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Proceedings of the International Symposium of Human Factors and Ergonomics in Healthcare 2013 2: 90
DOI: 10.1177/2327857913021017

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This German Research Foundation project aims to investigate the human-machine interaction of the operating theatre as a work system and from the results deduce measures and, using consolidated medical devices as an example, develop design guidelines for a prospective development of complex integrated technical systems.

Introduction

Laparoscopic surgeries have been established as a standard in several medical procedures, e.g. for intestinal resection like a laparoscopic elective sigmoid resection procedure. One reason for this is the advantages for patients, especially because the smaller wounds associated with laparoscopic surgery are less painful. But economic reasons also exist, such as shortened hospital stays caused by a faster recovery of patient's health (Kraft, 2008).
Laparoscopic surgeries require an operating theatre that is equipped with specialised medical devices as endoscopic cameras, OR-table, OR lights, insufflators for gas supply, suctions and irrigation pumps, HF device and/or ultrasonic device for tissue coagulation and dissection, monitor control and monitoring anaesthesia (Rassweiler, 2010). Often each medical device in the OR has an individual usability concept devised by its manufacturer. Even Integrated OR solutions, which provide a consolidated touch panel control of all medical devices from within the sterile area, have ergonomic deficiencies within the context of a surgery.

Methods

In the first phase in six reference hospitals throughout Germany (e.g. Charité Berlin), external observers monitored and retrospectively analysed workflows during surgery. Results for a sample of 87 standard laparoscopic procedures from the medical disciplines general surgery (e.g. cholecystectomy, intestinal resection), gynaecology (e.g. hysterectomy) and urology (e.g. nephrectomy) are being presented.
In the second phase a number of 512 error incidents (problems of use and malfunctions) were extracted for the purpose of further analysis and classification of errors by two independent raters.
Different human error taxonomies have been developed to categorize incidents occurring when human users process information. By way of classifying different types of errors into a system of categories it is possible to deduce remedies to avoid and prevent the issues leading to errors. The human error taxonomies developed by Reason (1990) differentiates between user problems pursuant to the level of information processing in which the error occurs. Reason categorises mistakes, slips, lapses and mode errors.
Zapf, Brodbeck and Prümper (1989) introduced an action-oriented taxonomy of errors, distinguishing between functionality problems, usability problems, interaction problems and inefficient behaviour. The usability problems were differentiated according to levels of action regulation and steps in the action process. Functionality problems were differentiated in how they affect the action process.

Results

The sample (N=87) comprises 49 operative surgeries in integrated operating theatres and 38 in a conventional operating theatre. In evaluating the sample, a total of 512 incidents occurred of which 98 were classified as malfunctions and 414 as problems of use.

Overall during 84 of the 87 surgeries problems of use were recorded (max of 16.4 on average, SD 3.3) in the sample. Malfunctions (e.g software errors, device not responding, wrong set-up) of the medical devices and instruments occurred during 50 of the 87 sampled surgeries (max of 5, 1.1 on average, SD 1.38).
The analysis of errors according to the taxonomy of Reason showed that the majority of problems of use (61%, N=414) were to be classified as "lapses" (omissions), i.e, the fact that one step in a sequential order was forgotten (and that this often coincided with an interruption of a procedure). Another 14,7% (N=414) were classified as Slips. Slips and Lapses are defined as actions not carried out as intended or planned. Whereas Knowledge-based Mistakes, which were categorized in 16% (66.5 of 414), do occur at the planning stage of human information processing.
Similar to the first applied taxonomy, the analysis according to Zapf showed that the majority of problems of use (38.5%, N=414) were to be classified as "omission errors". We accounted "inefficiency habit" errors for 22.7%, (N=414) of the error incidents.
At this point, it appears that 7.3% (N=414) of the error incidents observed were "sensorimotor errors".

The total of all error incidents was categorised with an interrater reliability (kappa) of 0.74 for Reason and 0.62 for Zapf and thus reached a satisfactory match of the assessment of the two independent raters (Prümper, 1991).
Within the third phase it is envisaged to implement measures developed in response to the results and to conduct a first trial in a laboratory study in April 2013 to validate ergonomic improvements based on both of the taxonomies that were applied as well as the questionnaire for the evaluation of the ergonomic quality of software products 9241/10-S (Prümper, 1992 and Prümper 1993). It is also planned to validate the thesis that the taxonomies of Reason and Zapf deliver different results from which guidelines for improvements in operating theatres can be deduced in the third phase.
Also, we will investigate the workflows in operating theatres where images based on CT Data are provided and hence the workflow reaches a higher level of integration to determine whether the number and type of human errors changes in correlation to increased complexity in integrated systems.

The analysis of human errors from a user perspective under both taxonomies confirms that two types of problems occur frequently
(i) Omissions Problems (user does not execute well-known sub-plan e.g. due to interruption, such as omission to change the position of the patient when the side of preparation in situ changes). One of the reasons for the high frequency of omission problems is the insufficient workflow-support of the surgery context, which undeniably is a great challenge for a consolidated system consisting of multiple medical appliances of different manufacturer and for a remedy of which standardisation will be required.
(ii) Knowledge-based Mistakes (actions which are intended to but do not achieve the intended outcome due to knowledge deficits) and "inefficiency habit" problems (well known effective sub-plans are not executed or feedback is ignored). For example the touch panel controls within the sterile are not used by the scrum nurse, and a rotating nurse instructed verbally to operate all controls from outside the sterile area instead.

Discussion

Due to the increasing integration of modern technology in the operating theatre both the manufacturers of medical devices and the medical personnel are subject to new challenges. Medical devices need to be improved in respect of their interaction with each other and medical personnel will need to acquire skills in neighbouring disciplines (such as the requirement for surgeons and nurses to interpret the intra-operative navigation based on medical imaging.
Currently, the medical personnel is not being prepared sufficiently for these requirements whether in their academic or professional training or the ongoing development in the clinics.
International standards of usability, such as those in DIN EN ISO 9241 (2008), have not yet been adapted to address complex integrated systems or safety-critical systems which experts use in collaboration.
Usability-Testing of medical devices as a well as integrated solutions for operating theatres by their manufacturers is often limited to laboratory studies and interviews conducted by manufacturers. We think that a realistic scenario in an operating theatre is hard to simulate in a laboratory since clinical work systems, in particular the work system operating room, are defined by a twofold human machine interaction (the surgery team and the patient), complex and often not predictable procedures, strong hierarchies in the distribution of tasks, ceiling effect in individual workload assessments (e.g. the personnel within the operating room always gives preference to the safety and comfort of the patient over their own safety and comfort.)
Our study is first in bringing an analysis based on human error tools such as human error taxonomies into the operating theatre and we are working with great focus on the further development of the international standard DIN EN ISO 9241, in order to improve complex integrated systems, such as an operating room. This course will need to be pursued further and across the board to eliminate human errors and increase efficiency as well as user satisfaction in complex systems.

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