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Use of Modeling to Identify Vulnerabilities to Human Error in Laparoscopy

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ABSTRACT This article describes an exercise to investigate the utility of modeling and human factors analysis in understanding surgical processes and their vulnerabilities to medical error. A formal method to identify error vulnerabilities was developed and applied to a test case of Veress needle insertion during closed laparoscopy. A team of 2 surgeons, a medical assistant, and 3 engineers used hierarchical task analysis and Integrated DEFinition language 0 (IDEF0) modeling to create rich models of the processes used in initial port creation. Using terminology from a standardized human performance database, detailed task descriptions were written for 4 tasks executed in the process of inserting the Veress needle. Key terms from the descriptions were used to extract from the database generic errors that could occur. Task descriptions with potential errors were translated back into surgical terminology. Referring to the process models and task descriptions, the team used a modified failure modes and effects analysis (FMEA) to consider each potential error for its probability of occurrence, its consequences if it should occur and be undetected, and its probability of detection. The resulting likely and consequential errors were prioritized for intervention. A literature-based validation study confirmed the significance of the top error vulnerabilities identified using the method. Ongoing work includes design and evaluation of procedures to correct the identified vulnerabilities and improvements to the modeling and vulnerability identification methods. Journal of Minimally Invasive Gynecology (2010) 17, 311–320 © 2010 AAGL. All rights reserved.

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Current methods of knowledge acquisition in medicine, including case reports, series, randomized controlled trials, and statistical analyses are comparative, and generally focus on single problems. The limitations of this narrow approach are now apparent, and an important question has emerged: How do we build a more generalized approach to knowledge acquisition that can be applied widely to complex clinical problems such as thoroughly understanding a surgical procedure? The answer could lie in the use of advanced modeling techniques [1,2].

A model is a formal representation of a system that explicitly depicts its elements and the relationships among them, and facilitates our understanding of those elements and relationships. Compared with our traditional way of clinical thinking, a model has the ability to encompass both broader scope and greater detail, thus overcoming human attentional limitations and facilitating consideration of a large number of interrelated facts simultaneously. Modeling, the process of developing a model, involves the identification and integration of fragments of knowledge into a descriptive overview. This creates a much broader and clearer fabric of knowledge through definition of the relationships among individual objects and facts. Modeling can become a new way of thinking for those in the medical domain to appreciate exactly what they do, how they do it, and why they should or should not do it.

Modeling offers hope for a particularly tough surgical problem, human error. Perhaps as many as 100 000 patients in the United States die each year in part as a result of medical error. Approximately 4% of hospital admissions are marred by an adverse event, with more than 40% occurring in the operating room [3–6]. The literature and the experiences of many operating room personnel clearly indicate that patients are at significant risk for additional morbidity and mortality during surgery because of human error, manifested in laparoscopy,

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for example, by trocar injuries [7–9]. Surgical personnel are generally not incompetent or reckless; rather, they are fallible human beings working in a system with complexity and dynamics that make it vulnerable to errors arising from their own innate fallibilities [10]. Thus, the problem of surgical error is an ideal candidate for modeling.

The objectives of the present study were to demonstrate the use of modeling and formal human factors analysis to identify laparoscopy operating room vulnerabilities to human error so that procedure, training, and equipment interventions to reduce or detect and mitigate errors can be designed, implemented, and evaluated. We focused on initial port creation in closed laparoscopy, in part to control scope but also because initial port creation is vulnerable to human error. The exact risk of initial port creation is unknown; however, Palmer [11] was early to call attention to it, and more recent literature strongly suggests that it is higher than we would like. For example, Saville and Woods [12] reported that during laparoscopy, the incidence of major retroperitoneal vascular injuries was about 0.1%. Crist and Gadacz [13], who surveyed 18 previous studies, reported rates ranging from 0.03% to 3% for a variety of needle or trocar injuries. In a mail survey of Canadian obstetrician-gynecologists by Yuzpe [14], about one-fourth of respondents reported they had caused injury with the Veress needle or trocar. Initial port creation is, thus, fertile ground for error vulnerability analysis. We set about not to rediscover known errors but to refine, demonstrate, and validate the method and to identify and better understand conditions and factors that create vulnerabilities to these errors.

Material and Methods

Our team of 2 surgeons (J. D. B. and D. T.) a medical assistant (M. R.) and 3 industrial engineers (K. H. F., T. L. D., and R. J. N.) used a highly structured and systematic method involving formal modeling and human factors analysis, presented here in overview form and detailed below: (1) process modeling to capture and formally document practitioner process knowledge; (2) task analysis to further detail the model and formally describe surgical tasks using a standardized vocabulary; (3) error identification to identify potential subtask errors, using the model, standardized task descriptions, and a human performance database; and (4) vulnerability analysis, using the model, task descriptions, and human performance database to identify vulnerabilities to errors that are likely, consequential, and difficult to detect soon enough to mitigate.

Process Modeling

The engineers first asked the surgeons and assistant to describe what it means to perform closed laparoscopy such as a laparoscopic hysterectomy or a laparoscopic cholecystectomy. They responded with an overview of the surgery: (1) to plan the surgery, (2) to prepare the patient for surgery, (3) to prepare the operating room system for surgery, (4) to perform the surgical procedure, (5) to initiate the patient's recovery, and (6) to restore the operating room surgical system for the next surgery.

The engineers then asked them what more specific activities are involved in performing the procedure, the fourth process in the previous description, and they responded with 5 additional detailed subprocesses. We continued this progressive elaboration, focusing the analysis on initial port creation. Our modeling yielded the process hierarchy shown in Fig. 1. Each process is represented by a box containing a descriptive verb phrase. Shaded boxes represent processes that were not analyzed further for this study.

This modeling technique, often called hierarchical task analysis [15,16], is simple, systematic, and thorough, and yields a representation that facilitates understanding and documentation of complex processes at multiple levels of detail. However, hierarchical task analysis is not sufficiently explicit and robust. It provides a useful overall roadmap but does not yield the depth of knowledge necessary to understand the process, and it obscures important relationships among subprocesses, personnel, and equipment, both within and across levels of abstraction. Moreover, it is a reductionist technique and, like all reductionism, risks emphasizing minor isolated details at the expense of missing broad and important features of the problem.

To strengthen our method, we used Integrated DEFinition language 0 (IDEF0) to model processes. IDEF0 is a standardized formal language for the structured graphic representation of systems [17]. The purpose of IDEF0 is to model a system as an integrated set of transformation processes, process relationships, and other entities (objects, information, attributes, and factors). In an IDEF0 diagram, a process is represented by a box, and other entities by arrows. Fig. 2, the top-level diagram in our IDEF0 model, elaborates the top box in the process hierarchy shown in Fig. 1. In Fig. 2, the box in the center represents closed laparoscopy as a transformation process. The process *transforms inputs* ([left arrows] a ready patient, a ready surgical system, and open documents) *into outputs* ([right arrows] a recovering patient, a restored surgical system, updated documents, specimens, and waste) *subject to controls* ([top arrows] the surgical goal, e.g, to remove a diseased ovary, fallopian tube, or appendix; patient factors, e.g., medical history and anatomy; surgical system factors, e.g., available equipment and supplies; and the philosophies, policies, procedures, and practices of the hospital and its operating room) *by means of mechanisms* ([bottom arrows] the surgical team, i.e., physicians, nurses, and technicians).

To elaborate this most general process, the team broke it down into simpler subprocesses and described and represented their inputs, outputs, controls, and mechanisms. Fig. 3 shows the IDEF0 model of the 6 subprocesses and their relationships showing, for example, how the ready patient is transformed to a recovering patient through a set of subprocesses, how the surgery planning subprocess produces subgoals for each of the other subprocesses, and that different surgical subteams perform different subprocesses.