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Ontology for assessment studies of human–computer-interaction in surgery

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ABSTRACT

Objective: New technologies improve modern medicine, but may result in unwanted consequences. Some occur due to inadequate human–computer-interactions (HCI). To assess these consequences, an investigation model was developed to facilitate the planning, implementation and documentation of studies for HCI in surgery.
Methods and material: The investigation model was formalized in Unified Modeling Language and implemented as an ontology. Four different top-level ontologies were compared: Object-Centered High-level Reference, Basic Formal Ontology, General Formal Ontology (GFO) and Descriptive Ontology for Linguistic and Cognitive Engineering, according to the three major requirements of the investigation model: the domain-specific view, the experimental scenario and the representation of fundamental relations. Furthermore, this article emphasizes the distinction of "information model" and "model of meaning" and shows the advantages of implementing the model in an ontology rather than in a database.
Results: The results of the comparison show that GFO fits the defined requirements adequately: the domain-specific view and the fundamental relations can be implemented directly, only the representation of the experimental scenario requires minor extensions. The other candidates require wide-ranging extensions, concerning at least one of the major implementation requirements. Therefore, the GFO was selected to realize an appropriate implementation of the developed investigation model. The ensuing development considered the concrete implementation of further model aspects and entities: sub-domains, space and time, processes, properties, relations and functions.
Conclusions: The investigation model and its ontological implementation provide a modular guideline for study planning, implementation and documentation within the area of HCI research in surgery. This guideline helps to navigate through the whole study process in the form of a kind of standard or good clinical practice, based on the involved foundational frameworks. Furthermore, it allows to acquire the structured description of the applied assessment methods within a certain surgical domain and to consider this information for own study design or to perform a comparison of different studies. The investigation model and the corresponding ontology can be used further to create new knowledge bases of HCI assessment in surgery.

1. Introduction

Automation plays a key role in high performance activities such as surgery up to the point when the human and the machine form an inextricable unit [1,2]. Automation is defined as a device or system that accomplishes (partially or in full) a function that was

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previously, or conceivably could be, carried out (partially or in full) by a human operator [3].

The use of automation in surgery aims to increase accuracy, efficiency, safety and flexibility of surgical tasks [4]. To reach this it is necessary to use human-centered automation concepts. At the same time the high level of complexity of automated processes creates new risks and dangers, especially within the high-risk field of surgery [5], and thus can lead to errors in the human–computer-interaction (HCI, alternatively called the man–computer-interaction or man–machine-interaction). HCI is the study which examines the interaction between humans and computers and to what extent computers are or are not developed for successful interaction with human beings [6].

The resulting demand is the mandatory investigation of HCI and the automation consequences in surgery, in order to avoid possible errors and to increase the quality of health care [7,8]. Geißler et al. [4] propose a review of the human-centered automation design in surgery and subdivide the possible consequences of automation to the user into eight categories, the so-called human performance consequences. The considerations of Geißler et al. emphasize that the area of HCI research in surgery is complex and requires wide-ranging assessment. Thus the adequate assessment requires approaches focusing especially on the domain of HCI in surgery. There is already a wide range of established approaches considering the HCI in general [3,9]. These approaches need comprehensive adoption to be applicable for the medical domain and further extension for the sub-domain of HCI in surgery. Other existing approaches consider either delimited automation fields [10] or exemplary several concrete automation consequences of automation only [11–13].

An adequate assessment approach has furthermore to comply with legal specifications concerning the investigation process in medicine, i.e. the Medical Device Act [14] and compulsory standards such as DIN EN ISO 14155 [15], DIN EN ISO 14971 [16] and IEC 62366 [17], etc. These legal specifications form the general normative framework for medical investigation.

In a previous work an investigation model for HCI in surgery was developed [18] to facilitate the planning and implementation processes of HCI studies. Furthermore it aimed at providing a framework for study documentation. This investigation model supports systematic assessment approaches for the HCI research, but its application requires an adequate formalization of the inherent concepts. Therefore this article examines three different formalization approaches: Unified Modeling Language (UML), database and ontology. The emphasis was put on assessment studies of HCI within the surgical domain, including clinical and preclinical (laboratory) research. This work shows further the advantages, as well as the limitations of the three formalization approaches and describes the application of an ontology to represent the investigation model. Furthermore, the formalizations provided by four top-level ontologies were compared. The main purpose of the presented work is to choose an adequate top-level ontology to formalize the developed investigation model and to apply this ontology to create an own ontology for HCI assessment studies in surgery.

2. Methods

2.1. Investigation model development

The representation of HCI assessment studies within the developed investigation model [19], proposed in this article, is based on two frameworks: the DIN EN ISO 14155 [15] standard and the framework of Jannin and Korb [10].

The DIN EN ISO 14155 standard for clinical investigation of medical devices for humans is a well-established legal framework within the clinical and scientific community. For the creation of the investigation model, in a first step the contents of the ISO standard were analyzed, and the comprised general requirements concerning the study planning, implementation and documentation were extracted. These requirements served as the basis for the investigation model. Within this development step the adaptation of the extracted contents was performed, with regard to the focus of the investigation model: the ISO standard is intended for general investigation of medical devices and thus focuses on the interaction between the medical devices and patients [15]. But the investigation model is intended for the investigation of HCI in surgery. In this manner the focus shifts to the interaction between the medical devices and surgeons (or other involved medical users). Therefor the extracted requirements were modified and extended accordingly. The choice of the ISO standard also provides an extensive benefit regarding the legal specification. Its requirements were reflected directly on the investigation model contents, thus the adequate application of the model should lead to compliance with legal requirements of the ISO standard and thus with the Medical Device Act.

The framework of Jannin and Korb [10] focuses on the image-guided interventions assessment based on a general hierarchy of levels with regard to assessed properties and study conditions. Jannin and Korb outline the complexity and diversity in image guided assessment. The framework was chosen because it provides a systematic order considering general health technology assessment methods, which are generally applicable for the assessment of medical devices. Within the development of the investigation model the methodology of Jannin and Korb was used to perform a further specification of the ISO 14155 standard requirements and their extension. Furthermore, the inherent systematic order was used to derive the modular structure of the investigation model.

The developed investigation model is subdivided into six major modules representing the several aspects and processes of study planning, implementation and documentation methodology. The Fig. 1 shows and Table 1 describes the six major modules within the model. Each of these major modules is also subdivided into sub-modules (hierarchical structure). The sub-modules consist of numerous specification and methodical items. Whereas the six major modules are more general and can be applied for studies outside the HCI assessment in surgery as well, inspired by the DIN EN ISO 14155 standard contents, the concrete items of the corresponding sub-modules explicitly focus on HCI research in surgery. I.e. the sub-module Product description contains the specification item Clinical procedures, which represents the surgical procedures concerning the HCI to assess. The provided numbering of the major modules indicates the order to follow because of the inherent dependence of its sub-modules on the sub-modules of the previous major modules. E.g. the specification of the Investigation design within the major module Study design specification is only possible after the definition of the study Objectives within the major module Preliminary considerations, or the Product description within the major module Product considerations deals with medical devices and the corresponding reference products to assess and their selection is dependent on the previous specification of the study Objectives and the Investigation design.

Fig. 2 shows exemplarily the contents of the sub-module Investigation design. The Investigation design considers the general specification for study implementation, consisting of Investigation design specification, the assessed Products and comparators, the study Subjects and the Experimental scenario. The item Investigation design specification focuses on the general specification of a HCI study and takes into account the investigation type specification, as a function of study objectives and hypotheses, and the corresponding endpoints of the study. Furthermore, the investigation design specifies the measures and procedures to assess, record