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Listening to Current Practice: Patient Involvement in the Pharmaceutical Packaging Design Process

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ABSTRACT

Multiple functional challenges in the use of pharmaceutical packaging reveal a great need of packaging to be designed inclusively. This study investigates patient involvement in the pharmaceutical packaging design process by analysing interview data from representatives of the pharmaceutical and packaging industry. Four main themes related to patient involvement were uncovered: patient expertise levels, patient involvement modes, factors encouraging patient involvement, and factors discouraging patient involvement. Passive patient involvement modes were found to be dominant due to regulations and a traditional perspective regarding physical testing. However, active patient involvement modes were identified, motivated by empathy and understanding of the lives of patients. The pharmaceutical packaging design process is complex and involves multiple stakeholders. The research findings can inspire more industry practitioners and policymakers to design pharmaceutical packaging that is inclusive and with consideration of a broader spectrum of patients' needs.

KEY WORDS

Design process, inclusive design, industry practice, pharmaceutical packaging, user involvement

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INTRODUCTION

Industrial choices made in design processes account for the final uses of products (design for users) and reflect the way the industry itself perceives and involves users in the design process (design with and by users) [1, 2]. For industries that are not traditionally user-oriented, it can be particularly challenging to be informed by user inputs during the design process. The pharmaceutical industry, associated with the packaging industry, is an example of an industry that is highly regulated and centred on science-based drug development [3], but an industry that has been challenged to deliver more inclusive and patient-centred alternatives to treatment and medication intake [4].

Inclusive design means that when designing products, one should take into consideration users with different skills and (dis)abilities – which makes sense when thinking about the different ways people are affected by a disease and the profound changes that can come to life during treatment. Regarding packaging, researchers have stressed the need for inclusive design in general [5, 6] and pharmaceutical packaging particular [7-13].

Despite its relevance, most of the previous research has focused on the functional difficulties created by pharmaceutical packaging, without paying attention to the participation of patients in the design process [14]. Because of its complex multidisciplinary development, pharmaceutical packaging usually relies on a design process conducted by what could be called a 'design collective' [15]. This means many important design decisions are often not even made by designers, but by people from business development, risk management, and manufacturing who lack training in how to involve users and address their needs by means of inclusive and user-centred design processes. The same kind of design collective as well as limitations to user involvement is expected in pharmaceutical packaging design, where patient involvement has been under investigated.

Thus, this study aims to explore current industry practices of patient involvement when designing pharmaceutical packaging. The point of departure is that independent of the type of medication, a pharmaceutical package will only suit patients' needs if those needs are understood by asking and letting the patients take part in the design process.

This study considers both prescribed medications (those only sold or given to patients prescribed by physicians) and over-the-counter medications (OTCs, medication products that can be marketed and sold to patients without a physician's prescriptions). When it comes to packaging, we consider the primary packaging system level [16], which includes both the inner packaging (in direct contact with the medication, such as blisters, plastic bottles, glass vials) and outer packaging (that contains the inner packaging, such as a carton board box or wrapping). We do so because inner and outer packaging are assessed together by regulatory boards and are viewed as a packaging system that protects and delivers the medication used by patients.

DESIGNING INCLUSIVE PHARMACEUTICAL PACKAGING: FROM MEDICALISATION TO EMPOWERED SELF-CARE

Inclusive approaches, such as universal design [17], inclusive design [18], and design for all [19], have motivated a new design methodology involving highlighting who would be able to use the products of interest and who would be excluded from using them because of their design [20]. Each of these inclusive approaches started at a different point in time and place, but they have a common goal of integrating the mainstream and subsets of the population (e.g., people with disabilities and older people) into the design process. However, inclusive

design approaches in practice often struggle to reach their main goals, either because it is demanding to change policies or because there are budget limitations, time constraints, and an overall lack of perception of the needs of different users [21].

Inclusive approaches to design call for attention to the level of user involvement. A predominant and traditional view of user involvement emphasises the 'expert view', where an expert is trained to observe and/or interview a selected group of users who perform different pre-delimited tasks, test prototypes, or simulate interaction scenarios [22]. As a result, users are a source of information, with passive involvement in the design process [23]. Conversely, a participatory approach unites the worlds of the user and designer and offers more creative and empathic design process techniques [24]. Currently, a participatory approach is often referred to as co-design, which means 'the creativity of designers and people not trained in design working together in the design development process' [22]. By participating and being involved, users are invited not only to perform pre-defined tasks or test already-made prototypes in the design process, but also to co-create and elaborate on concepts via enriched and hybrid forms of collaboration [25].

The call for user participation in design is not new [26]. However, it has only been in recent years that researchers have begun to show a growing interest in the experiences of patients as users of products and services that are essential for their care and directly affect their emotions and well-being [27, 28]. The increasing focus on patients is linked to important social and demographic changes, particularly those pertaining to ageing, with people living longer with chronic conditions and taking multiple medications every day [29]. The expansion of medication usage, referred as 'medicalisation' [30], draws attention to patients' in managing their own care and their agency in taking or not taking their medication [31].

How patients integrate a treatment into their lifestyle can determine its success. In that sense, the pharmaceutical industry constitutes a singular business case in which an inclusive design approach is necessary to come up with pharmaceutical packaging that can be used by a broad spectrum of patients [32]. To motivate the correct intake of medication and adherent behaviour by patients, healthcare agencies and policymakers have called for innovative solutions that can empower patients and make them more active in caring for themselves, especially in the long-term perspective [33]. This fuels the demand for well-designed medication products and tools [34].

A way forward to more inclusive pharmaceutical packaging is to involve patients in the design process. This study looks closer to industry practices in place for patient involvement and to the level of patient involvement in connection to the different phases of the existing design process.

METHODOLOGY

This research intends to answer two research questions:

- How are patients involved in the pharmaceutical packaging design process?
- What encourages or discourages patient involvement in the pharmaceutical packaging design process?

With these research questions as guidance, we opted to conduct semi-structured interviews with professionals who had experienced patient involvement in the pharmaceutical packaging design process. This was supported by a qualitative research approach [35], in which qualitative interviews were performed to gain 'in-depth information pertaining to participants' experiences and viewpoints of a particular topic' [36]. By doing that, researchers have the chance to learn from

accumulated experiences that they could not experience themselves and give the respondents the opportunity to reflect on their own practices.

Respondent selection

The initial respondents were selected via purposeful sampling [37], based on their past experiences with pharmaceutical packaging design and their many years of work experience within the pharmaceutical and/or packaging industry. Additional respondents were added through respondent-driven sampling [38], allowing access to otherwise hard-to-reach respondents within the same or related organisations. As recommended by the literature, we stopped reaching out to respondents when response saturation was achieved [39]. The organisations where respondents worked have an international profile, with products attending a range of markets across the globe, but mostly focused on the European and North American markets. One company is based in Asia. Table 1 presents the 25 respondents in the study.

Data collection

An interview script was prepared with open-ended and discovery-oriented questions, including questions about patient involvement and participation in designing pharmaceutical packaging. In addition to that, other relevant questions were added about the holistic process of pharmaceutical

Table 1. Respondent characteristics

Respondent identification	*Company*	*Position*	*Education*	*Main responsibility*	*Years of experience*
D1	Brand-owner pharmaceutical manufacturer	Director	PhD	Sourcing of new drug projects; experience in packaging/device development	20-25
P1	Brand-owner medical equipment	Executive Director	MSc	Main executive at the company	45-50
M2	Brand-owner medical equipment	Manager	MSc	Management of packaging usability and user experience	5-10
P2	Packaging supplier	Director	MBA	Coordination of packaging teams, product, and market strategies	15-20
P3	Packaging supplier	Manager	MSc	R&D, NPD, and management of the in-house tool shop	20-25
D2	Brand-owner pharmaceutical manufacturer	Manager	MSc	Device development projects	15-20
A1	Packaging association	Executive Board	MSc	Main business of the association, education services	5-10
P4	Packaging supplier	Executive Director	MSc	Management and development of the medical business area	25-30
D3	Brand-owner pharmaceutical manufacturer	Director	Technical background	Management of packaging and process technology innovation	30-35
P5	Packaging supplier	Manager	Bachelor	Product management of pharmaceutical packaging	5-10
M2	Brand-owner medical equipment	Director	PhD	New products and machinery; patenting	30-35
D4	Brand-owner consumer goods (OTC)	Senior Packaging Developer	MSc	Packaging development and packaging strategy	15-20

Table 1. Respondent characteristics, continued

D5	Brand-owner pharmaceutical manufacturer	Principal Scientist	Technical background	Packaging development and packaging strategy	30-35
D6	Brand-owner pharmaceutical manufacturer	Director	PhD	Management of packaging teams and packaging processes	15-20
D7	Brand-owner pharmaceutical manufacturer	Principal Scientist	PhD	Coordination of stakeholders for new technologies in packaging and devices	10-15
D8	Brand-owner pharmaceutical manufacturer	Manager	MSc	Management of packaging development	30-35
D9	Brand-owner pharmaceutical manufacturer	Director	MSc	Growth hacking activities, communication and innovation	10-15
P6	Packaging supplier	Manager	MSc	Portfolio management and market research	5-10
D10	Brand-owner pharmaceutical manufacturer	Manager	BSc	Management of packaging teams and packaging processes	25-30
D11	Brand-owner pharmaceutical manufacturer	Manager	MSc	Management of packaging usability and user experience	10-15
D12	Brand-owner pharmaceutical manufacturer	Manager	PhD	Management of packaging development	10-15
A2	Packaging association	Executive Board	PhD	Management of packaging development	25-30
P7	Packaging supplier	Executive Director	PhD	Opening new markets for the company	25-30
A3	Patient association	Project Leader	BSc	Internationalisation and collaboration	5-10
P8	Packaging supplier	Director	Technical background	Knowledge transfer and business development with customers	45-50

innovation and the packaging design process.

Over an eight-month-long period, one individual interview was conducted with each respondent, with durations ranging from 25 min to 2 h and 17 min, with an average of 1 h and 14 min. Face-to-face interviews were preferred, although telephone interviews were conducted due to geographic constraints in 10 of the 25 cases. Each interview was preceded by obtaining informed consent, and all of the respondents agreed to the audio recording of their conversations. Subsequent follow-ups were conducted via electronic communication and telephone calls for clarification.

Data analysis

All of the audio recordings were transcribed verbatim. Departing from the original research questions, we began by adapting the main steps of a general inductive approach for analysing qualitative data [40], which consisted in the following phases: Phase 0 – Preparation of raw data files and export to qualitative data analysis software (NVivo, QSRInternational); Phase 1 – Close reading of the interview data andinitial themes; Phase 2 – Creation of a theme scheme; Phase 3 – Refinement of the coded and uncoded text; Phase 4 – Assessment of trustworthiness. Figure 1 summarises the data analysis process.

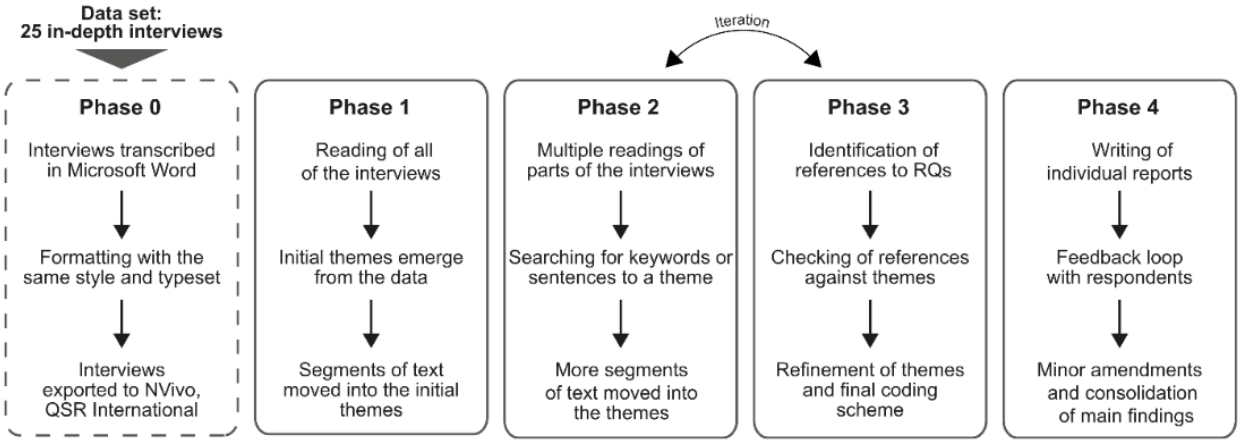

Figure 1. Data analysis process

Table 2. Final coding scheme

Main theme	***Subtheme***	***Main literature support***
Level of patient expertise	Pre-patient Experienced patient Patient advocate	[41] [42] [43]
Patient involvement modes	Ethnography Talks by patients Co-creation workshop Rapid prototyping and visualisation workshop Usability studies Formal patient feedback	[26] [44] [45] [1]
Factors encouraging patient involvement	Understanding actual usage Creating empathy with patients Compliance with regulations	[46] [47]
Factors discouraging patient involvement	Who to involve and when to involve them Available resources What is allowed	[21] [47]

By successive re-reading of the raw data, relevant segments of text were classified according to the initial unstructured themes and subthemes until four main themes clearly emerged by the end: patient expertise levels, patient involvement modes, factors encouraging patient involvement, and factors discouraging patient involvement. Table 2 presents the final coding scheme.

ANALYSIS OF KEY FINDINGS

In the following sections, we present and analyse the key findings that emerged from the interviews. Selected quotations illustrate how the respondents expressed themselves and synthesise some of the key findings. Minor edits of the quotations, enclosed in brackets, were made to facilitate comprehension – for instance, pauses or broken sentences were removed.

Patient expertise levels

Users have different expertise levels depending on their previous product usage [41]. We identified respondents were concerned with the patients' level of expertise and patients' awareness and acceptance of their own health conditions. Figure 2 illustrates the three patient expertise levels emerged from the interview data: pre-patient, experienced patient, and patient advocate.

Pre-patient

A pre-patient is considered a naïve patient who has just become aware of the disease or condition.

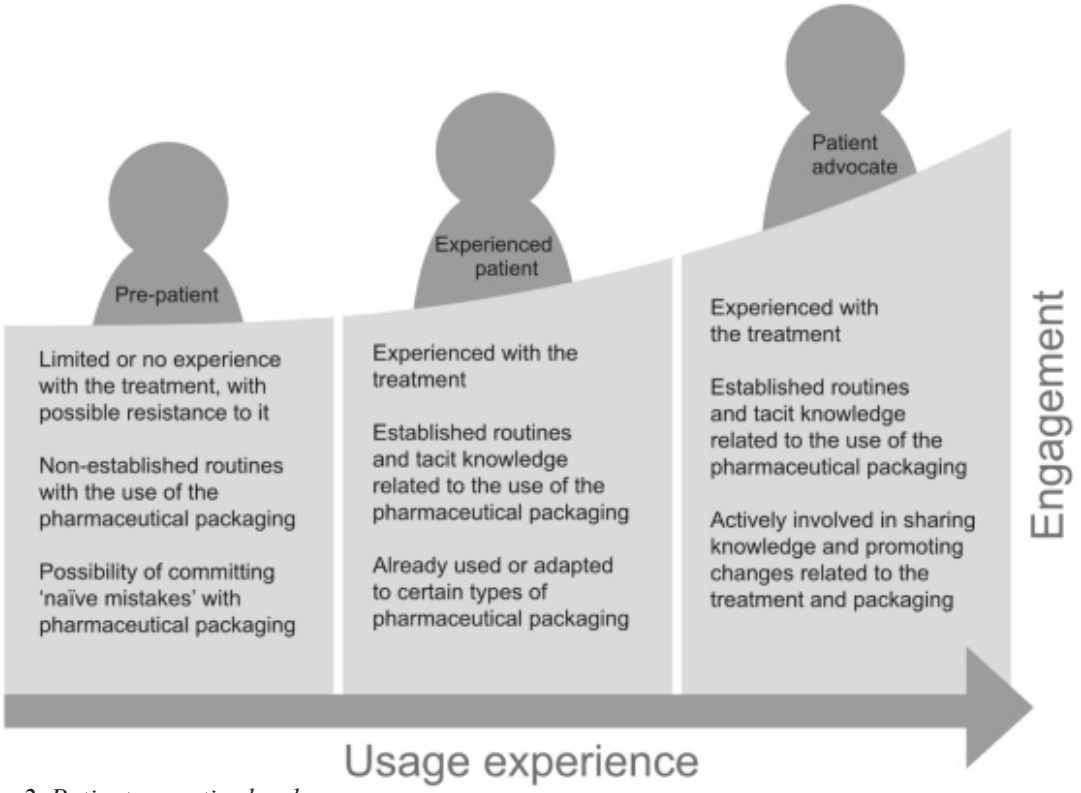

Figure 2. Patient expertise levels

In this sense, a pre-patient is also a future user of the medication. Commonly, pre-patients refuse or postpone the beginning of treatment [34]. Pre-patients often have high stress levels because they need to learn how to navigate their illnesses. The respondents perceived that packaging has a specific role in helping these patients to find guidance and instruction to carry out their treatment correctly. Independent of the disease, pre-patients are more likely to make mistakes or use the packaging in unexpected ways, which can help packaging teams uncover unexpected packaging use.

Experienced patient

Experienced patients are those patients who have lived with one or more diseases for a long time. They have tacit knowledge, which means they 'have in mind a pattern born of experience, which they can overlay on a particular problem and use to quickly detect a solution' [48]. Experienced patients are often of the greatest interest to packaging design teams, as those patients have extensive experience living with certain conditions and have developed their own strategies to cope with both their condition and the functional challenges that they might face with the medication and its packaging.

Patient advocate

The third level is the patient advocate level. In the literature, a closely related concept would be the 'lead user' [2]. Lead users combine expertise in the context of usage with the eagerness to innovate and perform product design changes. However, we could not identify patients as lead users in our interview data, as the patients were never mentioned as the initiators of pharmaceutical packaging innovations. Therefore, a more appropriate concept is 'patient advocate': a person who assumes the responsibility of advocating and talking about the needs of a whole group of users, as defined by [49].

Typically, patient advocates are members of patient associations, a network of patients engaged in their diseases, treatment, and quality-of-life improvement. Patient advocates are considered to be extremely involved in their diseases, which may demand caution from packaging teams, as not all patients will be as engaged as these patients.

Patient involvement modes

Arnstein [26] described a taxonomy of user involvement ranging from non-participation to tokenism and then citizen power. Similarly, Damodaran [44] defined three user involvement levels: informative (user provides information and passively helps generate data), consultative (user comments on pre-defined concepts or prototypes), and participative (user actively influences decisions). Kaulio [1] proposed another scale in which the design process is conducted for, with, or by users. In general, the prevalent idea behind these similar classifications is that user involvement will vary from passive to active, depending on when and how users enter the design process and to what extent they are allowed to influence it. Inspired by the literature on user involvement, our iterative coding process led us to identify and synthesise six patient involvement modes, presented in Table 3.

Ethnography

Respondents mentioned ethnography as one mode of patient involvement to discover the 'world of the patient'. Hence, ethnography worked as a sort of inspiration for defining patient needs, understanding the lives of patients, and identifying 'exactly how our products will live with the patients' (D12). Anthropologists at the company, or hired by the company, would travel across the globe to meet patients at their homes to observe the use of the medication and packaging in real-life situations.

> They [the anthropologists] got permission to follow a patient a whole day to see how he managed, administrated his medication.

Table 3. Patient involvement modes and levels

Patient involvement modes	***Purpose***	***Phase of packaging design***	***Level of patient involvement***	***Responsible***	***Locus***
Ethnography	To discover the patient's life and routines. To get the first insights for a new package design. To test a packaging concept of a potential new drug therapy.	Pre-project Early development Concept design	Consultative	Anthropologists, external research consultancy	Patient's home
Talks by patients	To discover the patient's life and routines.	Pre-project Early design Post-market launch	Informative	Staff from different departments	Company
Co-creation workshops	To co-create packaging concepts.	Early design	Consultative/ Participative	Packaging design team	Company
Rapid prototyping and visualisation workshops	To validate patient groups. To understand the experience with the packaging.	Early design Concept design	Consultative	Packaging design team	Usability laboratory, online platform
Usability testing	To validate the packaging design. To assure usability according to regulatory standards.	Prototyping/ Design specification	Informative/ Consultative	Packaging design team, external human factors consultancy	Usability Laboratory
Formal patient feedback	To respond to patients' complaints.	Post-market launch	Informative	Company's ombudsman service	Ombudsman service

> Where he [the patient] started, how he used it, and just looking at him, and following him the whole day. And that gives extremely good information for us to see where the hurdles are for him [the patient]. (D5)

The respondents also commented that ethnography is used to add stimuli to the reality of the patients, especially when testing preliminary packaging design concepts with a group of patients with one specific disease.

Talks by patients

Respondents commented that they had attended talks given by patients. These talks were arranged as very explorative and inspirational seminars at the companies' premises, where patients talked with staff from different departments about the reality of being a patient and living with a disease.

> We invite them here for seminars, we invite them to talk about their lives, you know. So, it's extremely important that we understand them thoroughly. (D1)

The talks permitted the patients to frame and phrase their realities, instead of having someone observe them. D6 commented that patients '[...] come and tell about the experience of having the disease, and how they perceive the products and the challenges'. For D5, the meetings with the patients focused on exploring 'what is a daily life for you with this disease?', rather than asking patients to assess specific medication or package.

Co-creation workshops

Another means of involving patients early in the development of new packaging designs is via co-creation workshops, during which the packaging design team and selected patients interact to develop new packaging concepts together and iteratively.

> We have gone off-site for a couple of days, and we've had different patients in and we had interview sessions, where essentially I conducted an interview with a patient for an hour, and then ten engineers would sit and listen to the patient, how they live, what their problems are, and then go away for an hour, and come back with three different concepts to improve their life, just the ideas, an app, a device, or anything it could be. (D12)

At these sessions, the patients worked with sketches or very rough mock-ups to visualise future packaging concepts, not necessarily connected to one new specific medication but related to a disease or condition patients had in common.

> So, we asked some people to do some drawings, for example, people said 'Ok, it should look like this'. And someone drew it, 'Yeah, but you need to be able to put it in your pocket and in your purse', you know, it should be small. So, we started with a problem, you know, and we tried to see how they would like to solve that. (D1)

Rapid prototyping and visualisation workshops

A common practice highlighted by the respondents is the presentation of rapid prototypes and visualisation workshops with patients (Figure 3). The prototypes were usually developed by in-house 3D printers or by packaging suppliers. As specifically commented by P4, workshops with rapid prototypes permitted designers and engineers to show patients possible solutions in one or more visual and tridimensional artefact, which could be helpful to start an in-depth discussion.

Usability testing

Several respondents commented on their experiences with or awareness of usability tests, performed according to strict documentation and standard protocols. For pharmaceutical manufacturers, usability testing is an obligatory phase for certain packages (e.g., child-resistant packages),

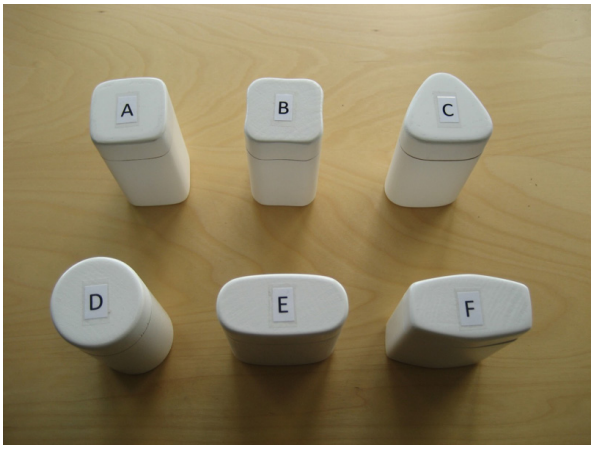

Figure 3. Examples of rapid prototypes tested by patients. Source: Respondent P3

during which the packaging design is validated. Regularly, the usability tests were filmed, and patients were asked to make comments during their interactions with the packaging.

> You put the system in the hand of the patient, and they have to operate the system. And the company has to document that the patient is able to use it. That they don't do dangerous mistakes and so on. So that is perhaps the most important feedback mechanism during development. (D6)

Formal patient feedback

Formal patient feedback was also mentioned by the respondents. Any formal feedback about the packaging reported by patients to the ombudsman service at the pharmaceutical manufacturer requires the packaging teams' attention, which has to analyse and discuss improvements. This situation is rare according to the respondents and should be prevented. There is also informal feedback about the packaging, which is gathered by sales people or marketing teams. Informal feedback does not require immediate responses from pharmaceutical manufacturers but serves to provide insights for future development.

> [...] so, we will take all the complaints, work why patients were complaining about it and then make some proposed changes to the pack. And again, just test those within a small number of people and see what they say. And hopefully launch a better pack, a new improved pack. (D10)

Factors encouraging patient involvement

By involving users, designers benefit from feedback at multiple phases and simultaneously create solutions that satisfy user needs [47]. In this research, patient involvement was found to be important when the packaging is a critical part of the treatment and a potential hazard causing failure and severe mistakes. Three subthemes emerged and are detailed in the following.

Understanding actual usage

Respondents are encouraged to involve patients to learn and understand the realities of drug product usage, especially during discovery-oriented stages of packaging design. Identifying the differences between the intended and actual usage is one of the major benefits of patient involvement in the packaging design process for pharmaceutical products:

> The user [patient] might think something is good and it'seasy to use, but if you observe how they use it, they might use it wrong, or they might have difficulty using it, even though they say they think it's easy. [...] How they actually use it, not how they think they use it. (D12)

> So actually, we observe to see if they don't use it as we intended, so from my point of view, it's very important that the designer that designed this box is observing instead of reading a report afterwards. (D11)

In another example, a participant told a short anecdotal story about facing the struggle of a patient with a package.

> There was a patient here, in a big meeting, and she was enthusiastic, and she said 'this is a fantastic product, it helps me very, very much', and she showed the [package] and she said 'well, it's very hard to get it out, because you have to press out this [name] product out of the [package], and I have arthritis also in my hands. I have a trick'. And she said 'I take a plastic bag and I put the [package] on that, and then I press it with my foot, and then I take it out and use it, and it works fine', she said. And it was really embarrassing hearing this, you know. (D1)

In this situation, the personnel involved with the medication project at the company had the opportunity to meet the patient to hear about her experience with the medical product. However, it turned out that the packaging was at the centre of attention. The unexpected method of getting the product out of the package provided the design team with insights about the packaging design.

Creating empathy with patients

Eagerness to empathise with patients was mentioned as an encouraging factor. Importantly, some of the respondents referred to empathy with patients as part of the organisational culture shared among the employees at the company level and extending beyond the packaging team.

> I saw a presentation of somebody [...] and one of his keywords was not designed for the patient, for the user, but with the user. He could show he changed the design of an injectable design packaging for RA [rheumatoid arthritis], with patients' involvement. (A2)

Meeting the patients was also an opportunity to be 'challenged by somebody who actually has this everyday use and be surprised by what their perception is compared to your perception of reality' (D11). By creating empathy with the patients, the packaging teams could elaborate on future solutions to facilitate medication intake and improve adherence rates.

Compliance with regulations

Our data show that patient involvement in packaging development is strongly influenced by the specific policies and regulations, which vary across different markets. It is the responsibility of pharmaceutical manufacturers to comply with regulations; however, packaging suppliers are also motivated to perform user tests to fulfil the regulations and queries of their customers (i.e., pharmaceutical manufacturers). For instance, one important piece of legislation mentioned is the Poison Prevention Packaging Act of 1970 (PPPA) for the US market [50], which requires child-resistant packaging for several household packages, including prescribed medication and over-the-counter products.

Factors discouraging patient involvement

We identified three factors that were particularly challenging according to respondents: who to involve and when to involve them, the available resources, and what is allowed.

Who to involve and when to involve them

Active and participatory involvement should start early in the development process. Our data revealed that it was difficult to define the right point of patient involvement. For instance, P2 commented that the company is global, which makes it difficult to select and work with local patient organisations in patient recruitment. Another respondent (M2) commented that interacting with patients in early phases without having a concept to discuss can be misguiding and impractical. On the other hand, bringing 'something that looks like a final product' (M2) is also not positive, as time would have passed in developing something that patients may dislike.

Additionally, patients living with a certain chronic condition are not always a homogeneous group, with a variety in their level of expertise as well.

Available resources

Another discouraging factor includes the operationalisation of patient involvement, such as budget, time, and extensive documentation. The development of a new medication takes many years and is a high-cost investment, which means packaging needs to be seen as a critical element for the medication project. For instance, this happens when a new medication requires additional protection or packaging features that cannot be supplied by a packaging that has been previously developed. Otherwise, pharmaceutical manufacturers will more likely use the packages already in their portfolio to decrease development costs and increase speed to market.

Moreover, developing inclusive packaging focused on patients' needs is embedded in the culture of some major pharmaceutical manufacturers, but it is not the priority for all companies involved with the packaging design process, as stated by one respondent:

> Many don't have the resources, don't have the leadership who demands this to happen. You can have companies very, very active, pro-active, and others are not, it's not part of their genes. (A2)

What is allowed

Most of the activities that involve patients need to be performed by consultancies or third parties outside the facilities of a company, which requires ethical considerations. As commented, 'pharmaceutical companies, they want to get patients involved but they have legal restrictions in their communication with patients that makes it difficult' (A1). For medications that are planned to be sold globally, there is an additional complication of dealing with different regulatory boards and guidelines that restrict patient involvement for major and global medication projects where many market opportunities are foreseen.

> 'cause it is quite a big investment to run a usability study, it takes time and it is a little bit complicated for the industry to interface and compensate the test participants for their time, and there is a lot of regulations on that, so it is important that we get good output for the pack. (M2)

DISCUSSION

Pharmaceutical packaging can put patients at risk when different design aspects are not considered [13]. As expected, one main factor encouraging patient involvement is proof that the packaging is safe for use and complies with the relevant policies and regulations. Therefore, it is imperative to understand the actual use of packaging by involving patients in situations that mimic their reality of medication usage. This motivation found in our results is not distant from what the literature suggests about involving users in design processes to achieve understanding of the context of use, getting access to first-hand knowledge about the contexts in which products are used [51].

Luck [52] affirmed that 'the social process of participatory design and design dialogue has enabled the transfer of user knowledge to designers who may be able to use this knowledge for the users' benefit'. However, it is not easy to transport the ideals of inclusive design into practice without the creation of user stereotypes and common disabilities [53, 54]. We found that stereotypes could be deconstructed when patients had the opportunity to share their stories. The talks given by patients provided an open environment for these patients to discuss what was important to them. As supported by previous research [55], patients sometimes showed creativity and a strong will to circumvent

difficulties to succeed in their treatment, surprising the professionals responsible for packaging development.

The discouragement factors for patient involvement identified relate to those already found by the literature [21]. These factors seemed to be stressed even more in the pharmaceutical packaging context as this is a highly regulated business with significant differences across countries, where forceful regulatory bodies control medication and packaging development to ensure patient safety [56]. The regulatory differences among borders create a difficult scenario for pharmaceutical companies, as one new packaging does not fit all the company's markets. This can make it particularly difficult to achieve the ideals of inclusive design, where packaging is intended to be designed for abroader range of the population but framed by regulations that impose different demands on the design process, and directly affect how a final package may look like. In practice, this means changing a packaging already launched will only be done when absolutely necessary, and not always motivated by the needs expressed by patients. Packages already launched tend to remain in the company's portfolio – and that explains why many pharmaceutical packaging designs that are functionally challenging to patients continue to be produced for decades [14]. Conversely, an opportunity arises when a new medication is under development with a need for a new packaging – in those cases, having patients involved in the design process seems to be particularly valuable to the creation of packaging that fits with patients' needs.

One interesting aspect was the level of expertise of the patients involved. Scholars have reported that user participation is often realised with the professionalisation of public participants [57]. This feature was partly identified in this study, as patients engaged in patient associations were a recurrent source of knowledge for the packaging teams. Experienced patients were repeatedly included, although patients with little or no experience were also involved, as different ranges of experience expanded the understanding of usage. However, it is important to consider that patients might also lack a systematic view of all the complexities that are embedded in pharmaceutical packaging development, from regulatory constraints to intricate supply chains around the globe. Even though we could identify many efforts made to involve patients, and a great interest of the professionals inlistening to patients' experiences, limitations on how the pharmaceutical business model is established make it challenging to have patient involvement that goes beyond informative and/or consultative roles or to pursuit packaging that is designed for inclusivity. Inclusive pharmaceutical packaging remains as an exception – a view to be challenged by the efforts of many different actors, from patient associations to regulatory bodies and other decision-makers.

CONCLUSION

This research has investigated industry practices of patient involvement for inclusive pharmaceutical packaging design. By asking: 'How are patients involved in the pharmaceutical packaging design process?', we explored the patient involvement modes and levels and the extent to which the professionals working with packaging design and patients in fact work together in the design process. Our findings revealed:

- Six modes of patient involvement were identified (ethnography, talks by patients, co-creation workshops, rapid prototyping and visualisation workshops, usability testing, and formal patient feedback) at different phases of packaging design process.
- The level of patient involvement was mainly informative or consultative, where patients

were asked to give their input on packaging concepts during development or to share their experiences of living with a disease or chronic condition.

- Long-term and in-depth patient involvement (e.g., ethnography) was limited in comparison to shorter and punctual mode of patient involvement.

We also asked: 'What encourages or discourages patient involvement in the pharmaceutical packaging design process?' The encouraging factors were:

- Understanding and comparing intended and actual usage of the medication and its packaging, by adding stimuli to the world of the patients.
- Creating empathy with patients to better understand their needs and the reality (and complexity) of being a patient.
- Compliance with regulations as a 'must-do', as packaging and medication need to be approved together at the end.

Conversely, discouraging factors were:

- Difficulty in knowing which patients to involve and when to involve them in the pharmaceutical packaging design process.
- Restricted availability of resources (time, budget for packaging design, human resources) to conduct studies with patients, combined with the view of packaging as an additional cost to the medication project.
- Long approval process in a highly regulated industrial context that add complexity to development, reducing the speed to market for the medication.

Overall, our study has stressed the singularities of designing for patients and with patients. Patient involvement is one part of the challenges of having more inclusive pharmaceutical packaging, because without involving patients or by involving them only passively, their actual needs cannot be fully addressed. By affecting the lives of millions of patients, the pharmaceutical industry can benefit from a vision of inclusion and participation in its design processes.

A research agenda can explore other complex themes related to designing inclusive pharmaceutical packaging in connection with major societal challenges. We suggest two themes related to this study that can be further explored:

- The extensive use of medication packaging and self-care: limited research exists presenting the routines and strategies followed by patients in their use of medication packaging in daily life. Studies in this area can apply different methods to gain insights about the complexities lived by patients, such as older patients, in their medication management.
- Methods for implementing gained insights into industrial design processes and for decision-making for inclusive design of pharmaceutical packaging: a path forward is to observe and research closely how packaging design teams work to manage and implement insights from patients in new or improved packaging concepts, and how decisions are made impacting on the packaging design.

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