USER INVOLVEMENT IN PHARMACEUTICAL PACKAGING DESIGN – A CASE STUDY

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Abstract

Different levels of user involvement in product design range from understanding user needs to co-designing with users. Previous research shows older patients face difficulties to handle the medication packaging. Yet the participation of older patients in pharmaceutical packaging design is underexplored. The purpose of this study is to explore the role of older patients in the design and development of pharmaceutical packaging. Two empirical examples of one drug manufacturer and one pharmaceutical packaging supplier build one case study. The findings reveal new pharmaceutical packaging development starts with market research about patients' populations. The packaging development is then led internally or with external partners. Later, patients test the packages concepts developed. These findings go in line with previous research about the involvement of users in industries with a high technology orientation. This study is aligned with the about limited resources in healthcare and contributes with a conceptual framework of user involvement, a useful tool for managers and developers to benchmark their design process.

Keywords: Case study, Design process, Older patients, Participatory design, Pharmaceutical packaging design

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1   INTRODUCTION

Users are an important source of information and critical actors to include in the design process. Demographic trends, such as population ageing, further fuel the debate about how products are developed for, delivered to, and received by older people. This study is particularly interested in looking into the involvement of older people in the design process. Research in the areas of participatory design, inclusive design and co-design evolved as a response to the insufficient knowledge about users, their needs, desires and capacities (Luck, 2003, Redström, 2006). The increasing number of older people puts pressure on the providers of products and services in general, and on health care systems in particular, to offer quality in the extended life (Stremersch, 2008). In contrast, older people are the experts in their process of ageing, and having older people actively involved in designing can help to develop solutions which are meaningful to them (Leong and Johnston, 2016). Recent studies show that users can become involved in co-designing their health care environment (Reay et al., 2016, Herriott, 2017, McColl-Kennedy et al., 2017). Additionally, design researchers express a growing interest in shifting the involvement of older people from later to earlier phases of product development (von Hippel, 2006, Essén and Östlund, 2011).

An important consequence of ageing is the extensive use of medication, especially due to the increase in chronic diseases such as arthritis, cancer and multiple sclerosis (Zadbuke et al., 2013). While patient-friendly medication (ease and rapidity of intake) can facilitate the treatment (Peláez et al., 2015), pharmaceutical packaging and devices are critical and neglected sources for the correct use and handling of medication. Older patients face many problems with the functional use of medication packages, e.g. difficulties opening the packages, and difficulties with medication management in general (Lorenzini and Hellström, 2016). Yet the understanding of older patients' needs with regard to the use and management of troublesome pharmaceutical packaging remains an understudied field of research (Ford et al., 2016). So far, packaging has been neglected in product development practices (Olander-Roese and Nilsson, 2009). Careful attention to the design and innovation of pharmaceutical packaging and devices is crucial to more effectively serve ageing societies and alleviate resource-limited health care systems, and the pharmaceutical packaging domain is a potential area for increased involvement of users (patients) in the design process.

The purpose of this study is to explore the current role of older patients in the design and development of medication packaging. Specifically, the study starts by asking the question: *How are older patients involved in pharmaceutical packaging development, by whom, and in which phases?* The study explores user involvement within the pharmaceutical context, through the empirical examples provided by a drug manufacturer and a pharmaceutical packaging supplier.

The expected contributions of the study are threefold. First, the focus is on older patients as a potential source to involve early in the design process, especially in the pharmaceutical field where many benefits for older patients can be expected when the design process includes them. Second, this study adds to the current literature on medication packaging, and the debate about involving older patients as possible resources for concept generation as opposed to merely passive users of medication. Third, this study establishes a connection with previous empirical evidence extracted from technically based industries.

Following this introduction, the second section of this paper reviews the literature on user involvement and the notions of older people and their potential as co-designing consumers and patients. The third section explains the methodology applied, based on case-study research. The fourth section then presents the main findings in themed sections, and is followed by a discussion of the findings in connection with previous research. The last section concludes the paper, highlighting the main implications of the study, as well as its limitations and future research.

2   LITERATURE REVIEW

In traditional engineering science, a technology-centred perspective governs (Persson, 2015). Consequently, many technical solutions are abandoned due to "their inability to meet the needs of the users or the organization they are developed for" (ibidem, p. 31). Design, on the other hand, works closely with the user. As a result, in a design perspective, a product is the negotiation between the designer and the communities of use (Buchanan, 2001). However, there are different levels through which users can be involved in the design process, from a user-centred perspective to co-design.

2.1 From user-centred design to co-design

Generally, user-centred design is understood as having an expert(s), who is (are) trained to observe and/or interview users; designer(s), who design(s) artefacts; and a selected group of users, who perform different pre-delimited tasks, test prototypes, create personas or simulate scenarios of interaction (Gould and Lewis, 1985, Sanders and Stappers, 2008). Although planned to permit some user influence on product concepts, the involvement between experts and users is indirect, since users are only allowed to test what has been already developed (Persson, 2015). In the level of user-centred design, one can argue that designers basically look at user needs, and as a result, users are a source of information, with a passive involvement in the design process (Helminen, 2011).

In the level of co-design, users are given the chance to be involved and to participate in the design process at a deeper level. Generally, co-design stands for "the creativity of designers and people not trained in design working together in the design development process" (Sanders and Stappers, 2008, p. 5). In design research, co-design relates to new terminology describing what the participatory design movement has been doing for the past five decades (ibidem).

Lettl (2007) provokes the discussion about the participation of users in the new product development process. According to him, having the right users at the right time and in the right form is an essential capability companies need to develop. Lettl (2007) affirms that a major challenge for involving users would be to systematically identify these users, and to effectively and efficiently interact with them. Lettl's work stresses particular issues of user involvement. Based on his argument, designers and developers should question who the key users or capable users are to involve in the creation process, and how many users should be involved, for how long, and at what cost.

Another important connection of co-design relates to the advancement of inclusive approaches which try to bring users from the margins to mainstream society, such as universal design, inclusive design and design for all (Lorenzini and Olsson, 2015). In general, these approaches have different origins. Ron Mace started universal design in the US, at the Centre for Universal Design at North Carolina State University (Mace et al., 1997). Universal design emerged together with the disability rights movement, and the growing field of assistive technologies. Inclusive design based in Cambridge, England started with posterior war conflicts (e.g. the Vietnam war) (Clarkson and Coleman, 2015). Design for all has its origins in Scandinavia, closely related to public and voluntary sectors (Burrows, 2013). Despite their different roots in time and place, these approaches have common ground. They brought to life a new line of thought as to who would be able to use products, and who would be excluded from using those products because of the design of the products (Clarkson and Coleman, 2015).

Importantly, these design approaches remind us that we are possibly acting in the middle of two extremes when it comes to the challenges of ageing. Either people are not consulted at all, and as a result end up using products which do not take any consideration of their capabilities; or designers focus on designing for older or people with disabilities, without necessarily involving them in the design process, which just perpetuates the stigmatisation of *being older* or *being blind*, for instance. To avoid this dichotomy of extremes, inclusion is necessary. Heylighen and Bianchin (2013, p. 97) reinforce this idea affirming that "inclusion requires not just to converge *ex post* on perceiving and judging design quality, but to cooperate in the production of it". Users have a lot of *tacit* or *sticky knowledge* – knowledge gathered from the experience of using artefacts – which can complement the explicit knowledge professional designers have about design and its principles (von Hippel, 2006).

2.2 The silver market: patients, consumers or co-designers?

Generally, older people are considered old when they achieve the retirement age, around 65 years (World Health Organization, 2016). By that time, people have entered the what is known as the third age, or as Essén and Östlund (2011) define it: "people fully or partially leave the job market, careers and the most demanding family obligations, but still live a life of relative independence from the support of others". Some authors label older consumers as the silver or greying market (Kohlbacher et al., 2008).

The silver market has two important characteristics: first, people now have a longer life, with many additional years, which stretch beyond their retirement age. This means more time as consumers of products and services of all sorts. Second, older people share characteristics of "the acquisition of progressive multiple, minor impairments predominantly related to sight, hearing, dexterity, mobility and cognition" (Coleman, 1999), which consequently might impact on the use of those products and

services. In becoming older, people might end up living with chronic diseases, which demand the use of supportive products for health care and a great intake of daily medication (Zadbuke et al., 2013).

The decrease in older people's abilities associated with the continuous use of medication commonly leads to the perception of older people as passive users of products. This passive view is judged negatively by authors in the design field. Schmidt-Ruhland and Knigge (2008, p. 48), for instance, point out the need to go beyond senior-friendly product design. These authors look at the basic design concepts, by which "(…) every product is an aid because there are many, many things people generally cannot do". In that sense, all of us are disabled in some way, and we use products as extensions of ourselves to support activities which would otherwise be impossible without those artefacts. However, the development of products and technologies does not always consider what is important for older people, what makes their lives meaningful, and how independently and capably they want to live (Leong and Johnston, 2016). It is relevant to give users a sense of ownership and to find a balance to mobilise these older adults, creating conditions for their participation in the design process (Botero and Hyysalo, 2013).

3 METHODOLOGY

This is a qualitative research paper, which follows an abductive process. Abduction is characterised by the iteration between theory and empirical data (Dubois and Gadde, 2002, Kovács and Spens, 2005). Our research started with the support of theoretical perspectives on participatory design and co-design. As Creswell (2014) explains, researchers can use theories or theoretical perspectives as lenses to guide them to shape questions and data collection in qualitative research. Our theoretical perspectives, as defined in Section 2, place the investigation of user involvement in a health care context. Conversely, the data was collected through an exploratory process, where the understanding of the presence or absence of user involvement was in focus.

In accordance with Yin (2014), the nature of the research questions and the limited knowledge in research about user participation in designing pharmaceutical packaging makes this research suitable for a case study. Case studies have the advantage of being representative examples which put researchers close to real-life situations, through a concrete context-dependent experience (Flyvbjerg, 2006). Furthermore, case studies permit data collection through different explorative methods such as interviews, observations and documents (Baxter and Jack, 2008), which facilitates the gathering of in-depth information from different actors (Yin, 2014, Eisenhardt and Graebner, 2007).

3.1 Selection of the companies and respondents

The case is built on the complementary perspectives of two actors representative of the process of designing medication packaging: a packaging supplier (Company A), and a brand-owner drug manufacturer (Company B). It is assumed these companies are each representative of their industry, and using standard industry practices. Accordingly, and in the same manner as Herriott (2017), no evidence demonstrates that these companies are atypical in their industrial context.

The packaging supplier has its expertise in medication packaging, with national and international projects in the pharmaceutical packaging business. The managing director and the new product development manager were the focal respondents.

The drug manufacturer is a multinational company. The interviews were conducted within the pharmaceutical technology and development area. This area of the company gets the information about the active medical substance for the project and works with the packaging for drug product project. The primary packaging manager, the devices manager, and the smart packaging associate scientist were interviewed.

All the respondents are senior managers, aware of the practices and routines of pharmaceutical development. The choice of respondents was made in consultation with the companies and candidates were selected from each organisation based on how involved they were in decisions and development relating to medication packaging.

3.2 Data collection and analysis

Each company constitutes one case which was cross-analysed and based on the pharmaceutical packaging development process as the unit of analysis. To increase the validity of the case study and

overcome possible biases, we triangulated data collection methods (Kazadi et al., 2016). We used three main data sources: interviews, publicly accessible documents from the companies, and internal documents provided by the respondents.

The interviews were in-depth, face-to-face, lasting an average of one hour and twenty minutes, and transcribed verbatim. The script for the interviews had seven major sections, each with five open-ended and discovery-oriented questions. The transcripts were analysed via thematic coding, inspired by previous research on patient involvement (Herriott, 2017).

We highlight that most of the empirical findings came from the interviews, whilst the documents were used to help the researchers to understand the companies' profiles within the industry, their flows of packaging development, and the companies' positioning in regard to the patients. The interviews with the supplier were conducted first, and with the drug manufacturer five months after. As an improvement in between interviews, at the drug manufacturer's, the respondents were asked to draw the pharmaceutical packaging development process as they perceive it. The drawings were combined into one figure sent to the respondents, and further developed based on their comments. For each case, a case description was sent to the respondents for approval and further changes.

4 EMPIRICAL FINDINGS AND DISCUSSION

In brief, Company A manufactures plastic bottles for medications, produced via injection blow moulding. The company has its own product development department, project managers and tool shop for developing new products. The company has limited internal design resources, and no human factors specialists were internally allocated. Company B is a large multinational drug manufacturer, with three main therapeutic areas for drug development. The site visited focuses mainly on developing primary packages (e.g. bottles, blisters, etc.) and devices (e.g. inhalers).

4.1 The pharmaceutical packaging process

In both companies, we identified two main routes for pharmaceutical packaging development; one via new packaging development, with higher costs and longer-term development, the other via platform packages. Platform packages are existing packages in the company's portfolio, approved according to relevant regulations, and ready for production.

At Company A, the commercial team promotes the platform packaging first to its customers, since these packages demonstrate optimal performance in terms of production and costs. New packages are often uncertain in terms of how they will behave with the drug product, and demand more testing to achieve the optimal performance for production. As a packaging supplier, Company A works to attend the demands of drug manufacturers.

At Company B, packaging development is dependent on drug development, which means the drug needs to pass major clinical testing before packaging development starts. The decision of developing a primary package or a device also depends on the type of drug product. The packaging team at Company B is multidisciplinary. For each project, a team is assembled to lead the process of developing pharmaceutical packaging and to give guidance to packaging suppliers. Figure 1 shows the process of pharmaceutical packaging development, as understood by the respondents at the drug manufacturer's.

	Development of packaging and devices					
Phase	Market assessment	Design and development	Drug product and adaptation	Validation	Technical transfer to operations	Post marketing surveillance
Description	User requirement specification	Concept generation, detailed design, and verification	Adaptation of existing packaging/ device to specific drug project	Human factors studies	Stability tests + manufacturing process validation	Post marketing
Internal responsible	Marketing	Packaging/ device development team	Drug project packaging/ device team			Operations
External partner	Marketing consultants	Design companies, packaging suppliers, special skills consultants		Human factors skill consultants	Packaging suppliers, manufacturers	

Figure 1. Pharmaceutical packaging development process

As shown in Figure 1, the packaging team involves a partner (e.g. a design consultancy, a packaging supplier, etc.) to develop the initial packaging concept. Importantly, the packaging team uses prototypes

or sketches to promote its ideas internally. The intention is to have members of the project to agree with a concept before moving to the detailed design phase. As explained by respondents from both companies, the most common scenario is to invest in platform packages, as they accelerate the process, and are often preferred.

4.2 User involvement methods in the design process

No clear user involvement methods were identified in the studied companies besides standard human factors testing for child resistance and senior-friendly packaging. Another remarkable fact was the focus on user (patient) needs, instead of user (patient) participation.

For new packaging development at Company B, the marketing team is responsible for bringing insights, in collaboration with an external marketing consultancy. For platform packaging development projects, the involvement of end users, e.g. older patients, is very rare and limited to final development phases when testing for child-resistant containers (CRCs) is required. However, for the development of devices such as inhalers, the device team conceptualises *personas*, to help in summarising characteristics and visualising the patient group. The personas are based on the information provided by marketing. Nevertheless, the contact with patients or users in the development of packaging or devices is limited to observations or access to the videos where patients test the new concepts.

Company A is limited in relation to user (patient) involvement, as its focus is on manufacturing and production. For customised projects, external partners can be involved – most likely human resources within the business group or local partners, and national universities. Exceptionally, this company develops its own projects with partners with a focus on usability, as easy-to-open packages. As an example, the development of a package together with a rheumatic patient association was described.

4.3 Challenges of co-designing with patients

By conducting the case study with the companies, one point of interest was to understand the existing barriers or challenges for co-design within the pharmaceutical context. One main finding regards the priorities at the companies. Protection of the drug product, regulations for child-resistant packages, and production costs and optimisation are among the top priorities for pharmaceutical packaging development, which can hinder user involvement.

Protection of the drug product: In the emphasis on design and innovation in Company A, three factors are emphasised: child-resistant features, dispensing ease, and packaging with sturdy sides. Similarly, in Company B, a broader picture shows the stakeholders they considered that are affected by packaging. A top priority is to protect the drug product from moisture, counterfeiting or access by children.

The dilemma of child resistance and senior-friendliness: The respondents are aware that child-resistant containers (CRCs) are not inclusive for patients with weak hands, or older patients, but they face difficulties changing CRCs, due to main regulations and traditions of packaging development in pharmaceuticals. As explained by Company A, some traditional CRCs are maintained in the portfolio because patients already know how to use them, even though product have not been inclusively designed for older people. On the other hand, not every drug manufacturer demands easy-to-open packages or inclusive designs.

Optimisation of operations: Drug manufacturers like Company B, often ask packaging suppliers to come up with new ideas and concepts which are too difficult or too expensive to produce. As explained at Company A, the packaging development team tries to listen to what the marketing or production departments at the customer's require, however the production department usually ends up with the final word. Similarly, respondents at the drug manufacturer's commented that operational activities in the supply chain add a barrier difficult to argue against, if new packaging adds costs to production or distribution.

Technology and adherence: The use of technology in connection with pharmaceutical packaging remains in its latent development, especially in relation to medication dispensing and adherence. Aspects of technology in packaging were more evident in the interview with the associate scientist responsible for smart packaging at Company B. The drug manufacturer works closely with partners to explore alternatives in terms of applications of technology to packaging. These partners come from technology-based firms, and not from active contributions from the users. Yet how to make the use of technology cheaper and how to use patient information in an ethical way are major challenges to overcome, as

emphasised by the associate scientist. The use of technology attached to pharmaceutical packaging has been under discussion, with more advanced explorations carried out by the drug manufacturer. Since internal expertise is lacking within the company, external partners are often involved. However, end users are not the ones leading innovation here and this is emphasised in the literature. The participation of users to explore technology in packaging is still an open opportunity for companies within the pharmaceutical industry.

5 FRAMING USER INVOLVEMENT

The abductive process in research makes possible to re-contextualise individual phenomena within a contextual framework, aiming for new insights and understanding (Dubois and Gadde, 2002, Kovács and Spens, 2005). Based on our abductive process, we can relate our empirical findings to what other researchers have identified.

Former research suggests that "the larger and more prolonged a project is, the harder it becomes to incorporate users in the design process" (Herriott, 2017, p. 2). Our findings align with such a statement. Pharmaceutical packaging development is a long process, where not only design features that attend patient's needs are in play. Nevertheless, we also agree with the following statement that "the need for user involvement (specifically patient involvement) is pronounced even as the difficulty of incorporating patient' preferences increases with scale" (ibidem, p. 2).

Our findings relate to previous evidence presented by Andersson and Lindström (2008). These authors developed a framework based on an extensive assessment of user involvement within engineering and technically based companies. The authors discovered that users have limited participation in detailed design phases when engineers lock themselves inside the firm to develop concepts. Only later users are brought to test prototypes. The findings in our case study in pharmaceutical packaging companies can draw on a similar framework, as presented in Figure 2.

The companies in our case study are part of the supply chain for packaging development, with a dominating technical approach in their businesses. The pharmaceutical business is grounded in drug development as its core (Petrova, 2014), and packaging is a major compulsory part, which focuses on robustness, production optimisation and cost reduction. More user-friendly packages may demand earlier involvement of patients, not only to assess pre-made packages, but also to help developers to create the concepts to be further developed. This is in line with Lettl's (2007) theoretical perspective, which states that engineering-based firms give users a passive role in their development processes. By that, engineers are the ones responsible for developing ideas, technologies and prototypes within the firm, whilst users are then involved at the prototype stage.

Additional evidence from the literature relates poor packaging and labelling design to inconvenience, serious harm and even death for users of medicines (Ward et al., 2010). Previous literature demonstrates that the functional use of medication packages, impaired vision, hand strength and manual dexterity are common difficulties in opening medication packages (e.g. Atkin et al., 1994, Beckman et al., 2005, Mühlfeld et al., 2012, Sormunen et al., 2014). To perform these studies, authors often select a group of patients under certain pre-defined characteristics and test the use of packages, prioritising certain tasks (Lorenzini and Hellström, 2016). The focus on user needs, instead of user participation, is also evident in research related to pharmaceutical packaging design. Moreover, it is noticeable that the stigma of older patients as passive users persists, in that they are not as involved in technological development as authors (e.g. von Hippel, 2006) advocate.
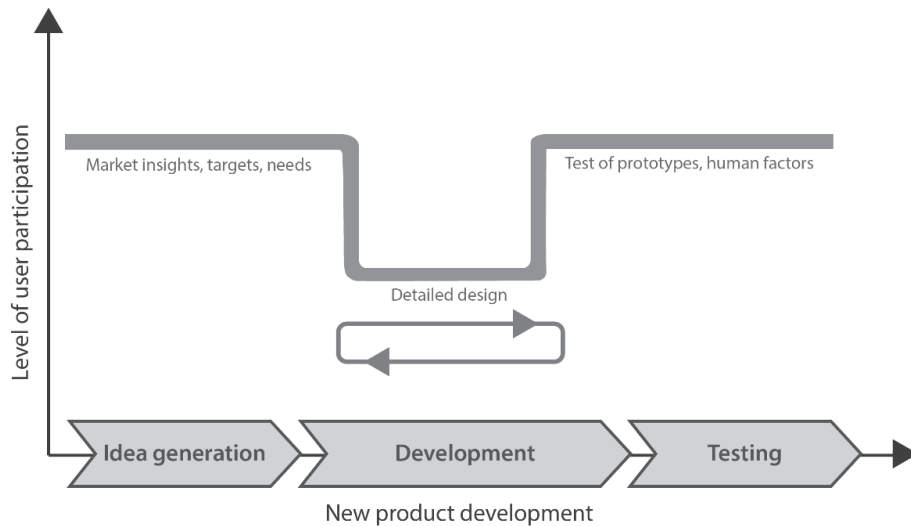
Figure 2. Level of user involvement in design processes

Adapted from Andersson and Lindström (2008)

6 CONCLUDING REMARKS

The case study presented here explores the development of pharmaceutical packaging; an immature field in terms of design and innovation by users. This is still an area where users, as patients, have been struggling with problems with their treatment, mainly because of the way packages are designed. Developing packages which are friendly to patients, but still efficient and effective in the supply chain, seems to be the greatest challenge and opportunity for pharmaceutical packaging development. So far, in the equation of pharmaceutical packaging development, the user part has been neglected.

Therefore, in terms of practical implications, this paper may help managers, designers and developers to facilitate increased user involvement throughout the development process. This research sheds light on the delivery of treatment to older patients. If so many treatments fail today because of the package used, we might consider that this is also because the process of conceptualising these packages and the delivery of the treatment *per se* are not optimal. In that sense, this paper may be helpful to the ones developing packages to reflect about current design practices within a highly technical and innovative industry. The findings presented here can also help packaging developers and managers to benchmark their processes and to review user involvement in the context of health care provision. This contribution is in line with the challenges of public health care. As populations are ageing, older patients often become responsible for being adherent to their treatment and for taking their medication at their own. Research that brings understanding and awareness to the fact that designing packages can help older patients to cope with their treatment represents a small, but yet significant contribution for future ageing societies.

Regarding the theoretical contributions, the agenda in medical research focuses on treatment and cure, where experimental clinical trials prevail. In studies of pharmaceutical packaging and older patients, this is particularly true. A design approach is lacking, and merely testing packages via experiments with older patients is no longer adequate. By taking an approach of investigation aligned with inclusive design theoretical perspectives and co-design, our study adds to the field of user involvement in a context where research is limited.

We understand that our study, designed as a case study, has limitations in term of generalisability of the findings. In addition, the framework presented is still conceptual. The framework reflects the main findings of our case, supported by previous evidence identified in technically based industries. Further research may be carried out to test the framework with other drug manufacturers and stakeholders involved in pharmaceutical packaging development.

Finally, opportunities which arise from patients' use of medication will require more action towards innovation of pharmaceutical packaging. As we foresee, after inspiration by the case presented here, action towards more user involvement will need to be taken collectively by the many stakeholders involved, and not only drug manufacturers.

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