Human centred criteria for healthcare design

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HUMAN CENTRED CRITERIA FOR HEALTHCARE DESIGN

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Abstract: Health devices or product are parts of a complex environment where misuses can conduct to heavy consequences. Directives and standards require to integrate human factors in the design process in order to reduce risks of misuses and to guide the design process. However, few studies present Human Centred Design criteria helping to design process. Therefore, we aim within this paper to observe the relevance and the use of Human Centred Criteria in a health context. Our paper presents then the Human Centred Design and health criteria and ways to use them over the design process. As result, we present a selection of criteria for each stage of the design process to help considering health constraints.

Keywords: Human Centred Design; Evaluation; Design Process, Health

INTRODUCTION

The World Health Organization defines health as a complete state of physical, mental and social wellness and not only a non-intendancy of disease or disability [1]. This explains why health industry gathers various sectors from pharmaceutical to food industry including sports, cosmetics and wellness industries. Innovations in healthcare sector increased and became a new field of interest these last decades. Financial supports for this sector increased by three to reach 102 M€ in France between 2013 and 2016 [2] and favour the development of products for silver economy, disease treatments or users' daily life. Those products result from a design process transforming an immaterial state (like idea, concept or function) to a material state [3] following the steps defined by Pahl & Beitz [4]: the task clarification, the conceptual design, the embodiment design and the detail design. The design evolves at each step and is subject to evaluation and selection to obtain a finalized product. To evaluate and select, designers need relevant criteria. The Human Centred Design (HCD) aim to develop a product respectful of the user. So, designers observe and analyse experiences of use to understand and improve it. The innovation by usage leads to a specific design process where the usage is the shared referential between actors including users [5]. Jordan proposed a pyramid of needs (see fig.1) presenting three fundamental characteristics of the product to meet HCD criteria [6].

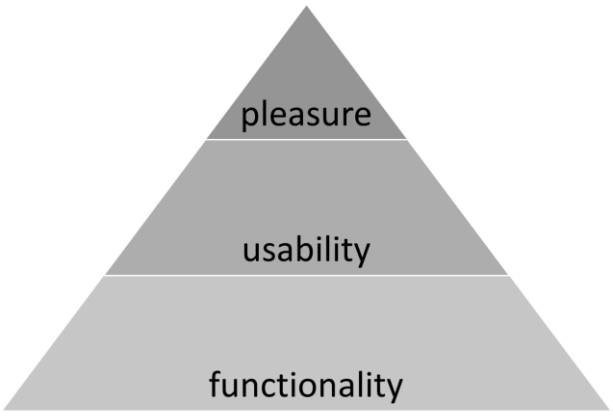

Figure 1: Pyramid of need [6]

The product requires functionality, usability and pleasure characteristics gathering specific criteria. The functionality is the capacity of the product to realise its function. At this level, the focus is on technical specifications. The engineering field presents some criteria like efficiency and feasibility [7][8][9].

The usability represents the capacity of the product to be understood and manipulated easily. At this stage, designers observe interactions between users and product, analyse experiences of use and correct potential misfunctions or misunderstanding, potentially sources of rejection or injuries. Some methods cover these interactions like Kansei Engineering, Emotional Design or more recently User Experience Design [10].

The pleasure enhances the experience by generating satisfaction and desirability. Many studies from Kansei Engineering and Emotional Design deal with this topic. Among them, authors explore correlations between physical properties of the product like colours or shapes, and users' emotions to provide a durable feeling of wellness [11].

These three levels gather criteria guiding the design process. Each of them depends on disciplines applied to the product context. In our case, we work with SC-Ergomedical, a company aiming to develop products for healthcare with a HCD approach. We try to solve customers' pain situations whether they are physical, mental and economic [12]. Our collaboration focuses therefore on criteria from three scientific fields: engineering, human and health to cover these points. Criteria of HCD could apply for the context of healthcare, but few studies present the way to use them within this context [13][14][15]. Therefore, which criteria are relevant and suitable throughout a HCD process for Healthcare?

In the next section, we present the existing criteria categorized within the levels of Jordan's pyramid. Then we observe them within steps of design process and propose a selection of criteria for each step of the design process.

1. EVALUATION CRITERIA OF THE PYRAMID OF NEED

1.1. Evaluation criteria for functionality's need

The functionality level, at the basis of the pyramid, treats the functional aspect of the product. Designers must pay attention to the technical performances of the product. The engineering field presents some criteria to evaluate them. Among them, the *efficiency*, the *feasibility* and the *potentiality* are recurrent.

The *efficiency* deals with the capacity of the product to realise its tasks. In the health care context, it means to guaranty the users' wellness in addition to other users' needs. This criterion is therefore dependant of the technical quality of design. Despite the design fulfil its desired tasks, the design needs to be technically feasible [7][8][9][16][17].

The *feasibility* focuses on the ability of the product to be technically realizable. However, even if the design can be achieved, the financial investment need to be taken into account. If the design is technically feasible but highly expensive, the viability can't be reached. Therefore, *feasibility* includes technological and financial dimensions allowing designers to estimate the design impact on the market. This introduces the following notion of potentiality [9][18].

The *potentiality* defines the potential of the design to fit the targeted market [9]. It requires the market understanding and therefore users understanding. The human dimension needs to be covered as much as the technical dimension as suggested by the second level of Jordan's pyramid.

1.2. Evaluation criteria for usability's need

The usability level of the pyramid deals with the use of the product. This involves not only the product manipulation but also information transmitted by the product to the user. Indeed, manipulation and understanding issues can lead to accidents causing physical and mental injuries. So, designers have to consider the *manipulability* and *understandability* criteria to reduce risks of injuries.

The *manipulability* focuses on the physical product properties to facilitate the use and prevent user physical injuries. Then, designers do not just validate technical characteristics of the design like its weight or its shape, but also the usage with the help of users. They can predict and correct painful situation induced by the design (musculoskeletal disorders or incorrect grab) while evaluating the design manipulation [20]. Even if designs reduce risks of injuries from manipulation, misunderstandings of use can also lead to injuries.

The *understandability* is linked to the intuitive characteristics of the product. It gathers all information helping users to use products, like signals (sound, light or vibrations), shapes (handle or symbols) leading to an automatic and unconscious use [21]. Intuitive and straightforward designs help reducing risks of rejection and generating pleasure and wellness for the user.

1.3. Evaluation criteria for pleasure's need

Pleasure level of the pyramid deals with the user satisfaction through the product experience [11]. At this level, designers must make the product desirable. However, to reduce the risk of rejection from the user, desire should not vanish while experiencing the product. The user experience varies over time and therefore belongs a dynamic dimension. Consequently, the pleasure level requires designers to focus on criteria of *desirability* and *durability*.

The *desirability* is used to evaluate the aptitude of the design to attract users. This notion mainly includes hedonic properties generating interest for both designers and users as colour, shape, touch or sound [9]. In addition to need and desire, the desirability includes a social dimension like the affiliation to social categories [22]. However, even if the design desirability provokes the act of purchase, the design must arouse users over time.

The *durability* is used to evaluate the aptitude of the product to generate satisfaction and wellness over time. Even if the product gives rise to a great experience at the beginning of the use, this feeling can decrease over time. Designers must move away from boredom as much as possible to keep arousing the user during the product experience [23][24][25].

All the criteria presented are used to evaluate and select designs within the design process. However, several are more relevant in early phases of the process and several seems to belong more to specific fields. The next section presents this criteria over the design process, the scientific field and the context of use.

2. HCD CRITERIA OVER THE DESIGN PROCESS

In this part, we present evaluation criteria from HCD within three phases of the design process defined by Pahl & Beitz [4]: the task clarification, the conceptual design and the embodiment design.

2.1. Criteria of the task clarification

A product only makes sense if it meets a need. It is therefore necessary to identify and define the need to develop tasks. The task clarification is the step of the design process aiming to understand and to translate the need into specifications [4].

During this stage, designers and engineers observe and exchange with users [26]. Observations in the field allow a better understanding of real practices and needs. However, observers need to make users explicit their experiences, perceptions and expectations to reach latent needs. So, engineers and designers combine observations with surveys, semi-structured interviews and focus group to collect information through semantic analyses [27]. Results help observers to translate expectations and desires into specifications. Furthermore, these results help observers to translate the level of user interest in the definition of need. In this way, they apply the *desirability* criterion during the task clarification.

Moreover, marketing services study the market positioning during the task clarification [28]. So, they realize the state of the art of existing solutions and then compare and classify them. It allows highlighting categories of the market where the concept is more susceptible to fit. Categories help also

to observe specificities of market and then translating them into specifications and to evaluate the *potentiality*.

Consequently, we observe, that engineers, designers and marketing services apply the criteria of *desirability* and *potentiality* (see Fig.2) to validate the task clarification and to move on the next step of the design process.

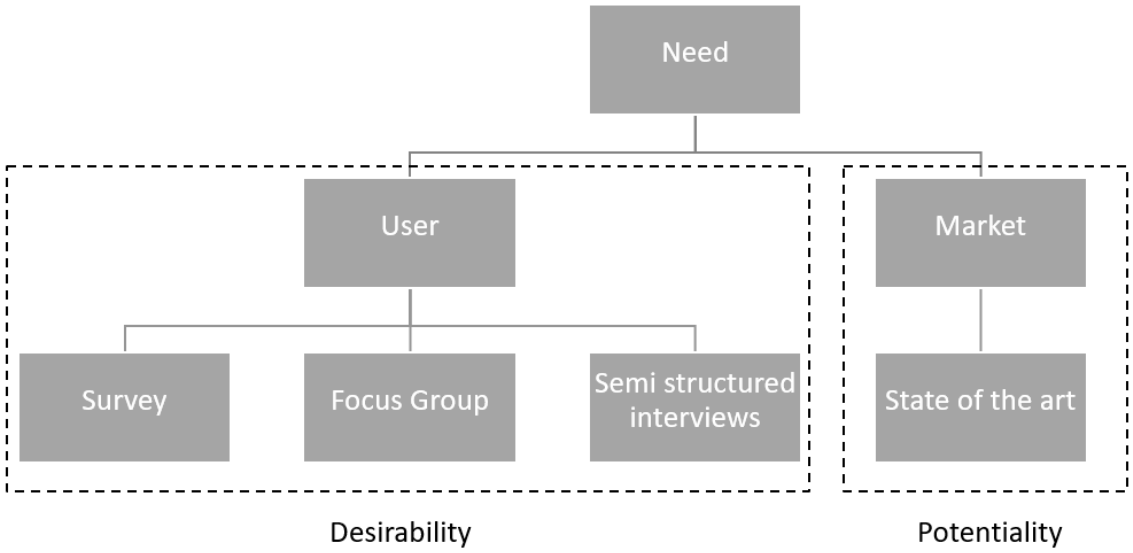

Figure 2: Criteria used during the task clarification

2.2. Criteria of conceptual design

Once needs are identified and understood, the design team must generate solutions. The conceptual design step aims to generate and select the bests solutions to develop [4]. During the conceptual design, two phases exists: the divergent and the convergent phase.

The divergent phase consists in generating solutions [4]. Various methods can be used at this step to stimulate creativity like Brainstorm or C-Sketch methods [16][18][29]. As results, creativity process provides illustrations of imagined solutions.

The convergent phase aims to select best solutions among the others. Evaluators estimate the quality of proposed solutions with surveys presenting Yes/No questions and semantics scales [9][30]. Binary survey consists on implementing a score at each Yes/No question [16]. The final score is then a global representation of the perceived quality of the solution. In contrast, semantics scales do not provide a global score but a quality profile of the illustrated solution. However, this profile must be divided on semantic criteria defining the quality like with the AttrakDiff form [31]. This questionnaire consists of pairs of opposing items to be evaluated on a Likert scale. Each opposite item is representative of a quality perception like complex/simple or confusing/clearly structured. However, it involves paying attention to the terms used in the survey to avoid misunderstandings [27][30][31]. According to various authors, quality evaluation induces the evaluation of workability, relevance and specificity [7][8][9].

Workability gathers two aspects of the quality [8][9]. Implementability, as the possibility to technically realize the illustrated solution and the acceptability representing all the known constraints of the illustrated concept (legal, political, economic). Workability refers thus to the *feasibility* criterion.

Relevance brings together the applicability and effectiveness [8][9]. The illustrated solution is effective if it satisfies design specifications. The applicability is the degree to which the idea clearly fits to the stated problem. Consequently, the relevance is referring to the *efficiency* criterion.

Specificity involves judging the relation between the desired action and the expected outcome (explicitness), the composition of the concept (completeness) and the degree to which the idea is

clearly communicated (clarity) [8]. Specificity gathers all properties of the comprehension of solutions. Consequently, it refers to the *understandability* criterion.

Feasibility, *efficiency* and *understandability* are not the only criteria used during the conceptual design. Ambrosino *et al*. propose to evaluate the *potentiality* with scales [9]. Illustrated solutions present technologies, shapes and other specificities which are comparable with the market positioning realised during the tasks clarification to evaluate *potentiality* criterion.

Illustration of solutions can generate positive or negative reactions and emotions depending of the subjectivity of the evaluator. It involves that the evaluation of *desirability* is possible at this stage. However, induced emotions result also from the appearance and clarity of the illustration. Thus, the *desirability* criterion is difficult to evaluate at this stage, because of the variability induced by individual, illustration's clarity and illustration's appearance.

In this way, we observe that designers, engineers, and marketing services apply criteria of *efficiency*, *feasibility*, *potentiality* and *understandability* for the conceptual design phase (see Fig.3) to select a solution to develop within the embodiment design.

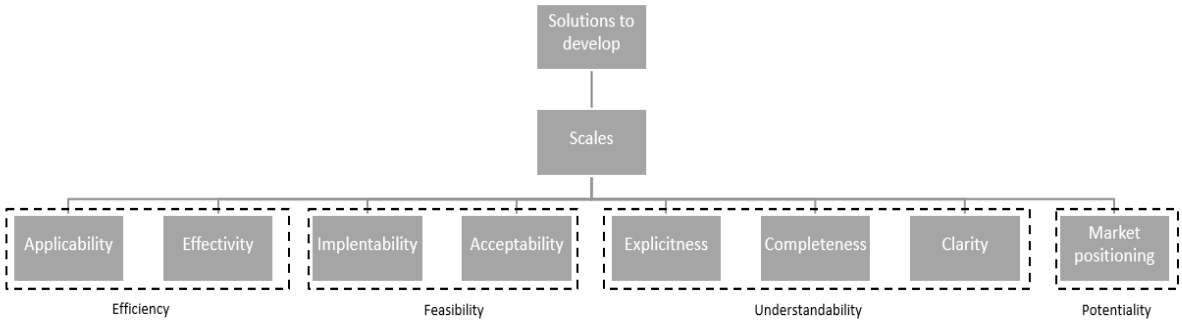

Figure 3: Criteria used during the conceptual design

2.3. Criteria of the embodiment design

The embodiment design stage aims to materialize the selected conceptual solution [4]. This step is composed of two phases: the materialization of the selected solution and the evaluation of the user experience.

During the first part of this phase, engineers and designers materialize the solution according to an iterative process. They realise one feature of the solution at the time and verify if it satisfies the specifications edited during the upstream phases. If so, it is then implemented to the mock-up, otherwise, designers and engineers rework it. Doing this iterative process allows the mock-up evaluation with the *efficiency* criterion. Furthermore, each iteration provides functional and economical information [4]. Indeed, designers and engineers gather information regarding constraints impacting parts and components like strengths, resilience or development process in addition to the cost required to realise features. Then, it is possible to evaluate the mock-up with the *feasibility* criterion.

The second phase of the embodiment design aims to evaluate this with the observation of user experience. During user tests, users are invited to manipulate intermediate prototypes regarding given instructions involving the realisation of various features of the device [32]. The simple observation of tasks' failure allows the identification of the design weaknesses. Yet, failures can result from ergonomic issues or from signal and feedback misunderstandings. So, observations are combined with interviews or think-aloud method, asking user to explicit what they do, what they think, what they feel, to understand reasons of failures [27]. Designers and engineers can evaluate the usability of intermediate prototype with *manipulability* and *understandability* criteria.

Nevertheless, satisfaction does not limit to functionality and usability criteria but integrate also pleasure [6]. As for the task clarification, surveys and interviews help designers and engineers to gather information and to evaluate the *desirability* of the designed solution with users. However, user

experience is a dynamic process [33]. It involves a variation of satisfaction over time. To accommodate this variation, users are asked at strategic time of the user experience, i.e. before using the product, while using the product and after using the product [33]. By focussing on these specific times of user's experience, the *durability* of the satisfaction is evaluated [24].

We observe then that engineers and designers use various criteria during the embodiment design (see Fig.4). *Efficiency* and *feasibility* are evaluated during the materialization phase while usability criteria (*manipulability* and *understandability*) are evaluated during users' tests as for the pleasure criteria (*desirability* and *durability*).

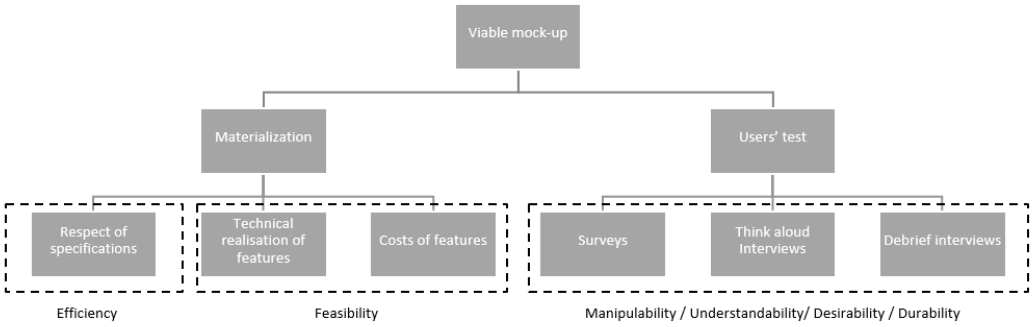

Figure 4: Criteria used during the embodiment design

3. CRITERIA FROM HEALTH FIELD

Products for health aim prolonging, sustaining, improving or supporting the human life by insuring physical, mental and social wellness [1][34].

According to standards and directives, insuring physical wellness requires from health devices to be efficient and safe [27][35]. If *efficiency* is a common criterion, *safety* criterion is more specific to a design process for health. *Safety*, as presented within the regulation, requires limiting and controlling the risk exposure for the practitioner and the patient [27][35]. For example, several syringes belong cap covering the needles when the product is not use (see Fig. 5). It involves evaluating the criticality of the product with the identification of critical parts like needles or blades. The identification of critical parts is possible not only during the embodiment design phase while materializing mock-ups but also at the conceptual design while selecting best solutions to develop. Consequently, *safety* criterion is referring to a degree of exposure of risks and can be evaluated in the conceptual design and the embodiment design stages of the design process.

Figure 5 : Example of needle cap

Insuring the mental wellness not only requires from health devices to be easy to use but also involves realising simple, clear and acceptable products [27][35][36]. Criteria of simplicity and clarity are already explored with HCD approach. Regarding the *acceptability*, this criterion refers to the implication of practitioner and/or patient to use the device. For example, the use of an Magnetic Resonance Imaging scanner is complicate for a claustrophobic patient. The confinement imposed by the device may lead the patient to refuse the medical examination. To evaluate this criterion, analysis of the

user experience is necessary. In this way, the embodiment design phase appears as the stage to evaluate with the *acceptability* criterion.

Insuring the social wellness requires from health devices to avoid the discrimination or exclusion of the user. Indeed, the use of health product can isolate the patient on one side in terms of accessibility (wheelchairs, plaster) and on the other side in terms of isolation from the other as for patients requiring a stool pocket after stoma (removal of bowel). In this way, the criterion of *social exclusion* is specific to a design for health field. Accessibility can be evaluated within the task clarification by the understanding of the need. Regarding isolation it can be evaluated within the conceptual design stage by thinking about the consequences of the illustrated solution. Furthermore, accessibility and isolation can be evaluated in the embodiment design by observing the user experience. Consequently, *social exclusion* is evaluable during the three phases of the design process focused in this paper

To summarized, designing for health involves integrating the *safety, acceptability* and *social exclusion* criteria within the design process in addition to HCD criteria.

SYNTHESIS AND CONCLUSION

In this paper, first, we identify criteria for the evaluation of needs defined by Jordan [6]. We observe criteria of *efficiency*, *feasibility* and *potentiality* to evaluate the functionality of the product. Design team can thus evaluate product's performances of the (*efficiency*), product's viability (*feasibility*) and product's potential (*potentiality*). Usability involves the use of the physiological (*manipulability*) and cognitive (*understandability*) criteria. Pleasure is evaluated through the interest and satisfaction from the device experience (*desirability*) generated by the use of the device over the time (*durability*).

In a second time, we identify the use of criteria throughout three phases of the design process. *Desirability* and *potentiality* criteria fit with task clarification. *Efficiency*, *feasibility*, *potentiality* and *understandability* are useful for evaluating conceptual solutions. For the embodiment design, we show the application of *efficiency* and *feasibility* criteria while materializing a solution and the use of *manipulability*, *understandability*, *desirability* and *durability* criteria during the users' tests.

Finally, we propose evaluation criteria specific to the field of health. S*afety, acceptability* and *social exclusion* are useful in addition to HCD criteria. *Safety,* as risk management, can be evaluated in the conceptual design and the embodiment design. *Acceptability,* fits to the embodiment design and the *social exclusion* criterion can be evaluated over the three phases of the design process focused in this paper.

Therefore, we propose to integrate these health criteria into the HCD design process as presented in Fig. 6.

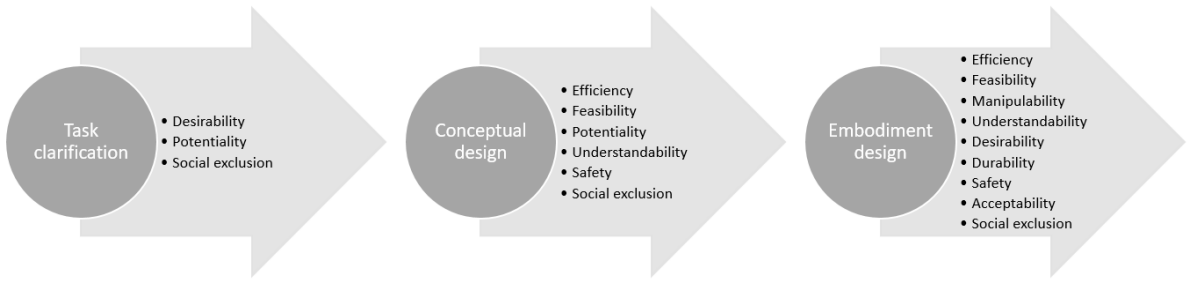

Figure 6: Proposition of criteria for Human Centred design process for health

In this paper we aimed to identify relevant criteria throughout a HCD process for Health. As result, we identified criteria of *safety*, *acceptability* and *social exclusion* in addition to HCD criteria. According to the regulation, designing for Health involves designing for Human. However, we saw that paying only attention to these criteria might lead to underestimate and ignore significant dimensions of the user experience. This omission may lead the patient to refuse its treatments or might cause injuries to practitioners and patients. These serious consequences are in contradiction to the definition of a health product. In this way, we argue to consider *safety, acceptability* and *social exclusion* as much as the HCD criteria. This result needs now to be confirmed by confronting this proposition with study case to validate

these criteria and their uses in a design process for health in collaboration with SC-Ergomedical. This work wanted to present a first step in an approach of design for health aiming to improve the user experience for products generally imposed by the necessity of care and often suffering from a negative images.

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