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ABSTRACT

Participatory design or co-design is defined as the active engagement of all stakeholders in a design process. However, in many co-design projects, only end users are involved. Participants are often considered as the traditional representatives of a generalized stakeholder group, without prior analysis made on each individual's specific interest. These assumptions fail to capture opportunities for integration and satisfy multiple stakeholders simultaneously, which is required to design successful products in complex systems like health care. To maximize the benefit of collaboration, it is important for designers to improve understanding of the participants and their role as a stakeholder in their product's ecosystem.

This study aims to contribute to this understanding by discussing a potential visualization method that maps different stakeholders' interest in the development of new products within the health care system. The method is based on a Multilevel Design Model and was tested by means of a research-based-modeling approach, in which several design experts were asked to map or position several design phenomena on a pre-defined template. Both the selection of the phenomena and the mapping results of the various experts were evaluated through comparison.

A positive correlation was found between the type of expertise of the different experts, and their specific interest in the innovation system. This led to the conclusion that the visualisation method may prove to be a useful instrument for analysing stakeholders at different levels of institutional and nontechnical systems. Therefore, it may potentially help to manage the problem of complexity and resolve equivocality in the design process.

Keywords: Health care systems, data visualization, stakeholder mapping and analysis, stakeholder collaboration, co-design, co-innovation,

1. INTRODUCTION

Involving various stakeholders during the development of new products and services is an increasingly important issue for designers (Binder et al., 2008). While much attention of designers is given to end-user involvement, for instance through concepts like participatory design, co-design and co-innovation, the role of other stakeholders in the design process is a relatively new area of attention. These various co-design approaches may be very helpful to create a better fit between the product and users' needs, and may certainly improve the satisfaction of end-users or customers. However, specifically in the area of health care innovation, the end-user is most often not the only stakeholder involved. First of all, in many cases several end-users can be distinguished, like health care professionals, technicians, patients and family. Furthermore, none of these end-users may end up to be the decision makers that decide to buy and adopt the product, as these decisions may be taken by the purchasers of the health care organization, or even by the policy makers that decides what

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products are eligible for reimbursement by the insurer. This means that designers need to take into account the demands of many other stakeholders and decision makers during the design of new health care related products.

One way to handle stakeholder involvement is to run co-design sessions, by bringing individuals together in non-hierarchical environments. Although participatory design, or co-design may be defined as the active engagement of all stakeholders in the design process- including employees, partners, customers, the general public, and end users (Binder et al., 2008, Floyd et al., 1989, Kujala, 2003) in most of those sessions only end users are involved. Besides, in these co-creation sessions the participants may often be considered as traditional representatives of a generalized stakeholder group. In most cases, there is no prior analysis made on the individuals about their potential contribution or their actual role in the innovation system. These role assumptions may fail to capture opportunities for integration and may miss out on the opportunity to satisfy multiple stakeholders simultaneously, which is required to design innovative products and entrepreneurial strategies (McVea and Freeman, 2005). To maximize the benefit of collaboration, it is important for designers to understand the role of the various stakeholders in a more exact manner. This will help to clarify their interest and position with regards to a new product's ecosystem.

This study, aims to help clarify the role of various stakeholders in the co-design process, by providing a potential new visual representation of individuals' interest, expertise and role within the health care innovation system. This stakeholder visualisation tool is based on a Multilevel Design Model.

In the following section, some more background information will be provided. First, the concept of stakeholder as being applied in this paper will be explained, and a short history on stakeholder analysis will be given. Then, it will be explained how end-users and other stakeholders are currently involved in the experience/ trial phase of new products in health care. Finally, the background of the Multilevel Design Model is being explained, including the reason for selecting this model as the basis of the new stakeholder-mapping tool.

1.1. STAKEHOLDER ANALYSIS AND MAPPING

A stakeholder can be defined as "any individual, group or organization, who can be positively or negatively impacted by, or cause an impact on the actions of a company, government, or organization" (Floyd et al., 1989, Freeman and McVea, 2001). In some areas, such as organizational management, governance and public policy, there are many stakeholders involved in the achievement of an action; therefore, an analysis is required to find out which groups or stakeholders are deserving or requiring a manager's attention, and which are not (Freeman and McVea, 2001, Mitchell et al., 1997)

Stakeholder analysis may therefore be considered as "an approach, a tool or a set of tools for generating knowledge about actors – individuals and organizations – so as to understand their behaviour, intentions, interrelations and interests and for assessing the influence and resources they bring to bear on decision-making or implementation processes" (Mitchell et al., 1997, Varvasovszky and Brugha, 2000). Stakeholder analysis and mapping is often performed to create a general strategy for the firm and to find out "the degree to which managers give priority to competing stakeholder claims" (Mitchell et al., 1997, Varvasovszky and Brugha, 2000). Therefore, the interests and power is pre-assigned by the companies and the focus of analysis is mostly on firm level.

Research specifically focussing on stakeholder management during the product design process is a relatively new field of expertise. Furthermore, most of the literature on stakeholder management doesn't so much focus on actual

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collaboration during the design process. Instead, it suggests ways of dealing with stakeholders such as: keep satisfied, monitor, manage closely and keep informed (Freeman, 2010). Tools that are focussed on actual collaboration during the design process may address limited parts of the system, such as workflow management or web-based-work-flow systems. These do not approach the involvement of various stakeholders during the design process in a holistic manner.

1.2. STAKEHOLDER INVOLVEMENT IN INNOVATION IN HEALTH CARE

In health care, end-users are being studied during the design process in order to understand the current product or service experience through their perspective. The approach is mostly based on inductive reasoning, creating general user needs that can be translated to specific product requirements, based on individuals' experiences. Some tools being used for this purpose are patient journey mapping, practitioner portrays and summary cards. Although each of these tools offers a valuable contribution to the design process, they most often specifically focus on the involvement of end-users, omitting the identification of all of the other essential stakeholders during the product design process

During development and trials of new health care related products, the incorporation of end-users is mostly performed following clinical trial guidelines. A clinical trial in health care design projects may be compared to a user trial in other areas of design, since it mainly aims at evaluating the intended effect of a new intervention, although it might also measure other than the user aspects. The difference of a clinical trial, compared to a classical product user trial, is the fact that the procedure is controlled by specific stakeholders holding certain responsibilities and authority, such as medical ethical and technical committees of hospitals. Also a clinical trial must be performed and reported under specific rules in the health system. In health care the intended effect of a new product is often called the 'efficacy of the intervention', and a clinical trial is mostly performed through randomized controlled studies (Abdel-Aleem, 2009; Mitchell et al., 1997). Furthermore, in regular user tests designers usually plan the sessions and tell the users about their plan, and then leave the decision of attendance to the user. However, in health care related projects, one more pre-step is involved: Any effects and possible side effects of an intervention (like the application of a new product) should be considered and reported to health organizations, in order to get permission to reach the end-users (Abdel-Aleem, 2009).

Greenhalgh et al (2010) reports that in health care innovation projects, the process of involving users was found far more time consuming and labour-intensive than the initial anticipations (Greenhalgh et al., 2010). Clinical trials end with a clinical trial report. A clinical trial report includes: 1) A definition of the product / prototype and the means and level of intervention 2) A description of the primary users, patients and health professionals including the level of interaction and the effect of intervention 3) The health organization and their involvement and requirements 5) The funding partner of the clinical study 6) The organization that the report intends to address the results to. Clinical Trials might be required in various stages of product development such as certification and reimbursement. Furthermore, as Berwick (2003) states, "unlike those in other industries, health care innovators tend to publish their work" (Berwick, 2003). So at the end of clinical trial processes, the results are in many cases shared with communities through academic journals (Berwick, 2003; Greenhalgh 2010). In this paper, some of those reports will be used as a data source.

1.3. SYTEMS APPROACH AND MULTI LEVEL DESIGN MODEL

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This paper will evaluate the potential use of a new stakeholder-mapping tool, which is based on an existing Multilevel Design Model (MDM). This is a design supportive model, which has been developed to give insight to designers in the development of a product or service in a holistic manner, by visualizing design and innovation processes, as well as societal transition processes, in a hierarchically structured way. It has been used to describe the design of new products and services, in relationship to the changes that may occur in the systemic ecosystems that these products and services are part of. The Multilevel Design Model combines two features of existing design and innovation models (Joore, 2010, Joore and Brezet, 2014)

1-) A cyclic iterative design process: Describes the main phases of development of a product or the change in a society in a similar manner. Process stages are: Reflection on the initial problem, Analysis (the plan to change the new situation), Synthesis (creating the solution which changes the situation) and Experience (experiencing the new situation), after which follows again a reflection, but now regarding the new situation. These phases are being described by the four columns in Figure 1 (See Figure 1).

2-) A hierarchical system approach: Provides extrapolation towards more specific (downward) or to more general (upward) system levels for each processes and action. Hierarchy Levels are: Product-Technology Level (P), which is focused on the physical product or artefact, Product-Service-System Level (Q) which is service related, focusing on the function that the product delivers for the end-users, Socio Technical Level (R), which is more organization related, also incorporating the necessary infrastructural elements, and Societal level (S) focusing on the change of society and the value the product contributes.

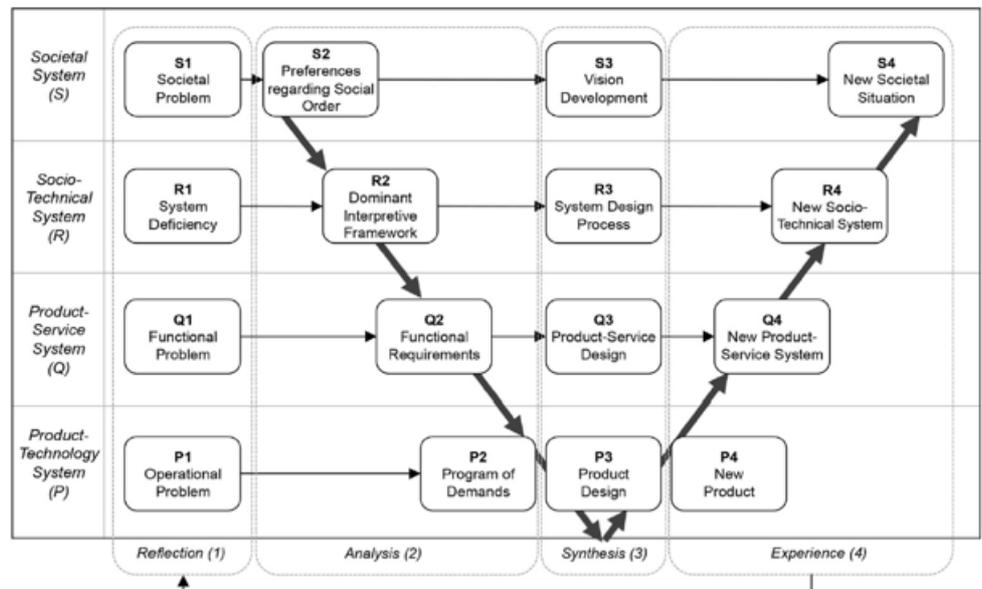


Figure 1 – Multilevel Design Model, representing four design typical phases and four hierarchical system levels (Joore and Brezet, 2014)

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2. RESEARCH METHODOLOGY

To investigate the potential benefits of the stakeholder visualization tool, four design experts applied the new analysis framework, which was based on the Multilevel Design Model. First, the experts were asked to analyse several health care design cases, based on scientific journal papers describing these design projects in a structured manner. From each of the cases, they were asked to identify all the phenomena or elements that, according to them, were most relevant to the product design process in health care. Then, they were asked to map these phenomena on the appropriate cells of the analysis framework, which is the new visualization tool. Then, a comparative analysis was performed, relating the results of the different experts to each other. The outcome of this comparison was presented to the experts to verify if they recognized the outcome of the analysis, for instance with regards to their specific interpretation of a certain phenomena. This feedback was included in the final outcome of the research. The research was divided in three main steps: 1) Selection of Data Sources, 2) Data collection and 3) Data analysis.

2.1. Selection of Data Sources

To compare several design projects in health care, a description of several empirical product development projects were used, based on scientific journal papers describing these projects. By using these papers, the description of the cases could not be influenced by the researchers themselves, which may have led to case description specifically tailored to suit the newly developed stakeholder analysis tool.

The case studies were focussed on empirical case studies and descriptions of user trial of new products. The description of the case studies was taken from secondary resources, being scientific journal articles (n=8), which were collected by a purposive sampling method through a peer-reviewed journal database (Scopus). Inclusion criteria were 1) to be a journal article, 2) to include user/clinical trials 3) to be published in English. The selection of the journal articles was performed by using the search words, databases and time slot as mentioned below:

Search words: "Online Gaming", or "Gaming", or "Games" or "Wii" or "X Box" or "Serious Games" or "Meaningful Play" AND "Healthy aging", or "Gerontology", or "Elderly". Database: SCOPUS. Timeslot: From 1980 to 2013

The scientific articles used by experts were listed in the appendices. (See Appendix 1)

2.2. Data Collection

The data collection was performed in six steps: 1) Selection of Experts; 2) Design of Analysis Framework; 3) Preparation of Data Analysis Package; 4) Selection of Design Phenomena by Experts; 5) Clustering of elements; 6) Mapping Elements on Analysis Framework.

Step 1: Selection of Experts I

The experts were reached through snowballing method and according to their background they were assigned to the various levels of MDM (See Table 1). To illustrate, the expert that works on medical device development as an engineer, may be working in the level of Product-Technology and Product Service systems, according to the MDM.

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EXPERT	BACKGROUND	POSITION IN MDM
E1	Specialist in elderly care The chair research group care technology	Product Service System
E2	Professor of Ergonomics Medical Device Development specialist	Product Technology System Product Service System
E3	Specialist in Strategy in innovation Management	Transition among levels from Product-Technology to upper levels
E4	Design Engineer Chair of Open Innovation Department	Overall transitions up to Societal level

Table 1 – Experts, their background and their position according to MDM level

Step 2: Design of Analysis Framework

An analysis framework was prepared to map the results of the case analysis. This framework can be considered as the preliminary stakeholder visualization tool, based on the Multilevel Design Model. Compared to the original version of the MDM, an extra column and an extra row were added to the model in able to perform as an analysis framework and potential visualization tool, in order to provide more freedom to experts (See Figure 2).

ANALYSIS SHEET

The Multi Level Design Model Matrix with an extra Column

	REFLECTION / PROBLEM	ANALYSIS	SYNTHESIS / DESIGN	EXPERIENCE/SIMULATION	OTHER (LEVEL RELATED) FINDINGS
SOCIETAL SYSTEM	Problem:	Analysis:	Synthesis:	Experience:	
SOCIO-TECHNICAL SYSTEM	Problem:	Analysis:	Synthesis:	Experience:	
PRODUCT-SERVICE SYSTEM	Problem:	Analysis:	Synthesis:	Experience:	
PRODUCT-TECHNOLOGY SYSTEM	Problem:	Analysis:	Synthesis:	Experience:	
FINDINGS OUTSIDE OF MDM	All other findings related to Medical Product Development Processes, Innovation Process and Health Care (including Elderly Care)				

Figure 2 - Analysis sheet with added areas to MDM illustration (based on Joore, 2010)

Step 3: Preparation of Data Analysis Package

A Data Analysis Package was prepared and sent to experts. The Data Analysis Package included a short description of the various MDM levels, a longer explanation of the model including several examples, the scientific journal articles that were selected for the analysis, an article analysis framework on A3 size, an example A3 form.

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Step 4: Selection of Relevant Elements by Experts

Experts were invited to make their individual sense of the data in the given articles. Each of the stakeholders was asked to identify the relevant phenomena or elements in the journal articles that, according to them, represented the most important elements in the health care innovation process. These were defined as the elements, which according to the experts had to be included in a model that describes the product development process in health care.

Step 5: Clustering of elements

Experts selected the relevant phenomena in the health care context and analysed populations, interventions, or outcomes in the texts of the scientific articles. These phenomena were then clustered, as some elements returned on several locations in the case descriptions.

Step 6: Mapping Elements on Analysis Framework

The experts were then asked to map the selected phenomena on the Analysis Framework by numbering the relevant elements and then mapping these numbers on the analysis sheet. At this stage, experts used the definitions and explanations of the MDM levels, which was included in the analysis package. If certain element couldn't be placed in the rows or columns of the provided analysis sheet, they could use the added extra column and row in the framework.

2.3. Data Analysis

To be able to investigate a relation between the background of the experts and the pattern of selection of design phenomena, and the placement of these elements on the analysis framework, the data analysis was performed in three stages:

Data Analysis stage 1: Comparing various expert regarding similar cases

The results of the various experts with regards to identical cases were compared with each other to identify the similarities and differences in their perception of the model. In this stage, the unit of analysis was if the results of different experts differ with regards to an identical case description / the same journal article. Therefore, by looking at the commonalities between the cells and the overall filled areas in the model, the results of the various experts were compared for each article.

{Article (1-n=8): Results (Expert 1, Expert 2, Expert 3, and Expert 4)}

Data Analysis stage 2: Comparing different cases made by one Expert

In this stage, the results of each expert where compared with regards to the different case descriptions that they analysed. This helped to see if the patterns of information selection and the overall filled areas in the model could perhaps show a certain identifiable pattern. In this stage the unit of analysis was if the experts have a recognizable pattern of information selection. Does the data selection pattern of an expert give clues about the background of the expert? Therefore, by looking at the commonalities between filled areas, the results of an expert were compared among all his/her articles.

{Expert (1-n=4): Article 1, Article 2, Article 3... and Article 8}

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Data Analysis stage 3: Feedback of results with experts

The initial analysis was made by the primary author of the paper. These preliminary outcomes were then presented to various experts. They evaluated and commented on the findings, based on which a final analysis was made.

3. FINDINGS

3.1. DIFFERENCES AMONG THE RESULTS OF DIFFERENT EXPERTS ON ONE ARTICLE & INTEREST AND POSITION

Comparing the results of various experts with regards to identical case descriptions / journal articles, it was seen that experts selected rather different data sets from the same article. By looking at the results of the experts it was seen that expert E2 (See the upper left result in Figure 3) specifically selected data on the product-technology level and the other relevant data about product and trials in the other levels. Expert E1, who is the expert on care technology, mainly selected data on the Product System Level (See the upper right result in Figure 3). Expert E3, who is an expert in strategy and innovation management, selected the transition related data between the levels (See the result at the bottom in Figure 3).

As can be seen from Figure 3, experts reported significantly different results for identical cases (see Figure 3). One possible conclusion of the result was that the experts were interested in the different data sets in the articles. The experts agreed on 'skipping the details of the data they are not so much interested in' and agreed on the correlation between 'the more detailed data selection' and 'their interest points or expertise points' in the articles.



Figure 3 - Example result showing the overview of data selection pattern (Red arrows) of different researchers for an article. (Readability of the text is not important)

3.2. SIMILARITIES AMONG THE RESULTS OF DIFFERENT EXPERTS ON ONE ARTICLE

As can be seen from Figure 4, different experts reported differently with regards to the same phenomena and cells in the analysis framework, with regards to the same case description / journal article (See Figure 4). When examined in detail, it was seen that the amount of data and the level of detail in the data set differed among the experts. It was suggested that the more and detailed data

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selection could be related to the familiarity of each expert in the area, and their specific field of expertise. The experts confirmed the correlation.

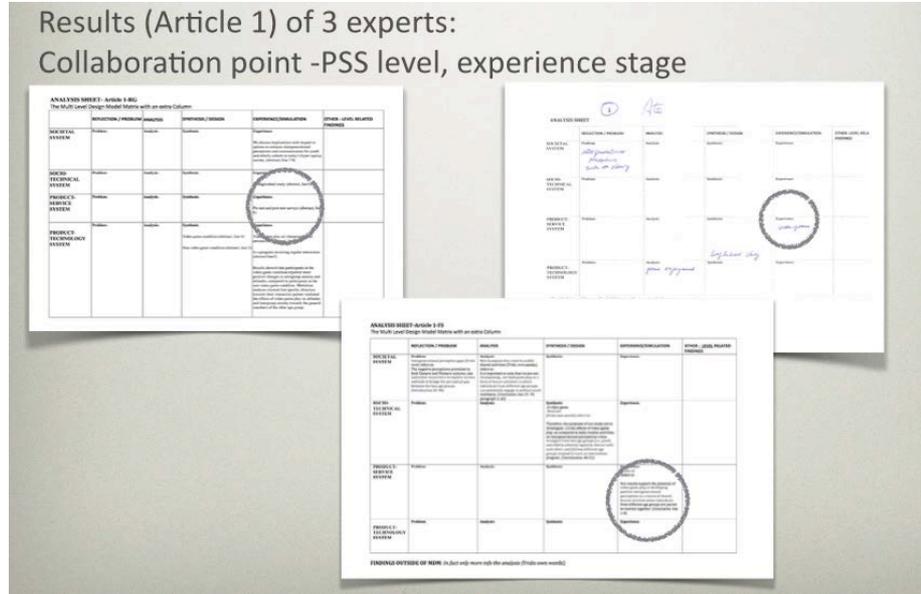


Figure 4 - Results of three experts for the same article, showing juxtaposition area (grey circle) of their findings (Readability of the text is not important)

3.3. DATA SELECTION OF ONE EXPERT FOR DIFFERENT ARTICLES (EXPERTISE)

The selection pattern of each expert appeared to follow similar patterns, with regards to different case descriptions. In Figure 5, the result of Expert E2 for different articles is being presented. With regards to the overall placement of the data of this expert, it can be seen that Expert E2 reported significantly more data on column 4 compared to the other columns (See Figure 5).

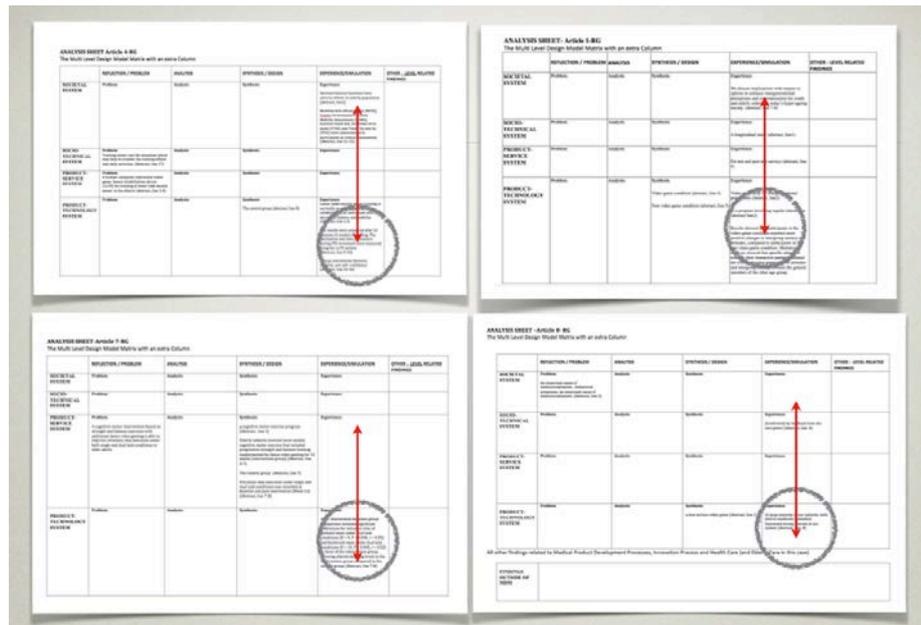


Figure 5 – Result of E2 for four different articles, the selection pattern is marked with red line (Readability of the text is not important)

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4. DISCUSSION AND LIMITATION

In this paper, several experts have been considered as representatives of various stakeholders involved in the product design process in the area of health care. By mapping certain design phenomena or elements to a predefined analysis framework, insights have been gathered regarding the potential benefits of this framework to be used as a stakeholder visualisation tool.

Trials with the design experts show promising results about the future application of the new model. This results show that an adapted version of the Multilevel Design Model may help to map and visualize the expertise and interest of different stakeholders with regards to the product design process in health care. On the one hand, the results of each expert with regards to different cases showed recognizable patterns, as for instance can be seen in Figure 5. On the other hand, the results of different experts with regards to identical cases showed remarkable differences, so it may be expected that the role and interest of specific stakeholders can be identified by means of the specific manner that they fill the analysis framework.

It should be taken into account that this research was conducted with a limited number of experts, so several important stakeholder groups were not represented in this study (Procurement managers, hospital managers etc.). Therefore, the study should be repeated with a broader group of stakeholders for further conclusion. For other stakeholder groups, using clinical trials as the test material might be irrelevant. In this research, as was mentioned above, the clinical trial reports, as written down in scientific journal articles, were particularly used to avoid selection bias while exploring the potential of the new analytical framework. When selection bias is not an issue anymore, other case material can be used, such as product descriptions, marketing reports, and user-trial plans.

Other follow up studies may focus on the reaction of a health technology assessment organizations or government organizations, to determine if the analysis framework could be used to map the interests of those stakeholders as well. Another approach would be to generate specific case material that could be used to determine and map the interest of specific stakeholders during a design project. In this manner, the framework could potentially help designers to select those stakeholders that are exactly necessary during a specific design phase or project.

5. CONCLUSION

By adapting a Multilevel Design Model, this research has made a first attempt to develop a visual mapping tool that may help to identify and map the interest of different stakeholders in a design process, specifically in the health care area. Visually mapping certain design phenomena or elements on a predefined template may help to identify the interest of certain stakeholders during the design process. The outcome of this study supported the expectation that this approach may potentially provide an overarching framework to visualize stakeholders' interest, expertise and intended role in the product design process, specifically with regards to the health care innovation system. The experts involved in the study appear to agree with the level that they represented in the analysis framework, and they also appeared to agree on the mapping of their expertise and interest on the framework. The findings presented here may potentially benefit designers and design managers in planning their collaboration efforts and may support the way that they involve different stakeholders during the design process.

This paper was aimed at new manners to better understand and visualize the involvement of different stakeholders during the design and development

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process in the health care area. In the paper, a new holistic approach regarding the identification and visualization of different stakeholders was offered. This may potentially help to broaden the focus of designers, encouraging them to not only focus on the involvement of end-users, but also to systematically involve other stakeholders in the design process.

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6. APPENDICES

6.1. APPENDIX I

The list of scientific articles used as a data source for experts.

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