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Visualization of Systems and Stakeholders in Health Care Innovation by means of a Multilevel Design Model

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Abstract

In health care, the design, development and commercialization of innovative products is often found frustrating due to the slow inefficient and difficult nature of its systems. One part of this problem is the fact that health systems are highly regulated complex systems that include various stakeholders and unique challenges. Nevertheless, designers and other innovators are often unaware of these unique features of health systems. It is important that designers and managers are able to understand the system, anticipate challenges and account for them in their work.

We therefore aim to establish and evaluate an overarching conceptual model, which can delineate both the systems of health care innovation process and the relevant stakeholders in these systems. This paper reviews the application and potential benefits of one of the promising models called Multilevel Design Model (MDM) by employing an expert-participatory testing on multiple cases in documented clinical reports (n=8). The evaluation of the MDM model followed by further adaptations and changes to the model itself, as well as to the accompanying user guidelines. With some adjustments, the MDM was able to visualize and explain the systems of the health care innovation process in a systematic and shared manner usable for health product designers, innovators and health organizations. We propose the adjusted MDM model for further use in the design and development of health care innovations in order to avoid the typical stagnation of product dissemination after implementation.

Keywords: Medical device design, Stakeholder Mapping, Stakeholder Collaboration, Health Care Systems, Co-design, Co-innovation

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Introduction

Technology, design and innovation play a crucial role to solve an existing need in health care. However, introduction and implementation of innovations is found slower and harder in the health care area as in other sectors (Berwick, 2003; Herzlinger, 2006; Porter and Teisberg, 2006). The complex nature of the healthcare systems with public procurement orientation, heavy regulation (Porter & Teisberg, 2006) and the presence of many incompatible stakeholders (Herzlinger, 2006; Kanter, 2011) are part of the problem. Designers and other innovators are oblivious of those problems (Christensen *et al*, 2009).

Focusing solely on the technology and the benefit of the user may lead to overlooking issues interfering with product implementation such as structures of health organizations and the potential conflicting regulations. Holistic understanding not only of the design process but also of the whole system of interactions and interrelations is thus paramount in the successful dissemination of new products and technologies. A stronger collaboration with stakeholders in all stages of the innovation process can mitigate some of the problems and help account for the needs of all involved parties.

An overarching conceptual model, which describes the healthcare system and explains the product development process in parallel to the development of service and care delivery, could help increase acceptance and implementation of health products. Such a model should visualize the way in which the new product/innovation interferes with the other processes (e.g. care service design, policy development, health technology assessment) within the whole system and help provide a shared understanding among all actors and stakeholders involved in the innovation process. By enabling involved parties to see how the innovation intervenes with their current responsibilities and what changes are needed from their part in the whole system, acceptance and understanding can be fostered. In this work we aim to evaluate the Multilevel Design Model (MDM) in order to see whether the model can serve as an overarching and holistic model for describing the product development, service development process and socio-technical processes in health care and if the model provides shared understanding among diverse stakeholders.

Key stakeholders of Health Care Innovation

There are three main stakeholders groups identified:

- Primary users: patients, care professionals or doctors
- Secondary users: maintenance workers, and operators
- Other stakeholders: health ministries, local, regional and general governments, public agencies, private sector, patient groups, professional groups. (WHO, 2010)

A magnetic resonance imaging (MRI) machine, for example, is approved by budget responsible, purchased by technical service, prescribed by physicians, operated by technicians and health

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professionals, used on the patient and finally cleaned and repaired by maintenance. If the designer only focuses on creating extra value for the patient or operators, the cheaper solution might be chosen over the better-value product (Porter and Teisberg, 2004).

Multi Level Design Model

MDM is a design-supportive model which has been developed to provide designers insight into the development of a product or service in a holistic way by combining two former models (Joore, 2010; Joore and Brezet, 2014) and visualising design and innovation processes as well as societal transition processes in a hierarchically structured way.

The cyclic iterative design process describes the main phases of product development and the societal changes similarly. The process stages are: reflection on the initial problem, analysis (plan to change the situation), synthesis (creating the solution) and experience (experiencing the new situation), after which follows another round of reflection now regarding the new situation (Fig. 1).

A hierarchical system approach provides extrapolation towards more specific (downward) or more general (upward) system levels for each process and action. Hierarchy levels are: product-technology (P), which is focused on the physical product or artefact, product-service-system (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 incorporating the necessary infrastructural elements, and societal level (S) focusing on the change of society and the value the product contributes (Fig.1).

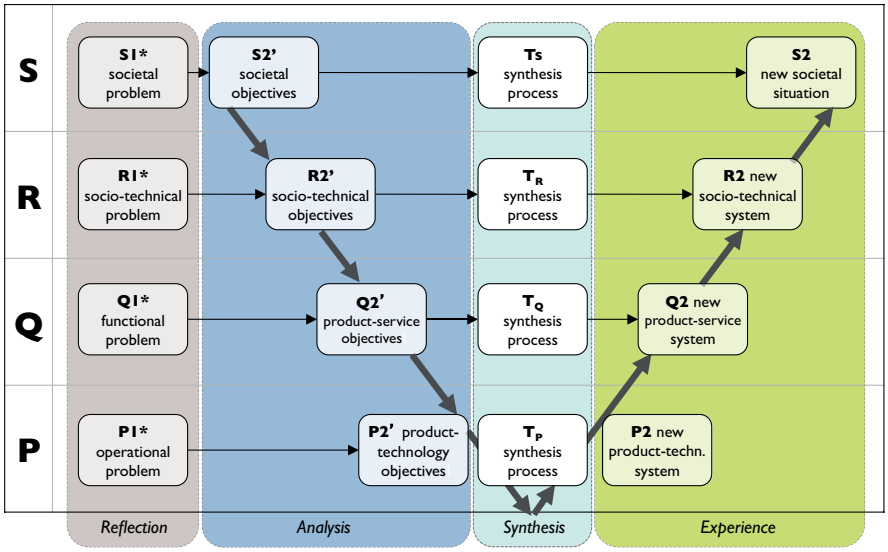

Figure 1: Multi Level Design Model, representing four design phases in four hierarchical system levels (Joore and Brezet, 2014)

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Methodology

The research included four parts: data preparation, data collection, data analysis, and synthesis, feedback and model adjustments. Figure 3 provides and overview.

1. **Data preparation:** Preparation of data analysis was undertaken in two stages 1) Empirical cases were selected though journals to avoid biased approach 2) Data preparation was performed by selecting experts and preparing data analysis package. The experts were selected according to their experience in the medical/ health care area. Four experts were chosen with a diverse experience in health innovation processes. Real empirical case studies were selected to avoid bias by tailoring scenarios to the model. Case studies were taken from published, peer-reviewed articles (n=8) employing a purposive sampling using the Scopus database. An analysis framework was prepared to see performance of the model among experts and it included the MDM model with empty cells, and cells for other areas added for findings that considered important but couldn't be placed in the MDM model (Fig. 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:	

All other findings related to Medical Product Development Processes, Innovation Process and Health Care (including Elderly Care)

FINDINGS OUTSIDE OF MDM	

Figure 2: Analysis Framework

2. **Data collection**: Experts were invited to identify the relevant phenomena the most important elements in the health care innovation process presented in the cases and to map the selected phenomena on the analysis framework by numbering the relevant elements and adding these numbers to the analysis sheet. At this stage, experts used the definitions and explanations of the MDM levels, which was included in the analysis

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package. If certain element could not be placed in the rows or columns of the provided framework, they could use the added to an extra column on the sheet.

3. **Data analysis:** The data analysis was performed in three stages: an *expert analysis* was done to investigate the relation between the background of the experts and their pattern of selection of design phenomena. Subsequently an *in-depth data analysis* was performed, investigating whether an overall hierarchy of similar data elements was used by different experts, analysing how experts placed data into the analysis framework (Fig. 3) and comparing which case phenomena were mostly used among experts. Finally a *case analysis* was performed to list similarities and differences related to the sought phenomena between cases.

Expert Analysis:
Experts were assigned to levels according to their background and occupation, which serves to understand where the expert stands within the overall hierarchy of the health care system.
In-Depth Data Analysis:
In order to gather insights into the experts' understanding of the stages and processes within the model, the use of hierarchy (rows in the framework) was investigated and different case results were compared within each expert to establish similarities and differences between the cases. Then each case result was compared between different experts to understand how different experts place similar phenomena into the framework.
Case analysis:
The phenomena (i.e. the elements considered to be a health care innovation by experts) identified for each case were analysed and sorted into three categories: 1) type of innovation, 2) properties of the trial performed and 3) the type of end-users involved in the trials.
The results of case analysis were used to evaluate the outcomes of the in-depth data analysis.

4. **Synthesis, feedback and model adjustments:** The findings of all three analyses (in-depth data analysis, expert analysis and case analysis) where synthesized in order to evaluate and explain the findings. During group-sessions the obtained results were presented and discussed and feedback was sought from the experts in order to confirm, adapt or dismiss our findings. During these sessions, other design models were included and compared, and the MDM model was adjusted according to the outcomes of the discussions (Fig 4).

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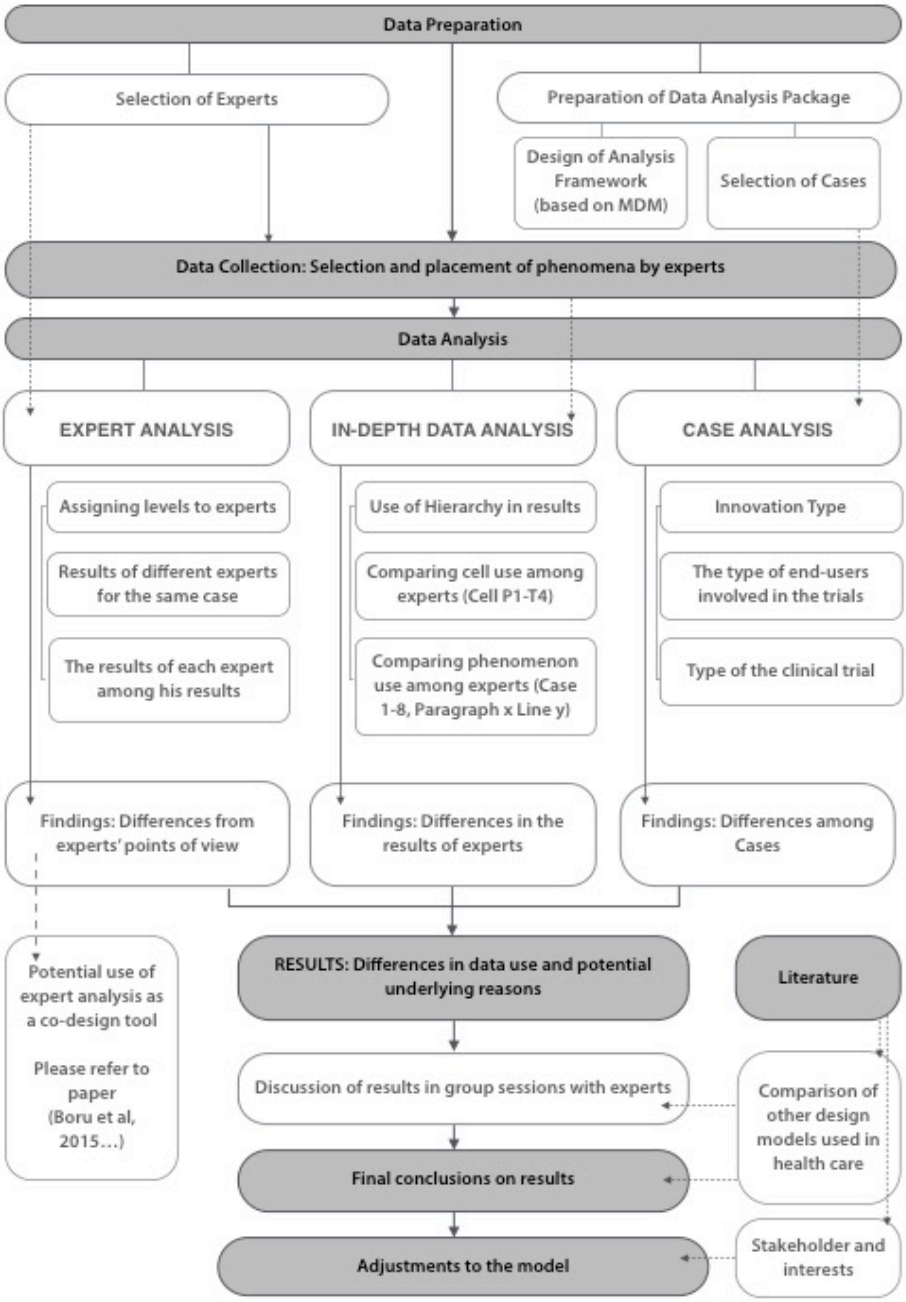

Figure 3: Overview of research methodology

Results

The general hierarchy of phenomena positioning within the framework showed a similar pattern among all experts. The phenomena "technological properties of the product" was consistently placed below the phenomena of "medical professional opinions" or phenomena related to

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hospital. Exceptions occurred between Socio-Technical and PSS levels, as well as between PSS and Product-Technology levels. On the example of "clinical trial" we observed that some experts (n=2) placed two different phenomena in the same level (PSS) while others separated it between Socio-technical and PSS levels. The column called 'reflection' gave the most similar results among experts. There were some differences in the synthesis cell, but most different results were seen in the "analysis "column. Experts selected similar phenomena in diverse levels. For example, all experts selected methodology or the tool of the clinical trials. While some experts (n=2) selected the details of the clinical trial and elaborated on its use in the model, others grouped it as clinical trial and placed it into one single cell. The findings of experts and the case analysis results were synthesized with the results of expert analysis and cases analysis in order to explain the main findings.

Underlying Reasons

Results were grouped as differences in the levels of the system, differences in the stages of the process and differences in the phenomena use. Similar elements in the different rows of the analysis framework can be explained either by confusion of understanding of the levels of the model or inadequacy of the amount of rows in the model. This will be illustrated by the following examples from the results.

Example 1: Cases including a technological product aiming at behaviour change

It was seen that if the case included a technological product aiming to change a behaviour (Case 1. A game to motivate elderly), 'the product properties and trial' (data element) was placed in the synthesis column = (by all experts, shared understanding). However, in the rows: it was placed in the different levels. The levels chosen and the reaction of experts are below:

- Product-technology level, Expert 2's reaction: "it is the basic function of the product"
- Societal level, Expert 1, 3's reaction: "technology is changing behaviour of people"
- Product service system, Expert 4's reaction: "health professionals were involved"

Example 2: Cases including a technological product aims to improve a complication of a patient tested with health care professionals

It was seen that if the case included a trial of a technological product on patients and the test was performed by health care professionals (Cases 2, 4). 'the trials' (data elements) was placed in the experience column (shared understanding). In the rows it was seen in different levels. The different levels and the reaction of experts are below:

- Product-technology level. Expert 1,3 reaction: "technology aims therapy (ie. muscle improvement)"

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- Product service system. Expert 2,4 reaction: "simulations with health professionals"

It was further discussed in the group session that clinical trials might be done in product technology Level: e.g. Therapeutic-effect measurement or PSS level, e.g. the efficacy of an intervention. Since clinical trials are important element of the design of medical or health devices, it was decided that the experience column might need to be more specific in each level.

Differences in the columns are related to cases in which pre- and post-intervention analysis is performed to measure interventions, experts placed pre and post results differently. Some experts divided pre-results to preparation and the others places both in experience.

'Societal problem', 'the product properties', 'the settings of the trial the methods of the trials', 'the health professionals', and 'the organizations' were the common important health innovation phenomena defined by experts. It was observed that background and interest of the experts was correlated to the detail of the data selection.

Stakeholders: Some experts (2) included stakeholders as important elements, and placed them in diverse cells in the process level. One expert (1) included and placed it next to the empty cells in the framework, and one expert (1) skipped the stakeholders as important elements. In the group discussions 'including stakeholders in the system' was found 'potentially useful'.

Adjusting MDM to Health Care Systems and Stakeholders

The following changes are recommended to explain the design and innovation processes and the unique properties of its socio-technical system specific to health care. The final model with adjustments can be seen in figure 5:

Adjustments for Health Care Systems

To adjust the layers, one more level between PSS and Socio-Technical system levels can be added, due to many organizations involved in the health care system. Socio-technical level in MDM might be divided into two different levels as 'organizational level' and 'socio-technical level'. Jones (2013) confirms the more layer hypothesis in the socio-technical system of health care systems; and defines the socio-technical system in three layers: work-unit level, organization level and industry level (Jones, 2013). Therefore, "organizational" level, as the intermediate level in the socio-technical system can be added under socio-technical level and above product service system level in MDM. We added stakeholder and interest columns to the model because providing an overview about the potential stakeholders or other actors is important.

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Adjustments to improve shared understanding among stakeholders

Results showed that there were some differences in the understanding of model by experts. In order for model to be understood and used correctly by various stakeholders, it should fit into the medical terminology and the jargon of health professionals and other stakeholders in health care.

The pre-and post-clinical trial results' were separated by some experts in to the cells of 'analysis' and 'experience'; while others put both pre-post results in the 'experience' cell. This diverse use might be because of the confusion related to a common use of the word "Analysis" differently by diverse stakeholders. For example, the word "analysis" is used in the process of user trials, clinical trials and in market analysis.

Changing the term "analysis" to "preparation" for example might bring further clarity. Explanation of the model might use the definition "the initial work that leads to design decisions" to refine the stage. These amendments help avoid, potential confusions. To clarify the function of the column, the word "trials" could be included in the definition of "Simulation" column along with guiding examples. Some explanations for "tests" and "tools" can be further explained. ('Tests' in this section might include, Clinical trials etc. Intervention studies, controlled study, 'Tools' in this section for the tests might include: Pre-Post tests, Clinical tests (e.g. One leg standing test), evolution of interest of patients over time, measurement of cognitive functions etc.)

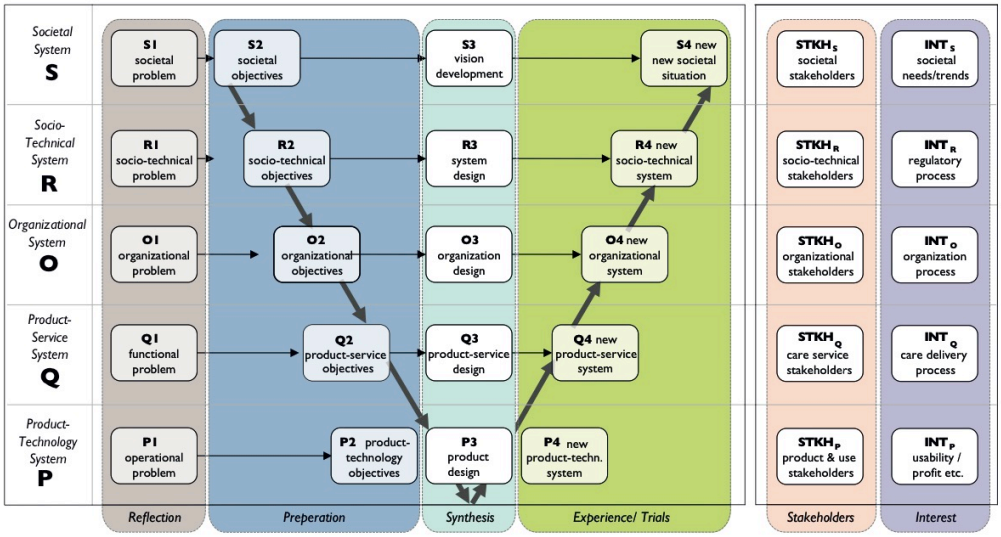

Figure 4: Visualization of health care innovation systems and stakeholders (Based on Peter Joore, 2010; Jones 2013)

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Limitations and Directions for Future research

This research was conducted with a limited number of experts acted like the representatives of stakeholders (medical device engineer, designer, design manager, health policy advisor) in their professions, and several other important stakeholder groups were not represented in this study (e.g. health assessment organizations, regulatory agencies). Therefore, feedback from health organizations and regulatory agencies would be valuable to confirm the suitability of the model in their development processes. For design managers other case materials can be included, such as product descriptions, marketing reports, and user- trial plans and policy documents to be used in their design projects.

Conclusions

Research reported in this article aimed to demonstrate if MDM could provide an overarching and holistic model for describing the product development, service development process and socio-technical processes in health care. It is concluded that an adapted MDM has the potential to achieve aforementioned. Those adjustments can be summarized as adding an organizational layer since organizations play an essential role and adding the stakeholder related columns to the model to guide the design/ innovation process. Adjustments related to use of the terminology and improvements in definitions are also required to prevent misunderstandings.

The article also contributes to the model development approaches in design science related to validation of theoretical models. The elements of the MDM provided "bins" containing categories such as 'problem in the product technology level', 'problem in the product service system level', 'experience in the product technology level', etc. Those bins helped in data collection to be selective – to decide which variable are most important, which relationships are likely to be most meaningful and, as a consequence, what information should be collected and analysed at the beginning (Miles and Huberman, 1994). In this way it helped to specify what should be explained in the model and what can and cannot be explained by the model.

Furthermore, the sub-findings related to expert analysis showed promising results about the application of the expert analysis methodology, as a co-design tool for designers and our future studies will include the development of such a tool.

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