

Scenarios and the Design Process in Medical Applications

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Abstract

Scenario has been largely used in design progression of different engineering disciplines, mostly in software engineering and Human-Machine Interaction. Scenario helps the software designers to border on the user and usage requirements. Although the design process in many fields of product engineering deals with tasks and functions, and step away from the final users, in medical and healthcare product design the understanding and specification of user requirements become an important issue. Thus, scenario can play an essential role as a tool for engineers to help them to identify and determine the usage of the medical devices. This paper investigates the use of scenarios in design development of healthcare products, and proposes a new concept of using scenarios in the evaluation phase of user dependent healthcare products. Our proposed model for scenario driven approach represents the confrontation between engineering (device design) and medical (usage), through the scenario specification. The new scenario specifies: cure procedure, device functions, usage situation and observation.

Keywords:

Scenario-Based Design (SBD), Medical Application, User integration

1. INTRODUCTION

Modern technology has transformed the practices in medical domains. Physicians and medical doctors are now able to see where they could not before, conducting the intervention and the operation with minimal trauma, intervene at the genetic level, replace whole natural organs with functional artificial ones, make rapid diagnoses, and peer into the workings of the brain. Much of the credit for these advances goes to the engineers, designers and industries who together identified what needed to be done, the science required to support it, and how it could be made practical. Engineering design for medical products took a large step to provide multifunctional solutions for new requirements.

Historically, medical engineers tried to bring new technical solutions to the medical applications. They imply various sciences such as biophysics, applied mathematics, physiological modelling, biomechanics and control, imaging, and electrical engineering to accomplish their advances. These developments and the particularity of the design process in medical domain have attracted the design researchers. The design process of medical devices has yet identified as participatory design [1], design for patient safety [2] validation based design [3] and so on.

Design and development of new healthcare devices needs the participation of the health agent, from the innovation phase at the beginning to the medical validation at the end [4]. From the medical point of view, surgeons consider themselves as the innovator [5]. Undoubtedly, health agent has an important role in the design, but, the development process is usually advanced by engineers. Regarding the discussion, a design approach should be developed in order to compromise user's ideas, medical requirements and technical possibilities.

The problematic of usage and user integration was not limited to the healthcare research. In Human-Machine Interaction (HMI) studies, the use of scenario has been surveyed by the researchers. Scenario-Based Design (SBD) and Usability Engineering have been proposed and used to help designers improving their understanding of the user requirements and the usage situation [6, 7, 8].

However, the scenario could help the medical and healthcare designers to integrate the professional user needs into the design process. This research asks this question: What would be the role and importance of scenarios in healthcare design process, and how designers in this field can use the scenario as a design tool.

In this paper, firstly the concept of the scenario and the evolution of use of scenario in design are reviewed. In section three, a survey of the use of scenario in the medical and surgical engineering is showed and discussed. Section four defines the characteristics of our proposed model for scenario driven approach which represent the confrontation between engineering (device design) and medical (usage). These characteristics are divided to four main categories: usage procedure (cure), device prototype functions, usage situation and observation. Finally we explain the scenario-based approach in design and the advantages of using this approach in some design cases.

2. SCENARIO AND THE DESIGN PROCESS

A substantial amount of current research and development activities is focused on creating a more user-oriented perspective on the new product development. One key element in this perspective is the user-interaction scenario, a narrative description of what users do and experience as they try to make use of new products. Thus, the first question would be what is the scenario and how does it look like?

2.1 Scenario; definition and usage

Scenarios are simply the stories about people and their activities [7], and these stories are more and more attractive for the researchers who try to find the logic of the design by studying the essential aspects of the problem and the birth of the solution. First researches about the scenario was about to characterize the story by a setting of elements [9]. In the same context, researchers made effort to discover new aspects of the scenario: *Agents and actors, goals and objectives, and actions and events* were being included as the main notions and in different domains, researchers started to use the scenario as a tool for design or introduce it consciously to the design process.

Historically, strategic gaming and military were the first use of scenario [10, 11]. In management and economy, scenario has been used for analyzing the consequence of actions and policies. By the first proposition of the use of scenario in Human-Computer Interactions (HCI) [12], researchers have employed scenarios as representation of system requirements to improve the communication between developers and users.

The scenario identifies the person as having certain motivations toward the system, describes the action taken and some reasons why these actions were taken, and characterizes the results in terms of the user's motivations and expectations [6]. The idea to recognize some consequences in the description of activities involving actors and details of the situation of manipulation makes the researchers use the "scenario-based" term in their methodologies. A superficial search leads to find lots of scenario-based methodologies in variant disciplines, such as decision making [13, 14], technology (in software) development [15], requirement analysis [16], accounting [17], and finally the design as the Scenario-based Design [6, 18, 19]. As some observation recognizes the scenarios like "one of the least understood recent success stories in the information technology (IT) and management areas" [20b], there are some main domains in which use of scenario stands out. Jarke et al. reviewed scenario from

three major disciplines: strategic management, human-computer interaction and software and system engineering, and propose an interdisciplinary framework for scenario management. They also concluded that despite of some diversity in terminology and use, two particular qualities emerge from their study. First, a scenario is a context-dependent and purposeful description of the word with the focus on task interaction. Second, scenarios are a mean of communication among stakeholders. Their findings are summarized by Hertzum considering the underlying role of scenario: to ground decisions in a sound and communicable understanding of the use situation [21].

The scenario is supposed to capture and explore the finer structure of the operative psychology in the situation of use [22]. Kurakawa proposes situation as the one of the three essential components of a scenario, and he defines the situation as "the setting surrounding the actor/agent and the state before and after the actor/agent takes a particular action or there occurs a particular event." [23].

Mostly, description of the situation of use is given by the scenario. This description desired to be narrative, detailed [22], and to be written very carefully [24], but unfortunately there is no accurate study about the situation of use, except for the issue of task analysis. The specification of the environment or the different elements of use situation are very important, particularly when we need to realize that an artifact could not be used free of environmental elements.

Scenario-based design provides a framework for managing the flow of design activity and information in the task-artifact cycle [7]. Designers can see their work as artefacts-in use and, through this focus, to realize usage and other use-related constraints in the design process. Moreover, researchers can use scenarios to analyze the varied possibilities afforded by their designs through many alternative views of usage situations. This concept is represented in Figure 1.

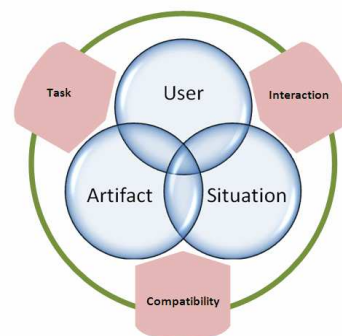


Figure 1 - Challenges and approaches in scenario-based design form [7]

Once scenario is defined and characterised from the original context, we should point out the next question: "How does the scenario help designers to make a good design in healthcare industry?" Considering the fact that the answer depends on the nature of product and could not be strict, a framework of procedures which explains what to do and how to do should be provided. A Scenario helps to clarify what the usage supposed to be and how the design can satisfy the predicted use. For instance, in the design process of surgical instruments, scenario by the classical perception is limited to the operation

procedure. On the contrary, scenario can serve as a more powerful tool and can contain more details.

In this paper, we used the scenario-based approach borrowed from HMI sciences as a concept for user integration in design progression. However, concepts and approaches in HMI could not be directly used for the healthcare design domain, but need modifications. Next section explains the specification of scenario in the healthcare design domain.

3. SCENARIOS IN HEALTHCARE DESIGN

There are a large number of studies on usability of medical devices. A survey on critical-care nurses shows that health agents are very much concerned about the usability and feels that manufacturers should place additional emphasis there. More over, a significant number of the surveyed would like a role in the development of future device [25]. How designers possibly solve this problem?

Scenarios have been used in the design of healthcare systems mostly to deal with the use activities and the work situation of clinicians and surgeons. By scenarios, researchers build a task-based workflow of what actors should do. Scenarios are even used to explore the user's knowledge [26]. Literature shows that scenarios used as design tools to demonstrate the situation in which the design artifact would be used. Table 1 shows some examples of using scenarios in the context of the healthcare. There are two vast use of scenario which are excluded from the table: first, scenarios only as surgical operation procedures (techniques of surgery) which is the subject of surgical publications (ex. J. of Surgery, American J. of Surgery). Second, scenario as a set of mechanical tasks for a new instrument, without human interference (ex. the automatic tasks of an artificial organ in body) which is very frequent in biomedical engineering devices design.

Regarding the literatures, scenarios are used to characterise the interaction between following subjects: the user, the design artifact and the environmental situation [32]. Figure 2 suggests a schematic view of these interactions. The user-artifact interaction is normally a treatment procedure through a device, like the incision in surgery. The artifact-situation relation concerns about the compatibility of the artifact with the other devices or subsystems in the context. The user-situation relation is the interaction of the user and his work atmosphere. This last becomes very important when the design subject is a

human system (for example teamwork in urgency units). However, in a real application all the three subjects are in relation. Scenarios in this context can be used to describe the relations in details and to help the designer to understand and take into account all important factors of the required solution.

Scenarios address goals and motivations of medical users, describe the design alternatives and demonstrate the medical environment in which the requirement should be satisfied. The use of scenarios acknowledges that the end users should play an active role in the design process themselves. But, is it possible to leave all the use aspect of the design progression to the healthcare users? Or on the contrary, is it reliable to let engineers imagine the clinical exigencies? Well, that is what we are facing in every design progression of a user centred healthcare artifact. The point is that the actual use of scenarios in design seems not to be the best way of user and usage situation integration in the design process. In the next section, a new insight of using scenarios in the design process of medical product is explained.

4. SCENARIO DRIVEN APPROACH

Designers can use many different approaches to become acquainted with the user. Perhaps the simplest approach is just to watch user perform a medical task and then talk to him. This step helps the designer to understand the basics requirement and may bring him some ideas about the solution. The next step is to come back with a solution, which is better to be a physical prototype, to hear the user's opinion about the prototype. User can comment anyhow on the design propositions, but to have a reliable evaluation from the expert user, the designer needs to

Figure 2 – User, artifact and situation in scenarios prepare a realistic usage environment. For instance, watching a surgery, a designer finds some basic idea to design or modify an instrument to help the surgeon. The after surgery discussion make the things more clear. In the following step, the designer prepares a prototype to show it to the surgeon to have his comments and critics.

Medical devices are often used in specialized environments (for example the operating room, the intensive care unit, etc) and it is not usually possible for researchers to simulate the necessary condition and obtain useful results from testing in a controlled environment. Moreover, surgeons need to manipulate the prototype in a near real situation. Some critical

Study Context	User	Usage Situation	Artifact	Source
EMS patient handling	Nurses	Hospital, emergency	handling devices	[27]
Wireless Connection in-hospital and e-emergency environments	Physicians nurses	Hospital, emergency	Connection system	[28]
practice skills and evaluate performance of a healthcare team	Training surgeon	Operating room	Computer Simulation	[29]
Identifying and studying a general problem about continuity in interaction	Surgery team	Operating room	Distributed medical workplace	[30]
Identify the overuse and underuse of medical procedures	Physicians nurses	Hospital	Evaluation criteria	[31]

Table 1: Use of scenarios in the design of medical devices and systems

researches claimed that the oral validation of surgeons on prototype is not always reliable and it should be tested by them in a real medical situation. Thus designers have to prepare a phantom of the concerned organ (for the case of surgery) or even use a cadaver, and they prefer to make the evaluation in an operating room, with all restrict and limits. Organising such a situation needs a prescript which we call a scenario or a part of the scenario.

Thus, by creating scenarios, the designer can prepare the evaluation step in a proper way. Scenario describes the required action for the artifact in use. It describes the usage situation which is important for the user's activities. In a former research of the authors, two other aspects of the design in medical application were discussed to be integrated to the scenario: the prototype functions and the observation [33].

In result, we define scenario as a document explaining which main functions of the future product are realized in the present prototype, for which usage activities the prototype is going to be tested, and under which situation. The forth proposed element, the observation, is become more and more important because of the complexity of usage and the limits of direct observation (for example in the case of minimally invasive surgeries). By the observation, we group all the ways that the designer use to capture the information during the user's evaluation. The simplest is to take notes and put a camera, but for more efficient observation more tools are needed, such as sensors, professional cameras, etc. One important issue in the observation is to record the expert user's comments and critiques on the prototype. Scenario also describes how the observation will be take place. Figure 3 shows a schematic form of a scenario integrated into our co-evolutive model.

The movement that we sketched above, from preparation of document (i), through prototype evaluation in the emulation, to data capturing and the analysis, often

involves a shift in the conceptual focus of the scenario. Scenario plays the role of a design guide document. Early preparation requires the medical experts' opinion to prepare the optimised usage situation, according to the actual prototype and usage. "Emulation" is the concept we used for the prototype evaluation by the expert user in the real situation. Scenario previses the tasks and activities and, based on this, the designer can setup the observation system. Finally, the analysis of scenario provides sets of causal relations among functions of the prototype, features of the use situation and behaviours of the user. In other words, scenario as a report shows what the prototype was suppose to have and what the user supposed to do, how it was going during the cooperation and what is needed for the next step: modifications on the prototype, on the usage procedure, on the usage situation and on the observation setup.

Table 2 shows an example of scenario in the context of design of a new surgical instrument. In this example, a new instrument is needed to perform a new operation, in order to transform an open surgery to MIS. Considering the (i) position, the prototype (i) is made, surgical procedure (i) is described, and, in the same way, the emulation situation and observation setup are described in the scenario.

In the design of a medical device, the physician-designer cooperation is the most important issue. Scenario is a tool to ameliorate the communication and to facilitate the decision making. Moreover, the design process in this context can be considered as a coevolutionary progression of the instrument and the usage, because from medical point of view the usage such as operation techniques, is a part of the design artifact and starts from an idea and step by step approaches a validated medical treatment. More details on the coevolutionary design model can be found in [34]. Nonetheless, by using scenarios, designers can trace the evolution of the prototype and the usage. Finally, some advantages of the scenario driven approach for user centred medical application are:

- Data accumulation of the progression of prototype-usage
- User participation and integration in the design process
- Analysis of the decision making based on tasks and criteria
- Organising and facilitate the communication

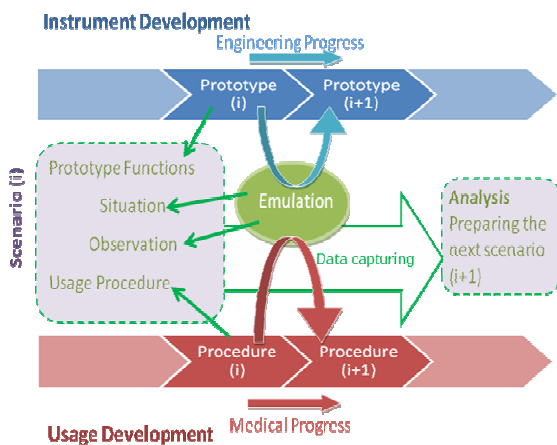


Figure 3 - Scenario driven approach, preparation, Data capturing and analysis




Surgical procedure			Instrument prototype	
Procedure for new operation	Actor	Objects (surgical instruments)	Functions	
Identifying fractured vertebra Positioning screws (3 pairs of screws on 3 vertebrae) Incision (1-2 cm) Insertion tubular retractor Position screw Inserting and fixing rod (2 times) Incision (0.5 cm) Insertion rod by rod holder Fix the rod in screws head Release the rod holder	Surgeon Surgeon Screw preparation by technician Surgeon Charging rod holder by technician		Receive the rod (swerving mechanism) Hold the rod during insertion Release the rod Evaluation criteria Ergonomic of handle Weight of prototype Size of rod housing part Feasibility of manipulation in presence of tubular retractor	
Usage situation			Observation	
Operation room at hospital Amplifier radio Mannequin: spine model with a fracture on L1, positioned in a box, filled by synthetic plastic ball, covered by artificial tissue			A general camera on operation site A frontal camera on surgeons head, capturing where he looks Sound recorder Photographs Notes by engineers	

Table 2: An example of scenario in the context of innovative surgical instrument design

5. CONCLUSION

The notion of scenario initiated from HMI sciences was reviewed and the specification of scenario-based approach in healthcare product design was discussed in detail. An aim of our research was to point out the importance of such an approach for the designer in healthcare domain. Designers need to understand and specify the requirements of their (professional) user. Our proposed approach used the coevolution concept and specified the scenario as a tool for design process, significantly for the evaluation phase which differs the design methodology in healthcare from the other design disciplines.

On one hand, as it is argued by other researchers, users of a device are mostly viewed by the designers as one of the subsystems of the global device [35]. On the other hand, the health agents would like to participate in the design process, and in new complex medical devices, the expert user integration in development is inevitable. Scenario-driven approach proposes a design tool which provides the organisation and design practices for designers, in a way that they can integrate their medical expert users in the development.

We have focused on supporting design situation in which the design process is coevolutionary and the artifact is a pair of instrument-usage, situation in which the designer is trying to have the medical expert user integrated in the design and the evaluation. This approach helps designers to increase the reliability of the expert evaluation phase.

Scenario supports a fluid exchange of reasoning between the prototype functions and the usage implementation, such that user know-how can inspire the new product and the new product can extend expert user manipulation.

Our research focused on a new medical product in which the user is professional or expert, and the design artifact is the couple of instrument and usage (operation). Nonetheless, the discussion is valuable for other medical devices and systems in which the user plays an important role.

This approach is being used at the University of Grenoble, in the Design for Technological & Surgical Innovation (DESTIN) project for design development of surgical instruments in collaboration with Grenoble Hospital and for design of musical instruments adaptation for handicapped children in collaboration with AE2M project.

However, the scenario-driven approach needs more details in "how to do" aspects and should be supported by a workflow management tool to be able to better serve the designers and project managers on which we are working on this at the present.

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