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Managing requirements for the development of a novel elbow rehabilitation device

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ABSTRACT

The development of new technologies for healthcare must take into consideration customer requirements from different stakeholders. The Voice of the Customer must be identified, analyzed and organized. This study aims to present a new approach of managing requirements from different product value chain stakeholders for a novel elbow rehabilitation device development. The Customer Value Chain Analysis tool was used to identify the product value chain stakeholders and the Quality Function Deployment tool to analyze and prioritize these requirements. The development is described in accordance with the engineering requirement process adapted to this case: 1) elicitation: the requirements come from the literature; benchmarking; questionnaires applied to all parties identified by Customer Value Chain Analysis application; 2) analyses: requirements were understood, and their overlaps, conflicts and prioritization were done by means of Quality Function Deployment (quality, product and part characteristics matrices); and 3) documentation: the identified construct of requirements were: ergonomics, functions, aesthetics, handling, materials, components/elements. The main parts that must be prioritized were: arm support, forearm support, support shaft, joystick, and support base. The association of these two tools is a novel and successful approach of identify different product value chain stakeholders and prioritize technical requirements for health product development.

1. Introduction

Successfully launching innovations is time sensitive and requires strategic and future-oriented thinking (Kolominsky-rabas et al., 2015). The different knowledge-generating paradigms drive innovation systems (Ivanova and Leydesdorff, 2015). The innovation process has often been represented as a linear process which funnels customer needs through business and process filters. This method may be appropriate for some consumer products, but in the medical device industry, there are some inherent limitations to the traditional innovation funnel approach.

In the medical device industry, there are a number of stakeholders who need to have their voices heard throughout the innovation process (Ana et al., 2013). Insights from many areas of science, engineering, medicine, the humanities, business and law are needed for the success of new medical devices. A clear, deep and unbiased understanding of the healthcare need for which a solution is to be developed is the critical starting point (Yazdi and Acharya, 2013). The standards of the country where the device is being developed are a mandatory point that should also be taken into consideration during the innovation process of a new medical device (Kolominsky-rabas et al., 2015).

Most of the models of product development process present a step of identification of ideas and opportunities (Pahl et al., 2007), followed by concept development and detailed design, up to the product or service launch and monitoring in the market. The product life cycle ends with the product (and its parts) discontinuity and recycling (Marx and Paula, 2011). The product development process should be formalized, clarifying the product, process and resource requirements.

The requirement is a feature that the system-product must have in order to satisfy a need or to achieve a stakeholder goal, being qualified by measurable conditions and bounded by restrictions. Therefore, the analysis of requirements from different stakeholders is an essential step in the innovation process of medical devices. However, inherent difficulties are present in the process of discovering and identifying stakeholders and their needs, and documenting these in a form that is amenable to analysis, communication, and subsequent implementation (Nuseibeh and Easterbrook, 2000).

Some tools have been developed to assist the process of allocating the requirements to product parts for incremental and radical projects, such as surveys, Customer Value Chain Analysis (CVCA) and Quality Function Deployment (QFD) tools. The CVCA is a strategic and tactical tool which was implemented from the organization business model that establishes a value map, in the product definition phase that

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contributes to a comprehensive identification of relevant stakeholders, their relationships with each other, and their role in the product life cycle. Thus, the CVCA tool adds value to the requirements identification in the project process, because it can be used for requirements elicitation and rating. It helps the innovation process for developing new medical devices, and shows resources and new ideas for novel products. The CVCA tool output can be the input for other tools, such as QFD (Donaldson et al., 2006), that aims at deploying these requirements throughout the product development process.

QFD tool was proposed to collect and analyze the Voice of the Customer (VoC) in order to develop products with higher quality to meet or surpass customer needs. The primary functions of QFD are product development, quality management, and customer needs analysis. Customer needs analysis is always the very first step of a QFD process. The QFD functions have been expanded to wider fields such as design, planning, decision-making, engineering, management, teamwork, timing, and costing (Chan and Wu, 2002).

Thus, this paper hypothesizes that the association of CVCA with QFD can assist in innovation and consequent creation of value for health products. The CVCA tool allows the process mapping, helping understanding the business unit, product value chain and identification of critical stakeholders (Donaldson et al., 2006); while the QFD method assists the requirements quantification to align concepts and resources, increasing the team ability to recognize the diverse product technical requirements, and their prioritization to define the product.

Based on this context, a research question was formulated: What could be a new and appropriated approach to manage requirements for the development of a novel elbow rehabilitation device in a more comprehensive way using CVCA tool associated with QFD, described in accordance with the requirements engineering process? This paper aims to present a new approach of requirements managing from different product value chain stakeholders for the development of a novel elbow rehabilitation device. The structure of this paper comprises the following sections: 1) the second section provides related literatures in new product development process, 2) the third section is for materials and methods with a model associating CVCA with the adapted QFD tool; 3) the fourth section presents (ii) study results of the development of a novel rehabilitation device, and the 4) (iii) the fifth section is a discussion with this model developed for the collection and prioritization of the requirements for the development of a novel elbow rehabilitation device; and 5) the last section provides a concluding remarks.

2. Literature reviews

Stakeholders are people who directly or indirectly use a system or the information it provides, as well as essential system characteristics such as performance, security, and dependability (Sommerville, 2005). Each stakeholder has diverse and unique needs, and the needs of one may highly affect the needs of another, and the relationships between them may be tenuous (Ana et al., 2013). No single individual or discipline alone has the ability to successfully create, develop, and implement an effective solution for a new product development process (Yazdi and Acharya, 2013). Moreover, the marketing assessment of potential consumers is an important step in new device development process for the health area (Marx et al., 2010).

Before developing any system, one must understand its target customer and technical requirements. At this moment, the objective of the system is being projected, and it is important to know how its use can support the goals of the individuals or businesses that would pay for that system. This involves understanding the application domain; the system operational constraints; the specific functionality required by the stakeholders; and essential system characteristics such as performance, security, and dependability (Sommerville, 2005).

Stakeholders (including paying customers, users, and developers) may be numerous and distributed. Their goals may vary and conflict, depending on their perspectives of the environment in which they work and the tasks they wish to accomplish. Their goals may not be explicit or may be difficult to articulate, and, inevitably, satisfaction of these goals may be constrained by a variety of factors outside their control (Nuseibeh and Easterbrook, 2000), for example, the balance between personalization and standardization of the health technology (Peine and Moors, 2015).

The management of requirements is a current research topic. User preferences need to be taken into account in order to enable the design of devices that will gain acceptance both in clinical and home settings. One way of understanding user preferences is through literature review, which has been used to identify, retrieve, and assess all studies evaluating user preferences from patient and clinician perspectives (Bergmann and McGregor, 2011). However, few researchers have identified that only the literature review is not enough to discover the customer preferences. In order to fill this gap, a few studies on requirements engineering have been published (Sommerville, 2005), as a new process to balance the stakeholders' voices (Ana et al., 2013) and a systematic proposal to manage requirements for the development process of sustainable products (Marx and Paula, 2011).

Hoffmann et al. (2014) point of view is that the requirements are developed based on the given facts of the environment and the mission to be achieved. In the course of a project, they become more concrete, more detailed, and also more complex. The closer the specification approaches atomic requirements, the more complex the relationship between them becomes: the requirements changes must be handled, the status of requirements must be updated according to the project phase, and tracing to other development artifacts should be established. Based on all of this, there is still a need for new studies that find good approaches to manage requirements, especially for the health product development.

3. Material and methods

This research is classified as a quali-quantitative study. Based on its main goal, the research is classified as an exploratory study, because it aims to offer more familiarity with the problem, making it more explicit (Gil, 2002). A model associating CVCA (Tanure et al., 2013) with the adapted QFD tool (Ribeiro et al., 2001) was developed to analyze the product value chain stakeholders, identify their needs, and analyze and prioritize their requirements, as shown in Fig. 1.

Both tools were analyzed by the research team and applied in an integrated manner. The CVCA tool stages were developed to carry out the value chain analysis and identify the product value chain stakeholders. The CVCA tool has seven stages: 1) definition of the initial business model and its assumptions; 2) delineation of the pertinent parties involved with the product; 3) determination of how the parties are related to each other; 4) identification of the relationships between the parties by defining flows between them; 5) analysis of the resulting Customer Value Chain to determine critical customers and their value propositions;6) inclusion of the information in Product Definition Assessment (PDA); 7) use of CVCA results in the product (Donaldson et al., 2006). The CVCA's seventh stage consists on using the results of the value network; the first five steps related to the customer value chain were developed in this study.

In order to analyze, define and prioritize the requirements, the QFD tool was deployed in three matrices: quality matrix, product matrix, and characteristics of the parts matrix (Buss et al., 2012). Results of CVCA and QFD applications were organized and described in accordance with the engineering requirement process adapted to this case: elicitation, analysis, and documentation (Sommerville, 2005). The elicitation and analysis are shown in this Section 3, and the documentation is the results shown in Section 5.

3.1. Elicitation

The requirements came from primary and secondary sources, as shown in Fig. 2. The primary sources include interviews with the