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Proposal of a user-centred approach for CPS design: pillbox case study

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Abstract: Product design greatly evolves for years, due to the increasing complexity of products, from simple monodisciplinary products to mechatronics systems then cyber-physical systems. Teams involved in the development of such systems are strongly interdisciplinary and require adequate engineering design methods. We propose hereafter a dedicated design process that integrates systems engineering approach, creativity tools and user-centered design methods. This design process has been implemented within a case study from e-health sector: a home-care provider asked us for developing and experimenting a 'connected' pillbox. After detailing main results of this development, we analyze them and propose methodological improvements. We finally conclude on some perspectives for studying engineering design in the context of global e-health systems.

Keywords: Systems Engineering, Human-Centered Design, Smart Human-Machine Interface, System Design, CPS for Health Care.

1. INTRODUCTION

Analysing the evolution of manufactured products among years it is noticeable that more and more are interdisciplinary products. Many mechanical products in the 20th century are now complex products integrating electronics components (Ullman, 2009) and embedded software. This evolution is due to several factors such as the increasing numbers of the addressed markets and at the same time the segmentation of traditional markets for a better adaptation of the products to customers' needs. Teams developing such products are now very extended interdisciplinary teams. Existing design methods have not been developed for that kind of interdisciplinary. Research in the early 2000 as in Roucoules et al. (2006) or Pol et al. (2007) was exploring interdisciplinary collaboration in specific domains such as mechanics: the design expert, the finite element expert, or the machining expert were three experts with different knowledge, but all were involved in the same 'vertical' discipline. Nowadays several design experts from different "horizontal" disciplines such as mechanics, automation, electronics, software, or IS architects, must work together. As a result, traditional companies intent to manage this heterogeneity with inadequate methods.

Efficient coordination and collaboration are much more challenging than ever to be able to develop products more "connected" and more "intelligent". Traditional approaches, even collaborative ones, are no longer available for designing such products. They are characterised by several dimensions of complexity: e.g. the high number of experts' domains; or the multiple ways to access to product through delocalised services or interfaces, etc. Our aim is to investigate the possible methodologies that can be applied for complex products, especially cyber-physical systems.

In this paper we propose to integrate user-centred approaches with systems engineering to develop CPS systems. We present the resulting design process and its implementation for designing a 'connected' pillbox. We point out the limits that we identified and the different axes that we must explore in the future before the formalisation of a global methodology for CPS design. In next section, we describe system engineering approach as defined by INCOSE (2015) for cyber-physical systems (CPS) design then the interest of user-centred approaches to manage the link between humans and CPS. In section 3 we introduce our case study. Section 4 develops the design process and its implementation.

2. DESIGN ENGINEERING FOR COMPLEX PRODUCTS

Most existing design methods do not consider the complexity of the product, such as methods based on Function-Behaviour-Structure concepts such as Roucoules et al. (2006), or sequential design processes (e.g. Pahl and Beitz, 1996), and even methods dedicated to specific goals such Design for X methods (e.g. Doumeingts et al., 1996) or innovation processes. System engineering, as defined by INCOSE (International Council of Systems Engineering), has been built with the aim of managing interdisciplinary between the stakeholders.

2.1 Systems engineering

System engineering is "*an interdisciplinary approach and means to enable the realization of successful systems. It*

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focuses on defining customer needs and required functionality early in the development cycle, documenting requirements, and then proceeding with design synthesis and system validation while considering the complete problem: operations, cost and schedule, performance, training and support, test, manufacturing, and disposal.", INCOSE (2015). System engineering is formalised through several standards such as ISO/IEC/IEEE 15288-2015 (2015) or ANSI/EIA–632 from ELECTRONIC INDUSTRIES ALLIANCE (1999). As an interdisciplinary approach, it proposes operational tools to facilitate the collaboration between stakeholders to allow them to formalise and share product knowledge in an understandable way. The formalism SYSML is the main tool for doing so. Different processes are proposed and defined for managing each stage and activity of the product development process with the aim of sharing the same way of working between all the stakeholders. All interdisciplinary teams are then working with the same 'language' and the same references. By this way, Faulconbridge and Ryan (2003) explains that user requirements are better addressed considering the different disciplines involved in the development process.

2.2 Cyber-Physical Systems

System engineering is dedicated to complex products development. CPS can be considered as a complex product (Guerineau et al. 2016) in the way it combines mechatronics components as mechanical parts and embedded systems and integrates data communication capabilities. According to Pannaga et al. (2013), "*Mechatronics is an interdisciplinary field, combining in a synergistic manner the classical knowledge of mechanical engineering, hydraulics, pneumatics, electronics, optics and computer science. A typical mechatronic system picks up signals from the environment, processes them to generate output signals*". CPS have been characterised recently as a system combining physical and non-physical sub-systems, some supporting controlling and coordinating activities, sometimes as offset activities managed by an external software by several authors such as (Rajkumar, 2012, Lee, 2008 or Zheng, et al., 2016).

Connectivity is a main characteristic of CPS, underlined by Abramovici (2015) and Plateaux et al. (2016). It is clear to understand, moreover considering our 'connected pillbox' case study, that sensors are an indispensable part of CPS. More and more, the concepts of Internet of Things (IoT) and "connected objects" including several sensors are applied in many different technical areas and CPS (Thramboulidis and Christoulakis, 2016). Moreover, the evolution of existing industrial manufacturing methods towards the Industry 4.0, resulting in new products and working procedures, will be based on CPS. Sensors should collect all necessary information from the environment, without forgetting that data must be useful for human end-users and stakeholders. Baheti and Gill (2011) conclude that human beings must be considered when developing future CPS: interactions between the CPS and human beings will be fostered and amplified due to technology evolution. Therefore, Porter and Heppelmann (2014) propose to define them as smart products, or smart connected products. We are convinced that developing Cyber-Physical Systems without considering their interactions with humans is a non-sense. User-centred approaches must be studied as they are dedicated to considering human as a future user of the product to improve the quality of design in front of customer requirements.

2.3 User-centred design

Some authors have already identified that user-centred design is a challenge for cyber physical systems. We find for example the word of Lee and sokolsky for Medical cyber physical systems (Lee & Sokolsky, 2010). In another field of application, Leitão et al. (2016) point out that, for industrial cyber physical systems, a better understanding of the completely different form of interaction between machines and humans, when both are having similar capabilities, i.e., service exposition or consume, autonomous decision-making and collaborative functions is still not adequately explored. For them, designing CPS for users is a real challenge. (Leitão et al., 2016). However, it appears that their work focuses on humans / users as consumers of data and on interactions between human and CPS but do not consider the use of CPS as product and as a whole.

However, design engineering methods integrate the user / consumer into design processes and address issues and models that have evolved over the last 15 years. The main progresses are first Kansei engineering which emerges in the early 2000s, and which aims to anticipate the emotions, sensations and semantics conveyed by the design of a product (Bouchard et al., 2003). Then, the Emotional Design (Desmet, 2002, Norman, 2005) which attempts to overcome certain limits of Kansei including those to define, measure and quantify emotions. The late 2000s - early 2010s marked a second important phase in the evolution of Product Design. Indeed, the coming of the Web 3.0 and the Internet of Things open the field of possibilities for the consumer: s/he can customize the products to her/his needs and desires. A consequence of this customization of products introduces a new complexity within the product design that must go beyond the design of "shape" and must offer an "experience" to the user. So, the User Experience, or UX Design, which originally is related to the field of software engineering, finds interest and applications in Product Design (Bongard-Blanchy and Bouchard, 2014).

Innovation is also a way to create a competitive advantage. However, certain methods can prevent innovation by an organization that is too rigid. How to develop a multidisciplinary product with a share of innovation focused on user while maintaining the constraints necessary for the development of these products?

In synthesis, the Human Centred Design (HCD) aims to develop a product respectful of user. Thus, designers observe and analyse experiences of use to understand it and improve it. Moreover, the innovation by usage lead to a specific design process where the usage is the shared referential between actors. Products must therefore fit to HCD criteria. In this way, Jordan proposed a pyramid of needs presenting three fundamental characteristics: Functionality, Usability and Pleasure (Jordan, 2000). According CPS is a complex product; we think that engineers must follow the HCD criteria in their design process of CPS.

3. CASE STUDY: PILLBOX DESIGN

Health Service Bayonne (HSB) is an establishment which coordinates two types of home care services to patients: home medical care instead of heavy hospital care (HAD 20%) and nursing home care (SSIAD 80%). It manages 225 people and cares nearly 500 patients with little of medium loss of autonomy. During the last four years, HSB has engaged a project for replacing the health case file of a patient in paper format, situated at patient's home, by a digitized health case file, accessible using a tablet PC with health care traceability software. This project is initially built for improving the HAD service and is motivated by different issues that are described by Borgiel et al. (2013): traceability, real-time information exchanges between nurses, improved decision support. As part of this project, HSB managers decided to digitalize the 'drug process', which is composed of four stages: prescription, medication preparation, medication catching, and in parallel monitoring and revaluation.

The "connected pill" is a concept that may greatly improve the drug process, especially the security during the preparation and catching phases:

- to improve drug catching by reducing the risk to forget it with e.g. visual or sonic alerts and by reducing the fact to take a wrong drug through a limited access to the drugs;

- to improve monitoring without a nurse by saving and/or sending in real time information about the events associated to the pill: opening a zone, closing it after, etc.;

- to control the access to the drugs by defining only authorized people for adding or removing drugs: nurse, patient if autonomous enough, family responsible, etc.)

After having implemented the digitized health case file of a patient, HSB started the connected pill project during summer 2016. The project was achieved in Nov.2017 and the team has been composed of researchers, engineering students, a design engineer specialised in mechatronics and ergonomics experts for helping in users' tests. In the next section we introduced the design methodology that we applied, based on both system engineering and user-centred approaches.

4. AN ADAPTED DESIGN PROCESS: PROPOSAL AND EXPERIMENTATION

4.1 Design context

A connected pill is a system involving several disciplinary experts: mechanics, electronics, and software architecture then programming. That is the reason why we decided to use system engineering approach. As a system, it is managed by a customer, but has distinct types of users. So, we need also to manage a user-centred approach to be sure to consider the specific requirements of all users.

Finally, HSB has already identified existing connected pills but they present several limitations: functional as well as operational. Nevertheless, HSB selected one existing connected pill, that we will call 'e-Pill', to be experimented in real conditions with HSB nurses and patients. We should introduce new concepts during design activities to propose a new kind of connected pill. Consequently, the context of the design process we must implement is characterized by a system engineering approach, coupled with a user-centred approach, and integrating relevant tools for generating and managing creativity. Moreover, we beneficiate of the evaluation of a "market" pill.

4.2 Proposal of an integrated design process

Due to this three-dimension context, we proposed to HSB a 3 phases-process based on a W cycle, as shown in Fig. 1:

1. First phase: Exploration (divergent top-down design);

2. Second phase: Synthesis (selection and unit tests);

3. Third phase: Development (convergent bottom-up design).

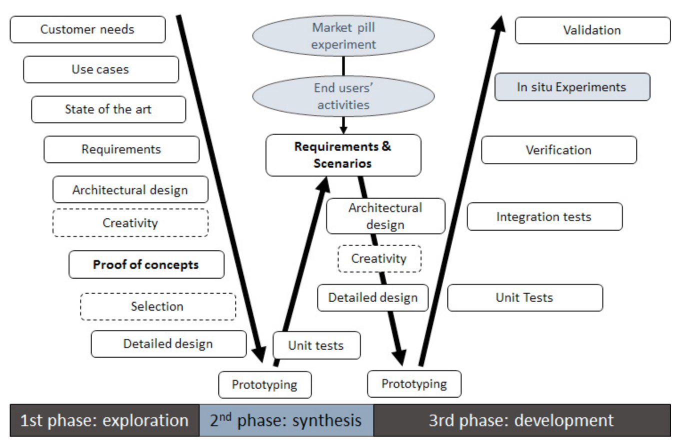

Fig. 1. Phases and steps of achieved design process.

Exploration phase focuses on the proposal of proof of concepts (1st branch of design process in Fig.1). We entrust engineering students involved in our MSc' first year with the design activities of this phase: analysing customer needs, making a state of the art of existing pills, proposing novel solutions then detailing them applying the decomposition steps of system engineering approach, similarly to Mehnni et al. (2014). Creativity techniques have been introduced during the architectural design to generate more concepts.

Second and third phases were managed by our design engineer. Second phase is dedicated to the selection of best concepts, to reduce creativity diversity (end of 1st branch in Fig.1, then 2nd branch). Then an improved concept has been proposed, designed, partially prototyped and tested. In parallel we applied a user-centred approach with ergonomics experts to evaluate the existing 'ePill' on real users' activities to improve design requirements and scenarios. Third phase (3rd and 4th branches in Fig.1) corresponds then to the choice and validation of the final concept, the architectural and detailed design then prototype steps, with final experiments to validate the whole product. Design process corresponds here also to the complete system engineering approach, integrating in-situ experiments based on the users' centred approach. Of course, each detailed design step is an iterative step based on the decomposition/integration principle from system engineering, according to the subsystem identified by the architectural step.

In the next section we detail and illustrate the results of this integrated design process as it has been achieved.

5. APPLICATION TO PILLBOX DESIGN AND PROTOTYPING

To evaluate the solutions identified during the state of the art and the concepts created by the engineer we proposed two performance variables: security level composed by 9 criteria and autonomy level composed by 3 criteria. These two levels represent the performance to maximize to reach the requirements design according to HSB and to user needs. In this way, we tried to maximize these two performance variables by the design and the improvement of concepts and thus to define Pareto-optimal solution.

The dominance is defined as: y dominates z iff i $[1 \ldots n]$, $f_i(y) \leq f_i(z)$ and k $[1 \ldots n] \mid f_k(y) < f_k(z)$.

Dominance in the Pareto approach is defined as: one solution $x^p \in X$ is Pareto-optimal if $x \in X$ such that x dominates x^p, and where: we consider a multi-objective problem: $min(F(x) = (f_1(x), f_2(x), \ldots, f_n(x)), n \geq 2$

With $x \in X$

X is the decision space

Y is the objective space (or performance space)

And $Y = F(X)$

The first phases of development were carried out by the students and allowed to analyse the customer needs, to define the use cases and to explore the state of the art. These first steps allow us to define the two performance variables of our design problem. The state of the art consists of 10 solutions available on the market. After their evaluation we identify 3 solutions that are non-dominated in the sense of Pareto: RxPense (2017), iMedipac (2017) and Memobox (2017). These solutions appear in red circles in Fig. 2.

The following three phases of requirements, architectural design and especially the creativity phase allowed the generation of Proof of concepts (PoCs). To reach the PoCs phase, students spent approximately 40 hours of development (from customer needs to Proof of Concepts). These phases resulted in a total of 22 PoCs validating at least the mechanical or mechatronic feasibility of the proposed concept. Among the 22 PoCs proposed, our engineer has selected 10, eliminating redundant ideas, and keeping the most complete concepts in terms of development and the most inspiring in terms of originality.

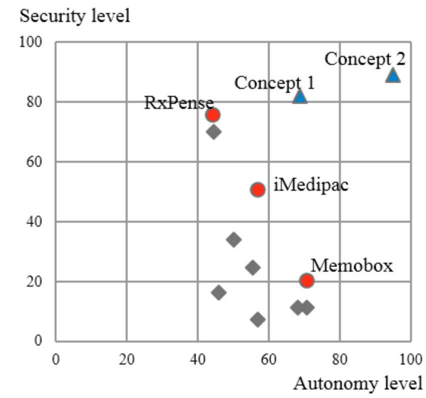

Fig. 2. Evaluation of products from state of the art and the concepts from the engineer.

The analysis and exploration of these 10 PoCs enabled our engineer to design a first prototype identified as "concept 1" in Fig. 2. Concept 1 is based on a rotating plate with a vertical supply. We can observe that this exploration has favoured the response to HSB expectations and user needs. Indeed, in Fig. 2. We note that the concept 1 (blue triangle) dominates in the sense of Pareto solutions RxPense and iMedipac but remains equivalent to the solution Memobox.

Following our engineer's first concept, a user-centric field analysis provided new specifications and recommendations for product design. Thus, the third phase of development has favoured the design of a new prototype identified by "concept 2" in Fig. 2. Concept 2 is based on a horizontal supply, with a set of components correlated to patient's autonomy. The contribution of the in-situ analysis with the users allows us to propose a solution which dominates in Pareto sense all products and concept 1 (see Fig. 2.).

In conclusion, our methodology has favoured the design of a pillbox (identified as concept 2) that has a real added value compared to the pillboxes of the market.

6. FEEDBACK AND DISCUSSION

Several considerations can be addressed considering the whole achieved design process: the different steps and the methods and tools used at each step, as well as the 'object' of the design, i.e. the product to be designed.

First, we must consider that designing such a connected pill corresponds to innovative design rather than only routine design. That is the reason why we introduced creativity steps and exploration phase with students. Our aim is to improve then the proposed design process for future design projects involving only our team of researchers and design engineer.

Introducing an exploration phase allow us getting a lot of information about the market that we address, and the concepts already used. Fostered by the creativity step, students generate a lot of ideas and concepts, based on a detailed list of customers' needs, and that was a very rich raw material for our design engineer. But creativity has been introduced too late in the design process: as architectural design has been achieved before, students focused on technical concepts, associated to subsystems, and do not think about more global concepts, centred on user's interactions. In fact, we must introduce two different steps of creativity (Fig.3): a first global one after the state of the art, then a second one later, between architectural and detailed design. Architectural step is no more useful in the first phase.

Finally, we promote an improved design process as described in Fig.3. First exploration phase ends with sketching to formalise proposed concepts. Considering that the results of the existing 'e-Pill' experiments were introduced very late in the design process, it is questionable to keep two prototypes: one corresponding to the 'best' concept but based only on customer needs; and one based on a different concept because users' experiment demonstrate customer' needs were not adequate nor relevant! Second phase is then focused on the user centred approach by integrating very soon in the design process the observations and interviews of the end users' activities, to generate very detailed requirements. By this way, in the third development phase the first and sole prototype will be based on both customer and end users' requirements.

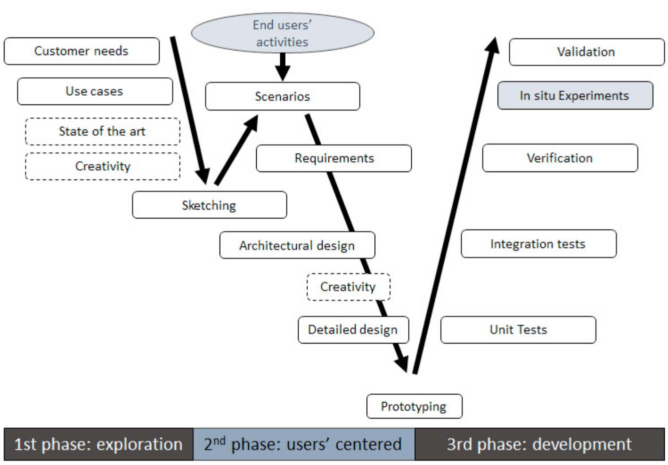

Fig. 3. Phases and steps of improved design process.

Designing a pillbox is a matter for designing a mechatronic product which can be considered as a CPS composed of a pillbox component and the ICT (Information and Communication Technologies) management system that interact with the pillbox to exchange data, visualise it and modify the pillbox scheduling. The experiments demonstrate to our partner HSB that even with very powerful and usable solutions, a connected pillbox alone has a low added value on the business process of a home care service provider. But it can be one essential element of a more global e-health system centred on a senior at home.

7. CONCLUSIONS AND PERSPECTIVES

In this paper we focus on the design of CPS systems which relates with interdisciplinary collaboration between the different experts. Such a design process is based on the use of systems engineering approach, steps and formalism to help formalizing product knowledge. Our case study consists in designing, prototyping and experimenting a 'connected' pillbox in real conditions. The pillbox must be innovative faced to existing pillbox, so we introduce creativity methods at relevant steps of the design process. Moreover, in health sector, human is very important, and we introduce a user centred approach based on patient and nurses' observation and on experimentation scenarios to evaluate both concepts of solution and prototypes. Our contribution consists in characterising an integrated design process, divided into three phases: 'exploration', 'user centred' and 'development'; and integrating steps from systems engineering, creativity and user centred approaches.

Our final aim is to address more global cyber-physical systems: the pillbox case study was a first goal, but now we must consider a more global CPS that can be described as an e-health system to improve "home care". The proposed design process is then inadequate, and a more global methodology must be studied, such as in Hehenberger et al. (2016), and we will focus from now our research on answering the following questions: how do we identify all the future customers and users of such a global CPS? How can we identify what are the various products / sensors / IT systems that may compose this CPS? How do we have to adapt the proposed design process to design, prototype, and evaluate each element of the CPS, to build an integrated and coherent global system?

Our intent is to apply MAS approaches to model and simulate the whole CPS (Hu et al., 2016). We will use agent modelling to represent sensors, actuators, controllers, mechatronic products, but also ICT systems, and human experts or patients. This modelling will help us coordinating the design of each sub-system such as the pillbox, other mechatronics systems, autonomous sensors, ICT tools, etc. In addition, the complexity of an e-health CPS creates a need for decision support tools. Indeed, the amount of generated information by this CPS is very important and it is therefore difficult for a decision maker supervising or interacting with the CPS to have an exhaustive understanding of the system. For an optimal decision, in this context, decision support tools, whether based on big data or knowledge management approaches, are becoming an issue that must be considered for the design of an e-health CPS to ensure that decision makers have the required overview of the situations to make optimal decisions for the patients at home.

For modelling the e-health CPS then designing each element of this CPS, we will have to manage the interactions between the different sub-systems and their interactions with many different users from different organisational structures (freelance nurses, doctors, hospitals, social services, etc.). In this context, it could be very interesting to integrate the points of view (the mental representations) of each of the stakeholders directly or indirectly involved in the design process. We talk about the different users (workers - nurses…- or patients), but also, we talk about the different researchers and expert engineers. Indeed, working from the mental representations of each actors, of its logics, allows to build a common reference. That allows to understand each other and to build compromises between the expectations of each one. This is one of the conditions to favour the appropriation of induced change when designing complex CPS in a multidisciplinary context.

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