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Towards a taxonomy of influencing factors for human reliability analysis (HRA) applications in surgery

Rossella Onofrio*, Paolo Trucco, Arianna Torchio

Department of Management, Economics and Industrial Engineering, Politecnico di Milano, Milan, Italy

Abstract

Despite the growing interest in HRA applications in healthcare and in particular in surgery, in literature there is a limited number of HRA studies that use the so called Performance Shaping Factors or Influencing Factors to describe the working context. These factors (IFs) are those human, environmental, organizational or task specific factors that positively or negatively affect surgeons' performance and the Error Probability. This study aims at developing an ad hoc taxonomy of Influencing Factors for surgery and it is meant to represent a first contribution towards the application of IF-based HRA in healthcare. The study methodology is twofold: firstly, literature review was used to identify and select personal and organizational factors that shape surgical performance; secondly, a field study was carried out to validate the preliminary list of IFs. Minimally Invasive Surgery (MIS) has been chosen as the field study domain. Ten factors have been extracted from the literature and classified according to the SHELL model. All the IFs in the taxonomy were observed throughout observation sessions. Furthermore, the observations prompted the addition of one more factor, namely "distractions". In order to arrive at a stronger validation of the taxonomy, further research is needed to develop extensive validation of the conceptualization, clustering and assessment of IFs, by eliciting surgeons' perceptions through multiple qualitative and quantitative methods.

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* Corresponding author. Tel.: +393288876311.

E-mail address: rossella.onofrio@polimi.it

1. Introduction

Over the last decade, although the benefits of transferring and applying to healthcare services risk analysis methods, traditionally implemented in industry, are fully recognized in the patient safety literature [1-2], healthcare organizations are characterized by reactive culture in their approach to safety [3]. It is strongly focused on the analysis of adverse events (ex post analysis) instead of approaches of anticipation and elimination of vulnerabilities in the system [4]. This limitation led some groups of experts [5-6-7-8] to test alternative solutions, including the Human Reliability Analysis (HRA), a discipline developed in industry, that aims at investigating and quantifying the human contribution to safety within the technical and organizational context. In particular an important feature of the HRA methodologies, which well fits the need to improve the patient safety in healthcare, regards the HRA anticipatory pattern rather than retrospective one. In detail, estimating the probability of error allows providing ex ante analysis before incidents or adverse events occur and identify appropriate corrective measures that can be implemented before the inadequacies of system can occur.

Although the growing interest on HRA methodologies and techniques in healthcare and in particular in surgery, some authors also recognise in the inherent complexity of healthcare operations the main barrier against the diffusion of Human Reliability Analysis (HRA) techniques in the same domain [8-9]. One of the main issues come out from literature is about the working environment modelling that is a relevant qualitative phase of HRA. In detail, in extant literature there are few HRA studies in healthcare that use Performance Shaping Factors (PSFs) or Influencing Factors (IFs) [10-11-12], i.e. those human, environmental, organizational or task specific influences that enhance or degrade human performance and impact on human error probability. This finding does not seem reflected in HRA theory and applications in the industrial sector, in which these factors play a relevant role [13]. Looking at IFs (in the following this term will be preferred to PSFs) industrial taxonomies, it is clear that their development and validation are strictly connected to the specific context features. This is the reason why some authors have highlighted that IFs taxonomies incorporated in the most common HRA techniques have been developed and validated in industrial contexts, and as such are not fully applicable to the healthcare sector [12-14]. Although human factors and ergonomics theory in healthcare gave a big contribution to the identification of factors that could influence surgeons performance, to the best of our knowledge there is no much literature available about validated IFs taxonomies in healthcare and surgery, potential input of Human Reliability Analysis applications. This study aims at developing an ad hoc taxonomy of IFs for HRA application in surgery.

This article is organized as follows: section 2 provides the theoretical background about the investigation of IFs in healthcare with particular focus on surgical context; section 3 defines research questions and research objective; section 4 presents the methodology; section 5 describes the study results; and section 6 claims the conclusion and further research.

2. Theoretical background

2.1. Influencing factors in HRA

Historically, the application of IFs, i.e. aspects of behaviour and context that impact human performance [13], taxonomies in human reliability analyses is part the Probabilistic Risk Assessment (PRA), that is a systematic approach that identifies the principal (or most likely) accident scenarios that can lead to unintended consequences and calculates the probability that they occur in complex systems. Several different taxonomies of IFs have been proposed in HRA industrial literature, in particular different taxonomies have been developed ad hoc for specific complex socio-technical contexts as aviation and nuclear sectors. The reason of that is because the IFs tend to be standardized at the higher level of the classification hierarchy, where factors are generally related to the basic factors of a generic working system (software, hardware, environment, live ware - SHELL) [15]. In the meanwhile, at a lower level of classification, the same taxonomies of IFs differentiate a lot, since they are connected to more contingent and detailed characteristics of the specific task or working system. This is also confirmed by the recent open debate in industrial literature about which IFs should be used in HRA and what is the appropriate number of IFs to include in a method or analysis. In fact, "There is considerable range in the number of IFs provided by

individual HRA methods, ranging from single factor models such as time - reliability curves, up to 50 or more IFs in some current HRA models.” [13].

2.2. Human factors in healthcare

Although the increasing interest in HRA applications in healthcare, in extant literature there are few HRA studies in healthcare that use IFs. This finding seemed to not be reflected in HRA theory and applications in the industrial sector, in which contextual and organizational factors play a relevant role and the attempt to incorporate them into new and more advanced HRA techniques represents a hot research line in this discipline since a long time. A closer look to the few papers describing HRA applications in healthcare where human and organizational factors are included in the quantitative or qualitative analysis reveals that all the authors dedicated particular attention to the choice of the most appropriate IFs. This modeling activity generally culminated in the decision to take into account only some of the factors covered by the selected HRA technique. Some authors also highlighted that IFs taxonomies incorporated in the most common HRA techniques have been developed and validated in industrial contexts, and as such are not fully applicable to the healthcare sector [11-12-14]. This methodological limitation of HRA applications in healthcare is particularly relevant in surgery where there are the majority of HRA applications [5-16-17-18-19-20-21-22]. In particular the most frequently HRA applied method is the Observational Clinical Human Reliability Analysis (OCHRA) – developed by Cuschieri and his research group [5-6-7]. These studies are mainly focused on the assessment of surgeons’ technical skills and their potential contribution to adverse events without considering personal, organizational, team and contextual factors, although the authors considered them as one of the most important dimensions of HRA in surgery [5].

Nevertheless, in the last decades, a key question facing surgical units relates to the identification of factors that can influence surgical outcomes and, therefore, how knowledge of these factors can be used to enhance surgical performance. Research efforts across the world have sought to identify factors that may influence surgical performance, and with recent advances in surgical technology a number of studies have focused on the association between surgical outcomes and surgical technology and the technical skills and types of training of surgeons. Though several authors have tried to identify personal and organizational factors that influence surgical performance, the investigation of these factors that could influence surgical performance has been the research topic of different research streams that apparently don’t interact each other: relevant literature contributions, as mentioned before, come from human factors and ergonomics studies, retrospective analyses, such as incident reporting analyses [23-24], studies on the evaluation and assessment of Non-Technical Skills of surgical team during surgical interventions [25-26-27].

Human factors and Ergonomics studies paved the way to the investigation of the influence of human aspects on surgical performance. The literature reports a big contributions of incident reporting analyses, i.e. ex-post analysis, based on data coming from systems Incident Reporting to analyze the factors that led to accidents; the framework of Vincent is a support for this type of analysis, to identify the factors that led to the accidents. Moreover, the recent spread of taxonomies of non-technical skills (Non-Technical Skills - NTS), has promoted the creation and the application of observational tools, which allow the assessment of the NTS during the surgical procedures, according to a real time analysis approach.

3. Research objective

In order to foster the diffusion of HRA in healthcare it is not enough to show how to apply the existing HRA techniques to the new context. A deep adaptation and revision of these techniques to healthcare environment are claimed by several researchers [11-12-14]. To this end, particularly attention should be addressed to the validation of a taxonomy of IFs that could shape the performance of the operator (e.g. surgeon or anaesthesiologist) under different contexts. Based on the theoretical background, the final objective of the present study is to develop an ad hoc taxonomy of IFs for HRA application in surgery starting from the healthcare literature contributions (cf. par. 2): i.e. human factors and ergonomics studies, incident reporting systems (ex-post analysis), NTS studies (real time

analysis) and IFs in HRA applications (ex-ante applications). Indeed, the general research objective can be turned into the following Research Questions:

RQ1: What are the personal and organizational factors (Influencing Factors - IFs) that can influence positively or negatively surgeons' performance?"

RQ2: Are these factors observable in the operating theatre?"

4. Methodology

4.1. Literature review

To answer the first research question as a first step to design a taxonomy of IFs for HRA application in surgery, a literature review in Human Factors literature has been performed to identify and select personal and organizational factors that shape surgical performance. The purpose of the literature search was not a systematic review, but the identification of the highest number of applicable personal and organizational factors - with particular attention to: i) factors investigated by ergonomics studies; ii) those factors reported in frameworks derived from incident reporting analyses; iii) the semantic categorization of skills into technical and non-technical. The literature search was performed within three different databases, i.e. Pubmed, Scopus, Web of Science, covering both medical and industrial literature. The Keywords were: i) Human Factors" AND "surgery"; ii) Ergonomics" AND "surgery; iii) Non-Technical Skills" AND "surgery". Among the results, we selected only studies that investigate the relationship between the factor and surgical performance. The main result was a preliminary list of factors, grounded in literature evidences, to be used as a knowledge base.

4.2. Field study

The second phase of the study aimed at validating and possibly expanding the taxonomy through observational activity in the surgical context during the real surgical pathway. The mini-invasive surgery has been chosen as the field study domain. In recent years, surgical practice underwent a remarkable change, thanks to the evolution of mini-invasive surgical techniques where the surgical goal is no longer limited to patient care, but it extends to minimize trauma due to the intervention and to ensure a faster postoperative recovery [28]. The increasing use of robotic surgery and its impact on surgeons and surgical team working conditions justifies the interest in the field.

We conducted the field study in Italy, where surgical volumes represent the 40% of the total admissions in hospitals and in recent years the use of mini-invasive surgery represents a fast growing practice. To this end, the preparation phase of our field study comprised the definition of the surgical pathway and the design of a specific observational protocol, including a template to be filled in during real time observations. In detail, to take into account the complexity of the surgical procedures, constituted by a large number of interrelated steps, the surgical pathway has been articulated in five phases (operating room preparation, patient preparation, anaesthesia induction, intervention execution, intervention closure). On the other hand, the information to be considered in the observational protocol was: i) Institution, team and procedure data; ii) Table of observations, divided accordingly to IFs and surgical phases; iii) Table of new factors; iv) Questions for running semi-structured short interviews to the operating room personnel. Two observers have been involved to watch surgical procedures in parallel and to compare and harmonize data into one final document. In particular fifteen robotic surgical interventions have been observed in nine Italian hospitals. The first two operations were observed without performing the analysis as familiarization phase without gathering data; in the other thirteen each observer filled in the protocol independently. Finally, short interviews with professionals, based on protocol questions, were also sometime possible at the end of the surgical operation. At the end of the day the two protocols were compared and reunited into one document. The number of observation and the types of observed procedures were established without any control by researchers, so the activity was structured as face validity [29-30-31] and the stopping rule was the observation of each IF at least one time. Furthermore interview analysis was done in a qualitative way, by the application of a technique meant to reduce the great variety of qualitative information inside a verbal document into a smaller set of information [32]. Once the interview has been transcribed, we analysed the text according to these phases: 1.coding text, 2.categories definition, 4. Patterns identification.

5. Results

We identified ten types of factors from literature review: Noise and background talk not related to the task, safety culture and safety climate, standardization, communication and teamwork, experience and team training, leadership, staffing and team member familiarity, workload, equipment HMI and space design.

Then we classified the factors into the categories of SHEL model [14], the most used models in HRA industrial literature to classify IFs; it is used by the National Safety Transportation Board to promote the human factors management plans for safety. This model supports the systemic view as it defines and classifies the components of a working process, since their mutual dynamic and flexible interactions represent the core of the process in itself. SHEL is an acronym for: i) Software: computational code, rules, procedures, practices; generally all the formal and informal rules that determine the mechanism of the interactions among the system components; ii) Hardware: each not human component, such as equipment and Instruments; iii) Environment: the physical, social, economic and political context in which the system components have to interact; iv) Liveware: the human factor and their relationship aspects and communication. In the table 1, all the IFs identified have been classified according to SHEL model.

For each factor we provide the definition (or description); the list of references that discuss its effect on surgeon's performance. Moreover we investigated the valence of the IF, i.e. the positive and/or negative effect on performance (see table 1). To give an example of the meaning of valence: the development of safety culture, the use of standardized protocols and the experience, have a positive impact on the surgeon's performance, whereas the presence of noise, workload and fatigue exert a negative influence. Moreover some IFs, e.g. "Equipment HMI and space design ", can have both positive and negative valence.

Furthermore to answer to the second research question about the observation capacity of the IFs by an external operator; for instance some factors as noise, standardization level, are directly observable, but factors as, communication and teamwork, safety culture and safety climate, team member familiarity - cannot be observed except through behavioral markers or interviews. Indeed we identified for each factor the elements that can be observed or asked in the interview from one external operator as reported in the last column of the table 1.

With the eleventh intervention observation all the factors have been observed; subsequent visits have only confirmed what has been previously observed. Indeed, the first step towards a comprehensive validation of this IFs taxonomy in surgery has been achieved. The observations prompted the addition of one more factor, namely "distractions". We observed that during the intervention, especially during prolonged interventions, the personnel involved in non – continuous tasks, as an anesthetist and nurses, use phones or computers. This is the reason why the first draft of the taxonomy has been modified, introducing a new IF, and labeled "distractions".

Table 1. Influencing factors classified according to SHEL model [33].

SHEL Classification	Factor Label	Description	Literature Evidence in Healthcare	valence	Observation/interview
Environment	Noise & back-ground talk not related to the task	Auditory stimulus that does not contain useful information to complete the task (Healey, Sevdalis, & Vincent, 2006).	(Beldi, Bisch-Knaden, Banz, Mühlemann, & Candinas, 2009; Catchpole et al., 2007; Haynes et al., 2009; Kurmann et al., 2011; Miskovic et al., 2008; Parker et al., 2010; Siu, Suh, Mukherjee, Oleynikov, & Stergiou, 2010; Wiegmann et al., 2007)	+/-	i) Presence of Continuous noise (Catchpole et al., 2007); ii) presence of sudden noise (Catchpole et al., 2007; Wiegmann et al., 2007); iii) Music (Hawksworth et al., 1997; Miskovic et al., 2008); iv) Alarms (Catchpole et al., 2007; Wiegmann et al., 2007); v) communication not related to intervention (Catchpole et al., 2007; Wiegmann et al., 2007); vi) Traffic of personnel (Beldi et al., 2009)
	Safety Culture and Safety Climate	Individual and group values, attitudes, perceptions, competencies and patterns of behavior of one Healthcare organization that determine the commitment, style and expertise in safety management (Health and	(Davies, 2001; Helmreich & Davies, 1996; Walshe & Offen, 2001; West, 2000; Bognár et al., 2008; Fleming, Smith, Slaunwhite, & Sullivan,	+/-	i) Management commitment to safety promotion (Trucco et al., 2009); ii) pressure exerted by the organization about the working safety (Trucco et al., 2009); iii) Attitude of neglecting safety procedures (Trucco et al., 2009); iv) operator involvement (Trucco et al.,

SHEL Classification	Factor Label	Description	Literature Evidence in Healthcare	valence	Observation/interview
		Safety Commission, 1993); Commitment with which individuals or groups carry on the vision of the organization and degree of adherence to procedures and policies established (Wahr et al., 2013)	2006; Hann, Bower, Campbell et al., 2007; Makary et al., 2006; Singer et al., 2009)		2009); v) Priority of safety rather than other problems (Trucco et al., 2009). i) Verbal references to protocol or procedures (Fleming et al., 2006); ii) Expressions of discontent from the team (Fleming et al., 2006).
Software	Standardization	Availability and adequacy of procedures, protocols and checklists.	(Arriaga et al., 2013; Christian et al., 2006; Ferran, Metcalfe, & O’Doherty, 2008; Haynes et al., 2009; West, 2000; Winters et al., 2009)	+/-	i) Availability and use of execution protocols (West, 2000); ii) Availability and use of checklists (Winters, 2009); iii) operating checklist use (WHO 2007); iv) written or oral Handover (Ferran et al., 2008).
Hardware	Equipment, HMI and space design	Features of the instrumentation, equipment and alarms; design characteristics of the surgical space.	(Berguer, Smith, & Chung, 2001; Cao & Rogers, 2006; Finley & Cohen, 1991; Jamjoom, Nikkar-Esfahani, & Fitzgerald, 2009; Schmid et al., 2011; Wiegmann, ElBardissi, Dearani, Daly, & Sundt, 2007; Wubben, van Manen, van den Akker, Vaartjes, & van Harten, 2010)	+/-	i) Robot Arms conflict (Cao & Rogers, 2006); ii) monitors number (Hanna et al., 1998); iii) claimed problems about surgical equipment; iv) missing tools in surgical cart. i) dimension (Brogmus et al., 2007); ii) position of surgical technological equipment; iii) presence of preparation room; iv) -space equipment (Brogmus et al., 2007); v) Cables and wires (Cesarano & Piergeorge, 1979);
Live-ware	Communication and teamwork	The way to share information related to the task among team members. The quality of the expression, the use of a correct phraseology and the audibility of the transmission. Process of the interdependent actions (sequence and time), or the management of simultaneous or synchronous activities through information exchange and mutual adjustment of action (Brannick, Prince, Prince, & Salas, 1993) to align the contributions of each member to achieve the final objective.	(Carthey, 2003; Catchpole et al., 2007; Christian et al., 2006; L Lingard, 2004; Nyssen & Blavier, 2010; Wiegmann et al., 2007) (de Leval, 1997; Lorelei Lingard, Reznick, Espin, Regehr, & DeVito, 2002; Salas, Wilson, Murphy, King, & Salisbury, 2008) (Christian et al., 2006) (Edmondson, 2003; Jehn & Mannix, 2001; Rosenstein & O’Daniel, 2006)	+/-	Tone of voices;; ii) number of misunderstood messages (Lingard et al., 2002); iii) frequency of questions; iv) number of not heard communication (Lingard et al., 2002); v) Coordination between console and patient table; vi) Anticipation (Christian et al., 2006); vii) Equipe Conflicts (Jehn et al., 1997); vii) Exemplar behaviors – OTAS (Undre et al. 2006).
	Experience and Team Training	Experience is the accumulation of information and knowledge gained through training and interaction with the system (Groth & Mosleh, 2012). Specific training for the team members to perform complex surgical procedures, at individual, and team level.	(Cowan, Dimick, Thompson, Stanley, & Upchurch, 2002; Critchley, Baker, & Deehan, 2012; Hall, Ellis, & Hamdorf, 2003)	+	i) Surgical Interventions volume (Critchley et al., 2011, Cowan et al., 2002); ii) interventions frequency (Critchley et al., 2011); iii) experience of operating room personnel; iv) training Intensity (Pugliese & Bayley, 2008); v) training continuity/discontinuity.
	Fatigue	Psychological and physiological inclination to not continue the task or to not start one new. It stems from prolonged physical or mental activities, nature, work environment, frequency of the personal commitment.	(Berguer et al., 2001; Sheikhzadeh et al., 2009; Mark et al., 2014; Zihni et al., 2014)	-	i) Fatigue claims.

SHEL Classification	Factor Label	Description	Literature Evidence in Healthcare	valence	Observation/interview
	Leadership	The team leader performs different types of behavior to encourage team efficacy; For example, it deals with, the structure of the team, aim definition, resources management and he helps the group members to increase their contributions and to use their collective resources to further the goals of the group. (Hackman & Wage man, 2005).	No evidence	+/-	i) Decisions in uncertainty situation (Rousseau et al., 2006); ii) Exemplar behaviors – OTAS (Undre et al. 2006).
	Staffing and team member familiarity	Composition of the surgical team and turnover during the working day; familiarity among team members, accumulated experience and stability as experience of working within a particular team.	(Brown et al., 2011; Carthey, 2003; Edmondson, 2003; ElBardissi, Wiegmann et al., 2008; Undre et al., 2006; Gillespie, 2010; Leong, Wilson, & Charlett, 2006; Zheng, Pantan, & Al-Tayeb, 2012)	+/-	i) Number of équipe members (Beldi et al., 2008); ii) Roles; iii) shifts (Beldi et al., 2008; Zheng, 2012). iv) Experience years as équipe (Healey et al., 2007); v) presence of new team members (Healey et al., 2007);
	Workload	Cost incurred by an individual, given his capacity, to achieve a particular execution level of a task with a specific physical and / or mental request.	(Berguer et al., 2001; Khon, 2000; Stefanidis, Scerbo, Korndorffer, & Scott, 2007; van der Schatte Olivier, Van't Hullenaar, Ruurda, & Broeders, 2009; Yurko, Scerbo, Prabhu)	-	Time allocated vs real time;

6. Conclusion and further research

This study is meant to represent a contribution towards the spread of HRA in healthcare. Despite the growing interest in HRA applications in healthcare and in particular in surgery, in literature there is a limited number of HRA studies that use the so called Influencing Factors (IFs) to describe the working context in which one human task takes place. This finding does not seem reflected in HRA theory and applications in the industrial sector, in which these factors play a relevant role and are key elements in the analysis.

From the methodological point of view, this study has led to bridge the literature gap with the creation of a taxonomy of IFs in surgery. In order to come out with a strong based conclusion on IFs validation, further research will be based on extensive validation of conceptualization, clustering and articulation of IFs investigating surgeons perceptions through focus group interviews. Furthermore one of the main gaps in the literature and in practice is still how measure the influence of these factors on surgical performance according to HRA approach. In this direction, further research will be based on the assessment of the perceived influence of IFs on surgical performance via experts' judgements elicitation.

Beyond the scope of fostering the HRA applications in surgery, there is also hope that the taxonomy will be useful for surgeons, organizations and technology providers, for the growth of awareness about influences on surgeon's performance and be applied, for example in support of training and ergonomic design of medical devices, in benchmark analyses and in the draft of checklists and best practices. Furthermore, the study would be a valuable contribution for practitioners in the healthcare to develop organizational programs.

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