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TOWARDS EMPATHIC DESIGN IN THE IRISH MEDICAL DEVICE INDUSTRY

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1. Introduction

Contemporary organisations must design innovative products using breakthrough technologies to gain competitive advantage in turbulent and dynamic environments. According to Saunders et al. [Saunders et al. 2009] an innovative product '*changes, or has the potential to change the nature of the marketplace by satisfying a new (or latent) need or by satisfying customer needs in a significantly new way*'. Clearly the ability to identify and define customers' needs is essential to the design and development of innovative products. However the identification of customers' needs, wants and expectations is not an easy task. Customers have difficulty articulating needs and defining the intangible aspects of products that please them. Ulwick [Ulwick 2002] states simply that '*customers do not know what they want. Customers only know what they have experienced. They cannot imagine what they don't know about emergent technologies, new materials and the like*'. Consequently many organisations do not listen to the voice of the customer too closely since it is believed the information they can provide is vague, inaccurate and incomplete. Cooper [Cooper 2008] asserts that' *upfront homework'* is not done and the front end of the new product development process is absent of structure and layout. However organisations that neglect this process can end up an adopters rather than innovators. Ultimatley they will lag behind the market because they fail to identify winning next generation ideas that delight the customer and differentiate their products.

In recent years, many researchers have written about the fuzzy front end of the product innovation process. Whilst some researchers have focused on models and processes to capture the voice of the customer (see [de Brentani and Reid 2012], [Griffin and Hauser 1996]) others have attempted to understand effective methods to identify and evaluate customer needs (see [Martinsuo and Poskela 2011], [Van Kleef et al. 2004], [Holt 1987]). Many of these researchers advocate that organisations adopt a user centred perspective to the design and development of their products. There is also a growing recognition by some researchers that the physical environment plays a significant role in this process. Consequently some researchers have emphasised the need to engage with customers in their own environment. McQuarrie [McQuarrie 1993] describes how a friend once said to him: '*a desk is a dangerous place from which to do business*'. He advises people to take a tour and observe – '*get out of the conference room*'. Cooper and Kleinscmidt [Cooper and Kleinscmidt 2007] also outline how people need to '*camp out*' with the customer in order to understand user needs and wants. Empathic design is an approach that has received some attention in recent years. It is lauded to effectively capture the voice of the customer so that specific and latent needs can be defined and infused into the product development process. Our research focuses on optimising the front end of the product development process in order to design and develop innovative products that meet the needs and expectations of customers and end users. We have studied the area of empathic design as a means of improving this space.

We note that empathic design has been studied from many different perspectives in the literature. For example, some authors have looked at empathic design strategies (e.g. [McDonagh 2011]); others have examined the empathic design process (e.g. [Leonard and Rayport 1997]) and other studies have focused on benefits and outcomes of building sustainable relationships (e.g. [Niinimäki and Koskinen 2011]). Despite this, we notice a dearth of studies that focus on the application of empathic design in specific industrial sectors. Our work attempts to bridge that gap. Therefore the goal of this study is twofold (a) to identify whether empathic design methods are used in the medical device industry in Ireland and (b) to identify the challenges faced by designers when implementing empathic design tools and techniques in this space. The research aims to inform designers, engineers and those contemplating using empathic design techniques about the experiences of those who have navigated the process. This paper provides a brief discussion of the concept of empathic design including the fundamental issues involved and the critical stages in the process. We also introduce a discussion of the limitations with the technique. Our primary research focuses on an exploratory analysis of the application of empathic design in the medical device industry in Ireland. We present a brief synthesis of the problems and requirements that arise in this domain. The remainder of the paper presents findings from an exploratory study that captures and synthesises the critical challenges faced by designers when implementing empathic design in the medical device industry in Ireland.

2. Emphatic design

Empathic design allows the design researcher to observe the user in their own environment and to empathise with the user. McDonagh [McDonagh 2006] defines empathy as '*the intuitive ability to identify with other peoples thoughts and feelings*'. Kouprie and Visser [Kouprie and Visser 2009] state that empathy is like '*smiling when you see someone else smiling*'. Steen et al. [Steen et al. 2007] explain how the researchers or designers knowledge and experience is '*privileged*' through empathic design as the researchers and designers attempt to '*experience something*', unlike other research methods where the designer or researcher is more detached from the experience. Van Kleef et al. [Van Kleef et al. 2004] describe empathic design, as a user centred technique where the design researcher develops empathy '*for the problems consumers encounter in their daily life*'. McDonagh [McDonagh 2011] stresses that empathic design strategies rely on the user being an active partner within the design process to ensure that more intuitive design outcomes are generated. Leonard and Rayport [Leonard and Rayport 1997] assert that the key element to empathic design is observation. They describe empathic design as being more close to anthropology than market research or design research. They advise researchers to '*watch consumers use products or services*' '*in the customers own environment – in the course of normal everyday routines*'. By doing this designers can better understand the relationships that customers build with products and also determine their criteria for assessing satisfaction. More recently, Van Rijn et al. [Van Rijn et al. 2011] explore the influence of different sources of information used in designing products for children with autism. The results show that direct contact brings empathy with users to design teams and positively influences the quality of the product concepts they produce. McDonagh and Lebbon [McDonagh and Lebbon 2005] outline how user's satisfaction from a product may be made up from several factors including aesthetic appeal, taste, usability, materials and sensory perceptions.

Niinimäki and Koskinen [Niinimäki and Koskinen 2011] found that an empathic approach can be of primary importance in promoting sustainable product relationships. Van Gorp [Van Gorp 2010] describes how people form relationships with products, and this relationship depends on how '*useful, usable and pleasurable the experience is*'. Suri [Suri 2006] gives some insight into the significance of empathy towards users when she describes how the 2005 Smart Design survey found that the emotional attributes of a product can have an even stronger influence than aesthetics. She also states that '*businesses now feel that understanding consumer's users in context is a competitive necessity*' and explains how '*at this moment ethnographic style research has acquired relatively favoured status within corporate culture*'. Leonard and Rayport [Leonard and Rayport 1997] state that empathic design has the '*potential to redirect a company's technological capabilities toward entirely new businesses*'.

It seems that product designers must effectively engage with customers to truly understand their needs in order to develop innovative products and services. However, emphatic design is a means to an end and not a panacea. There are certain limitations with the approach that should be considered. For example, cost is a key issue that must be considered however there seems to be conflicting opinions on the cost benefit analysis for observational research in the literature. Leonard and Rayport [Leonard and Rayport 1997] describe empathic design as a '*low cost low risk way*' to identify potentially critical customer needs. Kujala [Kujala 2003] on the other hand, describes the work of Curtis who outlines how field studies '*made a significant contribution to the organisations customer understanding but cost 50 engineer months and $65,000 gathering and analysing the data*'. She concludes that '*more cost efficient practices are needed*'. Kouprie and Visser [Kouprie and Visser 2009] also note that '*a process of empathy in design practice requires a structured investment of time'*. McDonagh [McDonagh 2006] also found that empathic design can be time consuming.
Empathic design is not an easy technique and designers often struggle with the ability to empathise with the end user. McDonagh and Denton [McDonagh and Denton 2005] describe how the limits of a designer or researcher to empathise beyond their own group are defined by things such as nationality, experiences and education. They also state that designers fall into a dangerous '*comfort zone*' and design '*for themselves (or people like themselves) when intuition and insight can be closely matched*'. Kouprie and Visser [Kouprie and Visser 2009] assert that designers must have an '*open attitude toward users*' and that designers require training in research skills. Letelier et al. [Letelier et al. 2003] assert that managers are can also be fearful of market research. They observe that market research '*does not allow them to determine if a radical innovation will succeed in the market place or not*' and '*most mangers end up believing that managerial intuition is better than customer research for the case of innovative concepts'*. Leonard and Rayport [Leonard and Rayport 1997] state that empathic design will require a culture shift in any company. They describe a typical reaction from a company to a need identified by the design researchers as '*users haven't asked for that*'. They state that by the time the customers do eventually ask for that feature, the competitors will have the same product ideas.

3. Empathic design process

In recent years research has centred on understanding the empathic design process. Leonard and Rayport [Leonard and Rayport 1997] outline a five step commercially oriented process. They argue that this process can help identify defined and unmet needs through observation and empathy with the user. Kouprie and Visser [Kouprie and Visser 2009] outline a four step process. This process describes how to better understand the user. Their work describes the mental process required to achieve empathy but does not make the link to innovation and commercial success. Van Kleef et al. [Van Kleef et al. 2005] describe empathic design as a '*need driven*' market research technique. They also present a four step process which has been derived from the work of Poylanyi, Leonard and Sensiper, Leonard and Rayport, and Ulwich. McDonagh [McDonagh 2006] provides a diagram showing a six stage process which focuses on the journey while Koskinen and Battarbee [Koskinen and Battarbee 2003] present an approach that aligns with the creative process. Whilst the authors vary somewhat in their description of the process, there are consistent themes throughout the methods that can be found. These include observation by cross functional teams, development of solutions and prototyping of the solutions. We outline the critical stages in the empathic design process. Important features or elements of empathic design are emphasised as it is understood these factors can significantly impact on the success or failure of the technique.

3.1 Define strategic focus and identify users

We argue that it is imperative to clearly articulate and communicate the strategic focus of the project before the design team begins to observe any problems, gaps or opportunities. A clearly defined strategy will help to create a common understanding among the design team of where the company wants to go in. Research suggests that this direction must align well with the strengths and competencies of the design and development team [Cormican and OSullivan 2004]. It is good practice to define key criterion to help develop a strategic focus. Examples of these criteria that may be used for the medical device industry may include; application domain (what technologies do we want to

pursue?); target market (who do we want to reach?); nature of technology (will the technology focus on science; engineering or information management?); level of innovation (will we aim for incremental or breakthrough innovations?); regulatory pathway (will we target CE marking; PMA or 510K certification?) etc. Opportunities can then be systematically and objectively evaluated against each defined criterion.

Once a decision is made to pursue an empathic design approach, the next significant decision surrounds who should be observed. For example, if the product is to meet the needs of a global market, consideration should be given to conducting observations in each key market region, taking things such as cultural differences into account. In addition, it is also important to establish exactly who the user is. This will ensure each category of user is observed and their needs are understood. Users should be considered in the broadest possible manner. For example, a user may be defined as the purchaser, the end user or the person responsible for maintenance and if an existing medical device exists and is currently used in a hospital it should be observed in use from delivery to disposal to ensure all opportunities to innovate are identified. There is never one single user and different users can be found throughout the lifecycle of the product. Users in the medical device industry could range from the purchasing manager in the hospital to the clinician using a device. It is good practice to observe and analyse as many potential users as possible.

3.2 Observe users and gather data

Next significant consideration must be given to the creation of the observation team. The literature recommends an interdisciplinary or cross functional team which will consist of key stakeholders representing functions such as human factors, engineering and product design. The observation team must work towards a common purpose and adhere to agreed operating principles and group norms. It is also essential that all members have the capacity to address conflict and are mutually accountable. We learned that successful teams focus on results and have a commitment to decisions and actions. The design researchers must also be equipped with sound process skills e.g. communication; problem solving and decision making. They must be open-minded, have the ability to note the observations of interest and communicate those to the design team without introducing any bias into the research.

The observation process should aim to capture contextual data such as the physical environment, work flows; steps in the procedure; sequences of actions; ergonomic and usability issues as well as interactions between people and products. The use of empathy probes is recommended at this stage of the process. These probes refer to specifically designed templates which can be given to users and observers to help document contexts and experiences. These probes may help the researcher to answer the following questions

- How do people cope with existing technologies and practices?
- What are the problems with the existing processes and products?
- What do people experience at the moment?
- Is time wasted?
- Do users modify existing products to satisfy their particular needs?

Whilst the focus of the study will determine what type of data will be gathered the ability to accurately capture of the data during the observation process is also another significant factor in empathic design. It is important to capture and describe actual behaviour rather than abstract generalisations about users' behaviour. Therefore appropriate means to capture observations should be tangible, descriptive and graphic. Subtle, fleeting, unexpected and involuntary cues can often be missed or lost either through interpretation or translation into words or numbers. The literature suggests that video recording, still photography and capturing notes in the users own handwriting can all assist the empathic design process.

3.3 Analyse data and reflect

In this stage of the process, the raw data and initial findings are shared with the broader team to afford them the opportunity to identify and classify needs from the research without any bias from those who were present. Designers who are unbiased by the context of the observation may see new opportunities

and issues. The observations from the field will need to be filtered so that the design team can focus on the critical few. They should be analysed against specific and agreed criteria of assessment that are aligned to the strategy of the organisation and the goals of the design team. Examples of such criteria in the medical device space could include the following:

- Effect on quality of life (what is the potential clinical impact of this problem?)
- Potential market size (how many people are affected by this problem at the moment?)
- Current treatment effectiveness (what technologies are currently available that target this problem?)
- Potential cost effectiveness (if we address this problem can we develop a solution that will be significantly cheaper to make and so make a good return on investment?)
- Strategic fit with existing product portfolio (does this problem area align with our current strategy and existing competencies and skills?)

This filtering process will result in a prioritised list of outputs. Needs statements will then be developed for a critical few observations. A needs statement should clearly define the problem and the change in outcome that is required to resolve the problem [Zenios et al. 2010]. The statements must address real customer needs. They must well scoped and targeted. If a statement is too broad it can result in a solution that does not effectively address the needs of the true target audience. If it is scoped too narrowly the design team could underestimate the size of the market opportunity. It is also imperative to ensure that the needs statement is problem not solution focused. In other words, it should focus on what should be addressed as opposed to how it should be addressed. Furthermore, at this stage in the process everything should be backed up with quantifiable data.

3.4 Brainstorm for solutions and prototype concepts

This process is used to transform the observations and challenges identified on the customer visits into potential solutions. Here, the team should generate product concepts which will address the needs identified from the research. There are many techniques described in the literature for concept generation such as brainstorming and TRIZ. Emphatic design processes emphasises the importance of generating prototypes. Prototyping involves making a physical representation of the design concept or solution. Prototyping can be achieved by a number of means from conventional, more time consuming manufacturing methods such as foam and duct tape to faster techniques such as rapid prototyping with SLA, SLS and rapid tooling techniques. What is critical here is that sufficient consideration is given to what must be achieved from building the prototype. This can determine whether, complete or partial prototypes are required and the quality level to which they must be built.

4. Research method

The research approach in this study can be described as inductive and exploratory, with the emphasis placed on gaining a deep understanding on what is happening in the medical device product innovation arena with regards to design research techniques. The research strategy is a combination of a case study and action research. Sixteen semi-structured interviews with individuals currently involved in medical device product innovation were conducted. This allowed a deep insight to be gained into current methods in action, their associated challenges and opportunities, and the challenges and opportunities that exist with discovering user needs. Purposive or judgmental sampling was used in combination with non-random sampling in order to identify participants with deep insight into the area of product innovation and design research. The participants work experience ranged in duration from 7 years to 31 years and all participants were employed in the medical device industry and engaged in product innovation. All participants are actively involved in the process of determining customer needs with their cross functional teams. Four of the participants have significant experience in the observation process having recently spent two months immersed in in a hospital observing a consultants team. Participant's roles included Product Design, R&D Management and Market Research with participants having educational backgrounds in Industrial Design, Polymer Engineering, Mechanical Engineering, Biomedical Engineering and Market Research. All participants were educated to primary degree level with four participants educated to doctorate levels. Data

analysis consisted of extracting the key responses from participants and summarising and grouping the voices of those interviewed to allow overall conclusions to be drawn about design research in the medical device industry.

5. Medical device industry in Ireland

5.1 Innovation in medical device industry

Innovation is seen as a key strategic focus area for all companies involved in our study. We found that innovation in the medical device industry in Ireland must focus on both effectiveness (designing and developing innovative new products and solutions) and efficiency (creating technologies and products that reduce the cost of goods sold). Furthermore we learned that to be successful, emerging innovations must:

- Focus on unmet medical needs so that there is not too much competition in the market
- Enable less invasive procedures requiring less hospitalisation
- Reduce diagnostic imaging and follow up requirements
- Be significantly cheaper to purchase and increase the return on investment
- Have an intuitive design and be easy to use
- Reduce the need for additional support requirements
- Minimise the lead time from concept to market and avoid design corrections late in the innovation process

The medical device industry in Ireland is very well placed to exploit potential opportunities that currently exist. Table 1 summarises some of the key strengths and opportunities in the industry.

Table 1. Strengths and opportunities in the Irish medical device industry

Strengths	Opportunities
Talented, highly educated and skilled workforce Favourable corporation tax rate (12.5%) Good regulatory bodies Proven track record in manufacturing excellence Entrepreneurial spirit Proven efficient and effective collaboration structures Attitude and enthusiasm for innovation	In a position to encourage early stage businesses from US who do not wish to pursue FDA certification Potential to adapt to reduce expenditure Improving clinical research infrastructure Increase in commercialisation focus in Irish universities High level of engineering skills

However while all participants in this study were involved in innovation at all levels ranging from simple changes and additions to the development of new to the world products, we found that the required enablers and tools are not in place to support this strategies. Although great efforts are made throughout the product innovation process to use tools such as customer interviews, voice of the customer, quality function deployment techniques, conjoint analysis and to engage with key opinion leaders and lead users the empathic design technique is currently not used. In fact, designers currently spend very little time in the customer's own environment. Furthermore, we found that the ability to uncover unmet needs and opportunities to innovate are limited. Despite design researchers best efforts, customer interview responses tend to be somewhat bounded by the scope of the interview prompts and questions used in interviews. Working specifically with lead users carries the risk of developing a specific device that is tailored to suit the lead user's needs, but these needs may not be indicative of what the global market requires at that time for a commercially successful product. We also uncovered examples where user needs are identified late in the innovation process resulting in design changes which ultimately had a major impact on the overall time to market of the new product.

5.2 Processes and tools

Medical Devices are lifesaving pieces of equipment and therefore the industry is highly regulated by agencies such as the United States Food and Drug Administration (FDA) and specifically the Code of Federal Regulations Title 21, Part 820. Activities such as product design, development and manufacturing are required to comply with these regulations and are therefore subjected to random audits or inspection by these bodies. Consequently it is no surprise the find that al participants follow a defined, documented process to develop new products in their organisations. The two key types of processes are:

- A regulatory based process, structured around FDA requirements and ISO13485 which provides the requirements for a quality management system for medical devices.
- Combined stage gate and regulatory process where the Stage Gate Process is 'overlaid' onto the regulatory process.

While our research finds that there is a very structured product development process in place little guidance is offered as to how the customer needs or requirements for the product are to be identified. Evidence is also found showing challenges with existing methods used to discover customer needs. Indications are that the design research methods chosen are somewhat dependent on the team members engaged at the time, as opposed to following a predefined best practice. It is possible that potential opportunities may be missed if the front end of the product innovation process is not optimised. Upon analysis it seems that the following specific requirements that should be addressed:

- Early and more thorough identification of customer needs.
- Better understanding of the customer's physical environment, mental workload and clinical practice.
- Fewer design cycles.
- Faster adoption tares of new products.

6. Challenges

Our study has identified some challenges to capturing the voice of the customer that must be addressed. These are individually addressed below.

6.1 Access to hospitals, clinicians and patients

Participants in this research who are experienced in medical device innovation highlighted the ability to gain access to hospitals and clinicians as a critical challenge. One participant described how they needed to '*get closer to the customer'*. Medical professionals are extremely busy people and their primary goal is to take good care of patients therefore it is not easy to schedule additional meetings. Furthermore medical professionals such as physicians and clinicians are not always aware of the value their voices and feedback can bring to the industry. Increased on site observation and the move towards co-creation will require a culture shift in the medical profession. We also learned that many design research teams do not focus on the patient. In fact, the ultimate end user is often ignored, with all the emphasis being placed on asking the clinician what their needs are. One participant stated '*we never talk to patients*'.

6.2 User behaviour

Our study revealed that there are challenges to be addressed in the end users site. For example focus groups and scientific advisory boards can be controlled by '*dominant voices'* or '*dominant characters*'. This makes it difficult to capture the voices of all participants. We also learned that end users are often too keen to look at 'solutions' to their existing problems, rather than stepping back to clearly help define the need or problem that must be addressed. Similar to other research we learned that clinicians tend to alter their behaviour under observation. However, all participants in our study felt that this risk could be overcome by informing clinicians of the goal of the visit prior to the observation taking place and building a rapport and trusting relationship with them. Nevertheless it should be noted that that these measures will increase the amount of time to be spent on each site visit which will have an impact on project research costs. One participant did emphasise that even if the

clinician's behaviour was changed under observation that this would still be a better scenario than having a designer working from the design office trying to visualise an operating theatre.

6.3 Observer skills

With respect to customer interviews, many participants again described the challenges with their current interview processes. Participants indicated that the success and value of the interview was largely dependent of factors such as:

- The personality or characteristics of the person being observed
- The scientific training and functional role of the observer
- The manner in which interview questions are phrased
- Their customers recent pain points
- The ability of the interviewer to probe the right thoughts
- The determination and tenacity of the interviewer
- The ability to deal with language barriers, translations and interpretations of interviews and transcripts
- The ability to accurately filter and evaluate observations based on robust criteria for assessment
- The ability to empathise with clinicians and patients, while simultaneously achieving their design research goals.

6.4 Health and safety in clinical environment

Participants noted that there are many health and safety challenges when entering a hospital to conduct observation. In this environment, the observer is exposed to many risks and, what seems less obvious, the designer or observer is also putting patients at risk as they may be unaware that they have a particular condition themselves. To reduce this risk, measures can be taken to protect designers, researchers and patients but these measures add complexity, cost and time to the process. It is essential that these aspects of the design approach in the medical device industry are dealt with appropriately to ensure researchers or patients are not put at any unnecessary risk. Furthermore, consideration should be given to end user (e.g. patient) consent and confidentiality where appropriate.

6.5 Cost-Benefit trade-off

Spending time, effort and energy capturing the voice of the customer should be used in the appropriate situation where the benefits outweigh the costs. We found that there is a need to clearly define who the customer is prior to any observation taking place. This ensures the maximum benefit is obtained from the technique. Consideration needs to be given to whether the customer is a commercial customer, e.g. a larger company purchasing from a smaller company, or whether the customer is an actual device user or patient. Costs associated with international travel also need to be built into the project business case to ensure it can be supported while not negatively affecting the overall financial attractiveness of the project. Potential cost savings must also be factored into any cost benefit analysis as they factors may significantly outweigh the costs of the research.

6.6 Ownership of intellectual property

There seems to be a lack of emphasis on ownership of intellectual property in the design research process. Some of our participants highlighted the need to ensure that ownership of intellectual property arising from the research should be clearly defined and agreed upfront prior to undertaking any design research. Failure to adequately address this topic will lead to disputes on the topic and possible legal battles between the company undertaking the empathic design and their customers.

6.7 Implementation of best practices

It seems that organisations in general are not familiar with established best practice methods. We found that organisations are not familiar with the various tools and techniques which are in use and described in the literature. Participants described frustrations with the fact that no best practice

documented processes is followed and that the design research process is used on occasion to '*solidify what the company already thinks they know about customer needs*'. Further best practice challenges that need to be addressed include:

- Insufficient use of cross functional observation teams
- Radical solutions and ideas are not always entertained
- Poor communication mechanisms (i.e. solutions which are not pursued must be explained to designers to avoid designer frustrations)

We also learned that insufficient time is dedicated in the project to processing and disseminating the information within the team when they return from the field. Companies must ensure the subsequent steps in the innovation process are also following a best practice to ensure commercial success is achieved. There is little value in using best practice to identify customer needs only for the project to fail commercially due to some other shortcoming in the innovation process.

7. Concluding remarks

Effective design research is crucial as information discovered, and subsequent decisions made, at this stage of the product development cycle will have a significant impact on the success of the innovations in the market space. Despite this, we found that organisations do not pay sufficient attention to this stage of the process. Many companies rely on interviews to understand their customers' needs but the literature highlights that this technique has its shortcomings. Interviews and focus groups are generally bounded by the questions posed and not effective in exposing unanticipated needs. Failure to use the correct tools and techniques at this stage of the innovation process can lead to poor product specification and long design cycles which significantly increases the potential for product failure.

Empathic design is an approach that enables designers and engineers to work with customers in their own environment to understand issues, identify needs and develop innovative solutions to address those needs.

Our research concludes that empathic design can be applied in the medical device industry to effectively expose customer needs wants and expectations. While we uncovered many challenges with design research in this industry, we believe that the technique will allow companies to gain a deep understanding of customer needs, across a broad range of customer types in the medical device hospital or homecare environments. Based on the challenges identified, it is essential that the technique is used in situations where the degree of innovation warrants the use of the tool and that the cost of conducting the research can be justified. Adoption of empathic design will also require experts to champion the technique and best practice procedures to guide the implementation of the process. Our future research will validate and verify the challenges identified with a wider audience and based on these findings we aim to design a best practice model for empathic design in the medical devices industry.

References

Cooper, R. G., "The Stage-Gate® Idea-to-Launch Process—Update, What's New, and NexGen Systems", Journal of Product Innovation Management, Vol. 25, No. 3, 2008, pp 213-232.

Cooper, R. G., and Kleinschmidt, E. J. "Winning Businesses in Product Development: The Critical Success Factors", Research-Technology Management, Vol. 50, No. 3, May-June 2007, pp. 52-66.

Cormican, K., O'Sullivan, D., "Auditing best practice for effective for product innovation management". International Journal of Technical Innovation and Entrepreneurship (TECHNOVATION), 24, 10, 2004, pp 819-829.

De Brentani, U., Reid, S., "The Fuzzy Front End of New Product Development for Discontinuous Innovations: A Theoretical Model". Journal of Product Innovation Management, Vol. 29, No. 1, 2012, p70-87

Griffin, A., Hauser, J. R., "Integrating R&D and Marketing: A review and analysis of the literature", Journal of Product Innovation Management, Vol. 13, 1996, pp. 191 – 215.

Holt, K., "User-oriented product innovation in theory and practice", Technovation, Vol. 6, 1987, pp 37 – 45.

Koskinen, I., Battarbee, K., "Introduction to User Experience and Empathic Design". Koskinen, I., Battarbee, K. and Mattelmäki T. (Eds.) Empathic Design. User Experience in Product Design. IT Press, Helsinki, 2003, pp 37-50.

Kouprie, M., Visser, F. S., "A framework for empathy in design: stepping into and out of the user's life", Journal of Engineering Design, Vol. 2, No. 5, 2009, pp 437 - 448.

Kujala, S., "User involvement: a review of the benefits and challenges", Behavior & Information Technology, Vol. 22, No.1, 2003, pp 1 – 16.

Leonard, D., Rayport, J. F., "Spark Innovation through Empathic Design", Harvard Business Review, November – December, 1997.

Letelier, M. F., Flores, F., Spinosa, C., (2003) "Developing productive customers in emerging markets", California Management Review, Vol. 45 No.4 pp 77-103

Martinsuo, M., Poskela, J., "Use of Evaluation Criteria and Innovation Performance in the Front End of Innovation". Journal of Product Innovation Management, , Vol. 28, No. 6, 2011, pp 896-914

McDonagh, D. C., "Empathic Design: Emerging Design Research Methodologies". Unpublished PhD Thesis. Loughborough University, Leicestershire, UK , 2006

McDonagh, D., "Disability plus relevant design: Empathic design strategies supporting more effective new product design outcomes", Design Journal, Vol., 13, No. 2, 2011, pp 180-198

McDonagh, D., "Empathic research approaches to support the designer: A supra-qualitative research for designing model", Design Issues, 2006.

McDonagh, P. D., Denton, H., "Exploring the degree to which students share a common perception of specific mood boards: Observations relating to teaching, learning and team-based design", Design Studies, Vol. 26, No. 1, 2005, pp 35-53.

McDonagh, P. D., Lebbon, C., "The emotional domain in product design", The Design Journal, Vol. 3, No. 1, 2000, pp 31-43.

McQuarrie, E., "Taking a road trip", Marketing Management, Vol. 3, No. 4, 1993, pp 8 – 21.

Niinimäki, K., Koskinen, L., "I love this dress, if makes me feel beautiful! Empathic knowledge in sustainable design" Design Journal Vol. 14, No.2, 2011, pp. 165-186

Saunders, M., Seepersad, C. C., Hölttä-Otto, K., "The Characteristics of Innovative, Mechanical Products", Proceedings of the ASME 2009 International Design Engineering Technical Conferences & Computers and Information in Engineering Conference IDETC/CIE 2009 August 30 - September 2, 2009, San Diego, California, USA

Steen, M., Kuijt-Evers, L., Klok, J., "Early user involvement in research and design projects –A review of methods and practices" Proceedings of the 23rd EGOS Colloquium (European Group for Organizational Studies) July 5–7, 2007, Vienna

Suri, J. F. "Saving Lives through Design", Ergonomics in Design, Summer 2006.

Ulwick, A. W. "Turn Customer Input into Innovation", Harvard Business Review, January, 2002.

Van Gorp, T., "Emotional Design with A.C.T. – Part 1". Available at http://boxesandarrows.com/view/emotional-design (Accessed 31 January 2011)

van Kleef, E., van Trijp, H.C.M., and Luning, P. "Consumer research in the early stages of new product development: a critical review of methods and techniques", Food Quality and Preference, No. 16, 2005, pp 181-201

van Rijn, H., Visser, F. S., Stappers, P. J., Ozakar, A. D., "Achieving empathy with users: the effects of different sources of information" Codesign-International Journal of Cocreation in Design and the Arts, Vol. 2, 2011, pp 65-77

Zenios, S., Makower, J., Yock, P., Biodesign: The Process of Innovating Medical Technologies Cambridge University Presss, 2010.

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