Scenarios and the design process in medical application

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Abstract

How to make healthcare products and systems fit the work they are to support is a question that has received growing attention over the last decade. In most of the studies trying to answer this question, engineers put an effort to provide the best possible technical solution, but they dispose the important position of users. Design studies in different domains indicated a focus on the users and proposed some methodologies and tools. Scenario-based design as a design method provided many advantages in design of products and artifacts dealing with users. This paper investigates the use of scenarios in design development of healthcare products, and proposes a new concept of using scenarios in the design of medical application.

Keywords:

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

1. INTRODUCTION

Modern technology has transformed the practices in medical domains. Physicians and surgeons 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. Medical engineering is now a known discipline performing in the process of developing medical advances.

On the engineering design side, many engineers try to bring the new 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 medial 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. Looking forward to this approach, this article discusses the Scenario- Based Design (SBD) as a potential approach.

The concept of "usability" that is explained later is employed by researchers in this domain, to define required use criteria and to make sure that products satisfy medical users' need. This paper is more focused on the new surgical product in which the design artifact is the instrument and the operation, and so the operation protocol is not designed by the designer but the surgeon. However, the discussion is valuable for other medical devices and system in which the expert user plays an important role.

In this paper, firstly the concept of the scenario and the evolution of use of scenario in design are reviewed. Then, 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 which represent the confrontation between engineering (device design) and medical (usage). These characteristics are divided to four main categories: cure procedure, device functions, usage situation and observation. Finally we explain the scenario-based approach in design and the advantages of using this approach in medical application.

2. SCENARIO AND THE DESIGN PROCESS

A substantial amount of current research and development activities is focused on creating a

more use-oriented perspective on the new product development. One key element in this perspective in the user-interaction scenario, a narrative description of what users do and experience as they try to make use of new products. Thus, 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 [6], 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 [7]. 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 uses of scenario [8, 9]. 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) [10], 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 [11]. 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 [12, 13], technology (in software) development [14], requirement analysis [15], accounting [16], and finally the design as the Scenario-based Design [11, 17, 18]. As some observation recognizes the scenarios like "one of the least understood recent success stories in the information technology (IT) and management areas" [19b], 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 [20].

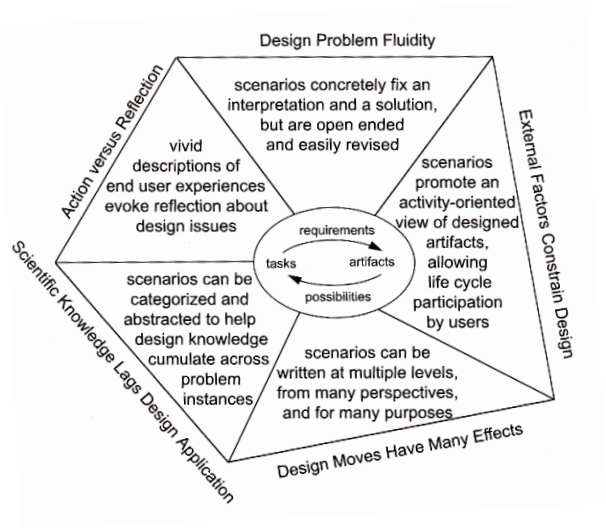


Figure 1: Challenges and approaches in scenario-based design form [6]

The scenario is supposed to capture and explore the finer structure of the operative psychology in the situation of use [21]. 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." [22].

Mostly, description of the situation of use is given by the scenario. This description desired to be narrative, detailed [21], and to be written very carefully [23], 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 [6]. 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.

We should point out a question here: "How does the scenario help designers to make a good design?" The answer is not strict and depended on the nature of product (a software versus a mechanical device). A Scenario helps to clarify what the usage supposed to be and how the design can satisfy the predicted use. In the design of surgical instruments, a scenario can be limited to the operation procedure, and it can serve as a research tool in surgeon's act analysis. In this study we adapted the concept of scenario borrowed from HMI sciences to organize and follow the proposed methodology.

We used the scenario-based approach as a concept for driving the emulation moments (see section 4) which have main role and importance in this methodology.

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 feel 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 [24]. 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 [25]. 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 as only surgical operation procedures (techniques of surgery) which is the subject of surgical publications; and second, scenario as mechanical tasks of a new instrument, without human interference which is very frequent in biomedical engineering devices design.

Table 1: Use of scenarios in the design of medical devices and systems (end of the paper)

Regarding the literatures, scenarios are used to characterise the interaction between following subjects: the user, the design artifact and the environment. 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-environment relation concerns about the compatibility of the artifact with the other devices or subsystems in the context. The user-environment 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.

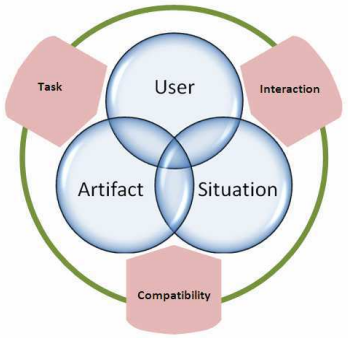


Figure 2 – User, artifact and situation in scenarios

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. Although the user can comment in any situation, but to have a reliable evaluation from the expert user, the designer needs to 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, many studies and experiments showed that surgeons need to manipulate the prototype in a near real situation. Some critical researches clamed that the oral validation of surgeons on prototype is not always reliable and it should be tested by them in a real medical situation. For this reason, designers desired to prepares 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 [26]. In result, scenario is 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 what 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 the 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 was of observation 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.

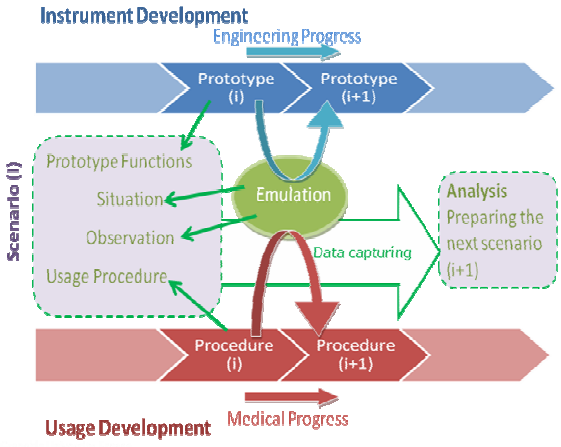


Figure 3: Scenario driven approach, preparation, Data capturing and analysis

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. And 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: Modification on the prototype, on the usage procedure, on the usage situation and on the observation setup.

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 [27]. Nonetheless, by using scenarios, designers can trace the evolution of the prototype and the usage. Finally, some advantages of the driving the design process in used depended medical application with this perspective of scenario is listed below.

- 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

5. CONCLUSION

An aim of our research is to develop methods and tools to ameliorate the design process, and, importantly for the medical devices and systems, in order to expert medical users can be better served with the technological solution to treat patients.

On one hand, as it is argued here and by the other researches, users of a device are mostly viewed by the designers as one of the subsystems of the global device [28]. 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 is a design model which provides the organisation and design practices for designers, in a way that they can integrate their medical expert users in the development.

Our work on the scenario driven approach explores the proposition of use of scenarios from HMI and software development can be recruited as a design tool in medical device-usage design, development and validation. We have focused on supporting design situation in which the design process is coevolutive 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. We want to help medical instrument designers to increase the reliability of the expert evaluation phase. We want to support 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.

REFERENCES

[1] G. Thomann and J. Caelen, "Proposal of a new Design Methodology including PD and SBD in Minimally Invasive Surgery," in *The International Federation for the Promotion of Mechanism and Machine Science (IFToMM)*, Besançon, France, 2007.

[2] P. J. Clarkson, P. Buckle, R. Coleman, D. Stubbs, J. Ward, J. Jarrett, R. Lane, and J. Bound, "Design for patient safety: A review of the effectiveness of design in the UK health service." vol. 15: Taylor & Francis, 2004, pp. 123 - 140.

[3] K. Alexander and P. J. Clarkson, "A validation model for the medical devices industry." vol. 13: Taylor & Francis, 2002, pp. 197 - 204.

[4] C. Lettl, "User involvement competence for radical innovation." vol. 24: Elsevier Science Publishers B. V., 2007, pp. 53-75.

[5] D. Riskin, M. Longaker, M. Gertner, and T. Krummel, "Innovation in Surgery: A Historical Perspective," *Annals of Surgery,* vol. 244, pp. 686-693, 2006.

[6] J. M. Carroll, *Making Use : Scenario-Based Design of Human--Computer interactions* Cambridge, MA: MIT Press, 2000.

[7] V. Y. Propp, *Morphology of the folktale*, 1958.

[8] H. Becker, "The role of gaming and simulation in scenario project. In: Stahl," in *Operational gaming: an international*
approach Laxenburg, Australia: International Institute for Applied Systems Analysis, 1983.

[9] S. Brown, "Scenarios in system analysis. In: Quade ES, Boucher WE (eds). Systems analysis and policy planning: applications in defense," *Elsevier,* pp. 298-390, 1968.

[10] M. Y. Richard and B. Phil, "The use of scenarios in human-computer interaction research: turbocharging the tortoise of cumulative science." vol. 17: ACM, 1987, pp. 291-296.

[11] J. M. Carroll, *Scenario-based design: envisioning work and technology in system development*. New York: Wiley, 1995.

[12] Y. Bontemps and P.-Y. Schobbens, "The computational complexity of scenario-based agent verification and design," *Journal of Applied Logic,* vol. 5, pp. 252-276, 2007.

[13] R. Blanning, "A decision support framework for scenario management," in *international symposium on decision support systems*, Hong Kong, 1995, pp. 657 - 660.

[14] K. Weidenhaupt, K. Pohl, M. Jarke, and P. Haumer, "Scenario usage in software development: current practice," *IEEE Software,* pp. 34 - 45, 1998.

[15] K. Jintae, K. Minseong, and P. Sooyong, "Goal and scenario based domain requirements analysis environment." vol. 79: Elsevier Science Inc., 2006, pp. 926-938.

[16] P. Pacharn and L. Zhang, "Accounting, innovation, and incentives," *Journal of Engineering and Technology Management,* vol. 23, pp. 114-129, 2006.

[17] H. Morten, "Making use of scenarios: a field study of conceptual design." vol. 58: Academic Press, Inc., 2003, pp. 215-239.

[18] T. Yin-Leng, G. Dion Hoe-Lian, L. Ee-Peng, L. Zehua, Y. Ming, P. Natalie Lee-San, and W. Patricia Bao-Bao, "Applying scenario-based design and claims analysis to the design of a digital library of geography examination resources." vol. 41: Pergamon Press, Inc., 2005, pp. 23-40.

[19] M. Jarke, X. T. Bui, and J. M. Carroll, "Scenario Management: An Interdisciplinary Approach," *Requirements Engineering,* vol. 3, pp. 155 - 173, 1998-03-01 1998.

[20] M. Hertzum, "Making use of scenarios: a field study of conceptual design," *International Journal of Human-Computer Studies,* vol. 58, pp. 215-239, 2003.

[21] J. M. Carroll and M. B. Rosson, "Getting around the task-artifact cycle: how to make claims and design by scenario," in *Proceedings of a workshop on Human-computer interface design : success stories, emerging methods, and real-world context: success stories, emerging methods, and real-world context* Boulder, Colorado, United States: Morgan Kaufmann Publishers Inc., 1995.

[22] K. Kurakawa, "A scenario-driven conceptual design information model and its formation," *Research in Engineering Design,* vol. 15, pp. 122-137, 2004.

[23] D. Diaper, "Scenarios and task analysis," *Interacting with Computers,* vol. 14, pp. 379-395, 2002.

[24] M. E. Wiklund, *Medical Device and Equipment Design: Usability Engineering and Ergonomics*. USA: CRC Press, Taylor & Francis Group, 1995.

[25] M. Offredy, S. Kendalla, and C. Goodman, "The use of cognitive continuum theory and patient scenariosnext term to explore nurse prescribers' pharmacological knowledge and decision-making," *International Journal of Nursing Studies,* vol. 45, pp. 855 - 868, 2007.

[26] R. Rasoulifar, G. Thomann, and F. Villeneuve, "Integrating an expert user in design process: How to make out surgeon needs during a new surgical instrument design," in *International Symposium series on Tools and Methods of Competitive Engineering (TMCE)*, Izmir, Turkey, 2008.

[27] R. Rasoulifar, G. Thomann, F. Villeneuve, and J. Caelen, "Proposal of a New Design Methodology in the Surgical Domain," in *ICED*, Paris, 2007.

[28] F. Darses and M. Wolff, "How do designers represent to themselves the users' needs?," *Applied Ergonomics,* vol. 37, pp. 757-764, 2006.

[29] K. M. Conrad, P. A. Reichelt, S. A. Lavender, J. Gacki-Smith, and S. Hattle, "Designing ergonomic interventions for EMS workers: Concept generation of patient-handling

devices," *Applied Ergonomics,* vol. 39, pp. 792-802, 2008.
[30] E. Klaoudatou, E. Konstantinou, G. Kambourakis, and S. Gritzalis, "Clustering oriented architectures in medical sensor environments," in *3rd International Conference on Availability, Reliability and Security*, Barcelona, SPAIN, 2008, pp. 929-934.
[31] K. Yaeger and J. Arafeh, "Making the move: from traditional neonatal education to simulation-based training," *J Perinat Neonatal Nurs,* vol. 22, pp. 154-8, 2008.
[32] E. Kaldoudi and D. Karaiskakis, "A service based approach for medical image distribution in healthcare Intranets," *Computer Methods and Programs in Biomedicine,* vol. 81, pp. 117-127, 2006.
[33] P. G. Shekelle, J. P. Kahan, S. J. Bernstein, L. L. Leape, C. J. Kamberg, and R. E. Park, "The Reproducibility of a Method to Identify the Overuse and Underuse of Medical Procedures." vol. 338, 1998, pp. 1888-1895.

Study Context	User	Usage Situation	Artifact	Source
EMS patient handling	Nurses	Hospital, emergency	handling devices	[29]
Wireless Connection in-hospital and e-emergency environments	Physicians nurses	Hospital, emergency	Connection system	[30]
practice skills and evaluate performance of a healthcare team	Training surgeon	Operating room	Computer Simulation	[31]
Identifying and studying a general problem about continuity in interaction	Surgery team	Operating room	Distributed medical workplace	[32]
Identify the overuse and underuse of medical procedures	Physicians nurses	Hospital	Evaluation criteria	[33]

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