

A Qualitative Study on Turkish Medical Device Manufacturers and the Attention They Place on Human-Centred Design

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Turkey has a rapidly growing medical device industry, yet the domestic market is mainly dependent on import trade products. It is also claimed that there is a prejudice against 'Made in Turkey' branded medical devices both in the domestic and Global market. In this research, it was hypothesised that the problem could be caused by the limited attention paid on human-centred design among Turkish medical device manufacturers; because the importance of human-centred design is drawing more attention in Today's healthcare industry. For this purpose, semi-structured interviews were carried out with manufacturers in Expomed 2017 Medical Devices Fair. Due to the fact that human-centred design is an umbrella term covering several aspects of good design, six of its important topics related to medical device designs were examined: Medical Device Usability, Patient Safety, User Interface, Use Errors, User Experience, and Ergonomics and Human Factors. The results suggested that although the manufacturers had an overall understanding of human-centred design, they mainly take its important aspects into account as much as the regulations oblige.

medical device design, human-centred design, Turkish medical device market

1 Introduction

The medical device market is one of the fast developing and competitive markets in the world. The global market is led by the USA with a market share of 49%; and Japan, German, China, France and the United Kingdom are other important competitors with their important manufacturers (The Ministry of Health, 2016). Although the size of the market also grows steadily in Turkey, it accounts only for the 1% of the Global medical device market (The Ministry of Health, 2016). According to "The Action Plan and Strategic Document of Turkish Medical Device Sector" published by the Ministry Health of Turkey, there are around 1000 medical device manufacturers in Turkey; however, most of them produce low-tech products, while the high-tech systems or materials are mainly



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imported from the leading countries. Besides, the domestic market is also mostly dependent on import trade products that cover the 85% of the overall market (Gumustekin, 2017).

Although Turkish medical device regulations are harmonised with the regulations of the European Commission, which means that a medical device produced in Turkey also needs to acquire a CE mark and then can be freely sold all through the EU market (The Ministry of Development, 2014), there is still a prejudice against the medical devices ‘Made in Turkey’, even within the domestic market. Design-related shortcomings could be an important cause of this issue; because it is hypothesised that currently medical device development processes are mainly engineering-oriented, and therefore, design-related improvements are necessary to change this negative image into positive in time. Supportively, the Technology Development Foundation of Turkey (in their report on medical devices sector of Turkey) also emphasises the importance of industrial design to provide products with high added value, yet argues on its undervalue within the R&D processes among manufacturers (Kiper, 2013).

On the other hand, as suggested by Buckle et al. (2003), when the medical system and its users are understood clearly, design can significantly enhance safety of both clinicians and patients. They also add that this helps the industry to add value and differentiate their products by providing good and safe designs (Buckle, 2013). Human-centred design comes into prominence in this respect; and as suggested by Harte et al. (2014), manufacturers with a lack of adherence to human-centred design during their development processes might even encounter product recalls due to unexpected device outcomes or product-user interaction problems. Therefore, human-centred design could be a key requirement to enhance the image and potential of Turkish medical devices industry; because a previous qualitative research conducted with medical device retailers in Turkey, which focussed on the usability aspect of Turkish production medical devices, also provided supporting results that manufacturers do not pay sufficient attention to usability when developing their medical devices, whereas the end users regard it as an important factor (Cifter & Eroglu, 2013). However, usability is only one aspect of human-centred design, which is an umbrella term covering several inter-related aspects of good design (Harte, 2014). As a part of this research, a literature review study was carried out in order to identify the other topics that are critical for designing medical devices; and six main topics in total were identified as: Medical Device Usability, Patient Safety, User Interface, Use Errors, User Experience, and Ergonomics and Human Factors. These aspects are shortly introduced in Table 1 with their relation to designing medical devices:

Table 1: Six human-centred design aspects for designing medical devices that are focussed within the scope of this research.

<p>Medical Device Usability</p>	<p>As suggested by Wiklund et al. (2011), the general usability of medical devices is directly related to device safety, and usability testing enables identifying the use-related hazards, which is important for the overall risk management procedure. In this respect, IEC 62366-1:2015 Medical Devices – Application of Usability Engineering to Medical Devices (IEC, 2015) provides a good process model and valuable guidance to designers and manufacturers of medical devices. There are several studies in the literature, focussing on the usability aspects of medical devices. For example, a study performed by Fung et al. (Fung, Igodan, et al., 2015; Fung, Martin, et al., 2015) on the usability of positive airway pressure devices for the treatment of sleep apnea revealed that lay users with physical and/or sensory impairments experience many design-related difficulties while using the devices; and such interaction problems may result in increased frustration for patients. Similarly, Schaeffer et al. (2015) identified several usability problems for lay users in their studies with infusion pumps, and they recommended that human factors methods be implemented in the design process to optimise device usability before product commercialisation. As could be seen, usability inspection is an important aspect of the medical device development procedure. Usability testing is also linked with hazard analysis that is also a topic of regulatory obligations for manufacturers of medical devices.</p>
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Patient Safety	Patient safety is a board concept, which not only covers reducing and mitigating medical errors, but also aims to improve wellbeing of clinicians (Carayon, 2014); because it is related to optimising their physical, cognitive and behavioural/social performances (Karsh et al., 2006). Under this topic, it is also critical to take into account the diverse needs of users, the range of scenarios and the environments in which the device will possibly be used (NHS, 2010). With the emergence of home use medical devices, all these aspects have become a challenge for designers (Gardner-Bonneau, 2011). In this respect, the design of the system is critical in reducing adverse outcomes, and a range of factors including "patient", "task", "technology and tool", "environmental", "organisational" and "external environment" (which means that any environment outside but related to that system) factors are important to take into account during the design process (Karsh et al., 2006). In addition, evidence-based design strategies, which mean using the design input from the best credible research available, are also recommended to ensure the patient-centeredness of the design outcome (Henriksen, 2014). There are many product adverse event reports caused by design related problems, which are available in MAUDE database of FDA, and that could be useful for designers as an input in their design processes.
User Interface	According to FDA (2016), user interface covers “all points of interaction between the user and the device, including all elements of the device which the user interacts (i.e. those parts of the device that users see, hear, touch)” (p. 1). Therefore it covers both physical and digital aspects of medical device designs. User interfaces are also closely linked with environmental factors and device users (FDA, 2016). In general, the users of medical devices can provide considerable information about present problems with products that emerge from the misfit between their capabilities and the device features such as their controls, displays and their arrangement in relation to each other (Henriksen, 2012). In this respect usability testing could provide valuable information about the design of the interface. For example, the research of Fairbanks and Caplan (2004) on the design evaluation of defibrillators presents a case study which highlights the importance of user interface design in the field of medical devices, in which they identified several usability problems directly related to user interface designs. User interface design is also linked with use errors and ergonomics and human factors aspects of medical devices.
Use Errors	There are three types of errors; i.e. slips, lapses and mistakes (ISO 14971, 2007). A slip occurs when the action is not conducted as intended, while lapses means misses of actions due to memory or attention failure (Kohn et al., 2010). On the other hand, mistakes happen when the action proceeds as planned but fail because it is the wrong action to achieve the intended outcome (to err is human). There are also violations, which are caused by deliberate deviations from safe operating practices (Vincent et al, 1998). On the other hand, as highlighted in ISO 14971, user interface design features such as physical design and layout, ergonomic features or hierarchy of operation can also contribute to the use errors if they are insufficiently cared during the design process. As recommended by Israelski and Muto (2014), “use error can be addressed and minimised by the device designer and proactively identified through the use of techniques such as usability testing and hazard analysis” (p. 477). Hazards could be categorised under three categories as use related hazards, device failure hazards and overlap hazards covering both failures; and they need to be assessed as a part of risk management procedure during medical device development processes (FDA, 2016).
User Experience	User experience design covers both short and long term experiences and should become a regular requirement for all medical products and services (Mival and Benyon, 2015). Thanks to the increase of home use medical devices in the healthcare market, today the users of medical devices are very diverse (Cifter, 2011); and all these users may have different expectations from the products they use. Negative user experiences may result in stigmatisation or frustration of patients (Harte et al, 2014), which might

	<p>result in decreased motivation in their treatments. As suggested by Wiklund & Weinger (2011), the “devices that are easy to use, as well as appealing to view and touch will engender greater user satisfaction” (p. 21). In this respect, the concept covers the needs and requirements of both professional users (e.g. doctors and nurses) and lay users (e.g. patients and nurses). The research of Lang et al. (2013) on PEP devices provides a good example of the significance of user experience in medical device industry, in which device designs are evaluated regarding their satisfaction among adolescent users and they recommend that design of the device should also support the socio-cultural and psychological needs for higher user satisfaction of their users.</p>
<p>Ergonomics and Human Factors</p>	<p>Hignett et al. (2013) argue that the human factors and ergonomics techniques have been increasingly applied to healthcare contexts since the past decade, and this provided an improved understanding and knowledge of the significance of the topic in relation to patient safety. It is also highlighted in medical device regulations of the European Parliament and of the Council that ergonomic features of medical devices must be paid attention during their design and development processes (EC, 2017). As suggested by Carayon et al. (2014), "many patient safety incidents are related to human factors and ergonomics (HFE) in the design and implementation of technologies, processes, workflows, jobs, teams and socio-technical system domains" (p. 196). They recommend four mechanisms to improve patient safety by implementing human factors and ergonomics into the process: (1) errors and hazards are likely to occur if a work system is not designed in accordance with human factors and ergonomics principles; (2) performance obstacles in a system can reduce the performance of clinicians and might prevent them from delivering safe care for patients; (3) resilience of the system is necessary in order to assist its users to detect, adapt to, and/or recover from errors, hazards and other negative disturbances; and (4) human factors and ergonomics cannot focus on one element in isolation, because the other components of the system are also likely to affect patient safety (Carayon et al., 2014). It is also important to work closely with clinicians and sustain long-term partnerships to understand the complexities of the system and shape it together (Hignett, 2013).</p>

As it can be seen from the table, all these six aspects are interlinked with each other, and in many cases, it is not possible to ensure one without taking the others into account. Although the relevant literature highlights the importance of these topics in relation to the human-centred design of medical devices, their levels of implementation during medical device development processes are not clear in Turkey. In this respect, this paper present the results of a study of semi-structured interviews with a group of Turkish medical device producers and evaluate their understanding of human-centred design by using these six aspects.

2 Study Method

Currently, there are limited written resources available, focusing on Turkish medical device domain from a human-centred design perspective; therefore, this research adopts a qualitative approach in an effort to reveal tacit knowledge. Face-to-face semi-interviews were considered to be appropriate for this research; because the main intention was to collect in-depth information (Tracy, 2013) directly from medical device manufacturers. Semi-structured interviews were used; because the interviewer had a list of questions, but in certain cases, modified or changed the order of questions based on the flow of the interview (Robson, 2011). This is a flexible approach and generally used in small scale researches where the interviewer is also the researcher (Robson, 2011).

All of the interviews were conducted in Expomed Eurasia 2017 Fair (29 March-2 April 2017 / TUYAP Istanbul). Expomed is one of the biggest fairs of Turkish healthcare industry, and this year there were 34,086 visitors, 4,972 of which were international visitors, coming from 86 countries (Expomed, 2017). In order to select the interviewees, four criteria were sought:

- Manufacturers were expected to be located in Turkey
- 50% of their products were expected to be of their own production
- An authorised person who had detailed knowledge about the R&D procedure of the company was required to be available
- Agreed to take part and share up to 30 minutes for the interview

Based on these criteria, face-to-face interviews were performed with 17 manufacturers, and it took around 15-20 minutes for each. Due to the predetermined criteria, purposive sampling was used as the main sampling method in this research (Robson, 2011; Yildirim & Simsek, 2016). During the interviews, the researcher took detailed field notes on ready-prepared interview templates prepared for each participant. Due to the fact that this research adopted a qualitative descriptive approach, thematic analysis was utilised for data analysis.

The list of companies and their details (sizes and production lines) are presented in Table 2. One of the companies did not agree to share information about their company size. In order to ensure the anonymity of the participant manufacturers, a unique code starting with “C” is given to each of them. Their sizes are determined with the number of people working in each of the participant company; i.e. Micro: 1-9; Small 10-49; Middle: 50-250; Large: 250+. As could also be seen from the table, the production lines of the companies cover a diverse range of products.

Table 2 Company sizes and production lines of participant manufacturers

CODE	SIZES	PRODUCTION LINE
C1	Medium	Wound & burn treatment
C2	Large	MRI machine
C3	Small	Anaesthesia devices, ventilators, surgical tables
C4	Small	Operating room integration systems, urodynamic systems
C5	Large	Surgical tables, operating room lighting systems, medical aspirators
C6	Small	CPAP device, sleep apnea detection devices, medical aspirators
C7	Small	Sterilisation devices
C8	Small	CPAP device, medical aspirators, nebulisers
C9	Medium	Intensive care and new-born units
C10	NA	Sterilisation devices, surgical tables, operating room
C11	Micro	Wearable ECG device
C12	Micro	Pulse oximeter, inhalers
C13	Small	CPAP device, ventilators
C14	Medium	ECG device, medical aspirators, nebulisers
C15	Medium	CPAP device, inhalation devices, defibrillator, surgical tables
C16	Medium	Sterilisation devices, surgical aspirators
C17	Medium	Surgical tables, medical lighting systems, surgical aspirators

3 Results

The open-ended questions enabled the collection of data in four areas, i.e. (1) the company structures of the participant manufacturers, (2) their considerations on the value given to industrial design in Turkish medical device industry, (3) their general product development processes, and (4) their understanding of human-centred design with respect to the six topics focussed in the scope of this research. These aspects are discussed separately in this section.

3.1 Company Structures of the Manufacturers

The results suggested that 11 out of the 17 participating manufacturers (65%) had an internal R&D Department and 4 of those also had an internal Design Department for their product development.

On the other hand, only 4 of the companies employed at least one in-house industrial designer. Seven manufacturers stated that they worked with local and/or international design consultancies in

order to meet their design related requirements. Other companies expressed that their design activities were carried out either by their engineers who were not gathered under a departmental establishment (3 participants) or company owners who had the product idea and were entrepreneurs themselves (3 participants). As it can be seen from the results, an important percentage of participants did not incorporate designers in their product development processes and rather adopted an engineering oriented approach.

3.2 Value of Industrial Design in Medical Device Sector in Turkey

The participants were asked about the value of industrial design in Turkish medical device sector and their responses were coded and gathered under 6 categories, which can be seen in Figure 1.

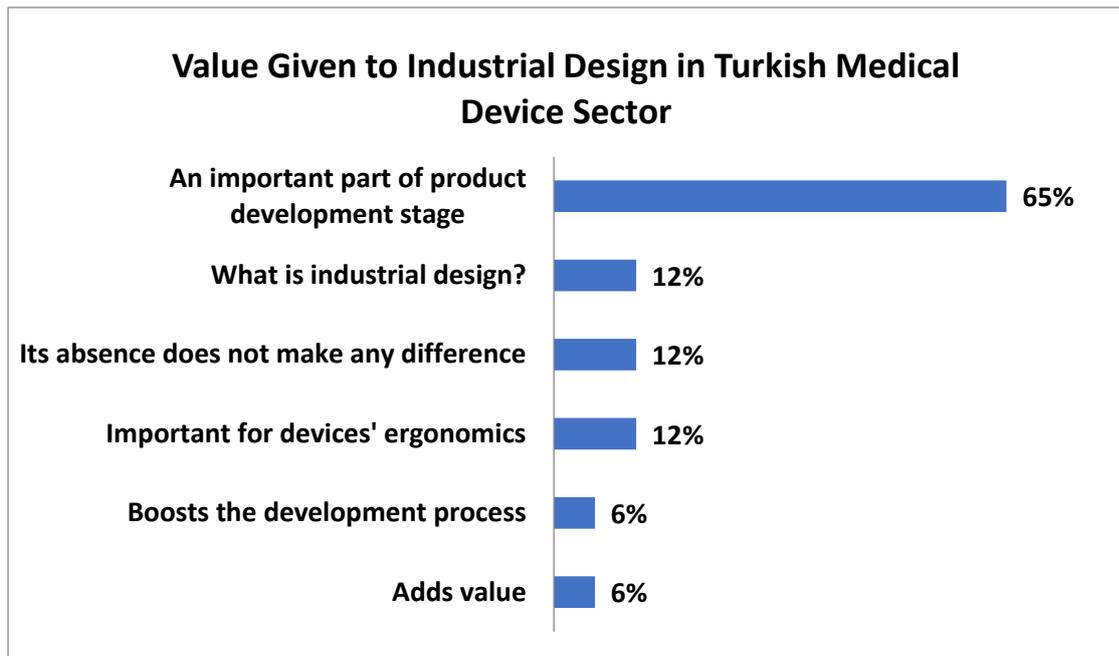


Figure 1: The value given to industrial design in Turkish medical device sector

The results suggested that more than half of the respondents qualified industrial design as an important part of the product development stage of medical devices. A number of manufacturers also highlighted the importance of design activity in their processes, because they thought that designers provide multifaceted solutions that are important in such a highly competitive and global market. They also indicated that a structured design process also reduces the time required for their products to get into market.

On the other hand, two respondents argued that industrial design was not an important aspect of a medical device development process when compared to engineering requirements and its absence did not make much of a difference. Surprisingly, two other respondents were not even aware of what industrial design was and asked about it to the researcher.

The results showed that the number of manufacturers preferred cooperating with design consultancies outnumbered the manufacturers that employed an in-house industrial designer. According to the results, the reasons are summarised below:

- Cooperating with design consultancies provides richer design solutions
- There is a lack of competent designers working in medical device sector
- Due to the fact that designers get involved in the product development processes only at certain stages, it is more cost effective to cooperate with design consultancies

As it can be seen from the results, the value of industrial design still requires further improvements in the sector and more competent design consultancies are needed to support this.

3.3 Product Development Processes of the Manufacturers

The companies were asked to summarise the stages of their product development processes and based on their responses; six common stages were identified as:

- Identification of user requirements
- Field research for developing design specifications
- Design and Development
- Design testing
- Design evaluation and verification
- Validation

Figure 2 presents the percentages of manufacturers that each of these stages applicable to their own product development processes.

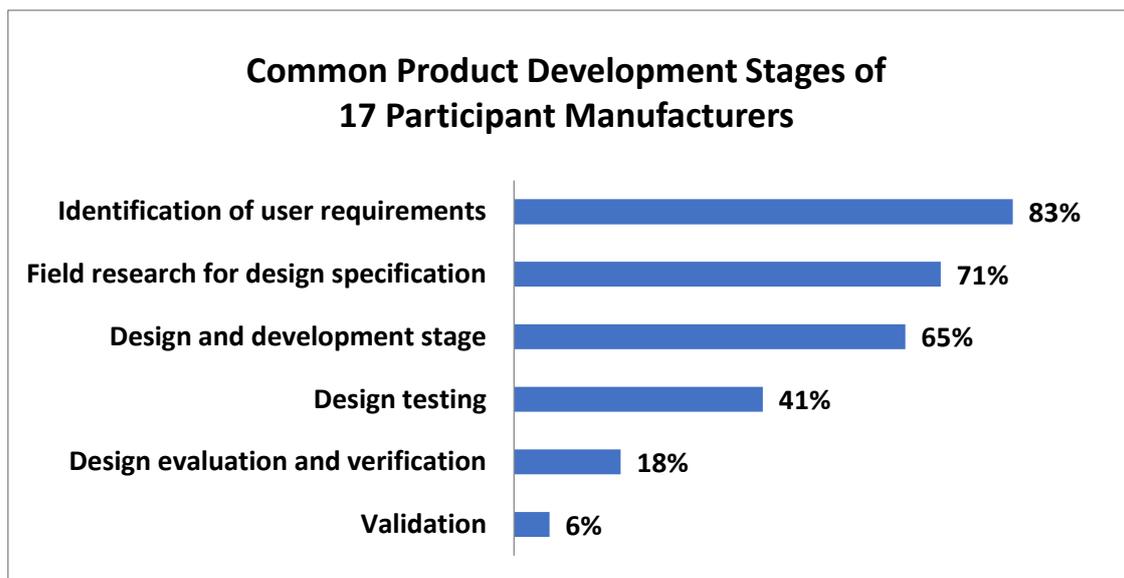


Figure 2: Common stages of product development of participant companies and their percentages

As it can be seen from the Figure, most of the companies expressed that they put effort in identifying user requirements as a part of their product development processes. For this purpose, they stated that they carried out user research activities (such as interviews) and market analysis as the first stage of their processes. They also expressed that in some cases, the product development started with a demand coming from medical professionals emerging from their professional requirements.

Field research for developing design specifications was also the second most mentioned stage by the participants; which means that the manufacturers valued collecting information directly from the context in which the device is intended to be used. Respondents mentioned that they worked closely with clinicians as consultants and observe their practices in this stage. As an outcome of this stage, they combine the information gathered from user research, market analysis and field research, and generate design specifications for their product development activity.

From the interviews, it was learned that participating the design and development stages of the manufacturers cover industrial design (N: 7/17), software development for electronic devices (N: 5/17), product engineering development (N: 8/17) and prototyping (N: 6/17) activities. The results suggested that most of the manufacturers did not treat industrial design as a specific stage of their product development processes.

It was seen that the design testing stage covered the introduction of a functional or semi-functional prototype to a limited number of clinicians and getting their feedback. This was not a clinical trial

stage, instead could be considered as an extension of design and development stage. This stage was mentioned by less than a half of the manufacturers during the interviews.

Three manufacturers also expressed that they had an evaluation and design verification stage, in which they assess whether they met the predetermined design criteria. This was mentioned by only 3 participant manufacturers as a specific part of their own product development processes.

Finally, only one manufacturer mentioned that they carried out a validation activity, which was highlighted as a unique stage of a medical device design development process in the relevant literature (FDA, 1997; Alexander et al., 2001).

As it can be seen from the results, although most of the manufacturers stated that they valued user requirements and carried out user and field researches as important stages of their product development processes, they mainly involved users at the initial part of their processes. Design testing, as a specific stage, was carried out by less than a half of the participant manufacturers, and user research and design/development stages were generally isolated from each other. This was considered to be the result of working with no designers/external designers (N: 6/17) and/or not being aware of the importance of human-centred design in this domain.

3.4 Human Centredness of the Design Processes of the Respondents

In order to understand the human centredness of the design processes of participant manufacturers, a specific question on each of the six human-centred design aspects was directed. Two of the interviewees did not answer these questions, because they argued that their design activities were completely carried out by external design consultancies. Therefore, they are excluded in the results in this section. The results regarding the percentages of manufacturers (N: 15) interviewed fulfilling each of these aspects "to a certain extent" are presented in Figure 3.

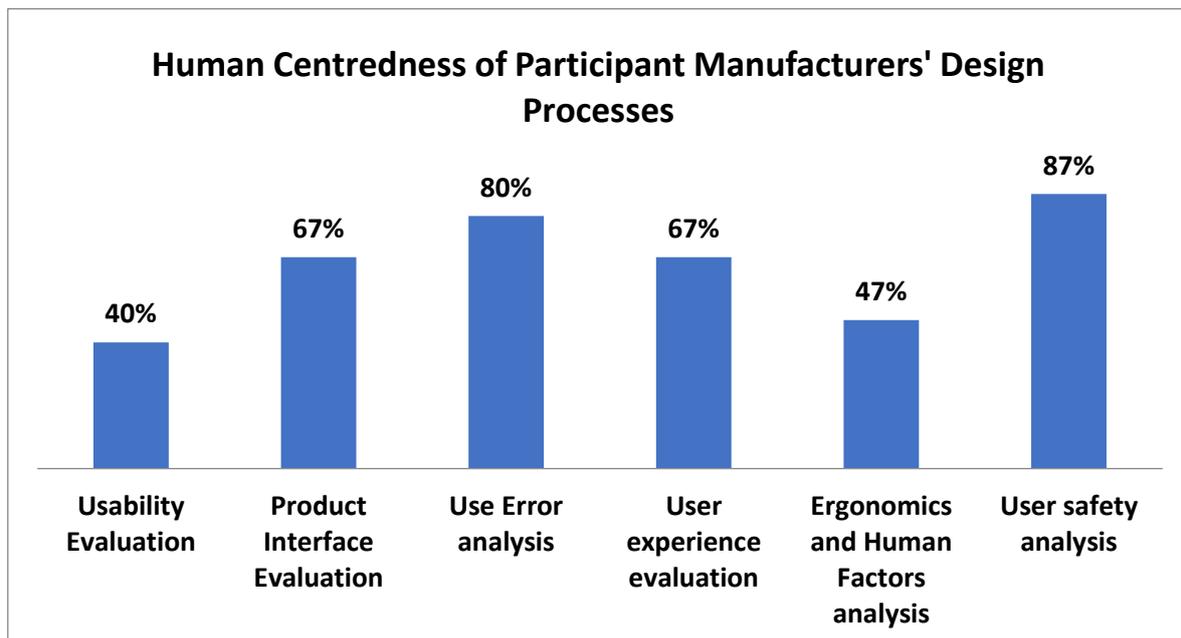


Figure 3: The percentages of manufacturers fulfilling each of the six aspects of human-centred design in their product development processes

As it can be seen from the Figure, most of the manufacturers claimed that they assessed their products in terms of user safety and use error. Regarding both aspects, the interviewees expressed that, as a part of the regulatory requirements, they had to carry out certain tests and analysis (such as clinical trials) and document them in order to obtain a CE certificate for their products. Only 4 out of the 15 participants stated that they conducted risk analysis activities. On the other hand, 3 participants mentioned that they provided user training activities for their customers to support prevention of use errors (C7, C15 and C16).

Regarding user experience, the participants expressed that they collected this data from the feedbacks of the users regarding the previous versions of the product, and used this information as a design input during the new product development process. 7 manufacturers also mentioned that they invited the potential users and got their feedbacks too. Similarly, for product interface evaluation, the manufacturers (N: 8) expressed that they kept in close contact with medical professionals (doctors, nurses and other hospital staff) who provide consultancy in the product development process and provide feedback based on their expert opinions. Only 4 participants (C5, C9 and C15) stated that they performed product interface evaluations, which are in fact conducted within the usability testing stage in an effort to meet the requirements of ISO 62366-1:2015 Medical Devices – Part 1: Application of usability engineering to medical devices. One of the problems emphasised for both user experience and user product interface evaluations was that it was not possible to test certain types of medical devices extensively with users before getting the necessary certification due to patient safety concerns. 5 participants stated that they sent “DEMO” products to hospitals and get feedback directly from the field after obtaining the certificate.

On the other hand, only 3 participants expressed that they conducted research regarding the ergonomics and human factors aspects of their products. Apart from this, other 3 participants stated that they took user and environment variety, as well as, possible diverse use conditions for their products into consideration during their processes.

Finally, the results showed that usability evaluation is the least met human-centred design aspect among the participant manufacturers. Only 5 participants expressed that they applied usability testing methods during their product development processes and this was for the purpose of meeting certain regulatory requirements for certification. 4 other participants stated that they inspected usability during clinical trials; however, they did not provide any hints of using specific usability inspection methods or a structured approach; therefore not included in the results.

4 Discussion and Conclusions

The marketplace demands medical devices that not only satisfy functional requirements but also user needs and preferences (Wiklund & Wilcox, 2005; Wiklund & Weinger, 2011), and this emphasises the importance of human-centred design in this sector. In this research, manufacturers from Turkish medical device sector were investigated in terms of their understanding of human-centred design and also to what extent they fulfil its requirements in their product development processes. For this purpose, six topics were identified from the literature, which were considered to be particularly important by covering critical aspects of human-centred design: i.e. Medical Device Usability, Patient Safety, User Interface, Use Errors, User Experience, and Ergonomics and Human Factors.

The results of the semi-structured interviews with 17 medical device manufacturers provided hints that the product development processes are mainly engineering-oriented in Turkey; and therefore, there is still a need for increasing the awareness of industrial design and its possible positive impacts within the industry. One of the critical issues of the sector is that there is lack of competent designers working in this sector, therefore very few manufacturers employ in-house designers. It was also seen that companies prefer working with design consultancies due to cost advantages, their experience in the field and rich design solutions they provide. For this reason, it could be inferred that design consultancies could play a vital role in increasing the awareness of human-centred design in medical devices sector of Turkey and change the prejudice against “Made in Turkey” branded medical devices by providing good and safe medical device designs to Turkish manufacturers.

Moreover, it was inferred that most of the manufacturers interviewed involve users and research into their requirements mainly in the initial stages of their design and development processes, and afterwards focus on technical solutions. In addition, although the participants had an overall understanding of most of the human-centred design topics questioned in this research, they mainly

take them into account as much as the regulations oblige them. Particularly safety related issues are paid more attention. On the other hand, no structured approaches were uttered during the interviews with respect to user experience and user interface evaluation aspects in particular. Therefore, these efforts are considered to be far from being adequate. Besides, ergonomics and human factors analysis and usability evaluation were the least met topics among the participant manufacturers in their product development stages.

Based on these findings, a number of recommendations are made for not only for Turkish medical devices industry, but also for other countries with growing medical device markets, so that they can use human-centred design as a catalyst for providing patient centred products and competing better in the Global market:

- The product development process of medical devices is more than meeting regulatory requirements of the target market. A human-centred design approach is necessary.
- Human-centred design is not only a stage in the process, therefore needs to be applied throughout the product development process of medical devices.
- Design consultancies with the knowledge and experience in medical device can play an important role in increasing the awareness of human-centred design among manufacturers in developing markets.
- Medical devices that are appealing, usable and developed with diverse user requirements in mind can provide safer products and better user experiences, which is necessary for competing in the Global market of medical devices.

One of the limitations of this research is that the number of manufacturers interviewed was very limited. Also, due to the busy environment of Expomed 2017 Fair, the interviews were kept short to maximum 30 minutes; hence, it was only possible to collect the overall information about the current state. As a following research, it is proposed to conduct follow-up interviews with the manufacturers whom are considered having an understanding of human-centred design, and get more in-depth information about the current barriers and possible actions that could be undertaken to assist Turkish medical device manufacturers.

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