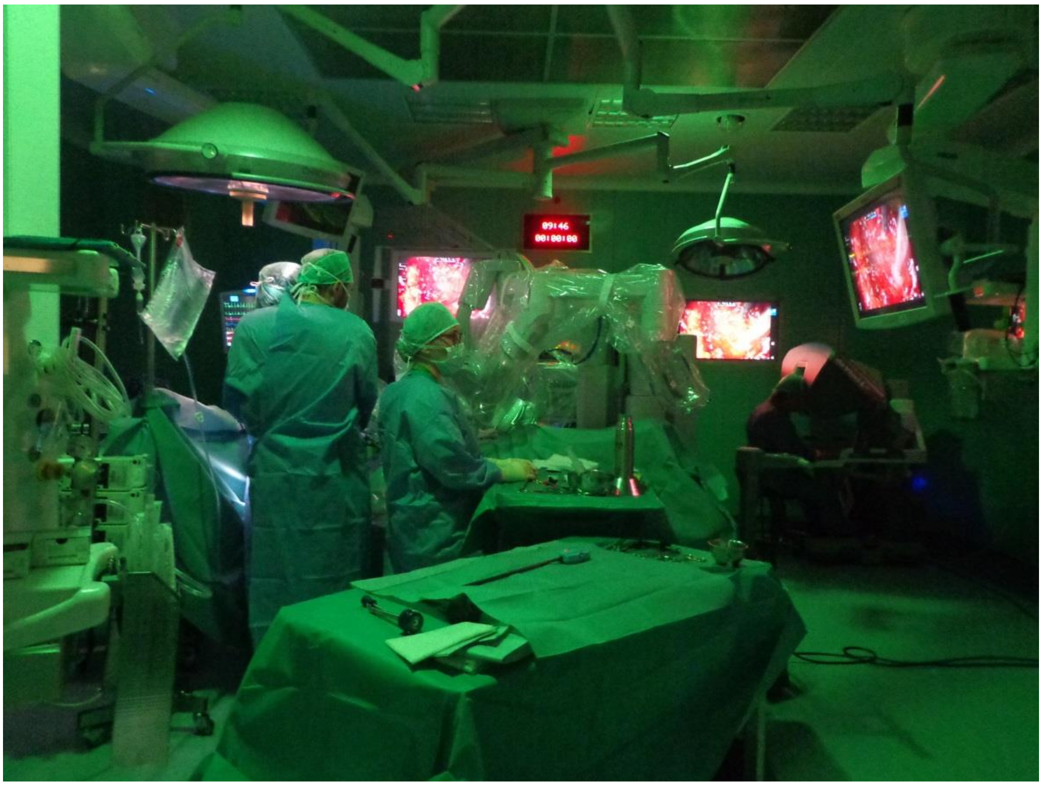

Figure 17: Operating room of the observational activity

4.1 Surgery Technique

The robot-assisted radical prostatectomy (RARP) has recently gained an increasingly important, changing general understanding of the surgical anatomy of the prostate. It has become very popular in the United States and Europe and it has been estimated that > 75% of radical prostatectomies are performed using the DaVinci platform (Tanimoto et al., 2015). Professor Francesco Rocco, Urology Director of IRCCS Foundation at Ca 'Granda Ospedale Maggiore Policlinico in Milan, underlines that robotic prostatectomy is a gold standard in Italy too, thanks to three-dimensional view (as opposed to the 2D vision of laparoscopy) and precision of the instruments that reduce to a minimum the possibility of complications (Rocco, 2014).

In 2010, it has been described a new access to the prostate for the robot-assisted radical prostatectomy, called “Bocciardi approach” (BA-RARP), which uses only access through Douglas, without opening the anterior compartment and the endopelvic fascia, and without the need to dissect the Santorini plexus (Galfano et al., 2010).

Briefly, the originality of this technique is to use a fully posterior approach, without opening the Retzius and passing through the Douglas, not only for the isolation of the seminal vesicles (such as from Montsouris technique), but for the whole isolation of the prostate and the anastomosis phase. The BA-RARP technique uses an unusual access to the prostate for the urologist. However, despite the initial apparent complexity of the technique, it allows to obtain excellent results both from the oncological and functional point of view. Moreover, by analysing results from the first 200 patients operated with this approach, at Niguarda Ca’ Granda Hospital in Milan, and with one-year minimum follow-up, it is possible to conclude that the oncological results have improved after a learning curve of 100 patients (Galfano et al., 2013).

The great strength of the “Retzius-sparing” technique seems to be the immediate recovery of continence. A week after the catheter removal, more than 91% of patients are being continent. The positive margins are similar to those described in the literature and reported in series of patients treated with the anterior technique (Galfano et al., 2013).

Thanks to robot technology it is possible to have little bleeding permitting to avoid transfusions and to have lower hospital stay (2 ½ days averaging) and thus it allows the patient to face the surgery with more serenity. Of course all this is possible in the early stages of the prostate cancer disease and the possibility of early diagnosis is crucial to permanently solve the oncology problem, priority of course, and to recover a full and unrestricted daily emotional, social and work life (Bocciardi, 2014).

Numerous studies show the benefits of robotic prostatectomy over traditional surgery, as shown in the following table:

Table 17: Benefits of robotic prostatectomy over open surgery

Outcome	Open	*da Vinci®*	P value
Cancer Control			
pT2 Positive Margin Rate	12.2%[2]	11.7%[2]	
Urinary Function			
Continence at 12 months	88%[2]	97%[2]	p=0.01
Mean time to continence (days)	75±116 days[2]	25±39 days[2]	p<0.001
Sexual function			
Potency at 12 months	49%[2]	81%[2]	p<0.001
Complications			
Estimated blood loss (EBL)	800 ml[4]	200 ml[4]	p<0.001
Length of stay (LOS)	6 days[4]	3 days[4]	p<0.001
Clavien I-IIIa	34.9%[1]	5.9%[1]	
Clavien IIIb-V	12.9%[1]	3.7%[1]	p<0.001
Recovery			
Return to normal activity *(days of sick leave)*	49 days[3]	11 days[3]	

4.2 Methodology application

The same structure of the methodology presented in the previous chapter has been used to develop the analysis of the case study. Starting from the development and validation of the BA-RARP task-analysis, the most critical tasks have been identified and modified HEART has been applied to the two most complex ones, in order to evaluate human unreliability associated to them. Finally, Scenario Analysis and possible improvement solutions have been proposed for the most critical Influencing Factors. The phases of the methodology are described in more detail below.

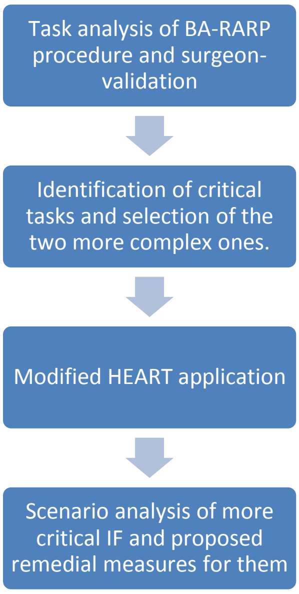

Figure 18: Methodology schema for the case study application

4.2.1 Task Analysis of robot-assisted radical prostatectomy (BA-RARP)

In order to gather information about BA-RARP surgery, it was asked the surgical department of Niguarda Ca' Granda Hospital for any kind of materials concerning the procedure. A document reporting chronological steps of the surgery and a list of the instruments used for it were obtained.

Investigation of terms, practices, surgical context and tools ware needed for the comprehension of the documents. Sometimes the text resulted to be very precise and descriptive, but many other times not so clear. In the text was presented the attempt to distinguish the operations carried out at the table and those in console, although only partially, without precise definitions of the beginning or the end of the tasks. It was also observed that, contributing to the confusion of the documents, there were the simultaneous presence of specific medical terminology, mixed with descriptions of tasks and terminology of the instruments used.

Consequently, in this work there has been the attempt to develop a more clear, complete and ordered tasks procedure, that highlights all main surgery tasks, placing in parallel operations performed at the table and those in console. This task required particular attention, because it was not always easy to distinguish operations carried out in the two different places and recognize time correspondence.

In a second time, a literature research was carried out, in order to gather information regarding surgical procedures in general and more specifically the one at issue. Videotaped RARP procedures were watched from ab Medica website, as well as from similar medical websites, and training manuals and technical protocol were consulted. From literature research it emerged that some studies have previously investigated healthcare task analysis to categorize patterns of failure and calculate human error probabilities. HRA techniques, based on observational methodology, have been applied in particular for laparoscopic cholecystectomy (removal of the gallbladder), requiring the division of the surgical procedure into component steps (Tang et al., 2004; Tang et al., 2005; Tang et al., 2006; Joice et al., 1998).

Additional information were integrated thanks to a web search, paying attention to the degree of detail required and to correctly select only pertinent and relevant material.

The next step consisted in the direct experience of two consecutive surgeries (at Niguarda Ca' Granda Hospital), to observe the procedure from within the context. As previously said, it was possible to assist two surgeries into the operating room, having the ability to move inside the room, take notes and even record with cameras from two different views. The support of the videos recorded during the surgeries and the direct experience were particularly useful in distinguishing and reporting operations carried out at the table and those in console. For the procedure steps which occurred within the body, it has been very useful to get hold video results from laparoscopic instruments. In fact, the endoscopic telescope/camera assembly only recorded pictures once it had been inserted into the patient's body.

Afterwards, a video was created with the double vision of the endoscopic camera video and the external one recorded in the operating room during the surgery.

Once all information have been summarized, a proposed task analysis was sent to the surgeon for evaluation. After some few corrections, the final validation of the task analysis proposal was obtained.

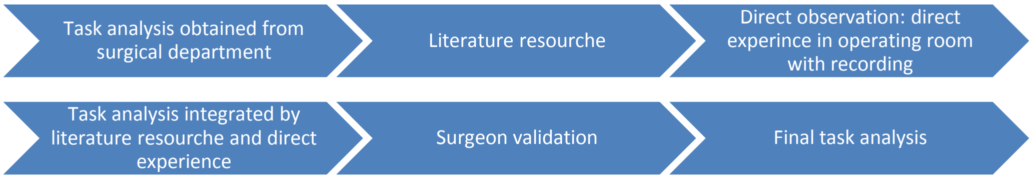

Figure 19: Task analysis identification for the case study

The task analysis divided the procedure into 11 main generic tasks, which could be found within most prostatectomy procedures.

4.2.1.1 BA-RARP Procedure

The surgical process can be briefly summarized into 5 major steps, as shown below, while a detailed task analysis procedure can be find in “Appendix”.

Figure 20: Main phases of the BA-RARP Procedure

- Anaesthesia:

The radical prostatectomy technique is performed under general anaesthesia. Therefore, there is total pain control and reduction of surgical duration. The minimally invasive impact of this technique allows patient to be able to drink and eat from the first day. Obviously, for the anaesthesia, is necessary to monitor all the haematochemical parameters and cardiovascular condition of the patient. For this reason, tests and medical examinations are essential in view of the intervention. The type of investigation required may vary between hospitals, depending on health conditions and age of the patient. Necessary preoperative tests are, for example, blood tests, urine tests, laboratory tests, electrocardiogram, chest X-ray, cardiological examination, usually performed 30 days before the surgery. In addition, anaesthetic visit and substitution of medical therapy treatments with anti-coagulant or anti-aggregate (at least 10 days before the surgery) are carried out.

- Preparation of the room, instrumentation and robot:

This is a crucial task, particularly significant in robotic surgery, given the importance of the technology component. Health personnel (i.e. instrumentalist) has responsibility for the preparation of the instrument cart, the tools used by surgeons, and the DaVinci robot. The preparation of the robot requires the connection of the power supply cables and connection between console area, patient cart and cart-vision; ignition of the robot; dressing of robot's arms and preparation of optical instruments.

- Patient preparation:

The patient must be previously informed of the surgery technique. During the preparation phase, the patient is positioned on the surgical bed, in the supine position, already pre-anesthetized in the preoperative room and with the inclusion of needle-cannulas and electrodes control heart-pressure. The patient is positioned with an inclination of the head downwards of 30° (Trendelenburg position) and it a mask for the assisted ventilation is placed.
The patient's body is covered with sterile towels, except for abdominal part, which is brushed with specific sterile disinfectant. On the abdomen of the patient they are identified and drawn the 6 strategic points for the robotic and laparoscopic doors.

- Surgery execution and monitoring

The robotic radical prostatectomy surgery involves the complete removing of prostate and, in some cases, also of the surrounding lymph-nodes. With minimally invasive *Da Vinci* surgery, surgeons remove the prostate through few small incisions - similar to traditional laparoscopy, instead of a single large incision of open surgery.
The first phase of the surgery execution consists in the patient's skin and subcutaneous tissue incision, the subsequently ports positioning and their attachment. The following step can be briefly summarized as:

- Peritoneum engraving and isolation of seminal vesicles;
- Suspension of peritoneum;
- Isolation of posterior surface of prostate and lateral pedicles;
- Isolation of bladder neck;

- Isolation of anterior surface of prostate and apex;
- Removal of prostate;
- Anastomosis;
- Drain positioning.

The execution time of the surgery is on average one hour and a half (Bocciardi, 2014).

- End phase:

The last phase of the surgery consists in the removal of trocars under vision and robot undocking. In the final stage cardio-circulatory parameters are monitored and indications for post intervention are given.

Once the surgery is done, timing is evaluated and monitor and video data are saved for any re-evaluations. The patient is able to get up from the bed already in the first day and, consistently with the natural recovery of his energy, it is increased his mobilization.

The hospitalization time after surgery can vary between 2 and 7 days. This variability is due to the fact that some Hospitals prefer to release the patient with bladder catheter and / or drainage at home, while others prefer to remove both before dismissing the patient.

4.2.2 Identification of critical tasks

As it is known, one of the requirements for the HEART technique application is the identification of the most critical tasks on which to perform the quantitative analysis. Based on a literature review, it was possible to find studies on laparoscopic and robotic prostatectomy in which most critical, dangerous or complex stages of the surgical procedure clearly emerge. Literature search shown that there are several studies regarding robotics training and, from these data, it was possible to deduce which are the most critical tasks that consequently need more training.

The literature research was carried out online by introducing key words in both medical and not-medical databased: PubMed, Scopus, Web of science and Google Scholar. Keywords used were: “Complex tasks Robotic Prostatectomy”, “Robotic Prostatectomy most complex task”, “Robotic Prostatectomy critical tasks”, “Robotic Prostatectomy Task Analysis” and so on.

After a careful reading of all the documents that appears from the research, the most relevant ones were identified. The following table summarises the results of the literature search.

Table 18: Literature review of critical prostatectomy procedure tasks

Authors	Title	Studies	Main features	Complex tasks
Binder et al. (2004)	"Robotic surgery in urology: fact or fantasy?"	Some of the relevant topic analysed in the document are: surgeon's working position and ergonomics, force feedback and inherent limitations in the system.	• Port positioning is a crucial task, because the table-side assistant is exposed to external and internal collisions with the robot arms (in fact minimal distance between ports is required) • Additional critical tasks indicated are: problem of communication due to the fact that the console surgeon is isolated from the table-side; lack of tactile feedback that can consequently results in tearing a polyglactin suture_when pulling a knot; suturing and dexterity skills and finally long setup time.	Port positioning Communication Suturing Setup
Samadi et al. (2006)	"From proficiency to expert, when does the learning curve for robotic-assisted prostatectomies plateau? The Columbia University experience"	Experience with robotic-assisted laparoscopic prostatectomies (RLPs), focusing on effect of learning curve and postoperative outcomes.	• The study points out the important skill based on the ability to visualize the surgical anatomy surrounding the prostate, including the neurovascular bundles and the dorsal venous complex.	Visualisation surgical anatomy around the prostate
Rashid et al. (2006)	"Robotic surgical education: a systematic approach to training urology residents to perform robotic-assisted laparoscopic	Method presentation for training residents to perform robotic-assisted radical prostatectomy (during 7-months period).	• The study procedure was divided into five steps: bladder take-down, endopelvic fascia and dorsal venous complex, bladder neck and posterior dissection, neurovascular bundles, and urethral anastomosis. Bladder neck and posterior dissection can be considered the most critical task because was	Bladder neck and posterior dissection

	radical prostatectomy”		evaluated with the lower score.	
Chandra et al. (2009)	“A comparison of laparoscopic and robotic assisted suturing performance by experts and novices”	Studies on laparoscopic skill level of experts and novices (comparing standard laparoscopic and robotic) on a standardized complex task: intracorporeal knot-tying.	• “Subjects were instructed to place sutures by entering the target on the right and exiting on the left using 3-0 Vicryl suture on a tapered needle then tying 1 surgeon’s knot and 2 subsequent square ties using alternating hands for a total of 3 knots. They were then allowed to practice manipulating the instruments with the DaVinci interface for 2 min prior to beginning the task”. • Suturing task performances quality evaluated are: total task time, total path length and smoothness of instrument movement. • Critical issues are assessing knot tying and suturing skills. • Intracorporeal suturing task may be a complex task for novices, but not necessarily for experts.	Intracorporeal suturing task (knot tying and suturing skills)
Lasser et al. (2012)	“Dedicated robotics team reduces pre-surgical preparation time”	Studies on preoperative RALRP setup time for the room, staff and surgical platform.	• Preoperative setup is a complex task consisted of: patient timeout protocol, anaesthesia induction, patient positioning and testing of toleration of steep Trendelenberg, patient prepping and draping, placement of trocars with establishment of pneumoperitoneum and docking of the DaVinci®surgical system. • It was highlighted that use of a consistent staff can decrease preoperative setup times and the overall length of surgery.	Preoperative setup
Ficarra et al. (2012)	“Prostatectomia robotica e laparoscopica: revisione	Educational session: learning curve and training	• Section of the bladder neck, mobilization seminal vesicles and urethral anastomosis are surgical	

	critica dei dati esistenti"	program analysis for Laparoscopic Radical Prostatectomy	steps in which it's possible to earn more time during the learning curve. • More frequent complications are: bleeding (from 0.3 to 8.9%), lesion of the rectum (1.5-2.5%), ureteral lesion (0-0.3%), anastomotic leakage (0-0.2%), lymphocele (0 to 2.2%), infection (0.2-0.7%), thromboembolic events (0.6 to 1.5%).	
Elhage et at. (2014)	"An assessment of the physical impact of complex surgical tasks on surgeon errors and discomfort: a comparison between robot-assisted, laparoscopic and open approaches"	Evaluation of individual surgeons' performance in vesico-urethral simulated suturing task, using open, laparoscopic and robot-assisted approaches.	• Anastomosis quality was quantified using scores for knot security, symmetry of suture, position of suture and apposition of anastomosis. • Recurring cycle of events: grasping the needle holder, driving the needle across the anastomosis edge, re-adjusting the needle holder, driving the needle across the other anastomosis edge, tying three knots and ending with thread cutting. • Possible errors are: more than one attempt at taking suture or tying a knot, dropping needle, slipping of knot after tying, failure to follow event sequence as instructed, thread snapping/having to do suture again, inability to finish the task. • Main criteria evaluated were: space between sutures, knot security, knot symmetry and suture position around the anastomosis.	Anastomosis (space between sutures, knot security, knot symmetry and suture position around the anastomosis)
Volpe et al. (2014)	"Pilot Validation Study of the European Association of Urology Robotic Training	A 12 weeks training curriculum was developed to train ten fellows. The curriculum included: e-	• The critical tasks, considered in this study, includes moving the camera and clutching, manipulating the endowrist, dissection and needle driving. • Tasks performed with	Move the camera and clutching, manipulating the endowrist, dissection and needle driving. Dissection of

	Curriculum"	learning, structured simulation-based training and supervised modular training for RARP.	lower final mark (that can be considered more critical) are: dissection of vasa and seminal vesicles, preparation and section of prostatic pedicles, dissection of neurovascular bundles and apical dissection.	vasa and seminal vesicles. Preparation and section of prostatic pedicles. Dissection of neurovascular bundles. Apical dissection.

Subsequently, the surgeon's opinion was asked, in order to compare results obtained from literature. He stated that the most critical tasks of BA-RARP procedure to be analysed are:

- Isolation of lateral peduncles and of posterior prostate surface;
- Anastomosis;
- Santorini detachment from the anterior surface of the prostate.

For the case study, it was established to analyse only two tasks, therefore it was decided to consider only the first two ones and not the "Santorini detachment from the anterior surface of the prostate" one. This decision is justified by the fact that the two selected tasks allow to already obtain fairly different analysis (i.e. different tasks categories and different Influencing Factors selections), which would be partially repeated in the third application.

Figure 21: Phases of the critical tasks identification and validation for the case study

4.2.3 Application of HEART technique

Once critical tasks to be analysed were determined, it was possible to apply HEART modified technique, presented in the previous chapter (3.2.1).

Three surgeons of Niguarda Ca' Granda Hospital, considered fully trained in the procedure, were asked to answer to a prepared questionnaire. In particular, referring separately to the first and second critical task selected, they had to identify, from the validated surgical taxonomy, which Influencing Factors are considered with major influence on human operations performance. They were also asked to assess PoA and PoA* for each of the chosen IF.

Afterwards, it has been possible to identify corresponding EPCs, calculate total PoA for each of them and the corresponding AssessedEPCAffect. Assessed Nominal Likelihood of Unreliability (ANLU) related to the two different complex tasks and %CUs were calculated, in order to identify which are the IFs to be considered as the most influencing ones, hence those requiring imperative remedial measures.

4.2.4 Scenario Analysis

As presented in the previous Chapter, Scenario Analyses have been carried out.

First of all, a Scenario Analysis has been performed on each relevant IF, in order to obtain the maximum range of the corresponding Assessed Nominal Likelihood of Unreliability (ANLU) value.

Then, the same analysis was performed on three main category scenarios referring to "Personal", "Team" and "Organizational" aspects. For each scenario, new ANLU value was calculated, considering the impact of only those IFs linked to the selected category.

Subsequently, for each scenario, some improvement actions have been identified, in general with no references to specific Tasks, and a surgeon was asked to give an estimation of potential percentage influence reduction that can be obtain by the category if strategies are implemented.

Finally the overall ANLU reduction was calculated in the case in which all the proposed remedial actions are implemented in each scenario.

CHAPTER 5: RESULTS

This chapter presents the results of the empirical observation and surgeons interviews and the analysis of the data with the application of the modified HEART methodology. Additionally, some improvement measures have been suggested for three different reference scenarios.

Through the empirical work we investigated which Influencing Factors (IFs) of the surgical taxonomy are met when performing the critical tasks of the case procedure, comparing those identified in the operating room during the observational phase and the ones directly selected by the surgeons. Thanks to the surgeons' responses to the questionnaire, it was possible to analyse the relevance for each IF.

In the quantitative phase of the work, the unreliability of the surgeon in each critical task has been estimated by applying the modified HEART technique. Specifically, the following parameters have been assessed:

- Assessed Proportion of Affect, which gives a measure of each EPC effect magnitude;
- Assessed Nominal Likelihood of Unreliability (ANLU) for the complex tasks "Isolation of lateral peduncles and of posterior prostate surface" and "Anastomosis";
- Percentage Contribution to Unreliability (%CU) of each relevant EPC.

Subsequently, Scenario Analysis was applied to investigate how Human Unreliability Rate changes under different operational and organisational scenarios. Scenarios have been specified considering separately 'personal', 'team' and 'organizational' aspects. Finally, some improvement actions have been identified and maximum potential ANLU variation was calculated in the case in which all improvement strategies were implemented.

5.1 Qualitative Analysis: Comparison between results of direct observations of surgical procedures and surgeons' perceptions

Some Influencing Factors, such as *noise and rude talk, poor management of errors, unclear communication, poor coordination, low awareness of the situation, inexperience, poor guidelines & procedures, poor ergonomics and fatigue*, were cited by all the interviewees as factors dramatically affecting surgeons' performance. We also clearly detected the same factors during the direct observation of the two robotic prostatectomy surgeries.

A first factor, regarded as crucial for the performance of the surgeon, is the *coordination* between team members and particularly among the first surgeon at the console and the other one at the operating table. Coordination usually comes from experience and familiarity, as well as standardization of procedures, and it contributes to assure time reduction.

During the observational activity, it has been possible to evaluate coordination factor as an essential one, which allows team members to anticipate needs of the surgeon, in order to avoid problems and to be familiar with states of the operations. Team members and surgeons have collaborated in a coordinated way for the whole duration of the surgeries.

The questionnaires show that coordination was found to be a factor with medium criticality for Task 1 (Isolation of lateral peduncles and of posterior prostate surface) and high level for Task 2 (Anastomosis) which requires greater attention and cooperation to avoid complex complications to the patient.

Another important factor, observed and confirmed by surgeons, is the *communication* between the surgeon at console and the assistant at the table: in fact, they can often experience problems of poor communication and misunderstanding of commands. All that is worsened by the fact that the console is placed far from the surgical table (in some cases may even be in a different room) and the main surgeon communicates via a microphone. Therefore, it is necessary that the surgeon verifies that his orders are received and are correctly understood by others.

From the observational activity, it has been observed the practical difficulty related to the use of microphones and the location of surgeons. At the same time, communications have been sufficient and have made up for tool and logistics inconveniences. During the surgeries some communication interruptions occurred, mainly due to phone calls and requests from other operators. It has been observed that the other surgeon did not readily receive the commands several times, and therefore they had to be repeated.

From questionnaires, ‘unclear communication’ was evaluated to be an influencing factor highly affecting the performance of the surgeon, in both tasks.

Additionally, failure to promptly and openly share information about errors and threats to patient safety can result in *poor management of errors*, which is another very relevant factor.

During the observational activities there were no obvious situations of failure in error management. However, in the second surgery, discomfort due to significant bleeding occurred, due to failure in suspending perioperative anticoagulant therapy. The surgery became more complex than expected and prolonged in duration for the need of repeated stanches and tools cleaning in the operative field. Despite that, discomfort did not compromise the successful completion of the intervention.

The questionnaires show that the three surgeons consider this IF with medium- high criticality, similar for both tasks.

Awareness of the situation and of its risks is an influencing factor that is fundamental and it is required for the whole duration of the surgery.

During the observational activity, it was found that surgeons maintained maximum attention on all phases of the procedure. The experience is certainly a contributing factor as well as the instrumentation availability and the ability of the operators to interact with advanced technological equipment.

Results of questionnaires show that awareness of the situation was considered with a high value, greater for Task 1 with respect to Task 2.

Moreover, the interaction between team members, during the observed surgeries, sometimes appeared unprofessional and inappropriate. It is important to maintain a serene atmosphere, also for the purpose of greater cooperation and synergy between team members, *avoiding rude talk and disrespectful behaviours*.

The interviewed surgeons investigated this factor only for Task 2 and provided uneven rates. This may be due to personal characteristics of the surgeons and their experiences.

In addition, *noise, background voices* and extraneous conversations are often present to the detriment of clarity of communication.

During the observed surgeries, less involved operators, such as room nurses and assistants, often used mobile phones for purposes other than those of the surgery and chatted with colleagues, generating disturbance. Another example, which occurred during the observed cases, was the noise due to the hand-over at shift change, which led distraction and poor concentration for the surgeon.

Several studies already investigated the effect of background noise during robotic surgeries, showing that noise degraded robotic surgical performance; however, it was demonstrated that the impact of noise on robotic surgery depends on the level of difficulty of the task to be performed (Siu, K.-C. et al., 2010).

The influence of this factor on surgeon's performance has also been confirmed by all three surgeons, as very significant to the successful completion of the two critical tasks.

Environmental stressors such as noise, poor acoustics, overcrowding and *inadequate ergonomics* of equipment and work place can interfere with safe patient care, inducing additional stress on surgeons and increasing errors when performing a critical task (Molloy & O'Boyle, 2005).

During direct observation of the surgeries, there have been no major disruptions related to inadequate ergonomics: in the operating room there were stools for team members (if tired) and sterilized additional medical coats available for all to compensate low temperature required in the room. On the other hand, frequent opening and closing of the doors of the operating room generated an annoying and disturbing noise.

From the results of the questionnaires it appears that this factor has been considered by all three surgeons only for Task 1, with a significant variation in their assessments.

Another factor, considered important by interviewees and observed in the operating room, is the *experience of surgeon and team members*, which not only influences surgeon's performance, but also affect the duration of the surgery. It must be stressed, however, the fact that any intervention is characterized by variables due to the state of the disease and the characteristics of the patient.

In the second observed surgery, the limited experience of the surgeon at the table was evident due to the fact that he was undergoing training and he required constant support, as well as numerous reminders, by the first surgeon and all that significantly prolonged surgery duration.

Inexperience was assessed by surgeons as a factor mostly influencing the Task 1.

Fatigue is another factor that influences surgeons' performance. The great mental and physical concentration required make it difficult to deal with more than two consecutive surgeries: in fact, in the cases observed, the surgeon was more fatigued and stressed in the second surgery (lasted 3h), occurred consecutively to the first one (lasted 2h). Fatigue was considered by all three surgeons only in Task 2, and with very limited alignment in their assessments.

The relevance of the above-listed factors is thus confirmed on the basis of what we directly observed in the operating, as well as on the surgeons' judgements (reported in Appendixes 5, 6 and 7).

5.2 Quantitative Analysis on the correspondence between EPCs and IFs

Thanks to the results of the questionnaires of the three surgeons it was possible to evaluate their opinions about how the EPCs of Williams' taxonomy well translate the IFs of the new surgical validated taxonomy.

Surgeons were asked, for each IF that they considered as relevant, to give an estimation of its correlation (PoA*) with its corresponding EPC* (EPC selected as the most similar to the IF).

For some of the factors, there has been perfect correspondence between IF description and corresponding EPC*. Moreover, thanks to questionnaires it was possible to confirm that there is not always complete agreement between Williams' EPCs and IFs. In fact, EPCs of traditional HEART methodology are not always able to fully explain and translate IFs of the validated surgical taxonomy. This is obviously due to the fact that the two taxonomies have been developed for two different operational environments and contexts.

The results of the comparison between Error Promoting Conditions and Influencing Factors are reported in the tables below both for Task 1 and Task 2. The two tables show the percentage of correspondence between IFs and EPCs obtained from averaging values given by surgeons. Percentages have been highlighted with three colours to emphasize matching between factors of Williams's taxonomy and those of the surgical one: red (low correspondence < 50%), yellow (medium correspondence), green (high correspondence > 83%).

Table 19: Percentage results of comparison between EPC* and IF_Task 1

	TASK 1	EPC														
		36	25	15	35	24	6	33	29	3	16	2	10	1	26	8
		Intervenion	Responsabilities	Inexperience	Work-sleep cycle	Need judgements	Mismatch model	Environment	Stress	Noise	Impoverished info	Shortage time	Transfer knowledge	Unfamiliar situation	Keep track	Capacity overload
IF	Noise									78,89						
	Music									95						
	Social Media									90						
	Interruptions	100														
	Errors management											83,81				
	Poor Guidelines														54,76	
	Rude Talk										80					
	Improper Procedures										75					
	Communication															59,17
	Coordination												71,67			
	Decision Making		100													
	Situation awareness													76,67		
	Experience			100												
	Fatigue				90											
	Time pressure											75				
	Poor leadership					90										
	Team familiarity										90					
	Poor use technology						100									
	Ergonomics							83,33								
	Preoperative Stress								100							

Table 20: Percentage results of comparison between EPC* and IF_Task 2

		EPC														
	TASK 2	36	35	24		33	29	3	16	2	25	1	15	10	26	8
		Intervenion	Work-sleep cycle	Need judgements	Mismatch model	Environment	Stress	Noise	Impoverished info	Shortage time	Responsabilities	Unfamiliar situation	Inexperience	Transfer knowledge	Keep track	Capacity overload
	Noise							58,17								
	Music							90								
	Social Media							90								
	Interruptions	90														
	Errors management									80,83						
	Poor Guidelines														61,11	
	Rude Talk								69,05							
	Improper Procedures								85							
	Communication															57,5
IF	Coordination													57,41		
	Decision Making										75					
	Situation awareness											77,78				
	Experience												70			
	Fatigue		83,33													
	Time pressure									85						
	Poor leadership			85												
	Team familiarity								85							
	Poor use technology				100											
	Ergonomics					85										
	Preoperative Stress						100									

From the two tables above, it is possible to observe that correspondences among IFs and EPCs are different between Task 1 “Isolation of lateral peduncles and of posterior prostate surface” and Task 2 “Anastomosis”. This finding is very important, because it is easily possible to imagine that by administering the same questionnaires for different tasks of the same BA-RARP procedure, different responses would be returned.

Consequently, the same would happen analysing different surgical procedures. Thus, it is apparent that the mapping of the taxonomy of surgery related IFs against the traditional EPCs of HEART is not only subjective (according to the perception of the surgeon), but also highly contingent to the type of procedure and the phases considered.

5.3 Numerical Analysis of HEART application

Starting from data obtained from questionnaires, it was necessary to find criteria in order to translate surgeons’ results into useful data for HEART application. As it is possible to see from the responses, only the first surgeon made a correct assessment of the most influencing factors of the taxonomy, identifying the corresponding amount of PoA and PoA* (Appendix 5). On the contrary, the other two surgeons (Appendix 6; Appendix 7), did not uniquely select the most significant IFs: they assessed PoA and PoA* values for the whole list of IFs. This misunderstanding in assigning the required values was justified by surgeons’ inexperience with HRA techniques.

Therefore, the first chosen criterion was to analyse only those factors that were commonly identified by all the surgeons. In fact, HEART methodology binds to choose only few factors, those considered the most influencing ones. This choice was also dictated by the fact that, in this way, it has been possible to make the average of the PoA and the PoA* values provided by the three surgeons, thus obtaining $PoA_{average}$ and $PoA^*_{average}$ for the selected IFs.

The PoA and PoA* values were used for the subsequent HEART calculations, i.e. Assessed EPC Affect, in accordance with the modified HEART method, described in Chapter 3. Additionally, by averaging assessors PoA and PoA* values -for each IF- it was possible to balance surgeons’ judgements, preventing overly optimistic or pessimistic results of the individual team member. The average criterion is in accordance with the one of Chadwick HEART application (Chadwick, 2011).

The identified Influencing Factors and their corresponding -individual and averaged- PoA and PoA* values, are shown in the tables below for both Task 1 and Task 2.

Table 21: PoA average and PoA*average for the selected IFs of Task 1

TASK 1											
	IF	PoA1	PoA2	PoA3	PoAaverage		EPC*	PoA* 1	PoA*2	PoA* 3	PoA*average
1	Noise&ambient talk	90	80	60	76,67	3	Low signal to noise ratio	60	56	60	58,67
5	Poor management of errors	70	70	70	70,00	2	Shortage of time for errors detection	50	56	70	58,67
6	Poor guidelines&procedures	70	90	50	70,00	26	No way to keep track of progress	10	45	50	35,00
9	Poor communication	80	100	50	76,67	8	capacity overload	30	40	50	40,00
10	Poor coordination	40	70	70	60,00	10	transfert knoledge from task to task	10	63	70	47,67
12	Poor situation awareness	60	100	90	83,33	1	Unfamiliar situation	30	80	90	66,67
13	Lack of experience	50	100	60	70,00	15	operator inexperience	50	100	60	70,00
19	Poor ergonomics	10	50	90	50,00	33	Hostile environment	10	25	90	41,67

Table 22: PoA average and PoA*average for the selected IFs of Task 2

	IF	PoA 1	PoA 2	POA 3	PoAaverage		EPC*	PoA* 1	PoA* 2	PoA* 3	PoA* average
1	Noise&ambient talk	80	70	60	70,00	3	Low signal to noise ratio	40	63	60	54,33
5	Poor management of errors	80	80	70	76,67	2	Shortage of time for errors detection	50	64	70	61,33
6	Poor guidelines&procedures	60	90	50	66,67	26	No way to keep track of progress	20	45	50	38,33
7	Rude Talk	20	80	70	56,67	16	Poor quality of info from procedures&person	10	80	40	43,33
9	Poor communication	80	80	70	76,67	8	Capacity overload	10	48	70	42,67
10	Poor coordination	90	100	80	90,00	10	Transfert knoledge from task to task	20	50	80	50,00
12	Poor situation awareness	50	90	60	66,67	1	Unfamiliar situation	30	81	50	53,67
13	Lack of experience	40	80	80	66,67	15	Operator inexperience	20	64	80	54,67
14	Fatigue	40	80	90	70,00	35	Disruption of normal work-sleep cycles	20	40	90	50,00

Subsequently, another criterion was applied in order to decrease the number of IFs to be considered for a quantitative appreciation of surgeon's unreliability.

From tables above it is possible to note that for some of the factors surgeons had misaligned estimations. Therefore, the second selection criterion was to consider only those factors which have not controversial assessments. In particular, it was observed the highest and the lowest values, among the three opinions of the surgeons on the same IF, and when the difference exceeded 30%, the factor was withdrawn.

Factors resulting from the application of the two criteria, were those subsequently submitted to the application of HEART methodology and

Scenario Analysis. The following tables show the list of factors judiciously chosen as those with the highest influencing potential on surgeon's performance and degree of accordance among surgeons.

Table 23: Final IFs selection from surgeons' questionnaires for Task 1

TASK 1												
	IF	PoA1	PoA2	PoA3	PoAaverage		EPC*	PoA* 1	PoA*2	PoA* 3	PoA*average
1	Noise&ambient talk	90	80	60	76,67	3	Low signal to noise ratio	60	56	60	58,67
5	Poor management of errors	70	70	70	70,00	2	Shortage of time for errors detection	50	56	70	58,67
10	Poor coordination	40	70	70	60,00	10	Transfert knoledge from task to task	10	63	70	47,67

Table 24: Final IFs selection from surgeons' questionnaires for Task 2

TASK 2											
	IF	PoA 1	PoA 2	POA 3	PoAaverage		EPC*	PoA* 1	PoA* 2	PoA* 3	PoA* average
1	Noise&ambient talk	80	70	60	70,00	3	Low signal to noise ratio	40	63	60	54,33
5	Poor management of errors	80	80	70	76,67	2	Shortage of time for errors detection	50	64	70	61,33
9	Poor communication	80	80	70	76,67	8	Capacity overload	10	48	70	42,67
10	Poor coordination	90	100	80	90,00	10	Transfert knoledge from task to task	20	50	80	50,00

HEART application

With the selected data and the methodological procedure described in Chapters 3 and 4, it has been possible to apply HEART modified methodology on critical Task 1 and Task 2. Following are described main steps of the technique application.

- *Selection of the generic category of the two Tasks*

TASK 1: "Isolation of lateral peduncles and of posterior prostate surface"

Category Task G: "Completely familiar, well-designed, highly practised, routine task occurring several times per hour, performed to highest possible standards by highly-motivated, highly-trained & experienced person, totally aware of implications of failure, with time to correct potential error, but without the benefit of significant job aids".

Task 1 has been considered a routinely task because it is performed many times per day (but not several times per hour, as expressed in the *Category Task G*), depending on the number of prostatectomy surgeries performed during the day.

Task 1 can be well labelled with the need to be performed to highest possible standards by highly-motivated-trained and experienced people, in addition to structured staff personals, totally aware of implications of failures.

TASK 2: “Anastomosis”
Category Task G and Category Task C: “Complex task requiring high level of comprehension and skill”.
It can be observed that, both *Category Task G and C* would be consistent with the considered task. On the other hand, it was evaluated that *Category Task C* is more appropriate to emergency situations, such as changes of techniques from robotic surgery to open technique (or vice versa). Therefore, this category cannot be extended to routinely operations. Thus, *Category Task C* was excluded from hypothesis of the case study, which is based on the analysis of critical complex routinely tasks, and not on emergencies.

The *Category Task G* is then considered as the most appropriate for this type of analysis and it has been applied for the analysis of both Task 1 and Task 2.

- *Assign a Nominal Human Unreliability (NHU)*

The Nominal Human Unreliability (NHU) was assigned using HEART Generic Categories reported in Williams’ taxonomy. Category G has a Nominal Human Unreliability of:

NHU (Category G) = 0,0004

- *Identification of corresponding EPCs from the list of IFs retrieved from questionnaires and calculation of corresponding PoA values*

  This phase has been performed using Excel program: starting from the list of critical IFs and their PoA and PoA*, corresponding EPCs were identified and corresponding PoA were calculated.

- *Calculate the Assessed EPC Affect* for each EPC selected, by using EPC_Multipliers from Williams’ list and PoA determined in the previous step.

- *Calculate the Assessed Nominal Likelihood of Unreliability (ANLU*), for both Tasks, using the equation:

$$ANLU = NHU * \prod_{i=1}^{n} Assessed\ EPC\ Affect_i$$

Considering that ANLU value provides an overall rate of unreliability for the task and it can only exist within the range 0 and 1, when it is found to be greater than one, then the probability of unreliability for the task is assigned equal to 1.

ANLU (Task 1) = 0,085

ANLU (Task 2) = 1,18 > 1 → *ANLU (Task 2)* = 1

- Calculate the relative Percentage Contribution to Unreliability (%CU)

The relative Percentage Contribution to Unreliability (%CU) is calculated for each EPC, using the equation :

$$\%CU = AssessedEPC\ Affect_i : \left(NHU + \sum_{i=1}^{n} Assessed\ EPC\ Affect_i \right) * 100$$

Tables below summarize all the results of HEART application on Task 1 "Isolation of lateral peduncles and of posterior prostate surface" and Task 2 "Anastomosis".

Table 25: Results of HEART application_ Task 1

TASK 1								
IF		EPC		EPC_Multiplier	PoA	Assessed EPC Affect	%CU	%CU_IF
5	Poor management of errors	2	Shortage of time for errors detection	11	58,667	6,867	0,330	0,49
		7	No means reversing unintended actions	8	2,8325	1,198	0,058	
		12	Mismatch: perceived & real risks	4	5,665	1,170	0,056	
		18	Conflict: long &immediate objectives	2,5	2,8325	1,042	0,050	
1	Noise&ambient talk	3	Low signal to noise ratio	10	58,667	6,280	0,302	0,30
10	Poor coordination	10	Transfert knoledge from task to task	5,5	47,667	3,145	0,151	0,20
		25	Unclear allocation of responsabilities	1,6	12,33	1,074	0,052	

For Task 1 the three IFs selected were traduced into seven EPCs showed in the table above. As it can be observed from Table 25, EPCs have been ordered for decreased criticality, showing decreasing values of Assessed EPC Affect and %CU.

The most significant Influencing Factors identified from the analysis is “Poor management of errors” (IF 5), which has a total %CU= 0,49. In particular, EPC 2 “Shortage of time available for error detection & correction” is the corresponding EPC having the greatest EPC Multiplier (EPC Multiplier= 11) compared to the others and it resulted to be the most critical factor, having the largest value of Assessed EPC Affect and Percentage Contribution to Unreliability (%CU= 0,33). The second place is occupied by IF 1 “Noise and Ambient Talk”, which is linked to EPC 3 “Low signal to noise ratio”. This EPC has the same value of PoA of the most significant one (PoA= 58,667), but its Multiplier is lightly lower than the previous one. Third –and last- position refers to “Poor coordination” (IF 10_ EPC 10 and EPC 25), which has lowest Assessed EPC Affect and %CU values.

Table 26: Results of HEART application_ Task 2

TASK 2								
IF		EPC		EPC_Multipli	PoA	AssessedEPC Affect	%CU (G)	%CU (G)_IF
5	Poor management of errors	2	Shortage of time for errors detection	11	61,33	7,133	0,259	0,39
		7	No means reversing unintended actions	8	3,84	1,268	0,046	
		12	Mismatch: perceived & real risks	4	7,67	1,230	0,045	
		18	Conflict: long &immediate objectives	2,5	3,84	1,058	0,038	
9	Poor communication	5	No means of conveying info	8	34,00	3,380	0,123	0,24
		8	Capacity overload	6	42,67	3,133	0,114	
1	Noise&ambient talk	3	Low signal to noise ratio	10	54,33	5,890	0,214	0,21
10	Poor coordination	10	Transfert knoledge from task to task	5,5	50,00	3,250	0,118	0,16
		25	Unclear allocation of responsabilities	1,6	40,00	1,240	0,045	

The four IFs, selected for Task 2, were traduced by nine EPCs showed in the Table above. It is possible to observe that, also in this case, IF 5 “Poor management of errors”, referred to EPC 2 “Shortage of time available for error detection & correction” results to be the most critical one, having the greatest value of Assessed EPC Affect and Percentage Contribution to Unreliability (%CU = 0,39). On the other hand, second position of criticality is occupied by IF 9 “Unclear communication”, which is an IF that was not commonly considered by all three surgeons for the Task 1 assessment. This IF is referred to EPC 5 and EPC 8: they both have medium EPC Multiplier and PoA values and contribute to obtain %CU= 0,24. Third and Fourth positions are occupied by IF 1 (%CU= 21) and IF 10 (%CU=16), respectively.

Discussion

Final ANLU value resulted to be for Task 2 greater than 1, because the analysis took into account a larger number of Influencing Factors, affecting negatively, at the same time, surgeon's performance during the execution of the task.

ANLU values confirm the concerns on the large number of IFs retrieved from surgeons' questionnaires. A feature of this modified methodology is that it requires a conversion of factors from one taxonomy to another. Therefore, the number of factors (IF) identified by the experts, already large and then reduced by selected criteria, was incremented, leading the analysis to consider a greater number of EPCs: in Task 1 from three IFs to seven EPCs, while in Tasks 2 from four IFs to nine EPCs. Here because, the contribution -more or less significative- of all Assessed EPC Affect, once multiplied together, contributes to generate, in Task 2, an ANLU value larger than 1.

Furthermore, comparing the analysis of two different Tasks it has been possible to note that, not only both tasks better refer to the same Generic Task Category G, but they also have the same most critical Influencing Factors, IF 5.

Surgeons seem to be highly affected by "Shortage of time available for error detection & correction" (EPC 2_IF 5), as seen by the corresponding EPC Percentage Contribution to Unreliability of 0,33% (Task 1) and 0,26% (Task 2). Remedial measures identify the need for surgeons to have adequate time to complete tasks to prevent errors. In particular, it is important to improve skills in sharing information promptly about errors and threats to patient safety. This concern can be dictated also by stress due to others surgeries planned for the same day and/or little practical use of the tools available for errors correction. Additional remedial measures will be discussed in the next paragraph.

Furthermore, surgeons are particularly concerned with "Unclear communication"(IF 9) for Task 2 and "Noise and ambient talk"(IF 1) for both Tasks: these issues have been significantly observed and discussed also during the direct observation of the two surgeries.

5.4 Analysis of Scenarios and proposed improvement measures

First of all, a Scenario Analysis has been performed on each IF with the aim to analysis the maximum range of Assessed Nominal Likelihood of Unreliability (ANLU) value referred to the studied factor. In order to do that, Nominal Human Unreliability for the chosen Generic Task (NHU_G = 0,0004) have been compared with ANLU value calculated by considering only the effect of a single IF. In this way, it is possible to observe how does the IF effects the ANLU value: when no IF acts on surgeon's performance, ANLU=NHU= 0,0004, when only one IF is present, then its maximum effect has been calculated. ANLU values for each IF have been investigated for both Task 1 and Task 2, basing on surgeon's averaged assessment of PoA values for the considered factor. The table below shows the maximum range of ANLU value for each Influencing Factor.

Table 27: Range of variation of ANLU value for each relevant IF

	Noise and Ambient Talk IF 1	Poor management of errors IF 5	Unclear Communication IF 9	Poor Coordination IF 10
Range of ANLU for Task 1	0,0004 - 0,0025	0,0004 - 0,0040	---------------	0,0004 - 0,00135
Range of ANLU for Task 2	0,0004 – 0,0024	0,0004 - 0,0047	0,0004 - 0,0042	0,0004 - 0,0016

From Table 27, it is possible to observe that greater range of ANLU is obtained form IF 5 "Poor management of errors" for both Task 1 and Task 2. This means that, in the execution of both Task 1 "Isolation of lateral peduncles and of posterior prostate surface" and Task 2 "Anastomosis", it is confirmed that IF 5 is the one that can have greater impact on surgeons' performance and it can lead to the largest value of Human Unreliability.

At this point, instead of considering separately the effect of each IF, three main scenarios have been studied in order to investigate their impact on ANLU value. Therefore, Influencing Factors have been divided into three categories, considering personal, team and organizational aspects. New ANLU value, for each scenario, was calculated, considering the impact of only those IFs referred to the selected category. Subsequently, by analysing the three scenarios, and considering the possibility of reducing the effect of Influencing Factors, some improvement actions have been identified. Afterwards, proposed remedial strategies -for each scenario- have been subjected to a surgeon. She/he was asked to give an estimation of percentage reduction of influence of IFs related to the category (i.e. percentage reduction of PoA related to IFs of that scenario, if strategies are correctly implemented). Finally, the overall ANLU reduction was calculated in the case in which all the proposed remedial actions are applied.

The Table below shows how Influencing Factors have been categorized, as referring to “personal”, “team” or “organizational” characteristics.

Table 28: Categorization of selected IFs

Influencing Factors		Category of Scenario
1	Noise and Ambient Talk	Team
5	Poor management of errors	Organizational
9	Unclear Communication	Team /Personal
10	Poor Coordination	Team/ Personal

Starting from the identification of the three categories of scenarios, based on the division of the IFs into “personal”, “team” and “organizational” aspects, a “Scenarios Analysis” has been performed on each category. This means that ANLU value has been calculated by considering only the effect of one category each time, in order to identify which category leads to the highest unreliability rate. This type of analysis has been performed both for Task 1 and Task 2. The chosen scenarios well represent possible situations occurring in real operation room, where these three categories of aspects are usually present separately or even together.

In the following, the three scenarios are introduced, with a brief description of key features, especially obtained from direct observation in the operating room.

5.4.1 First Scenario

The first scenario considered is related to personal factors that occur during the execution of a surgery. Among the factors analysed in the case study, “Communication” (IF 9) and “Coordination” (IF 10) were selected as Influencing Factors having strong impact on surgeon’s performance and easily detectable during the observational phase.

Unclear communication and poor coordination can be associate to the personal aspect because they can be related to the individual personality of the surgeon, although there are clear links with team aspects too. Therefore, these factors may be associated to both categories and benefit from common improvement actions.

Lingard and his colleagues have found that 31% of all communications could be categorised as a failure, whether the information was missing, the timing was poor, or where issues were not resolved (Lingard et al, 2004).

Influence of personal factors was experienced even with during direct observation of the two robotic surgeries, in which, for example, surgeon had sudden change the tone of his voice, probably due to moments of stress, fatigue and background noise. Several times, first surgeon drew the attention of the other surgeon who was not in efficient coordination and timing. Rude tone and yells were sometimes addressed to other members too, called several times to silence and attention. The surgeon was also annoyed by the numerous phone calls received for work issues. Furthermore, communication in assisted robotic surgery is disturbed by the dislocation of the two surgeons and the use of microphone: this makes communication more difficult because often it is not possible to properly understand commands and they need to be repeated more than one time.

<u>Improvement strategies and actions</u>

Improvement measures hypothesized for this scenario involve training simulation to educate people about communication and coordination during surgeries. Moreover, even classroom training (frontal training) can be useful to stimulate and educate to clear and efficient language, as well as transmission of information or commands without losses. During training activities it is important to consider that people of different status and sex have very different ways of communicating. Thanks to training activities it is possible to acquire appropriate, technical and consolidated vocabulary, allowing improved communication without misunderstandings and wrong interpretations.

Besides vocal communication between surgeons it is necessary to ensure correspondence with the actions that are taking place: if the surgeon asks to another surgeon for a tool or an operation, explicit vocal request is often not enough, but a visible feedback in the monitor is needed too (for example point out something or showing were the other person has to act). This is motivated by the fact that, surgeon in console and the one at the table cannot directly see each other and they can only communicate through microphone and monitors.

In addition, surgeon must ensure that his commands are always received and understood by the other surgeon: there should always be voice confirmation of receipt of the message.

These improvement actions can help to reduce, at least in part, personal difficulties of communication and coordination, thereby influencing consequently also the probability of Human Unreliability.

Improvement strategies, proposed for First Scenario, are summarized in the table below. In addition, Table 29 shows surgeon's opinion about percentage of improvement that these actions would have on the influence of the category (PoA of IFs corresponding to Personal Category).

Table 29: Improvement actions proposed for Scenario 1

Improvement actions for Scenario 1	**Percentage reduction of the influence of the category, thanks to remedial strategies**
1) Simulation Training to teach communication and coordination during surgeries.	80%
2) Frontal Training that encourages and educates to a clear and efficient transmission of information without losses.	50%

3) Surgeons must ascertain that their commands are always understood from the other surgeon (voice confirmation). 4) When possible, the communication should not only be vocal, but it must have some visual feedback on the monitor.	40% 20%

Scenario Analysis on Personal Category

Firstly, Scenario Analysis was performed on Personal category, which refers to IF 10 ”Poor Coordination” (for both Task 1 and Task 2) and IF 9 “Unclear Communication” (for only Task 2).

Scenario Analysis is based on the understanding of how does ANLU value changes, by varying the influence of IFs (i.e. IF 9 and 10 for Personal Category). In particular, ANLU value has a linear variation, by increasing and decreasing the impact of each Influencing Factor effect. Consequently, it was calculated new ANLU value when whole effect of Personal category is acting on the execution of the two Tasks and no others categories of influence are present.

For TASK 1, New ANLU=0,00135, which correspond to 98,4 % of ANLU percentage reduction from the starting condition of the case study (ANLU = 0,0851). For TASK 2 New ANLU= 0,0171, corresponding to 98,3 % of percentage reduction.

The graph below shows Human Unreliability rate when only Personal factors influence on surgeon’s performance. Since Task 2 considers both IF 9 and IF 10, while Task 1 takes into account only IF 10 (as personal) -with different PoA estimations-, ANLU resulted to be much greater for the second Task.

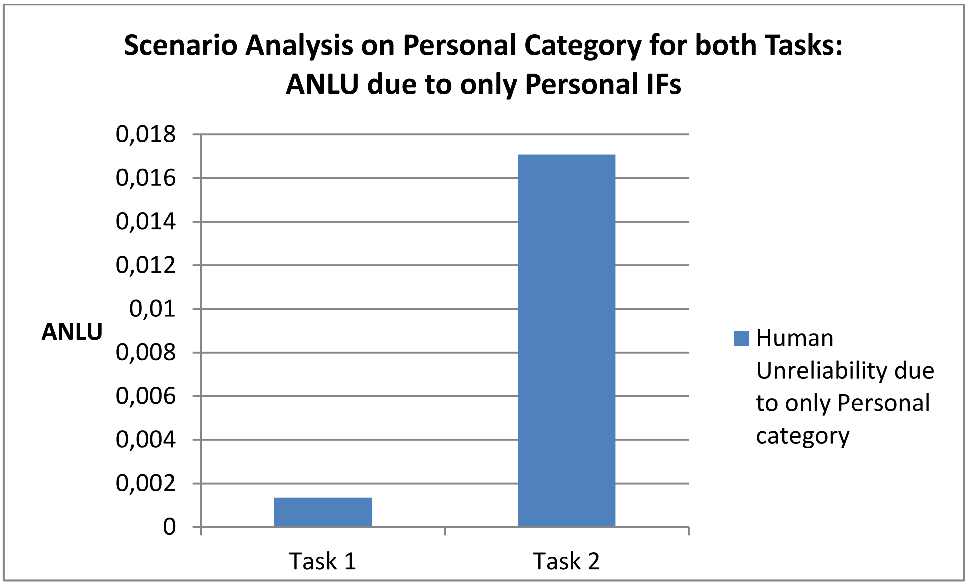

Figure 22: Histogram representing ANLU for Scenario Analysis on Personal Category

At this point it becomes interesting to investigate how these new ANLU values could change by implementing some remedial actions. In particular, starting from surgeon's estimation of possible reduction of the impact of the category, ANLU variation have been calculated for each proposed improvement action.

The graph below shows expected ANLU reduction obtained as difference between the initial value of the case study and the new ANLU value calculated when the strategy is implemented.

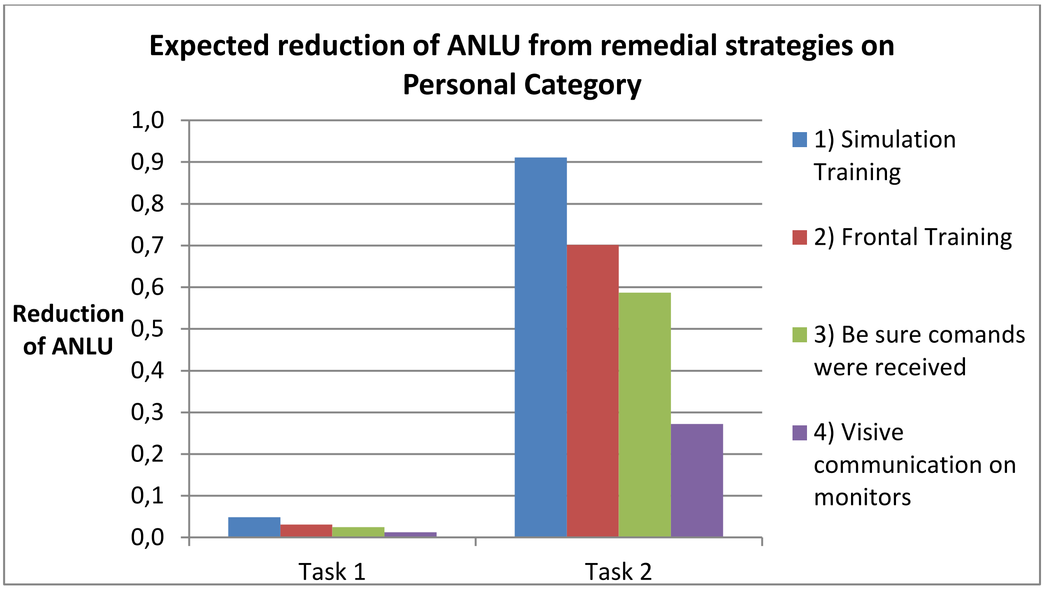

Figure 23: Expected reduction of ANLU due to singular remedial strategy on Scenario1

Figure 25 shows that, in accordance with percentage estimations of the surgeon, "Simulation Training" allows to get the greatest reduction of Human Unreliability rate, while "Visual communication" enables only about a quarter of the previous reduction.

Next, it was calculated the final ANLU when all improvement actions are implemented, one by one, starting with those that, from surgeon's estimation, can permit greater reduction.

The Line Graph below shows linear variation of ANLU value between Human Unreliability rate related to the scenario category ("*as is*"; $ANLU_{Task\ 1}$= 0,00135; $ANLU_{Task\ 2}$ = 0,01707) and the reduced value when all improvement actions are implemented ("*to be*"; $ANLU^*_{Task\ 1}$= 0,000443; $ANLU^*_{Task\ 2}$ = 0,000551).

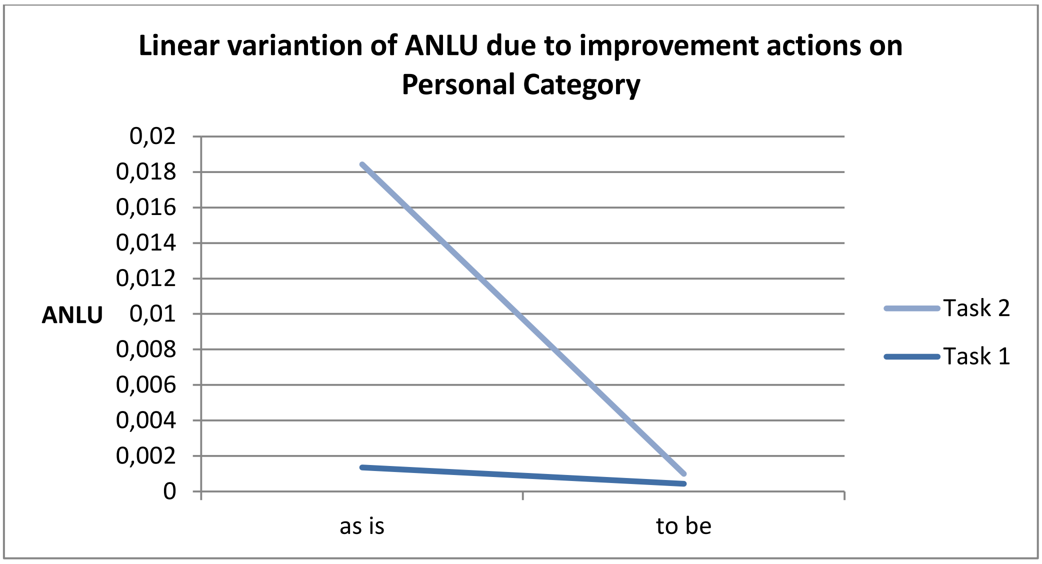

Figure 24: Line graph showing potential ANLU variation obtained with remedial strategies for Scenario 1

Same results can be represented also through the Histogram below, which shows ANLU potential reduction for both Task 1 and Task 2, when all proposed strategies are executed. The ANLU percentage reduction obtained for Task 1 is equal to 67 % and 96,8 % for Task 2.

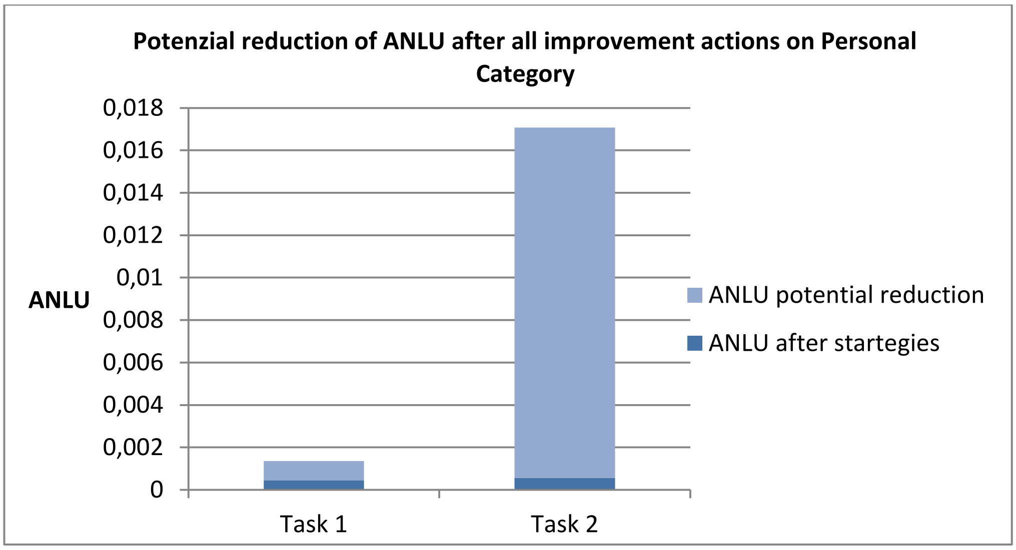

Figure 25: Potential reduction of ANLU by applying all remedial strategies for Scenario 1

5.4.2 Second Scenario

The second scenario is the one concerning the influence of the Team category, which refer to "Noise and Ambient Talk" (IF 1) and, as previously said, also the already mentioned factors “Communication” (IF 9) and “Coordination” (IF 10).

Team members are key elements of the system that always interact together and with surgeons; that is why coordination and clear communication are two important factors during surgery. These factors must be taken into account with progressive learning, identification, correction, and emphasis of aggravating moments of disorder and confusion. Coordination and communication can either occur explicitly or implicitly. Team members can intentionally communicate or they can anticipate, assist and adjust without verbal instructions, relying on shared understanding of the task and the situation. Team members are continuously involved in reciprocal process to send/ receive information that forms and re-forms a team’s attitudes, behaviours, and cognitions.

During the direct observation, it was noted clear familiarity with procedures, thanks to their standardization and compliance of protocols. Despite that, there have been disturbing actions that contributed to impoverish coordination. For example, presence of shift changes during the course of both observed surgeries, leading to the need for handovers, and the frequent use of social media by team members less involved in operations. The significant duration of the surgeries does not contribute to continuous concentration, on the opposite, it facilitates distraction, chatting and use of mobile phones. Disturbing voices in the background influence on concentration of surgeons and other people on the team. Additional noise and disruptive actions may derive from not available instrumentation which generate impoverished coordination between anaesthetist and surgeons. Consequently, members of the team have to look for required tools in the operating room or somewhere else, generating noise, for example related to doors, time off and decrease of concentration.

If team members are distracted or do not implement maximum coordination with surgeons, they are not able to optimally help surgeons in the execution of the tasks of the surgical procedure. In fact, the team should always share relevant technical information concerning the environment and the surgery, without loss of important data and, when possible, assistants should facilitate and anticipate the needs of surgeons.

Improvement strategies and actions

In this scenario, it becomes essential to implement some remedial actions. The identification of a team based approach for improving quality care requires the implementation of interprofessional education, training sessions and meeting involving the whole operating team to instill advanced knowledge, skills, and attitudes required for optimal teamwork. Raising of team's skills allows the develop automatisms and non-technical skills.

Another fundamental element is the team-stabilization: it is important to keep the surgical team, as much as possible, unchanged for similar surgeries that required analogous knowledge and skills. Moreover, familiarization between team members is another important factor, which contribute to better communication and coordination. Researches have shown that longer a team is together, better are its results also in terms of good communication (Lingard et al, 2004).

For these reasons scheduling of work shifts should take into account these issues and should avoid change of shift during the execution of a surgical procedure, in order to keep silent and concentration. Additionally, it is important to establish organisational and team policies about communication, for example which disallows distraction in the operating room.

However, stability and familiarity between team members is not always possible, as in contrast with quality requirements of flexibility and efficiency of operating room scheduling. Therefore, compensatory action, that allows to get a similar expected benefit, can be obtained by raising up skill and ability levels of the entire team through repeated training activities. It is recommended to train team member to develop open, adaptable, accurate and concise communication: implementation of interprofessional education should contribute to provide guidance on how implement information exchange protocols.

In order to avoid problems related to communication and coordination, it is also recommended to only use equipment or personnel that are strictly required. Resources in terms of staff and equipment have an effect on communication because they influence on team members' level of stress and confusion (Lingard et al, 2004).

Furthermore, the use of social media should be limited and planned in order to avoid distractions: it must be limited to the preoperative room, planning its use when necessary, with the identification of specific personnel who can filter important calls.

These actions should be identified and prevented, for example by the use of accurate checklists that allow and facilitate the control and implementation of preoperative phases (i.e. cell phones off, material properly positioned, ready tools available for intervention etc.). It is also recommended the implementation of protocols to maintain silence and use words only for necessary purposes.

Additionally, it is also suggested to introduce in the evaluation sheets of team members aspects related to “respect of protocols, use of personal mobile phones in the operating theatre, as well as the appropriate communication”.

The Table below lists proposed remedial actions for the Second Scenario and it shows surgeon’s opinion about their percentage improvement on Team Category influence on surgeons’ performance, if these strategies would be adopted.

Table 30: Improvement actions proposed for Scenario 2

Improvement actions for Scenario 2	Percentage reduction of the influence of the category, thanks to remedial strategies
1) Stability and familiarity between team members.	80%
2) Increase of skills and ability of the whole team, thanks to repeatedly training activities.	60%
3) Limited use of social media at the preoperative room. Use of checklist to make sure that this protocol is followed.	40%
4) Specific personnel who can filter important calls.	60%
5) Only use of equipment or personnel that are strictly required.	50%
6) Scheduling of work shifts that avoid shift-change during surgeries.	50%
7) Protocols to keep silent.	60%

8) Evaluation sheets of team members related to respect of protocols, use of personal mobile phones in the operating theatre, as well as the appropriate communication.	10%

<u>Scenario Analysis on Team Category</u>

For Task 1 Scenario Analysis on Team category have been performed by considering "IF 1: Noise and ambient talk" and "IF 10: Poor coordination". The new value of ANLU, obtained when only Team category is impacting surgeons' performance, is equal to 0,00848, which corresponds to 90 % of percentage reduction from the starting condition of the case study. For Task 2, Scenario Analysis on Team category have been performed on the previous two factors and also on IF 9 "Unclear communication", which is not considered in the analysis of Task 1. In this case, New ANLU= 0,1006, which corresponds to 89,9 % of percentage reduction.

The graph below shows the results of Scenario Analysis on Team Category for both Task 1 and Task 2.

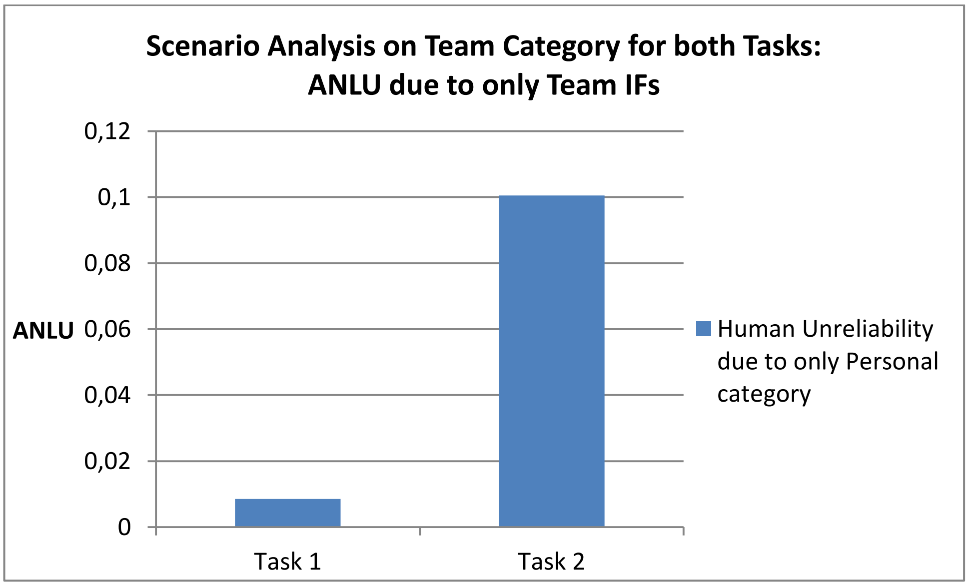

Figure 26: Histogram representing ANLU for Scenario Analysis on Team Category

As it was done for the previous category, it was investigated how each proposed remedial action reduces Human Unreliability rate. This calculation was based on estimations of the percentage reduction given by surgeon. The graph below shows expected ANLU reduction when singularly strategies are applied.

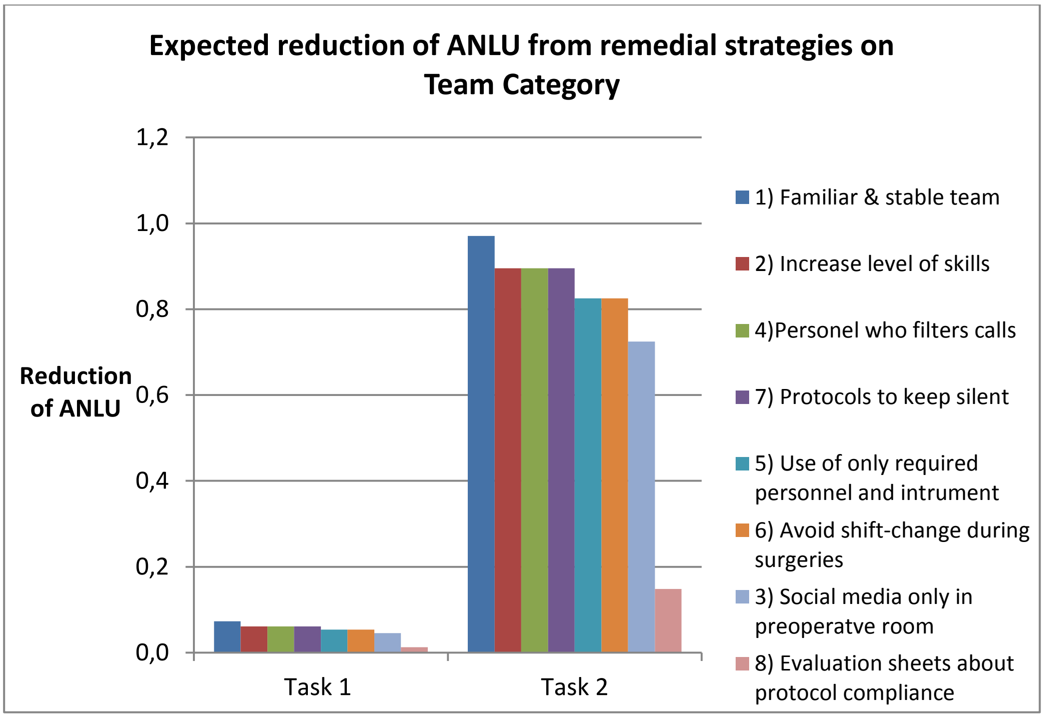

Figure 27: Expected reduction of ANLU due to singular remedial strategy on Scenario 2

Figure above shows that, in accordance with references (Lingard et al, 2004) and surgeon's opinion, considering Team scenario "Familiar and stable team" has the greatest impact on Human Unreliability reduction. Following, "increase level of skills of the whole time" has the same potential benefit of "presence of personal who can filter important calls" and of "protocols to keep silent". On the other hand, "evaluation sheet of team members that consider protocol compliance" results to be the improvement action having the lowest potential reduction of ANLU value.

At this point it was calculated the overall ANLU reduction when all remedial measures are implemented at the same time.

The Line Graph below shows linear variation of ANLU value between its value related to the scenario category ("*as is*"; $ANLU_{Task\ 1}$= 0,00848; $ANLU_{Task\ 2}$ = 0,10056) and the reduced value when all improvement actions are implemented ("*to be*"; $ANLU^*_{Task\ 1}$= 0,000405; $ANLU^*_{Task\ 2}$ = 0,000408).

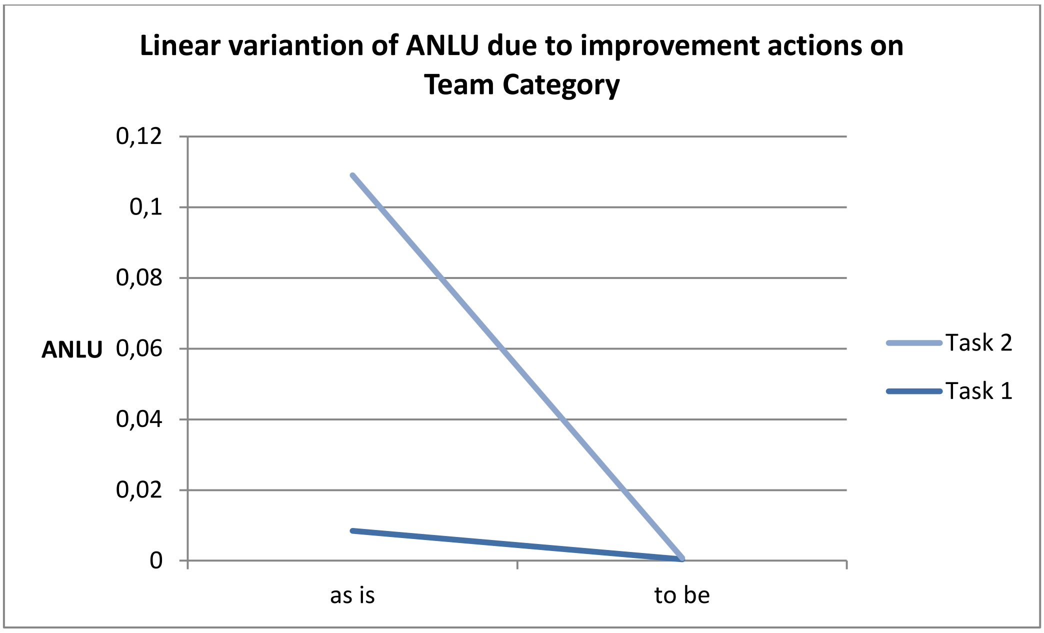

Figure 28: Line graph showing potential ANLU variation obtained with remedial strategies for Scenario 2

In the same way, the Histogram below shows ANLU potential reduction for both Task 1 and Task 2, when all proposed strategies are executed. The ANLU percentage reduction obtained for Task 1 is equal to 95,2 % and 99,6 % for Task 2. Also in this case, greatest percentage reduction of ANLU is obtained thanks to improvement actions on Task 2.

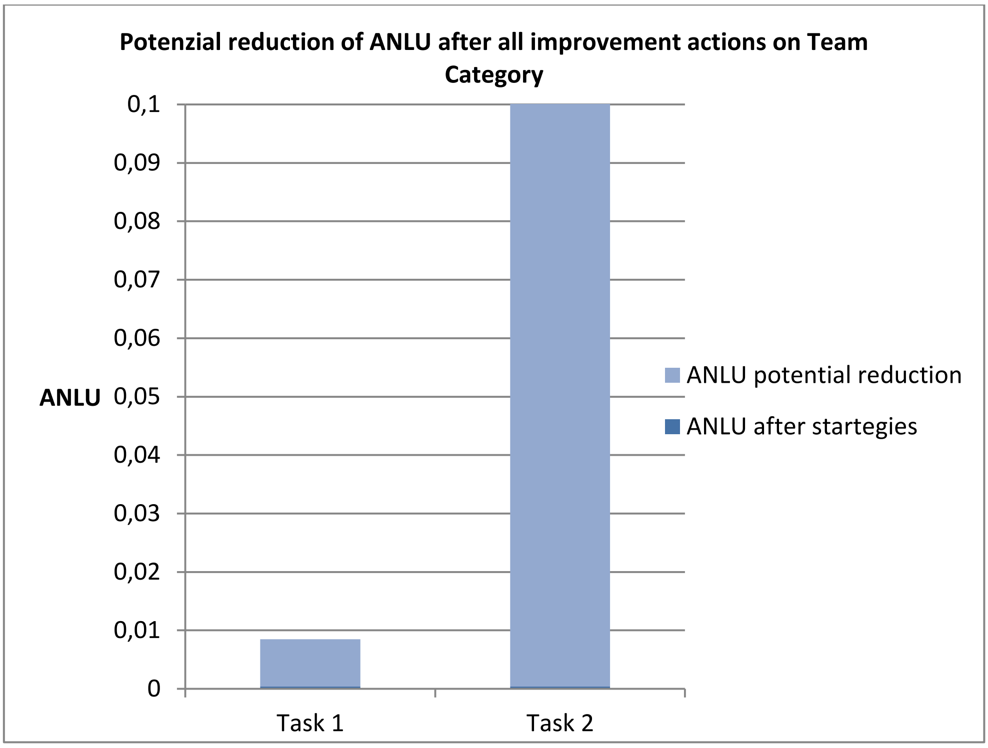

Figure 29: Potential reduction of ANLU by applying all remedial strategies for Scenario 2

5.4.3 Third Scenario

Finally it is necessary to consider Influencing Factor related to Organisational Category: “Poor management of errors” (IF 5).

During the direct observation of the second surgery, it occurred an event that caused difficulties in implementing the procedure. The patient, on anticoagulant therapy, had significant bleeding, because the anticoagulant therapy was not suspended, as usual, before the surgery. This resulted in the need of repeated cauterizations, stanches and cleaning of instruments and visible surgery field.

Another factor that can affect good error management is surgeon’s experience. The second surgery was characterized by the fact that surgeon at the table was in robotics training: on that occasion, the more experienced surgeon in console had to constantly supervise his work and to provide guidance on how to perform various tasks.

Furthermore, it was observed that, for both surgeries, the first part of the procedure was performed by a surgeon in the console, which left the operating room before starting anastomosis phase; thus, anastomosis was performed in the console by the surgeon who previously was at the table.

The analysed procedure was carried out in full compliance of protocols: few deviations adopted were due to special anatomical and pathological conditions of the patients, such as excessive fat or excessive bleeding.

Improvement strategies and actions

It is known that, standardization and compliance with protocols, which describe in detail each step of the procedure, are always adopted in every surgery. This is done because the same procedure could be repeated on different patients, always in the same way. It is very important that procedures are clear, complete, understandable, updated, well known and followed. It is also essential to have emergency procedures identified for possible scenarios of deviation.

It is important that surgeon is always aware of the situation and its possible consequences that can occur. It is necessary to have complete and correct knowledge of the state of health of the patient, and not only about specific data of the current surgery. This is because, in real life, there are always biochemical, anatomical and physiological interactions, which may contribute to modify and complicate the clinical situation. For this reason, it is recommended to increase training regarding the ability to read and interpret clinical and anamnestic data. There are researches that compare surgeons' talent with surgical duration, but there are no studies that also pay attention to the time dedicated to the understanding of the state of the patient, related to his age, his medical condition and previous therapeutic treatments.

It is also recommended the use of checklists to count instruments used during surgery (threads, needle, etc.) and verify their final number. It is necessary also to have a feedback that controls that those checklists are actually used every time.

In order to optimize economic resources, it is recommended to take advantage from daily surgeries as opportunities for sharing and comparing knowledges and abilities and to improve personal skills by learning from mistakes. From early stages when surgical techniques are taught, training activities should focus on how to manage possible errors and raise awareness of potential risks in the various tasks of the procedure.

Safety briefing is a simple and easy tool to use to ensure a shared approach that encourage sharing of information about emergency situations, actual and potential risks and possible error management actions retrieved from previous experience. Moreover, coaching may be useful to the enactment of leadership behaviours to establish and direct goals by encouraging team members to problem solving, coordination processes, and motivational states. It is important to identify risks related to various professionals and their responsibilities. Interprofessional education should incorporate activities focusing on role clarifications too.

It is fundamental to create a serene environment, which facilitates open communication of errors, not as a punishment, but as an opportunity for discussion and common growth. In this way it is possible to limit 'defensive common culture' based on blame others, protecting themselves from negative judgments.

In order to adopt better error management, it is important to recognize the value and potentiality of clinical documentation for clinical risks prevention and the analysis of the events related to it. For this purpose it is required to fill in a proper form all documentations to contribute to its achievement and an effective reporting system.

Finally, it is important to ensure good scheduling of surgeries during the workday: most critical and long surgeries need to be performed first, then less critical and shorter ones and finally those can be eventually postponed.

The Table below summarizes improvement strategies, proposed for Organizational Scenario, and it shows surgeon's opinion about reduction of influence of PoA values related to Organizational IFs.

Table 31: Improvement actions proposed for Scenario 3

Improvement actions for Scenario 3	Percentage reduction of the influence of the category, thanks to remedial strategies
1) Effective respect of standardized procedures.	80%
2) Use of checklists to verify used instruments and to check their final presence.	60%
3) Use surgeries as opportunities to learn from mistakes.	70%
4) Clarification of the roles and responsibilities of team members and surgeons.	30%
5) When possible, better scheduling of the surgeries during the workday.	80%
6) Structured training, right from the initial stages of learning, to raise awareness of potential risks and possible errors.	80%
7) Available clear emergency procedures well known from surgeons and team members.	60%

Scenario Analysis on Organizational Category

At the end, Scenario Analysis was performed on Organizational category, for both Task 1 and Task 2, by analysing impact of IF 5 “Poor management of errors”, involving the following EPCs: EPC 2: “Shortage of time for error detection”, EPC 7 “No means of reversing an unintended action” EPC 12 “Mismatch between real and perceived risks” and EPC 18 “Conflict between long and immediate objectives”.

For Task 1, New ANLU value is equal to 0,00401, which corresponds to 95,3 % of percentage reduction from the starting condition of the case study (ANLU = 0,0851). For Task 2, New ANLU value is equal to 0,00471 which corresponds to 99,5 % of percentage reduction of ANLU. The graph shows the value of ANLU due only to the presence of only Organizational factor (i.e., IF 5).

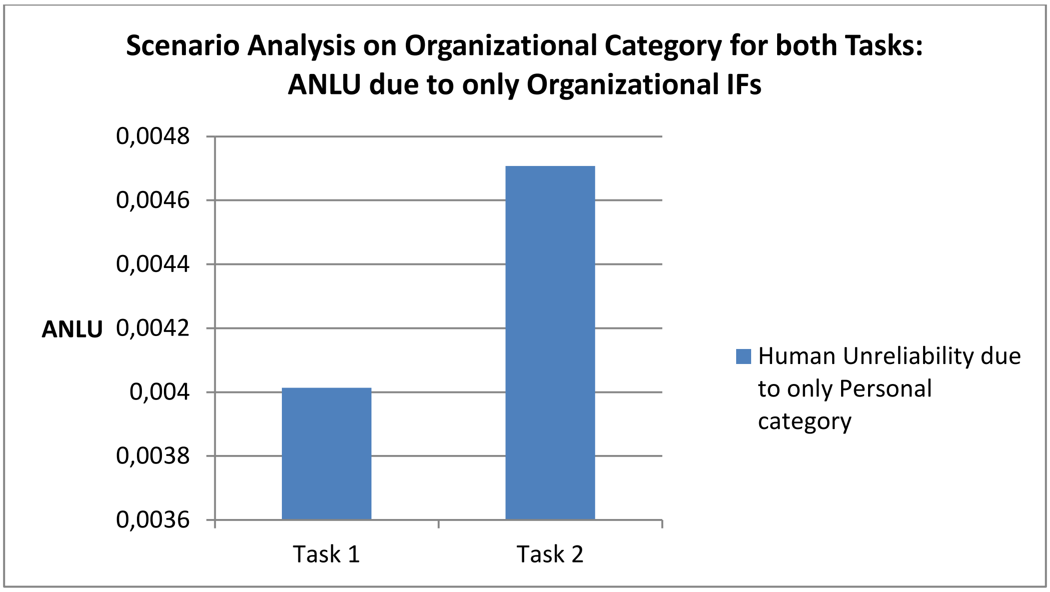

Figure 30: Histogram representing ANLU for Scenario Analysis on Organizational Category

The effect of improvement actions, proposed for this scenario, is represented by the expected reduction of ANLU value when one of this strategy is applied.

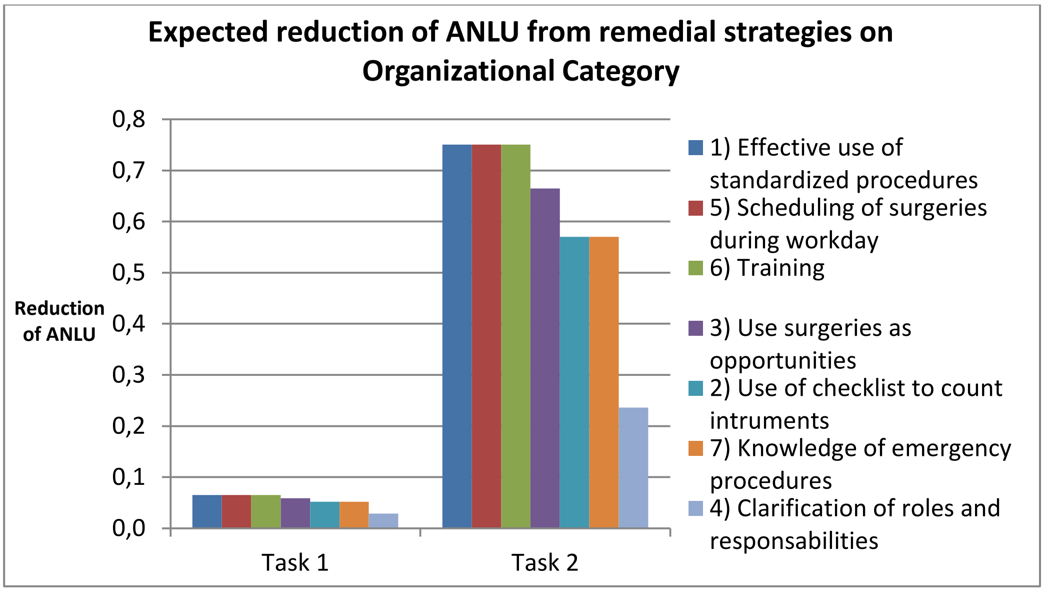

Figure 31: Expected reduction of ANLU due to singular remedial strategy on Scenario 3

From the Figure above it is possible to observe that "effective use of procedure", "scheduling of surgeries" and "training" can be considered compensative actions that allow to get the same potential greatest benefit. For this scenario "clarification of roles and responsibilities" resulted to be a strategy which lead to the lowest reduction of Human Unreliability.

Finally ANLU was calculated in the hypotheses that all improvement actions are applied and they can allow a percentage reduction of the impact of Organizational IF, as proposed by surgeon.

The Line Graph below shows linear variation of ANLU value between Human Unreliability rate related to the scenario category ("*as is*"; $ANLU_{Task\ 1}$= 0,004014; $ANLU_{Task\ 2}$ = 0,004708) and the reduced value when all improvement actions are implemented ("*to be*"; $ANLU^*_{Task\ 1}$= 0,000401; $ANLU^*_{Task\ 2}$ = 0,000401).

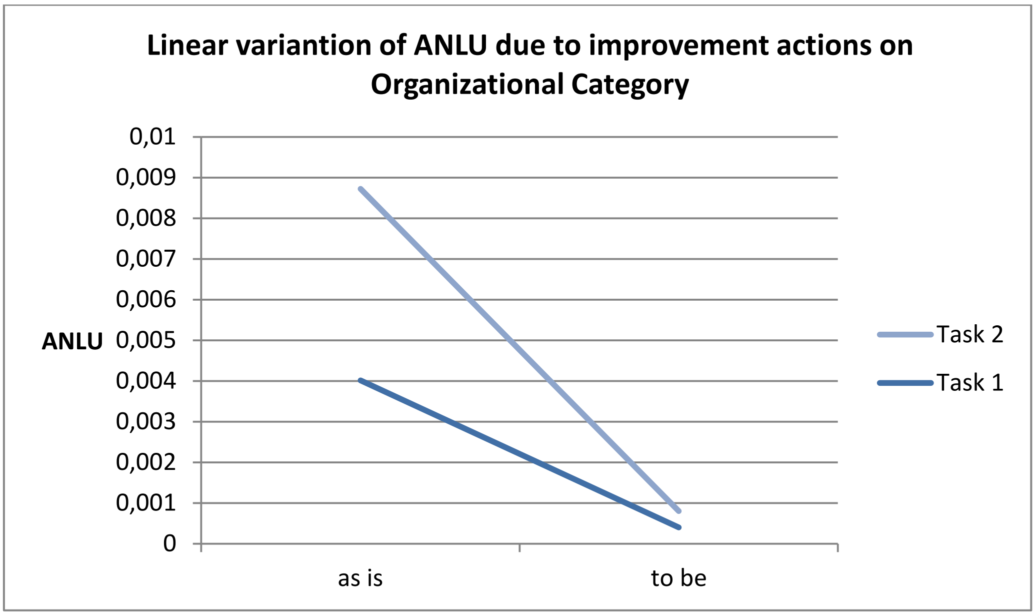

Figure 32: Line graph showing potential ANLU variation obtained with remedial strategies on Scenario 3

Same results are represented in the Histogram below, which shows ANLU potential reduction when all proposed strategies are executed. The potential

ANLU percentage reduction obtained for Task 1 is equal to 90 % and 91,5 % for Task 2.

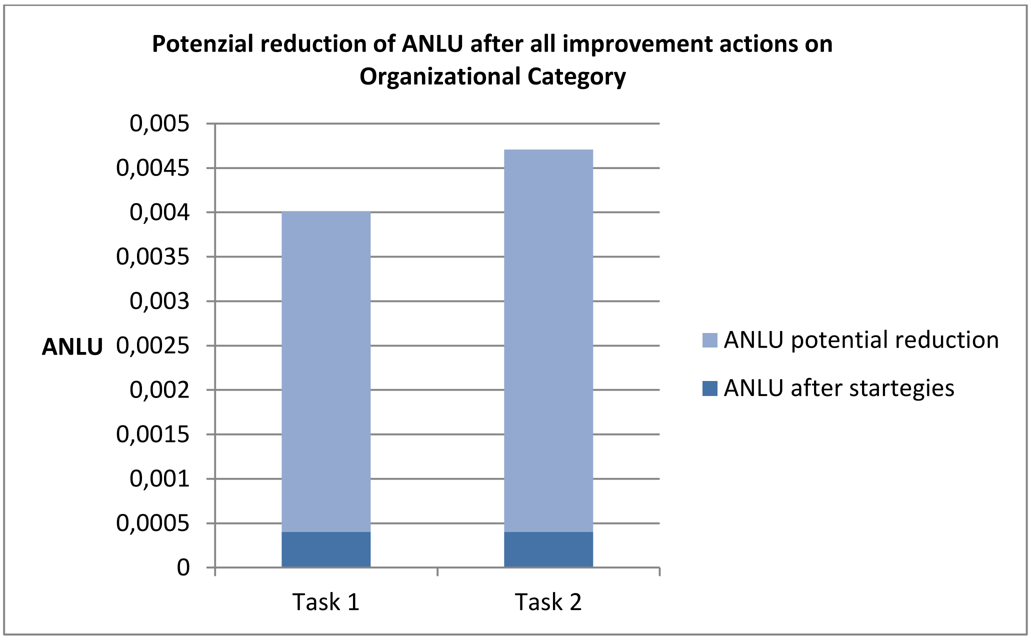

Figure 33: Potential reduction of ANLU by applying all remedial strategies for Scenario 3

5.4.4 Summary

From the Scenario Analysis performed on each relevant Influencing Factor it was possible to calculate Human Unreliability value due to the presence of the individual selected factor. Table 27 shows that IF 5 "Poor management of errors" leads to the larger possible value of ANLU. This means that, if we consider separately scenarios characterized by only one IF each time, with the estimations retrieved from surgeon's questionnaires, the scenario that consider only IF 5will be the most critical one.

By considering Scenario categories of personal, team and organizational aspects, it was possible to observe that, for both Task 1 and Task 2, Team Scenario resulted to be the one that can lead to larger values of Human Unreliability Rate. The two graphs below confirm the previous statement showing ANLU values obtained by Scenario Analysis, considering separately only effect of personal, team and organizational categories.

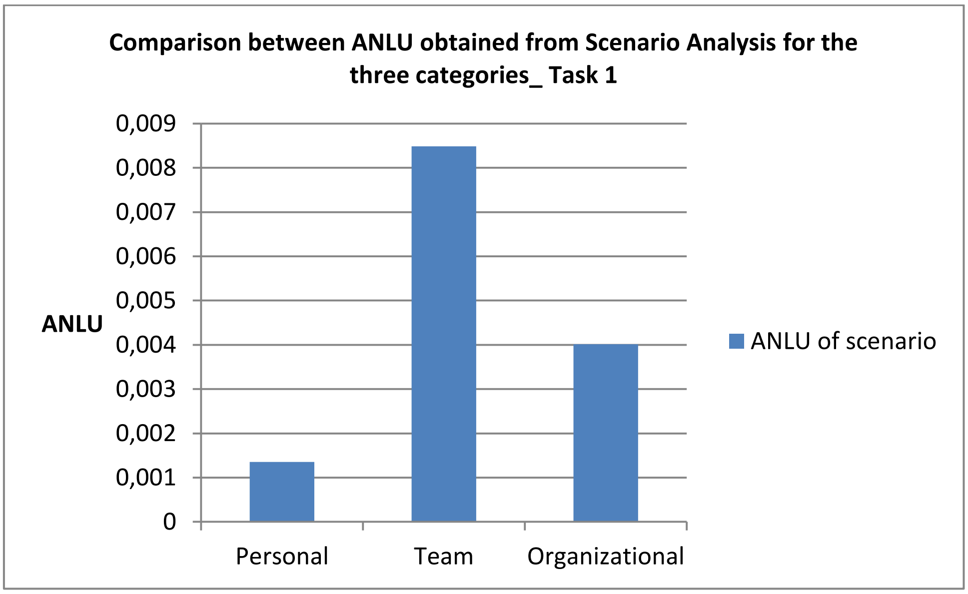

Figure 34: Histogram showing ANLU for Scenario Analysis on the three categories for Task 1

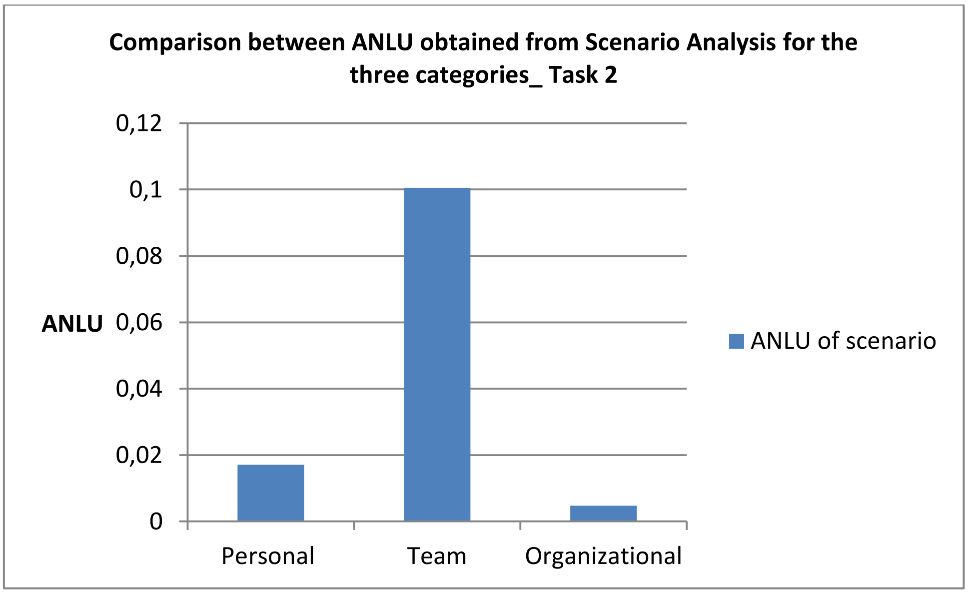

Figure 35: Histogram showing ANLU for Scenario Analysis on the three categories for Task 2

Finally improvement actions have been identified and new Human Unreliability rates were calculated in the case in which these action were implemented.

The Table below shows maximum percentage reduction of ANLU value of the scenario that is obtained when improvement strategies are implemented.

Table 32: Maximum ANLU percentage variation for scenarios due to remedial actions

Scenario Category	**ANLU**		**%Reduction thanks to improvement actions**	
	Task 1	Task 2	Task 1	Task 2
PERSONAL				
as is to be	0,00135 0,000443	0,01707 0,000551	67,2 %	96,8 %
TEAM				
as is to be	0,00849 0,000405	0,10056 0,000408	95,2 %	99,6 %
ORGANIZATIONAL				
as is to be	0,00401 0,000401	0,00471 0,000401	90,0 %	91,5 %

From the results of this case study application, it is possible to observe that Organizational Scenario, when improvement actions are applied, can obtain lowest values of ANLU for both Task 1 and Task 2 (ANLU “to be”= 0,000401). On the other hand, greater percentage reduction of Human Unreliability rate is obtained by adopting improving measures that allow to reduce negative impact of IFs on “Team” category, for both Task 1 and Task 2 (Potential percentage reduction: 95,2% for Task 1 and 99,6% for Task 2).

CONCLUSIONS AND FUTHER DEVELOPMENTS

This study allowed developing and testing a modified HEART methodology for application in the healthcare sector, and surgery in particular.

The attention was directed to the analysis of surgeon's reliability/unreliability in robotic surgery, since it is an innovative sector where minimally invasive surgery allows optimizing precision, speeding up recovery and limiting human errors.

Surgery of the future will always be less invasive, and therefore the use of Robot for high complexity interventions will be increasingly the standard in hospitals. The spread of high-tech minimally invasive techniques caused substantial changes in the workflow of the surgical team, in technical -and not technical - abilities required to surgeons and in new ergonomics adopted.

The importance of robotic surgery and the clear investment in future developments highlight the need to carry out studies and important researches in the field of Human Reliability Analysis, because (for now and the near future) the robot does not replace the surgeon but supports him in close cooperation and interaction. That's why the analysis and management of human error, and the application of HRA techniques, are fundamental and necessary.

The socio-technical complex system of healthcare organizations is characterized by reactive approaches, strongly focused on the retrospectively analysis (ex-post) of adverse events, such as incident data analysis. Instead, HRA techniques are also anticipatory analyses (ex-ante), which represent a new twist in the healthcare world that help to predict or eliminate vulnerabilities into the system.

Literature analysis underscored the importance made by HRA techniques in the few surgery applications and the need to reduce the gap of applicability between the industrial and healthcare sector.

The first aim of this work was to develop a modified HEART methodology 'ad hoc' for the healthcare field. In particular, the application of HEART technique in surgery required a series of modifications placed to translate and convert this technique from the original industrial setting to the new one, reducing disadvantages and weaknesses. Starting from the use of a taxonomy of Influencing Factors for high-tech surgeries (laparoscopic and robotic), the development of modified HEART technique and its first application reduce the gap observed in the literature and contributes to the development of Human Reliability Analysis methodologies designed for surgery applications.

The methodological steps developed to achieve the objectives were:

- Literature analysis of HRA techniques and their applications in healthcare, in particular focusing on the HEART methodology;
- Literature analysis of Task Analysis of Prostatectomy Robotics BA-RARP procedures, with identification of the most critical tasks;
- Empirical observational activity of two robotic surgeries;
- Modelling of HEART methodology: identification of required modifications to make it more feasible to the surgical practice;
- Collection of experts' data (i.e. three robotic surgeons);
- Application of the modified HEART methodology;
- Scenario analysis on the Influencing Factors considered more impacting surgeon's performances.

The observational activities and collaboration with team of robotic surgeons allowed to:

- Obtain a validation of the task analysis of BA-RARP procedure chosen for the case study;
- Have a discussion on the most critical tasks in the execution of the procedure;
- Get surgeons' opinions on the impact of Influencing Factors on two different Tasks of the selected surgical procedure;
- Acquire surgeon's opinion about the effect of the proposed improvement actions.

The qualitative analysis, based on the observation and investigation of Influencing Factors, allowed to identify the relevance of different factors of the surgical taxonomy already highlighted in the literature.

The quantitative analysis, with the application of the modified HEART methodology, confirmed the quantitative relevance of some factors on others, allowing to identify those ones that require remedial measures, aimed to limit their negative influence on the execution of the tasks of the procedure. The quantitative analysis was limited from the high variability of the obtained results. Anyway, it has been possible to identify, as desired, the most Influencing Factors on the surgeon's performances, in agreement with what observed in the operating room.

Finally, a Scenario Analysis was carried out to understand how Human Unreliability rate may vary, acting, with improvement actions, on certain categories of Influencing Factors (i.e. personal, team, organizational).

Theoretical implications and future research

Assessor Team's inexperience in HRA techniques, and in particular HEART method chosen for the application, has been confined by the use of the Influencing Factors taxonomy validated for surgery. Therefore, surgeons involved in the work faced a familiar and understandable list of factors. Despite this, there have been some misunderstandings and difficulties in assigning the required values, probably due to the fact that they had never previously faced HEART technique.

This is a limitation of the HEART method which involves the interface with a target of people not in precise knowledge of the applied methodology. Questionnaires were submitted to three surgeons of the Ca' Granda Niguarda Hospital of Milan and this represents a change from the traditional HEART method which involves only a single external expert assessors.

Surgeons were asked to identify and give an estimation of the effect of the most significant Influencing Factors (IFs) in the execution of two different Tasks. Additionally, for the selected IFs, they were asked to evaluate a quantitative correspondence with Williams' traditional list of Error Promoting Conditions (EPC). The results of the questionnaires showed great variability about surgeons' perceptions. In particular, it was observed that, if new tasks and procedures are analysed, it is always necessary to acquire new values required from HEART technique, since the results are not only subjective, according to the opinion of the surgeon interviewed, but also strictly contingent to the phases of the selected procedure. In fact, each operation is characterized by peculiarities and uniqueness that influence the choice of the most significant IFs, their quantitative impacts and also their correspondence with Williams's EPCs.

Moreover, it was observed that Task 2 "Anastomosis", which is lightly simpler to be performed compared to Task 1 "Isolation of lateral peduncles and of posterior prostate surface", obtained an ANLU value greater than the one referred to the other Task. Paradoxically, the more technically complex Task results to have a lower human error probability rate. This is rightly explained by the fact that, during the execution of Task 2, there are multiple factors that combine to create a context with greater level of disturbances and less control. Furthermore the complexity of the two Tasks, during HEART application, was equalled by selecting the same Generic Task Category G, assigning to them the same Nominal Human Unreliability (NHU) value equal to 0,0004. On the other hand, as already mentioned, from the Generic Task Category List proposed by Williams, both Tasks are represented by the Generic Task G, even if Task 1 has greater technical complexity.

It is important for the development of study improvements that other procedures and surgical settings could experience this modified methodology, enhancing its diffusion, in order that this work does not remain a mere exercise of study. On the other hand, it is necessary to take into account that the applicability in complex areas needs a long time and readjustments.

Implications and relevance for practitioners

We hope that this work will support future training of robotic surgeons and the design of new procedures, checklists and simulation scenarios. In fact, the study highlights major operational and organizational factors which influence surgeons' performance. Therefore, it is important to take those factors into account and try to reduce their effect by raising surgeons' awareness about errors promoting conditions and implementing improvement actions, such as those proposed in the study.

Additionally, the work represents a useful contribution to technology providers, as it shows the close relationship of human-machine interaction, displaying the impact of technology in human resources support and also highlighting critical aspects. Consequently, it is possible to deduce improvement actions, in order to develop implementations on the "tactile" functions, fusion image systems and network functions for real-time sharing of information, during the execution of a surgery, between specialized experts.

In fact, robotic surgery has not yet expressed its full potential. From future studies there will be developments in advanced simulations, warning launched by the robot before human mind could make a false move, 'surgical suits' for the patient with built-in sensors for continuous monitoring of vital functions and 'platelet-cameras' which can move freely in the abdominal cavity, eliminating the need to insert a video camera (Giulianotti, 2014). Robotic surgeries will be even more automatic: the surgeon will only need to set data of the individual patient and then control robot's operations.

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APPENDIX 1: Tools used for RARP procedure

Tools used for RARP- Procedure at Ca'Granda Niguarda Hospital (Milano)
Bisturi lama 11
Kocker curvo per divaricare sottocute
Bakhaus sulla fascia e tensione verso l'alto
2 Farabeuf piccoli
2 pinze (anatomiche, chirurgiche o Durante)
3 trocar robotici
1 ottica robotica 30°
1 trocar Airseal
1 trocar 5 mm
1 trocar 12 mm
1 Johanne laparo
1 forbici laparo
1 clip Bbraun DS M
1 clip Bbraun DS SM
1 clip Bbraun DS S
1 clip Aesculap solo piccolo
1 clip metalliche da 10 mm
1 Ago di Verres
2 Ethilon 2-0 con aghi retti
1 Vicryl rapid 3-0 ago HR 22 non tagliente
2 V-Lok (15 cm e 23 cm con ago a semicerchio non tagliente)
1 seta 1 ago tagliente per fissare il drenaggio
1 Vicryl 0 ago 5/8 non tagliente per fascia
2 Vicryl rapide 2-0 con ago tagliente da cute
1 aspiratore Elefant 45 cm
1 Forbice monopolare curva robotica
1 Cadiere robotica
1 Maryland robotica
1 portaaghi robotico
1 catetere Dufour 18 Ch Simplastic
1 set per cistostomia a palloncino Foley 14 Ch
1 drenaggio tubulare

APPENDIX 2: BA-RARP Procedure

Tecnica Prostatectomia Radicale Robotica Retzius Sparing sec. Bocciardi

<u>ACCESSO LAPAROSCOPICO E POSIZIONAMENTO DEL ROBOT</u>
Incisione di cute e sottocute
Kocker curvo per divaricare sottocute
Bakhaus sulla fascia e tensione verso l'alto
Ago di Verres
Trocar
Ottica verso l'alto per vedere le pareti addominali
Prima 3 porte robotiche, poi altre 2 laparoscopiche (12 e 5 mm)

<u>TEMPO ALLA CONSOLLE</u>

Aiuto: ottica verso il basso; aspiratore a sinistra, Johanne a destra

1. Lisi eventuali aderenze del sigma
2. Eventuale sospensione sigma/ileo (punto di Pansadoro - Monocryl o Ethilon 2-0, filo lungo, ago retto, da passare sul trocar dell'aspiratore)
3. Incisione del peritoneo a 1 cm dalla riflessione del Douglas (Grasp in alto e scollamento con Maryland)
4. Isolamento e sezione del deferente destro con mono/bipolare

Aiuto: clips piccole Aesculap 3 mm o clip Aesculap doppie monocarica a destra

5. Isolamento della vescicola seminale (clips su vasi)
6. Isolamento e sezione del deferente sinistro con mono/bipolare
7. Isolamento della vescicola seminale (clips sui vasi)

Aiuto: Portaghi braccio 1 (destra) e 2 aghi retti - Monocryl o Ethilon 2-0 mediali alle ombelicali, rasenti al pube (a circa 1 cm dalla linea mediana)

1. Tendine da destra e da sinistra (rasente il pube e mediali all'arteria ombelicale, prendere anche il detrusore)

Aiuto: Girare l'ottica (30 in alto) e forbici monopolari braccio 1

2. Trazione sulla base delle vescicole in alto con il grasp, si trova il piano intra-extrafasciale mediano-posteriore e lo si sviluppa lateralmente. Poi si continua lateralmente (clips sul peduncolo laterale)

3. Isolamento del peduncolo destro e clip
4. Isolamento del peduncolo sinistro e clip

5. Piano postero-laterale bilaterale
6. Direzione grasp in basso. Scollamento delle fibre del detrusore
7. Scollamento laterale verso il Santorini e visualizzazione del collo
8. Isolamento del collo
9. Passaggio della Maryland ad abbracciare il collo facendo trazione in basso per allontanare la prostata (fare attenzione che il braccio 2 non si incroci con il 3)
10. Incisione del collo piatto posteriore (compare il catetere)

Aiuto: Portaghi braccio 1 e punto di repere (Safil Quick 3-0 ago HR22, filo di 20cm)

11. Punto di repere sul collo ore 6 (mano sinistra: Grasp)

Aiuto: forbici, tagliare il filo; pinze, estrarre la coda

12. Con la Maryland mollare l'abbraccio sul collo e pinzare il repere delle ore 6
13. Strumentista: sgonfiare il palloncino e sfilare catetere; chiedere se V-Lok da 15 o da 23 cm
14. Punto collo ore 12 (mano sinistra: Grasp; repere con coda lunga)
15. Con la Maryland mollare il punto delle ore 6 e pinzare il repere delle ore 12. Trazione verso l'alto

Aiuto: Forbici monopolari braccio 1

16. Incisione completa del collo
17. Grasp: trazione in basso e cranialmente per scollare il Santorini dalla superficie anteriore della prostata
18. Isolamento dell'apice prostatico e dell'uretra
19. Sezione dell'uretra
20. Catetere appena al margine di sezione uretrale
21. Si completa l'isolamento della prostata
22. Endobag
23. Portaghi braccio 1
24. Lavaggio della loggia
25. Controllo emostasi (clips, bipolare e/o floseal)
26. Si estraggono gli strumenti per pulirli

Aiuto: Portaghi braccio 1; inserire Van Velthoven: se disponibile, V-Lok da15 o 23 cm a seconda delle dimensioni del collo vescicale; in alternativa, monocryl 3-0, ago a semicerchio HR22 con 10 nodi: dopo aver inserito il primo ago, fissare il secondo alla Johanne per tenere il filo destro lontano dal campo

Inizio semicirconferenza sinistra del piatto anteriore

1. Ore 12: Vescica fuori-dentro, uretra dentro fuori: si susseguono 3-4 passaggi (da ore 12 fino a ore 9, dipende dalla grandezza del collo); la mano sinistra usa il Grasp e non la Maryland
2. Tensione sulla continua ad ogni passaggio

3. Tendere la continua di sinistra con la Maryland
4. Mollare (poco) le tende sul peritoneo

Inizio semicirconferenza destra

1. Ore 12: Vescica fuori-dentro, uretra dentro fuori: si susseguono 5-7 passaggi (da ore 12 a ore 6, dipende dalla grandezza del collo); la mano sinistra usa il Grasp e non la Maryland
2. Tensione sulla continua ad ogni passaggio

Con il filo di sinistra si completa con tre passaggi l'emicirconferenza di sinistra

3. Passare il catetere definitivo
4. Si tende la sutura e si avvicinano i due fili
5. Prova di tenuta
6. Eventuale posizionamento di cistostomia sovrapubica

TERZA PARTE

a. Eventuale linfoadenectomia iliaca esterna, interna ed otturatoria bilaterale
b. Drenaggio al posto della Maryland
c. Allontanamento del robot
d. Rimozione delle porte sotto visione
e. Rimozione di prostata, vescicole seminali e linfonodi

APPENDIX 3: Validated Task Analysis of BA-RARP procedure

Tecnica Prostatectomia Radicale Robotica RETZIUS SPARING

https://www.youtube.com/watch?t=13&v=DS7ddQltHRY (Retzius-sparing Approach for Robot-assisted Laparoscopic Radical Prostatectomy) (Dicembre 2013)

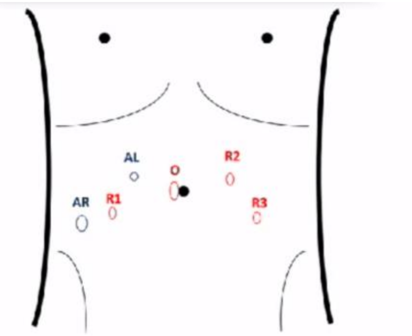
TASK ANALYSIS

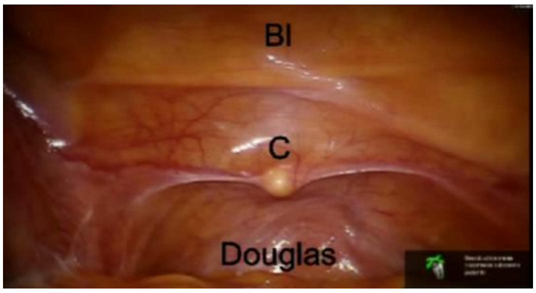
1) POSIZIONAMENTO DELLE PORTE

Per questo intervento vengono usati :

- 4 bracci robotici
- 2 trocars per gli assistenti

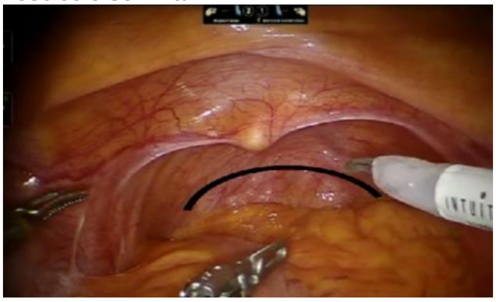
posizionati in modo standardizzato
Il GRASP viene posizionato nel secondo braccio robotico mentre la bipolare nel terzo, differentemente da quanto avviene nell'approccio anteriore.





2) INCISIONE DEL PERITONEO ED ISOLAMENTO DELLE VESCICOLE SEMINALI

L'operazione inizia con un'incisione di 5-7 cm nello spazio del Douglas in modo da isolare le vescicole seminali.



La prima struttura che si incontra è il deferente dentro:

- Il deferente destro viene isolato e sezionato.

- Le vescicole seminali destre vengono isolate grazie all'utilizzo di clips (grandi circa 3 mm).

La stessa manovra viene fatta a sinistra:

- Il deferente sinistro viene isolato e sezionato
- Le vescicole seminali sinistre vengono isolate usando delle clips

1) SOSPENSIONE DEL PERITONEO

Al fine di allargare lo spazio di lavoro a disposizione, vengono inseriti dall'assistente due punti con aghi retti, tangenziali all'area prepubica in maniera transaddominale. Questi passano attraverso il peritoneo (vicino alla vescica). Quelle che si vengono a creare sono come due 'tendine', una a destra e una a sinistra.

- Le vescicole seminali e il deferente vengono sospesi alle due 'tendine'

2) ISOLAMENTO DELLA SUPERFICIE POSTERIORE DELLA PROSTATA E DEI PEDUNCOLI LATERALI

- Viene aperto un piano intra-extrafasciale a seconda del livello oncologico del tumore
- Isolamento grazie all'utilizzo di clips delle vescicole seminali
- Isolamento peduncolo destro, con l'utilizzo di clips
- Sezione del peduncolo destro limitando l'utilizzo di energia
- Isolamento peduncolo sinistro, con l'utilizzo di clips
- Sezione del peduncolo sinistro limitando l'utilizzo di energia

In questo modo si ottiene lo spazio laterale della prostata.

3) ISOLAMENTO DEL COLLO VESCICALE

- Le vescicole seminali vengono trazionate verso il basso con il Grasp, in modo da avere una migliore esposizione del collo vescicale
- La giunzione vescico-prostatica viene raggiunta

Sia dal lato destro che da quello sinistro del collo vescicale si osserva che la vescica è situata sopra e la prostata sotto, differentemente dalla tecnica standard

- La giunzione vescico-prostatica viene sezionata e il collo vescicale viene risparmiato (se oncologicamente fattibile)
- Le fibre muscolari possono essere coagulate seguendo il piano che separa la vescica dalla prostata
- Passaggio della Maryland dietro il collo vescicale, in modo che abbracci il catetere
- Con le forbici monopolari viene incisa la parte posteriore del collo vescicale
- Il catetere appare
- Vengono posizionati due punti di cardinali alle ore 6 e 12, per facilitare l'identificazione del collo vescicale nella fase di anastomosi ed evitare la retrazione della mucosa del collo
- Pinzare il repere delle ore 6 (Primo punto)
- Il catetere viene tirato verso il basso
- Con la Maryland mollare il punto di ore 6
- Secondo punto a ore 12 sul collo vescicale, pinzare il repere delle ore 12
- Trazionare verso l'alto
- Completamento dell'incisione del collo vescicale: viene incisa la parte anteriore

4) ISOLAMENTEO DELA SUPERFICIE ANTERIORE DELLA PROSTATA E DELL'APICE PROSTATICO

- La parte anteriore e quella laterale della prostata vengono isolate per via smussa
- Evitare di entrare nel plesso del Santorini: senza sezionare, legare o aprire i vasi del complesso venoso del Santorini.
- Dissezione delle fasce laterali, quando possibile
- La dissezione continua verso l'apice prostatico

La differenza tra il metodo tradizionale è che in questo caso la vescica è posizionata al di sopra e non posteriormente alla prostata

- L'apice così è isolato e anche l'uretra viene identificata: è possibile vedere chiaramente le sue fibre longitudinali
- Sezione dell'uretra
- Appare il catetere
- La dissezione dell'apice prostatico viene completata con l'incisione della parte posteriore dell'uretra

5) POSIZIONAMENTO DELLA PROSTATA IN ENDOBAG
- La prostata è completamente isolata
- La prostata viene posizionata in una sacca: Endobag
- Rimozione della prostata
- Lavaggio della loggia
- La loggia lasciata dalla prostata viene controllata da eventuali sanguinamenti con l'utilizzo di clips
- Si estraggono gli strumenti per pulirli

6) ANASTOMOSI
- Quando è necessario possono essere utilizzate sostanze emostatiche
- Pulizia con una garza

L'anastomosi viene fatta prima nel lato sinistro e poi in quello destro. L'anastomosi viene eseguita secondo una tecnica di Van Velthoven modificata. Utilizziamo due fili di sutura V-Loc partendo dal quarto anteriore sinistro del margine uretrale, quindi al quarto destro anteriore e posteriore, infine al quarto posteriore sinistro. Al termine dell'anastomosi viene eseguita una prova di tenuta.

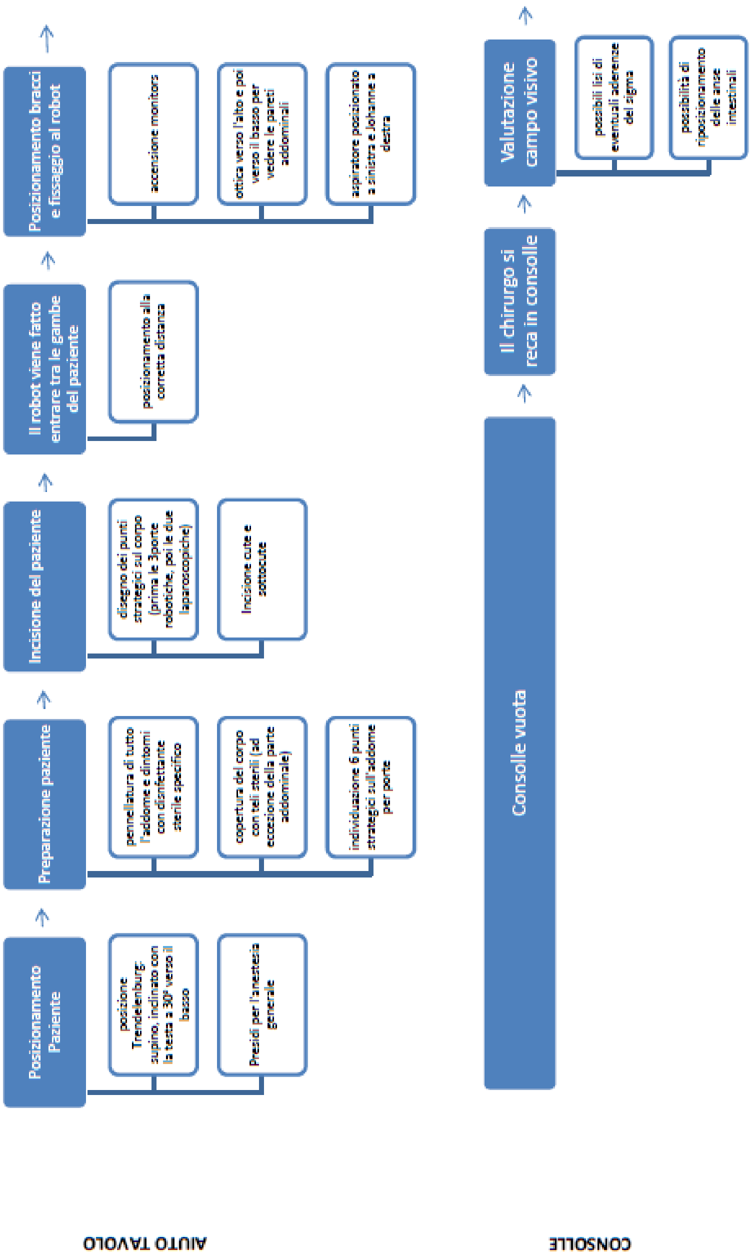
- Lato sinistro (quarto anteriore sinistro): passaggi fuori-dentro vescica, dentro-fuori uretra
- Il primo punto tira verso il basso il collo vescicale, dopo 3-4 passaggi (dipende dallo spessore del collo vescicale) si passa al lato destro
- Lato destro (quarto anteriore destro): 5-7 passaggi fuori-dentro vescica, dentro-fuori uretra

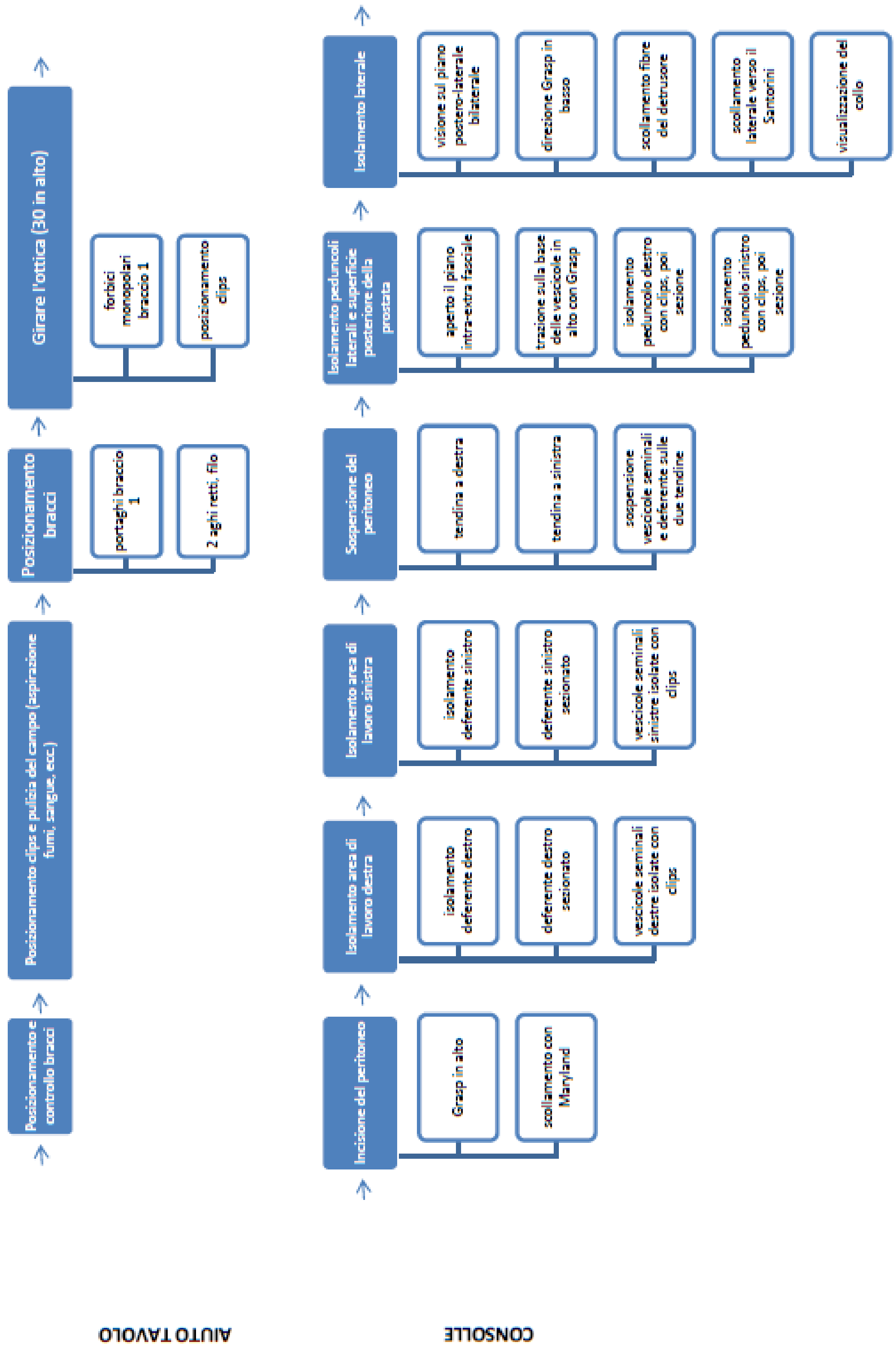
Il piano anteriore è completato, si passa ad eseguire il piano posteriore.

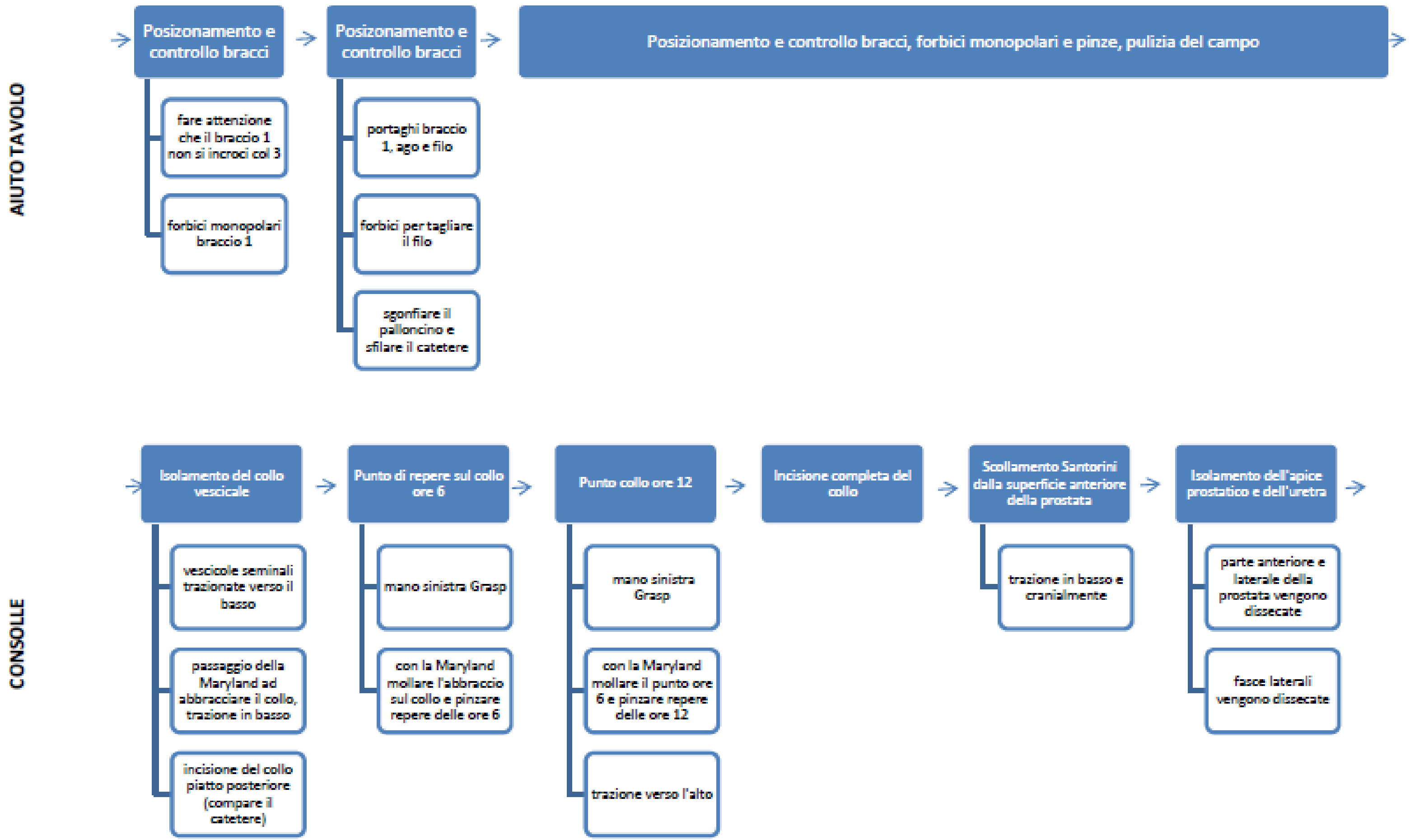
- Quarto posteriore destro: fuori-dentro vescica, dentro-fuori uretra
- Il filo di sinistra viene utilizzato ancora per 2-3 passaggi per completare
- I fili vengono tesi
- Il catetere viene fatto passare
- I fili vengono tagliati
- I fili delle due 'tendine' vengono tagliati
- La vescica viene riempita con soluzione fisiologica, in modo da testare l'anastomosi
- Se non ci sono controindicazione e l'anastomosi è a tenuta, posizioniamo una cistostomia sovrapubica e rimuoviamo il catetere uretrale

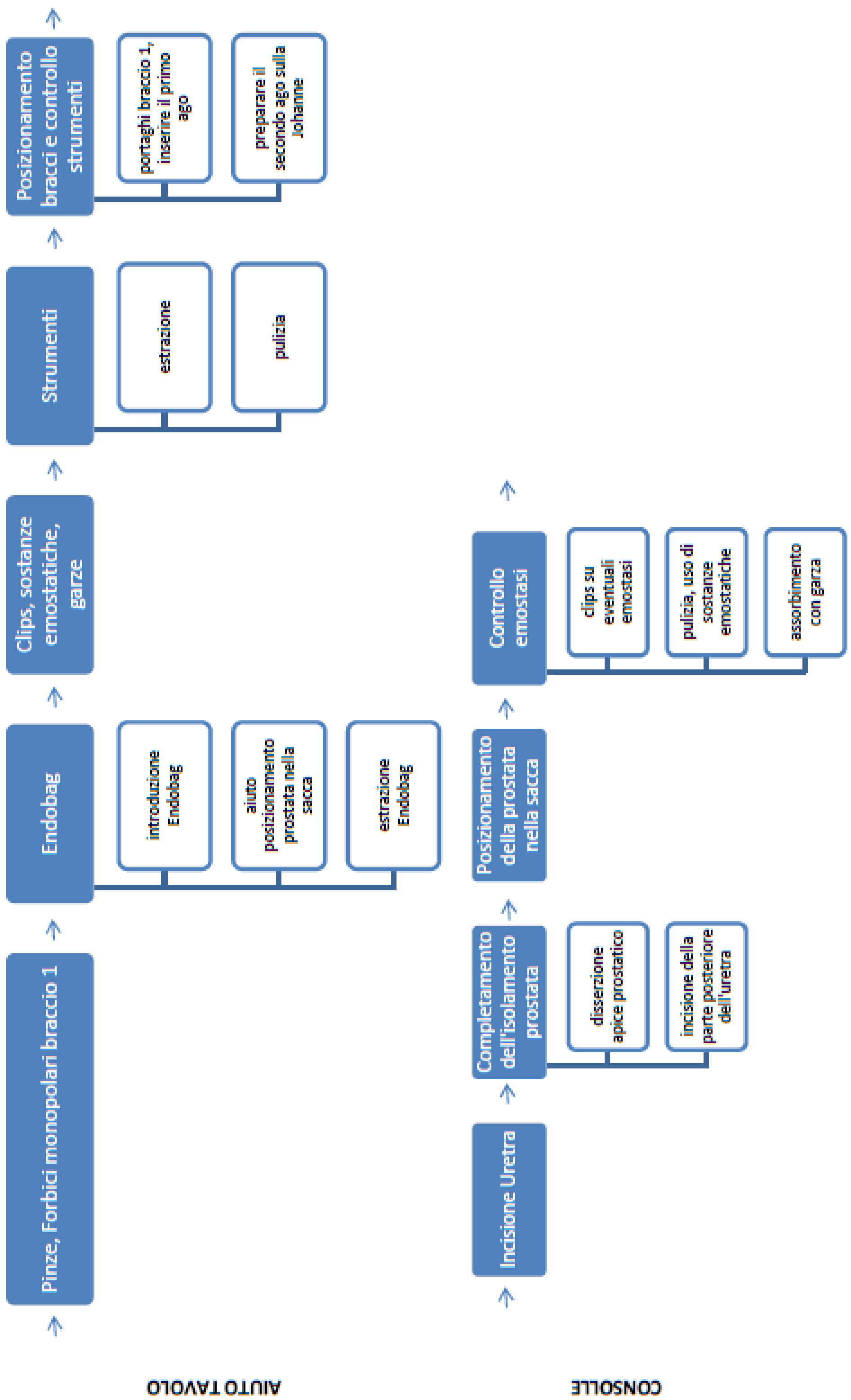
7) DRENAGGIO
8) ALLONTANAMENTO DEL ROBOT
9) RIMOZIONE DELLA PROSTATA E DELLE PORTE

APPENDIX 4: Validated Task Analysis-Parallelism between tasks performed at console and those at the table

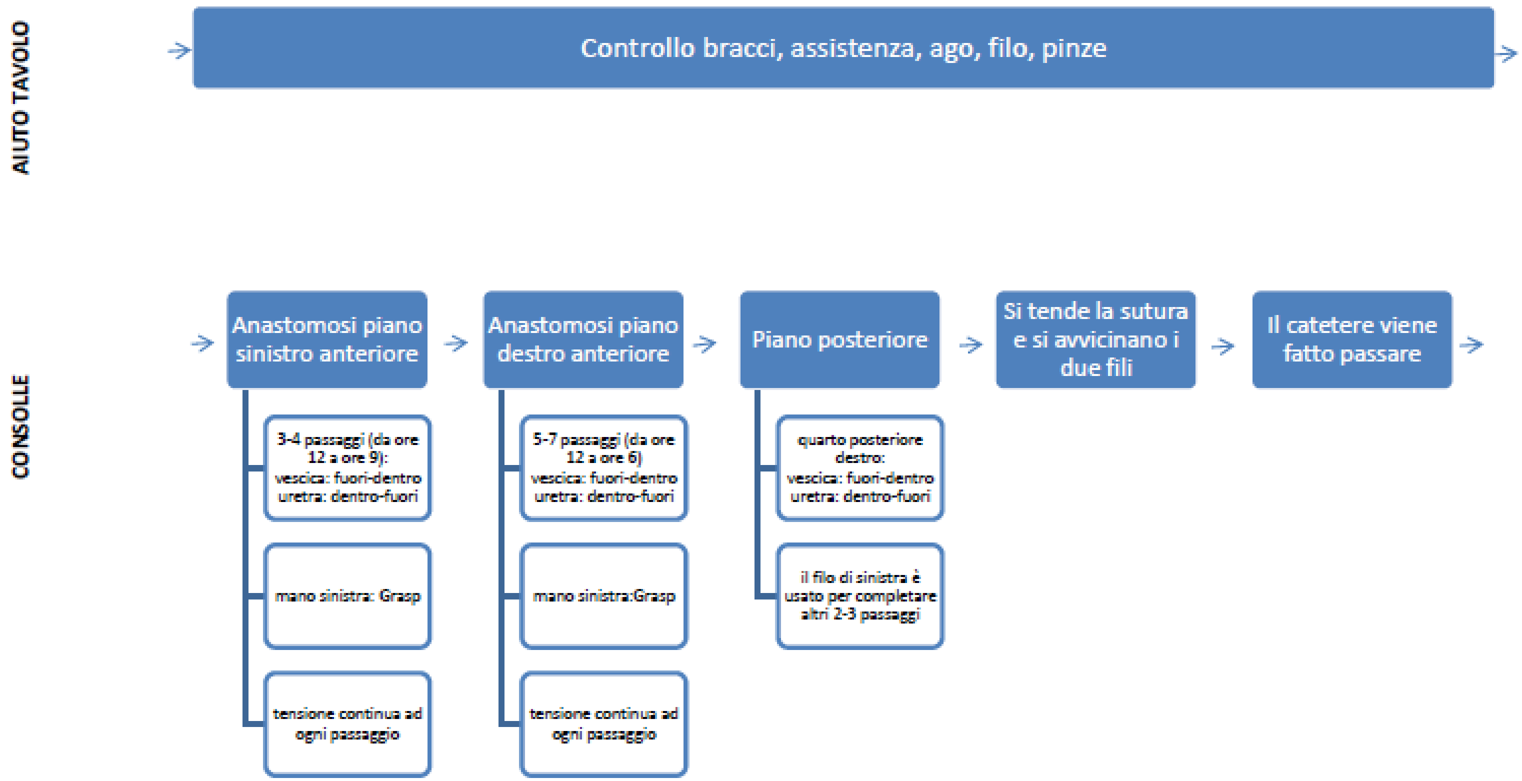


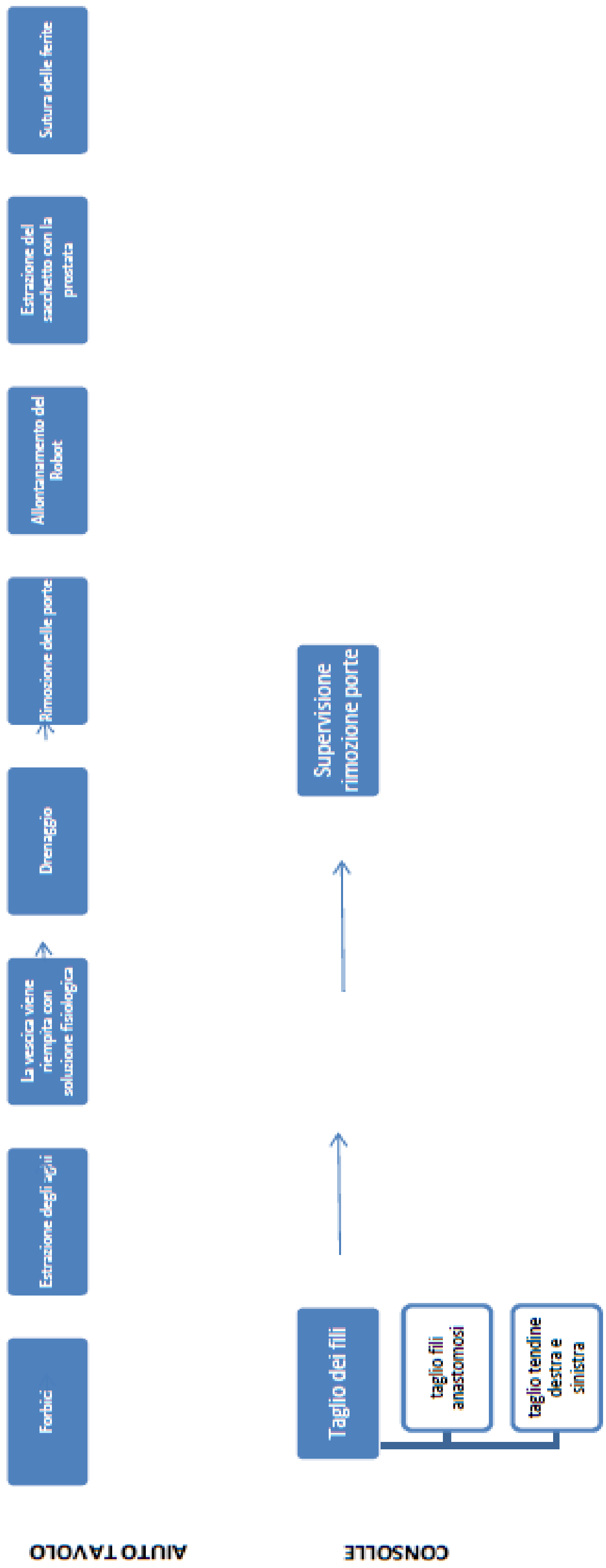

AIUTO TAVOLO
Posizionamento e controllo bracci
Posizionamento clips e pulizia del campo (aspirazione fumi, sangue, ecc.)
Posizionamento bracci
portaghi braccio 1
2 aghi retti, filo
Girare l'ottica (30 in alto)
forbici monopolari braccio 1
posizionamento clips
CONSOLLE
Incisione del peritoneo
Grasp in alto
scollamento con Maryland
Isolamento area di lavoro destra
isolamento deferente destro
deferente destro sezionato
vescicole seminali destre isolate con clips
Isolamento area di lavoro sinistra
isolamento deferente sinistro
deferente sinistro sezionato
vescicole seminali sinistre isolate con clips
Sospensione del peritoneo
tendina a destra
tendina a sinistra
sospensione vescicole seminali e deferente sulle due tendine
Isolamento peduncoli laterali e superficie posteriore della prostata
aperto il piano intra-extra fasciale
trazione sulla base delle vescicole in alto con Grasp
isolamento peduncolo destro con clips, poi sezione
isolamento peduncolo sinistro con clips, poi sezione
Isolamento laterale
visione sul piano postero-laterale bilaterale
direzione Grasp in basso
scollamento fibre del detrusore
scollamento laterale verso il Santorini
visualizzazione del collo


AIUTO TAVOLO
Posizonamento e controllo bracci
fare attenzione che il braccio 1 non si incroci col 3
forbici monopolari braccio 1
Posizonamento e controllo bracci
portaghi braccio 1, ago e filo
forbici per tagliare il filo
sgonfiare il palloncino e sfilare il catetere
Posizionamento e controllo bracci, forbici monopolari e pinze, pulizia del campo
CONSOLLE
Isolamento del collo vescicale
vescicole seminali trazionate verso il basso
passaggio della Maryland ad abbracciare il collo, trazione in basso
incisione del collo piatto posteriore (compare il catetere)
Punto di repere sul collo ore 6
mano sinistra Grasp
con la Maryland mollare l'abbraccio sul collo e pinzare repere delle ore 6
Punto collo ore 12
mano sinistra Grasp
con la Maryland mollare il punto ore 6 e pinzare repere delle ore 12
trazione verso l'alto
Incisione completa del collo
Scollamento Santorini dalla superficie anteriore della prostata
trazione in basso e cranialmente
Isolamento dell'apice prostatico e dell'uretra
parte anteriore e laterale della prostata vengono dissecate
fasce laterali vengono dissecate


AIUTO TAVOLO
Pinze, Forbici monopolari braccio 1
Endobag
introduzione Endobag
aiuto posizionamento prostata nella sacca
estrazione Endobag
Clips, sostanze emostatiche, garze
Strumenti
estrazione
pulizia
Posizionamento bracci e controllo strumenti
portaghi braccio 1, inserire il primo ago
preparare il secondo ago sulla Johanne
CONSOLLE
Incisione Uretra
Completamento dell'isolamento prostata
disserzione apice prostatico
incisione della parte posteriore dell'uretra
Posizionamento della prostata nella sacca
Controllo emostasi
clips su eventuali emostasi
pulizia, uso di sostanze emostatiche
assorbimento con garza

ANASTOMOSI: TECNICA DI VAN VELTHOVEN MODIFICATA




AIUTO TAVOLO
Forbici
Estrazione degli
La vescica viene riempita con soluzione fisiologica
Drenaggio
Rimozione delle porte
Allontanamento del Robot
Estrazione del sacchetto con la prostata
Sutura delle ferite
CONSOLLE
Taglio dei fili
taglio fili anastomosi
taglio tendine destra e sinistra
Supervisione rimozione porte

APPENDIX 5: Questionnaire Results of First Surgeon

Si chiede gentilmente a TRE CHIRURGHI di completare le seguenti tabelle, individualmente.

La prima tabella si riferisce al task critico "Isolamento peduncoli laterali e superficie posteriore della prostata", mentre la seconda al task critico "Anastomosi".

I tre chirurghi dovranno (separatamente) identificare quali tra i "20-FATTORI INFLUENZANTI" della tabella hanno una maggiore influenza sulla performance del chirurgo nel portare a termine il task. Si chiede di scegliere solo i fattori significativamente influenzanti e di assegnarne una stima dell'influenza con un valore da 0 a 100. Si chiede di fornirne inoltre la quantità (della stima del fattore influenzante) attribuibile al sotto-fattore corrispondente.

Esempio: Task 1_ Chirurgo 1

5	**MANCANZA DI GESTIONE DEGLI ERRORI** **Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.**	**60**	**Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore**	**40**

Si ringrazia per la cortese collaborazione.

FATTORI INFLUENZANTI **TASK 1:** **"Isolamento peduncoli laterali e superficie**	*stima* *tra 0 e 100* *dell'influenza del fattore a sinistra*	*SOTTO-FATTORE*	*Quantità, della stima precedentemente individuata, attribuibile al sotto-fattore*

	posteriore della prostata”			
1	**RUMORE E VOCI DI SOTTOFONDO** Rumore continuo o improvviso; il parlare dei membri del team; rumore provocato dal girovagare e il muoversi in sala.	90	Segnali disturbanti o confusi	60
2	**MUSICA** Presenza di musica di sottofondo in sala.	___	Segnali disturbanti o confusi	___
3	**USO RUMOROSO DI SOCIAL MEDIA** Condivisione inopportuna di contenuti di social media tra i membri del team.	___	Segnali disturbanti o confusi	___
4	**INTERRUZIONI VERBALI** Interruzioni verbali sia rilevanti per il paziente ma inopportune sia interruzioni verbali irrilevanti per il paziente.	___	Interruzioni causate dall’intervento di altre persone	___
5	**MANCANZA DI GESTIONE DEGLI ERRORI** Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.	70 ___	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	50 ___
6	**MANCANZA DI PROCEDURE STANDARD E CHECKLIST APPROPRIATE** Inadeguatezza delle esistenti procedure nella pratica lavorativa (procedure scarse, incomplete o troppo vincolanti).	70	Mancanza di strumenti per tracciare il progredire di un’attività	10
7	**MODO DI PARLARE RUDE E CON ALTO TONO DI VOCE** Commenti dispregiativi, comportamenti che denotano mancanza di rispetto tra i membri del team, scambio di informazioni severi e rudi toni di voce.	___	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	___

8	**INAPPROPRIATO USO DI PROCEDURE E CHECKLIST** L'improprio uso, o non uso, delle checklist chirurgiche della OMS (o simili), protocolli e procedure.	—	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	—
9	**COMUNICAZIONE NON CHIARA PER UNA COMPRENSIONE CONDIVISA** Mancanza di chiarezza o omissioni nel comunicare informazioni da condividere	80	Sovraccarico di informazioni ridondanti	30
10	**SCARSA COORDINAZIONE** Mancanza di coordinazione nelle attività del team; mancanza nell'anticipare i bisogni del chirurgo alla consolle (se chirurgia robotica).	40	Trasferimento di informazioni da un compito ad un altro, senza perdite	10
11	**CARENZE NEL PROCESSO DI 'DECISION MAKING'** Carenza nel considerare, selezionare e comunicare opzioni; inadeguatezza o ritardo nell'implementare e revisionare decisioni.	—	Non chiara allocazione di funzioni e responsabilità	—
12	**SCARSA CONSAPEVOLEZZA DELLA SITUAZIONE** Carenza nella raccolta e nella comprensione di informazioni o nell'anticipare stati futuri, problemi e stati dell'intervento.	60 —	Poca familiarità con una situazione che è potenzialmente importante	30 —
13a	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM** Mancanza di esperienza nella specializzazione chirurgica o con la procedura chirurgica o con la tecnologia richiesta.	50	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	50 —
13b	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM DI ANESTESIA** Mancanza di esperienza tra i membri del team dedicato all'anestesia, con la procedura anestesiologica o con la tecnologia.	—	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	—

14	**FATICA** Fatica mentale e fisica		Interruzione dei normali cicli di lavoro-sonno (affaticamento)	
15	**PRESSIONE TEMPORALE** Stress psicologico dovuto al dover svolgere compiti in meno tempo rispetto a quello richiesto o desiderato.	40 ——	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	20 ——
16	**MANCANZA DI LEADERSHIP** Carenza nell'impostazione e nel mantenimento di standard, nel supportare gli altri e nel reagire alla pressione.	——	Bisogno di giudizi assoluti che sono oltre le capacità o l'esperienza di un operatore	——
17	**FAMILIARITA' TRA MEMBRI DEL TEAM** Non familiarità tra Membri del team e tra le loro competenze.	——	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	——
18	**CARENZA NELLA FRUIBILITA' DELLA TECNOLOGIA** Inabilità o mancanza di abilità nell'uso della tecnologia disponibile (anche mancanza di capacità tecniche legate alla tecnologia).	——	Povero interfaccia tra sistema e utente	——
19	**ERGONOMIA INADEGUATA DELL'ATTREZZATURA E DELLO SPAZIO DI LAVORO** Attrezzatura, strumentazione e spazio di lavoro non progettate per ridurre la fatica e la non comodità dell' operatore.	10 ——	Ambiente povero o ostile	10 ——
20	**STRESS**		Alto livello di stress emozionale	

FATTORI INFLUENZANTI TASK 2: “Anastomosi”		*stima* *tra 0 e 100* *dell’influenza del fattore a sinistra*	*SOTTO-FATTORE*	*Quantità, della stima, precedentemente individuata, attribuibile al sotto-fattore*
1	**RUMORE E VOCI DI SOTTOFONDO** Rumore continuo o improvviso; il parlare dei membri del team; rumore provocato dal girovagare e il muoversi in sala.	80 ___	Segnali disturbanti o confusi	40 ___
2	**MUSICA** Presenza di musica di sottofondo in sala.	___	Segnali disturbanti o confusi	___
3	**USO RUMOROSO DI SOCIAL MEDIA** Condivisione inopportuna di contenuti di social media tra i membri del team.	___	Segnali disturbanti o confusi	___
4	**INTERRUZIONI VERBALI** Interruzioni verbali sia rilevanti per il paziente ma inopportune sia interruzioni verbali irrilevanti per il paziente.	___	Interruzioni causate dall’intervento di altre persone	___
5	**MANCANZA DI GESTIONE DEGLI ERRORI** Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.	80 ___	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	50 ___
6	**MANCANZA DI PROCEDURE STANDARD E CHECKLIST APPROPRIATE** Inadeguatezza delle esistenti procedure nella pratica lavorativa (procedure scarse, incomplete o troppo vincolanti).	60 ___	Mancanza di strumenti per tracciare il progredire di un’attività	20 ___
7	**MODO DI PARLARE RUDE E CON ALTO TONO DI VOCE** Commenti dispregiativi,		Qualità povera di informazioni	

	comportamenti che denotano mancanza di rispetto tra i membri del team, scambio di informazioni severi e rudi toni di voce.	20	derivanti dalle procedure e dall'interazione persona-persona	_10
8	**INAPPROPRIATO USO DI PROCEDURE E CHECKLIST** L'improprio uso, o non uso, delle checklist chirurgiche della OMS (o simili), protocolli e procedure.	___	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	___
9	**COMUNICAZIONE NON CHIARA PER UNA COMPRENSIONE CONDIVISA** Mancanza di chiarezza o omissioni nel comunicare informazioni da condividere	80	Sovraccarico di informazioni ridondanti	10
10	**SCARSA COORDINAZIONE** Mancanza di coordinazione nelle attività del team; mancanza nell'anticipare i bisogni del chirurgo alla consolle (se chirurgia robotica).	90	Trasferimento di informazioni da un compito ad un altro, senza perdite	20
11	**CARENZE NEL PROCESSO DI 'DECISION MAKING'** Carenza nel considerare, selezionare e comunicare opzioni; inadeguatezza o ritardo nell'implementare e revisionare decisioni.	___	Non chiara allocazione di funzioni e responsabilità	___
12	**SCARSA CONSAPEVOLEZZA DELLA SITUAZIONE** Carenza nella raccolta e nella comprensione di informazioni o nell'anticipare stati futuri, problemi e stati dell'intervento.	50 ___	Poca familiarità con una situazione che è potenzialmente importante	30 ___
13a	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM** Mancanza di esperienza nella specializzazione chirurgica o con la procedura chirurgica o con la tecnologia richiesta.	40	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	20 ___
13b	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM DI ANESTESIA** Mancanza di esperienza tra i		Inesperienza dell'operatore (ad esempio qualcuno	

	membri del team dedicato all'anestesia, con la procedura anestesiologica o con la tecnologia.	___	appena qualificato, ma non ancora divenuto "esperto")	___
14	**FATICA** Fatica mentale e fisica	40	Interruzione dei normali cicli di lavoro-sonno (affaticamento)	50
15	**PRESSIONE TEMPORALE** Stress psicologico dovuto al dover svolgere compiti in meno tempo rispetto a quello richiesto o desiderato.	___	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	___
16	**MANCANZA DI LEADERSHIP** Carenza nell'impostazione e nel mantenimento di standard, nel supportare gli altri e nel reagire alla pressione.	___	Bisogno di giudizi assoluti che sono oltre le capacità o l'esperienza di un operatore	___
17	**FAMILIARITA' TRA MEMBRI DEL TEAM** Non familiarità tra Membri del team e tra le loro competenze.	___	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	___
18	**CARENZA NELLA FRUIBILITA' DELLA TECNOLOGIA** Inabilità o mancanza di abilità nell'uso della tecnologia disponibile (anche mancanza di capacità tecniche legate alla tecnologia).	___	Povero interfaccia tra sistema e utente	___
19	**ERGONOMIA INADEGUATA DELL'ATTREZZATURA E DELLO SPAZIO DI LAVORO** Attrezzatura, strumentazione e spazio di lavoro non progettate per ridurre la fatica e la non comodità dell' operatore.	___	Ambiente povero o ostile	___

20	**STRESS EMOZIONALE PERIOPERATIVO** Ovvero indotto da fattori non direttamente riconducibili all' equipe e alle caratteristiche e all'evoluzione dell'intervento, quali responsabilità di budget e di altri obiettivi aziendali, problemi organizzativi di reparto, altri pazienti critici, cause legali.	—	Alto livello di stress emozionale	—

APPENDIX 6: Questionnaire Results of Second Surgeon

Si chiede gentilmente a TRE CHIRURGHI di completare le seguenti tabelle, individualmente.

La prima tabella si riferisce al task critico "Isolamento peduncoli laterali e superficie posteriore della prostata", mentre la seconda al task critico "Anastomosi".

I tre chirurghi dovranno (separatamente) identificare quali tra i "20-FATTORI INFLUENZANTI" della tabella hanno una maggiore influenza sulla performance del chirurgo nel portare a termine il task. Si chiede di scegliere solo i fattori significativamente influenzanti e di assegnarne una stima dell'influenza con un valore da 0 a 100. Si chiede di fornirne inoltre la quantità (della stima del fattore influenzante) attribuibile al sotto-fattore corrispondente.

Esempio: Task 1_ Chirurgo 1

5	**MANCANZA DI GESTIONE DEGLI ERRORI** **Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.**	**60**	**Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore**	**40**

Si ringrazia per la cortese collaborazione.

FATTORI INFLUENZANTI **TASK 1:** **"Isolamento peduncoli laterali e superficie**	*stima* *tra 0 e 100* *dell'influenza del fattore a sinistra*	*SOTTO-FATTORE*	*Quantità, della stima precedentemente individuata, attribuibile al sotto-fattore*

	posteriore della prostata”			
1	**RUMORE E VOCI DI SOTTOFONDO** Rumore continuo o improvviso; il parlare dei membri del team; rumore provocato dal girovagare e il muoversi in sala.	80	Segnali disturbanti o confusi	56
2	**MUSICA** Presenza di musica di sottofondo in sala.	40	Segnali disturbanti o confusi	36
3	**USO RUMOROSO DI SOCIAL MEDIA** Condivisione inopportuna di contenuti di social media tra i membri del team.	45	Segnali disturbanti o confusi	36
4	**INTERRUZIONI VERBALI** Interruzioni verbali sia rilevanti per il paziente ma inopportune sia interruzioni verbali irrilevanti per il paziente.	80	Interruzioni causate dall’intervento di altre persone	80
5	**MANCANZA DI GESTIONE DEGLI ERRORI** Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.	70	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	56
6	**MANCANZA DI PROCEDURE STANDARD E CHECKLIST APPROPRIATE** Inadeguatezza delle esistenti procedure nella pratica lavorativa (procedure scarse, incomplete o troppo vincolanti).	90	Mancanza di strumenti per tracciare il progredire di un’attività	45
7	**MODO DI PARLARE RUDE E CON ALTO TONO DI VOCE** Commenti dispregiativi, comportamenti che denotano mancanza di rispetto tra i membri del team, scambio di informazioni severi e rudi toni di voce.	100	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	60

8	**INAPPROPRIATO USO DI PROCEDURE E CHECKLIST** L'improprio uso, o non uso, delle checklist chirurgiche della OMS (o simili), protocolli e procedure.	80	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	40
9	**COMUNICAZIONE NON CHIARA PER UNA COMPRENSIONE CONDIVISA** Mancanza di chiarezza o omissioni nel comunicare informazioni da condividere	100	Sovraccarico di informazioni ridondanti	40
10	**SCARSA COORDINAZIONE** Mancanza di coordinazione nelle attività del team; mancanza nell'anticipare i bisogni del chirurgo alla consolle (se chirurgia robotica).	70	Trasferimento di informazioni da un compito ad un altro, senza perdite	63
11	**CARENZE NEL PROCESSO DI 'DECISION MAKING'** Carenza nel considerare, selezionare e comunicare opzioni; inadeguatezza o ritardo nell'implementare e revisionare decisioni.	70	Non chiara allocazione di funzioni e responsabilità	70
12	**SCARSA CONSAPEVOLEZZA DELLA SITUAZIONE** Carenza nella raccolta e nella comprensione di informazioni o nell'anticipare stati futuri, problemi e stati dell'intervento.	100	Poca familiarità con una situazione che è potenzialmente importante	80
13a	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM** Mancanza di esperienza nella specializzazione chirurgica o con la procedura chirurgica o con la tecnologia richiesta.	100	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	100
13b	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM DI ANESTESIA** Mancanza di esperienza tra i membri del team dedicato all'anestesia, con la procedura anestesiologica o con la tecnologia.	80	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	80

14	**FATICA** Fatica mentale e fisica	100	Interruzione dei normali cicli di lavoro-sonno (affaticamento)	80
15	**PRESSIONE TEMPORALE** Stress psicologico dovuto al dover svolgere compiti in meno tempo rispetto a quello richiesto o desiderato.	60	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	30
16	**MANCANZA DI LEADERSHIP** Carenza nell'impostazione e nel mantenimento di standard, nel supportare gli altri e nel reagire alla pressione.	70	Bisogno di giudizi assoluti che sono oltre le capacità o l'esperienza di un operatore	56
17	**FAMILIARITA' TRA MEMBRI DEL TEAM** Non familiarità tra Membri del team e tra le loro competenze.	90	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	72
18	**CARENZA NELLA FRUIBILITA' DELLA TECNOLOGIA** Inabilità o mancanza di abilità nell'uso della tecnologia disponibile (anche mancanza di capacità tecniche legate alla tecnologia).	100	Povero interfaccia tra sistema e utente	100
19	**ERGONOMIA INADEGUATA DELL'ATTREZZATURA E DELLO SPAZIO DI LAVORO** Attrezzatura, strumentazione e spazio di lavoro non progettate per ridurre la fatica e la non comodità dell' operatore.	50	Ambiente povero o ostile	25
20	**STRESS**	80	Alto livello di stress emozionale	80

FATTORI INFLUENZANTI TASK 2: **“Anastomosi”**		*stima* *tra 0 e 100* *dell'influenza del fattore a sinistra*	*SOTTO-FATTORE*	*Quantità, della stima, precedentemente individuata, attribuibile al sotto-fattore*
1	**RUMORE E VOCI DI SOTTOFONDO** Rumore continuo o improvviso; il parlare dei membri del team; rumore provocato dal girovagare e il muoversi in sala.	70	Segnali disturbanti o confusi	63
2	**MUSICA** Presenza di musica di sottofondo in sala.	20	Segnali disturbanti o confusi	16
3	**USO RUMOROSO DI SOCIAL MEDIA** Condivisione inopportuna di contenuti di social media tra i membri del team.	40	Segnali disturbanti o confusi	32
4	**INTERRUZIONI VERBALI** Interruzioni verbali sia rilevanti per il paziente ma inopportune sia interruzioni verbali irrilevanti per il paziente.	90	Interruzioni causate dall'intervento di altre persone	72
5	**MANCANZA DI GESTIONE DEGLI ERRORI** Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.	80 ___	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	64
6	**MANCANZA DI PROCEDURE STANDARD E CHECKLIST APPROPRIATE** Inadeguatezza delle esistenti procedure nella pratica lavorativa (procedure scarse, incomplete o troppo vincolanti).	90 ___	Mancanza di strumenti per tracciare il progredire di un'attività	45 ___
7	**MODO DI PARLARE RUDE E CON ALTO TONO DI VOCE** Commenti dispregiativi,		Qualità povera di informazioni	

	comportamenti che denotano mancanza di rispetto tra i membri del team, scambio di informazioni severi e rudi toni di voce.	80	derivanti dalle procedure e dall'interazione persona-persona	80
8	**INAPPROPRIATO USO DI PROCEDURE E CHECKLIST** L'improprio uso, o non uso, delle checklist chirurgiche della OMS (o simili), protocolli e procedure.	80	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	56
9	**COMUNICAZIONE NON CHIARA PER UNA COMPRENSIONE CONDIVISA** Mancanza di chiarezza o omissioni nel comunicare informazioni da condividere	80	Sovraccarico di informazioni ridondanti	48
10	**SCARSA COORDINAZIONE** Mancanza di coordinazione nelle attività del team; mancanza nell'anticipare i bisogni del chirurgo alla consolle (se chirurgia robotica).	100	Trasferimento di informazioni da un compito ad un altro, senza perdite	50
11	**CARENZE NEL PROCESSO DI 'DECISION MAKING'** Carenza nel considerare, selezionare e comunicare opzioni; inadeguatezza o ritardo nell'implementare e revisionare decisioni.	70	Non chiara allocazione di funzioni e responsabilità	35
12	**SCARSA CONSAPEVOLEZZA DELLA SITUAZIONE** Carenza nella raccolta e nella comprensione di informazioni o nell'anticipare stati futuri, problemi e stati dell'intervento.	90	Poca familiarità con una situazione che è potenzialmente importante	81
13a	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM** Mancanza di esperienza nella specializzazione chirurgica o con la procedura chirurgica o con la tecnologia richiesta.	80	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	64
13b	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM DI ANESTESIA** Mancanza di esperienza tra i		Inesperienza dell'operatore (ad esempio qualcuno	

	membri del team dedicato all'anestesia, con la procedura anestesiologica o con la tecnologia.	70	appena qualificato, ma non ancora divenuto "esperto")	70
14	**FATICA** Fatica mentale e fisica	80	Interruzione dei normali cicli di lavoro-sonno (affaticamento)	40
15	**PRESSIONE TEMPORALE** Stress psicologico dovuto al dover svolgere compiti in meno tempo rispetto a quello richiesto o desiderato.	60	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	42
16	**MANCANZA DI LEADERSHIP** Carenza nell'impostazione e nel mantenimento di standard, nel supportare gli altri e nel reagire alla pressione.	80	Bisogno di giudizi assoluti che sono oltre le capacità o l'esperienza di un operatore	56
17	**FAMILIARITA' TRA MEMBRI DEL TEAM** Non familiarità tra Membri del team e tra le loro competenze.	80	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	56
18	**CARENZA NELLA FRUIBILITA' DELLA TECNOLOGIA** Inabilità o mancanza di abilità nell'uso della tecnologia disponibile (anche mancanza di capacità tecniche legate alla tecnologia).	100	Povero interfaccia tra sistema e utente	100
19	**ERGONOMIA INADEGUATA DELL'ATTREZZATURA E DELLO SPAZIO DI LAVORO** Attrezzatura, strumentazione e spazio di lavoro non progettate per ridurre la fatica e la non comodità dell' operatore.	80	Ambiente povero o ostile	56

20	**STRESS EMOZIONALE PERIOPERATIVO** Ovvero indotto da fattori non direttamente riconducibili all' equipe e alle caratteristiche e all'evoluzione dell'intervento, quali responsabilità di budget e di altri obiettivi aziendali, problemi organizzativi di reparto, altri pazienti critici, cause legali.	80	Alto livello di stress emozionale	80

APPENDIX 7: Questionnaire Results of Third Surgeon

Si chiede gentilmente a TRE CHIRURGHI di completare le seguenti tabelle, individualmente.

La prima tabella si riferisce al task critico "Isolamento peduncoli laterali e superficie posteriore della prostata", mentre la seconda al task critico "Anastomosi".

I tre chirurghi dovranno (separatamente) identificare quali tra i "20-FATTORI INFLUENZANTI" della tabella hanno una maggiore influenza sulla performance del chirurgo nel portare a termine il task. Si chiede di scegliere <u>solo i fattori significativamente influenzanti</u> e di assegnarne una stima dell'influenza con un valore da 0 a 100. Si chiede di fornirne inoltre la quantità (della stima del fattore influenzante) attribuibile al sotto-fattore corrispondente.

Esempio: Task 1_ Chirurgo 1

5	**MANCANZA DI GESTIONE DEGLI ERRORI** **Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.**	**60**	**Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore**	**40**

Si ringrazia per la cortese collaborazione.

FATTORI INFLUENZANTI **TASK 1:** **"Isolamento peduncoli laterali e superficie**	*stima* *tra 0 e 100* *dell'influenza del fattore a sinistra*	*SOTTO-FATTORE*	*Quantità, della stima precedentemente individuata, attribuibile al sotto-fattore*

posteriore della prostata”

1	**RUMORE E VOCI DI SOTTOFONDO** Rumore continuo o improvviso; il parlare dei membri del team; rumore provocato dal girovagare e il muoversi in sala.	60	Segnali disturbanti o confusi	60
2	**MUSICA** Presenza di musica di sottofondo in sala.	50	Segnali disturbanti o confusi	50
3	**USO RUMOROSO DI SOCIAL MEDIA** Condivisione inopportuna di contenuti di social media tra i membri del team.	40	Segnali disturbanti o confusi	40
4	**INTERRUZIONI VERBALI** Interruzioni verbali sia rilevanti per il paziente ma inopportune sia interruzioni verbali irrilevanti per il paziente.	30	Interruzioni causate dall’intervento di altre persone	30
5	**MANCANZA DI GESTIONE DEGLI ERRORI** Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.	70	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	70
6	**MANCANZA DI PROCEDURE STANDARD E CHECKLIST APPROPRIATE** Inadeguatezza delle esistenti procedure nella pratica lavorativa (procedure scarse, incomplete o troppo vincolanti).	50	Mancanza di strumenti per tracciare il progredire di un’attività	50
7	**MODO DI PARLARE RUDE E CON ALTO TONO DI VOCE** Commenti dispregiativi, comportamenti che denotano mancanza di rispetto tra i membri del team, scambio di informazioni severi e rudi toni di voce.	70	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	70

8	**INAPPROPRIATO USO DI PROCEDURE E CHECKLIST** L'improprio uso, o non uso, delle checklist chirurgiche della OMS (o simili), protocolli e procedure.	40	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	40
9	**COMUNICAZIONE NON CHIARA PER UNA COMPRENSIONE CONDIVISA** Mancanza di chiarezza o omissioni nel comunicare informazioni da condividere	50	Sovraccarico di informazioni ridondanti	50
10	**SCARSA COORDINAZIONE** Mancanza di coordinazione nelle attività del team; mancanza nell'anticipare i bisogni del chirurgo alla consolle (se chirurgia robotica).	70	Trasferimento di informazioni da un compito ad un altro, senza perdite	70
11	**CARENZE NEL PROCESSO DI 'DECISION MAKING'** Carenza nel considerare, selezionare e comunicare opzioni; inadeguatezza o ritardo nell'implementare e revisionare decisioni.	80	Non chiara allocazione di funzioni e responsabilità	80
12	**SCARSA CONSAPEVOLEZZA DELLA SITUAZIONE** Carenza nella raccolta e nella comprensione di informazioni o nell'anticipare stati futuri, problemi e stati dell'intervento.	90	Poca familiarità con una situazione che è potenzialmente importante	90
13a	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM** Mancanza di esperienza nella specializzazione chirurgica o con la procedura chirurgica o con la tecnologia richiesta.	60	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	60
13b	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM DI ANESTESIA** Mancanza di esperienza tra i membri del team dedicato all'anestesia, con la procedura anestesiologica o con la tecnologia.	50	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	50

14	**FATICA** Fatica mentale e fisica	80	Interruzione dei normali cicli di lavoro-sonno (affaticamento)	80
15	**PRESSIONE TEMPORALE** Stress psicologico dovuto al dover svolgere compiti in meno tempo rispetto a quello richiesto o desiderato.	60	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	60
16	**MANCANZA DI LEADERSHIP** Carenza nell'impostazione e nel mantenimento di standard, nel supportare gli altri e nel reagire alla pressione.	90	Bisogno di giudizi assoluti che sono oltre le capacità o l'esperienza di un operatore	90
17	**FAMILIARITA' TRA MEMBRI DEL TEAM** Non familiarità tra Membri del team e tra le loro competenze.	80	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	80
18	**CARENZA NELLA FRUIBILITA' DELLA TECNOLOGIA** Inabilità o mancanza di abilità nell'uso della tecnologia disponibile (anche mancanza di capacità tecniche legate alla tecnologia).	80	Povero interfaccia tra sistema e utente	80
19	**ERGONOMIA INADEGUATA DELL'ATTREZZATURA E DELLO SPAZIO DI LAVORO** Attrezzatura, strumentazione e spazio di lavoro non progettate per ridurre la fatica e la non comodità dell' operatore.	90	Ambiente povero o ostile	90
20	**STRESS**	90	Alto livello di stress emozionale	90

FATTORI INFLUENZANTI TASK 2: **"Anastomosi"**		*stima* *tra 0 e 100* *dell'influenza del fattore a sinistra*	*SOTTO-FATTORE*	*Quantità, della stima, precedentemente individuata, attribuibile al sotto-fattore*
1	**RUMORE E VOCI DI SOTTOFONDO** Rumore continuo o improvviso; il parlare dei membri del team; rumore provocato dal girovagare e il muoversi in sala.	60 ___	Segnali disturbanti o confusi	60 ___
2	**MUSICA** Presenza di musica di sottofondo in sala.	50 ___	Segnali disturbanti o confusi	50 ___
3	**USO RUMOROSO DI SOCIAL MEDIA** Condivisione inopportuna di contenuti di social media tra i membri del team.	40 ___	Segnali disturbanti o confusi	40 ___
4	**INTERRUZIONI VERBALI** Interruzioni verbali sia rilevanti per il paziente ma inopportune sia interruzioni verbali irrilevanti per il paziente.	30 ___	Interruzioni causate dall'intervento di altre persone	30 ___
5	**MANCANZA DI GESTIONE DEGLI ERRORI** Carenza nel condividere informazioni prontamente e apertamente rispetto a errori e minacce di errore per il paziente.	70 ___	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	70
6	**MANCANZA DI PROCEDURE STANDARD E CHECKLIST APPROPRIATE** Inadeguatezza delle esistenti procedure nella pratica lavorativa (procedure scarse, incomplete o troppo vincolanti).	50 ___	Mancanza di strumenti per tracciare il progredire di un'attività	50 ___
7	**MODO DI PARLARE RUDE E CON ALTO TONO DI VOCE** Commenti dispregiativi,		Qualità povera di informazioni	

	comportamenti che denotano mancanza di rispetto tra i membri del team, scambio di informazioni severi e rudi toni di voce.	70	derivanti dalle procedure e dall'interazione persona-persona	_40
8	**INAPPROPRIATO USO DI PROCEDURE E CHECKLIST** L'improprio uso, o non uso, delle checklist chirurgiche della OMS (o simili), protocolli e procedure.	50 ___	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	50 ___
9	**COMUNICAZIONE NON CHIARA PER UNA COMPRENSIONE CONDIVISA** Mancanza di chiarezza o omissioni nel comunicare informazioni da condividere	70	Sovraccarico di informazioni ridondanti	70
10	**SCARSA COORDINAZIONE** Mancanza di coordinazione nelle attività del team; mancanza nell'anticipare i bisogni del chirurgo alla consolle (se chirurgia robotica).	80	Trasferimento di informazioni da un compito ad un altro, senza perdite	80
11	**CARENZE NEL PROCESSO DI 'DECISION MAKING'** Carenza nel considerare, selezionare e comunicare opzioni; inadeguatezza o ritardo nell'implementare e revisionare decisioni.	90 ___	Non chiara allocazione di funzioni e responsabilità	90 ___
12	**SCARSA CONSAPEVOLEZZA DELLA SITUAZIONE** Carenza nella raccolta e nella comprensione di informazioni o nell'anticipare stati futuri, problemi e stati dell'intervento.	60 ___	Poca familiarità con una situazione che è potenzialmente importante	50 ___
13a	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM** Mancanza di esperienza nella specializzazione chirurgica o con la procedura chirurgica o con la tecnologia richiesta.	80	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	80

13b	**MANCANZA DI ESPERIENZA DEI MEMBRI DEL TEAM DI ANESTESIA** Mancanza di esperienza tra i membri del team dedicato all'anestesia, con la procedura anestesiologica o con la tecnologia.	60___	Inesperienza dell'operatore (ad esempio qualcuno appena qualificato, ma non ancora divenuto "esperto")	60___
14	**FATICA** Fatica mentale e fisica	90	Interruzione dei normali cicli di lavoro-sonno (affaticamento)	90
15	**PRESSIONE TEMPORALE** Stress psicologico dovuto al dover svolgere compiti in meno tempo rispetto a quello richiesto o desiderato.	80 ___	Mancanza di tempo disponibile per il rilevamento o la correzione dell'errore	80 ___
16	**MANCANZA DI LEADERSHIP** Carenza nell'impostazione e nel mantenimento di standard, nel supportare gli altri e nel reagire alla pressione.	80 ___	Bisogno di giudizi assoluti che sono oltre le capacità o l'esperienza di un operatore	80 ___
17	**FAMILIARITA' TRA MEMBRI DEL TEAM** Non familiarità tra Membri del team e tra le loro competenze.	90 ___	Qualità povera di informazioni derivanti dalle procedure e dall'interazione persona-persona	90 ___
18	**CARENZA NELLA FRUIBILITA' DELLA TECNOLOGIA** Inabilità o mancanza di abilità nell'uso della tecnologia disponibile (anche mancanza di capacità tecniche legate alla tecnologia).	90 ___	Povero interfaccia tra sistema e utente	90 ___
19	**ERGONOMIA INADEGUATA DELL'ATTREZZATURA E DELLO SPAZIO DI LAVORO**		Ambiente povero o ostile	

	Attrezzatura, strumentazione e spazio di lavoro non progettate per ridurre la fatica e la non comodità dell' operatore.	90 ___		90 ___
20	**STRESS EMOZIONALE PERIOPERATIVO** Ovvero indotto da fattori non direttamente riconducibili all' equipe e alle caratteristiche e all'evoluzione dell'intervento, quali responsabilità di budget e di altri obiettivi aziendali, problemi organizzativi di reparto, altri pazienti critici, cause legali.	90 ___	Alto livello di stress emozionale	90 ___

APPENDIX 8: Surgeon's opinion about percentage improvement of proposed remedial strategies

Sono stati analizzati TRE SCENARI riguardanti strettamente gli aspetti "Personali", "Team" e "Organizzativi" che influenzano maggiormente l'esecuzione dei Task 1 "Isolamento dei peduncoli laterali e della superficie posteriore della prostata" e Task 2 "Anastomosi".
I fattori influenzanti (IF) analizzati sono stati:

IF		**Category of Scenario**
1	Noise and Ambient Talk	Team
5	Poor management of errors	Organizational
9	Unclear Communication	Team /Personal
10	Poor Coordination	Team/ Personal

Per tutti i fattori è stato analizzato come varia la Probabilità di Inaffidabilità Umana al variare dell'influenza del fattore. Viene riportato il range massimo di variazione (con variazione massima percentuale) della probabilità di Inaffidabilità.

	Noise and Ambient Talk	Poor management of errors	Unclear Communication	Poor Coordination
Task 1	0,0136-0,085 Riduzione 84%	0,0085 - 0,085 Riduzione 90%	----------------------	0,025- 0,085 (riduzione 70%)
Task 2	0,2 - 1,18 Riduzione 83%	0,10 - 1,18 Riduzione 92%	0,11 - 1,18 Riduzione 91%	0,29 - 1,18 Riduzione 75%

Di seguito si elencano le azioni migliorative proposte per i tre scenari analizzati.
SCENARIO 1
Il primo scenario considerato è relativo ai fattori personali che intervengono durante l'esecuzione dei Tasks. Tra i fattori analizzati dal caso studio, sono stati selezionati il fattore "Comunicazione" (IF 9) e "Coordinazione" (IF 10) in quanto ritenuti fattori di forte influenza e facilmente evidenziabili.

AZIONI MIGLIORATIVE	QUANTO PENSA CHE QUESTE AZIONI POSSANO PERCENTUALMENTE CONTRIBUIRE A RIDURRE L’INFLUENZA DEI FATTORI?
1_Training di simulazione per istruire alla comunicazione e coordinazione all’interno degli interventi	80%
2_Training in aula (training frontali) che stimolino ed educhino ad un linguaggio chiaro, pulito, efficiente e alla trasmissione di informazioni, comandi senza perdite di informazioni. Questo permetterebbe inoltre l’acquisizione di un linguaggio appropriato, tecnico e consolidato per una comunicazione senza incomprensioni e male interpretazioni	50%
3_Il chirurgo deve accertarsi che i propri comandi siano recepiti dall’altro chirurgo (ci deve essere sempre conferma vocale della ricezione dell’indicazione data)	40%
4_Quando possibile la comunicazione non deve essere solo vocale, ma deve avere dei riscontri visivi sui monitor (ad esempio facilitare la comprensione dei comandi richiesti con gli strumenti in mano, ad esempio indicando le zone di azione)	20%

SCENARIO 2

Il secondo scenario è quello inerente l’influenza dei fattori del Team, che si riferiscono al “Noise and Ambient Talk” (IF 1) e, come detto precedentemente anche i fattori già citati “Communication” (IF 9) and “Coordination” (IF 10).

AZIONI MIGLIORATIVE	QUANTO PENSA CHE QUESTE AZIONI POSSANO

	PERCENTUALMENTE CONTRIBUIRE A RIDURRE L’INFLUENZA DEI FATTORI?
1_La stabilità e familiarità tra membri del team.	80%
2_Innalzamento delle competenze ed abilità di tutto il team attraverso ripetute attività di training che permettono lo sviluppo di automatismi e non technical skills.	60%
3_Limitare l’uso di social media dei membri del team alla sala preoperatoria, uso di checklist e protocolli per assicurarne l’applicazione.	40%
4_Personale addetto che filtra le chiamate urgenti che devono arrivare al chirurgo	60%
5_Disposizione di strumenti e personale solo strettamente necessari per evitare confusione.	50%
6_Migliore programmazione dei turni di lavoro: evitare cambi di turno durante l’esecuzione degli interventi.	50%
7_Uso di protocolli da applicare per mantenere il silenzio rigoroso e utilizzare parole solo per fini necessari	60%
8_Introdurre nelle schede di valutazione dei membri del team il rispetto dei protocolli riguardanti l’uso di cellulari in sala e appropriata comunicazione	10%

<u>SCENARIO 3</u>

Infine viene considerato l’ultimo scenario inerente i fattori Organizzativi, che fanno riferimento a “Poor management of errors”.

AZIONI MIGLIORATIVE	QUANTO PENSA CHE QUESTE AZIONI POSSANO PERCENTUALMENTE

	CONTRIBUIRE A RIDURRE L'INFLUENZA DEI FATTORI?
1_Rispetto effettivo della standardizzazione delle procedure	80%
2_Utilizzo di checklists per verificare gli strumenti utilizzati (fili, ago, ect) e verificarne la presenza finale. Controllo effettivo delle checklists, ogni volta.	60%
3_Sfruttare gli interventi anche come momenti di condivisione e confronto per poter migliorare le proprie abilità imparando dagli errori.	70%
4_Chiarificazione dei ruoli e delle responsabilità dei membri del team e dei chirurghi, attraverso educazioni interprofessionali.	30%
5_Miglior organizzazione degli interventi durante la giornata lavorativa: assicurarsi che prima vengano eseguiti gli interventi più critici e lunghi, poi quelli meno critici e più breve ed infine quelli eventualmente posticipabili.	80%
6_Training strutturati fin dalle fasi inziali di apprendimento delle tecniche, per aumentare la consapevolezza di eventuali rischi ed errori possibili nei vari tasks della procedura.	80%
7_Avere a disposizione procedure di emergenza chiare e conosciute.	60%